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ALLOPLASTIC TOTAL TEMPOROMANDIBULAR JOINT RECONSTRUCTION: A 10 YEAR WITS EXPERIENCE

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0303663M

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master in Dentistry (MDent) in the branch of Maxillo-Facial and Oral Surgery

Johannesburg, March 2019

DECLARATION

I, Dr Mmathabo Gloria Sekhoto, declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Dentistry in the branch of Maxillo-Facial and Oral Surgery, at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



_____ (Signature of candidate)

on the ____11th_____day of____March_____2019

in __Parktown, Johannesburg_____

DEDICATION

In memory of my late parents,

Mmatsietsi Jane Sekhoto

1949 – 2001

and

Mpati Abraham Sekhoto

1943 – 2000

ABSTRACT

Introduction: The anatomical structure and function of the temporomandibular joint (TMJ) can be altered by trauma, pathology, degenerative or inflammatory processes resulting in end-stage TMJ diseases which necessitates TMJ reconstruction. The reconstruction (autogenous or alloplastic) aims to restore the anatomy, altered joint mechanics and to improve the quality of life. Innumerable studies have reported on the results of TMJ reconstruction with costochondral graft (CCG). There is however paucity of studies that have reported on the outcome of alloplastic TMJ reconstruction.

Aim: This study aimed to report on the objective outcomes (maximum mouth opening distance and occlusion), subjective outcomes (pain, diet consistency and chewing, quality of life) and complications after alloplastic total TMJ reconstruction.

Methodology: This was a retrospective cross-sectional study in which 31 patients who had alloplastic total TMJ prosthesis implanted at the Wits Oral Health Centre (between 2007 and 2017) were reviewed. Inclusion criteria was any patients who had total prosthetic TMJ joint placement with a minimum of 6 months post-operative follow-up. Patients who failed to return for follow-up, had less than 6 months follow-up period and with missing records were excluded from the study. Pre-operative and post-operative findings were analysed statistically.

Results: There were 16 females and 15 males with a mean age of 36.94 years (range 11 – 72 years). Patients had a mean follow-up period of 58.8 months (range 6 – 122 months). In total, 51 prostheses (20 bilateral, 11 unilateral) were implanted. The stock prostheses were used in 28 patients (90.32%) and only 3 (9.68%) were of custom-made type. Fifty eight percent of patients were diagnosed with temporomandibular joint ankylosis, 22.58% had degenerative conditions, 9.68% had pathology and 9.68% had malocclusion.

The results showed that there was improvement in maximum mouth opening distance (MMO) (P-value <0.0001) which showed trends of improving significantly at 3 months after surgery but decreased approximately 12 months post-operatively before it could stabilize, particularly in patients who had ankylosis. There was reduction in pain reported (P-value <0.0001) and improvement in diet consistency (P-value <0.0001) and quality of life (QoL) (P-value 0.013). Post-operative complications ranged from facial nerve injuries (N= 4), keloids (N= 2) and heterotopic bone formation (N= 2). One out of 4 patients who had nerve

injury had permanent paralysis of the temporal branch of facial nerve while the other 3 patients resolved completely in 3 to 6 months.

Conclusion:

TMJ alloplasts provide satisfactory clinical and functional outcomes for patients with end-stage TMJ diseases, evidenced by overall improvement in MMO, chewing ability and quality of life. An aggressive physiotherapy regimen is however imperative for successful rehabilitation and maintenance of the improved MMO, especially in TMJ ankylosis patients. An association exists between previous TMJ surgery and occurrence of complications post-implantation of total alloplastic joints.

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LIST OF ABBREVIATIONS:

CCG	– costochondral graft
CHBAH	– Chris Hani Baragwanath Academic Hospital
IVI	– intravenous injection
MMO	– maximum mouth opening distance
QoL	– quality of life
TMJ	– temporomandibular joint
TMD	– temporomandibular joint disorder
TMJ-A	– temporomandibular joint ankylosis
TMJ-R	– temporomandibular joint reconstruction
UHMWPE	– ultra-high molecular weight polyethylene
WOHC	– Wits Oral Health Centre

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CHAPTER ONE

1.1 INTRODUCTION

1.1.1. Temporomandibular joint anatomy

Temporomandibular joint (TMJ) is a ginglymoarthodial joint (from *ginglymus* and *arthrodia* denoting a hinging and sliding movement respectively) (Alomar *et al*., 2007). It is a bilateral synovial joint formed by the following (Fig. 1.1):

1) the glenoid fossa of the squamous part of the temporal bone and articular eminence superiorly,

2) the mandibular condyle inferiorly,

3) an articular disc and

4) a capsule & accessory ligaments.

The articular surfaces of the joint and the inner aspect of the capsule are lined by the synovial membrane which secretes synovial fluid. The synovial fluid maintains the joint well lubricated, thus preventing adhesions within the joint and friction during function (Fonseca *et al*., 2017). It also bathes the joint and assists in the delivery of nutrient and removal of waste products (Sinno *et al*., 2010).

The glenoid fossa is a concavity within the squamous part of the temporal bone that houses the mandibular condylar head. It extends anteriorly as an articular eminence which is a transverse, dense, convex shaped bone that forms an anterior articular lip and the posterior root of the zygomatic arch. The posterior articular lip is formed by the postglenoid process of temporal bone which separates the articular fossa from the tympanic part of the temporal bone. The articular eminence and the postglenoid process together with the capsule and accessory ligaments prevent the anterior, posterior and lateral dislocation of the mandibular condyle (Alomar *et al*., 2007; Fonseca *et al*., 2017).

The mandibular condyle consists of an ovoid head seated on a narrow neck which flares towards the mandibular ramus. It has a convex articulating surface. The condylar head is approximately 15 to 20 mm mediolaterally and 8 to 10 mm anteroposteriorly. It has a shorter lateral pole which extends slightly beyond the outer surface of the ramus and an elongated, broad medial pole which seats deep within the glenoid fossa (Alomar *et al*., 2007; Fonseca *et al*., 2017). Each pole has a rough tubercle which provides attachments to lateral and medial

collateral ligaments. The articular surface of the condyle is covered by thick fibroelastic tissue layer (David *et al*., 2016).

The glenoid fossa and the mandibular condyle are separated by an articular disc which divides the joint into the superior and inferior compartments. The disc is a biconcave, avascular, fibrocartilaginous structure that is divided into 3 parts i.e. anterior band, central intermediate band and posterior band. The anterior and posterior bands run in transverse direction and fuse anteriorly to lateral pterygoid muscle and to the joint capsule, while the intermediate band runs in an anteroposterior direction and is not medially and laterally attached to the capsule. The posterior band continues as a bilaminar zone which is a thick double layered connective tissue with profuse blood and nerve supply (Fonseca *et al*., 2017). It has been suggested that the main function of the disc is to absorb the loading forces acting on the joint.

The joint capsule is a thin fibroelastic tissue that encloses the joint and extends from cranial articular surface to the neck of the condyle (Fonseca *et al*., 2017). The capsule, together with the extracapsular ligaments stabilizes the joint and prevents dislocation of the condyle. The main extracapsular ligaments (the lateral temporomandibular and sphenomandibular ligaments) are supported by an accessory stylomandibular ligament (Alomar *et al*., 2007). TMJ plays an essential function in mastication, speech, airway support and deglutition (Mercuri, 2012; Giannakopoulos *et al*., 2009).

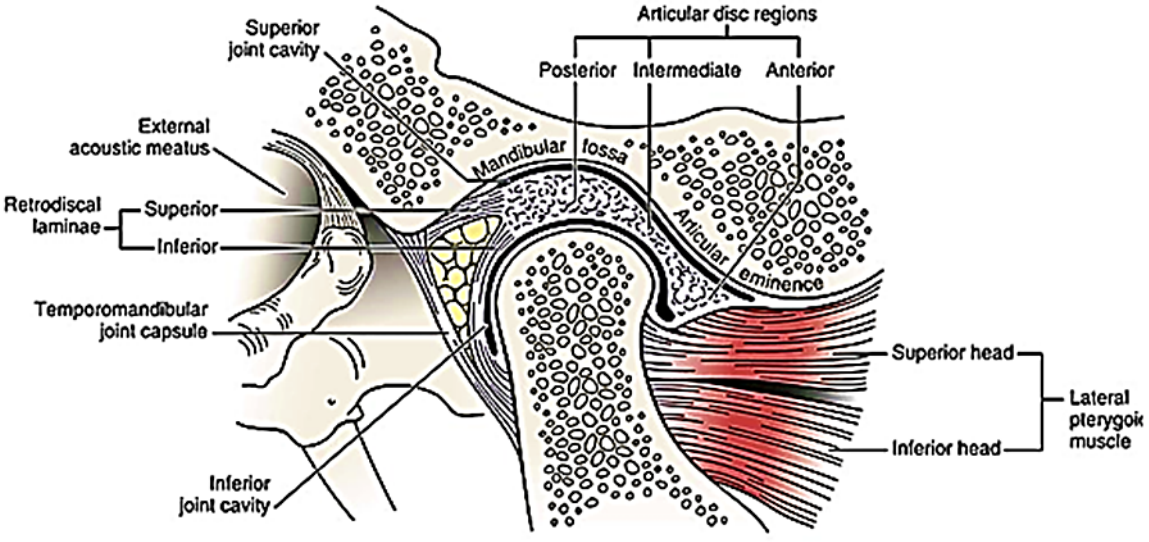


Figure 1.1 Temporomandibular joint structure
(https://clinicalgate.com/temporomandibular-joint)

TMJ has a very intricate & complex biomechanics. Its function is a combination of coordinated action of muscles of mastication, ligaments, articular bony surfaces, articular disc and the teeth (Alomar *et al*., 2007; David *et al*., 2016).

The movement of TMJ is 3-dimentional and occurs by simultaneous rotation and translation actions. The rotational movement occurs within the inferior joint compartment and can either be in horizontal direction to initiate mouth opening up to 20 mm/ hinging or in a vertical and sagittal axis to perform lateral excursion movements. The movement is effected by rotation of the condylar head within the fossa, along the rotation axis. Both these movements are facilitated by lateral pterygoid muscle. The translation or gliding movement occurs in the superior joint compartment and involves the movement of the condyle and the articular disc out of the fossa, down the articular eminence. This facilitates the forward movement of the mandible (protrusion) and also opening of the mandible beyond 20 mm. The suprahyoid muscles work together with lateral pterygoid muscle to effect translation movement and depression of the mandible. The mandibular elevation or jaw closing is facilitated by contraction of temporalis, masseter and medial pterygoid muscles ((Fonseca *et al*., 2017, Villamil *et al*., 2012)

The anatomical structure and function of the joint can be altered by traumatic, degenerative and inflammatory processes as seen in temporomandibular joint disorders, ankylosis and pathology.

1.1.2 Temporomandibular joint disorders (TMD)

Temporomandibular joint disorders (TMD) are a multifactorial group of pathologies that affect the TMJ. TMD involves TMJ, muscles of mastication, or both; and is broadly divided into articular (intracapsular) and non-articular (muscular) conditions (De Rossi *et al*, 2014; Guarda-Nardini *et al.*, 2008; Manfredini *et al*., 2011). Articular disorders are further classified into inflammatory rheumatic processes (such as rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, gout, and infectious arthritis); and noninflammatory arthropathies which are articular disc disorders (e.g. osteoarthritis, joint damage from prior trauma or surgery, or other cartilage or bone disorders) (De Rossi, 2014).

Pathogenesis of TMD is thought to begin with disequilibrium in the repair processes that involve chondrocyte proliferation, differentiation and degradation, coupled with increasing inflammatory mediators within the joint. In addition, genetic predisposition, female hormonal imbalances (high oestrogen levels), alteration in the mechanical loading and extracellular

matrix, exacerbate the degradation of the joint tissues and progressively result in internal derangement and irreversible joint damage (Wadhwa *et al*., 2008). Posttraumatic injuries like whiplash, even though controversial, have also been associated with development of chronic TMJ pain and delayed TMD symptoms (Fernandez *et al*, 2009)

TMD manifest with a constellation of signs and symptoms. In 1989, Wilkes classified the internal derangements of TMJ into five stages according to the structural, functional and radiographic alterations seen within the TMJ (Table 1.1).

Table 1.1. Classification of TMJ internal derangement as adapted from Wilkes C, 1989

Stage	Clinical Presentation	Radiographic features
I Early	Early clicking but no significant mechanical symptoms, no pain nor restriction in mandibular movement.	Normal disc anatomy with slight anterior displacement. Normal hard tissues anatomy.
II Early intermediate	Increase in intensity of clicking and early lock with reduction. Few episodes of intermittent pain, occasional joint tenderness.	Mild anatomic deformity of the disc with slight anterior displacement. Normal hard tissue anatomy.
III Intermediate	Multiple episodes of pain and joint tenderness, with closed lock, restriction in mandibular movement and pain with function	Significant anatomic deformity or prolapse of the disc with severe anterior displacement. No hard tissue anatomic deformity.
IV Late intermediate	Chronic pain with crepitus and restriction in mandibular movement	Increase in Stage III severity with associated early to moderate degenerative hard tissue changes
V Late gross (End – stage)	Variable and episodic pain, crepitus and grinding joint noise, chronic restriction in mandibular movement	Gross anatomic deformity of the disc and hard tissues with significant degenerative arthritic changes, osteophytic deformity and subcortical cystic formation

Although the prevalence of TMD varies significantly, it is estimated that approximately 10 - 25% of population is affected (Buljan D, 2010; Graff-Radford, 2016). TMD is considered to be the most common cause of chronic orofacial pain (Guarda-Nardini *et al.*, 2008). These disorders and associated orofacial pain have a negative impact on the psycho-social status of the affected individuals (Manfredini *et al*., 2010).

