Reducing Surgery Time and Improving Patient Outcomes for Eye Socket Fractures

Submission for the 2014 Canterbury DHB Quality Improvement and Innovation Awards

Medical Physics and Bioengineering Department
Department of Oral and Maxillofacial Surgery
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Project Information Sheet

Project title
Reducing Surgery Time and Improving Patient Outcomes for Eye Socket Fractures

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Word Count (limit 3000)
3565 (including literature review and references)
Abstract

Eye socket fractures occur when a blow is received to the eye/cheekbone. From 2009 to 2013 eye socket fractures have been repaired using commercial titanium plates costing approximately $1000 each. These were inserted at Christchurch Hospital theatres and a CT scan was performed the following day to verify the correct fit of the plate. Only one surgery could be scheduled for a morning or afternoon session as the plates had to be cut to size and bent to fit the eye socket in theatre, which was time consuming. Plates were often inserted several times into the eye socket before adjustments to the plate shape resulted in an adequate fit. Each attempt results in extra bruising and scar tissue for the patient. After the CT scan, 33% of cases were found to not fit correctly, resulting in a return to theatre to correct the shape of the plate, which caused further trauma and scar tissue to the patient and further costs for the theatre time.

The aim of this project over the period 2012-2014 was to reduce the number of patients returning to theatre which would reduce trauma to the patient, and reduce surgery time and costs. Three objectives were identified for this project which were:

1. Performing the operations at Burwood Hospital where the O-Arm scanner could verify the correct fit of the plate in theatre before the patient leaves (reducing return to theatre).
2. Producing a low cost 3D plastic model of the eye socket anatomy from a CT scan and using this to pre-shape the titanium plate so it doesn’t require significant modification in theatre (reducing surgery time).
3. Producing titanium plates in the MPBE workshop which cost approximately $26 each, and require less trimming in surgery (reducing time and cost).

As a result of these changes there have been

1. No return to theatre cases from 31 cases from 2013 to June 2014.
2. The plates usually fit perfectly the first time they are inserted which results in less scar tissue, reduced double vision, and reduced enophthalmos. Time to insert the plate has reduced from an average of 30 minutes to 13 minutes, meaning two surgeries can now be reliably planned for a morning or afternoon session instead of just one.
3. The cost of plates has been reduced dramatically which is good for surgery and when training registrars how to bend the plates. The improved plate design requires less trimming and de-burring which saves time.
Introduction and Background

The health care environment:
The Department of Oral and Maxillofacial Surgery, Christchurch Hospital provides surgery services for jaw and facial bone reconstruction. There are three surgeons responsible for doing the eye socket surgeries and there are approximately 30 eye socket surgeries performed every year in Canterbury. The three surgeons also train registrars in the techniques.

Medical Physics and Bioengineering provides scientific and technical services for safe, effective, and innovative patient care. There are thirty staff members in the Department. The eye socket fracture work fits well with the MPBE department as it combines medical imaging, bio-modelling and 3D printing to support medical practice.

Motivating or initiating factors:
Poor patient outcomes and high cost of surgery due to the difficulty of shaping the eye plate in theatre and lack of suitable in-theatre imaging, resulting in excessive scarring, a 33% return to theatre rate for revision surgery, and wasted theatre time. The return to theatre rate was calculated from the procedures performed at Christchurch Hospital where no in-theatre imaging was available. Publications on eye socket surgery support Christchurch Hospital’s return-to-theatre results as a typical rate.

The project team:
MPBE staff: Steven Muir, Nick Cook, Michael Sheedy, Johann Bader, Chris Morison.

Oral and Maxillofacial Surgery staff: Chris Lim and Jason Erasmus.

