A COMPARATIVE STUDY OF 3 TREATMENT MODALITIES FOR MANDIBULAR ANGLE FRACTURES.

Shailen Dulabh

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements

for the degree of

Master of Dentistry,

Maxillo, Facial and Oral Surgery

Johannesburg, 2017

DECLARATION

I, Shailen Dulabh declare that this research report is my own work. It is being submitted for the degree of Master of Dentistry at the University of the Witwatersrand, Johannesburg. It has not been submitted before for anydegree of examination at this or any other university.

____

Signature of candidate

17th day of May 2017

DEDICATION

I dedicate this workto my family,

For their love

Sacrifices

And unwavering support

In the realisation of my degree

“Don’t worry when you are not recognised,

But strive to be worthy of

Recognition”.

-Abraham Lincoln

ABSTRACT

Introduction: The mandibular angle fracture remains one of the most common mandibular fractures with a reported incidence of ~20 – 40%. Its treatment is rife with controversy with a reported global complication rate of ~30%.

Aim: The purpose of the study is to determine the optimum management of the compound, isolated mandibular angle fracture.

Methods and materials: A prospective, randomised, study was carried out within the department where all cases of isolated, compound, mandibular angle fractures were allocated to 1 of the three treatment groups: Group1: Superior border wire; Group2: Single miniplate; Group3: Double miniplate. The patients were assessed for the presence of post-operative infection, malocclusion and fixation failure and the outcomes were correlated. The data was analysed statistically and reported upon using STATA.

Results: 75 patients were included in the study with 25 patients per group. Complication rates were equal between the miniplate groups (16%), with the Superior border wire having the best outcomes. The average “days to surgical fracture repair post-injury” ($p = 0.08$) and the category of “severely displaced fractures” (>5mm) are the factors shown to increase the incidence of complications, $p = 0.02$. Overall a 13.3% complication rate was noted.

Conclusion: The use of 2 miniplates seems to offer no benefit over a single miniplate. In stark contrast to previous global findings, fixation using a superior border wire with intermaxillary fixation (IMF) showed the best outcomes with a 92% success rate and its usage should be reaffirmed as a cost-effective alternative in a resource-constrained environment.

ACKNOWLEDGEMENTS

This study was facilitated through the support of my supervisors, family and colleagues.

It is said that one's family is their strength and that their support is the shield that can shelter and resist against any storm.

To my family I salute you all.

I would like to thank the Department of Maxillo-Facial and Oral Surgery at the University of the Witwatersrand for the opportunities offered to me during my tenure in the department as well as theresources, time and assistance provided to me for this study

I would like to express my gratitude to Dr. Ephraim Rikhotso for your supervision of this research and for all your guidance and teaching throughout my training. I will forever be indebted to you.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1

1.0 INTRODUCTION

The human facial skeleton comprises numerous bones which occur singly or combine in pairs to give facial skeletal form. Even though the face is the most common representation of human form and features predominantly in the public eye, the underlying bones are subject to the same disruptions as long bones. In this regard a fracture through the angle of the mandible is one of the most common facial fractures (Braasch, 2013; Ellis, 2009) and over and above the well documented signs and symptoms, the management of these fractures has been controversial.

This controversy is related to the anatomic relations and complex mechanical aspects of the mandibular angle (Braasch, 2013; Danda, 2010; Ellis, 2009, 2010). Adding to the debate was a lack of consensus in the literature regarding a definition of an ‘angle’ fracture of the mandible (Ellis, 2009). Furthermore, the evolution of rigid fixation and the ability to provide adequate stability to the fractured segments in a myriad of ways has triggered further debate (Braasch, 2013; Ellis, 1994, 2010). These special anatomic and biomechanical features of the mandibular angle impact on the management of these fractures.

Biomechanically, a fracture involving the third molar region draws special attention as it causes an interplay between opposing forces. An unfavourable fracture through the angle causes a tussle between the mandibular elevator and depressor muscles groups, resulting in an unfavourable rotation of the ramus antero-superiorly and the anterior fractured segment inferiorly. The net result then is a greater discrepancy between the fractured segments (Braasch, 2013; Ellis, 2009) as depicted in figure 1.1, which warrants some form of fixation to reduce the fractured segments.

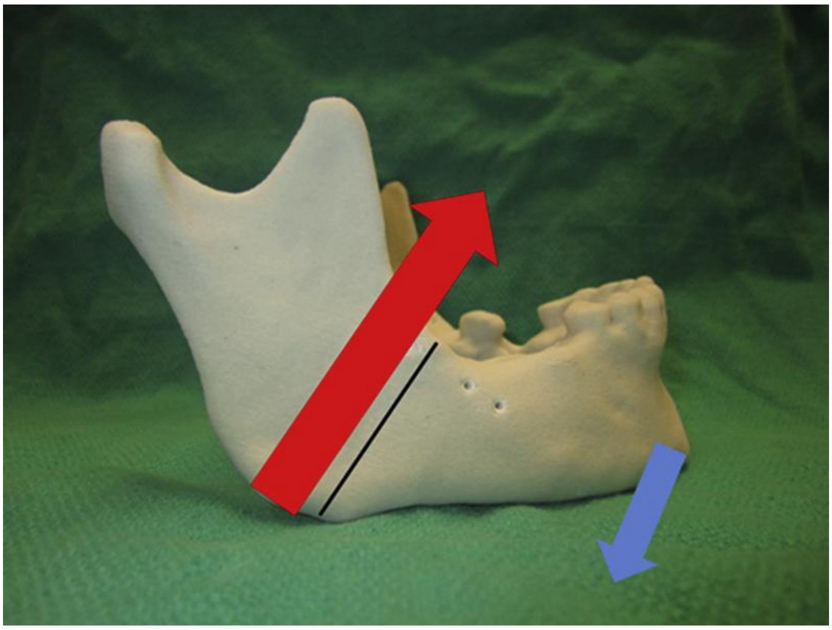

Figure 1.1 Mandibular model depicting an unfavourable fracture created by the pull of the pterygo-masseteric sling superiorly (red arrow) and suprahyoid muscles inferiorly (blue arrow), Braasch, 2013.

A variety of techniques have been used for internal fixation of mandibular angle fractures. These techniques include wire osteosynthesis (Passeri, 1993), a single superior border plate (Champy, 1978), a single inferior border plate (Ellis, 1992), 2 miniplates: 1 at the superior border and 1 at the inferior border (Siddiqui, 2007; Danda, 2010; Ellis, 2010), or a lag screw (Ellis, 1992). Since the introduction of the technique for fixation of mandibular angle fractures originally described by Michelet and colleagues (Michelet, 1973), there has been a great deal of controversy regarding the most appropriate method.

Currently, surgeons favour the predominant success of a single semi-rigid plate as described by Michelet *et al.* (Michelet, 1973) and later by Champy and co-workers (Champy, 1978). A 4-hole plate is twisted 90 degrees and positioned atop the anterior border of the ascending ramus and down the lateral surface of the mandible toward the external oblique ridge abutting the fractured segments. However, unforeseen consequences to this straightforward technique do occur and this is compounded by the fact that not all fracture patterns through the angle region are amenable to fixation using the Champy technique (Champy, 1978) and complications do arise.

Wound dehiscence and localised infections comprise the majority of the total number of ‘minor’ complications (Seemann, 2010; Siddiqui, 2007) while plate fracture and loosening of screws usually comprise a smaller portion of the ‘major’ complications (Kim, 2016; Seemann, 2010; Strasz, 2016) occasionally leading to fascial space infections warranting transfacial incision and drainage and hardware removal.

The position and number of plates to fixate a mandibular angle fracture have been extensively researched and reported on in the literature (Ellis, 2010; Kim, 2016; Schierle, 1997; Siddiqui, 2007; Spinelli, 2016; Strasz, 2016; Zix, 2007). Most investigators agree on the use of a single non-compression miniplate at the superior border for treatment of non-comminuted mandibular angle fractures (Ellis, 2010; Strasz, 2016; Seemann, 2010). Although many surgeons have accepted the superior border plate as the method of treatment of angle fractures, there are several other treatments options that can be used.

A single plate can be placed at the superior border along the lateral aspect of the mandible to act as a tension band and this has been shown to have a low complication rate of 12% to 16% (Al-Moraissi, 2014; Strasz, 2016). Several studies have shown no increased risk of complications when comparing the use of 1 plate with 2 plates (Danda, 2010; Ellis, 2010, 2004; Al-Moraissi, 2014) whereas other studies have actually shown a decreased rate of complications with the use of 1 superiorly placed noncompression plate. (Ellis, 2004, 2010; Kim, 2016).

The 2-plate technique involves placement of 1 plate at the superior border to act as a tension band and 1 plate at the inferior border to act as a compression band. In 1994, Ellis and Walker (Ellis, 1994) showed that the use of two 2.0-mm noncompression miniplates had an unacceptably high complication rate of 28%. A prospective randomized study by Danda (Danda, 2010) indicated no differences in the rates of malocclusion, infection, and wound dehiscence between a single plate placed with the Champy technique versus 2 plates. This suggests that the use of a second plate at the inferior border is not necessary for proper fixation and healing. Furthermore, the placement of the inferior plate increases operating time and often requires an extraoral approach, which introduces the risk of facial nerve damage and scarring.

Recently, a new plate configuration has been introduced for the treatment of mandibular angle fractures. The 3-Dimensional (3-D) or matrix plate is a straight or curved ladder plate that uses monocortical screws to provide stabilization along the lateral aspect of the mandible (Al-Moraissi, 2014; Zix, 2007). This plate configuration has been shown to have similar stability compared with the 2.0 miniplate but superior resistance to out-of-plane movements. (Zix, 2007; Kimsal, 2011). Passeri *et al.* showed complication rates of 17% using nonrigid wire osteosynthesis for angle fracture reduction along with a period of intermaxillary fixation (Passeri, 1993).

Even though the superior border wire seems to have fallen out of favour since the advent of miniplates, it is an acceptable means of treating mandibular angle fractures, especially in a resource-constrained environment where accessibility to miniplates is not always possible. While the angle fracture continues to be associated with the highest complication rates (Al-Moraissi and Ellis, 2014), the treatment of these fractures has witnessed a significant change in the recent past. The seemingly endless debate on the usage of 1 versus 2 plates for treatment of these fractures needs to be curtailed prompting the formulation of this research study.

CHAPTER 2

2.0 LITERATURE REVIEW

The angle fracture is still one of the most common fractures of the mandible reportedly accounting for approximately 30% of all mandibular fractures (Ellis, 2010; Al-Moraissi, 2014; Kim, 2016; Spinelli, 2016) and continues to be associated with the highest complication rates (Al-Moraissi and Ellis, 2014). While interpersonal violence or motor vehicle accidents are the most common reasons for these, other potential causes of mandibular fractures include falls, sporting or work-related accidents, gunshot wounds, and pre-existing pathology.

Various authors have reported on their management of angle fractures based on different treatment groups and study numbers such as those performed by Khiabane and Mehmandoost (2013) who reported upon 40 patients, Potter and Ellis, 46 patients (Potter and Ellis, 1999), Barry *et al.* 50 patients (Barry, 2007), 30 patients by Ellis (Ellis, 1991) as well as 30 cadaveric mandibles by Schierle *et al*. (Schierle, 1997)

Studies based on a substantial sample size do exist such Seemann *et al.* (322 patients) (Seemann, 2010), Ellis: 185 patients (Ellis, 2010), Strasz *et al.* (184 patients) (Strasz, 2016) and more recently Spinelli and colleagues who reported on 389 patients. (Spinelli, 2016). With a wealth of studies reporting upon management of the angle fracture, most represent cases whereby an angle fracture was treated simultaneously with other concomitant mandible fractures present (Ellis, 1999; Khiabane, 2013; Seemann, 2010; Spinelli, 2016) while amongst those reporting on isolated angle fractures there is an abundance of retrospective reports with outcomes of individual techniques (Barry, 2007; Strasz, 2016; Wan, 2012).

There remains a lack of randomised, prospective studies (Danda, 2010; Ellis, 2010; Kim, 2016) and among these only those by Kim *et al.* (Kim, 2016), Danda (Danda, 2010) and Siddiqui *et al.* (Siddiqui, 2007) show a randomisation strategy. Ellis in 2010 performed a nonrandomised, fixed pattern of assignment strategy for the patients in his study (Ellis, 2010) and the author recognised the scarcity (~12% incidence) of the unilateral isolated angle fracture and placed an emphasis on the cross comparison of comparable groups. Of importance it was mentioned that in order to negate the biomechanical forces at play, prospective studies depicting outcomes based on ***isolated*** angle fractures were important so as not to skew the results with the presence of concomitant fractures (Ellis, 2010). The rationale for our study therefore comes into effect.

2.1 Anatomy and biomechanics.

There are complex anatomical and biomechanical aspects that one needs to consider when treating fractures of the mandibular angle (Braasch, 2013; Danda, 2010; Ellis, 2009, 2010). Anatomically the angle is represented by the union of the bony mandibular horizontal dento-alveolar along with the vertical ramus components. This junction is thought to weaken the angle region due to the abrupt change in shape from horizontal to vertical forming the angle. The anatomy can further be weakened by masticatory muscle attachment, the presence of impacted third molar teeth as well as a narrower cross section of the mandibular angle in comparison to the dentate portions of the mandible. (Ellis, 1999).

Biomechanically, a fracture extending in the vicinity of the third molar region allows the muscles that elevate the mandible to rotate the ramus antero-superiorly. Congruently the action of the mandibular depressor muscles (anterior digastric, geniohyoid) displace the anterior fractured segment inferiorly and posteriorly making this movement even more likely

(Braasch, 2013; Ellis, 2009). An understanding of the forces at play may shed some light into the ideal fracture management.

These biomechanics are based on the mandible acting as a class 3 lever. If one were to extrapolate this specifically to the angle region then the muscular attachments create a tensile force at the superior border and a complementary compressive force at the inferior border. (Braasch, 2013). The area between the tension and compression zones is known as a *neutral zone* as depicted in figure 2.1.

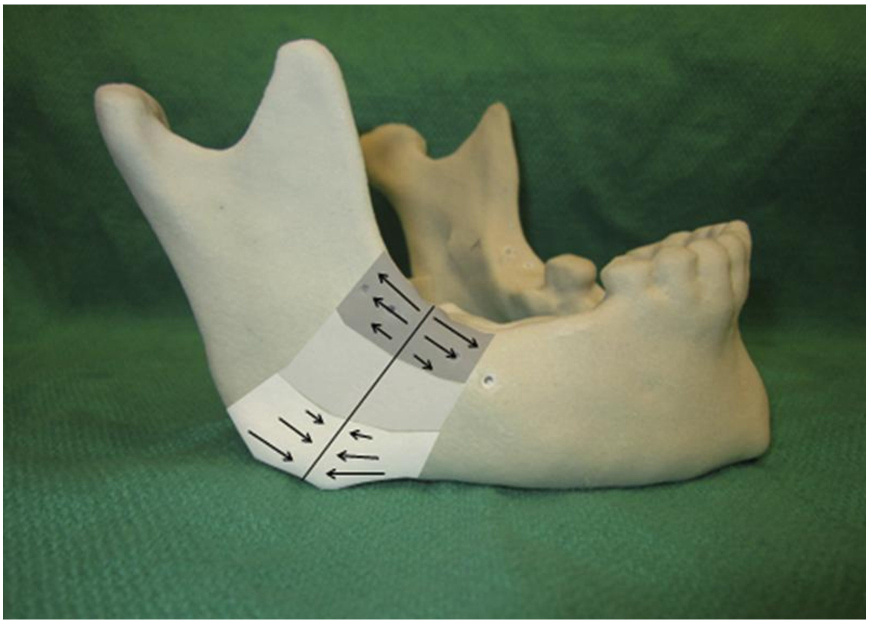

Figure 2.1 Model showing superior tension zone (divergent arrows) and inferior compression zone (convergent arrows), separated by an intervening neutral zone. (Braasch, 2013)

If one now considers the complex muscular activity as well as the intervening zones of tension and compression, it becomes clear that the angle fracture generally requires some form of fixation to control the position of the ramus. (Braasch, 2013; Ellis, 2009).