The initial TMD treatment is based on conservative management which includes patient's education, self-care (e.g. diet & home-physiotherapy), occlusal appliances, behavioural interventions and pharmacotherapy (e.g. anti-inflammatory, analgesics & muscle relaxant) (De Rossi, 2014). According to Graff-Radford *et al*. (2006) majority of patients with TMD will show improvement or resolution of symptoms (pain and dysfunction) with conservative treatment modality.

Articular TMD often results in extreme disarrangement and anatomical structural TMJ damages if not treated adequately or if the disease process does not respond to traditional conservative treatment (Mercuri, 2012).

1.1.3 TMJ ankylosis and Trauma

Temporomandibular joint ankylosis (TMJ-A) is defined as hypomobility of the mandible resulting from fibrous or bony union of mandibular condyle to the cranial base. The aetiological factors include trauma, infections, pathological processes and degenerative diseases (Güven, 2000).

Trauma involving the condylar process is reported to be the most common predisposing factor to TMJ-A (Ellis, 1998; Ferretti *et al.*, 2005; Murad *et al*, 2011). Although the sequence of events that culminates in TMJ-A following condylar fractures awaits elucidation, the following are considered to be risk factors (He *et al.*, 2014; He *et al.*, 2009; Ferretti *et al.*, 2005; Rikhotso *et al*., 2016) (Table 1.2):

- Age: TMJ-A is more common in children than in adults, because children have well vascularized condyle with high osteogenic turnover,
- Type of condylar fracture, particularly, intracapsular condylar fractures and those that are comminuted,
- The relationship between the ramus stump and the glenoid fossa plays an important role in the prognosis of condylar fracture and development of TMJ-A,
- Damage to the condylar cartilage and perforation or displacement of the disc.
- Prolonged mechanical immobilization or muscular splinting.

Table 1.2. Factors predisposing to development of TMJ ankylosis adopted from He *et al.*, 2014; He *et al.*, 2009.

	Low risk	High risk
Ramus – glenoid fossa relationship	Grade 0 - no contact between the ramus stump and the glenoid fossa	Grade 1 - the ramus stump is in contact with the glenoid fossa, Grade 2 - the ramus stump is displaced out of the fossa with tearing of the articular disc
Type of condylar fracture (sagittal intracapsular)	Type A - a fracture through the lateral third portion of the condylar head with reduction of the ramus height Type B - a fracture through the central-third portion of the condylar head without reduction of the ramus height	Type C, a fracture through the medial third portion of the condylar head without reduction of the ramus height Type M - a comminuted fracture
Status of the articular disc	No disc perforation nor displacement	Disc is perforated and/or displaced

Sawhney (1986) classified TMJ ankylosis into 4 groups.

- Type 1 - fibrous adhesion all around joint;
- Type 2 - bony fusion of the condylar head to the articular surface, limited to the lateral aspect of the joint;
- Type 3 - bony bridge between the mandibular ramus and the zygomatic arch; and
- Type 4 – the entire joint is replaced by the bony ankylotic mass.

1.1.4 TMJ and condylar pathology

Pathology affecting the TMJ and the condyle may result in changes in the structure of the TMJ and/ or condyle, pain, facial asymmetry, as well as malocclusion and functional disturbances.

Wolford *et al.,* (2014) described condylar hyperplasia as those conditions that cause excessive growth and enlargement of the mandibular condyle due to neoplasia, trauma,

infection and abnormal condylar loading. They classified condylar hyperplasia into four types.

Type 1: It is associated with accelerated and prolonged excessive growth of a normal condyle. It is a self-limiting condition that usually occurs during puberty until mid-20s and affects females more commonly. Type 1A affect bilateral condyles and type 1B occurs unilaterally.

Type 2: It is a unilateral condylar enlargement caused by osteochondroma. It can develop at any age. Type 2A is a vertical elongation and enlargement of the condylar head and neck, while type 2B has a horizontal exophytic tumour growth pattern.

Type 3: These are other benign tumours resulting in condylar hyperplasia e.g. synovial chondromatosis, chondroblastoma, osteoma etc.

Type 4: These are malignant tumours that originate in the condyle, causing enlargement e.g. chondrosarcoma, osteosarcoma, metastatic tumours etc.

Surgical management is indicated for end stage TMJ diseases, described by Dimitroulis (2014) as those joints that demonstrate severe structural changes and for which none of the joint components can be preserved. These conditions include joints damage by degenerative joint diseases, pathology, trauma and ankylosis. These require removal of pathologic structures and reconstruction of the joint (De Rossi, 2014; Dolwick, 1994; Giannakopouls *et al*., 2012; Park *et al*., 2017).

1.1.5 Reconstruction of TMJ

TMJ reconstruction can be accomplished by either autogenous grafts or alloplastic prostheses (Quinn, 1999). The aim of TMJ reconstruction is to restore the anatomy of the joint, improve jaw function and quality of life of affected individuals as well as to prevent further morbidity & disease process (Burgess *et al.*, 2014; Giannakopoulos *et al.*, 2012; Gonzalez-Perez *et al*., 2016).

Autogenous grafts involve harvesting of vascularized or non-vascularized tissue and contouring it to the shape of the condyle to restore the anatomy and function of TMJ. The most commonly used autogenous graft in TMJ reconstruction is non-vascularized costochondral graft (CCG). CCGs are most useful in skeletally growing patients because of their ability to retain their growth potential. However, they have variable biologic behaviour and are very unpredictable. They can result in undergrowth, complete resorption, ankylosis or

excessive growth. Another disadvantage of autogenous grafts is an additional surgical donor site and the associated morbidity (Quinn, 1999).

Alloplastic total temporomandibular joint reconstruction, on the other hand, involves the use of biocompatible prosthesis to replace the diseased articular components of TMJ in end-stage TMJ diseases.

Advantages of alloplastic joint reconstruction include immediate post-reconstruction physiotherapy and function, obviation of secondary donor site and its morbidities, reduced surgery time and decreased hospitalization period. In addition, it provides a higher occlusal stability and relatively higher predictability as compared to CCGs. Its disadvantages include high cost of the device, potential device failure (loosening of screw & material wear), foreign body reaction and restricted use in growing patients (Mercuri *et al*., 2007; Sinno *et al*., 2010; Quinn, 1999).

The complications of alloplastic TMJ reconstructed are mainly associated with the surgical procedure itself, with only a few resulting from the prosthesis. In addition to the usual inherent possible complications associated with any surgery like severe intra-operative haemorrhage, patients can have infections; pain or worsening of TMJ symptoms; facial nerve (Cranial Nerve 7/ CN VII) injuries; malocclusion; dislocation; metal hypersensitivity; keloid and hypertrophic scar formation; as well as formation of heterotopic bone around the prosthesis (Guarda-Nardini *et al*., 2014; Mercuri *et al*., 2017; NICE, 2014)

1.2 LITERATURE REVIEW

The advent of alloplastic joint prostheses was first reported by Sir John Murray Carnochan, a New York orthopaedic surgeon, in 1840 (Lotesto, 2017; Quinn, 1999). Since then, management of TMJ disorders and type of prostheses used have evolved.

Quinn (1999) and Driemel *et al.,* (2009) categorized these prostheses into three types, namely, the interpositional material used after gap arthroplasty, those replacing the fossa or condylar component only and those reconstructing both components.

The indications for total alloplastic TMJ reconstruction include the following (Burgess, 2014; Driemel *et al*., 2009; Giannakopoulos *et al*., 2012; Quinn, 1999):

- TMJ-A and recurrent TMJ-A with a history of heterotopic bone formation;
- Failed autogenous grafts that resulted in severe anatomic joint deformity, especially in the patient who has undergone many surgical procedures and as a result has scarred, poorly vascularized tissue bed;
- Severe polyarticular inflammatory and degenerated joint disease that affects the TMJ and is refractory to non-surgical therapies (e.g. osteoarthritis rheumatoid arthritis, psoriatic arthritis and gouty arthritis);
- Failed previous partial alloplastic reconstruction implants; and
- Change in vertical mandibular height and/or occlusal relationship as a result of bony resorption (e.g. idiopathic condylar resorption), condylar hyperplasia, trauma, developmental abnormalities or pathologic lesions with severe anatomic discrepancies.

The contraindications to alloplastic total TMJ replacement are relative and include active or chronic infection, known allergy to any materials used in the prosthetic component, systemic diseases with increased susceptibility to infections, skeletally immature patients, patients with compromised bone quality and quantity to support the prosthetic components, presence of severe hyper-functional habits (clenching, bruxism etc.) and those with mental or neurological conditions which will hinder patients to follow post-operative physical therapy exercises. (Giannakopoulos *et al*., 2012; Quinn, 1999)

Alloplastic total TMJ prosthetic systems can either be classified as stock prostheses or custom (patient-fitted) prosthetic joints. Stock joints come in various standard sizes and shapes while patient-fitted implants are designed and manufactured for a specific individual.

While studies have reported on the safety and efficiency of alloplastic total TMJ reconstruction (Giannakopoulos *et al*., 2012; Mercuri *et al*., 2007) and numerous articles continue to report on successful cases, its history is fraught with controversy and has been characterised by multiple failures due to inappropriate designs and material used. The 1990s negative experience with Vitek-Kent I prosthesis (V joint) which led to its discontinuation and removal, as well as the recall of all patients with these implants due to foreign-body reaction, has unfortunately continued to discredit this treatment modality (Driemel *et al*., 2009; Quinn, 1999). Newer and improved designs have however purged the weakness and overcome the shortcomings of previous V joints.

Dolwick *et al.,* (1994) reported in their review article that while there was an increase in surgical options and improvements in prostheses used, the case selection was prudent, since it affected, to some extent, the outcomes.

Nonetheless, the need for TMJ replacement continues to increase due to better understanding of TMD and other related TMJ pathologies, as well as more positive outcomes being reported in the literature. The 2016 study by Onoriobe *et al.,* projected that there will be a 58% increase in the need for TMJ replacement in USA only, by 2030.

Studies worldwide have continued to report on long-term improvement of symptoms and quality of life of affected patients after alloplastic total TMJ reconstruction.

Wolford *et al*., (2015) reported that 56 patients (approximately half of the 111 patients treated) who participated in their study, continued to function well even after an average of 20 year follow up after TMJ Concepts total joint replacement. Their study showed that there was significant association between the number of previous TMJ surgeries and post-operative pain and maximum mouth opening. However, they reported overall improvements in terms of pain, jaw function, ability to eat solid food and quality of life. A total of 48 (85.7%) patients reported improved quality of life, while 10.7% and 3.6% reported it as same as pre-operative and worse respectively.

A 10-year review of 300 patients reconstructed with the Biomet/Lorenz Microfixation TMJ replacement system by Leandro *et al*., (2013), in Brazil, reported statistically significant results in mandibular function and reduction in pain. Patients were reviewed for an average period of 3.5 years. The mean maximum mouth opening improved from 11.33 mm preoperatively to 41.8 mm 3 years post-operatively with no significant improvement from 4th year thereafter. Although the sample size is among the largest in the literature and the follow-

up period is significantly longer, the study does not assess the outcomes within different diagnostic groups, which could affect the results.

Giannakopoulos *et al.,* (2012) followed 442 Biomet Microfixation TMJ replacement system prostheses in 288 patients between 1995 and 2005 for a period of 3 years. Their results revealed a statistically significant reduction in pain intensity (67.5%, P-value <0.0001) and interference with eating (69.5%, P-value <0.0001) after surgery. The average maximum incisal opening improved by 44.6%, from 20.4 mm pre-operatively to 29.5 mm 3 years post-operatively (P-value <0.0001). The study also reported that out of 14 of the 442 implants that necessitated removal due to heterotopic bone formation or infection, none were due to device-related mechanical failures. Even though the authors reported on the level of satisfaction that the patients expressed about the surgery, the QoL was not assessed in the study.

A multicenter study which was conducted in Australia and New Zealand by Burgess *et al*., in 2014, used questionnaire to collect comprehensive subjective data from 52 patients. The mean follow-up period was 46.3 months. Visual analogue scale (VAS) was used to simplify the scoring system for assessed variants (pain, function, diet, QoL and adverse outcomes. They reported significant improvement of symptoms and QoL (P-value <0.05). Furthermore, they reported a 27% occurrence of adverse outcomes which correlated with the number of TMJ surgeries that an individual has had. There were no prostheses failure reported in their study which confirms the improvement of the prosthetic design and materials.

A fourteen year (mean 11.4 years) follow up study by Mercuri *et al*., (2007) also reported significant improvements (P-value <0.001) in both subjective outcomes (pain score; perception of mandibular function; diet consistency; quality of life) and objective outcome (maximum interincisal opening), in 61 patients who had 102 patient-fitted TMJ Concepts systems implants, inserted between 1990 and 2004. They reported that 30 (48.4%) patients had post-trauma TMJ disorder, 4 (6.5%) arthritic disorders, 9 (14.7%) primary symptoms associated with masticatory muscle spasms and 14 (22.9%) had disorders of unknown cause. However, the authors did not show the impact of diagnosis on the outcomes. Secondly, the study relied on patients to measure their maximum mouth opening distance which could also affect the results if patients did not apply the instructions properly. By contrast, literature review article by Arturo *et al*., (2013) revealed that the therapeutic outcomes of alloplastic total joint replacement with stock prostheses also yielded significantly satisfactory results.

1.3. RATIONALE FOR THE STUDY

In view of the controversial history associated with alloplastic total TMJ prostheses, it is imperative that those who continue to use this treatment option report their outcomes and complications, for the benefit of the entire discipline. At the time of conducting this research, there was only one published study in South Africa, which had reported on the outcomes of alloplastic TMJ reconstruction (Bütow *et al*., 2001). The Maxillo-Facial and Oral Surgery unit in our institution has been performing alloplastic total joint reconstruction since 2007 but clinical outcomes and complications have never been reported. Against this background, this study is undertaken to document the experience as well as to report on clinical outcomes of patients who had total alloplastic TMJ reconstruction at Wits School of Oral Health Sciences.

