

# A Study Protocol for a Randomised Controlled Trial Evaluating the Effects of Intraoperative Computed Tomography on the Outcomes of Zygomatic Fractures

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## Study protocol

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# Abstract

**Background** Zygomaticomaxillary complex (ZMC) and zygomatic arch (ZA) fractures are common injuries resulting from facial trauma and frequently require surgical management.<sup>1</sup> A substantial number of post-operative functional and cosmetic complications can arise from the surgical management of these fractures. These include scarring, inadequate facial profile restoration, facial asymmetries and diplopia.<sup>2-4</sup> Intuitively, most of these aforementioned complications arise as a result of inadequate fracture reduction, however current standard practice is to assess reduction post-operatively through plain radiographs or computed tomography (CT) scans. The role of intra-operative computed tomography (CT) scanning to assess the reduction of ZMC/ZA fractures and the potential impact on complications, has thus far not been established.

**Methods** This is a prospective randomised controlled trial currently being undertaken at the Royal Brisbane and Women's Hospital. All patients who require operative management of their ZMC or ZA fractures are offered enrollment in the trial. The patients are randomised into two groups: interventional (intra-operative CT) and control (no intra-operative CT). All patients from both groups will have post-operative radiographs taken. From these radiographs, the reduction of the ZMC and/or ZA fracture is graded by a blinded assessor. Patients will be reviewed in clinic at one and six weeks post-surgery. During these consultations, all patients will be assessed for scarring, diplopia, facial profile restoration and need for revision surgery.

**Discussion** Many complications associated with surgical management of ZMC and ZA fractures involve poor aesthetic results as a direct consequence of inadequate fracture reduction. Inadequate fracture reduction is predictable given that small incisions are used and only limited visualisation of the fractures is possible during the procedure. This is due to a desire to limit scarring and reduce the risk of damage to vital structures in an aesthetically sensitive region of the body. It follows that an intraoperative adjunctive tool such as a CT scan, which can assist in visualisation of the fractures and the subsequent reduction, could potentially improve reduction and reduce complications.

## Background

Zygomaticomaxillary complex and zygomatic arch fractures are a relatively common injury in Australia with the Royal Brisbane and Women's Hospital managing approximately 160 per year.<sup>1</sup> Many of these fractures require surgical reduction and fixation to restore either function or aesthetic form or a combination of the two. Precise reduction of zygomatic arch and zygomaticomaxillary complex fractures can be difficult due to limited visualisation of the fractured bones. Surgical exposure of the fractures is intentionally kept to a minimum to reduce facial scarring and protect vital structures in an aesthetically sensitive region of the body. Current surgical approaches usually produce minimal scarring and provide adequate protection of vital structures, however as a consequence of this minimalist approach, exposure of the fractures can be very restricted. A potential sequelae of minimal fracture exposure is inadequate reduction. This in turn can lead to poor cosmetic results such as facial asymmetry, poor facial profile restoration, facial scarring, limited mouth opening or restricted eye movement.<sup>2-4</sup> It is clearly of the highest priority to surgeons to avoid these potential adverse outcomes.

The current standard procedure for assessing fracture reduction is to perform plain radiographs or a computed tomography scan in the post-operative setting. This provides adequate assessment of the reduction however if

there are any inaccuracies, correction can only be achieved through a second procedure. With the increasing availability of intraoperative CT scans, it is surmised that this technology could improve ZMC and ZA fracture reduction and subsequently reduce post-operative complications. There currently exists, only a small number of studies that have investigated the use of intra-operative CT scans in the management of ZMC fractures.<sup>5-14</sup> Most of the studies involve small patient sample sizes and none provide level 1 evidence. Many of these studies conclude that the intraoperative CT scans can improve fracture reduction and revision surgery rates. However, to date there have been no randomised controlled trials (RCT) published to adequately assess this hypothesis.

This RCT aims to assess the use of intraoperative CT scans in improving radiographic fracture reduction, clinical outcomes and revision surgery rates for ZMC and ZA fractures. Due to the lack of current literature in assessing the potential for use of intra-operative CT scans, we feel that an RCT will provide invaluable knowledge to the medical literature.

