A NEW CLASSIFICATION AND TREATMENT PROTOCOL FOR MANDIBULAR CONDYLAR FRACTURES

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A thesis submitted to the Faculty of Oral Health Sciences, University of the Witwatersrand, in fulfilment of the requirements for the degree of Doctor of Philosophy

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DECLARATION

I, Risimati Ephraim Rikhotso, hereby declare that this thesis is my own work in design and in execution. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University. I also affirm that all reference material(s) contained herein have been duly acknowledged.

Signed---

Date: --------------------------------

Johannesburg

South Africa

DEDICATION

To my wife Maureen and my beloved son Nyiko for their dependable support, understanding and patience. To my brothers Lucky and Moses for their unwavering support and encouragement. To my late mum and dad for the wonderful legacy.

Above all, I wish to humbly dedicate this work to the Almighty God, whose bountiful and unmerited favour saw me through this research project and the degree program.

PRESENTATIONS

1. Rikhotso RE, Ferretti C, Reyneke JP. A system for decision-making process on whether to treat mandibular condylar fractures open or closed. **International Conference on Oral and Maxillofacial Surgery, Hong Kong, 2017**
2. Rikhotso RE, Ferretti C. Revised condylar classification: Wits classification of mandibular condylar fractures. **Congress of the South African Society of Maxillofacial and Oral Surgeons, Port Elizabeth, South Africa, 2015**

ABSTRACT

Introduction

Despite decades of study, a consensus on therapeutic approaches to condylar fractures remains elusive, and the vexing question of invasive (open reduction or surgical treatment) or non-invasive (closed treatment or non-surgical treatment) therapy remains to be definitively answered. This lack of a standardised treatment protocol for condylar fractures often results in the haphazard and often subjective application of treatment schedules. This study aimed to present a new classification system for mandibular condylar fractures. Furthermore, this randomised, clinical single-centre study compared the outcomes of mandibular condylar fractures treated by closed treatment with those treated by open reduction with rigid internal fixation. Factors which influence treatment outcomes of mandibular condylar fractures were also evaluated, and used to design a mandibular condyle scoring system and management protocol.

Materials and methods

Patients older than 18 years with Wits Types II, III and IV mandibular condylar fractures were prospectively randomised into the open and closed treatment groups. In the open reduction and internal fixation (ORIF) group fractures were approached via a retromandibular incision. In the closed treatment (CT) group patients were placed in intermaxillary fixation (IMF) for 1 week. In both groups, elastic guidance was used for 5 weeks and physiotherapy for 3 months. Both groups were assessed for parameters

such as mouth opening, occlusion, range of movement, TMJ function and complications at 1 and 6 weeks, 3, 6 and 12 months.

Results

A total of 116 patients with MCFs were included in the study. Of these, only 10 (9%) were female. There was a total of 132 fractures (100 unilateral, 16 bilateral). Of the 100 unilateral fractures 41 occurred on the left side and 59 on the right. The most common type of fracture was Type IIB (89.7%) followed by Type III (7.4%) and Type IV (2.9%). The aetiology of the fracture was alleged assault in 76 patients (65.5%), road traffic accident in 17 (14.6%) and falls in 16 (13.7%).

Symphyseal and parasymphyseal fractures were the most commonly associated fractures (n=75) followed by body (n=21) and angle fractures (n=7). Only 15 (13%) patients had isolated mandibular condylar fractures (MCFs).

Sixty eight (59%) patients were treated by CT and 48 (41%) patients were treated by ORIF. After a follow-up of 12 months, no significant differences were observed between the two groups for mouth opening, protrusion, pain, TMJ function and laterotrusive movements to the non-fractured side. Laterotrusive movements towards the fractured side in unilateral cases were, however, better in the closed group than in the open group ($p=0.038$). In the closed group, 14 (21%) patients had malocclusion and 18 (27%) patients had deviations greater than 2 mm. In the open group, 9 patients had transient facial nerve palsies which resolved within 3 months, 2 patients had hypertrophic scars, 3 had keloids, 4 had parotid fistulae which resolved within 6-8 weeks, 1 had malocclusion, and 3 had deviations.

Ramus height loss (RHL) ($p = 0.013$) and angle of displacement ($p = 0.0084$) were significantly associated with the presence of complications in the CT group. The risk of complications in the closed group was higher in patients with RHL >8 mm, >30 degrees angle of displacement, and dislocated fractures.

Discussion and Conclusion

Data provided by this randomised study indicates that both closed and ORIF treatment options for MCFs yielded acceptable results. More complications, however, (malocclusions and deviations in particular) were seen in the closed treatment group than in the ORIF group. Odds Ratio calculations showed that the odds of complications were significantly lower in the open group than in the closed group. Ramus height loss, bilateral fractures, type of fracture (II B and III) and angle of displacement were significant risk factors for the development of complications in the closed group. These factors formed the basis of the design of the mandibular condyle scoring (MCS) system. This scoring system has been developed to help identify patients who may benefit from selective open reduction and internal fixation of fractured mandibular condyles. The MCS system uses readily available preoperative data to establish a score that will guide therapeutic options. Based on this study, patients with an MCS of 9 and above should be considered for surgical treatment. The proposed classification and MCS system may act as a framework to improve the management of mandibular condylar fractures.

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ABBREVIATIONS

AOB: Anterior open bite

CHBAH: Chris Hani Baragwanath Academic Hospital

CHL: Condylar Height Line

CI: Confidence interval

CP: Condylar process

CRMMF: Closed reduction and maxillomandibular fixation

CT: Closed treatment

EA: Endoscopic assisted

FS: Fractured side

GLM: General Linear Model

GSW: Gunshot wound

ICF: Intracapsular Fractures

IMF: Intermaxillary fixation

IQR: Interquartile range

LCP: Lateral cortical plate

LS: Least-Squares

MCF: Mandibular condylar fracture

MCS: Mandibular Condyle Scoring

MIO: Maximum inter-incisal opening

ML: Mandibular line

MMF: Maxillomandibular fixation

MMO: Maximum mouth-opening

MO: Mouth opening

MRI: Magnetic resonance imaging

MSH: Melanocyte-stimulating hormone

MVA: Motor vehicle accident

N: No

NFS: Non-fractured side

NS: Non-surgical

OR: Odds ratio

ORIF: Open reduction and internal fixation

PA: Postero-Anterior

PVA: Pedestrian vehicle accident

RCT: Randomised controlled trial

RHL: Ramus height loss

RTA: Road traffic accident

S: Surgical

SD: Standard deviation

SMES: Standardised mean effect size

SORG: Strasbourg Osteosynthesis Research Group

TMJ: Temporomandibular joint

VAS: Visual analogue scale

Y: Yes

CHAPTER ONE: INTRODUCTION

1.1. Literature review

1.1.1. Anatomy of the Temporomandibular Joint

Osteology: The mandibular condyle articulates with the squamous portion of the temporal bone to form the temporomandibular joint. The concavity on the temporal bone where the mandibular condyle lies in the rest portion is called the glenoid fossa. Anteriorly is the articular eminence, which the condyle translates down during function. Posterior to the glenoid fossa is the tympanic plate, which tapers to the post-glenoid tubercle. The condylar head is roughly 15-20mm wide and 8-10mm long (Fletcher *et al*., 1992).

The articular disc: The articular disc or meniscus (a biconcave avascular connective tissue structure) lies between the mandibular condyle and temporal bone, separating the joint cavity into two compartments: superior and inferior (Fig.1.1). It is thought that it forms under compression during development from the posterior insertion of the lateral pterygoid muscle to the Merkel's cartilage (Rayne, 1987). The disc is commonly described as having three discrete zones: thick anterior and posterior bands bridged by a thinner intermediate zone. The anterior band is attached to the joint capsule, condylar head and superior belly of the lateral pterygoid muscle, whereas the posterior band attaches to the bilaminar or retrodiscal tissue, which is a rich neurovascular tissue. The bilaminar zone provides stability to the disc by attaching the posterior band of the disc to the mandibular condyle and the temporal bone (Fig.1.1) (Rayne, 1987; Aiken *et al.,* 2012*;* Walker and McLeod, 2017).

The fibrous capsule: The temporomandibular joint (TMJ) is surrounded by a capsule lined by synovial membrane (which is responsible for the production of synovial fluid that fills and nourishes the joint space) on the inner aspect. The capsule is formed by the medial and lateral capsular ligaments, which extend from the mandible to the temporal bone. Inside the capsule are the medial and lateral discal or collateral ligaments, which connect the disk to the medial and lateral poles of the condyle.

Ligaments: The temporomandibular (lateral) ligament overlies the capsule and extends from the lateral aspect of the temporal bone to the neck of the condyle. The lateral ligament consists of a horizontal component that resist posterior displacement, and an oblique component that limits rotational movement, and is considered to play a critical role in joint stabilisation. The function of the sphenomandibular ligament which extends from the sphenoidal spine to the mandibular lingula, and is derived from the Merkel cartilage, is not yet clear (Ögutcen-Toller, 1995). The morphogenesis of the human discomalleolar and sphenomandibular ligaments, and the stylomandibular ligament, which runs from the styloid process to the angle of the mandible, is not well established (Posselt, 1968; Ögutcen-Toller, 1995)

TMJ movements: The temporomandibular joint is a true synovial joint and has much in common with other synovial joints of the body. It is however a highly specialised joint and has certain distinguishing anatomic and functional characteristics (McKay and Yemm, 1998). The articulating surfaces of the bones are covered, not by hyaline cartilage, but by fibrocartilage. It is further characterised by two articulating complexes of bone which carry teeth, whose shape and position influence the movement of the joint. It is the only joint with a rigid end-point of closure that is away from the joint (Helms *et al.,* 1983). It has a bilateral articulation with the cranium, so that the right and left TMJ articulations must function together (McKay and Yemm, 1998). The human TMJ is capable of both sagittal and coronal rotational (hinge) as well as sliding (translation) movements (Ten Cate, 2003).

Translation movements occur in the upper joint space while rotation movements and some translation occur in the lower joint space. Such jaw movements can occur symmetrically in both joints, as when the mandible is closed, opened, protruded or retruded. Movements also occur in an asymmetrical manner, (when translation occurs on one side only, while the contra lateral side will rotate coronally or supero-inferiorly) to produce lateral jaw excursion. The muscles act upon the joint to produce two distinct types of movement: the first is an opening motion, which is pure rotation around a horizontal axis. This movement is effected by the anterior belly of digastric, the mylohyoid and geniohyoid muscles. The second is a gliding motion with the condyle and the meniscus functioning as a unit and translating anteriorly beneath the articular eminence (McKay and Yemm, 1998). This is achieved principally by the inferior head of the lateral pterygoid muscle. The superior head of the lateral pterygoid muscle is inactive during the opening phase of the mandible (Rayne, 1987). In addition, the lateral pterygoid muscles act to protrude the jaw and, if acting unilaterally, to produce lateral movements (Fig.1.1). The jaw-closing muscles, whose actions are responsible for rotating the condylar head to its rest position in the glenoid fossa after its displacement, are the masseter, anterior part of temporalis, medial pterygoid and upper head of the lateral pterygoid (Mohl, 1982; Ten Cate, 2003;). The posterior and intermediate parts of temporalis muscles retrude the jaw, moving the condylar head to its posterior limit in the glenoid fossa (Ten Cate, 2003).

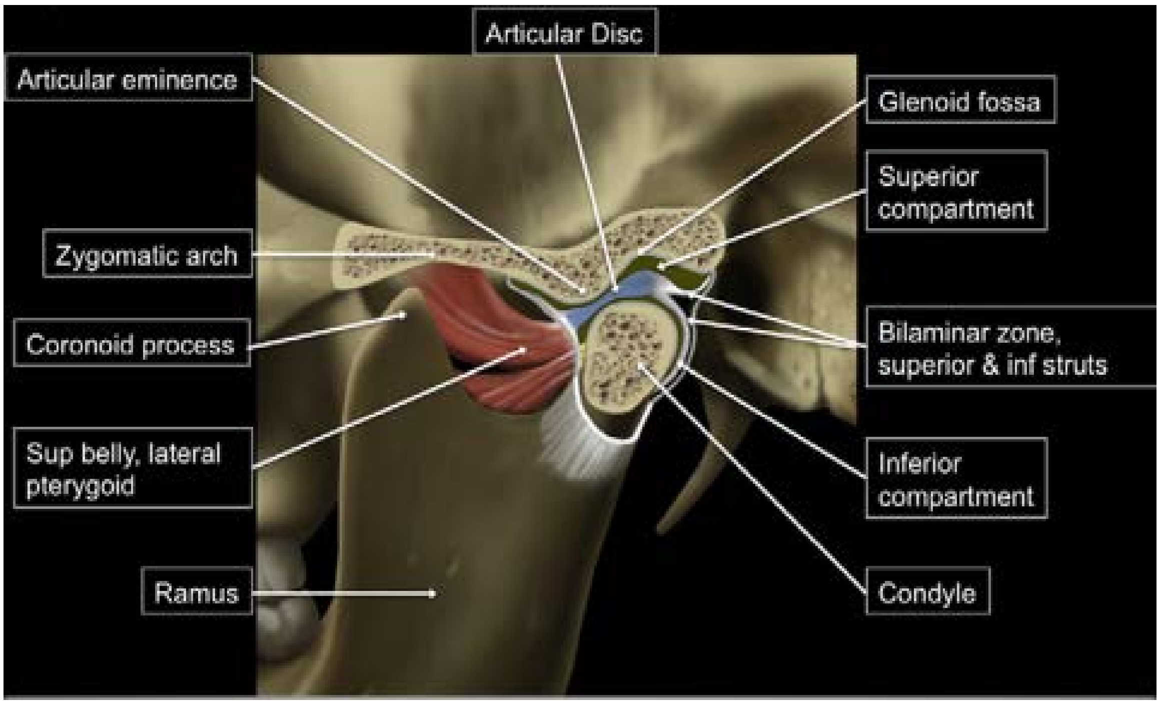

Figure 1.1 Anatomy of the temporomandibular joint (Aiken *et al*., 2012).

1.1.2. Biomechanics and epidemiology of mandibular condylar fractures

Trauma to the mandible may cause one of several injuries amongst which is fracture of the mandibular condyle. Fractures of the condylar neck and or base (defined by Loukota *et al*., 2003, as a fracture line running from the lowest point of the curvature of the sigmoid notch obliquely downwards and backwards below the surgical neck and behind the mandibular foramen) typically occur as a result of forces far greater than those that exist in the normal physiologic range (Tuchtan *et al.,* 2015). As a weaker area, fractures are often seen in the neck/subcondylar region, caused by tensile stress when a force is applied elsewhere, which supports the frequent finding of a second, distant mandibular fracture, such as a parasymphyseal fracture. This fracture is often considered as a potential defence mechanism that prevents intracranial intrusion of the condyle into the middle cranial fossa superiorly through the roof of the glenoid fossa, which can be less than a millimetre thick (Matsumoto *et al.,* 2005*).*

The mandible is considered a class III lever (Fig. 1.2), with the fulcrum of rotation being the condyle, the load occurring at the dentition, and the force exerted largely coming from the muscles of mastication (Sikes *et al*., 2000; Meyer *et al*., 2002; Ellis and Throckmorton 2005). Normal physiologic movement and the force vectors generated create lines of compression and tension within the mandible. The lines of tension at the condylar neck and base run approximately perpendicular to the posterior aspect of the ascending ramus following the curvature of the sigmoid notch and extending superiorly through the coronoid process. The lines of compression run approximately perpendicular to the lines of tension: they run parallel to the posterior aspect of the ascending ramus and then curve along the angle to continue parallel to the inferior border of the mandible (Wagner *et al.,* 2002). Ultimately, this results in a tension band at the anterior/superior (sigmoid notch) aspect of a condylar neck or base fracture and a compression band at the posterior aspect (Wagner *et al*., 2002; Walker and MacLeod*,* 2017). Knowledge of these physical stresses applied in the condylar area as described and illustrated (Fig.1.3) by Meyer et al., (2000) is fundamental since it dictates positioning of the fixation (Meyer et al., 2006).

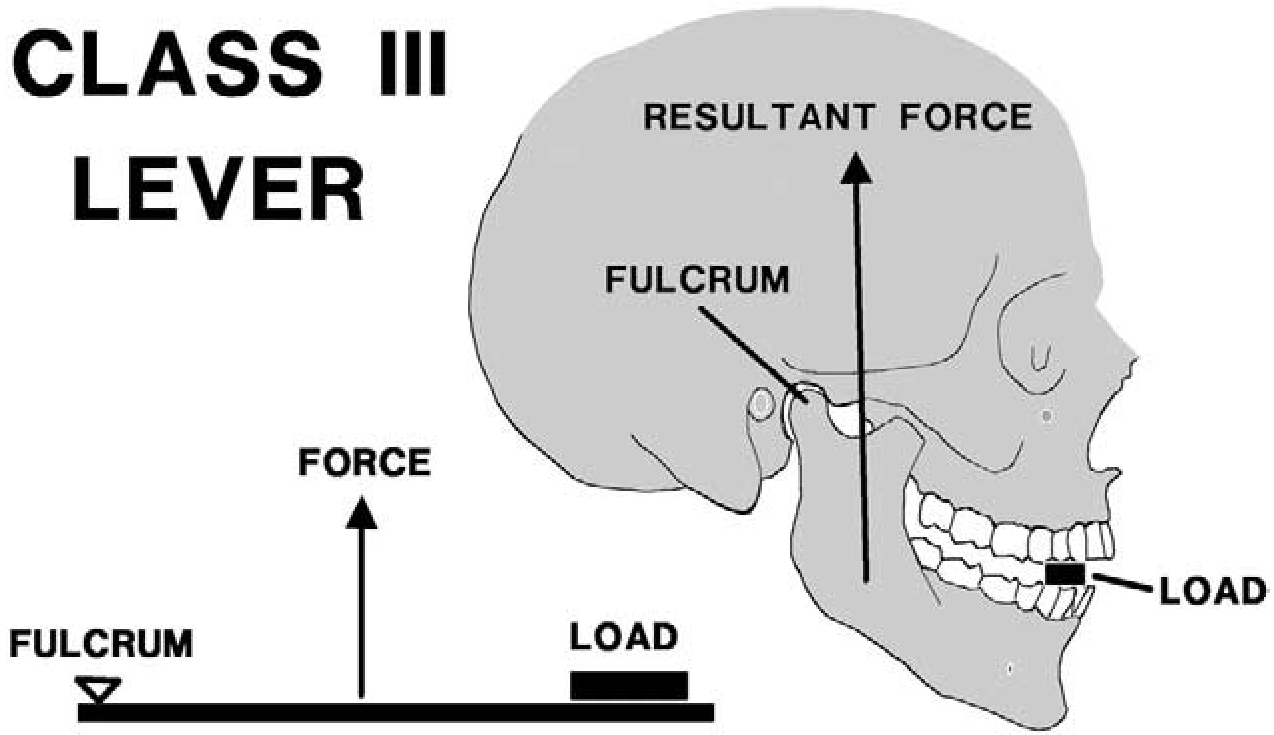

Figure 1.2 Illustration suggesting that the mandible functions as a class III lever system, where the muscle force is between the TMJ (fulcrum) and the occlusal load (as described by Ellis and Throckmorton, 2005).

Fracture of the mandibular condyle is amongst the commonest fractures of the mandible (Van Hoof *et al*., 1977; Fridrick *et al*., 1992), with a frequency that ranges from 26% to 57% (Larsen and Nielsen, 1976; Olson *et al*., 1982; Silvennoinen *et al*., 1992). Ellis *et al.,* (1985) studied 2,137 cases of mandibular fractures and found that fractures of the condyle were the second most common mandibular fractures. Similarly, Fridrick *et al.,* (1992) in their study of 1,067 patients, found the same. Interestingly, a review of sexual distribution consistently revealed a male predominance over females in a ratio ranging from 2:1 to 3:1 (Larsen and Nielsen, 1976; Bradley, 1985).

In their study of 382 patients with condylar fractures, Silvennoinen *et al.,* (1992) found that 84% of the patients had unilateral condylar fractures and 16% had bilateral fractures. Other studies have also reported similar findings, confirming the high prevalence of unilateral condylar fractures (Rowe and Killey, 1968; Bradley, 1985; Larsen, 1992). These authors also found that when classified according to the anatomical level, subcondylar and condylar neck fractures were more common than condylar head fractures.

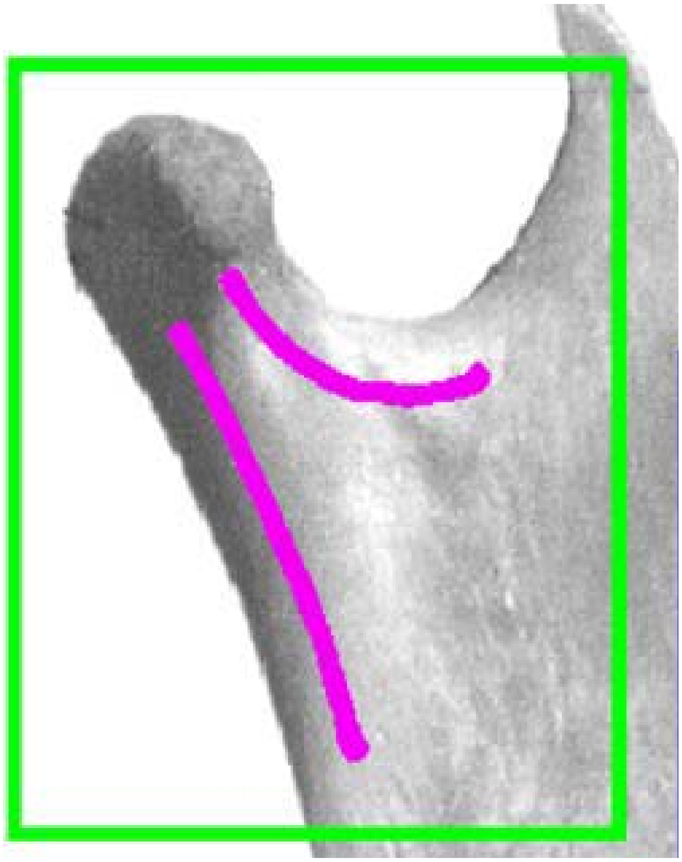

Figure 1.3 Ideal lines of rigid internal fixation in the condylar region as described by Meyer *et al*., (2000).

Numerous functional disturbances occur following fractures of the condylar process. Patients with fractures of the condyles have a limited range of motion (Chuong and Piper, 1988) which is primarily caused by voluntary restriction as a result of pain. Unilateral fracture of the condyle with significant displacement, results in deviation towards the affected side on mouth opening due to the active contraction of the lateral pterygoid muscle on the uninjured side not being balanced by a similar muscular movement on the injured side, with the result that the jaw is deviated towards the injured side (Proffit *et al*., 1980). There will also be limitation of lateral movement towards the uninjured side. Unilateral fractures may also be characterised by facial asymmetry caused by the decreased vertical height of the ramus on the side of the fracture (Chuong and Piper, 1988). Malocclusion, consisting of premature posterior contact on the fractured side and a contralateral open-bite may be seen in unilateral condylar fractures. Bilateral condylar displaced or dislocated fractures will often cause premature posterior contact on both sides, with no deviation of the midline, and an anterior open-bite (Ellis *et al*., 1985). This is due to the upward and posterior movement of the rami under influence of the contractile spasm of the elevator muscles. Importantly, previously undiagnosed fractures of the mandibular condylar process in children may be involved in 5-10% of all severe mandibular deficiency or asymmetry problems (Lund, 1974; Proffit *et al*., 1980; Amaratunga, 1987). According to Proffit *et al*., (1980), growth deficits following injury to the condyle could result from either loss of the stimulus to normal growth or secondary to mechanical restrictions created by scarring and loss of motion. Condylar fractures have also been noted to cause popping and clicking in 4-32% of childhood condylar fractures at long-term follow-up (Mitchel, 1997; Marker *et al*., 2000).

1.1.3. Condylar fracture management

There are few topics in the field of maxillofacial trauma that have generated as much discussion and controversy than that of mandibular condylar fractures and their management. Despite this, there is still no consensus regarding which mandibular condylar fractures should be treated with a closed or an open approach (or even reconstructed). Several factors are to be considered when making decisions on a therapeutic direction:

1. the anatomical level of the fracture (head, neck or subcondylar),
2. the degree of displacement or dislocation of the condylar process,
3. the presence of teeth,
4. associated injuries,
5. the health and
6. age of the patient.

Currently non-surgical treatment is the treatment of choice of condylar fractures in children (Norholt *et al*., 1993; Hovinga *et al*., 1999; Strobl *et al*., 1999; Thoren *et al*., 2001). In adult patients, however, a shift in treatment philosophy has occurred over the past decade (Ellis and Throckmorton, 2005). Although non-surgical treatment has been the mainstay of condylar fracture treatment for many decades, critical examination of treatment results has highlighted suboptimal outcomes in certain instances. It appears that whilst most patients can be adequately treated non-surgically, the selective application of invasive surgical techniques may prevent certain complications (Rikhotso and Ferretti, 2008). Advocates of open reduction argue that closed management of displaced or dislocated fractures will result in condylar deformity, mandibular dysfunction and asymmetry (Zide and Kent, 1983; Raveh *et al*, 1989). Shiju *et al*., (2015) have advocated the basic fracture principles of reduction, anatomical realignment and skeletal fixation as the best means of achieving an optimal result. In the opinion of this group, open reduction and internal fixation could significantly reduce the complication rate and allow for less disruption of normal activities and faster return to the normal, pre-trauma state. They stated that a decreased dependence on intermaxillary fixation improved post-treatment respiratory care, nutritional intake and oral hygiene (Posnick *et al.*, 1993). According to Eulert *et al*., (2007), the supreme objective of condylar fracture therapy is the recovery of the articulating joint surfaces in a physiologic relation to the disco-ligamentary structures. This is the prerequisite for re-establishing an undisturbed joint function with regular articulation and occlusion; and for this purpose, reconstruction of the affected hard and soft tissue structures is imperative. Deviations from the pre-traumatic state mostly allow compensation only on a lower scale (Eulert *et al*., 2007).

Proponents of the non-invasive approach to condylar fractures argue that management by closed reduction produces satisfactory results (Norholt *et al*., 1993; Hovinga *et al*., 1999; Strobl *et al*., 1999). Others have reported nearly equal clinical results when comparing patients with open *versus* closed treatment (Raveh *et al*., 1989; Thoren *et al*., 2001). However, it has been reported that invasive surgery on patients with condylar fractures is often difficult and time consuming, and that unwanted side effects including visible scars, wound infection, avascular necrosis of the condylar head, and damage to the facial nerve are not always avoidable (Dahlstroom *et al*., 1989; Hayward, 1947; Blevins and Gore, 1961). It has also been reported that the advantages that might be gained with an open procedure may not offset the morbidity and risks involved (Blevins and Gore, 1961; Maclennan, 1952; Beckler and Walker, 1969; Lindahl, 1977; Hayward and Scott, 1993).

A number of studies have been carried out to compare the outcomes of non-surgical (NS) and surgical (S) treatment of mandibular condylar fractures (Table 1.1). Takenoshita *et al.,* (1990) evaluated 36 cases of mandibular condylar fractures (MCFs) of which 16 (44.4%) were treated surgically and 20 (55.6%) non-surgically. Unilateral and bilateral fractures were included, as were any associated mandibular fractures. The 16 patients treated by open reduction and internal rigid fixation (ORIF) had more severe displacement and dislocation than the 20 patients treated non-surgically. Rigid IMF was applied for 3 weeks in both groups. Satisfactory postoperative function and occlusion were achieved in both groups without severe complications (Takenoshita *et al*., 1990). The main concern with this study is that patients with dislocated or severely displaced fractures were mainly allocated to the ORIF group, creating a bias in the selection process. In addition, variable rigid internal fixation methods in the ORIF group included miniplates, screws, stainless wires and Kirschner pins. Rigid intermaxillary fixation was also routinely used for both groups for a period of 3 weeks, probably necessitated by the unstable fixation methods employed in the study. A larger randomised study might have improved the credibility of the study. Nevertheless the authors are applauded for their valiant attempt to settle or resolve the perennial controversy of which condylar fractures can be treated by closed treatment or ORIF, notwithstanding the limitations of their study.

Table 1.1 Review of comparative studies between closed and open treatment of condylar fractures.