1.4. AIM

The aim of the study was to evaluate the clinical outcomes, complications and quality of life of patients who had undergone alloplastic total TMJ replacements.

1.5. OBJECTIVES

- To evaluate the objective outcomes (interdental/interalveolar mouth opening, occlusion) and subjective outcomes (pain, diet consistency and chewing function, quality of life) after alloplastic total TMJ replacement;
- To assess possible complications and how they affect patients; and
- To compare the findings to those reported elsewhere in the literature.

CHAPTER TWO

MATERIALS AND METHODS

2.1 STUDY DESIGN

This was a retrospective cross-sectional observational study of the outcomes of patients who had alloplastic total temporomandibular joint replacements between June 2007 and December 2017, at the Maxillo-Facial and Oral Surgery department, University of the Witwatersrand, in Wits Oral Health Centre (WOHC) and Chris Hani Baragwanath Academic Hospital (CHBAH).

2.2 SAMPLE SIZE

All patients who had undergone alloplastic total temporomandibular joint reconstruction, between June 2007 and December 2017 were considered for the study.

2.3 INCLUSION CRITERIA

All patients who had at least six months follow-up after unilateral or bilateral alloplastic total temporomandibular joint replacement between June 2007 and December 2017.

2.4 EXCLUSION CRITERIA

All patients who have failed to return for follow up
Patients who had less than 6 months follow up period,
Patients with missing records.

2.5 METHODOLOGY

All patient had undergone Biomet/Lorenz TMJ implant placement (Biomet Microfixation, Jacksonville, Florida, USA) after removal of diseased condyle (condylectomy) or ankylotic mass (gap arthroplasty). The Biomet/Lorenz system is available in both patient - matched type and stock type; and is comprised of a condylar/ ramus component made from chromium-cobalt-molybdenum alloy with a plasma spray titanium coating on the bone contacting surface to facilitate bone apposition and biologic fixation. Its fossa component is manufactured from ultra-high molecular weight polyethylene (UHMWPE) (Figure2.1). The fossa is secured to the zygomatic arch with four 2mm screws in 7 or 9mm lengths (Figure 2.1). Condylar prosthesis is secured with four to six 2,7mm screws (Figure 2.1).



Figure 2.1 Biomet/ Lorenz Microfixation TMJ replacement system (www.zimmerbiomet.com)

The departmental protocol for alloplastic total TMJ reconstruction was applied to all patients. Access to the TMJ was achieved via combined Alkayat-Bramley (modified preauricular) and Risdon (submandibular) approach. Kaban's protocol for management of ankylosis was used. After placement of prosthetic joint(s), the maximum mouth opening was rechecked (the target intra-operative minimum mouth opening of 35mm was achieved) and wounds were closed in layers using 3/0 vicryl (for deep layers) and 5/0 monocryl or nylon (for the skin). Patients had 5 day courses of Augmentin 1.2g IVI 8 hourly or Clindamycin 600mg IVI 6 hourly in case of allergy to penicillin. Aggressive physical therapy exercises were started 2-3 days post-operatively. Patients were then followed up at 1, 4, 6 weeks interval and 1 month interval for 3 months and then 1 year interval thereafter.

For the study, hospital records were used to collect patients' information. The following details were recorded: age at time of surgery; gender; diagnosis; side(s) affected; date of surgery; pre-operative and post-operative data (maximum mouth opening distance, occlusion status) as well as complications. Post-operative data at 6, 12, 18, 24 months were recorded.

Each patient was allocated a unique identification code to ensure identity protection and maintain confidentiality.

Maximum mouth opening distance was measured using calliper ruler and reported in millimetres. These were reported as interdental distance (interincisal distance measured

between opposing maxillary and mandibular incisal edges in dentate participants or intercuspal distance measured between maxillary and mandibular premolar/molar buccal cusps in cases where participants were missing all incisors) or interalveolar distance which was measured between maxillary and mandibular anterior alveolar ridges in cases when participants are edentulous.

Alloplastic TMJ – Reconstruction: Quality of Life (TMJ-R-QoL) questionnaire (APPENDIX IV), which was adapted from TMJ – Surgery: QoL questionnaire by Dimitroulis *et al*., (2010) was used to record all the subjective outcomes (pain; diet and chewing function; and quality of life).

2.6 DATA MANAGEMENT AND ANALYSIS

We conducted a data analysis of objective and subjective outcomes after TMJ replacement. Data was captured into Microsoft Excel spreadsheet ((Microsoft Office; Microsoft, Redmond, WA) and statistical analysis was carried out using Stata/ IC 14.2 software.

Continuous variables measured were:

- age described as the age of the patient at the time of surgery,
- maximum mouth opening distance (MMO) measured in millimetres (mm),
- pain score (0= no pain; 1= mild bearable pain not needing medication; 2= moderate pain alleviated by regular analgesics; 3=severe pain controlled only by strong analgesics; 4= severe pain which not controlled by analgesics; 5=Worst, most unbearable pain ever,
- diet consistency and chewing function (1= normal diet of any consistency; 2= most foods except tough consistency; 3= only soft foods; 4= foods cut into small pieces; 5= only foods put in a blender or liquids).

Categorical variables measured were age at time of surgery, gender, diagnosis and complications.

Continuous data was presented as mean (standard deviation) or median (ranges [minimum-maximum] or [25^{th} – 75^{th}] interquartile ranges). The mean MMO was stratified by age, gender, diagnosis, pre-operative and post-operative follow-up period, and complications. One way analysis of variance (ANOVA) was carried to compare multivariable data and Post Hoc Bonferroni test was conducted to check where the difference lied. The relationship between pre-operative and post-operative continuous and categorical data was compared using paired t-tests. In cases where data was nonparametric, a Wilcoxon singled-rank test was used to

analyse the data and results were recorded as median and 25th to 75th interquartile ranges. A P-values < 0.05 was considered statistically significant.

The comparison between categorical data was conducted using a chi-squared test or Fisher's exact was done when the expected cells <5.

After censoring all the patients who did not achieve MMO >25mm, Kaplan – Meier (time-to-events) graphs were plotted to demonstrate the trends in achieving and maintaining MMO (> 25mm) within the different categorical variables (age, gender, diagnosis and complications) over time. An st_summary was generated to illustrate the trends and a log – ranked test was performed to check the significance of the differences in mean MMO against categorical variables.

The multivariable linear regression coefficient test was carried out to assess the overall differences in mean MMO in relation to all the categorical variables when those <30 years at time of surgery, females and ankylosis were used as references.

2.7 ETHICAL CONSIDERATIONS

Ethical clearance (M180412) was granted by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand prior to commencement of the study (APPENDIX V).

Permission to access patients' records was obtained from the CEOs of Wits Oral Health Centre (WOHC) and Chris Hani Baragwanath Academic hospital (CHBAH) and the Head of Maxillo-Facial and Oral Surgery Department.

All participants who fulfilled the inclusion criteria were informed verbally and in writing about the study details. Written informed consent was obtained from participants or guardian in case of minors (younger than 21) APPENDIX II. Patient's personal information such as name, identity number and hospital number were kept confidential to protect their identity and unique identification codes were allocated to each patient.

CHAPTER THREE

RESULTS

3.1 DEMOGRAPHIC DATA

From 2007 to 2017, a total of 35 patients had undergone TMJ reconstruction. Out of these, 31 patients met the inclusion criteria while 4 were excluded due to missing records and failure to attend follow up. Sixteen patients (51.61%) were females and 15 (48.39%) were males (Fig. 3.1). The mean age at the time of surgery was 36.94 years (median 31 years, range 11 – 72 years, SD 16.28). The distribution of age is shown in Fig.3.2. Furthermore, the age at the time of surgery was categorized into two broad groups, namely, under 30 yrs old (N=14, 45.16%) and 30 yrs old and older (N=17, 54.84%).

Four (12.90%) patients had undergone total joint replacement as a second TMJ surgery for reankylosis after gap arthroplasty and/or for failure of costochondral graft, while 27 (87.10%) patients had only one surgery.

The average length of follow up was 58.8 months (range 6 – 122 months). All 31 patients had a minimum follow up period of 6 months, while only 26 (83.87%) were followed up for 24 months or more.

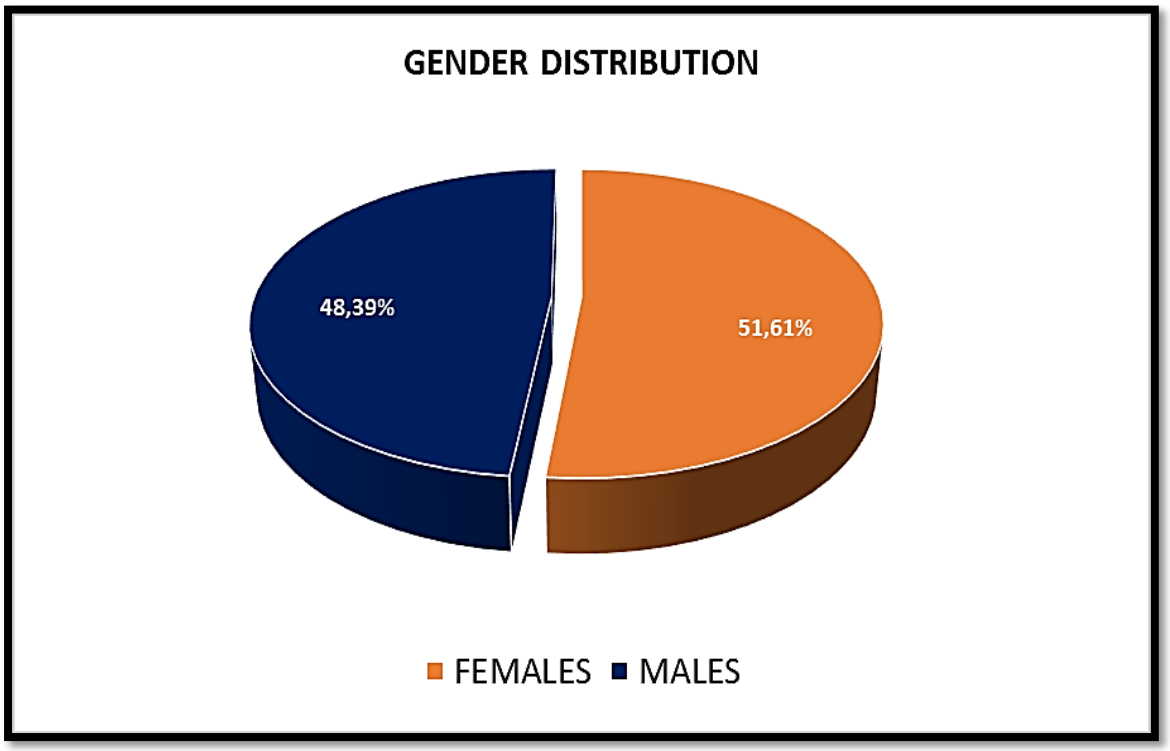


Figure 3.1 Gender distribution.

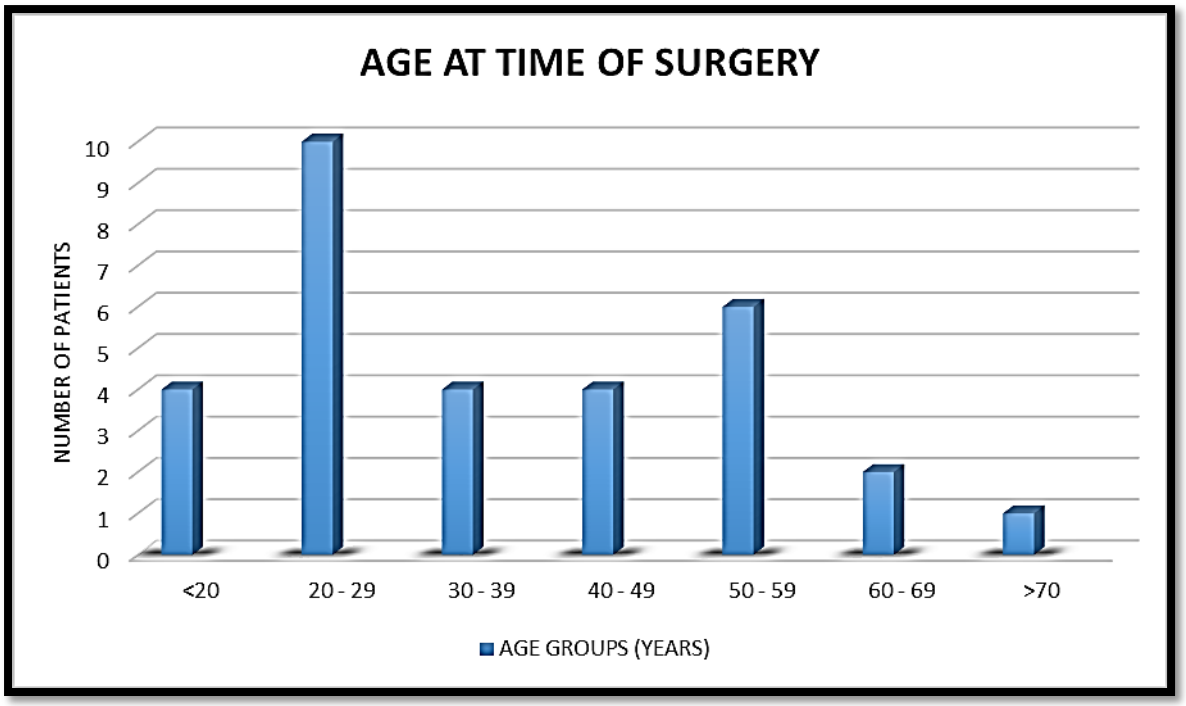


Figure 3.2 The distribution of age at the time of surgery

A total of 51 joint prostheses were implanted in 31 patients and 20 (64.52%) of them were bilateral while 11 (35.48%) were unilateral (6 right; 5 left) (Fig. 3.3). The stock prostheses were used in 28 patients (90.32%) and only 3 (9.68%) were of custom-made type.