2.2 Osteosynthesis concepts

Several concepts for fixating mandibular angle fractures exist. These techniques include wire osteosynthesis (Passeri, 1993), a single superior border plate (Champy, 1978), a single inferior border plate (Ellis, 1992), 2 miniplates: 1 at the superior border and 1 at the inferior border (Schierle, 1997; Siddiqui, 2007; Danda, 2010; Ellis, 2010), or a lag screw (Ellis, 1992).

With the advent of miniplate and screw fixation there has been considerable debate as to the most appropriate method for the management of mandibular angle fractures. The introduction of rigid fixation later on further fuelled the debate and several studies attempted to decipher a working formula. (Barry, 2007; Danda, 2010; Ellis, 1992, 1996, 1999, 2010; Levy, 1991; Schierle, 1997; Zix, 2007).

The *Association for the Study of Internal Fixation* (ASIF), founded in 1958 under the original German name ‘‘*Arbeitsgemeinschaft für Osteosynthesefragen*’’ (AO), was a working group dealing with questions regarding internal fixation of fractures. The AO developed techniques for bone healing using dynamic rigid compression plating to neutralize the forces developed during functional loading. The restoration of the tensile and compressive trajectories on the mandible was proposed to be a reliable method to achieve this.

The AO/ASIF Foundation now recommends the use of one miniplate for fixation of an angle fracture in cases of an isolated and simple fracture (Strasz, 2016) which means a non-rigid osteosynthesis. Independent from the AO Foundation's recommendation, two basic procedures regarding osteosynthesis of mandibular angle fractures are found in the literature.

The conventional treatment consists of anatomical reduction and rigid fixation. Supporters of this procedure favour the prevention of inter-fragment mobility during normal functioning using either thick plates on the lower margin with bicortical screws or two miniplates and monocortical screws (Danda, 2010; Levy et al, 1991).

In contrast, the Champy's concept (Champy *et al*., 1978) suggests non-rigid fixation of mandibular angle fractures through a single, small, easily bendable miniplate secured with monocortical screws and was validated in various clinical studies (Danda, 2010; Ellis and Walker, 1996; Schierle *et al*., 1997; Ellis, 1999; Siddiqui et al., 2007; Ellis, 2010). During their studies on the treatment for an angle fracture Champy *et al*. stumbled upon the 'ideal lines of osteosynthesis' meaning that the locations where bone-plate fixation would provide the most stable means of fixation were shown to be along the superior border of the mandible. (Champy, 1978).

Both the rigid AO concept and Champy's concept allow for direct bone healing with minimal formation of callus. One then needs to take into account factors such as lateral flaring of the buccal cortex at the inferior border once the superior plate is placed and whether or not this flaring warrants a second miniplate, type and method of fixation as well as the amount of desired post-operative functioning. A debate around these factors has previously spurred much controversy regarding the usage of 2 miniplates as opposed to one in an effort to provide rigid fracture fixation.

2.3 One miniplate versus two for fracture stabilisation.

At the mandibular angle, displacing forces are present at the superior border, which is perpendicular to the line of fracture. Therefore the placement of a superior border plate can provide resistance to such displacing forces. The method of fixation must however provide adequate stability at the fracture site enabling proper healing and a low complication rate. (Braasch, 2013).

In 1973, Michelet *et al.* (Michelet, 1973) reported using trans-orally placed, malleable, non-rigid compression plates with monocortical screws. Champy *et al.* (Champy, 1978) modified Michelet's technique and noted that immobilization of bone fragments using rigid fixation was not always necessary. The emphasis here was to provide '*semi-rigid*' and '*functionally stable fixation*' in an attempt to shift away from the dictum of rigid fixation. (Barry, 2007; Danda, 2010; Ellis, 1992, 1996, 1999, 2010; Levy, 1991; Schierle, 1997; Zix, 2007).

Several authors then applied Champy's model (Champy, 1978) to varying clinical and in vitro scenarios attempting to provide credible results. The position and number of plates to fixate a mandibular angle fracture have been extensively researched and reported on in the literature (Danda, 2010; Ellis, 2010; Kim, 2016; Schierle, 1997; Siddiqui, 2007; Spinelli, 2016; Strasz, 2016; Zix, 2007).

2.3.1 One miniplate

Most investigators agree on the use of a single non-compression miniplate at the superior border for the treatment of simple mandibular angle fractures as popularised by Champy *et al.* and depicted in figure 2.3.1.a (Ellis, 2010; Strasz, 2016; Seemann, 2010). Although many surgeons have accepted the superior border plate as the method of treatment of angle fractures, there are several other treatment options that can be used.

Figure 2.3.1a Champy superior border miniplate (Braasch, 2013)

A single plate as shown in figure 2.3.1b can be positioned along the superolateral aspect of the mandible to act as a tension band and has been shown to have a comparably low complication rate of 12% to 16%. (Braasch, 2013; Al-Moraissi and Ellis, 2014; Strasz, 2016). Plate fixation in this manner can be accomplished either via an intraoral or transbuccal approach using a transbuccal trocar and cannula. Wan and colleagues (Wan, 2012) have shown no significant differences regarding placement or complications in either technique.

This method appears to offer an advantage of maintaining the tensile strength of the plate as there is less 'in-plane' bending when compared to the Champy principle. Furthermore there is increased tissue available for mucosal closure along the lateral border thereby decreasing the chances of hardware dehiscence. The added mucosal coverage along with decreased plate adaptation seems to be in favour with some surgeons (Khiabane, 2013).

Figure 2.3.1b Miniplate placed along the supero-lateral border. (Braasch, 2013)

2.3.2 Two miniplates

Mandibular angle fixation using the 2-plate technique as shown in figure 2.3.2a, involves placement of 1 plate at the superior border to act as a tension band and 1 plate at the inferior border to act as a compression band. The superior plate may be placed either via a transoral ora transbuccal approach while placement of the inferior plate almost always requires assistance from a trocar and cannula.

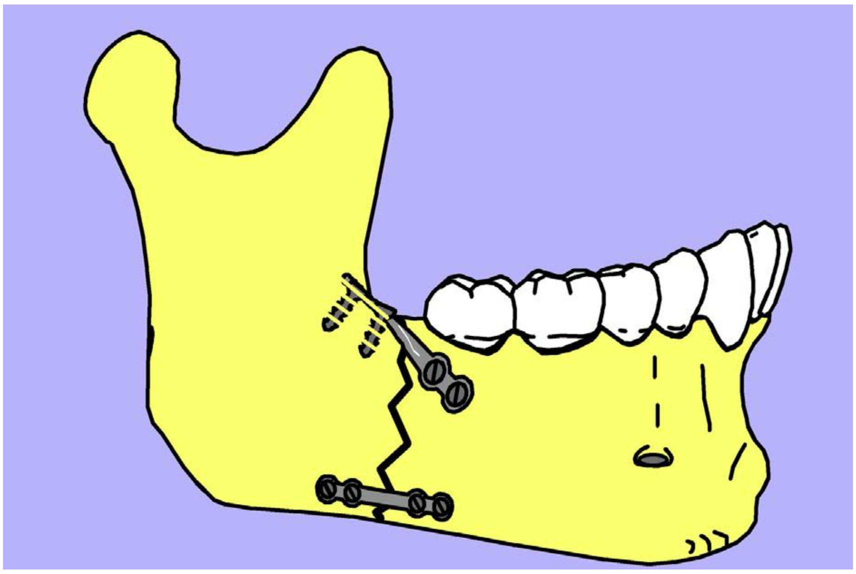

Figure 2.3.2a. Two miniplates. The superior placed as per Champy and the second plate placed at the inferior border. (Al-Moraissi and Ellis, 2014)

Proponents of the 2-plate technique prefer the added stability in the form of the rigid fixation that is offered by the inferiorly positioned plate. While Fox and Kellmann (Fox, 2003) have shown favourable results using the 2-plate scheme, Ellis and Walker in their study (Ellis, 1994) showed that the use of two 2.0-mm noncompression miniplates had an unacceptably high complication rate of 28%. A prospective randomized study by Danda (Danda, 2010) as well as a large-scale meta-analysis by Regev *et al.* (Regev, 2010) revealed a decreased incidence in the rate of malocclusion, infection, and wound dehiscence between 1 plate placed with the Champy technique when compared to 2 plates.

This suggests that the use of a second plate at the inferior border is not necessary for proper fixation and healing. Furthermore, the placement of the inferior plate increases operating time and may requires an extraoral approach, which introduces the risk of facial nerve damage and scarring. Biomechanically, Kimsal and colleagues (Kimsal, 2011) conferred that a single tension band fixation model shows similar stability to a 2 plate fixation scheme with the added advantage of decreased soft tissue manipulation and subsequent improved outcomes.

2.3.3 Three dimensional plates

Recently, a new plate configuration has been introduced for the treatment of mandibular angle fractures. The 3-Dimensional (3-D) or matrix plate is a straight or curved ladder plate that uses monocortical screws to provide stabilization along the lateral aspect of the mandible as shown in figure 2.3.3a below (Al-Moraissi and Sharkawy, 2014; Zix, 2007). Effectively this plate has the potential to function similar to a 2-plate configuration but it is technique sensitive. Over and above transbuccal trocar dexterity, one also has to pay attention to the position of the underlying neurovascular bundle.

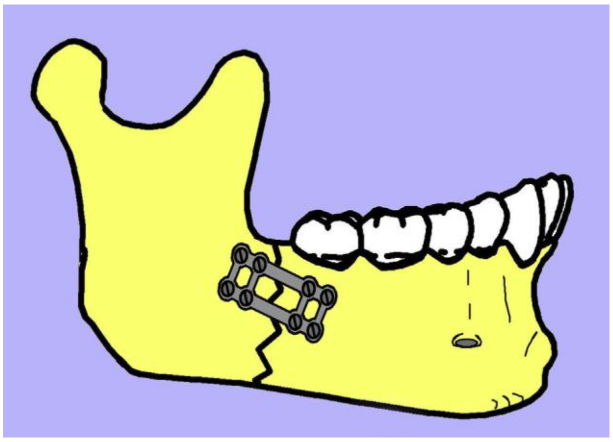

Figure 2.3.3a. A 3 Dimensional, geometric plate placed along the lateral surface of the mandible. (Al-Moraissi and Ellis, 2014)

This plate configuration has been shown to have similar stability compared with the 2.0 miniplate but superior resistance to out-of-plane movements. (Zix, 2007; Kimsal, 2011). In a recent meta-analysis carried out by Al-Moraissi *et al* (Al-Moraissi and Sharkawy, 2014), the authors claimed that the use of these 3 D plate fixation system has the potential to reduce post-operative complications by up to 58 % but further longer term studies are needed.

2.3.4 Nonrigid wire fixation and post-operative maxillomandibular fixation

A plethora of internal fixation devices have been used to provide some form of stability across the angle fracture ranging from a stainless steel wire to reconstruction bone plates. Before the advent of miniplate and screw fixation, intraosseous wiring to reduce fractured segments was the norm. When wire fixation is applied, postoperative maxillomandibular fixation (MMF) is required for at least 4 to 5 weeks to immobilize the fractured fragments and allow osseous union to commence. All other forms of internal fixation devices obviate the need for postoperative MMF (Ellis, 2009).

Ellis (Ellis, 2010) showed fair outcomes with wire fixation while earlier Passeri *et al* (Passeri, 1993) showed a complication rate of 17% when non-rigid wire fixation was used in conjunction with MMF. Recently a randomized controlled study by Kim (Kim, 2016) comparing different plating methods in patients with and without post-operative MMF showed no noticeable differences among groups who had post-operative MMF.

2.4 Complications and septic events

Currently, surgeons endure with the simplicity and success of a single semi-rigid plate as put forth by Champy *et al.* (Champy, 1978). The 4-hole miniplate is adapted to rest passively atop the anterior border of the ascending ramus and laterally in the vicinity of the external oblique ridge of the mandible. Yet, unforeseen consequences to this straightforward choice do occur. The treatment of mandibular angle fractures still retains the highest postoperative complication rate (17-30%) of all mandibular fractures (Al-Moraissi and Ellis, 2014).

These complications include but are not limited to minor pain and localised infections which comprise the majority; debridement of bone, hardware removal, and malunions. One has to take into account that these failure rates are attributed to a variety of factors such as material and host factors (Al-Moraissi and Ellis, 2014; Kim, 2016; Spinelli, 2016).

Material factors may include those that decrease the tensile strength of the miniplate such as the gross plate bending for adaptation to the underlying bone, inaccurate centric placement of screws, only 4 screw-holes (typical in the Champy technique), lack of rigidity, trans-oral angulation of screw placement and difficulty in screw-hole drilling access.Host factors include comminuted fractures, lack of available bone for fixation, obliqueness of fracture segments, retained teeth in the line of fracture and poor patient compliance post-surgery.

Several studies have shown no increased risk of complications when comparing the use of 1 miniplate with 2 (Ellis, 2010, 2004; Al-Moraissi, 2014) whereas other studies have actually shown a decreased rate of complications with the use of 1 superiorly placed noncompression plate (Al-Moraissi, 2014; Ellis, 2004, 2010; Kim, 2016; Strasz, 2016).

Ellis and Walker (1996) found a very high rate of major complications (28%), mostly infections, when angle fractures were treated with two miniplates when compared to the use of a single miniplate. In a previous study Seemann *et al*. (Seemann, 2010) showed osteosynthesis failure rates of 6.3% using a single miniplate and statistically equivalent 5.9% using two miniplates at the mandibular angle. The most common complications were wound healing disturbances with 15.3% and infections with 9.9% out of 335 treated fractures.

Similarly, clinical studies by Schierle *et al.*, Siddiqui and colleagues as well as Danda (Danda, 2010; Schierle, 1997; Siddiqui, 2007) all found that two-plate fixation does not offer advantages over single-plate fixation in general when treating fractures through the angle of the mandible.

In comparison to the meta-analysis carried out by Al-Moraissi revealing a complication rate of between 0-30% worldwide (Al-Moraissi, 2015), other more recent studies where a 2-plate fixation scheme was used such as those performed by Kim *et al.* (Kim, 2016), Strasz and colleagues (Strasz, 2016) as well as Spinelli and co-workers (Spinelli, 2016) reveal post-operative complication rates of 21.6%, 13.6% and 11.1% respectively.

The notion that a single miniplate outperforms those results obtained with 2-plates seems strange as the dogma would equate to the application of additional fixation providing better outcomes. In lieu of several published reports indicating no clear benefit to the placement of a second miniplate, the question must be raised as to whether or not taking the time to place it, enduring the aggravation as well as the additional cost implications are feasible.

However, it is clear that a single miniplate cannot always provide sufficient stability to a fractured mandibular angle. For example, a comminuted fracture through the angle of the mandible requires load-bearing fixation which is provided for in the form of a reconstruction bone plate that is secured with at least three screws on each side and that spans the area of the comminution (Ellis, 2009).

In cases of additional fractures of the mandible, concomitant fractures have to be treated by rigid osteosynthesis such as reconstruction plates or two miniplates to allow non-rigid osteosynthesis by one miniplate in the mandibular angle fracture (Ellis, 2009). In other cases of mandibular angle fractures such as comminuted or pathological fractures, osteosynthesis with one miniplate is not recommended, and a rigid reconstruction plate or two miniplates or geometric plates should be used. (Al-Moraissi and Sharkawy, 2014; Ellis, 2009).

