# PREVALENCE OF ORBITAL FLOOR RECONSTRUCTION IN ZYGOMATICOMAXILARY COMPLEX FRACTURES

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A research report submitted in partial fulfilment of the requirements for the degree of Master of Science in Dentistry to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg.

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### DECLARATION

I, Muhammad Sikander Gani, declare that this research report is my own work. It is submitted for the degree of Master of Science in Dentistry to the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Signed

..... day of ..... 2019

### ABSTRACT

#### **INTRODUCTION**

Zygomaticomaxillary Complex (ZMC) fractures are a common phenomenon and tend to cause functional and aesthetic problems. Orbital wall involvement is commonly associated with ZMC fractures. There is a lack of consensus regarding the best surgical approach to these fractures. Many surgeons prefer a transcutaneous lower eyelid approach to the infraorbital rim approach with exploration of the internal orbit whereas others prefer to avoid it and use a transconjunctival approach to the internal orbit only if necessary. Avoiding the transcutaneous approaches and unnecessary exploration of the internal orbit results in fewer lower eyelid complications. The current trend is a minimally invasive approach to limit skin incisions and thus minimise external scars. This study aims to determine the prevalence of orbital wall reconstruction in ZMC fractures over a seven-year period (1 January 2010 to 31 December 2016) at the Charlotte Maxeke Johannesburg Academic Hospital.

#### **METHODS AND MATERIALS**

This study included 150 patients with isolated ZMC fractures at the Charlotte Maxeke Johannesburg Academic Hospital from 1 January 2010 to 31 December 2016. Isolated zygomatic arch fractures and multiple facial fractures that included the zygoma were excluded. Data on gender, age, aetiology, orbital fractures, and reconstruction, as well the surgical approaches and treatment were recorded.

#### RESULTS

A total of 128 patients were male (85.31%) and 22 were female (14.67%) with a male to female ratio of 5.81:1. The ZMC fractures occurred mainly in the third decade (74 cases, 49.33%) of life with the left side being involved in 83 (55.37%) and the right side in 67 (44.67%) cases. Interpersonal violence (63%) was the main cause followed by road traffic accidents (34%). Orbital fractures were reported in 47 (31%) patients and orbital reconstruction was performed in 39(26%) patients. A statistical significance was noted with the infraorbital approach and orbital reconstruction. The majority of the patients (44%) had three surgical approaches (transoral maxillary vestibular, lateral brow, and infraorbital approaches) with 3-point fixation (46%).

#### CONCLUSIONS

Males comprised the majority of the patients in this study. The mean age was 31.5 years. A correlation between the infraorbital approach and orbital reconstruction showed that majority of the patients had transcutaneous approaches to the infraorbital rim even though orbital reconstruction was not required. This study shows that the international trends or protocols are not followed when treating ZMC fractures at this facility.

### **DEDICATION**

### "In the name of God, the most gracious, the most kind"

I would like to dedicate my work to my parents who nurtured me and raised me.

And most of all to my wife Mahnaaz and our son Isa for their unconditional love, support, understanding, and sacrifice. Without them, this would not be possible.

### ACKNOWLEDGEMENTS

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#### **INTRODUCTION AND LITERATURE REVIEW**

#### **1.1 APPLIED ANATOMY**

The word zygoma is derived from the word meaning *yoke* (i.e. a structure that connects various parts together).<sup>1</sup> The zygoma (cheek bone) is a quadrangular paired bone in the midface and occupies a key position in the anterolateral aspect of the face, contributing to set the midface width, and to define the shape and contour of the inferior and lateral orbital borders as well as the cheek prominence.<sup>2</sup> It lies on the inferolateral side of the orbit and rests on the maxilla. It forms the anterolateral rim, lateral wall, floor, and much of the infraorbital margin of the orbit. Furthermore, it forms parts of the temporal and infratemporal fossa. The zygomatic bone (See Figure 1.0 below) articulates with the frontal, sphenoid, temporal, and maxillary bones and forms the frontozygomatic (FZ), sphenozygomatic (SZ), zygomaticotemporal (ZT), and zygomaticomaxillary (ZM) sutures respectively.<sup>2</sup>

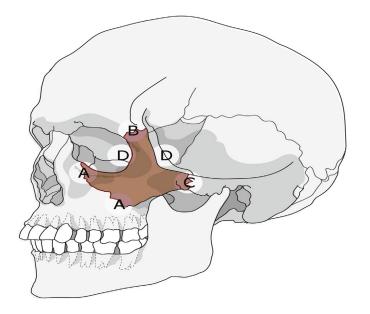


Figure 1.0: Zygomatic bone articulations: A, maxilla; B, frontal bone; C, temporal

bone; D, sphenoid bone.<sup>3</sup>

The zygomatic bone together with the greater wing of the sphenoid bone form the lateral orbital wall. The zygomatic bone and maxillary bone contribute to the formation of the floor of the orbit.<sup>4</sup>

#### **1.2 ZYGOMATICO MAXILLARY (ZMC) FRACTURES**

Zygomaticomaxillary complex fractures (ZMC) are the second most common fractures of the face and predominantly occur in males in the second and third decades of life.<sup>5,6</sup> The zygoma forms part of the important buttress system of the face between the maxilla and the skull. However, despite its strength and sturdiness, it is prone to fracture due to its prominent convexity and location. These fractures may occur as isolated ZMC fractures or in combination with Le Fort fractures as well as severe frontal bone fractures.<sup>7</sup> ZMC fractures are generally caused by a direct blow to the malar eminence. This may be as a result of interpersonal violence, road traffic accidents, sports injuries and falls. Moderate force may result in minimally or nondisplaced fractures at the suture lines. More severe forces result in medial, inferior, and posterior displacement of the ZMC. Comminuted fractures of the body and fractures at the suture lines are generally caused by high velocity motor vehicle accidents.

In general, displaced fractures involve the zygomaticomaxillary buttress, zygomaticofrontal suture, infraorbital rim and floor, as well as the zygomatic arch. When all four pillars of the zygoma are fractured, it is known as a tetrapod fracture. However, an isolated depressed zygomatic arch fracture may occur due to a direct blow to the arch.<sup>5</sup> In clinical practice, ZMC fractures are associated with orbital floor

fractures, although isolated orbital floor fractures may also occur such as pure blowout fractures.<sup>8,9</sup> The prevalence of the involvement of orbital floor fractures in ZMC fractures ranges between 5.5% to 68%.<sup>10-12</sup>

ZMC fractures are relatively rare in the paediatric population. This may be explained by the lack of pneumatisation of the paranasal sinuses, the immaturity of bone with an increased cancellous to cortical bone ratio and flexibility of osseous suture lines. Furthermore, the presence of tooth buds in the maxilla and thicker adipose tissue cushion the impact. In addition to the above, the relatively large size of the cranium and mandible provide protection to the midface.<sup>13-15</sup>

#### **1.3 CLASSIFICATION OF ZMC FRACTURES**

"There is no universal consensus on the classification of Zygomaticomaxillary Complex (ZMC) fractures. Several classifications have been proposed for these fractures due to a myriad of fracture patterns obtained which reflect the complex nature of construction of these bones. The objectives of these classifications were to help formulate clinical guidelines for patient management."<sup>1</sup>

Several classifications for ZMC fractures have been proposed in the literature. These include the Zing, Ellis, Henderson, Rowe and Killey, Larson and Thompson classifications.<sup>5</sup> None of the systems are accepted universally and most of them are based on the site of the fracture as well as its degree of comminution and displacement, whether inferior, medial, or posterior.<sup>16,38</sup>

Van Hout et al. used a few classification systems and came up with this simplified one.9

They classified the fractures as type A, B, and C based on the energy of injury and the degree of dislocation or comminution:

