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Article

Clinical Analysis of TMJ Replacement Using a Customized Prosthesis

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Abstract: The TMJ prosthesis is a valuable and effective tool in different clinical conditions. This study aims to uncover the variables related to the success of the intervention. A retrospective study was conducted on patients who underwent joint replacement surgery utilizing a customized alloplastic system between 2018 and 2023, comprising subjects with complete records for both the planning and follow-up phases. The Student's t-test was applied with a significance threshold of $p < 0.05$. Forty-eight subjects were admitted for initial analysis, and 31 subjects were evaluated with a minimum follow-up of 1 year and a maximum of 7 years with a mean age of 36.37 15.53. The TMJ diagnosis was mainly with degenerative TMJ disease followed by ankylosis and craniofacial syndromes, and an average of 2.1 1.2 previous surgeries were noted. Degenerative joint disease correlated with increased pain (p=0.0001) and a higher prevalence of prior joint surgery (p=0.0001). Thirty-one subjects were followed up with 47 prostheses installed; 74.4% underwent complementary surgery with other facial osteotomies. Significant improvements (p<0.0001) were observed when comparing pain levels pre- and postoperatively, with a decrease from 5.5 (2.3) to 2.2 (0.4). Concerning the interincisal opening, there was a significant increase (p<0001) from 25.85 (10.2) mm to 35.93 (± 4.2) mm in mouth opening. TMJ replacement treatment is efficient and effective, demonstrating stability in follow-up assessments for up to 7 years. The indications for replacement are diverse and may benefit patients who have not yet progressed to end-stage TMJ disease.

Keywords: TMJ prosthesis; orthognathic surgery; TMJ disease; patient-specific implant

1. Introduction

The temporomandibular joint (TMJ) replacement prosthesis is an increasingly used tool. Some analyses have shown that the volume of interventions for TMJ replacement by joint prostheses will increase by more than 60% in the coming years [1]. The market has provided answers to this demand with the entry of new players presenting a wide range of joint prostheses [2] built in different countries based on the concept of a component for the fossa and a component for the condyle.

The indication for the use of joint prostheses is currently in agree with international standards defined by patients and practitioners. Controversies have emerged regarding the indications for surgery in children and adolescents [3] and the optimal timing for its implementation. Early intervention may prevent significant changes in mandibular features and the stability in maxillomandibular function, and overall quality of life [4]. The TMJ degenerative disease, for example, shows the progressive reduction in patient's functional capabilities and quality of life,

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making the time from the onset of symptoms to the decision to use the prosthesis critical to treatment success [5].

The use of the TMJ prosthesis is typically related to degenerative TMJ disease, management of facial malformations, and conditions such as trauma and ankylosis. At least half of the cases require complementary orthognathic surgery [6], which involves a highly specialized network for surgical planning and development. It is always important to mention that patients' functionality before joint replacement surgery is compromised, showing limitations in various functional aspects, as well as in maxillomandibular anatomy [7], thereby presenting a complex challenge for the comprehensive restoration of the patient's function and quality of life.

This study aims to perform a medium and long-term clinical analysis of the function observed in patients undergoing uni or bilateral joint replacement and the characteristics of their surgical planning and execution.

2. Materials and Methods

A retrospective multicenter study evaluated the clinical condition of patients treated unilaterally or bilaterally with TMJ prostheses. Patients in Chile and Brazil who received joint prostheses with a sequential and organized clinical records and follow-up data were included. The group was divided into patients with diagnostic information and patients with follow-up data due to the loss of follow-up for some patients. Subjects with partial records in any of the analyses were excluded.

The patients underwent surgery from 2018 to 2023, with a minimum follow-up period of one year included in the study. All surgeries adhered to a standardized protocol utilizing the same prosthetic system (Enterprises, Artfix Implants, Pinhais, PR, Brazil), which comprises a fossa element made of high molecular weight polyurethane bonded to a titanium alloy alongside a condylar element featuring a ramus segment fabricated from titanium alloy and a condylar head composed of a metal alloy. All prosthetic systems were customized using a software system, from record acquisition to planning, printing, and device installation.