This change is due to improved understanding of the biomechanics of the mandible, the evolution in the patterns and types of fixation and advances in surgical techniques treating these fractures. Currently, assessment of outcomes based on isolated mandibular angle fractures are lacking as the majority of the available reports are carried out on patients who have bilateral mandible fractures including a concomitant angle fracture. As stated by Al-Moraissi, only an assessment on the treatment of isolated mandibular angle fractures will reveal their true morbidity. The presence of a second fracture in the mandible, especially a condylar fracture has the potential to skew the outcomes (Al-Moraissi, 2014).

CHAPTER 3

3. 0 AIMS

The purpose of the study is to determine the optimum management of isolated mandibular angle fractures.

3.1 Study objectives

- To compare treatment outcomes of stainless steel wire versus titanium mini-fixation plates.
- To compare the complication rates as well as the success rates using a set of defined clinical parameters such as the complication-free restoration to function, post-operative malocclusion, hardware failure and post-operative mouth opening.

CHAPTER 4

4.0 MATERIALS AND METHODS

4.1 Study design

A prospective, randomised, comparative human study was carried out within the department of Maxillo-Facial and Oral Surgery under the University of the Witwatersrand's (WITS) School of Oral Health Sciences for the years 2015 to 2016. This research was performed at Charlotte Maxeke Johannesburg Academic Hospital and Chris Hani Baragwanath Academic Hospital, the two hospitals that the department renders patients care services.

All patients who presented with clinically and radiographically confirmed isolated, unilateral, unfavourable mandibular angle fractures **only** were requested to participate in this study. Consent was obtained as per the **patient information document for study participation (Appendix 1)** and patient participation in this study was voluntary and did not impact the treatment rendered. The criteria as set out in table 4.1.1 was applied:

Table 4.1.1 Inclusion and exclusion criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
Age > 18 years old, human study only	Fractures presenting with clinical sepsis (pus discharge evident)
Dentate patients	Fractures in edentulous patients
Simple or compound only	Comminuted fractures
Initial presentation for a new injury	Previously treated fractures
Surgery performed within 14 days from date of injury	Fractures arising from gunshot wounds and penetrating trauma such as knife wounds
Fractures arising from trauma, occupational injury, sports injury, traffic accidents, dental extractions, falls	Fractures arising from pre-existing pathology (odontogenic cysts/tumours/osteomyelitis)
Pre and post-operative panoramic and postero-anterior (PA) mandible radiographs at the required intervals	Associated fractures involving condylar process, symphyseal, parasymphyseal, body regions of mandible
Unfavourable fractures	Concomitant facial fractures including fractures of maxilla and zygoma
	Bilateral mandible angle fractures

4.2 Study groups

Three treatment groups were created for descriptive and comparative purposes in this study.

Group 1:non-rigid fracture fixation using open reduction and **internal wire fixation** with 6 weeks of intermaxillary fixation (IMF).

Group 2: open reduction and internal fixation (ORIF) using a **single miniplate** placed along the superior border of the mandible or on the supero-lateral surface, using at least two 2.0-mm-diameter screws on each side of the fracture as described by Champy (Champy, 1978). In addition to the miniplate these patientshad 3 weeks of intermaxillary fixation.

Group3: open reduction and internal fixation (ORIF) using **2 miniplates**, 1 placed at the superior or supero-lateral border and 1 along the inferior border of the mandible laterally, attached with at least two 2.0-mm-diameter screws on each side of the fracture. As per group 2 patients, in addition to miniplates, these patients also had 3 weeks of intermaxillary fixation for comparison.

4.3 Patient allocation and randomisation

Raosoft®, an online sample size calculator was utilised and according to this calculation a sample size of 75 is suitable for measuring and comparing meaningful outcomes for this study.For randomisation, a balancing strategy was utilised. 75 pieces of equally cut cardboard paper (roughly 5 by 2 centimetres) were separated into 3 lots of 25 pieces each.

The words ***"wire"***, ***"1 plate"***, ***"2 plates"*** were written onto individual cut papers (1 per paper) so that twenty five pieces of cardboard paper had the words "***wire***"; another 25 had the words

"***1 plate***" and another 25 the words "***2 plates***" and placed in a sealed container face down and shuffled and retained by the researcher only. Upon consent and admission the patients were randomised and assigned to the study relevant group and allocated a study number (1 – 75).

The fractures were not considered as medical emergencies and were usually scheduled electively when operating room time permitted. However, for meaningful conclusions to be drawn the study patients were to have their fractures repaired within 14 days of the date of injury. All surgeries were performed under general anaesthesia by maxillofacial departmental consultants, the researcher and registrars who had completed at least 12 months of training. As the department renders services at 2 hospitals, the ability for all the surgeries to be carried out by the researcher only were not feasible. The level of seniority of the operator was also recorded on the data sheet (**Appendix 2**).

The clinical findings such as age, race, gender, site, presence of a tooth in the line of the fracture and mode of injury were documented on the data collection sheet (**Appendix 2**) along with the parameters listed below.

4.3.1 Pre-operative recordings (recorded by the admitting doctor)

1. Pre-operative mouth opening; measured as an inter-incisal distance with ruler graded in millimetres (mm).

2. Pre-operative functioningof ipsilateral inferior alveolar nerve and mental nerve branches. This will be performed with a wooden spatula pressed against the ipsilateral lower lip and teeth with the patients eyes closed. The findings were graded as: anaesthesia (complete loss of sensation); paraesthesia (partial sensory loss) and

nerve intact (no neural fallout). Intact sensory perception on the contralateral lip will serve as a control for this parameter.

3. Degree of inferior alveolar canal displacement: measured on the panoramic radiograph as the discrepancy between the superior corticated margins of the inferior alveolar canal on either side of the fracture (mm). This was graded as fracture displacement being *mild* (1-2mm), *moderate* (3-4 mm) and *severe* (5mm and greater).

4. Fracture favourability. All patients had 2 radiographs; a panoramic and a postero-anterior (PA) mandible radiographs. Vertical and horizontal fracture favourability was graded by researcher upon radiographic evaluation.

4.3.2 Surgical procedures

Surgical procedures were carried out as per standard practise and departmental protocols. The antibiotic regimen for this study can be seen in **Appendix 5**. Briefly, 1.2 grams of Augmentin® was given intravenously as a prophylactic stat dose intra-operatively (Clindamycin® 600mg if allergic) following nasotracheal intubation. After administration of local anaesthesia Xylotox E80 A®, 0.18 gauge stainless steel eyelet wires were placed interdentally as per standard practice.

For all cases a full thickness muco-periosteal intraoral incision was then made from the descending ramus region to the interproximal papilla between the mandibular first and second molars. If teeth in the fracture site were to be extracted, the intraoral incision included the attached gingiva around the involved tooth. Only the amount of soft tissue stripping necessary to visualize, reduce, and stabilize the fracture was performed. When present, the third molar teeth that were exposed in the line of fracture were removed.

Group 1 (Wire osteosynthesis): with intermaxillary fixation secured, 2 monocortical holes were drilled in the buccal cortex using a 701 fissure bur, one on either side of the fractured segment. A 0.20 gauge stainless steel wire was then passed circumferentially between the holes and tightened to reduce the fractured segment. The intermaxillary fixation was then released to allow suturing and throat pack removal prior to re-securing the IMF prior to extubation.

Group 2 (single plate fixation): once the fracture had been exposed as above and IMF secured, fracture reduction was carried out using a **single 2.0mm miniplate** placed either along the superior border of the mandible along the external oblique ridge as described by Champy *et al* (Champy, 1978) when permissible or on the supero-lateral surface, using at least two 2.0-mm-diameter monocortical screws on each side of the fracture. When the external oblique ridge was not amenable to fixation as per the Champy technique (Champy, 1978), the lateral border plate was placed transorally or using a transbuccal trocar and cannula as Wan *et al*. reported no difference in outcomes between the 2 techniques. (Wan, 2012). In addition to the miniplate these patients had 3 weeks of intermaxillary fixation.

Group 3 (double miniplate fixation): once the fracture had been exposed as above and IMF secured, fracture reduction was carried out using **two 2.0mm miniplates**. The first plate was to be placed either along the superior border of the mandible along the external oblique ridge as described by Champy *et al* (Champy, 1978) when permissible or on the supero-lateral surface, using at least two 2.0-mm-diameter monocortical screws on each side of the fracture. The second 2.0mm miniplate was then placed as close as possible to the mandibular lower border using a transbuccal trocar and cannula with at least two 2.0-mm-diameter monocortical screws on either side of the fracture. Patients were then placed in IMF for 3 weeks.

In cases of miniplate osteosynthesis, the 2.0mm titanium miniplate and screw systems are available for routine daily use for facial fracture fixation within the respective hospitals. Those utilised for this study were all available to the operator for selection at the institutions' state facility operating rooms. The array of selection included those from W. Lorenz®, Synthes®, KLS Martin®, Stryker Leibinger®, and Mondeal Omnimed® respectively. Post-operative radiographs (panoramic and PA mandible) were taken prior to discharge to assess the reduction obtained. The patients were discharged 1 day after surgery and a regime of oral hygiene was encouraged along with a liquid diet.

4.3.3 Intra-operative recordings

Total operating time was recorded (in minutes) from the time of placement of the first interdental eyelet wire to the time of placement of the last suture. This was recorded as T1 < 60 minutes or T2 > 60 minutes for the surgical procedures respectively.

4.3.4 Post-operative recordings (by attending doctor in out-patient department)

Week 1 post surgery review: the patient is reviewed where healing is inspected for the presence of wound breakdown or sepsis.

Week 3 post- surgery review: as per week 1 review and in addition the IMF wires will be released for group 2 and 3 patients.

Week 6 post-surgery review: as per week 1 review and in addition the IMF wires were released for group 1 patients. The eyelet wires were removed for all 3 groups and the relevant parameters recorded (mouth opening, nerve function etc.) and post treatment radiographs will be taken and retained.

3 months post-surgery review: as per 6 weeks post-surgical review with new radiographs.

4.4 Ethics

Permission to conduct the study was obtained from the WITS School of Oral Health's 'Faculty research committee' reference number (HRRC/JUNE/2016/1) as well as from the University's Human Research Ethics Committee; clearance number M151035. Strict confidentiality was maintained as the patients were allocated a study number (1 – 75) and an accompanying randomised treatment modality upon the **data collection sheet** (***Addendum 2***). All patient identifiers were removed and stored upon a **separate link file** (***Addendum 3***) for use by the researcher only. When compiling the data, the patient's data sheets were reviewed by the researcher only and records such as radiographs were retained by the researcher. Data collection sheets with the patients' allocated study number were updated by the registrars and medical officers at the respective institutions when the patients arrived for their scheduled post-surgical review appointments (***Addendum 2***).

4.5 Data Analysis

Once compiled, the data capturing, management and cleaning were done by the researcher using Microsoft Excel. The data was then imported into STATA®, Texas) for analysis. Descriptive analysis, where data were summarized using mean and standard deviation for numerical variables that were normally distributed, otherwise, median and interquartile ranges (IQR) were used. Proportions and frequency tables were used for categorical variables

Inferential Analysis was run using chi squared test to check association between 2 categorical variables and then a logistic regression analysis followed which included: Continuous data was assessed for normality and presented as means and standard deviations where possible. ANOVA and T-tests was used to test the differences between groups. Categorical data was presented as proportions. Chi – square tests was used to assess the relationships between categorical variables. All tests were performed at the 95% confidence interval.

4.6 Funding

There were no special funding requests anticipated in order to perform the study.

Photocopying and printing of data collection and patient information sheets were done in-house.

CHAPTER 5

5.0 RESULTS

5.1 Data interpretation.

The study was carried out over 2 years from 2015 to 2016 at the respective hospitals and the total number of participants was 75. This included 68 males and 7 females which ranged in age from 18 to 52 years (median: 27, IQR 24-33) as shown in Figure 5.1.1). 44 fractures were on the patient's left while 31 fractures were on the patient's right hand side. The mechanism of injury equated to 1 (1.3%) arising from a fall, 1 (1.3%) from a pedestrian vehicular accident, 4 (5.4%) from a motor vehicle accident and 69 (92%) arising from interpersonal violence.

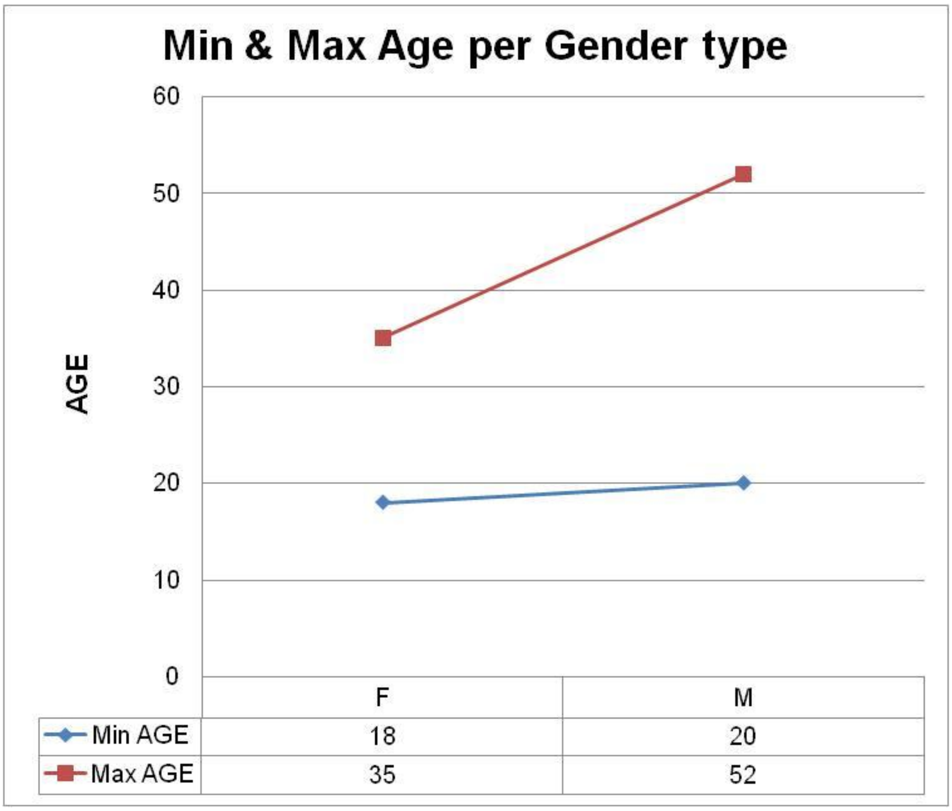

Figure 5.1.1 – Gender spread and Age demographic of study case patients.

There were 25 patients per group (for each of the three treatment groups). The average days from the date of the injury to the date of surgical repair was 10 days (range: 2 – 14, median: 10, interquartile range (IQR): 8 – 12). The fracture displacement ranged from 1 to 7 millimetres (mm) with an average of 2.5mm (SD = 1.3) and in terms of the pre-operative recordings this equated to the degree of displacement being mild in 45 patients, moderate in 24 and severe in 6 patients as shown in Figure 5.1.2.