Author/Year	Aim of Study	Treatment rendered & number of Patients	Follow-up	Results
Takenoshita *et al.,* 1990	To compare functional recovery after non-surgical (NS) and surgical (S) treatment of condylar fractures	16 patients ORIF 20 patients closed reduction and maxillo-mandibular fixation (CRMMF)	2 years	Average mouth opening (MO) in NS group was 50mm and 39mm in S group No significant differences in deviation, protrusive and laterotrusive excursion in both groups. All patients had good function & occlusion
Hidding *et al.,* 1992	To compare surgical and non-surgical treatment of dislocated MCFs	20 patients ORIF 14 patients CRMMF	5 years	64% deviation in NS group compared to 10% in S group Limitation of lateral excursion of less than 5 mm only in NS group Average MO in both groups of 40 mm No difference in protrusive movements in both groups 95% good anatomical reconstruction in S group versus 7% in NS group
Konstantinovic *et al.,* 1992	clinical and radiographic evaluation of S and NS treatment of unilateral condylar process fractures	26 patients ORIF 54 patients CRMMF	2.5 years	No statistically significant differences between S and NS in MMO, deviation & protrusion. Degree of reduction in S group 81% to 100% and ranged between 57.31% and 100% in NS group
Worsaae and Thorn, 1994	To compare S and NS treatment of unilateral low subcondylar dislocated fractures	28 patients CRMMF 24 patients ORIF		NS group: 39% complication rate: malocclusion, asymmetry reduced MO, pain S group: 4% complication rate all occurring in one patient: malocclusion, pain, impaired mastication
Oezmen *et al.*, 1998	MRI examination of the TMJ and functional results after NS and S treatment of MCFs	20 patients ORIF 10 patients CRMMF	2 years	MRI revealed 10% disc displacement in S and 30% disc displacement in NS group
Santler *et al.,* 1999	to compare outcomes from S and NS treatment of condylar fractures	37 patients ORIF 113 patients CRMMF	2.5 years	No statistically significant differences in jaw mobility, MMO, protrusion, occlusion and laterotrusion. Pain on MMO and weather sensitivity significantly higher in S group

Author/Year	Aim of Study	Treatment rendered & number of Patients	Follow-up	Results
Throckmorton *et al.,* 1999	to document changes in masticatory patterns after bilateral mandibular condylar process fractures	6 patients ORIF 14 patients NS	3 years	No perceivable differences between S and NS groups for mandibular motion or muscle activity
Palmieri *et al.,* 1999	to compare mandibular motion after closed and open treatment of unilateral condylar fractures	62 patients ORIF 74 patients NS	3 years	Surgical patients had greater mobility than NS patients
Ellis *et al*., 2000	to compare occlusal results after open and closed treatment of mandibular condylar fractures	65 patients ORIF 77 patients NS	3 years	NS patients had significantly greater % of malocclusion (22.2 to 28.6%) than ORIF patients No poor occlusions observed for the open treatment (S) group
Ellis *et al.,* 2000	to evaluate facial symmetry after closed and open treatment of unilateral MCFs	65 patients ORIF 81 patients NS	3 years	Patients treated NS had significant amount of shortening of posterior facial dimension (leading to facial asymmetry) on the fractured site than ORIF patients
Throckmorton *et al.,* 2000	to determine rate of recovery of mandibular and condylar mobility after closed and open treatment of unilateral MCFs	62 patients ORIF 74 patients NS	3 years	Patients treated surgically exhibit faster rate of recovery in MMO and maximum excursion
Ellis *et al.,* 2001	to compare maximum voluntary bite forces after open and closed treatment of MCFs	64 patients ORIF 91 patients NS	3 years	No significant differences in maximum voluntary bite forces after S and NS treatment of MCFs
Haug and Assael, 2001	to compare outcomes of open versus closed treatment of MCFs	10 patients ORIF 10 patients CRMMF	6 years	No statistically significant differences in occlusion, symmetry and contour, range of motion, motor and sensory function. NS group associated with chronic pain. S group associated with perceptible scars

Author/Year	Aim of Study	Treatment rendered & number of Patients	Follow-up	Results
De Riu *et al.,* 2001	to compare the results of open and closed treatment of MCFs	20 patients ORIF 19 patients CRMMF	5-6 years S group, 8-12years NS group	No significant differences for protrusion, laterotrusion and MMO in the S and NS groups. S patients had better occlusion, anatomical reduction and faster recovery rates
Throckmorton *et al*., 2004	to compare masticatory motion after surgical and non-surgical treatment for unilateral fractures of the mandibular condylar process	37 patients ORIF 44 patients CRMMF	2 years	Surgical correction had relatively little effect on the more standard measures (duration and excursive ranges) of masticatory function. Surgical correction however better normalizes opening incisor pathways during mastication on the side opposite the fracture
Eckelt *et al.,* 2006	to compare results of closed and open treatment of MCFs	36 patients ORIF 30 patients NS	6 months	Both S and NS groups yielded acceptable results. Surgical treatment yielded superior results in all objective and subjective functional parameters
Schneider *et al.,* 2008	to compare treatment outcomes of displaced condylar fractures and to assess whether radiographic fracture level was a prognostic factor in therapeutic decision-making between ORIF and CRMMF	36 patients ORIF 30 patients CRMMF	6 months	Better functional results were observed for ORIF compared to CRMMF, irrespective of fracture level (condylar base, neck or intracapsular head). In patients with bilateral fractures, ORIF was especially advantageous. Subjective discomfort level decreased with ascending level of the fracture.
Singh *et al.,* 2010	to compare ORIF with closed treatment and maxillomandibular fixation for management of subcondylar fractures of the mandible	18 patients ORIF 22 patients NS	6 months	Both S and NS groups yielded acceptable results. Operative treatment was however superior in all objective and subjective parameters except occlusion.

Author/Year	Aim of Study	Treatment rendered & number of Patients	Follow-up	Results
Danda *et al.,* 2010	to compare closed treatment with ORIF for displaced unilateral subcondylar and condylar neck fractures	16 patients ORIF 16 patients NS	42 months	No significant clinical difference between the two groups. Radiographically, better anatomic reduction of the condylar process was seen in the ORIF group
Shiju *et al*., 2015	To compare ORIF versus closed treatment of MCFs	25 patents ORIF 16 patients NS	6 months	No significant difference between the two groups for maximum inter-incisal opening (MIO), range of movement and TMJ pain. Statistically significant differences were seen in the anatomic reduction of the condyle, shortening of ascending ramus, occlusal status and deviation on mouth opening in the immediate post-operative phase

Hidding *et al*., (1992) reviewed 34 patients with dislocated neck and subcondylar fractures. Twenty patients were treated by ORIF (wire or plate osteosynthesis and maxillomandibular fixation for two weeks) and the other 14 managed non-surgically (maxillo-mandibular fixation for two weeks followed by postoperative physiotherapy for 2-3 months). The authors did not specify or explain the criteria for choosing wire or plate osteosynthesis and the need for 2 weeks intermaxillary fixation in the ORIF group. Sixty four percent of patients treated non-surgically had deviation on opening compared to only 10% treated by ORIF. Anatomical reduction was identified in 93% of the ORIF group but in only 7% of the non-surgical group. Limitation of laterotrusion was seen in 7% of the conservatively treated patients. No other differences were found between the groups for frequency of headaches, difficulty with mastication, protrusive movements or maximum interincisal openings (Hidding *et al*., 1992). Despite the differences in anatomical reduction and persistence of deviation in the conservative group, this study showed good clinical outcomes for dislocated condylar neck or subcondylar fractures in both the ORIF and the non-surgical groups when followed by post-treatment physiotherapy and reviewed over a longer period of time (1-5 years). The recommendation by the authors that dislocated condylar fractures should be treated by ORIF raised the question of whether functional or anatomical restoration is the primary goal for treating condylar fractures.

Konstatinovic and Dimitrijevic (1992) evaluated 80 patients with unilateral MCFs, of whom 26 (33%) were managed surgically by wire osteosynthesis and 54 (68%) were managed conservatively. Treatment results of these patients were evaluated by standardised clinical examination and by evaluation of computer-simulated graphic presentations of postero-anterior (PA) radiographs of the mandible. The authors found that the degree of actual anatomical reduction in the surgically treated group was between 81% and 100% of ideal. In the conservatively treated group, 78% had reduction within the same parameter, 19% had reduction between 61% and 80%, and 4% had less than 60% ideal reduction. No statistically significant differences were found between the two patient groups for maximum mouth opening, deviation or protrusion (Konstatinovic and Dimitrijevic, 1992). Once again, patients selected for the ORIF group had greater displacement than those for closed treatment. The selection process in this study was unclear but was certainly not random. This is particularly evident in regard to patient distribution between the two groups and to patient age, where only one of the 13 patients under the age of 20 underwent surgical treatment. Also, the type of closed reduction and period of immobilization are not elucidated. It is also not clear whether both groups were placed into rigid intermaxillary fixation or not. The authors, however, have brought additional insight into the controversy of treatment options for mandibular fractures. The major value of this study was its description of a unique analysis method, using a computer programme, to analyse preoperative and postoperative radiographs.

Worsaae and Thorn (1994) conducted a study to compare outcomes of 52 skeletally mature dentulous patients with unilateral low subcondylar dislocated fractures who were randomly treated by open reduction and wire osteosynthesis (24 patients) or by closed treatment (28 patients). Midface fractures were excluded from the study. Post-surgical maxillomandibular fixation (MMF) was used in both groups for 4-6 weeks. A complication rate of 39% (which occurred in 11 of the 24 patients) was noted in the closed treatment group. Eight of these patients developed malocclusions and the other three sustained mandibular asymmetries. In the open treatment group a 4%

complication rate was observed, with all complications occurring in only one patient. This patient sustained malocclusion, impaired masticatory function and pain (Worsaae and Thorn, 1994). This is one of the few prospective studies that randomly allocated the treatment. Unfortunately, a major disadvantage was that an unstable fixation method (wire osteosynthesis) was used for the open reduction cases which necessitated additional MMF. The use of stable internal fixation methods, not necessitating MMF, could have influenced the outcome of the study.

Oezmen *et al.,* (1998) used magnetic resonance imaging (MRI) and radiographs to compare the outcomes of 10 patients treated conservatively and 30 patients managed by ORIF. Magnetic resonance imaging revealed three cases and two cases of disk displacement in the conservatively and surgically treated groups respectively. Seven patients in the conservative group had disk remodelling compared with two in the ORIF group. Magnetic resonance imaging also enabled the identification of 8 patients in the conservative group with malaligned or deformed condyles but none in the ORIF group. The clinical examination revealed no significant differences between the two groups i.e. good functional results in all the patients independent of the mode of treatment (Oezemen *et al.*, 1998). Despite the relatively short follow-up period and limited number of cases treated, the authors were able to conclude that anatomical reduction of low, displaced or dislocated MCFs by ORIF may be of benefit for the functional recovery of the TMJ. In this study the results of the clinically assessed functional status were somewhat different from the MRI and radiographic findings (which showed severe restriction in condyle mobility in the 8 cases treated by closed). The authors seemed to think that the contralateral joint compensated for the mobility restriction of the affected side by increased non-rotational movements and suggested that the functional overload on the contralateral joint as well as the morphological alteration of the ipsilateral joint related to the fracture may finally result in arthrosis (Oezmen *at al*., 1998). Although this explanation seems plausible, it is not possible to predict that altered morphology in the condyle or disc (in the presence of function) will result in arthrosis. Not all patients treated closed sustain some form of internal derangement. A further critique is that of undertaking a costly postoperative special investigation in the form of an MRI to determine the position of the disc (in the presence of optimum function) without prior knowledge of its position preoperatively.

Santler *et al.,* (1999) carried out a study to compare the outcomes from surgical and non-surgical treatment of MCF. In the follow-up study, 150 patients with a mean follow-up time of 2.5 years were analysed using radiographic and objective and subjective examinations. Of these patients, 113 (75%) were treated non-surgically, (107 with MMF and 6 patients without MMF). Thirty-seven (25%) patients were treated surgically. No significant difference in jaw mobility, joint problems, occlusion, protrusion, laterotrusion, muscle pain or nerve disorders were observed between the two groups. Surgically treated patients, however, showed more weather sensitivity and pain on maximum mouth opening (Santler *et al*., 1999). Retrospective studies with too many variables such as this offer very little evidence on how condylar fractures should be treated. Different fractures (ranging from no dislocation, medium and severe dislocations) were included in the study, resulting in a selection bias in that surgical treatment was carried out for those with severe dislocations. There was also no mention of the kind of MMF and how long the MMF was used in the non-surgical group or explanation of why MMF was not used in some cases. Moreover, different internal fixation techniques such as wire osteosynthesis, miniplates, anchor screws, and microplates were used; each individual technique having an influence on the outcome.

The largest study series comparing outcomes of surgical and non-surgical treatment of MCF has been carried out by teams at the University of Texas (Throckmorton et al., 1999; Ellis *et al*., 2000); Ellis and Throckmorton, 2000, 2001, and 2005). Patients in this series were followed-up for a period ranging from 6 weeks to 3 years. None of the patients were placed in MMF post-treatment. The first study in the series by Throckmorton et al, (1999) evaluated changes in masticatory patterns following bilateral MCF. Six patients were managed by ORIF and 14 were treated non-surgically. Two patients were treated by a combined technique with one side treated open and the other treated closed. Each patient within the fracture group was matched to a control subject according to age and gender. Patients who selected non-surgical treatment underwent application of arch bars and rigid internal fixation of other fractures of the mandible or maxilla. No patient was placed into post-surgical MMF. Training elastics were used to assist the patient to occlude into the proper occlusal relationships. Patients in both groups were instructed in the same physiotherapy protocol, consisting of occlusal guidance with elastics and jaw mobility exercises. The authors reviewed incisor position in three dimensions, and masseter and temporalis muscle activity. Patients were examined at 6 weeks, 6 months, and 1, 2 and 3 years post-treatment. The study showed that patients with bilateral fractures of the mandibular condyles have some abnormal features to their masticatory cycles during the first 6 months after the fractures. However, they found no perceivable clinical differences between the surgical and non-surgical groups for mandibular motion or muscle activity (Throckmorton *et al*., 1999). The authors stated that after bilateral condylar process fractures, the ability of the lateral pterygoid muscle to protrude the mandible is limited and that this limitation is consistent with loss of anterior translation (and subsequently the changes in jaw movement during mastication) at the condyle during opening and protrusion. Because ORIF of the condylar process tends to restore anatomic integrity to the TMJ, the expectation was that patients treated with ORIF will exhibit fewer differences from controls than patients treated by closed treatment. This however was not the case in this study, suggesting that additional data are required to explain the changes in masticatory forces; it appears that loss of the lateral pterygoid is unlikely to be responsible as the sole contributor to these changes. This study was methodologically sound, and clearly demonstrated that bilateral condylar fractures produce alterations in the chewing cycle during mastication. Investigating changes in masticatory patterns after unilateral MCFs (which are far much more common than bilateral fractures and thus can be randomised between open and closed treatment) would have yielded more pertinent and meaningful information in a larger sample size.

Palmieri *et al.,* (1999) compared mandibular motion after closed and open treatment of unilateral MCF. Of the 136 patients, 74 (55%) were treated by closed and 62 (46%) by open methods. They underwent testing at 6 weeks, 6 months, and 1, 2 and 3 years post-surgery. A jaw-tracking device was used to assess mandibular motion. Radiographs that were traced and digitized were used to assess condylar displacement and condylar mobility. From this study they concluded that patients treated with ORIF had greater mobility than those treated with the closed method (Palmieri *et al*., 1999). However, patients selected their own preferred treatment, open or closed, a far from satisfactory research method as it resulted in patients with twice the amount of displacement and greater vertical overlap of the condylar process (CP) with the ramus being allocated in the open group. In addition, the number of condylar neck fractures in the closed treatment group was almost double that in the ORIF group. The inclusion of mid-facial fractures also created another variable which may have had an influence on mandibular motion. The credence and scientific value of this study was elevated by the excellent radiographic techniques (to quantify displacement), impressive method for recording mandibular movements and a clear post -fracture physiotherapy protocol.

Ellis *et al.,* (2000) assessed the occlusal results of 142 patients with unilateral neck and subcondylar fractures, of whom 77 (54%) were treated with ORIF and 65 (46%) closed. Standardised occlusal photographs obtained at several postsurgical time intervals were examined and scored by a surgeon and an orthodontist. The investigators concluded that after 3 years, patients treated closed had a significantly greater percentage of malocclusion (22.2% to 28.6%) than did those treated by ORIF (0%) (Ellis *et al*., 2000). This study was based on patient choice and not random assignment. As such, patients with significantly more displacements were treated by ORIF. Also, photographs, instead of clinical examination, were used to assess the quality of the occlusal outcome and no attempt was made to quantify the malocclusion. Despite these weaknesses, the study revealed that patients treated by closed treatment had a significantly greater percentage of malocclusion than those treated by ORIF, notwithstanding the fact that the initial displacement was greater in the ORIF group.

Furthermore, Ellis *et al.,* (2000) also compared vertical measures of mandibular and facial morphology after open and closed treatment of unilateral MCF. In this study 65 patients were treated with ORIF and 81 closed. Towne's and panoramic radiographs were used to quantify the displacement of the condylar fractures. Postero-anterior Cephalograms taken at 6 weeks, 6 months, 1 year and 2 to 3 years after treatment were used to assess posterior facial height and bigonial and occlusal plane angles. Panoramic radiographs were also used to assess ramus height. The authors found that patients treated by closed methods had a shorter posterior facial and ramus height than those treated by ORIF (Ellis *et al*., 2000). In spite of all the limitations discussed in these series of studies from the University of Texas comparing ORIF and closed treatment, this study showed that cases treated closed had a significant amount of shortening of the posterior facial dimension on the fractured side, resulting in facial asymmetry. Of interest is whether these patients would have developed facial asymmetry had they been placed on rigid IMF for several weeks after the surgery. Those treated by ORIF had no asymmetries. Surgical reestablishment of vertical ramus height by ORIF of the condylar process thus results in normal facial symmetry.

Throckmorton and Ellis (2000) conducted a study to determine the rate of recovery of mandibular motion in patients with unilateral MCF. In this study 74 patients were treated closed and 62 by ORIF. They underwent testing of mandibular and condylar mobility at 6 weeks, 6 months, and 1, 2 and 3 years post-treatment. A jaw tracking device was used to assess mandibular motion. The authors found that patients treated by ORIF exhibited a faster rate of improvement in maximum interincisal opening than patients treated closed (0.43mm/month *versus* 0.15mm/month respectively). Moreover, patients treated by ORIF exhibited a faster rate of improvement in maximum excursion toward the fracture side than those treated closed. The faster recovery appeared to be related to two factors: lack of post-surgical IMF and adherence to a strict physiotherapy protocol. The relationship between duration of IMF and post-surgical hypomobility is well established (Amaratunga, 1987). The study was silent on how old the fractures were when they were treated. Often in cases of older fractures due to late presentations it is necessary to use rigid IMF post-surgery. The role of physiotherapy in condylar fracture management is often understated and could be the key to successful rehabilitation after condylar fracture treatment, and the authors need to be commended for highlighting this fact.

Ellis and Throckmorton (2001) subsequently undertook a study to compare maximum voluntary bite forces after open (91 patients) and closed (64 patients) treatment of MCF. Maximum voluntary bite forces were measured at 6 weeks, 6 months, and 1, 2 and 3 years after treatment. At each trial, maximum voluntary bite force was measured at 4 different tooth positions bilaterally using a standard transducer. Electromyography of the masseter muscles was also recorded during the bite force measurements. No differences were observed in maximum voluntary bite forces between the two treatment groups at any time period. While working-to-balancing electromyogram ratios were greater on the side opposite the fracture, no statistically significant findings were noted between the two groups. The selection process, though, was once again questionable in this study: patients chose their method of treatment after explanation about open treatment surgery and being told that closed treatment entailed having their jaws wired together. It was deemed unethical to randomise the patients between the two groups because only one treatment involved surgery. The inclusion of not only other mandibular fractures but maxillary fractures also makes matters complex. The possibility of these concomitant fractures impacting on the bite forces exists, and must be taken into consideration when interpreting the results. The study showed that maxillary voluntary biting forces in patients treated for MCFs did not differ significantly between closed and open groups. Of importance is that all patients followed a set physiotherapy protocol and that the retromandibular approach was standardised as the surgical approach in ORIF cases.

De Riu *et al.,* (2001) compared the results of ORIF and closed treatment of MCF in 39 patients. Non-surgical treatment in 19 patients consisted of MMF for 5-7 days followed by elastics and physiotherapy. Twenty patients were treated surgically. In all surgical cases, MMF was performed for 3-5 days followed by light functional periods varying from 1-2 months. No significant differences were observed between the two groups for protrusive, lateral protrusive or opening movements. However, open reduction gave better occlusal results, anatomical restoration and faster recovery than non-surgical techniques 1). Though the non-surgical group was treated about a decade previously, the authors were able to design a comparable homogenous surgical (ORIF) group. Although there are benefits of ORIF over NS treatment, such as no or shorter duration of MMF, it is however not without problems. ORIF is generally indicated in cases where NS treatment cannot be used or guarantee *restitution ad integrum* but should not be recommended for all borderline cases (such as slightly dislocated or displaced fractures as recommended in this study).

Haug and Assael (2001) compared postoperative results of 10 patients treated by ORIF and 10 by closed reduction with MMF for 2 to 6 weeks. Each group was assessed by two blinded investigators for maximum interincisal opening, lateral excursion, protrusive movement, deviation on mouth opening, scar perception, occlusion, contour, perception of pain and motor or sensory function. There were no statistically significant differences between the two groups for ranges of motion, occlusion, contour and motor or sensory function. The ORIF group was associated with perceptible scars and the closed group with chronic pain. In this retrospective review of patients with only subcondylar fractures, only a limited number of patients were recalled. This limited the scientific value of this study, compounded by the perception of some scars by the blinded investigators in patients in the closed treatment group (in whom no extra-oral incisions were made). The study was also not clear on how the patients were allocated between the two groups, nor why intermaxillary fixation ranged from 2 to 6 weeks in the closed treatment group. It appears that a retrospective study such as this is unable to answer the question of how MCFs should be treated.

In a follow-up study, Throckmorton *et al*., (2004) sought to compare mandibular motion during mastication in 81 patients, but this time only in patients with unilateral MCFs (subcondylar or neck fractures) treated by ORIF (37) or closed treatment (44). Only male patients were included in this study. At 6 weeks, 6 months, 1 year and 2 years after treatment, the patients' chewing cycles were recorded using a magnetic sensor array. The chewing cycles were analysed using a custom computer programme. The two treatment groups did not differ significantly for any measure of cycle duration or any excursive range (except lateral excursions at one year post-treatment) at any of the intervals. The 3-dimensional cycle shapes of the two groups, however, did differ significantly at all time intervals. They concluded that ORIF of the unilateral condyle has relatively little effect on the more standard measures (duration and excursive ranges) of masticatory function. Surgical correction, however, better normalised opening incisor pathways during mastication on the side opposite the fracture

(Throckmorton *et al*., 2004). Despite the questionable selection criteria and the inclusion of only males, this study provided a near-accurate method of recording mandibular motion and outlined the role of the inferior head of the lateral pterygoid muscle and the temporomandibular joint ligament in the incisor pathway during the opening phase of chewing. ORIF of MCFs not only normalises condylar position but also assists in restoring normal function of the TMJ ligament disrupted by displaced condylar fractures. Females were excluded because of the differences in cycle shape and small number in the sample. Their inclusion could have yielded a different outcome.

Eckelt *et al.,* (2006), in a prospective randomised multicentre study, compared outcomes of open (36 patients) and closed (30) treatment of displaced MCF. Closed treatment involved placement of arch bars and elastic intermaxillary fixation (IMF) for 10 days. All fractures were displaced, being angulated between 10 and 45 degrees or the ascending ramus was shortened by more than 2 mm. Follow-up evaluations were done at 6 weeks and 6 months post-treatment and included radiographic measurements, clinical, functional and subjective parameters. Correct anatomical positions of the fragments were achieved significantly more often in the ORIF group than the closed treatment group. Regarding maximum mouth-opening (MMO)/lateral excursion/protrusion, significant differences were observed between both groups (open 47/16/7 mm *versus* closed 41/13/5 mm) respectively. The visual analogue scoring method revealed significant differences with less pain in the ORIF (2.9 mm) group, than in the closed (13.5 mm) group. The authors concluded that while both treatment options for MCF yielded acceptable results, the operative treatment was superior in all objective and functional parameters (Eckelt *et al*., 2006). This prospective randomised multicentre study had clear guidelines on the inclusion criteria and allocation of patients for the two groups which eliminated bias in the selection process. The authors were able to create a homogeneity between the two treatment groups (surgical *versus* non-surgical) in the various international centres and are commended for this. Different surgical approaches (submandibular, periangular, retromandibular, preauricular and transoral) were however used in the surgical group in the different centres (depending on the location and the degree of displacement of the fractures), resulting in the creation of a potential confounding factor to the results. Moreover, the selected methods for internal fixation (miniplates or lag screws) were surgeon-dependent. The outcome of this study would have been strengthened by a longer follow-up period beyond the reported 6 months.

Schneider *et al.,* (2008) conducted a prospective randomised multicentre (7 clinical sites) study to investigate treatment outcomes of displaced condylar fractures, and to assess whether radiographic fracture level was a prognostic factor in therapeutic decision-making between ORIF *versus* closed reduction and maxillomandibular fixation (CRMMF). A total of 66 patients (30 treated by CRMMF, 36 by ORIF) with 79 displaced fractures (deviation of 10-45 degrees, or shortened ascending ramus of greater or equal to 2 mm) were included in the study. The following clinical, radiographic and subjective parameters were measured 6 months after the trauma: mouth opening, protrusion, laterotrusion, deviation of fractured fragment, shortening of the ascending ramus, pain and discomfort. They found better functional results in the ORIF group than in the CRMMF group in unilateral fractures (53 patients), irrespective of fracture level (condylar base, neck or intracapsular head). The mean incisal distance for unilateral fractures was 42 mm after CRMMF (23 patients) and 46 mm after ORIF (30 patients) with the difference statistically significant at $p = 0.03$. For bilateral fractures, the incisal distance was 36 mm in the CRMMF group (7 patients) and 48.33 mm in the ORIF group (6 patients). The difference was also statistically significant ($p < 0.001$). The average pain level using the visual analogue scale (VAS 0 to 100) was 25 after CRMMF and 1 after ORIF ($p \leq 0.001$). Importantly, in patients with bilateral condylar fractures, ORIF was especially advantageous. Variable periods of elastic MMF were used depending on the presence or absence of complications. Furthermore, for the ORIF group, decisions about individual surgical procedures and surgical approaches were left to the individual surgeon, as was the choice and type of implant for internal fixation too. Multicentre studies such as this often result in the creation of too many variables. The authors' concluding remarks that fractures with a deviation of 10-45 degrees or a shortening of the ascending ramus ≥2 mm should be treated with ORIF, irrespective of the level of the fracture seemed rather premature and ignored other factors (such as associated fractures, state of the remaining dentition, feasibility of ORIF and age of the patient) that should have been considered when deciding on the type of treatment.

Danda *et al.,* (2010) reported on the results of their prospective randomised study comparing closed treatment (16 patients) and ORIF (16 patients) in patients with unilateral subcondylar and condylar neck fractures. The closed treatment group was treated by rigid maxillomandibular fixation for 2 weeks followed by elastic maxillomandibular fixation for 2 weeks. The ORIF group was treated with either one or two miniplate osteosynthesis followed by elastic maxillomandibular fixation for two weeks. They found no significant difference between the two groups in the maximum inter-incisal opening, protrusion, lateral excursion movement, malocclusion and temporomandibular joint pain. However, a statistically significant difference was seen in the radiographic anatomic reduction of the condyle, with better reduction of the CP seen in patients treated with ORIF. Despite a small sample size, this well-designed randomised study added to the growing substantial evidence that supports the view that functional outcomes of both open and closed treatment methods are similar. The effect of using one or two miniplates in the CP was, however, not analysed, and this study was limited to only patients that had a deviation of 10 to 45 degrees. Another weakness in this study was that different surgical approaches (preauricular, submandibular, transmasseteric anterior-parotid and retromandibular) were employed in the ORIF group.

Singh *et al.,* (2010) evaluated outcomes of open *versus* closed treatment of unilateral mandibular subcondylar fractures in 40 patients. In this prospective study, patients with displaced fractures, with angulation between 10 and 35 degrees or with shortening of the height of the ascending ramus by more than 2 mm were randomised between open and closed treatment. The closed treatment consisted of MMF with elastics for a period of 7 to 35 days. Surgery was performed by two surgeons via the retromandibular or antero-parotid transmasseteric approach. Patients were followed-up for a period of 6 months. They found that correct anatomical position of the fragments was achieved significantly in the open treatment group. As far as mouth opening/lateral excursion/protrusion, significant (p = 0.00) differences were observed between the two groups (open 39.6/12.5/5.9 *versus* closed 33.5/9.8/4.1 mm). No statistically significant difference was found between the two groups for occlusion (p = 0.86). Their conclusion was that both treatment options for MCFs yielded acceptable results. However ORIF was superior in all objective and subjective functional parameters except for occlusion. The limitations of this study included a short follow-up period (6 months) and small number of patients. The lack of statistically significant difference in the occlusal status between the two treatment groups was an unexpected finding. One would have expected a higher incidence of occlusal disturbances in the non-surgical group, attributable to the reduction in ramus height or condylar dislocation.

Shiju *et al.,* (2015) in a prospective randomised study, evaluated the superiority of ORIF of MCFs over closed treatment. A total of 50 patients (25 closed, 25 open treatment) with isolated unilateral displaced condylar fractures (subcondylar or condylar neck fractures with angulation between 10 and 45 degrees) were included in the study which had a 6 month follow-up. They concluded that both treatment options for MCFs yielded acceptable results (i.e. no significant difference in the MIO, range of movements and TMJ pain). However, a statistically significant difference was seen in the anatomic reduction of the condyle and there was no deviation on mouth opening in patients treated with ORIF, which suggested its superiority over the closed treatment method. Two extra-oral approaches (depending on the level of the fracture) were used: retromandibular or submandibular approach. The effect of using different surgical approaches and one or two miniplates on the condylar process in the ORIF group was, however, not analysed. Despite this, the study provided invaluable data in an attempt to resolve the controversy associated with treating MCFs. The enrolment of only patients with isolated MCFs eliminated the confounding variable that may be presented by associated mandibular fractures. The study also presented a clear post-treatment physiotherapy protocol. A longer follow-up however would have added more value to the results of this study.

