Twenty-Year Follow-up Study on a Patient-Fitted Temporomandibular Joint Prosthesis: The Techmedica/TMJ Concepts Device

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Purpose: To evaluate subjective and objective outcomes of patients receiving Techmedica (currently TMJ Concepts) patient-fitted temporomandibular joint (TMJ) total joint replacement (TJR) devices after 19 to 24 years of service.

Patients and Methods: This prospective cohort study evaluated 111 patients operated on by 2 surgeons using Techmedica (Camarillo, CA) patient-fitted TMJ TJR devices from November 1989 to July 1993. Patients were evaluated before surgery and at least 19 years after surgery. Subjective evaluations used standard forms and questions with a Likert scale for *1)* TMJ pain (0, no pain; 10, worst pain imaginable), *2)* jaw function (0, normal function; 10, no movement), *3)* diet (0, no restriction; 10, liquid only), and *4)* quality of life (QoL; improved, the same, or worse). Objective assessment measured maximum incisal opening (MIO). Comparison analysis of presurgical and longest follow-up data used nonparametric Mann-Whitney and Wilcoxon signed rank tests. Spearman correlations evaluated the number of prior surgeries in relation to objective and subjective variables.

Results: Of the 111 patients, 56 (50.5%) could be contacted and had adequate records for inclusion in the study. Median follow-up was 21 years (interquartile range [IQR], 20 to 22 yr). Mean age at surgery was 38.6 years (standard deviation, 10 yr). Median number of previous TMJ surgeries was 3 (IQR, 4). Presurgical and longest follow-up data comparison showed statistically significant improvement ($P < .001$) for MIO, TMJ pain, jaw function, and diet. At longest follow-up, 48 patients reported improved QoL, 6 patients reported the same QoL, and 2 patients reported worse QoL. Spearman correlations showed that an increased number of previous surgeries resulted in lower levels of improvement for TMJ pain and MIO.

Conclusions: At a median of 21 years after surgery, the Techmedica/TMJ Concepts TJR continued to function well. More previous TMJ surgeries indicated a lesser degree of improvement. No devices were removed owing to material wear.

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Patients with end-stage temporomandibular joint (TMJ) pathology can benefit from total alloplastic TMJ replacement. These conditions include *1)* multiply operated TMJs (≥2 previous surgeries); *2)* failed autogenous grafts; *3)* failed TMJ alloplastic implants, including Proplast-Teflon (PT; Vitek, Inc, Houston, TX) and silicone elastomers (Dow-Corning, Midland, MO); *4)* high or low inflammatory metabolic arthritic diseases; *5)* connective tissue or autoimmune diseases (ie, rheumatoid arthritis, juvenile idiopathic arthritis, scleroderma, Sjögren syndrome, lupus, etc); *6)* fibrous or bony ankylosis; *7)* absent or deformed anatomic structures resulting in loss of posterior mandibular vertical dimension (ie, fractured displaced condyles, absence of condyles and portions of the ramus as the result of previous trauma, surgery, pathology, or congenital deformity); *8)* tumors involving the TMJ and the adjacent mandible; and *9)* other end-stage TMJ pathologies. Autogenous tissue grafts (ie, costochondral, sternoclavicular, temporal myofascial, auricular cartilage, dermis, dermal fat, and sliding ramus osteotomy) have been advocated by some surgeons for TMJ reconstruction.[1] However, some of these aforementioned TMJ conditions can have an adverse effect on the viability of autogenous tissue grafts, resulting in a high incidence of graft failure.[2-4]

These pathologic conditions can considerably alter the anatomy in the TMJ area and mandible, resulting in an associated dentofacial deformity, malocclusion, functional impairment, airway obstruction, and pain. Mandibular advancement with or without counterclockwise rotation (rotating the anterior aspect of the maxillomandibular complex upward with or without rotating the posterior aspect downward) might be necessary to correct such deformities to achieve an optimal functional and esthetic result. These repositioning movements can create a large gap between the fossa and mandibular ramus and condyle structures. In these circumstances and those with altered anatomy from the TMJ pathology, a patient-fitted total joint prosthesis can provide accurate adaptation of a TMJ total joint replacement (TJR) device to the anatomic structures for each patient.[1,2,4]