- "A Incomplete fractures low energy fractures in which at least one pillar of the ZMC remains intact.
- B Tetrapod Fractures All four pillars of the ZMC are fractured.
- C High energy fractures, the ZMC is divided into 2 or more fragments by additional fractures through the lateral orbit, infraorbital rim or zygomatic body."<sup>9</sup>

Orbital wall fractures may be classified as isolated or combined when it is associated with a ZMC fracture.<sup>10</sup>

#### **1.4 SIGNS AND SYMPTOMS**

All patients who sustain midfacial fractures are initially attended to in the emergency and trauma centre of the hospital. They are managed according to the advanced trauma and life support (ATLS) protocols. Once the patient is stabilised, the secondary survey includes a detailed maxillofacial examination. This examination would include inspection and palpation of the fractures.<sup>1</sup> ZMC fractures are a common phenomenon and can present with a wide range of signs and symptoms depending on the kinetic force that caused the resultant damage.<sup>9,18</sup>

Periorbital ecchymosis, oedema, and subconjunctival haemorrhage are common signs of ZMC fractures.<sup>1,19</sup> This is caused by disruption of the orbital septum and thus bleeding into and around these tissues.<sup>19</sup> Posterior and inferior displaced fractures will result in depression of the malar eminence (loss of projection) and thus midfacial widening. Fractures that involve the floor of the orbit may result in hypoesthesia in the distribution of the infraorbital nerve. Dystopia, decreased ocular movement, and binocular diplopia may be present if the extra ocular muscles/tissues get entrapped into the fracture lines or the maxillary sinus. Disruption of the bony orbit generally results in herniation of the orbital contents and an increase in the orbital volume which results in the clinical sign of enophthalmos. Inferior displacement of the zygoma results in an antimongoloid slant of the palpable fissures and steps around the orbital rim and buttress. Limited mouth opening (trismus) may be present when the arch is fractured and impedes on the coronoid process or as a result of muscle injury. Furthermore, trismus may be due to a severely posteriorly displaced ZMC fracture with the malar eminence encroaching on the coronoid process.<sup>8,17-19</sup>

#### **1.5 ZMC FRACTURE TREATMENT**

The aims of treatment of zygomatic complex fractures include the restoration of normal facial contour and height, normal sensory nerve function, normal globe position, and normal masticatory function.<sup>37</sup>

A thorough ophthalmologic examination is required to evaluate and document ocular status. If a ruptured globe, retinal detachment, or traumatic optic neuropathy exists, treatment of these supersedes repair of the ZMC fracture.<sup>20,22</sup>

Literature suggests that Computer Tomography (CT) is the gold standard in imaging for diagnosing ZMC fractures.<sup>12,24,25</sup>However, many authors use plain radiographs such as the submentovertex and occipitomental views to assist in the management of these fractures.<sup>12</sup> Conventional radiographs are more cost effective and expose the patient to less radiation.<sup>12</sup> CT should be used when one suspects comminuted orbital floor fractures or type C fractures. Cone Beam Computer Tomography (CBCT) has gained

popularity in recent times as it is more cost effective than CT and the radiation dose significantly lower. The area of focus can be narrowed down and thus one may be able to assess the ZMC with the internal orbit in a 3D image. There is a pendulum shift to use a CBCT for all ZMC fractures. Intraoperative CT scans have gained popularity in recent times and have been used frequently in first world countries. It allows one to be less invasive when treating ZMC fractures as the adequacy of reduction can be visualised on the CT scan.<sup>8,9</sup> Thus, the surgeon will not have to use additional approaches to determine the adequacy of the reduction. Furthermore, the need for internal orbital reconstruction can be determined intraoperatively using the CT scan after reduction of the zygoma has been completed.<sup>8</sup> Van Hout et al. have stated that the use of intraoperative CT scan is likely to improve the treatment outcome in type C fractures.<sup>9</sup> However, not all ZMC fractures require an intraoperative CT scan.

The goal of treatment of ZMC fractures is 3-point alignment and 2-point fixation. Those that involve the orbit, the goal is to repair the orbital floor and release the entrapped extraocular muscle/tissues and establish orbital volume and globe position.<sup>21,35,37</sup>

The literature indicates that 10-50% of all ZMC fractures require conservative management, which includes a soft diet for 2-6 weeks and analgesics.<sup>37</sup> This applies where there is minimal or no displacement of the fractures and when there are no functional or cosmetic defects.<sup>8,23,37,39</sup>

Treatment varies amongst surgeons around the world. The differences are due to training and expertise as well as the influence of literature.<sup>8,37</sup> Some surgeons routinely expose 3 or 4 articulations to reduce and stabilise the fractured segments, irrespective

of the degree of displacement and amount of internal orbital disruption.<sup>8,35</sup> Traditional teachings advocate 3-point fixation for ZMC fractures based on mechanical studies (i.e. fixation at the zygomaticomaxillary buttress, infraorbital rim, and FZ suture).<sup>21,35,37</sup> Ji et al. found in their study of 502 ZMC fractures, that 2-point fixation was used in 72% of cases and 3-point fixation in only 11% of their cases.<sup>42</sup>

The type, number and location of fixation will be determined by the fracture pattern and degree of displacement as well as the surgeon's preference.<sup>8,37</sup> Ellis and Kittidumkerng have found that with proper reduction and stabilisation, there were no differences in the presence of post reduction displacement related to the number of plates used.<sup>18,37</sup>

Mild cases, such as a Type A fractures, may be treated with a minimally invasive approach.<sup>8,38</sup> The fracture can be reduced via an extraoral or intraoral approach using a Gillies temporal incision or maxillary vestibular incision respectively. If fixation is necessary, one miniplate may be used at the zygomaticomaxillary buttress area. Type B and C fractures may require several surgical approaches to both the zygoma and the orbital floor with fixation at multiple sites and reconstruction of the orbital floor if required.

However, literature suggests that there is a lack of consensus regarding the best surgical treatment of ZMC and orbital fractures.<sup>12,37</sup> Some authors prefer an intraoral approach with fixation at the ZM suture only,<sup>8</sup> while others perform a second point of fixation at the FZ suture.<sup>3,12</sup> However, the majority prefer the transcutaneous lower eyelid and the lateral brow approach with fixation at the infraorbital rim and FZ suture respectively,

and exploration of the internal orbit and repair if necessary.<sup>12</sup> Marinho and Freire-Maria<sup>3</sup> stated that the FZ and ZM buttress should be the first choices of fixation because they are the main points of stability in reconstructing the vertical buttresses of the face. They further stated that the infraorbital rim should be fixated as an addition in more unstable fractures.<sup>3</sup>

The goal of treating an orbital floor fracture is covering the bony defect and preventing the prolapse of orbital tissues into the maxillary sinus as well as maintaining orbital volume. This will result in the restoration of function and aesthetics.<sup>27,28</sup>

The orbital floor is always involved in ZMC fractures but it is not always necessary to explore and reconstruct it.<sup>37</sup> Ellis and Perez stated that the need for orbital wall reconstruction in ZMC fractures is 44%.<sup>8</sup> However, there is a lack of consensus regarding the objective criteria for exploration of the orbital floor and or its repair.<sup>37</sup> In some studies, the orbital floor was explored in 20% of the cases of ZMC fractures<sup>10</sup> while in others it was explored in 100% of ZMC fractures.<sup>12</sup> However, the orbital floor was not reconstructed in all the cases that were explored. Some studies revealed that 20% of the cases had the orbital floor explored but only 16% of them had an orbital floor reconstructed.<sup>10</sup> While others had the orbital floor explored in 58% of the ZMC fractures and an orbital floor exploration in ZMC fractures did not state if it was reconstructed or not.<sup>7</sup> Some studies showed that the orbital floor exploration and reconstruction was performed in 5, 71% of patients with ZMC fractures as a second surgery as the orbital fractures were not diagnosed before the first surgery.<sup>12</sup>

Marinho and Freire-Maia <sup>3</sup> have stated that surgical exploration of the orbital floor should be performed when the following signs and symptoms are present:

- Non-resolving oculocardiac reflex
- Primary diplopia
- Mechanical entrapment of the extraocular muscles
- Large defects (greater than 2cm<sup>3</sup>)
- Comminution at the infraorbital rim
- CT scan evidence of the need to reconstruct the orbital floor or walls.