## Methods

### Study objectives

The primary objective of the trial is to determine if intraoperative CT imaging improves clinical outcomes for zygomaticomaxillary complex and zygomatic arch fractures that are managed surgically. This will be assessed through the following variables:

- Post-operative radiographic reduction adequacy
- Need for revision surgery
- Number of intra-operative re-reductions
- Post-operative diplopia
- Facial profile restoration
- Surgical incision and scarring

The trial has a secondary objective to ascertain whether intraoperative CT imaging has a significant impact on length of surgery and whether it affects the outcomes of delayed versus early surgical treatment outcomes.<sup>15</sup>

### Study Design

This is a prospective, single centre, double-blinded, randomised controlled trial. It will be conducted by the oral and maxillofacial surgery department (OMFS) at the Royal Brisbane and Women's Hospital in Brisbane (RBWH), Australia. This is a tertiary teaching hospital and major trauma centre for the city of Brisbane and the state of Queensland. The study was approved by the Royal Brisbane and Women's Hospital Human Research Ethics Committee (reference number HREC/16/QRBW/18) on the 27<sup>th</sup> July 2016, prior to recruitment of patients. This study complies with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007). The trial was registered with the Australian and New

Zealand Clinical Trials Registry (registration number ACTRN12616000693426) on the 26<sup>th</sup> May 2016 prior to patient recruitment. Please see the SPIRIT figure (Fig. 1) for an illustration of the timeline for enrolment, interventions and assessments of the trial. The SPIRIT checklist has been completed for further information (additional file 1).

If there is any alteration to the trial protocol that has been submitted to the RBWH Human Research Ethics Committee and the Australian and New Zealand Clinical Trials Registry, these organisations will be informed of the amendments immediately.

## Recruitment and consent

All patients who present to the oral and maxillofacial surgery department of the RBWH, with an isolated zygomaticomaxillary complex fracture or an isolated zygomatic arch fracture, will be screened for a position on the trial. As RBWH is an adult hospital, all patients will be 16 years of age or older and they must require surgical management of their ZMC or ZA fracture to be included in the trial. Exclusion criteria from the trial includes the following:

- Pregnant women
- Patients who are unable to give informed consent
- Patients with concomitant non-zygomatic facial fractures (including orbital floor fractures) or bilateral zygomatic fractures
- Patients who do not wish to be part of the study

If a patient fulfils the criteria to participate in the trial, they will be informed verbally of what the trial involves, the risks associated with it and their role. They will also be given written information regarding the trial, risks involved and all of their rights, including the ability to withdraw at any stage. If the patient is happy to participate, they will be given a consent form to complete. The aforementioned tasks of obtaining informed consent and recruiting patients to the trial will be completed by an oral and maxillofacial surgery registrar (training surgeon) or consultant (surgeon).

## Randomisation

The patients who are recruited to the trial will be randomised into two groups, intraoperative computed tomography scan (intervention) and no intraoperative computed tomography scan (control). The randomisation of the patient will be conducted by the oral and maxillofacial surgery department nurse, who will blindly select a table tennis ball from a container. The container will hold only two balls, with one ball having the word "intervention" and the other ball having the word "control" written on them. Whichever ball is selected by the nurse, is the group to which the patient is allocated.

## Blinding

The patients will not be informed of which group they are randomised to. Concurrently, the clinician assessing the radiographic reduction of the post-operative films will be blinded to which arm of the trial the patient has been allotted. The surgeon operating on the patient will not be blinded as this is impossible, given they will be witness to an intraoperative computed tomography scan being performed or not. The doctor assessing the patient in clinic at both one and six weeks post-surgery, will not be blinded to the group the patient has been apportioned. Blinding of this assessment would be extremely difficult as the doctor assessing the patient will be involved with the operation and hence know the allocated group. The clinician assessing the post-operative radiographic reduction will not perform any of the operations for the trial.

## **Study groups (control and intervention)**

The intervention group of the study will undergo a computed tomography scan during their operation for their ZMC or ZA fracture. This scan occurs after the fracture has been opened, reduced and fixated or in the case of an isolated zygomatic arch fractured, opened and elevated. Once the scan has been completed the surgeon will review the scan and decide if the reduction is satisfactory. If they are satisfied with the reduction, the incisions will be closed and the operation completed. If there are inaccuracies with the reduction, the fixation equipment will be removed and the fractured adjusted to the correct position. It is then left to the discretion of the surgeon to decide if they wish to have another intraoperative CT scan performed or if they are satisfied with the reduction clinically. Once the surgery is completed, post-operative radiographs will be performed prior to the patient being discharged home. These radiographs will include a submental-vertex view (SMV), a posterior-anterior face (PA face) view and occipitomental 15 degree and 30 degree views (OM15 and OM30).

