LEARNING THROUGH SURGEON'S EYES: DESIGN, DEVELOPMENT, AND EVALUATION OF AN IMMERSIVE VIRTUAL REALITY TRAINING TOOL FOR ORAL AND MAXILLOFACIAL SURGERY

BY

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Copyright statement

In Simple terms

Lack of self-confidence affects four out of every ten novice surgeons before performing major surgery. This research project identifies the challenges in current surgical training methods and addresses them using virtual reality and motion sensing technologies. The research outcome is a validated novel application called VR Surgery (Virtual Reality Surgery), which provides an immersive experience of training in the operating room using an Oculus Rift and Leap Motion devices. The application uses a combination of 360-degree videos of the operating room, stereoscopic 3D videos of surgery and 3D interactive elements. This Thesis discusses the need, development, and evaluation of VR Surgery. Further, the impact of VR Surgery on surgical trainees' knowledge and self-confidence is presented.

Abstract

Background

Reduced training hours, over-crowded operating rooms, and lack of focus on non-technical skills are severely affecting surgical training. In specialities such as Oral and Maxillofacial Surgery, there is an increasing need for innovation in training. On the other hand, despite the application of technological advancements including virtual reality (VR) and augmented reality (AR), twenty-eight to forty percent of novice trainees are not confident in performing major surgery. The current research aims to address these challenges by finding a suitable way to develop an evidence-based immersive virtual reality (iVR) experience. Further, the research investigates the impact of this solution on the learning and confidence of trainees.

This research introduces VR Surgery, an iVR experience, to address the gaps in the knowledge. VR Surgery is the first multi-sensory, holistic surgical training experience demonstrating Le Fort I osteotomy, a type of maxillofacial surgery, using Oculus Rift and Leap Motion devices. This research demonstrates the design, development and evaluation of VR Surgery and provides a way for future studies on the use of immersive technologies for surgical education.

Methods

A design science research approach was followed to identify the problem, build the solution in collaboration with expert surgeons and evaluate it. Using a combination of multimedia, VR Surgery enables trainee surgeons to experience a realistic operating room environment, and interact with the patient's anatomy while watching the surgery in a close-up stereoscopic 3D view.

Consultant oral and maxillofacial surgeons in the UK evaluated VR Surgery for Face and Content validity. Surgeons commented on the content, usability and applicability of VR Surgery to surgical training. Further, to investigate the impact of VR Surgery on the perceived self-confidence of trainees, a single-blinded, parallel, randomised controlled trial (RCT) was performed. Surgical trainees (95) from seven dental schools took part in one of the first experiments to test the role of iVR on self-confidence. Experimental group participants learnt about the Le Fort I procedure using VR Surgery on an Oculus Rift. The control group used similar content in a standard PowerPoint presentation. The primary outcome measures were the self-assessment scores of trainees' confidence as measured on a Likert scale and objective assessment based on the knowledge.

Outcomes

The expert surgeons agreed with the validity of VR Surgery. The participants of the RCT were randomly divided into the experimental (51) and control (44) groups. Trainees had a mean age of 27·14, and they were 45·3% female students and 50·5% male students. A repeated measures multivariate ANOVA was applied to the data to assess the overall impact of receiving the VR surgery intervention over conventional means on the confidence of trainees. Experimental group participants showed higher perceived self-confidence levels compared to those in the control group ($p=0{\cdot}034$, $\alpha=0{\cdot}05$). Novices in the first year of their training showed the highest improvement in their confidence, compared to those in the second and third year.

Interpretation

Surgical trainees improve their knowledge and self-confidence levels after using an iVR training experience. The study proves that virtual reality applications such as VR Surgery have a substantial potential to bridge the differences in the quality of global surgical training. This research provides a framework for future researchers who use mixed reality for healthcare.

Keywords:

Immersive Virtual Reality, Experience, Expertise, Surgical Training, Oral and Maxillofacial Surgery, Self-confidence, Oculus Rift, Leap Motion, 360-degree video.

Dissemination of research in publications, conferences and news

The contributions of this research were disseminated in various national, international conferences; peer-reviewed publications and news websites.

Peer reviewed publications

- Pulijala Y, Ma M, Pears M, Peebles D, Ayoub A. Effectiveness of Immersive Virtual Reality in Surgical Training—A Randomized Control Trial. Journal of Oral and Maxillofacial Surgery. 2017
- PULIJALA, Y., MA, M. & AYOUB, A. 2017. VR Surgery: Interactive Virtual Reality Application for Training Oral and Maxillofacial Surgeons using Oculus Rift and Leap Motion. *In:* MA, M. & OIKONOMOU, A. (eds.) *Serious Games and Edutainment Applications: Volume II.* Cham: Springer International Publishing.
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Conferences and talks

- 2017 July - Innovation in haptics conference by The Royal Academy of Engineering, London, UK.

  Panel speaker - one touch beyond - the future of haptics
- 2017 June – HealthTechX Europe conference, London.

  Panel speaker – Doctor’s den - Panel discussion in which clinicians share their insights on HealthTech Innovation and adoption from the clinician's perspective

- 2017 June – 3 Minute Thesis, University of Huddersfield.
  Finals winner for the talk: VR Surgery, how virtual reality is changing surgery.
- 2017 March – VR Evolution Conference, London.
  Panel speaker – Real world impact of virtual reality
- 2017 March – TEDX SquareMile conference, London.
  Demonstration of VR Surgery
- 2017 January – Continuing Dental Education conference, Davangere, India.
  Talk and Demo: Role of virtual reality and augmented reality in surgical training.
- 2016 November – World Innovation Summit for Health, Qatar (WISH 2016).
  Innovation showcase on the role of virtual reality in healthcare
- 2016 October – Royal Society of Medicine, Enteric HTC conference, London.
  Panel speaker – Digital Healthcare.
- 2016 October – Games for Health Europe conference, Netherlands.
  Paper presentation – Title: Should Oculus Rift be used in training surgeons?
- 2016 September – PGR Conference, University of Huddersfield
  Poster presentation – Title: Oculus Surgery – Application of immersive Virtual Reality in training oral and maxillofacial surgeons
- 2015 December – Oxford University Digital Health Conference
  Invited speaker – How serious are serious games?
- 2015 November – PGR Conference, University of Huddersfield
  Paper presentation – Design and development of Oculus Surgery
- 2015 October – Games for Health Europe Conference, Netherlands
  Paper presentation - Title: Play before you cut, Oculus rift to change the surgical training methods in Oral and Maxillofacial Surgery.
- 2015 October – Glasgow City of Science Conference, Glasgow
  Talk title: 3D Visualisation from Mt. Rushmore to Medical Visualisation
- 2015 September – AMEE Conference, Glasgow
  Poster title: 3D Head and Neck project: Development of a novel visualisation tool for education, training and research in human anatomy.
- 2015 March – Joint Conference of Serious Games, Huddersfield
  Paper presentation: Design and Development of Sur-Face: An interactive mobile app for educating patients regarding corrective surgery of facial deformities.

News stories

- 2017 March - Virtual reality dental surgery training in development - http://www.dentistry.co.uk/2017/04/05/69354/
- 2016 Nov - Al Jazeera News Network; Virtual reality is changing healthcare.
- 2015 October - Virtual training aids doctors with their communication skills. https://www.hud.ac.uk/news/2015/october/virtualtrainingaidsdoctorswiththeircommunicationskills.php
- 2015 August - Research uses virtual reality technology to train dental surgeons. http://www.hud.ac.uk/news/2015/august/researchusesvirtualrealitytechnologytotraindentalsurgeons.php

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Dedication

मातृ देवो भव।
Maathru Devo Bhava
पितृ देवो भव।
Pithru Devo Bhava
आचार्यदेवो भव ।
Acharya Devo Bhava

-तैत्तिरीय उपनिषद् (Taittirĩya Upanishad, I.11.2, 6th century BC)

Translation

Be one to whom a mother is as God, be one to whom a father is as God, and be one to whom an Acharya (spiritual guide) is as God.

This PhD research and thesis are dedicated to

my beloved mother, Shobha Rani Pulijala,

my father, Yugandhar Rao Pulijala,

and Shri Shiridi Sai Baba.

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I take this opportunity to thank my parents, my sister, Tejaswi Pulijala and brother in law, Raghavendra Sumbharaju for their tremendous faith in me. I also extend my heartfelt wishes to my uncle, PremChand Sarikonda and aunt, Lavanya Sarikonda for their endless source of encouragement. Lastly, I also thank my teachers, friends and loving relatives from India without whom I would not have been where I am today.

List of Abbreviations

3D	3 dimensional
AR	Augmented Reality
CTA	Cognitive Task Analysis
DSR	Design science research
EWTD	European working time directive
FOV	Field of view
HMDs	Head mounted displays
HTA	Hierarchical task analysis
iVR	Immersive Virtual Reality
LCD	Liquid crystal display
LMIC	Lower and middle-income countries
MR	Mixed Reality
NOTSS	Non-technical skills for surgeons
OMFS	Oral and Maxillofacial Surgery
OR	Operating room
RCT	Randomised controlled trial
TGS	Target guided system
VR	Virtual Reality
VR Surgery	Virtual Reality Surgery

Definitions

Virtual Reality - Virtual reality (VR) is a human-computer interface, which simulates a real life setting and allows a user to interact with it in a computer generated 3D cyberspace (Burt, 1995).

Presence – Presence is an illusion of non-mediation (Lombard and Ditton, 1997, Lee, 2004) or the suspension of disbelief, which enhances the illusion created by the virtual medium (Slater and Usoh, 1993). Based on the level of presence experienced by a user, virtual reality technology can be broadly classified into immersive virtual reality and non-immersive virtual reality.

Immersive Virtual Reality (iVR) – iVR is a multisensory virtual reality experience which engages the user's attention. Generally, the user wears a head-mounted display or goggles to engage his visual sense, headphones to engage his auditory sense, and gloves to engage his tactile sense.

Augmented Reality – In augmented reality, the visible natural world is overlaid with a layer of digital content. This digital content can be computer generated 3D models or information in the form of text, images, or data.

Mixed Reality – In Mixed reality, virtual objects are integrated into—and responsive to—the natural world (Kelly, 2016). For example, a virtual light bulb can turn on the surrounding environment and cast shadows based on the objects in the room.

Personal Motivation

Ikigai (生き甲斐) is a Japanese concept, which translates to a reason for being (Schramko, 2016). In an important study on mortality, Sone et al. (2008) showed that people who found their ikigai have lived longer and led a purposeful life. There are four aspects to consider when findings one's purpose. They are doing work that one loves, work that the world needs, work that one is good at, and one can be paid for it. Figure 1.1 illustrates this concept. This section explains the researcher's Ikigai in doing this particular research and thus it is narrated in the first person.

Growing up in a community which lacked efficient healthcare, I wanted to be a surgeon and save lives. After entering the dental school, I developed a deep passion for the field of oral and maxillofacial surgery (OMFS). The General Medical Council defines OMFS as a surgical speciality involving the diagnosis and surgical treatment of diseases in mouth, jaws, face and neck (Woodwards, 2015). In addition to learning the complexity of surgical procedures, I experienced the difficulties in training first hand. Having a passion for technology and art, post-dentistry, I finished my Masters in Medical Visualisation at the University of Glasgow. During this time, I learnt how to use technology for healthcare purposes. Using 3D visualisation, gaming engines and modelling software, I have built mobile applications for patients, virtual reality applications and serious games for training purposes.

It was at this time in my Masters, I received a message on WhatsApp group from a dentist friend in Kenya, which showed a severely mutilated face of a young man. My friend said he was unsure about the treatment and asked in the group if anyone knows how to perform an emergency life-saving intubation (a medical procedure, which involves placement of a plastic tube into the trachea to maintain airway when a person's breathing is affected). Unable to address the need within a short duration, the patient lost his life. That day I realised the challenges in surgical training and their impact on the patients in the real world. Further research into this aspect led me to the growing need for improving the confidence of novices.

In my PhD research, I aimed to address these challenges based on my understanding and expertise in OMFS. As OMFS is one of the most difficult forms of surgery involving the complexity of head and neck anatomy, it was challenging to choose one specific surgery to demonstrate. After interviewing expert surgeons, Le Fort I osteotomy, a form of corrective surgery of jaws was chosen for this research. Le Fort I surgery involves the fracture of the maxilla (upper jaw) from the base of the skull and is prone to complications in the operating room. An evidence-based solution for such a complex procedure was an ideal test case to investigate the efficacy of novel technologies.

Further, In 2015, the global commission of surgery reported the increasing need to improve surgical training and enhance the workforce, as there is less than one surgeon for every 10,000 people in lower and middle-income countries (Meara et al., 2015). This was when I truly realised my research Ikigai (Sone et al., 2008). I found my reason for being, which combines the four essential elements including passion, profession, vocation and mission.

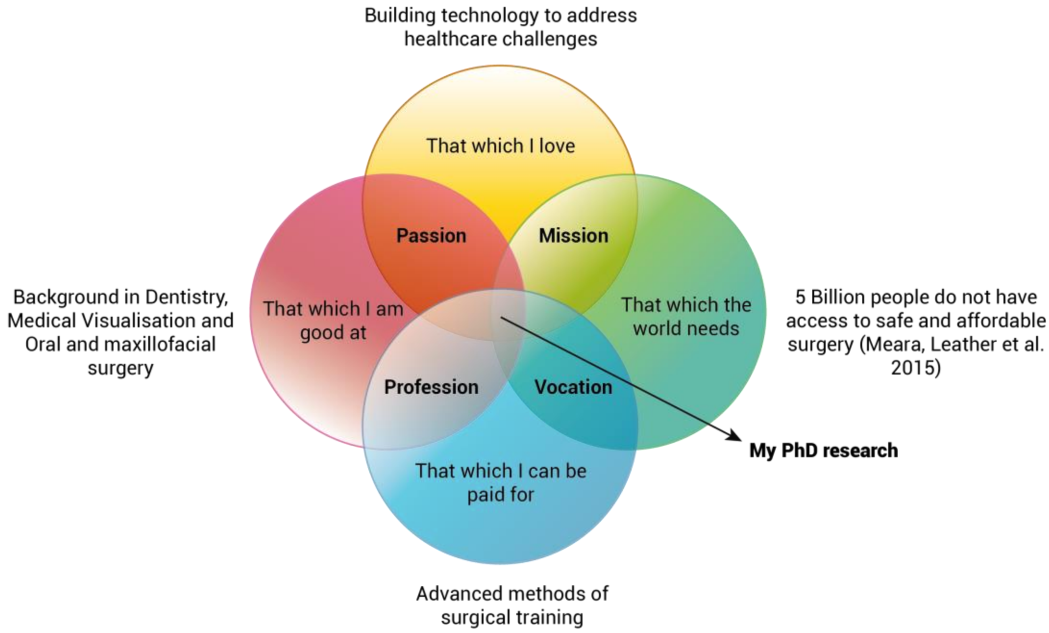


Figure 1.1 My research ikigai (Schramko, 2016)

When a person does work that involves all the four aspects, he/she is said to be in their 'element' (Robinson, 2017). My personal motivation to pursue this PhD research comes from the earlier challenges in surgical training, my background in Oral and maxillofacial surgery, and my passion for building advanced training tools for healthcare, for addressing a global problem. This research involves the use of immersive virtual reality and motion sensing technologies to solve a problem in oral and maxillofacial surgery training. The solution from this research can be used as a framework for other surgical procedures to address the global challenge.

Contributions of this research

There is a lack of evidence on how to design and develop immersive virtual reality (iVR) experiences for training surgeons, leading to a clear gap in understanding about what works, and what does not for surgical training purposes. Further, the application of immersive virtual reality experiences for maxillofacial surgeons is not well documented in the existing literature. There are no review articles in Cochrane database for keywords virtual reality (VR) and oral and maxillofacial surgery, demonstrating a need for the same. This shows there is a lack of evidence regarding the validation studies and efficacy trials to test the effectiveness of Oculus Rift based surgical training experiences. The present research addresses those needs through the following contributions:

- The research outcome, Virtual Reality Surgery (VR Surgery) is a novel contribution to surgical training, which provides a holistic training experience by combining multiple media on a head-mounted virtual reality headset and leap motion controller.
- VR Surgery is the first evidence-based immersive virtual reality (iVR) experience for maxillofacial surgery training. This work addresses the need for an advanced VR surgical training experiences in Maxillofacial Surgery.
- The principles of content creation, application design and clinical trials from this research will benefit the VR communities to create evidence-based surgical training experiences in the future.
- The multicentre randomised trial is the first study to our knowledge, which evaluated the impact of iVR experiences on the perceived self-confidence of surgical trainees. Our findings suggest that iVR experiences are useful for early stage surgical trainees to improve their knowledge base and confidence.
- The theory developed as a result of this research including the methodology and evaluation outcomes is a novel contribution to future research in surgical training.

The need and proposed use of immersive virtual reality experiences by surgical trainees were tested in this application, which has not been done in the past for maxillofacial surgery trainees.

Chapter 1 Introduction

This Thesis is a result of a full-time PhD research, which identified the needs in surgical training for oral and maxillofacial surgeons, developed a novel solution for a specific surgical procedure (Le Fort I osteotomy) and evaluated it. The first chapter provides a brief introduction to the research motivation, research questions, aim and objectives, scope, and the impact of the current research.

1.1 Research Motivation

Lancet report by the global commission for surgery reported 2/3rds of the world population lack access to safe and affordable surgery (Meara et al., 2015). The majority of the affected people are living in lower and middle-income countries, which have less than one surgeon for every 10,000 people (Lancet Global Surgery, 2015). Increasing surgical workforce, and enhancing surgical training, medical infrastructure and distribution of medication are among the goals for safer surgical care. However, financial and time constraints prevent the governments from taking prompt action in increasing the surgical workforce (Bridges and Diamond, 1999). Thus, enhancing the current surgical training through advanced learning methods is a feasible way of addressing the global challenges.

The necessity to reform the current surgical training methods lead to the introduction of novel solutions including immersive virtual reality (iVR) and augmented reality (AR) applications for the acquisition of surgical skills. However, there is a need to understand appropriate ways of developing these innovative training tools in a scalable manner. Further, there is a notable paucity of scientific evidence about the impact of iVR and AR experiences on learning and self-confidence of surgical trainees. This PhD project addressed those needs by introducing an immersive virtual reality (iVR) experience called Virtual Reality Surgery (VR Surgery) and evaluating it.

1.2 Research Questions

1. How could various teaching elements including the knowledge of anatomy, instruments and surgery be combined to create a holistic surgical training experience?
2. What are the essential design and technical elements to consider while developing an immersive surgical training experience using virtual reality and motion sensing devices?

3. What is the validity and effectiveness of using iVR applications for surgical training?

1.3 Aim and Objectives

The aim of this research is to design, develop, and evaluate an evidence-based iVR experience for training surgeons in oral and maxillofacial surgery, and to use it as an exemplar to investigate the validity and effectiveness of iVR in surgical training.

The researcher will meet the following objectives to achieve the aim.

1. Identify the challenges in the current surgical training methods of oral and maxillofacial surgery.
2. Build an immersive surgical training experience
   i. By using suitable hardware and software, and following the best practices in designing an iVR experience.
   ii. By obtaining the surgical knowledge, and creating visualisations using stereoscopic 3D videos, 360º videos and 3D animations.
   iii. By combining surgical knowledge with technology to build an enhanced operating room training experience.
3. Evaluate the efficacy of the solution
   i. By validating the content, usability and applicability of the application (VR Surgery) by expert oral and maxillofacial surgeons.
   ii. By testing the impact of the application on the knowledge and confidence of surgical trainees through randomised controlled trial.

1.4 Research Scope

The focus of this research is to create an iVR experience, not a surgical simulation. In a conventional surgical simulation, trainees are expected to learn skills by performing a set of tasks. On the other hand, in an experience like VR Surgery, the users feel their presence in an operating room ambience, observe the surgery, and interact with the content. The learning objectives are set by the trainees, instead of the simulator. This experience allows trainees to visualise information that cannot be seen otherwise in reality, for e.g., internal anatomy of the patient. As the experience is user-centric, trainees can either interact with surgical anatomy or watch a part of the surgical procedure, while observing how different people behave in the operating room. In this manner, multiple users can enter the same environment collectively and have a different experience, like in real life.

The scope of the current research is limited to the following:

i. Le Fort I osteotomy (Khan and Karra, 2013), a type of corrective facial surgery is the only procedure demonstrated in the application. Expert surgeon's opinion about the complexity of this surgery is the reasons to choose this procedure. However, the design of the application can be adapted to other surgical procedures as well.
ii. The research explains the use of various hardware and software solutions to design surgical training experience. The details of physics and principles behind the functionality of these devices are beyond the scope of this project.
iii. VR Surgery does not support haptic force feedback in its current version. Technology and time constraints in developing a realistic haptic force feedback prevented the researcher from implementing it. Future versions of the system would include haptic feedback.
iv. The validation of VR Surgery is limited to Face and Content Validity tests. Due to the early stage of development of the system, and time constraints, other forms of objective validity tests including concurrent, construct or external validity are beyond the scope of this project.

1.5 Research Path

This part of the chapter outlines the research path. After testing multiple models from social sciences (Saunders et al., 2009), computer engineering, and medicine, a structure that is inspired by narratology called monomyth was followed as shown in Chart 1-1. A 'Monomyth' or 'the hero's journey', is a term used by Joseph Campbell (Joseph Campbell Foundation, 2017) to explain the most recurring template in numerous stories, myths, narratology and psychotherapy around the world (Lawrence, 2006). The original structure of a monomyth contains 17 stages, which have been widely modified based on the need (Jolly, 2013). The process or the story begins in an ordinary world, where the protagonist faces a problem he needs to address. Identifying the problem, he tests existing solutions and faces multiple challenges. Mentors and external supporting agents help him to enter the special world where he can find the solution after multiple attempts. In the last phase, the protagonist enters the ordinary world with the solution and uses it for a greater purpose.

The monomyth structure was modified with 12 stages and three circles in it to explain the contributions of the current research. The outer circle explains each stage in brief, while the inner circle explains the research methodology. The innermost circle is divided into normal world and special world. In the current research, the normal world phases include current methods of surgical training and the phases of evaluation of VR Surgery. In the special world, the researcher explained the design and development of VR Surgery. The monomyth also includes four sub-stages of build-iterate-test cycles involved in the development of VR Surgery. Each cycle begins with a build phase, where a version of VR Surgery was developed with existing resources. It was then followed by test stage where feedback from user testing was collected. The third step is to iterate after modifying the application. The resultant build was taken to the next level of development. The entire design and development of VR Surgery resulted in four iterative versions of VR Surgery.

1.6 Outline of the Thesis

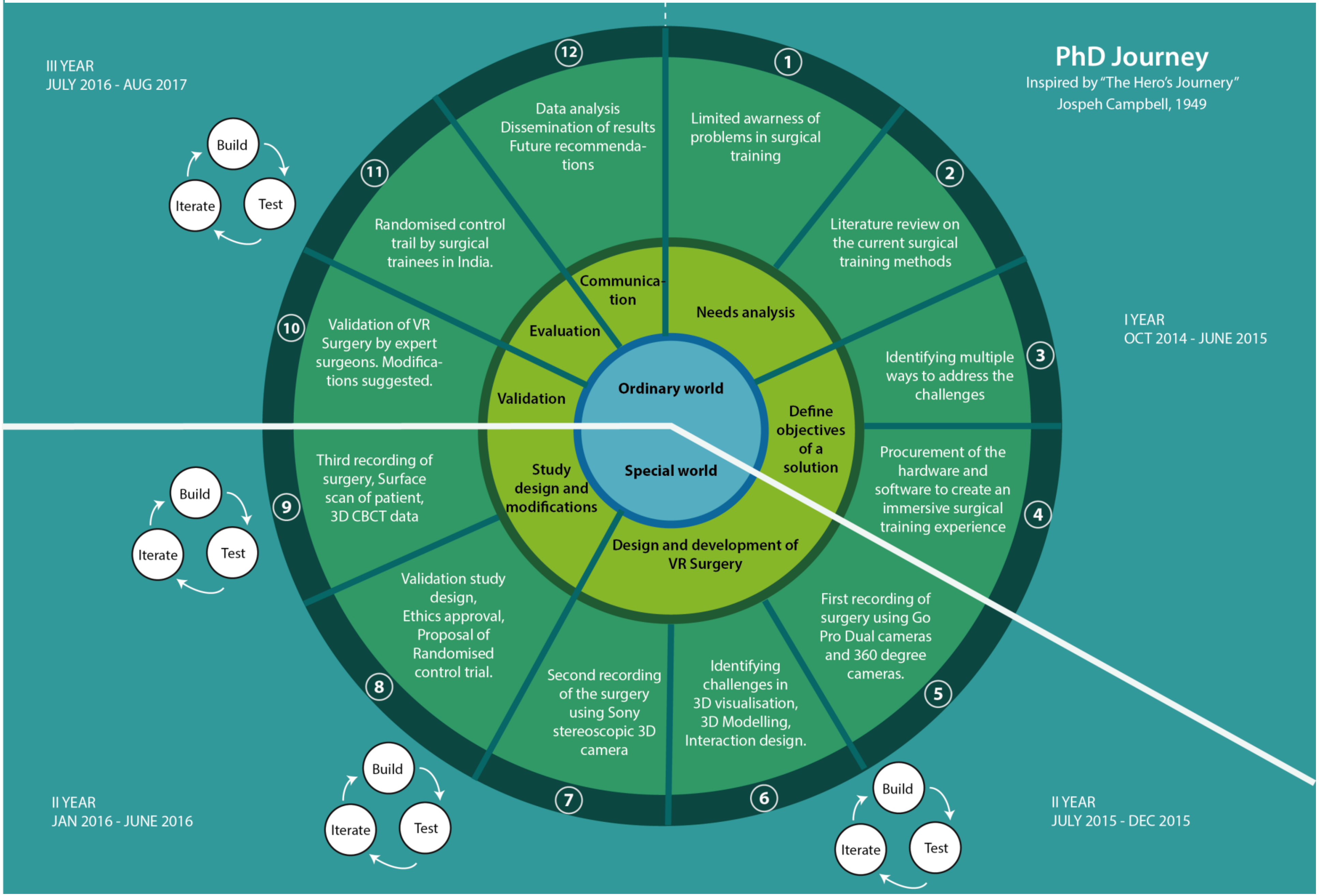
An image representing the outline of Thesis is shown in Chart 1-2. After a background information the second chapter discusses the problems in surgical training and outlines the existing solutions. Following which, it explains the challenges in current surgical training methods. The research in context section explains how the current research contributes to the gaps in existing knowledge. The third chapter explains the Design Science Research Methodology, and the path followed in conducting this research.

The fourth chapter describes equipment and functionality of VR Surgery. Analysis for various software and hardware used to build the solution, and the functionality of the application are discussed in chapter four. The fifth chapter explains the design and development of VR Surgery solution. The sixth chapter describes the Face and Content validation studies of VR Surgery. The seventh chapter explains Randomised Controlled Trial experiment performed to evaluate VR Surgery. The eighth chapter provides a general discussion of the research contributions, implications of the current work, and limitations of the research. This Thesis concludes by addressing suggestions for the future research in mixed reality for healthcare.

1.7 Summary

This chapter provided an introduction to the topic, outlines the research questions, and gave an overview of the scope and research path. The next chapter provides an in-depth understanding of the current literature, the advances in surgical training methods and the gaps in the knowledge.

Chart 1-1 The monomyth structure adapted to the current research



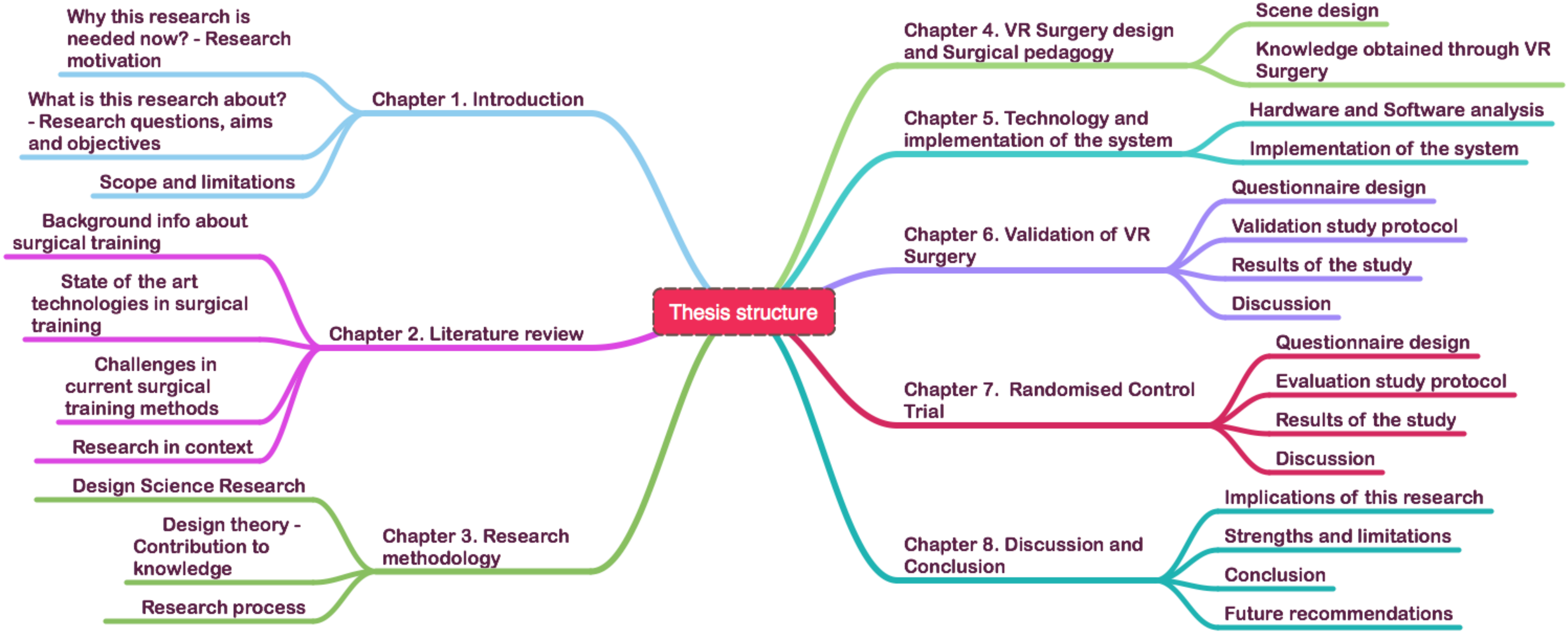


Chart 1-2 Structure of the Thesis

Chapter 2 Literature Review

This chapter provides an outline of the current methods of surgical training and their drawbacks. It further explains how surgeons learn, existing challenges in surgical training and the role of advances in mixed reality for surgical training.

2.1 Introduction

Lancet Commission on Global Surgery reported that five billion people in the world lack access to safe and affordable surgery (Meara et al., 2015). An additional 2.2 million surgeons, anaesthetists and obstetricians are needed by 2030 to meet the challenges in training. This target is hard to achieve with the current training methods. The report suggested an urgent need for reforms in the existing surgical training methods.

Conventionally, a lead surgeon assisted by a surgical resident or a junior trainee performs the surgery. To improve their expertise, surgical residents learn through observation and hands-on participation in the operating room sessions following a structured training program. This process, termed as Halsted's method of learning (Kerr and O'Leary, 1999), has been in practice for more than a century now. Gradual changes in the learning methods led to the introduction of more hands-on approach where surgical trainees assist and perform part of the procedure under the guidance of an experienced surgeon (Reznick, 1993). In addition to these sessions, the trainees undergo rigorous practice in skills lab to improve their manual skills including hand-eye co-ordination.

Despite all these methods of training, 28-40% of novice trainees are not confident in performing a major procedure (Geoffrion et al., 2013, Rodriguez-Paz et al., 2009). The lack of confidence in novices can lead to unintended mishaps in an operating room. However, few questions about surgical training need reasoning to develop a feasible solution. They include why do the trainees feel inadequately prepared? What are the challenges in the current surgical training methods? What are the existing tools which can improve their confidence and performance? This chapter attempts to answer these questions in five parts. The first part reports the background about how surgeons learn, the impact of self-confidence and the current status of surgical training. The second part elaborates on the problems in the existing methods of surgical training and emphasises on the needs for their transformation. This section also highlights unique challenges to Oral and Maxillofacial Surgery. The third part of the chapter reviews the application of multimedia, simulation, and serious games for surgical training purposes. The fourth section of this chapter presents the state-of-the-art mixed reality training tools in medicine and dentistry, with a focus on oral and maxillofacial surgery. Further a section explaining the technology review and design considerations is presented for a deeper understanding of the available technology and their usage in VR Surgery. The last section underlines the gaps in the existing literature and the research context. A schematic representation of the structure of literature review is provided in Chart 2-1.

A systematic search of several peer-reviewed literatures published in the last twenty years on PubMed, Cochrane Database of Systematic Reviews, Google Scholar and Scopus was performed. Additionally, updated information on the use of advanced technologies was cited from various websites. A combination of keywords including (surgical training*, or challenges in surgical training*, or medical training*, or oral and maxillofacial surgery*) AND (virtual reality*, or augmented reality*, or simulation*, or serious games*) were used. Further information about the initial methods of training, measurement of confidence, expertise and early attempts in virtual reality were referenced. The search focussed on non-technical skills for surgical training. The last search date before submitting this report was 05 July 2017. In addition to these, reference lists of various relevant articles were searched. No reports or comments on websites were excluded. News sites, blog posts, and social networking sites including Twitter and LinkedIn were also used to search for updated information on the use of mixed reality for medical training. Additional information from the websites of publishers and authors was also collected.

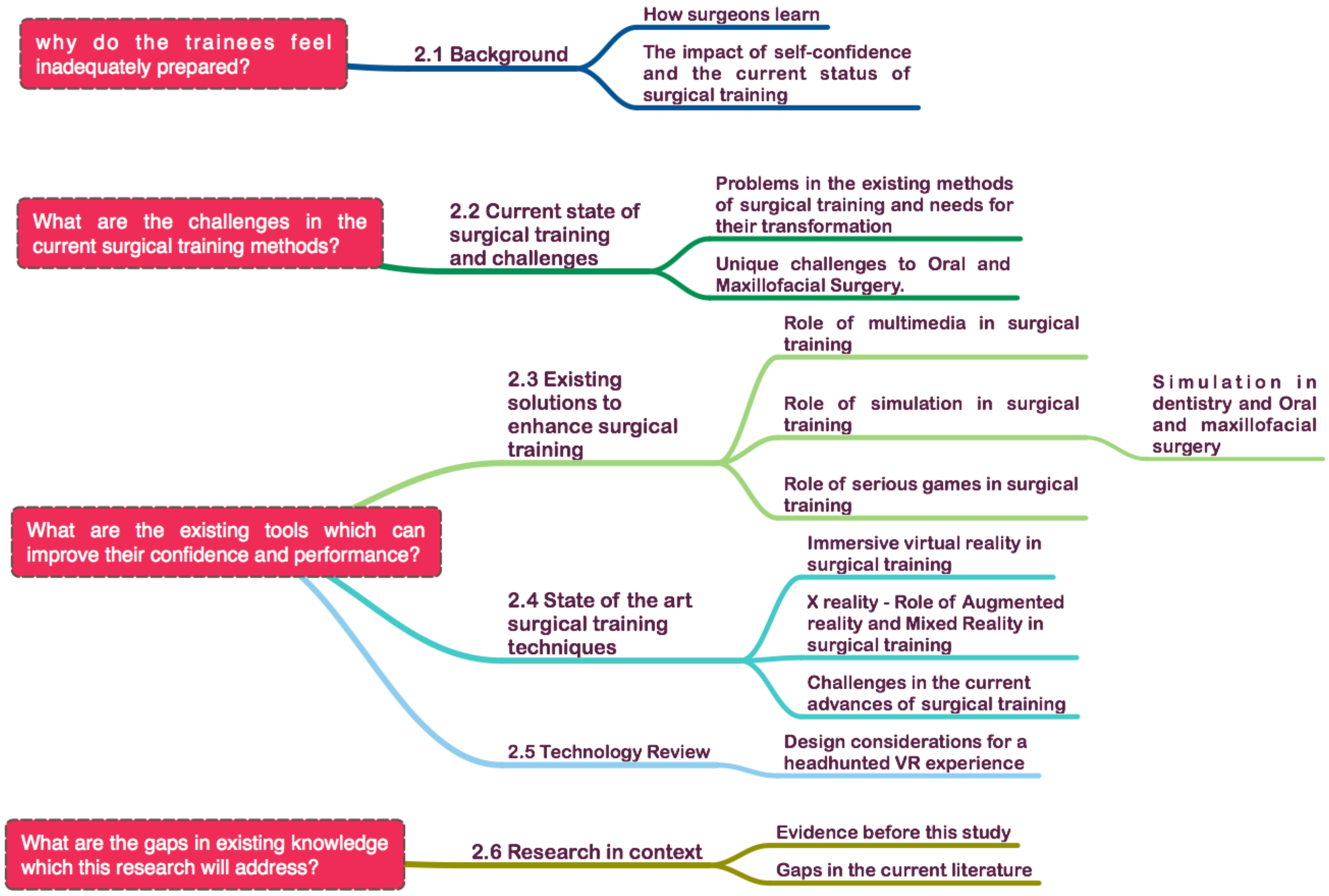


Chart 2-1 Structure of literature review

2.1.1 How surgical trainees become experts

Surgical trainees get trained for five to seven years before becoming practitioners (Woodwards, 2015). Abraham Flexner first suggested this form of post-graduate training in structured residences to the Carnegie Commission (Flexner, 2002). Further, the apprenticeship model of learning took over where trainees observe expert surgeons and learn. Ever since William Halsted proposed the optimal training experience, surgical training has not changed much in the last 100 years (Verrier, 2017).

As the training period is extended, it is important to understand what turns a novice surgeon into an expert, and how to transfer this expertise to trainees. Surgeons learn by performing a task and anticipating the potential complications in a particular task, and the ways to overcome those. A novice surgical trainee enters an operating room with a fundamental knowledge of surgery, anatomy and instruments. By understanding and negotiating the terms in the operating room, trainees learn what they know and what they need to know. This aspect of learning is exponential as the trainees move from unconscious incompetence to conscious incompetence as in Figure 2.1. Novices try to understand the topics at hand and avoid mistakes in the operating room. After attending some surgeries, a trainee gets to understand the surgery, the potential complications that can occur, necessary modifications to be made and alternative steps that can be performed. The next phase is the development of conscious competence by repeated practice. This phase of development is where the concept of deliberate practice comes into play (Ericsson, 2004).

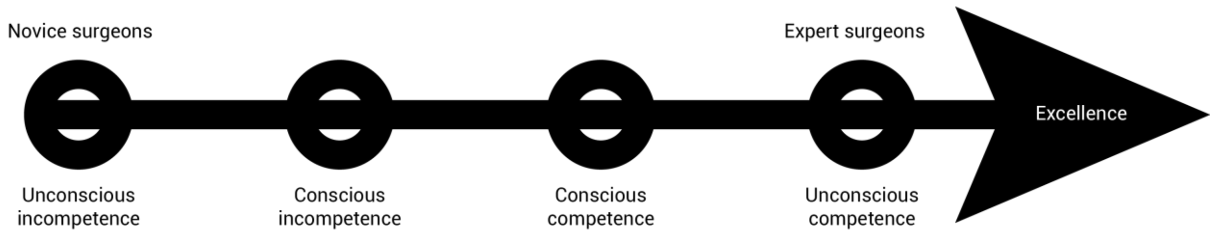


Figure 2.1 Path towards excellence for surgical trainees (Sanders, 2016)

After achieving a basic competence in the fundamental skills, a trainee must overlearn and get to the stage of unconscious competence. From then, they should cross train to develop complementary skills and perform without fear (Verrier, 2017). There has been significant research in the field of psychology to find out what turns a novice into an expert (Ericsson et al., 1993). In contrary to the current belief about expertise, Ericsson and his colleagues argued that experience does not equate to expertise. According to their research, “the major influence in the acquisition of expert performance is the confidence and motivation to persist in deliberate practice for a minimum of 10 years or

10,000 hours" (National Research Council, 1994 p. 173). Conventionally, medical training has focussed on competence, to test if the performance is adequate, instead of excellence. However, Ericsson (2004) comments that even after a surgeon/physician is considered competent and certified to practice, lack of continued training and testing will lead to reduced performance as in Figure 2.2. Excellence, on the other hand, is "the quality of being outstanding or extremely good", (Oxford Dictionary, 2017a). The achievement of superior, reproducible, expert performance requires mastery at different skills, which need continuous assessment and improvement of performance. Surgical mastery is less about physical abilities like hand-eye coordination, but more about familiarity, decision-making and judgement (Gawande, 2011).

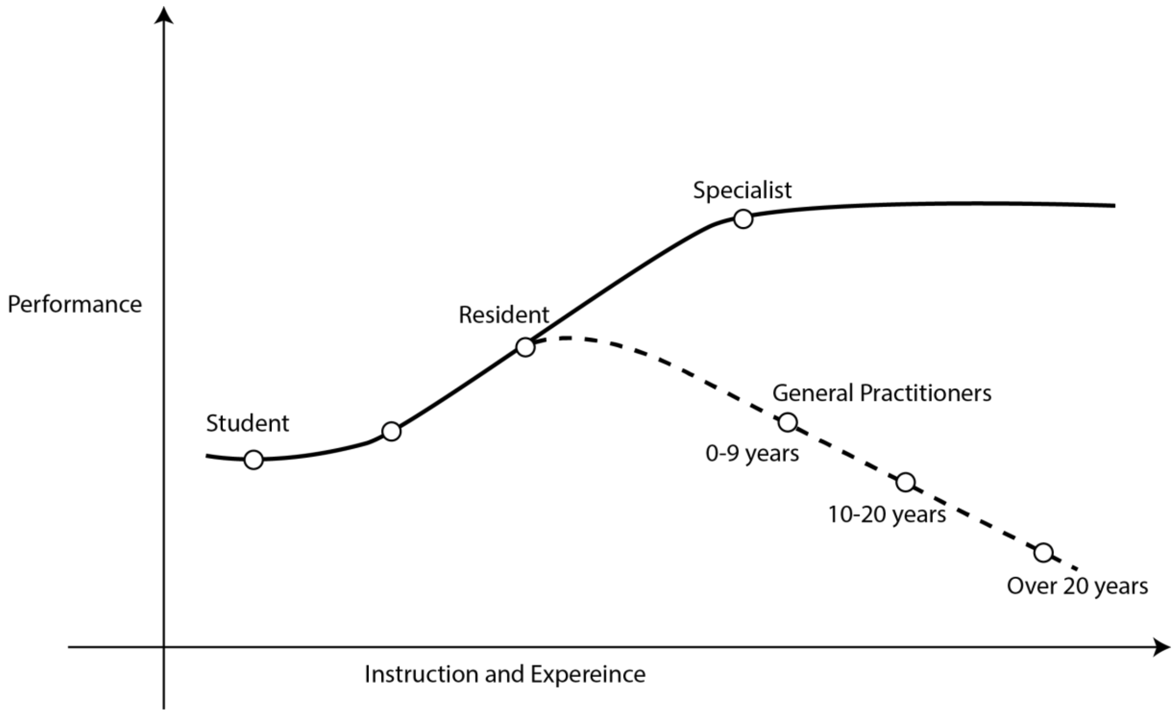


Figure 2.2 Development of performance as a function of medical expertise (Ericsson, 2004)

These skills require a growth mindset that understands the continuing development of competencies and abilities through deliberate effort, grit, and coaching (Verrier, 2017). Here is where self-efficacy and self-confidence play a major part.

2.1.2 Self-efficacy and self-confidence of surgical trainees

Self-confidence is considered as one of the most influential motivators and regulators of behaviour in people's everyday lives (Bandura, 2006). It impacts the motivation and predicts performance success (Cervone, 2000). The Oxford dictionary defines self-confidence as "a feeling of trust in one's abilities, qualities, and judgement", (Oxford Dictionary, 2017b). In a study assessing the errors committed by junior doctors (Baldwin et al., 1998), the results showed, the biggest cause for the minor and major errors is “feeling overwhelmed” (Baldwin et al., 1998 p . 804)

Multiple researchers suggested that a person’s perception of their ability or self-confidence is the most important factor of their achievements and efforts (Bandura, 1977, Ericsson et al., 1993, Harter, 1998). Literature in cognitive theories indicates a positive correlation between a person’s performance and their assessment (Bandura, 1989). That means those who think they can perform better are more likely to perform better than those who believe they perform poorly. These findings are in line with Rodriguez-Paz et al. (2009) as overwhelmed trainees can feel less confident in performing a procedure. Bandura (2006) distinguishes self-confidence from self-efficacy. “Self-Confidence refers to firmness or strength of belief but does not specify its direction; self-efficacy implies that a goal has been set” (National Research Council, 1994, 174). Self-efficacy, on the other hand, “is not concerned with an individual's skills, but, rather, with the judgments of what an individual can accomplish with those skills” (National Research Council, 1994 p, 174).

Using self-confidence as a performance metric for educational interventions in surgery was previously done by Esterl et al. (2006) and Hoover et al. (2008). A validated scale for measuring self-confidence of trainees was developed by Geoffrion et al. (2013) in Gynaecology. They found that self-confidence of a trainee varies with the number of procedures (hysterectomies here) performed by a trainee. Previous research by Mitchell et al. (2012) and Klingensmith and Brunt (2010) also showed that the self-confidence increases with the practical learning experience.

Confidence in handling a situation increases as the exposure to relevant scenarios increases (Binenbaum et al., 2007). Further, by reflecting on performance, a trainee can show an improved self-confidence, which is vital for continuing professional development. However, the challenge with reducing training hours affects trainees’ confidence. This finding and the previous works indicate a need to improve trainee’s confidence, without creating false positives (Dunning et al., 2003). Current training methods do not focus on this aspect of learning, as they are common for every surgical trainee. As self-confidence is found to improve the performance of trainee, more research is needed in this aspect of training. In specialities such as Oral and Maxillofacial surgery, there is a lack of education and assessment tools to improve trainee’s confidence. Further, questions have been raised if the current training is sufficient (Hupp, 2011).

2.1.3 Different forms of learning by surgeons

Surgical training comprises of two major aspects, namely technical skills and non-technical skills (Yule et al., 2006). Technical skills are the manual abilities required to perform the surgery, which is traditionally learnt through mentoring and hands-on practice (Satava et al., 2003). However, reduced opportunities for surgical trainees to undergo mentoring sessions led to the use of cadavers, plastic models, and technical skills labs (Anastakis et al., 2003). As a result, the majority of the current surgical training suites focus more on the technical skills (Wingfield et al., 2014). However, studies concerning major mishaps in the operating room have found that the underlying causes of the errors are poor non-technical skills of the surgeons (Bogner, 1994, Fletcher et al., 2004, Dedy et al., 2016). Lack of proper communication, cognitive skills, diagnostic and decision making skills lead to multiple unanticipated errors during surgery. This lead to the need for more focus on the non-technical elements of surgical training. Some researchers (Aggarwal et al., 2004, Hull et al., 2012) have highlighted the potential application of non-technical skills training in future simulations.

Non-technical skills include a broad range of competencies such as cognitive skills, which comprise of subject knowledge, teamwork and decision making skills, which integrates knowledge with expertise (Cuschieri et al., 2001, Baldwin et al., 1999). While most of the surgical training methods including recent advances did not focus on the cognitive skills, their role in learning was found to be quite significant (Kneebone, 2009, Aggarwal et al., 2004). Supporting this argument, Spencer (1978) suggested that, surgical training comprises of 75% of cognitive skills and 25% mechanical ability. A model of learning as proposed by Fitts and Posner (Wingfield et al., 2014) as seen in Figure 2.3 emphasises that, in the process of gaining various surgical skills, cognitive stage forms the base, followed by associative and automated stages (Shuell, 1990). In the beginning stages of training, novice trainees often depend on their cognitive skills, whereas experts work from automated stage. Hence, in the process of surgical training, experts tend to miss the most important cognitive stage leading to poor learning outcomes.

Focus on non-technical skills in the early stages of training will leave more time for trainees to practice their technical skills when they perform the procedure (Shariff et al., 2014). Also, experienced surgeons understand the importance of these skills in surgical training (Baldwin et al., 1999). Despite acknowledging their importance on overall improvement in the performance, the emphasis on cognitive training skills is limited to very few surgical specialities (Cuschieri et al., 2001)

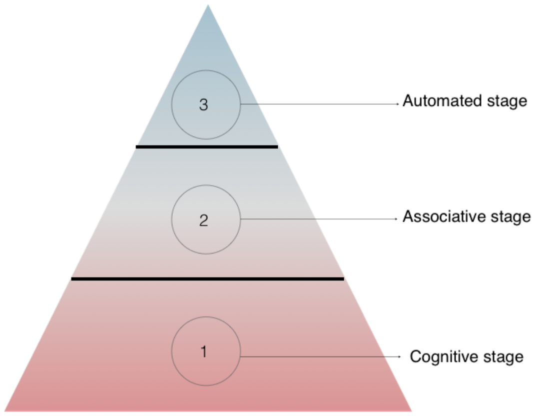


Figure 2.3 Fitts and Posner's education model (Wingfield et al., 2014)

Existing studies on the cognitive skills training revealed that in most of the cases, traditional educational forums, lectures, and other forms of self-directed learning were employed. In the next section, the current state of surgical training and their challenges are discussed.

2.2 Current state of surgical training and its challenges

2.2.1 Learning in operating theatres

Attendance to the operation theatre begins at the undergraduate level in most of the medical schools as a part of the curriculum. Lyon (2004) has given a detailed overview of learning methods in operation theatre by systematically interviewing medical students and surgeons about the training. This study reported that "operation theatre provides a sensory perceptual experience" (Lyon, 2003 p. 681) to help students develop a 'clinical memory' of the procedure. Trainees get to observe the involved pathology, touch and understand its spatial location and visualise the surgery at a greater detail. Hence it is vital for surgeons to utilise the teaching opportunity in operation theatres and spend longer hours exploring different procedures for gaining necessary knowledge to perform surgery. This aspect of cognitive expertise is critical, as lack of knowledge on how to perform a surgery can harm the patient (Wingfield et al., 2014).

According to Lyon (2003), learning in the operating room is divided into three domains. First, trainees understand how to negotiate the environment in operation theatre and cope up with the stress. Second, the trainees need to know the learning objectives of their attending the session. Undergraduate students and early stage surgical trainees experience stress related to operation theatre sessions secondary to the limited preparation and an insufficient orientation regarding the surgical procedures. Thirdly, they have to work comfortably with the rest of the staff at the operating theatre. The findings of these studies also suggest that non-technical skills including developing trust, understanding students' legitimate role in learning can result in a good learning experience in the operation theatre. A study on teaching in operation theatres by Roberts et al. (2012) suggested that even though the technical skills can be mastered in skills laboratories and virtual simulations, teaching within operating room remains the cornerstone of surgical education. Hence it is vital for surgeons to utilise the teaching opportunity in operation theatres.

2.2.2 Challenges in operating room training sessions

The average working week of UK medical trainees has been curtailed to 48 hours by European working time directive (EWTD) (Royal college of surgeons, 2014) to encourage the safety and health of workers in healthcare. However, more than 50% of the trainees feel that this 48-hour work week has severely affected their training (Hartle et al., 2014). Also, the number of procedures attended by the trainees have come down by 3000 due to the EWTD. Reduction of the training hours also affects the interaction between the trainer and the trainee. A recent review of various medical specialities' response to the EWTD by Lambert et al. (2016) showed a negative response by surgeons.

Restricted resident training hours and increased pressure on faculty to increase productivity are severely affecting surgical training within the operation theatre (Hartle et al., 2014). Moreover, an increase in public scrutiny for medical errors only meant that the surgeons could not allow training surgeons to perform complex cases. For these reasons, current trainees will have to carry out complex procedures on the patients without any prior practice. Previously, Lyon (2003) found that teaching in operation theatre is often under-utilised leading to poor training outcomes. This emphasises a need to reinforce the learning objectives and identify more realistic teaching objectives in the operation theatres (Roberts et al., 2012). Other problems including overcrowded operating rooms and limited visibility of the surgical site further increase the chances for poor training. Lack of preparation to the operating ambience and inability to handle the stress within the surgical environment adds to the mounting challenges in training. At the same time, current literature provides limited evidence of tools which address these challenges in training.

As the operating room is a multifaceted environment, it exposes trainees to many challenges. They include learning about a complex procedure, assisting under time pressure, expert evaluation, multitasking and distractions (Wilson et al., 2011). In the early stages of surgical training, it is difficult to take in so much of information and also learn at the same time (Royal college of surgeons, 2017). This aspect of training increases the cognitive load and reduces the quality of training. Early stage surgical trainees experience much stress related to operation theatre sessions because of the poor preparation and lack of orientation to the procedures (Meyer et al., 2016). Poor preparation of trainees to real world settings also shows a negative impact on their future performance (Lydon and Burke, 2012). These negative experiences trigger anxiety and reduce the overall self-confidence of trainees, deteriorating their performance.

2.2.3 Challenges in oral and maxillofacial surgical training

Oral and maxillofacial surgery is a surgical speciality that diagnoses and treats the diseases and deformities affecting the oral cavity, jaws, face and neck (Woodwards, 2015).

Surgical training in this field involves gaining expertise in the complex surgical anatomy of the face, comprehensive planning and prediction of expected technical difficulties while performing multiple duties in a tensed operating room environment. This makes the training process not only long but also less efficient (Buchanan, 2001). Reduction in the time for surgical training (Zuckerman, 2005) and increasing shortage of surgeons globally (AAMC, 2010) further escalate the need for training surgeons to learn by themselves and self-evaluate (Keerl et al., 1999). Especially in Oral and Maxillofacial surgery, where there is a high requirement for experiential learning and the percentage of working hours is largely over 48 hours a week as shown in Figure 2.4, this regulation brought a significantly adverse effect. Reduced training hours means not many surgical residents get to observe and practice the techniques until after they enter the operating theatre.