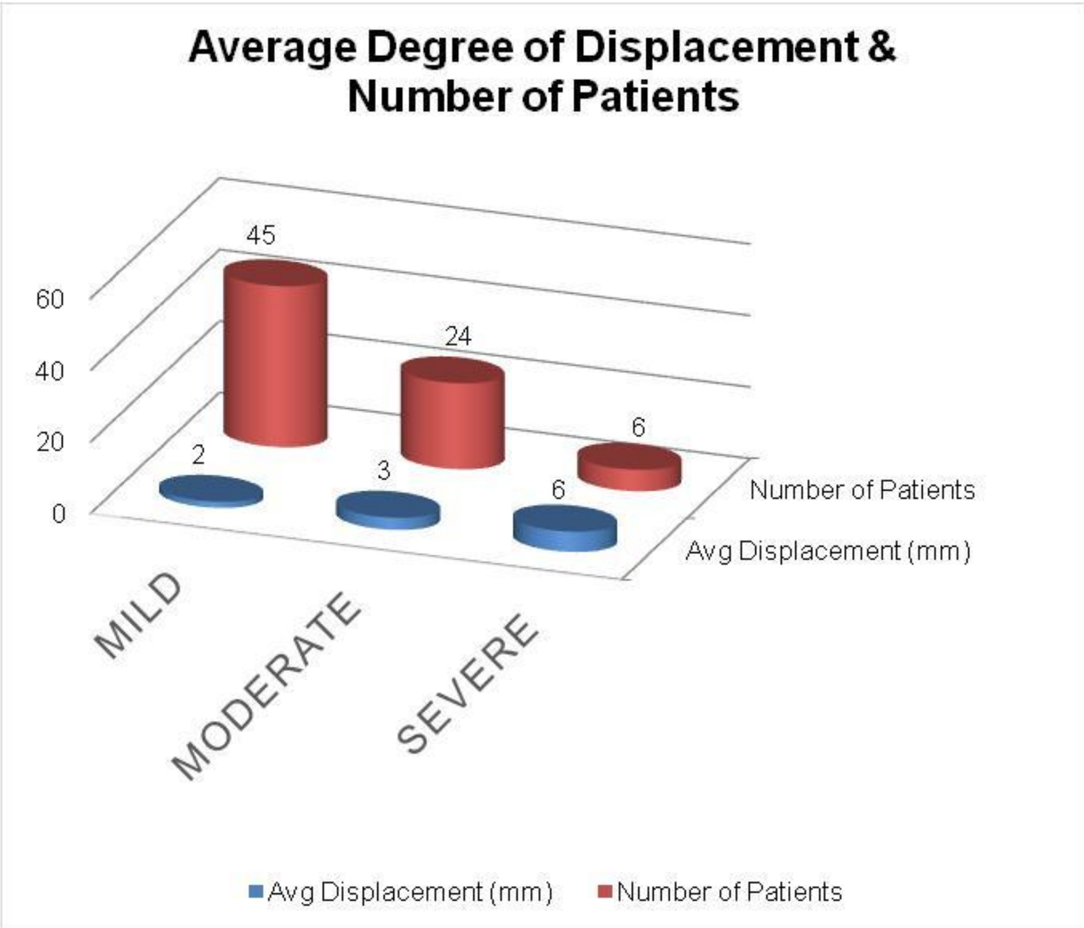

Figure 5.1.2. Average degree of displacement and number of patients.

The pre-operative mouth opening ranged from 7 to 38 mm (mean: 20.6, SD: 5.1) while the post-operative mouth opening ranged from 25 – 52 mm (mean 36.2, SD: 4.8) (Figure 5.1.3). Neurologically, 14 patients presented with pre-operative anaesthesia in the distribution of the mental nerve, 32 with paraesthesia and 29 with intact nerve function. Post-operatively lower lip anaesthesia persisted in 6 patients while 12 had paraesthesia and 57 had an intact nerve function.

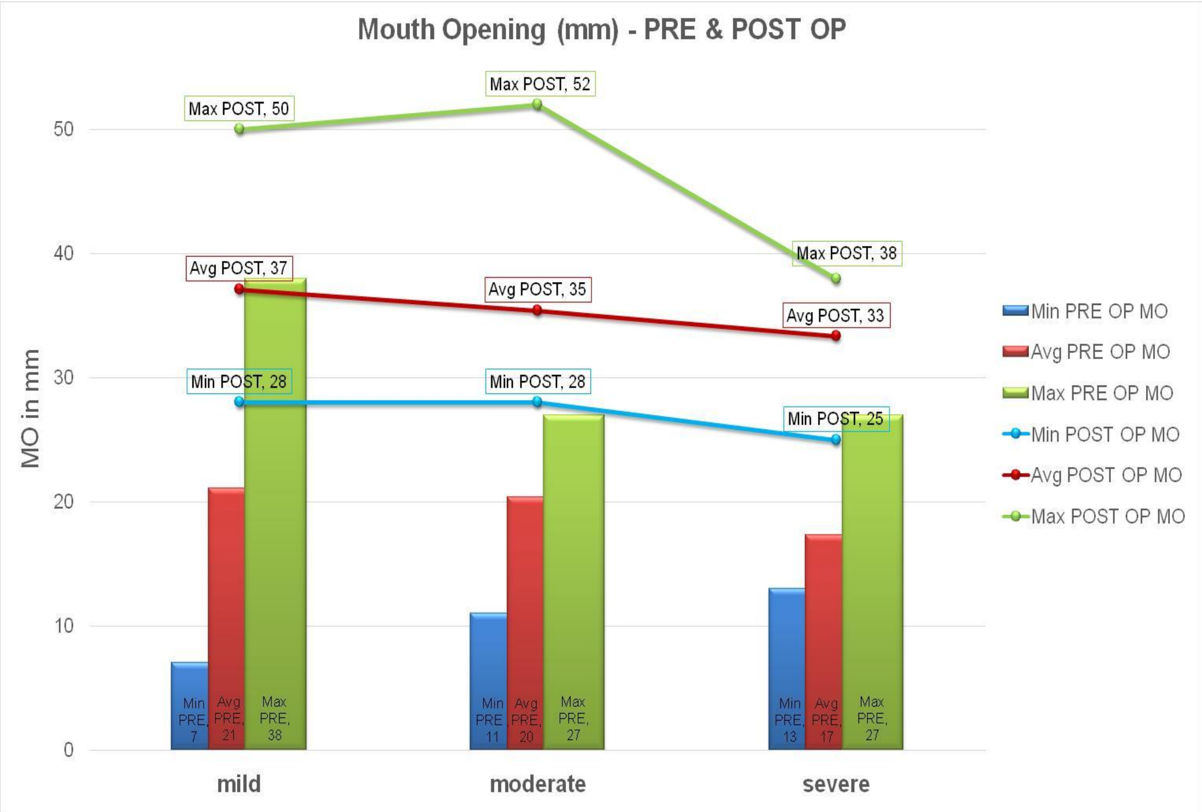

Figure 5.1.3. Pre and Post-operative mouth opening analysis.Vertical lines represent the minimum (blue), average (red) and maximum (green) mouth openings recorded *pre-operatively* whereas the horizontal lines represent the minimum (blue), average (red) and maximum (green) values of mouth opening achieved *post-operatively* with necessary figures shown.

The surgical operating time was recorded for all cases and revealed that this ranged from 26 to 100 minutes (mean 55.7, SD 18.3). The individual groups' average surgical times is represented below in Figure 5.1.4. When graded this was represented as T1 (<60 minutes –

48 cases, 64%) and T2 (>60 minutes – 27 cases, 36%). In the cases where post-operative septic events occurred, the sepsis was noted on average 21 days post-surgical repair.

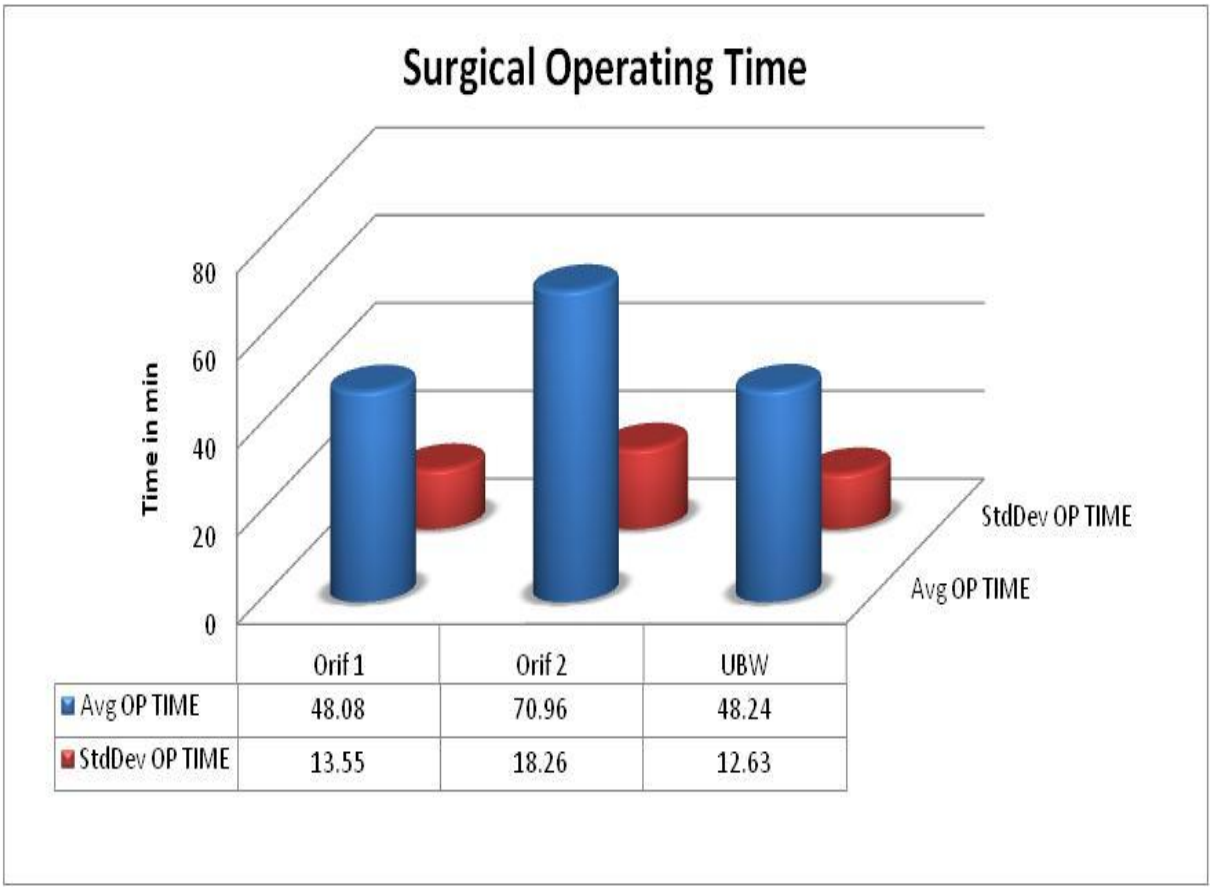

Figure 5.1.4. Surgical operating Time per Treatment type with relative Standard Deviation.

10 patients presented with post-operative complications including localised subperiosteal suppuration with fixation failure (Figure 5.1.5). Mobile screws and superior border wires were the primary cause amongst these 10 patients.

Amongst individual groups, 2 out of the 25 patients (8%) in the superior border wire group (Group 1) suffered septic sequelae due to wire loosening while 4 out of 25 (16%) patients in Group 2 (Single miniplate) sustained septic events, all due to mobile screws. In Group 3 patients (Double miniplate) 4 out of the 25 patients (16%) also sustained incidence of sepsis (due to loose screws in 3 patients while in the remaining 1 patient the cause was a combination of loose screws and fracture of the miniplates—Figure 6.7). This equated to an overall incidence of septic events arising in 10 out of a total of 75 patients or an overall complication rate of 13.3%, as seen in Figure 5.1.5.

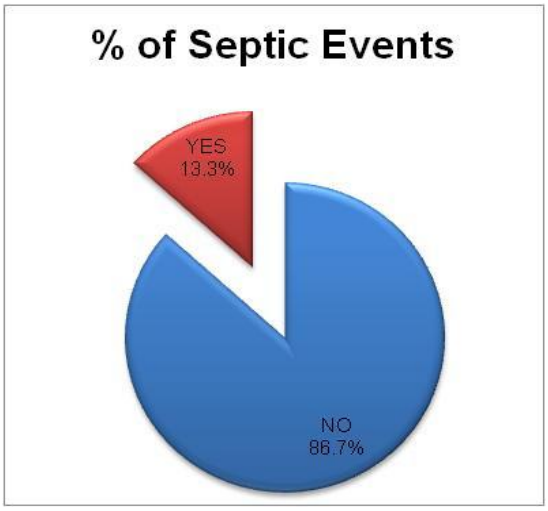

Figure 5.1.5. Percentage of Septic events from Total number of cases (75).

The 10 patients all had to have a 2nd surgical procedure under general anaesthesia whereby the mobile hardware/wires was removed. At the time of the repeat surgery the degree of fracture union/healing was deemed as a clinical union in 5/10 patients warranting no further intervention, a malunion in 3/10 patients and a non-union in 2/10 patients. The intermaxillary fixation (IMF) was re-secured for a period of 1 week in these patients with malunion and non-union and the sepsis was allowed to settle along with further intravenous antibiotics, in preparation for re-fixation.

The 2 patients with clinical non-union belonged to Group 1 (Wire) and Group 3 (double miniplate) respectively and this non-union persisted even after an additional period of IMF thereby warranting additional intervention. They were subsequently taken for rigid fracture fixation under general anaesthesia using an extraoral approach (Risdon's approach). These patients were followed through to the 3 month review and were complication-free at that point, both with residual ipsilateral lower lip anaesthesia.

Of the three patients with clinical malunion 1 belonged to Group 2 (single plate) and 2 belonged to Group 3 (Double miniplate). At the three month review, all 3 exhibited clinical union and an intact occlusion with > 30 mm mouth opening requiring no further surgical intervention.

A selected sample of cases across all three treatment groups as well their radiographic outcomes are depicted in figures 5.1.6, 5.1.7 5.1.8 and 5.1.9 below.

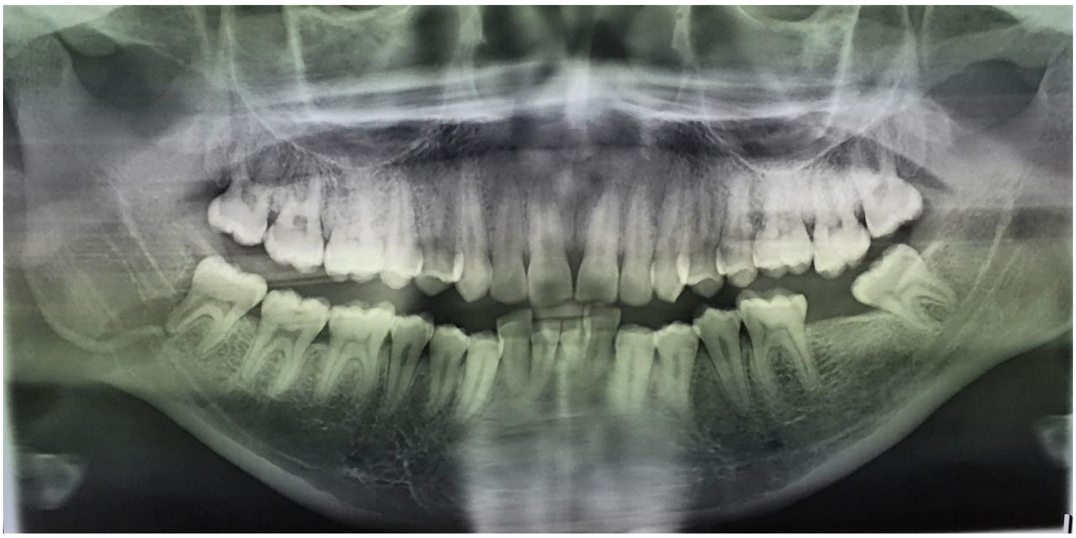

Figure 5.1.6a. A panelipse radiograph of patient 1 showing a right mandibular angle fracture with moderate displacement (4mm)

Figure 5.1.6b. An intra-operative surgical view of patient 1 showing the right angle fracture reduced using 2 titanium miniplates.

Figure 5.1.6c. A 3-month post-operative panelipse radiograph of patient 1 showing a healed fracture at the right mandibular angle.

Figure 5.1.7a. A panelipse radiograph of patient 2 showing a left mandibular angle fracture.