Background information
Eye socket or ‘blowout’ fractures occur when a blow is received to the eye/cheekbone. The wall and/or floor of the eye socket is fractured and intraorbital material may be pushed out into the paranasal sinuses. Before 2010 fractures were repaired using titanium ‘sugar mesh’ which is supplied as a perforated flat sheet, then cut and bent to shape. It was very difficult to bend in two dimensions and was more suited to small flat defects. From 2010 to 2013, blowout fractures have been repaired using commercial titanium plates costing approximately $1000 each, which were shaped to an average eye socket shape, then cut and bent to fit more accurately during surgery. These were inserted at Christchurch Hospital Theatres and a follow-up CT scan was performed the following day to verify the correct fit of the plate. Only one surgery could be scheduled for a morning or afternoon session as the plates had to be cut to size and bent to shape in theatre, to fit the eye socket, which was time consuming. Plates were often inserted several times into the eye socket before adjustments to the plate shape resulted in an adequate fit. Each attempt results in extra bruising and scar tissue for the patient. After the CT scan the following
day, 33% of cases were found to not fit correctly, resulting in a return to theatre to correct the shape of the plate, which caused further trauma and scar tissue to the patient and further costs for the theatre time.

Other centres using this initiative

Rapid prototyping of 3D models has been done in other centres for small numbers of patients, but not routinely for every patient. The combination of using pre-formed low cost plates, low cost plastic 3D models for every patient, and in-theatre imaging to verify the fit is unique to this method. Other papers describing the use of 3D models and pre-formed plates are summarised below. We are the only centre (internationally) to have the combination of using low cost plastic 3D models for every patient, using in-theatre imaging routinely, and producing our own low cost titanium plates.

Planning and Implementation

Summary of Existing Published Research

Two published papers (Hoeltze 2001 and Stuck 2012) describe the benefits of in-theatre CT scans for eye socket surgery, but these were not done in conjunction with 3D models or pre-fitted plates.

Kermer (1998) concluded that stereolithographic models were very useful for maxillofacial surgery planning.

Williams (2009) used an expensive laser sintering machine to produce a model for one patient with sufficient detail to reproduce the floor or the eye socket. Stereolithographic techniques did not provide adequate resolution.

Kozakiewicz (2006) used inexpensive fused deposition modelling printer to produce models for 6 patients and pre-shape plates and suggested it was an economic way to streamline eye socket surgeries.

Schon (2006) used pre-formed plates for 19 patients and found that “using preformed implants proved faster, more precise and less invasive, compared to ‘free hand’ efforts, for eye socket injuries using titanium mesh and calvarial grafts.” Followup imaging was performed post-operatively. A more expensive stereo-lithography printing technique was used and the eye socket was mirrored to get the preferred shape.

Metzger (2006) fitted 16 plates into human cadaveric heads and found the use of pre-bent plates improved the accuracy of placement. Plates were bent to an aluminium block that had been milled to shape (not as fine a resolution as fused deposition modelling).
Perry (1998) only made models for particularly complicated patients due to the cost.

**Site visit**

In November 2013 Steven Muir visited Royal Perth Hospital Bioengineering Workshops to discuss their rapid prototyping techniques. This was very informative and has influenced our capex proposals to purchase an improved printer.

**Costings**

Costings are given in the Pareto Chart below.

**Aim & objectives**

The aim of this project over the period 2012-2014 was to reduce the number of patients returning to theatre which would reduce trauma to the patient, reduce surgery time and costs. Three objectives were identified for this project which were:

1. Performing the operations at Burwood Hospital where the O-Arm scanner could verify the correct fit of the plate in theatre before the patient leaves (reducing return to theatre rate & excessive scarring).
2. Producing a low cost 3D plastic model of the eye socket anatomy from a CT scan and using this to pre-adapt the titanium plate so it does not require any significant modification in theatre (reducing surgery time & excessive scarring).
3. Producing titanium plates in the Medical Physics and Bioengineering Department workshop which cost approximately $26 and require less trimming and deburring (reducing cost). Often offcuts of medical grade titanium (purchased for making larger cranial plates) can be used to further reduce costs.

**Planning and approval**

The planning and approval process is recorded in the meeting decisions summary, available on site visit.