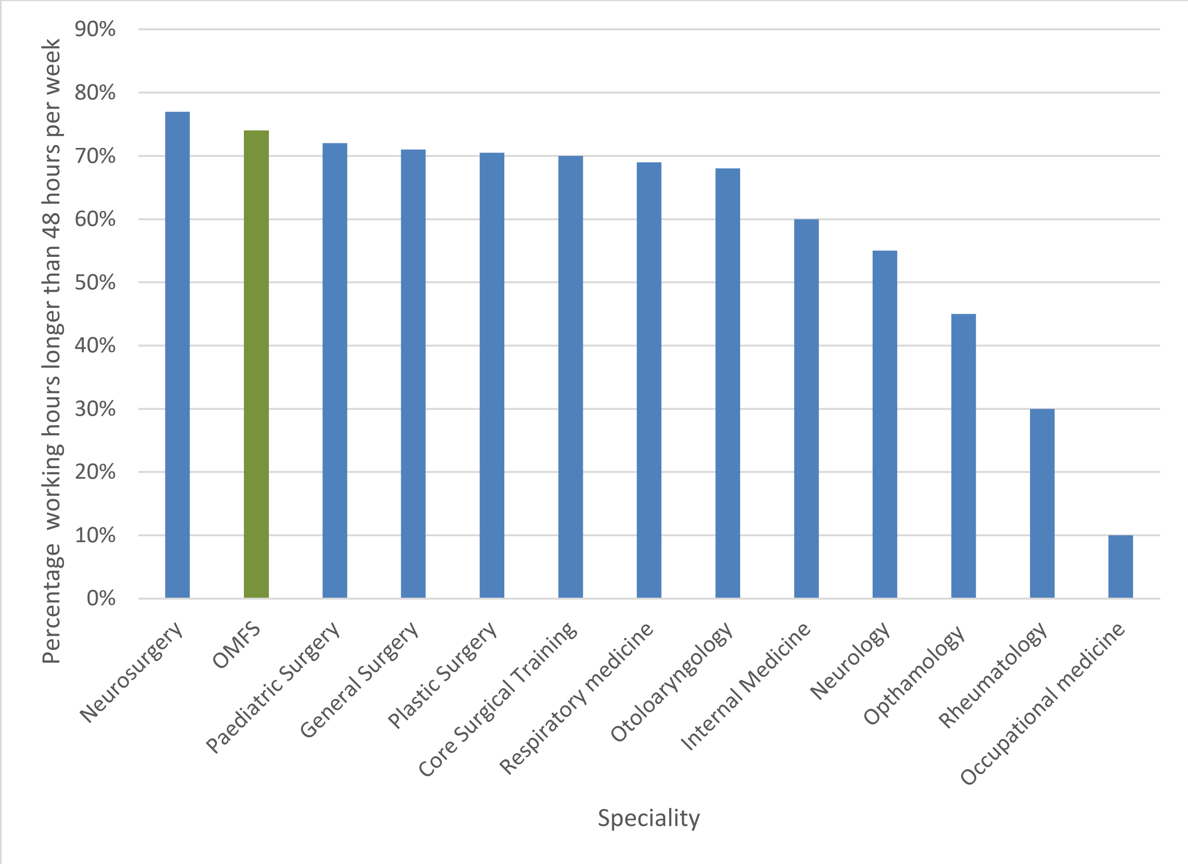


Figure 2.4 Normal working hours for different medical disciplines (Royal College of Surgeons of England, 2014)

Further, inherent complexities in procedures such as the Le Fort I osteotomy, which involve disjunction of maxilla from the base of the skull requires a trainee to be confident at the cognitive and technical aspects of the surgery. All the above findings indicate the need for advanced training methods.

2.3 Existing solutions to enhance surgical training

To address the challenges in surgical training, various adjunctive methods including multimedia aids, simulations, serious games were used. This section of the chapter discusses each one of them and addresses the challenges in these methods.

2.3.1 Use of multimedia in training surgeons

Recent studies on procedural based multimedia methods (Friedl et al., 2006, McQuiston et al., 2010, Luker et al., 2008, Maizels et al., 2008, Prinz et al., 2005) highlighted the advantages of multimedia methods over traditional forms of learning. Multimedia techniques, which stimulate the visual and auditory receptors were improving the understanding better than the conventional methods (Summers et al., 1999). The ability to interact with the content and flexibility in reviewing the material was found to be the key feature in the acquisition of knowledge through this technique.

Audio-visual aids including videos of the surgical procedures are an effective educational method and a primary source of learning for surgical trainees and surgeons equally (Tolerton et al., 2012, Cosman et al., 2007). Surgical videos disclose the anatomy, provide a scope for learning different techniques, and can be paused and reviewed for particular aspects of the surgery. These videos allow the trainees to connect remotely, and in some cases interact with the performing surgeon (Dinscore and Andres, 2010). Increased accessibility to surgical education allows hands-off media learning to geographically dispersed trainees (Mutter et al., 2011). Surgical videos were also found to improve practice-based learning among expert surgeons (Graves et al., 2015). Despite their benefits, capturing high-quality surgical videos is complicated and involves many challenges including appropriate positioning, compromised battery life and adjusting the lighting conditions.

The techniques of capturing video of the surgical procedures were previously studied by Cosman et al. (2007) and Graves et al. (2015). The position of the cameras in the operation theatre makes a significant difference in the video and the resultant learning. Traditionally cameras fixed to the operation theatre lights were used to capture the surgery. However, these cameras do not have a user interface and customs control of the recordings. Also, in surgical specialities involving body cavities, such as maxillofacial surgery, light fixed cameras cannot be used. To address this challenge, Graves et al. (2015) used commercially available Go Pro Hero 3+ cameras for plastic surgery procedures. Head mounted cameras were used to create first person visualisation of the surgery. The findings of this study showed that videos captured using narrow field were satisfactory as those captured with a wider field of view settings. Further, these videos created a satisfactory experience when watched on a computer. However, the performing surgeon failed to control the camera recording. Another challenge of the existing camera systems is the lack of extended battery life. As most of the maxillofacial surgical procedures are long and extensive, there is a need for cameras with a battery life longer than 3 hours. Alternatively, power banks would be necessary to support the recording. Finally, low lighting in body cavities including bowel and oral cavity is a major challenge. Conventionally operating room lights or laparoscopic cameras with internal halogen lighting were preferred, but the artificial lighting in low light conditions does not retain the details of the surgical field (Cosman et al., 2007).

Distribution of the surgical videos is another hurdle to overcome. Limited accessibility in university repositories and websites create a need for a better solution. A comprehensive analysis of different websites featuring surgical videos including YouTube, WebSurg (Ircad, 2015), OR live (Broadcast, 2015) showed a lack of uniformity of the content. As different surgeons perform the same procedure differently, a gold standard cannot be created. Also, the lack of narrative in few of the videos makes them difficult to understand. Moreover, very few high-resolution videos are available, which captured all the details of the procedure. Of all the existing websites, only SurgicalTheatre (2015) provides videos of Oral and Maxillofacial surgery along with other surgical specialities. Efforts to find suitable adjunctive to conventional training methods led surgeons to get inspired from the aviation industry and use simulation, serious games and virtual reality for training novice surgeons (Jackson and Gibbin, 2006).

2.3.2 Simulation in surgical training

Simulation suites provide surgeons with a safe environment for practising their skills multiple times without causing any damage to the patient (Issenberg et al., 1999). Multiple studies (Evgeniou and Loizou, 2012, Kapralos et al., 2014) have confirmed the positive implications of simulation for surgical training including skills transfer (Sturm et al., 2008) and improvement in training efficiency (Gurusamy et al., 2008). They also help in shortening the learning curve of surgeons (Patel et al., 2006). Based on the technology used and the complexity of skills trained, the classification of simulators can be made (Torkington et al., 2000). Simulators used in surgical training varied from physical simulators to computer-based virtual reality simulators (Sutherland et al., 2006). Physical simulators include cadavers, animal models and inanimate plastic models, foam suturing pads and box trainers for laparoscopic surgeons (Diesen et al., 2011, Vitish-Sharma et al., 2011). However, physical models suffered from a lack of realism; cadaveric dissections suffered from a lack of their availability, legal restrictions and ethical concerns limiting their use. These factors pushed researchers more towards technology based surgical simulations including serious games and virtual reality experiences (Sarker and Patel, 2007). Moreover, virtual reality based simulators were found to be more efficient in training surgeons than physical simulators (Orzech et al., 2012).

Compared to the traditional hands-on approach, simulation provided more cost effective and efficient opportunities for surgical practice (Devlin, 2002, Pan et al., 2011). Repeatable surgical techniques in a safe environment improved the learning curve of trainees and played a vital role in patient safety when transferred to the clinical environment (Kunkler, 2006). Before their application in healthcare, simulators were used in the aviation industry (Allerton, 2009). Further, they were applied to various aspects of the medical field including laparoscopic surgeries, cardiovascular emergencies and operating room emergencies (Lamkin, 1998, Gallagher et al., 1999, Székely and Satava, 1999).

Simulation in dentistry and oral and maxillofacial surgery

Out of all the surgical specialities, Oral and Maxillofacial surgery has seen the most number of changes in training methods (Devlin, 2002). Nevertheless, surgical residents do not practice surgical techniques until they participate and assist in live surgery. This approach requires extended training, and its efficiency is limited (Buchanan, 2001).

In Dentistry, the simulation was primarily used to bridge the gap between the pre-clinical sessions and clinical environment. Research on simulation based learning for pre-clinical training (Buchanan, 2001) suggests that virtual reality is an effective adjunct to conventional training methods when provided with 3D visualisation, haptic force feedback and real-time feedback on the procedure. Virtual reality was introduced by Székely and Satava (1999) to improve surgeon's knowledge of anatomy and surgical technique. The advances in general surgery then helped in the development of Image-guided implantology, where a trial surgery for placing implants could be done; however, it lacked the haptic feedback force. With further developments in the application of virtual reality training, Voxel Man simulator introduced for middle ear surgeries has been adapted to the field of dental surgery (Leuwer et al., 2001, Jackson and Gibbin, 2006, Von Sternberg et al., 2007).

Pohlenz et al. (2010) utilised Voxel Man Simulator for virtual apicoectomy procedure and found that out of 53 dental students who undertook virtual apicoectomy, 51 were positive regarding the positive impact of virtual reality simulation as an adjunctive training method. The trainees indicated that the integrated haptic feedback, 3D visualisation, and high resolution of the simulator were key features for virtual training of the dental surgical procedures. Trainees also developed the ability to self-assess their performance which is a valuable skill in surgery. Pohlenz et al. (2010) also proposed that application of virtual surgery using the 3D reconstruction of patient's anatomy might help surgeons to plan complex procedures. Kusumoto et al. (2006) proposed a study on bone drilling for placement of implants in the mandible and found that the results of virtual reality training were close to reality and hence can be used for training dental students and surgeons. Seymour et al. (2002) supported the above findings and suggested that use of virtual reality to reach specific target criteria significantly improved real life performance in operating theatres.

The applicability of using 3D visualisation in dental training was also reported by Anderson et al. (2013), where a haptic dental injection was developed for inferior alveolar nerve block injection as shown in Figure 2.5. To explore more complex surgeries of bone, Wu et al. (2014) developed a virtual training system called VR-MFS with advanced haptic feedback and immersive workbench.

Figure 2.5 Haptic dental injection (Pulijala et al., 2015)

In addition to drilling, VR-MFS system allowed cutting and milling aspects of the bones. 3D stereoscopic visualisation on an immersive workbench provided visual, tactile and aural feedback bringing it close to reality. Le Fort I maxillary osteotomy was simulated in VR-MFS; the cutting and drilling trajectories were compared with a preoperative plan for evaluation. Wu et al. (2014) found that expert surgeons' trajectories were close to the plan when compared to the novices. Though the experts believed that VR-MFS could be used for skill development, they pointed out that the system lacked realistic simulation that is required for effective training.

Most of the existing models of simulation focused on the technical skills of the surgical trainees. Non-technical skills including cognitive development, interpersonal communication, teamwork, and emergency management are hardly touched upon except in few studies (Aggarwal et al., 2004). The technical skills learnt by the trainees on the virtual surgery simulators are expected to transfer into a stressful environment of operation theatre. However, as a surgical procedure is a combination of expert anatomical knowledge, spatial visualisation, judgment and inter-professional teamwork, it is essential to give a holistic learning experience to the trainees (Verrier, 2017). Hence, there is a gap in the modern simulators developed for oral and maxillofacial surgery, which needs to be met adequately. Researchers attempted the use of serious games and gamification of simulations to overcome these training obstacles.

2.3.3 Serious games in surgical training

Though simulation and games seem to be closely related, they stand at different ends of user engagement and learning as shown in Figure 2.6 (Prensky, 2004). Simulations widely differ from games with higher fidelity and clear learning outcomes (Graafland et al., 2012). Serious games create a balance between simulations and games by providing measurable learning outcomes in a fun and engaging manner (Graafland et al., 2012). A detailed systemic review on the application of serious games in surgical training by Graafland et al. (2012) showed the gamification of surgical education for decision making, teamwork and cognition. Game-based training has also proved to improve situational awareness, an essential aspect of surgical training (Graafland et al., 2017). Issenberg et al. (2005) in their systemic review detailed the key aspects of simulations which can improve learning in medicine are feedback, ability to practice repeatedly, and introduction into the curriculum. Serious games with competitive elements including challenge drove to practice and incentives driven scoring techniques to play a major role in surgical training (de Wit-Zuurendonk and Oei, 2011).

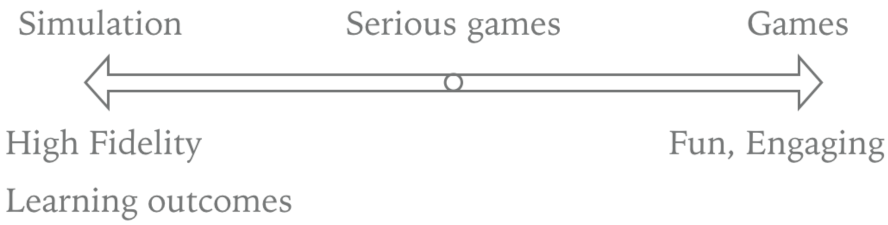


Figure 2.6 Differences between simulations and games

Challenge driven serious games can be applied where repeated practice is necessary to gain expertise, such as decision-making skills. Intra-operative decision making, one of the core competencies for surgical trainees can be learned through this technique (Michael and Chen, 2005) as serious games provide an opportunity for deliberate practice till a level of expertise is reached. Another application of gaming element for decision making is seen in Figure 2.7, a mobile app, Touch Surgery (Touch Surgery, 2015). This application trains the cognitive skills of surgeons through cognitive task analysis method (Wingfield et al., 2014) and tests their decision-making skills at the end of it. In addition to the aspects mentioned above, feedback in learning, intrinsic scoring and multiplayer performance in serious games helps the trainees to practice their teamwork skills. When such serious games are placed in a clinical environment (Paige et al., 2009) they will reinforce the communication and teamwork skills necessary to practice in real life emergencies. Immersive virtual reality based serious games were used to provide a sense of presence within a clinical environment.

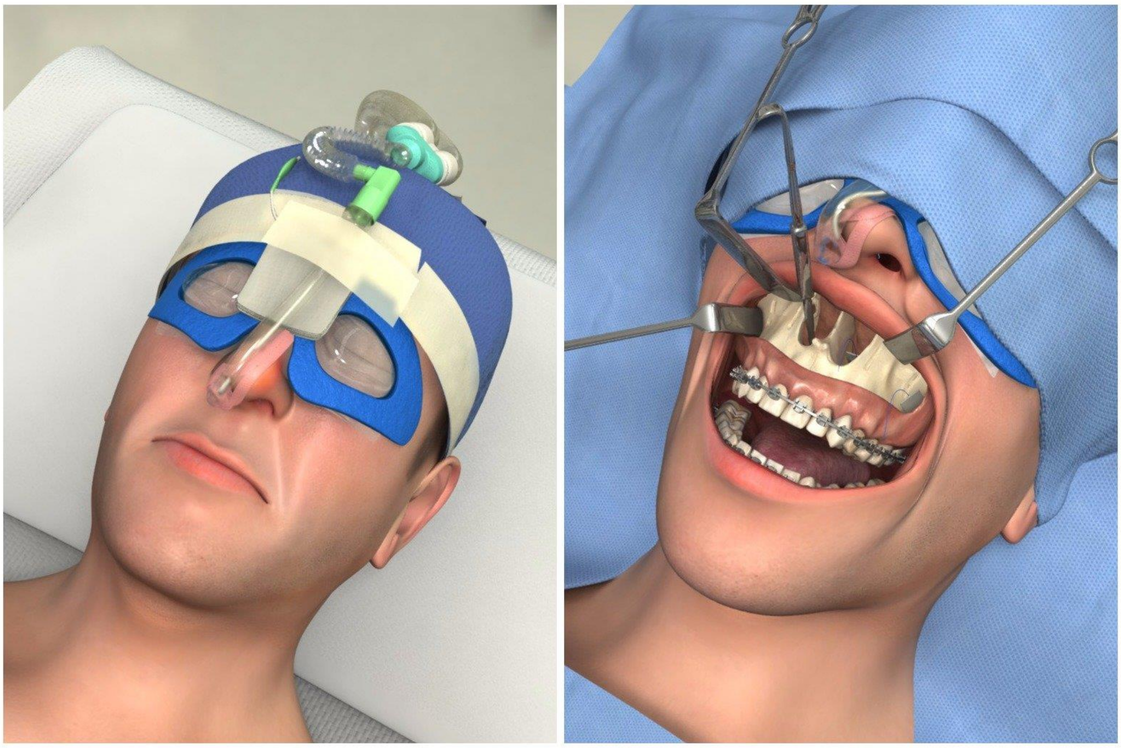


Figure 2.7 Le Fort I module in Touch Surgery mobile application (Touch Surgery, 2015)

The drawbacks in simulations, serious games and physical simulations led the researchers to explore the state of the art head mounted virtual reality and augmented reality technologies. The next section of this chapter outlines the research in those aspects.

2.4 State-of-the-art surgical training methods

2.4.1 Immersive virtual reality in surgical training

Virtual reality (VR) is a human-computer interface, which simulates a real life setting and allows a user to interact with it in a computer generated 3D cyberspace (Burt, 1995). The basic elements of every virtual reality experience include immersion, interactivity and involvement of the user within the virtual environment (Freina and Ott, 2015). The essential goal of virtual reality is to create a sense of being present in an environment. Early researchers described ‘presence’ as the illusion of non-mediation (Lombard and Ditton, 1997, Lee, 2004) or the suspension of disbelief, which enhances the illusion created by the medium (Slater and Usoh, 1993). Based on the level of presence experienced by a user, Virtual reality technology can be broadly classified into immersive virtual reality and non-immersive virtual reality.

Non-immersive VR involves computer generated experiences on a desktop, while the user interacts with a mouse, and still feels his real environment. Conventional surgical simulations fall under this category. For an immersive virtual experience, the user wears a head-mounted displays or goggles to engage his visual senses, headphones to engage his auditory senses, and gloves to engage his tactile sense. The first immersive experience was created using a mechanical device called the Sensorama; it provided an experience of riding a motorcycle including all the sensory stimuli to simulate presence.

Following Sensorama, earlier head-mounted VR displays created in 1965 were more complex and demanding on the computer power (Freina and Ott, 2015). The high cost and low accessibility of high computing power, which is required to remove any delay in processing (Gallagher et al., 1999) meant the lower adoption of these head mounted displays. Rapid advances in technology and research led to the introduction of commercially available high quality immersive virtual reality devices including Oculus Rift (Te, 2015), Google Daydream (Google, 2017a) Gear VR (Samsung, 2015), Google Cardboard (Google, 2015a) and HTC Vive (H. T. C. Corp, 2015). Among these Google Daydream, Gear VR and Google Cardboard headsets can create a portable virtual reality environment as they work with smartphones.

These lead physicians to explore the potential of immersive spherical videos in medical education. Flores-Arredondo and Assad-Kottner (2015) used a 360º virtual reality application in association with Jaunt VR technology to record ultrasound guided access in a perivascular disease and preparation of Medtronic’s Core Valve. The equipment allowed an immersive visualisation with head tracking technology which could be experienced on a VR headset. Shafi Ahmed, 2015 (Miller, 2015) recorded colorectal surgical procedures which could be watched on YouTube in 360 degrees. These videos give an experience of ambience to the user by removing the observer parallax thereby making the user feel his presence next to the surgeon. Further reduction in the costs of the virtual reality devices and an increase of their commercialisation are creating a greater demand for creation of compatible videos on these devices.

These immersive technologies are ideal for surgeons to experience real life scenarios, which are not faced frequently in their regular practice (Moorthy et al., 2006). A realistic simulation of operating room on these devices can not only provide and immersive experience but can also cut down the costs spent for training according to ASIT (2015) and (Bridges and Diamond). This creates the possibility of situated learning (Lave and Wenger, 1991) and contextualised learning (Kneebone, 2009, Kneebone et al., 2004), where surgeons can learn within a clinical environment such as an operating room. In addition to the context of the application, the amount of psychological immersion (Lombard and Ditton, 1997) in the task defines a trainee's involvement in performing a particular procedure. Applications of commercially available VR head mounted devices (HMDs) including Oculus Rift in medical education started with anatomy applications (Carson, 2015). Though limited literature is available on its application in surgery (Juanes et al., 2016), commercial projects are exploring this arena. The first known surgery that was viewed on Oculus was made by Moveo Foundation (2015) who produced a video on hip replacement surgery. The procedure was captured using Hero dual camera (Go Pro, 2014) to create a stereoscopic visualisation. They recently produced another video on shoulder's fracture surgery. Recently the same team demonstrated a live feed of a procedure (Quinn, 2016) where a surgery to resect bowel carcinoma was viewed by trainees all over the world. Applications like these show how global inequalities in surgical training can be fixed with virtual reality. At UCLA, neurosurgeons are exploring its application for viewing the internal structure of the brain and the tumours using medical data of the patients (Reuters, 2015). Advances in immersive VR are now combined with surgical training, and a new paradigm is being introduced. The next section briefly discusses Mixed reality and how emerging advances in surgical training methods are making an impact.

2.4.2 X reality – A new paradigm in experiencing reality

X reality (XR) (Somasegar, 2017) is a term recently coined to denote the advanced alternative experiences that combine digital and biological realities. Including a broad spectrum of devices and interfaces, X Reality(XR) encompasses Virtual Reality(VR), Augmented Reality(AR) and forms a part of the mixed reality continuum as in Figure 2.8. Irrespective of the advances in these technologies, there is a lack of clarity amongst the different terms including virtual reality, augmented reality and mixed reality. The next section aims to clarify these differences by addressing different technologies regarding their representation of reality. Additionally, emerging advances in surgical training and their challenges are outlined.

Reality and alternative realities

The reality is subjective to every creature, dependent on the senses and limited by its biological receptors (Eagleman, 2015). Eagleman argues there is no one objective reality and every living being perceives a part of the reality in its subjective manner, dictated by its biology. Thus, all the living creatures experience virtual reality in precise terms (Eagleman, 2015). The reality-virtuality continuum provides an understanding about the scope of alternative realities as shown in Figure 2.8 (Milgram and Kishino, 1994).

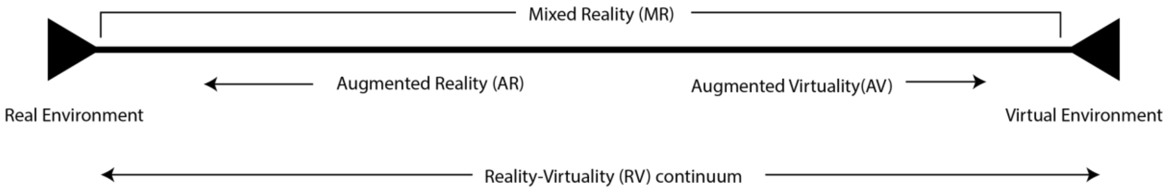


Figure 2.8 Mixed reality continuum (Milgram and Kishino, 1994)

On the extreme left is the real subjective environment. The right extreme is an entire computer-generated virtual environment and experiences. The continuum shows augmented reality where virtual information can augment the reality and augmented virtuality where real information augments the virtual environment. Brief descriptions of immersive virtual reality, augmented reality and mixed reality is provided below and explained in an article for Wired by Kelly (2016) as in Figure 2.9.

- Immersive virtual reality (iVR) occludes the natural environment of the user and places them in a different location; either computer generated or video. Head mounted Oculus Rift, HTC Vive, Google Daydream experiences fall under this category.
- In augmented reality, the visible natural world is overlaid with a layer of digital content. This digital content can be computer generated 3D models or information in the form of text, images, or data. Google Glass (Swider, 2017), Hololens (Griswold, 2017), and handheld devices like Google's Project Tango (Google, 2017b) fall into this category.
- In Mixed Reality, "virtual objects are integrated into—and responsive to—the natural world (Kelly, 2016)". For example, a virtual light bulb can turn on the surrounding environment and cast shadows based on the objects in the room.

Some applications of Microsoft Hololens and MagicLeap (2017) fall into this category.

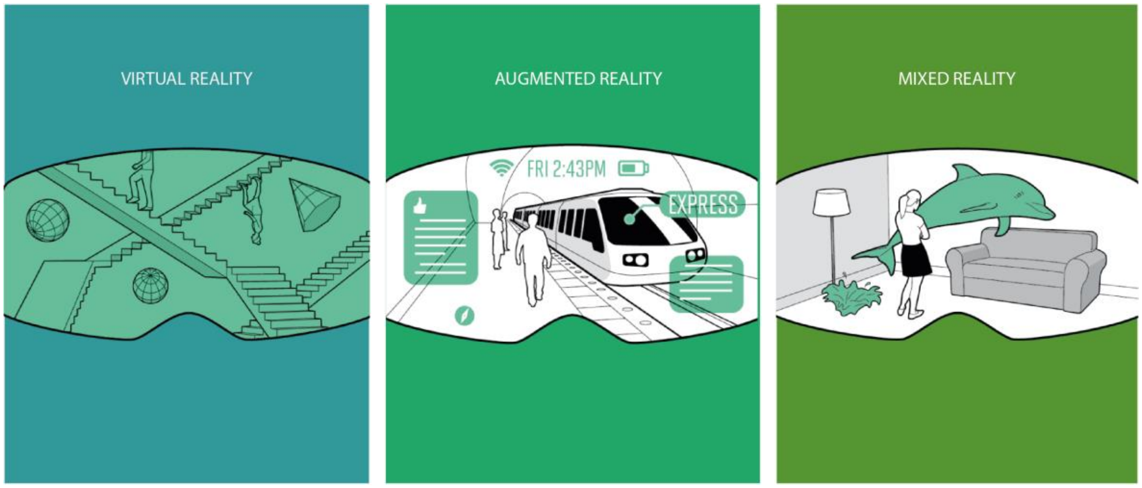


Figure 2.9 Virtual, Augmented and Mixed Reality representations (Kelly, 2016)

A combination of iVR and a 3D depth-sensing camera can create an enhanced augmented reality experience (Lee, 2017).

Emerging advances in surgical training methods

A recent Grand View Research report read the VR market growth size worth is $48.5 billion by 2025, with a compound annual growth rate of 46.7% (Grand View Research, 2017). With increasing evidence and demand for virtual reality tools, multiple research bodies and companies entered the space of X reality in the last three years (Flink, 2017). Following is a list of the recent advances in mixed reality applications for healthcare.

- A mixed reality dental treatment simulator combining Oculus Rift, Leap Motion and a go pro camera was demonstrated recently at the International dental show in Germany (Realize Mobile, 2017). The application of technology and dental science make this project similar to the current research. The application does not create 360-degree visualisations and is not showing surgical procedures currently. Also, the application of this system in training is not known.
- Mc Gill University Healthcare Centre uses AR for ENT surgery (Reporter, 2017, Scopis medical, 2017). They used Target guided surgery (TGS) by integrating it with operating room video endoscopy and provides the ability to observe and perform surgery. TGS identifies anatomical structures and surgical instruments in a 3D space. Surgical planning and actual surgery can be recorded to combine it as a training tool.

- Fundamental VR creates mixed reality experiences using AR and haptics (Fundamental VR, 2017)
- Case Western University, Hololens, Cleveland Clinic on using hololens and mixed reality for education and training (Griswold, 2017)
- Medical realities built a similar immersive VR experience to VR Surgery for laparoscopic surgical procedures (Ahmed, 2017)
- A team from University of Texas, Dallas created virtual patients for practising complex procedures (Varghese, 2017)
- A 360º visualisation of operating room was used in recreating videos of life-saving surgeries by Northern Arizona University (2017)
- Cambridge Consultants created an augmented reality application with HoloLens, which shows real-time patient information for minimally invasive surgery (Cambridge Consultants, 2017). Scopis built a similar navigational surgery application for spinal surgery (Scopis medical, 2017).

2.4.3 Challenges in the current advances

Despite all these advances, there are certain challenges in adopting immersive virtual reality training tools. The commercial versions of Oculus Rift and HTC Vive need high specifications of software and hardware for a satisfactory virtual reality experience (VR, 2016), but computers with high specifications are not easily available in University teaching hospitals and NHS (Serjeant, 2016). The cost of Oculus Rift can also act as a barrier in few cases. Lack of awareness about the innovative virtual reality technologies can be a reason for the trainees not to experience this mode of learning. Device based challenges including motion sickness, latency and lack of force feedback are other issues. These challenges will be met shortly, given the speed at which technology is being developed.

2.5 Technology review

Various head mounted virtual reality devices were considered to create an immersive visualisation in VR Surgery (Lamkin, 2017). The criteria for selection of a device was its ability to display a video in high resolution, without lag, and create an immersive visualisation. Devices including the Oculus Rift (Oculus, 2015b), HTC Vive (Htc, 2011, H. T. C. Corp, 2015) Gear VR (Samsung, 2015) and Google Cardboard (Google, 2015b) were identified. Oculus Rift DK2 head mounted display was selected due to its availability, cost and efficiency at the time of research. It is also compatible with motion tracking devices such as Leap Motion and Unity 3D game engine, which allows development of VR applications. Additionally, online support communities of Oculus Rift were useful in building this app.

As shown in Table 2.1, a comparative account of various VR devices is widely discussed (Lamkin, 2017, Eadicicco, 2017, Robertson, 2017, TechAdvisor, 2107). However, these devices were not available when the VR Surgery project was initiated.

Table 2.1 Comparative account of different VR headsets (Hall and Betters 2017)

	HTC Vive	**Oculus Rift**	**PlayStation VR**	**Gear VR**	**Cardboard**	**Daydream**
Resolution	1080 x 1200 per eye	1080 x 1200 per eye	1920 x 1080 per eye	1280 x 1440 per eye	Up to 1440 x 1280 per eye	1440 x 1280 per eye
Refresh rate	90 Hz	90 Hz	90-120 Hz	60 Hz	60 Hz	60 Hz
Field of view	110	110	100	101	60	90
Head tracking sensors	Yes	Yes	Yes	Smartphone	Smartphone	Smartphone
Positional tracking	Lighthouses	Optical	Optical	No	No	No
360 degree tracking	Yes	Yes- require extra tracking	Yes- require extra tracking	No	No	No

Room scale	Yes	Yes	No	No	No	No
Motion controllers	Yes	Yes	Yes	No optical controller available	No	No
Sound	Yes-not built in	Yes	Yes	No	No	No
Weight	555g	470g	610g	318g	220g	<100g
Wireless	No	No	No	Yes	Yes	Yes
Multiplayer	Yes	Yes	No	No	No	No
Price	$799	$599-799	$399	$100	$15	$79

However, majority of these devices suffer from challenges such as Screen door effect and VR Sickness. On a conventional liquid crystal display (LCD) screen, every pixel is subdivided into red, blue and green sub-pixels. The distance between the subpixels is called Pixel pitch. The number of pixels and their organisation defines a Pixel fill factor (Desai et al., 2014) as shown in Figure 2.10. If the screens have high pixel pitch, then the fill factor will be high, bringing more clarity to the image or video being played. In the case of Oculus Rift DK2, the pixel fill factor is adequate, but as the screen is placed close to the eyes, the dark gaps between the pixels appear as shown in the figure, leading to the screen door effect (Desai et al., 2014).

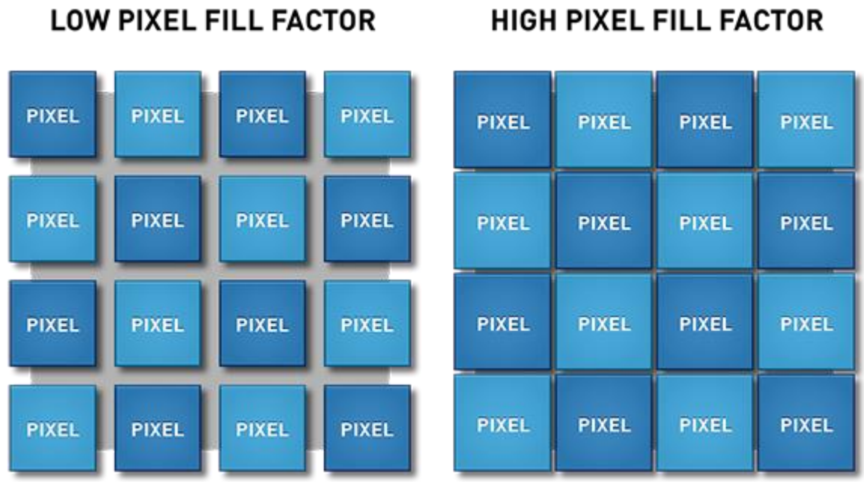


Figure 2.10 Pixel fill factor (Luckey, 2012)

On the other hand, VR sickness occurs when the virtual environment causes symptoms similar to motion sickness (Joseph J. LaViola, 2000). The commonest symptoms are nausea, vomiting, headache, and fatigue. Disorientation caused due to unwanted movement of the video causes this condition (Stanney et al., 1997). Virtual reality (VR) sickness is the major reason to omit head mounted camera recording in VR Surgery.

In addition to the limitations of the technology, there are specific considerations in the design of applications when head mounted devices are used. The next section explains the design considerations.

2.5.1 Design considerations for a head mounted VR experience

User Interface in Virtual reality is divided into Non-diegetic UI or Diegetic UI (Oculus VR, 2016). Non-diegetic UI is an overlaid text close to the screen showing fixed elements like the number of correct responses, and the life of a player. However, a rigid panel close to the camera in the head mounted VR creates a sense of holding a newspaper fixed to the view at all times. A fixed panel close to the point of view is a bad practice for VR and was not used in the design of VR Surgery. Diegetic UI, on the other hand, is a responsive and spatial UI that scales with user's position and is dynamic according to the movement of the head. Diegetic UI elements were used for labelling of the videos and different bones of the skull and quiz questions.

While using Oculus Rift DK2, the experience is limited to a seated position. Hence the UI design should consider the horizontal and vertical head movement. As a head mounted VR provides the user with freedom to interact in any direction, it is necessary to examine the different elements, which determine the user's freedom. They include the pitch, yaw, roll, distances (vertical and horizontal), the point of convergence and focus; and size of pupil's aperture as shown in Figure 2.11. It means the head tracking should be kept constant and active at all times as the user is free to rotate their head to any aspect of the scene.

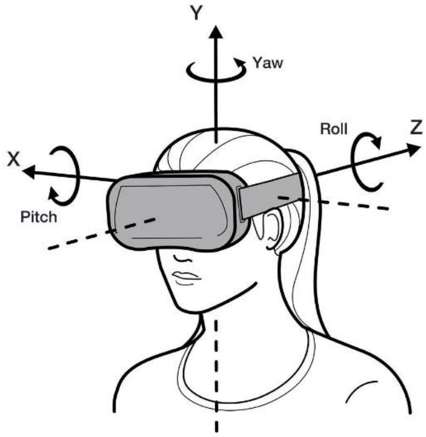


Figure 2.11 Different degrees of freedom (Oculus, 2015)

Ideal zones of horizontal head movement

Oculus Rift DK2 has a horizontal field of view of 94.2° when the user is looking straight. Users can rotate their head comfortably up to 30°and a maximum of +/- 55° to left or right as in Table 2.2(Chu, 2014). However, prolonged movement of the head to the limits strains the neck and disrupts the user experience. The horizontal head movement covers a 210-degree angle if a person completely rotates including his shoulders.

Table 2.2 Horizontal and vertical head rotation limits (Chu, 2014)

Orientation	Comfortable (Degrees from 0)	Maximum (Degrees from 0)
Left/Right	+/- 30	+/- 55
Up	+20	+60
Down	- 12	-40

Ideal zones of vertical head movement

A vertical downward movement of the neck more than 40° or vertical upward movement of the head more than 60° causes strain in the neck and medical issues like spondylitis as shown in fig Figure 2.12 (Marc, 2015). Eyes look around in a maximum angle of 100° and a circular pattern (Figure 2.13). The field of view (FOV) for the eyes is 70°. This means the content which needs to be read without rotating the head needs to be placed in a frame of less than 70° within the viewable space for an optimal user experience as in Figure 2.14. In the design of VR Surgery, the researcher followed these specifications for user interfaces and their placement in the operating room environment.

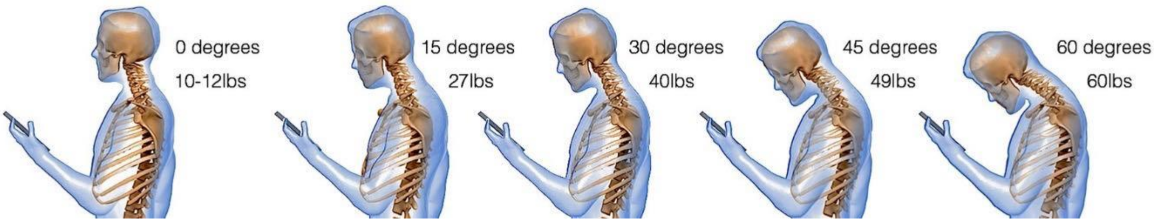


Figure 2.12 Vertical head movement is associated with tension beyond a point (Marc, 2015)

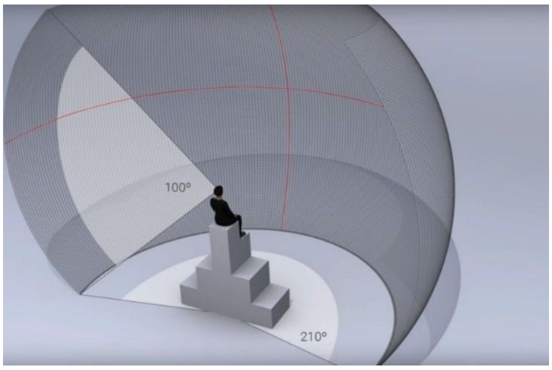


Figure 2.13 Field of view of human eyes (Faaborg et al., 2015)

Figure 2.14 Appropriate placement of text zone (Alger, 2016)

The third aspect is depth. The distance of the text and images from the eyes causes a sense of depth in Virtual reality interfaces. Human eyes have a potential to accommodation and convergence. When an object is too close to the eyes, the eyes converge to show the object in 3D. Any object placed less than 0.5 m from the eyes strains the user to be cross-eyed. Any object beyond 20 m does not appear 3D. Therefore, an ideal distance is between 0.5m to 20m as shown in Figure 2.15. In VR Surgery, the video content was at 5m away from the cameras.

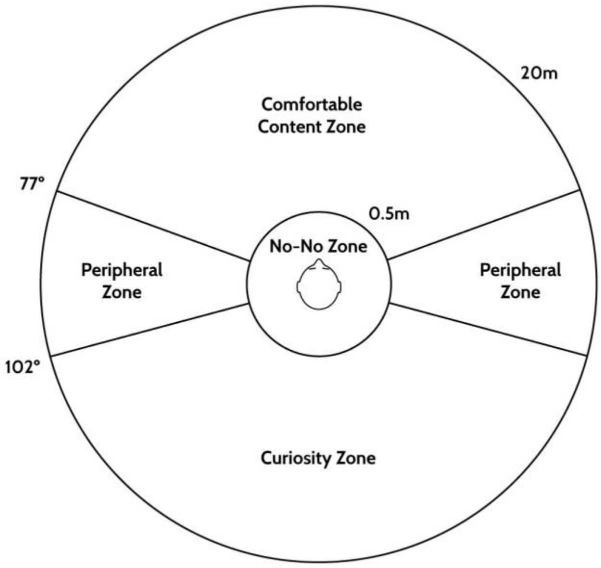


Figure 2.15 Goldilock zone for placement of text in VR (Alger, 2015)

Another aspect is the readability of text in VR. As the resolution of Oculus DK2 is 1920X1080, there was a noticeable pixelation of anything that occupies a few pixels in width and height. That is why the scale and font of the text are important in VR UI design. While the size of text and its distance is one aspect, the type of font itself affects the user experience. Thin fonts such as Roboto Ultralight, which is well appreciated in print and web media, shows hard edges on Oculus as shown in the Figure 2.16. Antialiasing will partially help, but the program will be heavy to run. Alternatively, the researcher used an effective pixel per unit count to soften the edges of text (Oculus VR, 2016).

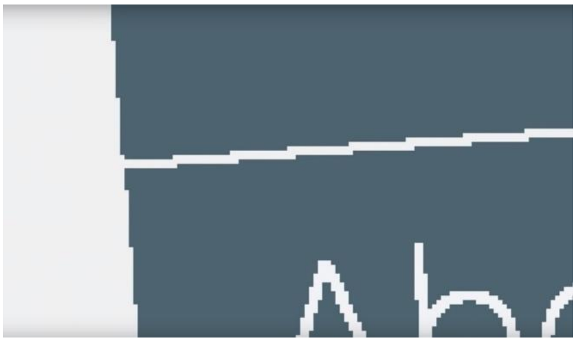


Figure 2.16 Hard edges to thin font (Alger, 2016)

Another challenge while developing content for head mounted VR is Vergence-accommodation conflict (Hoffman et al., 2008). It is a frequently reported technical issue in the current head mounted displays including Oculus Rift as everything is focussed at 1.2 m from the eyes. While watching stereoscopic 3D videos, the introduction of non 3D elements including menu buttons or other 3D elements such as hand user interface disrupts the user experience. This reduces visual performance and causes fatigue because of the vergence-accommodation conflict (Hoffman et al., 2008). Normally, vergence and accommodation work together to provide a satisfactory viewing experience. While watching stereoscopic content, the left and right eye offset creates a closer appearance of an object and causes the eyes to converge as shown in Figure 2.17. However, a 3D object placed at a longer distance confuses the eyes with a different focus and vergence points.

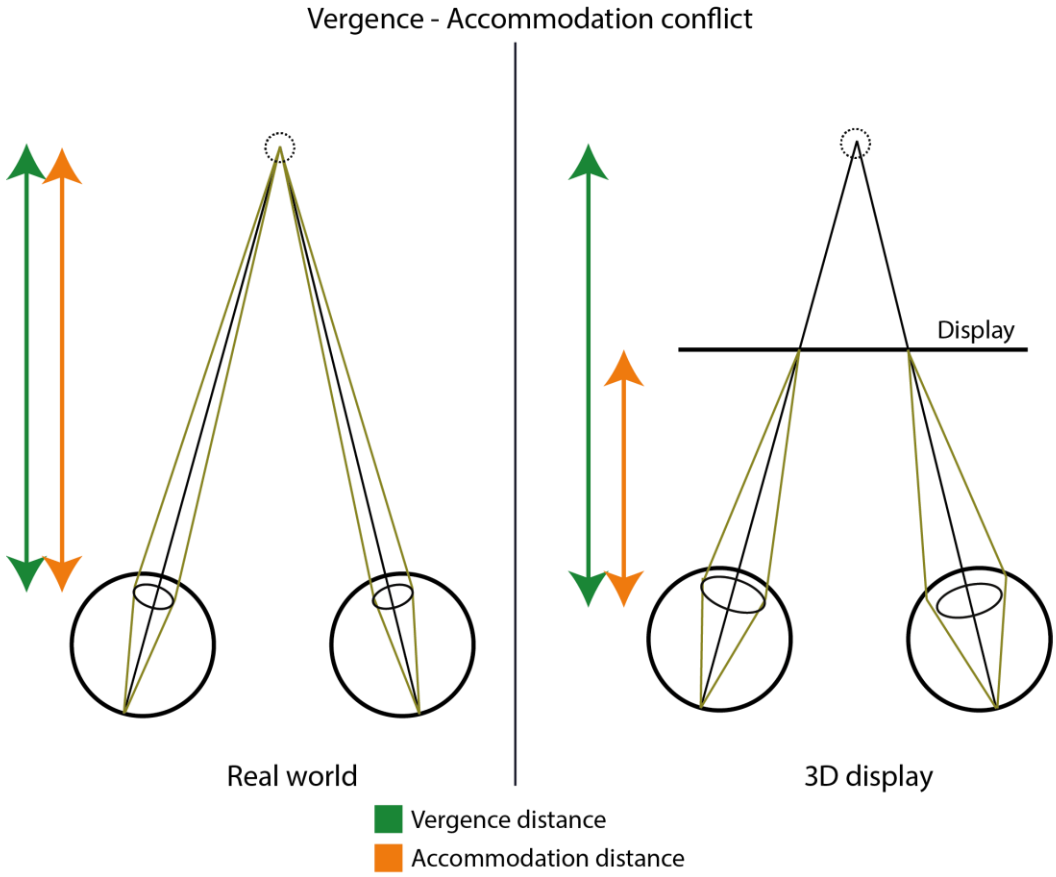


Figure 2.17 Vergence- accommodation conflict (Hoffman, Girschick et al. 2008)

2.6 Research in context

This part of the chapter puts the current research in context to what was already present, highlighting the gaps and outlining the contributions of this study.

2.6.1 Evidence before this study

The Lancet Global Commission on Surgery's report (Meara et al., 2015) emphasised the need to enhance the surgical workforce and improve the quality of training to address the global challenges in surgical care. The majority of the training still happens in operating rooms, and more than 50% of the trainees feel inadequately trained with the 48-hour work week (Hartle, Gibb and Goddard, 2014). Despite multiple studies

(Baldwin et al., 1998, Geoffrion et al., 2013, Rodriguez-Paz et al., 2009) suggesting the drawbacks of current training methods, surgical training has not changed much in the last 100 years (Verrier, 2017).

The majority of the current research in virtual reality simulations is about Laparoscopic Surgery and technical skills (Kowalewski et al., 2017, Tarcoveanu et al., 2011). A recent systemic review covering virtual reality simulators in ENT (Piromchai et al., 2015) established the importance of non-technical skills in training, but the know-how of introducing these skills into virtual reality training modules was not explained. There is a lack of supporting evidence on the application of immersive virtual reality experiences for surgical training except for a few studies (Juanes et al., 2016, Badash et al., 2016). A recent review article on virtual and augmented reality applications in neurosurgery (Pelargos et al., 2017) outlined various devices, available applications, their advantages and limitations.

2.6.2 Gaps in literature

- There is a lack of evidence on how to design and develop immersive VR experiences for training surgeons, leading to a clear gap in understanding about what works, and what doesn't for surgical training purposes.
- Application of immersive virtual reality experiences for maxillofacial surgeons is not well documented in the existing literature.
- Validation studies and efficacy trials to test the effectiveness of Oculus Rift based surgical training experiences are not well documented.
- Evidence on the impact of iVR experiences on a trainee's self-confidence and learning are not documented.

2.7 Summary

This chapter begins with a background in to how surgeons learn and what affects their self-confidence. A state of the art technology review is then provided to highlight the advances in surgical training methods. The chapter further describes the existing literature in surgical training and a context about the gaps in the knowledge. The contributions of the current research are focussed towards addressing these gaps. Further, the next chapter presents the research methodology with a focus on design science research.

Chapter 3 Research Methodology

3.1 Introduction

This chapter explains the process followed by the researcher to articulate and address the research questions. The overarching aim of this research is to find whether immersive virtual reality provides an effective solution to meet the deficiencies in the current surgical training systems. By investigating the existing methods of surgical training and their challenges, the following research questions were deduced:

1. How could various teaching elements be combined to create a holistic surgical training experience?
2. What are the essential design and technical elements to consider while developing an immersive surgical training experience using virtual reality and motion sensing devices?
3. What is the validity and effectiveness of using iVR applications for surgical training?

To address these questions, the researcher reviewed the existing solutions in surgical training. Based on the understanding of the needs, and availability of the technology, head mounted virtual reality technology and motion sensing technology were chosen. The outcomes of this research are a technological solution, an evidence-based pipeline to build advanced surgical training tools using iVR, design and research principles in development and evaluation of the solution.

Conventionally, the nature of research outcomes determine the research methodology and the type of the study. In most of the natural and social sciences, which focus on analysing and understanding the present world, the theory is the primary research product (Venable, 2006). However, the sciences of artificial (medicine, engineering) change the current world into a better one by explaining how to do a process, which in turn provides a theory with clear prescriptions for constructing a solution (Simon, 1996). In the current research, the outcomes include an innovative solution, which enhances the quality of surgical training. Knowledge contribution in the form of an artifact is called ‘Theory for Design and Action’ by Gregor (2006). As the design elements of solution were combined with theoretical knowledge and understanding of science, this research follows the ‘Design Science Research (DSR)’ methodology. Typically, researchers follow this approach to build solutions that can solve real life challenges.

The next part of the chapter outlines the philosophical standpoint of the researcher. After a brief introduction to DSR, the reasons behind this research approach are explained. A clear positioning of DSR is established by differentiating it from design practice and action research. Additionally, the pathway followed in the research is highlighted with individual steps explaining the progress of the application. The structure of the research path explained in this chapter is later followed in the rest of the Thesis. Further, the research outcomes and the contribution to knowledge are highlighted. Though the research methodology was planned ahead of the work, it has been modified in the process of the project. A timeline showing how the research evolved into its current state is presented at the end of this chapter.

3.2 Philosophical standpoint

Before dwelling into the research methodology, it is important to examine the underlying research philosophy to understand the nature of the research. The following text briefly explains the philosophical standpoint from an ontological, epistemological and axiological perspective of the researcher and justifies the research methodology.

The Oxford dictionary defines Philosophy as “the study of the fundamental nature of knowledge, reality and existence, especially when considered as an academic discipline (Oxford Dictionary, 2016).” The philosophical standpoint in research is explained regarding ontology, epistemology and axiology (Saunders et al., 2009). Ontology explains about the reality, the perception of reality and its influence on the behaviour. Ontologically, a researcher can take a stance at any point in the continua between two different points, which are widely known as objectivism and constructivism. This research takes a pragmatist approach and recognises that there are many ways of interpreting reality and undertaking research. A single point of view can never give the entire picture, and there may be multiple realities (Phillimore and Goodson, 2004). Epistemologically, the researcher follows Interpretivism or Anti-Positivism, where the researchers act as social actors, and their concepts and theories shape the world (Norris, 2005). Axiologically, this research is value biased as the application is developed through the impact of values and opinions of the researcher, which affect the data collection and data analysis. As the principal investigator is a dentist, and as he designed the application for maxillofacial surgeons, the content, design principles and questions were developed in line with their learning goals. Based on this philosophy, the primary researcher approached the research questions as the only objective to be addressed, irrespective of the methods.

3.3 Research Approach

The two most important research approaches include Deductive and Inductive approaches. The deductive approach starts with a theory and tests the hypothesis (Winter and Aier, 2016). However, VR Surgery follows the alternative, which is the Inductive approach. This method involves researching to create a theory, which starts with a research question, observation, description, and analysis eventually giving rise to a theory. As VR Surgery is one of the first applications in immersive virtual reality for maxillofacial surgical trainees, there is a limited theory on which a hypothesis can be based. As described previously, this research will help in building theory regarding the essential ways of design and techniques to be followed for creating virtual reality surgical experiences. Hence it follows the Design Science Research (DSR).

3.3.1 Design science research approach

Design science research (DSR) was a research paradigm and now increasingly accepted as a research method in Information Systems (IS) research (Von Alan et al., 2004). This method creates artifacts to solve organisational problems (Simon, 1996). Von Alan et al. (2004) provided the following seven guidelines for Design Science Research as in Table 3.1. Following these guidelines, the current research involves designing an iVR training tool (guideline 1), which addresses the challenges in surgical training (guideline 2). The solution was tested for validity (guideline 3) and evaluated for its efficacy (guideline 5). This solution was further iterated and modified based on the state of the art technology and feedback from the participants (guideline 6). The outcomes of this research were an objective solution, the theory behind its creation and the knowledge for future researchers in this area (guideline 4 and guideline 7).

Table 3.1 Guidelines for Design Science in IS Research (Von Alan et al., 2004, Venable, 2006)

Guidelines	description
Design as an artifact	A design artifact, which is viable and identifiable must be produced.
Problem relevance	A relevant and important problem must be adressed by the design.

Design evaluation	Research rigour must be applied to test the utility, quality, and efficacy of the design artifact.
Research contributions	The contribution to knowledge must be well defined and verifiable. These contributions can arise out of the novelty, generality, and significance of the designed artifact.
Research rigor	Research methods must be rigorously applied.
Design as a search process	Research must be conducted with the knowledge of alternative approaches and should address the process in a cyclical problem-solving process, in which solutions are tested against each other and their efficacy for solving the full problem.
Communication of research	The results should address the rigour requirements of the academic audience and the appropriate needs of the professional audience.

