EGYPTIAN DENTAL JOURNAL
www.eda-egypt.org
VOL. 70, 1147:1157, APRIL, 2024
PRINT ISSN 0070-9484 • ONLINE ISSN 2090-2360
ORAL SURGERY
Submit Date : 23-01-2024 • Accept Date : 18-03-2024 • Available online: 05-04-2024 • DOI : 10.21608/EDJ.2024.264237.2915

LONG TERM EVALUATION OF PATIENT SPECIFIC ALLOPLASTIC TEMPOROMANDIBULAR JOINT REPLACEMENT PROSTHESIS: A 5-YEAR FOLLOW-UP

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ABSTRACT

Background and objective: This is a retrospective study that was conducted aiming at evaluating the 5-year Quality of life (QoL) outcomes for patients who underwent TMJ total prosthetic joint replacement with custom prosthesis.

Materials and Methods: Twenty patients with a total of thirty-three total joints replaced were recalled 5 years postoperatively for clinical evaluation of pain (VAS), mouth opening and QoL outcomes. This was done after the regular follow up that was made four years earlier, 1 year from execution of the procedure. Prosthetic joints placed were composed of a condylar portion made of medical titanium alloy grade 4 extra low interaction and a fossa component made of ultra-high molecular weight polyethylene.

Results: All patients reported a positive outcome regarding quality of life with various degrees, improvement in mouth opening and pain in patients who suffered from hypomobile joints was noted.

Conclusion: Total joint replacement is the best course of action for a variety of conservative and minimally invasive resistant conditions. TMJ-S-QoL is a validated post-surgical questionnaire. The responses provided by the individual are subjective and impacted by a variety of factors, including their personality traits and attitudes at the time. QoL is difficult to evaluate since patient conduct and sentiments connected to it might vary over time and with experience.

KEYWORDS: Temporomandibular joint, Total joint replacement, Quality of Life, custom made.

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INTRODUCTION

Amongst all joints in the human body, the temporomandibular joint (TMJ) is the considered the most dynamically active joint emanating movements of more than 2000 times in the everyday activity whether chewing, swallowing or talking.[1] Being such a critical entity in our daily life, preservation and replacement - if need be - of the TMJ owing to its value is of prime importance. TMJ is exposed to various debilitating factors whether traumatic insults, ankylosis, pathology or end-stage degenerative disease. Replacement of the TMJ is sometimes unavoidable when all else have failed or yielded disappointing results.

Since that the TMJ is a principally composed of the condylar part of the mandible and the articular fossa of the temporal bone,[2] then temporomandibular joint replacement (TJR) prosthesis constitutes a condylar component fixed to the mandible and a fossa component fitted on the articular fossa. Temporomandibular ankylosis (TMJA) is one the most common occurrences at childhood that requires surgery and costochondral grafting to allow for function restoration and mandibular growth when still not completed.[3] TJR is the corner stone in treatment of TMJA in adults when growth has already caught up and has shown an undeniable success in restoring movement, function, aesthetics as well as preventing re-ankylosis.[4,5]

TJP are available as either customised or off-the-shelf stock devices. The two most popular off-the-shelf stock options are Biomet micro-fixation and Nexus CMF systems (formerly Christensen, TMJ Implants Inc., Salt Lake City, UT, USA), however they are also available as patient-fitted prostheses. [6] The advantages of off-the-shelf devices include adjustable fitting, cost-effectiveness, and fast availability in case of injuries or cancer excision. The limited anterior and inferior movement of the jaw, however, is a major drawback. A skilled surgeon is also required to choose the best fit for the patient right away.[7]

Conversely, patient-tailored TJR devices are specifically built to fit the anatomy of the patient offering more anterior-inferior mandibular movements and are superior stability in comparison to stock devices. However, the cost is high, and the fabrication process takes longer.[8] Custom TMJ TJR components are made utilizing a stereolaser (SL) design generated from a protocol-computed tomography (CT) scan, taking into account each patient's specific anatomical situation. Therefore, the components of the fossa and ramus can be designed and modified to match any unique or complex anatomical host bone scenario.