There have been very few prospective randomised trials of the treatment for mandibular condylar fractures (Worsaae and Thorn*,* 1994, Danda *et al.,* 2010, Schneider *et al.,* 2008, Singh *et al.,* 2010, Shiju *et al.,* 2015), with one of the difficulties being the classification of individual fractures, development of criteria for diagnosis, treatment and objective assessment of outcomes. The study by Worsaae and Thorn (1994) is one of the most commonly cited prospective randomised studies for MCFs. Unfortunately, a major disadvantage of that study was that they used an unstable fixation method (wire osteosynthesis) for the open reduction cases which necessitated additional MMF. The use of stable internal fixation methods, not necessitating MMF, could have influenced the outcome of the study.

The major shortcoming with non-randomised studies is that more complicated displaced or dislocated fractures are more likely to receive operative treatment and less displaced fractures are more likely to receive closed treatment. These kinds of studies therefore offer very little evidence and guidelines as to how different MCFs should be treated.

Despite decades of study, a consensus on therapeutic approaches to condylar fractures remains elusive, and the vexing question of invasive (open reduction or surgical treatment) or non-invasive (closed treatment or non-surgical treatment) therapy remains to be definitively answered. This lack of a standardised treatment protocol for condylar fractures often results in the haphazard and often subjective application of treatment schedules.

Whether the patients are treated surgically or non-surgically, complications may occur after the treatment of condylar fractures (Ellis, 1998; Ellis *et al*., 2000). The most commonly observed complication is malocclusion, which may result from no treatment or inadequate treatment. Deviation towards the side of injury has been demonstrated in about 50% of patients, presumably due to diminished lateral pterygoid function or pseudoarthrosis on the side of the fracture. Asymmetrical mandibular growth has been reported to occur in about 25% of patients who had condylar fractures during the growing years (Proffit *et al*., 1980). Mandibular hypomobility ranging from limited mouth opening to frank ankylosis may also occur following condylar fractures. Temporomandibular joint ankylosis is however extremely rare and has been estimated to occur only in 0.2-0.4% of condylar fractures (Ellis, 1998). Temporomandibular joint dysfunction (e.g. internal derangement) and condylar degeneration are other potential complications which have been reported in the literature (Ellis, 1998).

1.1.4. Classification of mandibular condyle fractures

Many classifications of condylar fractures exist highlighting the inadequacies of current classification systems. Wassmund (1927) distinguished between fractures of the condylar head and the condylar neck. Condylar head fractures were identified as either comminuted or chip fractures not affecting continuity. Condylar neck fractures were subdivided into:

a) vertical neck fractures secondary to shearing
b) transverse neck fractures secondary to bending
c) oblique fractures caused by a combination of shearing /bending

In 1934 Wassmund once again re-described dislocated fractures into 3 types:

i) Type I: 10-40 degrees angulation of condylar head with bony contact between the fragments

ii) Type II: 50-90 degrees angulation of the condylar head with slight bony contact between the fragments

iii) Type III: severe medial displacement with no contact between the bony fragments

Thoma (1941) categorised mandibular condyle fractures by the degree of displacement as well as dislocation (fracture with displacement, fracture without displacement, fracture-dislocation, and fracture dislocation with complete displacement of the condyle).

MacLennan (1952) devised a classification of condylar fractures based on the relationship of the fractured condylar fragment to the distal mandibular fragment (Table 1.2) while Rowe and Killey (1968) classified condylar fractures based on the relationship to the temporomandibular joint capsule and concomitant injury. Their categories were intracapsular fractures, extracapsular fractures, fractures associated with injury to the capsule, ligaments and meniscus, and fractures involving the adjacent bone. Intracapsular fractures included those that involved the articular surfaces or fractures above or through the anatomical neck (also termed high condylar fractures). Extracapsular fractures were those that “run from the lowest point of curvature of the sigmoid notch obliquely downwards and backwards below the surgical neck of the condyle to the posterior aspect of the upper part of the ramus” (also termed low or subcondylar fractures) (Rowe and Killey, 1968). Furthermore, they stated that the condylar head may be split in the sagittal plane, the split extending through the neck and producing a combined intra- and extra-capsular fracture.

Dingman and Natvig (1964) devised a classification system that incorporated the insertion of the lateral pterygoid muscles at the condylar neck. They classified condylar fractures as high, middle and low. High fractures occurred at or above the level of the lateral pterygoid muscle, middle below this attachment, and low at the base of the condylar process (fracture begins at or below the sigmoid notch and extends to the posterior border of the mandibular ramus) .

Spiessl and Schroll (1972) classified condylar fractures into six types and attempted to include fracture height and condylar head in relation to the glenoid fossa and the mandible. This classification had the advantage of considering not only the fracture site but also the extent of displacement or dislocation of the proximal segment (Table1.3).

The Lindahl (1977) classification system (Table 1.4) included the level of the fracture, displacement at the point of fracture and relationship of the condylar head to the articular fossa as the basis for classifying condylar fractures. The most useful component of the system was the delineation of the levels of the fracture as condylar head, condylar neck and as subcondylar. A subcondylar fracture was defined as one from the sigmoid notch to the region of the posterior border of the mandible just below the neck of the condyle. A condylar neck fracture was through the thin, constricted region just below the head of the condyle. A condylar head fracture occurs at or above the ligamentous attachment (horizontal, vertical or compression fractures).

The MacLennan (1952), Spiessl and Schroll (1972) and Lindahl (1977) classifications of condylar fractures are the most commonly cited (see Tables 1.2, 1.3 and 1.4 below).

Table 1.2 MacLennan classification of condylar fractures (1952).

CLASS I	Non- displaced: a linear fracture in which the proximal condylar fragment retains its usual anatomical relationship with the distal mandibular fragment (no bending).
CLASS II	Fracture deviation (bending): demonstrate deviation at the fracture line where there is simple angulation of the condylar fragment in relation to the major mandibular segment.
CLASS III	Fracture displacement: where there is overlap between the condylar fragment and the distal mandibular fragment but the condyle remains within the glenoid fossa.
CLASS IV	Fracture dislocation: where part of the condyle is displaced from the glenoid fossa.

Table 1.3 Spiessl and Schroll's classification of condylar fractures (1972).

TYPE I	Non-displaced fracture
TYPE II	Low fracture with displacement
TYPE III	High fracture with displacement
TYPE IV	Low fracture with dislocation
TYPE V	High fracture with dislocation
TYPE VI	Condylar head fracture (intra-capsular fracture

Table 1.4 The Lindahl classification system for mandibular condylar fractures (1977).

FRACTURE LEVEL	
Condylar head	(at or above the ligamentous attachment)
Condylar neck	(thin constricted region below head of the condyle)
Subcondylar	(sigmoid notch to the posterior mandible just below the neck of the condyle)
RELATIONSHIP OF CONDYLAR FRAGMENT TO MANDIBLE	
Undisplaced	
Deviated	
Angulation with lateral override	
Angulation without override	
Fissure	
RELATIONSHIP OF CONDYLAR HEAD TO FOSSA	
No displacement	
Displacement	
Dislocation	

Loukota *et al.,* (2005) argued that the subjective descriptions of "high" and "low" should be clarified, and suggested that the terms fracture of the condylar neck and fracture of the condylar base should be adopted. They presented the following Strasbourg Osteosynthesis Research Group (SORG) subclassification and definitions of fractures of the condylar process of the mandible (Fig. 1.4):

a) Diacapitular fracture (through the head of the condyle): fracture line which starts in the articular surface and may extend outside the capsule

b) Fracture of condylar neck: fracture line starts above line A and runs for more than half above line A

c) Fracture of the condylar base: fracture line runs behind mandibular foramen and for more than half below line A.

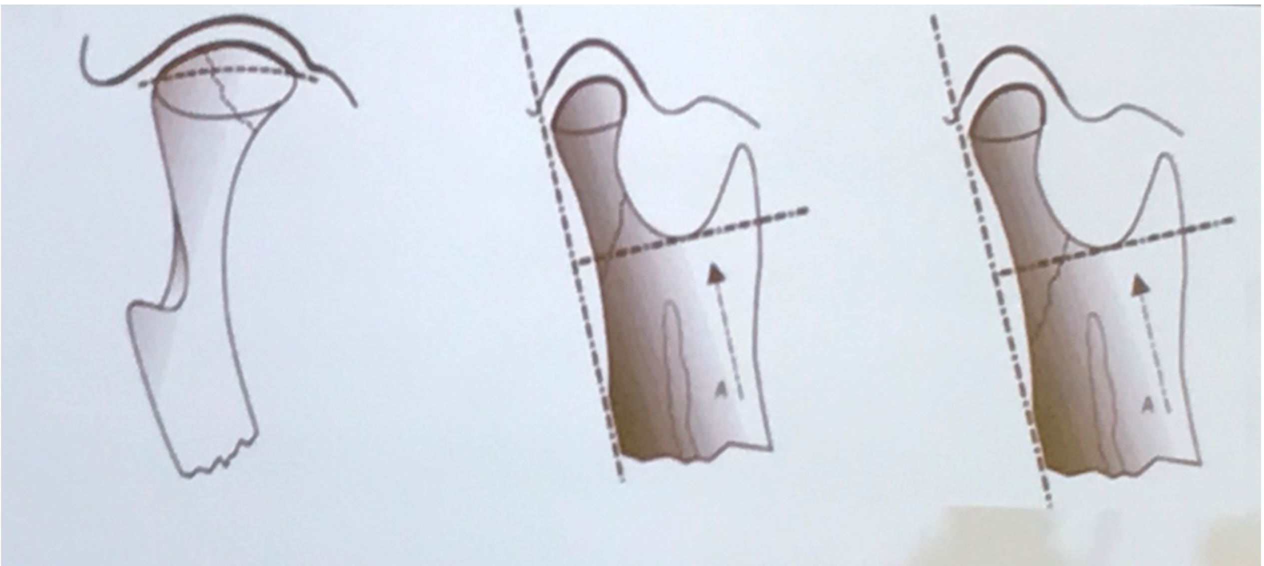

Figure 1.4 SORG classification of condylar process fractures. Adapted from Loukota *et al*., (2005).

Currently there is a trend towards subclassifying the anatomically accepted (yet difficult to delineate) intracapsular and subcondylar fractures. This, however, further complicates the existing complexities involved in describing mandibular condylar fractures without improving therapeutic guidelines. In this regard, Neff *et al.,* (1999) classified intracapsular condylar fractures into 3 types, based on the location of the fracture line:

Type A is a fracture through the medial pole of the condylar head with no loss of vertical mandibular dimensions,

Type B is a fracture through the lateral pole of the condylar head with reduction of mandibular ramus height and

Type M is a fracture that has multiple segments of the condylar head (comminuted fractures). CT Scans are necessary prerequisites for this classification (Fig. 1.5).

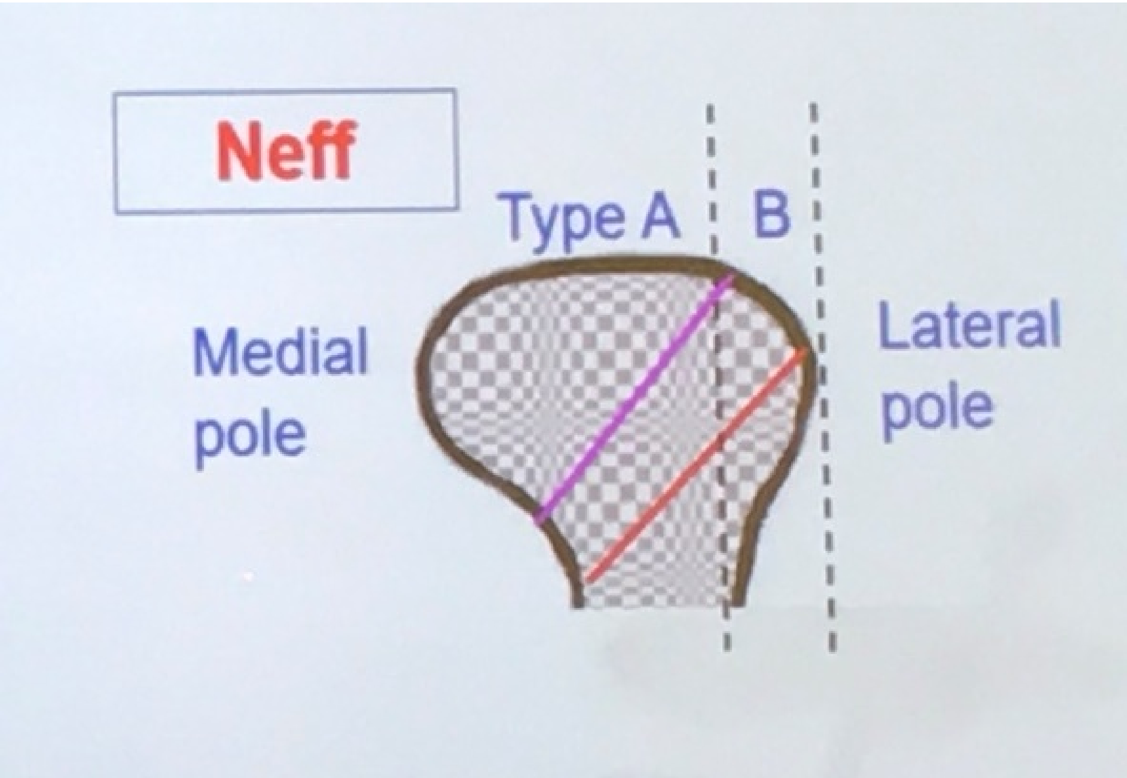

Figure 1.5 Intra-capsular classification by Neff *et al*., (1999).

He *et al.,* (2009) modified Neff *et al*'s (1999) classification system and, on the basis of axial and coronal CT scans divided the condylar head into 3 portions: lateral third, central third and medial third and then classified intracapsular fractures (ICF) as 4 types according to the location of the fracture line (Table 1.5 and Fig.1.6):

Table 1.5 Classification of Intracapsular fractures according to the location of the fracture line (He et al., 2009).

TYPE A:	a fracture line through the lateral third of condylar head with reduction of ramus height (Neff's Type B fracture)
TYPE B:	a fracture line through middle third of condylar head without ramus height reduction
TYPE C:	a fracture line through medial third of condylar head without ramus height reduction (Neff's Type A fracture)
TYPE M:	a fracture that has multiple fragments (greater or equal than 3) of the condylar head (Neff's Type M fracture: comminuted condylar head fracture)

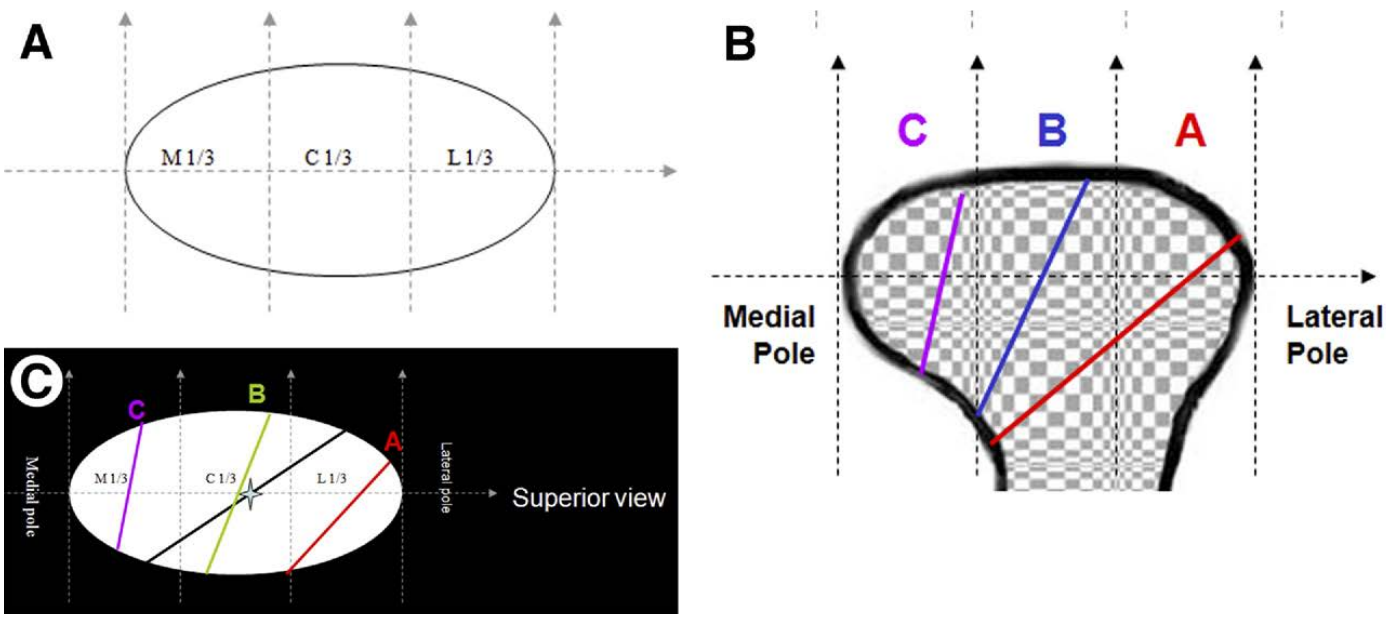

Figure 1.6 Illustration of the condylar fracture classification by He *et al*., (2009). A: Zoning of the condylar head, B: Classification of ICF according to the location of the fracture line, C: The location of the central point of the fracture line (×) which determines the type of the fracture. *Abbreviations: M - medial, C – central, L– lateral, A: Type A fracture, B: Type B fracture, C: Type C fracture*

1.2. Revised classification of mandibular condylar fractures: The Wits Classification System

The majority of the existing mandibular condylar fracture classification systems are anatomically based, usually found on radiography, and not the functional assessment of the patient. Though the anatomical position of the fractured condyle is the most critical component of any classification system, management decisions are however not based solely on the anatomical site of the fracture, but on therapeutic implications or impact on the patient. It is thus of no value to know what the anatomic location of a fracture is without the ability to formulate a concrete guide for therapy (Assael, 2003). Moreover, many of these classifications are unnecessarily complex and fail to consider the impact of a fracture pattern on the patient. For example, the difference between high and low dislocated fractures is certainly irrelevant from a management point of view; and the Lindahl classification system (1977), though highly accurate in terms of describing the location of the fractures, is unwieldy and difficult to commit to memory (Prowers, 2017).

Although the Loukota *et al*., (2005) classification describes the location of the fracture, it is insufficient in determining the degree of displacement and dislocation of the condyle, which can lead to functional consequences (Merlet *et al*., 2017). Furthermore, the Spiessl and Scroll (1972) classification, though it describes both the fracture site and displacement or dislocation, does not explicitly demarcate the degree of displacement or dislocation, which could be relevant to the treatment and prognosis.

An anomaly also exists regarding the inaccurate description of some fractures as being intracapsular when they are often through the head of the condyle extending in a sagittal direction through the condylar head but extending to the medial aspect of the condylar neck in an extracapsular position. This anomaly was first raised by Rowe and Killey (1968) and more recently by Loukota *et al*., (2005). These intracapsular-extracapsular fractures can however only be discerned in coronal CT scans (which are not routinely used to diagnose mandibular condylar fractures) and not on plain film views (Panelipse, PA mandible and Reverse Townes).

The therapeutic value (clinical usefulness) of the current classification systems have not been objectively determined. As such, the need for a simplified, contemporary classification that addresses inconsistencies whilst providing a framework for management decisions is necessary.

Joos and Kleinheinz (1998) stated that the choice of treatment for mandibular condylar fractures should be based on objective measurable quantitative condylar changes. They concluded (based on a mathematical model) that the following objective factors are of major importance in evaluating MCFs:

a) Level of the fracture
b) Degree of dislocation (or degree of fracture displacement)
c) Extent of loss of vertical height

Some of the classification systems discuss the nature of displacement to some degree and quantify the amount of displacement. On the basis of Townes' and panoramic radiographs, Bhagol *et al.,* (2011) categorised subcondylar fractures into 3 classes based on ramus height shortening and degree of fracture displacement:

i) Class 1 (minimally displaced): fracture with ramal height shortening of <2mm and/or degree of fracture displacement of <10 degrees

ii) Class 2 (moderately displaced): fracture with ramal shortening of 2-15mm and/or degree of fracture displacement of 10-35 degrees

iii) Class 3 (severely displaced): fracture with ramal height shortening of >15mm and/or degree of fracture displacement of greater than 35 degrees.

In their study comparing surgical *versus* conservative treatment of unilateral condylar fractures, Konstantinovic and Dimitrijevic (1992) found that the majority of surgically treated patients had a degree of dislocation of between 81% and 100% before treatment. They concluded that the degree of dislocation determined from the radiograph was an important factor in selecting the treatment approach. In addition, 26 of the surgically treated patients had condylar fractures with medial or lateral override i.e. with shortening of the vertical dimension of the mandible, which is an additional factor in determining therapy.

Silvennoinen *et al.,* (1994) analysed possible factors leading to problems after non-surgical treatment of MCFs. They found two major problem groups in the study: patients with displaced fractures with marked reduction in ramus height and those with condylar heads dislocated from the glenoid fossa.

The literature is thus replete with classification systems for mandibular condylar fractures. The many classifications highlight inadequacies of the current classification systems, which amongst others fail to direct management alternatives beyond closed treatment. Furthermore, the distinction between high and low condylar fractures (when classified according to fracture height) and extracapsular/intracapsular (when classified according to anatomical level) is often subjective. The question therefore remains as to what is the best way to classify mandibular condylar fractures in a manner that not only describes the fracture but offers therapeutic guidelines too.

The Wits School of Oral Health Sciences has experience of treating in excess of 5,000 mandibular fractures and this experience, together with this review of the literature, indicates that there are two main factors influencing the treatment approach or type of therapy required for MCFs:

1. **The position of the condylar head relative to the glenoid fossa** (still in the fossa or displaced out of the fossa) and
2. The **status of the ramus height** (mandibular ramus height maintained or loss of height) (Silvennoinen *et al.*, 1994; Konstantinovic and Dimitrijevic, 1992; Joos and Kleinheinz, 1998).

These two factors should form the basis for any classification of condylar fractures, and it is therefore here proposed that a new classification called the **Wits Classification System of Mandibular Condyle Fractures** be established, based on the two above mentioned principles (Figure 1.7). In this classification system, fractures are grouped into patterns that have similar treatment outcomes and implications for patients and thus similar management requirements. The fractures are classified as Type I, II, III and IV in increasing order of severity.

TYPE I	Undisplaced fracture
TYPE II	Displaced fractures: **II A** No ramus height loss **II B** With ramus height loss
TYPE III	Dislocated fractures
TYPE IV	Comminuted fractures

Figure 1.7 The proposed Wits Classification System of Mandibular Condylar Fractures.

A Type I fracture is defined as a linear fracture in which the proximal condylar fragment retains its usual anatomical relationship with the distal fragment and glenoid fossa. There is no displacement observed in this type.

A Type II A fracture is defined as a fracture in which the condyle remains in the fossa but there is movement or overlap of the condylar fragment in relation to the mandibular segment. The fragment is displaced in either a lateral, medial or antero-posterior direction. In Type II A there is no ramal height loss.

Type II B fracture is the same as Type II A, but there is a shortening in the height of the ramus.

A Type III fracture (dislocated) occurs when the condylar head is partially or totally displaced from the glenoid fossa (either medial, lateral, anterior, posterior or superior dislocations).

A Type IV fracture describes comminuted condylar fractures.

Fractures were further described as unilateral or bilateral.

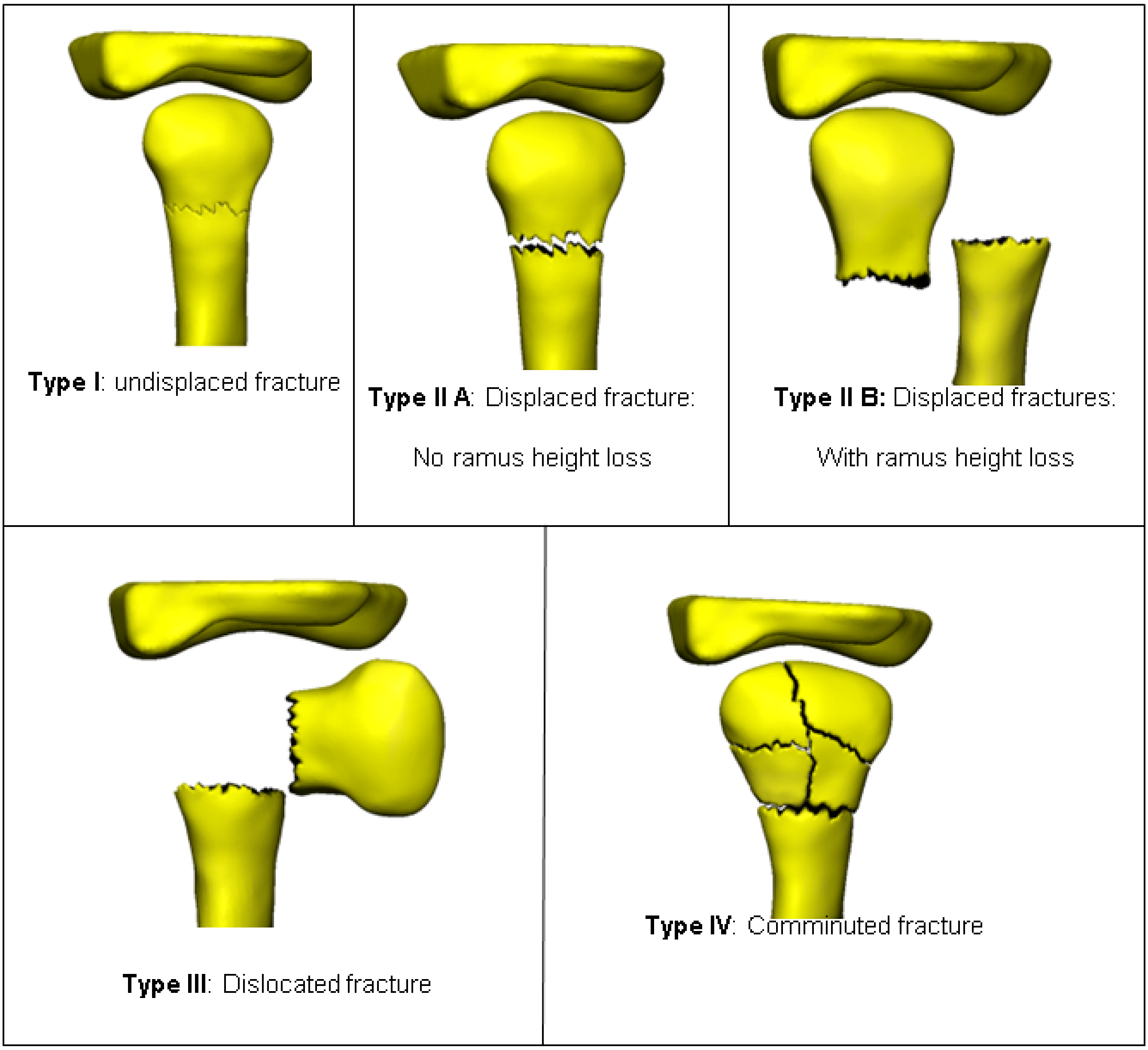

Figure 1.8 Illustration of the classification system of mandibular condylar fractures (Types I-IV).

The Wits Classification is simple, easy to differentiate and manageable. The fractures can be easily diagnosed with fewer plain radiographs (panoramic, PA mandible and Reverse Townes), which are often the only available radiographs in resource-constrained centres. Moreover, this classification combines the anatomy and fracture morphology in a clinically relevant manner. The distinction or determination of whether there is ramus height loss or not and whether the condylar head is in the fossa or not provides a framework for management decisions.

1.3. Aim of the study

Against this background, the aim of this prospective randomised study was to compare the outcomes of mandibular condylar fractures treated by closed treatment and open reduction with rigid internal fixation. The results would be compared to previously reported studies in the literature. It was envisaged that viable recommendations would emerge from this exercise, which would enable the development of evidence-based protocols to improve the clinical outcomes of mandibular condylar fractures.

1.4. Study objectives

The objectives of the study were:

a. To present the evolution of a new condylar fracture classification system, The Wits Classification of MCFs (presented in section 1.2)
b. To determine the effect of treatment group on the outcome variables
c. To determine whether there was any association between fracture displacement and treatment outcome
d. To determine whether there was any association between ramus height loss and treatment outcome

e. To assess the effect of type of fracture and treatment, RHL, angle of displacement and delay in treatment on the presence or absence of complications
f. To determine factors that influence treatment outcomes of MCFs, and based on these factors, to design a MCF scoring system which would guide the decision-making process in our treatment approach

CHAPTER TWO: METHODOLOGY

2.1. Study design

This was a prospective randomised controlled clinical trial (RCT). Randomised controlled clinical trials, especially those containing an element of blinding in their design, provide the highest experimental evidence in clinical care. It forms the basis for sound systemic reviews and meta-analyses, which is the highest level of evidence to provide highest quality of clinical care (Kumar *et al*., 2018; Levin, 2007). The study design was an experimental longitudinal study with 154 subjects recruited, monitored over six time frames (repeated measures) and examined for the outcome measures of interest. The patients included in the study were divided into two groups, the closed treatment (CT) group and the open reduction and internal rigid fixation (ORIF) group.