As the current research involves creating a solution to meet the problems in surgical training, the solution is an artifact. Artifacts in design science can be either descriptive or prescriptive (Winter and Aier, 2016). Descriptive artifacts such as principles, patterns, and theories are used to find the truth about the object of analysis through statements. On the other hand, prescriptive artifacts are used to address a goal or purpose. As explained by Winter and Aier (2016), they can be technological rules, management principles, and educational interventions. One of the outcomes of the current research is a prescriptive artifact. Artifacts are further divided by Gregor and Hevner (2013) into the following five types.

- **Constructs** – Provide the necessary vocabulary to understand the problems/solutions. For example, in the current research, the artifact explains the terminology of virtual reality, immersive virtual reality, presence, immersion, and surgical training.

- **Models** (Problem or solution) – Mathematical or conceptual models to represent problem or solutions.
- **Methods** – Algorithms or recipes for performing a problem solution task. Teaching/learning methods fall under this category. Algorithms used in building Leap Motion interactions and Cognitive task analysis technique used in building VR Surgery falls under this category.
- **Instantiations** –The entire VR Surgery application can be considered as an instantiation as it is a physical realisation that can be used for training novices.
- **Design theory** – Abstract prescriptive knowledge that describes the principles of form, function, and justification to develop the artifact. The theoretical outcomes from the current research fall under this category.

The current research artifacts fall under 'Construct' type of descriptive artifacts and Methods, Instantiations, and Design Theory types of prescriptive artifacts. It is not abnormal to have an artifact, which is of different types, as the artifact types are not to be treated as separate ideas, but as interdependent concepts, as shown in Figure 3.1 (Gregor and Hevner, 2013).

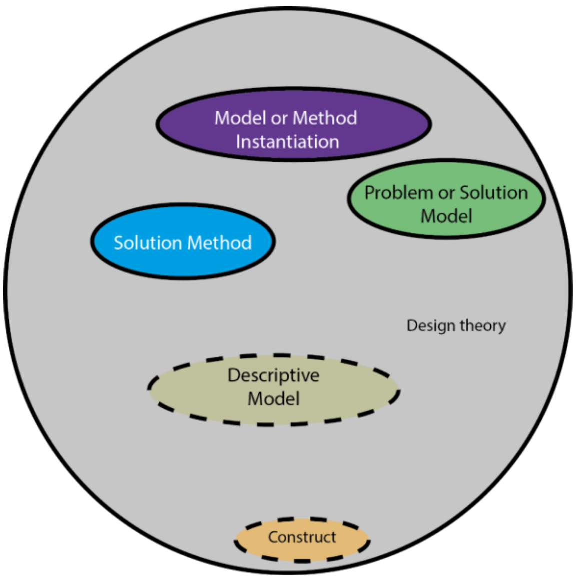


Figure 3.1 Artifact types in business innovation research with solid lines as prescriptive and dashed lines as descriptive artifacts (Gregor and Hevner, 2013)

3.3.2 Positioning current research

In the field of DSR, there are related and similar aspects including Design Practice and Action Research. It is essential to address if the current research is a design practice or a design science research or an action research while describing the contribution to knowledge.

Design practice involves building practical solutions to specific problems in specific cases in specific conditions. On the other hand, Design science (research) is not limited to solution search for problems but a wider application of knowledge to other fields with relevant problems. Though VR Surgery is a training tool for surgical trainees in Oral and Maxillofacial surgery, the principles of this application can be applied to other forms of surgical training. Further, this research does not involve only using technology but creates knowledge in how to build immersive training tools for surgical training. This essential contribution of the current research makes it a Design science, and not Design practice (Venable, 2010).

3.4 Contribution to knowledge – Design theory

Contribution to knowledge is the foremost criterion for research in Information Systems (Straub et al., 1994). As previously mentioned, the theory is considered as the main form of knowledge contribution in natural sciences and social sciences (Simon, 1996). However, in the sciences of artificial, knowledge contribution can be a combination of partial theory, and a design artifact (Gregor and Hevner, 2013). This type of theory which formalises knowledge contribution in DSR is called Design theory.

The contributions to knowledge from the current work include the iVR solution as the viable artifact, and the resultant knowledge as the abstract theory as shown in Table 3.2. This research established a generalised understanding of iVR apps for surgical training from VR Surgery to enhance the external validity of the current research. Gregor and Hevner (2013) gave a classification to knowledge contribution from less abstract to more abstract with different maturity types.

Table 3.2 Types of contribution from Design Science Research (Gregor and Hevner, 2013)

	Contribution Types	Example Artifacts
More abstract, complete, and mature knowledge	Level 3. Well-developed design theory about embedded phenomena	Design theories (mid-range and grand theories)
More specific, limited, and less mature knowledge	Level 2. Nascent design theory—knowledge as operational principles/architecture	Constructs, methods, models, design principles, technological rules.
	Level 1. Situated implementation of artifact	Instantiations (software products or implemented processes)

The current research belongs to Level 1 and Level 2 with VR Surgery and its design principles. The understanding of building training tools for other surgical procedures comes under Level 3 of knowledge contribution as shown in Table 3.3.

Table 3.3 Type of knowledge contribution by the current research

Contribution type	**Artifacts**	**Justification**
Level 3	Generalizable knowledge, which can be transferred to other surgical specialities	The theoretical contribution of this research combines multiple elements to create a training tool. This understanding is transferrable in building other surgical training tools.
Level 2	Design principles in building immersive virtual reality training tools	The design principles of VR Surgery explain how to use multiple media and combine them together to create a training tool for surgeons
Level 1	VR Surgery	VR Surgery application is an instantiation for surgical trainees in oral and maxillofacial surgery.

Another aspect of understanding the level of knowledge contribution in a DSR is the “newness” of the created information. Understanding the contributions regarding ‘problem maturity’ and ‘solution maturity’, Gregor and Hevner (2013) proposed a 2x2 matrix as in Figure 3.2. The horizontal axis represents the maturity of the problem solved whereas the vertical axis represents the maturity of the artifacts as solutions to the research questions.

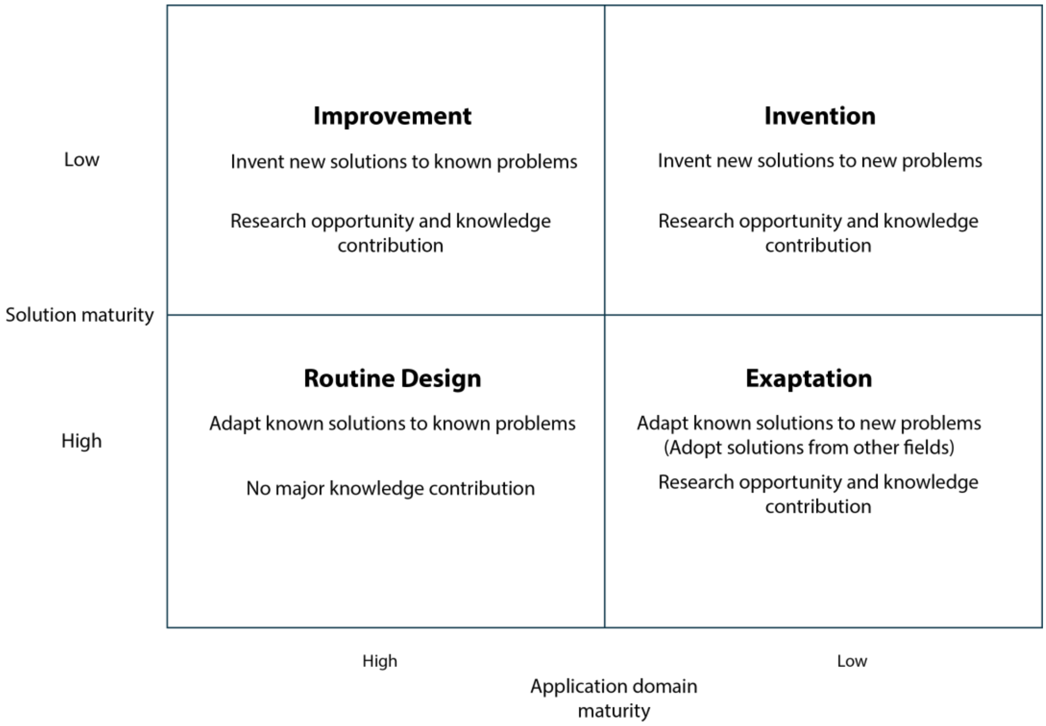


Figure 3.2 DSR Knowledge contribution framework (Gregor and Hevner, 2013)

As VR Surgery is a new solution to existing problems in surgical training, this project falls under ‘Improvement’. According to Gregor and Hevner (2013), the key challenge in improvement quadrant is to prove that the new solution is an effective alternative to the existing sub-optimal solution. Two important aspects to be demonstrated are the ability to represent and communicate the artifact design, and the evaluation of the artifact to show evidence of improvement over current methods.

3.5 Research process

This part of the chapter explains the research process. The current research follows a process similar to the DSR process suggested by Peffers et al. (2007). However, it was challenging to demonstrate the various phases in problem assessment, identifying the appropriate solution, designing and evaluating it while collaborating with multiple teams. Further, multiple sub-stages in the research made it difficult to explain the research process concisely (Knox, 2004). To explain this process, we used the 'Monomyth' structure as explained in chapter 1. The individual steps in Design Science Research (DSR) are explained below.

3.5.1 Identifying problem

The DSR process model begins with addressing the problem to be solved (Peffers et al., 2007). It is essential to identify the problem and divide it into sub-problems. Addressing why the problem needs to be solved is an essential requirement. The maturity of existing solutions as in Figure 3.2 shows Henver's 2x2 matrix where the current solutions are to be placed. The understanding of application maturity enhances the value of the proposed solution to the problem. In addition to a thorough literature review, the state-of-the-art practices in solutions need to be identified.

The current research began with understanding the challenges in the current methods of surgical training. Ineffective training in crowded operating rooms warranted a need for advanced solutions. The research further identified sub-problems regarding the necessity of a clear visualisation of surgery, a need for holistic surgical training experience, and need to improve the self-confidence of surgical trainees in oral and maxillofacial surgery.

The literature review identified the challenges in teaching within the operating room. The researcher further outlined how surgical trainees learnt using advanced simulators and what made the learning more engaging. The process of identifying existing solutions and their use in training was not limited to scientific literature but also included the knowledge from advances in technologies.

3.5.2 Define the objectives for a solution

Based on the understanding of the problem and the domain, the objectives for a solution need to be described (Winter and Aier, 2016). The objectives can be quantitative in improvement solutions, describing the dimensions in which the new solution can be compared to the existing ones.

Based on these requirements, the researcher set out to create an iVR training tool, which combines the operating room learning experience with interactive training. The second objective is to identify the appropriate method of creating these immersive experiences which enhance the training of surgeons by testing different software and hardware. The application will then be compared to the existing methods of surgical training on the knowledge gained and the improvement in self-confidence by trainees.

3.5.3 Design and development

Design and development are the steps where the artifacts are created. "Conceptually, a design research artifact can be any object in which a research contribution is embedded in the design" (Peffers et al., 2007 p. 55). Based on how the design was made, inductive (data-driven) or deductive (theory driven) approaches can be identified.

The current research involves identifying specific hardware and software components and testing them through iterative phases of design. The background knowledge was based mostly on other artifacts (VR apps) and their developments. In addition to the application model, the content has been developed based on the understanding of the knowledge required by a trainee before entering an operating room as explained by expert surgeons. Further, human factors including cognitive task analysis and the hierarchical task analysis were used to identify the structure of the content. Thus both inductive and deductive processes were followed in the iterative development of the solution. A detailed description of the design and development is presented in chapter 4 and 5.

3.5.4 Demonstration

Demonstration involves testing the validity of the solution. It tests if the artifact works as expected and addresses the needs as planned. Experimentation, simulation, case study demonstrates the effectiveness of an artifact (Peffers et al., 2007). Demonstrating VR Surgery took place in two different forms. Surgical trainees and expert surgeons tested the system in the process of development. Further, a face and content validity test by expert surgeons tested VR Surgery on various aspects such as content, usability, applicability to curriculum and overall satisfaction levels. Validity is defined as 'an extent to which an instrument measures what it is designed to measure'(Carter et al., 2005 p. 1524). These measurements may be subjective or objective. Based on their nature, validity measurements are classified into different types including face validity, content validity, construct validity, concurrent validity, discriminate and predictive validity (Gallagher et al., 2003).

Face validity tests if the system "looks like" the way it should look. Typically performed by experts in the field, face validity is the most basic form of subjective validity test (Gallagher et al., 2003). Participants check the resemblance of the system to the real world activity (Carter et al., 2005). *Content validity* is defined as "an estimate of the validity of a testing instrument based on a detailed examination of the contents of the test items"

(Gallagher et al., 2003 p. 1526). This validity test measures the degree to which the system in question covers the subject. Content validity is also a subjective test, based on the experts' knowledge and understanding of the materials used. Objective assessments include Construct validity, Concurrent validity and Predictive validity. *Construct validity* tests "the degree to which the assessment can discriminate between different ability or experience levels"(Carter et al., 2005 p .1524). This means the experiment involves experts and novices testing the system to replicate the difference in their levels of expertise. *Predictive validity* compares the outcomes of a system with those of existing standard tools/systems. Predictive validity provides the strongest evidence among all the validity tests (Carter et al., 2005). A detailed description of validity tests is described in the chapter 6.

3.5.5 Evaluation

The need for evaluation to determine the efficacy of the artifact in solving the problems and achieving the objectives as in step 1 and step 2. Though there are a variety of elements which are used in the evaluation of an artifact (Gregor and Hevner, 2013, Venable, 2010), "utility" is central to the assessment in DSR (Gregor and Hevner, 2013)

An evaluation framework in DSR was proposed by Venable et al. (2012). However, this is where the current research takes a different approach. The current research output, VR Surgery should be treated as an educational intervention. To maintain the research rigour and evaluate the system, a randomised controlled trial, a gold-standard in sciences (Sibbald and Roland, 1998) was chosen. A detailed description of evaluation of VR Surgery is presented in chapter 7.

3.5.6 Communication

The final step in the research process is the communication of research and practice. The communication of DSR artifact should include the severity of the problem to be addressed, the need for a solution, the potential of the artifact to solve the problem, the rigour in testing, and the artifacts' effectiveness (Winter and Aier, 2016). To effectively communicate these elements of contribution, Gregor and Hevner (2013) proposed guidelines in structuring the communication. They proposed the structure as follows, introduction, literature review, methods, artifact description, evaluation, discussion and conclusion. The current structure of this Thesis follows the same order as suggested by Gregor and Hevner (2013).

3.6 Summary

This chapter explained how the current research follows the design science research methodology in addressing the research questions. The researcher outlined the different steps involved in design science research and explained how the current research follows that methodology. Further, explanation regarding the thesis outline and the The next chapter is about the design of VR Surgery, technology evaluation and the implementation of the solution.

Chapter 4 VR SURGERY – DESIGN AND SURGICAL PEDAGOGY

Introduction

VR Surgery provides an immersive learning experience for surgical trainees through pre-recorded stereoscopic 3D videos of surgery and interactive models of patient’s anatomy using an Oculus Rift headset. The surgical procedure demonstrated in this application is Le Fort 1 surgery, a type of maxillofacial surgery, performed to correct lower midface deformities (Miloro et al., 2004).

The design and development of VR Surgery are the most challenging parts of this project. Each section of this chapter involves an understanding of the background information, development of VR Surgery and lessons learnt in the process.

In the background, the researcher discussed basic aspects of surgical training in operating rooms and how it influenced the design of VR Surgery application. This part of the chapter also provides an introduction to ‘Semiosis’, a less researched topic in surgical training. The next part of the chapter discusses the surgical pedagogy of VR Surgery. It elaborates on various scenes in the application including surgical knowledge, knowledge of anatomy, knowledge of instruments, and pre-surgical planning. Procedural knowledge part highlights the details of Le Fort I surgery, the division of content based on cognitive task analysis and how we included different steps of surgery in it.

4.1 Background

The design of VR Surgery application relies on various aspects learned by surgical trainees in the operating room sessions. The knowledge of tacit skills in surgical training is vital because if simulations are not applied appropriately, there is always a scope for erroneous belief by the trainees that simulations will not work (Gallagher et al., 2005). The three most important elements of immersive VR experience in VR Surgery are the 3D visualisation of surgery, the 360-degree experience of the operating room and 3D interaction with instruments.

Cope et al. (2015b) identified different themes of learning in the operating theatre for trainees, surgeons and consultants. Amongst these topics, factual knowledge including the anatomy, knowledge of instruments, steps of surgery and the order in which they should be undertaken are absolute requirements before a trainee performs surgery. Additionally, knowledge regarding the indications for a surgical procedure, the potential complications and the resultant actions to be taken are deemed to be essential. When novices are not confident about the factual knowledge of surgery, it increases their cognitive load in the operating room. In the design of VR Surgery, essential elements of anatomy, instrumentation and surgical sequence were included to build the trainee's self-confidence.

Sensory semiosis, which was defined by Cope et al. (2015a) as the 'ability of a learner to make meaning of what he or she was seeing or feeling' is an under-researched major theme which also influenced the design of VR Surgery. Sensory semiosis can be further split into visual and haptic semiosis, which includes visual and tactile cues used to translate what was seen during surgery into a known theoretical knowledge found in the textbook. Among visual and haptic cues, one predominates other depending on the surgical procedure. In maxillofacial surgeries, a trainee needs an equal amount of visual and haptic feedback for their learning as they are dependent on the knowledge of anatomy and also experience the tactile feedback while handling instruments. On the contrary, while performing a laparoscopic surgery or open surgery, the tips of the long instruments feel the tissues, leaving less scope for haptic cues. In advanced robotic surgery, surgeons sitting at a remote console would only be able to experience visual cues. Because of the general advancement in surgical techniques, visual cues are relatively more important. Further, expert surgeons rely on the rich bank on visual exemplars for their performance. They acquire these through a period of deliberate practice, which is an essential element in becoming an expert (Ericsson et al., 1993). Considering these aspects in learning, VR Surgery provides a detailed 3D visualisation of the surgical anatomy and close-up videos of surgery.

Currently, in the see one do one and teach one approach of learning, a trainee observes a procedure in the operating room, repeats this process multiple times and practices on physical models before performing in the operating room (Di Saverio et al., 2016). A trainee needs the deliberate practice of psychomotor and non-technical skills for an extended period to gain expertise at every aspect of the surgery. Expert surgeons expect trainees to know and understand the sequence of steps, anatomy and instruments before performing the procedure. At the same time, novice surgical trainees, who are new to the operating room have to learn multiple aspects of the surgery while understanding how to negotiate different terms in the operating room.

Multiple aspects of learning demand greater attention and makes the learning more complex.

At the same time, misinterpretation of the visual cues during surgery leads to operative errors (Way et al., 2003). A major reason for this misinterpretation is because conventionally in textbooks, knowledge is presented in the form of simple drawings of anatomy that are not beneficial when a trainee has to identify a structure in a blood filled surgical field. It is necessary for trainees to have a rich repository of realistic visual cues of the surgical anatomy in their working memory to understand the intricate details in a surgical field (Bleakley et al., 2003). Developing a mental model of visual exemplars warrants more attention from surgical trainees while observing surgical procedures in the operating rooms. However, reduced training hours and over-crowded operating rooms prevent them from meeting their targets. As a result, there is a need for better representation of surgical content emphasising visual cues. Addressing this need, VR Surgery replicates surgical field at depth using stereoscopic 3D videos and close-up 2D videos.

In a previous study Gallagher et al. (2005) proposed that didactic teaching of surgical knowledge in an operating room be affected by the ambience and interaction of the trainees with the patient and instruments. The importance of situational learning in surgical training was also emphasised by Aggarwal et al. (2004). To recreate the realistic ambience of the operating room, we used 360-degree videos of operating room and computer generated 3D models. The next part of this chapter discusses various software and hardware solutions utilized for the design of VR experience and provide a justification for their use.

4.2 Scene design

In the design of this application, different scenes are arranged based on their sequence in the operating room. The best practices for user experience design for virtual reality were followed. The pathway taken by a user when they experience VR Surgery is shown in the Figure 4.1. A tutorial scene helps users to understand different gestures used in the application and their functionality. A user can always go back to the main menu scene or quit the application at any time.

The next part of this chapter discusses the development of individual elements in VR Surgery including the operating room experience, stereoscopic 3D videos of surgery, VR experience design, and user experience design.

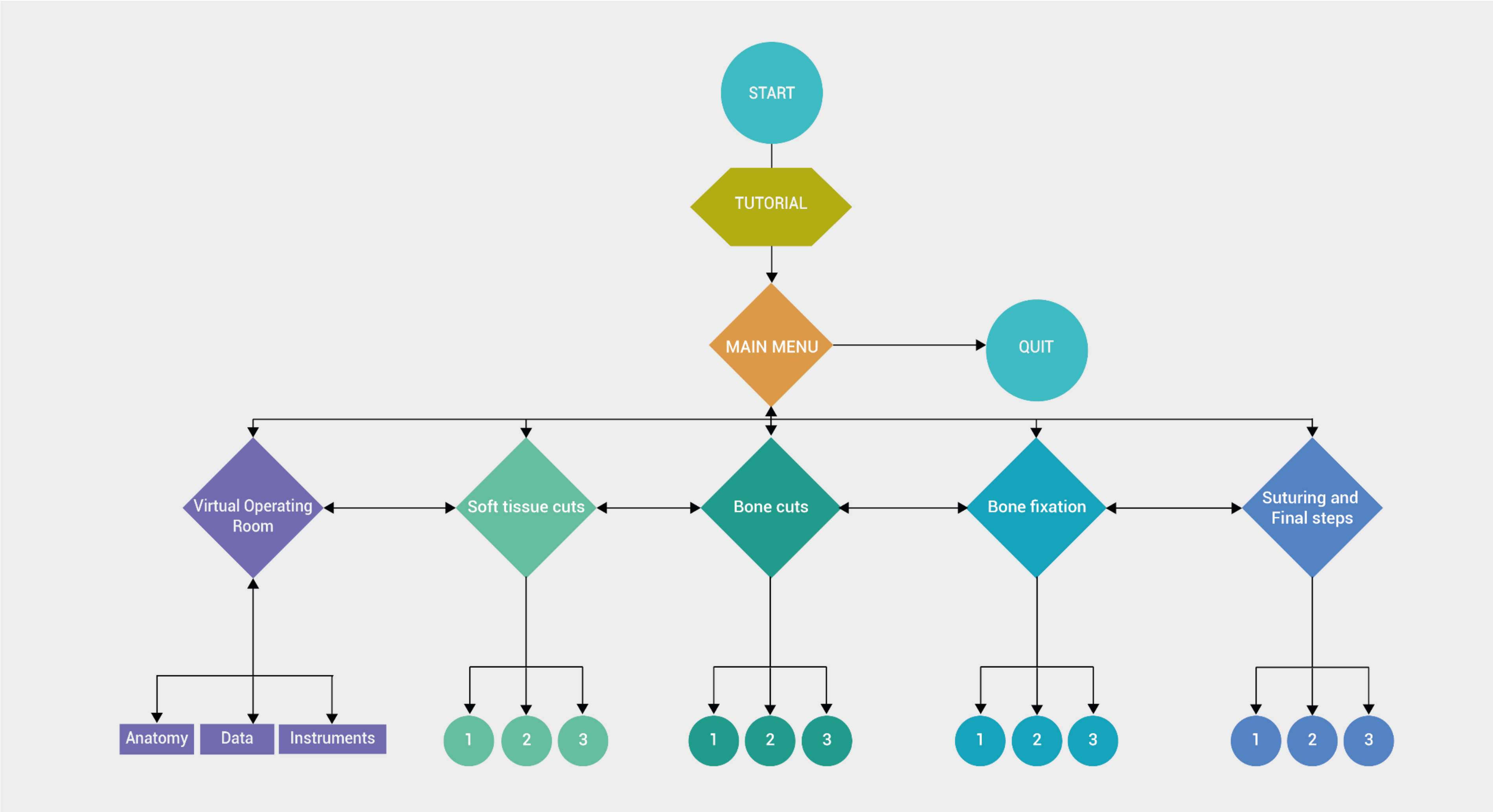


Figure 4.1 VR Surgery path showing different scenes and their pathway.

4.3 Knowledge obtained through VR Surgery

VR Surgery works in an Experience one, Interact one and Teach one approach for surgical trainees in Oral and Maxillofacial Surgery (Vozenilek et al., 2004). In the design of VR Surgery, the researcher focussed on the visual experience of surgery as it enhances the sense of immersion (Huynh-Thu et al., 2011). Understanding a complex surgical procedure by watching it over a surgeon's shoulder in a crowded operating room is a challenge (Reid, 2007). During maxillofacial surgery procedures, it gets more challenging as there are always up to four hands covering the patient's face. To improve the way trainees learn, VR Surgery was built based on Kolb's learning model (Kolb et al., 2001) as shown in Figure 4.2.

As discussed in Chapter 2, conventionally, knowledge in surgical training may be obtained by observation or through hands-on practice. The hands-on practice could be on virtual simulators or patient cadavers. As one of the goals of VR Surgery is to impart knowledge, the design of knowledge elements follows the Kolbs' learning model.

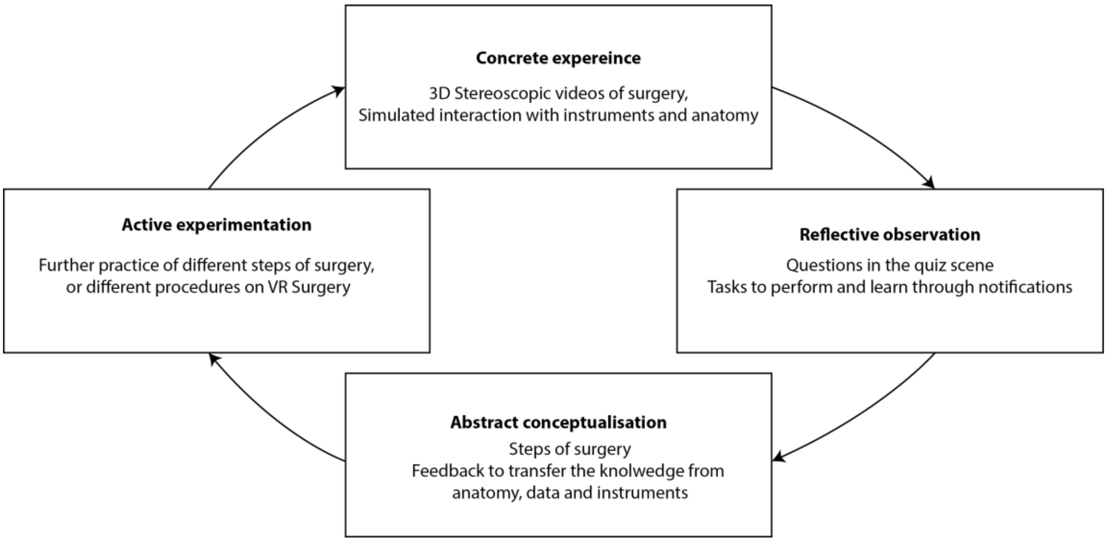


Figure 4.2 Kolb's learning model applied to VR Surgery

Stereoscopic 3D videos of the surgery provide the necessary surgical knowledge and represent the concrete experience aspect. Feedback on performance through questions and tasks helps trainees to reflect on their observation. Quiz scene in the application allows trainees to test their knowledge and identify the areas where they need to improve. Alternatively, trainees can also answer questions relevant to a part of the surgery by selecting the suitable questionnaire at the end of a particular section. Choice based multiple responses to questions, image based identifications and 3D interactions were included in the questions. A trainee needs to select the most suitable response or select a particular image as shown in Figure 4.3.

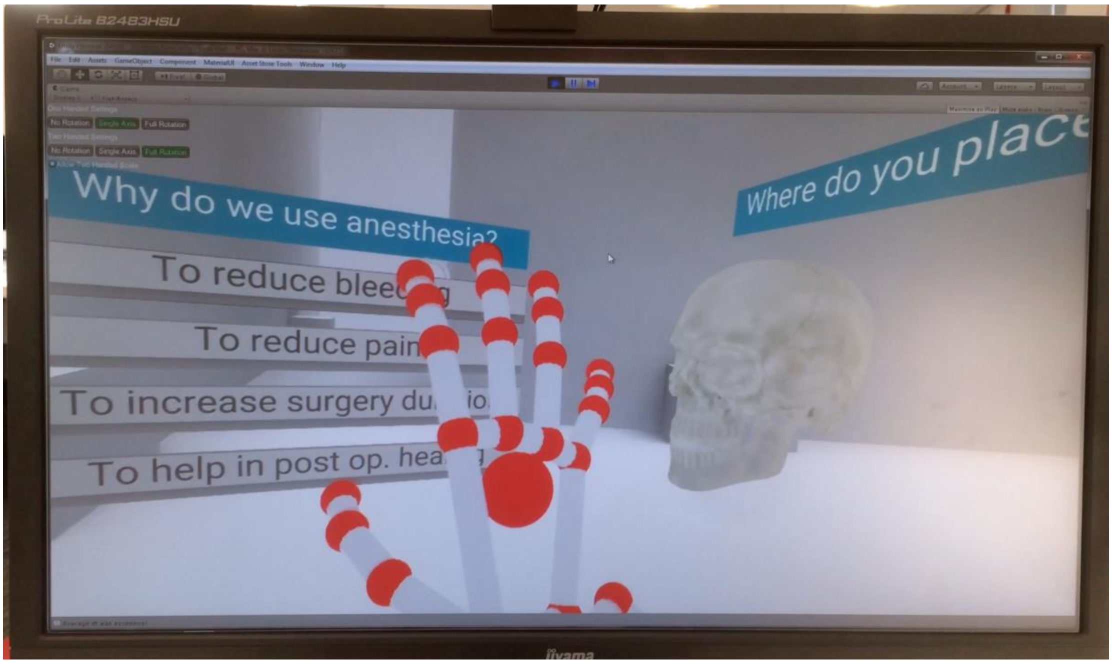


Figure 4.3 Quiz scene in VR Surgery

This reflective observation is guided through scores and notifications. Abstract conceptualisation aspect is represented by the steps to improve the performance of trainees, such as revising their knowledge regarding anatomy and instruments by interacting with the 3D models. A trainee can return to the application and answer a set of new questions and take up the tasks regarding the surgical procedure, representing active experimentation phase.

Thus VR Surgery addresses different aspects of learning and engages the users at various levels. A schematic representation of various levels of user's learning experience on VR Surgery is shown in Figure 4.4.

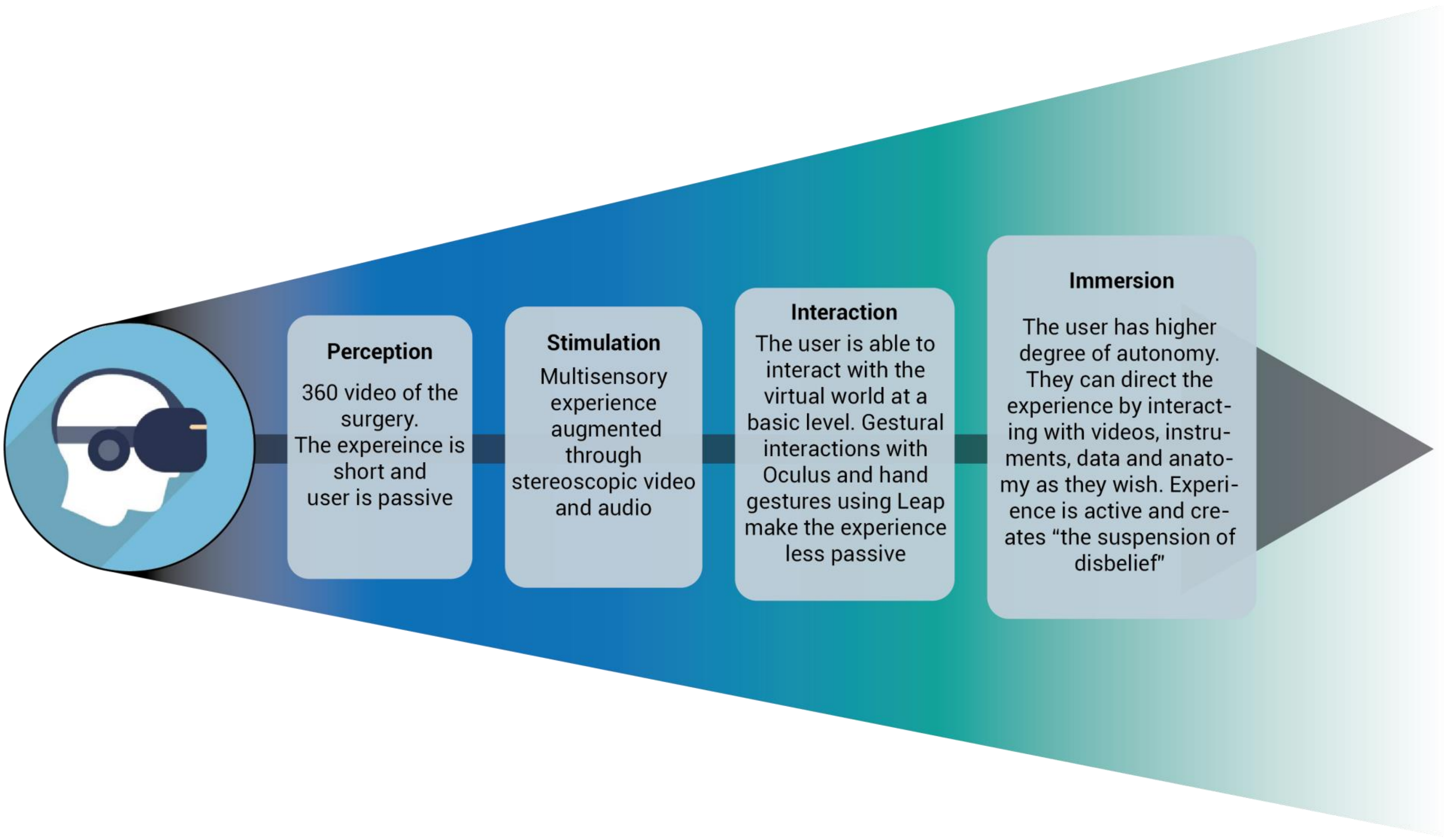


Figure 4.4 Different levels of experience and knowledge gained in VR Surgery

A summary of key features in various scenes of VR surgery and the purpose behind their use is shown in Table 4.1.

Table 4.1 Scene design of the VR Surgery

Scene	Purpose
1.3D stereoscopic video	Orthognathic surgery involves the movement of the bones in a 3D space. As 3D stereoscopic videos enhance depth perception, they were chosen over standard 2D videos to provide greater details.
2.3D Interactions	3D interactions help the user in understanding the surgical procedure from different perspectives. This involves: 1. 3D Animations of the surgery 2. Interactions with 3D Anatomy 3. Interaction with instruments 4. Interaction with patient's data
3.360º Video of Surgery	The ambience of the operating room sounds in the theatre and teamwork are essential cues in surgical training. To create a realistic learning environment and to create a sense of "presence", 360º videos were used. Trainees can look around and feel their presence in an operating room.
4.Virtual operating room	During training, various elements affect the learning other than the surgery itself. They include mastering non-technical skills like leadership, negotiating the terms of the operating room and understanding interpersonal relations. The virtual operating room scene provides an interactive learning experience to learn these skills.
5.Quiz	While watching a surgical procedure, trainees are asked questions about the anatomy of the patient, surgical procedure, potential complications and instruments used. This helps them to connect

	various elements and reinforce the knowledge with the experience. Real-time feedback will improve their learning.
6.Instruments	Le Fort 1 surgery uses a wide variety of instruments. As surgical trainees need to know the tools and their order of usage, this scene shows various instruments, and their clinical use.
7.Anatomy	Learning the surgical anatomy is an essential cognitive skill before any procedure. Users can touch and learn different aspects of head and neck anatomy. Scenes showing potential complications of Orthognathic surgery are also introduced in VR Surgery.
8.Tutorial Scene	This scene guides a trainee to learn 1. How to identify different objects based on their gaze 2. How to interact with Leap Motion controller
9.Pre-Surgical Planning	Before the surgical procedure, understanding why the surgery needs to be done using the CT scan data of the patient is essential. This scene allows the trainees to interact with the patient's CT scan data and also dental scans.

The content of VR Surgery can be split into surgical knowledge, procedural knowledge, surgical anatomy, pre-surgical data and instruments. These aspects are explained in more detail in the following sections.

4.3.1 Surgical Pedagogy

Orthognathic surgery is one of the types of jaw surgery, involving the movement of jaws to correct facial deformities. Due to the high level of complexity, high probability for complications, and lack of innovative training tools, expert surgeons suggested Le Fort I osteotomy (Miloro et al., 2004) for VR Surgery. Le Fort I Procedure or Horizontal Maxillary Osteotomy involves the fracture line or osteotomy at the base of the upper jaw above the tooth apices. The content design for VR Surgery followed the guidelines from the Intercollegiate surgical curriculum (Woodwards, 2015).

The entire content of Le Fort I surgery is arranged in the following sequence as shown in Figure 4.5.

1. Patient preparation: This part involves the induction of the general anaesthesia, transfer of the patient into the operating room and the disinfection of the patient.
2. Local Anaesthesia: Local anaesthesia is injected in the muco-buccal fold for vaso-constrictive purposes. The surgeon asks questions regarding the purpose of anaesthesia in this part of the surgery.
3. Vertical height and horizontal width measurement: The purpose and the method of the measurements of vertical height, and alar base widths were shown. Placement of K-wire for the measurement of vertical height was shown in the videos.
4. Soft tissue incision: After injecting anaesthesia, this step demonstrates the marking of the lines of the incision, placement of the soft tissue cuts, and diathermy of the mucosal tissues.
5. Soft tissue reflection: Using Howarth’s periosteal elevator, the buccal mucosal tissues were elevated to expose the underlying maxilla.
6. Bone cuts and separation: The next step after the reflection of the soft tissues is the bone cuts. The extent and the procedure of the bone cuts were demonstrated.
7. Down Fracture of Maxilla: The stereoscopic 3D videos were about Pterygo-maxillary disjunction. Down fracture is a complex procedure, which can be done using curved osteotome or Smith spreaders.
8. Mobilisation of bones: Forward and downward movement of maxilla using Rowe’s disimpaction forceps was demonstrated.
9. Forward mobilisation of Maxilla: Tessier’s mobilisers was shown in this aspect of surgery. Potential injury to the greater palatine artery during the downward movement of the maxilla is highlighted here.
10. Downward mobilisation of maxilla and removal of nasal spine were shown.
11. Fixation of bones: Four plates and sixteen screws were used to stabilise maxilla in its new position.
12. Closure: VY Sutures and Alar Cinch base sutures were clearly demonstrated in the videos. This part also included mucosal suturing.

Along with the knowledge of the procedure, trainees need to be competent about the sequence of steps, anatomy, instruments and pre-surgical data.

4.3.2 Procedural knowledge

Procedural knowledge including the sequence of steps also provides essential Information about the Le Fort I maxillary osteotomy. Cognitive task analysis(CTA) method helps in identifying individual steps of surgery. This method creates a logical sequence of knowledge so that decision making and other cognitive skills can be learnt in a structured approach (Li, 2005). Multimedia methods applying cognitive task analysis were found to enhance learning (Luker et al., 2008, Clark et al., 2012, Wingfield et al., 2014). However, the challenge with an elaborate procedure like Le Fort I surgery is that there are more than 20 steps in succession, making the trainee forget or lose control of what is happening. In the design of VR surgery, the researcher followed Hierarchical Task Analysis (HTA) structure to identify the sequence of steps. Hierarchical task analysis originating in human factors is an objective structured approach to describing the performance of a particular procedure. Based on this structure, the Le Fort I surgery was divided into following five steps and arranged them in a sequence called Path.

i. Soft tissue cuts
ii. Bone cuts
iii. Bone mobilisation and fixation
iv. Genioplasty
v. Suturing and Finishing up

In addition to the procedural knowledge, users were asked questions regarding the stages of surgery, the previous step, and the next step to be performed. Further, the questions focussed on anatomy, surgical knowledge, instruments, and decision making as shown in Table 4.2.

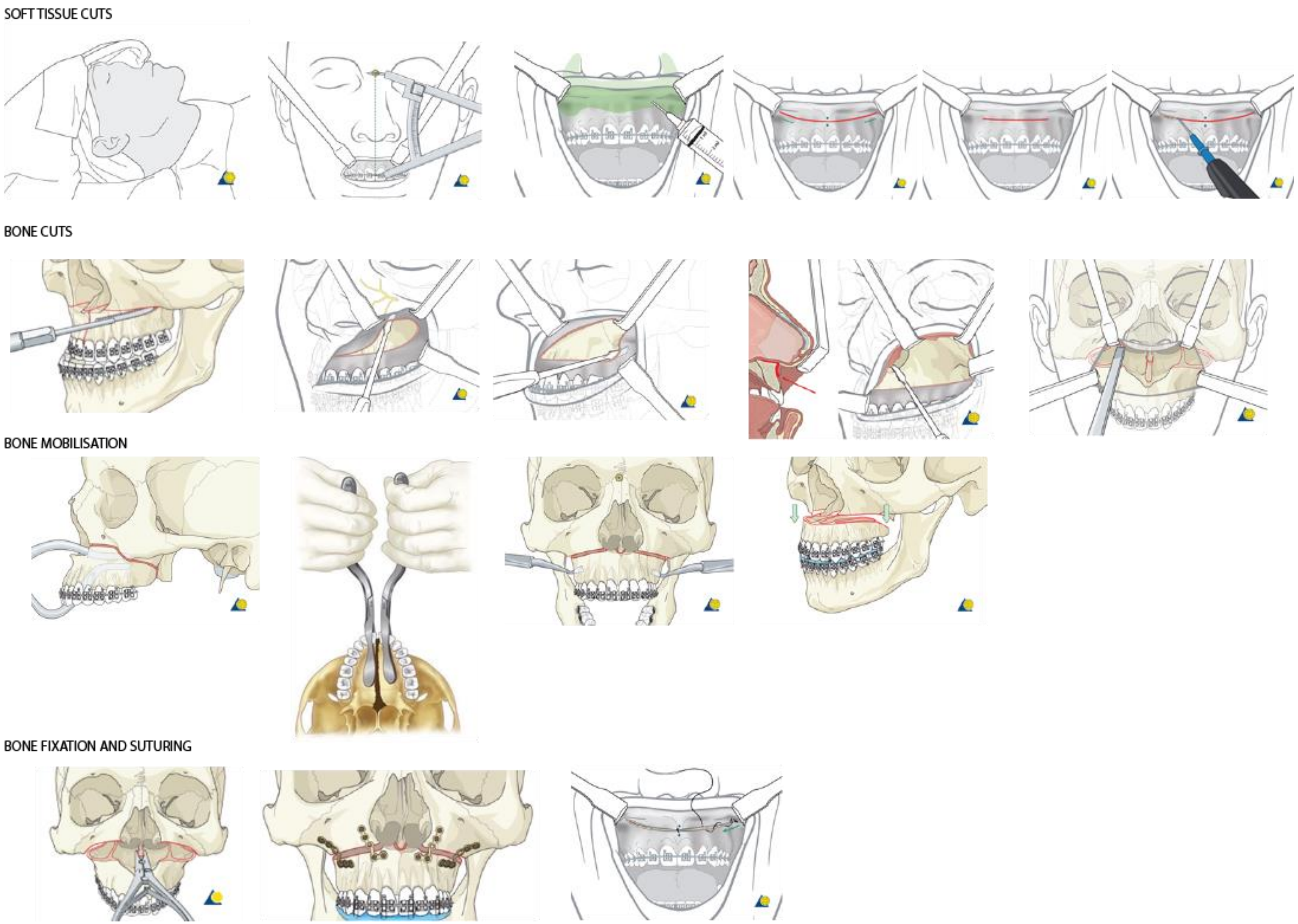


Figure 4.5 Sequence of steps in Le Fort I surgery

Table 4.2 Classification of the content for the questions

Type of Question	Pre-Surgery	Soft tissue Cuts	Bone Cuts and Mobilisation	Bone Fixation	Suturing and Final Steps
Anatomy	Where should the K-wire be placed?	How far should the reflection of the mucosal flap be?		In which directions the occlusal wafer adjust the final position of the maxilla before fixation?	
Instruments			Which instrument is usually used for pterygomaxillary disarticulation?		Which suture material is used for VY Suturing?
Surgical Knowledge	Why is it necessary to insert k wire before surgery?		How many bone cuts are required to allow the separation of the maxilla at Le Fort I level?		
Decision making	Which part of the face should be prepped before surgery?		What are the main risks of using surgical osteotome for pterygomaxillary disarticulation?	Where would the plates and screws be placed?	Which suturing technique would prevent nasal flaring after the surgery?

4.3.3 Knowledge of surgical anatomy

Knowledge of surgical anatomy is mandatory learning for trainees in the operating room. Further, Le Fort I surgery involves complex anatomy of head and neck with multiple blood vessels, nerves and bones in a closely arranged space. Potential complications in surgery can be prevented by understanding the relative positioning of anatomic structures and their connections with other structures around them.

Multiple researchers reported the benefits of 3D visualisation of human anatomy (Codd and Choudhury, 2011, Locketz et al., 2017, Medical, 2017). The addition of anatomy knowledge and their interactions is an essential feature in VR Surgery. 3D models of head and neck anatomy from multiple sources including the 3D CBCT scan data and artistic renderings of 3D anatomy were used. Users can interact with the anatomy using gaze for selection of a structure and Leap Motion interactions for moving individual elements of the anatomy. Trainees can also tap and select sub-anatomical structures within a 3D model as shown in the Figure 4.6.

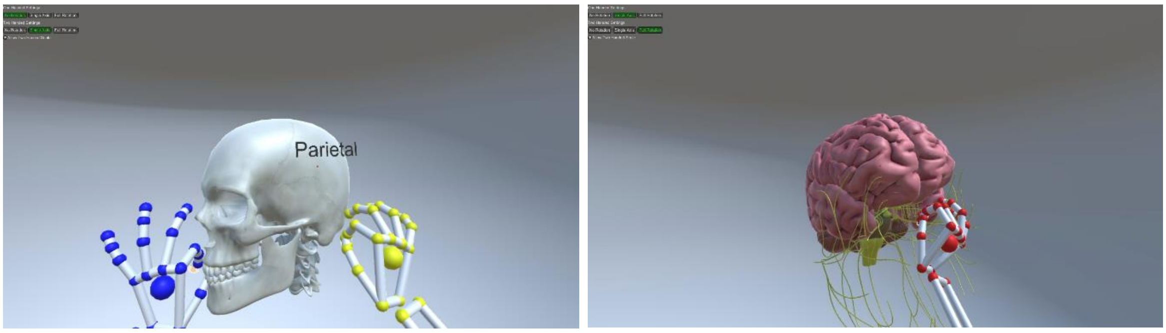


Figure 4.6 Interaction with 3D anatomy

Pre-set orientations and free rotations are provided for an interactive learning experience. Surgical trainees can also pause a specific video and click on the relevant anatomical structures. Expert oral and maxillofacial surgeons guided the placement of different anatomical structures and landmarks in the application based on the stage of surgery. Some of the surgically relevant structures included in VR Surgery, and their anatomical significance are as follows:

1. The infraorbital nerve was shown as it is exposed on subperiosteal dissection.
2. Descending palatine vessels were shown as they are ligated to prevent bleeding.
3. Internal Maxillary Artery was shown as it may be damaged during the down fracture of Maxilla.

4. At the superior repositioning of the maxilla, the preservation of descending palatine arteries is recommended due to the significant stretching of the palatine pedicle. Hence the descending palatine arteries were shown.

Different anatomical representations including a real-time 3D visualisation of internal anatomy were attempted as shown in Figure 4.7. Using layered visualisation on Unity 3D, an animated model of the skull was overlaid on the stereoscopic 3D video plane. Users could view the skull or make it transparent by using a slider. Scripts that act on the object's transparency were used to create this overlaid effect. However, surgical trainees explained they do not need to look at the internal anatomy while watching the surgery. Based on their feedback, two different scenes were used to demonstrate the internal anatomy and videos in the application.

Trainees asked if they can interact with a specific anatomic structure, while simultaneously understanding its overall orientation. This functionality was provided by using replacement shaders for anatomical structures, which greyed out the entire 3D model except for the selected object as shown in Figure 4.8.

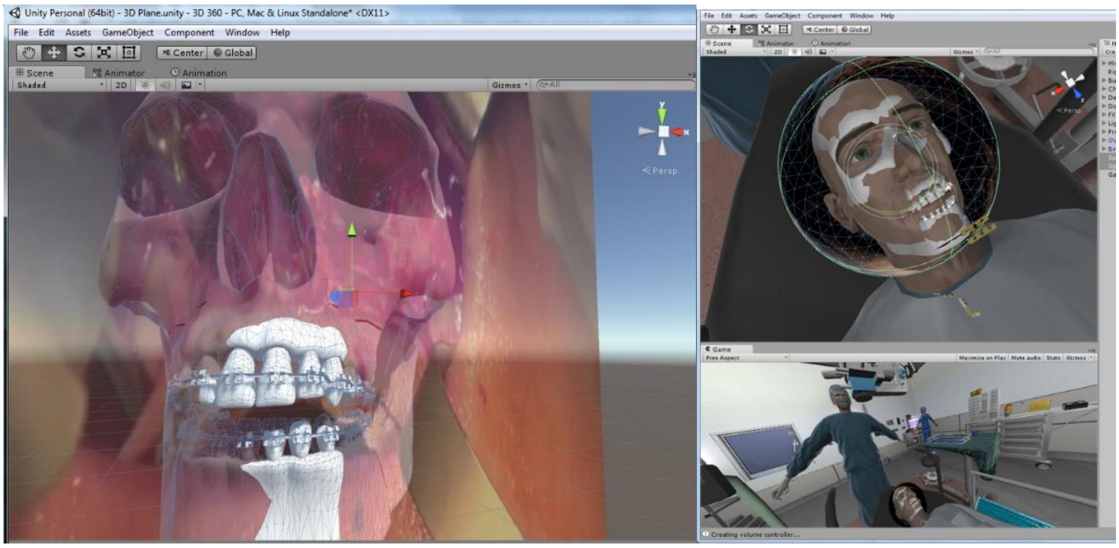


Figure 4.7 3D visualisation of internal anatomy

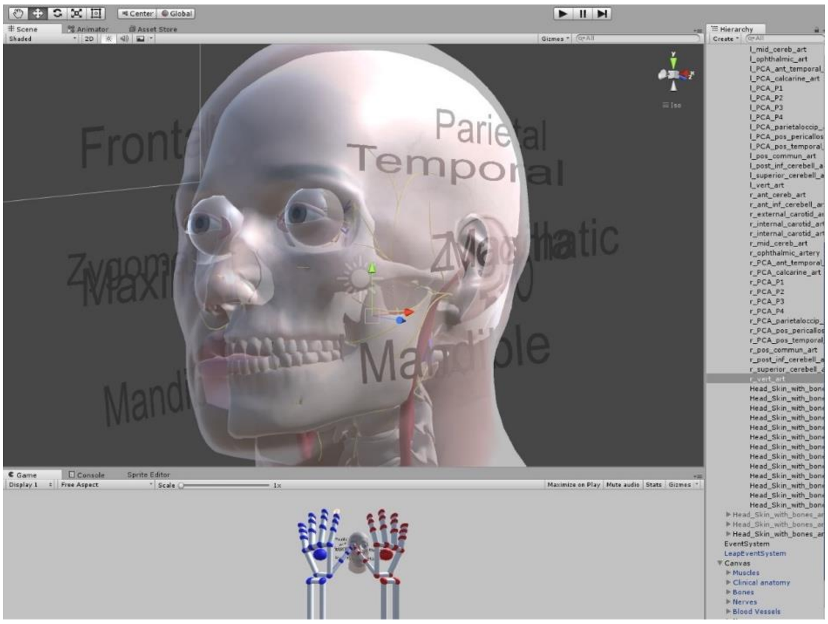


Figure 4.8 Selective visualisation of 3D anatomy

4.3.4 Knowledge of the surgical instruments

Knowledge of instruments used in surgery is imperative before a trainee participates in a surgical procedure. There are three aspects to the knowledge of surgical instruments. First, the trainees have to identify the instruments appropriately. Second, they should understand the usage of each instrument. Trainees who assist in the surgery need to know the instruments used in different aspects of the surgery. This involves knowledge regarding the sequence of steps in surgery and the specific instrument used. The third aspect is to know how to use a specific instrument. VR Surgery addresses the first two needs of the trainees by showing different instruments, their indications and application in the surgery. As haptic force feedback is required for the trainees to learn how to use a specific surgical instrument, this function was not included.

Expert Oral and Maxillofacial surgeons were consulted to identify the tools to be shown in the application. Based on their suggestion, ten 3D models of instruments were used. Additionally, an original image of the instruments was also included as shown in Figure 4.9. The selected instruments are as follows:

1. Rowe’s Disimpaction Forceps
2. Bone Cutting Reciprocating Saw
3. Septal osteotome
4. Lateral nasal osteotome
5. Plates and screws

6. Ruler
7. Tessier’s mobilisers
8. Pterygopalatine osteotome
9. Cheek retractor

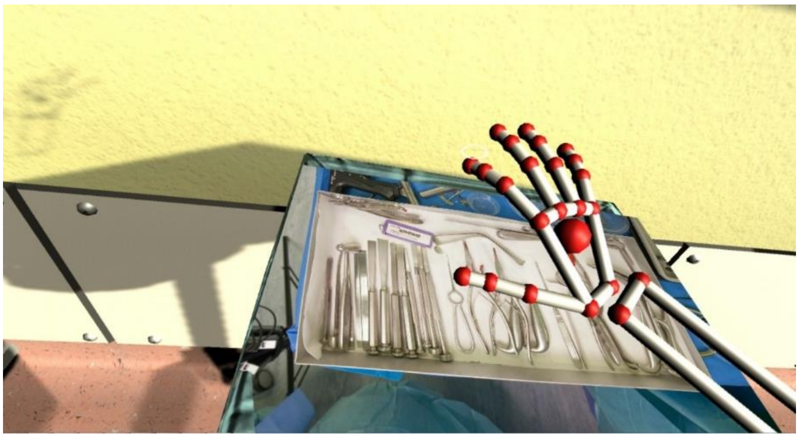


Figure 4.9 Selecting instruments using Leap Motion

The interaction scene begins with the set of instruments on a table to be identified by the trainee using their gaze. Trainees can identify each instrument by turning their gaze towards the instrument. A Ray-cast method was used with the ray projected from the centre of the camera (represented by headset). As the gaze of the headset is tracked, the 3D objects of instruments pop-up when they are activated. Each tool is attached to a rigid body, which when triggered activates a script that calls for the upward movement of the instrument as shown in Figure 4.10.

