Design and development of a new Scalp cooling Cap: Stage 1

Confidential Research Report
On Behalf of PAXMAN ltd

A Report by:

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1. Introduction & Project History:

Paxman received a Smart award for £229,000 as a contribution from the Technology Strategy Board towards the development of their scalp cooler to enable the product to meet the needs of a global market, together with improvements to efficacy and patient experience. The development includes improvements to the cap which will take into account anthropometric data from all over the world, and the smart user interface which will provide, in a simple and usable form, all the information that the key stakeholders require. The overall project value amounts to £508,000.

This project represents a collaboration not only with the University but also other external partners Dr Wim Breed and Blue Print Product Design and clinical trials at Baylor, Houston, USA. The remit was to develop an improved prototype design for their scalp cooler. This involved working with Product Design academics Dr Ertu Unver and Chris Howard in the University's School of Art Design and Architecture. They conducted research into global human head sizes and shapes and generated 3D and IGS data that led to a new working prototype. This involved working with Paxman's cap supplier Primasil to improve the design of the silicone cooling cap leading to improved fit and comfort for the patient and also improved manufacturing efficiencies for the company. Development is on-going using data from the biologists at Huddersfield to optimise the use of the cooling cap so that patients derive maximum benefit.

2. Project Aims and Objectives:

Following meetings between the Paxman team, Primasil Silicone Ltd and the University of Huddersfield 3D team, the project was divided into two stages. Stage-1 included creating a single working prototype cap to fit a single UK head size to allow testing of performance and fit. Stage-2 included design and development of a new cap to meet all the performance requirements but also to fit the variety of head sizes and shapes for a global product.

a- Stage 1:

- Preliminary Research into European/Far-East human head size/shape data and availability.
- Agreement on a suitable head size for testing and prototyping (a Paxman Volunteer)
- 3D Scanning of the volunteer's head, processing of the acquired cloud data and surface construction to achieve usable scan data.
- 3D CAD model of single agreed UK head size from 3D Scan to produce NURBS surface data in IGS format.
- 3D Rapid Prototype (RP), printing of the model head to enable trials for fit and surface contact.
- Proposals to produce suitable method of cap design & construction.
- In collaboration with Paxman toolmaker and staff team the Design Proposal was finalised to meet the following objectives:-
    - Improve Conductivity
    - Improve Cap Fit

- Improve Patient Comfort and Ergonomics
- Improve the Ability to Mass-Produce
- Minimise the number of size options
- Where possible reduce Manufacturing Cost
- Indentify optimal flow pattern within the Cap Design

- Digital 3D CAD model of the agreed cap design. (using head reference data)
- Liase with Primasil to create a Working Prototype of the agreed design to fit the agreed head size.
- Design Modifications following testing.

b- Stage 2

UK head sizes:

- Creation of 3D CAD models of multiple UK head sizes, the variation depends on the design solution produced in stage one.
- Working with Primasil, to produce relevant mould and tools, pattern, etc for each UK sizes which can be used for mass production (Mould making may include Metal Sintering)

Far East head sizes:

- Research into Far East head sizes, 3D Rapid Prototyping of a single head & supplying IGS data
- Creation of 3D cad models of multiple head sizes for Far East
- Working with Primasil, to produce relevant mould and tools, pattern, etc for each Far East sizes which can be used for mass production (Mould making may include Metal Sintering)

3- Paxman History

The Paxman Scalp Cooling System was designed using similar principles and technologies used in the beer cooling side of their business and followed Glenn Paxman's wife losing her hair whilst receiving chemotherapy for breast cancer. Although she was treated with an early version of a cooling cap, the cooling therapy did not work for her. Glenn, realising how traumatic the subsequent hair loss was, developed a system that did work. The first prototype of the cooling cap was installed at the Huddersfield Royal Infirmary in 1997.

Paxman Coolers was formed in 1998 and after extensive trials in the 10 years that followed, several hundreds of systems were produced, treating many thousands of patients by creating a system that works, is user friendly and is cost effective. It has been accepted by doctors, nursing staff and patients.

The Paxman system is used extensively throughout the UK both in NHS hospitals and Private Clinics. The company has also established the product in many other countries throughout Europe and is currently on trial and evaluation in other continents throughout the World. The company's office and manufacturing facility is based at International House in

Huddersfield, West Yorkshire. The company has expanded its facilities with capacity to meet the current and future global demand for its scalp cooling systems. The premises are the centre of the operation for manufacture, servicing and international distribution.

a- Introduction to the Paxman Hair Loss Reduction System:

Scalp cooling is a method used to reduce hair loss for patients undergoing chemotherapy treatments for cancer. Many patients experience great concern over the possibility of hair loss, which is a constant reminder of the disease to the patient, their family and in the wider social environment of work and leisure. Scalp cooling reduces hair loss with many prescribed chemotherapy drugs. It can result in a high level of retention or complete hair preservation which can improve patient's self-confidence leading to a positive attitude to their treatment and recovery.

Benefits and Features of Scalp Cooling are:

- Greatly reduces the risk of hair loss and improves patient's self-confidence,
- Preserves self-image leading to positive attitudes towards treatment and cure,
- Allows continued social activities,
- Maintains the scalp at a constant temperature,
- Comfortable and pain free during treatment and avoids the sudden chill of some other systems,
- High level of patient tolerance and acceptability,
- Simple to use and easy to understand for both medical staff and patients,
- Proven success rates.

The Paxman Hair Loss Prevention System is currently available in two models. *The Orbis I* provide cooling for a single patient and is suitable for the small chemotherapy suite or private bed. *The Orbis II* provides cooling for one or two patients simultaneously with each cap working independently.

The system consists of a small compact refrigeration unit containing a special coolant which is circulated at -4°C through coolant lines to specially designed cooling caps. The coolant lines are supported by an adjustable arm, providing maximum patient comfort. Consideration and care has gone into the design of the system in order to meet the needs of both the patient and nursing staff. It is simple to operate with no complicated dials or controls, easy to read touch screen displays, allowing instant visual monitoring. The compact nature and manoeuvrability of the system ensures an efficient use of space. In confined areas, the cooling unit can be easily placed near to chairs or beds. In large chemotherapy suites, several machines can be operated at the same time. Reliability has been of primary importance in the design of the Paxman Hair Loss Prevention System. Only components with a long history of quality and performance have been used, ensuring that the system is maintenance free and requires only the recommended annual service.

Features of the Orbis:

- Dual patient treatment with independent temperature controlled cooling cap,
- Touch screen visual display with system status graphics,
- Simple switch operation, no complicated programming or controls,

- Specially developed new low temperature non viscous coolant with ultra-efficient heat transfer properties,
- Caps can be used immediately when connected to the system with instant cooling capability,
- Visual and audible alarms for restricted and no flow coolant conditions,
- Countdown timer facility, all touch screen access with visual displays,
- System diagnostics access for operators,
- Coded access for service engineers,
- High ambient warning alarm.

b- Cooling Caps

The most important feature of the Paxman Hair Loss Prevention System is the specially designed lightweight cooling caps. (Small cap weighs only 795 gms) The caps are soft, flexible and provide a snug, close fit around the patient's head. Manufactured from high grade silicone material, the **5 different cap sizes** in the range are colour coded and ensure most head shapes are catered for Coolant passes through the cap, extracting heat from the patient's scalp. Inline temperature sensors ensure the cap maintains the scalp at an even, constant temperature. The cap is provided with a neoprene cover to improve the efficiency and operation of the system by both insulating the cap from high room temperatures and absorbing condensation. Adjustable chin straps ensure maximum contact with the patients' head, which is essential for successful treatment. Caps are attached to the system with easy to operate, non-drip, quick release plastic couplings. Extended inlet and outlet lines make connection and disconnection from the system simple, with minimal disruption to the patient. Upon termination of cooling, caps are disconnected from the cooling lines and washed with soap and water or detergent in preparation for the next patient.

Procedure: The success of the treatment is affected by the degree of control in maintaining the scalp at a constant temperature. The system is very simple to operate. The machine is switched on and allowed to reach operating temperature, which takes approximately 30 to 40 minutes and is indicated on the touch screen display. A cooling cap is selected and connected to the system then placed on the patients head. Pre-cooling of the scalp takes 20 to 30 minutes prior to commencement of drug infusion. This ensures the scalp is at the required temperature before chemotherapy is administered. Patient preparations can take place during the pre-cooling period. The cap continues to be worn throughout the administration of the chemotherapy drugs and for a period of time afterwards, dependent on the drug regime being administered. The system is flexible for patients and requires minimal nursing supervision.

Patient Flexibility: Due to the lightweight nature of the caps, patients can relax during the cooling process, engage in a number of activities and visit the bathroom without affecting their treatment.

Nursing Flexibility: The system is simple to operate with easy to read digital displays. Because the equipment is compact and manoeuvrable, nursing staff do not need to be in attendance with patients during cooling.

Termination of Cooling: On completion of cooling, a nurse will assist with the removal of the cap. The patient is then left to acclimatise before leaving the hospital. The system can be either left running for continuation of the second patient, left running awaiting a new patient, or switched off.

The refrigiration unit is 29.5kg and dimensions are 640x320x420mm. Height can be extended to 1650mm. The cap size changes from 795g to 850g depending on the size selected. Temperature is controlled by electronic thermostat with EDMS touch screen controller and coolant flow rate and coolant temperature continuously monitored with visual and audible alarm. CFC free R134A refrigerant OrbisC coolant is hermetically sealed into the system. The device has CE mark in accordance with annex V of the Medical Devices Directive 93/42/EEC for a Class IIa Device. Electric classification conforms to BS EN 60601-1: 2006 for medical electrical equipment, and BS EN 60601-1-2: 2007 electromagnetic compatibility.

4- Research into effectiveness of scalp cooling

Hair that is formed during chemotherapy is much thinner and more brittle because of the suppression of cell production. This reduced cell production may lead to localized thinning of the hair. There are many studies in the literature describe the use of scalp cooling from the 1970s onwards. From simple, ice pack turbans, have largely been superseded by specially designed cryogel caps. In general, these are simpler to prepare, more comfortable and do not melt. More recent commercially available systems use cooled air blown over the scalp, or as in the Paxman Scalp Cooler, liquid coolant circulated through a refrigeration unit attached to a special cap.