Therefore, routine orbital floor exploration is unnecessary and should only be performed when indicated.<sup>3,37,39</sup>

An important and controversial factor in the treatment of orbital fractures is the choice of the material used for reconstruction.<sup>29,30,33</sup> There are a variety of materials that are used which fall into the categories of autogenous grafts, autologous and xenografts, grafts and alloplastic materials.<sup>30,33</sup>

Autogenous grafts include bone and cartilage from donor sites of the same individual. Autogenous bone grafts have been considered the "gold standard" in orbital fracture repair by many surgeons around the world.<sup>29,31,32</sup> Potential donor sites include the calvarium, iliac crest, mandibular symphysis, maxilla and ribs.<sup>28,30,32</sup> They are useful because of their biocompatibility, strength, osteogenic, osteoinductive and osteoconductive potential.<sup>28,31</sup> Moreover, they are resistant to infection, are not rejected and give good structural support.<sup>31</sup> Because autologous bone grafts are incorporated as living tissue and do not elicit an immune reaction to self-antigens, foreign body reactions such as infection, extrusion, capsule formation and ocular tethering are minimised.

The main disadvantage is donor site morbidity such as pain, haematoma, scarring, infection and other complications related to an additional site of surgery.<sup>28,30,31,33</sup> Furthermore, there is an increase in the surgery time, they have variable resorption rates with suboptimal volume correction and it is difficult to contour the grafts into the appropriate shape.<sup>28,30-32</sup>

Autogenous cartilage is another option in orbital floor reconstruction with the same advantages of autogenous bone grafts with regards to biocompatibility.<sup>31,32</sup> Potential sites of cartilage are the nasal septum, auricular cartilage, nasal concha and rib cartilage.<sup>31</sup> Cartilage has a favourable application due to the ease of access, harvesting, malleability and reliable support with less resorption compared to autogenous bone.<sup>31</sup> Furthermore, cartilage has characteristics that include a low anaerobic metabolism and relative avascularity.<sup>32</sup> This allows cartilage grafts to survive with a minimal requirement for oxygen perfusion, thereby improving graft viability and reducing resorption rates.<sup>31</sup>

The main limiting factor of cartilage is donor tissue availability and, thus, it should only be used in small orbital floor defects.<sup>31,32</sup>

Allografts are transplanted tissues such as demineralised (banked) bone or lyophilised dura mater from another human being.

The advantages of allografts include preoperative customisability, decreased operation time, and the absence of donor site morbidity if harvested from a cadaver. Furthermore, demineralised (banked) human bone is available in abundance.<sup>31</sup> Lyophilised dura was used frequently in the past for small orbital floor defects because of its biocompatibility

(lack of tissue reaction) and strength.<sup>31-33</sup> It has become a controversial material of recent times due to the fact that there were reported cases of disease transmission with these transplants.<sup>31,33</sup>

The main disadvantage of allografts is their resorption rate is substantially higher than that of autogenous bone and cartilage.<sup>32</sup> Furthermore there is a risk of viral transmission, such as HIV and the Hepatitis C Virus as well as the need for immunosuppressive therapy.<sup>32</sup>

Xenografts are transplanted tissue from a different species such a porcine bone.<sup>31</sup> However, xenografts are not recommended in orbital reconstruction because there is a high risk of disease transmission, immunological reactions, and transplant rejection as well as high and unpredictable resorption rates.<sup>33</sup>

There are a variety of synthetic (alloplastic) materials available with the advantages of a decreased operation time, no donor site morbidity and availability in abundance. While most the alloplastic materials are well tolerated by the recipient, complications such as infection, extrusion, and inappropriate adaptability and contour do occur. <sup>33</sup>The choice of the material is generally determined by the cost, preference and experience of the surgeon.<sup>27, 31</sup>

Alloplastic implants can be either resorbable or nonresorbable (metallic or nonmetallic).

Nonresorbable, non-metallic implants include silicone, nylon, polyethylene sheets, bioactive glass and many others. All these materials are used in orbital floor reconstruction with great success.<sup>30, 31</sup> However, they all have drawbacks.

Silicone implants have been used for many years due to its attractive properties,

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including biological inertness, ease of handling, flexibility and low cost.<sup>32</sup> However, over the years some studies have reported unacceptable incidence rate of various silicone implant related complications such as, infection, extrusion, infra-orbital cyst formation, and implant displacement.<sup>31,32</sup>

Polyethylene, also commonly known as MEDPOR®, <sup>32</sup> has been used successfully over the past three decades.<sup>31</sup> They can be easily adapted and contoured to the orbital floor defect. The presence of pores promotes tissue growth and implant vascularisation, it also reduces foreign body reactions and capsule formation. Most studies report porous polyethylene sheets to be more suitable than other alloplastic materials in orbital floor reconstruction.<sup>31</sup> Many studies have reported very low complication rates with this material but Fialkov et al have registered higher infection rates when compared to other alloplastic materials.<sup>17</sup>

Nylon is a relatively new material used in orbital reconstruction with reports of low complication rates. It has been advocated in the use of small orbital floor defects.<sup>31-34</sup>

Bioactive glass has been used for many years in orbital reconstruction with great success and minimal complications. However, its brittle nature makes it difficult to contour to the defect and thus should only be used in small orbital floor defects.<sup>31,32</sup>

Titanium mesh is the most popular nonresorbable, metallic implant used in orbital floor reconstruction as well as in other forms of dental and maxillofacial surgery.<sup>28,31,34</sup> Titanium is highly biocompatible and has the ability to oseointegrate and incorporate into the surrounding tissues. Its mechanical properties and other properties make it an attractive material for reconstructing large orbital defects.<sup>31,34</sup> Guo et al. compared the effectiveness between calvarial bone and individual prefabricated titanium mesh in the reconstruction of orbital floor fractures. Their study revealed that individual digitally

designed titanium mesh was more accurate than calvarial bone.47

Titanium implants may be difficult to remove due to its mesh structure and the possible ingrowth of fibrous tissue. Furthermore, the implant may be traumatically driven back to the orbital apex causing injury to the optic nerve.<sup>29</sup>

Another disadvantage of titanium implants, especially computer specific designed, is the high cost.<sup>31,33</sup>

Resorbable materials offer the benefits enjoyed by alloplasts, but theoretically eliminate a chronic foreign body reaction and long term sequelae.<sup>32</sup>

Resorbable implants include polydioxanone (PDS), polylactides, polyglycolic acid, and some others. Complete resorption occurs from 3 months up to a few years later. To date, bioresorbable materials used for orbital reconstruction still have a variable incidence of delayed tissue reaction after implantation.<sup>30</sup>

The main drawback of the available resorbable materials is that they are unable to provide adequate support for new bone formations, with the resultant scar being too weak to support the overlying orbital tissue and contents. Furthermore, the smooth surface of these implants makes them prone to the formation of a fibrous capsules, thus resulting in capsule related complications.<sup>30,33,34</sup>

Becker et al considered resorbable implants suitable in reconstructing small orbital fractures (<2 mm), whereas the use of non-absorbable materials was suggested for large defects.<sup>48</sup>