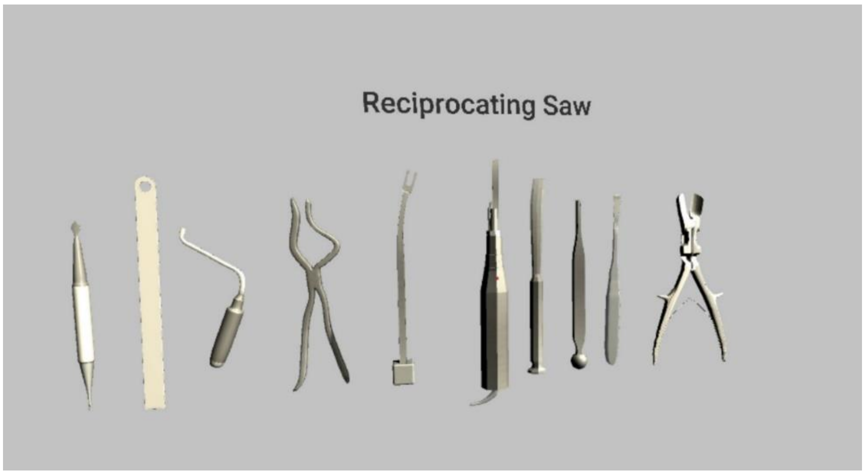


Figure 4.10 Naming the instruments

When a trainee watches the surgical procedure, they can select the tools used in that particular step. They can hold the instrument and interact with it, while simultaneously watching the stereoscopic 3D video of surgery as shown in Figure 4.11.

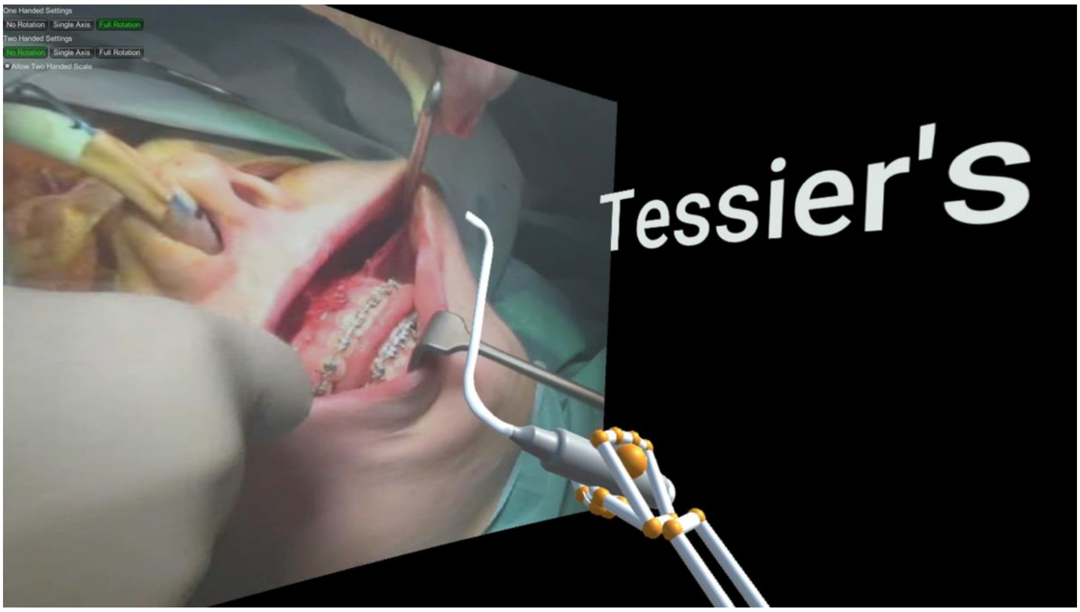


Figure 4.11 Interaction with instruments

Users can increase or decrease the size of the tools, pick them up and rotate them in 3D using one or two hands. The researcher also considered adding physics interactions to the instruments but the real time physics slowed down the functionality of the application. Expert surgeons also informed that the application of Physics engine is of no importance when haptic force feedback is not added. Alternatively, it causes false perceptions in a trainee about the real life behaviour of an instrument.

Questions which needed a real-time response by the participant were also included. For example, while the user is interacting with the instruments section, they were asked to point out at specific instruments in the operating room while naming them simultaneously.

The lessons learnt in instrument interaction were as follows:

1. Identifying the tools and their usage is the most important requirement.
2. Expert surgeons supported the use of real images of instruments in place of 3D models for the identification aspect.
3. Lack of haptic force feedback meant the usage of instruments is limited to their knowledge.

4.3.5 Pre-surgical patient information

Conventionally, pre-surgical CT and MRI scan data of patients are used to understand the skeletal deformity and plan the surgery. Soft tissue planning and hard tissue planning are done separately on special pre-surgical simulations. These data are then transferred to physical casts for making dental splint or wafer. The wafer will be used in the operating room to align the jaws in their new position and fix them in place. Before performing the surgery, the lead surgeon explains the desired bone movement to the trainees in operating rooms using the CT scan data as shown in Figure 4.12. However, in most cases, the data is a two-dimensional visualisation of the three-dimensional object. Unless the trainees are experienced, they will find it difficult to transfer their knowledge of the data to the operating site. 3D interaction with patient's data was introduced to address these needs.

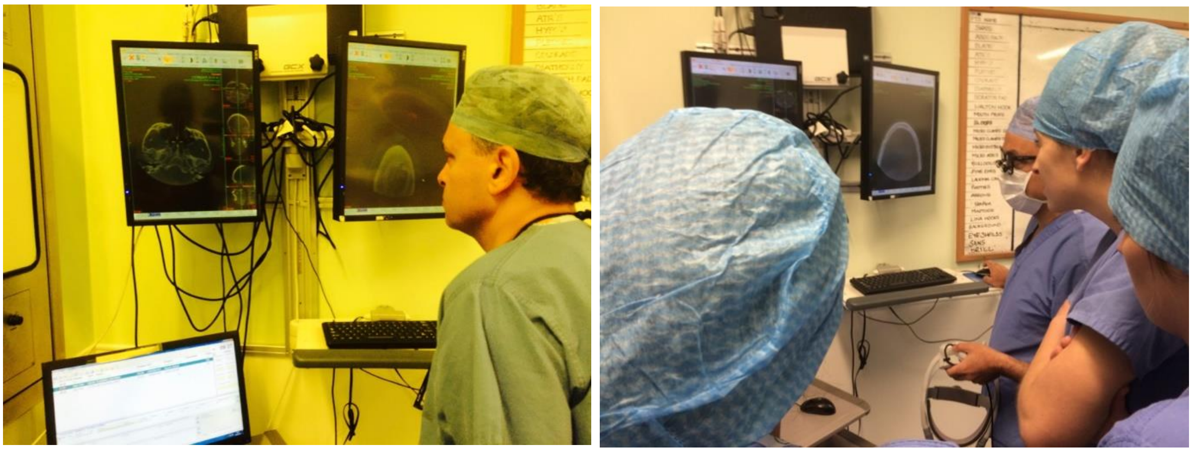


Figure 4.12 Visualising CT scan data in operating room

The 3D data of the patients from CBCT scans were obtained in STL format. These data are then converted into a low poly .OBJ format files on Autodesk Maya. Following this, the data are imported into Unity 3D. Along with the pre and post-surgery scan data, 2D images were used to represent the changes. Surface scan data of the patient using the Sense3D scanner and 3D models of dental casts with splint add further information. Similar to other user interactions, the users can interact with the internal anatomy as shown in as shown in Figure 4.13 and Figure 4.14. Questions regarding the scanned data and their implementation for performing the surgery were also asked.

Figure 4.13 3D Interaction with patient's data

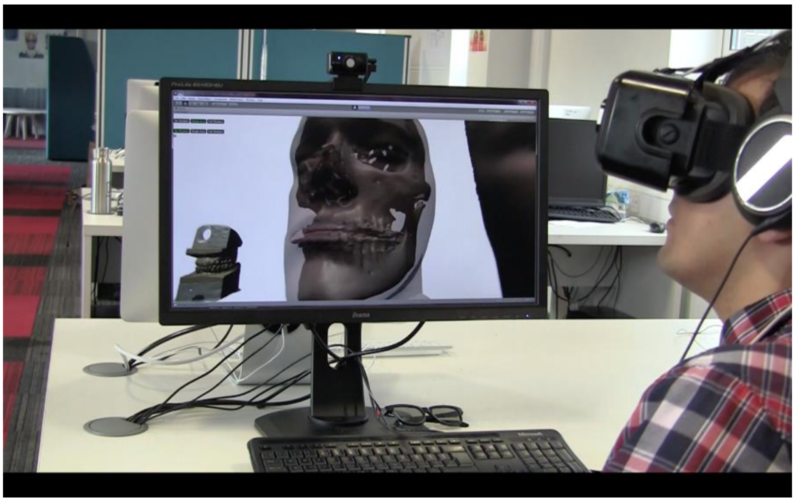


Figure 4.14 Interactive 3D visualisation of CBCT data

4.4 Summary

The researcher discussed the design of VR Surgery and the surgical pedagogy in this chapter. In addition to the scene design, the chapter explains how different elements of knowledge regarding Le Fort I Osteotomy are presented. The next chapter explains the details in technology evaluation and the implementation of the application.

Chapter 5 Technology evaluation and Implementation of VR Surgery

This chapter discusses the technology evaluation and the implementation of VR Surgery. Multiple steps involved in the development of VR Surgery are explained along with their functionality.

In the technology evaluation section, various hardware and software components involved in the design of VR Surgery are presented. The researcher further justified the reason for using Oculus Rift DK2 and Leap Motion devices for this research. Game engines, 3D authoring tools and software development kits are outlined.

The implementation of VR Surgery design explains how multiple media are represented in this application. The operating room experience elaborates on the need for context in learning, 360º visualisation of the operating room and 3D virtual operating room setting. The visualisation of surgery discusses the details in recording 3D stereoscopic videos of the surgery. The researcher further explored how 3D scans were combined with the 3D models to create an immersive experience.

The last part of this chapter focuses on the user experience design of VR Surgery. The design of the user interfaces, stereoscopic content, interactions, transitions, environment, and sound are highlighted here. In explaining the design of user interfaces, the need for natural user interfaces in contrast to handheld controllers is highlighted. In the Interaction design aspect, the functionality and design of Oculus based interactions and leap motion based interactions are discussed.

5.1 Technology evaluation

We used multiple hardware and software solutions for different purposes in building VR Surgery. Based on the purpose they were used for, the hardware and software equipment were classified as shown in Table 5.1.

Table 5.1 Hardware and software equipment used in building VR Surgery

Functionality		Hardware	Software
Data Collection	3DVideo	Go Pro Cameras Hero Dual Camera Rig Sony HXR-NX3D1E	Adobe Premiere Pro Sony Vegas Pro Final Cut Pro iMovie
	360-degree video	Go Pro Cameras Freedom 360 rig Bubl camera	Go Pro Video import AutoPano AutoStitch Kolor 360
	3D Scanning	Sense 3D Scanner iPhone 5S	Sense 3D Autodesk 123D Catch
	Audio	Zoom H4N Voice recorder	GarageBand Logic Pro
Virtual Reality devices		Oculus Rift DK2 Gear VR Google Cardboard	
Motion Sensing devices		Leap Motion Microsoft Kinect	Hovercast plugin
Displays		Windows desktop – GTX 980, 16 GB RAM, 250 GB HD Windows Laptop – GTX 1080,16GB RAM, 250SSD. Macbook Pro	
3D Modelling and Development of application			Autodesk Maya Autodesk 3DS Max Unity 3D

5.1.1 Data Collection devices and software

Stereoscopic 3D Video

As described by Cosman et al. (2007), the process of recording a video of surgery is complex. Operating room lights are too bright and often create a blown out appearance in the videos. A camera whose white balance and focus can be controlled while recording the surgery was needed to compensate for the bright lights in the operating room. To capture the surgery and the ambience of the operating room in high definition, we used Sony stereoscopic 3D camera and Dual Hero Go Pro cameras. We edited the white balance of the cameras before placing the patient on the operating table as shown in Figure 5.1.

Figure 5.1 Setting focus on the bright surgical field

For the first recording, we used a GO PRO dual hero rig with two cameras, where each lens represents one eye. The rig is as shown in the Figure 5.2a and 5.2b.

Figure 5.2a and 5.2b Dual Go Pro Hero Rig

However, this camera unit has the following advantages and disadvantages:

1. The cameras were small and could be placed anywhere.
2. With a separate left eye and right eye footage, the editing of videos was straightforward.
3. The cameras could not capture fine finger movements of the surgeon.
4. In a Le Fort I surgery, there will be constant movement of hands in the surgical field. The continuous movement of surgeon's hands fluctuates the focus between the surgical site and the hands of the surgeons. This inability to have a real time auto focus on surgical site was a challenge.
5. Adjusting the white balance of the cameras was not effective leading to a blown-out view of the surgical field.
6. Inability to see a live preview of the recording was another drawback.
7. The battery life of each camera is 1 hour 30 minutes. As the Le Fort I surgery takes longer than 3 hours, this set up of two go pro cameras was not very beneficial.
8. As the cameras were encased in a glass hosting, the audio recorded from the cameras was muffled.

To overcome these issues in Go Pro Hero cameras, the researcher considered hiring a consultancy to record the 3D stereoscopic videos, but it was not feasible for this project. Further, a Sony HXR-NX3D1E camera was used as shown in Figure 5.3 to record the surgery in close-up 3D. The ability to zoom into the surgical field and have a live stereoscopic preview of the surgery made it the most suitable camera. The high resolution of the camera, low cost and ease of availability were other advantages. Moreover, technical issues including the white balance, real-time focus and video resolution were solved. A detailed description of the different approaches of recording is provided in the close-up video section of this chapter.

Figure 5.3 Sony Stereoscopic 3D camera used to record videos in VR Surgery

360º video capture equipment

To recreate the operating room ambience, various solutions were used to record the surgery in 360º. Before using 360-degree videos, an iPhone with Google photosphere app was used to capture spherical photographs as shown in Figure 5.4. The spherical panoramic image was overlaid on the inner surface of a sphere to watch it in 360º (Roehl, 2014). Working with spherical photographs was useful to understand the intricacies in spherical video recording.

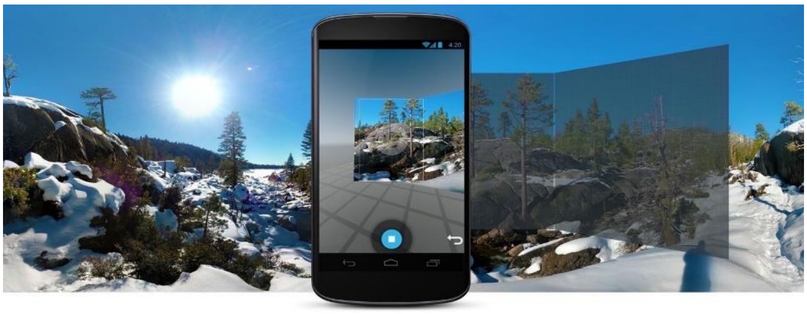


Figure 5.4 Google Photosphere (Google, 2015b)

Initially, a handheld Bubl camera was used to record the operating room in 360-degrees. The Bubl camera contains four cameras which are directed at acute angles to each other and records a field of view of 120º as in Figure 5.5. The overlapping footages from each camera were then stitched to form a spherical panorama. The best feature of Bubl cameras was the simplicity in recording the video. The camera contains a blue button, which once pressed begins recording. A mobile app could control the camera, and the video could be live-streamed. However, when the videos were viewed in Unity, the resolution was downscaled as shown in Figure 5.6. Additionally, handheld video recording added further challenges to video stitching and left seam lines visible.

Figure 5.5 Bubl Camera

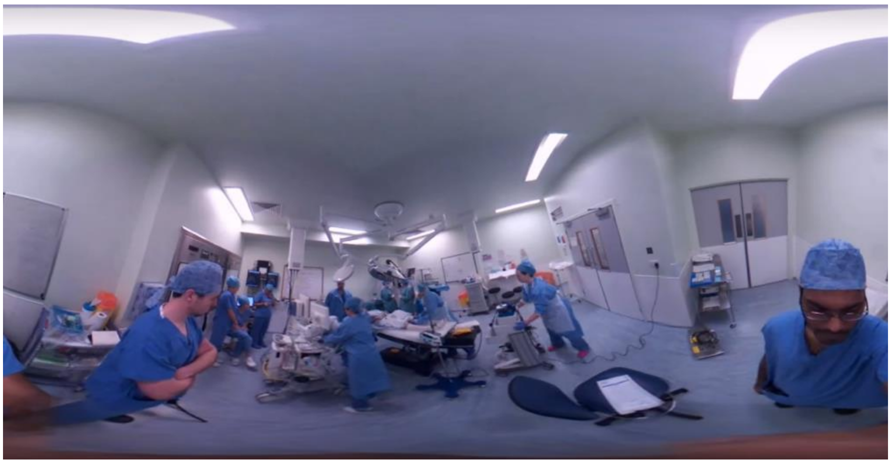


Figure 5.6 A 360º video output from Bubl camera

For the second attempt, the researcher used six Go Pro cameras arranged in a Freedom 360º rig to record the operating room and surgical procedure in all the directions as shown in Figure 5.7. A combination of six Go Pro cameras rendered a high-resolution 360º video.

Figure 5.7 Six Go Pro cameras in Freedom 360 setup

Go Pro video management software was used to import individual videos from the 360-degree cameras. Autopano Autostitch was used to edit the 360-degree videos and stitch them together. iMovie, FCP, Adobe after Effects, and Adobe Premiere were used to post-process the videos for display on Oculus. Kolor 360 was used to play the spherical videos before importing into Unity 3D (Kolor, 2015).

3D Scanning

To create realistic 3D interactions with the patient's data, the researcher used 3D scanned models of the soft tissue, dental casts and 3D models of the pre-surgical plan. For the soft tissues and dental casts, we tested different scanning solutions from a mobile app to handheld 3D scanners.

Autodesk 123d Catch

We used Autodesk 123D (Lievendag, 2016) catch on an iPhone to scan the surface of smaller objects including dental casts. Scanning an object with this app takes place in four steps namely data capture, data processing, review, and publish. For the data capture, the user has to capture multiple images of an object from different angles. The application guides the photo-taking process using gyroscope on the phone. The indicator in the app shows two 360-degree circles, arranged one over the other as illustrated in Figure 5.8. The bottom circle is for capturing 18 pictures facing the object, and the top circle is for capturing six pictures from other angles. Alternatively, the indicator can be turned off, and the user can take up to 70 pictures from all the angles. The app highlights the zones already photographed and thereby provides a stepwise support to the user. A specific photograph can be shot again without affecting the resultant mesh negatively.

In the processing stage, all the photos have to be uploaded to the cloud. The uploading time of the pictures varies based on the picture quality and the Internet speed. In the final step of reviewing and publishing, the user gets a preview of the 3D object scanned. However, there is no clean-up functionality, requiring the user to edit the 3D objects in modelling software including Autodesk Maya and 3DS Max. To post process the objects in an external software, the user can download 3D meshes in .OBJ or .STL format as in Figure 5.9 and Figure 5.10.

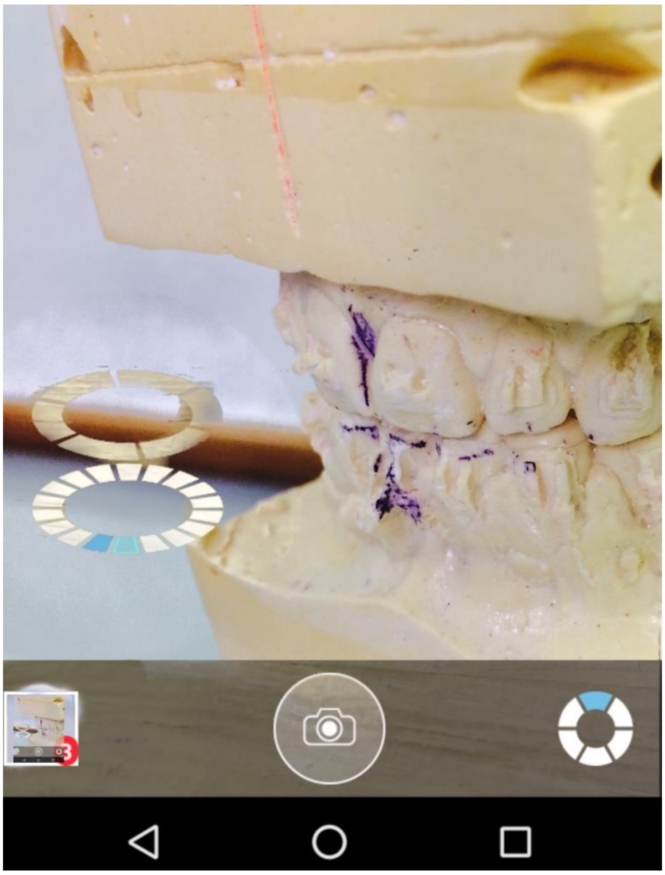


Figure 5.8 123d Catch app interface with two circles

Figure 5.9 3D mesh using 123d Catch app

Figure 5.10 Textured 3D model after processing

SENSE 3D Scanner

A Sense 3D scanner (3D Systems, 2017) was used to scan the patient’s face, 3D models of instruments and 3D models of dental casts. Sense 3D scanner application provides default options to scan faces and smaller objects. The hand-held scanner has to be at a distance of 35-50 cm away from the surface of the subject matter as in Figure 5.11. As the scanner is orbited around an object, a real-time registration of the 3D model will be shown on the Sense 3D app as in Figure 5.12. The camera captures the surfaces and depths of the object while creating an indirect visualisation of the surfaces scanned.

Figure 5.11 Scanning process using 3D Sense scanner

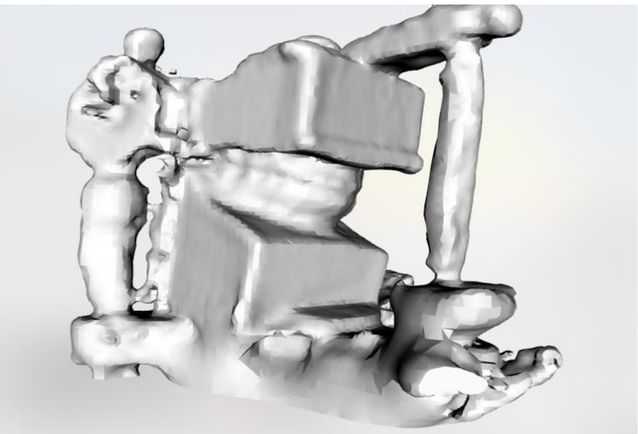


Figure 5.12 3D Mesh from Sense scanner

Advantages of the Sense scanner includes a high-resolution textural registration of the 3D objects. Real-time registration on the app provides control to the user by providing a preview of the 3D mesh. The software works effectively even in dark environment. A clean-up feature allows the user to edit the 3D model in the same software. A functionality called 'fill hole' allows the users to cover any spots which were not scanned. The data obtained from scanning a person's face includes a texture map, a 3D mesh and a composite of the two as shown in Figure 5.13 and Figure 5.14a and 5.14b.

Figure 5.13 Texture Map of the patient's face

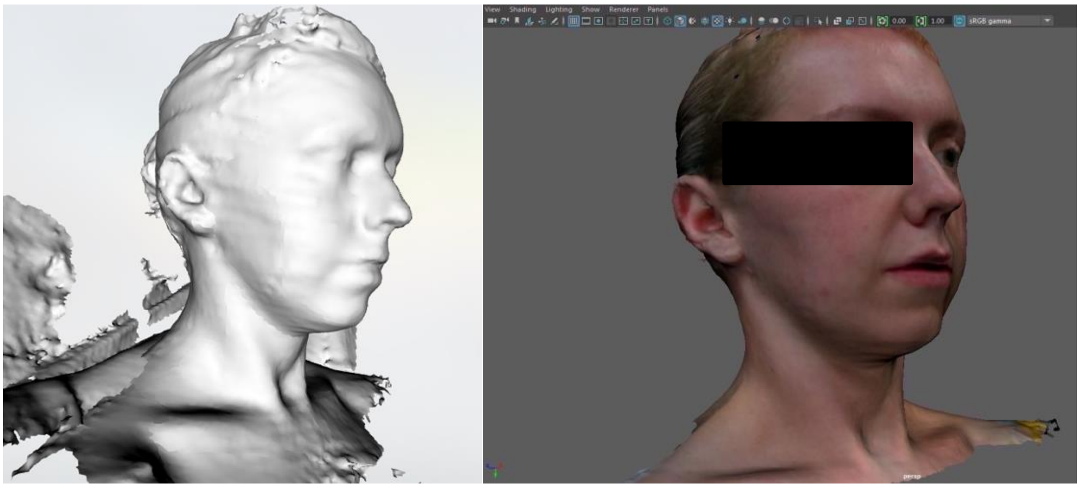


Figure 5.14a and 5.14b 3D Mesh of patient

On the downside, if the tracking is lost at any time, it is hard to restart the tracking as the application takes longer than 3 minutes to re-register the object. This intermittent loss of tracking can happen because of inadvertent movement of the hand or when the objects are beyond the scanning span of the cameras. Other challenges while using this app include a limited length of the cable attached to a laptop or computer. So the subject to be scanned needs to be close to the laptop. As the scanner is handheld, it affects the user's ergonomics.

The researcher found that the 123D Scan app is appropriate for smaller objects, as the mesh size was smaller and the image resolution was better. On the other hand, Sense 3D produced pixelated textures when smaller 3D objects were scanned.

Audio

An audio recording of surgery in the operating room is challenging as there are many extraneous noises in addition to user instructions and conversations. To record the voice of the surgeon, a Zoom H4N stereo voice recorder was used as shown in Figure 5.15 (Zoom, 2017). The recording mic was attached to the surgeon from inside his sterilised gown. Audio from this device was used only for recording the surgeon's conversations in the operating room.

Figure 5.15 Zoom H4N Voice recorder

Sony stereoscopic 3D camera was used to record the audio from the surgical site. Further, voice over instructions were recorded in a sound recording suite at the University of Huddersfield. Apple GarageBand and Logic Pro software were used to edit the sounds for VR Surgery. In the application design, 3D sounds were used by placing multiple audio sources at different positions.

5.1.2 Virtual Reality devices

Out of the available VR headsets in 2014, the researcher chose Oculus Rift DK2. In addition to using it as a virtual reality headset, it was used to integrate with the Leap Motion tracker. The Oculus Rift DK2 headset was a suitable device to create virtual reality experience, but there were some inherent technical issues including the screen door effect of the headset.

Challenges in Oculus Rift DK2

1. Screen door effect

Screen door effect appears due to low pixel fill factor as black lines on a moving image or as gaps in between the pixels. In VR Surgery, stereoscopic 3D videos of surgery are affected by screen door effect, thereby disrupting the sense of 'presence'. The overall user experience was improved by upgrading the graphic card of the computer to NVIDIA GTX 980, and by importing higher resolution videos.

2. Flicker

There was a significant flicker in the Oculus Rift headset while watching 360-degree videos. Multiple attempts were made to reduce the flicker, including the change of lenses in the Oculus HMD. The headset is provided with a default set of lenses named

‘A’. By changing the lenses to the second set, the image appeared less pixelated, smoother and less detailed. The researcher later realised that the flicker was due to the graphic card and compromised processing power of the system. When the application was used on a high-end Laptop with 1080 GTX graphic card or desktop computer with NVIDIA 980 GTX, the flicker disappeared.

5.1.3 Motion sensing devices

The introduction of gesture detection allows the users to interact with the various aspects of the application intuitively and enhances their user experience. Currently available hand-held Oculus Touch controllers (Lamkin, 2017) were not developed for interaction with Oculus DK2. Hence, motion sensor devices including Microsoft Kinect (Financial Times, 2015) and Leap Motion (Leap Motion, 2015) were considered. For VR Surgery, the motion sensor should track precise movements of the fingers like picking up an instrument, exploring the anatomy of a bone, and placing sutures on the surface of the model. Microsoft Kinect detects bodily movements. The fine movements of fingers were not tracked.

On the other hand, Leap Motion tracks the position of the hand bones. With a size of just over three inches long, an inch wide and less than half an inch in thickness, leap motion effectively recognises the hand gestures using infrared sensors. The functionality of Leap comes from its cameras and Infrared optics. However, its tracking is limited to a field of view of 150º (Leap, 2015). The Infrared sensor can track all the ten fingers up to 1/100th of a millimetre. The tracking rate of over 200 per second plays a role in effectively understanding the hand movements in the air (Robertson, 2016). Lighting conditions and IR sensing are responsible for proper functioning of the device. Leap Motion was chosen for its low cost and ease of use with Oculus Rift and Unity 3D application as shown in Figure **5**.**16** and Figure 5.17. The informative representation of hands by Leap Motion is useful for interaction with 3D models in VR Surgery. It can also be integrated with mobile VR devices to create natural user interfaces (Qualcomm, 2017).

Figure 5.16 **Leap Motion sensor**

Figure 5.17 Oculus and Leap Motion setup

5.1.4 Displays

A custom configured high-powered laptop was used to support the virtual reality devices and the applications. The specifications of the laptop as suggested by Oculus Rift are shown in Table 5.2.

Table 5.2 Oculus specifications of a VR ready computer to run virtual reality applications (VR, 2016)

Video Card	NVIDIA GTX 970/AMD R9 290 equivalent or greater
CPU	Intel i5+4590 equivalent or greater
Memory	8 GB+ RAM
Video Output	Compatible HDMI 1.3 video output
USB Ports	3x USB 3.0 ports plus 1x USB 2.0 port
OS	Windows 7 SP1 64 bit or newer

By using a laptop whose configuration was VR ready, the researcher was able to create a satisfactory VR experience.

5.1.5 3D Modelling and development of the application

Unity3D software was used to integrate all the components of the application and build VR Surgery. There were challenges regarding the video quality, integration with Oculus and Leap Plugins and further challenges with the mesh sizes of 3D objects because of the native renders used by Unity. Unreal Engine is an alternative to Unity 3D, but due to the availability of Oculus and Leap plugins at the time of research, Unity 3D was chosen. Further, Unity 3D offers inbuilt virtual reality support and example scenes, which were used in creating VR Surgery. The extensive online support for Unity 3D also favoured it over Unreal Engine.

The 3D models of patient's skull, instruments, animations and anatomy were designed on Autodesk Maya. The animated models were imported into Unity 3D in .OBJ or .FBX format. Few 3D models including the scanned information of the patient, the dental casts and animations of Le Fort I osteotomy needed the mesh reduction to make the application run smoothly. By reducing the polygon count and reducing the texture sizes, the researcher was able to handle the 3D animations on Unity 3D. Due to the close integration of Autodesk Maya and Unity 3D, it was efficient for cross collaboration.

5.2 Implementation of the VR Surgery design

The different methods used in creating operating room ambience in VR Surgery are discussed in this chapter. Videos showing operating room in 360º and 3D virtual operating room environment were used in VR Surgery to create a realistic operating room experience. Research proved that high fidelity ambience in Virtual Reality improves the participation, learning and mental rehearsal of the trainee (Wu et al., 2014). Further, contextualization of training with realistic environment enhances the sense of immersion in healthcare simulations (Engström et al., 2016). Multiple steps involved in the implementation of VR Surgery are shown in Figure 5.18.

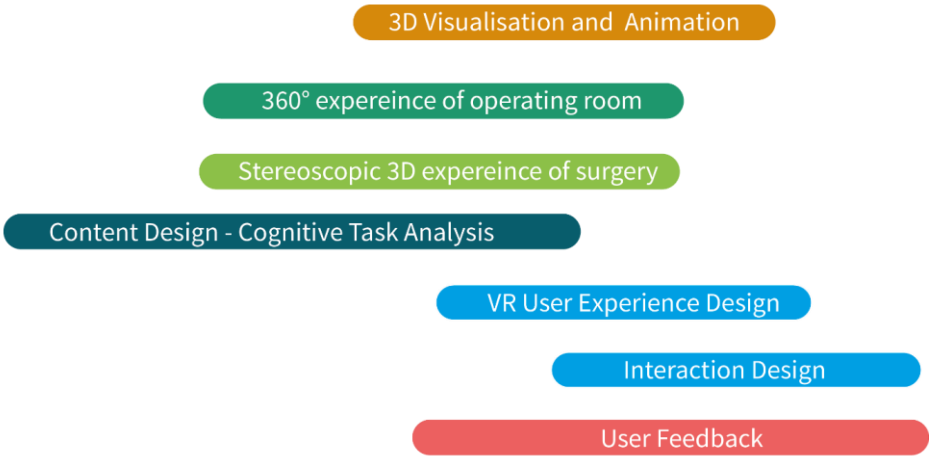


Figure 5.18 Design elements of VR Surgery

5.2.1 360º Videos of the operating rooms

Use of 360-degree videos of the operating room is one of the best approaches in recreating a sense of presence in the operating room. When a surgical trainee watches this video, she/he can observe different people in the room and their actions in the first person. When they turn around, they can observe sterile and non-sterile zones with the instruments, patient's data and other equipment. Multiple devices were used in this project to create 360-degree visualisation as discussed in the hardware and software components of chapter 5.

Production and rendering of a 360º video involves multiple steps. A detailed description of producing 360-degree videos including the required equipment is presented by multiple users in an open source book called Making 360 (Soudiere, 2016). The process of development and production of 360 degree videos is divided into five steps namely.,

1. Setting up the rig in operation theatre
2. Shooting workflow
3. Importing and checking the footage
4. Stitching and rendering the 360º video
5. The projection of 360º video

Setting up the rig in operating room

By collaborating with a consultant VR specialist, the operating room was captured in 360 degrees and 3D stereoscopic views (Miller, 2015). Six Go Pro cameras were mounted on a Freedom 360º camera rig. Before recording the surgery, each camera and its corresponding graphic cards were labelled with the same number as on the rig. After emptying the graphic cards, individual camera settings and white balance were standardised to run the cameras in unison and to prevent any irregularities in the recordings. Settings including 2704 X 1524 resolution, 16:9 aspect ratio, 30FPS, with a CAM RAW white balance on each Go Pro camera were used to record the video in best resolution. All the cameras, along with the rig were fixed on a tripod as in Figure 5.19.

Figure 5.19 Go Pro Freedom Rig in operating room

Shooting workflow

After switching on all the cameras, record button was pressed simultaneously using a Wi-Fi remote. The cameras were rotated to and fro to perform motion synchronisation and enable an error free video stitching at later stages (Kolor, 2015). Motion synchronisation prevents any offset in the footage on the timeline. Before starting the recording process, the audio was synced by clapping close to each camera. Another potential problem while recording with multiple cameras is Parallax, a condition where objects at different distances move at various rates as the camera moves (Weissig et al., 2012). The suggested preventive measure is to place the camera rig at least 10 feet away from people (Fletcher, 2014). This was a challenge in the operating room. The inherent challenges of sterility, blood filled surgical field within an operating room environment were negotiated by positioning the cameras away from the surgical field (Association, 2003). By placing the tripod at different locations, multiple videos were recorded based on the best angle for viewing the procedure.

Importing and checking the footage

As a best practice, while recording the 360º video, the footage of each camera was imported and verified for every hour of the recording. However, this was not possible in all the recordings as the number of people handling the 3D, and 360º cameras were limited. Though this method helped the researcher to focus on the surgery, it is not suggested for future work, as a failed recording identified early can save time and energy instead of checking it at the end. Go Pro Studio software was used to import the footages from each camera. Once all the videos were checked for corrupt files and frozen cameras, the videos were prepared for stitching.

Stitching and rendering the 360-degree video

AutoPano's Autostitch software (Kolor, 2015) was used to stitch the footages from individual cameras. The software identifies specific camera outcomes and overlaps the footage to create a spherical panorama. The software also stabilises the video to remove any unintended motion caused in the process of recording.

Projection of the 360º video

The rendering of the spherical video should create a realistic ambience to the application. Different forms of projection of the 360º video in virtual reality were used. Initially, the 360º videos were projected on the inner surface of a dome. However, the videos got stretched and appeared pixelated. The researcher used a shader, which renders the image on the inner surface of a 3D model, for rendering the video on a sphere. After placing the camera in the centre of a sphere, the user can look around and experience the operating room. Both the dome and spherical projects are shown in Figure 5.20 and Figure 5.21.

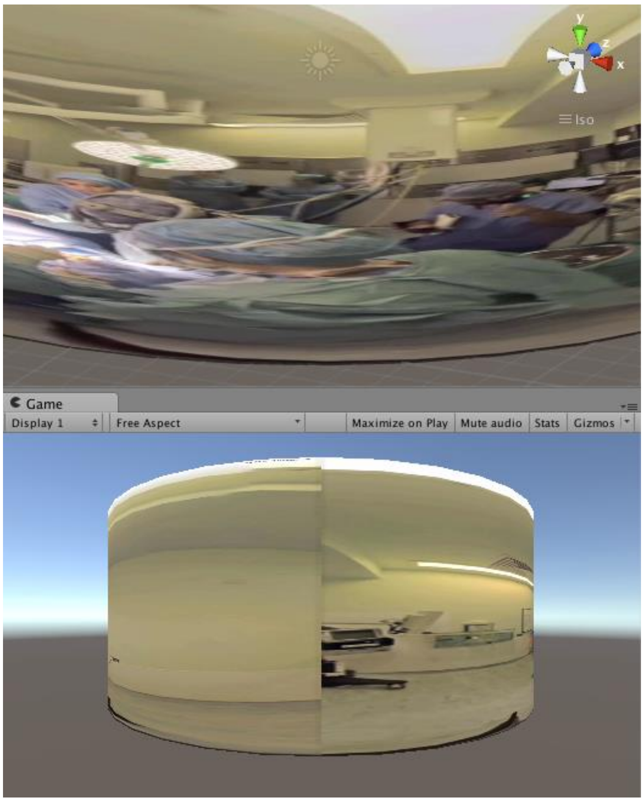


Figure 5.20 360º video projected on a dome

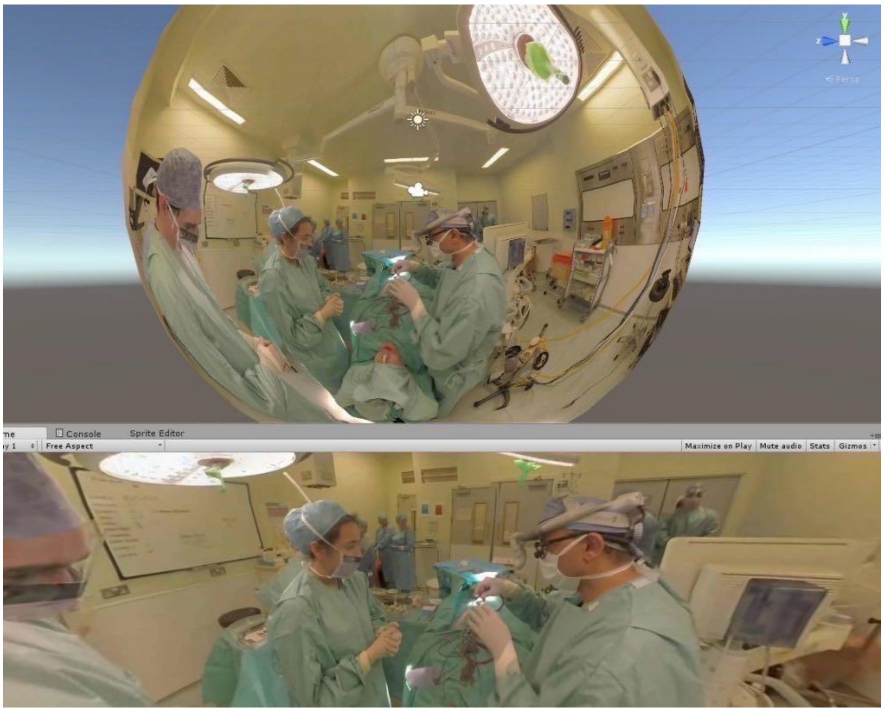


Figure 5.21 360º video projected inside a sphere

Challenges faced, and lessons learnt

i. Though the Go Pro cameras are flexible and provide a suitable solution, the limited battery life is a challenge that needs to be addressed. The Hero 3 cameras had a battery life of one hour and thirty minutes. The researcher negotiated this drawback by using a power bank attached to all the cameras and by turning off the cameras when not in use. Further, only selected aspects of surgery were recorded in 360º.

ii. The second issue in using multiple cameras is that occasionally the cameras can get frozen. In one of the recordings, the camera was frozen, and the researcher lost the time where only five cameras recorded the scene.

iii. The position of the cameras in operating room was not satisfactory. By placing the 360-degree camera rig at a distance and height, one can appreciate the different zones of the operating room and the people working in it. However, bird's eye view of the surgery was not useful for trainees Figure 5.22.

Figure 5.22 Bird's eye view of the operating room

iv. The position of the camera needs to be close to the surgeon. The height of the camera needs to be adjusted to replicate a realistic view from an eye level. This change in position of the camera comes with parallax error caused due to movement of people near the camera. As the operating rooms are overcrowded, it is almost impossible for recording the operating room ambience without any disturbance from the people moving around.

v. When the cameras were placed next to the surgeon, the results were better. However, while recording from a point close to the surgeon, the cameras need to be sterilised and protected from touching any unintended object in the operating room. Further, the users cannot appreciate the detailed view of surgical field in a 360-degree camera view. A close-up stereoscopic 3D camera needs to be used to appreciate this aspect of training.

vi. 360º videos from AutoPano did not render in Unity 3D directly as the Unity needs the videos in .ogg Theora format. Further, the quality of videos was scaled down.

vii. Audio recorded from 360 degree cameras was not used in the application as the cameras recorded surrounding noises including the conversations of the nurses and erroneous sounds in the operating room.

viii. Surgical trainees' feedback showed that they are more focused on what is happening in the surgical field. Though the 360-degree videos create an immersive ambience, the need to constantly observe others will decline after some time into the operating room. Therefore, the VR Surgery application has 360-degree videos at selected times.

ix. Inability to view the procedure from different positions (unless captured from multiple 360º camera rigs) is the second drawback with this approach. In a 360º video, there is a lack of interaction with any of the content viewed and limited mobility from the centre without distorting the video.

5.2.2 Virtual operating room

When creating the virtual operating room ambience, the researcher compared a 360º video with the 3D virtual environment as shown in Table 5.3. Both the experiences have their strengths and drawbacks. By having a 3D model of operating room environment, whose details are close to reality, a trainee can immerse in the experience. This understanding can be achieved by scanning the operating room in 3D or by creating a computer-generated 3D model of the operating room (Vertigo Games, 2014).

Table 5.3 Differences between the 360º video of operating room and 3D virtual environment

360-degree video	3D virtual environment
1. Realistic	1. Less realistic
2. Single point of view	2. Multiple points of views
4. Interactivity is compromised	4. Interactive animations can be added.
4. Video-Stitching issues	4. No stitching issues
5. The user cannot move in a video	5. The user can move within the virtual operating room
6. Resolution of the videos are dependent on the quality of graphic card	6. Low poly virtual operating room works without much compromise of the quality

In VR Surgery, operating room assets from Unity 3D Asset Store as shown in Figure 5.23 were used. These assets were modified according to the 360º videos of the operating room in Glasgow to maintain the uniformity. Following the user feedback, parts of the surgery where the 360-degree video are needed are combined with the parts of the surgery where interaction is required.

A combination of video and 3D environment was created, where the users can first experience the operating room (OR) environment, see the details of the medical data and other essential information. After that, users get an option to choose to attend the surgery, or learn anatomy, or take a quiz.

Figure 5.23 Virtual Operating Room asset in VR Surgery by Vertigo Games

A better method to create the ambience of the OR is to record this environment from multiple views so that the user can translocate between them. This allows the user to have multiple perspectives and also change the view according to his/her convenience. Recent advances in 360-degree cameras record an environment using light field technology (Gershgorn, 2017). This provides six degrees of freedom as in the 3D virtual environment. Advanced virtual reality experiences are currently exploring this form of recording.

A 360º experience of the operating room creates the necessary environment to learn. However, for a surgical trainee, the most important aspect to understand is the surgery itself. The next part of the chapter explains creating this experience using stereoscopic 3D videos of the surgery.

5.3 Stereoscopic 3D videos

The surgery was recorded in stereoscopic 3D looking over the surgeon's shoulder to create an uninterrupted view of the surgical field. Multiple recording styles were planned and tested before arriving at the current solution. The different options that were explored in the process of recording three surgeries are explained below.

5.3.1 Head mounted rig

Initially, it was planned to record the surgery by asking the surgeon to wear a dual go pro hero rig on his head while performing the surgery. A head mounted camera provides a first person perspective (Crecente, 2014). However, new challenges emerged when the videos were tested on an Oculus Head Mounted Device (HMD).

Head mounted video recording challenges

1. The constant movement of the surgeon's head causes virtual reality sickness when watched on a head mounted VR device.
2. Unless a live video stream is available, recording through a head-mounted go pro camera does not produce required results. As the surgeon would not know what is being recorded, the surgical field might not be recorded as necessary.
3. The cameras cannot focus on the surgical field as the Go Pro cameras cannot be controlled in real time, once they start recording.
4. Having a surgeon wear Go pro camera limits their ability to manage the settings as their hands are often engaged in the surgical process.

5.3.2 Cameras on the operating room lights

Figure 5.24 Placement of Go Pro dual hero rig in the operating room

For the second recording, dual Go pro hero camera rig was attached to the operating room lights as shown in Figure 5.24.

Following are the advantages and disadvantages of this approach

1. The cameras could record all the interactions in the operating room.
2. Parts of surgery involving upper jaw were recorded properly.

3. As the surgical field was far away from the camera, the procedure could not be appreciated well. It was more challenging to appreciate smaller structures in the oral cavity, like the blood vessels and nerves as shown in the Figure 5.25.

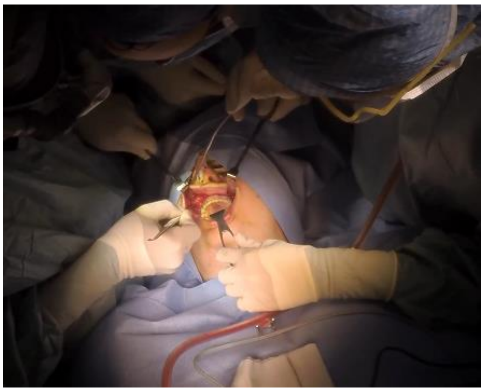


Figure 5.25 Long distance from surgical field led to low quality of the videos

4. Whenever the surgeon moved and covered the operating field, the cameras could not record the surgical field as the surgeon's hands blocked them. Lack of a live camera feed further worsened this situation shown in Figure 5.26.

Figure 5.26 Video feed showing the blocked surgical field

5. Fixed camera positions had challenges with unchangeable white balance, inability to refocus the cameras and inability to monitor what is being recorded.

5.3.3 Lessons learnt in recording stereoscopic 3D videos using Go Pro cameras

- Proper recording of the surgery needs multiple cameras because view gets obstructed too often with a single camera.
- Even after recording with multiple cameras, each camera needs to be operated to find the best angles.
- The best angle of view is always behind the surgeon’s head, but because surgeon keeps moving while performing the surgery, the angle is often obscured.

- Head mounted cameras would not work well in VR, due to simulator sickness, unless the footage was displayed on a virtual monitor. This creates a frame of reference for the user, which helps to avoid simulator sickness.
- Flexible arms would make it easier to physically move the cameras close to the surgical site.
- A ring of cameras could be used to surround the entire scene, but this still only offers horizontal movement, and not vertical movement. With this setup, however, the angles could be interpolated, to create free viewpoint video.
- The GoPro cameras offered no live preview while recording, which meant some clips were not angled correctly, which lead to incorrectly exposed imagery because the cameras are auto-exposed.
- A television screen in operating rooms showing the live preview would be useful for both camera operator as well as students in the operating room.
- The field of view needs to be tighter. This was not possible at the time, due to the arrangement of the 3D cameras. To achieve a comfortable 3D in tighter field of view, a different camera setup was needed. This can be created by moving the stereo pair closer together either with a mirror rig or motorised aperture
- Having high-resolution cameras in the overhead lights would be ideal, allowing the surgeon to move as needed. However, there are still issues with obstructing the views.
- Cameras had to have batteries replaced after every 90 minutes or a power bank is needed for every camera.
- Having power cables close to the surgical field is potentially dangerous.
- GoPro cameras do not serve as an ideal capture device, due to a wide field of view, battery life & lack of manual controls.

Post recording, expert surgeons requested a better positioning of the cameras as this did not give good results. They asked if the cameras can be brought closer and recorded from a different position. Given the sterility challenges and complexity of the surgery, an experiment was performed to check different options to record the surgery.

5.3.4 Experiment to find the appropriate method of recording 3D video of surgery

Two Go Pro 3+ Hero cameras in a dual hero 3D rig captured the oral cavity of a volunteer. The researcher tested the video feed by changing the camera positions, using handheld and fixed recordings.

Go pro cameras recorded all the details of the oral cavity when placed at a distance less than 25cms from the subject. However, to get a proper stereoscopic visualisation, the cameras need to be at least 3 feet away from the subject (Go Pro, 2015). The well-known 1/30 rule of stereo separation states that the inter-axial distance between the two lenses should be 1/30th the distance from cameras to the closest subject (Dashwood, 2011).

Placing the camera close the subject brings new challenges as the surgeon needs space to move the instruments in the surgical field. These movements cause loss of focus on the object being recorded. Tripod fixed camera recordings are better compared to hand-held camera recordings. This means a special rig is needed in the operating room to record the surgery in a close-up position.

In the next step, different camera rigs and pivot positions were tested by simulating the positioning of the cameras in the virtual operating room environment as shown in Figure 5.27. The camera needs to be perpendicular to the surgical field with the rig placed above the surgical interaction zone to create the best viewing experience.

Figure 5.27 Virtual camera placed perpendicular to the operating zone

5.3.5 Stereoscopic 3D Camera based recording

After testing different equipment and orientations, a Sony HXR-NX3D1E camera was used to record the video. This camera was chosen for its small size, autostereoscopic recording, and easily adjustable focus. A real-time preview of the 3D video on this camera allowed the researcher to understand what was being recorded without losing focus. The cameras also recorded a high-quality audio quality from this camera. The video was recorded over the surgeon's right shoulder. However, the camera was moved according to the surgeon's position while recording the surgery. This flexibility allowed the researcher to have a satisfactory video quality throughout the recording. For example, when the surgeon was performing the correction of the chin (augmentation genioplasty), the camera was moved behind the patient's head as in the Figure 5.28.

Figure 5.28 Moving the camera according to the surgeon's position

Challenges in recording 3D stereoscopic video of the surgery:

- Placing the camera next to the surgeon, without disturbing the flow of the surgery was complicated.
- The output from this camera was in a single file format, which could be edited only using Sony Vegas Pro. Converting a video from Sony Vegas Pro to Premier Pro and re-editing it to fit the sequence of surgery was time taking.
- Changing the camera's position made it hard to refocus for a stereoscopic manner. For example, while recording 3D video of Rowe's disimpaction, the surgeon wanted a zoomed-in video. However, when a user watches a stereoscopic video which zooms in and out on an Oculus Rift, it disturbs the presence and causes VR sickness. To eliminate the issues concerning the zoom levels, a single video was edited as two separate videos.

5.3.6 Types of representation of stereoscopic 3D video

There are many formats to represent the 3D stereoscopic videos in Unity. A Side-by-side (SBS) layout was used for the videos as shown in Figure 5.29. The Left/Right video feed of the surgery shows individual outputs of each lens, with an offset. There was no vertical offset, but the horizontal offset was maintained at a value of 0.5 for each lens.

Figure 5.29 Side by side representation of stereoscopic videos

Different surfaces like Sphere and Plane were used to project the videos. However, when the video was projected on a sphere as in Figure 5.30, a visible distortion of the video occurred towards the periphery. To eliminate the distortion, a planar projection was employed.