Preoperative variables like diagnosis, pain conditions, type of diet, maxillomandibular function, and surgery variables such as inclusion of orthognathic surgery were analyzed. For the follow-up stage, variables such as pain, kind of diet, opening and closing conditions, among others, were studied.

The data analysis was performed with the Graph Prism software version 10.4.1. The Shapiro-Wilk test was used for the normal distribution analysis. The Student's t-test was used to evaluate and compare the variables, considering the value of $p<0.05$ as a significant difference.

3. Results

Of the 48 joint prosthesis candidates (Table 1), degenerative joint disease (52.08%) was the most frequent, followed by ankylosis (14.58%), craniofacial syndrome (12.5%), condylar tumor (12.5%), and idiopathic condylar resorption (8.33%). In relation to the affected joint side, subjects with ankylosis, craniofacial syndrome, and condylar tumor had a greater incidence of unilateral disease ($p=0.06$), whereas subjects with degenerative joint disease had a higher prevalence of involvement in both TMJs ($p=0.03$).

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Table 1. Descriptive analysis of the clinical characteristics at the diagnostic stage and their relationship with joint pathologies.

	Degenerative diseases (n:25)	Condylar resorption (n:4)	Craniofacial syndrome (n:6)	Ankylosis (n:7)	Tumors (n:6)	
	N	N	N	N	N	P<0.05
Unilateral affected TMJ	9	2	5	4	6	0.06
Bilateral affected TMJ	16	2	1	3	0	0.03*
Presence of joint pain	25	2	0	2	2	0.0001*
Previous TMJ surgeries	23	4	3	6	2	0.0001*

Forty-eight subjects treated with TMJ replacement with a mean age of 36.37 ± 15.53 were included. When analyzing the diagnosis of facial deformity (Table 2), more subjects had facial asymmetry, followed by subjects with class II deformity (CII) and subjects with class III deformity (CIII). The TMJ diagnosis showed that 93.75 % of the CII subjects presented degenerative TMJ disease, while in the subjects with facial asymmetry, 34.48 % presented degenerative TMJ disease, followed by 24.13 % with ankylosis and 20.68 % with craniofacial syndromes. CIII facial deformity was observed only in subjects with condylar tumors.

Table 2. Description of the diagnosis of pathologies affecting the TMJ in relation to sex and facial deformity.

	Sex		Facial Deformity		
	M (n:11)	F (n:37)	CII (n:16)	CIII (n:3)	Asymmetry (n:29)
Degenerative disease	2	23	15	0	10
Idiopathic condylar resorption	2	2	1	0	3
Craniofacial syndrome	2	4	0	0	6
Ankylosis	4	3	0	0	7
Condylar tumor	1	5	0	3	3

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Concerning pain and prior surgeries, 70% of the subjects exhibited pain with an opening range of 27.76 ± 12.68 mm and an average of 2.1 ± 1.2 previous surgeries, with arthrocentesis, discopexy and disectomy being the most frequent. Degenerative joint disease was associated with a greater presence of pain (p=0.0001) with an average VAS scale of 5.8 ± 2.4 and a higher prevalence of previous joint surgeries (p=0.0001).

Due to the study's design and the patients' follow up, 17 subjects lacked sufficient data; therefore, the analysis of patient follow-up and surgical details was performed on 31 subjects in the cohort.

The average age of the 31 subjects who underwent joint replacement surgery was 37.16 ± 17.82 years; 5 (16.12%) were male, and 26 (83.87%) were female. Regarding facial diagnosis, 19 had facial asymmetry, and 12 had a CII facial deformity. In the TMJ diagnosis, 18 had osteoarthritis, 5 unilateral condylar tumor, 3 ankylosis, 3 hemifacial microsomia, 1 rheumatoid arthritis, and 1 idiopathic condylar resorption; 67.74% had significant restrictions in oral opening.

