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Sensing Swelling: Towards Remote Monitoring of Craniectomy Patients

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Abstract. Decompressive craniectomy (DC) is a surgical procedure where a portion of the skull is removed to relieve potentially fatal brain swelling. As the swelling can take months to subside, the patient is discharged from an acute care facility to recover prior to cranioplasty (reconstruction surgery). Cranioplasty is associated with complications due to infection, seizure, haematoma and death. The interval between these surgeries is potentially a modifiable risk factor to reduce the rate of complication. We aim to allow clinicians to remotely monitor patients to facilitate an optimal pre-operative review. We have developed a platform technology encompassing a 'smart' device fitted into a skullcap to measure physiological parameters, such as changes in brain swelling, and a clinician portal that allows remote viewing of the patients' physiological data. The use of patient generated data during the transition between craniectomy and cranioplasty has the potential to significantly improve neurorehabilitation outcomes for patients.

Keywords. Craniectomy, cranioplasty, remote monitoring, sensors, wearables

1. Introduction

Brain swelling as a result of stroke or traumatic brain injury (TBI), can lead to elevated levels of intracranial pressure (ICP). A decompressive craniectomy (DC), where part of the patient's skull is temporarily removed, can reduce ICP by allowing the patient's brain to expand beyond the skull boundary. DC is usually followed by an extended period of rehabilitation and recovery. A randomised controlled trial comparing medical management and DC in 155 adults with severe TBI found that DC was more effective at controlling ICP and reduced the length of stay in the intensive care unit [1]. DC is, however, associated with more unfavourable outcomes such as death, vegetative state, or severe disability at six months [2].

Cranioplasty aims to reconstruct the skull using either the patient's own (stored) bone flap or a custom synthetic prosthesis. It is associated with a complication rate of 15-35% [3,4] including infection (3.1-26.4%), hydrocephalus (1.4-13.5%), bone resorption (2.1-6.5%), seizure (1.6-15.6%), haematoma (0.7-7.4%), and death at 30 days (0.0-3.2%) [5-11]. The interval between DC and cranioplasty is viewed as a potential modifiable risk factor to reduce the rate of complication.

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Following DC, there is a vulnerable defect in the cranium, where the scalp overlays the missing skull area. Patients are often prescribed an 'off the shelf' (OTS) helmet, a sports or an orthotic helmet, to cover the defect. OTS helmets are known to be unhygienic stigmatising, conspicuous, bulky, and uncomfortable. To improve compliance and aid psychological recovery, Anatomics developed SkullPro1 (SKP1), a silky skull cap housing a thin, tough nylon shell, which sits inside a hypo-allergenic washable fabric pocket adjacent to the defect. SKP1 offers all the protection of a helmet, but is fashionable enough to wear alone, and slim enough to wear under a wig or scarf.

While SKP1 minimises the negative aspects of helmet therapy, it has the potential to further maximise the positive benefits through the incorporation of a smart device that would guide pre-operative planning. A recent review found while there was no consensus for the optimal timing of cranioplasty, it was driven by five core factors – surgeons' preferences, overall patient condition, infection status, neurological concerns and brain swelling [12]. Current surgery scheduling methodologies include:

- inpatient review (ICU, ward, inpatient rehabilitation, inpatient brain injury unit),
- direct examination at a routine follow-up clinic at fixed or defined intervals,
- indirect patient assessment by reviewing radiology,
- referral by community clinician for review in a follow-up clinic,
- routine scheduling of surgery at a time determined by the clinician, or
- arbitrary scheduling of surgery.

We hypothesise that patient-specific factors are especially relevant in determining the optimal timing of cranioplasty. A monitoring device able to assess brain swelling and relay the information to the clinical team could facilitate planning of cranioplasty surgery, timely scheduling of appointments and a more personalised approach to cranioplasty.

In 2021, a team from CSIRO and Anatomics completed the CSIRO ON Prime program (an innovation and entrepreneurship program designed to help researchers in translating their research to real world products with impact) with a view to delivering a product that would provide surgeons with an optimal timing to conduct cranioplasty surgery. ON Prime involves identifying customer segments, understanding requirements by conducting interviews, and defining the ecosystem and value pathways. The findings from the program [13] formed the foundation for the development of SkullPro2 (SKP2).

2. Methods

Based on the On Prime interviews demonstrating strong market appeal [13], and a user needs analysis (Section 2.2), we developed a platform technology comprising:

a) a device fitted with sensors that collects physiological data (the device); and
b) a clinician portal accessible via webpage to view physiological data (the portal).

2.1. Developing the Device

Device specifications included but were not limited to: replicate contour and geometry of SKP1; be less than 7mm thick and 100g; removable; nonabsorbent; sterilizable; free from heat/electrical/radiation risk; able to withstand impact and immersion; not exert pressure on skin or neural structures; be a single, regulatory compliant, cable free unit able log collected data for 90 continuous days and support integration with a mobile/IP connected device for uploading data to private, secure cloud storage.

The device includes sensors able to measure head deformation without direct contact with the skin; skin and ambient temperature; tissue oxygenation, pulse rate, ambient barometric pressure and relative ambient humidity. An accelerometer and a nine axis inertial measurement unit provides information about head orientation and movement; and a combination of multiple sensors values are used to infer device compliance.

2.2. Developing the Portal

Following privacy assessment, low risk ethics approval was granted (CHMHREC 2021_104_LR) for a user needs analysis for the portal. The study was conducted by online survey (N=19) and follow-up interviews (n=3) with clinicians who treat, manage, or have been involved in the care of patients who have undergone DC. Results were analysed qualitatively and will be followed up with prototype evaluation and pilot trial.