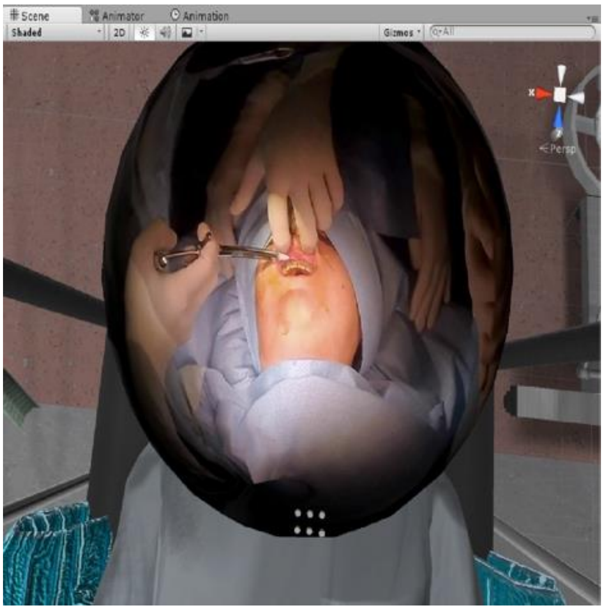


Figure 5.30 Spherical projection of stereoscopic 3D videos

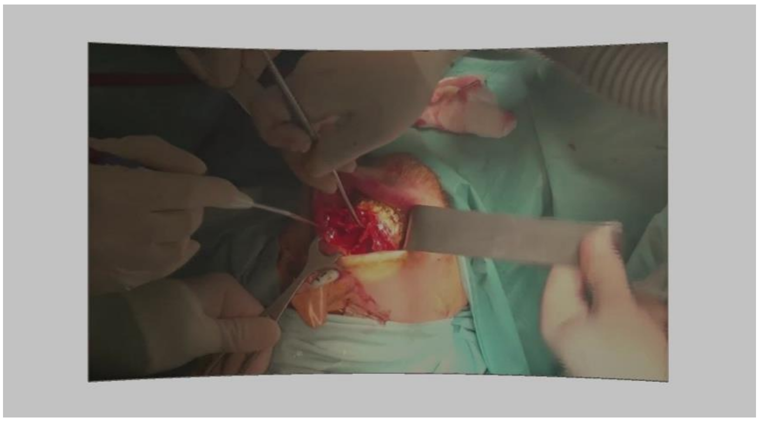


Figure 5.31 Planar projection of stereoscopic 3D videos

When the video was projected on a plane, there were no distortions, but the sharp edges of the planar surface were visible in the Oculus Rift. Following the design principles for the virtual reality user interface, which are discussed later in this chapter, videos were projected on a curved plane as shown in Figure 5.31.

The next challenge was in creating an immersive virtual reality experience as the trainees watch these videos to learn the procedure. To achieve a satisfactory user experience, different background options were tested.

i. 3D stereoscopic video in a 360º video background

Using a curved planar projection, the 3D stereoscopic video was played in a 360º video background as in Figure 5.32. Trainee surgeons mentioned watching two videos at the same time distracted them. Also while watching two videos simultaneously, the performance of the software slowed down, causing a disturbance in the experience.

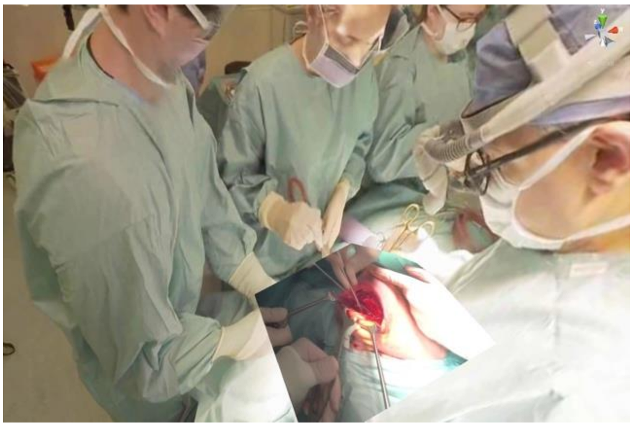


Figure 5.32 Stereoscopic 3D video in a 360-degree video background

ii. 3D stereoscopic video in a blurred 360º background

Following the advice of trainee surgeons, the background was changed to a blurred 360º video of the operating room as shown in Figure 5.33. The trainees mentioned an improvement in their experience. However, the software still slowed down affecting the quality of VR experience.

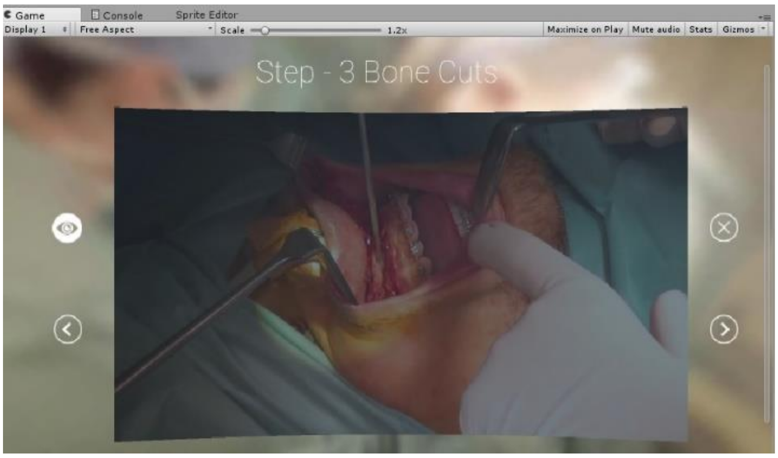


Figure 5.33 Blurred 360-degree video as a background

iii. 3D Stereoscopic video in a virtual operating room ambience

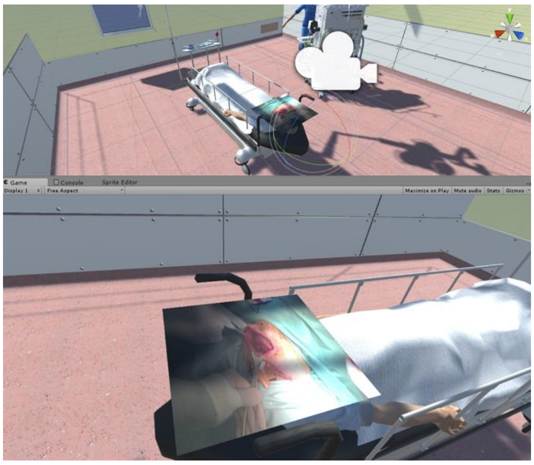


Figure 5.34 3D Video in virtual operating room ambience

3D stereoscopic video on a patient model in a virtual operating room ambience was used as shown in Figure 5.34. Trainees mentioned that this technique did not improve their experience, but distracted them from watching the surgery. In the end, by eliminated all the background information, the stereoscopic videos were played on a neutral background as shown in the Figure 5.35.

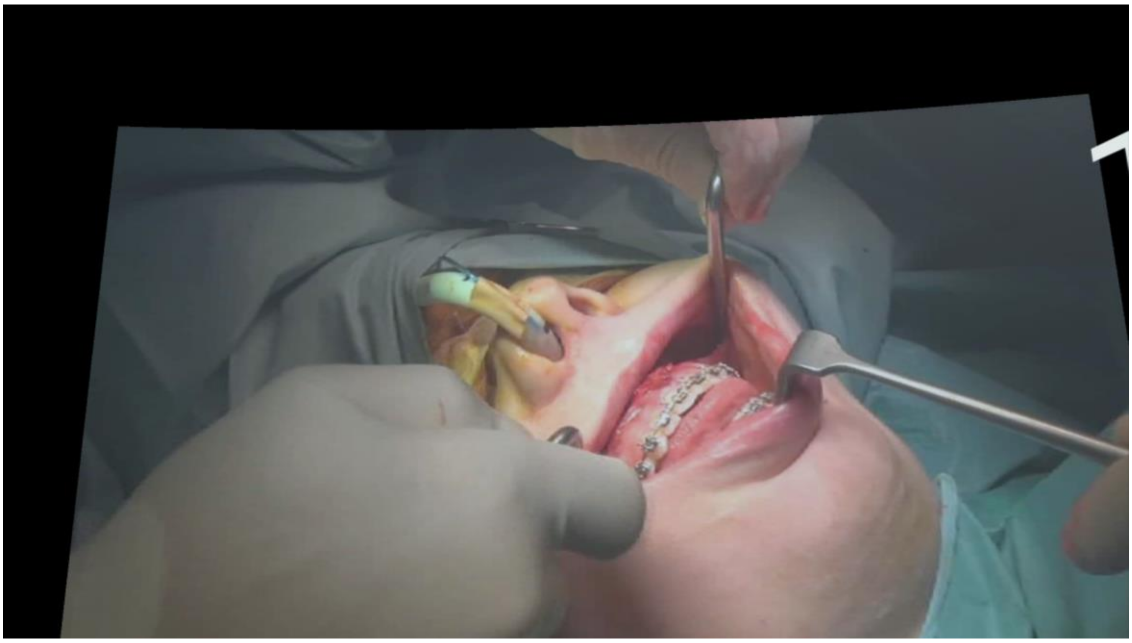


Figure 5.35 3D video of surgery on a neutral background

5.4 User experience design

User experience includes the quality of the content, appropriate placement of various elements, and ability to provide a realistic sense of presence to the user. There are various principles for designing user experiences for VR (Alger, 2015, Anderson, 2015, Oculus VR, 2016). Few of them include creating an interactive, comfortable and easy to use experience. In designing VR Surgery, these principles were followed to enhance the experience of the users.

5.4.1 User interfaces

Interfaces used in VR Surgery were designed considering the specifications for Oculus Rift DK2 and Leap Motion controller. Various aspects of designing UI elements based on the devices are discussed below.

Leap Motion user interface

This project used Leap Motion as an input device as it provides a natural user interface of a person's hands. Watching their hands within virtual reality environment enhances a sense of presence to the users by reinforcing the spatial experience (Colgan, 2016). Leap Motion provides a proper registration of user's hands in the virtual environment. Additionally, Oculus Rift DK2 is not compatible with other handheld input devices including Oculus Touch.

Developing user interfaces for Leap Motion involves different considerations to that of Oculus. The basic elements of best practices in Leap interactions should include below shoulder level, easy to learn, and fewer interactions (Leap Motion, 2015). Understanding the intractable zone is vital for Leap motion. For a head mounted device, there is a goldilocks zone for placement of user interfaces and appropriate interactions as shown in the Figure 5.36. The second aspect in Leap interface design is the height at which the leap gets activated. Ideally, placing the hands in the field of view makes it active. However, moving the hands too close or too far away to the device disrupts the hand registration. Interactions placed too low can lead the user to hit the real desk, and thereby disrupt the experience. An interface placed too high causes strain on the shoulder. Hence the user interfaces should always be in the goldilocks zone, and below the shoulder level.

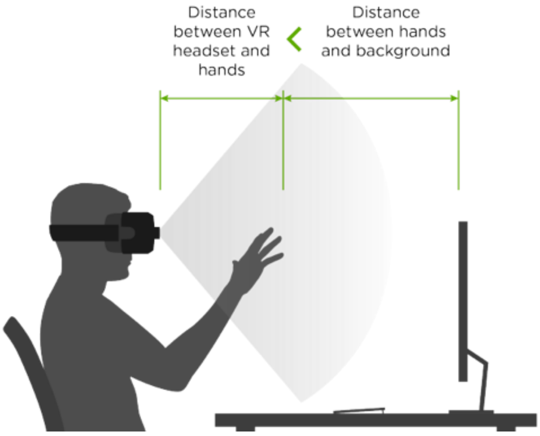


Figure 5.36 Goldilock zone for placing leap interfaces (Leap Motion, 2015)

Interaction with user interfaces works well in the horizontal and vertical axis. However, when the user has to push a button, they have to assess the depth. Understanding the depth is difficult in a 3D world. VR Surgery initially had buttons which needed depth assessment. However, user tests showed the buttons required to be replaced as the users found it difficult to assess their state (pressed/not pressed) as shown in the Figure 5.37.

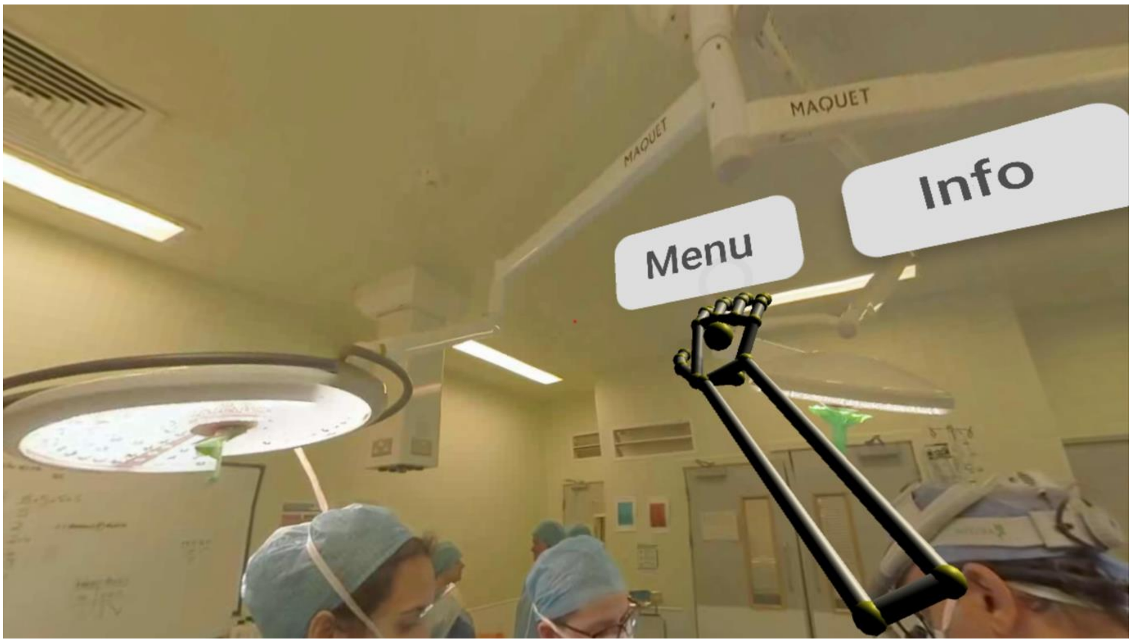


Figure 5.37 Buttons which needed depth assessment

Hand user interface

To overcome the drawbacks of a game based UI and to integrate well with the virtual reality user interface, the researcher adapted a Hand based UI (Kinstner, 2016) as shown in the Figure 5.38. Hover Cast UI plugin was used for this project, as the users get access to an interface attached to one of the hands. Further, a hand based UI is easily accessible whenever the user looks at their palm. This interface also provides navigational functions within menus. In VR Surgery, hand UI was used for accessing instruments while watching close up videos of surgery.

An arc-shaped menu attached to the fingers of the left-hand gets activated based on the direction of the palm towards leap motion. A perfect alignment shows the menu clearly; as the hand moves away, the menu fades away naturally. To click a button, the user has to use their right index finger. The tip of the right index finger represents a selectable trigger. When the right index finger comes close to the buttons, they show a change in colour from transparent to blue to green. A button turns completely green when selected. In addition to the visual cues, a loading sound provides significant audio cues to the user.

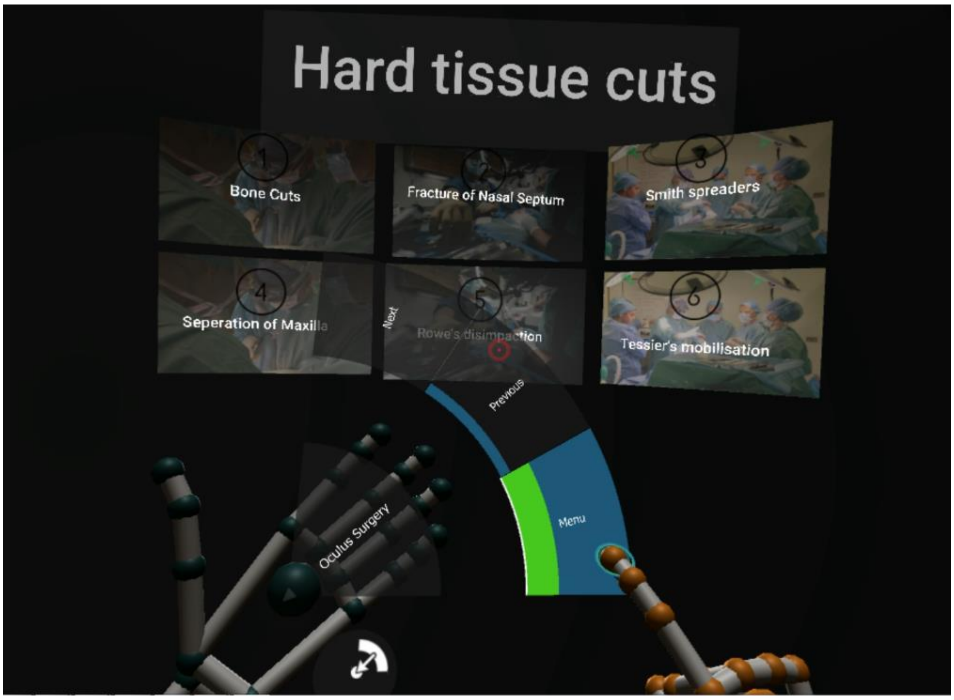


Figure 5.38 Hovercast UI plugin was used to develop hand user interface in VR Surgery

Though the functionality of the hand based UI is engaging to the user, it involves a long development phase with many modifications to suit the project (Pulijala, 2016).

5.4.2 Stereoscopic content

The videos need to be placed in a suitable position and scale in the VR scene to create a satisfactory stereoscopic experience to the users. The stereoscopic 3D videos of surgery in the application were rendered on two separate screens, each playing the right eye or the left eye video. To prevent any rendering issues due to different positions, the researcher duplicated the first screen but changed the material to play a different video. Two cameras (Left and Right) were placed at the same distance from the screens to render the videos in 3D. Following the suggestions from Google I/O 2016, the screens were placed at 5m away from the point of view Figure 5.39.

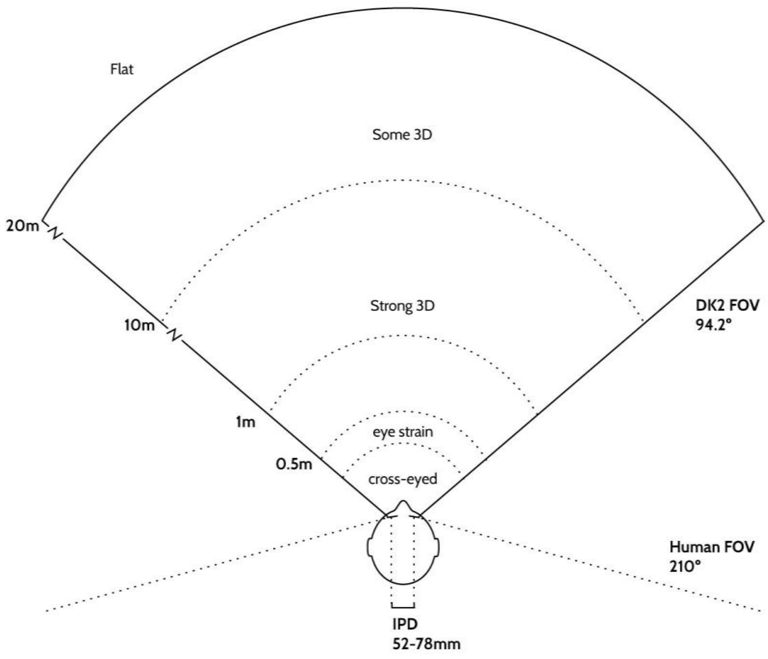


Figure 5.39 Appropriate placement of 3D content

Curved screens were used to display the stereoscopic 3D videos and menus in the application. The curved screen displays and semi-circular arrangement of the panels make use of the peripheral vision of the users to provide an immersive presence in the environment Figure 5.40.

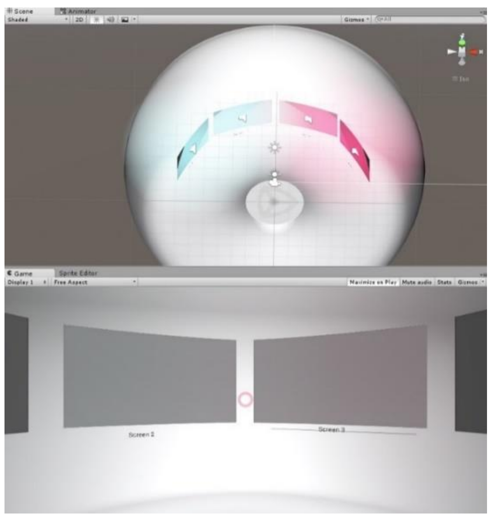


Figure 5.40 Curved Screens UI for VR Surgery

In VR Surgery as the eyes try to accommodate to the screen, they also converge to a distance further off to see the 3D object. When the user brings their hand into the field of view, a clear mismatch causes a vergence-accommodation conflict. To prevent this, the users were asked to look away from the screen while interacting with their hand UI.

5.4.3 Designing interactions

The user interactions in VR Surgery are based on UI input methods of Oculus Rift headset or Leap Motions.

Oculus based interactions

Oculus uses gaze pointer to detect the user's head movement and to interact with VR. To determine the position of a user's gaze, a reticle was used. A reticle is a two-dimensional circle that is overlaid on the camera's field of view. When the user looks at an interactive object, the reticle turns into a faded circle which can be filled as shown in the Figure 5.41. An inactive reticle is represented by a dot and shows where the user looks. An active reticle animates the object which is gazed at as shown in Figure 5.42 and Figure 5.43. This form of gaze interaction makes the user more conscious of where they are looking. In VR Surgery, this functionality was used to select a menu item, name different bones in the skull, and name various instruments based on where they look.

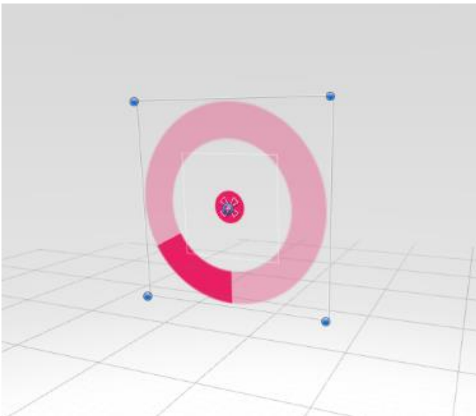


Figure 5.41 Reticle was used to determine the gaze of the user

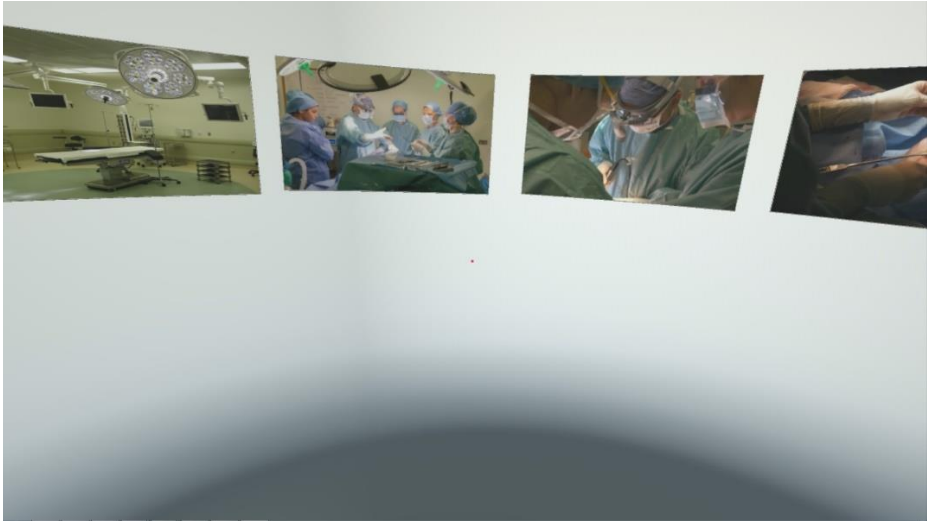


Figure 5.42 Inactive reticle shown as red dot

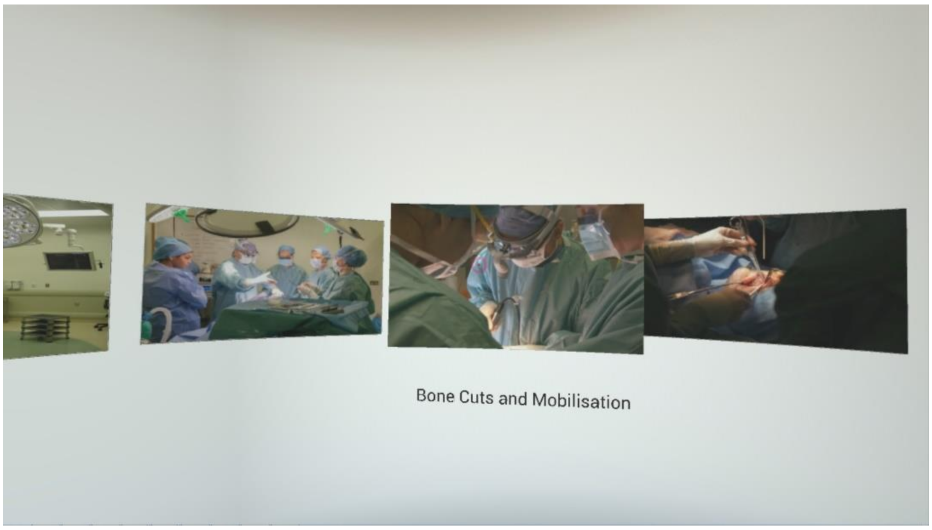


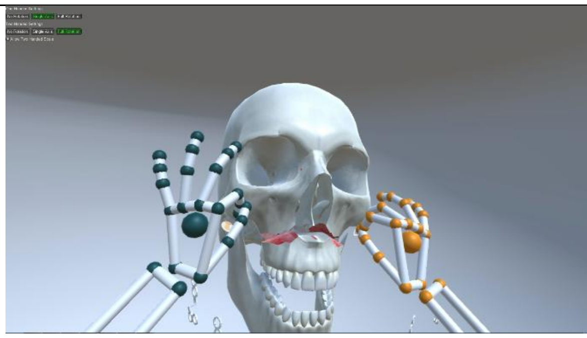
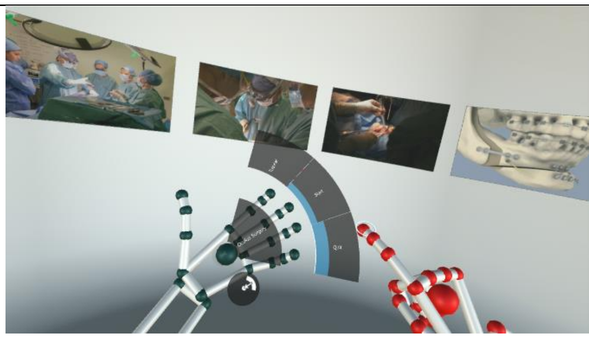
Figure 5.43 Active reticle showing the name of selected panel

However, the reticle forces the user's eyes to focus on it as it is attached to the camera. To prevent this, the reticle was reduced in size, scaled along with its position and always overlaid on top of other 3D surfaces.

Leap Motion interactions

Leap Motion based interactions in VR Surgery allow the user to interact with the patient's anatomy, instruments, and data. To facilitate these interactions, various gestures with special detectors of Leap Motion were used (Colgan, 2016) as shown in Table 5.4.

Table 5.4 Gestures used in VR Surgery

Type	Function	Image
Pinch	Select a menu button Pick up an object Rotate an object along the vertical axis.	
Touch, Point	Push a clickable button Select an instrument	
Two-handed interaction	Rotate an object in all directions. Scale the object smaller or bigger based on the distance between the hands	
Grab gesture	Picks up an instrument Grab a particular anatomical structure.	
Hand based UI	Accessible UI Two-handed interaction. Left-hand shows menu; right index finger has the click zone	

Pinch gesture is the core selection gesture in VR Surgery. Here, a Logic Gate (AND gate) was used to identify the fingers which are folded and which are extended. If the distance between thumb and index finger is less than a threshold distance, the pinch gesture gets activated. Different functions including selection of menu buttons were activated whenever the trainee uses a pinch gesture.

Two handed interactions were made using a special script in Leap plugin called Leap RTS. It functions based on the proximity detector, which identifies the distance between an object and the hand. If the user brings one hand close to the subject matter and pinch, the hand can pick up the object. If both the hands are brought closer to the object, the user can scale the size of the object based on the distance between the hands as shown in the Figure 5.44. Leap motion development portal (Leap Motion, 2016, Plemmons and Mandel, 2016) provides necessary guidelines to design these gestures.

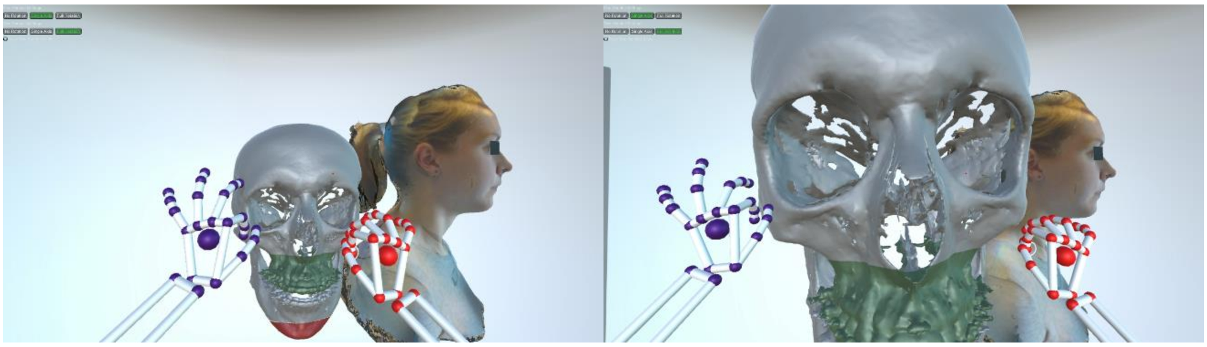


Figure 5.44 Scaling an object in VR Surgery

Drawbacks and Challenges

1. Unintended grasp – when the users move their hands down with closed fists, the Leap Motion device detects a pinch gesture, which leads to unintended grasp. To prevent unintended grasping, pinch gesture should only be activated when the user gazes at the specific object of interest.
2. In VR Surgery, the user is not allowed to interact with the surface scan of the patient's data. This limitation in functionality was introduced as a response to the raising ethical concerns in Virtual Reality (West, 2016). However, this design element was against the human nature of trying to interact with objects close to the user. The presence of hands in the environment makes this experience worse as the user expects to interact with any object close to the interaction zone (Leap Motion, 2017). However, this challenge was not addressed in the current version of VR Surgery.

3. While selecting the instruments, the input commands from Oculus and Leap can conflict and prevent the proper interaction with the instruments. This issue was solved by incorporating hand UI.
4. The addition of Physics engine to instrument interaction is not useful if haptic force feedback is missing.

5.4.4 Scene transitions

Scene transitions and movement within VR are important aspects in the head mounted Virtual Reality experience design. A sudden unexpected transition disrupts the immersive experience of the users. Every disruption to this experience consumes time for the user to get back to the experience once again. To prevent this, a dissolve or fade through the black transition was provided between the scenes. As the scene dissolves, the camera tracking was maintained. A constant audio between the scenes using a special script further enhanced this experience and prevented any obvious disruptions. A blink transition is another seamless way to change scenes, but the current research has not explored blink transitions in VR Surgery (Forsyth, 2014).

In VR Surgery, users cannot walk around, except in the virtual operating room. In the virtual operating room, the users were teleported to the desired point through a fade transition. User testing showed that a first person controls to move in the operating room ambience causes nausea and VR sickness. The design of the application ensured that the user can control all the animations. By maintaining the same position of the stereoscopic 3D video scenes, similar affordances in menu interactions and the same audio across different scenes, a sense of presence was created. A full-screen fade to black animation was applied on the camera as the users moved between the scenes.

5.4.5 Environment design

To enhance the immersion levels, the environment in virtual reality applications needs consideration. In VR Surgery, both the 3D operating room ambience and 360º video of an empty operating theatre were used as a background while the user interacts with the main menu as shown in the Figure 5.45. Using the 360º video ambience enhanced the realism and improved the user experience. However, when the user interacts with the buttons simultaneously with the hand interface, the functionality of the application was disrupted. To reduce this effect and enhance the user experience, the researcher replaced the 360º video with a spherical image of the operating room on a bigger sphere.

Figure 5.45 360 degrees environment design for VR experiences

By placing spheres with 360-degree images in layers, a sense of depth can be created. This aspect of environment design was not explored in VR Surgery yet.

5.4.6 Sound design

The sound is an essential element to enhance the immersion in the virtual reality experience. Spatial audio creates a sense of presence to the users (Oculus VR, 2016). In VR Surgery, the researcher attempted to recreate operating room sounds, voice feedback, user interface cues and enhance the user experience in multiple ways.

The audio from different cameras used in building VR Surgery was as following:

1. Dual Go Pro camera rig produced muffled audio, as the cameras were enclosed in a case. These cameras are used to record overall ambience sound only.
2. The six Go Pro camera setup used to capture 360º video also captured high-quality audio.
3. Mic worn by the surgeon was used to record his instructions while performing the surgery. Audio from this device was the best in the clarity. However, the recording was stopped abruptly as the surgeon lost the connection of the sound source while performing the procedure. Once the mic is clipped to the operating surgeon, it is not possible to modify the position or work the functionality in between as it disturbs the flow of the surgery. This inability to control the audio is a drawback.

4. The audio from Sony stereoscopic 3D cameras provided the most efficient sound, as it was placed next to the surgeon.

In addition to the operating room sounds, the researcher recorded audio instructions for the application at the University of Huddersfield with the help of colleagues as in Figure 5.46. A script providing audio guidance to the application was designed to assist the usage of VR Surgery.

Figure 5.46 Voice recording for VR Surgery

Audio cues were also provided for gaze detection. In addition to the visual feedback, the location of user's gaze was identified with specific audio cues. The audio played whenever the user passes their gaze onto an intractable object. Unity 3D and Oculus provides a library of audio files to be used as background music or audio cues. User interface interactions were also supported by audio feedback, including pushing a button or swiping across the slider or picking up an object. These audio files enhanced the user experience and improved how they interacted in VR Surgery.

5.5 User testing

Feedback on usability, design and content were gathered from surgical trainees in maxillofacial surgery, supervisors, and colleagues throughout different steps in the design of the application. The user testing and their feedback helped the system to be robust and comfortable for usage, especially in viewing stereoscopic 3D content and in designing Leap Motion based interactions. An image of the users testing VR Surgery can be seen in Figure 5.47.

Figure 5.47 Users interacting with VR Surgery

User interaction tests were carried out every fortnight, where non-medical participants tested different features of the application and provided their feedback. Based on their suggestions a modified version was shown to them once again. The researcher observed how different participants were interacting with the system and modified any difficult manoeuvres. Changes to VR Surgery based on users' suggestions were as follows:

1. Users suggested that addition of audio feedback is improving the interaction with the interfaces.
2. The users found interacting with Leap Motion was sensitive and involved a learning curve. A tutorial scene was added to help the users with interactions.
3. Users found it unnatural to use "pinch" gestures to click a button.
4. Users found it difficult to assess the depth of the buttons in scenes involving 360º videos of the operating room. Need to evaluate the depth was removed by using hand interfaces.
5. Hand interface with buttons positioned in the same spot in consecutive scenes led to unintended interactions. The challenge with unintended interactions was overcome by delaying the interactions between the scenes.

6. The researcher observed that the surgical trainees found it difficult to watch all the videos in succession. To overcome this issue, stereoscopic videos were combined with 3D interactions.
7. Stereoscopic 3D videos recorded at different depths and zoom levels created a vergence-accommodation conflict. This issue was resolved using multiple videos at different zoom levels or fade to black transitions among the various zoom levels.
8. Based on the suggestion of surgical trainees, the background of the videos was left blank.
9. Surgical trainees suggested the resolution of videos need to be improved. The angle of recording should be perpendicular to the patient's head and not covering surgeon's hand while performing the surgery.

5.6 Summary

This chapter gives an in depth understanding into the technology used in the development of VR Surgery. Further, the researcher explained the implementation of VR Surgery and the challenges faced in the process. In the next chapter, the researcher describes the validation of VR Surgery by expert surgeons.

Chapter 6 Validation of VR Surgery

Following the Design Science Research (DSR) methodology, VR Surgery was evaluated in two stages. In the first phase, expert oral and maxillofacial surgeons validated the content, functionality and usability of the application. After modifying the application based on their suggestions, surgical trainees tested the efficacy of VR Surgery through a randomised controlled trial (RCT). The following two chapters will discuss the validity study and evaluation study respectively.

6.1 Introduction

The need to improve existing surgical training tools introduced the usage of a wide variety of simulators and virtual reality experiences as discussed in chapter 2. As these training tools influence real life performance, it is important to identify necessary evidence about the potential impact of surgical simulations. However, 94% of medical simulators in the market are not validated, suggesting an increasing need to evaluate surgical training tools for validity (Stunt et al., 2014).

Various guidelines and best practices followed in the design of VR Surgery need evaluation in a medical setting (Oculus VR, 2016, Leap Motion, 2015). Multiple sources of media ranging from stereoscopic 3D videos of surgery, 360º videos of the operating room, 3D surface scans of the patient and 3D animations were used, which needed experts' opinion about their usability, acceptability and application in training. As the system uses different interfaces including gestural interfaces and hand interfaces (Kinstner, 2016) to interact with various elements in the application, it was essential to check the usability and acceptability in training surgeons. Though VR Surgery is not a simulation, it creates an immersive experience by replicating the operating room environment and demonstrating surgical procedures in the environment. Hence, it is essential to validate the need the application in the light of existing research. Consensus guidelines for validation of virtual reality surgical simulators were followed in testing VR Surgery (Carter et al., 2005).

This chapter explains the role of different validity tests, focussing on face and content validity tests used in this research. Further, the research protocol, questionnaire design and results of the validity tests are presented. This is followed by a discussion of the results and a section on modifications made to VR Surgery based on expert surgeons' feedback.

6.1.1 Validity, types and justification

Validity is defined as ‘an extent to which an instrument measures what it is designed to measure’(Carter et al., 2005 p. 1524). These measurements may be subjective or objective. Based on their nature, validity measurements are classified into different types including face validity, content validity, construct validity, concurrent validity, discriminate and predictive validity (Gallagher et al., 2003). As VR Surgery is an innovative training tool and the first immersive surgical training experience in oral and maxillofacial surgery, it is essential to complete the subjective evaluation of experts. Therefore, the scope of the current project is to test the face and content validity of VR Surgery.

6.2 Questionnaire design

Two separate questionnaires were intended to check the validity of VR surgery. A pre-intervention questionnaire to understand the training needs and a post-intervention feedback to comment on the efficacy, usability and acceptability of the system. These questions were developed based on the previous face and content validity tests (Moglia et al., 2016, Sugand et al., 2015) and working with expert surgeons in oral and maxillofacial surgery.

A pilot test was performed to check the time taken for the study and make necessary modifications before the study.

6.2.1 Pre-intervention questionnaire

Once the experts signed the consent form, the pre-intervention questionnaire was given to them to assess their inclusion criteria. This questionnaire contained general questions including demographics, the experience of surgeons and experience in training novices. Questions unique to Le Fort I surgery including the most difficult step to perform, most challenging step to teach and the part of surgery where human errors are maximum were asked. A couple of questions in this questionnaire are negatively worded to prevent the users from acquiescence or response set behaviours (Jackson and Gibbin, 2006). For example, the statements including ‘The order of steps in Le Fort I surgery are not shown correctly in this application’ were used. Specific questions regarding the type of educational methods used and the extent to which they use technology in teaching were asked, as the user’s expectations about a new technology can influence their satisfaction levels (Olsson et al., 2013). In addition to that, previous experience of using head-mounted displays was asked to know if the user was familiar with the head mounted VR. Questions regarding awareness and certification for the Non-technical skills for surgeons (NOTSS) were asked.

6.2.2 Post-intervention questionnaire

The post-intervention questionnaire contained questions relating to the content of the application, usability and application in training. A five-point Likert rating scale was used to rate the quality of videos, 3D models of instruments and anatomy. Each scoring element ranged from strongly disagree/disagree/neither/agree/strongly agree. Space for additional open comments was provided, and the participants were encouraged to make use of it. Additional suggestions regarding future developments needed in the application were taken from the surgeons. The necessity of few elements like the 360-degree videos and interactive animations of 3D patient scan data were asked. Questions comparing the impact of 2D videos versus 3D videos and the sequence of steps in surgery were asked to learn about the differences in different media and their role in learning.

Based on (Bangor et al., 2008)'s System Usability Scale, five-point Likert scale ratings were used to rate the comfort of using the headset, accuracy and appropriateness of hand tracking, and quality of the audio and videos in the application. The last section asked the experts regarding potential applications of the VR Surgery in training surgical trainees. Their opinions on the use of the VR Surgery for training, benefits of its use for multiple procedures and acceptability into curriculum were questioned. The effectiveness of VR surgery on the understanding and confidence of users was also asked. In line with current studies (Davis, 2016), the surgeons were asked if they considered VR surgery as an effective adjunct to current training methods. Question regarding the inclusion of non-technical skills was added to the feedback. Both the pre and post intervention questionnaire are available in the Appendix –III.

6.3 Face and Content validity study protocol

There is a lack of literature on the specific guidelines of validity tests for immersive Virtual Reality experiences. The current study was designed based on the previous studies, which evaluated face and content validity for virtual reality simulators (Sugand et al., 2015). A detailed study protocol explaining the selection criteria, methods of data collection, data analysis, questionnaires and ethics approval are provided in Appendix I and Appendix III. This part of the chapter explains the study design, recruitment of the participants, and intervention.

6.3.1 Study design

Expert surgeons were invited to take part in the study and provide feedback. The aim and objectives of the research along with the challenges in using head-mounted displays were informed to surgeons. The inclusion criteria for the participants was that they have to be consultant surgeons in Oral and Maxillofacial Surgery and be involved in training novices. Participants who left the study incomplete were not analysed. The study received ethics approval from University of Huddersfield Ethics Committee.

Primary Hypothesis

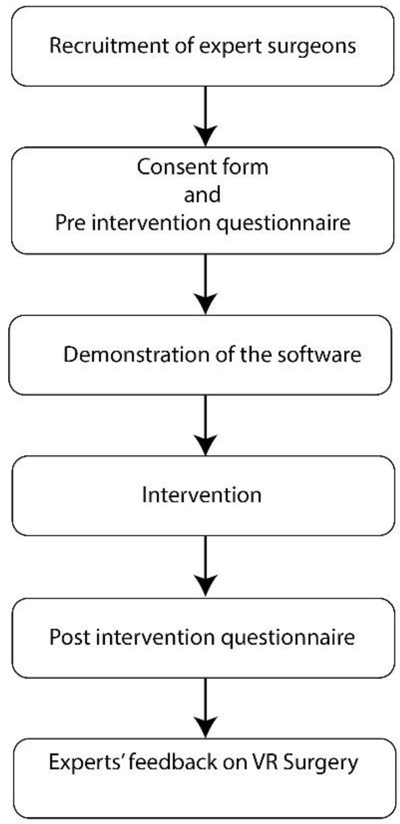
VR Surgery looks and functions as a valid surgical training experience for Le Fort I osteotomy.

Secondary Hypothesis

- VR Surgery has a satisfactory level of usability.
- VR Surgery could be added to the current surgical training curriculum.

The implementation of the study followed the following sequence as in Chart 6-1.

Chart 6-1 Flowchart showing the study outline



6.3.2 Recruitment of the participants and consenting

Expert Oral and Maxillofacial Surgery consultant surgeons were invited by email and informed about the objectives of the study. Based on the availability of the surgeons, nine consultant surgeons voluntarily took part in the validation process. A consent form outlining the aims and objectives of research was given to the participants. Following the safety measures before using the headset (Oculus, 2015a), all the participants were asked if they suffered from any psychiatric disorders including attention deficit hyperactive disorder, epilepsy or if they are on any anti-psychotic drugs. Any previous history of motion sickness and seizures was also recorded to prevent unintended recurrences.

6.3.3 Intervention

Following a tutorial and demonstration on how to use the system, the participants used VR Surgery application by themselves. Surgeons used the virtual operating room scene with virtual anatomy, patient data and instruments. Feedback was provided following the use of different aspects of the application. The sequence of steps and 3D Stereoscopic videos of individual steps of Le Fort I surgery were watched by the surgeons and commented on the quality and accuracy. 360º videos showing the surgery in the operating room from a first person perspective was then shown to the surgeons. After using the application for 45 minutes, surgeons completed the post-intervention questionnaire.

Statistical Analysis

IBM SPSS version 22 (IBM Analytics, 2017) was used to analyse the data in this study. Similar to the previous face and content validity tests (Moglia et al., 2016, Sugand et al., 2015). Multiple Likert type questions were posed to experts to validate the application's accuracy, functionality, usability and applicability in the curriculum. The analysis of Likert Scale responses depends on the kind of data obtained through the study (Boone and Boone, 2012). As the researcher was asking individual questions, which relate to a particular aspect of the application, the composite score of individual questions was calculated on an interval scale. To analyse these questions, the mean value for individual questions was calculated and an average of all the means was calculated. For the questions representing ordinal data, descriptive statistics were used.

6.4 Results

Nine expert surgeons, who work at NHS and train novices at multiple universities including Manchester, Leeds and Glasgow took part in the validation of VR Surgery. Out of these, seven (77.8%) have responded to the questionnaire while two surgeons have not completed the assessment. The mean age of the participants was 41.83, with all the participants being male and a mean experience of 15.50 years. None of the experts currently use head-mounted displays in training. However, they intend to know and explore the potential of using it. All the experts suggested the surgical training in an operating room is the best form of learning, and 57.1% of the surgeons mentioned that videos are currently used as an adjunctive method of training. All the surgeons have answered bone cuts as the most difficult step while training novices for Le Fort I surgery. The surgeons have rated VR Surgery on a five-point Likert scale for its content, instrumentation, anatomy, usability and role within the curriculum.

6.4.1 Content

The mean value of scores for the questions about the content determines the validity. A mean value of 4.5 shows a strong agreement of validity for the video content shown in the application. The negatively worded question about the order of steps in surgery showed a low mean value of 2.71(Question 3). Only 3 out of 7 surgeons realised it as a negatively worded question. After checking all the videos in the application, the surgeons did not find a missing step in Le Fort I surgery. The mean score for the benefits of various elements used in the application was 4.46. A question-wise response to the content quality is shown in the Chart 6-2. As none of the surgeons answered Disagree for the question, it was eliminated. An overview of the mean scores on the content of the application shows an overall agreement with the validity as in Table 6.1.

Chart 6-2 Experts response to the questions regarding the content

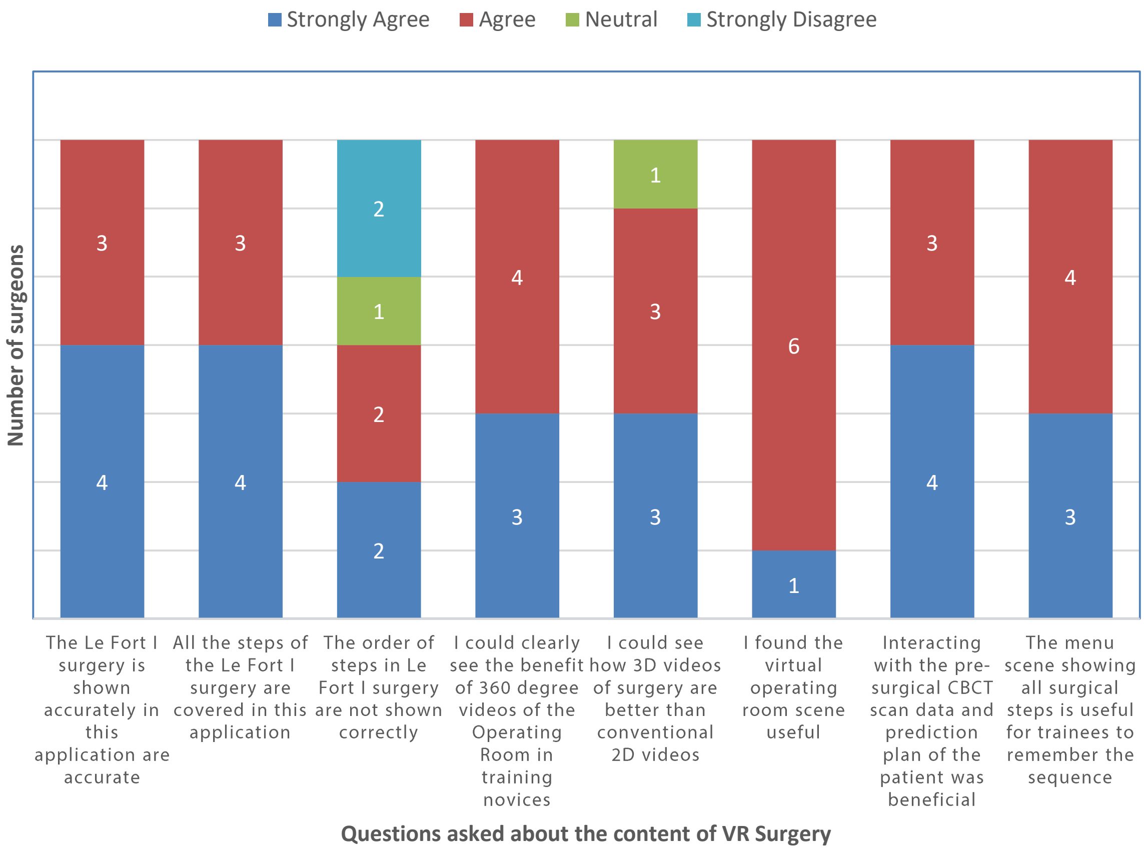


Table 6.1 Mean scores about the Content of VR Surgery

		Surgery content	Steps of surgery	Sequence of steps	Benefits of using 360 deg. video	3D videos are better than 2D	Virtual operating room	3D patient data	Menu scene
N	Valid	7	7	7	7	7	7	7	7
	Missing	2	2	2	2	2	2	2	2
Mean		4.571	4.571	2.718	4.429	4.29	4.14	4.57	4.43
Median		5.000	5.000	4.000	4.000	4.00	4.00	5.00	4.00
Mode		5.0	5.0	1.0[a]	4.0	4[a]	4	5	4

a. Multiple modes exist. The smallest value is shown

6.4.2 Instrumentation

The expert surgeons validated the appearance, use and realism of the instruments. The total score for the questions on instruments is 4.6. Some surgeons added instruments including retractors and guarded osteotomes to the list. They have also commented on the interaction with the images, instead of 3D representations of the instruments. A question-wise response to instruments is shown in the Chart 6-3. An overview of the mean scores of the instruments in the application shows an overall agreement with the validity as in Table 6.2

Chart 6-3 Experts response to the questions about surgical instruments

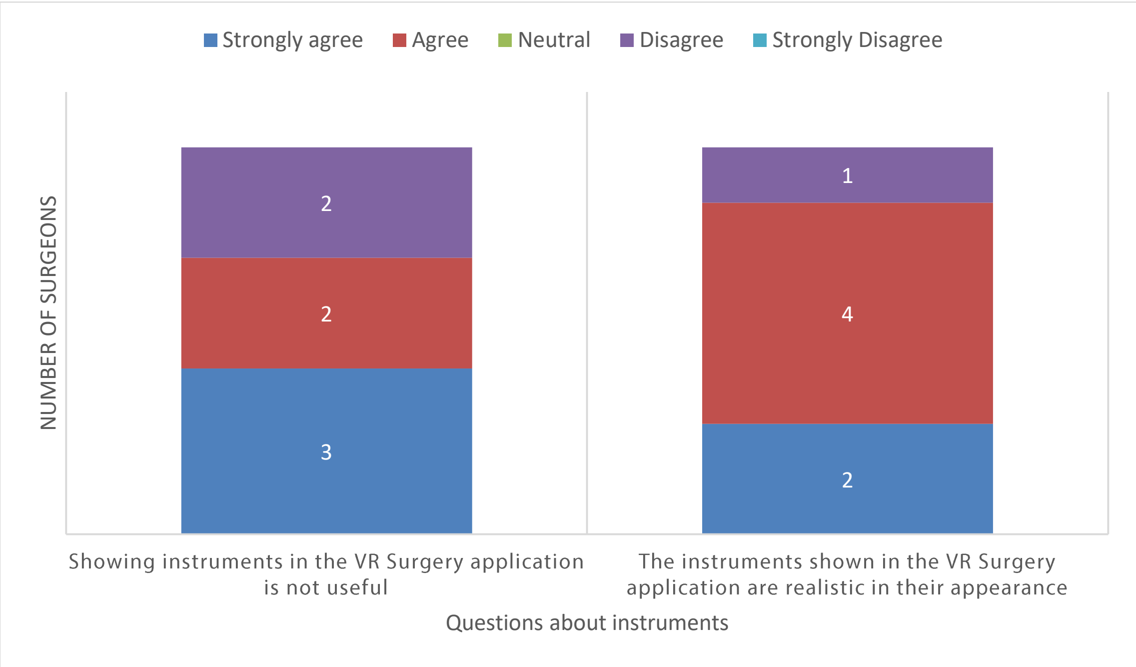


Table 6.2 Mean scores about the instrumentation

		Usefulness of instruments in VR Surgery	Realism of instruments in VR Surgery
N	Valid	7	7
	Missing	2	2
Mean		3.86	4.00
Median		4.00	4.00
Mode		5	4

6.4.3 Anatomy

Questions regarding the anatomy got an overall mean score of 4.5, showing a strong agreement with the face and content validity. The questions ranged from measuring the accuracy of the anatomy, accuracy of the 3D models and the need for anatomy in this application. The overall agreement supports the validity of VR Surgery. A question-wise response to anatomy is shown in Chart 6-4 and the mean values are shown in Table 6.3

Chart 6-4 Experts response to the questions about anatomy

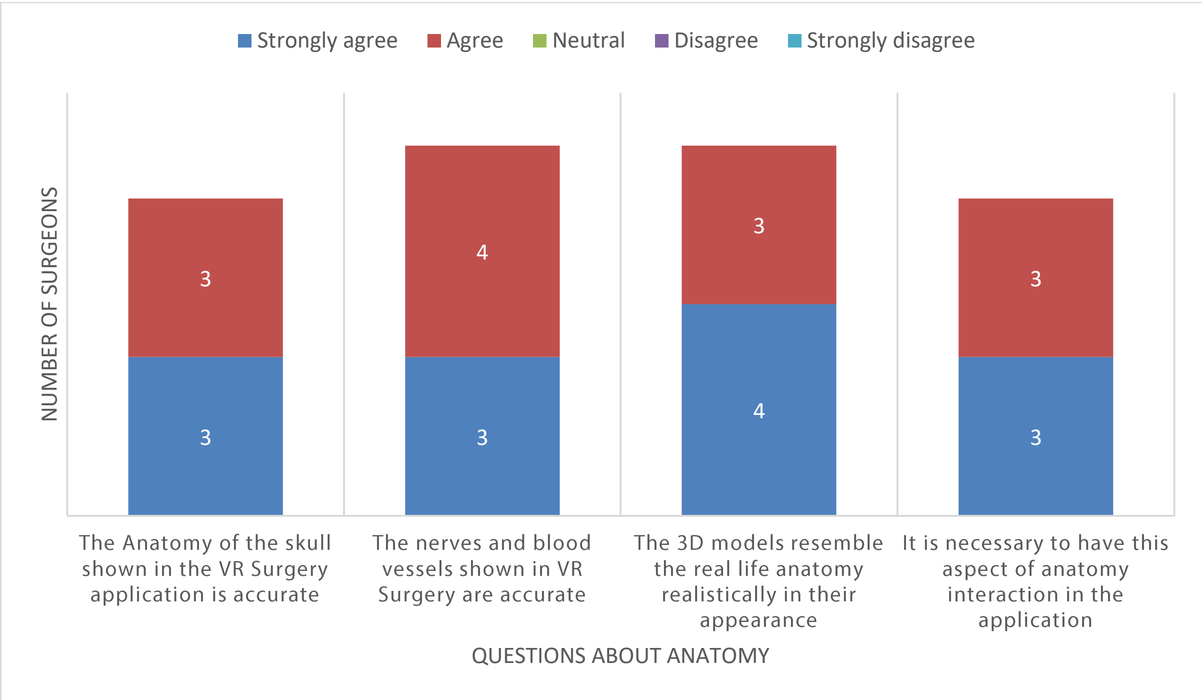


Table 6.3 Mean value of the anatomy

		Anatomy of skull	Anatomy of blood vessels and nerves	Realism of 3D models	Necessity of anatomy in VR Surgery
N	Valid	6	7	7	6
	Missing	3	2	2	3
Mean		4.50	4.429	4.571	4.50
Median		4.50	4.000	5.000	4.50
Mode		4[a]	4.0	5.0	4[a]

a. Multiple modes exist. The smallest value is shown

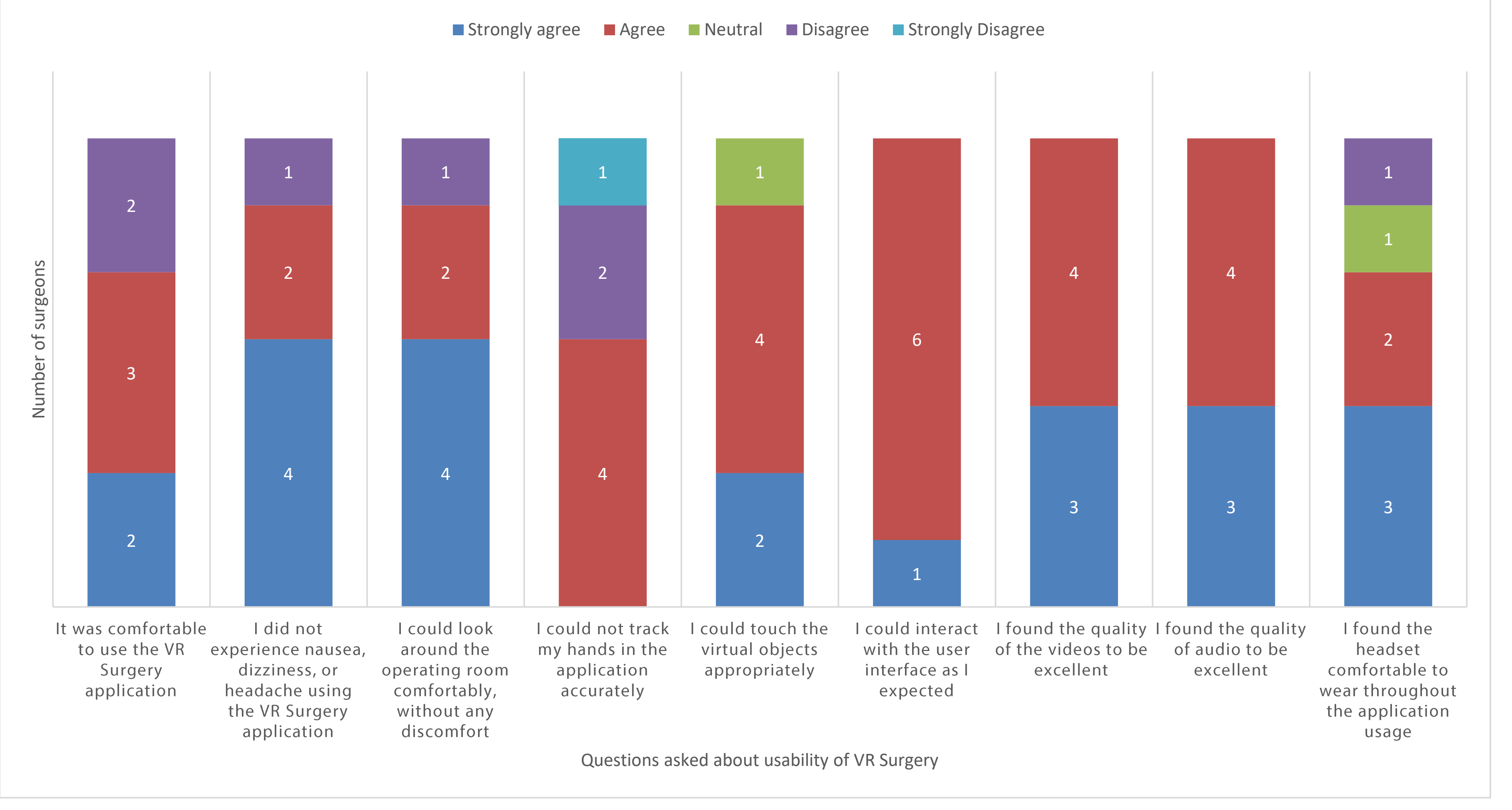
6.4.4 Usability

Qualitative questions regarding the comfort of the user, accuracy of hand tracking, quality of the media used, comfortability in wearing the headset and overall usability were asked in this section. The mean scores for various questions regarding the usability are as shown in Table 6-4. A question relating to the comfortability of the headset was rated 3.7, and the negatively worded question regarding the interaction got a mean score of 3. Rest of the issues in the usability got a mean value of above 4 showing an agreement. A question-wise response to applicability is shown in the Chart 6-5.