Chemotherapy in the treatment of cancer relies for its effectiveness on the ability of the drugs to attack rapidly dividing cells which may be both malignant and normal. Certain drugs, or chemotherapy may cause partial or total atrophy of the hair root bulb, causing the hair shaft to break off spontaneously. The hair may also be weakened, by a narrowing of the hair shaft adjacent to the scalp this has been suggested as associated most frequently with standard dose chemotherapy. Measures to reduce or eliminate alopecia during chemotherapy have been investigated since the 1960s with varying degrees of success. They have included mechanical methods such as tourniquets, and physical methods such as scalp cooling and use of biological agents. In recent times, scalp cooling has received increased attention, and the cumbersome and uncomfortable mechanical techniques have become obsolete. There are few studies comparing different methods of scalp cooling, but one study has suggested that cold air circulation is more effective than cryogel packs, as a lower temperature can be maintained for a longer period. (Massey SM, 2004)

a- Scalp Cooling Prevention:

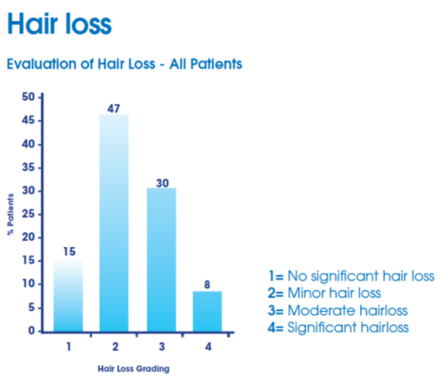
Scalp cooling works by inducing vasoconstriction and reduction of metabolism. Vasoconstriction leads to reduced blood flow to the hair follicles in the period of peak plasma concentration of the relevant chemotherapy agent. In the past decades, scalp cooling has been achieved by a number of techniques, such as simple bags with crushed ice, frozen cryogel packs, and packs with an endothermic cooling reaction. Examples of precooled caps are ChemoCap™ (ChemoCap,Canada), Elasto-Gel™ Cold Caps (Southwest Technologies, Akromed Inc.) and Penguin Cold Caps (Medical Specialities Of California). These methods require frequent cap changes due to thaw-effects and are labour-intensive for the nursing staff. It can also be very uncomfortable for patients due to the cap's heavy weight. Continuous cooling systems have been adopted where caps are cooled by fluid or chilled air. These continuous cooling machines are more convenient for the nursing staff because no cap changes are needed. Cooling machines that use liquid circulation are the systems of **Paxman** (PCS-1 and 2, Orbis) and **Dignitana** (DigniCap™), while **Amit Technology** (SCSII™) uses chilled air. The advantage of a system with air cooling is that it is a one-size-fits-all system. Thus, there are no problems fitting the cap to the scalp. Detail [Medscape]:

b- Paxman Scalp Cooling experiment in UK (1997-2010):

UK observational study reports an 89% success rate following use of the Paxman System in breast cancer patients, with only 11% with severe hair loss requiring wigs. Patients reported high comfort and acceptability levels with low numbers of withdrawals from scalp cooling. 85% of patients reported they were comfortable, reasonably comfortable, or very comfortable during the scalp-cooling period. 12% of patients reported they were uncomfortable with an additional 3% very uncomfortable. Only 5% of patients discontinued scalp cooling before the end of chemotherapy treatment, with discontinuation because of discomfort seen in one patient. Headaches at some time during treatment cycles were reported in 32% of patients.

c- Norwegian observational study (2000-2001):

Norwegian observational study reports a 92% success rate following use of the Paxman System in 54 breast cancer patients being treated with chemotherapy in the neo-adjuvant, adjuvant or palliative settings in single Norwegian centre between 2000 – 2001. 89% of patients described scalp cooling as acceptable, with minimal discomfort caused by the longer treatment period. 15% of patients considered coldness to be a major problem. 2% of patients considered headaches to be a major problem. One patient discontinued treatment because of discomfort.



Hair loss graph

Authors concluded that scalp cooling is an effective method for avoiding alopecia in patients receiving FEC or weekly paclitaxel. 89% of patients described scalp cooling as acceptable, with minimal discomfort caused by the longer treatment period. 15% of patients considered coldness to be a major problem. 2% of patients considered headaches to be a major problem. One patient discontinued treatment because of discomfort

d- Netherland study -1 (2006 - 2010)

The research involved 166 cancer patients from 11 hospitals in the Netherlands, carried out in 2 phases, to determine the effectiveness and tolerance of scalp cooling. Randomised study in the Netherlands shows that a reduction in scalp cooling time to 45 minutes, did not reduce the effectiveness of the PSCS in preventing hair loss in docetaxel treated cancer patients. Pre-infusion cooling time was 30 mins and • Cooling was maintained during the infusion period. Post-infusion cooling time: Phase I: 90 mins ; Phase II: 90 mins vs 45 mins

Patients were age range 35-79 years, mean age 44, with Docetaxel 75 mg/m2 (39%); 100 mg/m2 (61%) 36% male. Breast cancer (49%), prostate cancer (33%), lung carcinoma (23%). Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse. Success rates (no wig or head cover required) varied according to regimen. Mean success rate of 48% (range 8 – 80%). Headaches were only reported in 20% of patients, with only 5% of patients discontinuing scalp cooling. Headache: 80% no headaches; 13% mild headache and 7% moderate / severe headache and 5% of patients discontinued scalp cooling because of intolerance

e- Netherland study – 2 (2006 - 2010)

This study shows the summary of effectiveness and tolerance of the Paxman Scalp Cooling System. Three independent observational studies demonstrated the effectiveness of the Paxman Scalp Cooling System in the prevention of chemotherapy induced hair loss with widely used chemotherapy dosages and regimens. Recommendations for post infusion cooling times are based on peak plasma concentrations, drug half life, potential interactions, recent trials and the experience of current users of the Paxman Scalp.

The docetaxel post-infusion cooling time was based on a randomised comparative study It is recommended that patient's hair is dampened with water, and hair conditioner (ph neutral) is applied to improve scalp contact and reduce the insulation effect of hair. Where liver function and metabolism of the cytotoxic agent is impaired, scalp cooling may be less effective Results with Afro-Caribbean hair are less successful, and it is advisable to increase cooling times by ½ to 1 hour. The Dutch Scalp Cooling Group are conducting future research to determine optimal cooling times for various chemotherapy regimens

f- Research by Massey SM (2004)

This research studied to determine the efficacy and patient acceptability of scalp cooling using the Paxman Scalp Cooler. This was an open, non-randomised, observational study conducted at eight sites involving 94 patients. The study describes the use of Paxman scalp cooler and states that a scalp temperature below 15 to 22C is required for hair preservation. In their experiments the average scalp temperature of the three volunteers recorded, was 15.5 C but variations from 11.31C to 18.91C were observed from probes positioned in four areas of the scalp, one on the crown, one on either side of the head and one at the back of the head, demonstrating that it was not possible to achieve an even temperature reduction.

Study also recommends a good fit of cap as alopecia is associated with loosely fitted caps. Also the patient’s hair was dampened, and a small amount of conditioner was applied before fitting the cap, in order to achieve a closer contact with the scalp. A pre-cooling time of 15–20 minutes was recommended to allow time for an adequate reduction in scalp temperature. The cap remained on the scalp during the infusion period, which varied according to regimen, and then for the recommended time after infusion of the agent causing the alopecia. The same cooling cap was worn throughout the whole period of pre-cooling, infusion and post-infusion cooling. A post-infusion cooling time of 2 hours was recommended for the majority of patients in this study.

Although over 80% of the patients were successfully treated and did not require a some patients reported side-effects during the scalp-cooling period including feeling cold or suffering from headaches or boredom. The side-effects reported were found to be minor and reversible with coldness alleviated by a blanket and headaches usually treated with commonly prescribed painkillers.

Eleven patients had problems with the pressure and tightness of the scalp-cooling caps, which in some instances lead to pain in the forehead. Two patients reported feelings of dizziness during treatment. Only one patient reported patchy alopecia and was evaluated as a treatment failure due to significant hair loss on the crown. A cap could be described as uncomfortable, but the discomfort experienced may be acceptable to a patient who wishes to avoid the hair loss associated with chemotherapy treatment.

g- Research by Wim PM Breed, Corina JG van den Hurk and Mijke Peerbooms, (2011)

This article provides an overview of the incidence and severity, presentation and impact of chemotherapy-induced alopecia (CIA), one of the most common and distressing side effects of cancer therapy. Furthermore, prevention of CIA by scalp cooling is described, as well as suggestions for improvement of scalp cooling application and clinical research approaches. Scalp cooling is described as effective but not for all chemotherapy patients and it is recommended that scalp cooling should be available in every hospital, and every suitable patient should be given the opportunity, after being well informed by their doctor or nurse, to choose for scalp cooling.

The following published medical research by lists significant findings for the Huddersfield design team in the development of new products:

Temperature

There is a relation between the degree of decrease in scalp temperature and the protective effect against hair loss in patients treated with doxorubicin. A nonclinical study conducted by

Janssen concluded that for doxorubicin the superficial scalp skin temperature should be less than 19 °C. Van de Sande *et al.* reported a decrease of scalp skin temperature from 19.5 to 16.8 °C by use of conditioner. Scalp cooling influence on core temperature and the temperature decreasing effect of hair conditioner. It is difficult to carry out scalp temperature measurements during cooling, and the degree of scalp hypothermia cannot be predicted from the decrease of the temperature of cooling fluid or heat extraction of the cooling device. The reason is that the heat gradient from cold cap to scalp skin varies considerably between individuals.

Wetting of the Hair: Wetting of the hair is often used in the UK, and is strongly advised by Hunt *et al.* However, there are no comparative studies regarding the influence of wetting on scalp temperature and scalp cooling success rates.