Patients in the control group will undergo their relevant surgery as normal but will not have any intraoperative imaging performed. After completion of the surgery, control groups patients will undergo the same post-operative radiographs as described for the intervention group above. No other concomitant care or interventions are prohibited during the trial.

Surgical incisions for both groups are identical for both groups but at the discretion of the operating surgeon. Direct access to fracture sites is via the upper blepharoplasty incision, subtarsal incision, or upper buccal sulcus transoral incision. Elevation is either via a "Gillies" temporal incision or upper buccal sulcus incision.

All procedures will be performed by, or under the direct in theatre supervision of one of three Oral and Maxillofacial Specialist surgeons. All three have extensive experience in the management of facial trauma with a minimum of three hundred zygomatic complex fractures each.

## **Follow-up and Outcomes**

All patients within the trial will have post-operative SMV, PA face, OM15 and OM30 radiographs taken either on the day of surgery or the following day, prior to discharge. These radiographs will be assessed by a blinded oral and maxillofacial surgeon who will not be involved in any of the operations, pre or post-surgical clinical assessments. The reduction adequacy of the fractures will be based off of the radiographs and the quality of the reduction will be evaluated as "good", "fair" or "poor".

- Good: equivalent to pre-morbid
- Fair: minor discrepancy but unlikely to require reoperation
- Poor: major discrepancy, reoperation required

Patients in the trial who are undergoing ZMC open reduction and internal fixation will stay overnight in hospital and barring any complications, be discharged home day one post-surgery. Patients undergoing open reduction of their isolated zygomatic arch fracture will, unless there are any unforeseen complications, be discharged on the same day as surgery. All patients will be followed-up in the oral and maxillofacial surgery outpatient department at one and six weeks post-surgery. During these outpatient appointments, the registrar or consultant reviewing the patient will assess them for diplopia, surgical site scarring and facial profile restoration. These parameters will be graded by the OMFS registrar or consultant and their assessment will be recorded on a standardised form (Figure 2 and 3). The need for revision surgery at any timepoint until 3 months following the completion of the study and a number of other variables (see Figure 2 and 3 for a full list) will also be recorded on the form.

## **Data Collection, Management and Confidentiality**

Data from the post-operative radiographic assessments will be entered directly into the trial excel spreadsheet. All data recorded on the postoperative assessment forms (Figure 2 and 3) will be transferred to the trial excel spreadsheet. This excel file will be stored on a single, password-protected personal computer. At the completion of the trial, the excel spreadsheet will be transferred to a password-protected computer within the oral and maxillofacial surgery department at the RBWH. It will be stored on this computer for 15 years. All physical copies of the consent and post-operative assessment forms will be stored in a designated trial folder, which will be stored in the OMFS department, in a locked room at the Royal Brisbane and Women's Hospital. At the completion of the trial, this folder will remain in the OMFS department for 15 years. The final trial data set will only be accessible to the authors of the trial.

Patients names, date of birth, gender, address and occupation will not be included on any data being collected. Patients will only be identified by their unique record number (URN) otherwise known as a medical record or hospital record number. Prior to statistical analysis being performed, the URN's will be removed from the data pool.

## **Withdrawal**

Patients are entitled to withdraw from the trial at any stage. Their withdrawal will have no implications for their ongoing management. Any patient who elects to withdraw, will have their trial data deleted and this will not be used in the statistical analysis.

If trial participants fail to attend their one or six week follow-up appointments, any data previously recorded for them, will be included in the trial data and analysed accordingly.

## **Evaluation of outcomes**

A two sample t-test will be used for continuous variable analysis. A chi-square test will be used for categorical variable analysis and for all data, p-values of  $< 0.05$  will be considered significant. The software program SPSS will be used for all statistical analysis. A subgroup analysis based on the severity of the fractures will also be conducted. Patients will be analysed as per their treatment but non adherence will be considered in the final presentation of data. An interim analysis will be also be undertaken. There are no other audits of trial conduct planned.

## **Adverse Outcomes**

Any adverse outcomes involving trial participants such as surgical site infection, metalware infection, excessive bleeding, change in vision, death or common perioperative complications such as deep vein thrombosis, pulmonary embolism or pulmonary infections will be documented and treated accordingly. If warranted, referral to other medical specialist teams will be made. Post-trial care and compensation, if required, will be as per Queensland Health standard arrangements.