3. Results

3.1. Developed to Provide Additional Benefit Over 'Off The Shelf' Helmets.

The original SKP1 skull cap was fitted with a nylon 3DP plate weighing 50g, contoured to fit most cranial shapes, available in three sizes to accommodate variations in head circumference, and left and right options as required. The plate was secured to the head using elasticated fabrics and cushioned by neoprene fabric. Our 'smart' device builds on SKP1 with the sensors, electronics, communications, and battery housed within the plastic plate and insulated by a food-grade PolyEthylene Terephthalate Glycol (PETG) housing. Despite the new plate being thicker (x2) and heavier (100g) due to the extra components, it still fits in the original fabric pocket of the skull cap. SKP2 interfaces via Bluetooth with a mobile app on an iPad which in turn sends data to a portal for visualisation by clinical teams (Figure 1).

Figure 1. Craniectomy patients wear a skullcap fitted with a sensor able to transmit data to a mobile app. Images a. doi.org/10.1186/s41983-019-0077-8; b. Anatomics Pty Ltd; c,d. CAD; e. Getty Images.

3.2. Clinicians' Preferences Indicate a Need for a Customisable Dashboard

Of the clinicians surveyed, 7/19 had research interests regarding craniectomy and cranioplasty, suggesting the portal would be used primarily to determine cranioplasty timing, but also as an explorative tool to assess variables that impact recovery. Clinicians were interested in remote assessment of a number of variables including headgear compliance (n=16, 84%), brain swelling (n=15, 79%), patient inactivity (n=11, 58%) and skin temperature (n=10, 53%), with alert frequency ranging from daily to monthly. Participants felt the portal should have an information (i) button for each variable with

rationale for inclusion in monitoring, and notes sections for ad hoc information such as storage of bone, presence of internal stitches and family wishes.

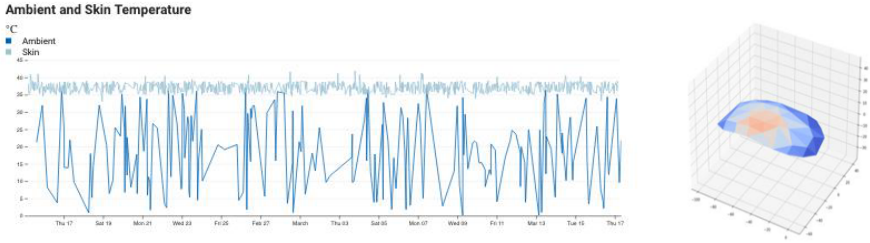

Figure 2. Clinicians view data, such as temperature or brain swelling, remotely through a web-based portal.

4. Discussion

We developed a telemetric monitoring device able to remotely assess temporal changes in brain swelling by measuring the relative distance between the convexity of the brain to the margins of the DC defect along with other physiological parameters of clinical interest. The device relays the information to the clinical team through integrated cloud-based software accessible via web page (clinician portal). We are currently collecting benchtop data using a craniectomy phantom (in both 3D and computerised version) to demonstrate performance and viability of the alpha prototype.

Where SKP1 improved helmet compliance and psychological recovery by providing a low profile, contoured, lightweight, aesthetic and inconspicuous alternative to "off-the-shelf" helmets (Table 1), SKP2 adds potentially significant clinical value through remote monitoring. The platform could facilitate early planning of cranioplasty surgery, timely scheduling of pre-operative appointments and a personalised approach to cranioplasty.

Table 1. Comparative benefit of the SkullPro smart device and skull cap relative to off the shelf helmets.

Characteristic	OTS helmets	SkullPro 1 & 2 (SkullPro 2 only)
Covers the cranial defect	ü	ü Allows head wear (e.g. scarf) to be worn on top
Minimises direct injury to soft tissue	ü	ü Nylon shell minimises the risk of injury to soft tissue, PETG layer added to protect sensors
Stigmatising, conspicuous, bulky, and uncomfortable	ü	û Low profile, contoured, lightweight, aesthetic and inconspicuous
Requires chin straps	ü	û Does not use a chin strap
Breathable or moisture wicking	û	ü Breathable, moisture wicking fabrics
Patients monitored in community	û	ü Platform offers a means to monitor patients remotely in their own home
Patient environment and movement monitoring	✗	✓ *Independently measures the patient head movement and their environment*
Connection to clinical team	✗	✓*Relays information to clinical team*

* OTS: Off the shelf; PETG: PolyEthylene Terephthalate Glycol (food grade)

Our engagement with clinicians indicated a need for a customisable dashboard able to prioritise variables of interest and set individual alerts. Prototype evaluation will provide insight into user experience and the utility of data visualisation and exploration.

5. Conclusions

Remote monitoring will allow scheduled clinical review to be based on physiological parameters rather than on generic factors or set timing. Currently, there are no devices on the market that facilitate a remote study of the patient-specific factors relevant to determining optimal cranioplasty timing or likely to affect outcome. We expect our device to be available by 2024-25, subject to regulatory processes. Our sensor and portal will ensure improved quality of care through using patient-generated data during the transition between craniectomy and cranioplasty. Facilitation of optimal pre-operative review has the potential to significantly improve neurorehabilitation outcomes.

This platform will also enable the integration of more sophisticated solutions including electroencephalogram (EEG) monitoring, neuromodulation, or near-infrared technologies to assist neurorehabilitation with issues such as sleep, seizure management, pain therapy, and neural recovery.

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