Cap Application: Fitting *of the Cap* Contact between the cold cap and the scalp skin is decisive for scalp temperature. It is evident that optimal fitting of the cap is an important factor for success. Often, bald areas are seen where the cap did not fit properly.

Scalp Cooling Times: The cooling time after infusion of chemotherapy (the post infusion cooling time [PICT]) should be related to the half-life time of the used cytostatic, their active metabolites and the duration of infusion. However, research on PICT is very scarce. The manufacturers of cooling systems, Paxman and Dignitana, recommend very different cytostatic-specific PICTs. Both manufacturers do not mention that the duration of cooling during the actual administration of chemotherapy is also important. In daily practice, these administration times of specific schedules differ greatly.

Hair Characteristics: In cases of Afro–American hair, scalp cooling is less successful. It is unknown whether the sometimes advised increase of PICT, wetting the hair or lowering the temperature of liquid coolant are useful to improve these results. A lower temperature of liquid coolant seems more reasonable to improve hair preservation in these situations because thickness of the hair layer is one of the most important variable factors for scalp temperature.

Liver Function & Liver Metastases: The influence of liver function and liver metastases on the success of scalp cooling is controversial. In 13 studies, liver function or the presence of liver metastasis were taken into consideration for the hair-protective effect of scalp cooling. In six out of these 13 studies, impaired liver function seemed to be related to less benefit from cooling.

Hair care: All issues regarding hair care remain to be clarified. Attention to hair care in periods before, during and after scalp cooling (washing, colouring, drying and the use of hot rollers or curling irons and products containing alcohol or peroxide, avoiding hot air and hot water and hard brushing, and using gentle products). However, none of this advice is evidence based. Nevertheless, since exposure to heat affects the strength of the hair, it seems logical to avoid the use of extreme heat applicators.] It also seems logical to advise the use of a wide-toothed comb or soft bristle and avoid excessive combing and brushing because breakage of thinned hair is an important factor in CIA.

Side Effects & Tolerance

In general, scalp cooling is well tolerated. Tolerance can be graded by a Visual Analogue Scale of 0– 10, in which 0 represents 'not tolerable' and 10 means 'really well tolerable'. Mean scores vary between 6.9 and 8.0. No serious side effects have been reported. The most common reported side effects are headaches, unpleasant feelings due to the heaviness of the cap and coldness, dizziness and transient light-headedness

Scalp Skin Metastases

Scalp cooling has been somewhat controversial in the curative chemotherapy setting. The concern is regarding the risk of scalp metastases, which may have a negative influence on the course of the disease, as a result of the decreased drug exposure by the decrease of scalp blood perfusion. However, a negative influence on the course of the disease by scalp cooling has only been reported in one patient with mycosis fungicides and one patient with leukaemia (which is a contraindication for scalp cooling). It has never been reported in patients with solid tumours. In conclusion, for breast cancer patients the theoretical risk of scalp cooling during adjuvant chemotherapy seems to be minimal. In visceral malignancies other than breast cancer, the risk associated with scalp cooling will be even lower, because the incidence of cutaneous metastases is lower.

Scalp cooling should not be applied in cases of:

Haematological malignancies: leukaemia, multiple myeloma, non-Hodgkins and other generalized lymphomas Cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia and cold traumatic dystrophy Melanoma patients with adjuvant or curative chemotherapy

Cost–Effectiveness of Scalp Cooling

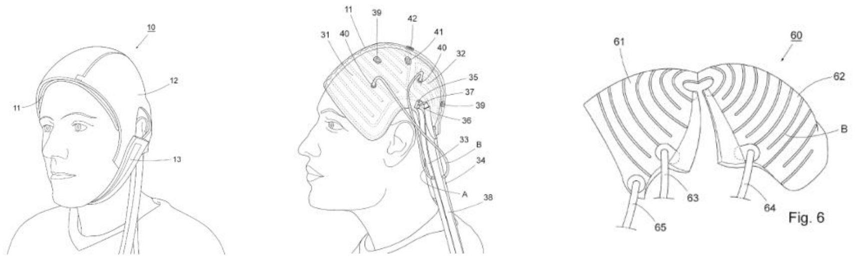
It appeared that the total costs (costs of scalp cooling, wigs and other head covers and hair dressers) were considerably lower when scalp cooling was applied. In the Dutch situation, scalp cooling saved €252 per patient. The hospital spent a mean of €200 per scalp-cooled patient. Health insurance companies saved a mean of €292 per scalp-cooled patient and the patient saved €160. Reducing costs.

Research also discusses the use of Elastogel™ caps used in the past for many years but to have switched to a cooling machine for cost–effectiveness and time-investment reasons as Elastogel-caps had to be replaced regularly due to a rising temperature during wearing the cap. Moreover, the time invested by the nurse in each cooling session was much less if a cooling machine was used than when caps had to be changed regularly. One can expect that the use of cooling machines is cheaper unless there are only a few cooling sessions in a hospital. Although scalp cooling requires an extra time investment, most nurses report that they offer it with pleasure.

5- Patent Search

a- Inventor: Johan Stormby, Malmo, Patent No / Pub No: US 2010/0186436 A1

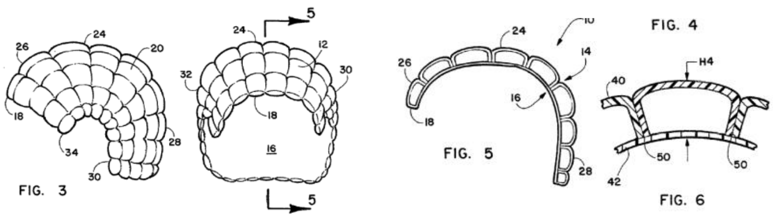
This patens is granted for a thermal head cooler exchange cap with covering installation. It is claimed that current head coolers is not easily adaptable to the size, shape of the head and neck also cooling of eyebrows is not possible. The system includes flow passages for cooling fluid to be circulated. This design include sensors attached helps to control the temperature



The cooler have overlapping edge portions which are slid able against each other. Head cooler compromise an inner head cover consisting of flattened bag of flexible material forming a lining on the inside of the thermal exchange cap. Head cooler also includes air or gas mixture under pressure to the flow passage system or to the cavity to evacuate the cooling fluid from the bag.

b- Inventor: Carole Lee, Patent No / Pub No: US 2002/0058976 A1

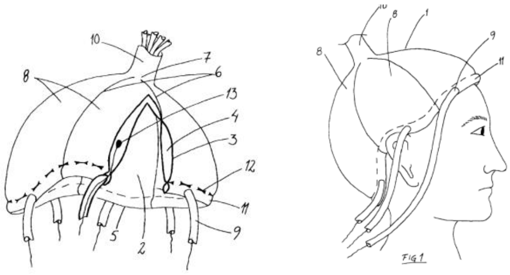
This patent is granted for a temperature indication cap shaped headwear device that is worn on a patient's head while patient is having chemotherapy treatment. The headwear device has an outer layer of sheet material vertically spaced from an inner layer of sheet material.



The cap has convex outer and concave inner curvatures, where sheet metal material is used to create cells which were filled with temperature indicating gel or powder, or fluid material that can be cooled to a predetermined temperature. Sheet material could be plastic or paper for used a one-time disposable product. For forming individual quilted cells are stitches or heat welded seams.

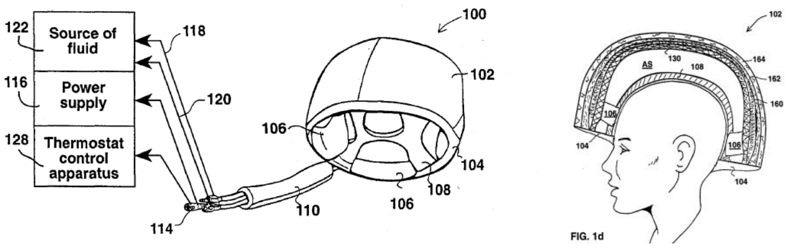
c- Inventor: Yvonne Olofsson, Patent No / Pub No: 6,156,059

This invention is relates to an apparatus for regulating the temperature of the scalp of a person. The apparatus includes a plurality of chambers that extends from the edge of the head covering up towards the crown.



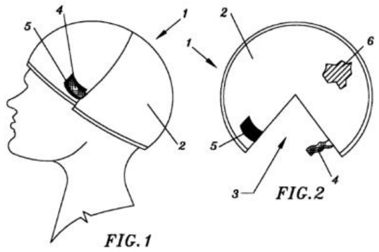
d- Inventor: Freddy Pachys, Patent No / Pub No: 5,603,728

This scalp apparatus is design to regulate the temperature of the scalp of the wearer. The apparatus is used for coolant and heating of the head. The design consist of an helmet air space between helmet and scalp, regulator with thermoelectric element, a source of fluid, and piping.



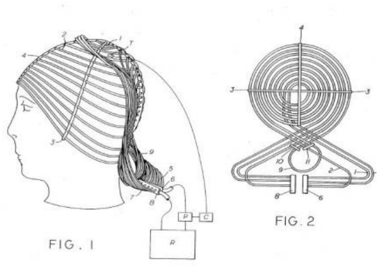
e- Inventor: Randy Leong, Patent No / Pub No: 5,950,234

This cooling pack with cooling substance containing within it constructed as a bowl shape to cover the scalp portion of the head for preventing loosing hair during medical treatment as well as the item could be worn as hats, helmets.



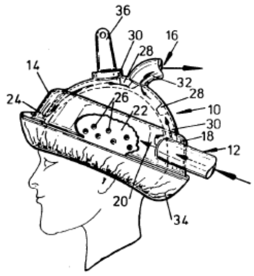
f- Inventor: Robert W. Kramer, Patent No / Pub No: 4,566,455

This scalp cooling device is designed to circulate a liquid coolant to reduce and control scalp temperature. The unit consist of serious tubes adjustably position. It is claimed that the use of series of tubes provides more accurate control and reduces temperature drop



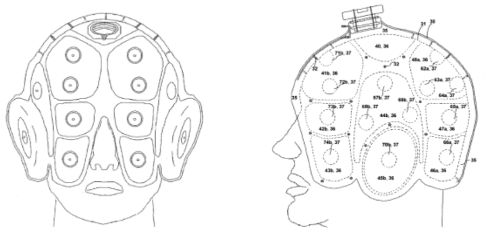
g- Inventor: Kenneth J. Maxted, Patent No / Pub No: 5,342,411

This scalp cooling device consist of an airflow recirculated to reduce entrained moisture resulted from evaporation from the scalp. The design include an air delivery gallery which direct air onto the scalp and hairline through a number of profile drillings.



