COMPARATIVE ANALYSIS OF ZYGOMATICUS IMPLANTS PLACED WITH THE INTRA-SINUS TECHNIQUE AND THE EXTENDED SINUS LIFT TECHNIQUE

By

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DECLARATION

I, Dr Rikotamenee Hange, the undersigned, hereby declare that the work contained in this dissertation: Comparative analysis of zygomaticus implants placed with the intra-sinus and extended sinus lift technique over a period of 96 months in the Maxillo Facial and Oral Surgery unit at Charlotte Maxeke Johannesburg and Chris Hani Baragwanath Academic Hospitals, is my original work and that it has not been previously in its entirety or part submitted at any University for a Degree. I also declare that all sources or information used in the writing of this thesis has been appropriately referenced.

R.Hange ***23/04/2020***

Rikotamenee Hange

ABSTRACT

Introduction

Posterior maxillary atrophy in particular presents a challenge for implant-supported dental rehabilitation. The discovery of the zygomaticus implant by Branemark and its modifications has brought a much-needed window of hope to most patients with atrophic maxilla. Techniques ranging from intrasinus to extended sinus lift technique are used to place zygomaticus implants. There is paucity of studies that have reported on the outcome of zygomaticus implants using these two techniques.

Aim: The aim of the present study was to compare treatment outcomes of zygomaticus implants placed via the extended sinus lift technique and the intra-sinus technique.

Materials and Methods: This was a retrospective record-based study of patients treated with zygomaticus implants after removal of tumors, trauma to the facial skeleton or edentulous maxilla due to premature loss of dentition. Records of patients restored with zygomaticus implants using the above two techniques were analyzed. Data such as age, gender, and type of treatment were recorded. The complications and success rates of the two techniques were analyzed using the assessment criteria designed by Aparicio (2010) (Annexure B). Data were analyzed and results presented as frequencies and percentages.

RESULTS: Over the period of the study, 60 (87.0%) of the study participants received zygomaticus implants via the extended sinus lift technique as compared to the intra-sinus cases where only 9 (13.0%) cases were treated**.** The success rate of the intra-sinus technique over the 96 months was found to be 77.8% while the success rate for the extended sinus lift technique was 100 %. Both univariate and multivariate analyses confirmed the association between sinus complication and type of procedure: more sinus complications were noticed in the intra-sinus

group than in the extended sinus lift group (66.7% vs. 1.7%), which was statistically significant (p value <0.001). The intra-sinus technique was also associated with a Lund –Mackay score of 14 (58%), compared to a score of zero with the extended sinus lift technique.

CONCLUSION: The extended sinus elevation technique has been shown in this study to have a superior advantage over the intra-sinus technique in reducing the risk of maxillary sinusitis, or other maxillary sinus complications. We however advise that the results of this study be interpreted with caution as there was a disproportionate distribution of patients between the two groups or two techniques. We also recommend that more large scale and balanced studies be undertaken to validate the findings of our study.

DEDICATION

I dedicate this research work to the Alpha and the Omega, the one who gives wisdom and direction and who helps those in needs with a joyous heart. I also dedicate this work to my three year old daughter, who during this needy time always accompanied me during the data collection stage, when her mother was not well.

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ABBREVIATIONS

CTCB: Computed tomography cone beam scan

CT: Computed tomography scan

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CHAPTER 1

Introduction and Literature Review

Restoring an edentulous and atrophied posterior maxilla is a challenging procedure for both the Maxillo-Facial and Oral Surgeon and the prosthodontist. Edentulous patients with an extremely atrophied maxilla present with a rather difficult situation for implant-prosthetic rehabilitation. Aparcio et al., (1993) found that the progressive bone resorption in the posterior maxilla, the pneumatisation of the maxillary sinus associated with an edentulous maxilla and the associated anterior alveolar resorption can substantially make it impossible for the restoration of these patients with fixed implant supported prosthesis. Typically these patients need extensive bone augmentation procedures in combination with sinus elevation procedures.

According to Branemark et al., (2001) bone grafting often require long theatre hours, extended hospital stay and longer period of healing before implants can be placed, which makes it practically impossible for immediate implant placement. Most of these patients are elderly patients with extensive co-morbidities that may hinder repeated surgical procedures and time-consuming treatment protocols.

Since the first pioneering work on zygomaticus implants by Aparicio et al., (1993), the zygoma has increasingly become a bone of interest in the facial skeleton, not only because it supports and gives shape to the facial skeleton but because it has become a window of hope for patients who have undergone extensive maxillectomy and elderly edentulous patients who at first could not obtain any practical mastication.

Hahn et al. (2001) studied human zygoma, using computed tomography and histo-morphometry. They found that the zygomatic bone consists of trabecular bone, which is unfavorable for placement of implants. The main factor determining the stability of the zygomatic implants was placement of the implants across four portions of cortical bone. From the above studies it was

found that the presence of wider and thicker trabeculae at the apical end of the fixtures promoted the initial fixation of the zygomatic implant.

Uchinda et al., (2001) measured the maxillary and the zygoma bones in 12 cadavers. They observed that the apex of a 3.75 mm-diameter implant requires a zygoma of at least 5.75 mm in thickness. They further on concluded that an angulation of 43.8 degrees or less increases the risk of perforating the infratemporal fossa or the lateral area of the maxilla, however if the angulation was more vertical, 50.6 degrees or more it was found to have an increased risk of perforating the orbital floor.

The zygomaticus implant was pioneered by Branemark in (1997) as a successful solution to the restoration of the challenging edentulous posterior maxilla. He found that the success rate of zygomaticus implants was 97% over a five-year period. The introduction of the zygomaticus implants has made it possible for clinicians to reduce the restoration time of the atrophic maxilla shorter by eliminating the need for elevation of the maxillary sinus floor for placement of maxillary implants. The introduction of short and bulbous implants, initially showed promising results, however latest data shows that their stability and retention is questionable and hence the zygomatic implant still remains the most predictable option.