The TMJ TJR patient-fitted devices used in this study were originally developed in 1989 by Techmedica (Camarillo, CA) and manufactured until July 1993, when the US Food and Drug Administration (FDA) halted production of all TMJ devices. In 1996, the FDA permitted the new owners, TMJ Concepts (Ventura, CA), to manufacture the device under the 510K provision and granted full approval of these Class III devices in 1999. The Techmedica and TMJ Concepts devices are computer-assisted designed (CAD) and computer-assisted manufactured (CAM) devices that fit the specific anatomic, functional, and esthetic requirements of each patient.

The purpose of this study was to evaluate long-term surgical outcomes in a cohort of patients treated for TMJ pathology with the Techmedica TJR from 1989 through 1993 by 2 experienced oral and maxillofacial surgeons in relation to TMJ pain, jaw function (JawFn), diet, quality of life (QoL), and jaw opening. The aims of this study were to *1)* evaluate the longevity of these devices; *2)* analyze subjective and objective outcome parameters comparing before surgery with longest follow-up; *3)* assess the effect of number of previous TMJ surgeries on outcomes; and *4)* identify any factors that would require removal of any of the devices, such as material wear or failure.

Patients and Methods

This prospective cohort study was originally developed in 1989 by Techmedica, in which standardized pre- and postsurgical data forms were used, with the presurgical data collected before the TMJ TJR surgery and the postsurgical data collected at designated postsurgical intervals with no follow-up time limit. All patients from all surgeons using the Techmedica TJR system were initially enrolled into the study. Data from this study were used by Techmedica and then TMJ Concepts for premarket approval with the FDA. This prospective cohort study was extended to include the long-term data on patients treated by 2 of the surgeons (L.M.W. and L.G.M.) who were originally involved in the study.

PATIENT SAMPLE

The first 111 consecutive patients operated on by 2 surgeons using the Techmedica CAD and CAM patient-fitted total joint prostheses from November 1989 to July 1993 were enrolled in this prospective cohort study. The research protocol was reviewed by the Baylor University Medical Center institutional review board (Dallas, TX) and was granted exempt status. The indications for placing the Techmedica TMJ TJR are outlined in the first paragraph of the introduction. Inclusion criteria for patients were *1)* end-stage TMJ pathology in at least 1 joint requiring TMJ TJR, *2)* surgery by 1 of the 2 surgeons from November 1989 to July 1993, *3)* able to be contacted and evaluated, *4)* adequate records, and *5)* agreement to participate in the study. The exclusion criterion was loss to follow-up.

Beginning in 2011, the authors began attempting to locate and contact each of the enrolled 111 patients for long-term evaluation using available medical records information, the Intellus Internet search (http://www.Intellus.com), and multiple letters and telephone calls.

VARIABLES

Patients were evaluated by the 2 surgeons using data recorded on standard forms before surgery and at the longest follow-up appointment. For objective evaluation, preoperative maximum incisal opening (MIO) was compared with the longest follow-up recorded MIO. MIO was measured between the incisal tips at maximum unassisted opening. In patients with anterior open bites, the amount of open bite was subtracted for the MIO measurement, and in deep bites, the amount of vertical overlap was added to the measurement for accurate determination of MIO. Subjective evaluations (Table 1) compared presurgical with longest follow-up values using Likert scales for *1)* TMJ pain (0, no pain; 10, worst pain imaginable), *2)* JawFn (0, normal function; 10, no movement), *3)* diet (0, no restriction; 10, liquid only), and *4)* QoL (improved, the same, or worse). The specific questions that the patients were asked in relation to TMJ pain, JawFn, diet, and QoL are listed in Table 2.