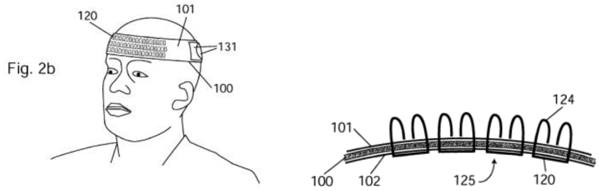
h- Inventor: Pedro J. Fontanez Mayaguez, Patent No / Pub No: US 2008/0184456 A1

This blind head cooling helmet covers fully the head contours including eyes, cheeks, and ears having a lid arrangement with internal air ducts. An air pump generates small and slow volume of air that is transferred to the blind head cooling helmet via C shaped tube.



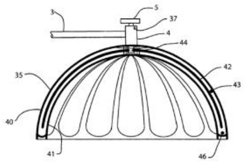
i- Inventor: Ted Nathan Strauss, Patent No / Pub No: US 7,721,349 B1

This patent is granted for a system where cooling of the skin for human or animal through thermally conductive elements with fluid wicking surfaces, ways to flexibly interconnect the elements for storing and distributing the fluid.



j- Inventor: Ted Nathan Strauss, Patent No / Pub No: US 7,721,349 B1

This cooling system includes a pressurised liquid refrigerant source having a liquid refrigerant and a cooling garment coupled to the liquid refrigerant source.



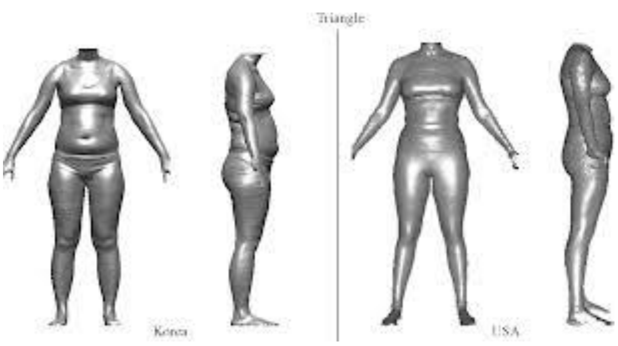
k- Other related patents include

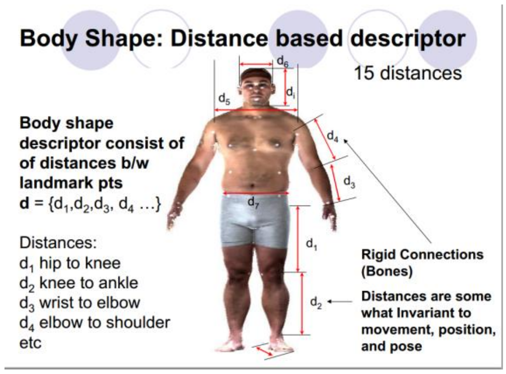
- International patent: A42C 5/04 A61F 7/10, (personalised temperature control device)
- US patent: 5,169,384 (Termal Energy application device for face)
- US patent: 5,469,579 (Head Cooling device)
- US patent: 5,630,230 (Cooling Cap Element)
- US patent: 5,802,865 (Evaporate Personal Cooler)
- US patent: 6,427,467 (Water Mist Cooling system)
- US patent: 6,681,590 (Head Cooling Compress with Removable Fabric Cover)
- US patent:US 2005/0132468 A1 (Hat including active ventilation)
- US patent:US 2009/0054958 A1 (A method / Apparatus for Neurological Disorders)
- US patent:US 2010/0319110 A1 (Brain Cooling Device)
-

6- Head Size Research

a- CAESAR Project

Research team evaluated where and what type of 3D Anthropometric data could be obtained. Initially CAESAR: Civilian American and European Surface Anthropometry Resource is investigated at: http://store.sae.org/caesar/index.htm,





CAESAR Project details: http://wear.io.tudelft.nl//files/Banff08/Afzal.pdf

CAESAR 3-D Anthropometric Database, North American Edition: This extensive database product includes measurements from the entire North American population sample (2,400 male and female subjects, aged 18-65). This database includes 3-D model scans in addition to traditional 1D measurements. The camera views from the 3-D scan have been accurately stitched together to provide complete 3-D models of each pose. Scanned poses include standing, relaxed seated, and coverage poses. In addition the database contains 40 traditional (1-D) measurements that were done with a tape measure and caliper. Extracted 1-D measurements using landmarks from the scans - standing and relaxed seated poses are also included.. Several reports are also included that cover protocol of how the database was generated for the population of the United States of America (18-65). *Price: $10,000 for full or $3,500 for light version.*

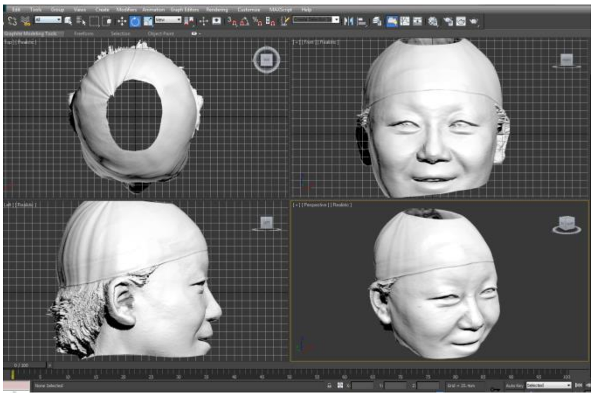
CAESAR 3-D Anthropometric Database, European Edition: This extensive database product includes measurements from the entire European population sample (2,000 male and female subjects, aged 18-65. This database is the first to include 3-D model scans in addition to traditional 1-D measurements. The camera views from the 3-D scan have been accurately stitched together to provide complete 3-D models of each pose. Scanned poses include standing, relaxed seated, and coverage poses. In addition the database contains 40 traditional (1-D) measurements that were done with a tape measure and caliper. Extracted 1-D measurements using landmarks from the scans—standing and relaxed seated poses are also included. All measurements are presented in both English and metric units. Several reports are also included that cover protocol of how the database generated for the population of Europe (18-65) *Price: $10,000 (50% off original price) $3,500 for light version.*

b- Size China Project

The team then evaluated **SizeChina: A 3D Anthropometric Survey of the Chinese Head.** http://www.sizechina.com/publications.php where as part of an PhD study Chinese head sizes analysed and a database is produced. Research states Chinese head shape differs from Western head shape so designing products that fits the Chinese population, it is critical that you use measurements and 3D models based on Chinese head shapes. SizeChina offers 3D scans, anthropometric landmark data and physical models for Chinese head shapes through More info: Certiform.org.

The SizeChina Project created the first-ever digital database of Asian head and face sizes for use by manufacturers and designers internationally. Through 3D digital scanning, measurement data were collected from males and females in six different target zones on the Chinese mainland in collaboration with Chinese universities and local industries with experience in ergonomics and human factors. The six scanning locations are: Guangzhou, Chongqing, Hangzhou, Langzhou, Beijing, and Shenyang. The raw scanning data in the form of point clouds were brought into advanced CAD software for sorting and statistical synthesizing, creating a reference description of the form of digital modeling of average head and face shapes of the Chinese population. http://www.sizechina.com/scanning_process.php

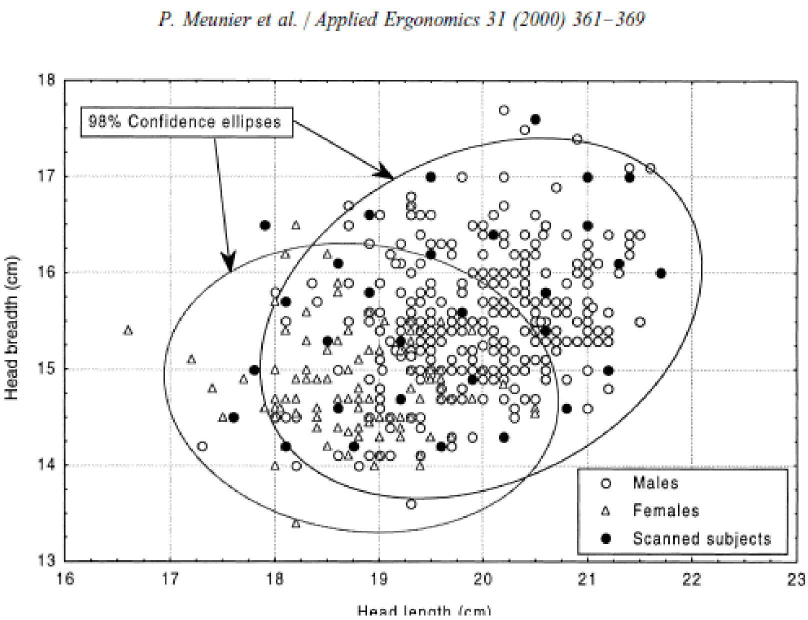
The company sells 3D IGS and STL data through http://certiform.org/product/CH0006.html and charges US$40,000 for set of 6 Chinese Faceforms processed including 1500 scan files not processed can be purchased separately for US$28,000 or basic data for US$7,900



Size China Project

There are other research and Master thesis such as “Parametric human body modeling for virtual dressing” by Basar Ugur, 2005. Also research by Reyes Enciso, Alex Shaw , Ulrich Neumann, and James Mah discusses 3D head anthropometric analysis. Another research by Zouhour Ben Azouz Chang Shu and Anja Mantel shows Automatic Locating of Anthropometric Landmarks

on 3D Human Models. An interesting research by Pierre Meunier!, David Tack, Angela Ricci, Linda Bossi, Harry Angel shows Helmet accommodation analysis using 3D laser scanning . Research paper shows head size analysis as show in the graph below.