Dubois et al. <sup>33</sup> have proposed a treatment algorithm for orbital wall fractures based on the reconstruction material

- "Small-sized, low-complexity defects: Most materials are suitable, biological behaviour is most important and resorbables may be used in these cases.
- Medium sized, medium complexity defects: Apart from the biological behaviour of an implant, the experience of the surgeon with specific types of orbital implants will benefit the outcome. Various materials can be used, from autologous materials to alloplasts.
- Large sized, high complexity defects: Stability and contour become more significant, and pre-bent or patient specific titanium mesh is the preferred reconstruction material." <sup>33</sup>

#### **1.6 APPROACHES FOR OPEN REDUCTION AND INTERNAL FIXATION**

Ideal surgical access should provide maximum necessary exposure of the fractured segments, minimise potential injury to facial structures and enable good cosmetic results.<sup>18</sup>

Several approaches for open reduction and internal fixation of ZMC fractures with internal orbital exploration and or repair have been described in the literature, with the most common incisions being the transoral maxillary vestibular approach, lateral brow, upper eyelid (blepharoplasty) incision, transcutaneous lower eyelid approaches (subciliary, subtarsal and infra orbital), and the transconjunctival approach with/without canthotomy.<sup>8,41,45</sup> Existing scars or lacerations would influence the transcutaneous incisions and thus one may opt to use them as the direct approach.

The transoral maxillary vestibular approach is safe, rapid, and an effective technique for the reduction of the zygomatic body and arch fractures.<sup>39,44</sup> The advantages of this approach are:

- No skin scar
- Closer and more precise application of force by the operator
- Simplified antral bone harvest if needed
- Simple mucosal closure.<sup>44</sup>

Some studies advocate the use of the transoral approach to access the infraorbital rim, but it appears to be a rare technique.<sup>35,37</sup>

The most commonly used surgical approach to access the infraorbital rim and internal orbit is via a transcutaneous lower eyelid skin incision.<sup>45</sup> Bartoli et al.<sup>10</sup> have reported that the lower eyelid approach was used in 76% of patients with ZMC fractures. Some authors prefer the subciliary approach as they feel it's quick, provides full access to the infraorbital rim and orbital floor and allows for easy identification of the important eyelid structures.<sup>43</sup> Choung and Kaban stated that this approach should be used when there is evidence of enophthalmus, a positive forced duction test and evidence of comminution at the infraorbital rim.<sup>26</sup>

The transconjunctival approach has gained popularity over the past two decades due to the fact that there is a better cosmetic result when compared to the transcutaneous lower eyelid approaches and there is no evidence of a postoperative scar.<sup>41,43,45</sup> Furthermore,

it allows medial extension. However, most authors believe that it provides limited access to the floor of the orbit and thus should only be used when extensive fixation procedures are unnecessary.<sup>45</sup> The incision is made through the conjunctiva of the inferior fornix, from the caruncle medially to the lateral fornix, using a retroseptal approach to avoid dissection of the lower eyelid planes.<sup>21</sup> The criticism of limited exposure has been overcome by the addition of a lateral canthotomy.<sup>21,41</sup> The advantage of this addition is it provides a wide exposure of the infraorbital rim and orbital floor as well as exposure of the lateral orbital rim and FZ suture.<sup>41</sup> Therefore, there would not be a need for a lateral brow incision to access the FZ suture. However, the advantage of a non-visible skin scar is lost with the cathotomy.<sup>43</sup>

### **<u>1.7 COMPLICATIONS WITH APPROACHES TO THE INFRAORBITAL RIM</u>** AND ORBITAL FLOOR

Soft tissue deformities resulting from exposure in and around the orbit can be more noticeable than bony defects or malpositions treated. A decision to place an incision on the face should be carefully weighed to determine whether the benefit of that incision outweighs the potential complications that they may cause.<sup>8</sup> Transoral and upper lateral brow incisions very rarely create a noticeable deformity or scar.

Although the transcutaneous lower eyelid approach provides adequate access to the infraorbital rim and internal orbit, it results in many complications.<sup>41,43</sup> Some of the postoperative complications related to these approaches are facial asymmetry, noticeable scars, enophthalmus, ectropion and entropion, and scleral show.<sup>41,43,45</sup> Most common complications from approaches to the orbital floor are lower eyelid malpositions (LLM).<sup>45</sup> Ellis and Perez have stated that lower eyelid malposition's occur

in up to 42% of lower eyelid approaches, whether it be a transcutaneous or transconjunctival approach.<sup>8</sup> Ridgway et al <sup>49</sup> reviewed the literature and found that the incidence of ectropion was highest in subciliary incisions (12,5%), followed by subtarsal (2,7%) and 0% in the TC incisions. Ishida revealed that complications resulting in lower eyelid deformity were at 6,9% after the subciliary approach and they used the transcutaneous lower eyelid approach as low as 16% of the time and the transconjunctival approach as high as 80% of the time.<sup>21</sup> As such, some clinicians seem to prefer the transconjuctival approach to the transcutaneous lower eye lid incision. Most surgeons agree that the subciliary and infraorbital approaches are good for training young surgeons.<sup>44</sup>

The transconjunctival approach might reduce the risk of postoperative complications but it is very technique sensitive. It requires meticulous care and surgical expertise.<sup>36</sup> Many studies show that the rate of complications with the transconjunctival approach is minimal when compared to other lower eyelid approaches.<sup>21,41</sup> However, when complications such as entropion occur, they are more difficult to correct and are more troubling to the patient.<sup>8,45</sup> If this approach involves a lateral canthotomy and the lateral canthus is not correctly reattached, the risk of entropion and lower eyelid malposition might be inevitable.<sup>45</sup>

Ellis and Perez<sup>8</sup> developed a protocol for treating ZMC fractures with the intention to minimise the number of surgical approaches. The first step was to determine if orbital floor reconstruction was required on a preoperative CT. If deemed unnecessary, then the reduction should be performed closed. If there is no stability, then a transoral approach to access the zygomaticomaxillary buttress should be the first surgical

approach. Then if further required, the lateral brow approach should be used. Following this stepwise approach minimises the number of surgical approaches and decreases the risk of lower eyelid complications as approaches to the infraorbital rim and floor are avoided.<sup>8</sup> The Amsterdam University protocol is very similar, but the difference is that the first choice of access is the FZ area via lateral brow incision.<sup>12</sup>

The current trend is a minimally invasive approach to limit skin incisions and thus minimise external scars. When the internal orbit requires exploration/repair, the transconjunctival approach has shown to be superior to the transcutaneous lower eyelid approach in terms of postoperative lower eyelid deformity and scars.<sup>21,40</sup> Ellis and Perez recommended that one should use approaches to the floor of the orbit only if necessary, and further stated that the goal should be to avoid incisions to expose the infraorbital rim and orbital floor, thus omitting iatrogenic cosmetic deformities.<sup>8,9</sup> Anecdotal evidence suggests that the transcutaneous lower eyelid approach is still used at Maxillofacial unit at the Charlote Maxeke Johannesburg Acadamic Hospital (CMJAH) with minimal complications except for a noticeable scar.

#### **1.8 SIGNIFICANCE OF THE STUDY**

The current literature suggests that approaches to the floor of the orbit should be used only when reconstruction of the orbit is going to be performed. This study seeks to determine the approaches used to manage ZMC fractures with special attention on the infraorbital rim and orbit and their indications. Secondly, this would be the first time that a study of this nature will be conducted in this unit.

#### **CHAPTER 2: AIMS AND OBJECTIVES OF THE STUDY**

#### AIM

To determine the prevalence of orbital floor reconstruction in patients with ZMC fractures.