According to Garcia et al. (2007), the original Branemark customized zygoma fixture was designed to be placed from the palatal aspect of the resorbed maxilla in the region of the second premolar, through the maxillary sinus into the compact bone of the zygoma. The initial design had features of a conventional implant; however the length and diameter were increased in the zygomaticus implant due to the longer path of insertion into the zygomatic bone. It was a self-tapping titanium implant with a machined surface and was available in a wide range of sizes, from 30-52.5 mm as described by Branemark et al., (2004). He also described that the threaded apical part had a diameter of 4mm and the crestal part had a diameter of 4.5 mm. The original connection was an internal hex to the implant abutments, with later modifications the implant head was modified to an angle of 45 degrees. The surface of modern day zygomatic implant has advanced to a moderately rough oxidised thread surface.

Aparicio, (2012) found that the zygoma implant has varied indications, which include the following.

- Severely atrophic edentulous maxillae, where bone augmentation /sinus lifting or other grafting procedures are not feasible with the current status of the maxilla.
- Total edentulism compounded by reduced maxillary bone height
- Bilateral free end saddles in the maxilla with insufficient bone height
- There is severe pneumatisation of the maxillary sinus and severe resorption of anterior maxilla
- Maxillary reconstruction after partial or total maxillectomy, mostly in cancer patients
- Used as a fixation method for maxillary obturators

The use of zygomaticus implants in patients who are medically compromised is contra-indicated in most surgical institutions. Patients with pre-surgical acute sinusitis, severe limitations of opening and inadequate anterior maxillary bone for placement of adequate conventional maxillary implants are not best candidates for placement of the zygomaticus implant

According to Bedrossian (2010), the maxilla has been traditionally subdivided into three zones, which are very pivotal in treatment planning of the edentulous maxilla. These zones are

- Zone I, the premaxilla
- Zone II, the premolar area
- Zone III, the molar area

Based on the above anatomical zones, Bedrossian (2010) discovered different surgical approaches or treatment options based on these important zones of the maxilla, especially the edentulous maxilla. There are traditionally four zones in the maxilla, and all of the anatomical zones are managed according to the presence of bone or not. An example if there is insufficient bone in all the zones explained above then the use of four zygomaticus implants is advocated. Traditional axial implants are used when bone is present in zone I, II and III and four tilted normal implants are best used when there is bone around zone I and II.

1.1. Methods of placement for Zygomatic Implants:

According to Corvello et al., (2010), there are two main methods of zygomatic implant placement described in the currently available literature on implant dentistry. The original technique was devised and described by the father of implantology, Branemark, and is known as the intra-sinus technique. This is the standard technique which has been used until the advent of the extra-sinus technique. The intra-sinus technique is a technique where the implant passes through the maxillary sinus with a window technique; it is most commonly used when the concavity formed between the maxillary sinus, ridge crest and the site of implant placement is small.

The extra-sinus technique as described by Aparicio et al., (1993) implies that the implant passes outside the maxillary sinus; it is commonly used when there is a bigger concavity in the area formed by the maxillary sinus, the ridge crest and the site of implant placement.

Stella et al., (2000) introduced a modification (The slot technique), which featured a minimal opening of the sinus wall via a narrow slot and following the contours of the malar bone and introducing the implant into the zygomatic process. They concluded that this technique avoided the need for fenestration of the sinus wall. Other researchers have since come up with modifications on the initial Branemark and Stella techniques.

Boyes-Varley et al., (2003) from a South African perspective however seems to not favour the sinus slot technique at all, since there is an increased risk of perforation of the posterior antral wall due to lack of visibility.

Recently Chow et al., (2010) proposed a new method of placement (placement of zygomaticus implants with extended sinus lift), which he described as having an added advantage of being associated with low risk of rhino sinusitis. This is a technique which is reported to attain a balance between zygomaticus implants stability and a healthy maxillary sinus. A lateral sinus lift with or without a bone graft is done at the time of placement of zygomaticus implants. The implants are

then placed in the potential space between the sinus membrane and the lateral wall of the maxillary sinus/medial wall/body of the zygoma. Both autogeneous and allografts have been successfully used for this technique.

The intra sinus technique is the traditional technique where zygomaticus implants are placed via or through the maxillary sinus at the time of placement.

The initial protocol of placement of zygomaticus implants as suggested by Branemark et al., (2004) involved placement of two to four maxillary implants in the anterior maxilla (paranasal) in addition to the two zygomaticus implants.

These implants were placed as below

- At the Ridge Crest
- The sinus floor
- The roof of the maxillary sinus
- The superior border of the zygoma

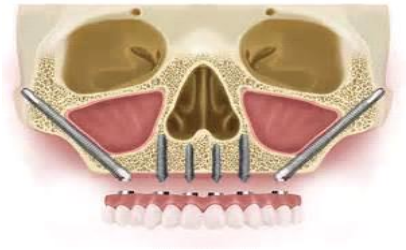

Figure 1 Branemark zygomaticus Implant technique (Branemark et al. 2004)

1.2. Complications of zygomaticus implants

Zygomaticus Implants are generally placed in close proximity to the maxillary sinus and like any surgical procedure/treatment; there have been evidence of complications.

The complications include the following, as reported by Aastha and Rajeev, (2016):

- Postoperative sinusitis
- Oro-antral fistula formation
- Periorbital and subconjunctival hematoma or oedema
- Lip lacerations, pain, facial oedema
- Temporary paresthesia to permanent anesthesia
- Epistaxis, gingival inflammation and orbital penetration/injury

Other complications, which are mainly associated with the palatal emergence of the zygomaticus implant, include defects in speech articulation and the inability of the patient to maintain good oral hygiene.