Table 6.4 Mean Score for usability

		Comfortability	Nausea in using VR Surgery	Head tracking	Leap Motion (Neg. question)	Leap motion accuracy	UI	Video quality on Oculus	Audio quality on Oculus	Comfortability of headset
N	Valid	7	7	7	7	7	7	7	7	7
	Missing	2	2	2	2	2	2	2	2	2
Mean		3.714	4.29	4.286	3.000	4.14	4.143	4.43	4.43	4.000
Median		4.000	5.000	5.000	4.000	4.000	4.000	4.000	4.000	4.000
Mode		4.0	5	5.0	4	4	4.0	4	4	5

Chart 6-5 Experts response to the questions regarding the usability of VR Surgery



6.4.5 Role of VR Surgery in current training

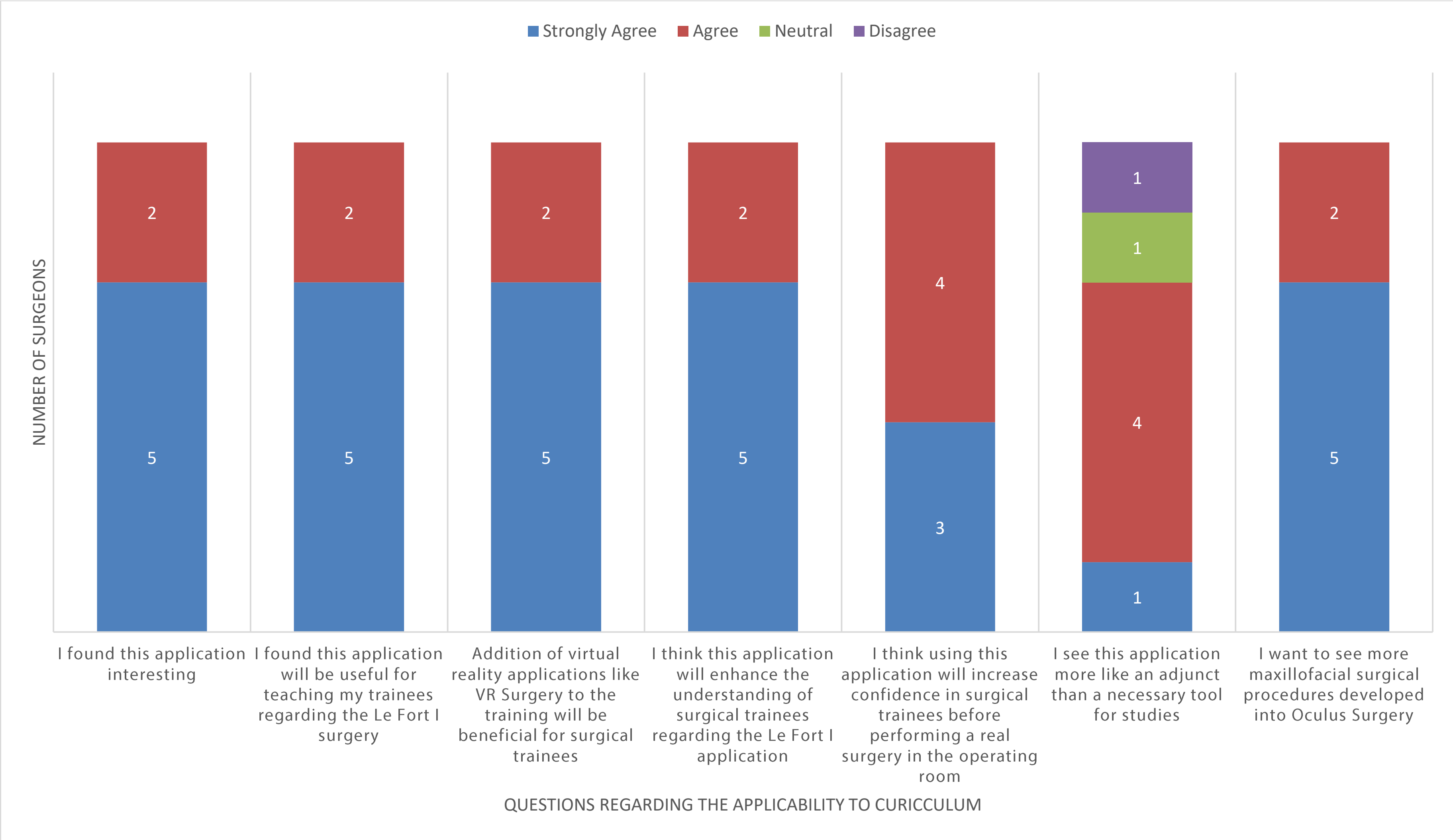
Questions regarding the application of VR Surgery within current surgical training showed a mean value of over 4.7 for most of the questions as shown in Table 6-5. This shows a strong agreement towards the applicability of VR Surgery into the curriculum. A question concerning the applicability of the software as an adjunct tool was rated low, as some surgeons commented, this is indeed a necessary addition, not an adjunct.

A question-wise response to applicability is shown in the Chart 6-6.

Table 6.5 Mean score for applicability of VR Surgery into curriculum

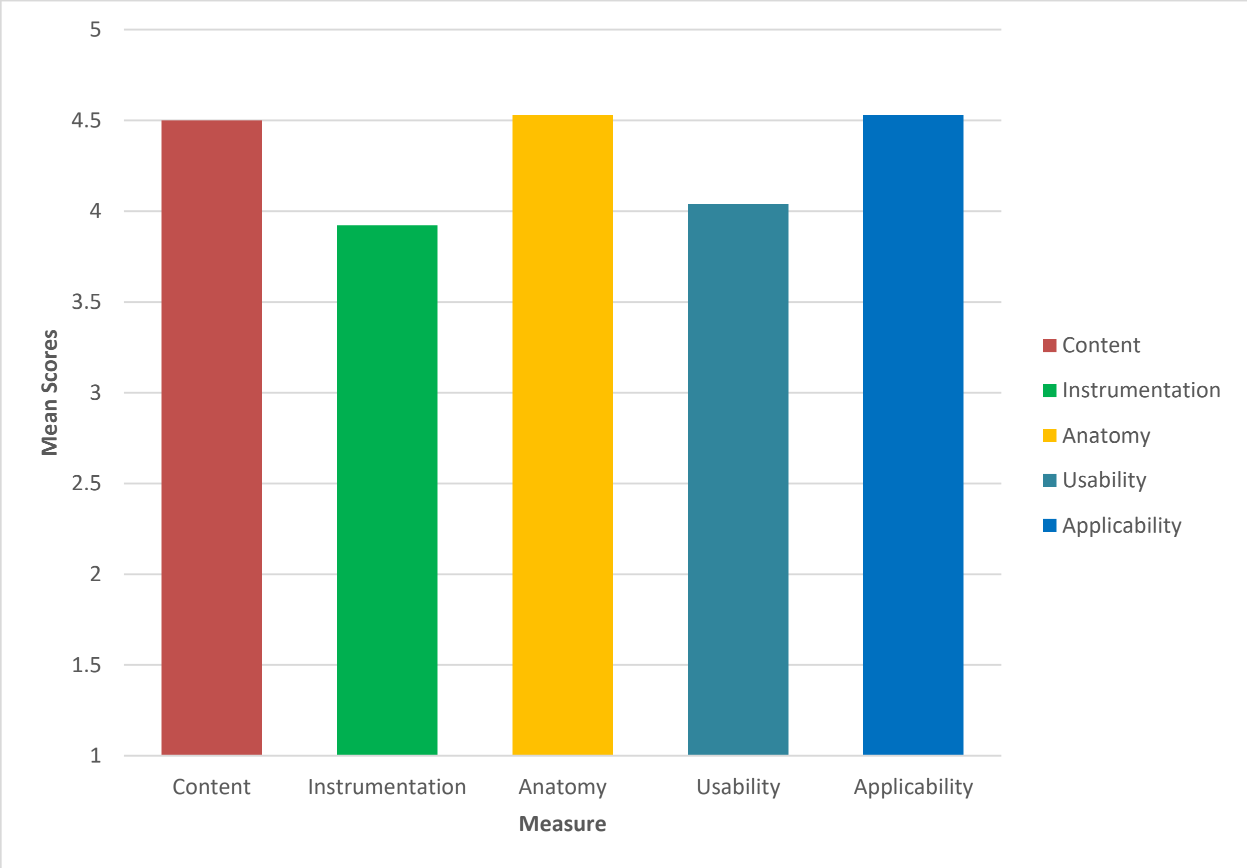
		Interesting to use	Usefulness	Beneficial for training	Understanding	Confidence	Adjunct training method	More procedures are needed
N	Valid	7	7	7	7	7	7	7
	Missing	2	2	2	2	2	2	2
Mean		4.714	4.714	4.714	4.71	4.43	3.714	4.714
Median		5.000	5.000	5.000	5.00	4.00	4.000	5.000
Mode		5.0	5.0	5.0	5	4	4.0	5.0

Chart 6-6 Experts' response to the role of VR Surgery in current training



Overall, the surgeons ranked VR Surgery as a valid training tool as shown in the Chart 6-7.

Chart 6-7 Overall mean score of VR Surgery



6.5 Discussion of the validity study results

The results showed experts' agreement with the face and content validity of VR Surgery. In addition to rating the quality and accuracy of the content, they provided qualitative feedback on individual elements of the application such as the contents, drawbacks and potential modifications as shown in Table 6-6.

Experts appreciated VR Surgery's interactivity and the ease of use. However, they commented on the learning curve for the system. The introduction of the tutorial was beneficial in giving them a hands-on demonstration before using it. They suggested the addition of haptic feedback and realistic interaction with instruments would make a better experience. When interacting with multiple objects, the experts pointed out the lack of control in the system and suggested if the interaction could be individualised for each part. For example, when interacting with the bones of the skull, the ability to choose individual structures and learn about their anatomical orientation was suggested.

Surgeons felt the advantage of VR Surgery lies in its interactivity. Interactive 3D anatomy and instruments were the most appreciated features in the application along with the 360º video of the operating room. Surgeons found the ability to interact with different aspects of surgery to be more beneficial than just watching them. Also, they asked if it is possible to pause an aspect of surgery and take part in it virtually. Though this is an achievable task, it is beyond the current timelines. They also suggested necessary modifications be made in the 3D animations.

Some surgeons felt that the quality of stereoscopic 3D videos on Oculus is reduced. This reduced video quality was due to the screen door effect (Desai et al., 2014), which is discussed in detail in the Oculus Rift section of chapter 4. Because of the screen door effect, the user perceived a grid of fine lines, i.e. the space between pixels, while watching the stereoscopic 3D videos. Screen door effect is more prominent in the development kits of Oculus Rift as the low-resolution screen is placed just inches away from the eyes. They also commented if the videos were recorded at an angle just above the patient's head, they would have given better results. Recording the video of surgery above the patient's head was tried, but if the camera cannot be controlled due to distance and sterility in the operating room, the output will be compromised. A deeper discussion of this aspect is in the stereoscopic 3D video section of chapter 5.

"Anatomy of the application would be better if annotations were added to all the structures demonstrated" was suggested by one surgeon. Further, selective interaction with various structures could improve learning of trainees. Further challenges in showing the annotations towards the camera's field of view are discussed in the design of the application. Some surgeons reported preset orientations would provide better visualisation than the ability to rotate in all directions.

Regarding the interactivity, surgeons suggested individual movements of the bones is more beneficial than moving the entire skull. They also suggested highlighting an aspect of the interaction would be more beneficial. Both these suggestions were followed, and the system was modified accordingly.

Two surgeons commented 'interactions with instruments could be more realistic.' Different forms of instrument interactions were built into the system where the trainee can gaze, identify and interact with them. However, when adding physics interactions to the instruments, the application was found to be more processor intense. The tradeoff between the physics, computational power and the need for interaction to be hyper-realistic made the researcher choose the existing design model.

Suggested future improvements include developing animations for the entire orthognathic surgery, role playing scenarios in the operating room using a tree-shaped architecture. They also felt the technology could be applied for other dental procedures like dental extractions, removal of impacted teeth, raising a flap and cancer removal. Surgeons suggested to include multiple levels of complexity for basic, intermediate and advanced levels with various levels of knowledge and interaction. The introduction of haptic force feedback and real-time feedback with data interaction was suggested.

Few expert surgeons acknowledged the learning curve involved in interacting with user interfaces in the application. Challenges in the position of buttons on the hand UI and their relative position in between the scenes showed the modifications to be made in the system. Gaze was removed when not needed. Air tap was introduced to select and interact with the objects.

Table 6.6 Expert surgeons' comments on VR Surgery

Expert Surgeons	Positive features of VR Surgery	Negative features of VR Surgery	Other comments
Expert 1	Interactive Easy to use Shadows in the 3D anatomy scene are realistic	There are loading delays between the scenes showing 360-degree videos	Time taken for the study can be increased to improve the quality of the feedback Role play in the operating room: Possible roles in the operating room Haptic feedback would be beneficial The video recording would have been better if the video was recorded at the patient's head instead of placing it over the surgeon.
Expert 2	Interactive application for learning	There is a visible fog due after extended usage of the headset.	This technology could be applied for other dental procedures for e.g. Flap reflection, 3rd Molar removal. The system is sensitive to gaze and click User training is needed. Interaction with the instruments could have been more realistic
Expert 3	Overall very good	3D videos were not so beneficial than an HD 2D video	Cameras should have been placed right on top of the patient's head

			Animations are good; it would be more useful to have more animations for other forms of orthognathic surgery like genioplasty. This application can be used to demonstrate extractions, flaps, anaesthesia This application could be a formal training tool for orthognathic surgery if more details can be added as in what is the defect and why the surgery is done.
Expert 4	Ability to interact with a topic with minimal materials	Learning curve in interacting with the system	Try developing three levels of expertise - Basic/entry level; Intermediate and Advanced level (Experienced surgeons can prepare for difficult scenarios; Scenarios can include severe bleeding).
Expert 5	Excellent implementation Interactive 3D Anatomy is most interesting	Unless the quality of the videos is improved, videos shown in 2D HD are much better	VR Surgery has many practical applications e.g. Training junior doctors; Training Senior House Officers; Acute Traumatic Life Support scenarios Would like to use add VR Surgery to teaching modules

			Emergency scenarios can be made with tree-like architecture using 360º videos
Expert 6	Best feature is the Quality of the visuals	360º video scene shows some lag and causes nausea Slightly heavy headset	
Expert 7	Excellent application 360º videos are excellent	2D videos in HD would be much better than 3D videos Loading delays: The delay in scene transition was addressed by changing the menu scenes' background from a 360º video to a still image of the operating room.	Excellent teaching aid for Trauma, Tracheostomy, Neck Dissection 360º videos can be used to train nurses, anaesthetists

6.6 Modifications made to the VR Surgery application

Despite recording the surgery over the surgeon's shoulder, experts felt an upright position to the patient's head would benefit the trainees. As this was not feasible in the current setting, the researcher edited the videos to remove any hand interferences. An expert surgeon suggested adding videos with formal narration explaining the operational steps. As the aim of VR Surgery application is to provide realistic operating room experience, the formal recording was not introduced. However, the researcher agrees that a formal narration with subtitles would add value to the application when the content is distributed globally.

Following the suggestions regarding the 3D anatomy, multiple organ selections, annotations, reset functionality, and preset orientations were added to the application. Initially, the application allowed all the movement of all the anatomical structures at once. However, surgeons felt that this adds to the cognitive load of the trainees, and asked us to separate individual movement of the bones. These interactions were modified by highlighting the object in a different colour and providing a visual feedback that the object is selected.

Experts suggested the use of laser scanned data for dental casts, but as the size of files was large for adding interactions on Unity 3D, they were omitted. Based on the suggestions, the researcher made modifications to the 3D Animations in VR Surgery, such as correcting the exaggerated movements of the maxilla and modifying the texture animations. Some surgeons also suggested replacing 3D models of instruments with the real images of the same. Following this suggestion, an individual scene was developed where the user gets to see instruments used in the operating room in the form of an image.

The surgeons asked if the pre and post-surgery CBCT scan data could be overlapped to emphasise the changes in patient's anatomy. In the current version of VR Surgery, data is overlapped with anatomy models, and it also showed pre and post-surgery images to appreciate the changes. Expert surgeons expressed difficulty in learning how to interact with gaze and hand gestures. To train the usage of VR Surgery application, the researcher introduced a tutorial, which allows the users to interact with basic shapes like cube and sphere as shown in Figure 6.1, Figure 6.2, and Figure 6.3. Users can select individual objects by clicking, highlight based on their gaze and practice interactions by moving them across, and pinch to change the size. After introducing this learning module into the application, experts rated the system high for its usability.

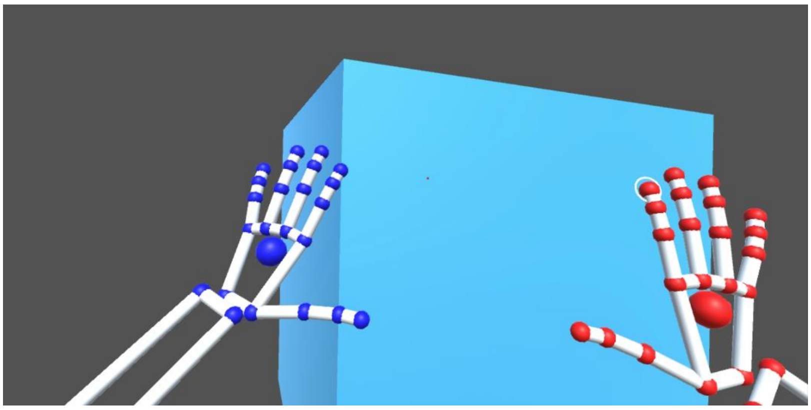


Figure 6.1 Basic hand gestures to move the cube

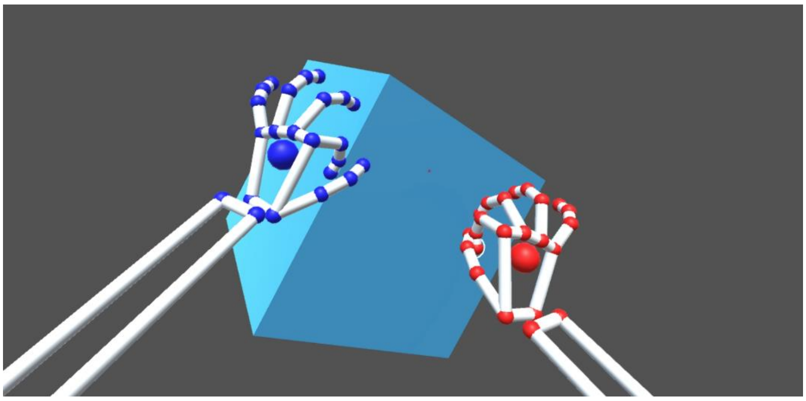


Figure 6.2 Pinch gestures to change the size of the objects

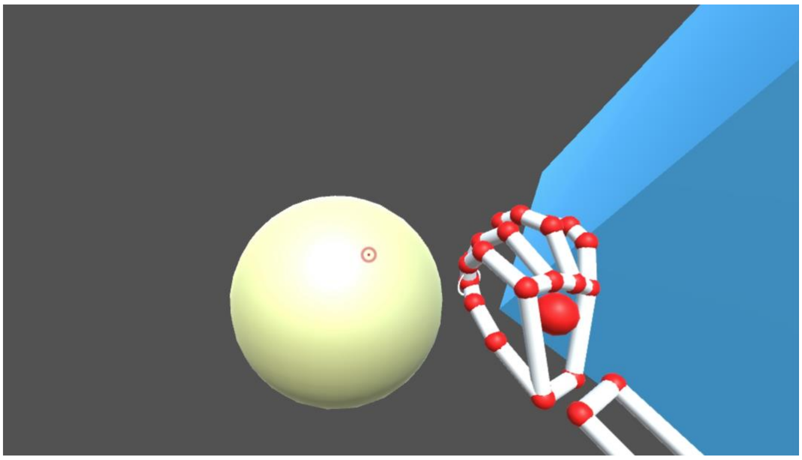


Figure 6.3 Gaze to select and pinch to pick up objects

6.7 Summary

The validity study of VR Surgery is one of the significant contributions of this research. In addition to getting a real time feedback from the expert surgeons, the researcher identified necessary modifications to be made to the system. However, validation can only explain if an artefact is scientifically accurate or not. Evaluation of the artefact in comparison to existing technology will show the effectiveness of the system. Evaluating the effectiveness of the artefact differentiates the design science research from design theory. The next chapter discusses the evaluation of the system when tested with surgical trainees through a randomised control trial.

Chapter 7 Randomised Controlled Trial (RCT)

Following the validity studies, the researcher evaluated VR Surgery for its efficacy in training novices. As the research rigour is highest for the randomised controlled trials (Sibbald and Roland, 1998), a multisite parallel single-blind randomised controlled trial was chosen. Novices in the experiment were surgical trainees who assisted in less than 20 Le Fort I osteotomies (Crispen and Hoffman, 2016).

As the trainees in the UK are distributed amongst different NHS, they were not available in the given time span of the research. Therefore, the researcher chose to perform the study elsewhere. As the number of trainees and their availability was higher in India than in the UK, and as the researcher has a well-supported network in India, this place was chosen. Further, the syllabus and the training modules are not significantly different in India compared to that of the UK (Kumar, 2009).

This chapter outlines the background of the research, study design, data analysis, results and discussion. The background section explains the aim and objectives of the study, followed by the null hypotheses. The research outcomes and the rigour are discussed here. In the second section, the study design outlines the research protocol and the questionnaire design. The research protocol explains the selection of the participants and the intervention. Following the intervention, the data collection and analysis were explained. The results of the study are outlined with details of the experiment, qualitative and quantitative feedback from the trainees. This is followed by a discussion of the results.

7.1 Introduction

The aim of this randomised controlled trial was to test the impact of VR Surgery on the perceived self-confidence of trainees. To achieve this aim, the study tested the difference in the self-confidence levels and knowledge levels before and after intervention in both experimental and control group. Further, the study evaluated if the results are affected by the stage of surgical training.

The null hypotheses stated that there will be no difference in the perceived self-confidence after intervention between the experimental and control groups. The alternative hypothesis was that the self-confidence levels of experimental group would be different to that of the control group after the intervention. The primary and secondary outcome measures were used to test these hypotheses.

The primary outcome measures were the comparative evaluation scores of the perceived self-confidence levels before and after the intervention, as measured on a five-point Likert scale. The secondary outcome measures were the comparative evaluation scores of the knowledge as measured using the multiple choice questions before and after the intervention. Details about the other aspects of the study are explained in the study design.

7.2 Questionnaire design

Three questionnaires were designed for this study. Demographics and pre-intervention questionnaires provide the baseline data, while the post-intervention questionnaire shows the impact of the intervention (Appendix –iv). This section will discuss each one of them in detail. All the three questionnaires were co-designed with expert oral and maxillofacial surgeons. The researcher validated the questionnaires by performing a pilot test with expert surgeons. Following their suggestions, the researcher worked with experts in cognitive science to identify important aspects of self-confidence and how they can be enquired.

7.2.1 Pre-intervention Demographics

The pre-intervention demographics questionnaire was provided to find basic information about the training experience of the participants. Questions related to the of the participants' demographics, stage of study and the place of the study were asked. Following this, the number of procedures observed and the number of procedures assisted by trainees were asked to understand the level of training. Lyon (2004) mentioned that the learning in the operating room is challenging because trainees are not able to view most of the procedure. To understand the current state of the surgical training, researchers introduced questions regarding the learning experience. Further, participants were asked about the alternative educational resources when they do not receive all the required information in the operating room. Specific questions about the Le Fort I surgery procedure was asked, including the most difficult step to understanding and most difficult step to perform.

Advances in surgical training have led to the introduction of novel training methods. To find the use of these approaches, trainees were asked about their usage and frequency of computers, smartphones and tablets, surgical simulators and VR/AR applications. Knowledge and frequency of use of these devices affect the training experience. To test these factors, trainees were asked about the Knowledge of head-mounted displays (HMDs). If the HMDs are not frequently available, and if the trainees have not used them before, the results might be affected by novelty bias (Mather, 2013). Trainees were asked about their perceived self-confidence regarding the knowledge of anatomy, instrumentation, and the sequence of surgery.

7.2.2 Pre-intervention assessment

This results of this questionnaire were intended to form the baseline of the trainee's knowledge about the Le Fort I surgery before the intervention. 12 out of 15 questions of them were regarding the pre-surgical information, anatomy knowledge, surgery and instruments. Three questions that test the non-technical skills of the trainees were included in the end to find out the level at which a trainee responds when challenged with an unexpected complication in the operating room (Mitchell, 2009, Mitchell and Flin, 2008).

Based on the operating room experience, questions concerning the teamwork were asked. In addition to these, questions regarding Le Fort I specific sensory information were asked. As previously described, these questionnaires were developed based on the expert surgeon's questionnaires.

7.2.3 Post Intervention assessment

This questionnaire with 20 questions was built based on the previous research on the perceived self-competence by Bandura (2006). To develop a self-confidence scale for surgical trainees in oral and maxillofacial surgery, the self-competence questionnaire was modified under experts' guidance. The questionnaire accommodates various elements of confidence needed for a trainee in Oral and Maxillofacial surgery. A five-point Likert scale was used to measure the scores with one being least confident to 5 being most confident. Trainees were asked about their perceived self-confidence in the surgical anatomy of the maxilla, instruments used in the maxillary osteotomy, and the sequence of steps. Additional questions, which tested the knowledge of the trainees were included to counter the inappropriate self-assessment of trainees' confidence (Dunning et al., 2004). This ensured a positive correlation between self-confidence and skill levels as many factors can cause confidence but negatively affect skill levels. To assess the level of situational awareness and decision making, three questions enquired how trainees responded to unexpected complications in the operating room and found their weaknesses.

Individual opinion about the intervention was asked in the last part of the questionnaire. Trainees answered about the importance of data, 3D videos and 360º views of the operating rooms. The last two questions were regarding the best and worst features of the application. To compare the effects of the intervention, questions regarding the knowledge and confidence were asked before and after the intervention.

7.3 Research protocol

The research protocol with details of study design, sample selection, inclusion and exclusion criteria, data collection and analysis are explained in detail in the Appendix II and Appendix IV

7.3.1 Ethical consideration

University of Huddersfield Ethics Commission has provided the Ethics approval for this research. As there are no patients or biological material involved, the study does not require NHS ethical approval. As the participation is voluntary, all the participants had to sign the consent form. Any malpractices during the study will be reported to the University of Huddersfield Ethics Committee.

7.3.2 Recruitment of the participants

An A priori power calculation using G*Power Analysis (Faul et al., 2009) for MANOVA showed the requirement of 72 members as a sample size for a power of 95 and α value of 0.05. An A priori power calculation using G*Power Analysis for t-test showed the required sample size as 88, for a Power of 75, at an effect size of 0.5. To achieve the recruitment target within the timeframe, the study was performed in India. The researcher contacted the head of Oral and Maxillofacial surgery departments from ten dental schools in India and invited their trainees to take part in the study. Seven schools responded. After obtaining the necessary permissions, a total of ninety-five trainees from three years of training participated in the study. The number of participants was raised to prevent the loss of data through attrition. Inclusion criteria included trainees in the master's course of Oral and Maxillofacial Surgery.

7.3.3 Randomisation and blinding

A simple parallel randomisation approach was used following a randomly generated number series to assign the participants to experimental or control groups.

This, however, resulted in an unequal number of sample size by the end of the study as shown in Figure 7.1

7.3.4 Intervention

Based on previous pilot testing with surgical trainees, 45 minutes was decided as an intervention time to watch the videos and interact with the system. All the participants took 45 minutes to undergo the intervention. Independent researchers separately guided the participants in the experimental and control group. Two supervisors observed the protocol throughout the study period. The experimental group used VR Surgery on an Oculus Rift with Leap Motion tracker, while the control group used power point presentation, which had similar content. For the participants in the experimental group, the lead researcher demonstrated the usage of the system. Following this, the trainees interacted with the anatomy, data and instruments that are routinely used in the surgery. Participants were invited to watch all the videos regarding the bone cuts, bone mobilisation, and bone fixation.

For the control group, stereoscopic 3D videos were replaced with 2D videos. Interaction with 3D models of anatomy were replaced with two-dimensional images of head and neck anatomy. 360º videos of operating room were shown on a desktop version of 360° video viewer, where the trainee could scroll across the scene with the mouse to watch the operating room ambience. All the other content remained the same between the groups.

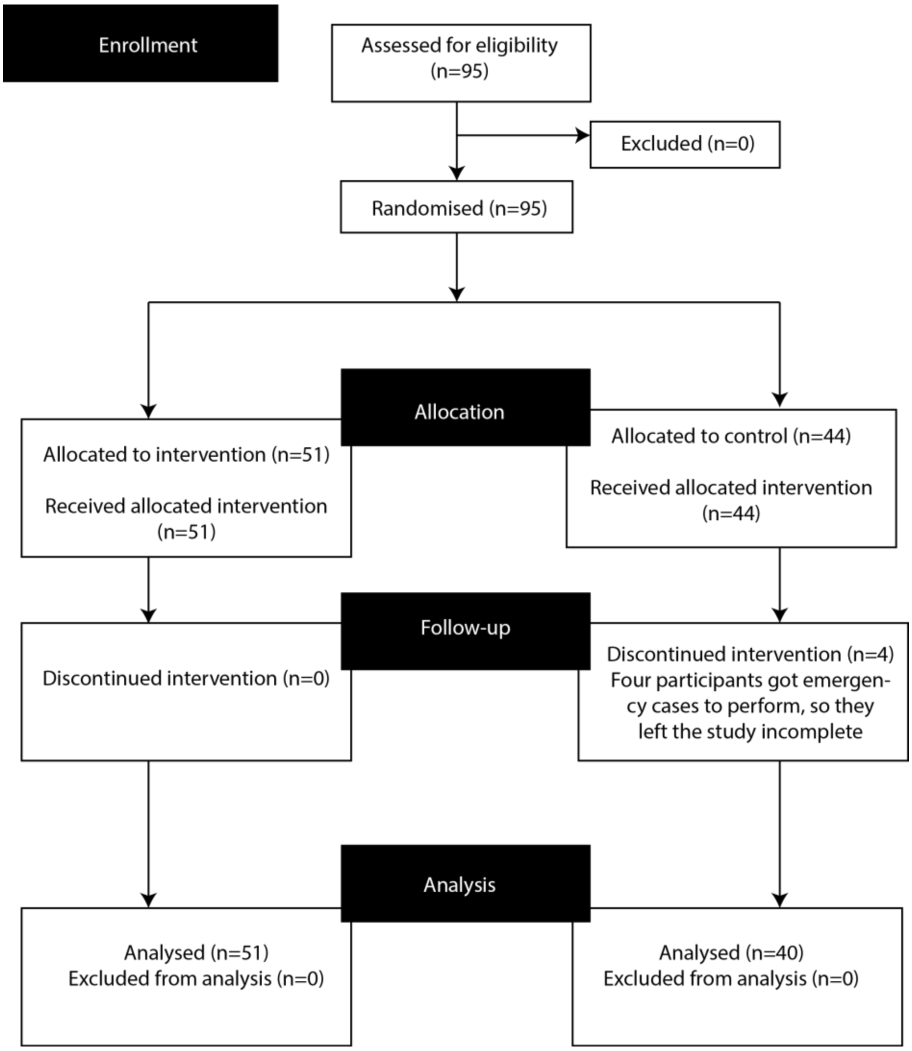


Figure 7.1 Consort Flow Diagram for the Randomised control trial

7.3.5 Data analysis

IBM SPSS version 22 (IBM Analytics, 2017) was used to analyse the data in this study. Trainees rated their subjective assessment of self-confidence levels on a five-point Likert scale. To measure the effect of the intervention on the self-confidence levels of surgical trainees, multiple repeated measures ANOVA was selected. As multiple studies have shown that parametric tests can be used to analyse Likert scale responses (Sullivan and Artino, 2013, Carifio and Perla, 2008, Norman, 2010), and as multiple dependent variables may interact to affect the data, a MANOVA was selected. Although several t-tests could have been used to compare the responses of participants in each condition, this would have led to many separate t-tests and have increased the risk of a type 1 error (Coolican, 2014).

Multiple choice questions were used to test the knowledge of the trainee. As the data gathered is supporting all the assumptions needed for parametric tests, t tests were selected to analyse the results (Laerd Statistics, 2017). As the hypothesis assumes the outcome to be different between the two groups, a paired sample t-test was used to check the scores before and after the intervention amongst each group. An independent samples t-test was performed to ensure that the participants in either group are not different before the intervention.

7.4 Results

Ninety-five surgical trainees were divided into 51 (n=51) in the study group (53.6%) and 44 (n=44) in the control group (46.3%) by simple randomisation. Excluding four participants who left the study incomplete, there were 48 male trainees (50·5%) and 43 female trainees (45·3%), with a mean age of 27·14 years.

Based on the training experience questions, 29.5% of participants did not assist even a single Le Fort I osteotomy, whereas 57.9% of the trainees have assisted in at least 1-5 osteotomies. Similar results were found when trainees were asked about the number of procedures observed in the operating room. 14.7% of participants have not even observed one Le Fort I osteotomy, and 71.6% of the participants have seen at least 1-5 operations. The majority of the trainees in the first year of the surgical training have not assisted in at least one Le Fort I osteotomy as shown in the Table 7.1. Seven trainees have not answered this question.

Table 7.1 Number of procedures where the trainees assisted based on the stage of training

		Number of Le Fort I osteotomies assisted					Total
		none	1-5	6-10	11-15	16-20	
Stage_of_Study							
	First Year PG	14	9	0	0	0	23
	Second Year PG	6	24	2	1	0	33
	Third Year PG	3	20	3	0	1	27
	Staff/Faculty	1	0	0	0	0	1
Total		24	53	5	1	1	84

The question on training in the operating room showed only 16.8% of the trainees, who can watch the entire surgery. The majority of the trainees can watch it partially, with 40% of the trainees able to watch most parts of the surgery, 26.3% of the trainees watch some parts of the surgery, and 8.4% of trainees watch very few parts of the procedure. There were also 3.2% of trainees who mentioned they could not see anything in the operating room. As discussed before, learning in the operating theatre is the cornerstone of surgical training (Roberts et al., 2012). However, the lack of uninterrupted visualisation of surgery to the majority of trainees shows a need for a novel solution in training surgeons as shown in Chart 7-1. However, inefficient learning in the operating room raises the need to approach alternative learning methods.

Based on the current study, 60% of the trainees use textbooks, 17.9% watch videos on YouTube, and 12.6% of the trainees use both the methods. However, these methods do not provide a complete understanding of the procedure. When asked about the alternative learning technologies, 73.7% of trainees mentioned they use computers, 16.8% use smartphone apps, and only one trainee mentioned they use surgical simulations or virtual/augmented reality applications as shown in Chart 7-2. This shows a clear understanding that the trainees who participated in the study do not have prior experience of using virtual reality applications.

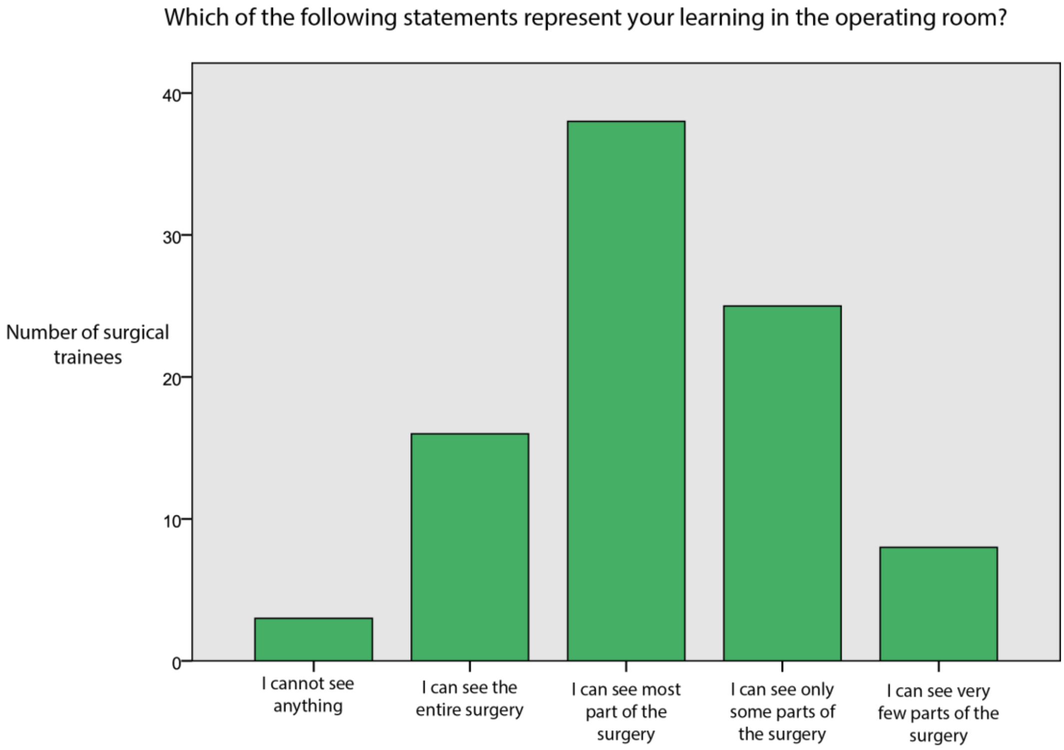


Chart 7-1 Learning quality in operating room

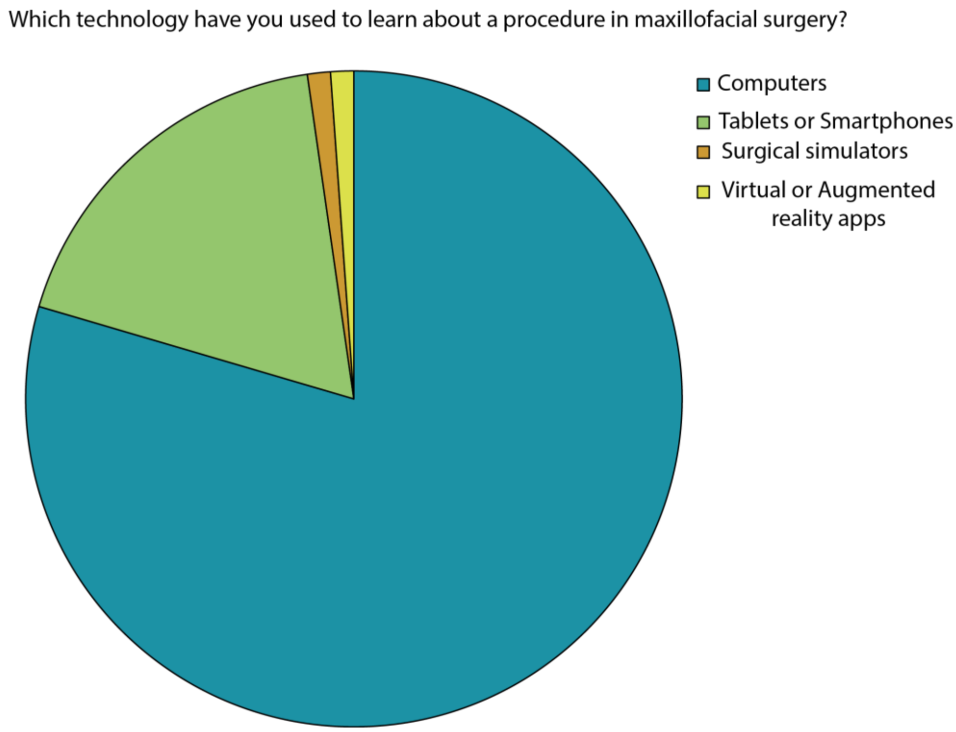


Chart 7-2 Use of technology in surgical training

Also, the interviews with surgeons in various dental schools showed the unavailability of advanced surgical simulators. Need for improved visualisation in the operating rooms and a lack of surgical simulations in oral and maxillofacial surgery can be understood from these results.

When the trainees were asked about the Le Fort I osteotomy in specific, bone cuts was chosen as the most difficult step to understand. In the validation of VR Surgery, expert surgeons also chose bone cuts as the most difficult step to teach. These findings demonstrated a need for enhancing current surgical training methods.

Next, the pre-intervention assessment questions were analysed. A Kolmogorov-Smirnov test of normality ($p>0{\cdot}05$) was applied to the data as the sample size was over 30 (Field, 2016). A visual inspection of the corresponding normality Q-Q plots and histograms showed that the participants' responses were normally distributed for both control and experimental conditions. The Independent sample t-test before intervention showed no significant differences ($t= 0{\cdot}421$, $df= 93$, $p= 0{\cdot}674$) between the participants in two groups as in Table 7.2.

Table 7.2 Independent Sample Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Difference in means	Equal variances assumed	0.885	0.349	0.421	93	0.674	0.20009	0.47489	-0.74295	1.14312
	Equal variances not assumed			0.416	83.957	0.679	0.20009	0.48136	-0.75716	1.15733

The next aspect of the analysis involved comparing the pre-intervention self-confidence levels with that of post-intervention. Based on the expert surgeon's guidance, the test measures trainee's self-reported confidence levels about the sequence of steps, Anatomy and Instruments.

The experimental group participants have watched different steps of surgery as individual screens, whereas the control group was provided with the sequence of steps as bullet points on a slide. After the intervention, the frequency of participants who strongly disagreed about their confidence levels, moved towards agreement in both the groups as shown in the Chart 7-3 and Chart 7-4.

In the experimental group, 37.2% of participants have disagreed before the intervention, but they all have moved to an agreement or neutral states after the intervention. A similar trend is observed in Control group. However, when the strongly agree scores are compared, experimental group participants showed an improvement after the intervention, whereas the control group participants score went down.

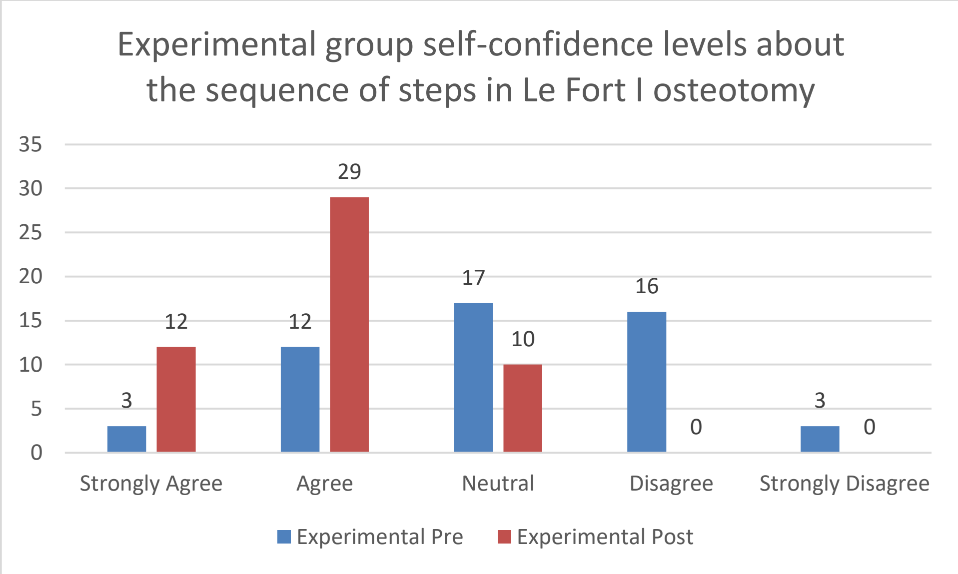


Chart 7-3 Experimental group - changes in the self-confidence levels for sequence of steps

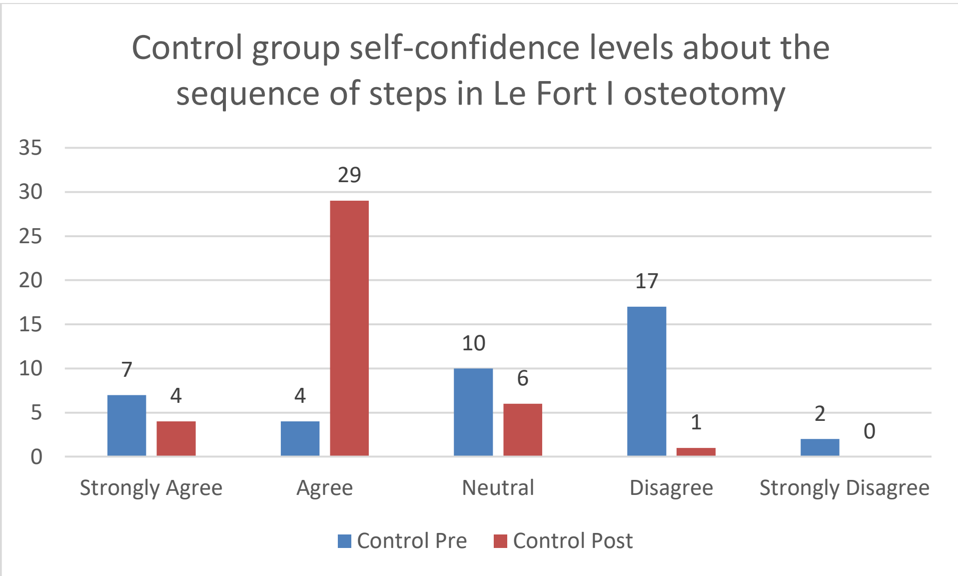


Chart 7-4 Control group - changes in the self-confidence levels for sequence of steps

The second question was about the anatomy, where trainees who were in the experimental group used 3D models of anatomy, whereas the control group used 2D images of anatomy. The experimental group participants have reported an improved self-confidence score compared to that of the control group. The change in the confidence scores can be appreciated in the Chart 7-5 and Chart 7-6.

