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Review Article

Temporomandibular Joint Total Replacement Stock Prostheses-Current Available Knowledge A Literature Review

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Abstract

This study provides a review of the current available knowledge of temporomandibular joint total replacement stock systems. An electronic search of the National Library of Medicine's Pubmed, Scopus, Scielo and Science Direct databases were performed to identify English, Spanish and Portuguese language, peer-reviewed articles published during the years 1990–2013. 25 references including reviews, clinical trials or case series, and single-patient case reports were the type of articles found and considered for review. The main indication for a total joint replacement is the presence of a severely damaged or mutilated joint, which can result from different types of severe joint diseases or failure of previous surgeries. As described by the consulted authors, the surgical procedure is an established and standardized protocol .Therapeutic outcomes were encouraging for all the revised articles. An evolution of this TMJ stock prosthetic devices have been made over time with satisfactory results, transforming this type replacement system an optimal solution in severe cases of joint alterations. Further studies are recommended to continually validate these replacement systems.

INTRODUCTION

The temporomandibular joint (TMJ) is an atypical diarthrodial synovial joint capable of performing both translation and rotation movements, formed by the mandibular condyle and glenoid fossa of the squamous part of the temporal bone, and separated into upper and lower cavities by the presence of an articular fibrocartilaginous disc [1-4].

In the cases extreme disarrangements such as ankylosis, severe resorption, or irreparable joint degeneration, reconstruction by installation of prosthetic TMJ devices has become the best therapeutic choice and provides a safe and viable alternative [2,3,5,6].

When compared to other reconstructive procedures such as costochondral grafts, the use of TMJ prosthetic devices can

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reduce the duration of surgery, morbidity since a donor site is not required, can also lead to shorter hospitalization times, and provides immediate function, with no need for postoperative intermaxillary fixation (IMF). However, the TMJ prosthesis may also present some disadvantages, including the lack of predictability for a surgical revision, prosthesis failure secondary to either loosening of a screw or fracture of the prosthesis from metal fatigue, the limited fit of stock prostheses, the loss of laterality and protrusion movements due to detachment of the lateral pterygoid muscle, and its high cost [7, 22].

In recently, many prosthetic systems have been developed and marketed but in the long term have given unsatisfactory clinical results and have led to postoperative complications of great importance. Nowadays, just three of these devices are still in use and have been approved by the US Food and Drug Administration (FDA) [5].

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MATERIALS AND METHODS

A electronic search of the National Library of Medicine's Pubmed, Scopus, Scielo and Science Direct databases were performed to identify English, Spanish and Portuguese-language, peer-reviewed articles published during the years 1990–2013. The key words (research algorism) "temporomandibular joint", "temporomandibular joint surgery", "temporomandibular joint alloplastic prosthesis", "alloplastic prosthesis" and "temporomandibular joint alloplastic reconstruction", alone and combined with each other, were used to search for references eligible for review. Other relevant citations were identified by searching among the related articles in the databases.

25 references were considered for review. Of these references, reviews, clinical trials or case series, and single-patient case reports were the type of articles found. The selected citations were then analyzed in terms of their usefulness in providing and specific data on stock prostheses. (The prosthetic system, Indications, Surgical Procedure and therapeutical Outcome).

LITERATURE REVIEW

Prosthetic system

In recent decades, many prosthetic systems have been developed and marketed but in the long term have given unsatisfactory clinical results and have led to postoperative complications of great importance. Nowadays, just three of these devices are still in use and have been approved by the US Food and Drug Administration (FDA): TMJ Concepts (Ventura CA, USA), TMJ Implants (aka Christensen) (Golden, CO, USA), and Biomet/Lorenz (Jacksonville, FL, USA) [5].

The total TMJ replacement system is a "ball and socket" type prosthetic joint similar to a hip or femoral implants, in all three available systems [8].