2.2. Study population

Patients presenting to the Department of Maxillo-facial and Oral Surgery at Chris Hani Baragwanath Academic Hospital (CHBAH) with mandibular condylar fractures over the time period January 2011 to December 2015 formed the study population.

2.2.1. Exclusion criteria

a) Condylar fractures older than 2 weeks
b) Patients with posterior cross-bites
c) Edentulous patients
d) Patients with pre-existing skeletal discrepancies with malocclusion
e) Patients less than 18 years old
f) Patients with associated midface fractures

g) Lack of posterior occlusal support (insufficient dentition to reproduce occlusal relationships or no molar occlusion on the fractured side)
h) Refusal to participate in the study
i) Medically unfit to undergo surgery

Informed consent was obtained from all participants who were enrolled in the study after they received an explanation of the advantages and disadvantages of open and closed treatment. Participants were requested to read and sign a consent form (Annexure A).

2.2.2. Data collection

The following data were recorded (Annexure B) by the principal investigator:

- **Demographic data:** age, sex, and relevant medical history.
- **History:** date of injury, mode of injury and date of presentation. Patients were also asked if they felt they were intoxicated at the time of injury.
- **Clinical examination:** patients were clinically examined and data on the status of the occlusion at maximum closure, inter-incisal mouth opening in millimetres (measured using a set of callipers), presence of deviation on mouth opening and the presence of associated mandibular injuries were recorded.
- **Radiographic examination:** radiographic analysis was with panoramic, postero-anterior mandible and reverse Towne's views, and CT scans were indicated for suspected sagittal split fractures of the mandibular condyle.

- **Classification:** fractures were classified into the four types according to the **Wits Classification System for mandibular condylar fractures** following radiographic examination (See above, Figs. 1.7 and 1.8).
- **Treatment:** the specific treatment rendered for both the fractured condyle and any associated mandibular fractures was recorded. The patients included in the study were divided into two groups, the CT and the ORIF groups. Randomisation was done by lots drawn using closed envelopes. All the associated mandibular fractures in both groups were treated by open reduction, combined with internal rigid fixation. Treatment was carried out by a single operator.
    a) **Closed treatment (CT):** consisted of placement of arch bars and rigid intermaxillary fixation (IMF) for 1 week followed by guiding elastics for 4 weeks and physiotherapy for 3 months.
    b) **Open reduction and internal fixation (ORIF):** consisted of placement of arch bars followed by fracture reduction via direct visualisation through an open approach. Open reduction was performed via retromandibular incision, followed by placement of two miniplates over the fracture lines on the condylar process.

An experimental analysis by Meyer *et al.,* (2006) concluded that one straight plate afforded poor primary stability in the condylar region (Fig. 2.1), and resulted in the condylar fragment slipping postero-inferiorly (after loading) by 1 mm with a significant posterior anti-clockwise rocking motion. This led to an antero-superior gap of 2 mm in the fracture line, resulting in poor bone healing and plate fracture (Fig. 2.2).

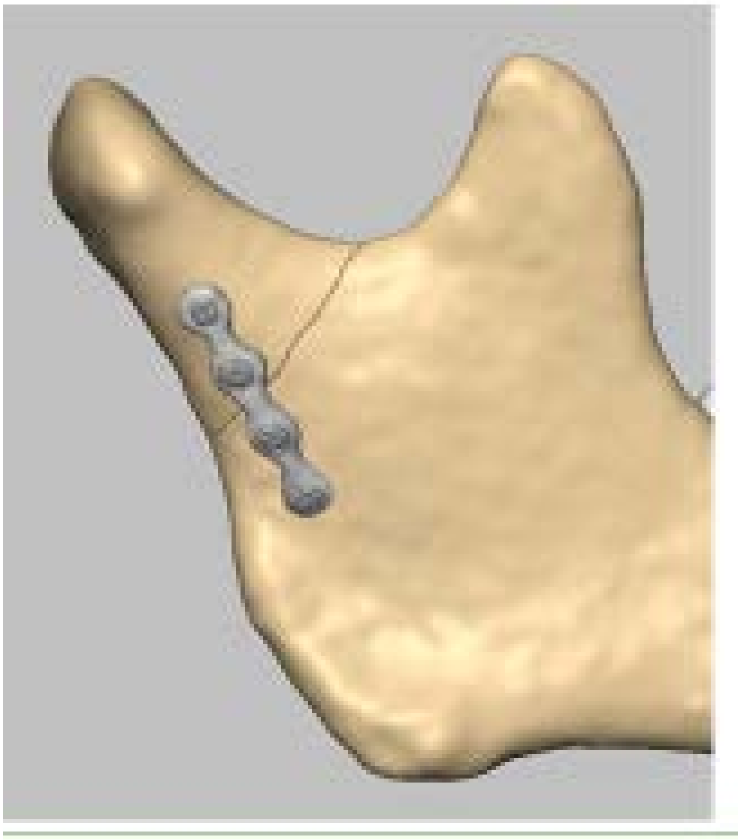

Figure 2.1 Illustration of a single mini-plate used for the condyle fracture (as described by Meyer *et al*., 2006).

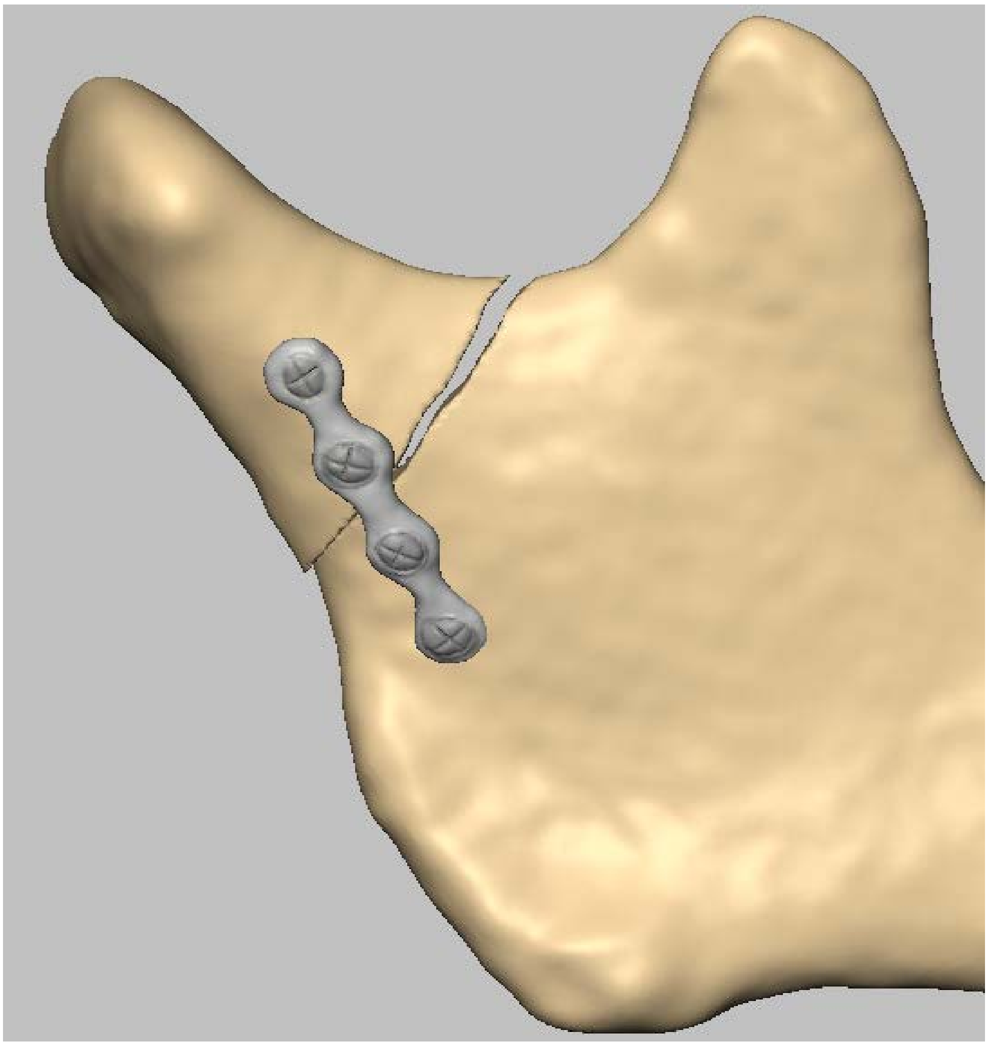

Figure *2.*2 Illustration of poor stability with a loaded miniplate resulting in a counterclockwise rotation (as described by Meyer et al., 2006).

For this reason, it was decided to use two plates in the fractured condyle for the ORIF cases: first plate placed in the condylar neck axis along the posterior border and the second plate placed below the mandibular notch (Fig. 2.3)

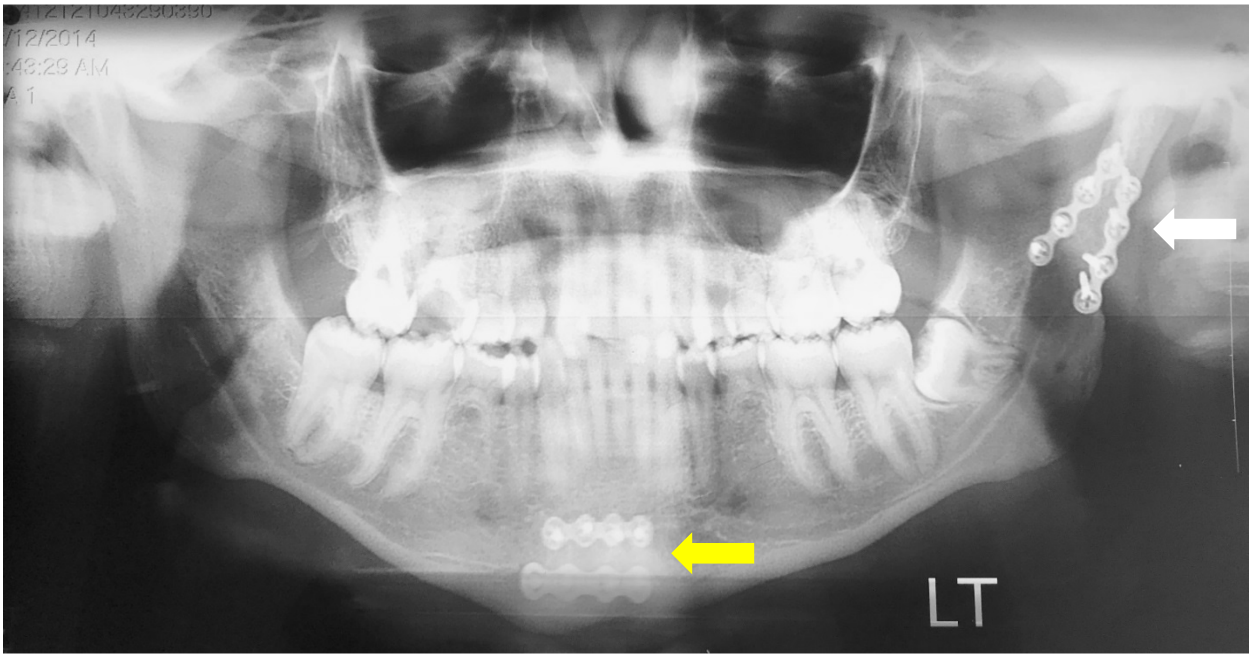

Figure 2.3 Panoramic X-ray showing two plates (white arrow) in the left condylar region. Also shown are two plates (yellow arrow) in the symphyseal region.

- **Follow up.** With the post-operative assessment the following variables were recorded: duration of maxillo-mandibular fixation, maximum mouth opening, status of the occlusion, absence or presence of deviation on mouth opening, and pain. This assessment was done at 1 week, 6 weeks, 3 months, 6 months and 12 months post-treatment. Upon release of the maxillo-mandibular fixation (MMF), patients were instructed to follow a physiotherapy protocol. The physiotherapy included occlusal guidance with elastics and jaw mobility exercises undertaken by physiotherapists for a period of 3 months. Patients were also instructed to remain on a soft diet for 3 months. Radiographic examination was performed at 6 weeks, 3 months, 6 months and 12 months.

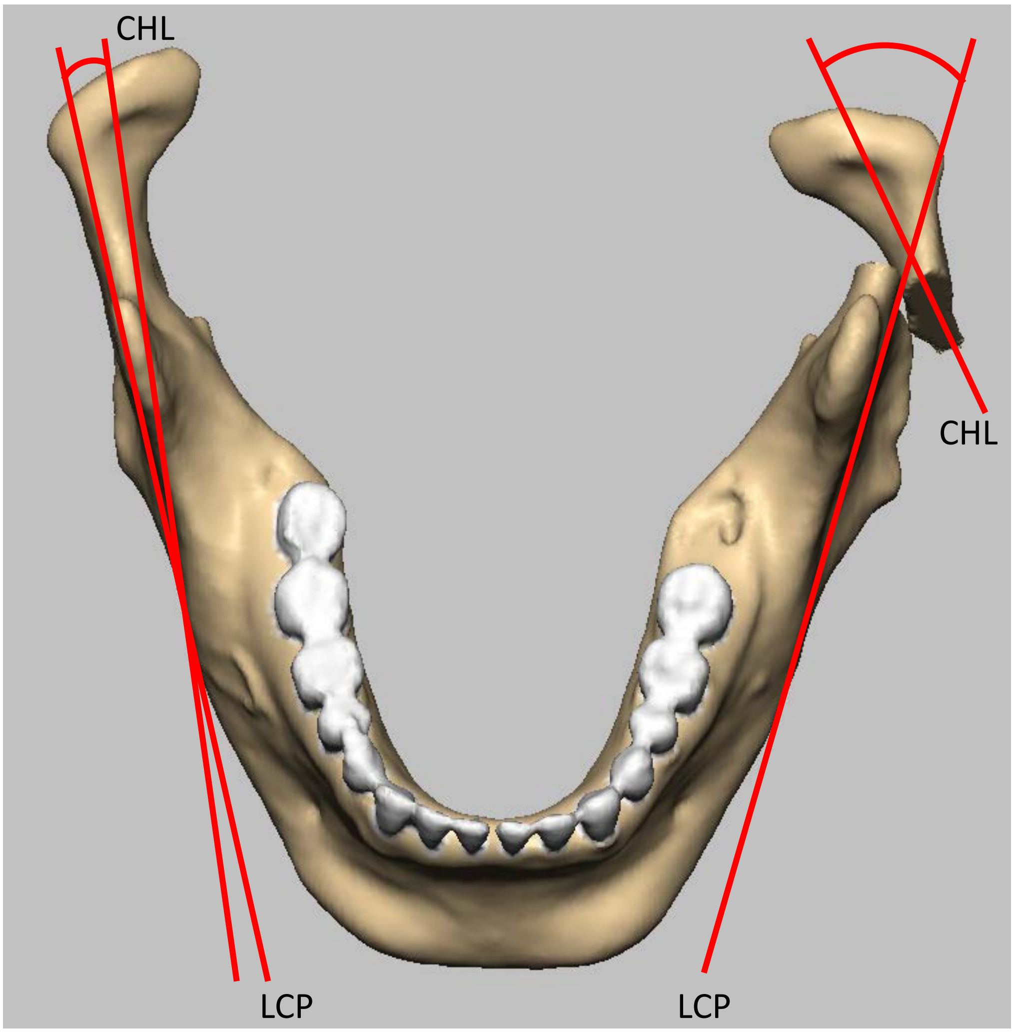

Figure 2.4 Measurement of angle of displacement as described by Silvennoinen *et al*., 1994. Angulation of the fractured and non-fractured condylar process was measured in the Reverse Townes' views as the difference between midcondylar line (CHL) and a line drawn along the lateral cortical plate (LCP) of the mandibular ramus. Angulation of the fractured site was represented by the difference in degree between the fractured and non-fractured sides.

2.2.3. Measurements and tests

a. Coronal displacement of the fractures was measured on Reverse Townes' views as the angle between a line drawn between the medial and lateral poles of the condyle and a line drawn through the lateral surface of the mandibular ramus. Displacement was described as mild (0-15 degrees), moderate (15-30º) and severe (> 30º). Figure 2.4 shows how the angle of displacement was measured on a Reverse Townes radiograph.

b. Ramus height was measured on the panoramic image by using a perpendicular distance between a point located on the most superior point of the glenoid fossa and the bigonial line. Reduction of the ramus height was divided into three classes: 0-4 mm, 5-8 mm and > 8 mm. Figure 2.5 shows how RHL was measured on a panoramic radiograph whilst Fig. 2.6 shows RHL on a 3-D reconstruction of the mandible.

Figure 2.5 Panoramic X-ray illustrating measurements of VHL as described by Silvennoinen *et al*., (1994). Ramal height was measured as the distance

between the mandibular line (ML) and a tangent to the superior point of the condyle (CA) measured along the ramus line (RL) on the fractured and non-fractured sides (from point A to D). Reduction of ramus height was represented by the difference in length between the fractured side (FS) and non-fractured side (NFS), represented as AD NFS minus AD FS. The ML represents the tangent to the lower border of mandible.

Figure 2.6 Illustration of ramus height loss on 3-D reconstruction of the mandible.

c. Treatment outcomes were objectively and subjectively assessed at each follow-up visit using a slight modification of Walker's objectives (Walker, 1988) of treating mandibular condylar fractures as follows:

   I. Pain free mouth opening: this was assessed with a visual analogue scale (VAS) with values from 0 (no pain) to 10 (strongest pain).

II. Restoration of normal mouth opening in excess of 35 mm: maximum mouth opening was recorded as moderately reduced (25–35 mm) and severely reduced (< 25 mm). Interincisal distance was measured with a Willis gauge. A mouth opening of 35 mm was used as a cut-off point as described by Dijkstra *et al*., (2006).

III. Acceptable movement of the jaw: all excursions were measured as the range of movement as given by mouth opening, extent of protrusion and lateral excursion.

   Protrusion of less than 6 mm and laterotrusion of less than 8 mm were defined as hypomobility. Protrusion was measured by asking the patient to move the mandible from his or her physiologic rest position to the anterior without tooth contact - the distance from the incisal edge of the maxillary central incisor to the incisal edge of the mandibular central incisor was then measured in this position.

   Lateral excursion was evaluated by asking the patient to slightly open his or her mouth from the physiologic rest position and move the mandible as far as possible toward the right or left. Movement was measured by a millimetre ruler from the labio-incisal embrasure between the maxillary central incisors to the labio-incisal embrasure of the mandibular incisors.

IV. Return to pre-injury occlusion of the teeth: occlusion was assessed clinically and by asking patients whether they felt that the current occlusion corresponded to pre-trauma occlusion. Occlusion was clinically evaluated and rated as good (normal for the patient), poor (abnormal for the patient) and undecided (could not decide from the observation).

V. Stable temporomandibular joint: a modified version of Helkimo's TMJ dysfunction index as described by Thilander *et al.,* (2002) was used to evaluate stability of the TMJ. The clinical signs were scored as follows at 12 months:

- Maximum mouth opening: 0: > 35 mm; 1: 25–34 mm; 2: < 25 mm.
- Mandibular deviation on MO: 0: < 2 mm; 1: 2–5 mm; 2: > 5 mm.
- TMJ function: 0: no impairment; 1: palpable clicking; 2: evidently clicking; 3: locking and luxation.
- TMJ pain: 0: no pain (pain VAS = 0); 1: palpable pain (pain VAS ≥ 1); 2: palpebral reflexes.
- Muscle pain: 0: no pain (pain VAS = 0); 1: palpable pain (pain VAS ≥ 1); 2: palpebral reflexes.

Thilander *et al.,* (2002) then used the sum of the scores to create a grading of TMJ dysfunction as follows:

GRADE 0 = no dysfunction

GRADE I = mild dysfunction (1-4 points)

GRADE II = moderate dysfunction (5-9 points)

GRADE III = severe dysfunction (> 9 points)

Measurements and assessment were done twice by the investigator and once by a specialist surgeon who was not blinded to the study. The average of the two measurements was used as the final values for data analysis.

2.2.4. Sample size estimation

Sample size estimation was based on the key research question to be answered, in this case the comparison of 12 month outcomes between treatment groups, and controlling for type of fracture, type of fracture versus treatment group, time delay, laterality, angle of displacement, and medial/lateral displacement. The majority of the 12 month outcomes were continuous, so the sample size estimations were based accordingly. For the detection of a small, medium, or large between-treatment group difference (d = 0.2, 0.5 and 0.8 respectively) with 80% power at the 5% confidence level, sample sizes of 788, 128, and 52, respectively, were required. Typically, the aim is detection of a medium effect size, should it exist, thus requiring a sample size of 128.

To determine if the sample size was large enough for inclusion of all the desired covariates in the analysis, the G*Power sample size calculator (Faul, 2007) was used. This required the estimation of eight parameters, which requires:

- For multiple regression (continuous outcomes): 8 * (5 to 10) = 40 to 80 cases. The actual sample size of 116 was thus reasonably adequate for the purposes of the study.
- For logistic regression (categorical outcomes): 10 cases per parameter to be estimated, in the smallest outcome group. Considering a binary outcome, this translates to a minimum sample size of 8*10*2 = 160. The actual sample size was thus not adequate for logistic regression, and some variables had to be excluded from the model (how many depended on the composition of the outcome variable).

2.3. Data analysis

Descriptive analysis of the data was carried out as follows: categorical variables were summarised by frequency and percentage tabulation, and illustrated by means of bar charts. Continuous variables were summarised by the mean, standard deviation, median and interquartile range, and their distribution illustrated by means of box-and-whisker plots. Baseline variables were compared using the standardised mean effect size (SMES) (Woodward, 2013). The effect of the treatment group on each of the 12 month outcomes was assessed as follows:

- For continuous outcomes (mouth opening, protrusion, laterotrusion fractured side (FS), laterotrusion non-fractured side (NFS), pain score, deviation), a General Linear Model (GLM) was used. The outcome was the dependent variable. Treatment group, grade of injury treatment group interaction, ramus height loss, time delay, site (unilateral/bilateral), angle of displacement, and medial/lateral displacement, were the independent variables. *Post-hoc* tests were carried out using the Tukey-Kramer adjustment for unequal group sizes.
- For categorical outcomes (TMJ dysfunction, TMJ grading, complications), logistic regression was used. Independent variables were as specified for the continuous outcomes.
- Prior to these analyses, the pair-wise association between each of the independent variables was assessed to identify any strongly associated variables which should not be used together in the regression analyses. Pairs of categorical variables were assessed by the Chi-square test (or Fisher's exact test for 2 x 2 tables where the assumptions of the Chi-square test were not met). Pairs of continuous variables were assessed by Pearson's correlation coefficient (or Spearman's rank correlation coefficient where the data did not

meet the assumptions of this test). Combinations of categorical and continuous variables were assessed by the t-test (or ANOVA for more than two categories) and where the data did not meet the assumptions of these tests, a non-parametric alternative, the Wilcoxon rank sum test (or the Kruskal-Wallis test for more than two categories) was used.

- The effect of the type of fracture, ramus height loss, time delay, single/bilateral, angle of displacement, and medial/lateral displacement on the presence / absence of complications within each treatment group, was assessed by univariate logistic regression.

Data analysis was carried out using SAS (version 9.4 for Windows). The level of significance was set at 0.05.

2.4. Ethical considerations

Ethical approval was obtained from the Human Research Ethics Committee (Medical) at the University of the Witwatersrand (Ethics number M080442). Written informed consent was obtained from the participants after the objectives of study were explained to them. Lots were drawn to randomly allocate patients into the two groups. The allocation posed a potential ethical problem because the one treatment option involved open surgery and the other option did not. Both are, however, accepted treatment modalities for MCFs.

CHAPTER THREE: RESULTS

3.1. Descriptive analysis

3.1.1. Biographical and clinical characteristics of the participants

A total of 154 patients (who met the inclusion criteria) with 173 mandibular condylar fractures were treated between January 2011 and December 2015. Of the 173 fractures, 135 were unilateral and 19 were bilateral. Of the 154 patients, 38 failed to return for the requisite 12 month follow-up and were therefore excluded from the study.

Of the remaining 116 patients, females constituted 9% (n=10) and males were by far the majority of the participants at 91% (n=106). The 116 patients had a total of 132 fractures (100 unilateral, 16 bilateral). Of the 100 unilateral fractures 41 occurred on the left side and 59 on the right. Table 3.1 shows the baseline clinical and biographical data of the study patients.

Table 3.1 Baseline clinical and biographical data between the two treatment groups.

Variable		Closed (n=68)		Open (n=48)	
		n	%	n	%
Gender	Male	59	86.8	47	97.9
	Female	9	13.2	1	2.1
Aetiology	Assault	46	67.6	30	62.5
	MVA	9	13.2	8	16.7
	Fall	9	13.2	7	14.6
	PVA	1	1.5	2	4.2
	GSW	2	2.9	0	0
	Sports	1	1.5	1	2.1
Side	Left	34	50	27	56.3
	Right	34	50	21	43.8
Unilateral/Bilateral	Unilateral	59	86.8	41	85.4
	Bilateral	9	13.2	7	14.6
Type of fracture	IIB	61	89.7	45	93.8
	III	5	7.4	3	6.3
	IV	2	2.9	0	0
Associated injuries	None	10	14.7	5	10.4
	Right angle	3	4.4	0	0
	Right body	6	8.8	5	10.4
	Parasymphysis	3	4.4	6	12.5
	Symphysis	40	58.8	26	54.2
	Left body	5	7.4	5	10.4
	Left angle	2	2.9	2	4.2

The aetiology of the fracture was alleged assault in 76 patients (66%), motor vehicle accident in 17 (15%) and falls in 16 (14%). The most common type of fracture was Type II B (89.7%) followed by Type III (7.4%) and Type IV (2.9%) fractures. Figure 3.1 shows an example of a Type II B fracture. Ninety-four (71.2%) of the fractures were laterally displaced whilst only 20 were medially displaced or dislocated (Figs. 3.2 and 3.3). Two patients had comminuted fractures (Type IV) post-gunshot wounds. Symphyseal and parasymphyseal fractures were the most commonly associated fractures (75) followed by body (21) and angle (7) fractures. Only 15 (13%) patients had isolated MCFs.

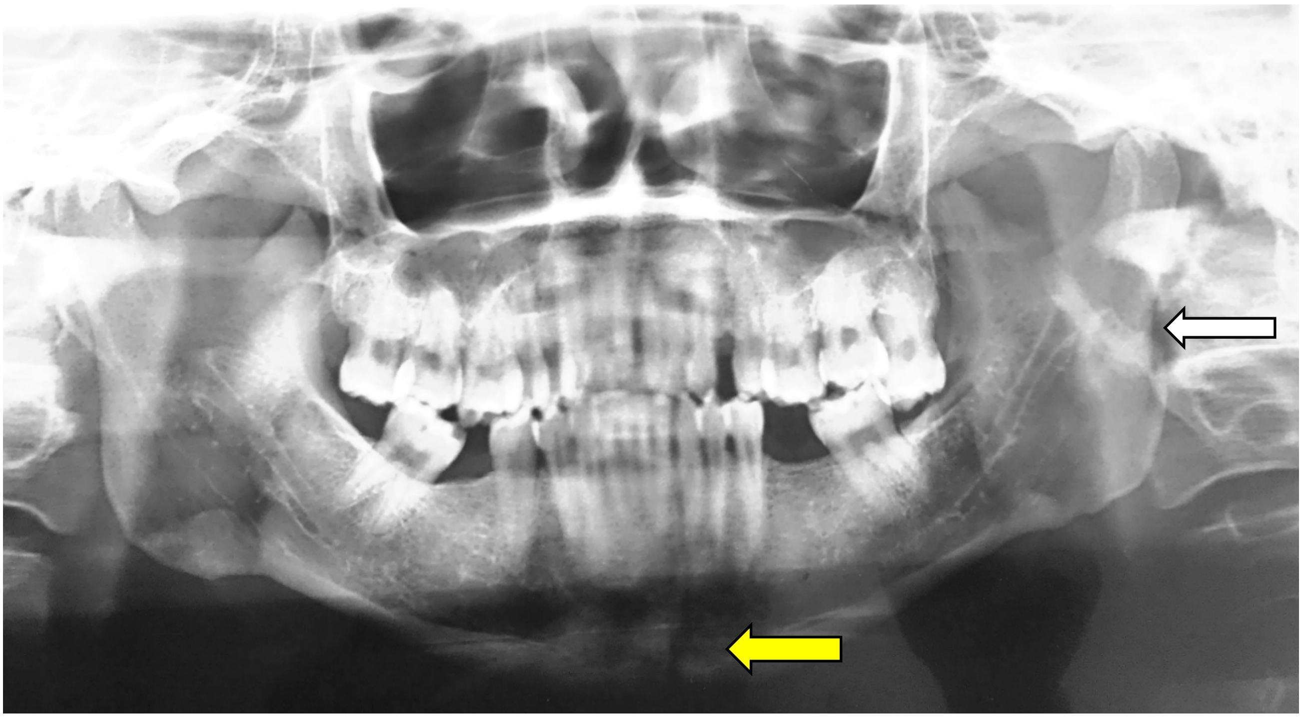

Figure 3.1 Panoramic X-ray: a WITS Type II B fracture (white arrow) on the left side with a symphyseal fracture (yellow arrow).