#### **OBJECTIVES**

- To determine the mean age and gender of patients that were treated with ZMC fractures
- 2. To determine the frequency of orbital floor reconstruction in ZMC fractures
- **3.** To determine if there is a relationship between the use of the transcutaneous lower eyelid incision and orbital floor reconstruction

#### **CHAPTER 3: MATERIALS AND METHODS**

#### **3.1 STUDY DESIGN**

This research report is a retrospective, cross-sectional study of patients with ZMC fractures managed in the Maxillofacial and Oral Surgery (MFOS) unit of the CMJAH.

#### **3.2 DATA COLLECTION**

The sample size included all patients admitted and treated with the diagnosis of ZMC fractures over a seven-year period (1 January 2010 to 31 December 2016). Data was retrieved from the department of Maxillofacial and Oral Surgery's admission and theatre logbooks. The patients' records were then retrieved from the hospital's archives. A total of 150 patients' records were collected.

The data collected included the following:

- Patients' demographics (i.e. gender, age).
- Presence or absence of an orbital floor fracture
- Orbital floor reconstruction
- Surgical approaches used to treat the ZMC fracture
- Side of the ZMC fracture
- Points of fixation

#### **3.3 DATA ANALYSIS**

Descriptive statistical analysis was used to analyse the following:

- 1) The mean age and range of the patients
- 2) A definitive male: female patient ratio
- 3) The frequency of orbital wall reconstruction

#### 4) The frequency of surgical approaches and points of fixation

The Pearson test was applied to help determine the correlation between the infraorbital incision and orbital floor reconstruction.

The data was entered into a Microsoft Excel Spreadsheet and imported into Statistica version 12 (Statsoft U.S.A.) for statistical analysis. It was then presented in the form of pie charts, bar graphs, and tables.

#### **3.4 INCLUSION CRITERIA:**

• All patients admitted to ward 384 CMJAH with the diagnosis of ZMC fracture over the specified time period.

#### **3.5 EXCLUSION CRITERIA:**

- Patients with multiple facial fractures that include the zygoma
- Patients with isolated zygomatic arch fractures

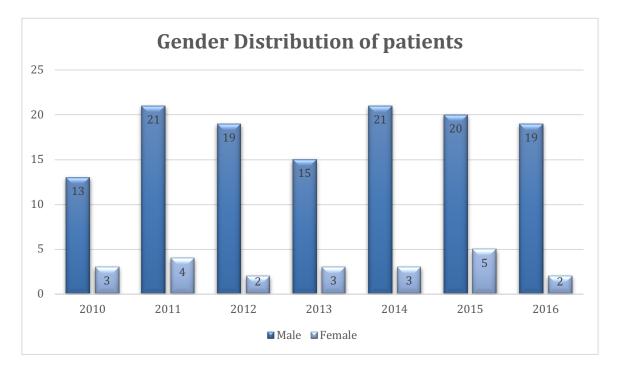
#### **3.6 ETHICAL CLEARANCE**

The permission to conduct this study was granted from the Human Research Ethics Committee (Medical) for the Faculty of Health Sciences, University of the Witwatersrand, who unconditionally approved the research protocol (Clearance Certificate Number M170735). Permission to use the patients' records at CMJAH and the Wits Dental hospital was granted from the CEO and Hospital Research Committee, and the School of Oral Health Science respectively.

#### **CHAPTER 4: RESULTS**

#### 4.1 GENDER

There were a total of 150 patients admitted with the diagnosis of zygomaticomaxillary complex (ZMC) fractures from 2010 to 2016. The majority of these patients were male 128 (85,33%), while only 22 (14,67%) were female. The male to female ratio was 5,8:1. Figure 4.1. below illustrates this observation as well as breaks it down by year.



## FIGURE 4.1: Graphical depiction of patients according to gender per year of the study conducted

#### 4.2 AGE

The ages ranged from 14 to 67 years with a mean age of 31,5 years. The ages were defined by decade for ease of use and comparative studies. The majority of patients that were treated were in their 3<sup>rd</sup> decade. The frequency of the two extremes of age (very young and elderly) were very low.

Figure 4.2 graphically demonstrates the distribution of patients according to their age group and numbers.

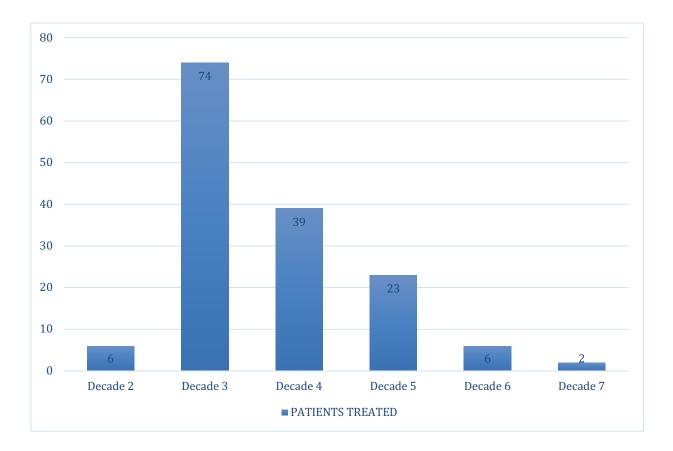


Figure 4.2: Patient age distribution in decades

#### 4.3 MODE OF INJURY

There were 5 different recorded causes of the fractures. The most common cause being interpersonal violence (63%), followed by motor vehicle accidents (27%), pedestrian vehicle accidents (7%), sport injuries (2%) and there were only 2 (1%) reported case of injury caused from a fall. Males were involved in interpersonal violence in 66 (67.18%) cases, whereas females were involved in 9 of the reported cases (40.9%). The majority of the ZMC fractures in females (45%) were a result of road traffic accidents (i.e. MVA or PVA) whereas the majority of the ZMC fractures in males resulted from

interpersonal violence. Road traffic accidents were the cause of 31% of ZMC fractures in males.

Figure 4.3 below graphically displays the various mode of the injuries while Figure 4.4 below graphically depicts the mode of injury based on gender.

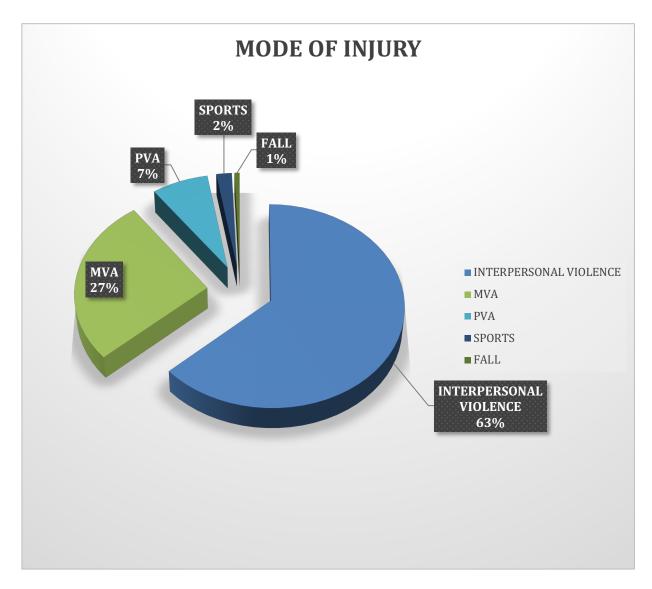


Figure 4.3: Distribution of various modes of injury

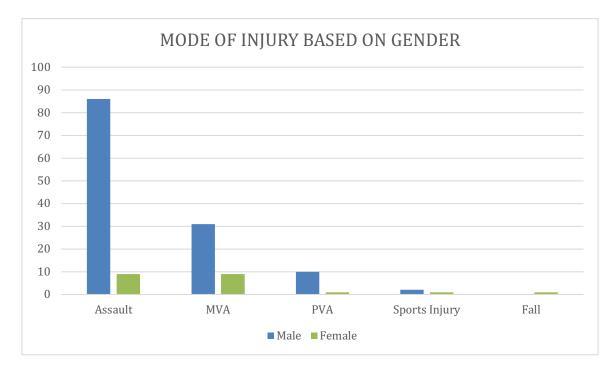


Figure 4.4: Distribution of mode of injury based on gender

#### **4.4 SITE OF FRACTURE**

The right side was affected in 67 patients (44.67%), whereas the left side was affected in 83 patients (55.33%) with ZMC fractures. Majority of the left ZMC fractures were associated with assaults (35.33%), whereas motor vehicle accidents were associated with 14% right sided ZMC fractures and 13% left sided ZMC fractures.