Head size data

Another research by Afzal Godil, Sandy Ressler studies the Retrieval and Clustering from a 3D Human Database based on Body and Head Shape based on CAESAR data.

Due to the high cost of obtaining ready data, the team decided to utilise the head size information available and create our own 3D scan data from the current standard CAP size used by Paxman.

7- Experiments:

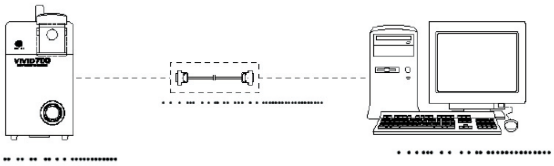
First stage of the project was to create standard 3D head. Current caps are designed to be lightweight with 3 years of life expectancy. The caps are soft, flexible and provide a snug, close fit around the patient's head and manufactured from high grade silicone material which ensures most head shapes are catered for and are supplied in 5 different sizes, colour coded for ease of identification. Current manufacturing methods includes draping silicone tubes manually around the model wooden head and bonding the using silicone. This process is time consuming and requires skilled full time workers manually producing limited number of parts. The coloured sections of the caps are made from different shore hardness silicone tube which is also used for size identification but adds extra work.

Current caps

Phase one of this project requires designing a new method for creating caps which will fit a selected individual better than the current standard model but also adjustable so cap size number will be reduced from five to three. The team decided to create middle size of the products which is the standard size. Being having a standard size head, **Patrick Burke, Technical Manager** from Paxman volunteered to be 3D scanned to create a 3D head.

a- Non-contact 3D Laser Scanning and Processing

The scanner at Huddersfield uses laser triangulation to plot the contour of the scanned surface to produce a point cloud, which is then edited to form the scanned object. The 3D laser scanner captures surface of an object in the form of 3D points. These points are developed from a laser beam capable of generating and capturing hundreds of thousands of points per second. 3D non-contact lasers are used to capture shapes by repeated scanning of the required objects from different angles. The 3D laser scanner used in the School of Art & Design is a tripod-mounted portable device, which can be rotated 360º on a ball and socket joint. The device has three interchangeable lenses; a wide, a mid - range and a telescopic lens for use in focusing on different sized objects and to enable the scanning of objects up to 1.5 metre in diameter. The scanner can be quickly and easily connected to a laptop or a PC computer system as illustrated in figure below.

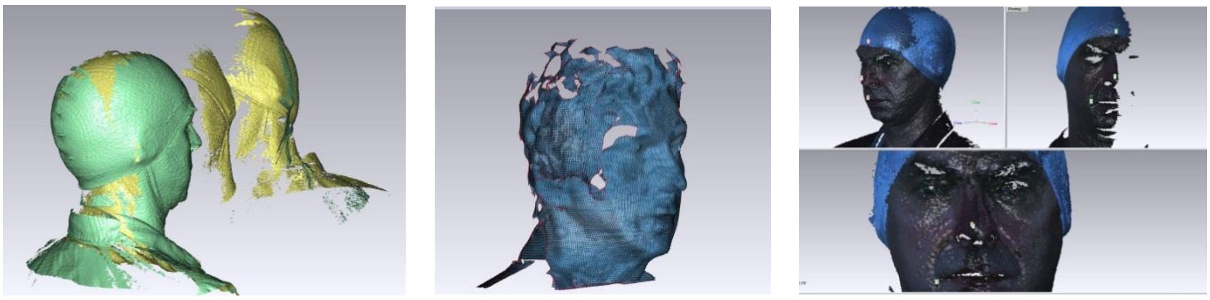


3D Scanning equipment

The scanner captures the surface of the object from a single position, so suitable adjustments via height and lens selection may be required. Once activated, the laser beam moves quickly across the object, and the light is reflected back and captured as data in the form of a 'cloud' of 300k points (cloud data) in high resolution mode in few seconds.

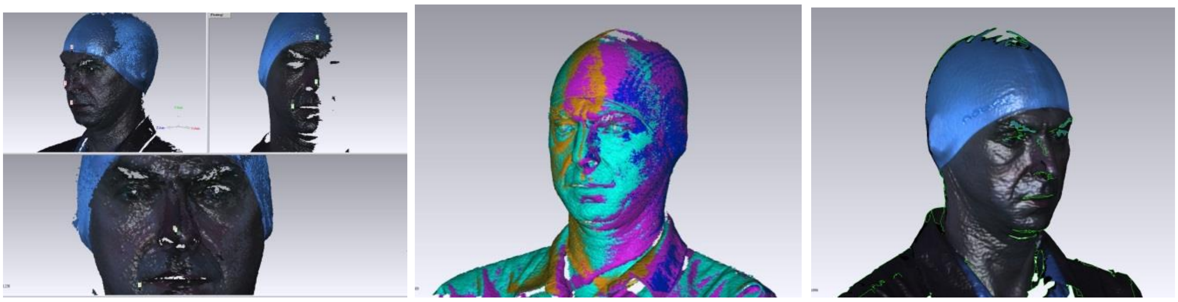
Photos taken during 3D scanning

Although over twenty different scans were taken from various angles, only eight scans were used to create an accurate surface as seen in figure. The scanning process took just over an hour. Geomagic Studio software is used for the processing of data including capturing and cleaning.



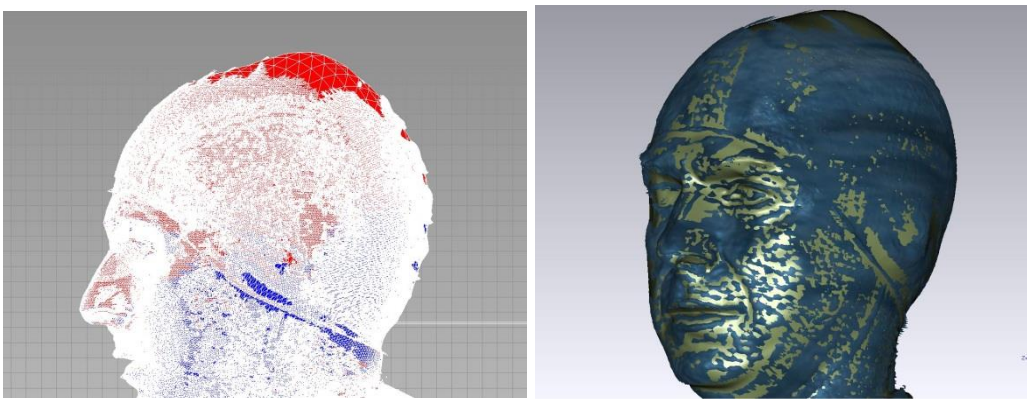
Processing 3D Scan data

The scanning processes involve point data collection, polygon editing and surface generation for the scanned object to be exported as a 3D NURBS (Non-Rational B-Spline) model for further 3D CAD modelling. The eight scan data file is opened in the Geomagic software as a collection of 3D data clouds. The unwanted background information is cleaned on each scanned data. The next stage in the process is to align the scan surfaces, using manual and global registration tools by enabling aligning the roughly positioned scans, refining their alignment to minimize deviation when merging the scan data together.



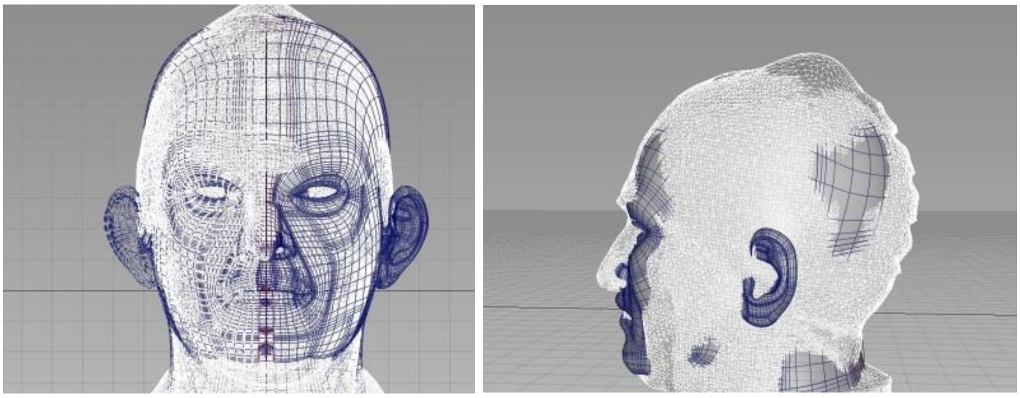
Surface creation using scan data

After the data is merged, the inaccuracies in the surface of the object become visible as seen in figure above. Holes and other irregularities in the object are cleaned, filled and smoothed. During this stage of the process, a mesh is created from which the surface is formed which can be transferred to any 3d modelling software. This process took approximately half a day. Unfortunately the whole of this process is repeated twice, as the first scan is carried out using a fast scan / low resolution mode where resolution is only ¼ of the full scan. This resulted in most of the features of the head and face details being simplified and therefore is not good enough for the design process. Also, rather than using the hair in the second scan an elastic swimming cap is used to get the exact shape of the head. Hair is always difficult to scan because of its colour and thickness.

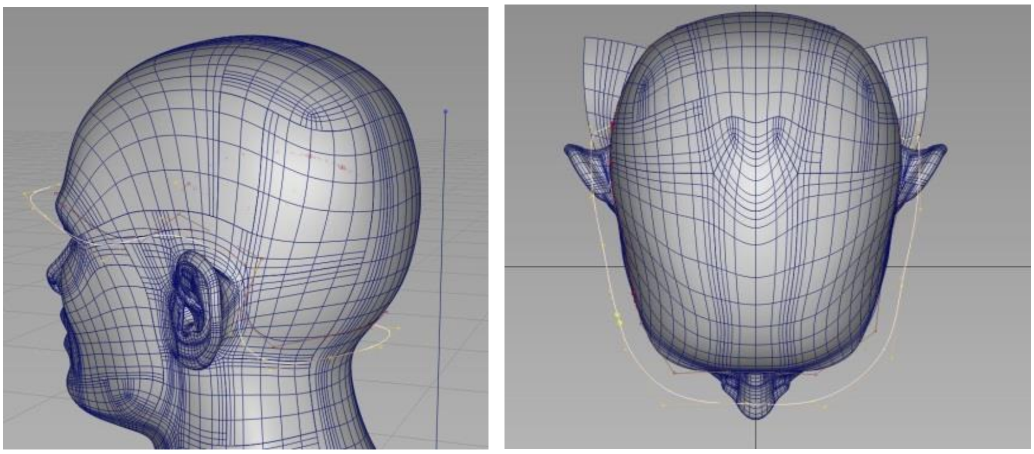


Processed polygons and surface creation

The 3d scanned data enabled the team to construct a 3D surface of a full head which was used as a reference to construct a NURBs surface . This process involves using using a standard 3D human head and modifying the head shape to fit the scan data manually as seen figure below.