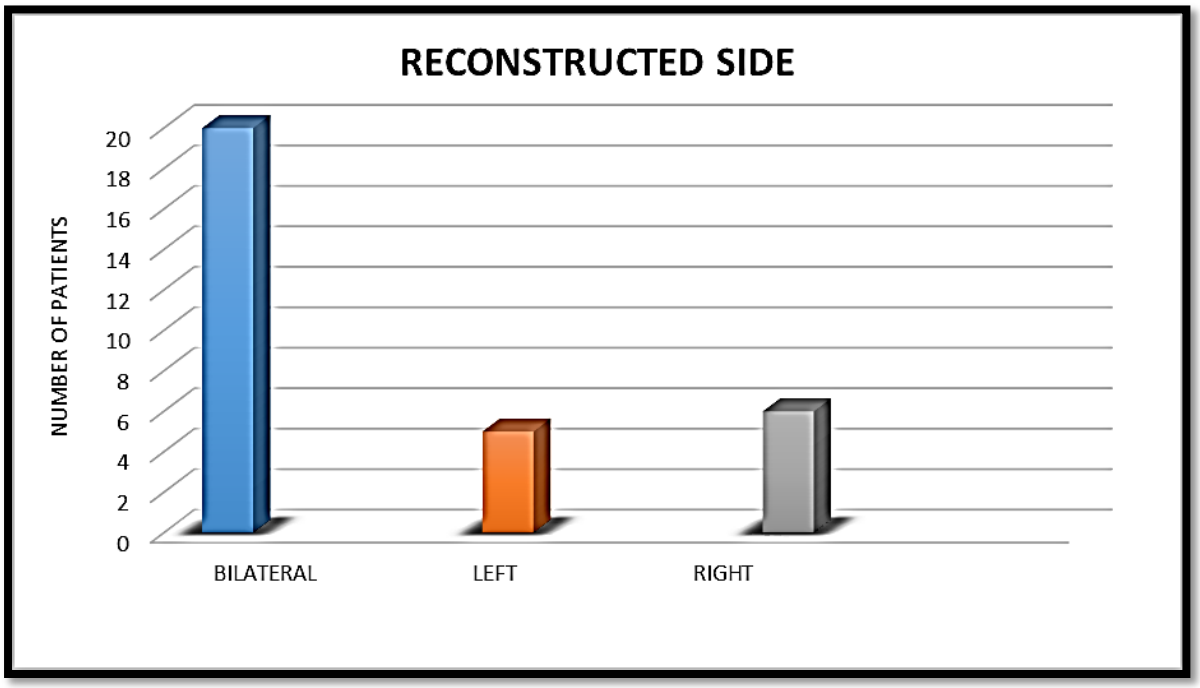


Figure 3.3 The TMJ side(s) reconstructed with joint prosthesis.

3.2 DIAGNOSIS

The pre-operative diagnoses were categorized into 4 groups, namely, ankylosis; degenerative conditions; pathology and malocclusion (Table 3.1 and Fig. 3.4). Ankylosis (58.06%) had the highest prevalence followed by degenerative conditions (22.58), pathology and malocclusion, each at 9.68%.

Table 3.1. Diagnosis frequency table.

DIAGNOSIS	NUMBER	PERCENTAGE (%)
Ankylosis	18	58.06
Degenerative conditions (TMD, osteoarthritis, rheumatoid arthritis etc.)	7	22.58
Pathology (synovial chondromatosis, osteochondroma and rhabdomyosarcoma)	3	9.68
Malocclusion associated with altered condylar anatomy due to trauma and idiopathic condylar hyperplasia	3	9.68
Total	31	100

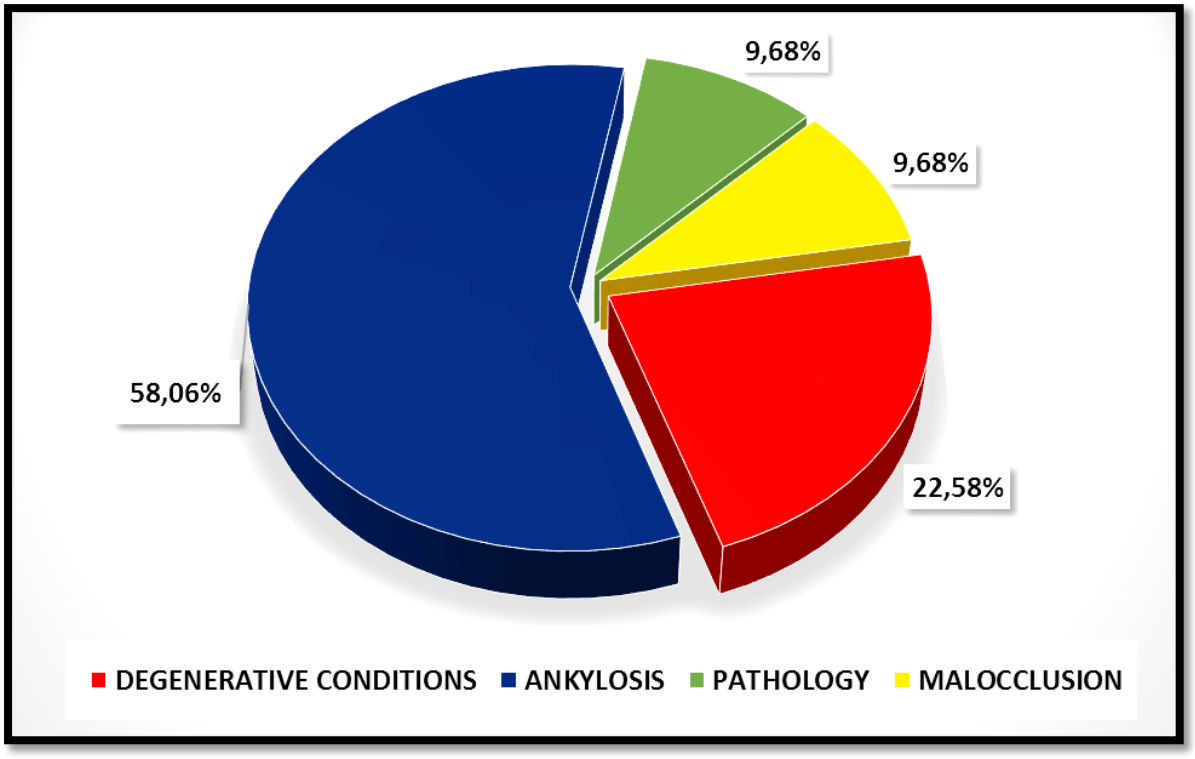


Figure 3.4 Diagnosis categories

The mean age for ankylosis group was 30 years (range 13 – 44 years, median 28 years); 30.29 years (range 11 – 72 years, median 55 years) for degenerative conditions; 40 years (range 20 – 50 years, median 50 years) for pathology and 46.33 years (range 20 – 50 years, median 50 years) for malocclusion.

Gender distribution within different diagnosis categories is illustrated in Table 3.2

Table 3.2. Frequency distribution of gender within the diagnosis categories.

DIAGNOSIS	FEMALES	MALES	TOTAL NUMBER OF PATIENTS
Ankylosis	N = 8 (44%)	N = 10 (56%)	18
Degenerative conditions	N = 6 (86%)	N = 1 (14%)	7
Pathology	N = 0	N = 3 (100%)	3
Malocclusion	N = 2 (67%)	N = 1 (33%)	3
Total	16	15	31

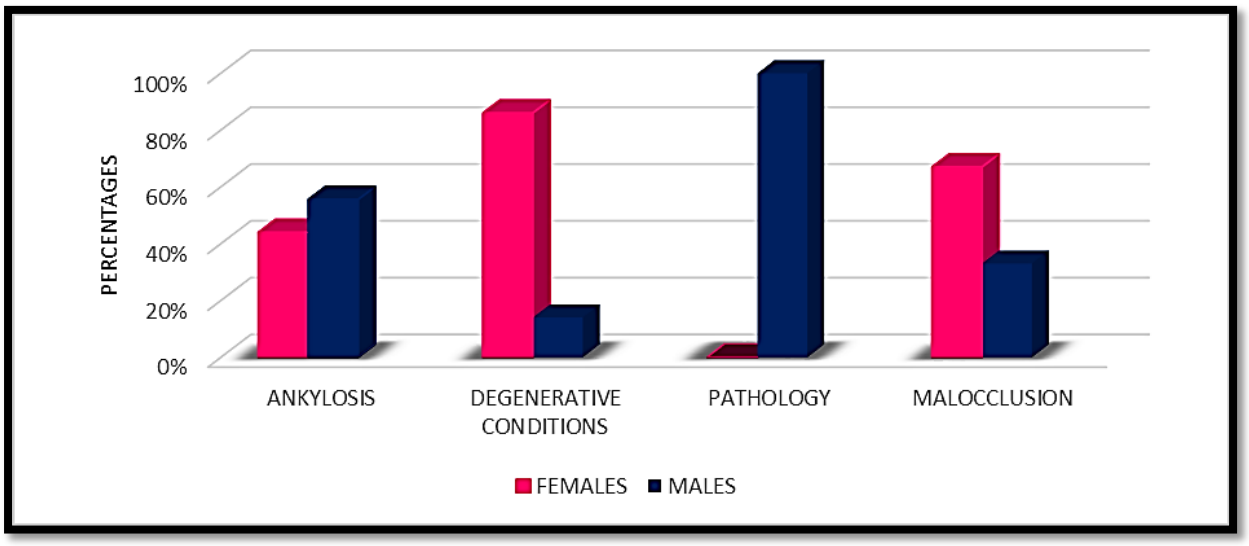


Figure 3.5 Frequency distribution of the relationship between gender and diagnosis

3.3 OBJECTIVE DATA

The objective variables that were measured included maximum mouth opening distance (MMO) and the status of occlusion. Paired t-test was used to evaluate the pre-operative and post-operative differences. The results showed that there was statistically significant improvement between the pre-operative and post-operative MMO outcomes at 3 months and 24 months (P-value <0.05). Therefore, MMO analysis will be limited to pre-operative, 3 months post-operative and 24 months post-operative intervals.

3.3.1 MAXIMUM MOUTH OPENING (MMO)

The table below shows the MMO of all patients at different time-frames which were statistically significant:

Table 3.3 Pre-operative, 3 months post-operative and 24 months post-operative MMO (mm).

MOUTH OPENING	Number of patients	Mean (mm)	Ranges (mm)	Standard deviation
Pre-operative	31	7.32	0 – 32	9.55
3 months Post-operative	31	32.30	20 – 40	6.71
24 months Post-operative	26	28.77	6 – 40	9.50

The maximum mouth opening distance improved significantly after total TMJ replacement. Paired t test performed to compare pre-operative and 3 months post-operative MMO yielded a P-value < 0.0001 and that between 3 months and 24 months post-operatively was P-value 0.0014.

For the purpose of analyzing the relationship between age at the time of surgery and the MMO at different time-frames, the sample was divided into 2 groups, namely those <30 years old and those >30 years of age. Paired t-test showed the following results (Table 3.4):

Table 3.4. Comparison of pre-operative and post-operative MMO in different age groups

	N (observations)	Mean MMO (mm)	SD	P-value
< 30 years of age				
Pre-operative	14	4.25	8.27	<0.001
3 months Post-operative		30.36	6.64	
3 months Post-operative	12	31.67	6.15	0.060
24 months Post-operative		28.25	7.96	
> 30 years of age				
Pre-operative	17	10.91	8.94	<0.001
3 months Post-operative		33.12	6.43	
3 months Post-operative	14	34.64	5.04	0.013
24 months Post-operative		29.21	10.94	

The results showed that the MMO improvement in both groups were almost similar between pre-operative and 3 months post-operative. However, MMO change in those who were younger than 30 years of age at the time of surgery was not statistically significant (P-value 0.060) as those who were older than 30 years of age (P-value 0.013).

Maximum mouth opening distance between and within the 4 diagnostic groups was statistically significant at pre-operative phase (P-value <0.001), particularly between the ankylosis and other non-ankylosis (degenerative conditions, pathology and malocclusion). Postoperative MMO between the 4 groups was however insignificant at the 3 and 24 months post-operative period (P-value 0.37 and P-value 0.19 respectively).

Tables 3.5, 3.6 and 3.7 show the frequency distribution of number of patients within each diagnostic category.

Table 3.5 Pre-operative MMO in relations to diagnosis categories

PRE-OPERATIVE MMO					
DIAGNOSIS	N (Number of Patients)	Mean (mm)	Range (mm)	SD	P-value
Ankylosis	18	1.83	0 – 5	1.89	<0.001
Degenerative Conditions	7	17.43	5 – 32	9.55	
Pathology	3	13.33	5 – 25	10.40	
Malocclusion	3	16.66	10 – 20	5.77	

Table 3.6. MMO in relations to diagnosis categories at 3 months post-operatively

3 MONTHS POST-OPERATIVE MMO					
DIAGNOSIS	N (Number of Patients)	Mean (mm)	Range (mm)	SD	P-value
Ankylosis	18	30.72	18 – 40	6.90	0.37
Degenerative Conditions	7	31.43	25 – 40	5.56	
Pathology	3	34.00	25 – 42	8.54	
Malocclusion	3	37.67	35 – 40	2.52	

Table 3.7. MMO in relations to diagnosis categories at 24 months post-operatively

24 MONTHS POST-OPERATIVE MMO					
DIAGNOSIS	N (Number of Patients)	Mean (mm)	Range (mm)	SD	P-value
Ankylosis	15	25.53	6 – 40	9.98	0.19
Degenerative Conditions	5	31.60	20 – 38	7.09	
Pathology	3	32.33	22 – 40	9.29	
Malocclusion	3	36.67	30 – 40	5.77	

3.3.1.1 THE TRENDS IN TIME TAKEN TO ACHIEVE AND MAINTAIN MEAN MAXIMUM MOUTH OPENING (MMO)

The average postoperative MMO for all the analyzed categories was 28.77 mm and therefore, 25 mm was considered the target MMO. All the time-to-events Kaplan-Meier graphs were plotted for those who achieved this target and the time it took to maintain the MMO ≥25 mm was determined and compared (Fig. 3.6).