Table 4.2 below depicts the site distribution of the fracture.

 Table 4.1: Distribution of the site of ZMC fracture

	SIDE	PERCENTAGE
RIGHT	67	44,67%
LEFT	83	55,33%

## **4.5 ORBITAL FRACTURE**

The orbital floor was the most common of the orbital walls that was associated with ZMC fractures. The orbital floor was fractured in 45 patients (30%) whereas the medial wall was fractured in 2 patients (1%). There were no reported fractures of the lateral orbital wall. There was no orbital fracture in 105 patients (69%). The distribution of specific orbital walls affected is graphically demonstrated in Figure 4.5 below.

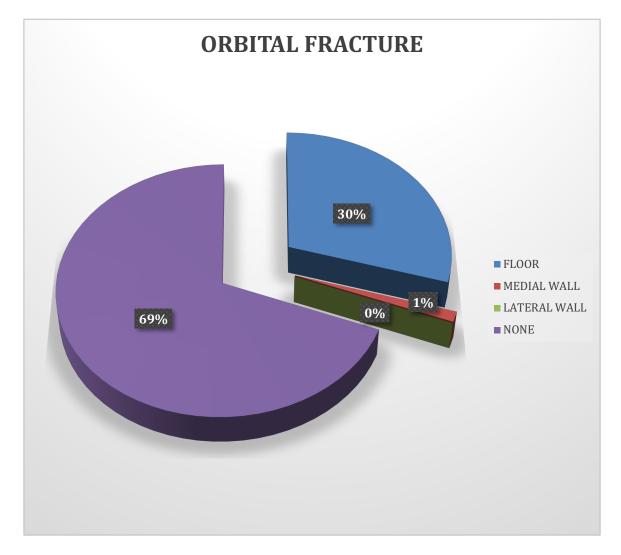


FIGURE 4.5: DISTRIBUTION OF ORBITAL WALL FRACTURES

## **4.6 ORBITAL RECONSTRUCTION**

There were 47 reported orbital fractures with 39 of them being reconstructed (86.6%). Orbital reconstruction was performed in 26% of the total patients with ZMC fractures. In order to gain insight into the lower eyelid approaches and orbital reconstruction, a Pearson Chi square analysis was performed to determine if there was an association between the use of the infraorbital approach and orbital wall reconstruction.

Table 4.3 and Figure 4.6 display the results below.

## **Table 4.2: Frequency of Orbital Reconstruction**

Orbital Reconstruction	Number (N)	Frequency (%)
Yes	39	26.00
No	111	74.00
Total	150	100.00

Orbital	Surgical Approach -	– Infraorbital		
Reconstruction	Yes No		Total	
Yes (N)	36	3	39	
%	38.30	5.36	26.00	
No (N)	58	53	111	
%	61.70	94.64	74.00	
Total (N)	94	56	150	
%	100	100	100	
Pearson chi square = 19.7918 Pr = 0.001				

Figure 4.6 Analysis of the infraorbital approach and orbital reconstruction

## **4.7 SURGICAL APPROACH**

The most commonly used surgical approach was the transoral maxillary vestibular approach which was used in 110 patients followed by the infraorbital approach which was used in 94 patients. The lateral brow approach was used in 87 patients. The transconjunctival, subciliary and subtarsal approaches were hardly used. Table 4.4 displays the distribution of the surgical approaches used.

SURGICAL APPROACH	NUMBER	PERCENTAGE
1. Transoral Maxillary Vestibule	110	34.40%
2. Lateral Brow	87	27.19%
3. Transconjunctival	1	0.31%
4. Subciliary	2	0.63%
5. Subtarsal	1	0.31%
6. Infraorbital	94	29.69%
7. Gillies Temporal	24	7.50%

#### Table 4.3: Distribution of surgical approaches used

## **4.8 SURGICAL APPROACHES PER PATIENT**

The number of surgical approaches per patient ranged from 1 to 3. A single transoral approach was used in 13 patients, infraorbital in 12 patients and the transconjunctival approach solely in 1 patient. Two surgical approaches were used per patient in the combinations of the transoral and lateral brow on 14 patients and the transoral and infraorbital on 8 patients. Lateral brow and infraorbital in 6 patients. Three surgical approaches were used in combinations of the transoral, lateral brow, and infraorbital approaches on 64 patients. The subciliary and subtarsal approaches were used in 2 and

1 patients respectively in combination with the transoral and lateral brow approaches.

The Gillies temporal approach was used in 24 patients.

Figure 4.7 graphically displays the surgical approaches per patient.

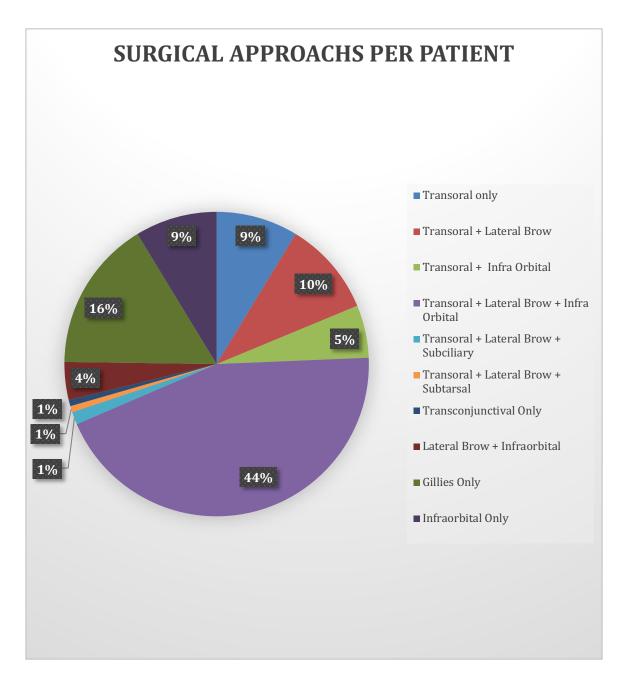


Figure 4.7: Distribution of surgical approaches per patient

## **4.9 POINTS OF FIXATION**

The number of points of fixation ranged from 0 to 3. Closed reduction by a Gillies temporal approach was used in 24 patients (16%) and thus no points of fixation. One point of fixation was performed at the zygomaticomaxillary (ZM) suture in 13 of the patients (8.66%) and at the infraorbital suture in 13 of the patients (8.66%) in this study. Two-point fixation was performed at the ZM suture and ZF suture in 15 of the patients (10%), at the ZM and infraorbital suture in 9 of patients (5.56%), and lastly at ZF and infraorbital sutures in 6 of the patients (4%). Three-point fixation was performed at the ZM, ZF, and infraorbital sutures in 69 of the patients (46%) in this study.

Figure 4.8 graphically displays the number of points of fixation.