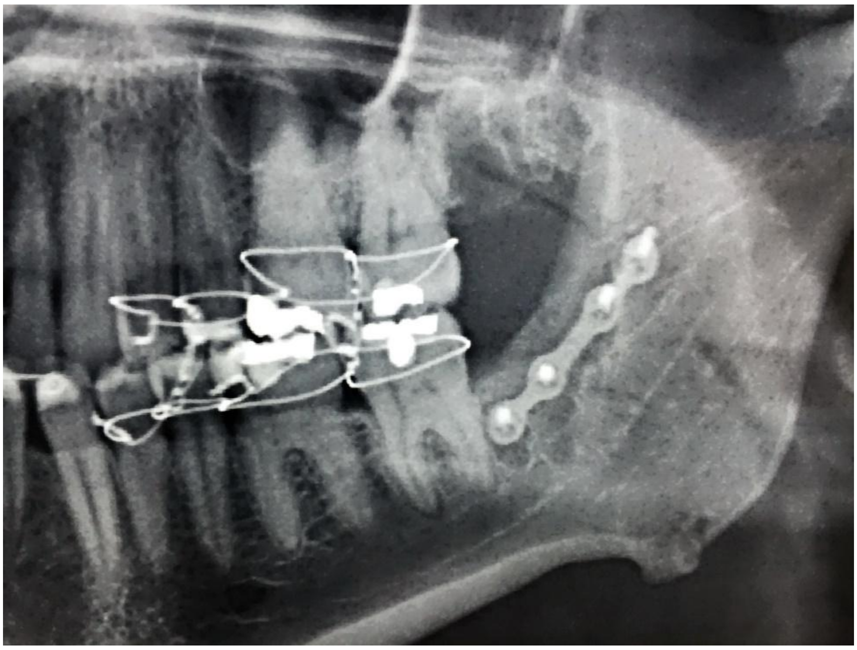

Figure 5.1.7b. A cropped image of an immediate post-operative panelipse radiograph of patient 2 showing the left mandibular angle fracture reduced using a single miniplate on the lateral border in a tension-band type method.

Figure 5.1.8a. A preoperative panelipse radiograph of patient 3 showing a right mandibular angle fracture.

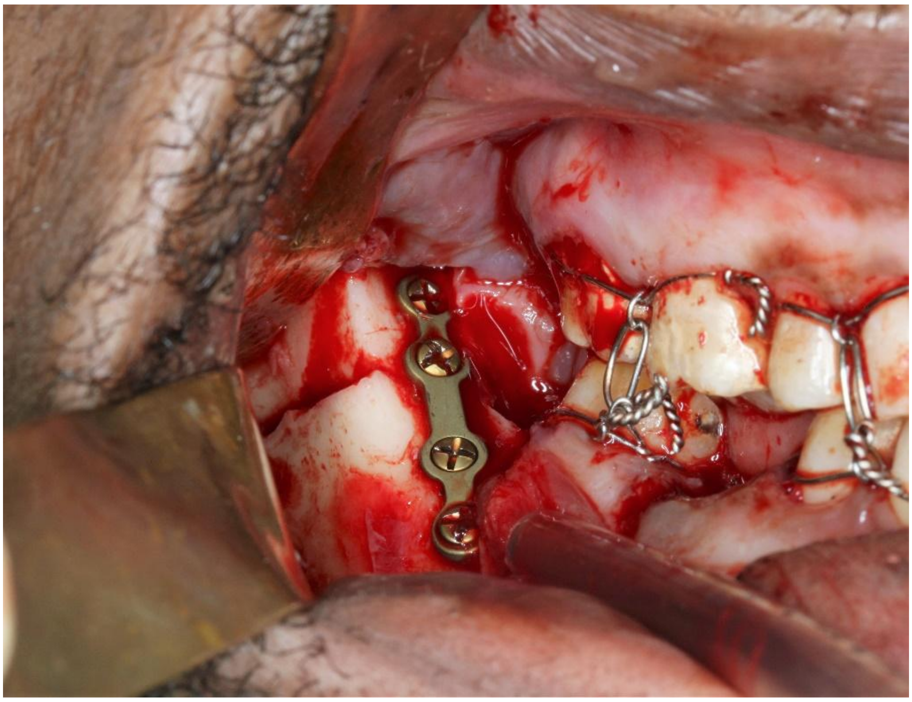

Figure 5.1.8b. Intraoperative image of patient 3 showing the right angle fracture post-reduction with a single miniplate placed along the superior border.

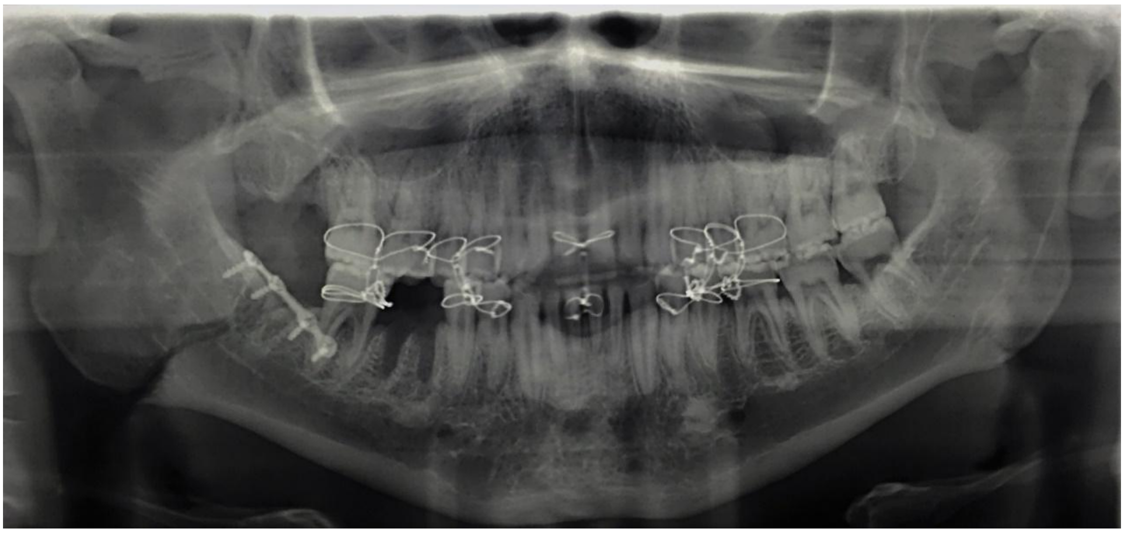

Figure 5.1.8c. An immediate post-operative radiograph of patient 3 showing the right mandibular angle fracture reduced using a superior border miniplate.

Figure 5.1.9a. A cropped image of the left mandibular angle fracture of patient 5.

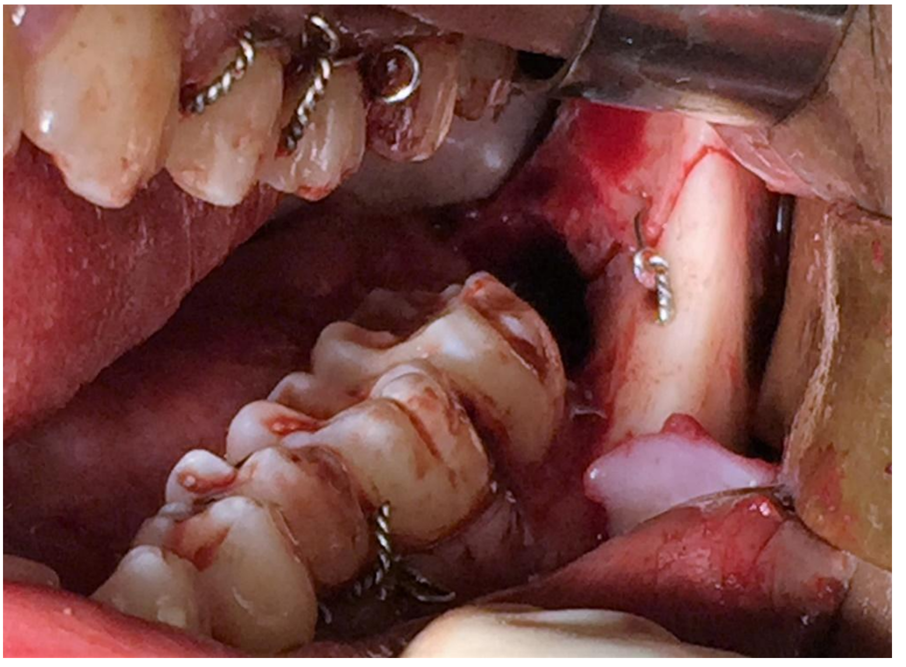

Figure 5.1.9b. An intraoperative image of patient 5 showing the left angle fracture reduced with a superior border wire.

Figure 5.1.9c. A cropped image of a 3 month post-operative panelipse of patient 5 showing the superior border wire reduction of the left angle fracture, the superior aspect of the fracture has shown near-complete ossification.

5.2 Statistical analysis – Logistical regression analysis

A logistic regression analysis is a statistical method for analysing a dataset in which there are more than one independent variables that determine the outcome. The outcome is measured with a variable in which there are only 2 possible outcomes. A stepwise logistic regression was carried out comparing septic events and the relevant variables (patient age, number of days to operation, average operating time, degree of fracture displacement and type of treatment rendered) all used as continuous variables using a univariate and multivariate analysis.

5.2.1 Univariate logistic regression analysis of factors associated with Septic Events

The relevant variables were all tested against the incidence of a septic event occurring and are all are presented as continuous variables below (Table 5.2.1).

5.2.1.1 Septic event and age as continuous variables

There was no correlation found between patient's age and the incidence of a septic event occurring ($p = 0.932$).

5.2.1.2 Septic event and the number days to operation as a continuous variable

In order to determine if there was any significance in the incidence of sepsis based on the number of days to surgery, a logistic regression test was performed using the interquartile range (8 – 12) of the number of days to surgery as a continuous variable. There was a marginally significant relationship that was noted between the number of days to operation and the incidence of a septic event ($p = 0.074$). However when this was compared to the incidence of sepsis occurring more in those cases operated in the 1st versus the 2nd week post-injury, then no significant relationship was noted (p = 0.3).

5.2.1.3 Septic event and degree of fracture displacement categories

The results of the univariate analysis indicate that there is a statistically significant relationship between the incidence of a septic event and the degree of fracture displacement especially when one considers a 'severely displaced' fracture (p = 0.01) when compared to mildly displaced fractures.

5.2.1.4 Septic event and operating time as a continuous variable

The results indicated that there is no association between the operating time and the incidence of a septic event (p = 0.91). When the incidence of sepsis was compared to the operating time categorised by those cases that were operated within the 1st hour versus those operated beyond the 1st hour then there remained a statistically insignificant association (p = 0.77).

5.2.1.5 Septic event and type of treatment

There was no association between the type of treatment carried out and the incidence of septic events between Group 1 (UBW) and Group 3 (2 plates) when compared to Group 1 (1 plate) patients p = 0.39 and p = 1.0.

5.2.2 Multivariate logistic regression analysis of factors associated with septic event

In order to perform the multivariate analysis, we keep in the model only factors that have been found significant or marginally significant in the univariate analysis (Days to operation, and Degree of displacement). The variable 'Age' was kept in the final model as a demographic characteristic (Table 5.2.2.)

5.2.2.1 Septic event and the number days to operation as a continuous variable.

The results of the multivariate analysis confirms that there is a marginally significant association between the number of days to operation and the incidence of septic events ($p = 0.08$).

5.2.2.2 Septic events and degree of fracture displacement categories

The results of the multivariate analysis confirms that there is a statistically significant association between 'severely displaced fractures' and the incidence of sepsis when compared to 'mildly displaced' fractures ($p = 0.02$). No similar correlation exists when one compares the incidence of septic events to 'moderately displaced fractures' ($p = 0.53$).

TABLE 5.2.1 – LOGISTIC REGRESSION ANALYSIS OF FACTORS ASSOCIATED WITH SEPTIC EVENT (Univariate)

SEPTIC EVENT AGAINST:	ODDS RATIO	(95% CONFIDENCE INTERVAL)	P VALUE
1. Age	1.00	0.91 - 1.10	0.93
2. Number of Days to operation	0.82	0.66 - 1.01	0.074
3. Degree of displacement categories:			
a. Mild	Base	Base	Base
b. Moderate	1.46	0.30 - 7.15	0.63
c. Severe	10.25	1.53 - 68.62	0.01
4. Operating time	1.00	0.97 - 1.03	0.91
5. Operating time categories:			
a. First hour	Base	Base	Base
b. Second hour	1.21	0.31 – 4.75	0.77
6. Type of treatment:			
a. UBW	0.45	0.75 – 2.75	0.39
b. Orif1	Base	Base	Base
c. Orif2	1.00	0.22 – 4.53	1.00

TABLE 5.2.2. LOGISTIC REGRESSION ANALYSIS OF FACTORS ASSOCIATED WITH SEPTIC EVENT (Multivariate)

SEPTIC EVENT AGAINST:	ODDS RATIO	(95% CONFIDENCE INTERVAL)	P VALUE
1. Degree of displacement categories:			
a. Mild	Base	Base	Base
b. Moderate	1.61	0.31 - 8.50	0.57
c. Severe	11.3	1.51 - 85.6	0.02
2. Number of Days to operation	0.81	0.64 - 1.02	0.08
3. Age	0.99	0.89 - 1.10	0.93

5.2.2.3 Significance between type of treatment carried out and post-operative mouth opening achieved

In order to determine if there was any association an independent variable that was tested was the post-operative mouth opening achieved versus the type of treatment that was carried out. A Bartlett test for equal variances (ANOVA) was performed and showed no statistical relationship between the post-operative mouth opening achieved versus the type of treatment that was performed, p = 0.604.

CHAPTER 6

6.0 DISCUSSION

With a reputation of being the most common fracture of the mandible, the angle fracture reportedly accounts for approximately 30% of all mandibular fractures (Ellis, 2010; Al-Moraissi, 2014; Kim, 2016; Spinelli, 2016) and its management continues to arouse debate. Various causes of angle fractures are known and while some of the lesser known causes include sporting or work-related accidents, accidental falls, traumatic dental extractions, gunshot wounds, and pre-existing pathology, the findings of this study shows blunt trauma due to interpersonal violence to be accountable for the vast majority of the fractures (92%).

In keeping with this finding, 59% of these isolated angle fractures were sustained on the patient's left side accounting for a predominantly right handed assailant and an astounding 91% of the patients in the study sample were male. The entire study sample consisted of 75 patients ranging in age from 18 to 52 years with a median of 27 years.

This sample size compares favourably with other similar studies that explored the ideal management of the angle fracture based on different treatment groups such as those performed by Potter and Ellis, 46 patients (Potter and Ellis, 1999), Danda 53 patients (Danda, 2010), Barry *et al.* 50 patients (Barry, 2007), 30 patients by Ellis (Ellis, 1991) as well as 30 cadaveric mandibles by Schierle *et al*. (Schierle, 1997) and Khiabane and Mehmandoost (2013) who reported upon 40 patients.

There are also studies in the literature which reported on a larger sample size such as Seemann *et al.* (Seemann, 2010) who included 322 patients with 335 angle fractures, Ellis:

185 patients (Ellis, 2010), Kim: 134 patients (Kim, 2016), Strasz and co-workers with 184 patients (Strasz, 2016) and more recently Spinelli and colleagues who reported on 389 patients (Spinelli, 2016).

Amongst the plethora of studies reporting upon the ideal angle fracture management, most large scale studies represent cases whereby an angle fracture was treated in the presence of other concomitant mandibular fractures (Ellis and Walker, 1996; Khiabane, 2013; Seemann, 2010; Spinelli, 2016; Zix, 2007) while amongst the isolated angle ones the vast majority are retrospective in nature (Barry, 2007; Spinelli, 2016; Strasz, 2016; Wan, 2012). From the remaining ones very few of these are actually prospective studies (Danda, 2010; Ellis, 2010; Kim, 2016) and among these only those by Kim *et al.* (Kim, 2016) and Danda (Danda, 2010) and Siddiqui *et al.* (Siddiqui, 2007) show a randomisation strategy.