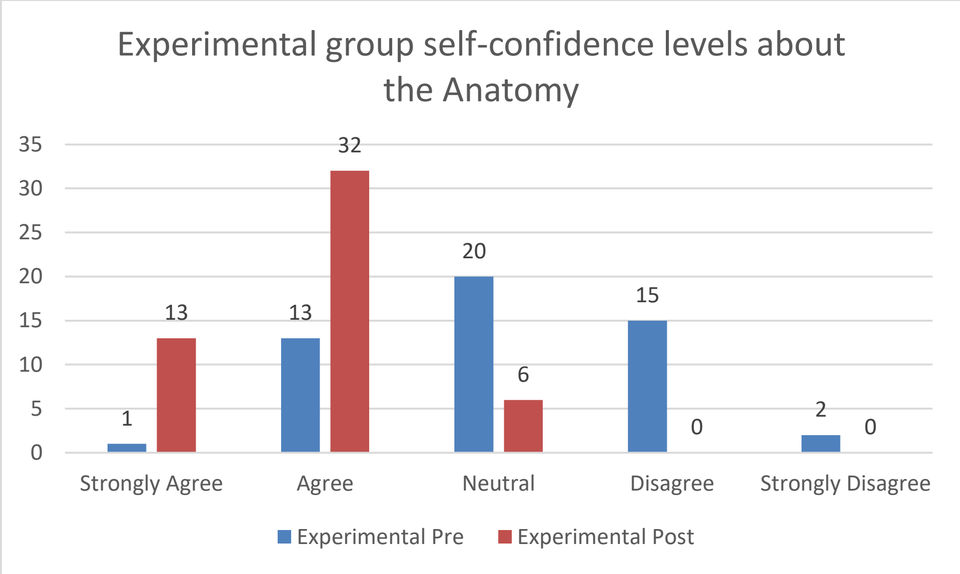


Chart 7-5 Experimental group - changes in the self-confidence levels for Anatomy

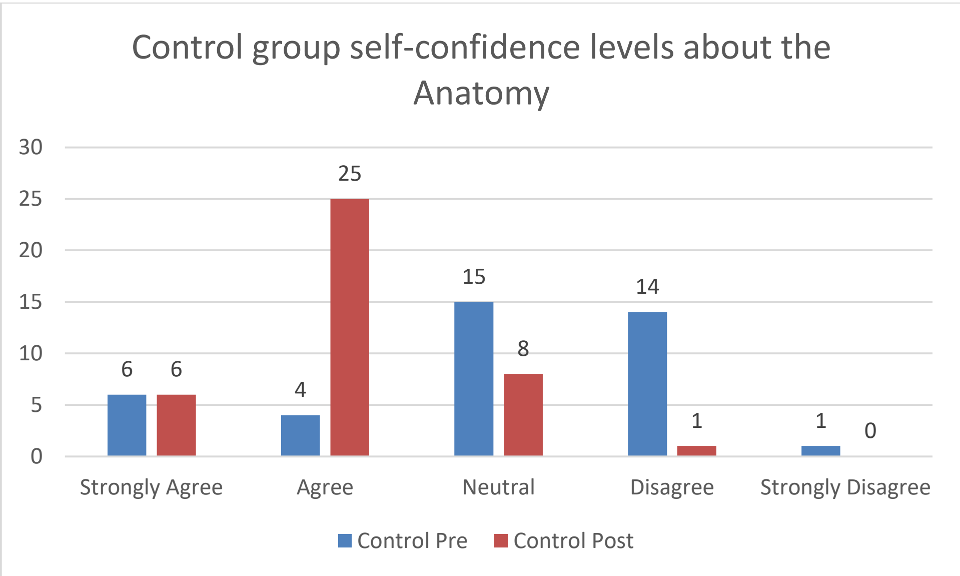


Chart 7-6 Control group - changes in the self-confidence levels for Anatomy

Significant improvement was found in the third question when trainees were asked about surgical instruments as shown in Chart 7-7 and Chart 7-8. Participants using VR Surgery learnt the names and functions of various surgical instruments by interacting with the 3D models, whereas participants in the control group have learnt about the instruments using images of real instruments.

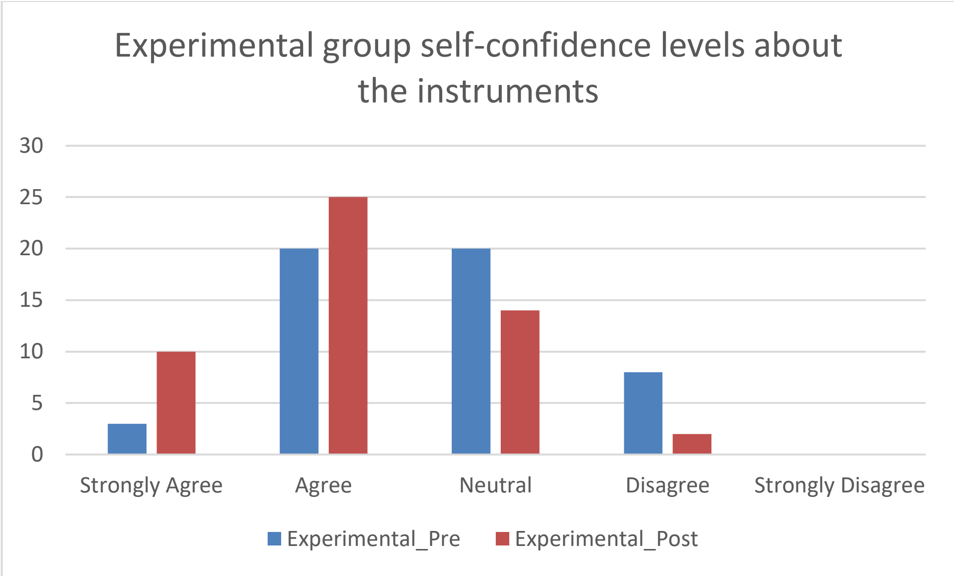


Chart 7-7 Experimental group - changes in the self-confidence levels about surgical instruments

The change in confidence can be identified by a reduction in strong agreement and increase in disagreement in the control group after the intervention, whereas the study group have shown an improvement in self-confidence scores.

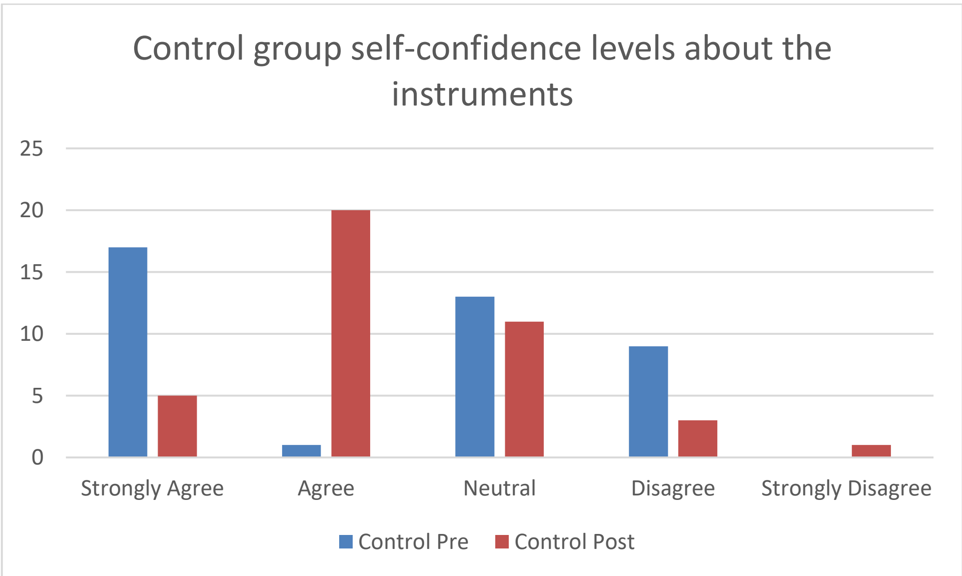


Chart 7-8 Control group - changes in the self-confidence levels about surgical instruments

Two other questions which do not have a comparative question in pre-intervention question were asked to find the effects of the intervention. They included the self-confidence levels in understanding the teamwork required for operating room and identifying complications.

To assess the overall impact of the intervention on the self-confidence levels of trainees, a repeated measures multivariate ANOVA was applied to the data. Pre and Post intervention question pairs and intervention groups (experimental or control) were the within subject's factors. The stage of the training was between subject's factor. Homogeneity of variance assumption by an ANOVA was not violated as a Levene's test showed no significant results. The results showed a significant increase in self-confidence levels (f (1,85) =65·71, p=0·000) in both the groups after the intervention. Wilks Lambda multivariate test on control group showed a significant improvement (p=0.002) with a small effect size of 0·234 and an observed power of 0·906. On the contrary, the experimental group increased their confidence significantly (p=0.000) with a medium effect of the size of 0·642, and an observed power of 1·000. Comparing the relative improvement in the confidence levels, the experimental group participants showed significantly higher self-confidence scores than the control group participants (p=0·034) as shown in the Table 7.3 and Chart 7-9, thus rejecting the null hypothesis.

Table 7.3 Multivariate Tests Results

Between-Subjects Factors			
		Value Label	N
Group	1·00	Control	40
	2·00	Experimental	51
Stage_of_Study	1	First Year PG	31
	2	Second Year PG	33
	3	Third Year PG	27

Multivariate Tests

Effect		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[d]
Pre_Post	Pillai's Trace	0·436	65·717[b]	1·000	85·000	0·000	0·436	65·717	1·000
	Wilks' Lambda	0·564	65·717[b]	1·000	85·000	0·000	0·436	65·717	1·000
	Hotelling's Trace	0·773	65·717[b]	1·000	85·000	0·000	0·436	65·717	1·000
	Roy's Largest Root	0·773	65·717[b]	1·000	85·000	0·000	0·436	65·717	1·000
Pre_Post * Group	Pillai's Trace	0·052	4·643[b]	1·000	85·000	0·034	0·052	4·643	0·568
	Wilks' Lambda	0·948	4·643[b]	1·000	85·000	0·034	0·052	4·643	0·568
	Hotelling's Trace	0·055	4·643[b]	1·000	85·000	0·034	0·052	4·643	0·568

Roy's Largest Root	0·055	4·643[b]	1·000	85·000	0·034	0·052	4·643	0·568

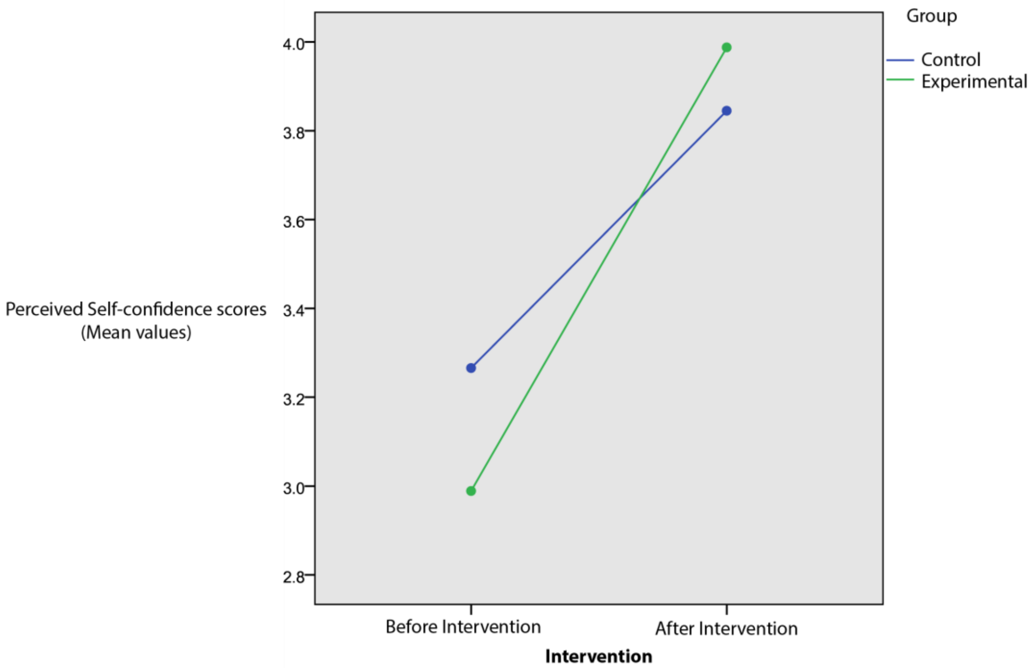
a. Design: Intercept + Group + Stage_of_Study + Group * Stage_of_Study
Within Subjects Design: Pair + Pre_Post + Pair * Pre_Post

b. Exact statistic

c. The statistic is an upper bound on F that yields a lower bound on the significance level.

d. Computed using alpha = .05

Chart 7-9 Improvement of self-confidence amongst novices



The between subject's results showed there was a significant effect on the stage of training (f (2, 85) = 7·57, p = 0·001, partial eta^2 = 0·153) for participants. The post hoc Bonferroni test results showed a significant difference between first year trainees and third year trainees (p=0·001) as shown in Table 7-4. However, there was not a significant difference between the second year and third year group (p=0·360). VR Surgery increases the confidence of early stage surgical trainees.

Table 7.4 Post-hoc results analysis between different levels of training

	(I) Stage of study	(J) Stage of study	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Bonferroni	First Year PG	Second Year PG	-0.30	0.136	0.096	-0.63	0.04
		Third Year PG	-0.52*	0.144	0.001	-0.87	-0.17
	Second Year PG	First Year PG	0.30	0.136	0.096	-0.04	0.63
		Third Year PG	-0.22	0.142	0.360	-0.57	0.12
	Third Year PG	First Year PG	0.52*	0.144	0.001	0.17	0.87
		Second Year PG	0.22	0.142	0.360	-0.12	0.57

Based on observed means.

The error term is Mean Square(Error) = 0.297.

The mean difference is significant at the 0.05 level.*

Self-reported confidence in surgical training depends on multiple factors including factual knowledge, stage of training, and relative experience. A paired t-test was performed on each group to assess the effect of the intervention on the knowledge gained. The test measured the changes in the mean scores of participants before and after respective interventions. The paired t-test showed a significant increase in scores for both the control (t= 2·327, df= 43, p= 0·025) and experimental groups (t= 2·331, df= 50, p= 0·024) as shown in Table 7.5 and Table 7.6. Based on the topic on which the questions were based, ten pairs of questions were selected, and their mean scores were compared. The experimental group participants showed a greater mean score for a total number of correct answers than the control group. They have also outperformed the control group for the questions concerning the instruments and sequence of steps.

Table 7.5 Paired Samples T-Test for the CONTROL group

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Mean_Pre_Correct_Compare - Mean_Post_Correct_Compare	-0.88636	2.52629	0.38085	-1.65443	-0.11830	-2.327	43	0.025

Table 7.6 Paired Samples Test for the STUDY group

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Mean_Pre_Correct_Compare - Mean_Post_Correct_Compare	-0.68627	2.10229	0.29438	-1.27755	-.09500	-2.331	50	0.024

To know the intervention with most benefit, a difference in means is calculated, and an Independent sample t-test was performed. The test showed no significant difference in knowledge gain between the two groups as shown in Table 7.7.

Group Statistics

	Condition	N	Mean	Std. Deviation	Std. Error Mean
Difference in means	Control	44	0.8864	2.52629	0.38085
	Experimental	51	0.6863	2.10229	0.29438

Table 7.7 Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Difference in means	Equal variances assumed	0.885	0.349	0.421	93	0.674	0.20009	0.47489	-0 .74295	1.14312

	Equal variances not assumed			0.416	83.957	0.679	0.20009	0.48136	-0.75716	1.15733

A 2(before intervention or after intervention) X 2 (experimental or control group) ANOVA performed to compare the scores of participants aligned with the non-significant improvement in knowledge, but a clear pattern of overall improvement as shown in Figure 7.2. Participants who used VR Surgery performed better than the control group.

To test the influence of stage of training on the knowledge scores, a crosstabs analysis was performed. The test showed no significant difference between the groups. However, participants in the third year of training performed better than the second year and first year trainees. On the other hand, the results showed highest improvement in the first-year surgical trainees, followed by second and third-year trainees both the groups.

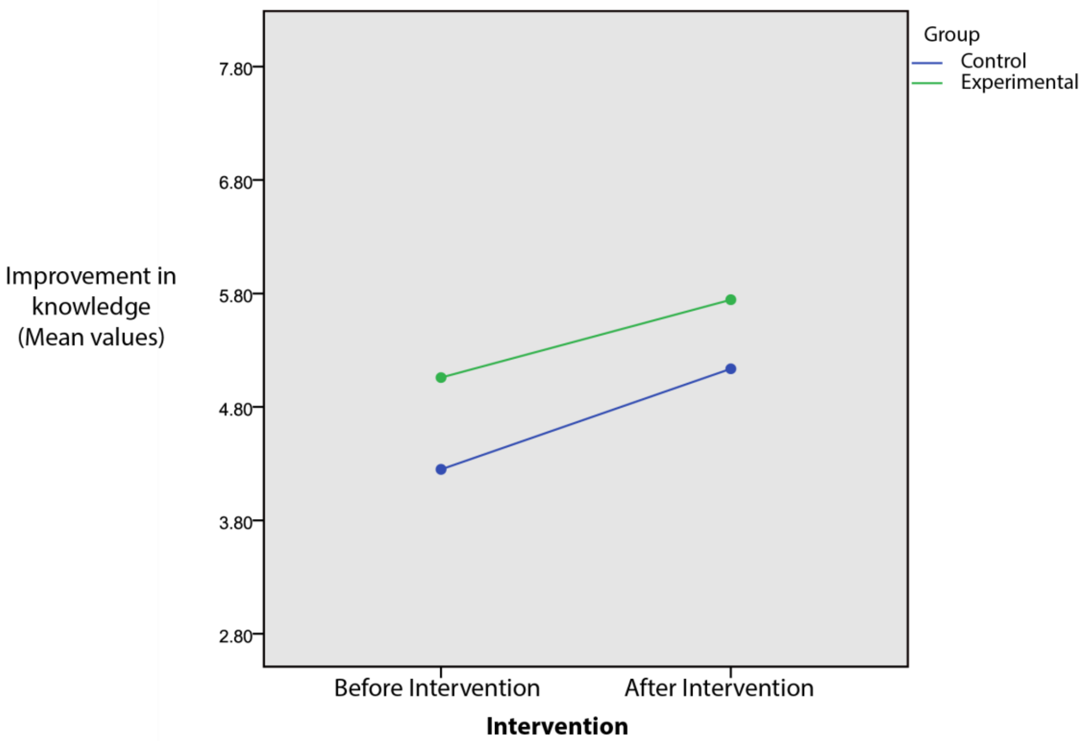


Figure 7.2 Knowledge before and after intervention in both the groups

7.5 Discussion of the randomised control trial results

The pre intervention questionnaire also showed that majority of the surgical trainees do not get to observe the procedure in its entirety. This results in gaps in their knowledge which become evident when they are asked to perform a particular procedure. The lack of availability of surgical simulators further add to the necessity of novel advances like VR Surgery.

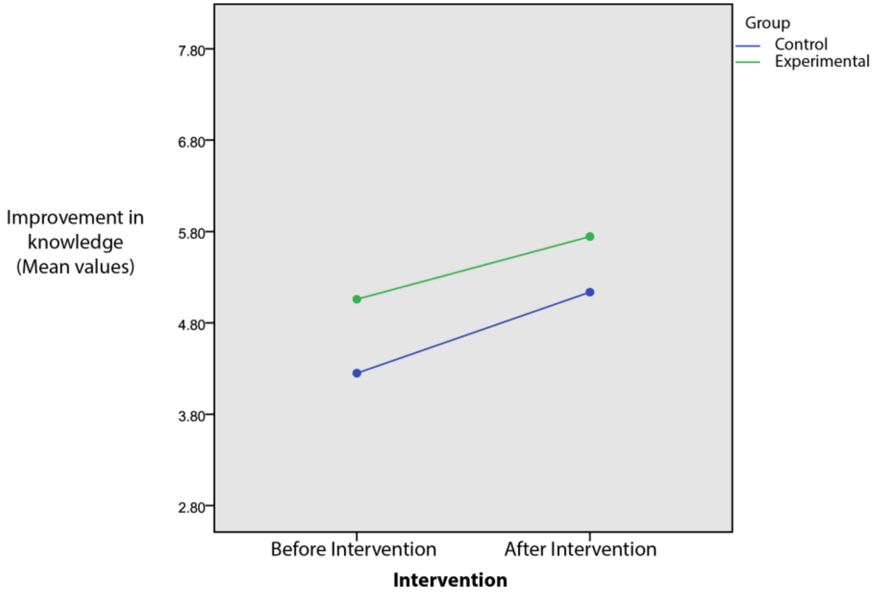
The results of this study revealed that the participants in both the groups had a statistically significant ($p<0.05$) improvement in their self-confidence and knowledge scores after the intervention. This means irrespective of method of training, the surgical trainees did show an improvement in their cognition. However, the challenge was around the self-confidence levels. When the levels of self-confidence were tested, the participants in the experimental group gave a significantly higher score to their self-confidence compared to that of the control group. Thus the primary null hypothesis can be rejected, and the alternative hypothesis, which states that VR Surgery will make a difference in self-confidence levels can be accepted. A recently published paper in the Journal of Oral and Maxillofacial Surgery explains this further (Pulijala et al., 2017). As previous studies have found that surgical trainees do not feel adequately prepared in performing a surgical procedure (Geoffrion et al., 2013), the findings of this study hold prime importance. The increase in self-confidence with a simultaneous increase in clinical knowledge is what is needed for a successful performance.

Overall, the objective measures of the trainees' knowledge showed an improved score. When the mean value of correct answers for individual questions was measured, participants in the experimental group performed significantly better for questions about the instruments and sequence of surgery. As VR Surgery is a unique training tool, all the participants in the experimental group were provided with a tutorial for ten minutes. Hence the participants who used VR Surgery took the time to get acclimatised to the technology and compromised their learning time. On the other hand, the control group had a minimum learning curve as power point presentation is the norm in training. Despite these differences, the experimental group outperformed the control group. This shows that there may be a higher improvement in learning, which the data does not demonstrate.

7.5.1 The Knowledge - Confidence paradox

It is logical to assume that with an enhanced knowledge of surgery, anatomy and instruments, participants feel more confident. However, for an enhanced knowledge which is not significantly different between the groups, trainees in the experimental group showed a significant increase of confidence than the control group. As a person’s self-confidence is complex and involves multiple elements of assessment (Bandura, 2006), these led to further questions about surgical trainees’ assessment of their self-confidence and the knowledge-confidence paradox (Figure 7.3).

Why did the trainees feel more confident in using VR Surgery compared to a conventional training method? What made VR Surgery more beneficial than other methods? As a person’s confidence is not an objective measurement, is there a scope for misinterpretation of the results? Does VR Surgery improve the confidence or the trainees only feel that it does? What is the impact of the stage of training on the confidence? The next part of this discussion attempts to address few of these questions.



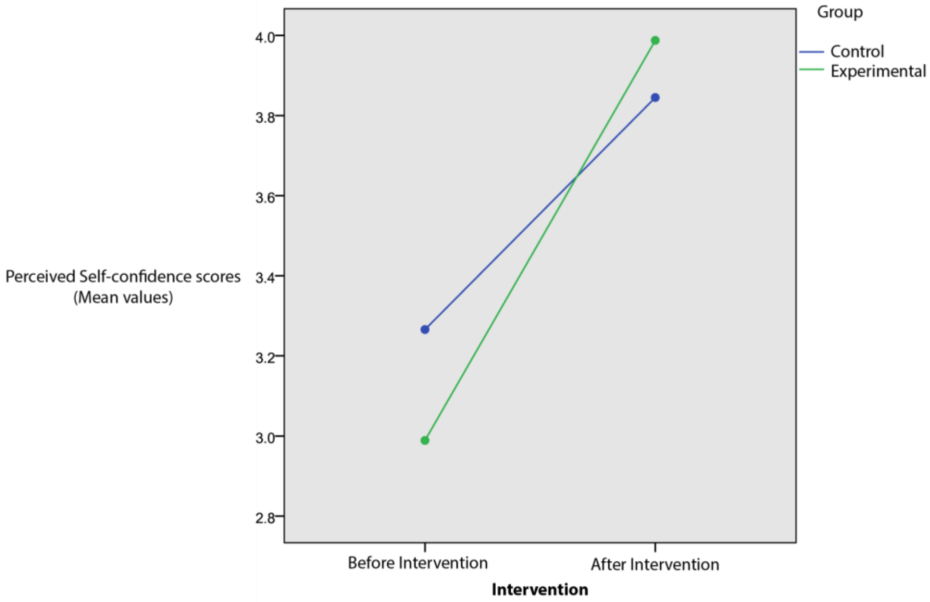


Figure 7.3 The knowledge-confidence paradox

Though experimental group outperformed the control group in the knowledge-based questions, the difference in the improvement of knowledge is not statistically significant. On the other hand, the experimental group showed a significantly higher improvement in their perceived self-confidence post intervention compared to the control group. Despite scoring lower than the experimental group, the control group participants felt more confident before the intervention compared to the experimental groups.

7.5.2 Why did the trainees feel more confident while using VR Surgery?

Participants in the experimental group were provided with a brief tutorial on how to interact with the system. Following this, the surgical trainees were asked to go through the entire application in a sequence by watching individual videos of surgery, interact with the 3D patient data, anatomy, instruments and 360º videos of the operating room. Overall, all the participants mentioned that they were engaged while using VR Surgery and provided positive feedback. However, the reason for the improvement in confidence could not be pointed out by the trainees themselves. When the participants were interviewed after the study, some surgical trainees mentioned the best part of the application was 3D interactions with anatomy and instruments. Other participants credited the 360º videos of the operating room. The majority of the participants suggested stereoscopic 3D videos were more beneficial compared to conventional 2D videos. Despite addressing the benefits of VR Surgery experience, the trainees did not answer if the entire experience or a particular aspect of the application improved their sense of confidence. This inadequacy in explanation lead the researcher into cognitive science and produce assumptions which need further testing.

Assumption 1 – Immersive virtual reality has made the difference in self-confidence

VR Surgery is an immersive virtual reality surgical training experience where trainees can watch a surgery, uninterruptedly. The application and learning objectives are directed by the user, unlike conventional surgical simulations. In addition to watching the surgery in stereoscopic 3D, trainees can use their hands to interact with the objects. This novel multisensory learning experience might have made the trainees in the experimental group feel more confident than their peers.

This assumption can be tested by performing a similar study to the current one in a different domain such as orthopaedic or laparoscopic surgery. Overall if trainees are feeling more confident while using immersive virtual reality experiences, a new model of learning needs arises.

Assumption 2 -Holistic training experience made the trainees feel more confident

Analogous to a pleasant experience, which is because of a medley of minor stimuli, the enhanced sense of confidence in trainees after using VR Surgery might be because of its holistic learning experience. The multiple elements of VR Surgery, which combine a trainee’s factual knowledge with procedural understanding in an interactive and realistic ambience might have enhanced their sense of confidence. Unlike a conventional operating room learning, VR Surgery provides a real-time interaction with anatomy, data and instruments while watching close-up stereoscopic 3D videos of surgery. In addition to improving the knowledge of trainees, which it did, VR Surgery enhances the sense of presence in an operating room, which might further increase the trainee's level of self-confidence.

To test this assumption, future work involving different types of VR Surgery application, individualising the presence or absence of a particular element (3D stereoscopic videos, 360º videos, 3D interaction) needs consideration.

Assumption 3 - The novelty bias

96% of all the participants in the current study did not experience a virtual reality headset before. Hence almost all the participants are using VR Surgery as their first immersive virtual reality experience. As described in a recent study by Huber et al. (2017), the novelty of surgical training experience on a virtual reality headset might have influenced the results. This newness might have led the trainees to believe they are more confident than they are. However, mere-exposure effect or familiarity principle (Mather, 2013) challenges our assumption about novelty as the reason for higher self-confidence. Familiarity principle is a psychological phenomenon where people tend to favour things they are familiar with than a novelty. In that case, control group participants who used standard PowerPoint presentation should favour this form of learning instead of iVR. Therefore, this assumption should be dealt with scepticism and tested effectively.

If novelty is the reason, then the inflation of self-confidence can be easily tested once the novelty fades off. However, the current study was limited by time and resources to perform multiple trials. By performing trials in different surgical procedures on trainees who are used to virtual reality, experiences will test the assumption.

Assumption 4 – Observer-expectancy bias

This study was a single-blinded randomised controlled trial; the primary researcher guided the participants in the experimental group. There is a minor possibility for observer – expectancy bias, where the researcher might have unconsciously influenced the cognitive decision-making skills of the experimental group. Further, a conformity bias to assess the results in favour of the hypothesis is a possible assumption.

However, this assumption could be ruled out as the experiment was supervised by two experts who were unbiased towards the results. A second researcher anonymised the data before analysing it.

Further tests with different versions of VR Surgery, in a different domain by different researchers would rule out these assumptions. However, the primary researcher believes the reasons for the improvement in confidence might be the immersive experience and the freedom to choose between *whole and part practice* (Naylor and Briggs, 2012) in VR Surgery. Trainees can decide if they want to watch part of a procedure or an entire aspect of surgery including the anatomy and instruments. As all the information is readily available in a single application, trainees might have felt more confident and secure. Another aspect of interest in the current research is the impact of stage of training on the self-reported confidence levels.

7.5.3 What is the effect of expertise on a subject's self-confidence levels?

The results of this study showed that the stage of training did not have an overall influence on the self-reported confidence levels, but the post-hoc studies revealed that the first year trainees reported a significantly greater improvement in their confidence levels compared to the second year and the third year trainees. As described previously, trainees in the first year of the training have not observed as many procedures as second and third years. This lack of experience in the operating room might be the reason why first-year trainees have improved the most amongst all the groups. For novices in their early stages of training, improvement in self-confidence is vital as it makes them more prepared for the undesirable outcomes. However, when the change in confidence was compared to the knowledge score, trainees in the third year of training have performed the best, compared to second and the first years. These findings lead to the next question, is there a chance that the trainees in early stages are overestimating their self-confidence?

A person's perceived self-confidence can be subject to Dunning – Kruger effect, a condition where the ignorant overestimate their ability and performance (Dunning et al., 2003). According to the highly cited work of Kruger and Dunning (1999), unskilled individuals suffer a dual burden. "Not only do these people reach erroneous conclusions and make unfortunate choices, but their incompetence robs them of the metacognitive ability to realise it" (Kruger and Dunning, 1999,p.1131). The research claims that metacognition (Chick, 2015) or the self-monitoring skills are essential to realise the competence or incompetence in an individual. Dunning et al. (2004) point out that novices in the early stages of training are more prone to miscalibration of their self-assessments. Compared to the experts or trainees in higher levels, novices lack the experience and understanding to have realistic expectations of themselves and others as shown in the Chart 7-10.

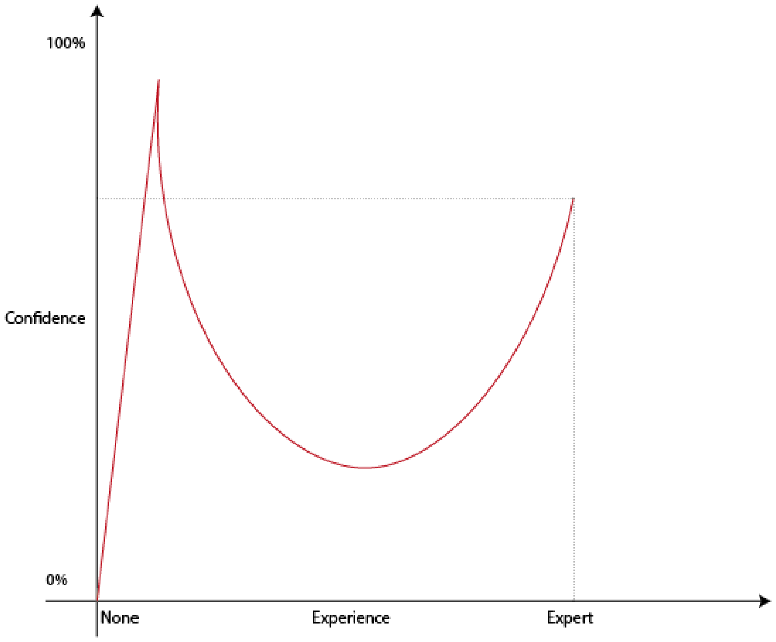


Chart 7-10 The change in confidence levels with expertise (Kruger and Dunning, 1999)

One of the significant findings of Dunning-Kruger effect is that the competence of an individual enhances their calibration (Kruger and Dunning, 1999). This means training individuals improve their competence and thereby enhances their ability to measure accurately. The effect of competence on measurement was seen in the current study where trainees in the experimental group rated themselves less confident before the intervention when their knowledge score is higher than the control group as shown in Figure 7.3 The knowledge-confidence paradox. The under-estimation got corrected itself when the trainees underwent the intervention. As the trainees watched the surgical procedure and answered the second set of questions, their responses have varied. Previously under-confident trainees in experimental group have shown an increased agreement of their confidence levels than the control group.

In addition to the factual knowledge, the quiz scenes in VR Surgery, questions regarding the potential complications and decision-making skills provide immediate feedback to the trainees. This knowledge moved the trainees from unconscious incompetence to conscious incompetence. As discussed in Chapter 2 the first step towards expertise is evident in the current study. VR Surgery has provided the necessary information to trainees to learn about their current state and assess their competence. Based on the validity studies and expert opinions, the researcher predicts that a frequent interaction with VR Surgery will move trainees from conscious incompetence to conscious competence. However, further studies are needed to identify the precise frequency that improves training. VR Surgery in its current state of development supports the first three phases in the path to expertise as shown in Figure 7.4.

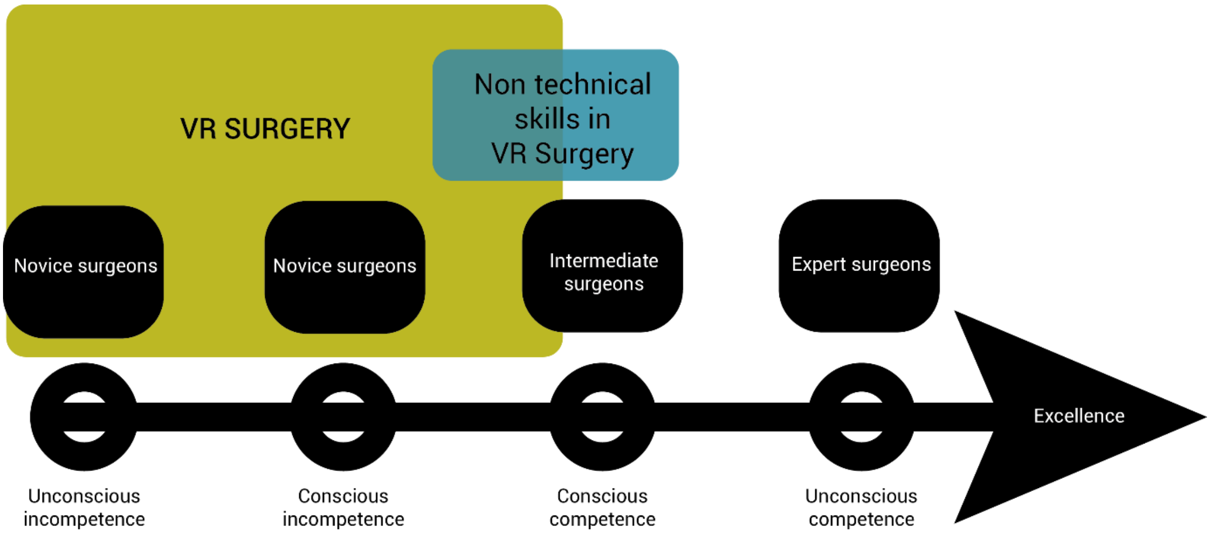


Figure 7.4 VR Surgery's role in the path to expertise

7.5.4 Summary

The current randomised control trial is effective in understanding the impact of VR Surgery on the objective knowledge and subjective confidence levels. However, the lack of understanding of why VR Surgery was more efficient demands further research.

A further study should involve testing the impact of VR Surgery in a different surgical domain to verify the reliability of these findings. Different versions of the application must be prepared and tested on multiple groups to identify which aspects of VR Surgery are more beneficial for training. Future research should involve a bigger sample size to determine the effect of VR Surgery on individual aspects such as expertise, gender, ability to interact. Moreover, as participants tend to report an improved sense of confidence immediately after an intervention, there is a need to test their retention levels of self-confidence over a period. The impact of these scores on the performance in the operating room also needs to be tested.

VR Surgery is the first immersive virtual reality experience for surgical trainees in oral and maxillofacial surgery. Further research into the introduction of non-technical skills including decision making, situational awareness, teamwork and leadership is being explored. These elements will be subsequently introduced into the future versions of the application.

Chapter 8 General Discussion and Conclusion

This chapter summarises the research project and outlines the implications of the findings of the current research. A general discussion of the Thesis outlines different research questions and the way they were answered. This is followed by implications, strengths and limitations of the current research. The chapter further highlights the future work involved in this project and ends with a conclusion.

8.1 General Discussion

This research aimed to design, develop and evaluate an evidence-based immersive virtual reality (iVR) experience for surgical training in oral and maxillofacial surgery and use this application as an example to investigate the validity and effectiveness of iVR in surgical training.

The research set out to answer three broad questions. The first question was how various teaching elements could be combined to create a holistic surgical training experience. This issue was addressed by using close-up stereoscopic 3D videos of surgery for essential steps, hierarchical task analysis technique for dividing each job into individual steps, and 360º videos to create a realistic ambience of the operating room. Further, 3D interactions with anatomy, instruments and patient data were introduced to enhance the holistic learning experience.

The second question was to identify essential design and technical elements to consider while developing an immersive surgical training experience using virtual reality and motion sensing devices. To address this question, head mounted Oculus Rift DK2 and Leap motion devices were used. Best practices for virtual reality and motion sensing experiences (Oculus VR, 2016, Leap Motion, 2015) were followed while capturing the data, designing the interactions, and developing the application. Co-producing the content with expert surgeons and surgical trainees allowed a user-centric approach to the application design and a satisfactory user experience.

The third question was to investigate the validity and effectiveness of using immersive VR applications for surgical training. VR Surgery was evaluated for its face and content validity by expert oral and maxillofacial surgeons. A questionnaire based on previous face validity experiments (Schout et al., 2010) was used for the study. Expert surgeons' feedback on its content, usability and potential applications to surgical training was collected and analysed. Additionally, they provided suggestions on what to include in the application. Based on the results of this survey, it is concluded that VR Surgery could be considered as a valid training tool for surgical training. Additionally, a single-blinded parallel randomised control trial with 95 surgical trainees evaluated the efficacy of VR Surgery. The results of this experiment show the impact of VR Surgery on training and expertise as participants who used VR Surgery have performed better and have also improved their confidence significantly. Thus, the current research addressed three research questions it set out to answer by following a design science research approach.

8.1.1 Implications of the current research

The development of VR Surgery and its evaluation was a multidisciplinary project. The primary implication of this research includes the application of VR Surgery for other surgical specialities including plastic surgery, ENT and orthopaedic surgery. The contributions of this research have wider implications in training medical students, nursing staff, and educating patient. Further, the technological advances in this research will be beneficial for research in virtual and augmented realities. Following are few of the potential implications of this research project.

Medical, dental and nursing training

- The feedback by expert oral and maxillofacial surgeons demonstrated the applicability of VR Surgery to other procedures including cleft surgery, head and neck oncology, and other orthognathic surgical procedures.
- Continuing professional development is a necessity in multiple specialities including surgery. Currently available videos of surgery do not recreate the operating room environment. Expert surgeons can use the combination of stereoscopic 3D videos of surgery and 360-degree videos of the operating room in VR Surgery as a practice based learning tool. However, further evidence is needed in this regard for the use of virtual reality as a self-learning tool (Verrier, 2017).
- In addition to the videos of surgery, VR Surgery provides interactive 3D anatomy models of head and neck anatomy, and surgical instruments for Le Fort I osteotomy. The same application can be used for head and neck anatomy education (Wei, 2016), dental education (Roy et al., 2017, Bracken, 2017) and training nurses (Elliman et al., 2016) before the surgery.

- The 3D scanned data of the patient collected before and after surgery can be used for educating patients about the outcomes of a surgical procedure and also support in the consenting process. Applications similar to VR Surgery have been used for patient education in preparing them for surgery (Bekelis et al., 2017) and radiotherapy (Marquess et al., 2017).
- Use of cognitive psychology elements including hierarchical task analysis, decision-making elements support further development of non-technical skills into VR Surgery (Bracken, 2017).
- The evidence from the validation and evaluation studies of VR Surgery adds to the growing research in advanced surgical training methods (Huber et al., 2017).

Technological implications

- VR Surgery provides a pipeline for developing future surgical training experiences using mixed reality and motion sensing technologies.
- The guidelines used in capturing 360-degree videos and 3D stereoscopic videos will be useful for future work involving videography in the operating rooms (Takano et al., 2017).
- The lessons learnt in content creation, application design, user testing, evaluation and deployment for head-mounted virtual reality devices are valuable for future research in advanced medical training technology (Wei, 2016).
- The commercialisation of VR Surgery puts this research in a growing market of virtual reality and augmented reality solutions (Merel, 2017).

Academic implications

- The validity and evaluation studies of VR Surgery contributes to the growing research and literature in advancing the current surgical training methods (Badash et al., 2016).
- The cognitive scientific aspects of VR Surgery including the hierarchical task analysis, research on self-confidence and surgical expertise enhances future work in the development of non-technical skills for surgical training.
- The application of cognitive psychology aspect in current research led to another PhD research by a colleague from the school of Psychology, University of Huddersfield (Bracken, 2017, Huddersfield, 2017). The second research will involve the introduction of non-technical skills for surgical training into VR Surgery.

- The theory developed through the design science research methodology including the artefact development, the lessons learnt and the route to market is a model, which can be replicated in multiple fields including fashion, architecture and construction amongst others.

Further, commercial application of VR Surgery is a potential outcome of this research. Producing a low-cost version and partnering with private companies (GateVentures, 2017) will provide opportunities for the real world application of this research in addressing the global challenges in surgical training.

8.1.2 Strengths and Limitations of this research

The key strength of the present study is in combining technology (virtual reality, motion detection), cognitive science, and surgical knowledge to create an evidence-based immersive surgical training experience. The validation studies of this research add more value to the work. Maintaining the research rigour and performing a randomised control trial to test the efficacy is one the significant strengths of this research. Novel concepts combining self-confidence, expertise, virtual reality and surgical training were introduced through this study. The contributions and implications of this research already mentioned above also highlight the strengths of this study. Irrespective of maintaining the research rigour while working with a multidisciplinary team, there are limitations to the current research.

Technological limitations of this research include the lack of haptic force feedback. Availability of suitable technology and time constraints in developing a realistic haptic force feedback prevented the researcher from implementing it. However, future research on VR Surgery aims to implement haptic feedback into the application. The application was built using Oculus Rift DK2 and Leap Motion devices. The need for expensive headsets and high specification computers makes this solution unaffordable for an individual surgical trainee at this point. Development of a low-cost version using Google Daydream (Google, 2017a) or Google Cardboard (Google, 2015a) is the key to addressing this issue.

The validation of VR Surgery is limited to Face and Content Validity tests only. Due to the early stage of development of the system, and time constraints, other forms of validity tests including concurrent, construct or external validity are beyond the scope of this project. Further, the current research addresses topics such as the role of expertise in self-confidence and role of non-technical skills including decision making. However, as this studies contain a limited sample size, the generalizability of these findings needs to be dealt with caution.

8.2 Conclusion

Given the enormity of the global challenges in surgical training, a holistic approach to problem-solving is needed. As the current way of training does not promote this aspect of learning, virtual reality can play a significant role. This research project set out to address the challenges in surgical training and realised its aim by successfully demonstrating the design, development and evaluation of VR Surgery, a novel prototype for training surgeons using immersive virtual reality (iVR). This Thesis discusses the problem in detail, explains relevant solutions and proposes a new system. It then describes the methodology and evaluation through a randomised controlled trial.

The results showed higher perceived self-confidence levels in the experimental group compared to those in the control group ($p=0{\cdot}034$, $\alpha=0{\cdot}05$). Novices in the first year of their training showed the highest improvement in their confidence, compared to those in the second and third year. The results demonstrated that VR Surgery helps early stage trainees to enhance their knowledge and perceived self-confidence. Following the evaluation, a discussion on expertise and self-confidence of trainees explains the role of deliberate practice and a need for novel solutions.

As commercially available virtual reality and augmented reality experiences are increasingly used for surgical training (Khor et al., 2016), a framework to build effective iVR solutions is needed. This research attempts to address that challenge by using a three-step process of build, evaluate and iterate with expert surgeons and trainees. Further, for a global application of these emerging technologies, they should be made more affordable to reach the lower and middle-income countries (LMIC) with maximum need. Once the challenges are met, applications like VR Surgery provide an alternative way of learning and can reduce the time taken in training surgeons in operating rooms (Vinden et al., 2016). Moreover, the ability to experience surgery remotely changes the way surgeons learn in many ways.

Despite their benefits, technological advances alone are not sufficient in solving the healthcare challenges. International organisations like WHO and all the nations should come together to identify global epidemics that increase the healthcare burden of the globe. Countries of the world should invest in healthcare research and reduce the need for life-saving surgeries. On the other hand, effective surgical training should be made available at an affordable cost. A multi-disciplinary approach to address these issues is the way forward. The current research's contribution forms a part of this solution.

In addition to its use in maxillofacial surgery, the research methodology for VR Surgery forms a pipeline to build training tools for other surgical specialities. This research provides a framework for future researchers who use mixed reality for healthcare.

8.3 Future recommendations

This research has addressed the questions it set out to answer, but through the development and evaluation of the solution, a need for further research arose.

It would be necessary to address the technical challenges in VR Surgery by including the screen door effect (see Chapter 4), the addition of haptic force feedback, and improving the interactions with instruments. Content wise, it is suggested to identify a better technique to record the surgery in stereoscopic 3D, have a constant 360-degree operating room ambience, and annotate all the anatomical structures. Developing a low-cost version of VR Surgery will enhance the affordability and acceptability of this solution.

It is recommended that future research involve objective validity tests such as concurrent and predictive validity with a bigger sample of expert surgeons. Further evidence regarding the retention of knowledge and confidence by surgical trainees is needed. It is advised to validate the self-confidence scale developed in this research for its reliability. The questions raised by the randomised control trial (RCT) to find why surgical trainees feel more confident while using VR Surgery need to be addressed by further research. Future RCTs should involve bigger sample sizes to determine the impact of age, expertise and number of procedures observed on the self-confidence of a trainee. With further research, immersive Virtual reality applications such as VR Surgery have a substantial potential to bridge the differences in the quality of global surgical training.

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I. Appendix - Validation study protocol

- Authors, investigators, experts and advisors involve in the trial

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- Sponsor and Monitor

University of Huddersfield

- Trial site(s) and institutions involved in the study

Queen Elizabeth University Hospital, Glasgow

Glasgow Dental School

Leeds Medical and Dental School

Manchester University

- Protocol details

Face and Content validity study – Final version

Date: 23.07.2016

- List of all abbreviations and definitions

    VR – Virtual Reality

    iVR – Immersive Virtual Reality

    RCT – Randomised controlled trial

    3D – 3 Dimensional

Summary

Aim of the study

To test the face validity and content validity of VR Surgery

Rationale of the study

VR Surgery was built following various design principles (Oculus VR, 2016) (Leap Motion, 2015) and assumptions, which needed verification in a medical setting. Multiple sources of media ranging from stereoscopic 3D videos of surgery, 360º videos of the operating room, 3D surface scans of the patient and 3D animations were used, which needed experts' opinion about their usability, acceptability and application in training. Though VR Surgery is not a simulation, it creates an immersive experience by mimicking the operating room environment and demonstrating surgical procedures in the environment. Hence, it is essential to test the need for various elements in the application and their potential use. As the system uses different interfaces including gestural interfaces and hand interfaces (Kinstner, 2016) to interact with various elements in the application, it was essential to check the usability and acceptability in training surgeons.

Summary of trial

Expert oral and maxillofacial surgeons will be invited to take part in the study. The study involves three steps. Experts would first sign the consent and answer a pre-intervention questionnaire. The questionnaire will collect information about the demographics and the current surgical training methods. This will be followed by the intervention, where they will use different aspects of VR Surgery on a laptop. The post-intervention questionnaire will be a feedback on the realism, content, usability, and applicability to the curriculum.

Primary and Secondary objectives

Primary Objectives

- To test if VR Surgery is an effective surgical training experience for Le Fort I osteotomy
- To test if the content (Stereoscopic 3D videos, 3D models of anatomy, instruments, and data) shown in the VR Surgery application is appropriate for the surgical trainees in Oral and Maxillofacial Surgery

Secondary Objectives

- To test if the application is easy and comfortable to use
- To test if VR Surgery can be added to the current surgical training curriculum.
- To find the necessary modifications to be done in VR Surgery.

Brief description of methods

Expert surgeons who are consultants in Oral and Maxillofacial surgery will participate in the study. They will use the VR Surgery application for an hour and test various elements of it including the videos of surgery, 3D models of anatomy, instruments and patients' data. Further, they will rate the application on different aspects of the appearance and functionality. A five-point Likert scale will be provided for the rating of the application. Descriptive statistics of the output will check for the validity of the application.

Background

The need to improve existing surgical training tools introduced the usage of a wide variety of simulators and virtual reality experiences as discussed in chapter 2. As these training tools influence real life performance, it is important to identify necessary evidence about the potential impact of surgical simulations. However, 94% of medical simulators in the market are not validated, suggesting an increasing need to evaluate surgical training tools for validity (Stunt et al., 2014).

We followed the Consensus guidelines for validation of virtual reality surgical simulators in testing VR Surgery (Carter et al., 2005).

Validity, types and justification

Validity is defined as 'an extent to which an instrument measures what it is designed to measure.'(Carter et al., 2005). These measurements may be subjective or objective. Based on their nature, validity measurements are classified into different types including face validity, content validity, construct validity, concurrent validity, discriminate and predictive validity (Gallagher et al., 2003).

Face validity tests if the system looks like the way it should look. Typically performed by experts in the field, face validity is the most basic form of subjective validity test (Gallagher et al., 2003). Participants test the resemblance of the system to the real world activity (Carter et al., 2005).

Content validity is defined as "an estimate of the validity of a testing instrument based on a detailed examination of the contents of the test items" (Gallagher et al., 2003, p. 1526). This validity test measures the degree to which the system in question covers the subject. Content validity is also a subjective test, based on the experts' knowledge and understanding of the materials used.

Objective assessments include Construct validity, Concurrent validity and Predictive validity. Construct validity tests "the degree to which the assessment can discriminate between different ability or experience levels" (Carter et al., 2005 p. 1524). This means the experiment involves experts and novices testing the system to replicate the difference in their levels of expertise. Predictive validity compares the outcomes of a system with those of existing standard tools/systems. Predictive validity provides the most powerful evidence among all the validity tests (Carter et al., 2005).

As VR Surgery is an innovative training tool and the first immersive surgical training experience in oral and maxillofacial surgery, we need to begin with the basic forms of subjective evaluation. Therefore, the scope of the current project is to test the face and content validity of VR Surgery.

Trial objectives and design

- Purpose of research

This study will be done as a requirement for the PhD research project. It is non-commercial, without any conflict of interest.

- Statement of the primary and secondary outcomes (at what point in the trail would these be measured?)

Expert surgeons will use a five-point Likert scale to rate the accuracy, realism and the quality of content. The mean scores will be calculated. All the outcomes will be measured by the primary researcher at the end of the trial.

8.3.1.1.1.1 Primary Outcome

The average scores for each question to show the level of agreement to by expert surgeons.

8.3.1.1.1.2 Secondary Outcome

Qualitative feedback on the application.

Clear description and justification of the type of design

Based on the previous studies which evaluated the face and content validity for virtual reality simulators (Sugand et al., 2015), we designed the face and content validity study.

The implementation of the study will follow the following sequence as in

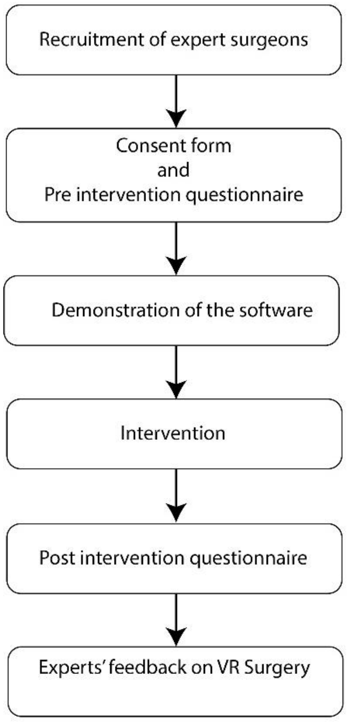

Figure 8.1 Flowchart showing the study outline

Subject selection

The inclusion criteria include Consultant Oral and Maxillofacial Surgeons who are involved in performing and training novices about Le Fort I osteotomies.

Exclusion criteria include any surgeon with psychiatric disorders including attention deficit hyperactive disorder, epilepsy or if they are on any anti-psychotic drugs. Surgeons with a previous history of motion sickness and seizures were also excluded from the study to prevent unintended recurrences.

Ten consultant oral and maxillofacial surgeons who work at NHS, UK and train novices at multiple universities including Manchester, Leeds and Glasgow are expected to participate in the study.

Subject recruitment

Expert surgeons were invited by email and informed about the objectives of the study. Based on their availability, nine consultant surgeons volunteered to participate in the validation process. Participation in the study is entirely voluntary, and no payment will be made to the study participants. All the participants will be acknowledged in the publications of the research.

All the participants were informed about the virtual reality headset and the potential motion sickness it can cause. Following the safety measures before using the Oculus Rift headset (Oculus, 2015a), all the participants will be asked if they suffered from any psychiatric disorders. Questions about the previous history of mental illnesses and motion sickness will also be included in the consent form to assess the trail suitability.

The standard voluntary consent form provided by the University of Huddersfield was used to add further information regarding the study and obtain the consent.

Trial interventions

Following a tutorial and demonstration on how to use the system, the participants used VR Surgery application by themselves. The sequence of the steps followed included the virtual operating room scene with virtual anatomy, patient data and instruments. Feedback was provided following the use of different aspects of the application. The sequences and 3D Stereoscopic videos of individual steps of Le Fort I surgery were watched by the surgeons and commented on the quality and accuracy. 360º videos showing the surgery in the operating room from a first person perspective was then shown to the surgeons. After using the application for 45 minutes, surgeons completed the post-intervention questionnaire.

Data collection and analysis

The data will be primarily collected through paper-based questionnaires. The qualitative feedback on the application will be noted. The primary researcher will collect all the questionnaire responses and subjective comments. The data will be anonymised to conceal the identity of the participant. Data from the pre-intervention questionnaire will be collected before the surgeons use VR Surgery. Data from the post intervention feedback forms and personal comments will be collected after the surgeons used the VR Surgery application.