Sixteen bilateral joint replacements and 15 unilateral replacements were performed, for a total of 47 prostheses installed. Of the 31 subjects, 77.41% had complementary surgery with other facial osteotomies. Of the 16 subjects who required bilateral prostheses, 11 underwent Le Fort I maxillary surgery, and 6 underwent genioplasty. Of the 15 unilateral joint replacements, 10 required maxillomandibular surgery, and 3 required only mandibular surgery. It was noted that subjects with bilateral joint replacements have a significantly higher rate of Le Fort I osteotomy (p<0.003).

Total surgery time was 9.05 ± 3.2 hours for bilateral prostheses and 7.8 ± 2.2 hours for unilateral prostheses. The average follow-up was 38.09 ± 26.6 months with a range of 12 to 104 months. It was observed that 38.7% of the subjects presented some type of localized facial nerve alteration, one subject presented muscle pain, and another a postoperative occlusal alteration. All subjects underwent postoperative physiotherapy, and no further surgery was required to correct or modify any aspect of the TMJ prosthesis. Regarding the assessment of pain using the VAS scale (Table 3), was observed significant differences (p<0.0001) when comparing pain in the pre- and postoperative pain levels, with a reduction from 5.5 ± 2.3 to 2.2 ± 0.4. In relation to the interincisal opening, there was a statistically significant increase (p<0001), improving from 25.85 ± 10.2 mm to 35.93 ± 4.2 mm after follow-up. No prosthesis was removed, and no infectious process was observed on the follow-up.

Table 3. Comparative analysis of pain and interincisal opening at the diagnostic (T0) and postoperative (T1) stages.

	T0	**T1**	
	X	**X**	**P<0.005**
Pain VAS	5.5 ± 2.3	2.2 ± 0.4	0.0001*
Incisal opening	25.85 ± 10.2	35.93 ± 4.2	0.001*

4. Discussion

The results of this study show a stable surgical protocol with favorable follow-up outcomes extending up to 7 years for TMJ replacement using a customized system comprising a fossa component and a condyle component

Today, TMJ prostheses are a reliable and efficient option for managing joint-destructive diseases. All management of TMJ dysfunction requires initial non-surgical or conservative treatment [8,9] because a large percentage of patients will be able to improve their functional condition with the initial therapy. However, a smaller group of patients will have repeated failures with these techniques and will require early and advanced surgical management to obtain favorable results and

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mitigate potential complications [10,11]. The subjects included in this study underwent surgery beginning in 2018, indicating significant time for managing.

Patients treated with TMJ prostheses have a history of joint disease; Amarista et al.[12] reported on a series of 28 patients undergoing replacement surgery for TMJ ankylosis or fibrous ankylosis, where 75% of the patients had 1 or more TMJ surgeries before prosthesis installation, the main etiology being trauma or degenerative TMJ disease. In this series, there was an average of 2.1 ± 1.2 previous joint surgeries and no statistical relationship with patient behavior was observed. In another sequence of 129 patients undergoing joint surgery with a diskectomy, 75% were successful during follow-up. In contrast, 11.7% of patients were indicated for joint replacement on average 7.8 years after the diskectomy [13]. In these cases, the quality of life of patients who required TMJ prosthesis was not documented; however, it is possible to infer that it was suboptimal, leading to the need for prosthetic intervention.

Other studies have shown that patients with 1 or more previous surgeries are more likely to have pain even after joint replacement [14]. In our sample, only one subject had increased pain after prosthesis installation, likely associated with previous conditions related to long time conservative treatment, bad selection of treatments in the surgical phase, or psychiatric and pain factors. In addition, Gerber & Saeed [14] noted that in 73 patients treated with joint replacement, severe pain decreased from 50.7% to 6.8%, and moderate pain decreased from 27.4% to 9.6%, demonstrating that some cases maintain pain even after TMJ prosthesis. In our series, the intensive use of physical therapy and occlusal controls reduced the pain condition, and although there was a reduction from 5.5 (± 2.3) to 2.2 (± 0.4), the mild postoperative pain could be controlled by the patient until the time of this study.