Recognising that the isolated unilateral mandibular angle fracture is a rare occurrence, Ellis in 2010 formulated a fixed pattern of assignment for the patients in his study with comparable groups (Ellis, 2010). Of importance it was mentioned that in order to negate the complex biomechanical forces at play, studies depicting outcomes on isolated angle fractures such as the one carried forth here were important so as not to skew the results with the presence of concomitant fractures.

6.1 Study sample size

For comparative outcomes, this study provided comparable treatment groups. A total of 75 patients were randomly allocated to one of the three treatment groups i.e. 25 patients per group, which is similar to the method employed by Danda (Danda, 2010) and in contrast to the nonrandomised, fixed pattern of treatment group allocation as assigned by Ellis. (Ellis, 2010) who had 60, 62 and 63 patients per treatment group respectively.

6.2 Number of days to operation

The results of the multivariate analysis confirms that there is a marginally significant association between the number of days to operation and the incidence of septic events ($p = 0.08$). This is based on the interquartile range of 8-12 days which tells us that greater than 50% of the patients were operated in this time frame. The average time lapse to treatment in our study was 10 days. This is much higher than that reported by Kim *et al.* (2.43 days), Ellis (5.2 days) and Spinelli *et al.* (2.5 days) (Ellis, 2010; Kim, 2016; Spinelli, 2016).

Of the ten patients with septic events, 3 occurred on surgery performed within the first week while 7 occurred in patients in whom the surgery was performed in the second week ($p = 0.3$)

6.3 Degree of fracture displacement

Our study revealed an average fracture displacement of 2.5 millimetres (mm) with a range from 1 to 7mm (SD = 1.3) equating to the degree of displacement being mild (1-2mm) in 45 patients, moderate (3-4mm) in 24 and severe (>5mm) in 6 patients. Zix *et al.* used the same model of displacement on a series of 20 patients and reported 16, 2 and 2 patients per category respectively (Zix, 2007).

We also reveal a statistically significant association between the severely displaced fractures and the incidence of sepsis when compared to ‘mildly displaced’ fractures (p = 0.02). No similar correlation exists when one compares the incidence of septic events to ‘moderately displaced fractures’ (p = 0.53) regardless of the type of treatment that was rendered. A severely displaced fracture may therefore be a predictor for the occurrence of a septic event.

6.4 Mouth opening and neurological assessment

The mouth opening post-treatment ranged from 25 – 52 mm (mean 36.2, SD: 4.8) which is similar to that reported in other studies (Barry, 2007; Ellis, 2010; Spinelli, 2016). Neurologically, a pre-operative paraesthesia of the lower lip as a result of the fracture in 32 patients had resolved by 3 months in 20 patients leaving 12 with transient post-operative paraesthesia. 14 patients presented with pre-operative anaesthesia in the distribution of the mental nerve and this persisted in 6 patients leaving a permanent sensory deficit of 8 % which is similar to the outcome reported by Barry and Kearns(Barry and Kearns, 2007;Figure 6.1)

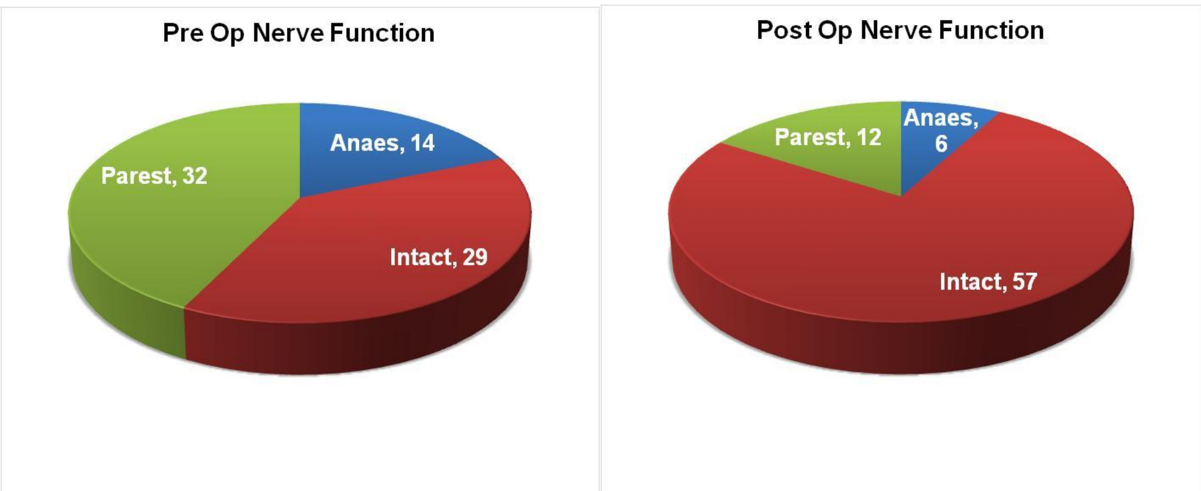

Figure 6.1. Pre and Post-operative nerve function depicted by number of patients.

6.5 Average operating time

The surgical operating time as depicted in figure 5.1.4, ranged from 26 to 100 minutes (mean 55.7, SD 18.3) which is comparable to the studies by Ellis (29.5 minutes), Zix *et al.* and Spinelli *et al.* (65 minutes).

6.5.1 Group 1: Superior border wiring

When compared to the results of Ellis' 27.8 minutes (Ellis, 2010), the average surgical time for the patients in Group 1 (Wire) in our study was 48.24 minutes (SD 12.63), p = 0.43. (Figure 6.3).

6.5.2 Group 2: Single miniplate

When compared to Ellis' 23.5 minutes (Ellis, 2010), the average surgical time for the patients in Group 2 in our study was 48.08 minutes (SD 13.55), p = 0.67. (Figure 6.3).

6.5.3 Group 3: Double miniplate

When compared to Ellis' 37 minutes (Ellis, 2010), the results of our study indicate that the average surgical time for the patients in Group 3 were markedly longer at 70.96 minutes (SD 18.26), p = 0.86. (Figure 6.3).

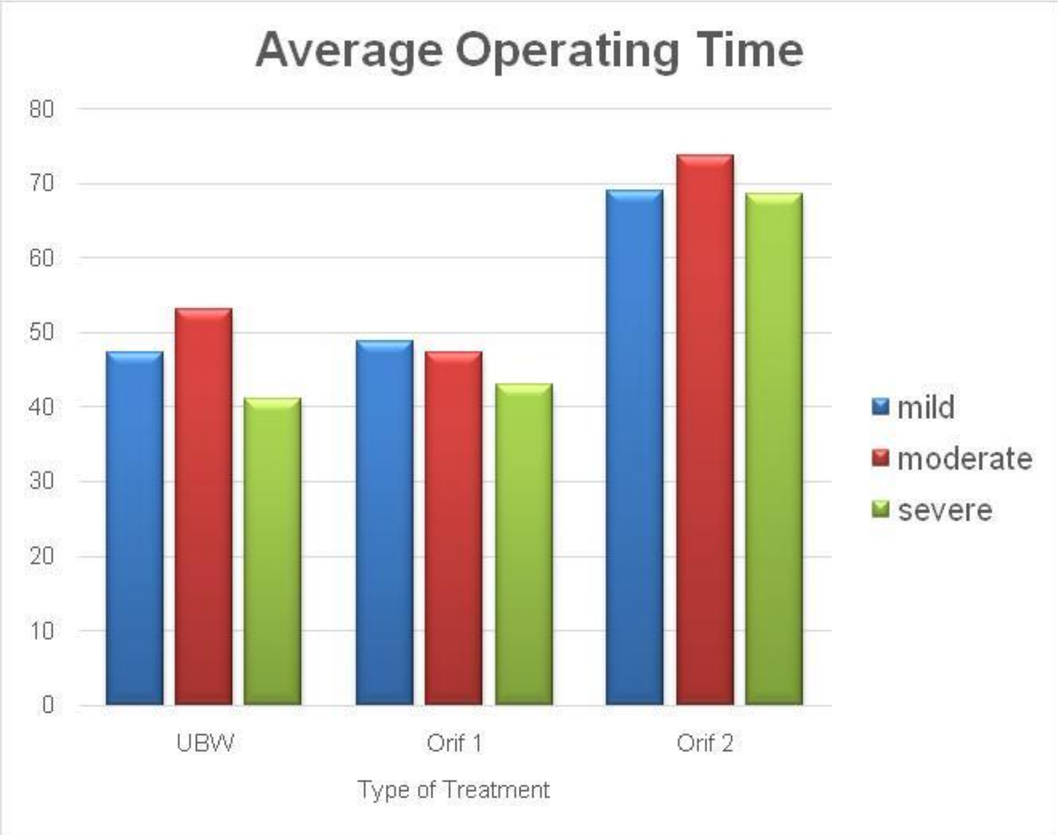

Figure 6.3. Average operating time per Treatment type and Degree of displacement.

When graded this was represented as T1 (surgery < 60 minutes – 48 cases, 64%, Figure 6.4) and T2 (surgery > 60 minutes – 27 cases, 36%, Figure 6.5). In the 10 cases where post-operative septic events occurred, the sepsis was noted on average 21 days post-surgical repair. Within this group of 10 patients, 4 belonged to the category of 'surgery > 60 minutes' and 6 in the category of 'surgery < 60 minutes'. Three out of the four (75%) patients belonging to the time category of surgery beyond 60 minutes were patients in whom 2 miniplates were placed and subsequently removed. Overall 3 out of the 4 patients who sustained septic events in the double plate group had surgery which lasted more than 1 hour and subsequently returned with complications.

Figure 6.4. Operating time T1 (< 60 min) *vs.* Number of Septic cases

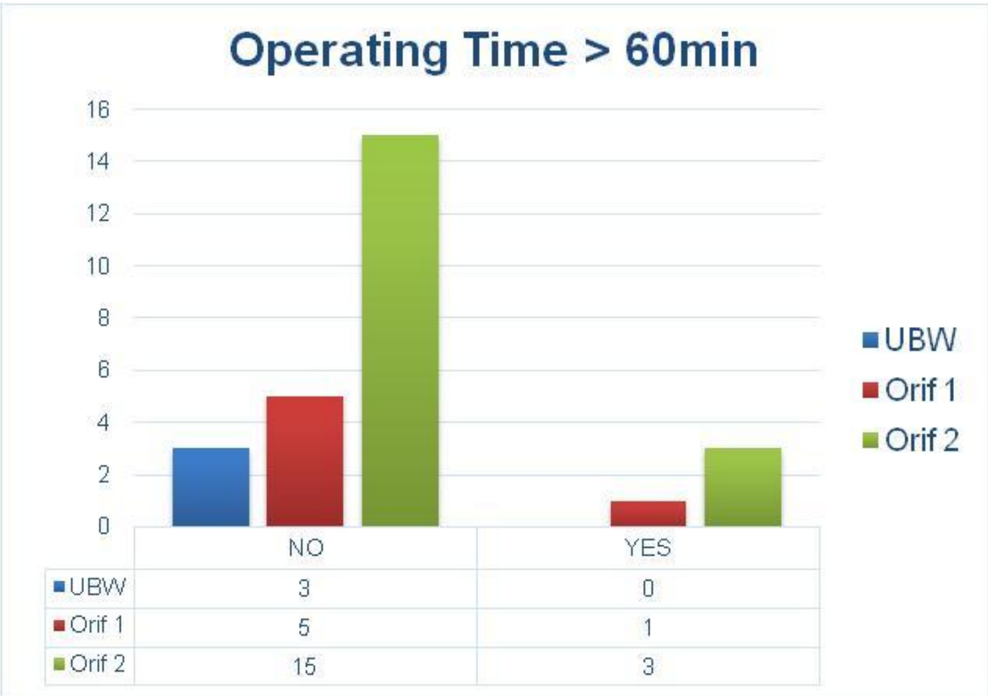

Figure 6.5. Operating time T2 (> 60 min) *vs.* Number of Septic cases

The results indicated that there is no association between the operating time and the incidence of a septic event ($p = 0.91$). When the incidence of sepsis was compared to the operating time categorised by those cases that were operated within the 1st hour versus those operated beyond the 1st hour then there remained a statistically insignificant association ($p = 0.77$).

6.6 Septic events/complications and type of treatment rendered

Ten patients presented with post-operative complications including localised subperiosteal suppuration with fixation failure. This was attributable to mobile screws and wires and equated to an overall incidence of septic events or an overall complication rate of 13.3% which is comparable to those achieved by Ellis and Walker (16%), Spinelli *et al.* (13.6%), Strasz *et al.* (17.4%), Kim *et al.* (19.4%), Seemann and co-workers (20%) and Barry and Kearns (12%) (Barry, 2007; Kim, 2016; Ellis and Walker, 2010; Seemann, 2010; Spinelli, 2016; Strasz, 2016). There was no correlation found between the incidence of sepsis and type of treatment that was carried, $p = 0.39$ (Figure 6.6.).

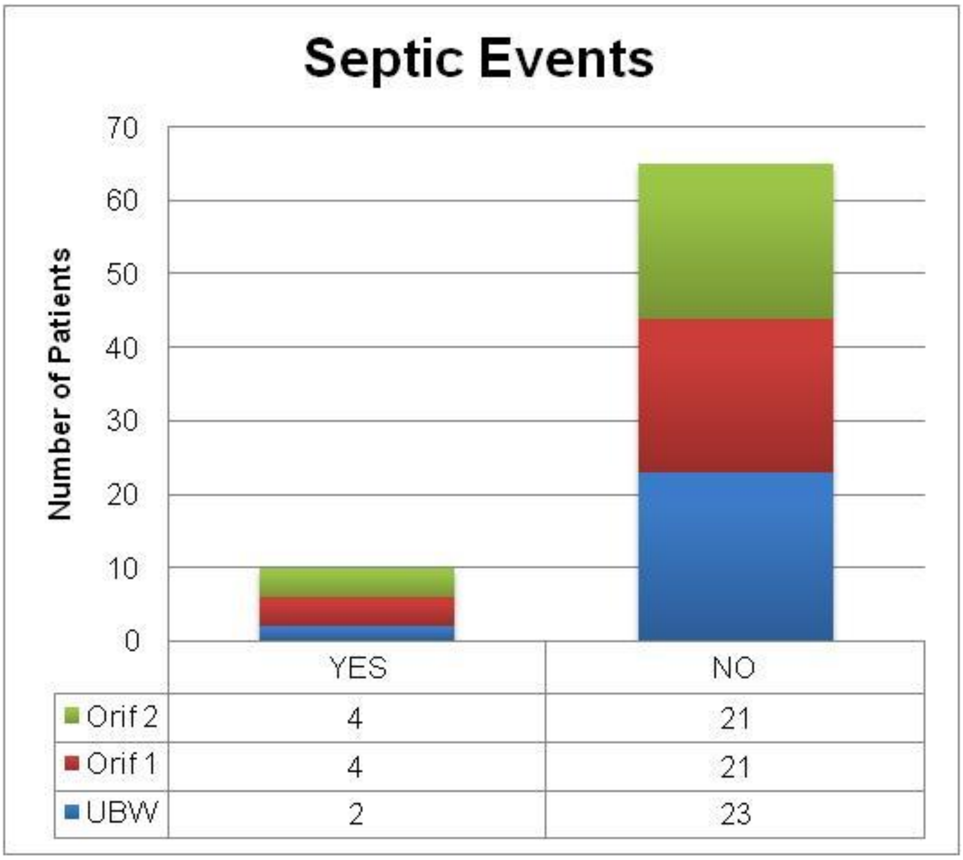

Figure 6.6. Number of Septic events per Treatment type group.