STATISTICAL ANALYSIS

Patients' ages and MIOs were normally distributed, so they are described using mean and standard deviation (SD). The change in postoperative MIO was analyzed using the parametric paired *t* test. All other variables were not normally distributed and thus are described using median (50th percentile) and interquartile range (IQR; 25th to 75th percentile). The postoperative changes in these variables were analyzed with the nonparametric Wilcoxon signed rank test. Spearman correlations were computed to examine the relation between the numbers of prior surgeries and the objective and subjective outcomes. An α level of 0.05 was used for all tests.

Table 1. BASELINE CHARACTERISTICS OF PATIENTS WHO COMPLETED THE STUDY VERSUS THOSE LOST TO FOLLOW-UP (N = 111)

Variables	Completed Study	Lost to Follow-Up	*P* Value
Patients, n (%)	56 (50.5)	55 (49.5)	—
Age at surgery (yr), mean (SD)	38.6 (10.0)	39.9 (7.9)	.223
Follow-up (yr), median (IQR)	21.0 (2.0)	—	—
Women, n (%)	52 (92.9)	54 (94.5)	.714
Previous surgeries (n), median (IQR)	3.0 (4)	4.0 (6)	.199
Interincisal opening (mm), mean (SD)	25.8 (9.8)	22.5 (12.7)	.076
Pain score, median (IQR)	8.0 (2.0)	8.2 (2.5)	.721
Function score, median (IQR)	7.5 (3.0)	8.2 (1.8)	.063
Diet score, median (IQR)	7.0 (3.0)	7.5 (4.1)	.328

Abbreviations: IQR, interquartile range; SD, standard deviation.

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TECHMEDICA AND TMJ CONCEPTS PATIENT-FITTED TMJ TJR DEVICE SPECIFICATIONS

The Techmedica TMJ TJR device implanted in this study was designed and developed using materials and biomechanical principles that have been used successfully since 1960 in orthopedic TJR.[5] After obtaining a protocol TMJ computed tomogram, the data captured were processed using a rapid prototyping system to produce an anatomically accurate 3-dimensional (3D) polymer model of the maxillomandibular skeleton, teeth, and TMJs. This model allowed the surgeon to selectively reposition the mandible into a predetermined functional and esthetic position and to perform the required condylectomy and recontouring of the fossa and ramus as dictated by the specific anatomic and functional requirements. The patient-fitted total joint prosthetic fossa and ramus components were designed and manufactured using this 3D model (Fig 1).

The patient-fitted fossa component is composed of a commercially pure (CP) titanium shell covered on both sides with a CP titanium mesh designed and manufactured to conform to the specific anatomy of the patient's glenoid fossa, articular eminence, and lateral rim of the fossa. The CP titanium mesh allows the fossa component to be fixated to the zygomatic arch with screws and provides a framework for bone and soft tissue ingrowth. This maximizes the long-term stability of the fossa component. The mesh also provides a secure attachment for the fossa's articulating surface composed of ultrahigh-molecular-weight polyethylene (UHMWPE) bonded to the mesh of the fossa titanium base (Fig 1). The UHMWPE articulating surface geometry is identical to the ramus component condylar head geometry, thereby decreasing the potential for point contact and subsequent wear. The fossa component has a posterior stop to provide a centric relation position for the condylar head of the prosthesis, which is important when the TMJ TJR is combined with orthognathic surgical procedures.

The mandibular component is manufactured from wrought titanium alloy (90% titanium, 6% aluminum, and 4% vanadium). The condylar head of the mandibular component is composed of cast

Table 2. SUBJECTIVE ASSESSMENT

TMJ pain	no pain	0	1	2	3	4	5	6	7	8	9	10	worse pain imaginable
Jaw function	normal	0	1	2	3	4	5	6	7	8	9	10	no jaw movement
Diet	no restriction	0	1	2	3	4	5	6	7	8	9	10	liquids only
Postsurgical quality of life	improved	Same											worse

Note: The assessment used the following questions. *1)* Rate your average daily level of TMJ pain on a scale of 0 to 10, where 0 equals no pain and 10 equals the worst pain imaginable. *2)* Rate your jaw function, which is the ability to open your jaw, move it side to side, and chew, where 0 equals normal function without any impairment and 10 equals no function (ie, jaws are "frozen"). *3)* Rate your diet, where 0 equals the ability to chew any consistency of food without difficulty and 10 equals liquids only. *4)* What effect has the surgery had overall on your quality of life (improved, the same, or worse)?.