Regarding the only stock system available today (The Biomet/Lorenz Microfixation TMJ replacement system), this TMJ prosthetic system received approval of its Investigational Device Exception from the FDA in July 1995, and later received Premarket Approval (PMA). It is a stock prosthetic system composed of three main components [22].

(1) The fossa (temporal) component: made of ultra high molecular weight polyethylene (UHMWPE) this is designed to replace the mandibular fossa and articular eminence of the temporal bone. It is available in three sizes: small, medium, and large.

(2) The mandibular component: this is designed to replace the mandibular condyle and is made of cobalt chromium alloy with its undersurface coated with titanium plasma spray for increased bony integration.

It is presented in two different designs, standard and narrow, and is also available in three sizes: 45 mm, 50 mm, and 55 mm.

(3) The fixation screws: made of 6AL/4V titanium, the screws are self retaining and self-tapping to facilitate ease of insertion. The fossa component fixating screws are 2.0 mm in diameter and the mandibular component screws are 2.7 mm in diameter.

Indications

The available data in all the studies suggest that the main indication for a total joint replacement is the presence of a severely damaged or mutilated joint, which can result from different types of severe joint diseases or failure of previous surgeries [8,23].

Case selection is not homogeneous between the different studies; there is no discrimination with regard to age, gender, race, or dental or occlusal conditions.

Most of the authors consider that all patients considered candidates for joint reconstruction should underwent clinical and imaging examinations (panoramic radiography, computed tomography scans (CT), and, if necessary, magnetic resonance imaging (MRI)) – evaluations that allowed the diagnosis of severe joint changes such as ankylosis, condylar resorption, and articular changes resulting from previous surgical procedures or trauma sequel this to being the us common criterion of inclusion in the studies analyzed [8,22,23].

Surgical Procedure

The surgical placement of the prosthetic stock devices follows an established protocol well described by several authors [7,14,15,16,22,23]. Specifically using the descriptions of the procedures by Leandro, et al and De Souza, et al. [22, 23], the basic idea of the surgical procedure follows this protocol:

All patients undergo surgery under general anesthesia with nasotracheal intubation and complete muscle relaxation. During anesthetic induction, a prophylactic antibiotic and steroid antiinflammatory are administer.

After infiltration of local anesthetic with vasoconstrictor in the preauricular region, the TMJ is access through a preauricular incision, dissection of the superficial muscle layers, and careful identification and preservation of the facial nerve, until the identification of the joint capsule, which is incise on its lateral portion to expose the condyle and articular fossa.

Under continuous irrigation an arthrotomy cut is perform at the level of the sigmoid notch for removal of the compromised condyle. In cases of ankylosis, the ankylotic mass is carefully removed with chisels and round burs. The mandibular fossa is then flattened and the temporal component template of the prosthetic system can be adapted and installed after checking the stability and parallelism to the zygomatic arch.

Temporary inter maxillary blockage (IMF) is then perform to preserve or restore the vertical dimension and occlusion, and the mandibular ramus is access through a Risdon incision and communication of the accesses is achieve. The lateral surface of the mandibular ramus is regularized and the mandibular component template can be installed and secured to articulate with the previously installed temporal component.

The inter maxillary blockage is then remove, and occlusion, vertical dimension, and mandibular movement must be checked. In the case of occlusion or vertical dimension instability, the templates can be repositioned and a new occlusal evaluation must be performed. In the case of movement restrictions, a

J Surg Transplant Sci 1(1): 1002 (2013)

second osteotomy, or, if necessary, a coronoidectomy can be performed and the templates will be reinstalled.

Once no changes were detected, the templates are then replaced for the final prosthetic components and a new mouth opening evaluation is perform. The wounds must be carefully rinsed with saline solution and then closed with 4-0 absorbable sutures (polyglactin 910) for the deeper layers and 5-0 nylon sutures for the skin. In the opinion of these authors none of the patients should receive postoperative IMF. Postoperative medications (antibiotics, anti-inflammatory medications, and analgesics) must be prescribed for all patients.