According to Chow et al., (2010) conventional placement of zygomaticus implant into the zygomatic bone with the traditional intrasinus technique is increasingly being associated with high failure rates mainly due to chronic sinusitis. There have been suggestions that the placement of zygomaticus implants with the extended sinus lift technique has a more predictable outcome compared to the traditional method.

Contradicting results on the outcomes of both intrasinus technique and extended sinus technique have been reported in literature. Davo et al., (2008) found no sinusitis in patients managed with intrasinus technique. Similarly, Chow et al., (2010) reported no sinusitis in patients treated with extended sinus technique.

Davo et al. (2008) evaluated 36 patients with 71 immediately loaded zygomaticus implants over 42 months and found no clinical signs or symptoms associated with the maxillary sinus. They concluded that maxillary sinus penetrated by zygomaticus implants maintained normal anatomy in the majority of patients. Chow et al., (2010) conducted a prospective study where the extended sinus lift procedure was used with a follow up period of 6-24 months. There were no reported incidents of failed implants or of sinusitis over the 2-year period, hence they concluded that the

extended sinus lift technique was predictable and fulfilled the purpose of lowering maxillary sinusitis.

Antonio et al., (2006), carried out a retrospective cohort study of patients who underwent zygomatic implant rehabilitation in the department of MFOS at the University of Verona with the intrasinus technique. The sample comprised of 41 patients, of whom 12% had preoperative sinus finding. After placement of zygomatic implants 46% of patients demonstrated sinus findings.

There is paucity of studies with long-term clinical trials to give a relationship between zygomaticus implant and rhino sinusitis. Anecdotal evidence however suggests that zygomatic implants placed with the extended sinus lift technique have an aided advantage and fewer complications as compared to the traditional intrasinus technique.

CHAPTER 2: RESEARCH DESIGN

2.1 Aim:

To compare treatment outcomes of zygomaticus implants placed via the extended sinus lift technique and the intra-sinus technique.

2.2 Objectives:

- To measure the success rate of zygomaticus implants placed with the intrasinus technique and the extended sinus lift technique
- To compare the complications associated with each of the techniques.

2.3 Significance of the Study

This study will add valuable data to the ongoing debate on the best technique for placement of zygomaticus implants. It is also envisaged that the recommendations from this research will enable the department of MFOS at the University of Witwatersrand to develop evidence based standard protocols for the rehabilitation of an edentulous maxilla or rehabilitation of patients who have undergone surgery for head and neck oncology and other benign tumors.

2.4 Hypothesis

There is no difference in the success rate between zygomaticus implants placed with the extended sinus lift technique and with the intra-sinus technique.

2.5 Materials and Methods

2.5.1 Methodology

This was a retrospective record-based study of patients treated with zygomaticus implants after removal of tumors or trauma to the facial skeleton. All implants were placed by one surgeon/operator from January 2008 to December 2016. Implants were placed using the intra-sinus technique (traditional technique where zygomaticus implants trespass the maxillary sinus at the time of placement) and the extended sinus technique. With the extended sinus lift technique, an extended rectangular bone window is cut according to the level of the sinus floor and sinus roof. The bony window is retained on the underlying mucosa while the sinus membrane is slowly and carefully elevated from the sinus walls. The retained bony window acts as a shield to protect the sinus membrane from direct damage the zygomaticus implant osteotomy. In addition, the implants were then placed in the potential space between the sinus membrane and the lateral wall of the maxillary sinus/medial wall/body of the zygoma. Both autogenous and allografts have been successfully used for this technique (when needed).

A  B 

Figure 2 (A) Extended sinus lift performed with retained bone. (B)Retained bone protect the sinus membrane from damage by the drills

Records of patients restored with zygomaticus implants using the above two techniques were analyzed. Patients records were allocated into two groups for easy of comparison and data analysis. The following information was taken from the records: age, gender, complications, and type of loading, indication for treatment and the outcomes of treatment.

Data were recorded in the data collection sheet (**Annexure A**). The complications and success rate of the two techniques were analyzed using the assessment criteria as designed by Aparicio (2010) (**Annexure B**). According to these criteria, four factors are used as the grading tools for success of zygomaticus implants:

- Zygomaticus Implant Stability (Individually tested)
- Associated Sinus Pathology
- Peri –implant soft tissue condition
- Prosthetic offset

Success of the zygomaticus implant is whereby there is no mobility of the individual implants, no associated pain, no recession around the implant surface and a prosthetic offset of less than 6mm. Lanza and Kennedy score (Lanza, Kennedy, (1997) records whether there is associated sinus pathology post placement of the zygomatic surface or not. This was used concurrently with the Lund- Mackay score (as used by Aparicio 2010 in **Annexure B**). The Lund- Mackay staging is a radiographic staging system of chronic rhino-sinusitis. This is a patient based score where patients' records with a score of zero are considered normal and those records with a score greater than zero are considered a failure.

Success rate was when there was no sinus pathology and thus the Lanza and Kennedy score was negative, and failure was when the score was positive. A Lund- Mackay score of zero is considered a success and a score greater than zero is considered failure as used by Aparicio (2010); however, this varies from one country to another. In this study a Lund-Mackay score greater than 2 was considered a failure while anything in the range of 1- 2 was considered borderline and any score less than zero was considered a success of the zygomaticus implant in terms of rhino sinusitis complications. Maxillary sinusitis and the bone loss around the implant fixtures were assessed using Cone Beam Computed Tomography (CBCT) Scans.