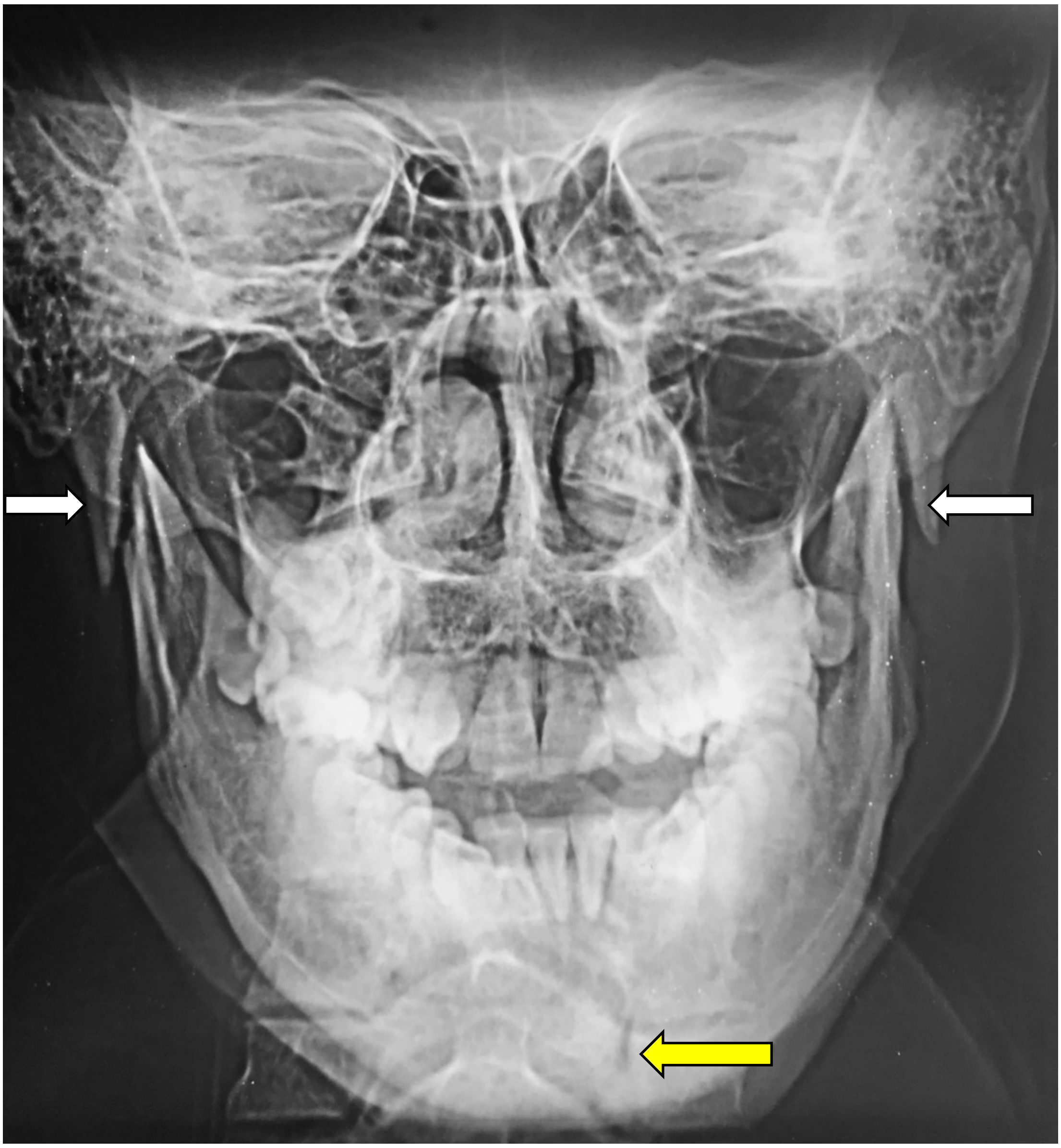

Figure 3.2 PA Mandible showing bilateral WITS Type II B fractures (laterally displaced: white arrows) with a left parasymphyseal fracture (yellow arrow).

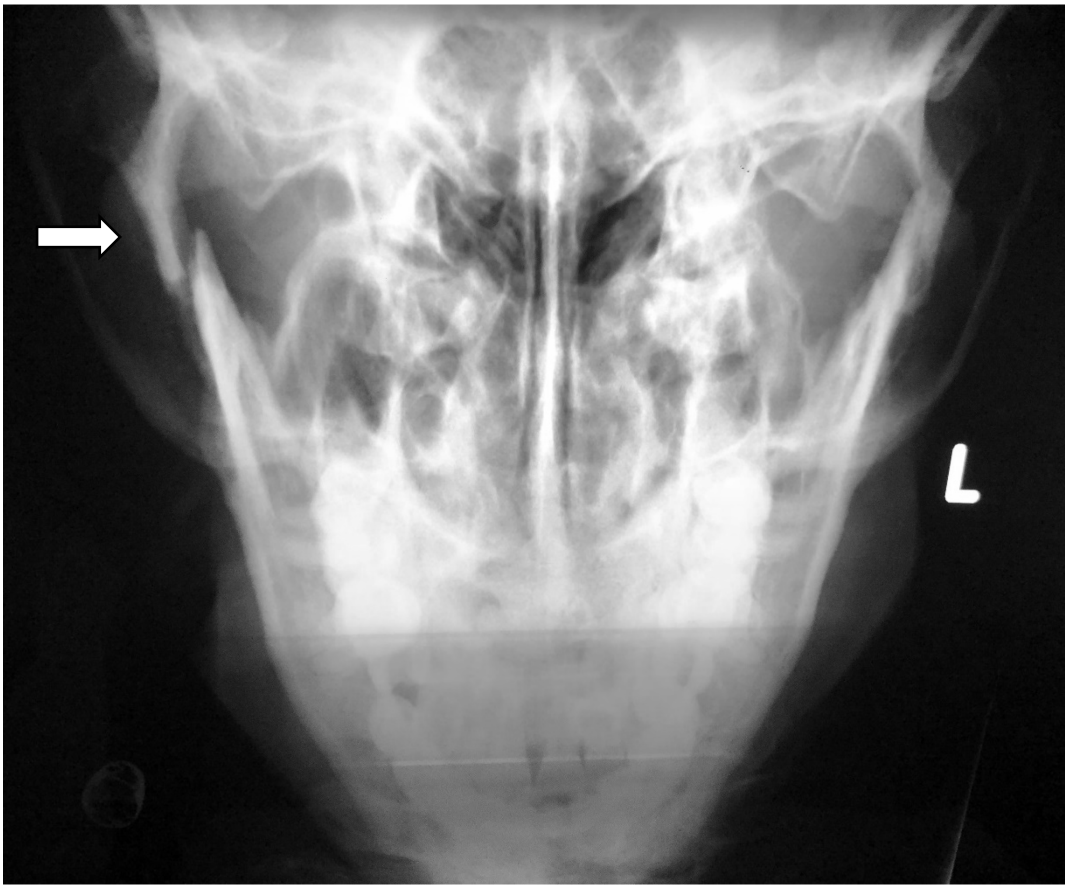

Figure 3.3 Reverse Townes' view illustrating a laterally displaced WITS Type II B fracture on the right side (white arrow).

Of the 116 patients, 68 (59%) were treated closed and 48 (41%) were treated by open reduction and rigid internal fixation. Figures 3.4 and 3.5 show pre- and post-operative PA mandible and panoramic X-rays of bilateral condylar fractures with associated symphyseal fracture respectively. All the associated mandibular fractures in both groups were treated by open reduction and rigid internal fixation (Fig. 3.5).

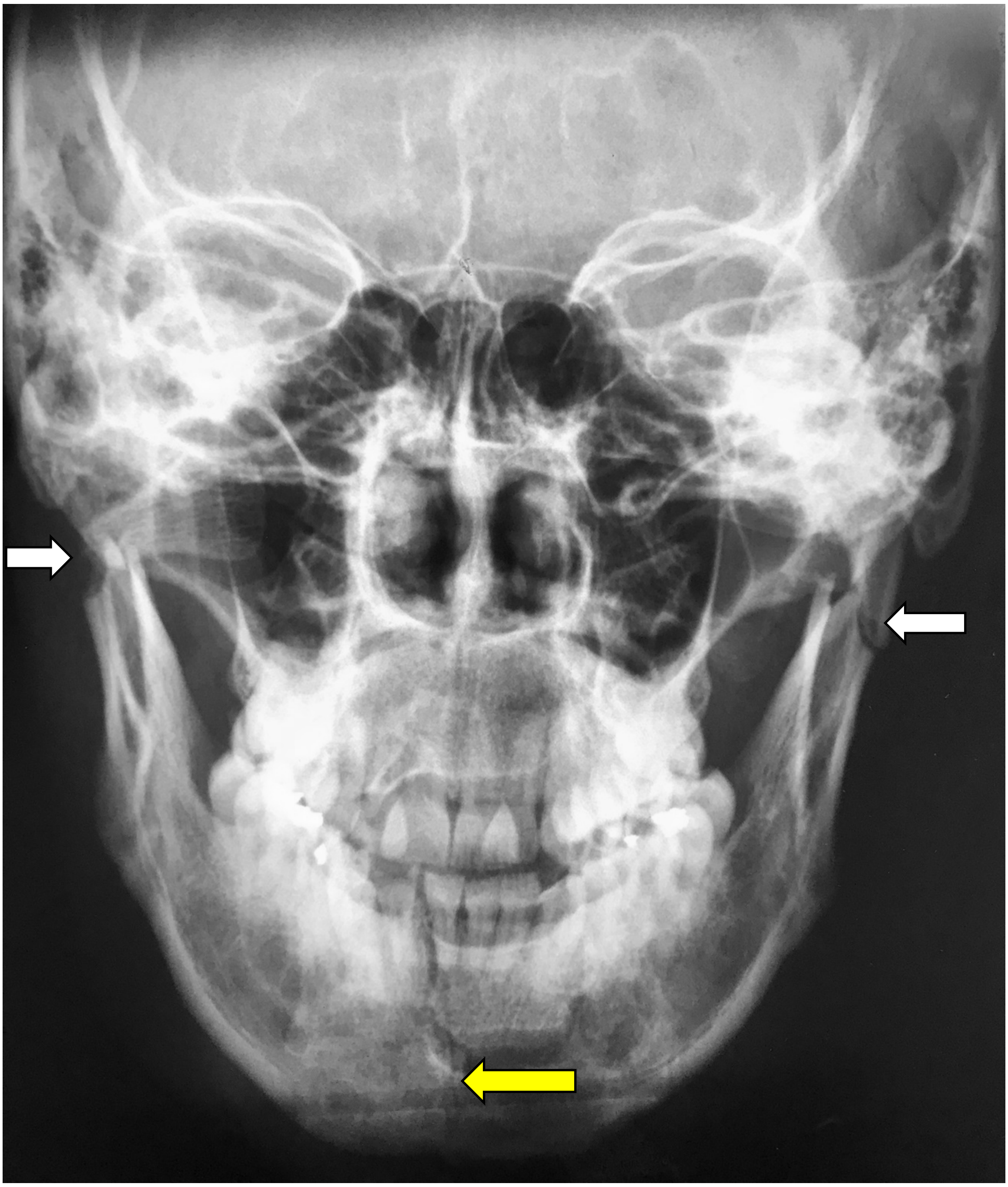

Figure 3.4 Postero-Anterior (PA) mandible preoperative X-ray showing bilateral condylar fractures (white arrows: WITS Type III right and Type II B left sides) with a symphyseal fracture (yellow arrow).

Figure 3.5 Postoperative panoramic X-ray following open reduction and internal fixation (white arrows: two plates at left and right condyles) of the case shown in Figure 3.4

Figure 3.6 Associated symphyseal fracture plates (two plates).

Figure 3.7 shows the preoperative panoramic radiograph of a unilateral condylar fracture with associated symphyseal fracture. Closed treatment was performed for the condylar fracture whilst ORIF was done for the symphyseal fracture. Figure 3.8 shows the postoperative panoramic radiograph at 6 weeks.

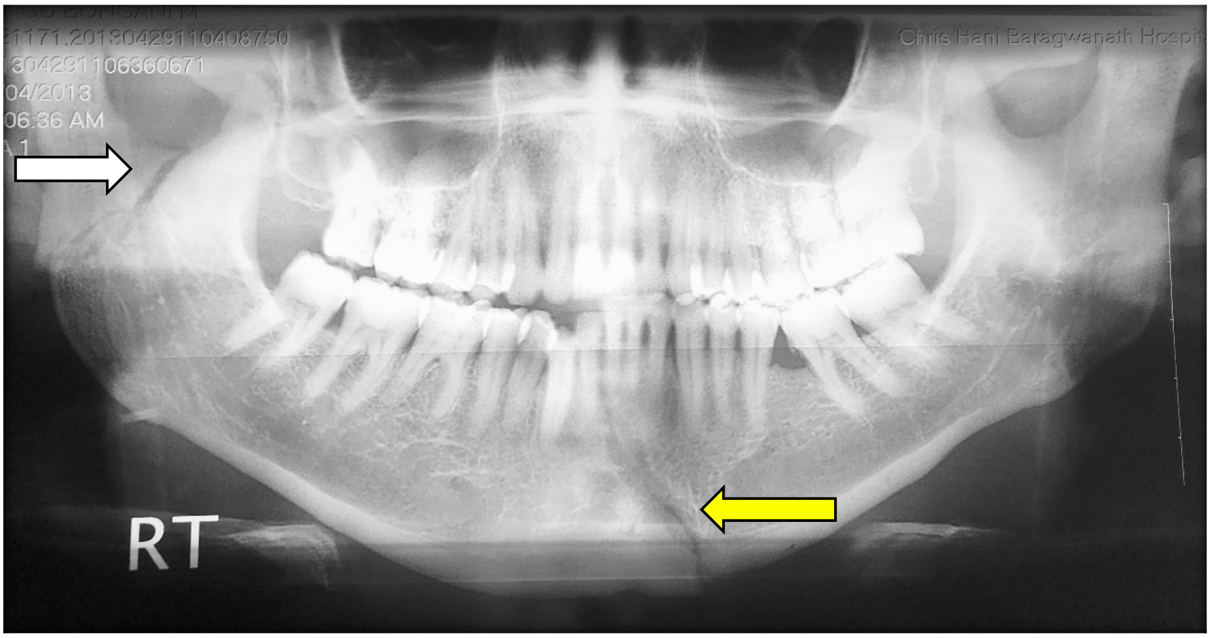

Figure 3.7 Preoperative panoramic X-ray showing Type II B fracture (white arrow) and symphyseal fracture (yellow arrow).

Figure 3.8 Closed treatment: Postoperative panoramic X-ray (at 6 weeks) of the patient in Fig. 3.6. Note remodeling of the fracture (white arrow).

For the closed group, the age ranged from 18-58 (median 29; IQR: 25-33,) whilst for the ORIF group the range was 20-45 (median 31; IQR: 24-36) as illustrated in Fig. 3.9.

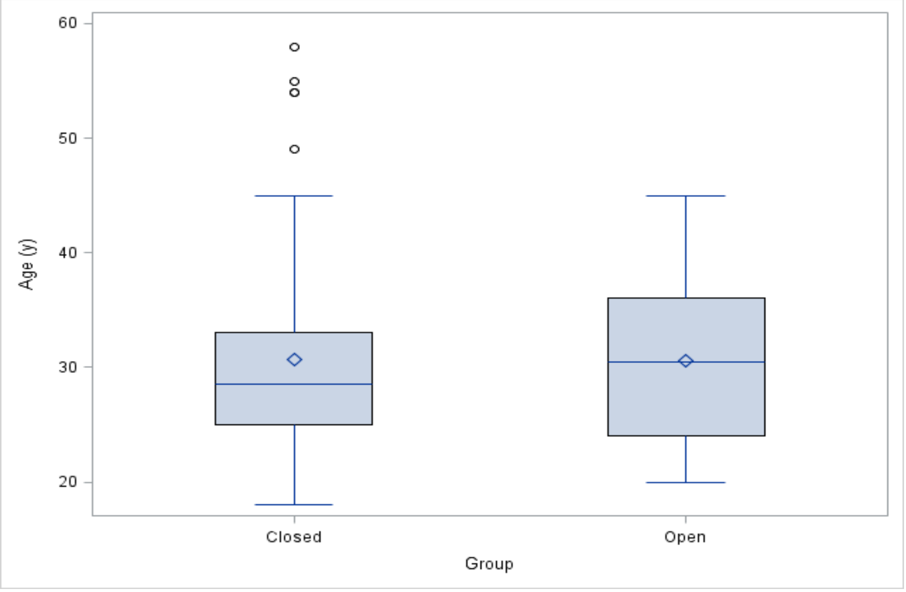

Figure 3.9 Box-and-whisker plot of age distribution in the two treatment groups.

The angle of displacement ranged from 0-90 degrees (median 8; IQR 4-18) in the closed group, whilst in the open group the range was also from 0-90 degrees (median 12; IQR 7-25). Figure 3.8 illustrates the angle of displacement in the two groups.

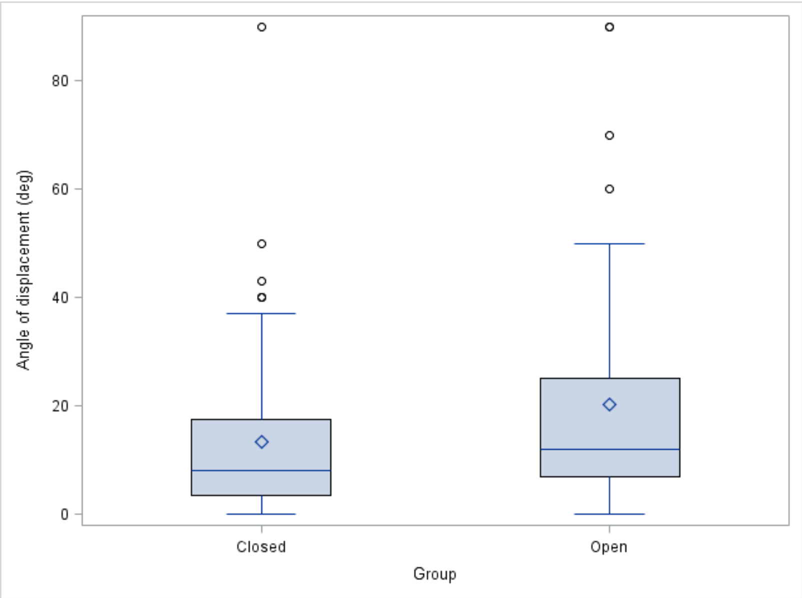

Figure 3.10 Box-and-whisker plot of angle of displacement in the open and closed treatment groups.

For the closed group, ramus height loss (RHL) ranged from 0–13 mm (median 8; IQR 4-10)). The RHL range for the open group was 4-15 mm (median 10; IQR 8-10) (Fig. 3.11).

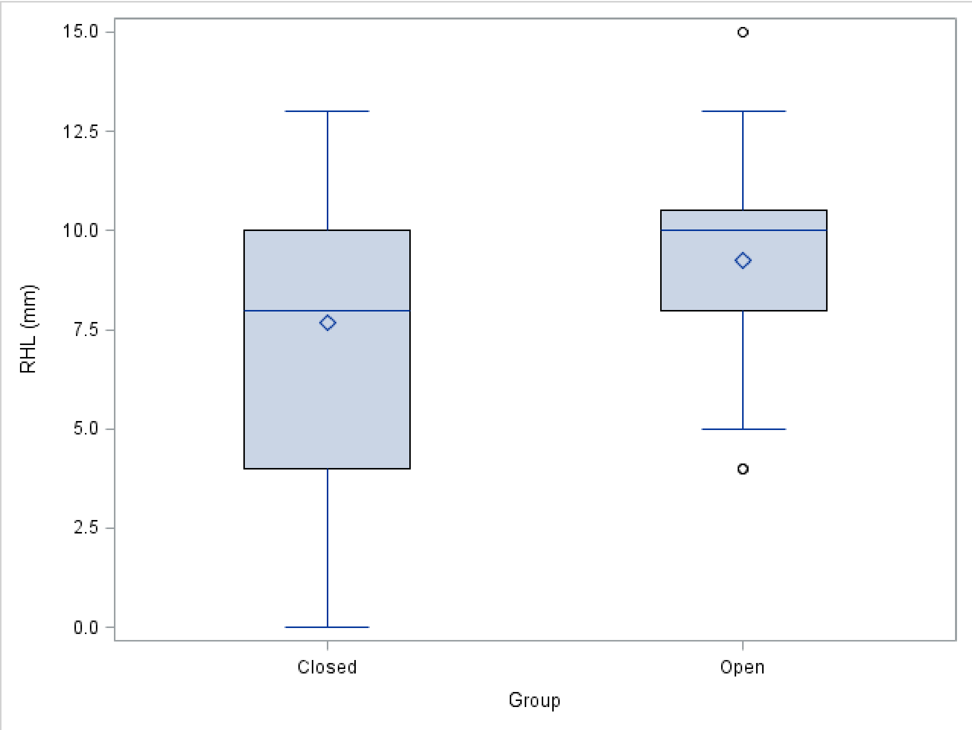

Figure 3.11 Box-and-whisker plot of ramus height loss measurements for closed and open treatment groups.

Delay in treatment ranged from 3-14 days (median 9; IQR 7-12),) in the closed group. In the open group, delay in treatment ranged from 2-14 days (median 10; IQR 9-12). Figure 3.12 illustrates the delay in treatment in the two groups.

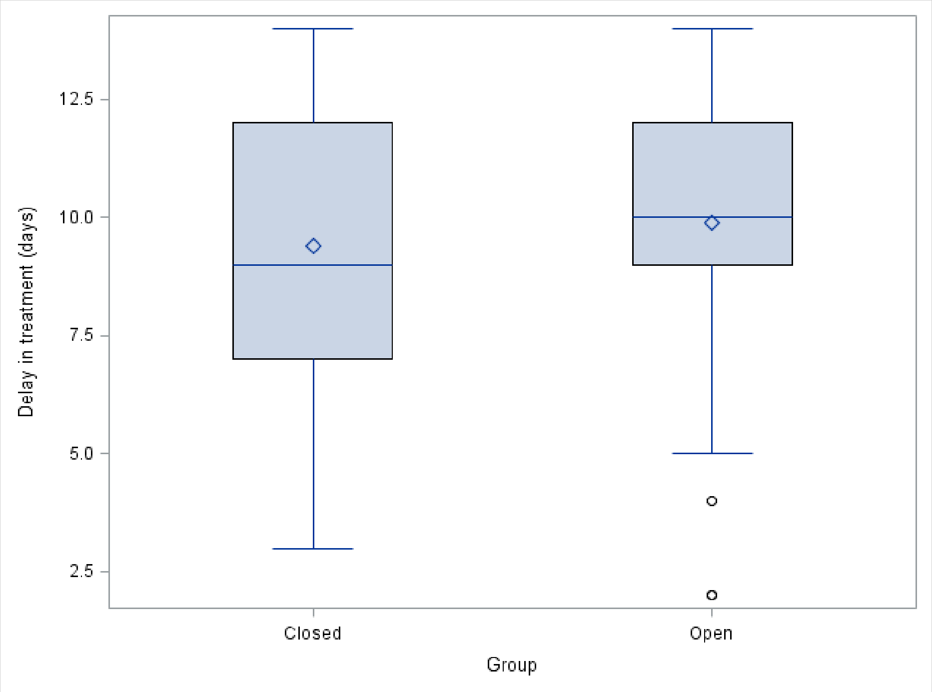

Figure 3.12 Box-and-whisker plot of delay in treatment in both the closed and open treatment groups.

Table 3.2 shows the age, RHL and delay in treatment distribution in the two treatment groups.

Table 3.2 Age, ramus height loss (RHL), angle of displacement and delay in treatment in both the closed and open treatment group.

Variables	Closed (n=68)			Open (n=48)		
	Median (IQR)	Min	Max	Median (IQR)	Min	Max
Age (years)	29 (25-33)	18	58	31 (20-45)	20	45
Ramus height loss (mm)	8 (4-10)	0	13	(4-15)	4	15
Angle of displacement (degrees)	8 (4)	18	90	12 (7)	25	90
Delay in treatment (days)	9 (7-12)	3	14	10 (9-12)	2	14

3.2. Gender, RHL and angle of displacement: baselines with large Standardised mean effect size (SMES)

The SMES of the baseline variables are tabulated in Table 3.3.

Table 3.3 Presentation of the baseline variables between the two treatment groups.

Variable	**SMES (%)**
Age	5
Gender	42.9
Aetiology	
Assault	10.8
Side	12.5
Unilateral/Bilateral	3.9
Grade	
IIB	14.7
III	4.4
IV	24.6
Associated injuries	
RHL	20.7**
Angle of displacement	20.4**
Displacement	
Lateral	0.9
Medial	6.8
Comminuted	17.3
None	17.3
Delay in treatment	8.1
Mouth opening (week 0)	7.1

****Large SMES with effect on outcome**

Normally a threshold of 10% for the important imbalances is used, but this was not used in this study as many variables exceeded this threshold. The focus was rather on those variables with a large SMES, but which did not correspond to categories with a small number of patients, and the variables with large SMES within these. These variables were gender, RHL and angle of displacement. These factors only matter if these variables are prognostic for outcomes. In this case gender is not prognostic for the outcome, but RHL and angle of displacement do have an effect on the outcome. This suggests that the baseline variables for RHL and angle of displacement for both the closed and open groups were different, calling into question the randomisation process. However, this could be explained by the small sample size of the study and the effect of the 38 patients who did not return for the 12 month review.

3.3. Effect of the treatment group on the outcome variables

3.3.1. Mouth Opening

The median mouth opening (mm) at weeks 12, 26 and 52 in the closed group was 40 mm (IQR 35-45), 45 mm (IQR 40-51) and 50 mm (IQR 43-54) respectively. In the ORIF group, the figures at weeks 12, 26 and 52 were 35 mm (IQR 30-40)), 43 mm (IQR 37-48) and 45 mm (IQR 40-50) respectively (Table 3.4, and Figs. 3.10 and 3.11).

Table 3.3 Presentation of Mouth Opening at weeks 0, 6, 12, 26 and 52.

Mouth Opening (mm)								
	Closed (n=68)				Open (n=48)			
Week	**Median**	**IQR**	**Min**	**Max**	**Median**	**IQR**	**Min**	**Max**
0	20	16-20	15	30	20	17-20	15	30
6	30	24-33	15	50	25	20-30	10	36
12	40	35-45	22	54	35	30-40	20	52
26	45	40-51	30	58	43	37-48	29	55
52	50	43-54	33	60	45	40-50	36	60

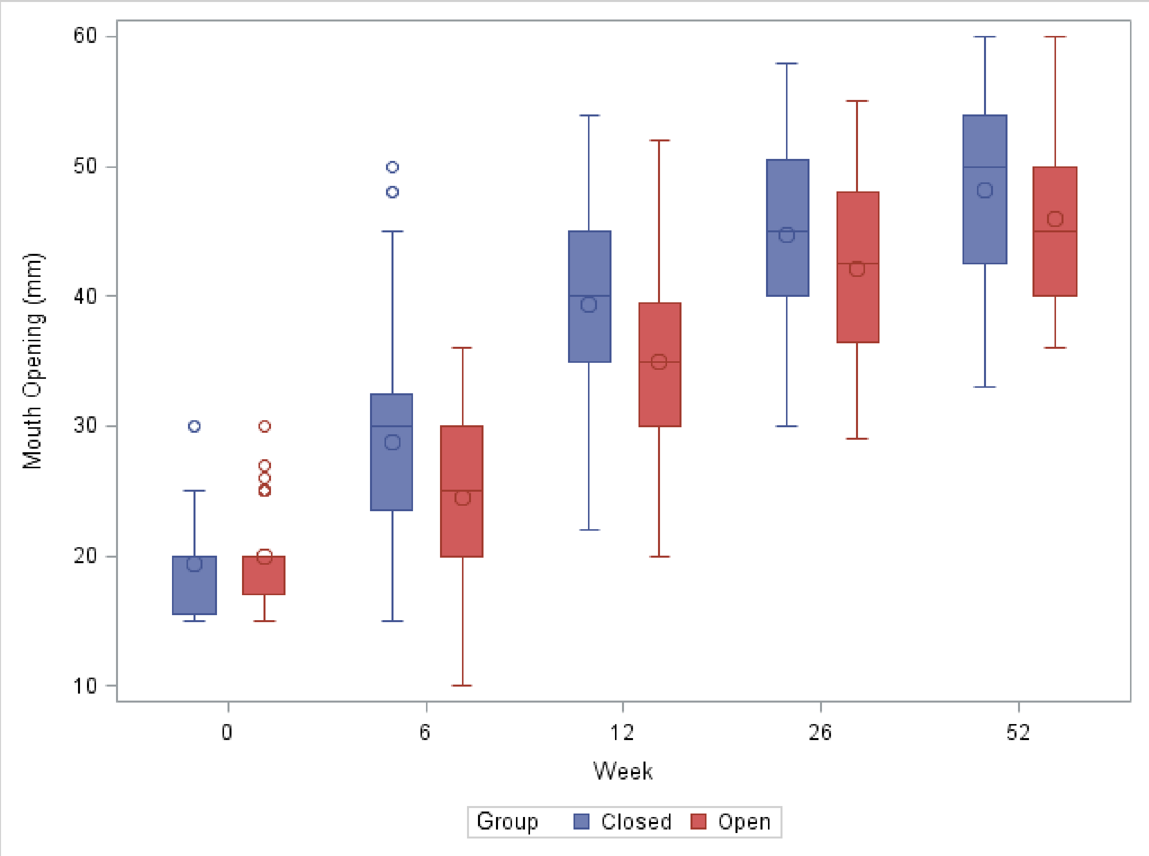

Figure 3.13 Box-and-whisker plot of mouth opening measurements for closed and open treatment groups from week 0 to 52.