The first TMJ prosthesis to utilize materials that have a strong track record in orthopedics for joint replacement was the custom-made complete joint prosthesis from TMJ Concepts. The cobalt-chromium-molybdenum (Co-Cr-Mo) condylar head and wrought titanium alloy (Ti6AL4V ELI) body make up the mandibular body. While the articular fossa is constructed of a mesh backing of commercially pure, unalloyed titanium and an ultra-high-molecular-weight polyethylene (UHMWPE) fossa articulating surface. An all-titanium prosthesis is utilized in place of the chromium-cobalt alloy in patients who are allergic to one of its constituent elements. [9–11]

For stability and endurance, all implanted alloplastic devices rely on the fixation component bio-integration principle (in the case of TMJ devices, screws). The term "bio-integration" refers to the direct incorporation of fixing elements into bone without the need for a growing phase of fibrous tissue. The conditions for bio-integration are similar to those for initial fracture healing in that forces from the implant must be sent to the bone without interruption and vice versa without any relative motion. The primary stability of the components at implantation is a requirement for TMJ TJR success on a long-term basis. [12]

Such prosthesis should generally provide a set of functions that allow pain-free movement in all directions with a reliable functionality regarding

speech, mastication, and deglutition, in a way that manages and withstands the applied load and forces that generally enables a sustainable quality of life (QoL). The aim of this study is to evaluate the 5-year QoL outcomes for patients who underwent TMJ total prosthetic joint replacement with custom prosthesis.

MATERIALS AND METHODS

Study design

This retrospective study was undertaken on patients who had undergone TJR with custom TMJ prosthesis and completed a five-year follow – up. Twenty patients with a total of thirty-three joints had undergone the procedure, all of which were performed by the same surgical team at the Oral and Maxillofacial surgery department operating room, at the Faculty of Dentistry, Cairo University. All TJR were designed by the same surgeon through data obtained from each patients' CT scans through Mimics and 3-matic software. All patients' records were maintained and traced starting from their demographic data (age, sex, replacement cause, number of replaced joints) all the way through their functional data regarding pain intensity according to visual analogue scale (VAS), range of jaw movement and general patients' satisfaction.

Patients included in this study were:

- Above 20 years of age of both sexes
- Suffering from pathological conditions non-responsive or those that negate conservative therapy (Table 1)
- Free from any medical illness that would compromise expected results.
- Willing to adhere to follow-up visits.

A TMJ-S-QoL questionnaire was administered to patients who met the study's inclusion requirements during their 5-year post-operative evaluation. Regarding pain, speech, swallowing, and social aspects, patients answered questions on their pre- and post-operative TMJ TJR experience. Answers were given on a scale of 1 to 5, with 1 representing the most favorable reaction and 5 the least favorable. (Fig. 1).

Surgical technique

All patients underwent the same surgical procedure with the same surgical team under general anesthesia. After nasal intubation, patients were scrubbed using betadine surgical scrubbing solution in the standard manner, a sterilized cotton plug soaked in betadine was placed in external auditory meatus. An endaural approach was used for insertion of the fossa component that was secured by titanium mini screws. Ultra-high molecular weight polyethylene material was used. The mandibular component of the prosthesis is also constructed from medical titanium alloy grade 4 extra low interaction (TiGr4 ELI). This alloy is rigid, hard and has high biocompatibility. Accurate positioning was confirmed by a surgical splint for maintenance of the occlusion. The desired design of the condyle and fossa has been manufactured through milling utilizing the CAD-CAM technology, the process was done at **Arab Engineers for designs and medical instrumentation.**

The ramal component on the other hand was accessed via a retromandibular approach where patient specific splints with both cutting and drilling guides were used for accurate positioning and fixation to the mandibular body to which it was fixed with titanium screws. A peri-umbilical abdominal fat graft was placed around the neck of the condyle to prevent extra skeletal bone formation.