Failure of zygomaticus implants is, according to the clinical parameters listed above, when there is clear clinical mobility, (which can be assessed by two factors which include rotation of the implant or presence of pain) and the presence of or evidence of disintegration of the apical part of the implant. A positive Lanza and Kennedy test was considered failure as well as Lund-Mackay

score greater than zero. When there was recession or more than seven exposed threads this was considered a failure as well as a prosthetic offset of greater than 15 mm. (Lund, Kennedy et al, (1997).

The following complications of zygomaticus implants were recorded:

- Bone loss around implant
- Mobility of the implant fixture
- Threads exposure and recession
- Prosthetic offset
- Fractured zygomaticus implants
- Incidences of rhino-sinusitis and this were graded by the Lund- Mackay and Kennedy scores.

The complications above were recorded on the data collection table per each anonymous record and analyzed accordingly. An inter-observer was used during the analysis of the records.

2.5.2 Sample Size

Due to limited number of patient's records, convenience sampling was used. A total number of sixty nine patient files were analyzed.

2.5.3 Inclusion Criteria

- Patients followed up for a minimum of 3 months
- All patients rehabilitated by the operator at the practice concerned with the two techniques in comparison from January 2008 to December 2016.

- All patients who had both immediate and delayed loading and had functioned with their prostheses for a minimum follow up of 3 months.

2.5.4 Exclusion criteria

- Patients operated by different surgeons
- Patients with follow up period less than 3 months
- Patients with active bone pathology or undergoing chemotherapy or radiotherapy were excluded
- All patients with presurgical history of sinusitis were excluded.
- Patients with inadequate data or missing file

2.6 Data analysis

Data from the findings was captured into Microsoft Excel spread sheet. After cleaning the data, it was imported into Stata IC/13 software for analysis. Descriptive statistics were used to analyze the results. Bar charts, tables and graphs were used to illustrate the results. Fischer's exact test was conducted instead of Chi-square to test for significant group differences between categorical variables because some of the cells had less than five responses. A T-test was carried out to test the group differences of age, the only continuous variable. Multivariate logistic regression was then used to determine the variables associated with the outcome. P value of less than 0.05 was considered statistically significant.

2.7 Ethics

Clearance for the study **M190250 MED 19-02-013 (Annexure C)** was granted by the Human Research and Ethics Committee of Witwatersrand University. Permission to use clinical records was given by the operator (**Annexure D**). Anonymous codes were allocated to the patients. The identifiers to the codes were only accessible to the principal researcher.

Dissemination Plan

The findings of the research are intended to be published in one of the peer-reviewed journals.

CHAPTER 3: RESULTS AND ANALYSIS

3.1 Demographics

A total of 69 patient files were reviewed for this study, 35 (50.7%) of them were females while 34 (49.3%) were males. Over the period of the study, 60 (87.0%) of the study participants received zygomaticus implants via the extended sinus lift technique as compared to the intra-sinus cases where only 9 (13.0%) cases were treated**.** The total number of implants placed was 147 (123 for the extended sinus lift group and 24 for the intrasinus group). Mean age for the extended sinus lift and intrasinus groups was 55.6 and 61.1 years respectively**.** Table 3.1 shows the baseline clinical and demographic data of the study patients.

Table 3.1: Patient demographic and clinical characteristics

Characteristic	**Extended sinus lift technique (n=60) N (87.0%) %)**	**Intra-sinus technique (n=9) N (13.0%) %)**	**p-value**
Gender			0.734
Male	29 (48.3)	5 (55.6)	
Female	31 (51.7)	4 (44.4)	
Age (years)			0.3021
Mean(SE)	55.6 (1.98)	61.1 (4.45)	
Number of Implants			0.010*
1	18 (31.0)	3 (33.3)	
2	24 (41.4)	0 (0.0)	
3	1 (1.7)	0 (0.0)	
4	15 (25.9)	5 (55.6)	
5	0 (0.0)	1 (11.1)	

Follow-up (months)	60 patients	9 patients	0.228
1-6	10 (16.7)	1 (11.1)	
7-12	16 (26.7)	5 (55.6)	
>12	34 (56.7)	3 (33.3)	
Sinus Complications			<0.001*
No	59 (98.3)	3 (33.3)	
Yes	1 (1.7)	6 (66.7.)	

*P value <0.05

As shown in Table 3.1, the proportion of patients who went for either the extended sinus lift or an intra-sinus procedure did not differ by gender (p=0.734), age (p=0.302) or follow-up (p=0.228). However, for the extended sinus lift procedures, the majority of the patients had two implants placed while in the non-grafted group 5 of the nine patients had four implants placed (p=0.010).

Table 3.2: Factors associated with the use of the extended sinus lift procedure (univariate analysis)

Characteristic	**Crude Odds ratio**	**p-value**	**95% Confidence Interval**
Gender			
Male	1.0		
Female	0.350	0.231	0.063-1.948
Age	0.975	0.299	0.928-1.023

Number of implants	0.568	0.057	0.317-1.018
Follow up (months)			
1-6	1.0		
7-12	0.320	0.329	0.033-3.153
>12	1.133	0.918	0.106-12.129
Sinus Complication			
No complication	1.0		
Complication	0.006	<0.001*	0.0005-0.0731

*P-value <0.05

In the univariate analysis, only sinus complication was associated with the types of procedure. Patients who had complications were less likely to have undergone an extended sinus lift procedure (Crude Odds ratio: 0.006; 95% Conf. Int: 0.0005-0.0731) **(Table 3.2)** compared to those who had no complications. The p-value of number of implants was slightly above 0.05, this tended to show that the more the number of implants the lower the likelihood that the patient would have undergone an extended sinus lift procedure. However, other factors were not associated with the type of procedure, extended sinus lift procedure or an intra-sinus procedure The extended sinus elevation technique recorded a Lund-Mackay score of zero in terms of maxillary sinus complications, which denotes a healthy sinus where no abnormality was detected in all the cases, apart from the 1 case that presented with suppuration of the maxillary sinus and could not be part of the Lund-Mackay calculation. The intra-sinus technique had an overall Lund-Mackay score of 14 which is about 58.3% of the total maximum score (24) which is expected as the zygomaticus implants transverse the maxillary sinus (**Table 3.3**).