Abbreviation: TMJ, temporomandibular joint.

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cobalt-chromium-molybdenum alloy that consists of approximately 64% cobalt, 28% chromium, 6% molybdenum, and 2% trace elements of nickel, iron, carbon, silicone, manganese, and nitrogen. The functional surfaces of the cobalt-chromium-molybdenum alloy and the UHMWPE functional interface represent the gold standard for orthopedic joint replacement for wear and structural stability.[6]

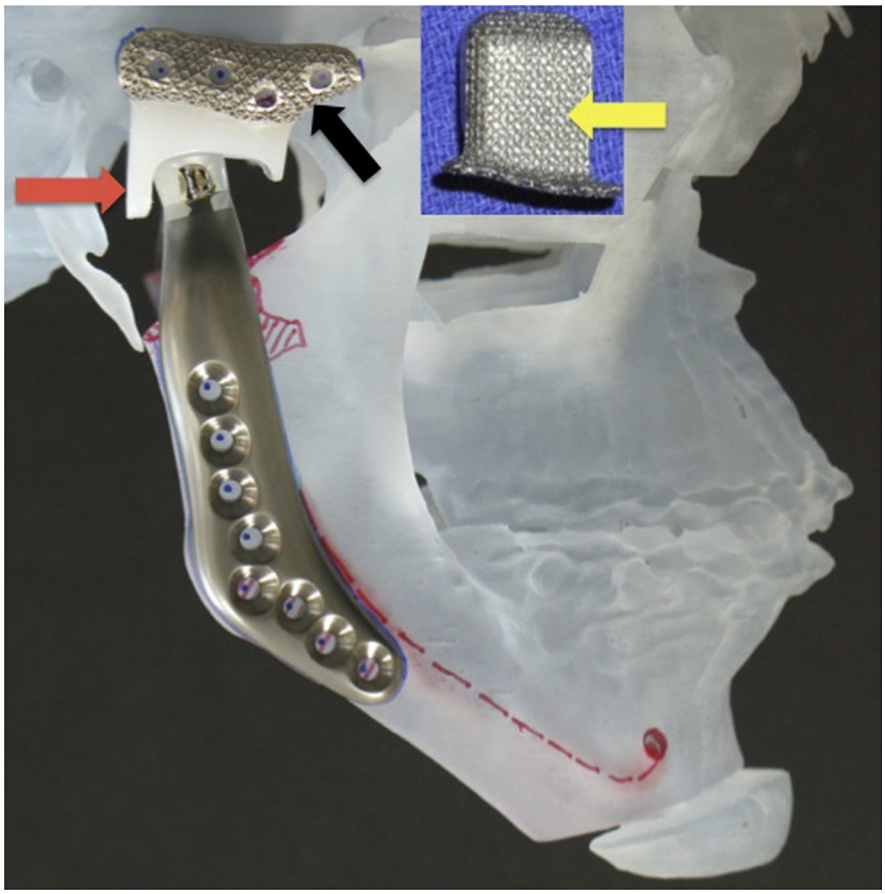

FIGURE 1. Three-dimensional polymer model prepared with Techmedica and TMJ Concepts total joint replacement constructed to fit the individual patient's specific anatomic requirements. In this illustrative case, the maxillomandibular complex was rotated counterclockwise into the final position for the construction of the total joint replacement. Depicted are the posterior stop on the fossa, an essential component for temporomandibular joint, skeletal, and occlusal stability (*red arrow*); the patient-fitted metal backing for the fossa component, with titanium mesh covering the titanium shell on the lower side providing a method of attachment of the polyethylene articulation component (*black arrow*); and the titanium mesh on the upper surface of the fossa providing a mechanism for bone and soft tissue ingrowth to maximize stability (*inset, yellow arrow*).