Clinical studies have revealed moderate to advanced symptomatology in cases of degenerative TMJ disease, which do not appear to correlate precisely with a terminal condition of the TMJ [15]. For example, in a cohort of 39 patients with inflammatory disease and connective tissue disorders, a preoperative mouth opening greater than 20 mm and moderate pain were noted; the installation of TMJ prostheses in these patients proved to be highly successful, yielding functional improvements alongside facial morphology correction [16]. In our series, pain presented a significant reduction, and mandibular mobility also improved significantly ($p<0001$) with an opening increase from 25.85 (± 10.2) mm to 35.93 (± 4.2) mm. In those cases, the preoperative functional limitations cannot be deemed totally severe; nevertheless, the use of prosthesis enhanced the patient's overall condition. It is possible to think that in cases with advanced damage of the TMJ, the TMJ replacement may be necessary; the advances cases usually show more with pain by long term and psychological conditions could be involved in a reduce response of the patient to the prosthesis performance.

This study includes patients treated exclusively with customized prostheses using a single system (Enterprises, Artfix Implants, Pinhais, PR, Brazil) and a standardize protocol and methodology for planning and surgery. Kanatsios et al. [17] conducted a study to compare the clinical condition between stock and customized systems, concluding that both can provide patients with adequate function. They included patients between 45 and 55 years old who were mainly unilateral, and their most frequent complications were associated with nerve injury. We consider that using customized prostheses improves surgical management, using an ideal implant for TMJ replacement, in agree with other authors [18]. Complementary orthognathic surgery is a common procedure for using TMJ prostheses [6]. In this series, 77.41% of the patients underwent other maxillomandibular osteotomies, demonstrating that the complexity of the cases is optimized with virtual planning and patient-specific implants with good postoperative outcomes [19].

Since the customized prosthesis is produced individually for each patient, the manufacturing process is highly relevant to the procedure's success. It has been shown that different commercial brands of prosthetic systems may exhibit differences in microstructure and electromechanical properties, potentially affecting the success and corrosion resistance of current systems [20]. In this study, a unique system was used to define the planning protocol as one of the study variables, and the system used has been presented in other publications [21,22], demonstrating efficacy in all

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analytical contexts. Of the 47 prostheses installed and with an average follow-up of 38.09 ± 26.6 months (12 to 104 months), no need for removal, exchange, or admission to revision surgery was observed. However, some publications show conditions that could be related to this situation [23]

The recent publication by Olate et al. [6] reports the indication for TMJ prosthesis due to the need for removal of a previously installed prosthesis; this may be associated with metal allergy, infection, presence of heterotopic bone, or failure in the manipulation and installation of the prosthesis [24]. Our series of patients was planned and treated by 4 surgeons with more than 15 years of experience in using and managing TMJ prostheses, which may contribute to treatment success [4]. In addition, the volume of interventions performed on TMJ prostheses is high, a factor that significantly affects better postoperative performance [25].

5. Conclusions

We can conclude that TMJ replacement with an alloplastic customized implant, as described in this study, demonstrates efficiency and effectiveness, with stability for up to 7 years. The indication for joint replacement is diverse and may be warranted in patients who have not yet reached the terminal phase of TMJ morphology and function.

Author Contributions: Conceptualization, SO VR; methodology, SO VR CG; software, VR RV; validation, SO, VR, RV RG; formal analysis, SO VR RV; investigation, SO RG CG; resources, SO, VR, CG RG; data curation, SO VR; writing—original draft preparation, SO, VR, CG; writing—review and editing, SO, VR, CG, RV, RG; visualization, SO CG RV; supervision, SO; project administration, SO VR CG. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data are available upon request from the corresponding author.

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