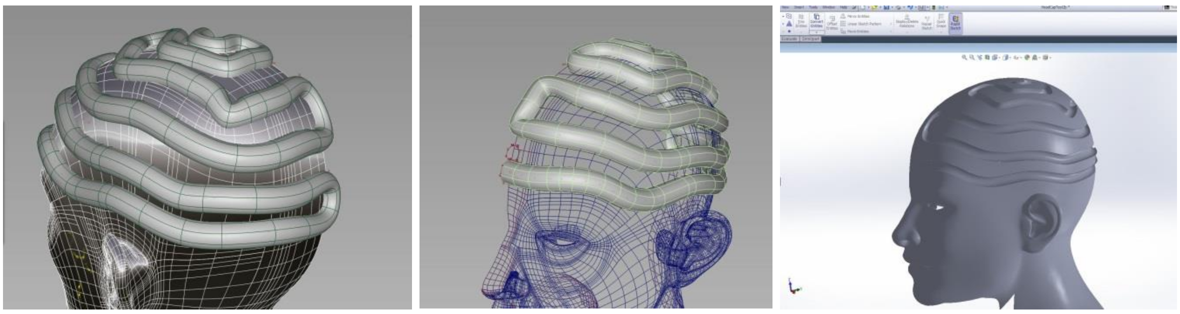
Creating NURB head surface



Use of 3D NURB data

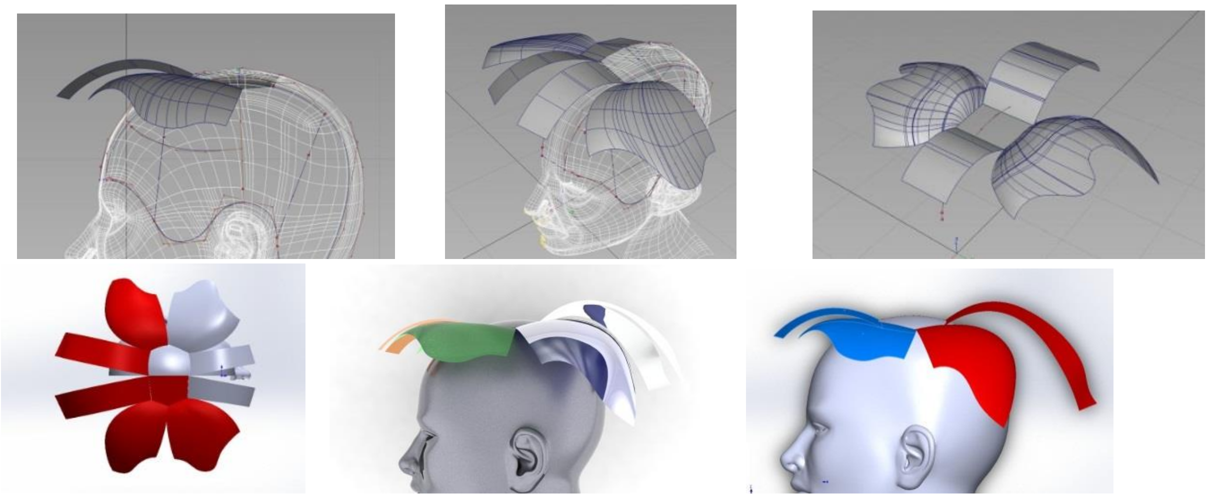
b- Concept Development:

Next phase of the project is to develop a manufacturing system for creating mass manufactured silicone cap. Some of these development phases are explained initially such as creation of 3D tubes around the head to demonstrate the idea of water flowing through as seen in figure below.



Concept for channels

This work showed that the channels can be created to fit the scan data. But the method to create a mould form sheet silicon was the first challenge. After this initial work the team met for a brain storming session, where a number of potential directions are discussed. First idea was to create the cap for the head from multiple smaller sections. But how to split the head shape to multiple sections that can be used to create mould(s) similar to the injection moulding process was the challenge. Initial constraints included the design must be easy to fold, be a good fit, easy to use and cost effective to manufacture tooling and the manufacture of silicon parts.

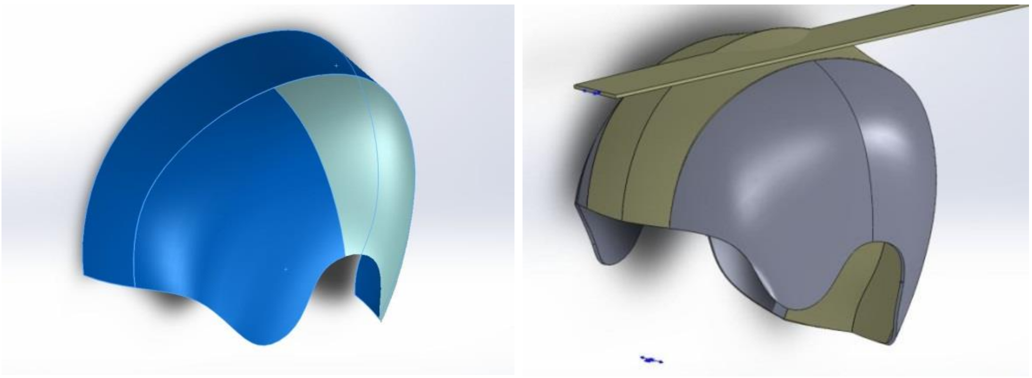


Concept development

One of the important features required is to consider continuous fluid flow in each section, therefore design should consist of minimal folding but also, when folded fluid flow should not be restricted, so there should be minimal resistance. Therefore, although other folding shapes are considered and simulated, the 3D design and Paxman technical team decided to produce the shape shown below.

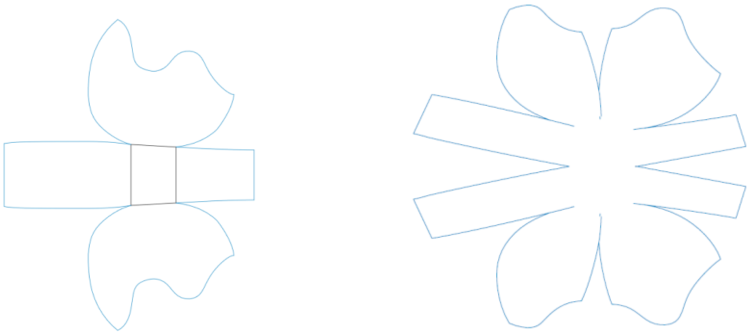
Concept evaluation

The team then decided to evaluate the design using flat middle section to simplify the moulding process . The surface data is taken to a Solid modelling package to evaluate how and where the mould could be generated. The image below shows the cap is divided in to three sections where the top could be moulded as flat and the side of the face sections could be constructed from the pieces.



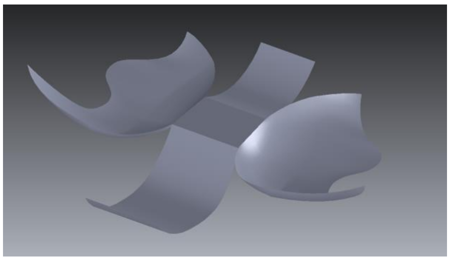
Further concept evaluation

These parts were flattened to create vector based 2D data so the physical parts can be cut in a laser cutting machine



2D form generation for quick laser cut test

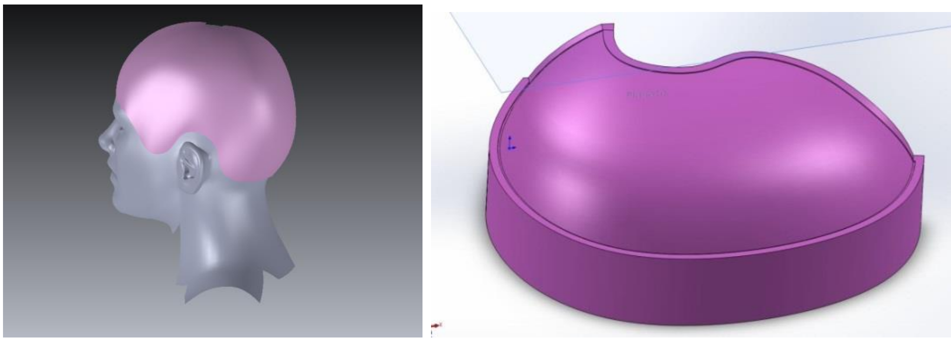
The following images shows the final concept for creating the 3D folded cap where two side surfaces are shaped to fit the side of the head and the top surface when flattened will be folded on to the head.



Concept chosen

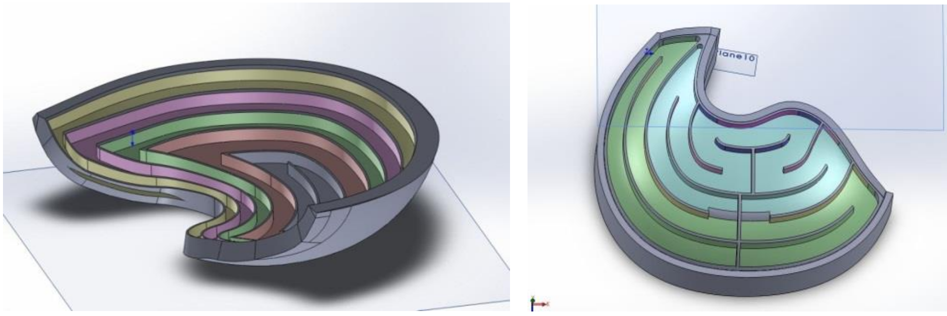
c- Tool Design

After the concept chosen the team started working on a method to create surfaces which could be converted in to a tool where hollow water channels could be created..