Table 3.3: The Lund –Mackay analysis of the results

Complication	**Extended sinus lift technique**	**Intra-sinus technique**
Opacified maxillary sinus	Score: **2** Number of Cases: 0 **Score : R+ L =0**	Score: **2** Number of cases: 2 **Score :R + L = 8**
Maxillary rhino sinusitis (Mucosal thickening /Inflammation	Score: **1** Number of Cases: 0 **Score L+R : 0**	Score: **1** Number of Cases 3 **Score :L+R = 6**
No Abnormality	Score : **0** Number of cases: 59 **Score R+ L = 0**	Score : 0 Number of cases: 3 cases **Score R+ L = 0**
Total Lund-Mackay Score	**0** *****0/24*100= **0%**	**14** *14/24 *100 = **58.3** %

Multivariable logistic regression was carried out to see the association between both sinus complication and number of implants and the type of procedure. Only sinus complication was significant, p<0.001 **(Table 3.4)**.

Table 3.4: Factors associated with the use of the extended sinus lift procedure (multivariate analysis)

Characteristic	**Adjusted Odds Ratio**	**p-value**	**95% Confidence Interval**

Sinus complication			
No complication	1.0		
Complication	0.006	<0.001	0.0005-0.0731

The number of sinus complications was 6 (66. 7%) for the intra-sinus technique as compared to 1 (1.7%) in the extended sinus elevation technique (Table 3.5). Of note is that, the one case in the extended sinus elevation technique was not due to frank rhino sinusitis but rather an infective process of the sinus mostly. The cases that presented with an opacified maxillary sinus were also more (2) in the intra-sinus group and as compared to the extended sinus elevation technique which had no cases presenting with an opacified maxillary sinus. Both the extended sinus and intra sinus technique all presented each with a case of suppuration from the maxillary sinus. All the other complications were not observed between the two groups, which included among them, periapical radiolucency, prosthetic fracture, numbness and or pain

There were 2 implants that failed and had to be removed from the intra-sinus group due to mobility (greater than 3 mm) associated with sinus complaints of the implants but none in the extended sinus elevation technique. The success rate over the two-year period was 100% and 77. 8% for the extended sinus lift elevation and the intra-sinus techniques respectively.

Table 3.5: Comparison of the Complications of the two techniques used

Complications	**The extended sinus elevation Technique (%)**	**The intra-sinus technique (%)**

Sinus Complications (Total)		
No	59 (96.7)	3 (33.3)
Yes	1 (1.7)	6 (66.7)
Suppuration maxillary sinus		
No	59(98.3)	8 (88.9)
Yes	1(1.7)	1(11.1)
Opacified Maxillary sinus		
Yes	0 (0.0)	2 (22.2)
No	60 (100)	7 (77.8)
Mobility of implants (>3mm)		
No	60 (100)	7 (88.9)
Yes	0 (0.0)	2 (22..2)
Radiographic Evidence of Peri-implant radiolucency		
Yes	0 (0.0)	0 (0.0)
No	60(100)	9(100)
Prosthetic fracture		
Yes	0 (0.0)	0(0.0)
No	60 (100)	9(100)
Others: Paraesthesia and pain		

Yes	0 (0.0)	0(0.0)
No	60(100)	9 (100)

P<0.001

CHAPTER 4 : DISCUSSION

The success rate of osseointergrated dental implants, especially when used in the posterior edentulous maxilla is significantly lower as compared to implants placed in the mandible, (Meyer et al 2001). The main factors which contribute to the higher failure rate of osseointergrated implants in the maxilla are poor quality and quantity of bone. Generally, maxillary bone has a lower bone density than mandibular bone (especially in the posterior regions) which makes it a challenging site for placement of osseointergrated dental implants.

The anatomy of the edentulous maxilla in terms of morphology and configuration has over the years proven to contribute to very low survival rates for conventional dental implants (Haung et al., 2014).

The restoration of the edentulous maxilla is quite a challenging process, especially the restoration of the posterior edentulous maxilla. Posterior maxillary atrophy in particular presents a challenge for implant-supported dental rehabilitation. There are a few factors which need to be considered carefully when planning restoring an atrophic maxilla, especially the posterior maxilla. Extensive pneumatisation of the maxillary sinus and inherent bone resorption associated with the posterior maxilla are major drawbacks to the restoration of the maxilla. The challenges surrounding the restoration of the edentulous maxilla has led to multiple emerging restorative options. The following treatment modalities have been suggested by Cawood et al., (1986) to address implant reconstructive challenges associated with severely resorbed maxilla:

a. **Bone augmentation/placement of normal dental implants**: Bone augmentation procedures can include procedures such as ridge split osteotomy, sandwich technique, interpositional and block grafts. According to Block et al., (2009), the survival rate of implant is lower for grafted maxillae compared to non-grafted maxillae, especially in the posterior region. In the same article, they reported that the use of autogenous grafts lead to a success rate of 87-95%. Keller et al, (1993) reported a success rate of 87% in the 248 implants placed in grafted maxillary bone.