Therapeutic outcome

In general therapeutic outcomes in the different types of TMJ prostheses reported in the literature tend to differ between the authors, this basically, because the different types of evaluations performed, the patients' perception, and the protocols applied or not of post-operatory physiotherapy.

As reported by Guarda-Nardini L, Manfredini D, Ferronato G. [8], the therapeutic outcomes were encouraging for all three total prosthetic needs for re-surgery in those patients who underwent failure of such implants. Even though the exact nature of the adverse reaction which leads to the high failure rate of both Proplast-Teflon and Silastic implants has not been established, these two systems were withdrawn from sale. The need for reconstruction of severely damaged joints that were previously treated with these materials is one of the main indications for a total joint replacement [8].

Guarda-Nardini L, Manfredini D, Ferronato G. [8] also, cite an important article by Wolford et al.[24], they showed results at 5 years of 69 TMJ Concepts implants in 38 patients operated by the same surgeon. The patients were re-examined at an average time of 73.5 months after surgery, and the drop-out rate was about 10% with respect to the original sample of 42 patients. All the patients but one was female. Despite the occurrence of complications which required minor re-operation in six patients, the authors reported a significant improvement in objective (incisal opening) and subjective (pain level, jaw function) parameters, with significant reduction only in the lateral excursion values.

Until recent years, none peer-reviewed papers were available for the Biomet/Lorenz prosthesis [22]. The first to address the Therapeutic outcome of the stock prostheses was Quinn [25], who recorded significant improvements at 3 years in a group of patients rehabilitated with a total of 69 joints.

Quinn P [7] in 2000, in one of the first works describing the Stock Prostheses (Biomet/Lorenz) described that until that date, they have placed a total of 59 implants in 42 patients (25 unilateral and 17 bilateral). The gender breakdown is, predictably, 91% female and 9% male. According to the Wilkes' classification, 6% of the patients were Class III, 44% were Class IV, and 50% were Class V.56 The mean number of prior surgeries for patients enrolled in the study was 5.7 (range, 0 to 13). 22 of the patients have had the joints in function for longer than three years. In that group, the mean preoperative opening was 17.1 mm, and the mean postoperative opening at 36 months was 29.2

J Surg Transplant Sci 1(1): 1002 (2013)

mm. The pain intensity visual analog scale showed a mean score preoperatively of 8.6 with a score of 1.9 at 36 months. Interference with eating (0 = no interference, 10 = liquids only) showed a mean preoperative score of 8.9 and a postoperative mean of 1.9. Of the 59 joints, we have had one complication of a staph scalp infection, necessitating the removal of fossa prosthesis. This patient had had bilateral prosthetic joints for approximately 10 months before the complication occurred. Even after removal of the fossa prosthesis, she continued to function well, with the only result being a 3-mm to 4-mm deviation toward the side where the fossa prosthesis had been removed on terminal opening. The clinical study will continue until the majority of the patients have been followed for five years.

Jones RH [15] described that the early results indicated success with both types of Joint replacement (TMJ concepts and Biomet/ Lorenz). All patients had an acceptable mandibular opening with minimal pain and no signs of implant failure as indicated by their stable occlusion and lack of open bite deformity. The study also shows acceptable results regarding maximum opening before surgery and at the last visit (range 6 months to 3 years). The pain score was rated as an analogue scale with 0 being no pain and 10 being extremely painful along with the score at the last visit. The dental occlusion refers to the stability of the occlusion and therefore the prosthesis. A trend towards a Class II malocclusion is an indication of loosening and wear.

Two patients of that study had dislocation of the mandibular condyle out of the glenoid fossa in the early postoperative period requiring relocation under general anesthesia and the placement of intermaxillary elastics for control.

Giannakopoulos et al. [14], describe in the results of their research that there was statistically significant improvement in pain level (P .0001), jaw function (P .0001), and incisal opening (P .0001) in the patients that underwent TMJ reconstruction using a stock prostheses. Although there were complications necessitating the removal of 14 of 442 implants (3.2%), and there were no device-related mechanical failures.