The data will be ordinal in nature from the five-point Likert scale rating. Answers from the open-ended questions will be used to develop the system. Subjective opinions of the participants will be recorded.

All the data will be collected at the end of the study by the primary researcher. The data will be used only for educational and research purposes. All the information will be secured by adhering to Data Protection Act 1998 (Legislation.gov.uk, 1998), in the University repositories and K drive on the University computers. The data will be anonymized and analysed by a research associate. IBM SPSS version 22 (IBM Analytics,

2017) will be used to analyse the data in this study. Descriptive statistics is showing the frequencies and Mean value will be utilized for the ordinal data obtained on a Likert scale. Answers to the open-ended questions will be subject to thematic analysis. The records will be retained by the University of Huddersfield and will be stored in their archives for ten years.

The questionnaire about the application is designed based on the contents and their functionality. Following previous face validation study experiments (Moglia et al., 2016, Schout et al., 2010), the questionnaires asked about the application's realism. Based on Bangor et al. (2008) system usability scale, the questions about usability were designed.

Compliance, withdrawal and data monitoring

The primary researcher and research associate will guide the validity studies. All the study outcomes will be reported to the supervisors who check the compliance. All the subjects are free to withdraw from the study at any time. Data will not be analysed from the participants who left the study incomplete. To prevent the loss through attrition, more surgeons will be contacted to take part in the study. The analysis of the data will be done after the completion of all the subjects' participation.

Ethical consideration

University of Huddersfield Ethics Commission has provided the Ethics approval for this research. As there are no patients or biological material involved, the study does not require NHS ethical approval. As the participation is voluntary, all the participants must sign the consent form. Any malpractices during the study must be reported to the University of Huddersfield Ethics Committee.

Financing and Insurance

This study is a result of full-time PhD project at the University of Huddersfield, School of Art, Design and Architecture. Celina-Kilner Scholarship funded the development of VR Surgery project.

Reporting and dissemination

The results from the study will be published after the agreement of all the authors. Study participants will be duly acknowledged after their consent. The participants of the study do not make a decision on the publication process. All the responsibilities of publication will be handled by the primary researcher of the study.

II. Appendix - Randomised Control Trial Protocol

Title – Efficacy of immersive Virtual Reality surgical training experience on perceived self-confidence of trainees in Oral and Maxillofacial Surgery – Randomised controlled trial

Names (titles), roles and contact details:

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- Prof Ashraf Ayoub, School of Medicine, Dentistry and Nursing, Glasgow University Dental School, UK.

Sponsor and Monitor

- University of Huddersfield
- QR Research Fund by HEFCE
- Santander fund

Trial site(s) and institutions involved in the study

i. Manipal College of Dental Sciences, Manipal
ii. Manipal College of Dental Sciences, Mangalore
iii. College of Dental Sciences, Davangere
iv. Government dental college, Goa
v. SDM Dental College, Dharwad
vi. Nair Dental College, Mumbai
vii. KLE Dental College, Belgaum

Protocol details

1. Randomised study protocol – final version
2. Date - Approved and Submitted to University of Huddersfield ethics committee on 17.08.2016

List of all abbreviations and definitions

VR – Virtual Reality

iVR – Immersive Virtual Reality

RCT – Randomised controlled trial

3D – 3 Dimensional

Summary

- Aim of the study

1. To evaluate the impact of VR surgery on the knowledge and confidence of surgical trainees in maxillofacial surgeons.
2. To assess the usability and feasibility of delivering training on VR Surgery.
3. To understand the necessary aspects of building immersive virtual reality surgical training tools.

- Rationale of the study

The impact of immersive virtual reality on the confidence and training of surgical trainees is not reported. The majority of the current studies in virtual reality and surgical training are limited to Laparoscopic Surgery and technical skills. Current research on the role of immersive VR in oral and maxillofacial surgery is not well reported. There is a lack of understanding of how to build iVR experiences for surgical training. All these findings warrant an evidence-based method which describes the delivery of training material using iVR.

- Summary of trial disorder/interventions/measures

i. We will evaluate the efficacy of VR Surgery in training novices through a multisite parallel single-blind randomised controlled trial.
ii. The Null Hypotheses states that there will be no difference in the perceived self-confidence after intervention between the experimental and control groups.
iii. The Alternative Hypothesis was that the self-confidence levels of experimental group would be different to that of the control group after the intervention.

- Primary and Secondary objectives

i. The main objective of the study is to test the impact of innovative VR training solutions on the confidence and knowledge of trainees.
ii. The secondary objective of the study is to verify the impact of stage of training on the knowledge and confidence changes before and after the intervention.

- Brief description of methods

Participants will be randomly divided into experimental group and control group. The experimental group will use VR Surgery application on an Oculus Rift. The control group will use the same content on a power point presentation. We will test the effect of the intervention on the knowledge and perceived self-confidence of trainees before and after the intervention using questionnaires.

Background

- Explain why study is important

With increasing applications of immersive virtual reality and augmented reality in surgical training, there is a need for a clear understanding of the impact of these technologies on various aspects of learning. A randomised control trial comparing iVR with current training methods is necessary to know how effectively iVR can improve the learning.

- Limitations of the current training methods

Conventionally, surgical residents learn through observation and hands-on participation in the operating room sessions following a structured training programme. This process, termed as Halsted's method of learning (Kerr and O'Leary 1999) has been in practice for more than a century now. Gradual changes in the learning methods led to the introduction of more hands-on approach where surgical trainees assist and perform parts of the procedure under the guidance of an experienced surgeon (Reznick 1993). In addition to these sessions, trainees undergo rigorous practice in surgical skill labs to improve their manual skills including hand-eye coordination. Despite all these training methods, 4 out of every ten novice surgeons are not confident in performing a major procedure (Rodriguez-Paz, Kennedy et al. 2009, Geoffrion, Lee et al. 2013). Further, overcrowded operating rooms, reduced training hours and poor visibility of surgical site are multiplying the intensity of their problem. VR Surgery was designed to meet this need in surgical training by providing cognitive training for maxillofacial surgeons.

- Intervention under investigation including reference to any previous evidence of its usefulness

Immersive virtual reality experiences provide a sense of 'presence' to the user. They require the user to wear a head mounted display or goggles to engage visual senses, headphones to engage auditory senses and occasionally gloves to engage tactile sense. Applications of Oculus Rift in medical education started with anatomy applications (Carson 2015), whereas their role in surgical education began with Moveo foundation

(Rousseau 2014). The first immersive surgical experience was recorded using a head mounted Dual Hero Go Pro camera rig to provide a first person perspective of the surgical process. Immersive technologies are ideal for surgeons to experience real life scenarios, which are not faced frequently in their regular practice (Moorthy, Munz et al. 2006). A realistic simulation of operating room on these devices can cut down the costs spent in training surgeons (Bridges and Diamond , ASIT 2015). Oculus Rift based experiences create the possibility of situated learning (Lave and Wenger 1991) and support the idea of contextualised learning (Kneebone, Scott et al. 2004, Kneebone 2009), where surgeons can learn within a clinical environment, such as operating room (Lee 2016). Recently a 360º experience of surgery on a head-mounted display was demonstrated by a UK based colorectal surgeon, Shafi (Quinn 2016) where a surgery to resect trainees viewed cancer all over the world. Applications like these show how global inequalities in surgical training can be solved with virtual reality. However, the existing and developing VR surgical training applications suggest the need for more evidence on their impact on surgical training, which the VR Surgery project is aiming to provide.

- What would be worthwhile improvement to study outcomes and what evidence there is that the treatment under investigation may achieve this

i. IVR experiences can improve a trainee's knowledge and performance

ii. It will be useful to know which aspects of an iVR experience are beneficial to trainees. VR Surgery was built under the guidance of expert surgeons considering the training needs of novices throughout the development phases.

Study design

The purpose of Research: This study will be a part of the PhD research, which involves building an immersive virtual reality surgical training tool and testing its impact on training.

Define and distinguish primary and secondary objectives

i. The primary objective of the study is to test the impact of innovative VR training solutions on the confidence and knowledge of trainees.

ii. The secondary objective of the study is to test the impact of stage of training on the knowledge and confidence changes before and after the intervention.

Statement of the primary and secondary outcomes

(at what point in the trail would these be measured?) Comparative evaluation of the perceived self-confidence levels before and after the intervention, as measured on a five-point Likert scale. These outcome measures would be measured after the trainees complete the intervention and both the questionnaires.

- Clear description and justification of the type of design

The proposed study is a parallel, single-blind randomised controlled trial

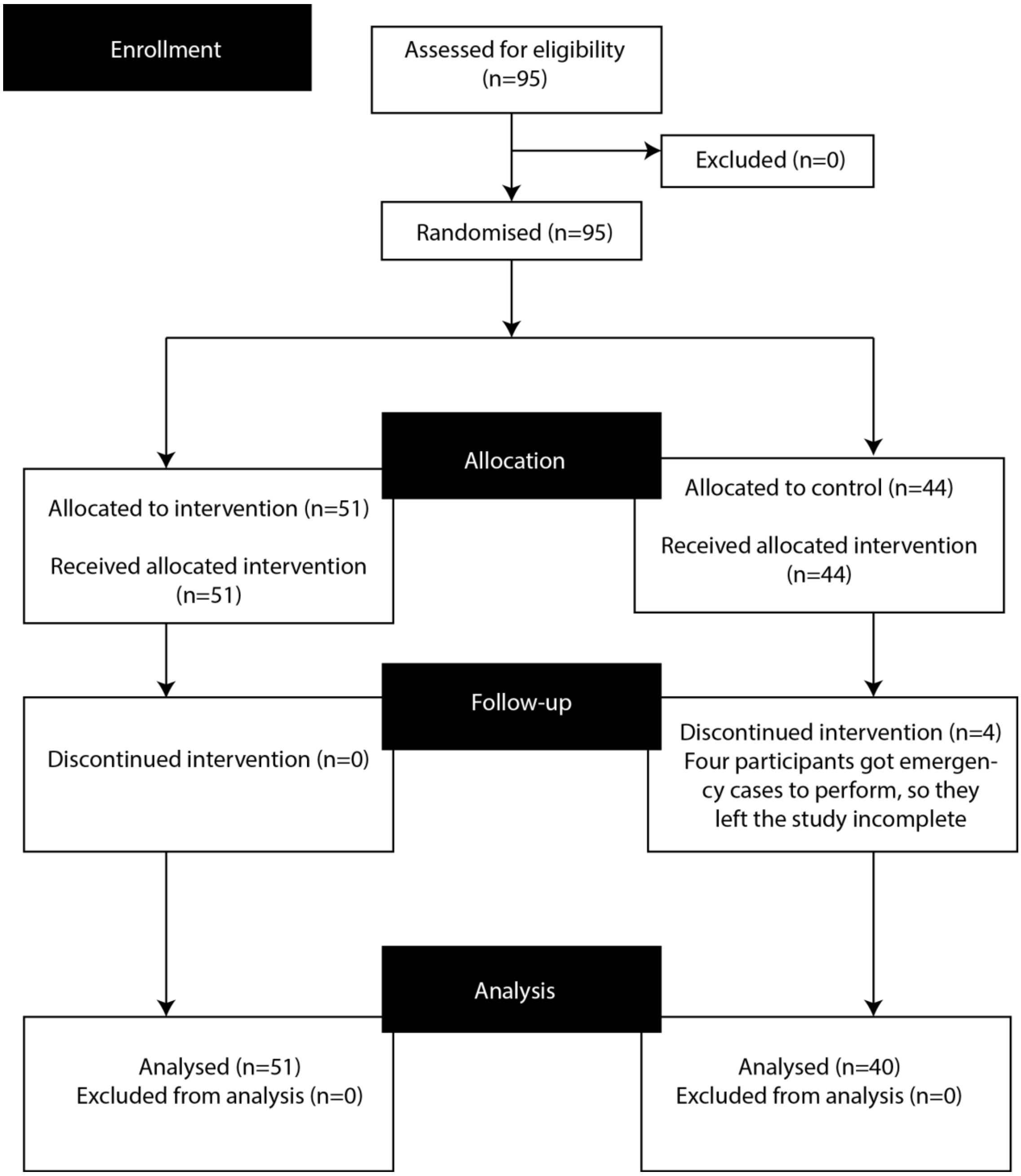
- Type of trial (Pilot study/main trial)

This is the main trail testing the impact of VR Surgery on the knowledge of trainees.

- Summary of treatments being compared with reasons for choice of comparison group

Le Fort, I training module on VR Surgery, is compared to similar content on PowerPoint presentation. We chose power point presentation as it is the norm in conventional surgical training. Virtua reality and motion sensing technologies are compared to traditional learning on a power point presentation.

Schematic diagram(s) of the trail design, procedures, stages and data collection



Recruitment of participants

- Source of subjects (Where they come from and why is this group appropriate)

VR Surgery demonstrates Le Fort I surgery, a form of maxillofacial surgery. Hence, surgical trainees in oral and maxillofacial surgery are selected as study participants. Given our sample size requirement and timelines, we chose India to select our study participants. Participants should be training in any of the three years of surgical training.

- Number of centres involved

Ten dental schools in India were invited to take part in this study to reach the target of 72 trainees and have adequate power to the study.

- Subject inclusion and exclusion criteria

Inclusion criteria

Participants should be surgical trainees in any of the three years of surgical training in oral and maxillofacial surgery.

Exclusion criteria

1. Participants who left the study incomplete

2. Participants who have the previous history of motion sickness, any psychological conditions which prevent them from using virtual reality

3. Participants who suffer from critical conditions including Epilepsy.

- Expected number of participants available per year and proportion of these expected to agree

Every dental school in India has a minimum of six and maximum of 18 trainees combining all the three years. We expect at least six dental schools to participate in the study with 70 trainees between them.

Subject recruitment

- Method of recruitment

We will contact the dental schools in India by email and invite them to take part in the study. The participating universities will be informed of the aims and objectives of the study. Informing the experts and head of the departments of the study by email and finding their availability.

- Payment of participants

No payment will be made to the participants. Their participation is entirely voluntary.

- Details of procedures, tests, screenings carried out to assess trial suitability

Trainees should be enrolled in a surgical training course in Oral and maxillofacial surgery. They should have less than 5 years of experience.

- Participant information sheet

Attached

- Participant consent – How consent was obtained, who will gain consent, whether a witness will be present, how long the subjects have to decide, arrangements for non-English speakers, special groups (Mentally ill, children, those suffering from dementia)

The participant's consent will be obtained in person by the researcher. The subjects will be informed about the objectives and explained the information on the consent forms. Trainees will be asked to read through the consent and sign in before they take the pre-intervention questionnaire. They will also be asked to sign a consent for recording a video of their participation. All the trainees will be taught in English so that the consent forms will be designed in English. Participants with any mental and physical challenges would not be included in the study as the intervention requires them to use the virtual reality system for over an hour.

- Details of enrolment procedure

All the prospective study participants will be contacted before the study through the school's administration. On the day of the study, participants will be enrolled based on their availability. The consent form, pre-intervention questions and demographics will be collected at the time of the study.

Intervention

- Intervention under investigation and any non-placebo control.

VR Surgery is the intervention under investigation. The participants in the experimental group will use VR Surgery application. Participants in the control group will use power point presentation with the same content. The participants are tested for the impact of immersive virtual reality experience and motion sensing technologies on their knowledge and perceived self-confidence.

- General information about the intervention/control treatments including previous use and current evidence of risks/benefits

The intervention group will use VR Surgery application on an Oculus Rift DK2 and Leap Motion device, which is connected to a Laptop. The trainees will watch various steps of Le Fort I osteotomy using the stereoscopic 3D videos of soft tissue cuts, bone cuts, bone fixation and bone mobilisation. Further, they will interact with the 3D models of anatomy, instruments and data. They will also observe the 360º videos of the operating room. Participants will have a guided session for ten minutes. They will then use the application for 45 minutes.

The control group will use a standard power point presentation to watch the same content on a laptop. Anatomy, instruments and patient data will be shown in the form of images. Instructions regarding the navigation of PowerPoint will be provided to the participants. Both the groups will watch the same videos about the surgery.

- A detailed description of the interventions/treatments that will be provided, including how they will be administered by whom.

The primary researcher will apply the intervention, and the research administrator will handle the control group. The participants in both the groups will be handled separately. Both the study and control groups will be monitored by supervisors independently.

- Arrangements for continuation of the intervention for study participants after the end of the trial

The experiment will be conducted as a one-off trial. However, we are planning to run a similar experiment the year after to test the impact of the simulations on real life behaviour of trainees.

- Other treatment/therapies permitted during the trial – consider the confound results

No other interventions are allowed during the trial to remove the confounding bias.

Randomisation

- Type of randomisation

Simple

- Use of equal or unequal allocation between treatment arms

Evidence shows the possibility of inequitable distribution of participants into the study and experimental groups. However, the difference between the groups is not significant.

- How randomisation schedule will be generated – Which software used, who used it?

Random numbered series by GraphPad will be used to recruit the participants for the study. The primary researcher will use this software to generate the randomised number series.

- Information regarding how the randomisation will be implemented

The randomly generated number series will be allotted on the questionnaires. They will be then given to participants based on their availability.

- Approach to be used to conceal allocation

The randomisation will be done on a software away from the participants. The numbered questionnaires will be distributed among the possible participants. Based on their group, they will be separately handled by a primary researcher or research associate.

- Define the circumstances under which the randomisation codes may be broken and any procedure for doing it

The randomisation code will only be broken if a participant withdraws from the study midway. The following generated number will be used to allow the trainees to control or intervention group.

Blinding

- Details and justification for measurement to be blinded

This experiment is a single blinded trial. The participants in the study would not know if they belong to the experimental or control group. On the other hand, the primary researcher will be aware of the group.

- Level of blinding

Single-blinded

- How blinding will be implemented

Students were divided, and the study will be performed at different places

- Describe any other methods of avoiding bias

i. None of the intervention methods will be treated as a special method.
ii. Participants will be independently studied
iii. All the participants will get a chance to experience both the interventions.

Data

Two separate questionnaires were designed to test the validity of VR surgery. A pre-intervention questionnaire to understand the training needs and a post-intervention feedback to comment on the efficacy, usability and acceptability of the system. A pilot test was performed to check the time taken for the study and make necessary modifications before the study.

- Pre-intervention questionnaire:

Once the experts signed the consent form, the pre-intervention questionnaire was given to them to assess their inclusion criteria. This questionnaire contained general questions including demographics, the experience of surgeons and experience in training novices. Questions unique to Le Fort I surgery including the most difficult step to perform, most challenging step to teach and the part of surgery where human errors are maximum were asked. A couple of questions in this questionnaire are negatively worded to prevent the users from acquiescence or response set behaviours (Jackson and Gibbin, 2006). Specific questions regarding the type of educational methods used and the extent to which they use technology in teaching were asked, as the user's expectations about a new technology can influence their satisfaction levels (Olsson et al., 2013). In addition to that, previous experience of using head-mounted displays was asked to know if the user was familiar with the head mounted VR. Questions regarding NOTTS certification and previous knowledge regarding the non-technical skills were asked as the future work of this research focuses on the application of non-technical skills in VR Surgery. These non-technical skills include teamwork, leadership, decision-making and questions regarding the NOTTS certification.

- Post-intervention questionnaire:

The post-intervention questionnaire contained questions relating to the content of the application, usability and application in training. A five-point Likert rating scale was used to rate the quality of videos, 3D models of instruments and anatomy. Each scoring element ranged from strongly disagree/disagree/neither/agree/strongly agree. Space for additional open comments was provided, and the participants were encouraged to make use of it. Additional suggestions regarding future developments needed in the application were taken from the surgeons. The necessity of few elements like the 360-degree videos and interactive animations of 3D patient scan data were asked. Questions comparing the impact of 2D videos versus 3D videos and the sequence of steps in surgery have been invited to learn about the differences in different media and their role in learning. Based on (Bangor et al., 2008)'s System Usability Scale, five-point Likert scale ratings were used to rate the comfort of using the headset, accuracy and appropriateness of hand tracking, and quality of the audio and videos in the application. The last section asked the experts regarding potential applications of the VR Surgery in training surgical trainees. Their opinions on the use of the VR Surgery for training, benefits of its use for multiple procedures and acceptability into curriculum were questioned. The effectiveness of VR surgery on the understanding and confidence of users was also asked. In line with current studies (Davis, 2016), the surgeons were asked if they considered VR surgery as an effective adjunct to current training methods. Question regarding the inclusion of non-technical skills was added to the feedback.

The consent form and pre-intervention data will be collected before the intervention. The post-intervention will be collected after the intervention at the same time.

The primary researcher will collect questionnaires from the experimental group. The research associate will collect questionnaires from the control group.

The questionnaires on self-confidence are developed from Bandura's questions on self-efficacy (Bandura, 2006). In addition to these, the questions on knowledge of surgery, the sequence of steps, anatomy and instruments were developed by working with expert surgeons in Oral and Maxillofacial surgery. Two expert surgeons took part in modifying the questions and providing feedback.

All the data will be anonymised and collected for analysis. The data will be collected in the form of paper-based questionnaire responses. Video interviews of participants will be collected for feedback on the application. The collected data will be stored in University of Huddersfield repositories and archives, and stored securely for ten years. The data will be analysed on University machines, and it will be subsequently stored in K drive of the university computers. The data will only be used for education and research purposes. The researcher will adhere to the data protection act, 1998 in collection, analysis and storage of the data. The primary researcher will collect all the data and manage it for research purposes only.

Statistical considerations

- Who calculated the sample sizes?

Sample sizes are calculated by the primary researcher, taking analytical support from the School of Psychology, University of Huddersfield.

- Details of the Apriori power calculation

To compare the effect of

G* power analysis for MANOVA showed the requirement of 72 members as a sample size for a power of 95 and α value of 0.05.

F tests - MANOVA: Repeated measures, between factors

Options: Pillai V, O'Brien-Shieh Algorithm

Analysis: A priori: Compute required sample size

Input: Effect size f = 0.25

α err prob = 0.05

Power (1-β err prob) = 0.95

Number of groups = 2

Number of measurements = 3

Corr among rep measures = 0

Output: Noncentrality parameter λ = 13.5000000

Critical F = 3.9777794

Numerator df = 1.0000000

Denominator df = 70.0000000

Total sample size = 72

Actual power = 0.9518848

Pillai V = 0.1578947

An A priori power calculation using G*Power Analysis (Faul et al., 2009) for t test showed the required sample size as 88, for a Power of 75, at an effect size of 0.5.

- Estimate of the recruitment period for the trial

To understand the appropriate accrual time for recruiting 72 participants from ten dental schools in the study, we consulted expert surgeons in the UK. We also contacted dental schools in India to identify the required time. Based on the availability of trainees, timelines of dental schools and participating surgeons, we have allotted two months of time to recruit the participants.

Variables to be used to assess baseline comparability of the groups and how these will be reported (Standard deviations/means/medians/proportions)

- The mean scores of knowledge levels will be compared between the study and control groups before the intervention.
- Trainees' perceived self-confidence scores will be measured on a five-point Likert scale, where one stands for not confident and five means confident. The mean value of scores will be compared between the study and control group before and after the intervention. The change in the confidence will also be measured.
- The impact of the stage of training on the scores will be measured as another dependent variable.

Summary methods to be reported

- An independent sample t-test will be performed to compare the participant's knowledge before the intervention.
- A paired sample t-test will be used within each group to compare how the participants have improved their scores before and after the intervention.

- A MANOVA will be applied to compare the effects of the intervention on multiple scores including the participant's knowledge and confidence while comparing their stage of training.
- Plans for handling the missing data, non-compliers and withdrawals in analysis

As the study participants are surgical trainees in residence, there is a possibility of them attending emergency cases during the study period. This leads to missing data or withdrawals and non-compliers in the experiment. To minimise the possibility of missing data, we plan to follow few of the suggested methods (Little et al., 2012).

1. We intend to work with participating universities' schedules to find days where there are no operating room sessions

2. We plan to increase the recruitment sample size.

3. Monitor the adherence to the study after every university.

4. Keep contact information for all the participants, so they can be contacted and requested to participate in the two months' period.

- Plans for predefined subgroup analyses

There are no plans to perform a subgroup analysis. The power calculation is done for the overall impact of VR Surgery on the trainees. However, the impact of the technology on the stage of trainee will be calculated.

- Statement regarding the use of intention of treat analysis

N/A

- Who will carry out the analysis and at what point

The primary researcher will conduct the analysis blinded to the study sample. The study analysis will be conducted at the end of the survey.

- Details of any non-statistical methods that might be used (Qualitative methods)

Compliance and withdrawal

- Procedures for monitoring

Two expert supervisors will monitor the study group and control group separately. Two researchers will separately monitor participants. Any potential discomfort to the participants will be noted and informed to the supervisors.

- Recording their compliance

Video recording of the participant's actions is planned. Participants have a choice to opt out of this method of data capture.

- Details of follow-up of non-compliance participants

Non-compliant participants will be requested to discontinue the study. They will not be re-joined into the experiment, but they will be provided with an option to experience the software at the end of the research.

- How subjects will be withdrawn from the trial

Subjects can withdraw from the experiment at any point in time. Given that the subjects are surgical trainees; they might have emergency cases to attend. Any participant who has a case of urgency, or who has problems with the VR experience are free to withdraw from the study. They need to inform their reason for withdrawal to the PI for the records.

- Details of the documentation to be completed on subjects who drop out of the trial or who are withdrawn from the trial

All the details from participants who have withdrawn from the study will be collected. The questionnaires will be labelled "Discontinued" for the purpose of analysis. The data from these participants will not be considered for analysis.

- Whether and how subjects would be replaced

Attrition is expected in medical schools due to the busy schedules of the participants. The researcher will approach a number of students to compensate the withdrawals. The withdrawn subjects will not be replaced.

Interim analysis and data monitoring

- Stopping/discontinuation rules and breaking of randomisation code

If the participants suffer from any adverse effects while taking part in the experiment, they would be requested to discontinue the study, and the randomisation code will be broken to use the next number in the series. Also, as the participants were surgical trainees, they are bound to have cases to attend. If the participants have to leave the study in between, the next participant will be allotted to a group based on the random series of numbers.

- Monitoring, quality control and assurance

The primary researcher will perform interim analysis at the end of the day and the end of every trial site or university. The supervisors on duty will assess this interim monitoring. This analysis will maintain the quality of the study.

- Assessment of safety

All the participants will be informed about potential side effects of immersive virtual reality experiences. They will be continually assessed for safety. After completion of the intervention, the study group participants will be asked to remain seated as the stereoscopic visualisation in VR Surgery can affect their postural balance.

- Any adverse effects expected

Virtual reality sickness is the only adverse effect expected. A headache, stomach awareness, nausea, vomiting, pallor is commonly mentioned symptoms for VR sickness. Postural instability and retching are also described in the literature (Joseph J. LaViola, 2000 {Stanney, 1997 #382)}.

Watching stereoscopic 3D content for long can cause symptoms of nausea, oculomotor disorientation and sickness, especially for women with sensitive visual-vestibular system and participants with the previous history of motion sickness. (Solimini, 2013)

- How will they be recorded

Participants will be monitored during the study and immediately afterwards. They will be checked for any symptoms of VR sickness.

- What will be done to protect the participants

All the participants will be monitored for the potential side effects and informed before their participation in the study. Further, all the precautions were followed in the design of the application to reduce the chances of VR sickness. Participants who are not comfortable with closed environments will be prevented from watching the stereoscopic 360º video of the operating room.

- Any non-adverse effects

A mild headache or strained eyes might occur in participants. These will be monitored during and after the study.

- Type and duration of follow-up for subjects after adverse events

If any participant suffers from adverse effects of VR Sickness, they will be transferred to medical care. We will inform all the participating dental schools about the potential side effects that can occur.

Ethical consideration

- Description of ethical issues for the trial

There are no ethical issues for conducting the trial. Informed consent from the patient was obtained for recording the videos, scanning the surface of the face and using the pre-surgical scan data in the application.

- Approvals

The randomised control trial received ethical approval from the University of Huddersfield Ethics Committee. The ethics approval is subject to a condition of taking informed consent from every participant of the research.

- Informed consent

All the participants will sign an Informed consent outlining the research aims and objectives and the purpose of the experiment. The principal investigator of the research will explain the contents of the consent form to all the participants. Participants will also be asked if they could be interviewed and photographed after the study.

- Allowances for special groups?

No special provision for particular groups is planned at the time of designing this protocol.

- Withdrawal/discontinuation

The participants in the trial are free to withdraw from the study at any point in time. Alternatively, if the participants in the study are feeling any discomfort while using the virtual reality headset, they are free to discontinue the study.

- Trial monitoring

The trial will be monitored by two expert researchers along with the primary researcher and research associate.

Finance and insurance details

Celina Kilner scholarship by the University of Huddersfield supported the development of VR Surgery project. QR research fund by HEFCE supported travel expenses for the RCT data collection by YP and MM. Santander Fund supported travel expenses for the RCT data collection for MP and DP. The funders of the study had no role in data analysis, data interpretation, or writing of the report.

Reporting and dissemination

- Details of publication policy

We will publish relevant scientific information in leading medical journals subject to the following policies:

1. All the data will be anonymised.
2. The identity of the study participants will not be revealed.
3. Ethical approval from the University of Huddersfield should be obtained.
4. Data protection policy will be followed.

- Will there be access to raw data by all the investigators of the study?

The raw data will be made available to all the investigators of the study on the University of Huddersfield Repository.

- Specify planned publications/conferences

The results of this study will be disseminated in leading medical journals.

1. The protocol of the study will be published in University repository

2. The results of the study will be published in leading international medical journals.

III. Appendix - Validity Study Consent form and questionnaires

Consent form

Thank you for accepting to participate in the validation of VR Surgery. It is important that you read, understand and sign the consent form. Your contribution to this research is entirely voluntary, and you are not obliged in any way to participate, if you require any further details, please contact your researcher.

I have been fully informed of the nature and aims of this research ◻

I consent to taking part in it ◻

I understand that I have the right to withdraw from the research at any time ◻ without giving any reason

I give permission for the results of my data to be analysed used in ◻ publications/conferences (with use of pseudonym and not identifiable in any way)

I understand that the information collected will be kept in secure conditions ◻ for a period of five years at the University of Huddersfield

I understand that no person other than the researcher/s, ◻ marker/s, and facilitator/s will have access to the information provided.

To check for your eligibility, we ask participants must not have had suffered from epilepsy or Attention Deficit Hyperactive Disorder, or had been on any anti-psychotic or anti-depressant medication. If you have or have had any of the above, within the year to date, please inform a research member. Alternately, you may contact a researcher to cease your participation, without reason. If you have no further question and are satisfied that you understand the information, please tick the box aligned to each sentence and print and sign your name below.

Signature of Participant: [e-signature if available] Print: Date:	Signature of Researcher: Print: Yeshwanth Pulijala Date: 15/11/2016

(one copy to be retained by Participant / one copy to be retained by Researcher)

Face and Content Validity Pre-intervention questionnaire

Thank you for your time and interest in this study. This questionnaire is intended to be filled in by yourself before using the 'VR Surgery' Training system.

The questionnaire invites you to answer questions about your experiences, knowledge, and perceptions of select technology and methods of education. Additionally, some questions will ask you about your cognitions/thoughts about your experiences with Le Fort 1 procedures carried out.

Allow approximately 10-15 minutes to complete this questionnaire. Thank you for your collaboration! Please write/circle your answer where appropriate.

Q1: Please write your

a. Age –
b. Sex –
c. Years of Experience -

Q2: How many times have you approximately <u>performed</u> a Le Fort 1 procedure?

a. 1-9 b. 10-29 c. 30-49 d. 50-69 e. 70+

Q3: How many times have you <u>taught</u> a Le Fort 1 procedure?

a. 1-9 b. 10-29 c. 30-60 d. 50-69 e. 70+

Q4. Which of the following task in Le Fort 1 Osteotomy is the most difficult to teach?

a. Soft tissue flap
b. Bone cuts and mobilisation
c. Bone fixation
d. Suturing

Q5. What part of a Le Fort 1 Osteotomy are <u>human errors mistakes</u> most likely to occur?

a. Soft tissue flap
b. Bone cuts and mobilisation
c. Bone fixation
d. Suturing

Q6. Are you aware of <u>Non-Technical Skills</u> for Surgeons?

Yes ☐ / No ☐

Q7. If so, have you been on a NOTSS (Non-Technical Skills for Surgeons) training course or similar?

Yes ☐ / No ☐

Q8. Among the following options, please rank the top 3 methods of educational delivery to teach trainees about a maxillofacial surgery procedure.

- Lectures
- Power point presentations
- Videos
- 3D Animations
- Operating room sessions
- Textbooks

Q9: Which among the following technology have you used to teach your trainees about a maxillofacial surgery procedure?

e. Computers
f. Tablets/Smartphone
g. Surgical Simulators
h. Virtual and Augmented Reality applications

Q10: How much do you like to apply technology in teaching and learning about procedures in maxillofacial surgery?

I **do not** include use of a tablet, PC, or smartphone to aid in surgical education ☐
I **sometimes** include use of a tablet, PC, or smartphone to aid in surgical educat ☐
I **always** include use of a tablet, PC, or smartphone to aid in surgical educatior ☐
I **depend upon** use of a tablet, PC, or smartphone to aid in surgical education ☐

Q11: Which statement best describes your knowledge about Head Mounted Displays?

I have never heard of Head Mounted Displays ☐
I have heard of Head Mounted Displays, but I do not know their uses ☐
I know a little about the uses of Head Mounded Displays ☐
I know a lot about Head Mounded Displays and their uses ☐

Q12: Which statement best describes the usage of Head Mounted Displays?

Our facility does not use Head Mounted Displays in research/education ☐

Our facility intends to use Head Mounted Displays in research/education ☐

Our facility uses Head Mounted Displays in research/education ☐

Q13: If you have used a Head Mounted Display, what was the content?

Q14: If you have not used a Head Mounted Display, would you be interested in finding out more information about them, to aid in your institutions research/teaching?

☐es / N☐ /

Thank you for completing this questionnaire. The next step in your participation will be to meet with the researcher on your chosen date and provide feedback after testing 'Oculus Surgery'. If you have any questions regarding the dissemination of your data, please contact the researchers by the following methods:

Yeshwanth Pulijala

07492744575

Yeshwanth.pulijala@hud.ac.uk

VR Surgery Face validity and Content validity questionnaire

Thank you for participating in the assessment stage of 'VR Surgery'. Your feedback is crucial in the face, construct, content, and external validity, along with the inter-rater reliability of the VR surgical training tool.

Once you have used 'VR Surgery', please complete the following questionnaire. Each question is accompanied by a 5-point Likert Scale, which measures the likeliness of the statement. Ratings are made on a numerical scale from 1 to 5.

At the end of every question, a comments section/blank space is provided for you to express your opinion, make comments and justify your choices. You are strongly encouraged to use this space. Additional paper can be provided if you request it.

This questionnaire is divided into five sections for you to complete:

1. The content
2. The instrumentation
3. The anatomy
4. The usability of application
5. The role within the current dental curriculum.

This questionnaire will take approximately 20 minutes to complete, and depends on the depth of your feedback.

1. **The content** - this part of the study is for you to test the *quality* of the content in the application.

1. The Le Fort I surgery is *shown accurately* in this application

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

2. *All the steps* of the Le Fort I surgery are covered in this application

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

3. The *order of steps* in Le Fort I surgery are not shown correctly

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

4. Is there any step of the surgery that is missing in this application?
   If yes, please provide further explanation regarding this in the box below:

5. I could see the *benefit of 360*-degree videos of the Operating Room in training novices

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

6. I could see how 3D videos of surgery *are better* than conventional 2D videos

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

7. I found the virtual operating room scene *useful*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

8. *Interacting* with the pre-surgical CBCT scan data and prediction plan of the patient *was beneficial*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

9. The menu scene *showing all* surgical steps *is useful* for trainees to remember the

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

sequence

Comments:

10. Is there anything that was missed in the application which you would like to be added?

2. **The instrumentation -** this part of the study is for you to test the *instruments* shown in the application.

   1. Showing *instruments* in the VR Surgery application is not *useful*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

   2. The *instruments* shown in the VR Surgery application are *realistic* in their

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

appearance

Comments:

   3. Is there any instrument which was *missed* or which you think needs to be *added/improved* in the application?

d. What else needs to be added to this scene to make it more useful?

3. **The Anatomy -** this part of the questionnaire tests the anatomical accuracy, realism, and need in the application.

1. The *Anatomy of the skull* shown in the VR Surgery application is *accurate*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

2. The *nerves and blood vessels* are shown in the VR Surgery application are *accurate*

Comments:

3. The 3D models resemble the real life anatomy realistically in their appearance

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

4. It is necessary to have this aspect of anatomy interaction in the application

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

5. Were any anatomical references missed which are required for Le Fort 1 surgery?

4. **The Usability of VR Surgery** - this part of the questionnaire tests the comfort, ease of use, and interface of the application.

a. It was *comfortable* to use the VR Surgery application

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

b. I *did not* experience *nausea*, *dizziness,* or a *headache* using the VR Surgery

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

application

Comments:

c. I could look around the operating room *comfortably*, without any discomfort

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

d. I could not *track my hands* in the application *accurately*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

e. I could *touch* the virtual objects *appropriately*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

f. I could *interact* with the user interface *as I expected*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

Strongly disagree	Disagree	Neither	Agree	Strongly agree

1	2	3	4	5

g. I found the quality of the videos to be excellent

Comments:

h. I found the quality of audio to be excellent

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

i. I found the headset comfortable to wear throughout the application usage

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

j. Is there something that you want to share about the usability, but we missed asking you?

5. The role within current training - this part of the questionnaire tests the value, usefulness, and possibilities of the Oculus Surgery application in training oral and maxillofacial surgeons

1. I found this application *interesting*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

2. I found this application will be *useful for teaching my trainees* regarding the *Le Fort*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

I surgery

Comments:

3. Addition of virtual reality applications like VR Surgery to the training will be

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

beneficial for surgical trainees

Comments:

4. I think this application will enhance the understanding of surgical trainees regarding the Le Fort 1 application

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

5. I think using this application will increase confidence in surgical trainees before performing a real surgery in the operating room

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

6. I see this application more like an adjunct than a necessary tool for studies

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

7. I want to see more maxillofacial surgical procedures developed into VR Surgery

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

Q6. Are there any non-technical/cognitive features that you would like the VR Surgery to be able to teach trainees? (e.g. decision making, thinking ahead, error spotting)

Q7. What are the best aspects you like about VR Surgery?

Q8. What are the not so good aspects of VR Surgery?

End of the questionnaire. Thank you for your participation, - please inform a researcher you have finished. A debrief form will now be provided. If you have any more feedback or questions regarding the dissemination of your data, please contact the researcher by the following methods:

Email: Tel:

IV. Appendix RCT Consent form and questionnaires

VR SURGERY Consent form

Consent form (Participant Number:)

Thank you for accepting to participate in the validation of VR Surgery. It is important that you read, understand and sign the consent form. Your contribution to this research is entirely voluntary, and you are not obliged in any way to participate, if you require any further details, please contact your researcher.

I have been fully informed of the nature and aims of this research

□

I consent to taking part in it

□

I understand that I have the right to withdraw from the research at any time

□

without giving any reason

I give permission for the results of my data to be analysed used in

□

publications/conferences (with use of pseudonym and not identifiable in any way)

I understand that the information collected will be kept in secure conditions

□

for a period of five years at the University of Huddersfield

I understand that no person other than the researcher/s,

□

marker/s, and facilitator/s will have access to the information provided.

This event will be photographed and video recorded for further records and marketing of this international collaboration. If you are happy, please tick the box. If you do not want to be photographed, please inform the researcher. □

To check for your eligibility, we ask participants must not have had suffered from epilepsy or Attention Deficit Hyperactive Disorder, or had been on any anti-psychotic or anti-depressant medication. If you have or have had any of the above, within the year to date, please inform a research member. Alternately, you may contact a researcher to cease your participation, without reason. If you have no further question and are satisfied that you understand the information, please tick the box aligned to each sentence and print and sign your name below.

Signature of Participant: [e-signature if available] Print: Date:	Signature of Researcher: Print: Date:

RCT Novice Demographic Questionnaire

(Participant Number:)

This questionnaire asks you about your background and education regarding Le Fort I procedure. Please write/circle your answers where appropriate.

1. Please write your:
   a. Age – b. Sex –
   c. Stage of study- d. College -

2. How many times have you approximately?

   i. Performed or assisted a Le Fort I procedure?

      b. 1-5 b. 5-10 c. 15-20 d. More than 20

   ii. shadowed a surgeon while performing a Le Fort I procedure in the operating theatre?

      b. 1-5 b. 5-10 c. 15-20 d. More than 20

3. When you are in an operating theatre, which of the following statements is the closest to your learning experience?
   a. I can view the entire surgical procedure
   b. I can view most parts of the procedure
   c. I can view some parts of the procedure
   d. I can view very few parts of the procedure

   Comments:

4. When you do not get necessary information in the operating theatre, how do you compensate your learning needs? (Circle one or more answers)
   a. Textbooks
   b. YouTube videos
   c. Journals

d. Attend more surgeries

5. I find this aspect of Le Fort I surgery most difficult to understand. (Circle one answer)

   a. Pre-surgical management
   b. Soft tissue cuts
   c. Bone cuts
   d. Bone mobilisation
   e. Fixation and placement of plates and screws
   f. Suturing
   g. Post-surgical management

   Comments: why this is the most difficult to understand?

6. This is the most difficult step to perform in Le Fort I surgery. (Circle one answer)
   a. Pre-surgical management
   b. Soft tissue cuts
   c. Bone cuts
   d. Bone mobilisation
   e. Fixation and placement of plates and screws
   f. Suturing
   g. Post-surgical management

   Comments (can you provide more specific detail?):

7. Which technology have you used to learn about a maxillofacial surgery procedure? (Circle one or more answers)

   a. Computers b. Tablets/Smartphone c. Surgical Simulators d. Virtual or Augmented Reality applications

8. How much do you use technology in your day to day learning?
   a. I **do not** include use of a tablet, PC, or smartphone to aid in surgical education ☐
   b. I **sometimes** include use of a tablet, PC, or smartphone to aid in surgical education ☐
   c. I **always** include use of a tablet, PC, or smartphone to aid in surgical education ☐

d. I mostly **depend upon** the use of a tablet, PC, or smartphone to aid in surgical education ☐

9. Which statement best describes your knowledge about Head Mounted Displays?
   a. I have never heard of Head Mounted Displays
   b. I have heard of Head Mounted Displays, but I do not know their uses ☐
   c. I know a little about the uses of Head Mounded Displays ☐
   d. I know a lot about Head Mounded Displays and their use ☐

10 Please select one of the options based on your confidence levels

a. I feel confident about the sequence of the steps involved in Le Fort I surgery

Strongly disagree Disagree Neither Agree Strongly agree

10b. I feel confident about the information regarding different instruments used in Le Fort I surgery

Strongly disagree Disagree Neither Agree Strongly agree

10c. I feel confident about the anatomy involved in Le Fort I surgery

Strongly disagree Disagree Neither Agree Strongly agree

Thank you for completing this questionnaire, please now complete the 'Pre-intervention Assessment

VR SURGERY Novice Pre-Intervention Assessment

(Participant Number:)

Thank you for your time and interest in this study. This questionnaire is regarding your experiences, knowledge of tools/anatomy, and cognitive processes of the Le Fort I procedure. Allow approximately 10 minutes to complete this questionnaire.

Please complete the following questions without any help. Write/circle your answers where appropriate.

1. Which part of the face should be prepped before surgery?
    a. Lower midface starting from nasal bridge to mandible
    b. The whole face, from the supra-orbital rim to the neck, and from one ear to the other
    c. Infra orbital rim to mandible
    d. Infra orbital rim to neck

2. Arrange the following steps in the right sequence

a. Anaesthesia b. Placement of K-wire c. Measurement of the vertical height of maxilla

d. Diathermy

3. What is the value of having access to the patient's CBCT during surgery?
    a. Evaluation the position of vital structures including nerves.
    b. Check the position of sinus cavities.
    c. To check for any impacted 3rd Molar and disclose their position.
    d. All the above

4. Where will you place the external reference point to measure the vertical height?

a. At the Nasion point or the top of the bridge of the nose
b. Above the right and left maxillary central incisors
c. At the Gnathion
d. Below the medial canthus of right and left eyes.

5. Why is it important to measure the alar base width before surgery?

    a. To match the vertical dimension measurement

b. To avoid nasal flaring because of Le Fort I osteotomy
c. To check the required forward movement in maxilla
d. To check the required maxillary impaction

6. How extensive should the exposure of the maxillary bone be before surgery?

The soft tissue flap extends from the:

a. first premolar region of one side to the first premolar of the opposite side.
b. second premolar region of one side to the second premolar of the opposite side.
c. first molar region of one side to the first molar of the opposite side.
d. second molar region of one side to the second molar of the opposite side.

7. Which instrument is used for Pterygo-maxillary disarticulation? Circle it in the picture below.

a. Smith spreaders b. Rowe's forceps c. Curved Osteotome d. Retractor

8. Which instrument is used to fracture the nasal septum?

a. Reciprocating saw b. Single-guarded Osteotome c. Double-guarded Osteotome d. Curved Osteotome

9. What will you do after the elevation of nasal mucosa?

a. Mark the maxilla for bone cuts b. Maxillary disjunction c. Dis-impaction of maxilla
d. Osteotomy of lateral nasal wall

10. As you perform forward mobilisation of the maxilla, you encountered severe bleeding. Which blood vessel needs monitoring?

a. Pterygoid venous plexus **b**. Greater palatine artery **c.** Anterior palatine artery **d.** Sphenopalatine artery

11. Where should you palpate while fracturing the medial nasal septum?

a. Lateral nasal walls b. Maxillary tuberosity c. Junction of hard and soft palate
d. Anterior surface of maxilla

12. How would you maintain the increased alar base width to its original pre-surgical dimension?

a. Cinch stitch b. Apply pressure on the mucosa c. Mucosal suturing d. VY Closure

13. During a Le Fort I Operation something unexpected happens. There is no procedure available. You have seconds to make a decision to attempt to prevent a bad outcome, what is the best thing to do?
    a. Consider all the possible options, and select the best.
    b. React the best you can to the situation based on your experience.
    c. Ask your supervisor/teacher to take over and make the decision.
14. The surgeon is making a decision during a Le Fort I that you believe will cause a small error/issue. You are aware of an important piece of information that the surgeon may have missed that may change their decision. What should you do?
    a. Trust that the surgeon did not miss/overlook this piece of information
    b. Interrupt the surgeon and inform him/her before they make the decision
    c. Ask a team member if they think the piece of information is important
    d. Watch to see if an error occurs and after operation explain why it may have occurred
15. How do your senses help you when opening the smith's spreaders to down-fracture the Maxilla? What can you feel, hear, see?

    Answer:

Thank you for completing the questionnaire, please inform a researcher you have finished.

Note: If you are interested in being interviewed today into your cognitions regarding Le Fort I Osteotomy, please inform a research member ***now*** to book a time.

VR SURGERY Post-Intervention Assessment

(Participant Number:)

This final questionnaire invites you to answer 25 questions regarding your knowledge, and your feedback about the intervention. At the end of every question, a comments section/blank space is provided for you to express your opinion, make comments, and justify your choices. Additional paper can be provided if you request it.

Allow approximately 10 minutes to complete this questionnaire. Please complete the following questions without any help. Write/circle your answers where appropriate.

1. What is the common instrument used for the forward mobilization of the maxilla? Can you select the instrument in the image below?

a. Paul Tessier mobilizes b. Rowe's forceps c. Smith spreaders d. Curved Osteotome

2. What are the main risks of using curved surgical Osteotome for Pterygo-maxillary disarticulation?

a. Injury to the infra orbital nerves b. Tearing of the nasal mucosa c. Fracture of the palatine bone d. Bleeding, and fracture of the pterygoid plates

3. Which complication should be avoided while mobilising the maxilla downwards and forwards?

a. Injury to ptregyoid venous plexus b. Damage to the greater palatine artery c. Tearing of nasal mucosa d. Injury to the pterygoid plates

4. Arrange the following steps in the right sequence

a. Reduction of maxilla b. Intermaxillary fixation

c. Placement of wafer d. Final positioning of Maxilla

5. What is the next step after performing the bone cuts?

a. Pterygo maxillary disarticulation b. Forward mobilisation of maxilla

c. Down fracture of maxilla d. Inter-maxillary fixation

6. How many mini-plates are usually used for fixation of the maxilla in its pre-planned position?

a. Four plates on each side, two at the pyriform aperture and two at maxillary buttress
b. Two plates on each side, one at the pyriform aperture and one at the maxillary buttress
c. One plate on each side, at the maxillary buttress
d. Two plates on each side, both are placed at the maxillary buttress

7. Why it is essential to release the inter maxillary fixation following the placement of plates and screws?

a. To remove the throat pack and facilitate postoperative recovery
b. To facilitate maxillary advancement
c. To prevent relapse of maxilla after the surgery
d. To secure the plates and screws in place.

8. Which suture material is usually applied for stitching of the buccal mucoperiosteal flap?

a. 4(0) Vicryl rapid
b. 2(0) Vicryl rapid
c. 3(0) Nylon
d. 4(0) Nylon

9. What is the technique that is usually applied during suturing the soft tissue to lengthen the upper lip and allow eversion of the vermilion border?

a. V-Y closure
b. Cinch suture
c. Mucosal suturing
d. Apply hydrocortisone to lips before suturing

10. Arrange the following steps in the right order

a. Alar base measurement   b. Placement of wafer   c. Reduction of maxilla   d. Cinch sutures

Answer:

11. After this session, I feel more confident about the **sequence of the steps** involved in Le Fort I surgery

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

12. After this session, I feel more confident about **the instruments** used in Le Fort I surgery

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

13. After this session, I feel more informed about **the anatomy** involved in Le Fort I surgery

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

14. After this session, I feel more informed about **the team work in operating room**

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

environment

Comments:

15. After this session, I am confident that I can **identify the complications** within the Le Fort I surgery

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

- Application feedback

16. I could clearly see the *benefit of 360* degree videos of the Operating Room

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

17. I think conventional 2D videos of surgery *are better* than 3D videos

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

18. *Using* the pre-surgical CBCT scan data and prediction plan of the patient *was beneficial*

Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	2	3	4	5

Comments:

Strongly disagree	Disagree	Neither	Agree	Strongly agree

1	2	3	4	5

19. This session helped me to remember the sequence of steps performed in Le Fort I surgery

Comments:

20.

a. What is the best thing in this application?

b. What is not so good about this application?

You have now finished the study. Thank you for your time and participation. Please collect a ‘Debrief’ Form, and inform a research member you have finished.

V. Appendix - Patient Consent Form

1403945004
FERGUSON F
Lynn 14/03/1994
RIVERDALE
Strathaven, Lanarkshire
ML10 8QF

Request and consent to photograph, video recording and surface 3D scanning.

Your provider will need to photograph and/or video record the surgical procedure you are about to undergo to create Oculus Surgery project, an innovative learning tool using virtual reality training tool.

I hereby authorize the Yeshwalla or Prof Ayoub (Name), including the attending doctor or other designated persons, to photograph or video record me during the surgery for the following purposes. Check **YES** or **NO**.

	YES	NO
1. For the advancement of **not for profit** medical purposes, including teaching, research and education. I understand that education is an important part of the hospital's commitment to teaching younger healthcare providers.	✓	
2. To show or release the current or future surgical trainees for the purpose of education and consultation. I understand these photos or videos can be taken at any time during my treatment which includes pre-treatment, post-treatment, pre-operative, intra-operative, post-operative photos, videos, 3D scan of my treatment, surgery and/or procedure.	✓	
3. To be included in the **external not for profit** educational purposes outside University of Glasgow and Huddersfield such as lectures, presentations and publications.	✓	

I consent to photograph, video and/or 3D scanning under the following conditions:

- Copies of the photos, videos, and/or 3D scanning data may be released to me if I ask for them.
- I can refuse to have my photos and/or video taken without any change in my medical care.
- I understand and agree that although my name will not be used, it may be possible to identify me from a photo and/or video and
- I understand that once released outside the University of Huddersfield or Glasgow Dental School, the universities and the researchers do not have control over the photos or videos.

VI. Appendix - Ethics approval

THE UNIVERSITY OF HUDDERSFIELD

ADA

Reviewer Proforma.

Project Title:	VR Surgery- Design and Evaluation of an immersive virtual reality experience for trainees in maxillofacial surgery
Name of researcher (s):	Yeshwanth Pulijala
Supervisor (where appropriate):	Minhua Ma
Reviewer names	Song Wu, Kaushal Keraminiyage, Angela Lee

Issue	Advice / Comments to applicant
Aim / objectives of the study	
Research methodology	
Permissions for study?	
Participants	
Access to participants	
How will your data be recorded and stored?	
Confidentiality	
Anonymity	

Could the research induce psychological stress or anxiety, cause harm or negative consequences for the participants (beyond the risks encountered in normal life).	
Retrospective applications.	
Supporting documents (e.g. questionnaire, interview schedule, letters etc)	
Other comments	

OVERALL RESPONSE

APPROVE	
APPROVE SUBJECT TO RECOMMENDATIONS [please specify]	
APPROVE SUBJECT TO CONDITIONS [please specify]	This is approved however you must ensure that all data is stored in conjunction with the university data storage policy. You also need to complete the title on the participant information and consent forms. Each participant must give their individual consent.
FURTHER INFORMATION REQUIRED [please specify]	
REJECT [please specify reasons]	

Date 17.08.2016

Where the project is deemed to potentially represent a significant risk it should be forwarded to SREIC for consideration.