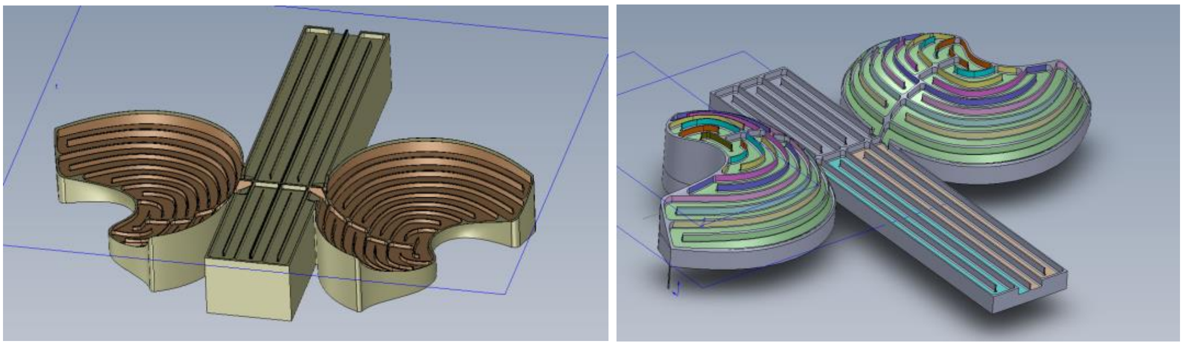
Modelling the tool using scan data

From the 3D NURBs surfaces created 3D solid model created which was used to cut the grooves required for the moulding process.

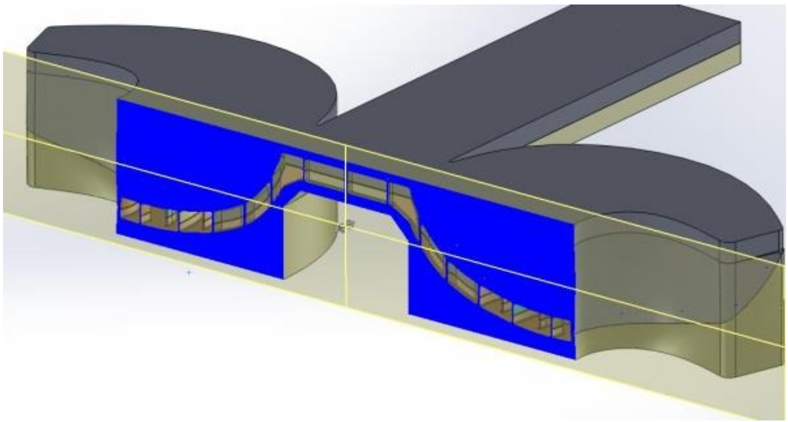


Creation of channels for fluid flow

Initial testing of grooves as seen above proved that two parts of the moulding can be created and apply to this process. After modelling the male part of the mould as seen above, the female mould is created using the male for reference. The two parts are assembled to produce the channels with 1.0mm dividers as seen below for minimal space between each cooling channel. The total height of the channels are set to 5mm but set to normal to z direction for easy moulding for each section of the mould with total height of 10mm which produce the required volume of liquid per second similar to the current system. Although the width is varied, it is calculated to achieve the same section area therefore same volume of the channels along the surfaces.

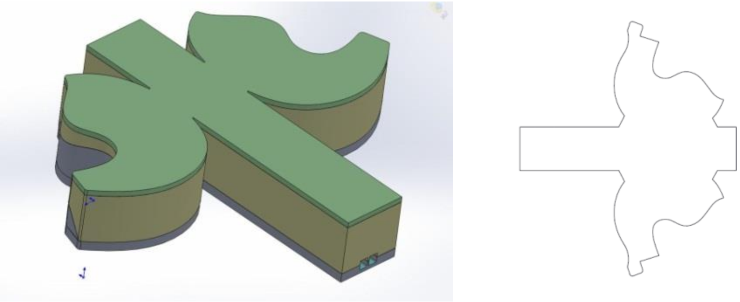


Tool design



Tool design and assembly check

When the moulds are completed, the back of the mould is shelled to create a hollow area with 10mm outer shell which was required for a vacuum. The team visited Primasil in Hereford to identify how the vacuum is to be applied for sheet silicon forming. The meeting revealed that hundreds of 1mm holes are required for the vacuum which are then connected to vacuum pump.



Laser cutting of outher surface for Vacum

The images, Solidworks and edrawings data shown above were sent to Primasil and Paxman. Both companies agreed that the shape and manufacturing methods were feasible, so the Research team evaluated which 3D printing methods to use. Although University of Huddersfield has three 3D printing machine including Zcorp 650 Powder based, Stratasys plastic based and Zcorp plastic based machines are available. The team evaluated the material properties, minimal thickness can be printed, temperature and pressure the 3d Prints can be used. Another important issue was tolerances of the printed parts compared to the cad data. Unfortunately although the 3d Print has revolutionised how the parts can be manufactured, depending on the machine type, technology is nowhere as good for engineering and dimensional tolerances.

d- Prototyping

The team decided to use the EOS 3D laser sintering machine with PA2200 material.(Fine Polyamide PA 2200 for EOSINT P). PA 2200 is suitable for use in all EOSINT P systems with recommended layer thickness is 0.15 mm. Typical applications of the material are fully functional prototypes with high end finish right. They easily withstand high mechanical and thermal load. Material properties are shown below.

Material Properties:

Average grain size	Laser diffraction	60	µm
Bulk density	DIN 53466	0,435 - 0,445	g/cm³
Density of laser-sintered part	EOS-Method	0,9 - 0,95	g/cm³

Mechanical Properties:*

Tensile Modulus	DIN EN ISO 527	1700 ± 150	N/mm²
Tensile strength	DIN EN ISO 527	45 ± 3	N/mm²
Elongation at break	DIN EN ISO 527	20 ± 5	%
Flexural Modulus	DIN EN ISO 178	1240 ± 130	N/mm²
Charpy - Impact strength	DIN EN ISO 179	53 ± 3,8	kJ/m²
Charpy - Notched impact strength	DIN EN ISO 179	4,8 ± 0,3	kJ/m²
Izod – Impact Strength	DIN EN ISO 180	32,8 ± 3,4	kJ/m²
Izod – Notched Impact Strength	DIN EN ISO 180	4,4 ± 0,4	kJ/m²
Ball indentation hardness	DIN EN ISO 2039	77,6 ± 2	
Shore D - hardness	DIN 53505	75 ± 2	

Also thermal properties are one of the main factor for choosing this material as melting temperature of PA 2200 is around 180C. Although this was the one of the main factor, the required surface quality, print size, required minimal thickness value and details, and material specification required for heat and pressure was another important reasons for choosing this laser sintering method.

Thermal Properties:

Melting point	DIN 53736	172 - 180	°C
Vicat softening temperature B/50	DIN EN ISO 306	163	°C
Vicat softening temperature A/50	DIN EN ISO 306	181	°C

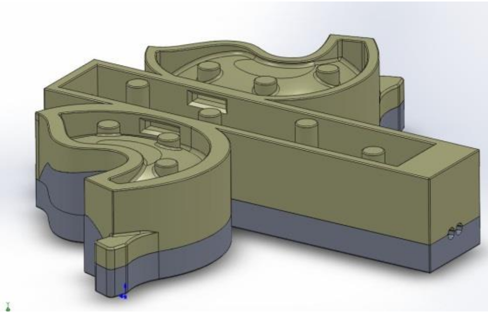
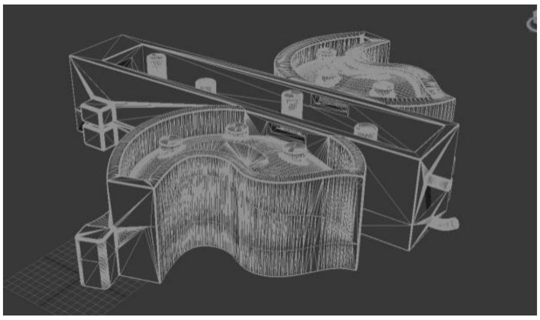
The team then approached to 3T ltd for 3D Printing. After arranging a confidentiality agreement the Sterelithography files are sent to 3T. 3T supplied the parts after 5 days. The Printing process and processing phase are shown below.

Rapid Prototyping ising EOS laser Sintering Machine

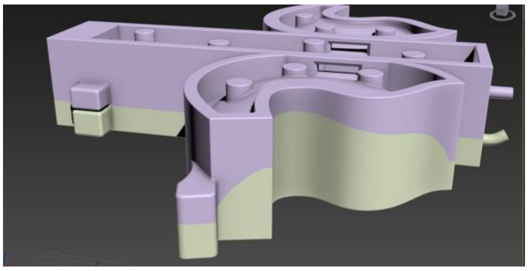
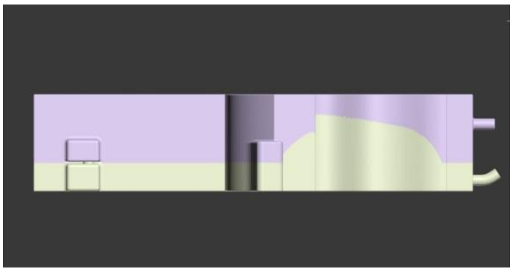
Unfortunately the parts could not be placed to the machine because of the large surface area on the base of the machine. EOS machines enables to print larger parts on Z direction therefore 3T team could not fit the parts. But 3T team not only positioned the parts on a smaller face but also aligned this at 45 degrees on the EOS machine resulting in unexpected problems on tolerance as show below. The parts do not align at all. Male and female parts are just over 10mm off tolerances. Huddersfield team discussed the matter with 3T and they accepted responsibility of the mistake after the following test.