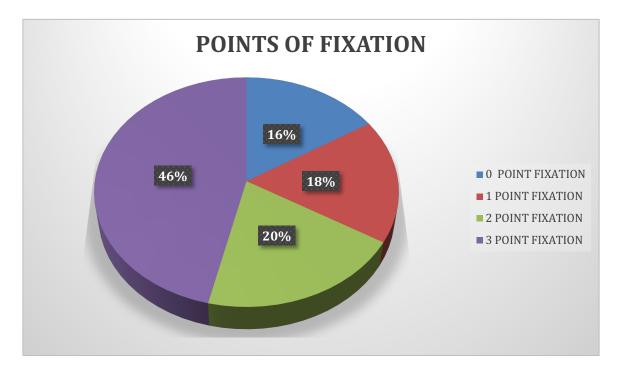


Figure 4.8: Distribution of points of fixation

#### **CHAPTER 5: DISCUSSION**

When considering midface fractures, ZMC fractures are the most common, mainly due to the instinctive nature to turn ones' head when anticipating a blow to the midface in order to protect the eye.<sup>1</sup> Furthermore the prominent position of these bones within the facial skeleton makes it prone to injury.<sup>16</sup>

Overall, in this study, 128 patients were male (85.33%) and 22 were female (14.67%) with a male to female ratio of 5.81:1. This marked male predominance is similar to the epidemiological studies conducted in many other countries.<sup>8-10,12,42,43</sup> This also compares favourably with previous studies conducted in South Africa on midfacial fractures.<sup>1</sup> These findings are however in contrast to the studies done in India<sup>41</sup> and Japan,<sup>21</sup> where the authors report a higher female incidence but still a male predominance. "Kostakis et al. stated in their study that men are probably more frequently involved in social activities than women and therefore, men are thought to be more susceptible to road traffic accidents, assaults, and work accidents." <sup>46</sup>

If one considers age range, 75% of the individuals were in the 3<sup>rd</sup> and 4<sup>th</sup> decades of life with the highest incidence of ZMC fractures reported in the 3<sup>rd</sup> decade (49.33%) and a mean age of 31.5 years. This is in accordance with studies done by Bartoli et al,<sup>10</sup> Forouzanfar et al.,<sup>12</sup> Kumar and Shubhalaksmi,<sup>36</sup> and Sharma et al.<sup>41</sup> However, studies done by Ji et al,<sup>42</sup> Rascheke et al.,<sup>43</sup> and Yasmani et al.<sup>44</sup> contrast these findings and report a higher incidence in the 4<sup>th</sup> decade of life with mean ages above 40 years. Khan et al reported that young adults (20-30 years) are more vulnerable to ZMC fractures at this stage of their lives due to being actively involved in outdoor activities such as sports, social activities, high speed transportation and interpersonal violence etc.<sup>20</sup>

The aetiology of ZMC fractures in our study varied considerably with blunt trauma due to interpersonal violence accounting for 63% of all injuries sustained. This finding is similar to other studies conducted in South Africa on midfacial fractures which indicated that interpersonal violence was the main cause of ZMC fractures.<sup>1</sup> This study's findings are also in accordance with studies done in Texas America<sup>8</sup> and Heidelberglaan Netherlands.<sup>9</sup>

In this study, road traffic accidents accounted for 34% of all ZMC fractures. This contrasts with studies done by Fourouzanfar et al.,<sup>12</sup> Ji et al.,<sup>42</sup> and Yamsani et al<sup>44</sup> who noted that road traffic accidents accounted for more than half of ZMC fractures in Amsterdam Netherlands,<sup>12</sup> Ulsan Korea,<sup>42</sup> and Hyderebad India.<sup>44</sup> However, Fourouzanfar et al. reported that in recent years, interpersonal violence has increased and surpassed road traffic accidents as the main cause of ZMC fractures in European countries.<sup>12</sup> Furthermore, developed countries have significantly lower prevalence of traffic accidents by implementation of rigid traffic laws.<sup>20</sup>

Sports injuries (2%) and falls (1%) were the lowest contributors to ZMC fractures in this study. Similar epidemiologic data was reported in previous epidemiologic studies on midfacial fractures in South Africa.<sup>1</sup> Ji et al.<sup>42</sup> reported falls as the second highest cause of ZMC fractures whereas others report a relatively low percentage of falls as the etiologic factor but higher than in our study.<sup>8,9,12,43</sup>

Out of the 150 patients who reported with unilateral ZMC fractures, 67(44.67%) saw the right side affected, whereas 87(55.33%) had the left side affected. The left side predominance can be explained by the fact that most assailants are right handed, and that interpersonal violence was the main cause of ZMC fractures in this study. This is in accordance with many other studies that report a high prevalence of interpersonal violence and majority left-sided ZMC fractures.<sup>8,11</sup>

In this cohort, the orbit was involved in 47 patients (31%) with orbital floor fractures accounting for 45(30%) and medial wall fractures for 2(1%). These findings are similar to those conducted by Ellis and Perez<sup>8</sup> who reported 40% involvement of orbital fractures with ZMC fractures. Out of the 47 reported orbital fractures, 39 orbital reconstructions (87.77%) were performed and all of them were of the orbital floor. The results of this study are similar to that of Chuong and Kaban<sup>26</sup> who reported the prevalence of orbital reconstruction in ZMC fractures as 22%. Our results contrast with the study done by Fourouzanfar et al.<sup>12</sup> who reported a low 2.9% orbital reconstruction, and the study by Ishida<sup>21</sup> who reported a high prevalence of 58.8% orbital floor reconstruction in ZMC fractures. An analysis of orbital floor reconstruction and the infraorbital approach showed a statistical significance (P<0.05). This suggests that the infraorbital approach was used on many patients even though no orbital floor exploration was recorded and thus many patients could have had a lower eyelid approach with an orbital floor exploration but no reconstruction.

There is a lack of consensus when it comes to the treatment of ZMC fractures and the ideal surgical approaches with many surgeons preferring to expose multiple articulations with 3-4-point fixation. They believe that the greater the number of fixation points used, the greater the stability and outcome of the fracture treatment. However, using this theory involves an approach to the lower eyelid which poses the risk of an aesthetic scar deformity as well as a lower eyelid complication.<sup>8,9</sup> Lately, there has been a shift from an extended ORIF to a minimally invasive approach in the treatment of ZMC fractures. Many surgeons now categorise ZMC fracture treatment as

a form of cosmetic surgery and thus avoid transcutaneous incisions as well as approaches that may affect facial aesthetics. Ellis and Perez stated that ZMC fractures with minimal functional deficits should be treated solely for cosmetic reasons.<sup>8,9</sup>

Ellis and Perez advocate a stepwise approach when treating ZMC fractures by ORIF. He first advises that the maxillary vestibular approach should be the first surgical approach, followed by lateral brow and infraorbital approaches if deemed necessary.<sup>8</sup> Of course, severely displaced and unstable fractures will require more than one approach. However, his algorithm allows one to avoid additional or unnecessary surgical approaches and thus avoid the risk of iatrogenic damages with regard to placing transcutaneous incisions on the face. The approaches with the most complications are those that access the orbital floor and infraorbital rim. Furthermore, the deformities that may result from these approaches may be more noticeable than the displaced zygoma being treated.<sup>8</sup>

In this study, the transoral maxillary vestibular approach was the most common approach with the infraorbital and the lateral brow approaches also commonly used. The maxillary vestibular and infraorbital approaches were used as single approaches in 13 patients (8.66%) each. The most common approaches were the combination of the maxillary vestibular, infraorbital, and the lateral brow approaches (44%). The infraorbital approach was used in 95 of the patients (63.33%) whereas orbital floor reconstruction was only performed in 39 of the patients (26%). These finding suggests that the infraorbital approach was used even though orbital reconstruction was not required or planned. The results of this study are similar to those of Ishida<sup>21</sup> who performed lower eyelid approaches in 90% of his patients whereas only 58.8% required orbital floor reconstruction. However, he used the transconjunctival approach instead

of the infraorbital approach which results in a better aesthetic outcome. Choung<sup>26</sup> used the maxillary vestibular approach on only 1.4% of patients and the infraorbital approach on 69.6% of the patients in his cohort . The results of this study contrast those of Ellis and Perez<sup>8</sup> who recorded the use of approaches to the lower eyelid as low as 34.7%. They avoided the lower eyelid approach and internal orbital exploration using his algorithm. Furthermore, the need for orbital reconstruction was determined preoperatively or with an intraoperative CT scan.