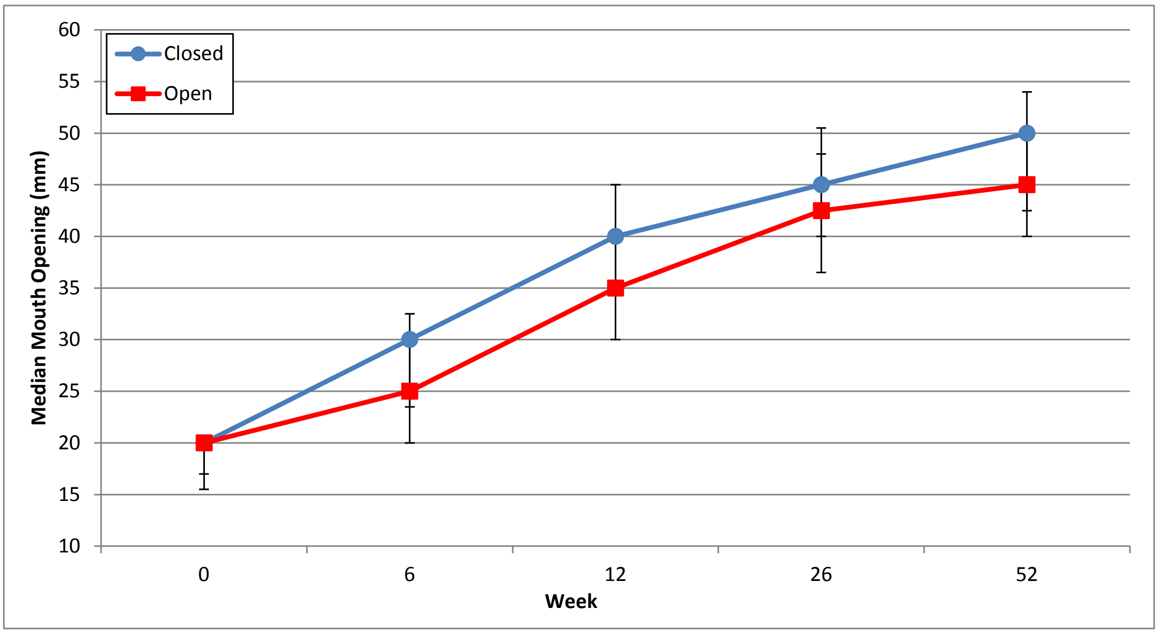

Figure 3.14 Median mouth opening for closed and open treatment groups. Error bars denote the IQR.

Table 3.4 Results of the General Linear Model (GLM) for mouth opening.

Source	DF	Type III SS	MS	F	p-value
Group	1	1.73	1.73	0.04	0.84
Type of fracture	1	0.19	0.19	0.00	0.95
Group*Type of fracture	1	5.37	5.37	0.12	0.73
Unilateral/Bilateral	1	95.81	95.81	2.19	0.14
Displacement	1	46.35	46.35	1.06	0.31
RHL	1	2.05	2.05	0.05	0.83
Angle of displacement	1	76.96	76.96	1.76	0.19
Delay in treatment	1	64.80	64.80	1.48	0.23

The results of the GLM tabulated in Table 3.5 show the following, after controlling for all the other variables in the model:

- The treatment group did not have a significant effect on this outcome, either alone ($p = 0.84$) or as an interaction with injury grade ($p = 0.73$).
- The angle of displacement was not significantly associated with this outcome ($p = 0.19$).

Likewise, the number of fractures (Unilateral/Bilateral), displacement, RHL, and delay in treatment were not significantly associated with this outcome, controlling for all the other variables in the model.

The association between each pair of independent variables was examined to determine whether there were any strong associations, which could be problematic in later analyses. The results are summarised in the Table: 3.6. There were no strong associations, so all the selected independent variables were included in the models.

Table 3.5 Results of association between each pair of independent variables.

	Treatment group	Grade of injury	Laterality	Displacement	RHL	Time delay to treatment	Angle of displacement
Treatment group							
Grade of injury	p >0.99 phi=0.03						
Unilateral / Bilateral	p>0.99 phi=0.01	p=0.0013 phi=0.38					
Displacement (medial / lateral)	p=0.81 phi=0.03	p=0.031 phi=0.23	p=0.035 phi=0.21				
RHL	p=0.027 r=0.20	r=0.034 r=0.19	p=0.99 r=0.00	p=0.22 r=0.11			
Time delay to treatment	p=0.38 r=0.08	p=0.73 r=0.03	p=0.081 r=0.16	p=0.17 r=0.13	p=0.34 r=0.0002		
Angle of displacement	r=0.030 r=0.20	p=0.013 r=0.24	p=0.34 r=0.09	p=0.99 r=0.00	r=0.07 p=0.67	r=0.05 p=0.61	

Results in black indicate Fisher's Exact test; Results in Blue indicate Wilcoxon rank sum test; Results in Red indicate Spearman's rank test.

3.3.2. Protrusion

The mean protrusion for the closed group at 12, 26 and 52 weeks was 6.3 mm (SD 1.7), 7.3 mm (SD 1.9) and 8.0 mm (SD 2.0) respectively. For the open group, the mean protrusions at 12, 26 and 52 weeks were 5.7 mm (SD 1.1), 7.2 mm (SD 1.2) and 7.8 mm (SD 1.4) respectively (Table 3.7, and Fig. 3.15).

Table 3.6 Presentation of protrusion between the closed and open groups at 0, 6, 12, 26 and 52 weeks.

Analysis Variable : Protrusion (mm)						
					95%CI	
Group	Week	N	Mean	SD	Lower	Upper
Closed	0	0				
	6	68	4.6	1.3	4.3	4.9
	12	68	6.3	1.7	5.9	6.7
	26	68	7.3	1.9	6.8	7.8
	52	68	8	2	7.5	8.4
Open	0	0				
	6	48	4.4	1	4.1	4.7
	12	48	5.7	1.1	5.4	6
	26	48	7.2	1.2	6.8	7.5
	52	48	7.8	1.4	7.4	8.2

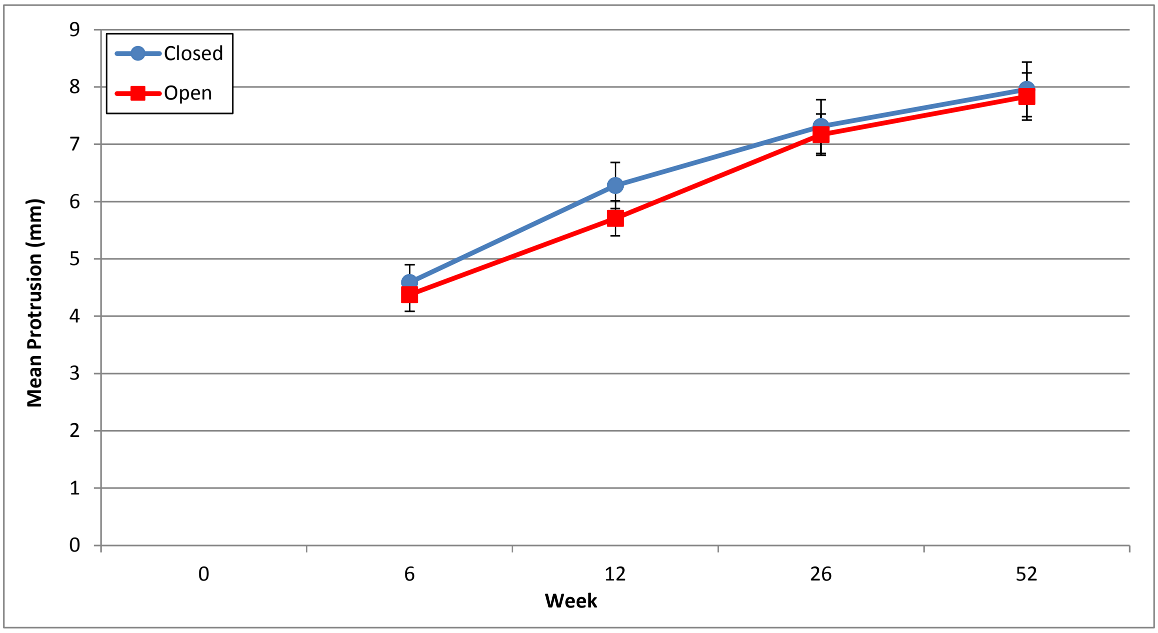

Figure 3.15 Mean protrusion measurements for closed and open treatment groups. Error bars denote the 95% confidence interval for the mean.

The results of the GLM are shown in Table 3.8.

Table 3.7 Results of the GLM showing protrusion.

Source	DF	Type III SS	MS	F	p-value
Group	1	1.02	1.02	0.34	0.56
Grade	1	1.21	1.21	0.40	0.53
Group*Grade	1	2.37	2.37	0.79	0.38
Laterality	1	4.54	4.54	1.51	0.22
Displacement	1	1.40	1.40	0.47	0.50
RHL	1	3.51	3.51	1.17	0.28
Angle of displacement	1	2.44	2.44	0.81	0.37
Delay in treatment	1	0.01	0.01	0.00	0.95

The results of the GLM in Table 3.8 show the following, after controlling for all the other variables in the model:

- The treatment group did not have a significant effect on this outcome, either alone (p = 0.56) or as an interaction with injury grade (p = 0.38).
- The angle of displacement was not significantly associated with this outcome (p = 0.37).

Likewise, the number of fractures (Unilateral/Bilateral), displacement, RHL, and delay in treatment were not significantly associated with this outcome, controlling for all the other variables in the model.

3.3.3. Laterotrusion fractured side (FS)

Laterotrusion FS assessed the lateral excursion of the mandible towards the fractured side. The mean excursion for the closed group at 12 months was 10.5 mm (SD 1.6, range 6-15). For the open group the mean excursion was 9.9 mm (SD 1.8, range 5-15 mm) (Table 3.9, and Fig. 3.16).

Table 3.8 Presentation of laterotrusion to FS at 12 months.

Analysis Variable : Laterotrusion FS (mm)						
Group	**Mean**	**SD**	**Median**	**IQR**	**Min**	**Max**
Closed (n=68)	10.5	1.6	10	10-11	6	15
Open (n=48)	9.9	1.8	10	9-11	5	15

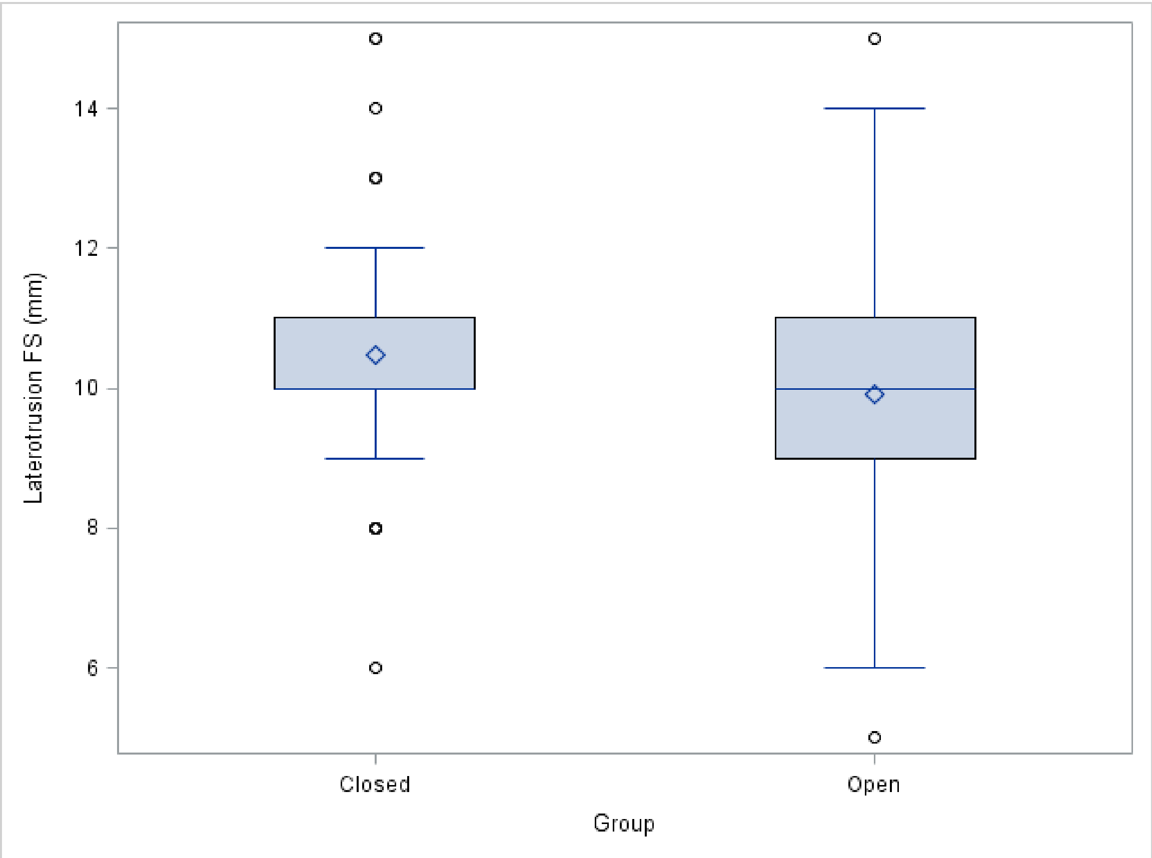

Figure 3.16 Box-and-whisker plot for laterotrusion FS of closed and open groups at 12 months.

The results of the General Linear Model are shown in Table 3.10.

Table 3.10 Results of the General Linear Model (GLM) of laterotrusion FS at 12 months.

Source	DF	Type III SS	MS	F	P-value
Group	1	11.70	11.70	4.42	0.038*
Grade	1	5.37	5.37	2.03	0.16
Group*Grade	1	4.38	4.38	1.65	0.20
Laterality	1	14.43	14.43	5.45	0.022*
Displacement	1	1.40	1.40	0.53	0.47
RHL	1	0.09	0.09	0.04	0.85
Angle of displacement	1	12.31	12.31	4.65	0.033*
Delay in treatment	1	0.00	0.00	0.00	0.98

*p<0.05

These results reveal the following, after controlling for all the other variables in the model:

- The treatment group had a significant effect on this outcome (p = 0.038). The estimated Least-Squares (LS) mean for this outcome for the closed group was 9.9 ± 0.8 mm (mean ± 95% confidence interval for the mean), compared with 8.3 ± 1.3 mm for the open group.
- The angle of displacement was significantly associated with this outcome (p = 0.033). An increase in the angle of displacement of 1 degree was associated with a 0.03 mm increase in the outcome.
- Laterality (Unilateral or Bilateral) had a significant effect on this outcome (p = 0.022). The estimated Least-Squares (LS) mean for this outcome for the unilateral group was 9.7 ± 0.8 mm, compared to 8.5 ± 1.0mm for the bilateral group.
- Displacement, RHL, and delay in treatment were not significantly associated with this outcome.

3.3.3.1. Laterotrusion non-fractured side (NFS)

Laterotrusion NFS assessed the lateral excursion of the mandible towards the non-fractured side. The mean laterotrusion for the closed group was 8.5 mm (SD 1.6, range 5-12) and 8.1 mm (SD 2.3, range 0-12) for the open group at 12 months (Table 3.11, and Fig. 3.14).

Table 3.11 Presentation of laterotrusion NFS at 12 months.

Analysis Variable : Laterotrusion NFS (mm)						
Group	**Mean**	**SD**	**Median**	**IQR**	**Min**	**Max**
Closed (n=68)	8.5	1.6	8	7-10	5	12
Open (n=48)	8.1	2.3	8	8-9	0	12

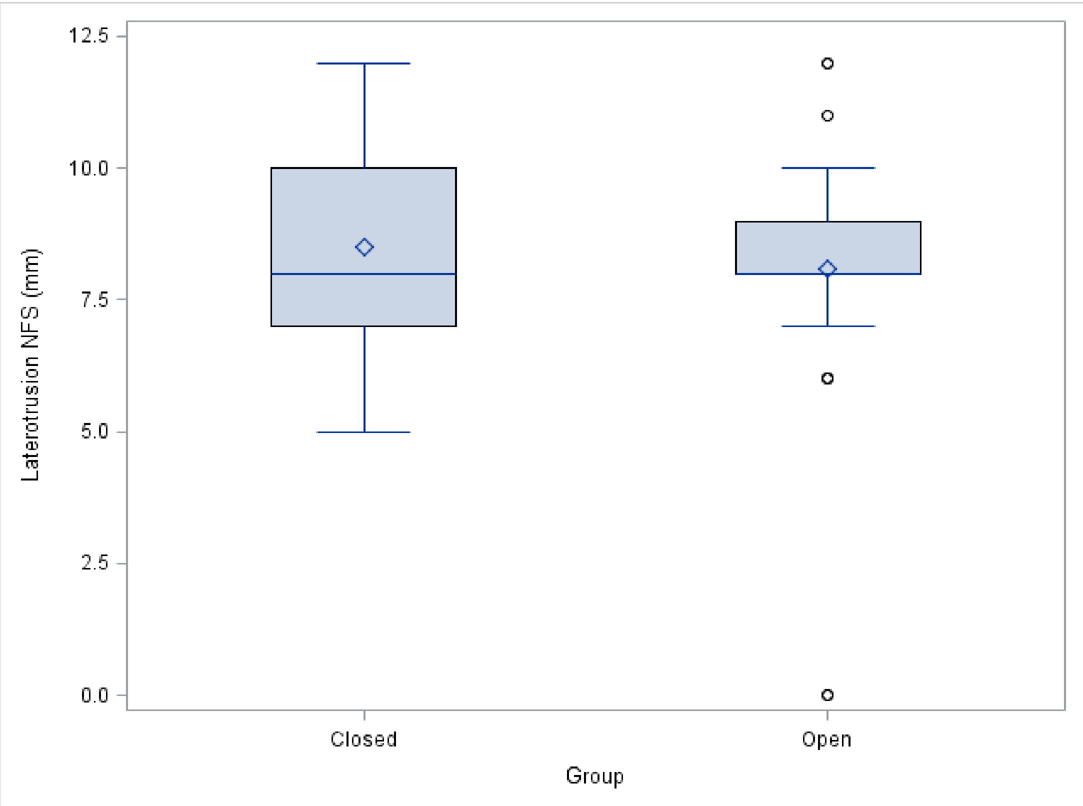

Figure 3.17 Box-and-whisker plot of laterotrusion NFS measurements of open and closed treatment groups at 12 months.

The results of the General linear model for laterotrusion NFS are shown in Table 3.12.

Table 3.12 Results of GLM for laterotrusion at 12 months.

Source	DF	Type III SS	MS	F	P-value
Group	1	0.01	0.01	0.00	0.96
Grade	1	3.42	3.42	1.09	0.30
Group*Grade	1	0.93	0.93	0.30	0.59
Laterality (Uni-or Bi-lateral)	1	42.84	42.84	13.65	0.0004*
Displacement	1	9.64	9.64	3.07	0.083
RHL	1	0.52	0.52	0.17	0.69
Angle of displacement	1	1.01	1.01	0.32	0.57
Delay in treatment	1	0.00	0.00	0.00	0.98

*p<0.05

These results indicate the following, after controlling for all the other variables in the model:

- The treatment group did not have a significant effect on this outcome, either alone (p = 0.96) or as an interaction with injury grade (p = 0.59).
- The angle of displacement was not significantly associated with this outcome (p = 0.57).
- Laterality (Unilateral or Bilateral) had a significant effect on this outcome (p = 0.0004). The estimated Least-Squares (LS) mean for this outcome for the unilateral group was 7.5 ± 1.2 mm, compared to 4.7 ± 1.9 mm for the bilateral group.
- Displacement, RHL, and delay in treatment were not significantly associated with this outcome.

3.3.3.2. Deviation

The median deviation at week 52 was 2.0 mm (IQR 1-3) for the closed group and 1mm (IQR 0-1) for the open treatment group (Table 3.13).

Table 3.13 Presentation of deviation in the two groups at 52 weeks.

Analysis Variable, Deviation (mm)	Closed (n=68)	Open (n=48)
Median	2	1
IQR	1-3	0-1
Minimum	0	0
Maximum	5	3
Mean	2	0.8
Standard deviation	1.5	0.8

Table 3.14 Results of GLM for deviations at 12 months.

Source	DF	Type III SS	MS	F	P-value
Group	1	37.12	37.12	26.75	<0.0001*
Grade	1	0.01	0.01	0.01	0.92
Group*Type of fracture	1	12.82	12.82	9.24	0.003*
Unilateral/Bilateral	1	2.67	2.67	1.92	0.17
Displacement	1	1.36	1.36	0.98	0.32
RHL	1	0.21	0.21	0.15	0.70
Angle of displacement	1	3.50	3.50	2.52	0.12
Delay in treatment	1	0.42	0.42	0.30	0.58

*p<0.05

The results of the GLM for deviations at 12 months are shown in Table 3.14 and indicate the following, after controlling for all the other variables in the model:

- The treatment group did have a significant effect on this outcome, both alone ($p < 0.0001$) and as an interaction with injury grade ($p = 0.0030$). *Post-hoc* tests showed that there was no significant difference in mean deviation between fracture types for the open group, but that (a) the mean deviation for both fracture types (Type II and Type III) for the closed group were significantly higher than those for the open group, and (b) for the closed group, the mean deviation was significantly higher for Type III injuries compared with Type II B injuries (Fig. 3.19).
- The angle of displacement was not significantly associated with this outcome ($p = 0.12$).
- Likewise, laterality, displacement, RHL, and delay in treatment were not significantly associated with this outcome.

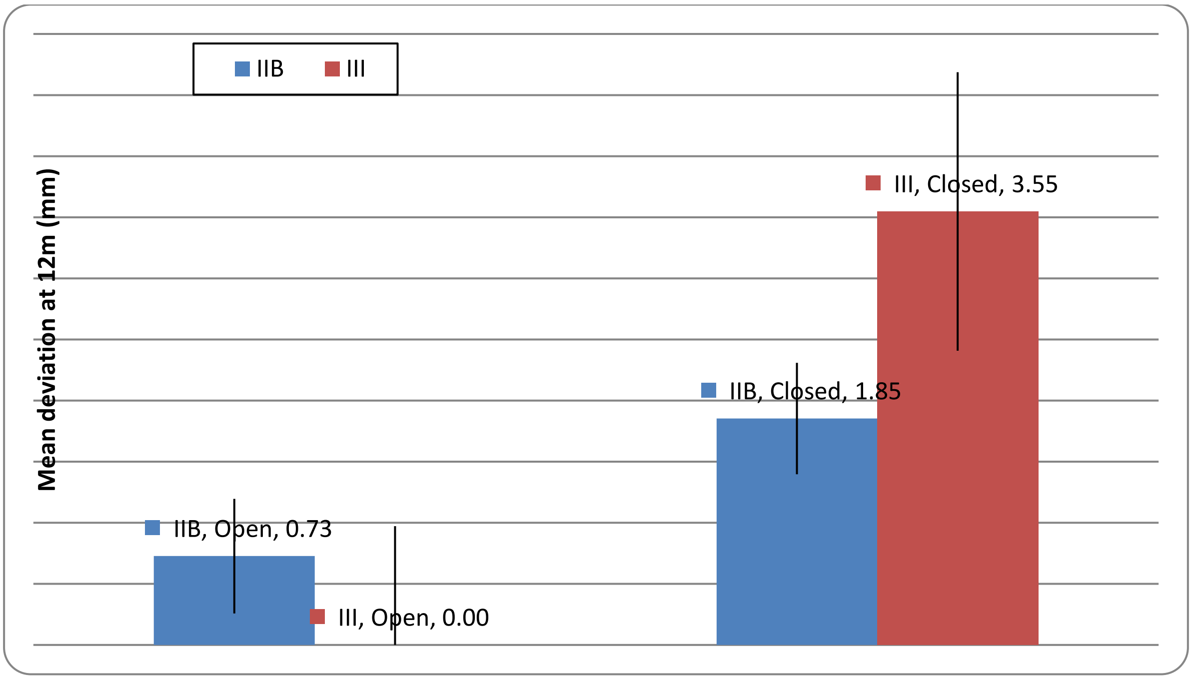

Figure 3.18 Estimated LS-mean deviation for each combination of treatment group and type of fracture (error bars denote the 95% confidence interval for the mean).

3.3.4. Pain (VAS)

Median pain scores decreased from 4 (IQR 3-4) at 6 weeks to 0 (IQR 0-0) at 52 weeks and 6 (IQR 5-6) at 6 weeks to 0 (IQR 0-0) at 52 weeks in the closed and open groups respectively. There were only 3 patients with a non-zero pain score at 12 months (Table 3.15 and Fig. 3.20), thus as a result, this outcome was not analysed.

Table 3.15 Presentation of median pain scores at weeks 0 to 52.

Pain (VAS) (m)								
	Week	**N**	**Mean**	**SD**	**Median**	**IQR**	**Minimum**	**Maximum**
Closed	0	0						
	6	68	3.8	1.2	4	3-4	2	7
	12	68	1.5	1.1	1	1-2	0	4
	26	68	0.2	1.1	0	0	0	9
	52	68	0	0	0	0	0	0
Open	0	0						
	6	48	5.5	1.1	6	5-6	3	8
	12	48	2.4	1.4	2	2-4	0	5
	26	48	0.4	0.7	0	1	0	3
	52	48	0.1	0	0	0	0	2

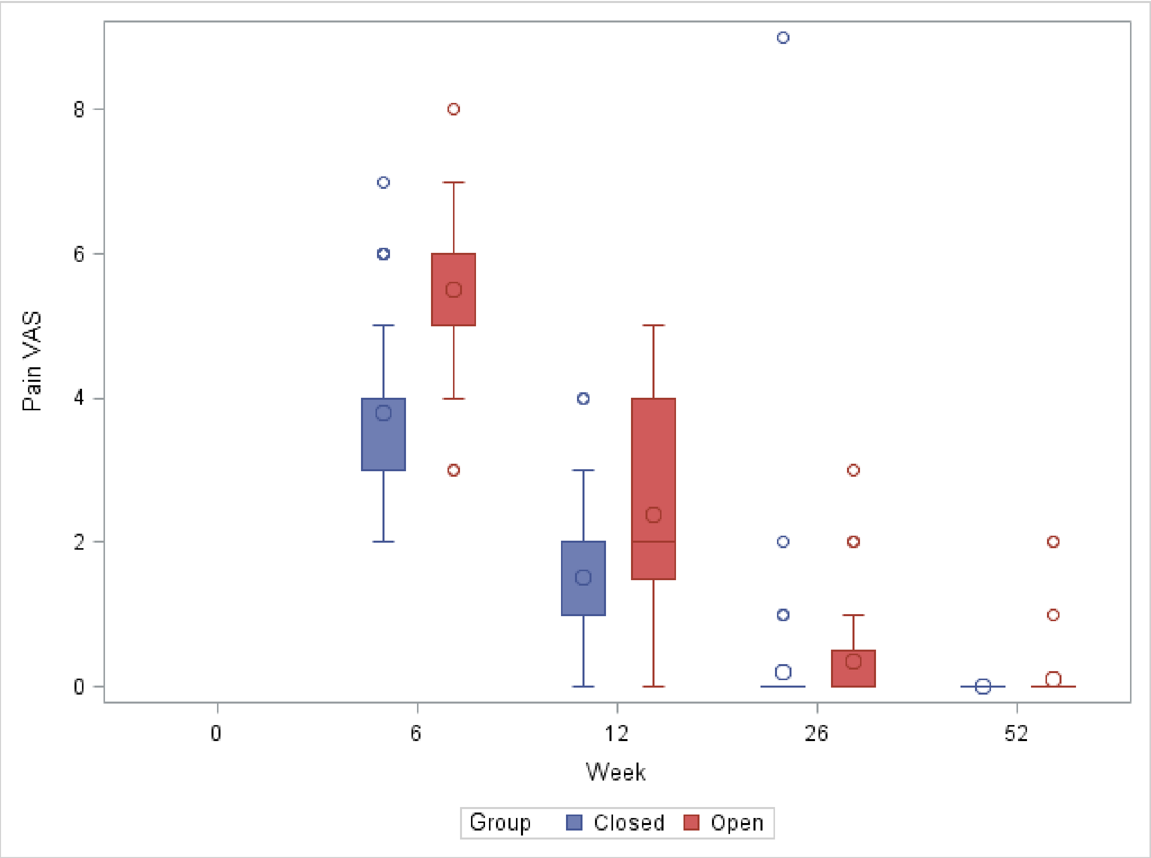

Figure 3.19 Box-and-whisker plot of median pain scores (VAS) of open and closed treatment groups (from 6 to 52 weeks).