These augmentation procedures can be done 3 months or in some cases 6 months prior to implant placement and at the time of implant placement in selected cases (Davo et al., 2008). The above

augmentation procedures, according to Fazard et al., (2006), have greatly improved outcome of implants in the rehabilitation of the atrophic maxilla.

b. Use of shorter bulbous implants (SOUTHERN IMPLANTS, MAX 6, 7, 8): These implants feature a body with a larger-than conventional diameter implants and they were initially designed to be placed on molar extraction sockets... Many clinicians are increasingly using them in large numbers especially in the posterior maxilla when there is extensive pneumatisation of the maxillary sinus and extensive bone resorption. Tellerman et al., (2011) conducted a randomized control trial and reported that placement of shorter implants, (less or equal to 7mm) in length is a predictable alternative for the rehabilitation of the atrophic posterior regions. They found that the survival rate and marginal bone loss between longer and shorter implants systems is comparable, and there is no significant differences in the survival rate reported between short and conventional implants. Reasons cited in the literature by Tellerman et al.,(2011) for the predictable success rate of shorter implants is that shorter implants' crest module is more involved in load bearing while lower stresses are transferred to the apical portion. From the above studies it can be concluded that the use of max implants has become a predictable method for rehabilitation of the edentulous posterior maxilla.

c. Sinus floor lifting /with bone augmentation: this novel procedure involves sinus floor lift with or without bone augmentation and simultaneous or delayed placement of normal osseointergrated implants. It has been used successfully with greater success rate as high as 90 % according to Aparicio et al, (1993). The shortcomings with this procedure commonly cited in the literature include infection of the graft, donor site morbidity, and unpredictable primary stability and inability to immediately load the implants in most cases.

The discovery of the zygoma implant by Branemark and its modifications has brought a much-needed window of hope to most patients with atrophic maxilla. The zygomaticus implant circumvents reliance on the atrophic maxilla as a site of implant placement but rather uses the zygoma body to place a long implant in the range of 32.5 mm to 55mm (Aparicio et al., (2010). The zygoma implant eliminates the need for bone graft (such as sinus augmentation or guided bone regeneration) which is often associated with increased donor site morbidity. The total treatment time is also greatly reduced by omission of the bone graft, as the usage of the bone graft may prolong the rehabilitation process by 3 to 6 months. Outcome of zygomaticus implant as reported

in the literature is said to supersede any bone grafting/implant technique for managing patients with severely resorbed maxillae. The use of zygomaticus implants is associated with shorter hospitalization as the bone grafting procedure is avoided. The zygomaticus implant also allows usage of the patient's own dentures as a temporary restoration. The cost of the zygomaticus implant is almost similar to the graft used with the placement of conventional implants. The number of supporting implants is greatly decreased with the use of the zygomaticus implants and this correlates to low complications rates.

The main drawback to the use of the zygomatic implant is the complexity of implant placement as well as the emergence of implant head in the palatal region resulting in an excess bulk of the prosthesis, negatively affecting the patient's speech and comfort. The difficulties to articulate and to perform oral hygiene adequately are some of the common issues associated with excess protrusion of the implant head. The zygomatic implant may be associated with complications such as maxillary sinusitis, oroantral fistula formation, periorbital and conjunctiva hematoma and oedema, temporary paresthesia in the distribution of the infra-orbital nerve, epistaxis and or orbital injuries (Block et al., in 2009).

Pre-existing sinus pathology, perforation of the sinus membrane, marginal bone loss around zygomatic implants and inadequate oral hygiene at zygomatic implant sites have been proposed as aetiologic factors for the development of maxillary sinusitis. Chen et al., (2009) also found that the limited intra-operative visibility, complexity of anatomical structures and intricacies of zygoma curve has made this procedure technically demanding.

Clinicians involved in placement of zygoma implants surgery have traditionally used either the intra sinus technique or the complete extra sinus technique. Both of the two pioneering techniques have been shown to have a few shortcomings. The traditional intrasinus technique has been associated with an increased number of cases presenting with rhino sinus complications. This was shown by a substantial number of studies with longer follow-ups, among them Antonio et al., (2006).

Even though the extra-sinus technique has been shown to have a low incidence of sinus complications post placement of the zygomaticus implants, anecdotal evidence suggest that it is

less stable than the other techniques. It is also associated with an increased risk of implant threads exposure, which is a major esthetic challenge (Aparicio et al, 1993).

Given the challenges cited in the literature with the current techniques of zygomaticus implants placement, there is a need for extensive research in order to find the technique with minimum complications for placement of zygomaticus implants. In trying to expand on the current evidence and to towards the body of knowledge of zygomaticus implants, this retrospective analysis was undertaken to assess treatment outcomes of patients rehabilitated using intra-sinus and the extended sinus lift technique and elucidate complications that occurred in these cases.

Over the period of the study, 60 (87.0%) of the study participants received zygomaticus implants via the extended sinus lift technique and only 9 (13.0%) cases were treated with the intra-sinus technique. The mean age of patients where the extended sinus elevation technique was used was 55.6 years, and 61.1 years for the intra-sinus technique. This study is in agreement with the common trend on most zygomaticus implants studies, which have demonstrated a higher mean age for patients requiring zygomaticus implants (Chow et al, (2010). It is the elderly patients who generally presents with severe atrophy of the alveolar ridges. In addition, patients with post ablative defects are generally not young patients.

4.1. SUCCESS RATE OF ZYGOMATICUS IMPLANTS PLACED WITH THE INTRA-SINUS VS THE EXTENDED SINUS ELEVATION TECHNIQUE

The success rate of the intra-sinus technique was found to be 77.8% while the success rate for the extended sinus lift technique was 100 %. The schirmer test was applied to the above results and this was statistically significant with a P value<0.05.