**Feasibility study**

Following the literature research, site visits and data review, a fishbone analysis and Pareto analysis were undertaken to determine feasibility are shown below.
**Fishbone Analysis**

A fishbone diagram is shown below, showing the causes that lead to high cost and poor patient outcomes for eye socket surgery. The difficulty of shaping a plate in theatre and verifying that it is fitting correctly was noted to be one of the major causes of returns to surgery with the associated poor patient outcomes and higher costs. The expense of obtaining biomodels and plates was also a problem.

[Diagram showing the causes of high cost and poor outcomes for eye socket surgery.]

- Plate is expensive and difficult to obtain.
- Limited range of eye plates available.
- Plates are oversized and require trimming results in wastage of time and materials.
- Biomodels are too expensive and not available for most patients.
- Plates are difficult to fit correctly due to shape and time-consuming.
- Plate shape must be checked several times which causes scarring and bruising.
- Difficult to see if plate is fitting correctly and cannot be verified without scanner so repeat surgery often required.
- Availability of surgeons, nurses, and anaesthetists limited.
- CT scan not available in theatre.
- Orbital retractor difficult to use.
- Only one surgery possible for a morning or afternoon session.
- Repeat surgeries waste theatre time for other operations.
- Budget constraints mean biomodels not possible for every patient.
Pareto Analysis

Two Pareto charts are shown, one for detrimental patient outcomes, and one for surgery cost. An average eye socket surgery takes 105 min (average from 2013 data) and based on the ACC theatre rate of $43/min, each surgery costs approximately 105 min x $43/min = $4515. If returns to theatre occur in 33% of cases and results in a further 105 min surgery, this adds an extra cost per patient of 33% x $4515 = $1445. The time taken to insert the actual plate was on average 30 min, which makes up $1290 of the total surgery costs. It could be seen that reducing the return to theatre rate would have the biggest impact on improving patient outcomes and reducing costs. Further gains could be made by reducing the theatre time and reducing the cost of the titanium plates. Detrimental patient outcomes are based on estimations by surgeons as no measurable data exists other than for return to theatre rates.
### Legal Ethical & Risk Analysis

No legal or ethical issues were identified from team meetings as a result of the changes in practice. A full risk matrix is available on site and the table of surgery risks are shown below with the 2012 risks on the left and the 2014 risks on the right. It can be seen that the high risk items from 2012 (red and orange) have all been reduced to a more acceptable level with the changes in practice implemented.

#### MPBE Failure Modes and Effects Analysis

<table>
<thead>
<tr>
<th>Process or Product Name:</th>
<th>Eye orbit surgery for blowout fracture</th>
<th>Started by:</th>
<th>Last updated by:</th>
<th>Steven Muir 2014</th>
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<tbody>
<tr>
<td><strong>Key Process Step or Input</strong></td>
<td><strong>Potential Failure Mode</strong></td>
<td><strong>Effects of Failure</strong></td>
<td><strong>SEV</strong></td>
<td><strong>PROB</strong></td>
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<tr>
<td>Eye Socket Fractures</td>
<td>Plate Damage during sterilization</td>
<td>Plate no longer suitable to be implanted</td>
<td>3</td>
<td>3</td>
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<td>Plate becomes sharp/ there are burrs</td>
<td>Plate no longer suitable to be implanted</td>
<td>3</td>
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<td></td>
<td>Wrong plate used</td>
<td>Patient discomfort/ injured and/or cosmetically affected</td>
<td>5</td>
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<td></td>
<td>Plate weakened in theatre</td>
<td>plate may weaken or crack and become unsuitable before implanting</td>
<td>4</td>
<td>3</td>
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<tr>
<td></td>
<td>Plate does not fit correctly and requires rebending and reinserting</td>
<td>extra scarring to patient</td>
<td>4</td>
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<tr>
<td></td>
<td>plate fit is not correct after surgery and 2nd surgery is required</td>
<td>extra scarring to patient, wasted theatre time &amp; expense</td>
<td>5</td>
<td>4</td>
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<tr>
<td></td>
<td>required plate shape is not available from Synthes</td>
<td>surgery cannot proceed</td>
<td>4</td>
<td>2</td>
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<td></td>
<td>orbit retractor difficult to use</td>
<td>slower surgery</td>
<td>2</td>
<td>4</td>
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Involvement with stakeholders
Team meetings with Maxillofacial and MPBE staff were held as required to develop the processes. A summary of the decisions made at these meetings are available on site if required.