The trend illustrated below in figure 3.6. and table 3.8, shows that overall, only 25% of the patients could maintain MMO ≥25 mm at 3 months, while 50 % achieved it at 6 months and 75% at 24 months post-operative.

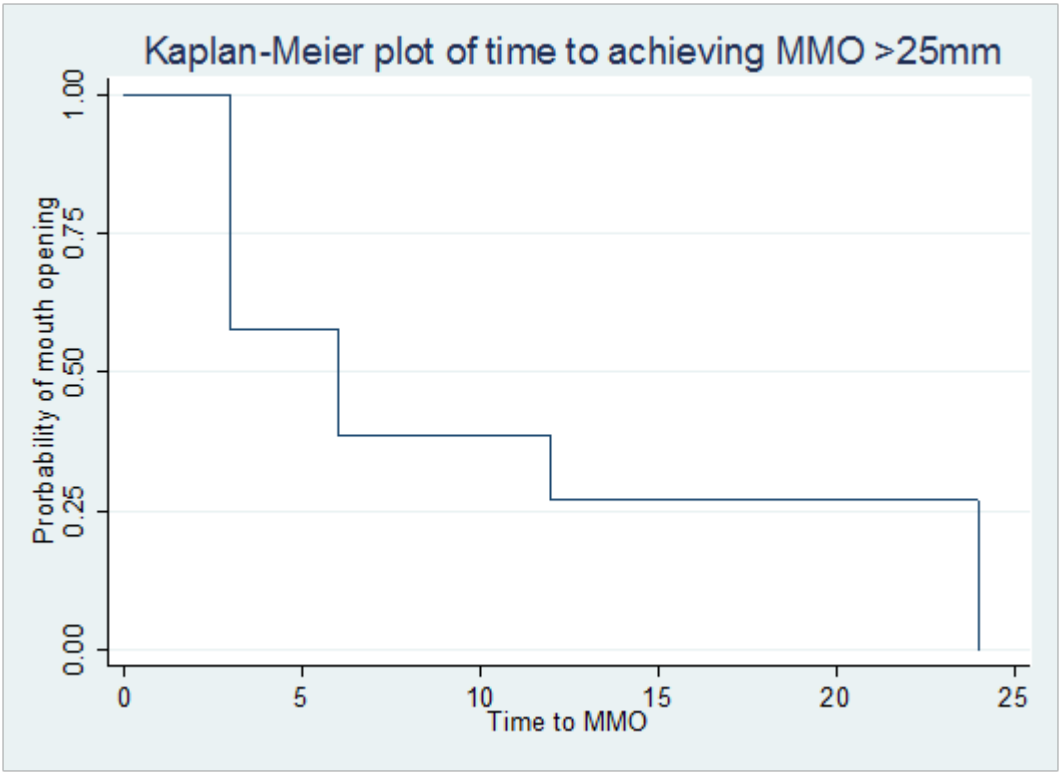


Figure 3.6 The trends of patients to achieve mean maximum mouth opening (MMO) of 25 mm or more, over time.

Table 3.8. Summary of time (months) to maintain MMO ≥25 mm

	Total time to >25mm (months)	Incidence Rate	N (Observations)	% of total sample size to achieve ≥25mm		
				25%	50%	75%
Time (months)	267	0.097	26	3	6	24

3.3.1.2 THE TRENDS FOR TIME TAKEN TO MAINTAIN MAXIMUM MOUTH OPENING (MMO) BY GENDER OVER 24 MONTHS FOLLOW-UP

The results showed that males got to the maximum mouth opening faster than females. Seventy-five percent of males could maintain their MMO at 6 months post-operatively while females took 24 months to achieve theirs. This was statistically significant with P-value 0.0157 (Fig. 3.7 and Table 3.9).

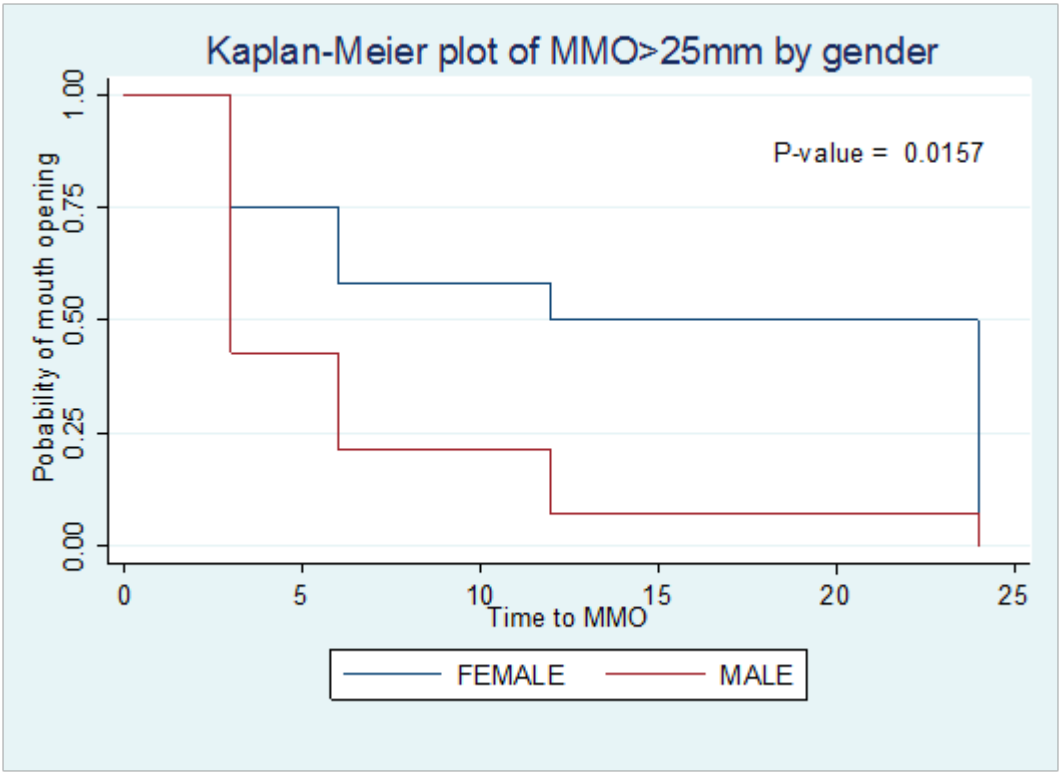


Figure 3.7. The trends of mean maximum mouth opening (MMO) at different time-frames, when compared against gender.

Table 3.9 Summary of time (months) to maintain MMO ≥25 mm by gender

	Total time to >25mm (months)	Incidence Rate	N (Observations)	% of total sample size to achieve ≥25mm		
				25%	50%	75%
Female	177	0.068	12	3	12	24
Male	90	0.156	14	3	3	6
Time (months)	267	0.097	26	3	6	24

3.3.1.3 THE TRENDS OF MEAN MAXIMUM MOUTH OPENING (MMO) BY AGE GROUPS (AT TIME OF SURGERY OVER 24 MONTHS FOLLOW-UP

Kaplan – Meier graph (Fig. 3.8 and Table 3.10) indicates that 75% of younger patients reached and maintained their target MMO earlier at 12 months post-operative as compared to older patients who achieved their stable MMO at 24 months post-operative. However, the difference was not statistically significant (P-value 0.5478).

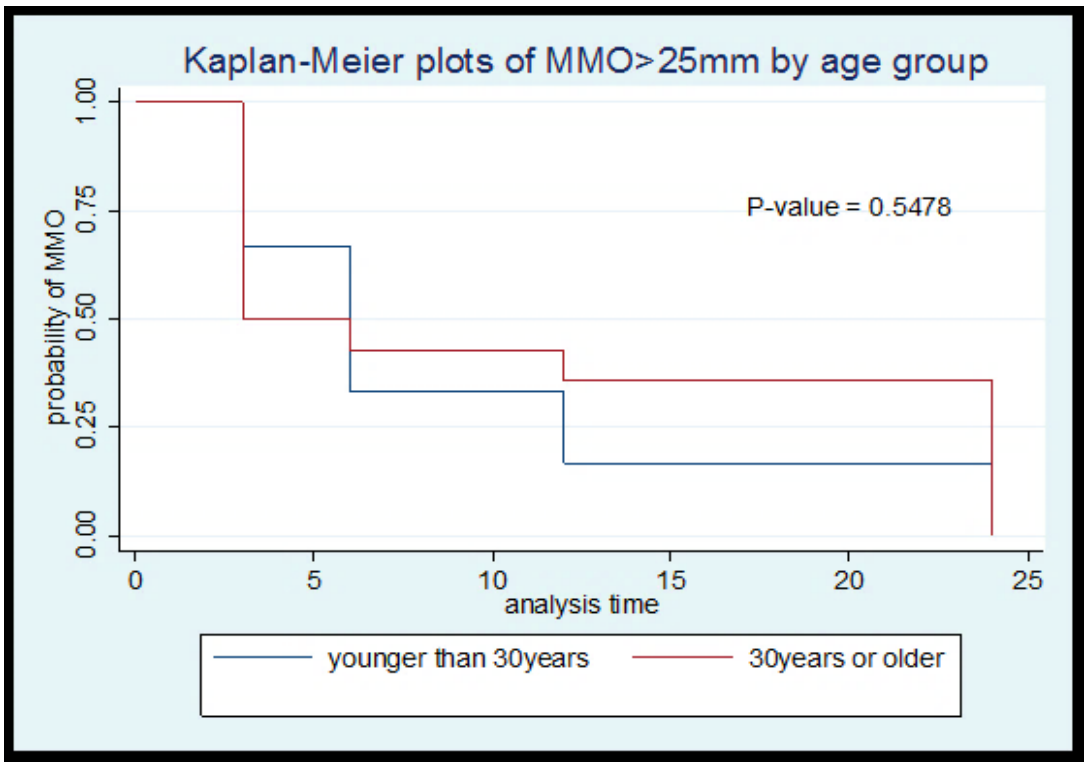


Figure 3.8. The trends of mean maximum mouth opening (MMO) at different time-frames, when compared against age groups (at time of surgery)

Table 3.10 Summary of time (months) to maintain MMO ≥25mm by age group

	Total time to >25mm (months)	Incidence Rate	N (Observations)	% of total sample size to achieve ≥25mm		
				25%	50%	75%
<30 yrs	108	0.111	12	3	6	12
≥30 yrs	159	0.088	14	3	3	24
Time (months)	267	0.097	26	3	6	24

3.3.1.4 THE TRENDS IN MAINTAINING THE MEAN MAXIMUM MOUTH OPENING (MMO) WITHIN DIAGNOSIS GROUPS, AT DIFFERENT TIME-FRAMES

The maximum mouth opening distance from pre-operative to 24 months post-operative had a similar trend amongst the diagnosis groups (Fig. 3.9 and Table 3.11). It showed a very steep upwards trend which demonstrates drastic increase in mouth opening from pre-operative to 3 months post-operative. Thereafter, the graphs (Fig.3.9) assume an almost straight constant line with stabilization of the results from 18 months after the surgery. Malocclusion had a better MMO as compared to other diagnosis groups, with ankylosis having the lowest ranges.

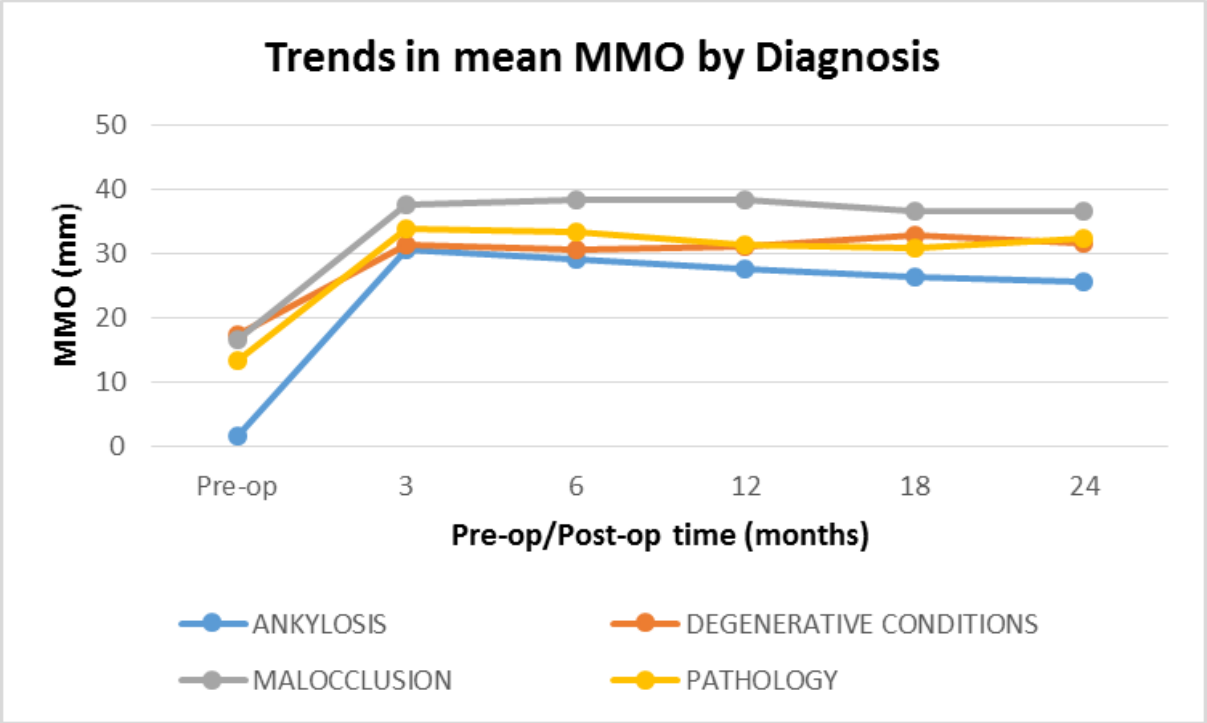


Figure 3.9. The trends of mean maximum mouth opening (MMO) in relation to diagnosis when compared at different time-frames.