The high success rate in the extended sinus lift technique in the present study as compared to the intra-sinus technique is comparable to many recent studies. Chow et al., (2010) followed up 16 patients from 6 months to 24 months in which the extended sinus lift technique was used. There were no failed zygomaticus implants, and no instances of maxillary sinusitis in all the cases. The success rate in their study (defined asymptomatic function with a fixed prosthesis, clinical stability

without mobility and lack of sinus infection clinically and radiographically) was 97%. They concluded that the approach that combined the placement of zygomaticus implants with the extended sinus lift procedure was very predictable and fulfilled the purpose of lowering the risk of maxillary sinusitis. These findings concur with our findings in that in the 60 patients where the extended sinus elevation technique was used, there were no failed implants or implants that had to be removed due to adverse complications. Similar higher success rates or lower complication rates associated with the extended sinus lift technique were also reported by D'Amato et al., (2017).

Ji-Youn et al., (2010) also conducted a study to evaluate the effectiveness of the extended sinus technique. In all the eleven patients restored with the extended sinus elevation technique, they found that all the zygomaticus implants were well maintained after five years of function with a cumulative success rate of 100%. The mean residual bone height, augmented bone height, crown to implant height and marginal bone loss were 4.1+/- 1.64 mm, 8.76 mm, 1.21 mm and 0.34 mm, respectively. These findings are coherent with the findings of the current study where a success rate as high as 96.7% was recorded when the extended sinus elevation technique was used.

To further evaluate the behavior of the maxillary sinus after the placement of zygomaticus implants with the intra-sinus technique in patients with severe atrophy, Hilario et al., (2017), conducted a 10-15 year retrospective follow up study. In the 18 patients they reviewed with a total of 34 zygomaticus implants placed, seven failed, resulting in a survival rate of 79.5%. Seven patients (38.8%) had involvement of the maxillary sinus. One of the patients was diagnosed with rhino sinusitis and 6 with odontogenic sinusitis. A total of 3 implants were removed due to mobility and four implants had their coronal component cut off through a window in the sinus. These results closely resemble our findings with the use of the intra-sinus technique. Their sample size was however slightly higher than ours. Other studies have also shown the same trend with the two techniques, demonstrating that the intra-sinus technique is associated with the higher cases of postoperative sinusitis when compared with the extended sinus technique, (Antonio, 2006). This is consistent with the fundamental principle that the sinus membrane has an osteogenic potential and at the same time it is a very sensitive environment which can react to foreign objects transversing the sinus, hence the recorded higher cases of rhino sinus disease with the intra-sinus technique (Anderson et al., 2008).

Another issue with the intra-sinus technique is palatal emergence of the implant head which cause serious difficulties with phonetics, comfort, hygiene and its effect on the future of the prosthesis (Branemark, Stella et al., 2000). For this reason, where possible, extra-sinus implants are preferred since they can improve the intra-oral emergence towards a more crestal position as well as reduce sinus complications (Nocella et al., 2020).

Contrary to the findings in this study, Davo et al., (2008) and Balshi et al., (2009) have reported higher success rates with the intrasinus technique (95% and 96.37% respectively).

4.2. COMPLICATIONS

In the present study there were more sinus complications in the intra-sinus group than in the extended sinus lift group (66.7% vs. 1.7%, which was statistically significant $p<0.001$).

In the nine patients in whom the traditional intra-sinus technique was used, a total of 6 patients had rhino sinus complications. These sinus complications involved 3 cases with chronic maxillary sinusitis, 2 patients with suppuration from the maxillary sinus and 2 patients with an opacified sinus on the CTCB. The cases that presented with an opacified maxillary sinus were also more in the intra-sinus group, i.e. two cases (3.3%) as compared to the extended sinus elevation technique which had no cases presenting with an opacified maxillary sinus. Both the extended sinus and intra sinus technique presented with a case each of suppuration from the maxillary sinus which could have been due to contamination of the implant or the sinus at the time of placement. Candel-Marti et al., (2012) reviewed all studies from 1987 to 2010 to evaluate the success of zygomaticus implants. They found that the weighed success rate was 97.05%, and that the most frequent complication was maxillary sinusitis, especially in the patients where the intra-sinus technique was used (observed frequency of maxillary sinusitis of between 1.85 and 18.42%).

This clearly supports the findings of the present study. In the nine patients where the intra-sinus technique was used, six cases had maxillary sinus complaints/complications. The maxillary sinus is an inert and versatile environment which when transversed by a foreign body, an implant in this case, does form a foreign body reaction to the offending object, which can be either immediate or delayed. The reaction was a delayed one in the present study. It is for this reason that placement

of zygomaticus implants is contra-indicated in patients with active maxillary sinus pathology (and those with a history of use of IV bisphosphonates and recent radiation), hence their exclusion from this study. There is however a growing body of evidence that seems to suggest that the presence of chronic sinusitis is not an absolute contra-indication for zygomaticus implants placement (Weyh et al., 2020), however long-term studies are required to validate this hypothesis.

Other complications such as periapical radiolucency, prosthetic fracture, numbness and or pain such as were not observed in both study groups.

Hinze et al., (2013), also conducted a cohort study on zygomaticus implants placed with the extended sinus elevation technique and found an implant survival rate of 90.9% for zygomaticus implants. They reported that the clinical indicators which were probing pocket depth, keratinized tissue plaque and bleeding index were good in all patients. They concluded that this technique leads to successful prosthetic function for all patients. Both the potential for biologic complications and exposed implants threads within the maxillary antrum were minimized using the extended sinus elevation technique. All the other factors assessed however recorded a 0% complication rate for both the intra-sinus and the extended sinus lift technique. This confirms that the major factor of comparison between the two techniques is indeed maxillary sinusitis.