Links to CDHB & National strategic goals
This fits with the Canterbury DHB’s strategic goals of being more people-centred, increasing patient safety, and being more effective, efficient, and timely. It also aligns with the national health targets of DHBs living within their means.

Description of innovative aspects of this project
As far as we are aware we are the first project in the world to combine in theatre imaging, routine use of low cost 3D models and, in-house built titanium plates. These have large potential to reduce surgery time, save costs and improve the patient journey.

Obtaining signoff
Approval to proceed was given by the surgeons after reviewing the accuracy of the 3D models and design of the titanium plates. Sight the summary of meeting decisions for details. Patient permission for the surgery was obtained during pre-surgery consultations by the surgeons. Specific permission to insert MPBE designed plates was not considered necessary as they were of comparable or superior quality to previously accepted techniques.

Key decision dates were:
- January 2013 - eye socket surgeries were transferred to Burwood Hospital for as many cases as possible. First surgery occurred for 8/2/13.
- July 2013 - 3D models are verified to be accurate to within 1mm based on Inteleviewer measurements. Approval to produce a 3D model for every eye orbit surgery was granted.
- August 2013 design of the standard titanium plate for eye sockets was reviewed, and the approval to produce the plates was granted. The first MPBE plate was inserted 16/8/13.
- April 2014 three other designs of smaller & larger plates were approved.
### Implementation of the project

A Gantt chart showing the project timelines is shown below.

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<td>review costs of eye orbit surgery</td>
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<td>review return to theatre rate for eye orbit surgeries</td>
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<td>Implement surgery at Burwood using the O-Arm</td>
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<td>Investigate 3D modelling options from external providers</td>
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<td>Implement surgery using the Synthes plates prefitted to MPBE model</td>
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<td>Develop MPBE protocols and staff training for 3D modelling</td>
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Eye Socket Fractures  

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2014 CDHB Quality Improvement & Innovation Awards
Overview of the implementation process

In-theatre imaging

Two published papers (Hoeltze 2001 and Stuck 2012) clearly describe the benefits of in-theatre CT scans which give accurate 3 dimensional images at an acceptable radiation dose. The arrival of the Medtronics O-Arm portable CT at Burwood Hospital in February 2012 opened up the possibility of verifying the correct placement of the plate while still in theatre. Surgeries were transferred to Burwood in February 2013. Dose assessments were made which showed the patient would receive no more radiation from in-theatre imaging than they would from a standard follow-up CT scan the day after their operation. Because the O-Arm was not purchased by CDHB and requires less staff to operate, it results in less cost for imaging to the CDHB than running a CT scanner.

Use of 3D models for every patient

Published papers (above) describe how 3D models are extremely useful in improving the accuracy of eye socket surgery. In 2012 - 2013 several trial models were made by a local engineering company, at a cost of approximately $800-$1000 each. However these could only be used for extremely complicated cases due to budget constraints. Three models were also made at the University of Canterbury but poor quality and difficulty of producing them in a timely manner for clinical work meant it was not feasible for an ongoing service. The purchase of a low cost 3D printer ($1800) by the MPBE that could produce a model for less than $70 in a few hours, meant that models could be made for every eye socket surgery. After verifying the accuracy of the models, they were routinely produced from July 2013 for pre-fitting plates before surgery.

MPBE made titanium plates

The use of commercially available plates was reviewed in April 2013 and an improved design of plate was developed that did not require trimming for most patients and cost approximately $26 to produce.

Monitoring progress

The spreadsheet of surgery outcomes are available on the site visit which includes surgery time, time spent inserting the plates in surgery and the number of CT scans required in theatre, which indicates how many attempts at re-shaping the plate occur.