Testing the 3D printed tool

The research team investigated the problem and checked the STL 3D files sent to 3T for printing. The image below shows the CAD data generated in Solidworks and images on the right are from

Testing the 3D printed tool

Testing the 3D printed tool

The STL files imported to 3D Studio Max for tolerance checking and fit. The test showed that the CAD data are perfect fit but printed models are not 1 mm off but more like a centimetre off and do not fit.

The team contacted 3T about the issue and after an investigation 3T confirmed that they have positioned the part vertically and with 45 degrees to the bottom surface to minimise the height and printing time. This resulted the printed parts to be distorted due to the two parts own weight. 3T accepted this tolerances are not acceptable and decided to print the parts second time with vertical and parallel to bottom surface. This method proved to be successful and second pair printed aligned male and female well as shown below.

3D printed tool

This tool was then sent to Primasil where Silicon moulding machines used to create the new cap as seen bellow. The moulded silicon showed that the method is feasible and can be used for cap manufacturing. This production method applied by Primasil is confidential and will not be published here.

Testing the prototypes

Although the principle of the method was a success, unfortunately the sheet silicon thickness is increased from 0.5mm to 1.5 mm because of the bonding and tearing which resulted in some of the channels close to middle section is blocked so the team decided to redesign the channels size so larger and deeper water channels are discussed with Paxman and Primasil.

Further test of the prototype

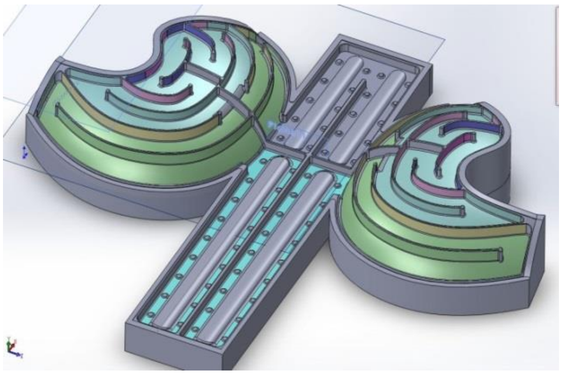
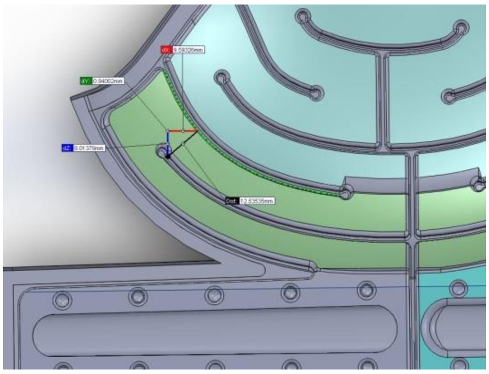
For the first experiment the method was a big success but product development and improvements were required. As the tool tolerances, number of coolant channels, depth and width of the channels as well as some minor dimensional changes were needed. The issue with the two silicon moulds in some places did not form the hollow structure required for fluid flow therefore the team required more Experiment 2:

e- Experiment 2

After the first experiment some coolant channels were blocked during the vac forming process, the potential reasons could be;

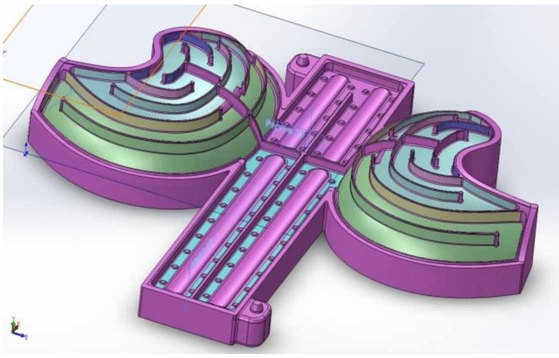
- Depth or the length of individual channels
- Low vacuum negative pressure applied during the process
- Wall thickness of the sheet silicon material used
- Surface tolerances of the 3d printed tool
- The issue with human error and issues with silicon moulding inhibitor used

The team decided to create a new mould with larger channels increased externally from 10mm to 15mm which also reduced the number of grooves as seen in the figure below.

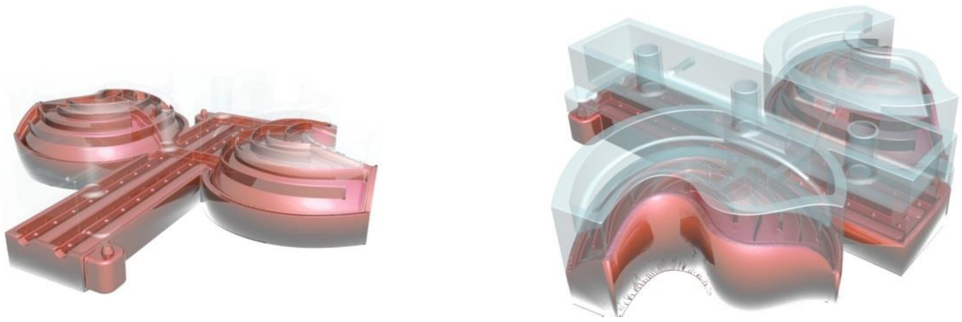
Design and development of mould tool

This modelling process normally takes around a week with the right tolerances and detail. After the male and female models completed using 3T ltd the parts are printed in PA2200 again as seen below.




Detailing and prototyping of mould tool


Second 3D printed parts



Digital Renderings and animation created using the model

8- Findings and Conclusion of Stage 1

The current cap in usage is shown below and has been available for over 10 years now. Ability to use Rapid Prototyping in tool making in the last few years has enabled the boundaries of current manufacturing methods to expand, while reducing costs. This process has enabled the creation of innovative designs, which were impossible to manufacture in few years ago. Designers now can create new innovative products using additive manufacturing with not following core engineering design and manufacturing methods...

Current cap

As seen on the images below, the new design consist of three flexible sections where the coolant enters to the cap from the end and travels around the surface of the head through channels without leaving any gaps. The coolant exits the caps from the rear section.

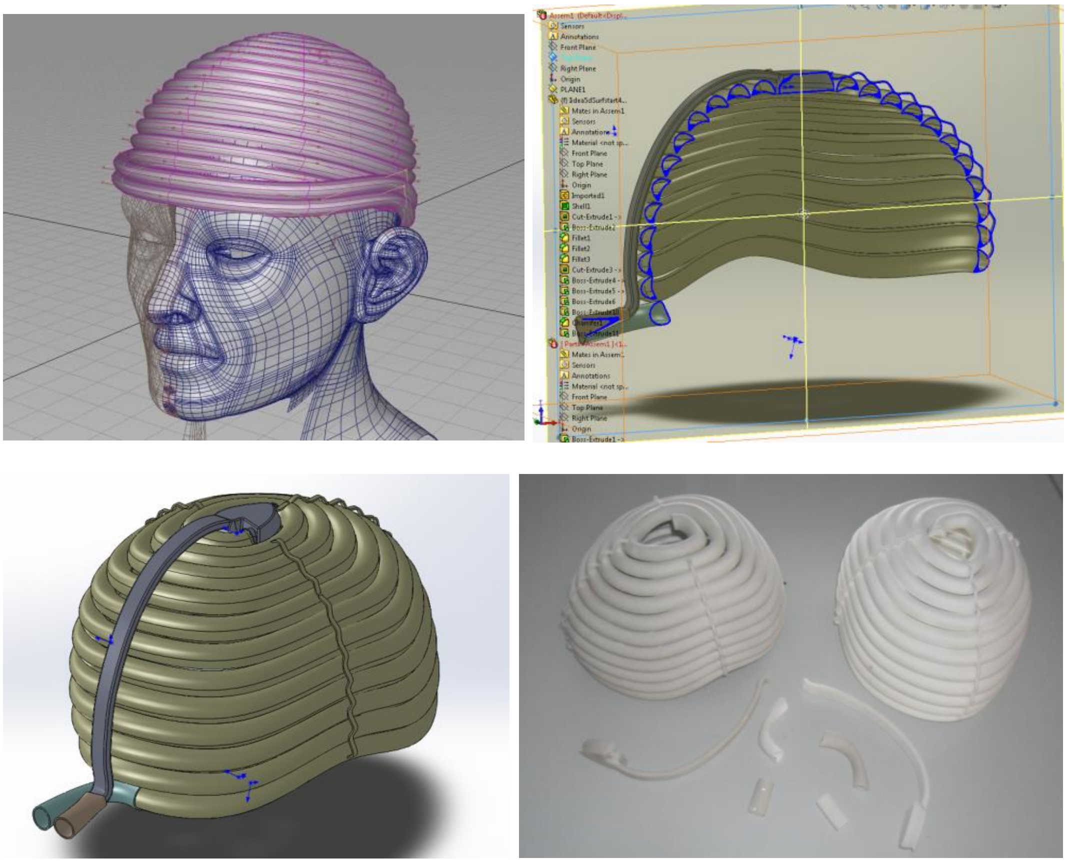
Prototypes using Silicone sheet and designed mould

Further testing

a- Future Work

The team has finished the design work. They have also manufactured a number of prototypes. Issues with sealing in the channels are being tested in the pressured environment. The team is also working with Paxman Cooler Ltd employees who have volunteered to test the cap. 3D team is investigating the methods to create metal tool currently further testing is undertaken using Bismuth Alloy, Aluminium 3D laser sintering, Laser sintering / 3D printing with PA 2200 and Alumide.

We are also evaluating additive manufacturing methods to create bespoke cap directly in 3D printing using flexible 3D printing material. The initial CAD model as seen below, is created using facilities at the 3M Buckley Centre (http://www.3mbic.com/) the 3D printing of the parts using the EOS laser Sintering machine has just been tested for additive manufacturing. Currently cost analysis and a method to extract powder from the channels have been researched as well as how to implement bespoke products.



New Concept for Additive manufacturing

Finally the team also considering to utilise and extend the first experiment, evaluating and researching methods to create the silicone mould tools from 2 or 4 pieces to directly create the cap from silicone.

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