3.3.5. TMJ dysfunction

The three TMJ dysfunction outcome groups were so small that they had to be grouped for analysis. There were two outcome groups in this category: None (n=95) and TMJ dysfunction (n=21). Of the 21 patients, 9 had palpable clicks (7 closed, 2 open group); 9 patients were evidently clicking (4 closed group, 5 open) and 3 patients had locking and luxation (all 3 from the closed group). Eighteen of the 21 patients had Type II B fractures and 3 had Type III fractures.

The smallest outcome group (n=21) allowed the estimation of two parameters at most. The whole model (which required the estimation of 8 parameters) could thus not be fitted. Instead, the effect of group and each of the other independent variables were considered in turn. The results of the logistic regression are shown in Table 3.16

Table 3.16 Results of logistic regression of TMJ function at 12 months.

	Wald Chi-square	p-value
Group	0.78	0.38
Grade	0.22	0.64
Group	0.85	0.36
Laterality	2.01	0.16
Group	0.85	0.36
Displacement	0.74	0.39
Group	1.47	0.22
VHL	2.48	0.12
Group	1.27	0.26
Angle of displacement	1.95	0.16
Group	0.78	0.38
Delay in treatment	0.03	0.87

These results showed the following:

- Treatment group did not have a significant effect on this outcome, controlling for any of the other independent variables.
- None of the independent variables were significantly associated with this outcome, controlling for the treatment group.

3.3.6. Dysfunction Index

There are two outcome groups: Grade 0 (n=57) and Grade 1 (n=59). Of the 59 patients, 43 were from the closed group and 13 from the open group. The smallest outcome group (n=57) thus only allows the estimation of five parameters at most. Table 3.17 shows the results of the logistic regression.

Table 3.17 Results of dysfunction index at 12 months.

Effect	Wald Chi-square	p-value
Group	19.67	<0.0001*
Grade	2.54	0.11
Laterality	0.55	0.46
RHL	1.4	0.24
Delay in treatment	1.04	0.31

*****p<0.05

This reveals that treatment group had a significant effect on this outcome (p<0.0001), controlling for all the other variables in the model. None of the other remaining variables in the model were significantly associated with the outcome.

The odds ratios (ORs) for TMJ Grade 1 *versus* Grade 0 are shown in Table 3.18.

Table 3.18 Odds ratio for presence of complication.

Variable	Odds Ratio for presence of complication		
	Estimate	95% Confidence Limits	
Group: Open *vs* Closed	0.12	0.05	0.30
Grade: III vs IIB	6.87	0.64	73.44
Laterality: Bilateral *vs* Unilateral	1.68	0.43	6.54
RHL	1.10	0.94	1.28
Delay in treatment	1.08	0.94	1.24

These results are interpreted as follows:

- The odds of a TMJ Grade 1 outcome were significantly lower in the open group compared with the closed group (OR 0.12; 95% CI 0.05-0.30), controlling for all the other variables in the model.

3.3.7 Complications at 12 months

Of the 116 patients, 52 had complications ranging from deviation to keloid. The majority of the complications were in the closed group (44 patients), and only 8 patients in the open group had complications (see Table 3.19).

Table 3.19 Results of complications in the two groups at 12 months.

Variable		Closed (n=68)		Open (n=48)	
		n	**%**	**n**	**%**
Complication at 12m	None	24	35.3	40	83.3
	One or more	44	64.7	8	16.7
Complication at 12m (if any)	AOB	4	9.1	1	12.5
	Crossbite	2	4.5		
	Malocclusion	8	18.2		
	Deviation<2mm	14	31.8		
	Deviation 2.1-5mm	18	40.9	2	25
	Hypertrophic scar			2	25
	Keloid			3	37.5

The following complications were noted in the closed group:

- Anterior open bites: 4 patients (all had bilateral Type II B and or Type III fractures)
- Cross-bite: 2 patients with posterior cross-bites (both of them with no previous history of cross-bites)
- Malocclusion: 8 patients
- Deviation (less than 2 mm): 14 patients
- Deviation: (2.1-5 mm):18 patients

In the open group, the following complications were observed at 12 months:

- Deviation: 2 patients
- Transient facial palsy: 9 patients
- Parotid fistula: 4 patients
- Hypertrophic scar: 2 patients
- Keloid: 3 patients (Fig. 3.21)

- Anterior open bite: 1 patient (had plate dehiscence in the symphyseal region with subsequent removal of the miniplates and replacement with a reconstruction plate following debridement)

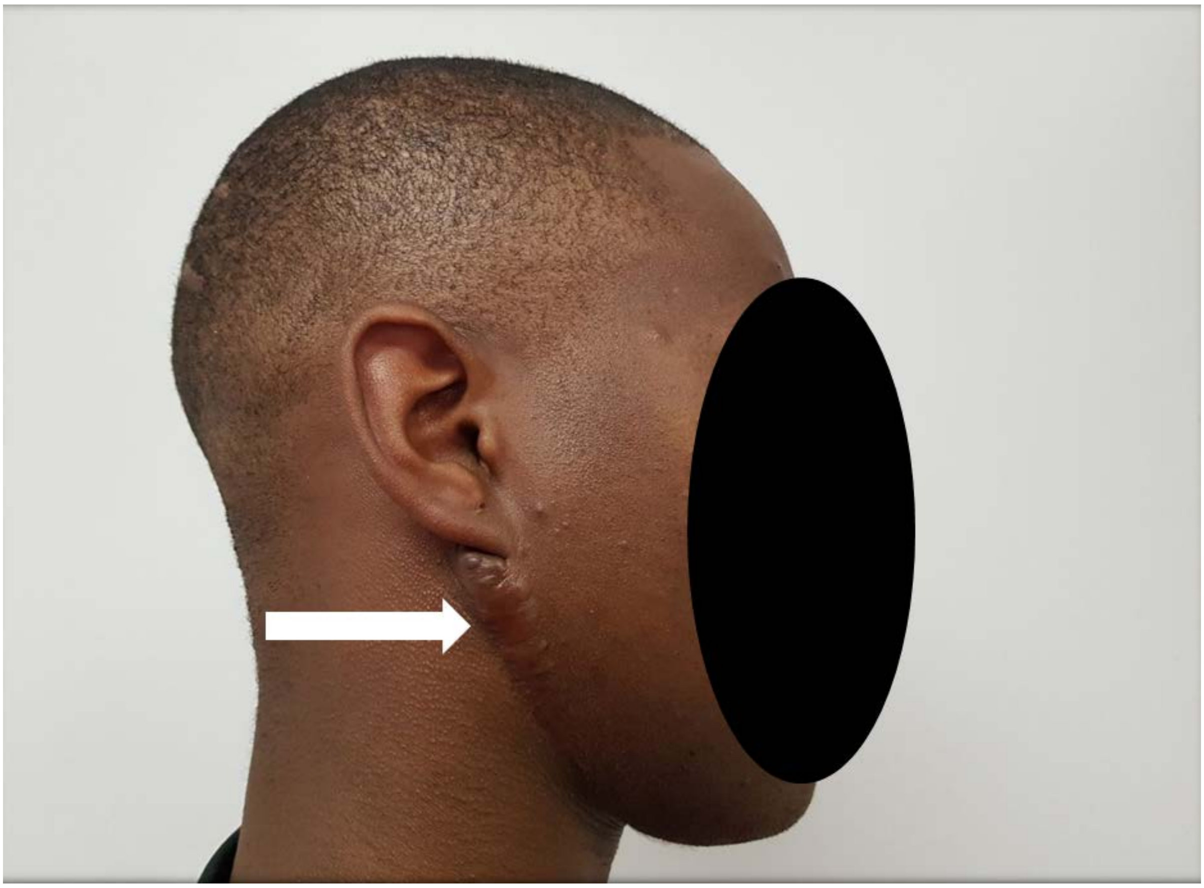

Figure 3.20 Keloid in the right retromandibular region (white arrow).

The facial nerve palsies (9 patients) and parotid fistulae (4 patients) observed in the open cases all resolved within 6-8 weeks post-surgery. The results of the logistic regression for complications are shown in Table 3.20.

Table 3.20 Results of logistic regression of complications

Effect	DF	Wald Chi-square	p-value
Group	1	26.58	<.0001*
Unilateral/Bilateral	1	1.52	0.22
RHL	1	3.82	0.051
Angle of displacement	1	1.29	0.26
Delay in treatment	1	1.99	0.16

*p<0.05

The results revealed the following:

- Treatment group had a significant effect on this outcome (p<0.0001), controlling for all the other variables in the model.
- None of the other remaining variables in the model were significantly associated with the outcome.

The odds ratios (ORs) for the presence of complications at 12 months are shown in Table 3.21 and are interpreted as follows:

- The odds of complications were significantly lower in the open group compared with the closed group (OR 0.05; 95% CI 0.02-0.16), controlling for all the other variables in the model.

Table 3.21 ORs for the presence of complications in open and closed groups.

Variable	Odds Ratio for presence of complications		
	Estimate	95% Confidence Limits	
Group: Open *vs* Closed	0.05	0.02	0.16
Laterality: Bilateral *vs* Unilateral	2.41	0.59	9.78
RHL	1.18	1.00	1.39
Angle of displacement	1.02	0.99	1.04
Delay in treatment	1.12	0.96	1.30

3.3.7.1 Assessment of the effect of type of fracture, RHL, time delay, displacement, angle of displacement, unilateral/bilateral fractures on the absence/presence of complications

Each of the possible factors contributing to complications was assessed on its own. Given the small group size of the complications in the open treatment group (n=8), this allowed an estimate of only one parameter in the logistic regression.

<u>ORIF group</u>

None of the independent variables were significantly associated with the presence/ absence of complications in this treatment group. The effect of type of fracture could not be determined statistically since all 3 cases with Type III fractures had no complications; likewise, the effect of displacement could not be determined statistically since all 9 medially displaced fracture cases had no complications.

<u>Closed treatment group</u>

RHL ($p = 0.013$) and angle of displacement ($p = 0.0084$) were significantly associated with the presence/ absence of complications in this treatment group (Table 3.22). The results of the analysis reveal that the odds of complications increased by 1.26 for every 1 mm increase in RHL (Table 3.23). Figure 3.22 shows a plot of the predicted probability of complications as a function of RHL. The probability of complications exceeds 80% at RHL greater or equal to 10-11 mm.

Table 3.22 Relationship between RHL, angle of displacement and complications.

Effect	DF	Wald Chi-square	p-value
Type of fracture	1	not estimable: all Grade III cases had complications (n=5)	
Uni/Bilateral	1	1.98	0.16
Displacement	1	1.29	0.26
RHL	1	6.18	0.01*
Angle of displacement	1	6.96	0.01*
Delay in treatment	1	2.98	0.09

Table 3.23 Odds ratio for presence of complications.

Variable	Odds Ratio for presence of complication		
	Estimate	95% Confidence Limits	
VHL	1.26	1.05	1.51
Angle of displacement	1.12	1.03	1.22

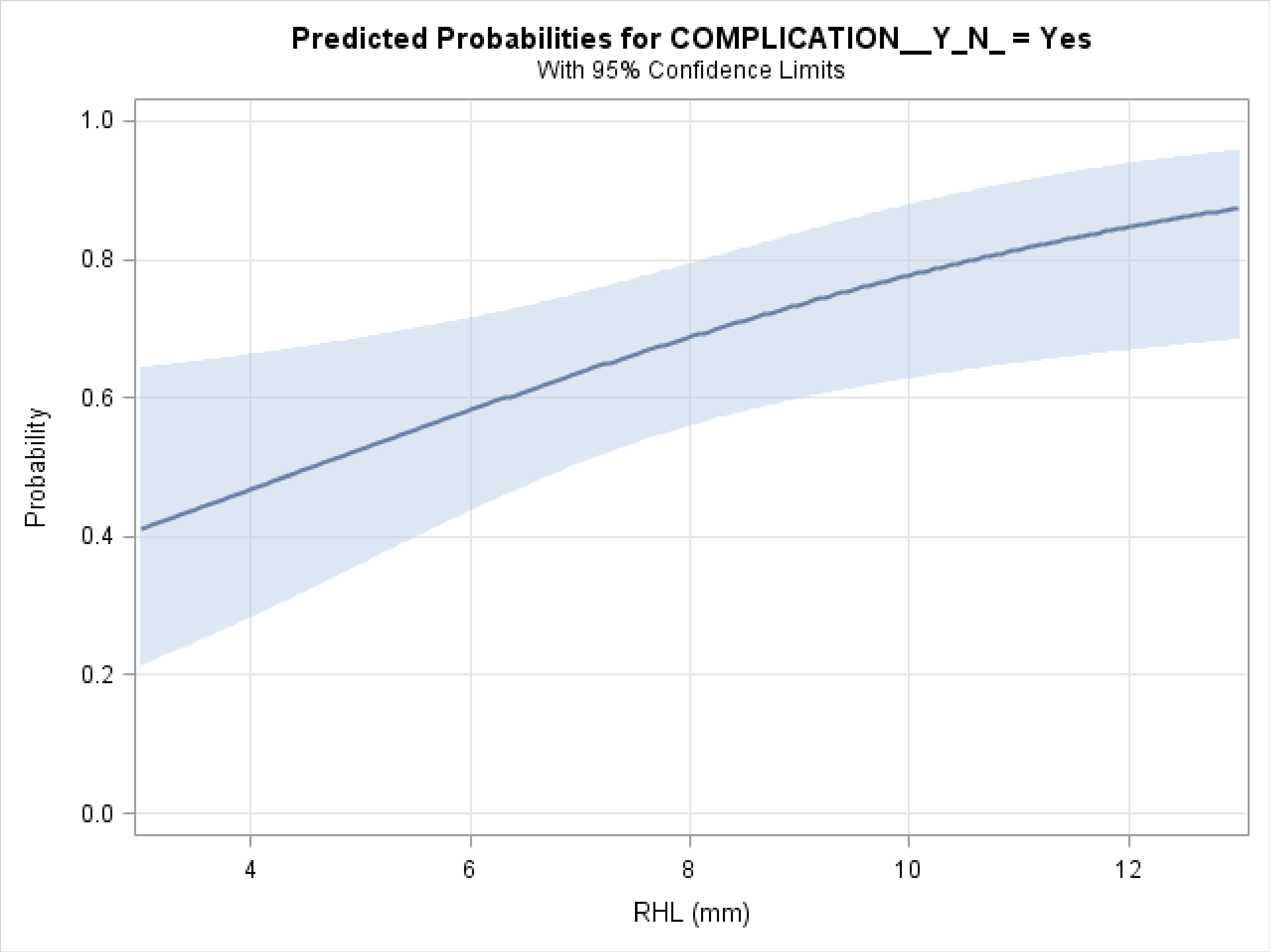

Figure 3.21 Predicted probability of complications as a function of RHL.

Combining RHL and angle of displacement in one model left only the angle of displacement as a significant contributor to complications. The odds of complications in this treatment group increase with increasing angle of displacement (OR 1.12 per degree; 95% CI 1.03-1.22) (Table 3.22). Figure 3.22 shows a plot of the predicted probability of complications as a function of angle of displacement. The probability of complications exceeds 80% at angle of displacement greater or equal to 15 degrees.

The effect of type of fracture could not be determined statistically since all 5 cases with Type III fractures had complications.

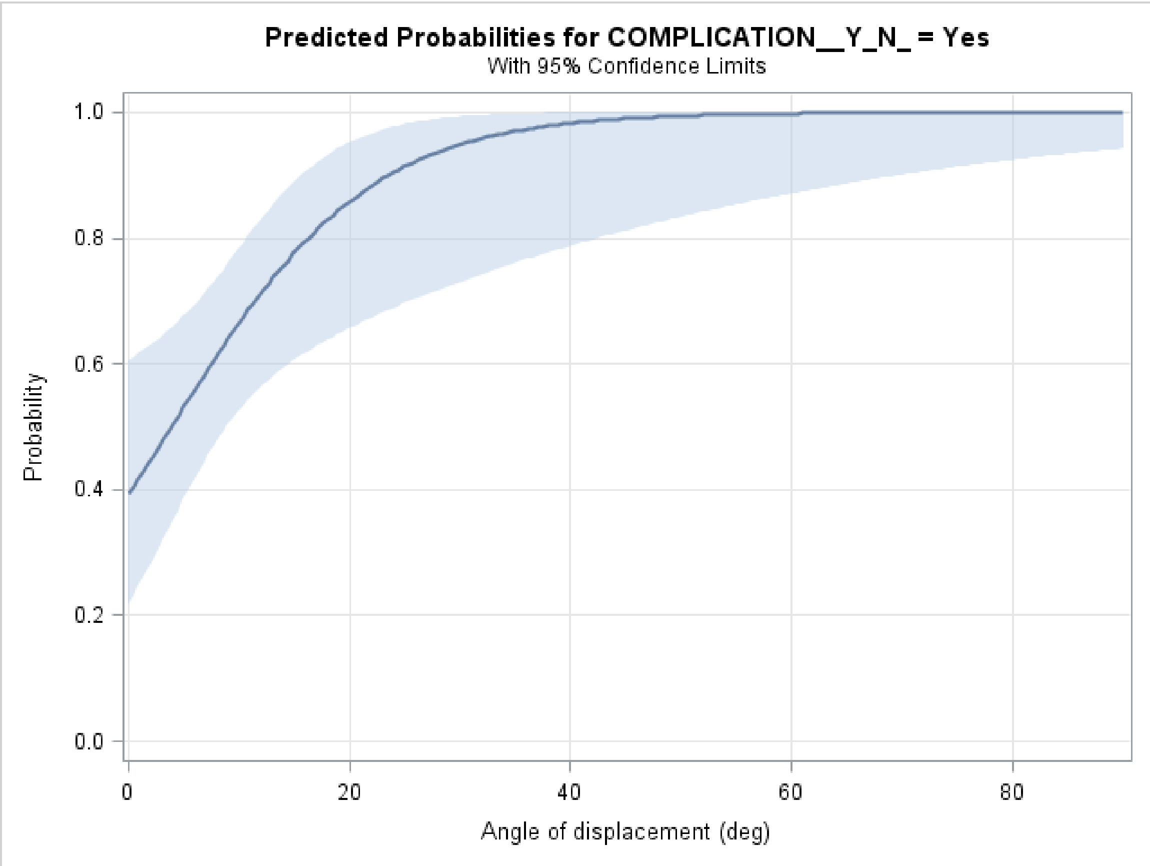

Figure 3.22 Predicted probability of complications as a function of angle of displacement.

CHAPTER FOUR: DISCUSSION

Several aetiological factors result in condylar fractures, and although there are global variations, interpersonal violence features prominently (Larsen and Nielsen, 1976; Fridrick *et al*., 1992; Silvennoinen *et al*., 1994), followed by road traffic accidents and falls. Ellis *et al.,* (1985), Silvennoinen *et al.*, 1992, and Mitchell (1997) have found that violence and assaults are the most common causes of condylar fractures. This is similar to our findings in that two-thirds of the fractures were related to violence and assaults (65.5%), followed by motor vehicle accidents and falls (14.6% and 13.7% respectively). Only two patients (2%) out of the 116 patients sustained condylar fractures due to sports injuries. The percentage (65.5%) of condylar fractures caused by assaults or interpersonal violence in this study is, however, much higher than that reported by Ellis *et al.,* (1985) *at* 54.7% and Silvennoinen *et al.,* (1992) at 44%. This highlights the unfortunately high prevalence of interpersonal violence in this country. In contrast, Fridrick *et al., (1992);* Marker *et al.,* (2000); Danda *et al.,* (2010) and Singh *et al* (2010), have shown in their studies that road traffic accidents predominated in the cause of mandibular condylar fractures, followed by assaults and falls. Larsen and Nielsen (1976), Bastian (1989), and Merlet *et al*., (2017) found that falls were the most common causes.

The trends with regard to gender and age of patients with mandibular condylar fractures were similar to those reported in previous studies (Ellis *et al.,* 1985*;* Silvennoinen *et al., 1992;* Marker *et al.,* 2000; Danda *et al.*, 2010). Of the total sample in this study, 91% were males and 9% were females. The mean age of occurrence was 33.1 years. Studies have also found that the highest frequency of condylar fractures occur among patients aged 20-40 years (Larsen & Nielsen, 1976; Bradley, 1985; McGuirt and Salisbury, 1987 Larsen, 1992).

This study has demonstrated once again that one of the greatest difficulties in research of maxillofacial injuries is the high failure rate of patients requested to attend follow-up. Of the 154 patients, 38 failed to return for the requisite 12-month follow-up. This lack of patient compliance has been noted in previous studies (Brook and Wood, 1983; Marciani *et al*., 1990). The known correlation between facial injuries and unemployment (Shepherd et al., 1986) and alcohol consumption (Hutchison *et al*., 1998); may have a strong bearing on the difficulty of follow-up. The large number of patients in this study with no employment is again consistent with the association of facial injuries and social deprivation (Smith, 1982).

More dislocated (6 of the 8 dislocated fractures) condylar fractures were associated with road traffic accidents (RTA) and falls. These findings suggest that a relationship exist between the type of fracture (and the degree of displacement) and the cause of the fracture. Marker *et al.,* (2000) have also that causes that involved transfer of considerable forces to the bone (RTA and falls) are more likely to result in dislocations and bilateral fractures. On the contrary, causes that involved less force (assaults) caused considerably more subcondylar fractures and were less likely to result in dislocations. In a study by Oikarinen and Malmstrom (1969) subcondylar fractures were most commonly due to assault or interpersonal violence. Similarly, Silvennoinen *et al.,* (1992) found that dislocated fractures were more frequently observed in falls and RTA than in assaults. Greater forces (RTA and falls) were more likely to result in bilateral fractures, dislocated fractures and fractures higher in the condylar process (head and neck) than those due to lesser forces (assaults), which were more likely to result in unilateral and more subcondylar fractures.

There were 15 patients (13%) with isolated MCFs in this study; the remaining 101 patients had associated mandibular fractures. This suggests that isolated condylar fractures are not very common and that most mandibular condylar fractures occur with concomitant mandibular fractures. This is understandable as condylar fractures result not from direct force to the condyles themselves but as a result of forces acting primarily on the mandibular body and symphyseal regions. The most commonly associated mandibular fractures in this study were symphyseal and parasymphyseal fractures (75), followed by body (21) and angle (7) fractures respectively. Other studies have also found a high incidence of associated mandibular fractures (mostly in the symphysis and body regions) with MCFs (Silvennoinen *et al*., 1992; Chen *et al*., 2011)

Silvennoinen *et al.,* (1992*)* also concluded that condylar fractures were more often severe when isolated than when associated with other mandibular fractures. Their explanation was that in the latter group the force is absorbed by the horizontal part of the mandible on fracture, thus saving the condylar region from high impact.

The average maximum inter-incisal opening (MIO) for both open and closed groups from 12 weeks onwards was greater than the 35 mm defined as the functional cut-off point for limitation of MIO according to Dijkstra's definition (Dijkstra *et al.*, 2006). Treatment group did not have a significant effect on mouth opening, either alone ($p = 0.84$) or as an interaction with type of fracture ($p = 0.73$). Similar results were described in other studies (Hidding *et al.*, 1992; Konstantinovic and Dimitrijevic, 1992; Worsaae and Thorn, 1994; Haug and Assael, 2001; Danda *et al.*, 2010). Our results indicate that MIO increased from 39.4 mm (at 12 weeks) to 44.7 mm (52 weeks) in the closed group; and from 34.9 mm (12 weeks) to 46.0 mm (52 weeks) in the open group. The initial lower MIO for the ORIF patients could be explained by postoperative pain, muscle stripping and possibly scarring associated with the surgery itself. The findings in this study also corroborate the findings by Joos and Kleinheinz (1998) that even though there is a decrease in MIO post intermaxillary fixation release in patients treated closed, if intensive functional treatment (physiotherapy) is followed after the IMF release, mouth opening will gradually increase. Palmieri *et al.,* (1999) have also shown that early restriction in mandibular mobility resolves after 6 weeks, but that post fracture physiotherapy plays an important role. This underscores the fact that the key to successful rehabilitation after condylar fracture treatment is early mobilisation and active jaw movement with strict follow-up. Physiotherapy should thus be seen not as an afterthought but as an integral part of condylar fracture management and must be continued for a period of at least three months.

Schneider *et al.,* (2008) have cautioned that MIO must be considered a less sensitive parameter than other jaw movements because a higher rotational component may compensate for a deficit in the translational movement of the condyle in the glenoid fossa. However, mouth opening is not a passive process. Even if the initial movement in mouth opening is pure rotation effected by the suprahyoid muscles, the second gliding movement is effected by the inferior head of the lateral pterygoid muscles on both the meniscus and condyle as they translate anteriorly beneath the articular eminence. Any compensation by the suprahyoid muscles would be unable to produce meaningful translation movement of the condyle.

This study has found that the mean protrusion for the closed group at 12, 26 and 52 weeks was 6.3 mm (SD 1.7), 7.3 mm (SD 1.9) and 8.0 mm (SD 2.0) respectively. For the open group, the mean protrusions (mm) at 12, 26 and 52 weeks were 5.7 mm (SD 1.1), 7.2 mm (SD 1.2) and 7.8 mm (SD 1.4) respectively. Treatment group did not have a significant effect on this outcome, either alone (p = 0.56) or as an interaction with injury grade (p = 0.38), controlling for all the other variables in the model. Danda *et al.,* (2010) also found (average follow-up 21.5 months) no statistically significant difference for protrusion between closed and open treatment groups (mean of 6.9mm and 7.3mm for closed and open groups respectively). Similar findings were reported by Hidding *et al.*, (1992); Konstatinovic *et al.*, (1992); Worsaae and Thorn, (1994); Haug and Assael, (2001); and Shiju *et al.,* (2015).

Contrary to the findings in this study, Singh *et al.,* (2010*)* found that after 6 months, the average range of protrusion of 4.13 mm for the closed group was significantly less (p = 0.00) when compared with 5.94 mm for the surgically treated groups. Similar results were also reported by Schneider *et al.,* (2008) in their 6 month review. It thus appears that better protrusive movements can be expected with longer follow-up.

In this study it was found that after 12 months, movement towards the FS appeared to be better in the closed group (mean 10.5 mm) than in the open group (mean 9.9 mm). This was statistically significant (p = 0.038). The angle of displacement (p = 0.033) and unilateral fractures were significantly associated with this outcome. It appears that pain and scarring associated with ORIF may result in initial limitation of movement in the open group. This, however, subsequently improved with time.

At 12 months, the mean laterotrusive movement towards the NFS was 8 mm for the closed group and 8.1 mm for the open group. This was not statistically significant ($p = 0.96$). Danda *et al.,* (2010) also found no statistically significant differences for mean lateral excursive movements between their group I (closed) and group II (open). They however found that the mean lateral excursive movements on both the fractured and non-fractured site for the open group (8 mm and 8 mm respectively) were slightly higher than those for the closed group (6.5 mm and 7.5 mm respectively). Rastogi *et al.,* (2015) and Shiju *et al.,* (2015) also found no significant differences of movement of jaws towards the ipsilateral and contralateral sides in their 6-month review of isolated unilateral MCFs.

Contrary to the findings in this study, Singh *et al.,* (2010) found statistically significant differences for mouth opening, protrusion and laterotrusive movements in their comparative study between open and closed treatment groups in patients with unilateral mandibular subcondylar fractures. Worsaae and Thorn (1994) also showed that laterotrusive movement towards the non-fractured side, when compared with laterotrusive movement towards the fractured side, was only significantly reduced ($p = 0.05$) for non-surgically treated patients. Silvennoinen *et al.,* (1998) also reported restricted lateral retrusive movement towards the NFS than towards fractured site during function. Deviation and restriction of laterotrusive movements towards the NFS are caused by the limited translational movement of a fractured TMJ.

Schneider *et al.*, (2008) using the sum total of both sides' laterotrusive movements, found that the difference between closed and open was statistically different, in that operative treatment statistically obtained better efficacy in lateral excursive movements.

The differences in the laterotrusive movements, whether statistically significant or not, do not impair function on these patients, and overall the clinical results remain acceptable in both groups.