Communication processes

Communication for this project has been via face to face meetings. Phone calls and emails. Stakeholders were very enthusiastic about the changes and no resistance to change was encountered.
Documentation and procedure development

Maxillofacial staff have staff meetings at which the new techniques are described and new registrars observe more experienced staff for one to three years, developing surgical skills on simpler surgeries, before performing an eye socket surgery themselves.

MPBE staff have developed detailed procedures for the making of the 3D models which are in Medical Implant Procedures (MIP) section 4.12 3D Biomodel Design and Manufacture. This includes details of using the software to create an accurate 3D model, managing the process of how a surgeon orders a model, how the correct patient data is used to create the model, how to ensure the model is of the correct size, and how to ensure the surgeon gets the correct model for the patient.

MIP 4.13 describes the manufacturing of the titanium plates, including ensuring the titanium is of adequate quality, getting the correct shape and size, surface finishing and making specialised plates for unusual patients/injuries.

MPBE 4.19 describes the record keeping requirements for medical implants.

MPBE processes and procedures are accredited to AS/NZS ISO 9001:2008 “Quality management systems – Requirements” and ISO 13485:2003 “Medical devices – Quality management systems – Requirements for regulatory purposes”. They are audited internally every two years and externally by Verification NZ every year to ensure they are kept up to date.
Results and Findings

The revised Pareto charts show the dramatic improvement in patient outcomes and reductions in surgery costs. It was surprising to surgeons that over the 31 surgeries performed at the time of writing, there have been none that required a return to theatre. This has exceeded expectations about the success of the project. Ongoing savings in theatre time for inserting the plate are likely to be greater than those shown in the graph, which include surgeries where surgeons were unfamiliar with the new theatre, plates and models and so took more time. The most recent surgeries often take only four minutes to insert the plate (compared to 13 minute average for the new technique, and 30 minute average for the old technique).

![Pareto analysis - frequency of detrimental patient outcomes](image_url)
There are approximately 30-35 blowout fracture operations performed every year, resulting in savings of at least:

- Reduced surgery time: 30 x $731 = $21,930
- Repeat surgeries: 10 x $4515 = $45,150
- In-house titanium plates: 30x$1,000 = $30,000
- Total = $97,080 per year.

Conclusions and Future Direction

**Overall evaluation of the project**

The review of eye socket surgery procedures has been extremely effective in reducing the number of returns to theatre from 33% to zero, resulting in less scarring to the patient, faster treatment time, and has doubled the number of procedures that can be performed in a morning or afternoon operating session. There have also been huge cost savings by reducing theatre time and return to theatres, as well as by manufacturing the plates in the MPBE department.

**Ongoing monitoring activities**

Statistics for operating times, number of CT scans performed in theatre, and returns to theatre will continue to be measured to ensure the method continues to work effectively.
Future directions
The benefits of 3D models for surgery planning could be extended to other departments, and this will be explored over the next year. The design of commercially available eye orbit retractor tool was highlighted as one of the risks in the surgery risk analysis process. An improved design made by MPBE staff is planned for development from late 2014-2015.

Communication of knowledge
Chris Lim is submitting a paper to the Craniomaxillofacial Trauma and Reconstruction journal and presenting it at the Australian & New Zealand Association of Oral and Maxillofacial Surgeons conference in Auckland (October 2014). This will provide opportunities to discuss how these improved techniques could be used throughout New Zealand.

Michael Sheedy (MPBE Dept.) is presenting a paper at the Australian Biomedical Engineering Conference (ABEC) 2014 20 - 22 August 2014 in Canberra. A low cost process for creating 3D bio-models for use in reconstruction of orbital fractures. Michael is also planning to submit a technical note in the ACPSEM journal.

Retention of Knowledge
The knowledge gained from this project is documented within the MPBE quality system procedures, and in Oral & Maxillofacial Department protocols to ensure new staff are familiar with the processes.

Recognition strategies
Proposed article in CDHB News. Innovation award application.
References