## **Power calculation**

An estimated 200 patients will be required for a sample size that will produce significant results. This is based on two-sided testing with a power calculation of 80% and is established from local department outcome estimates and results from studies by Van Hout et al, Hurrell et al and Van Den Bergh et al.<sup>10,15,16</sup> Post-operative radiographic reduction adequacy was the variable with the largest projected sample size necessary for a statistically significant result. The power calculation was performed by Dr Michael David, a biostatistician from the University of Queensland (UQ) School of Population Health.

Due to the low level of evidence available in the current literature, the sample size calculations may not be reliable and estimates were not possible for all variables being proposed in this study. Subsequently, a mid-study analysis will be conducted to more accurately assess the predicted sample size calculations. It is estimated that from the average number of yearly presentations of ZMC and ZA fractures at the RBWH, this study will take approximately 2 years to complete. If the mid-study analysis finds a statistically significant result, the study will potentially be terminated early. The decision to terminate the trial or continue after the mid-study analysis will be at the discretion of the study authors.

## **Ethical considerations**

The standard practice for post-operative assessment following a ZMC or ZA fracture at the RBWH is for a patient to have four plain radiographs (OM15, OM30; PA face and SMV). Occasionally post-operative CT scans are ordered in-lieu of plain films. In this study, the interventional group will receive an intra-operative CT scan and the control group will not receive any intraoperative imaging. Both groups will have four plain radiographs taken post-operatively. It is estimated that the interventional group will receive 1.5millisieverts (mSv) and the control groups will receive 0.4mSv of ionising radiation. The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), a department of the Australian Government, estimates that a domestic airline pilot will be exposed to 2mSv of cosmic radiation per year.<sup>17</sup> ARPANSA also states that there is “no direct evidence

of human health effects” up to 10mSv of ionising radiation.<sup>17</sup> As such, the increased dose of radiation to the interventional group is not considered harmful to the patient and by performing post-operative radiographs on both groups, blinding of the assessing surgeon is made possible. If the results of the study show that intraoperative CT scans should be used for ZMC/ZA fracture management, the need for post-operative imaging would be eliminated, thus reducing the radiation exposure further. This is supported by a paper published by Van Hout et al, which states that “intraoperative imaging rarely increased patient exposure to ionizing radiation as the intraoperative imaging obviates postoperative imaging.”<sup>10</sup>

The use of intraoperative CT scan in the interventional group, is likely to increase the overall operative time for these patients. It is estimated that intraoperative CT scan will increase the operation duration by ten minutes.

## Discussion

Surgical management of ZMC and ZA fractures can be complex and challenging due to a number of factors. Visualisation of the fractures is frequently difficult due to the aesthetically sensitive region of the body and critical structures such as the facial nerve. This study aims to determine if better visualisation of the fractures through intraoperative CT scans, will improve fracture reduction and post-operative clinical outcomes. As with all therapies and adjunctive treatments in medicine, the risks and benefits to the patient and cost to the health care system must be considered in earnest. Computed tomography scans do increase the radiation exposure to the patient, albeit by a margin that is considered well below internationally recognised harmful levels. In addition, the act of performing a CT scan will increase operative time. Theatre time is an incredibly valuable and expensive resource with mean costs estimated to be approximately \$US37 per minute.<sup>18</sup> Consequently, the implementation of any device that consumes more of this precious resource must be evaluated judiciously and proven to be of benefit prior to any recommendation of regular and widespread use. Conversely, inadequate ZMC and ZA fracture reduction can result in poor cosmetic and functional outcomes for patients.<sup>19,20</sup> The personal harm to patients of a poor fracture reduction and the financial burden placed on hospitals when revision surgery is required cannot be underestimated. As there are no level 1 evidence studies published to answer all of these aforementioned questions, we feel that this randomised controlled trial is of significant importance in the future management of zygomaticomaxillary and zygomatic arch fractures.

## Trial Status

The final version of the trial protocol is dated 5<sup>th</sup> April 2016. Recruitment for the trial began in August 2016 and is estimated to finish in September 2019.

## List Of Abbreviations

*CT* Computed tomography *ZMC* zygomaticomaxillary complex *ZA* zygomatic arch *RBWH* Royal Brisbane and Women’s Hospital *ARPANSA* Australian Radiation Protection and Nuclear Safety Agency *RCT* randomised controlled trial *NHMRC* Nation Health and Medical Research Council *SMV* submental vertex *PA* posterior anterior *OM15* occipitomenital 15 degrees *OM30* occipitomenital 30 degrees *OMFS* oral and maxillofacial surgery *mSv* millisievert *UQ* University of Queensland

## **Declarations**

## **Acknowledgements**

The authors would like to thank Mrs Su Smyth and Ms Pamela Patel for their assistance in coordinating theatre allocations and admissions for trial patients. The authors would also like to thank all of the maxillofacial surgery registrars and residents of the RBWH who have assisted with the trial.