Patients were postoperatively evaluated both clinically through assessment of pain level, mandibular range of motion, occlusion, and quality of life immediate postoperative, at one month, 3 months and 1 year and radiographically through follow up CTs immediately and 1 year. Data were collected and compared to the value attained after 5 years together with a follow up CT for a long-term follow-up assessment.

TMJ - SURGERY QUALITY OF LIFE QUESTIONNAIRE (FMJ-S-QOL)

A Pain?
1. I have no pain.
2. There is mild pain, but I do not need medication.
3. I have moderate pain which requires regular analgesics like paracetamol.
4. I have severe pain controlled only by strong analgesics like panadeine forte.
5. I have severe pain which cannot be controlled by analgesics.

B. Diet & chewing?
1. I can chew and eat whatever I like.
2. I can chew most things except tough foods like meat and apples.
3. I only stick to soft foods such as pasta and soft bread.
4. I need to cut up all food into small pieces.
5. I can only eat food that has been put through the blender.

C. Speech?
1. My speech is normal.
2. I have difficulty in seeing some words.
3. I have difficulty in being understood over the phone.
4. Only my friends and family can understand me.
5. I cannot be understood at all.

D. Activity?
I. I am as active as I have ever been.
2. There are times where I can't 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 very often because I don't have the strength.
5. I am usually in bed or chair and don't leave heme.

E. Recreation?
1. There are no limitations to recreation at home or away from home.
2. There are a few things I can't do but I still get out and enjoy life.
3. There are many times where I wish I could get out more but I'm not up to it
4. There are severe limitations to what I can do mostly at I stay at home and watch IV.
5. I can't do anything enjoyable.

F. Mood?
1. My mood is excellent and unaffected by my TMJ disorder.
2. my mood is generally good and only occasionally affected buy my TMJ disorder.
3. I'm never in a good mood nor depressed about my TMJ disorder.
4. I'm somewhat depressed about my TMJ disorder.
5. I am extremely depressed about my TMJ disorder.

G. Anxiety?
1. I'm not anxious about my TMJ disorder.
2. I'm a little anxious about my TMJ disorder.
3. I am very anxious about my TMG disorder and finding it difficult to cope with
4. I am severely anxious about my TMJ disorder and I'm not coping with it at all.

H. Which issues have been uppermost in your mind during those past five years (circle up to 3 answers)
1. Nothing
2. Pain
3. Diet & chewing
4. Speech
5. Activity levels
6. Recreation
7. Mood
8. Anxiety

I) Compared to the month before you had your TMJ surgery how would you rate your overall health related quality of life?
1. Much better
2. Somewhat better
3. About the same
4. Somewhat worse
5. Much worse

J. In general, what would you say about your health-related quality of life during the past five years?
1. Excellent
2. Very good
3. Good
4. Fair
5. Poor

K. Considering everything in your life that contributes to your personal well-being such as family friends spiritually and personal leisure activities please rate your overall quality of life over the last five years?
1. Excellent
2. Very good
3. Good
4. Fair
5. Poor

I. If a relative or a friend had experienced TMG problems very similar to what you had would you:
1. Recommend TMJ surgery as the primary treatment.
2. Recommend TMJ surgery only if other measures such as physiotherapy and splint therapy and medications fail.
3. Recommend TMJ surgery only as a very last resort.
4. Do not recommend TMJ surgery at all.

Fig. (1) The University of Washington Quality of Life Questionnaire (Weymuller et al., 2001) for patients with head and neck cancer served as the model for the TMJ surgery-specific quality of life questionnaire (TMJ-S-QoL), which was initially published by Dimitroulis et al., 2010.