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Results

Of the original cohort of 111 patients, the authors were able to contact and include 56 patients (50.5%) in this analysis of at least 19 years. All patients contacted agreed to participate in the study. Ten patients (9%) were known to be deceased and were excluded from the study. The remaining 45 patients (40.5%) were not included because they could not be located and contacted.

Table 1 lists the baseline characteristics of those patients who completed the study and those who were lost to follow-up. There were no statistical differences (tests outlined below; $P > .05$), thus supporting the contention that patients lost to follow-up were missing at random and did not differ substantively from those who completed the study. Also, differences were not found between the 2 surgeons' results, so they were combined in all the analyses.

Of the 56 study patients, 52 were women (93%) and 4 were men (7%). There were 43 patients (77%) who received a bilateral total joint prosthesis and 13 who received a unilateral total joint prosthesis (23%), for a total of 99 Techmedica total joint prostheses implanted. The mean age at surgery was 38.6 years (SD, 10.0 yr; range, 15 to 59 yr).

Thirteen patients had 19-year follow-ups, and 43 had 20- to 24-year follow-ups. The median follow-up was 21 years (IQR, 20 to 22 yr). The median number of previous TMJ surgeries was 3 (IQR, 4; range, 0 to 27; Table 1).

The mean preoperative MIO was 25.8 mm (SD, 9.8 mm) and at longest follow-up was 36.2 mm (SD, 7.8 mm), indicating a statistically significant improvement ($P < .001$). The median preoperative TMJ pain score was 8 (IQR, 2) and the median postoperative TMJ pain score was 3 (IQR, 6), indicating a statistically significant decrease in pain ($P < .001$). The median JawFn score improved from 7.5 (IQR, 3) preoperatively to 3.0 (IQR, 4) postoperatively ($P < .001$), as did diet (median score, from 7 [IQR, 3] to 3 [IQR, 4]; $P < .001$; Table 3).

At longest follow-up, 48 patients (85.7%) reported their QoL was improved, 6 patients (10.7%) reported that it remained the same, and 2 patients (3.6%) reported that their QoL was worse (Table 4).

Spearman correlations showed significant associations between the number of previous surgeries and postoperative TMJ pain ($\rho = 0.38$; $P = .004$) and limitations in jaw opening ($\rho = 0.36$; $P = .006$). The number of previous surgeries was not statistically associated with the other outcome variables.

Discussion

This study showed that patients receiving the Techmedica patient-fitted TMJ total joint prostheses reported considerably less TMJ pain, improved JawFn, the ability to eat solid food, and improved QoL after an average of 21 years of service. None of the 56 patients who completed the study had failure of the prostheses, signifying great durability. However, it must be noted that only approximately half the original patients could participate in this final analysis, despite repeated attempts to locate and contact all of them using several methods. Such a high dropout rate raises concerns of bias, for example, that the dropouts were worse off to begin with or had worse outcomes, and the authors do not know about them. Mitigating against this possibility is the comparison of baseline characteristics of those who completed the study and those who were lost to follow-up showing no statistically significant differences ($P > .05$). This supports the contention that the loss of patients to follow-up occurred at random and does not represent a biased sample. Conversely, it should be noted that patients lost to follow-up did trend toward being more impaired with regard to interincisal opening ($P = .076$) and JawFn ($P = .063$); differences in the other 5 baseline variables did not come close to being

Table 3. LONG-TERM RESULTS (N = 56)

Measurement	Preoperative	Postoperative	Significance of *P* Value
Maximum interincisal opening (mm)	25.8 (9.8)	36.2 (7.8)	<.001
TMJ pain	8.0 (2)	3.0 (6)	<.001
Jaw function	7.5 (3)	3.0 (4)	<.001
Diet	7.0 (3)	3.0 (4)	<.001

Note: Values are presented as mean (standard deviation) for interincisal opening and the *P* value was determined by paired *t* test comparing pre- and postoperative values. All others variables were measured on a scale of 0 to 10 and had non-normal distributions and thus are reported as median (interquartile range); *P* values were determined by Wilcoxon signed rank test.