## **Funding**

The costs of treating all patients involved with the trial will be covered by The Royal Brisbane and Women's Hospital (Queensland Health), who are solely owned and operated by the State Government of Queensland. There are no sponsors and no other funding sources for this trial. The Royal Brisbane and Women's Hospital and Queensland Health will have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

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## **Availability of Data and Materials**

The data collected during the trial will not be made publicly available. At the completion of the trial, the results will be published in full, in a peer-reviewed journal.

## **Authors Contributions**

MH and MB designed the study. AH is responsible for recruitment of patients, collection and storage of the data, drafting of the manuscript and is the principle investigator of the trial. MB is responsible for drafting of the manuscript and analysis of the post-operative radiographs. RH and GF are responsible for operating on the patients in the study. MD is responsible for statistical analysis of the data. All authors read and approved the final manuscript. No professional writers have been used to complete this protocol.

## **Ethics Approval and Consent to Participate**

The study was approved by the Royal Brisbane and Women's Hospital Human Research Ethics Committee (reference number HREC/16/QRBW/18) 27<sup>th</sup> July 2016 prior to recruitment of patients. Please see Figure 4 for

an example of the consent form used in this trial. Informed consent will be obtained from all study participants, prior to inclusion in the trial.

## Consent for Publication

Not applicable

## Competing Interests

The authors declare that they have no competing interests

## References

1. Huang W, Lynham A, Wullschlegler M. Orbitozygomatic Fracture Repairs: Are Antibiotics Necessary? *Craniomaxillofac Trauma Reconstr.* 2015;8(4):271-6.
2. Ellis E, 3rd, Kittidumkerng W. Analysis of treatment for isolated zygomaticomaxillary complex fractures. *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons.* 1996;54(4):386-400.
3. Yang RS, Salama AR, Caccamese JF. Reoperative midface trauma. *Oral and maxillofacial surgery clinics of North America.* 2011;23(1):31-45.
4. Kloss FR, Stigler RG, Brandstatter A, Tuli T, Rasse M, Laimer K, et al. Complications related to midfacial fractures: operative versus non-surgical treatment. *International journal of oral and maxillofacial surgery.* 2011;40(1):33-7.
5. Heiland M, Schulze D, Blake F, Schmelzle R. Intraoperative imaging of zygomaticomaxillary complex fractures using a 3D C-arm system. *International journal of oral and maxillofacial surgery.* 2005;34(4):369-75.
6. Maheedhar AV, Ravindran C, Azariah ED. Use of C-Arm to Assess Reduction of Zygomatic Complex Fractures: A Comparative Study. *Craniomaxillofac Trauma Reconstr.* 2017;10(1):35-43.

7. Morrison CS, Taylor HO, Collins S, Oyelese A, Sullivan SR. Use of intraoperative computed tomography in complex craniofacial trauma: an example of on-table change in management. *Craniofacial Trauma Reconstr.* 2014;7(4):298-301.
8. Stanley RB, Jr. Use of intraoperative computed tomography during repair of orbitozygomatic fractures. *Archives of facial plastic surgery.* 1999;1(1):19-24.
9. Singh M, Ricci JA, Caterson EJ. Use of Intraoperative Computed Tomography for Revisional Procedures in Patients with Complex Maxillofacial Trauma. *Plastic and reconstructive surgery Global open.* 2015;3(7):e463.
10. Van Hout WM, Van Cann EM, Muradin MS, Frank MH, Koole R. Intraoperative imaging for the repair of zygomaticomaxillary complex fractures: a comprehensive review of the literature. *Journal of cranio-maxillo-facial surgery : official publication of the European Association for Cranio-Maxillo-Facial Surgery.* 2014;42(8):1918-23.
11. Wilde F, Lorenz K, Ebner AK, Krauss O, Mascha F, Schramm A. Intraoperative imaging with a 3D C-arm system after zygomatico-orbital complex fracture reduction. *Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons.* 2013;71(5):894-910.
12. Shaye DA, Tollefson TT, Strong EB. Use of intraoperative computed tomography for maxillofacial reconstructive surgery. *JAMA facial plastic surgery.* 2015;17(2):113-9.
13. Hoffmann J, Krimmel M, Dammann F, Reinert S. [Feasibility of intraoperative diagnosis with a mobile computed tomography scanner]. *Mund Kiefer Gesichtschir.* 2002;6(5):346-50.
14. Imai T, Michizawa M, Fujita G, Shimizu H, Ota Y, Kitamura T, et al. C-arm-guided reduction of zygomatic fractures revisited. *The Journal of trauma.* 2011;71(5):1371-5.