A drawback of our study is that no postoperative data was available. This is a difficult task in our setting as most patients do not return for postoperative check-ups and thus complications related to lower eyelid approaches such as ectropion and lower eyelid droop are not recorded. It is well documented in the literature that transcutaneous incisions to the lower eyelid such as the infraorbital, subciliary, and subtarsal result in high complication rates and poor aesthetic outcomes.<sup>3,9,18,41,44</sup> The transconjunctival approach is favoured over transcutaneous incisions due to the fact that it results in an invisible scar and lower complication rates have been recorded.<sup>11,18,36</sup> However, when complications such as entropion do occur, they are more difficult to correct.

Regardless of the complication rates associated with the lower eyelid approaches, the majority of the studies indicate that the risks of these approaches need to be taken into consideration. The lower eyelid approaches should be limited to ZMC fractures that require orbital floor reconstruction as well as those with severe infraorbital disruption.<sup>8,9</sup>

Stable fixation with miniplates is the gold standard for treating displaced zygomatic fractures that require an ORIF. Traditional teachings advocate 3-point fixation based on mechanical models of stability.<sup>21,35</sup> However, there has been a shift from these

teachings with the current literature advocating an individualised approach per ZMC fracture.<sup>8,9</sup>

In our cohort, 3-point fixation was the most common (46%) followed by 2-point (20%) and 1-point (18%) fixation. Closed reduction with no points of fixation was performed in 24(16%) of the patients. Our results are in accordance with the study done by Sharma et al.<sup>41</sup> and Ishida<sup>21</sup> who report very similar findings. However, it contrasts with the studies done by Ellis and Perez,<sup>8</sup> Chuong and Kaban,<sup>26</sup> and Ji et al.<sup>42</sup> who report a predominance of 2-point fixation and minimal 3-point fixation. Ellis and Perez state that post reduction displacement is not affected by the number of points of fixation if proper reduction and stabilisation has been achieved.<sup>8</sup> Furthermore, the number of points of fixation will be determined by the fracture pattern and the degree of severity. However, most of the recent publications favour less points of fixation with minimising the surgical approaches and thus treating ZMC fractures as a form of cosmetic surgery.

## **CHAPTER 6: CONCLUSION**

Interpersonal violence was the main cause of injury, followed by road traffic accidents. The study revealed that the mean age was 31.5 years with a male to female ratio of 5.8:1. The frequency of orbital reconstruction was 26% in this sample. A correlation between the infraorbital approach and orbital reconstruction showed that the infraorbital approach was used in most of the patients even though orbital reconstruction was not required. Furthermore, this study shows that the department of Maxillofacial and Oral Surgery at the CMJAH is not following the international trends when it comes to the treatment of ZMC fractures with special attention to the surgical approaches and orbital reconstruction.

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## ANNEXURE A: ETHICAL CLEARNACE CERTIFICAT

	AND TO A SAME WITH AND THE AND
R14/49 Dr MS Gani	
	RESEARCH ETHICS COMMITTEE (MEDICAL) EARANCE CERTIFICATE NO. M170735
NAME:	Dr MS Gani
(Principal Investigator) DEPARTMENT:	School of Oral Health Sciences Department of Maxillo-Facial and Oral Surgery Medical School
PROJECT TITLE:	Prevalence of orbital floor fractures in zygomatico- maxillary complex (ZMC) fractures
DATE CONSIDERED:	28/07/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr M Mabongo
APPROVED BY:	Professor CB Penny, Co-Chairperson, HREC (Medical)
DATE OF APPROVAL:	26/09/2017
This clearance certificate	is valid for 5 years from date of approval. Extension may be applied for.
DECLARATION OF INVES	
I/We fully understand the com- undertake to ensure complian approved, I/we undertake to re	e and ONE COPY returned to the Research Office Secretary on 3rd floor, Phillip V Tobias of the Witwatersrand, Johannesburg. ditions under which I am/we are authorised to carry out the above-mentioned research and I/we nee with these conditions. Should any departure be contemplated from the research protocol as esubmit to the Committee. <u>I agree to submit a yearly progress report</u> . The date for annual re- after the date of convened meeting where the study was initially reviewed. In this case, the study given by the HREC (Medical).
Principal Investigator Signa	ature Date
PLE	EASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

## **ANNEXURE B: PERMISSION TO CONDUCT RESEARCH**



# CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries: Ms. N. Mzila Office of the Clinical Director Tell: (011): 488-4812 Email: Nolwazi.Mzila@gautemg.gov.za 09 October 2017

GP 201710\_001

Dear Dr. M. S. Gani

## STUDY TITLE: Prevalence of Orbital Wall Reconstruction in Zygomaticomaxillary Complex (ZMC) Fractures.

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

- 1. Charlotte Maxeke Johannesburg Academic Hospital will not anyway incur or inherit costs as result of the said study.
- 2. Your study shall not disrupt services at the study sites.
- 3. Strict confidentiality shall be observed at all times.
- 4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or sister in charge to agree on the dates and time that would suit all parties.

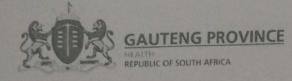
Kindly forward this office with the results of your study on completion of the research.

Supported / not supported

Dr. M.I. Mofokeng **Clinical Director** DATE: 10/10 201

Approved/not approved

Ms.G. Bogoshi **Chief Executive Officer** Date: 11.10.2017



## WITS ORAL HEALTH CENTRE

Private Bag X15 Braamfontein, Johannesburg, 2017 Enquiries: Ms Tumelo Marule Tel: (011)488-4893, Fax 086 406 3196 E-mail: Tumelo.Marule@wits.ac.xa

21 August 2017

Dr MS Gani MSc Dent Student (Maxilo Facial and Oral Surgery) Faculty of Health Sciences University of the Witwatersrand Johannesburg

## REGARDING: <u>PERMISSION TO CONDUCT RESEARCH BY ACCESSING PATIENT FILES</u> <u>," PREVALENCE OF ORBITAL FLOOR RECONSTRUCTION IN</u> <u>ZYGOMATICOMAXILLARY (ZMC) FRACTURE".</u>

# REFERENCE :HRRC/AUG/05/2017

It is my pleasure to grant final approval to utilize resources at Wits Oral Health Centre in order to conduct your research.

The Hospital Research and Risk Committee allocated a unique reference number to this application – Kindly quote this reference number in all future correspondence regarding this research.

Please note that the Hospital Research and Risk Committee should be informed of the estimated date the research will commence, as well as regular status reports until the research has been concluded. Within a month after conclusion of the research project, a written report must be submitted to the Head of School/CEO, summarizing the final result/outcome as well as the recommendations made based on the research concluded.

Regards,

ceret MS Nemutandani CEO/Head of School

## ANNEXURE C: TURN IT IN REPORT

# Dr by Muhammad Gani

Submission date: 26-Feb-2019 08:35AM (UTC+0200) Submission ID: 1083991533 File name: Gani\_Mohammed.docx (1.02M) Word count: 9645 Character count: 54942

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