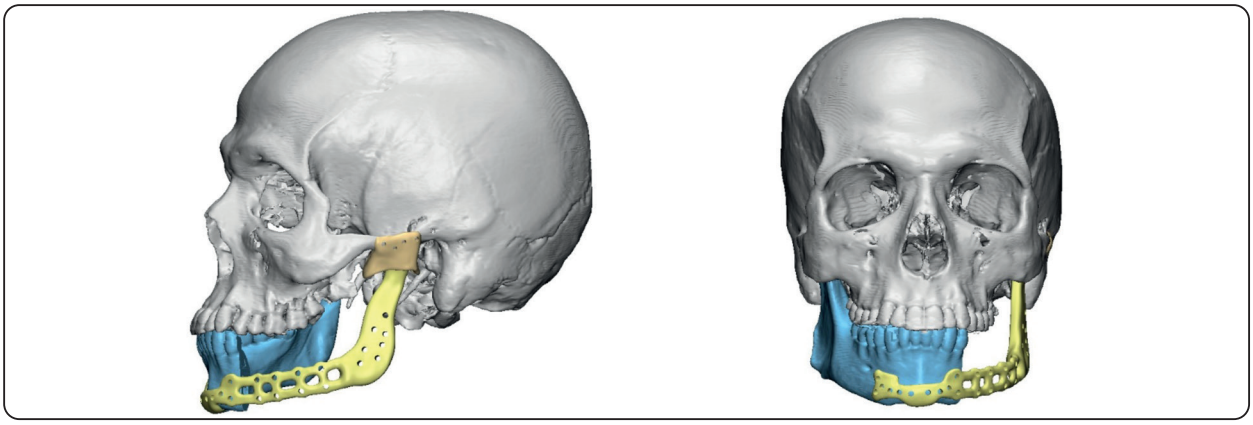

Fig. (2): 3D design for the condyle and fossa component on 3-matic software for accuracy, fit and symmetry.

Fig. (3): Condylar segment on a reconstruction plate made of TiGr4 ELI together with the fossa component made of UHMWPE.

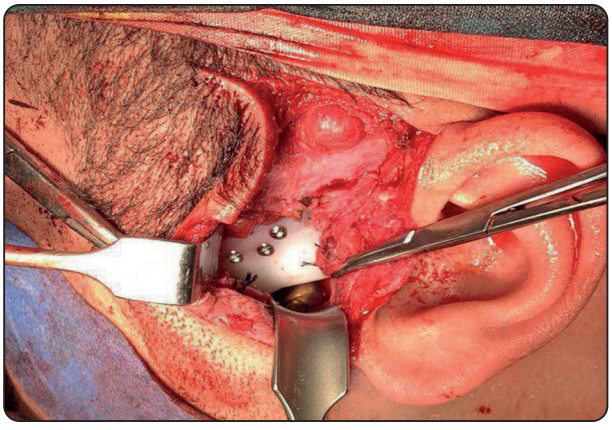

Fig. (4): Intraoperative picture showing the condylar component and the UHMWPE fossa in place.

Statistical analysis

Using a Microsoft Excel spreadsheet all data was recorded, and SPSS software V2.1 was used for statistical analysis. A paired t-test was used to assess the statistical significance of the QoL survey responses after they were divided into positive and negative outcomes. Using a paired t-test to compare pre- and post-operative data, the functional measurement data was statistically evaluated to seek statistical significance. P values ≤ 0.05 were considered to be statistically significant.