Table 3.11 Mean maximum mouth opening (mm) in relation to the diagnosis groups

	Pre-operative	3	6	12	18	24
Ankylosis	1.83	30.72	29.12	27.61	26.42	25.53
Degeneration condition	17.43	31.43	30.57	31.17	33.00	31.60
Malocclusion	16.67	37.67	38.33	38.33	36.67	36.67
Pathology	13.33	34.00	33.33	31.33	31.00	32.33

When it comes to the diagnoses, the results (Fig 3.10 and Table 3.12) showed that there was no significance in the time taken for patients in each group to maintain the MMO ≥25 mm (P-value 0.2152). Patients in ankylosis group got to their target MMO at 12 months post-operatively. Those patients who had degenerative conditions took longer to maintain their stable MMO (Time = 24 months).

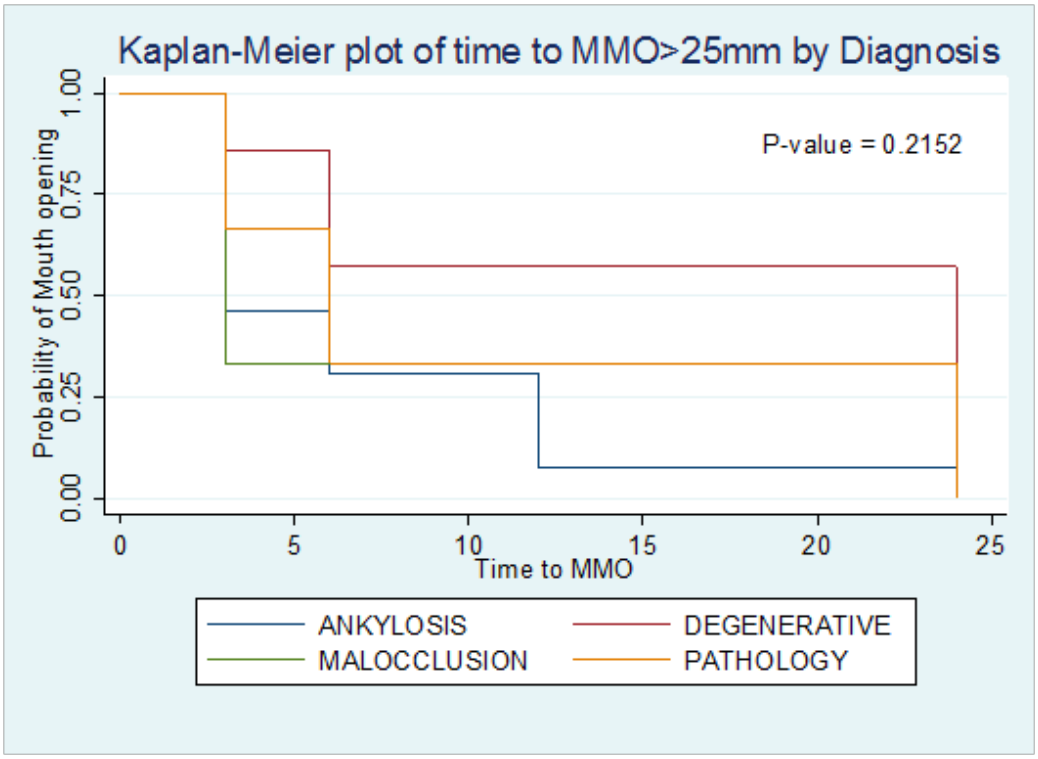


Figure 3.10. The trends of mean maximum mouth opening (MMO) at different time-frames, when compared against diagnosis groups

Table 3.12 Summary of time (months) to maintain MMO ≥25mm by diagnosis group

	Total time to >25mm (months)	Incidence Rate	N (Observations)	% of total sample size to achieve ≥25mm		
				25%	50%	75%
Ankylosis	93	0.1397	13	3	3	12
Degenerative Conditions	111	0.063	7	6	24	24
Malocclusion	30	0.100	3	3	3	24
Pathology	33	0.091	3	3	6	24
Total time (months)	267	0.097	26	3	6	24

3.3.1.5 OVERALL MEAN MAXIMUM MOUTH OPENING (MMO) COMPARISON

Linear regression analysis was performed to compare the relationship between mean MMO and age, gender, diagnosis and complications. MMO changes were determined when all variables were compared against ankylosis, under 30 years old at time of surgery and females were used as references. The regression coefficients, P-values and 95% confidence intervals are illustrated in Table 3.13 below.

The regression analysis showed that for the diagnosis, ankylosis had better MMO outcomes as compared to other diagnosis groups. Moreover, it also indicated that those patients with ankylosis improved far better than those with degenerative conditions (-11.47), followed by pathology (-4.67) and least by malocclusion (-3.67). The difference was significant for degenerative condition (P-value 0.017) but not statistically significant for pathology and malocclusion since P-value was <0.05 (0.509 and 0.402 respectively). However, when all the diagnosis groups were compared, the mean MMO difference was not statistically significant since all the P-value was >0.05 (multivariable P-values).

The analysis also showed that males performed better than females when it came to post-operative mouth opening distance, with coefficient of 7.04, and the difference was significant (P-value 0.051). Furthermore, those who were younger than 30 years, did statistically better than those who were older than 30 years, even thought it was only by a small margin.

Table 3.13 Linear regression analysis between MMO and diagnosis, gender and age

	UNIVARIABLE COMPARISON			MULTIVARIABLE COMPARISON		
diff2	Coef.	P-value	[95% CI]	Coef.	P-value	[95% CI]
DIAGNOSIS						
Ankylosis	Ref	Ref	Ref	Ref	Ref	Ref
Degenerative conditions	-11.47	0.017	-2.21-20.72	-8.37	0.236	5.92 - 22.67
Malocclusion	-3.67	0.509	7.66 – 14.99	-2.50	0.694	10.56 - 15.55
Pathology	-4.67	0.402	6.67 – 15.99	-7.32	0.240	5.29 - 19.94
GENDER						
Females	Ref	Ref	Ref	Ref	Ref	Ref
Males	7.04	0.051	14.12 – 0.04	5.72	0.182	14.35 - 2.91
AGE AT TIME OF SURGERY						
< 30 yrs	Ref	Ref	Ref	Ref	Ref	Ref
> 30 yrs	-6.35	0.081	0.85 – 13.54	-0.014	0.993	0.335 - 0.338

3.3.2 OCCLUSION

Six (19.35%) patients presented with pre-operative malocclusion which was corrected by TMJ reconstruction in 4 patients. For the remaining 2 patients who still had malocclusion after surgery, one had restoration of occlusion after occlusal equilibration while the other required orthodontic correction. Fisher's exact test yielded a P-value of 0.034 which shows statistical significance.

3.4 SUBJECTIVE DATA

Subjective outcomes measured were pain, diet consistency and chewing function, and quality of life.

3.4.1 PAIN

Seventeen (54.84%) of the 31 patients reported pre-operative pain. Of these only two patients (6.26%) reported post-operative pain which was of less severity when compared to their pre-operative pain score (one patient expressed improvement from 4 to 2 while the other patient, from 3 to 1) (Table 3.14).

The Wilcoxon signed-rank test carried out to compare the difference between pre-operative and post-operative mean pain score was statistically significant (P-value <0.001). The pre-operative and post-operative median pain score and 25% - 75% interquartile range (IQR) were 1 (0 – 2) and 0 (0 – 0) respectively.

Table 3.14 Frequency distribution of pre-operative and post-operative pain score.

	PRE-OPERATIVE PAIN SCORE		**POST-OPERATIVE PAIN SCORE**	
	Number	Percentage (%)	Number	Percentage (%)
0 (no pain)	14	45.16	29	93.54
1 - mild pain requiring no medication	4	12.91	1	3.23
2 - moderate pain requiring regular analgesics e.g. Paracetamol	6	19.35	1	3.23
3 - severe pain controlled only by strong analgesics e.g. Opioids	6	19.35	-	
4 - severe refractory pain by analgesics	1	3.23	-	
5 - Worst, most unbearable pain ever				
Total	31	100	31	100

3.4.2 DIET CONSISTENCY AND CHEWING

Diet consistency and chewing function significantly improved. The P-value from Wilcoxon signed-rank test was <0.0001, while pre-operative and postoperative median and IQR was 5 (3 – 5) and 1 (1 – 1) respectively. Thirty (96.77%) patients expressed improved ability to biting and chewing normal diet as compared to having liquids or blenderized foods before the surgery. Only 1 patient reported that the diet consistency remained the same (diet score of 2) (Table 3.15).

Table 3.15 Distribution of diet consistency.

DIET CONSISTENCY	PRE-OPERATIVE	POST-OPERATIVE
1 = everything including tough foods	-	N = 30 (96.77%)
2 = most foods except tough foods	N = 3 (9.68%)	N = 1 (3.23%)
3 = soft food only	N = 8 (25.80%)	-
4 = food cut into small pieces	N = 3 (9.68%)	-
5 = only liquids or blenderized foods	N = 17 (54.84%)	-
Total	N = 31 (100%)	N = 31 (100%)

3.4.3 QUALITY OF LIFE (QoL)

Only one patient (3.22%) reported QoL as fair due to limited mouth opening. The other 30 patients reported improvement in quality of life after TMJ replacement, 6.45% (N = 2) reported QoL as excellent; 16.13% (N = 5) as very good; 64.52% (N = 20) as good and 9.68% (N = 3) as somewhat better due to generalized arthralgia from severe rheumatoid arthritis.

The improvement was statistically significant with paired t-test P-value of <0.013. The pre-operative QoL had a median of 5 [IQR (5 – 5)] and post-operative median of 3 [IQR (2 – 3)].

3.5 COMPLICATIONS

Twenty three (74.19%) patients had no complications. Three (9.68%) patients had transient facial nerve (temporal branch) weakness which resolved completely within 6 months post-

operatively. One (3.23%) patient had permanent paralysis of temporal branch of facial nerve with only forehead involvement.

Of the 31 patients, 2 (6.45%) developed keloids and 2 (6.45%) had heterotopic bone formation Table 3.16 and Figure 3.12 show complications observed in the 8 patients.

Table 3.16 Post-operative complications

COMPLICATIONS	Frequency	Percentage (%)
Transient CN VII weakness	3	9.68
Permanent CN VII injury	1	3.23
Heterotopic bone formation	2	6.45
Keloids	2	6.45
Total	8	25.81

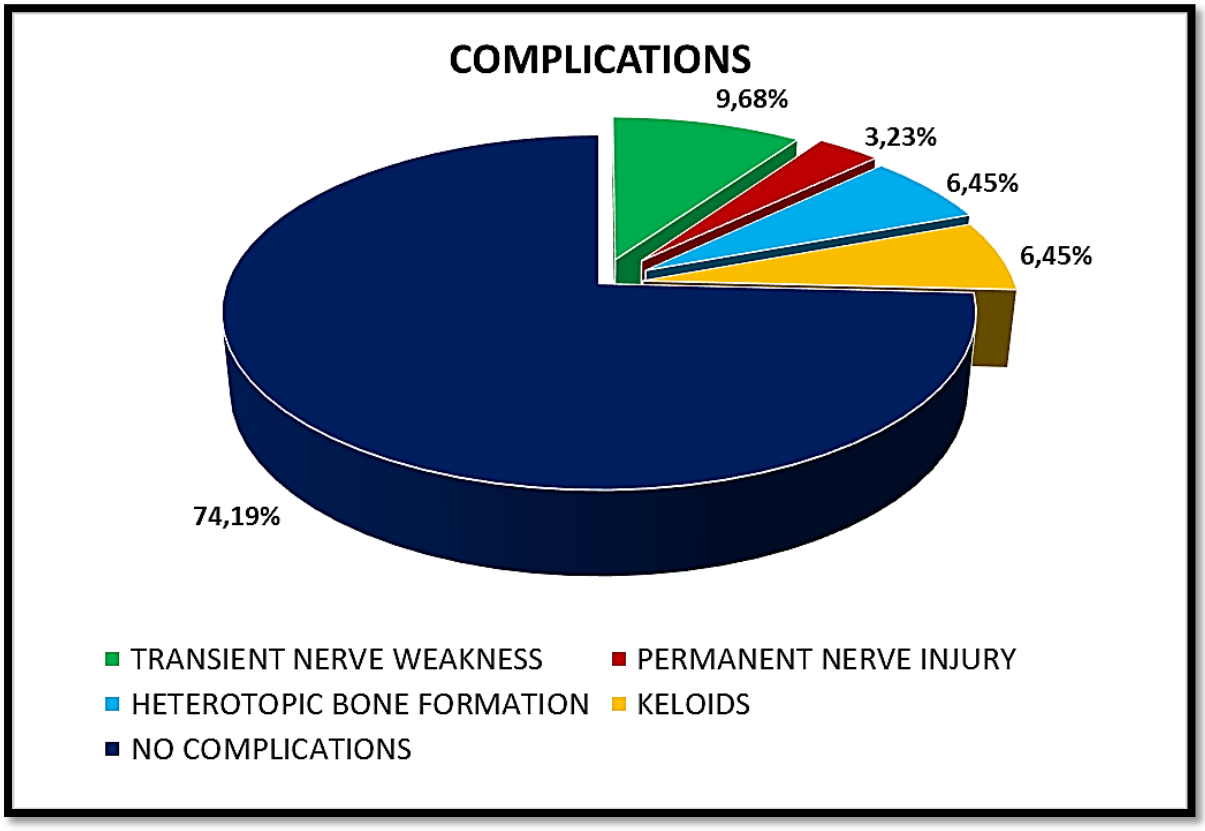


Figure 3.11. Distribution of post-operative complications.