6.6.1 Septic events per individual groups

An 8% complication rate was noted in Group 1 (Wire), with 2 out of 25 the patients sustaining septic sequelae due to wire loosening. Four out of the twenty five (16%) patients in Group 2 (Single miniplate) sustained septic events, all due to mobile screws. In Group 3 patients (Double miniplates) 4 out of the 25 patients (16%) also sustained incidence of sepsis whereby in 3 patients this was due to loose screws while in 1 the cause was a combination of loose screws and fracture of the miniplate (figure 6.7). The 10 patients all had to have furthersurgeriesto remove the hardware/wire.

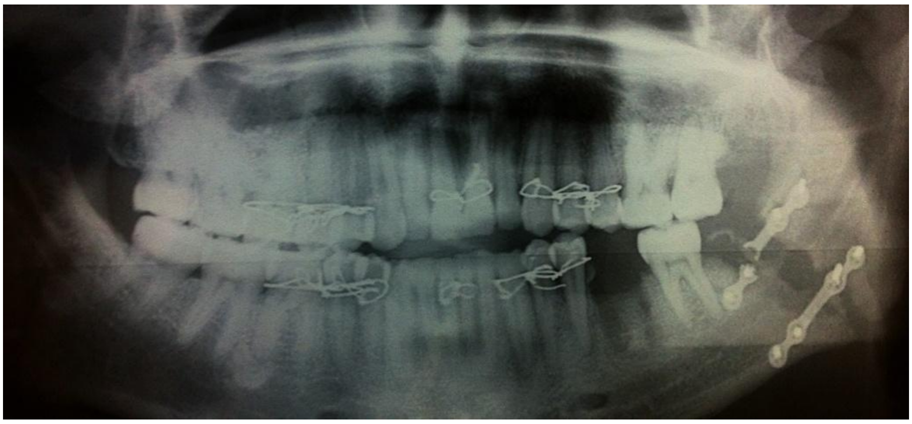

Figure 6.7. Fixation failure. A panelipse radiograph of patient 6 showing fracture of the superior border plate with loosening of the screws. At the time of removal, a non-union was noted.

At the time of the 2nd surgery and wire/plate removal the degree of fracture union/healing was noted and deemed as a clinical union in 5/10 patients, a malunion in 3/10 patients and non-union in 2/10 patients. The intermaxillary fixation (IMF) was re-secured for a period of a further 1 week for non-united and mal-united fractures and the sepsis was allowed to settle in preparation for the 2nd surgery.

One patient from Group 1 (Wire) and one from Group 3 (double miniplate) respectively had clinical nonunion requiring further fixation after the additional 1 week of IMF. Under general anaesthesia and utilising a Risdon’s approach, these patients had the placement of rigid fracture fixation in the form of a 2.4mm reconstruction plate. These patients were followed through to the 3 month review and were complication-free at that point, both with residual ipsilateral lower lip anaesthesia.

Of the three patients with clinical malunion 1 belonged to Group 2 (single plate) and 2 belonged to Group 3 (Double miniplate). At the three month review, all 3 exhibited clinical union and an intact occlusion with > 30 mm mouth opening requiring no further surgical intervention.

6.7 Age and gender correlation for septic events

It is known that the elderly have a slower healing progression when compared to the youth and logically one would anticipate an increased complication rate in older patients. When one considers age and gender as possible predictors for the incidence of septic event we noted that there was no correlation found between patient's age and the incidence of a septic event occurring ($p = 0.932$). The patient's age was left within the pool in order to compare demographic data. Furthermore, the patient's gender could not be used to draw conclusions as there were no female patients with septic sequelae within the study sample.

6.8 Fracture fixation

There has been considerable debate as to the most appropriate method for the management of mandibular angle fractures (Barry, 2007; Danda, 2010; Ellis, 1992, 1996, 1999, 2010; Levy, 1991; Schierle, 1997; Zix, 2007). The AO/ASIF Foundation recommends the use of one miniplate (Strasz, 2016) using a non-rigid osteosynthesis. However, proponents of rigid fixation prefer conventional treatment consisting of anatomical reduction and rigid fixation favouring the prevention of inter-fragment mobility during normal functioning by utilising bi-cortical screws or 2 miniplates. (Danda, 2010; Ellis, 1996; Levy et al., 1991).

Champy's concept (Champy, 1978) however suggests non-rigid fixation of mandibular angle fractures through a single, small, easily bendable miniplate secured with monocortical screws and was validated in various clinical studies (Danda, 2010; Ellis and Walker, 1996; Schierle *et al*., 1997; Ellis, 1999; Siddiqui et al., 2007; Ellis, 2010).

Several studies exist which compared the outcomes of single versus double miniplates for the angle fracture. (Danda, 2010; Ellis, 2010; Spinelli, 2016, Kim, 2016). The consensus appear to be a single miniplate as described by Champy (Champy, 1978) with several meta-analyses confirming their superiority and functional stability while to date, only Fox and Kellmann (Fox, 2003) have shown favourable results using the 2-plate scheme. Ellis and Walker (Ellis, 1994) showed the use of two 2.0-mm noncompression miniplates had an unacceptably high complication rate of 28%.

A prospective randomized study by Danda (Danda, 2010) indicated no differences in the rates of malocclusion, infection, and wound dehiscence between 1 plates placed with the Champy technique versus 2 plates.Similarly Regev *et al.* in a large scale review reported markedly decreased rates of infection, hardware removal and re-operation when using only a single miniplate (Regev, 2010). Our study shows identical outcomes for those fractures treated with a single and double miniplates (16%).

This suggests that the use of a second plate at the inferior border is not necessary for proper fixation and healing. Furthermore, the placement of the inferior plate increases operating time and increased surgical access with tissue stripping and proficiency with a transbuccal trocar. Biomechanically, Kimsal and colleagues (Kimsal, 2011) reported that a single tension band fixation model shows similar stability to a 2 plate fixation scheme with the added advantage of decreased soft tissue manipulation and subsequent improved outcomes.

Ellis (Ellis, 2010) showed fair outcomes with wire fixation while earlier Passeri *et al* (Passeri, 1993) showed a complication rate of 17% when non-rigid wire fixation was used in conjunction with MMF. The results of our study show the best outcomes with nonrigid wire fixation with 6 weeks of IMF, showing a complication rate of only 8 percent. Recently a randomized controlled study by Kim (Kim, 2016) comparing different plating methods in patients with and without post-operative MMF showed no noticeable differences among groups who had post-operative MMF.

CHAPTER 7

7.0 CONCLUSION

There remains a plethora of techniques available for reducing fractures of the mandibular angle. The AO/ASIF Foundation recommends the use of one miniplate for fixation of an angle fracture in cases of an isolated and simple fracture (Strasz, 2016) which means a non-rigid osteosynthesis. Independent from the AO Foundation's recommendation, a two-pronged debate has raged on between campaigners for rigid fixation and non-rigid, functionally-stable fixation as proposed by Champy *et al.* (Champy, 1978).

Currently, surgeons endure with the simplicity and success of a single semi-rigid plate as put forth by Champy *et al.* (Champy, 1978). Our study shows no differences in fractures reduced using single or double miniplate fixation. The incidence of septic sequelae was 16% in both groups (4 out of 25 patients each). Overall when all other factors were controlled, both groups showed identical rates of sepsis secondary to fixation failure, similar healing potential with no differences in post-operative mouth opening and functionality achieved. This study therefore mirrors the outcomes of other global studies showing that there is no benefit to a second miniplate in those fractures that show displacement of 1-4mm.

Our study has shown a stark contrast to worldwide outcomes regarding usage of superior border wire fixation. We have achieved a 92% success rate on the fractures reduced with a superior border wire along with 6 weeks of post-operative IMF (23/25 patients). These patients (at the completion of the study) had regained full functioning and achieved mouth opening that was comparable to the other 2 groups. Our 8% complication rate in the superior border wire group is markedly lower than previously published outcomes (Ellis, 2010;

Passeri, 1993) and we feel that warrants a re-think on current protocols. Our overall complication rate of 13.3% compares favourably with other global results(Ellis, 2010; Kim, 2016; Spinelli, 2016).

While most may view the extended period of IMF as a being cruel or a hindrance, in those patients where compliance may be questionable and where the fracture is amenable to wire fixation, we recommend this as first line treatment. Furthermore in a resource-constrained environment or one where miniplates and screws are not easily available, it is encouraging to note that wire fixation provides superior outcomes in our small-scale study. Furthermore, this study re-iterates the importance of a randomised, cross-controlled sample with comparable groups.

In addition to the wide literature available, this study will add to the substance to the worldwide data as this is a prospective study on isolated mandibular angle fractures. Future prospective randomised studies on isolated mandibular angle fractures with larger sample sizes will add more value to studies such as ours.

CHAPTER 8

8.0 APPENDICES

8.1 Appendix 1: Patient information document for study participation

8.2 Appendix 2: Data collection sheet

8.3 Appendix 3: Antibiotic regime

8.4 Appendix 4: Ethics clearance certificate

8.5 Appendix 5: Permission to conduct study

8.6 Appendix 6: Raw Data

8.1 Appendix 1: Patient information document

Appendix 1

PATIENT INFORMATION DOCUMENT FOR STUDY PARTICIPATION

<u>Study title</u>: **A COMPARITIVE STUDY OF 3 TREATMENT MODALITIES FOR MANDIBULAR ANGLE FRACTURES.**

Dear Sir/Madam,

I hereby invite you to participate in a research study. I, Dr. Shailen Dulabh, am conducting research on fractures of the angle of the mandible (lower jaw). Research is just the process to learn the answer to a question. In this study we want to learn which treatment option will have the best result for your recovery. This is a research study which does not differ from current standard national & international treatments. However, there are different treatment options with regards to post-operative jaw wiring time periods and fixation methods and thus we would like to see which will be the best as there is no one favoured treatment.

I hereby request for you to take part in this research study. If at any point during the study you feel that you would no longer want to participate then you may freely withdraw from the study and this will not impact your treatment.

There will be 3 (three) groups for the 3 (three) treatment options to which you will be randomly placed into 1 (one) group (explained verbally).

As we have identified your injury to be an isolated mandible angle fracture, you now qualify to participate in this study. Please be rest assured that we will attend to you with the best of our ability.

- As per standard procedure, your operation will be performed under general aneasthesia, we will attempt to reduce and align (place into the correct position) your fractured segments (broken bone).
- Once you are randomly allocated to your group, we will then fixate (hold into place) your fractured segments (broken bone) in one of the 3 (three) ways as explained to you. We will repair your fracture using stainless steel wire or titanium plates. Kindly note that no one treatment is better than the other.
- Your jaws will then be wired together for a period of 3-6 weeks depending on which group you fall into.
- The operation will take place at the Chris Hani Baragwanath or Charlotte Maxeke Hospital.
- Operating time will vary between 1-2 hours.
- The study will run over a period of 3 months. We will require you to maintain good mouth-care during your participation. Over and above your normal check-up visits, I will require you to attend a 3 month post-treatment follow up

appointment where I will measure your maximum mouth opening and take x-rays.

There are no immediate risks for you to participate in the study.

Other than the benefit of having your broken jaw repaired, you will also be assisting the department in choosing the best treatment option for other patients in the future who may have this same type of injury. There is no cost difference to you as this study will be funded through our departmental resources.
You will be given pertinent information on the study while involved in the project and after the results are available.

Participation is voluntary, that means refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and that you may withdraw participation at any time without penalty or loss of benefits to which you are otherwise entitled.

There will be no money given to you for your participation in this study.

Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee and the Medicines Control Council (where appropriate).
If results are published, may lead to cohort identification.

Contact details of researcher:

- **Name** | Dr. Shailen Dulabh
- **Mobile** | 083 555 1982
- **Email** | shaylu06@yahoo.com

I, ____, agree to participate in the study that Dr. Dulabh is carrying out. All the benefits and risks have been explained to me.

______________________	____________________	_____________________
Patient Signature	Date	Contact Number

8.2 Appendix 2: Data collection sheet

Appendix 2 **DATA COLLECTION SHEET**

ISOLATED MANDIBULAR ANGLE FRACTURE STUDY

Patient number (1-45): ____________________

____

Gender: Male / Female Age (years): ______________________

(Patients must be age 18 years and above)

Race: Black / White / Asian / Coloured

Mode of injury: Occupational injury / Sports injury / Assault / MVA / PVA / Fall / post-dental extraction

Site of Unilateral Angle Fracture: Right / Left (bilateral angle fractures, septic fractures and comminuted fractures excluded)

Teeth in Fracture line extracted: 48 / 47 / 37 / 38

Parameters to be recorded

	Pre - operative	**Post - op (at 6 weeks)**	**Post – op (at 3 months)**
Mouth opening (mm)	.... mm	.... mm	.... mm
Nerve Function (please circle appropriately)	(Anaesthesia / Paresthesia / intact)	(Anaesthesia / Paresthesia / intact)	(Anaesthesia / Paresthesia / intact)
Degree of Inferior alveolar canal displacement on Panoramic radiograph (mm)	.... mm (mm=millimeters)	.... mm **(measure superior**	.... mm **border discrepancy)**
Fracture favourability (pre-op)	Fracture Horizontally favourable? (Yes / No) Fracture Vertically favourable? (Yes / No)		

Panoramic radiograph must be taken and kept at 6 week and 3 month follow up appointment for all cases

Type of treatment received (circle): Upper Border wire / ORIF (open reduction internal fixation)

Number of plates if fracture was (circle): 1 / 2

(Please note: Intermaxillary fixation (IMF) period for ORIF with 1 or 2 plates is standardised to 3 weeks, while patients who are treated with an upper border wire will have an IMF period of 6 weeks).

Average operating time, measured from time of 1st incision to time of the last suture placed(minutes):

____

Name of plating set used for fracture fixation (circle):

W. Lorenz Trauma 1 / W. Lorenz CMF / Synthes Matrix / Synthes Compact / KLS Martin / Mondeal Omnimed / Stryker Leibinger

Seniority of operator (circle): MO/Junior registrar/Senior registrar/Consultant

Complication (circle) sepsis/hardware failure/wound dehiscence/malocclusion/malunion

noted at ____ days post Rx

COMPLICATION		**ACTION UNDERTAKEN** (specify and circle please)
Hardware failure (circle)	None / Plate fracture / loose screw	Plate removed: Yes / No Screw/s removed Yes / No IMF re-secure Yes / No Repeat ORIF/Wire Yes / No (please specify treatment performed under LA / GA)
Wound dehiscence (circle)	Yes / No	Conservative Mx / localised flap closure
Presence of sepsis (circle)	Yes / No	Removal of plate: Yes / No Removal of screw: Yes / No LA / GA
Fracture healing (circle)	Clinically united / malunion / non-union	None / Repeat surgery
Dental Occlusion (circle)	Intact / malocclusion	None Stick exercises Yes / No Elastic guidance Rx: Yes / No

____

8.3 Appendix 3: Antibiotic regime

Appendix 3 Antibiotic regimens

Table 1: Intra-operative antibiotic and intravenous medication regimen

MEDICATION	DOSAGE, ROUTE, FREQUENCY	IF ALLERGIC
Augmentin	1.2 grams, Intravenous, stat dose intra-operatively	Clindamycin 600mg, Intravenous, stat dose
Dexamethasone	8 milligrams (mg), intravenous, stat dose, intra-operatively	None

Table 2: Post-operative antibiotic regime

NO PENICILLIN ALLERGY	PENICILLIN ALLERGY
Amoxicillin 500 mg capsules, orally, three times daily for 5 days	Clindamycin 150 mg, qid, orally for 5 days
Analgesia and anti-inflammatory as required	Analgesia and anti-inflammatory as required
Chlorohexidine mouthrinse	Chlorohexidine mouthrinse

8.4 Appendix 4: Ethics clearance certificate

R14/49 Dr Sheilen Dulabh et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M151035

NAME: (Principal Investigator)	Dr Sheilen Dulabh et al
DEPARTMENT:	Maxillo Facial and Oral Health Surgery Charlotte Maxeke Johannesburg Academic Hospital Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	A Comparative Study of 3 Treatment Modalities for Mandibular Angle Fractures
DATE CONSIDERED:	30/10/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Ephraim Rikhotso
APPROVED BY:	Professor P. Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	15/06/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated,from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review in October and will therefore be due in the month of October each year.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

8.5 Appendix 5: Permission to conduct study

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

WITS ORAL HEALTH CENTRE

Private Bag X15 Braamfontein, Johannesburg, 2017
Enquiries: Ms. MS Raphalo/Ms. T Marule
Tel: (011)488-4893/4851, Fax (011)488-4869
E-mail: Synthia.Raphalo@wits.ac.za
Tumelo.Marule@wits.ac.za

02 June 2016

Dr S Dulabh
Maxillo-Facial and Oral Surgery
Faculty of Health Sciences
University of the Witwatersrand
Johannesburg

REGARDING: PERMISSION TO CONDUCT MDent RESEARCH STUDY

REFERENCE: HRRC/JUNE/2016/01

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 risk encountered during the research.