RESULTS

Twenty patients with a total of thirty-three total joints were replaced and postoperatively followed up for 5 years. Thirteen patients had bilateral joints while seven had only unilateral joints replaced. The mean age was 46 years with a slight predilection to females over males (11 females and 9 males). The necessity of surgery according to the preoperative diagnosis is shown in Table 1. CT scans done immediately postoperatively was to confirm accurate condylar positioning and alignment in relation to the fossa and proper fixation of the device. Follow-up was carried on for one year postoperatively and then reassessed at five years to fit with our study. All patients who had undergone TJR due to degenerative joint diseases (DJD) had undergone various TMJ surgeries whether open or minimally invasive surgeries in the form of arthrocentesis. Six out of the eight patients suffering ankylosis had also undergone open surgeries in the form of ankylotic mass release and gap arthroplasty. All skin incisions were healed uneventfully without disfiguring scars. Only one case reported an infection 2 weeks after surgery. Infection was related to the fossa component and required surgical intervention for removal of the fossa followed by drain placement and extension of systemic antibiotics. Facial nerve weakness was non-existent except in two patients who showed slight weakness related to the frontal and zygomatic branches and was improved 1 month postoperatively.

TABLE (1) Reasons for joint replacement surgery and their number

Diagnosis	Number of patients	Total Joints replaced
Ankylosis	8	16
Degenerative joint disease	7	11
Benign lesions resection	4	4
Post trauma	1	2

Pain VAS scores, mandibular range of motions in the form of maximal mouth opening (MMO) and lateral excursions were recorded in mm for each patient for 1 year and compared to 5 years postoperatively. Pain values and mandibular range of motion were not a significant complaint for patients who had resection for benign lesions. Pain was also not reported for patients with TMJ ankylosis, yet the limitation is mandibular movement was obvious and recorded. Other patients' pain scores indicated a preoperative mean value of 7.6, a significant improvement at one year of 1.2, and a continued decline in that value to become 0.9 at five years. At 1 and 5 years after surgery, MMO exhibited significant improvement from a preoperative mean value of 18.5 mm to 36.8 mm and 37.1 mm, respectively. At 1 and 5 years after surgery, respectively, lateral excursions improved from a preoperative value of 6.7 mm to 11.8 mm and 12.1 mm.

One month postoperatively, all patients reported very positive feedback regarding TJR surgery in the

TABLE (2) VAS scores, MMO and lateral excursions comparative values at different time periods

Timing	Pain (VAS)		MMO		Lateral Excursions	
	Mean	P-value	Mean	P-value	Mean	P-value
Preoperative	7.6[a]	-	18.5[c]	-	6.7[c]	-
1 year postoperative	1.2[b]	<0.0001	36.8[a]	<0.0001	11.8[a]	<0.0001
5 years postoperative	0.9[c]	<0.0001	37.1[b]	<0.0001	12.1[b]	<0.0001

: Significant at P ≤ 0.05** ***Means with different superscript letters within the same column are significantly different at P ≤ 0.05.

QoL questionnaire. A noteworthy improvement was also seen when the answers to questions that directly addressed how patients felt their quality of life had changed were analyzed. Fourteen patients (or 70%) said that their quality of life in terms of their general health was "much better" than it had been a month before their TMJ surgery. Following the procedure, five patients (25%) reported a "good" degree of personal well-being, whereas fifteen patients (75%) characterized it as "very good." Inquiries were also made of the patients regarding whether they would suggest TMJ surgery to a friend or relative who was having TMJ issues. Of the patients, nine (45%) said they would suggest TMJ surgery as the main course of action. In a similar vein, five patients (or 25%) stated that if more cautious methods failed, they would advocate it.