They also described the pain intensity and interference with eating, measured as visual analog scores, were significally decreased postoperatively, and these decreases were sustained for 3 years. There were no significant differences at 1, 1.5, and 3 years after the initial surgery. The preoperative mean for pain intensity was 8.0 (standard deviation [SD], 2.65; 95% confidence interval [CI], 7.7 to 8.3); and at 3 years, the postoperative mean was 2.6 (SD, 2.26; 95% CI, 2.3 to 2.9), demonstrating a statistically significant decrease in pain The results show an increase in mandibular opening from the preoperative average of 14.4 mm, (range 2-25 mm), to an average opening of 29.7 mm postoperatively (range 25-35 mm) and an average pain score of 1.7 (range 0-3 with a possible maximum of 10), where as the preoperative average was 6.7 (range 3–8). The authors also described that there were three patients who had minor complications. One patient, a 75-year-old female patient with severe osteoarthritis, had bilateral paraesthesia of the inferior dental nerves following her surgery which was a result of poor positioning of the ramus component of the prosthesis and also resulted in a Class II occlusion postoperatively. The paraesthesia is slowly resolving [14].

Westermark A [16] comments his experience in 12 patients who underwent temporomandibular joint (TMJ) reconstruction with Biomet total joint prostheses. The follow-up ranged between 2 and 8 years. Amongst the ankylotic patients the mean jaw-opening capacity increased from 3.8 mm preoperatively to 30.2 mm 1 year after surgery, and in most of those patients the opening capacity remained stable over the years. The other patients maintained a mean opening capacity of more than 35 mm. Joint related pain and interference with eating were eliminated after TMJ reconstruction. There were no permanent facial nerve disturbance, no postoperative infections and no device related complications.

De Souza et al. [23] in a sample of 15 patients in a period of 8 years reported no complications before or after the surgical procedure after clinical and image (tomography, Magnetic Resonance, Panoramic Radiograph) evaluations. No cases or postoperatory pain, joint sounds or alterations were reported. Only few cases of headache and muscular fatigue were acknowledged.

Leandro et al. [22] followed 300 patients in a the period of 10 years who underwent total reconstruction of the TMJ with the installation of the prosthetic Biomet/Lorenz TMJ Reconstruction System (total of 399 prostheses) clinically and radiologically. The average period of follow-up was 3.5 years (SD 2.1, range 1-10 years). At the first interview 96 patients (32%) described severe pain as their principal symptom, 57 patients (19%) described mouth opening reduction, 66 patients (22%) presented mild to severe neuromuscular disorders, and 81 patients (27%) reported osteoarthritis. After surgery, all patients showed significant improvement in the four variables studied (MIO, function and speech, diet, and pain) at the time of the postoperative evaluation at 7 days as reported by the authors. Maximal Interincisal Opening data showed an average increase of 16.8 mm in the immediate postoperative period, and at the end of 3 years, the average amplitude of mouth opening was 41.8 mm (ranging from 26 to 49 mm). Jaw function and speech showed significant and constant improvements, and at the end of the third year after surgery, only four patients reported mild mandibular limitation occasionally. The Authors associated these results to the intense physical therapy and the absence of postoperative IMF.

The pain scores were greatly decreased at just 7 days after the surgical procedure. Regarding diet, despite the improvement after 7 days of surgery, the main significant results were found by the authors at the 1- month follow-up. This is basically due to two factors: the natural swelling present during the first postoperative week and particularly the fear of patients with regard to applying chewing force on the prosthetic components. However, with a gradual gain in confidence, all patients began to eat normally and at the end of 1 year only 13 patients still had mild limitations of diet [22].