Regards,

Prof SL Shangase
Acting CEO/Head of School

8.6 Appendix 6: Raw Data

No	AGE	M/F	DAYS TO OP	SIDE	Rx	NO. OF PLATES	IMF	OP TIME MINS	PRE OP MO (mms)	POST OP MO (mms)
1	37	M	6	L	UBW	0	6	40	16	40
2	27	M	9	L	Orif 2	2	3	65	22	35
3	37	M	11	R	Orif 1	1	3	60	18	32
4	30	M	11	L	UBW	0	6	40	15	36
5	20	M	12	L	Orif 1	1	3	40	17	37
6	41	M	12	R	Orif 1	1	3	35	19	37
7	27	M	11	L	UBW	0	6	42	21	39
8	29	M	14	L	Orif 2	2	3	35	23	38
9	25	M	13	R	Orif 1	1	3	33	23	42
10	29	M	8	L	Orif 1	1	3	33	21	37
11	22	M	6	L	UBW	0	3	41	27	32
12	29	M	14	L	Orif 1	1	3	45	27	41
13	25	M	7	L	Orif 1	1	3	32	26	42
14	24	F	8	R	UBW	0	6	40	23	38
15	24	F	10	R	Orif 1	1	3	30	11	39
16	23	M	13	R	Orif 1	1	3	40	12	36
17	22	M	7	R	Orif 1	1	3	26	19	34
18	24	M	14	L	Orif 1	1	3	35	12	32
19	26	M	14	R	Orif 1	1	3	35	14	28
20	22	M	3	R	UBW	0	6	42	19	37
21	24	M	10	R	Orif 2	2	3	45	21	31
22	32	M	8	R	Orif 2	2	3	41	24	34
23	39	M	10	L	Orif 1	1	3	43	15	25
24	29	M	10	R	Orif 2	2	3	49	18	38
25	22	M	6	R	Orif 1	1	3	50	31	41
26	26	F	7	R	Orif 2	2	3	50	25	52
27	26	M	11	L	UBW	0	6	60	26	35
28	35	M	4	R	Orif 1	1	3	62	25	32
29	20	M	14	R	UBW	0	6	36	15	32
30	26	M	11	R	Orif 1	1	3	65	7	39

No	AGE	M/F	DAYS TO OP	SIDE	Rx	NO. OF PLATES	IMF	OP TIME MINS	PRE OP MO (mms)	POST OP MO (mms)
31	24	M	11	L	Orif 1	1	3	60	T1	1
32	25	M	3	L	Orif 1	1	3	65	T2	1
33	30	M	9	R	Orif 2	2	3	70	T2	2
34	43	M	14	R	Orif 2	2	3	70	T2	3
35	33	M	13	R	UBW	0	6	45	T1	1
36	51	M	6	R	UBW	0	6	28	T1	1
37	24	M	9	R	Orif 2	2	3	70	T2	4
38	26	M	13	L	Orif 2	2	3	90	T2	2
39	29	M	11	L	UBW	0	6	60	T1	2
40	26	F	8	L	Orif 2	2	3	80	T2	1
41	20	M	13	L	Orif 1	1	3	65	T2	2
42	24	M	11	L	Orif 2	2	3	75	T2	3
43	39	M	8	L	Orif 1	1	3	65	T2	3
44	27	M	13	R	UBW	0	6	55	T1	4
45	33	M	14	L	UBW	0	6	52	T1	3
46	33	M	13	L	UBW	0	6	57	T1	2
47	38	M	10	R	UBW	0	6	30	T1	2
48	35	M	11	R	Orif 2	2	3	62	T2	2
49	27	M	8	R	Orif 2	2	3	100	T2	3
50	23	M	12	R	Orif 2	2	3	85	T2	3
51	36	M	12	L	UBW	0	6	65	T2	2
52	32	M	9	L	Orif 2	2	3	90	T2	6
53	28	M	11	L	UBW	0	6	60	T1	1
54	28	M	14	R	UBW	0	6	50	T1	1
55	29	M	9	L	Orif 2	2	3	83	T2	6
56	26	M	9	R	Orif 1	1	3	48	T1	3
57	37	M	9	L	UBW	0	6	38	T1	2
58	35	F	14	L	UBW	0	6	47	T1	2
59	36	M	14	L	Orif 2	2	3	87	T2	2
60	23	F	13	R	UBW	0	6	28	T1	4

No	AGE	M/F	DAYS TO OP	SIDE	Rx	NO. OF PLATES	IMF	OP TIME MINS	PRE OP MO (mms)	POST OP MO (mms)
61	30	M	9	L	Orif 1	1	3	50	T1	3
62	18	F	3	L	Orif 2	2	3	80	T2	4
63	25	M	9	L	UBW	0	6	50	T1	2
64	25	M	8	L	UBW	0	6	55	T1	3
65	32	M	10	L	Orif 2	2	3	55	T1	2
66	20	M	11	L	UBW	0	6	70	T2	1
67	24	M	10	R	Orif 2	2	3	95	T2	2
68	32	M	6	L	Orif 2	2	3	85	T2	4
69	27	M	5	L	Orif 2	2	3	70	T2	4
70	25	M	10	L	Orif 2	2	3	90	T2	3
71	26	M	10	L	UBW	0	6	75	T2	3
72	52	M	12	L	Orif 2	2	3	52	T1	5
73	36	M	11	L	Orif 1	1	3	60	T1	2
74	28	M	2	L	Orif 1	1	3	60	T1	2
75	28	M	12	L	Orif 1	1	3	65	T2	3

No	SEPTIC EVENT	POST OP DAY	REASON	ACTION	UNION	RE-ORIF FRACTURE PLATE	RESOLUTION WITH CRFM	3 MONTH REVIEW DONE
1	NO							YES
2	YES	25	PLATES FRACTURED	2 REMOVED	NONUNION	YES	YES	YES
3	NO							YES
4	NO							YES
5	NO							YES
6	NO							YES
7	YES	20	LOOSE WIRE	WIRE REMOVED	UNION	NO	YES	YES
8	NO							YES
9	NO							YES
10	NO							YES
11	YES	15	LOOSE WIRE	WIRE REMOVED	NONUNION	YES	YES	YES
12	NO							YES
13	NO							YES
14	NO							YES
15	NO							YES
16	NO							YES
17	NO							YES
18	NO							YES
19	NO							YES
20	NO							YES
21	YES	24	LOOSE SCREWS	2 REMOVED	MALUNION	NO	YES	YES
22	NO							YES]
23	YES	27	LOOSE SCREWS	1 REMOVED	MALUNION	NO	YES	YES
24	NO							YES
25	NO							YES
26	NO							YES
27	NO							YES
28	YES	15	LOOSE SCREWS	1 REMOVED	UNION	NO	YES	YES
29	NO							YES
30	NO							YES

No	SEPTIC EVENT	POST OP DAY	REASON	ACTION	UNION	RE-ORIF FRACTURE PLATE	RESOLUTION WITH CRFM	3 MONTH REVIEW DONE
31	NO							YES
32	NO							YES
33	NO							YES
34	NO							YES
35	NO							YES
36	NO							YES
37	NO							YES
38	NO							YES
39	NO							YES
40	NO							YES
41	NO							YES
42	NO							YES
43	NO							YES
44	NO							YES
45	NO							YES
46	NO							YES
47	NO							YES
48	NO							YES
49	NO							YES
50	NO							YES
51	NO							YES
52	NO							YES
53	NO							YES
54	NO							YES
55	YES	20	LOOSE SCREWS	2 REMOVED	UNION	NO	YES	YES
56	YES	24	LOOSE SCREWS	1 REMOVED	UNION	NO	YES	YES
57	NO							YES
58	NO							YES
59	NO							YES
60	NO							YES

No	SEPTIC	POST OP	REASON	ACTION	UNION	RE-ORIF	RESOLUTION	3 MONTH

	EVENT	DAY				FRACTURE PLATE	WITH CRFM	REVIEW DONE
61	YES	26	LOOSE SCREWS	1 REMOVED	UNION	NO	YES	YES
62	NO							YES
63	NO							YES
64	NO							YES
65	NO							YES
66	NO							YES
67	NO							YES
68	YES	14	LOOSE SCREWS	2 REMOVED	MALUNION	NO	YES	YES
69	NO							YES
70	NO							YES
71	NO							YES
72	NO							YES
73	NO							YES
74	NO							YES
75	NO							YES

CHAPTER 9

9.0 REFERENCES

Al-Moraissi E.A., El-Sharkawy T.M., El-Ghareeb T.I., *et al.* 2014. Three dimensional versus standard miniplate fixation in the management of mandibular angle fractures: A systematic review and meta-analysis. *Int J Oral Maxillofac Surg,* 43:708-16.

Al-Moraissi E.A., Ellis E. 2014. What Method for Management of Unilateral Mandibular Angle Fractures Has the Lowest Rate of Postoperative Complications? A Systematic Review and Meta-Analysis. *J Oral Maxillofac Surg,* 72:2197-2211.

Al-Moraissi E.A. 2015. One miniplate compared with two in the fixation of isolated fractures of the mandibular angle. *Br J Oral Maxillofac Surg,* 53:690-8.

Barry C.P., Kearns G.J. 2007. Superior Border Plating Technique in the Management of Isolated Mandibular Angle Fractures: A Retrospective Study of 50 Consecutive Patients. *J Oral Maxillofac Surg,* 65:1544-49.

Braasch D.C, Abubaker A.O. 2013. Management of Mandibular Angle Fracture. *Oral Maxillofacial Surg Clin N Am,* 25:591–600

Champy M, Loddé JP, Schmitt R, Jaeger J.H, Muster D. 1978. Mandibular osteosynthesis by miniature screwed plates via a buccal approach. *J Maxillofac Surg,* 6:14-21.

Danda AK. 2010. Comparison of a single noncompression miniplate versus two noncompression miniplates in the treatment of mandibular angle fractures: A prospective, randomized clinical trial. *J Oral Maxillofac Surg,* 68:1565-7.

Ellis E, Karas N. 1992. Treatment of mandibular angle fractures using two mini-dynamic compression plates. *J Oral Maxillofac Surg,* 50:958.

Ellis E. 1993. Treatment of Mandibular Angle Fractures Using the AO Reconstruction Plate. *J Oral Maxillofac Surg*, 51:250-4.

Ellis E, Walker L. 1994. Treatment of mandibular angle fractures using two noncompression miniplates. *J Oral Maxillofac Surg*, 52:1032–6.

Ellis E, Walker L. 1996. Treatment of mandibular angle fractures using one noncompression miniplate. *J Oral Maxillofac Surg*, 54:864-71.

Ellis E. 1999. Treatment methods for fractures of the mandibular angle. *Int. J. Oral Maxillofac Surg*, 28:243-52.

Ellis E. 2002. Outcomes of patients with teeth in the line of mandibular angle fractures treated with stable internal fixation. *J Oral Maxillofac Surg*, 60:863–5.

Ellis E. 2009. Management of fractures through the angle of the mandible, *in* Current Controversies in Maxillofacial Trauma. *Oral and Maxillofacial Surgery Clinics of North America*, 21:163-174.

Ellis E. 2010. A Prospective Study of 3 Treatment Methods for Isolated Fractures of the Mandibular Angle. *J Oral Maxillofac Surg*, 68:2743-54.

Fox A.J., Kellman R.M. 2003. Mandibular angle fractures: two-miniplate fixation and complications. *Arch Facial Plast Surg*, 5:464–9.

Khiabani K.S., Mehmandoost M.K. 2013. Transoral Miniplate Fixation of Mandibular Angle Fracture with and without 2 Weeks of Maxillomandibular Fixation: A Clinical Trial Study. *Craniomaxillofac Trauma Reconstruction*, 6:107–114.

Kim M.-Y, Kim C.-H, Han S.-J., *et al.* 2016. A comparison of three treatment methods for fractures of the mandibular angle. *Int. J. Oral Maxillofac. Surg*, 45:878– 83.

Kimsal J, Baack B, Candelaria L., *et al.* 2011. Biomechanical analysis of mandibular angle fractures. *J Oral Maxillofac Surg,* 69:3010-14.

Levy F.E., Smith R.W., Odland R.M.,*et al*. 1991. Monocortical miniplate fixation of mandibular angle fractures. *Arch Otolaryngol Head Neck Surg*, 117(2):149-54.

Michelet F.X., Deymes I, Dessus B., et al. 1973. Osteosynthesis with miniaturized plates in maxillofacial surgery. *J Maxillofac Surg*, 1:79–84.

Passeri L.A., Ellis E III, Sinn D.P. 1993. Complications of non-rigid fixation of mandibular angle fractures. *J Oral Maxillofac Surg,* 51:382.

Potter J, Ellis E. 1999. Treatment of Mandibular Angle Fractures With a malleable Noncompression Miniplate. *J Oral Maxillofac Surg,* 57:288-92.

Regev E, Shiff J.S., Kiss A., *et al.* 2010. Internal fixation of mandibular angle fractures: a meta-analysis. *Plast Reconstr Surg*, 125:1753-60.

Schierle H.P., Schmelzeisen R, Rahn B.,*et al.*1997. One- or two-plate fixation of mandibular angle fractures? *J Craniomaxillofac Surg*; 25:162–8.

Seemann R, Schicho K, Wutzl A.,*et al.* 2010. Complication Rates in the Operative Treatment of Mandibular Angle Fractures: A 10-Year Retrospective. *J Oral Maxillofac Surg,* 68:647-650.

Siddiqui A, Markose G, Moos K.F., *et al.* 2007. One miniplate versus two in the management of mandibular angle fractures: a prospective randomised study. *Br J Oral Maxillofac Surg,* 45:223–5.

Spinelli G, Lazzeri D, Arcuri F.,*et al.* 2016. Management of Mandibular Angle Fractures by Two Conventional 2.0-mm Miniplates: A Retrospective Study of 389 Patients. *Craniomaxillofac Trauma Reconstruction,* 9:206–210.

Strasz M, Wolschner R, Schopper C., *et al.* 2016. Miniplate osteosynthesis for mandibular angle fractures – A retrospective comparative study of 3 concepts in a temporal cohort. *Journal of Cranio-Maxillo-Facial Surgery*, 44:56-61.

Wan K, Williamson R.A, Gebauer D., *et al*. 2012. Open Reduction and Internal Fixation of Mandibular Angle Fractures: Does the Transbuccal Technique Produce Fewer Complications After Treatment Than the Transoral Technique? *J Oral Maxillofac Surg,* 70:2620-8.

Zix J, Lieger O, Iizuka T. 2007. Use of Straight and Curved 3-Dimensional Titanium Miniplates for Fracture Fixation at the Mandibular Angle.*J Oral Maxillofac Surg, 65:1758-63.*