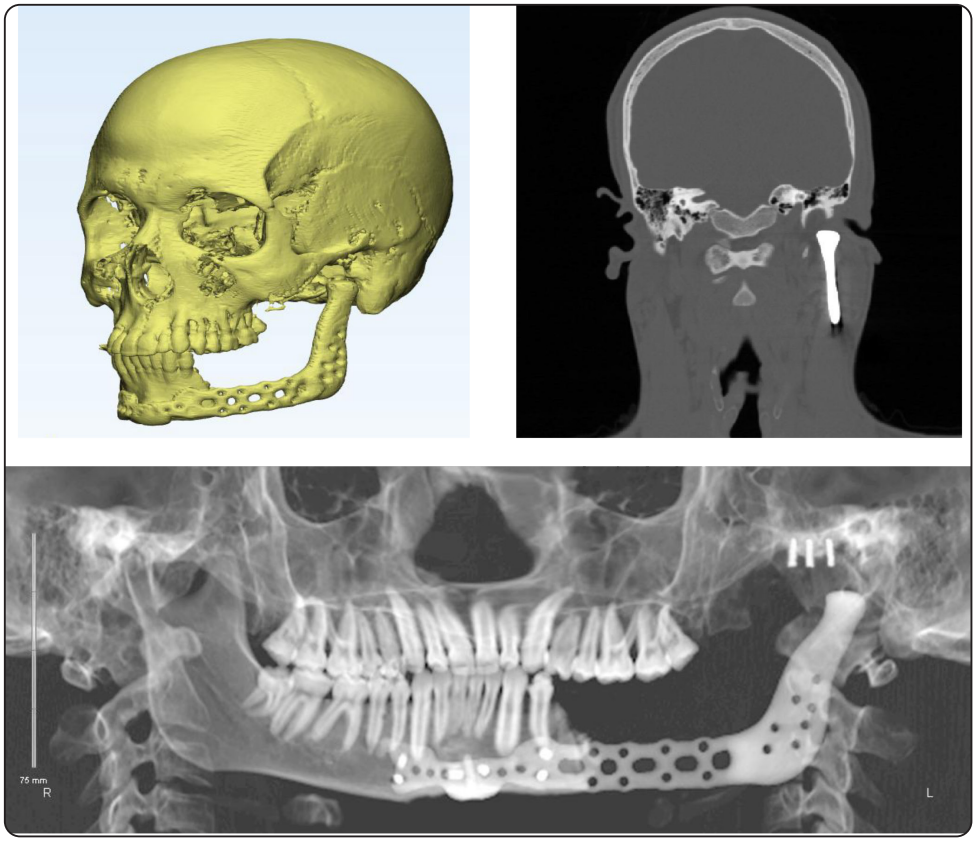

Fig. (5) Showing 3D reconstruction, coronal view and panoramic CT view after 1 follow-up.