DISCUSSION

The TMJ can be affected as a result of various types of changes that can significantly compromise the functioning of the stomatognathic system [3,5]. In most cases, the TMJ and the associated muscles are affected by a heterogeneous group of multifactorial origin changes triggering a series of signs and symptoms such as pain in the preauricular region and/or the

J Surg Transplant Sci 1(1): 1002 (2013)

muscles of mastication, abnormal jaw movement, joint sounds such as clicking and/or crepitus during mandibular movements, ear pain, neck pain, and headache, giving rise to what is called a temporomandibular disorder (TMD) [2–5,8,22].

These cases are usually treated by conservative procedures such as the installation of intra-oral devices, physical therapy, correct reestablishment of occlusal contacts, drug therapy, and psychological treatments, and can thus promote clinical remission and restore the patient's quality of life [3,5,22].

However, the TMJ can also be affected by more severe changes associated with trauma (direct or indirect), pathological processes, or even due to an unsatisfactory response to the clinical treatment of TMD, leading to limiting or even disabling disorders, creating problems of chewing, digestion, speech, and appearance, including access to routine dental treatment, even having an impact on the patient's psychological development. In these cases the therapeutic option is surgical treatment of the joints [1,3,4,8,22].

In some cases the clinical evaluation and imaging studies lead us to a diagnosis of severe joint changes with concomitant and significant structural damage to the anatomical components, for which conservative surgical procedures such as arthroplasty, eminectomy, or discopexy would be ineffective [3,22].

For many years, the technique of autografts for reconstruction of the TMJ was performed using autogenous bones, such as fibula, metatarsals, clavicle, iliac crest, and rib [1].

However this procedure is associated with several disadvantages and complications. In addition to the morbidity caused by the need for a second surgical site, the long period of hospitalization required, difficulty of graft setting (as the metatarsal bone fragments), overgrowth of the costochondral graft, malocclusion, and recurrent ankylosis, among other factors that could result in therapeutic failure, led to the search for a new surgical option [10,11,22].

When compared with autogenous grafts, prosthetic systems have numerous advantages such as: lack of donor site morbidity, reduced intraoperative surgical time, the potential for decreased hospitalization, immediate functional ability, and maintenance of stable postsurgical occlusion (since there is no implant remodeling) [22].

However, despite these advantages, some prosthetic systems have not presented the ideal characteristics for a prosthetic device such as: bio-compatibility, functionality, lightness, adaptability, stability, corrosion resistance, and non-toxicity. Such systems have thus presented poor long-term results due to failures in components or due to exacerbated inflammatory reactions, which have resulted in the necessity of a new surgical procedure for removal of the prosthesis. As a result, these prostheses have fallen into disuse and have been withdrawn from the market [7,11–13,22].

Currently, only three TMJ prosthetic systems are available and are approved by the FDA: TMJ Concepts, TMJ Implants/ Christensen, and the Biomet/ Lorenz Microfixation TMJ Replacement System [5].

With regard to the Biomet/Lorenz prosthesis, the case series describing the manufacturer's statistics was published in a nonpeer reviewed paper and the literature presents only a few studies with a limited sample of patients evaluated. However, despite the reduced number of studies, the results obtained for these systems have generally been satisfactory and encourage their use. This was so until the 2012 publication of Giannakopoulos et al. [14] and Leandro et al. [22] in which they describe their experience using the Biomet/Lorenz system in an important number of patients.

Jones [15] assessed the joint reconstruction in seven patients with a total of 12 joint replacements using either the TMJ Concepts system (two patients/three joints) or the Biomet/Lorenz joint system (five patients/nine joints), achieving significant positive results for maximum mouth opening aperture and remission of pain for both systems during follow-ups ranging from 6 months to 3 years.

Westermarck [16] evaluated 12 patients who underwent TMJ reconstruction with Biomet total joint prostheses (five unilateral procedures, seven bilateral procedures) with follow-up ranging from 2 to 8 years, demonstrating an increased mean jaw opening capacity from 3.8 mm preoperatively to 30.2 mm at 1 year after surgery in ankylotic patients, while non-ankylotic patients maintained a mean opening capacity of more than 35 mm. Joint-related pain and interference with eating were eliminated after TMJ reconstruction. The results obtained in our study corroborate the data presented in these papers.