This study was unable to show any association between TMJ dysfunction (internal joint derangement) and treatment group. In addition, none of the other independent variables (RHL, angle of displacement, delay in treatment etc.) were significantly associated with TMJ dysfunction (controlling for treatment outcome). Of the 21 patients with TMJ dysfunction, those with unilateral fractures had clicking or locking on both fractured and non-fractured TMJs. In these cases, it would have been interesting to assess any damage to structures such as the disk and capsule with an MRI. Magnetic resonance imaging however is not part of this institution's condylar fracture management protocol. However, the presence of clicking or locking on both fractured and non-fractured TMJs in unilateral fractures is similar to previous findings by Lundberg *et al*., (1972*)*, Lindahl *et al*., (1977), and Silvennoinen *et al.*, 1998. Unlike Silvennoinen *et al.*, (1998), who reported that clicking was often present in association with dislocated fractures, this study found no correlation between the type of fracture and the presence of TMJ dysfunction. Lundberg *et al*., (1972) also reported more tenderness on palpation in the main masticatory muscles on the fractured side than on the non-fractured side. It is thought that this may result from anatomical changes in the working directions of the muscles, because of shortening of the ramus and dislocation of the condyle. Raustia *et al.,* (1990) showed a decrease in the size of especially the lateral pterygoid muscle after condylar fractures.

In the present study, 59 patients (46 closed, 13 open) had a mild TMJ dysfunction index (Grade I). The difference between the two treatment groups was statistically significant ($p \leq 0.0001$). The odds of a TMJ Grade I outcome was significantly lower in the open compared with the closed group (OR 0.12; 95% CI 0.05-0.30).

The 38 patients who failed to return for the requisite 12 months follow-up in this study have demonstrated once again that one of the greatest difficulties in research of maxillofacial injuries is the high failure rate of patients requested to attend follow-up. This lack of patient compliance has been noted in previous studies (Brook and Wood, 1983; Marciani *et al.,* 1990). The known correlation between facial injuries and unemployment and alcohol consumption may have a strong bearing on the difficulty of follow-up (Shepherd *et al*., 1986).

4.1 Complications

The overall complication rate in this study, which ranged from deviations to keloid formation, was 45% (52 patients of the 116). Of these, 44 (38%) were in the closed group and 8 (7%) were in the open group. The treatment group thus had a significant effect on the presence or absence of complications ($p < 0.0001$). The odds of complications were significantly lower in the open group than in the closed group (OR 0.05; 95% CI 0.02-0.16).

This study corroborates previously reported studies that closed techniques have significantly greater percentages of malocclusion (Yasuhara et al., 1990; Worsaae & Thorn, 1994; Ellis *et al*., 2000; Smets *et al.*, 2003; Rastogi et al., 2015). Only one patient (2%) had a malocclusion in the open treatment group. In the closed group, our results showed 21% with malocclusion. Shiju *et al.,* (2015) also found that malocclusion was greater in the closed treatment group in contrast with the ORIF group, which was statistically significant. Unlike Ellis *et al.,* (2000) who used photographs to assess occlusion in their retrospective study, we assessed occlusion clinically and also by asking patients whether the current occlusion corresponded to pre-trauma occlusion. Quantification of malocclusion was however not considered. Contrary to the findings in this study, Danda *et al.,* (2010) found no significant difference in the occlusal status between open and closed techniques, as did Takenoshita *et al*., (1990); Santler *et al*., (1999); Haug and Assael (2001); and Singh *et al.,* (2010). .

Thirty-two of the 68 patients (47%) in the closed group had deviations on mouth opening at the 12 month review (14 patients deviation less than 2 mm; 18 patients deviation of 2.1 mm to 5 mm) compared with 2 patients (4%) in the open group. This was statistically significant both alone ($p < 0.0001$) and as an interaction with the type of fracture ($p = 0.0030$). The mean deviations for Type II and Type III fractures for the closed group were significantly higher than those for the open group. For the closed group, the mean deviation was significantly higher for Type III injuries compared with Type IIB injuries. This is a sign of compensatory movements by the lateral pterygoid muscles on the contralateral joints due to shortening of the ramus height on the ipsilateral side, resulting in deviation of the chin towards the affected side. This was particularly seen in patients with marked reduction in ramal height and in patients with Type III fractures. This finding is in line with previously reported studies (Silvennoinen *et al*., 1992; Smets *et al*., 2003; Singh *et al*., 2010; Rastogi *et al*., 2015; Shiju *et al*., 2015;). Eckelt *et al*., (2006) also reported in their multicentre study that 20 of 30 patients (66%) in the closed treatment group had deviations (the average deflection from the midline was 3.1 mm (range 1–7 mm). In contrast, a deflection was observed in only 7 cases (10%) with an average of 2.6 mm (range 1–7 mm) in the open group. The difference was significant between the two groups ($p = 0.03$).

Facial nerve injury, resulting in temporary or permanent paralysis of the muscles of facial expression, is one of the most worrying complications of ORIF of MCFs. The prevalence of facial nerve injury following ORIF of MCFs ranges from 1% to 48% (Hall *et al*., 1985 and Downie *et al*., 2009; Yang and Patil, 2012). The reported injuries to the facial nerve are fortunately mostly temporary, and most cases resolve by 3-6 months after surgery. A meta-analysis study by Al-Moraissi *et al.,* (2018) concluded that the risk of permanent facial nerve injury is low for all surgical approaches to the condyle: 2.2% incidence for the low submandibular approach, 0.3% for the pre-auricular and 1.4% for the retromandibular transparotid approaches respectively.

In this study, transient facial nerve weakness occurred in 9 patients (19%) in the open group, with the frontal being the most commonly affected branch. This on average resolved 2-3 months postoperatively. This is in accord with the findings of Ellis *et al.,* (2000) who described an incidence of 17.2% facial nerve weakness at 6 weeks postoperatively but 0% at 6 months. Neff *et al.,* (2001) and Scholz *et al.,* (2005) showed in their clinical studies that the risk of permanent damage to the facial nerve is so slight that it cannot be used as a reason to refuse open treatment of mandibular condylar fractures. The risk of facial nerve injury varies from case to case: prolonged traction on the operative site, experience of the surgeon, post-injury oedema, type of injury, surgical approach and other factors causing difficult wound access, such as obesity, might increase the risk of nerve injury (Rastogi *et al.,* 2015; Shiju *et al*., 2015; Al-Moraissi *et al*., 2018). Contrary to our findings, Worsaae and Thorn (1994), Shiju *et al.,* (2015*)* and Rastogi *et al.,* (2015) found no damage to the facial nerve in their patients.

Extra-oral approaches to the condyle such as the retromandibular access employed in this study are inevitably associated with visible scars as 10% of the patients (2 hypertrophic scars and 3 keloids) in the open group developed scars (all Black Africans). The 3 patients with keloids were referred to the plastic surgeons for local excision of the keloids and subsequent triamcinolone injections but the keloids recurred. Hypertrophic scars and keloids that develop following skin damage represent the ends of a spectrum of healing by scarring (Ahuja *et al*., 2015). Structurally and biochemically, hypertrophic scars have more type III collagen compared with keloid scars, which contain a higher type I: type III collagen ratio. Skin pigmentation is one of the major risk factors for development of keloids. Keloids are observed in people of all races, except albinos. People with dark skin are more susceptible to keloid formation, with reported incidence of 6-16% in African populations (Niessen *et al*., 1999). It is thought that there is increased sensitivity to melanocyte stimulating hormone (MSH), which leads to a 20 fold increase in the likelihood of keloid formation. Keloid forming tendency is also increased in puberty and pregnancy (also because of increased MSH activity) (Niessen *et al*., 1999; Ahuja *et* *al*., 2015). Preoperative consent information in these susceptible groups should thus also include counselling about the potential risk of keloid formation.

Four patients (8%) developed a transient salivary fistula, which resolved within weeks after application of pressure dressings and prescription of antisialagogues such as atropine. Vesnaver *et al* (2012) reported that 3 patients (7%) also had a transient fistula postoperatively. Ellis *et al.,* (2000) found 3 patients with a transient parotid fistula and Shiju *et al.,* (2015) reported one patient with a fistula. The retromandibular approach used in these reports, including the approach used in this study, transects the parotid capsule, which if not repaired adequately can lead to parotid fistula formation. The layer that contains the parotid capsule should thus be routinely closed very tightly by using running horizontal vicryl sutures.

The endoscopic-assisted (EA) transoral approach is a fast-growing, minimally invasive surgical procedure that has been reported to improve the sequelae of ORIF regarding the incisions and visible scars. It is reported to leave no facial scars, and to have a minimal risk of injury to the facial nerve (Troulis and Kaban 2001; Schön *et al*, 2003). Apart from decreased morbidity, the EA transoral approach allows for faster recovery times when compared to conventional extra-oral approaches. A study by Nogami *et al*., (2012) compared the retromandibular and endoscopic approaches and reported that both showed good results in fracture reduction, while facial nerve palsy was observed in 47% of the retromandibular group. Studies by Lee *et al*., (1998); Lee *et al*., (2001); Schön *et al*., (2002) and Miloro, (2003) revealed that the risk of facial nerve injury with EA ORIF ranges from 0-22% but that all resolved within the period of follow-up. The facial nerve palsy resulting from most traditional extra-oral approaches ranges from 7.5-30% (Ellis *et al*., 2000; Haug and Assael, 2001; Manisali *et al*., 2003) but as demonstrated in the present study with the retromandibular approach, this is also transient and patients rapidly return to preoperative function. It is not possible therefore to promote this as one of the major advantages of EA surgery over the traditional approach (Haug and Assael, 2001).

Endoscopic-assisted ORIF patients can be left with some scars when using transcutaneous trocars, such as in cases where a submandibular stab incision is used. These scars have been reported as invisible or acceptable (though not confirmed by blinded investigators) by the protagonists of EA ORIF (Lee *et al.,*1998*;* Lee *et al.,* 2000; Miloro *et al.,* 2003; and Schön *et al.,* 2003*).* Thus, although EA ORIF of MCFs has been touted as a superior and better substitute for traditional extra-oral approaches to the condyle, it is not without complications and disadvantages. The technique is technically very challenging and has a steep learning curve (Kellman, 2003). The average operating time has been reported to range from 45–408 minutes (Lee *et al.,* 1998*;* Lee *et al.,* 2000*;* Miloro *et al.,* 2003; Schön *et al.,* 2003) when compared to the traditional approach which has been reported as having an average operating time of 40-120 minutes (Hyde *et al*., 2002). In addition to the inordinate amount of time spent in theatre are the start-up costs for the initial outlay for endoscopic equipment (Haug and Brandt, 2004).

Seeman *et al.,* (2011) (who used postoperative panoramic X-rays to predict factors which may increase the risk of osteosynthesis failure) observed osteosynthesis failure in the condylar region in 12% - 17% of their patients. The best predictor of osteosynthesis failure was based on the ramus height. In cases of reduced or normal ramal height after plating, the odds of osteosynthesis failure were significantly reduced by a factor of 10. An increased ramal height after plating of the condyle had a 7.8 fold higher risk of osteosynthesis failure than a normal or decreased ramus height. Their explanation for lower failure rates in reduced ramal heights after plating was the reduced chewing force in those cases. Also, there was a significantly higher risk of osteosynthesis failure when no other mandibular fracture existed, presumably because postoperative morbidity is low and patients do not follow a soft diet regimen (Seemann *et al*., 2010 and 2011). They also found that higher osteosynthesis failure was observed in the single miniplate group than the two miniplates. No plate fracture was recorded in the present study: possible explanations include the two miniplates were used along physiologic tension lines and the fact that very few patients with isolated MCFs were treated by open reduction and internal fixation. The ORIF patients were also placed under guidance elastics immediately post-operatively for a period of 4 weeks, which helped in restricting immediate resumption of a normal diet.

Temporomandibular joint dysfunction (e.g. internal derangement) and condylar degeneration are other potential complications which have been reported in the literature (Ellis, 1998). Unfortunately, these conditions are also very prevalent in the general population, so it is difficult to relate them to condylar fractures.

4.2 Mandibular condylar system and management protocol for MCFs

Based on this study, the following appear to be risk factors for the development of complications when MCFs are treated by closed treatment:

1. Bilateral fractures: of the 16 patients with bilateral fractures (Type IIB and Type III), 9 were treated with closed treatment. Four of the 9 patients had anterior open bites at 12 months. This illustrates that bilateral fractures have increased risk of complications when treated closed. Baker *et al.,* (1998), Schneider *et al.,* (2008), and Danda *et al*., (2010) all reported that ORIF should always be considered in bilateral fractures because of their poor prognosis when treated with closed treatment.
2. Ramus height loss: RHL ($p = 0.013$) was significantly associated with the presence of complications in the closed treatment group. The odds of complications increased by 1.26 for every 1 mm increase in height. The probability of complications exceeds 0.5 (50%) at vertical height loss greater than approximately 5 mm. Silvennoinen *et al.,* (1998) also found that reduction in ramal height (mean 8.8 mm) seemed critical in relation to the persistence of a malocclusion. Smets *et al.,* (2003) also concluded that for patients with RHL of 8 mm or more, it is fair to consider ORIF to prevent poor outcomes associated with closed treatment. Other authors have recommended that shortening of the ascending ramus (≥ 2mm) should be treated by ORIF, irrespective of the level of the fracture (Schneider *et al*., 2008). Whilst it is accepted that RHL has an impact on treatment outcome, results from this study would imply that a 2 mm RHL on its own is too low a threshold to guide treatment of MCFs.
3. Type of fracture: Treatment of nondisplaced or displaced fractures with no RHL (Type I and Type II A fractures respectively) is not a subject of major controversy. These are managed non-surgically in our institution. This explains the exclusion of both Type I and Type II a fractures from the study as their

inclusion would not have added any meaningful contribution or value to the debate at hand.

4. Of the remaining fracture types, the highest number of complications was seen in Type III fractures managed by closed treatment. This study corroborates studies which have reported that non-surgical treatment for Type III (dislocated fractures) yields suboptimal outcomes (Silvennoinen *et al*., 1994; Worsaae and Thorn, 2008; Singh *et al*., 2010; Shiju *et al*., (2015)).
5. Angle of displacement: angle of displacement ($p = 0.0084$) was significantly associated with the presence of complications in the closed treatment group. The odds of complications in this treatment group increased with increasing angle of displacement (OR 1.12 per degree; 95% CI 1.03-1.22). The probability of complications as a function of angle of displacement exceeds 80% at an angle of displacement >15 degrees. Others have reported that MCFs with an angle of displacement of ≥45 degrees must be treated by ORIF. Schneider *et al.,* (2008), however, concluded that fractures with deviations of 10-45 degrees should be treated by ORIF.

Together with the age of the fracture, the aforementioned risk factors form the basis for a Mandibular Condyle Scoring system (Table 4.1). In this system, points ranging from 0-3 are allocated for the four significant parameters: fracture type, angle of displacement, age of the fracture and vertical height loss. The addition yields an individual score for each patient. Based on the different score values, a recommendation for therapy is made. The final score will serve as a guide to whether the MCF can be treated closed or open. The lowest score is a 3 and the highest score that can be obtained is 12. The total points are calculated out of 12, and the scoring system is interpreted as outlined in Table 4.2. In patients with a score greater than 9, closed treatment will often yield suboptimal results, and therefore open reduction and internal fixation of the fractured mandibular condyle is recommended.

Table 4.1 Mandibular Condyle Scoring (MCS) system.

	POINTS			
	0	1	2	3
Fracture Type		**I, II A, IV**	**II B**	**III**
Ramus Height Loss	**0mm**	**1-3mm**	**4-7mm**	**≥ 8mm**
Age of Fracture		**24-48 hours**	**1 week**	**1-2 weeks**
Angle of Displacement		**0-15**	**15-30**	**>30**

This scoring system will aid surgeons in the process of determining treatment for mandibular condylar fractures. It uses readily available preoperative data to establish a score that immediately influences the therapeutic option.

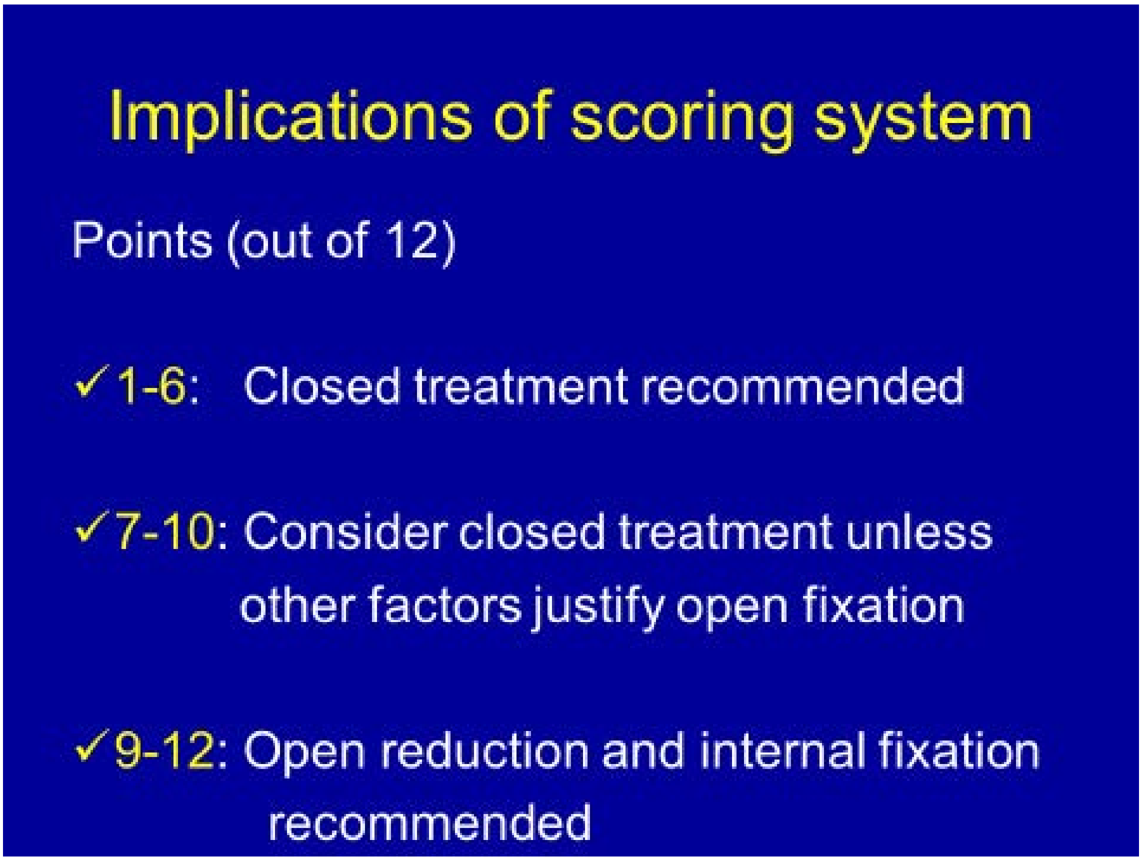

Figure 4.1 Interpretation of scoring system.

Three additional points need to be appended to the proposed treatment guide:

a) because of the poor outcomes associated with displaced, bilateral MCFs with vertical height loss, ORIF of at least one side must be considered in order to re-establish ramus vertical height.

b) non-surgical treatment is generally the treatment of choice in children

c) ORIF of the intracapsular/condylar head is not advocated. ORIF increases the risk of avascular necrosis, osseous and fibrous ankylosis in these types of fractures (Haug and Assael, 2001). It is also very difficult to locate, reduce and fix this small segment without stripping it from the lateral pterygoid muscle and destroying the condylar cartilage.

CHAPTER FIVE: CONCLUSION

5.1. Summary

The study has shown that blunt trauma due to inter-personal violence is overwhelmingly responsible for condylar fractures in this institution, with males (914%) being in the majority by far. Only 15 patients (13%) had isolated mandibular condylar fractures. The most commonly associated mandibular fractures were seen in the symphyseal and parasymphyseal regions. Bilateral MCFs were seen in 16 patients (14%). More bilateral fractures and dislocated fractures (Type III) were associated with falls and road traffic accidents.

A new classification of mandibular condylar fractures, *the* ***Wits Classification system*** of MCFs is presented, based on two main factors which influence the type of therapy required for MCFs: **the *position of the condylar head relative to the glenoid fossa* and the *status of the ramus vertical height*.**

This study, one of the largest single-centre prospective studies, evaluated and compared treatment outcomes of MCFs treated by ORIF and those treated by closed treatment. The influence of the fracture type, angle of displacement, unilateral or bilateral fractures, condylar head position in the glenoid fossa and the ramus height loss on the treatment outcomes were also assessed. After a follow-up of 12 months, no significant differences were observed between the two groups for mouth opening, protrusion, pain, TMJ function and laterotrusive movements to the non-fractured side. Laterotrusive movements towards the fractured side in unilateral cases were, however, better in the closed group than in the open group.

More complications (malocclusions and deviations in particular) were seen in the closed treatment group than in the ORIF group. The odds of complications were significantly lower in the open group than in the closed group. Ramus height loss, bilateral fractures, Type of fracture (II B and III) and angle of displacement were significant risk factors for development of complications in the closed group. These factors formed the basis of the design of the mandibular condyle scoring (MCS) system. This scoring system has been developed to help identify patients who may benefit from selective open reduction and internal fixation of fractured mandibular condyles. The MCS system uses readily available preoperative data to establish a score that will guide therapeutic options. Based on this study, patients with an MCS of 9 and above should be considered for surgical treatment. Irrespective of the treatment regimen employed, active physiotherapy and follow-up are imperative for successful rehabilitation of patients with MCFs.

The proposed classification and MCS system may act as a framework to improve the management of condylar fractures. It is envisaged that they will result in the development of contemporary meaningful condylar fracture treatment decisions and the elimination of haphazard application of treatment protocols.

The results of this study show that by following this new, simpler and manageable classification and its associated MCS scoring system, treatment guidelines and outcomes may be improved when compared with previously suggested classifications.

Factors such as the patient’s age, medical and dental history, dental status, the severity of the injury, associated injuries and behavioural patterns should of course also be taken into consideration in the decision-making process of how MCFs should be treated. Each fracture must be assessed individually in relation to the patient as a whole prior to executing a therapeutic regimen that is most likely to produce a favourable outcome.

5.2. Limitations

The limitations of this study were as follows:

1. Inclusion of patients with associated mandibular fractures, in particular those with bilateral MCFs. Patients with bilateral MCFs treated by closed treatment are said to be more likely to develop asymmetry, malocclusion and an open bite (Ellis *et al*., 2000). Treatment outcomes of unilateral fractures have been reported to be significantly better than those of bilateral MCFs in terms of objective and subjective criteria (Schneider *et al*., 2008; Talwar *et al*., 1998). Bilateral MCF is thus a predictive factor for a poor outcome and a confounding factor for the outcomes. Of the 16 patients with bilateral fractures (Type IIB and Type III), 9 were treated with closed treatment. Four of the 9 patients had anterior open bites at 12 months. The number of patients with bilateral MCFs was, however, small in this study.
2. It is also believed that a second fracture elsewhere in the mandible can confound the results because fixation requirements for a double fracture are different from those for an isolated fracture (Ellis, 2013; Al-Moraissi and Ellis, 2015). Isolated MCFs are uncommon. Only 15 patients in this study had isolated MCFs. Most mandibular condylar fractures occur with concomitant mandibular fractures because condylar fractures result not from direct force to

the condyles themselves but are a result of forces acting primarily on the mandibular body and symphyseal regions.

3. Quantification of malocclusion: in this study one patient (2%) had a malocclusion in the open treatment group. In the closed group, the results showed 14 patients (21%) with malocclusions. The appraisal of posttraumatic malocclusion is compromised by the mostly unknown pre-traumatic state (Eulert *et al*., 2007). Nevertheless, attempts should have been made to quantify the malocclusion using preoperative and postoperative study models. This opportunity to quantify malocclusion using study models is limited to sporadic situations and could possibly not have been practical for all patients in this situation.
4. Short follow-up period and smaller sample size: the follow-up period in this study was 12 months. A longer follow-up would have added value to this study. Further RCTs comparing closed and open treatment of isolated MCFs with larger sample sizes and longer follow-up periods are necessary to answer some of the controversies surrounding management of MCFs in adult patients. It has been pointed out (Chrcanovic, 2015) that it is also hard to define what would be considered an adequate follow-up period for the evaluation of post-treatment outcome, complications in particular. The unintended consequence of much longer follow-up periods is attrition in the patient sample, resulting in loss of crucial data and subsequent weakening of the study.
5. Disproportionate distribution between closed and open treatment patients. The majority of the 38 patients who did not return for the requisite 12 month follow-up were treated by ORIF, potentially resulting in the creation of a bias in the study. This resulted in many patients in the closed group (68 patients) and fewer

patients in the ORIF group (48), constituting a weakness in the study. Future studies with similar distribution of patients between the two groups are necessary to further substantiate and give statistical support to the present trends. However, lack of compliance regarding follow-up is a very well-known inherent problem in maxillofacial traumatology studies.

6. Another shortfall of the study was the lack of blinding regarding data collection, data analysis or the intervention received. Blinding by any person unrelated to the management of the patients would have elevated the credence and scientific value of this study.

Notwithstanding its limitations, this study has provided viable recommendations that form the basis for optimum treatment of MCFs.

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ANNEXURE A: PATIENT INFORMATION SHEET

Good Day

My name is Dr Ephraim Rikhotso and I am a Specialist in the Department of Maxillo-Facial and Oral Surgery at Chris Hani Baragwanath Hospital.

Following clinical and radiographic (X-ray) examination, you have been diagnosed with a fracture of the lower jaw. In the past the treatment of these fractures has not produced good results. In order to improve the treatment, I have formulated a new arrangement of care which uses existing treatment methods in a very standard way.

I am undertaking a study to assess treatment results of these lower jaw fractures using the new treatment methods. I would like to use information from your clinical records and the routine X-rays and shall be very grateful for your permission to do this. A code number, not your name, will be used in the study so no one can identify you. Whether you allow me to do this or not it will not affect your treatment which will is the standard treatment given to all patients presenting in our unit with fractures of the lower jaw.

In order to obtain meaningful information it will be most helpful if you can return for check-up appointments to monitor your progress. I would like to see you at 1 week, 6 weeks, 3, 6 and 12 months following treatment. These check-up appointments are routine procedures for all patients irrespective of whether you are part of the study or not.

Participation in this study is voluntary and should you not wish to be involved it will not affect your treatment in any way. Furthermore, you are free to withdraw at any time during the study if you so wish, also without compromising your treatment. You will be repaid for reasonable travel costs when you return for the check-up appointments. Money for this payment will be donated by Selective Surgical (Walter Lorenz). If you are willing to participate in the study outlined above please sign the outlined consent.

Thank you

DR E RIKHOTSO

DIVISION OF MAXILLOFACIAL & ORAL SURGERY, WITS UNIVERSITY

CHRIS HANI BARAGWANATH HOSPITAL

(Contact cell no: 0834695839)

ANNEXURE B: CONSENT FORM

I............................ .... have been fully informed of the requirements of a study to determine treatment outcomes of lower jaw fractures. I understand that participation in this study is voluntary and that I can withdraw at any time during the study if I so wish.
I also understand that I have to come back for check-up appointments from a period ranging from one week to twelve months after treatment.

It has also been explained to me that I will not be paid to participate in the study but that my transport costs will be repaid adequately.

Patient's Signature---Witness------------------------------

Investigator's Signature---Date----------------

ANNEXURE C: CONDYLAR FRACTURE MANAGEMENT AUDIT FORM

Patient Information:

Name: ____ Hosp no: ______________

Contact no:____________________________________ Age: ______ Gender: M / F

Date of Injury: _______________ Mode of Injury: _____________

Date of Presentation: ____ Intoxicated YES/ NO

Clinical Examination:

Maximum mouth opening: _______________

Deviation:	Right
	Left
Occlusion at maximum closure:	Intact
	Deranged

Associated Injuries: ____

Radiographic Examination:

X-ray:____ CT:--------------------------------

TYPE	RIGHT	LEFT
I		
IIA		
IIB		
III		
IV		

Ramus Height Loss

	1-3 mm	4-7 mm	>8mm
Right			
Left			

Fracture displacement *(Coronal)*

	Mild (0-15^0)	**Moderate** (15 – 30^0)	**Severe** (>30^0)
Right			
Left			

Management:

Date of Surgery: ________________

Condyle:	Conservative	Right	Left
	Close Reduction	Right	Left
		MMF period:	Weeks
	Open Reduction	Right	Left
		MMF period:	Weeks

Associated injuries: ____

Follow-Up:

	MMO			OCCLUSION		
	(<25mm)	**(25-35mm)**	**(>35mm)**	**Good**	**Poor**	**Undecided**
1 Week						
6 Weeks						
3 Months						
6 Months						
12 Months						

	DEVIATION			PAIN	
	(<2mm)	**(2-5mm)**	**(>5mm)**	**TMJ**	**Muscle**
1 Week					
6 Weeks					
3 Months					
6 Months					
12 Months					

	PROTRUSION		LATEROTRUSION	
	(<6mm)	**(>6mm)**	**(<8mm)**	**(>8mm)**
1 Week				
6 Weeks				
3 Months				
6 Months				
12 Months				

	TMJ DYSFUNCTION			FACIAL SYMMETRY	
	No impairment	**Clicking**	**Clicking & locking**	**Normal**	**Deranged**
1 Week					
6 Weeks					
3 Months					
6 Months					
12 Months					

	TMJ DYSFUNCTION INDEX			
	Grade 0	**Grade 1**	**Grade 2**	**Grade 3**
6 Months				
12 Months				