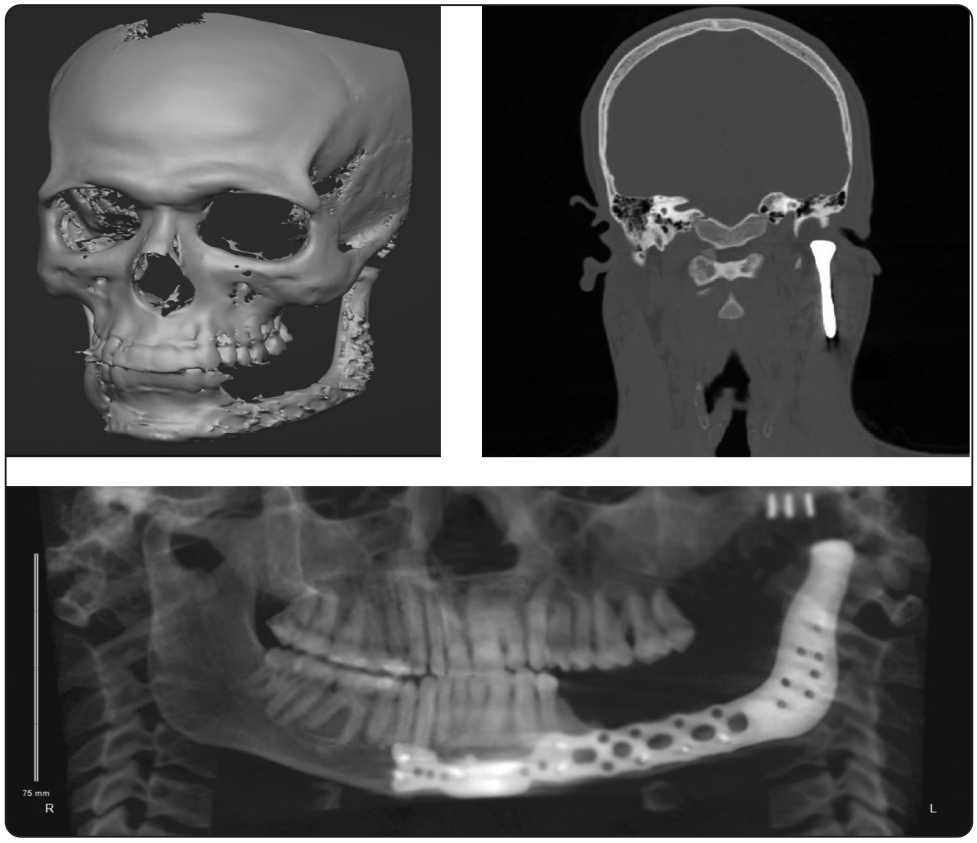

Fig. (6): Showing 3D reconstruction, coronal view and panoramic CT view after the 5-year follow-up.

DISCUSSION

For years now, TJR for TMJ through alloplastic prosthesis has been considered as the definitive treatment solution for various conservative and minimally invasive resistant cases as well as terminal TMJ pathologies. Alloplastic TJR's primary benefit is that it closely resembles the architecture of the TMJ. TMJ TJR offers a biomechanical option for TMJ reconstruction as opposed to a biological one. [13] Despite being a major surgical intervention, TMJ TJR is considered as a safe reliable and highly dependable option for restoring normal functions required by such complex joint system whether speech chewing or appearance.[14] Immediate physiotherapy with return to normal function and significant reduction in recurrence chances is a prime advantage of such device. In a cohort analysis conducted on 56 patients with TJR in 2015, ***Wolford and Mercuri*** reported no device failure.[15]

Besides being involved in a pathological or irreversible traumatic insult, TMJ prosthesis replacement is typically recommended in cases of stage V end-stage TMJ disease and TMJ Ankylosis. [3,16] As a result , the patients' main incapacitation comprises pain and motion limitation which in return compromises speech, chewing, diet which in turn affects social interaction, mood and recreational abilities. As such, these same parameters are considered success factors are appropriately treated and managed.

This retrospective study was targeting twenty patients on which TMJ TJR was done, yet only sixteen patients were successfully contacted (80%) and recalled for a 5-year follow up CT, clinical

evaluation and a QoL questionnaire. Two patients (10%) have relocated to another country and offered to participate through filling the questionnaire but seeing they won't be able to be available for clinical evaluation they were excluded from the study together with another two patients whom the authors were unable to contact.

No device failures were reported after the 5-year follow-up period. CT scans showed no signs of infection, screw loosening or wear. Patients showed very positive feedback about the prosthesis and their positive impact on their lives. Only one patient showed signs of infection with the fossa component shortly after the surgery, he was managed by extension antibiotic injections and irrigation through a drain which was removed later-on after resolution of infection signs.

All ramal components were introduced by retromandibular approach except in one case where the patient had mandibular segmental resection with joint disarticulation for treatment of an ameloblastoma in the mandible via an intraoral approach yet the fossa component in all cases was placed through an endaural approach.

The fossa component was made of UHMWPE, which when combined with the TiGr4 ELI condylar part provides predictable joint loading. This is thought to lessen the long-term wear linked to polyethylene debris and foreign body reactions that are common in orthopedic hip and knee replacements. According to studies conducted at 10 years and up to a maximum of 21 years, there is currently no evidence of polyethylene wear debris causing failure.[15][17]. In contrast, clinical evidence of "cold flow" occurs upon removal of these prostheses.[18] Because of this characteristic, UHMWPE change shape under load instead of generating particulate matter, which emphasizes the stability and predictability of these joints.[17]