The number of sides operated on and the type of prosthesis used had no statistically significant effect on the development of complications (P-value 0.677 and 0.672 respectively). None of the patients needed removal of the prosthesis.

COMPLICATIONS AND HOW THEY AFFECTED THE QUALITY OF LIFE

Fisher's exact test showed no statistically significant difference in the post-operative QoL between those with complications and those without complications (P- value 0.245). Amongst patients who had complications, significance could not be tested due to a small sample size. However, we relied on the responses of the patients to determine any improvement in QoL (Table 3.17).

Table 3.17 The responses to the QoL questions of patients with complications:

	PRE-OPERATIVE QoL	POST-OPERATIVE QoL
Permanent CN VII injury	Fair	Very good
Transient CN VII weakness1	Fair	Good
Transient CN VII weakness2	Fair	Very good
Transient CN VII weakness3	Fair	Good
Heterotopic bone formation1	Fair	Fair
Heterotopic bone formation2	Fair	Somewhat better
Keloids1	Fair	Excellent
Keloids2	Fair	Good

Furthermore, Pearson's chi-squared test was performed to test a null hypothesis that there was no association between complications and QoL. Since the P-value was 0.287 and is >0.05, we failed to reject the null hypothesis and therefore concluded that there was no association between the QoL and complications.

CHAPTER FOUR
DISCUSSION

For the past 10 years, Maxillo-Facial and Oral Surgery department at the University of the Witwatersrand has been implanting alloplastic total TMJ prostheses. The results of 31 patients who were met our inclusion criteria are discussed in this chapter. All variables are discussed in isolation and later on, the relationship between all the variables and how the categorical variables affect the outcomes will be discussed.

4.1 GENDER

The sample had more females than males (N=16, 51.61% and N=15, 48.39% respectively), even though it was only by a small margin, possibly due to a small sample size. Most studies showed female predominance (Burgess *et al*., (2014); Giannakopoulos *et al.,* (2012); Mercuri *et al*., (2007); Wolford *et al*., (2015)). There were more females (86%) in the group with degenerative conditions. This is consistent with the previous reports which suggest that female biological and/or hormonal factors could contribute to the pathogenesis of TMD (Wadhwa *et al*., 2008). The study by Bagis *et al.,* in 2012, which looked at the gender prevalence in TMD also reported a high female prevalence. In the present study, the group with TMJ-A had more males (N=10, 56%) which is similar to the studies by Eltohami *et al*., (2017) and Murad et al., (2011) which reported a 66.6% and 64% male predominance respectively. This could possibly be due to trauma being the most common cause of TMJ-A (Ellis, 1998; Ferretti *et al.*, 2005; Murad *et al.*, 2011) and males being more commonly affected by trauma than females.

4.2 AGE

The mean age at the time of surgery was 36.94 years and our sample had a wide age range (11 – 72 years). The overall age distribution was consistent with 38.6 years (15-59 years) and 41 years (15-68 years) reported by Wolford *et al.,* (2015) and Mercuri *et al*., (2007) respectively. By contrast, the TMJ-A group had a younger median (28 years) as compared to the non-ankylosis group (degenerative conditions = 55 years; pathology = 50 years and malocclusion = 50 years). This is due to high prevalence of TMJ-A in younger patients as a result of childhood trauma (predominantly due to falls), with subsequent mandibular condylar fracture(s) that were overlooked or never attended to. Moreover, Ellis (1998); Ferretti *et al.,*

(2005); Murad *et al.,* (2011) and Zimmermann *et al.,* (2006) reported that trauma is the most common predisposing factor to TMJ-A. Majority of ankylosis patients are only diagnosed later on in their early adulthood when they are more concerned about aesthetics and functional problems related to the facial asymmetry, restricted mouth opening and mandibular retrognathism. Some of the patients are referred by dental general practitioners when routine dental treatments pose a challenge due to limitations in jaw opening.

The findings in this study suggest that those patients requiring TMJ reconstruction are much younger (mean age of 36.94 in this study) when compared to those requiring hip and knee orthopaedic joint reconstruction, whose reported average age is 65 years (Fang et al., 2015).

4.3 DIAGNOSIS

This study has shown a high prevalence of post-traumatic TMJ-A, (N=18, 58.06%) consistent with the findings by Mercuri *et al*., (2007) that trauma was the main cause of TMJ problems.

Contrary to the findings in this study, Giannakopoulos *et al.,* (2012) and Wolford *et al*., (2015) reported osteoarthritis as the most prevalent diagnosis. Although there are global variations, the findings in this study (notwithstanding the small sample size) suggest that trauma and degenerative joint disorders feature prominently in the aetiology of end-stage TMJ diseases.

4.4 MAXIMUM MOUTH OPENING DISTANCE (MMO)

The pre-operative mean MMO between the 4 diagnosis groups was 1.83 mm for TMJ-A and 17.43 mm for degenerative conditions, 13.33 mm for pathology and 16.66 mm for malocclusion. These results were significant (P-value <0.0001) and the Post Hoc Bonferroni analysis showed that the difference lied mostly between TMJ-A and degenerative conditions. However, the results indicated that, beyond 3 months post-operative, the mean MMO was not different when all the diagnosis groups were compared (P-value > 0.05). The overall MMO significantly improved after total TMJ replacement (P-value <0.0001). The mean MMO improved by approximately 4-fold from pre-operative (7.32 mm) to 3 months post-operatively (32.3 mm) and decreased by 12.27% (to 28.77 mm) at 24 months post-operatively. However, the trend showed that MMO stabilized from 18 months post-operatively.

When MMO was analyzed against 2 different groups of age at the time of surgery (>30 years and <30 years), the results showed that those patients who were younger than 30 years had better outcomes than those older than 30 years. This could be due to the fact that most of the younger patients had ankylosis and their initial MMO was less than 5mm as compared to the non-ankylosis group where most of the >30 years old patients belonged. The post-operative MMO gained in the ankylosis group was many-folds more than that observed in non-ankylosis group. Even though the younger patients with TMJ-A improved better than the other groups, their MMO range remained lower than all the groups and the incidence of relapse was much higher as compared to the non-ankylosis groups. At 3 months post-operatively, the mean MMO improvement was higher in the ankylosis group which showed approximately fifteen-fold increase than in the non-ankylosis group. The degenerative condition group showed improvement of 44.54%, while pathology had 60.79% and malocclusion had 55.77%. It was also noted that in most patients, the MMO started to regress at approximately 12 months after surgery. At 24 months, the mean MMO decreased by 20.33% in ankylosis, 5.16% in pathology, 2.72% in malocclusion while it increased by 0.54% in degenerative conditions. Based on these results, one can infer that approximately 12 months post-operatively, most patients become complacent and stop doing the necessary mouth opening physical exercises.

There are number of factors that could also contribute to relapse in MMO, most of which are due to failure of patients to do jaw exercises:

- Muscle shortening and atrophy during the period of ankylosis which needs further stretching and lengthening during post-operative physiotherapy,
- Reduction in jaw function as a result of pain muscle and joint, as well as surgical site, and
- Healing of the surgical site with fibrosis of the tissues resulting in scar formation or heterotopic bone formation around the joint

Only one patient (3.23%) presented with mouth opening of less than 20 mm at 3 months after surgery. However, 5 (16.13%) patients had MMO measuring less than 20 mm at 24 months after surgery. Furthermore, in two patients, the mouth opening progressively reduced at approximately 10 – 12 months after surgery due to heterotopic bone formation. All these were observed in patients who reported to not be performing the post-operative mouth opening exercises.

THE TRENDS IN THE MEAN MAXIMUM MOUTH OPENING (MMO) COMPARED AGAINST GENDER, AGE, DIAGNOSIS AND COMPLICATIONS, AT DIFFERENT TIME-FRAMES

The general trend shown in this study was that 75% of patients could maintain MMO ≥25 mm at 24 months post-surgery, with only 25% able to maintain it as early as 3 months. Most males were fast in maintaining their MMO ≥25 mm and at a significant time of 6 months (P-value 0.0157) as compared to females who took longer (24 months). Those who were younger than 30 years of age at the time of surgery achieved the target relatively earlier than older patients (P-value 0.5478).

The difference between the times taken to maintain MMO ≥25 mm was not significant (P-value 0.2152), however, ankylosis patients achieved the target MMO at 12 months while all the other diagnosis groups took 24 months. Perhaps this could be as a result of enthusiasm expressed by patients who had TMJ-A when they can finally open their mouths. Likewise, only 4 of those with post-operative complications managed to achieve MMO ≥25mm and took only 3 months to do so. Majority of patients without complications took 24 months to maintain their MMO but the difference was not significant (P-value 0.1406).

The linear regression test analysing relationship between MMO and gender, age at the time of surgery and diagnosis, confirmed the trends on the Kaplan-Meier graphs. It showed that males, those under 30 years of age, and in ankylosis group did better in terms of MMO over time, as compared to females, those older than 30 years of age, and in non-ankylosis groups respectively.

4.5 OCCLUSION

Occlusion can be greatly affected by any change in the anatomical morphology of the condyles. Assessment of occlusion forms an important part of TMJ assessment and assist in grading the severity on the TMJ disease. Those patients who present with malocclusion before TMJ surgery, will benefit from a treatment option which can address both problems simultaneously. This could pose a challenge to the surgeons especially in cases where the malocclusion is severe. A decision could be made on whether the surgery should be a one-stage or multi-stage management.

Of the 31 patients in this study, 6 (19.35%) presented with pre-operative malocclusion. Occlusion remained unchanged in all patients who presented with an intact pre-operative occlusion. However, out of the 6 patients who presented with deranged pre-operative occlusion, only 2 patients remained with malocclusion after surgery. The causes of the malocclusion included unilateral idiopathic condylar hyperplasia, CCG overgrowth, TMJ ankylosis, trauma and pathology (osteochondroma). The degree of malocclusion ranged from mild with a few millimeters open bite (either anteriorly or posteriorly) to a more severe form associated with obvious facial asymmetry. In those who had post-operative malocclusion, restoration of occlusion was achieved after occlusal equilibration in one patient while the other patient required orthodontic correction due to the severity of malocclusion. The latter had severe malocclusion and facial asymmetry that a one-stage TMJ reconstruction using custom-made prostheses and orthognathic surgery (Le Fort I maxillary osteotomy and genioplasty) had to be performed.

4.6 PAIN

There was statistical significance in the reduction of pain after TMJ replacement with a P-value <0.05. The general improvement is similar to the results reported in other studies. However, our study had a pre-operative pain score median of 1 [IQR (0 - 2)] due to the fact that 58.06% of patients had ankylosis and did not report pain, as compared to other studies with most of their patients diagnosed with degenerative conditions and report moderate to severe pain (Leandro et al., 2013; (Giannakopoulos *et al*., 2012).

Twenty seven (87.10%) patients reported no post-operative pain while only 4 patients expressed post-operative pain. Two of these patients had complete pain resolution at 2 months and 6 months after surgery respectively. The other 2 patients had pain remission but generally improved from 1) severe unbearable pain not responding to analgesics, to moderate pain requiring regular analgesics; and 2) severe pain controlled only by opioids, to mild pain requiring no medication. Both of these patients were females. The former had severe form of rheumatoid arthritis associated with bilateral TMJ ankylosis and generalized polyarthralgia, while the other one suffered from osteoarthritis. This observation is similar to the one made by Mercuri *et al*., in 2007, where they noted that post-operative pain severity is highly dependent on pre-operative pain severity. In their study, those patients who reported severe pain before operation also reported a higher pain score after operation.

4.7 DIET AND CHEWING FUNCTION

Diet consistency and chewing function improved significantly after TMJ reconstruction (P-value <0.0001). None of the patients could have solid tough foods pre-operatively and 54.84% of our sample could only have liquid diet. Thirty (96.77%) patients expressed improved ability in eating normal solid foods as compared to having liquids or blenderized foods before the surgery. Only 1 patient reported that the diet consistency remained the same. This was not due to any restrictions in jaw function or pain but rather due to patient's preference.

4.8 QUALITY OF LIFE (QoL)

The quality of life after total TMJ replacement was significantly better than before the surgery (P-value <0.013). Furthermore, our results found that the QoL was not affected by relapse in post-operative MMO, pain and complications. Even those patients with post-operative complications, still reported better QoL (Table 3.7). The observation was similar to that seen in Burgess *et al*., (2014) study, where they noted that QoL remained significantly better even in those patients who reported long-term complications. Sanovich *et al*., (2014) also reported that pain and functional outcomes did not affect the QoL of the patients.