There were two implants that failed and had to be removed from the intra-sinus group due to mobility (of more than 3 mm) associated with sinus complication but none in the extended sinus elevation technique. While this was the case with the intra-sinus technique, the opposite was found with the extended sinus lift technique, where no implant had clinical mobility. This finding is similar to that described by Chow et al., (2010), where they followed up cases where the extended sinus lift technique was used from 2007 to 2009. There were no failed zygomaticus implants in their study either due to mobility of the implants or fracture, and no incidences of maxillary sinusitis.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

Posterior maxillary atrophy presents a challenge for implant-supported dental rehabilitation. Zygomaticus implants allow for optimum and predictable implant-supported dental rehabilitation whilst avoiding the morbidities associated bone-augmentation procedures. Chronic sinusitis is the most common complication associated with zygomaticus implants. This study aimed to compare treatment outcomes of zygomaticus implants placed via the extended sinus lift technique and the intra-sinus technique.

Over the period of the study, 60 (87.0%) of the study participants received zygomaticus implants via the extended sinus lift technique as compared to the intra-sinus cases where only 9 (13.0%) cases were treated**.** The success rate of the intra-sinus technique over the 96 months was found to be 77.8% while the success rate for the extended sinus lift technique was 100 %. Both univariate and multivariate analyses confirmed the association between sinus complication and type of procedure: more sinus complications were noticed in the intra-sinus group than in the extended sinus lift group (66.7% vs. 1.7%), which was statistically significant (p value <0.001). The intra-sinus technique was also associated with a Lund –Mackay score of 14 (58%), compared to a score of zero with the extended sinus lift technique.

The findings of this retrospective review seem to support the null hypothesis that the extended sinus elevation technique has a superior advantage over the intra-sinus technique in reducing the risk of maxillary sinusitis or other maxillary sinus complications.

The major drawback to our study is the retrospective nature of the study and the disproportionate distribution of the cases between the two groups. In addition, a longer and standardized follow-up would have added value to the study.

Notwithstanding its limitations, this study has added some data to the growing evidence of the superiority of the extended sinus lift technique over the intra-sinus technique. Future prospective randomized studies with a balanced representation of both techniques are recommended.

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ANNEXURE A: DATA COLLECTION SHEET

Unanimous Number				Variables used				
	Age	Gender	Indications	Technique used	Follow-up period	Type of loading	Outcomes of Treatment	Complications
A								
B								
C								
D								
E								
F								

ANNEXURE B: APARICIO ASSESSMENT CRITERIA

Table 5. Zygomatic Success Code

Criteria	Condition I Success grade I	Condition II Success grade II	Condition III Success grade III	Condition IV Failure
Criterion A: zygomatic implant stability (individually tested)	No mobility No pain	Light clinical mobility No pain	Clear clinical mobility (no evidence of disintegration of the apical part of the implant or rotation) No pain	Clear clinical mobility (evidence of disintegration of the apical part of the implant) Rotation and/or pain
Criterion B: associated sinus pathology (Aparicio et al. (9))	Lanza and Kennedy test (−) Lund-Mackay score = 0	Lanza and Kennedy test (+) Lund-Mackay score = 0	Lanza and Kennedy test (−) Lund-Mackay score >0	Lanza and Kennedy test (+) Lund-Mackay score >0
Criterion C: peri-implant soft tissue condition	No recession	Light recession. Implant head is visible (yuxta-gingival) No exposed threads	Recession. Up to seven exposed threads	Recession. More than seven exposed threads
Criterion D: prosthetic offset*	0 mm ≤ D ≤ 6 mm −3 mm ≤ D ≤ 0 mm	6 mm < D ≤ 10 mm −4 mm ≤ D < −3 mm	10 mm < D ≤ 15 mm −5 mm ≤ D < −4 mm	D > 15 mm D < −5 mm

Description of the specific criteria (A, B, C and D) classifying zygomatic implants as successful (Grades I, II or III) or failed (Grade IV). The green color indicates success. The red color is considered as unacceptable (implant failure). Zygomatic implants are scored using a code consisting of four digits, each representing one specific criterion of success. A number is given depending on the condition of each criterion (for example, 1/3/2/1). The success grade of the implant is determined by the worst condition of the four criteria (i.e. 1/3/2/1 would be classified as success Grade III).
*Prosthetic offset (D): distance from the center of the implant head to the center of the residual alveolar ridge. Positive values correspond to zygomatic implants placed palatally and negative values correspond to zygomatic implants placed buccally to the alveolar crest.

ANNEXURE C: ETHICAL CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Rikotamenee Hange

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M190540

NAME: (Principal Investigator)	Dr Rikotamenee Hange
DEPARTMENT:	Maxillo Facial and Oral Surgery Dr Boyes Varley Practice Sandton
PROJECT TITLE:	Comparative analysis of zygomaticus implants placed with the extended sinus lift technique and the intrasinus technique
DATE CONSIDERED:	31/05/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr B Varley and Prof E Rikhotso
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	31/05/2019

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 **May** and will therefore be due in the month of **May** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

ANNEXURE D: CONSENT TEMPLATE AND PERMISSION TO USE DATA

Department of Maxillo-Facial and Oral Surgery
Telephone: 0117172130
E-mail: liza.huygen@wits.ac.za

06/03/2019

Dear Dr R Hange

PERMISSION TO USE DATA FROM DR BOYES VARLEY PRACTICE

As per your letter dated 30/12/2017 ,where you requested for permission to use the clinical data on the patients files restored with zygomaticus implants using the intrasinus and extended sinus techniques over a period of 8 years.

It is with great pleasure that I grant you full permission to use the clinical data for the purpose of the above research as requested. Kindly note this is confidential information and it must be used for the purpose of research. It is envisaged that this research will benefit our patients and the University of Witwatersrand. Patients have granted the operator and the registrar to use the data for the purpose of teaching and research.

The results of the above research must be made available to the practice at which the research is being carried out.

Yours sincerely,

Dr G. Boyes Varley
Maxillo facial and Oral Surgeon
Morningside Private Hospital