Comparing wear of contemporary Co-Cr-Mo alloy metal-on-metal complete hip prostheses to Co-Cr-Mo alloy metal-on-UHMWPE prostheses, the former results in 4.5-8.5 times more metal loss..[19,20] Although TiGr4 ELI was used not Co-Cr-Mo, but generally speaking from a histological point of view, in contrast to metal-on-metal TMJ prosthesis, which frequently exhibit visual and histological indications of metallosis from wear-related debris, metal-on-UHMWPE has demonstrated very little wear-related debris.[21] As a result, the hypersensitive reaction with TMJ prostheses with metal on UHMWPE is comparatively uncommon.[22] Throughout the prosthesis' lifetime, hypersensitivity can manifest at any time and to any extent; anecdotally, it appears to be an early adverse reaction.

Abdominal fat grafting around the articulation area of the prosthesis, the technique of applying fats around the joint has been published in many studies and papers to significantly improve the post operative results.

A retrospective cohort research conducted by Wolford evaluated patient records with TMJA from a single private practice between 1992 and 2011. The patients received fat grafts and total joint prostheses from TMJ Concepts (Ventura, CA) and Techmedica (Camarillo, CA). Preoperatively, the median incisal openness measured 14.5 mm, however at the longest follow-up, it was 35 mm. The mean value for TMJ pain decreased from 8.0 to 1.5. These improvements were substantial, and the authors came to the conclusion that a feasible and reliable approach to treating TMJA is to use a patient-fitted total joint prosthesis from TMJ Concepts in conjunction with fat grafting around the prosthesis' articulation area. This will improve pain levels, function, and quality of life while also preventing re-ankylosis.[23]

The centre of rotation for an optimal prosthesis is roughly 15 mm below the centre of rotation of the mandibular condyle, according to research published in a number of articles on the biomechanics of the TMJ. Both rotatory and translatory movements can be produced by rotating the mandible about this point,

but these translatory movements are challenging to achieve with the existing prosthetic design unless a disc can be incorporated into the joint. [24,25] The pure rotating movement was enjoyable in contrast to the previously restricted mobility or the excruciating non translational movement of the patients with severe arthritis. We adhered to the same ideas when repairing and creating the custom-made joints. Since patients are usually pain-free, can open their mouths to a reasonable extent, and function quite regularly, it does not appear that the loss of normal mobility or lateral movement will be difficult for them to accept.

Limitation in mouth opening and lateral excursions was reported only in fifteen patients, namely those who had TMJA and DJD. Yet due to the ankylotic bony mass no pain was reported in the TMJA patients, yet it was debilitating in the seven patients suffering from DJD. Joint pain was significantly improved together with jaw motions. TJR due to traumatic injuries was done to only one patient who had bilateral irreparable condylar head fractures due to motor vehicle accident. The four patients who had joint replacement surgeries had no pain and no limitation in jaw motion, yet their input in the QoL evaluation was important to evaluate the impact of the normal joint movements postoperatively and comparing the feel of the same movements in the preoperative values especially that those patients are familiar to their normal joint movements unlike those who have had a long-standing locked jaw condition.

Only one patient of those who had segmental resection and disarticulation had had a tooth bearing area involved in the resected margin and had undergone another surgery of reconstruction of the dentate area (premolar – molar) in an iliac crest bone graft for future implant placement this was a year before the final 5 year follow up evaluation.

Despite the satisfactory results yielded by our study, it's only fair to state that this study has its limitations since that the results of patient satisfaction could be skewed because of the ongoing patient-surgeon relationship. QoL can be a challenging measure to evaluate because of the multitude of factors that influence patients' perceptions of TMJ TJR surgery and its effects on their quality of life. There isn't a validated pre-surgical QoL questionnaire available at the moment, but the TMJ-S-QoL is a validated post-surgical questionnaire. The responses provided by the patients form the basis of the study's findings. The responses provided by the individual are subjective and impacted by a variety of factors, including their personality traits and attitudes at the time. QoL is difficult to evaluate since patient conduct and sentiments connected to it might vary over time and with experience.

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