The study of Leandro et al. [22], although being one of the biggest case report in any kind of TMJ total replacement system, address an important subject that must articles doesn't, the post operatory physiotherapy. They studied and followed in 300 patients (201 unilateral, 99 bilateral) Treated with the Biomet/ Lorenz stock prostheses system. Objective data (maximum interincisal opening; MIO) and subjective data (function and speech, diet, and pain) were collected preoperatively and at postoperative evaluations performed over a 10-year period (mean 3.5, standard deviation 2.1 years). The MIO measures were obtained using a caliper rule. Subjective data were evaluated using a visual analogue scale with scores ranging from 0 to 5 for each variable. The results were analyzed with the paired t-test (two-sided, a = 5%). Each patient showed significant improvements for all of the variables at evaluation on postoperative day 7. The results for MIO, function and speech, and diet, showed improvements at each postoperative evaluation over a maximum of 3 years, with stabilization of the results from the fourth year. Complaints of pain decreased considerably up to the 1-month postoperative evaluation, and no patient reported severe pain at 6 months after surgery.

Leandro et al. [22] described that an Intensive physical therapy was initiated 48 h after the procedure. In the first 2 postoperative weeks physical therapy consisted of mandibular opening and closing exercises and stimulation of maximum mouth opening by keeping the mouth open at the wider range limit for a few seconds. From the third postoperative week on, forced mouth opening exercises were introduced with the help of wooden spatulas inserted between the posterior teeth bilaterally, alternating sides, or simultaneously for 2–3 min. The proposed

therapy was performed at weekly sessions for a minimum period of 2 months. Patients were encouraged to maintain the exercise routine at home, doing them 3–5 times a day over a period of at least 12 weeks.

The orthopedic literature reports potential problems with metal-on-metal prostheses, including high frictional torque that could result in loosening. Besides, the wear debris is potentially toxic due to significantly increased levels of cobalt and chromium in the body, whose long-term effects are unknown. These metals may cause cellular toxicity, hypersensitivity, and carcinogenicity [7,13,22].

In presenting his experience with TMJ metal-on-metal total joint prostheses that required revision, Wolford¹³ found obvious metallosis from wear debris and in at least 10% of the cases a crack or fracture of the fossa component was present. Given the risks of using metal-on-metal joints, studies in the orthopedic area have led to the development of new knee and hip prosthetic, articulating metallic or ceramic components with UHMWPE, obtaining high rates of success [7,17,22].

Based on these results, Biomet/Lorenz incorporated this composition in the development of their prosthetic components, presenting a mandibular component composed of cobaltchromium-molybdenum and a temporal component composed of UHMWPE. Given the reports of accentuated wear of UHMWPE components by stress in knee replacement devices due to its thinness, the fossa components of the Biomet/Lorenz have a minimum thickness of 4 mm in the mid-point of the fossa itself [7,17,18]. Laboratory studies submitted to the FDA, simulating its use for a period of 20 years, showed no significant signs of wear on the prosthetic components [16,19,22].

From the biomechanical point of view, Van Loon et al.[20,21] reported an important consideration based on the mandibular anatomy, particularly with regard to the installation of a unilateral prosthesis. The natural movements of the mandible include translatory and rotatory components. Since during the installation of the prosthetic system the lateral pterygoid muscle is detached, it must be admitted that the translational motion ability of the prosthetic side is compromised. In consequence, since TMJs are both connected, the functioning of the prosthetic side directly influences the contralateral TMJ movements and the distribution of the masticatory loads, probably as a result of compensatory muscle recruitment [2,20,21].

An evolution of this TMJ stock prosthetic devices have been made over time, through the association of biocompatibility and biomechanical principles, making their use safe and reliable, with satisfactory results, transforming this type replacement system an optimal solution in severe cases of joint alterations. Further studies are recommended to continually validate these replacement systems.

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