15. Hurrell MJ, Borgna SC, David MC, Batstone MD. A multi-outcome analysis of the effects of treatment timing in the management of zygomatic fractures. *International journal of oral and maxillofacial surgery*. 2016;45(1):51-6.
16. Van den Bergh B, Goey Y, Forouzanfar T. Postoperative radiographs after maxillofacial trauma: Sense or nonsense? *International journal of oral and maxillofacial surgery*. 2011;40(12):1373-6.
17. Australian Radiation Protection and Nuclear Safety Agency. Fact Sheet – Ionising Radiation and Health. 2015.  
<https://www.arpsa.gov.au/sites/default/files/legacy/pubs/factsheets/IonisingRadiationandHealth.pdf>. Accessed 17 Jan 2016.
18. Childers CP, Maggard-Gibbons M. Understanding Costs of Care in the Operating Room. *JAMA surgery*. 2018;153(4):e176233.
19. Zhang X, Ye L, Li H, Wang Y, Dilxat D, Liu W, et al. Surgical navigation improves reductions accuracy of unilateral complicated zygomaticomaxillary complex fractures: a randomized controlled trial. *Scientific Reports*. 2018;8(1):6890.
20. Lee EI, Mohan K, Koshy JC, Hollier LH, Jr. Optimizing the surgical management of zygomaticomaxillary complex fractures. *Semin Plast Surg*. 2010;24(4):389-97.

## Figures



## Intra-op CT RCT – Post-op Assessment

Unique Record Number (Hospital I.D.): \_\_\_\_\_

Age at surgery (years): \_\_\_\_\_

Date of injury: \_\_\_\_\_

Date of surgery: \_\_\_\_\_

Length of surgery (In Proc Time – Out Proc Time, RBWH Operation Report)(mins): \_\_\_\_\_

Number of intra-operative CT scans taken: \_\_\_\_\_

### Group:

- Control       Intervention

### Diagnosis:

- Zygomatic arch fracture
- ZMC fracture without significant orbital involvement
- ZMC fracture with significant orbital involvement

### Surgical treatment:

- Elevation only
- Elevation + ORIF
- 1 site    2 sites    3 sites    4 sites

### Surgical Incision site/s:

- Temporal (Gillies)
- Transoral (Keen)
- Superolateral orbital rim
- Lower eyelid
- Coronal
- Other: \_\_\_\_\_

### Surgical incision scarring at week 1:

- No scarring visible, specify site/s: \_\_\_\_\_

## Figure 2

Intra-op CT RCT - Post-op Assessment pt 1

Scarring detectable but acceptable, specify site/s: \_\_\_\_\_

Scarring unsatisfactory, specify site/s: \_\_\_\_\_

**Surgical incision scarring at week 6:**

No scarring visible, specify site/s: \_\_\_\_\_

Scarring detectable but acceptable, specify site/s: \_\_\_\_\_

Scarring unsatisfactory, specify site/s: \_\_\_\_\_

**Facial profile restoration at week 1:**

Ideal facial profile

Facial profile restoration not ideal but acceptable

Facial profile restoration unsatisfactory

**Facial profile restoration at week 6:**

Ideal facial profile

Facial profile restoration not ideal but acceptable

Facial profile restoration unsatisfactory

**Post-operative diplopia at week 1:**

No diplopia

Diplopia clinically present with no functional limitations

Diplopia clinically present with functional limitations

**Post-operative diplopia at week 6:**

No diplopia

Diplopia clinically present with no functional limitations

Diplopia clinically present with functional limitations

**Need for revision surgery**

Yes

No

### Figure 3

Intra-op CT RCT - Post-op Assessment pt 2

# CONSENT FORM

A randomized controlled trial evaluating the effects of intra-operative (Computed Tomography) CT on the outcomes of zygomatic fractures

Oral and Maxillofacial Unit, RBWH

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person Taking Consent  
(If different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

1 copy for patient, 1 copy for research, 1 copy to be kept with hospital note  
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## Figure 4

Consent form

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [supplement1.doc](#)

- [supplement2.docx](#)