4.9 COMPLICATIONS

Eight patients reported post-operative complications, of which only one was permanent. There were 4 patients who presented with facial nerve injury, all of which involved only the temporal branch. Three of these patients had transient facial nerve weakness which resolved completely within 6 months post-operatively. The other patient had permanent paralysis of temporal branch of facial nerve with only forehead involvement. Although the preauricular approach has been widely reported to offer better access with less risk of facial nerve injury, Dolwick *et* al. (1982) reported a 32% incidence of post-operative nerve complication. In their study, 9 out of 28 patients had transient nerve weakness which resolved within 6 months after surgery.

Of the 31 patients, 2 (6.45%) developed minor keloids and 2 (6.45%) had heterotopic bone formation. One of the patients with heterotopic bone formation was re-operated on and the

bone was carefully removed from the fossa component. The mouth opening distance improved after surgery.

The number of sides operated on and the type of prosthesis used had no statistical significant effect on the development of complications, (P= 0.677 and P= 0.672 respectively). However, there was association between those patients who were operated previously and the occurrence of complications. Four (12.90%) patients had undergone previous TMJ surgery before alloplastic total TMJ reconstruction ranging from gap arthroplasty to gap arthroplasty and CCG. None of them had received alloplastic prosthesis previously. Three patients in this group presented with post-operative complications. Burgess *et al*., (2014) also reported similar results where the higher the number of previous surgeries each patient had, the more frequent the occurrence and the more permanent the complications were.

No periprosthetic joint infection was reported in the present study. TMJ prostheses infection is very uncommon and is mostly due to skin microflora which is introduced into the surgical site and onto the surface of the prosthesis at the time of placement (McKenzie *et al.*, 2017).

Only one revision surgery was performed for one of the patient with heterotopic bone formation, where careful removal of the bone which was only confined lateral to the fossa component of the joint, was performed. Long-term follow-up will determine if this prosthesis will need removal.

CHAPTER FIVE

CONCLUSION

5.1 SUMMARY

This retrospective study sought to report on the outcomes of patients who had alloplastic total TMJ replacement over a 10 year period in our institution. A total of 31 patients were included in the study. Temporomandibular joint ankylosis and degenerative joint diseases were the most common indications for alloplastic TMJ reconstruction. The mean age at the time of surgery was 36.94 years (median 31 years, range 11 – 72 years, SD 16.28). Patients diagnosed with ankylosis showed the most post-surgical improvement in terms of MMO, however, it also had 20.33% decrease in MMO 24 months after surgery. The overall MMO measurements stabilized from 18 months post-operatively in those patients who continued with or improved on the physical therapy exercises.

These results underscore the value of post-operative physiotherapy in the successful rehabilitation following TMJ reconstruction. Physiotherapy thus plays a pivotal role in the achievement of better outcomes.

Furthermore, the results suggest that more attention should be paid to motivating patients particularly from 1 year post-operative in order to prevent relapse in MMO.

We also found in this study that the presence of complications did not affect the quality of life of patients and that the occurrence of complications increases when patients have had previous TMJ surgeries. No prostheses complications were reported.

Comparatively, albeit our results showing general improvement in MMO, which is similar to that reported in literature, MMO in some patients decreased to some extent at approximately 18 months post-operative as compared to most reported studies where MMO increased (Leandro *et al*., 2013; Giannakopoulos *et al*., 2012; Mercuri *et al*., 2007).

Finally, our study demonstrated overall statistically significant improvement in all the measured variables which were similar to other studies that have been published on the outcomes of alloplastic total TMJ reconstruction. Our results showed that both objective and subjective outcomes significantly improved after joint replacement, confirming published data that alloplastic joints provide satisfactory clinical and functional outcomes.

5.2 RECOMMENDATIONS

Aggressive post-operative physiotherapy protocol is recommended to prevent relapse in mouth opening as well as close monitoring of patients and early assistance of those patients who present with restriction in mouth opening after TMJ-R surgery. In this regard, we recommend the following physiotherapy regimen to minimise the risk of heterotopic bone formation and other hypomobility disorders (Figure 5.1):

PROPOSED POST-OPERATIVE PHYSIOTHERAPY REGIMEN

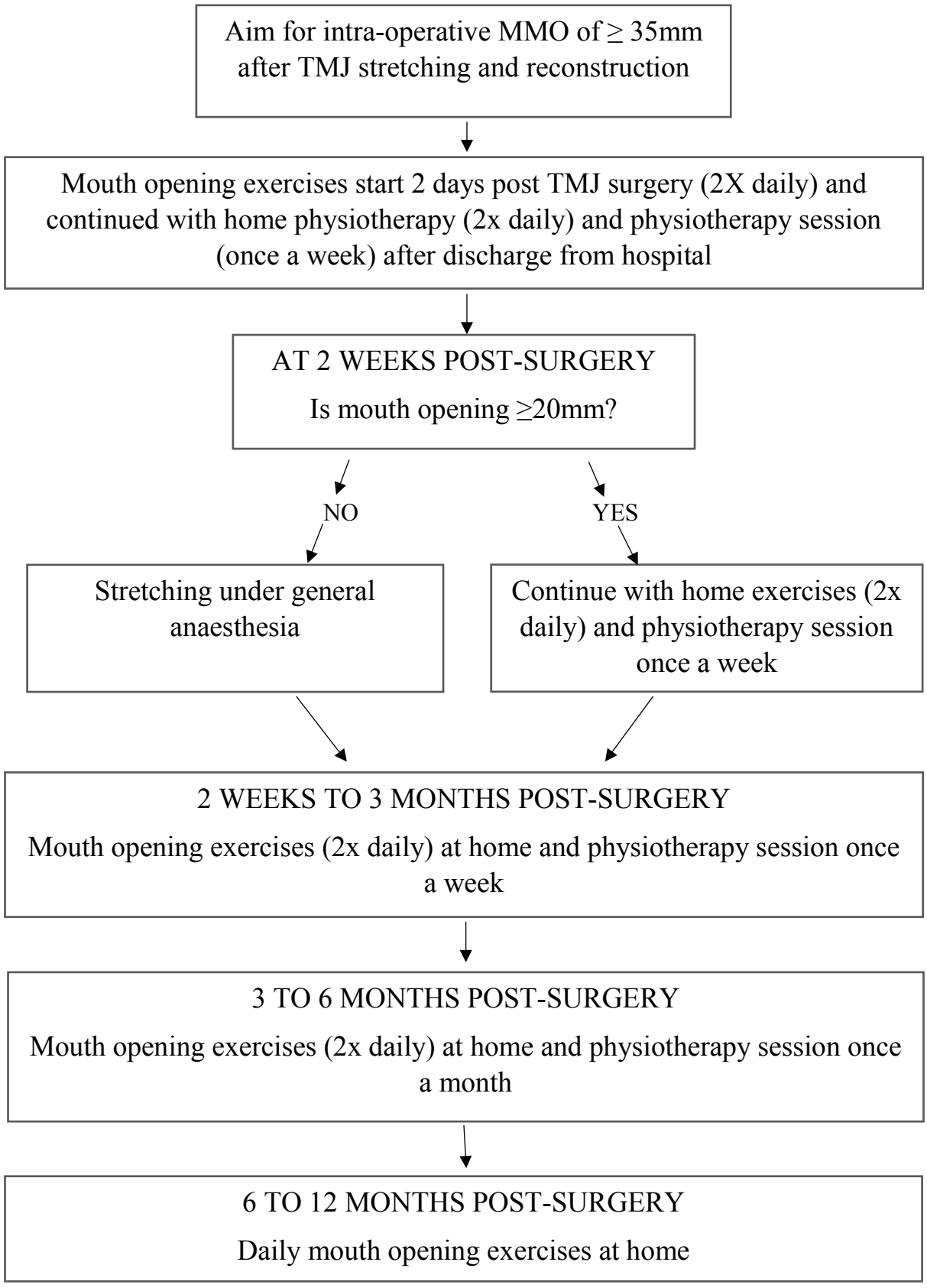


Figure 5.1. Proposed post-operative physiotherapy regimen

5.3 LIMITATIONS

Notwithstanding its limitations (such as the small sample size), this study has demonstrated that alloplastic joints are an efficacious option when TMJ reconstruction is indicated in adults. A larger sample size will assist in validating and strengthening the results in this study. Future studies will have to report on longer follow-up outcomes to validate these results and continue to report on long-term outcomes as well as complications. In particular, a prospective longitudinal study should be conducted to address some of the deficiencies associated with retrospective studies like unavailability of records.

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https://clinicalgate.com/temporomandibular-joint

www.zimmerbiomet.com

APPENDIX I:

INFORMATION SHEET

Department of Maxillofacial and Oral Surgery
School of Oral Health Science
University of Witwatersrand

Research: Total Alloplastic Temporomandibular Joint Replacement: A 10 Year Wits Experience

Good day.

My name is Mmathabo Gloria Sekhoto and I am a Registrar in the Department of Maxillo-Facial and Oral Surgery at School of Oral Health Sciences at the University of the Witwatersrand. I am undertaking this research project as part of my MDent training.

The aim of the study is to evaluate the clinical outcome of the artificial joint(s) that was used to replace your/ your child's diseased joint. I would like to use information from your/ his or her clinical records and the routine X-rays. Your/ his or her name and other personal details will not be used in the study and a specific identification code will be allocated to protect your/ his or her identity and maintain confidentiality. Your/ his or her participation in the study is completely voluntary and will not affect your/ his or her treatment.

In order to obtain meaningful information, it will be most helpful if you/ (s)he can return for check-up appointments to monitor the function of the joint(s). These check-up appointments are routine procedures for all patients irrespective of whether you are part of the study or not.

This study may give us a better understanding of how these artificial joints perform and will provide important information for the improvement of treatment.

If you are willing to participate in the study outlined above, please sign the informed consent form below.

Thank you

_____
MG Sekhoto
Principal Investigator

You can report any complaints/ problems to:

Human Research Ethics Committee, University of the Witwatersrand
Tel: (011) 717 1234

APPENDIX II:

INFORMED CONSENT

I, patient/guardian,..……..,
hereby give consent for myself/ my child, ……to be part of the study. I have been fully informed of the requirements of a study to determine the outcome and performance of artificial joints.

Patient/ guardian signature ……..

Date (DD/MM/YYYY) …….....

At (Place) ……

Principal Investigator …….
Mmathabo Gloria Sekhoto

Date (DD/MM/YYYY) …….....

At (Place) ……...

Witness: …….

Date (DD/MM/YYYY) …….....

At (Place) ……..

APPENDIX III:

FOLLOW UP FORM

Patient's Name & Surname: Hospital File Number: Age: Gender: Contact Details:	
Allocated Identification Code	
Diagnosis	
History of Diagnosis	
Date of Surgery (Year)	
Type of Prosthesis (Stock/Custom)	
Reconstructed side (Unilateral Right/Left or Bilateral)	
Pre-operative interdental/interalveolar mouth opening (mm)	
Post-operative interdental/interalveolar mouth opening (mm)	
Pre-operative occlusion	
Post-operative occlusion	
Follow-up Period	
Post-operative Complications	
Do above-mentioned complication(s) affect your day-to-day life? If Yes, how?	

APPENDIX IV:

ALLOPLASTIC TMJ –RECONSTRUCTION: QUALITY OF LIFE QUESTIONNAIRE

(TMJ-R-QoL)

A. PAIN?
0. I have no pain
1. There is mild pain but I do not need medication
2. I have moderate pain which requires regular analgesics e.g. Paracetamol
3. I have severe pain controlled only by strong analgesics e.g. Opioids
4. I have severe pain which is not controlled by analgesics
5. Worst, most unbearable pain ever

B. DIET and CHEWING?
1. I can chew and eat whatever I like
2. I can chew most things except tough foods like steak
3. I only stick to soft foods such as soft porridge and bread
4. I need to cut up all food into small pieces
5. I can only eat food that has been put through a blender or liquids.

C. Which issues have been uppermost in your mind before TMJ surgery?
a. Nothing
b. Pain
c. Limitation in mouth opening
d. Diet and chewing
e. Speech
f. Activity levels
g. Recreation
h. Mood

D. In general, how would you rate your health-related quality of life?
1. Excellent
2. Very good
3. Good
4. Somewhat better
5. About the same
6. Fair
7. Somewhat worse
8. Poor

MODIFIERS:

ACTIVITY?
1. I am as active as I have ever been
2. There are times when I cannot keep up with my old pace, but not often
3. I am often tired and have slowed down my activities though I still get out
4. I do not go out or do what I used to do very often because I do not have strength
5. I am usually in bed or chair and do not leave home

RECREATION?

1. There are no limitations to recreation at home or away from home
2. There are still few things I cannot do but I still get out and enjoy life
3. There are many times where I wish I could get out more but I am not up to it
4. There are severe limitations to what I can do, mostly I stay at home and watch TV
5. I cannot do anything enjoyable

MOOD?

1. My mood is excellent and unaffected by my disorder
2. My mood is generally good and only occasionally affected by my TMJ disorder
3. I am neither in a good mood nor depressed about my TMJ disorder
4. I am somewhat depressed about my TMJ disorder
5. I am extremely depressed about my TMJ disorder

(Question A to D should be answered for both pre-operative and post-operative assessment)

Alloplastic TMJ-R-QoL Questionnaire was adapted from the TMJ-S-QoL Questionnaire (Dimitroulis *et al*., 2010).

APPENDIX V:

ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Mmathabo Gloria Sekhoto

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180412

NAME: (Principal Investigator)	Dr Mmathabo Gloria Sekhoto
DEPARTMENT:	Wits Oral Health Care Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Alloplastic total temporomandibular joint reconstruction : A 10 year Wits experience
DATE CONSIDERED:	04/05/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Risimati Rikhotso
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	18/09/2018

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in April and will therefore be due in the month of April each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 25-09-2018

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX VI:

"Turnitin" REPORT

Dr

by Mmathabo1 Sekhoto1

Submission date: 13-Dec-2018 08:33AM (UTC+0200)
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