Abbreviation: TMJ, temporomandibular joint.

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Table 4. POSTSURGICAL QUALITY-OF-LIFE OUTCOME (N = 56)

Quality of Life	Patients, n (%)
Improved	48 (85.7)
Same	6 (10.7)
Worse	2 (3.6)

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statistically significant (ie, $P \geq .20$ for all comparisons). The authors cannot be absolutely certain that unfavorable outcomes contributed to some patients being lost to follow-up, perhaps inflating success and improvement rates. A more plausible explanation for the high rate of loss to follow-up relates to the highly mobile nature of the US population. That approximately half the patients were lost to recall is not unexpected or excessive because 20 years is a very long time in this transient society; people move frequently and unlisted cellular and home telephone numbers have made it more difficult to locate patients. Also, because 93% of the patients were women, marriage and divorce can result in name changes; this further complicates patient tracking. In addition, some patients lost to follow-up could have died, unbeknown to the authors. Even if slightly inflated, the success and improvement rates in the present study suggest that experienced surgeons can expect good, if not excellent, longevity and performance with this prosthesis.

The longevity of a prosthesis for any joint is dependent on materials, design, stability, and functional loading. When the Techmedica patient-fitted CAD and CAM TMJ prosthesis was first introduced, the only guide for joint replacement device longevity was based on the orthopedic literature, because this prosthesis was composed of the same materials considered the gold standard in orthopedics.[6] However, orthopedic stability studies could not be applied because hip prostheses were stabilized and fixated by different methods, including wedging and bone cements. An important issue contributing to hip prosthesis failure involves functional loading that is based on design, materials, articulation, size of articulating components, and body weight. This results in a functional load that can range from 3.5 to 6 times the body weight.[7] Theoretically, the functional load delivered to the hip articulation in a 180-pound individual would be 630 to 1,080 pounds. For running and jumping, the load could be 10 times the body weight or 1,800 pounds. It is difficult to determine the functional load for the TMJ prosthesis. For the average adult, the biting forces generated at the molars is approximately 60 pounds and that for the incisors is 35 pounds.[8] Many patients requiring TMJ TJR could have had considerably lower biting forces, creating even lower functional loads. This could explain the longevity of the Techmedica patient-fitted CAD and CAM TMJ prostheses because none of the patients in this study required replacement because of wear issues.

Techmedica developed and initiated clinical trials with the CAD and CAM patient-fitted TMJ total joint prosthesis in 1989. In July 1993, the FDA halted the manufacture of all total and partial TMJ replacement devices developed after 1976, after a review of the clinical problems that arose from the use of the Vitek PT-containing devices for the TMJ.[9] Mercuri[10] discussed the rationale for the use of patient-fitted devices for TMJ TJR.

Based on clinical trial outcome data contained in a 5-year follow-up study by Wolford et al,[11] a multicenter study by Mercuri et al,[12] and the technical merit of its design and material content, the Techmedica CAD and CAM patient-fitted TMJ TJR device was approved for marketing and production in 1996 under the FDA 510K provision by the new owner, TMJ Concepts. The TMJ Concepts patient-fitted total TMJ prosthesis received full FDA approval as a safe and effective Class III device in July 1999.

Patients exposed to failed TMJ implants, such as devices containing PT or silicone rubber (SR), have particulates of these materials that migrate and penetrate into the adjacent bone and soft tissues.[13,14] It is impossible to remove all these microscopic particles with surgical debridement. These residual particles lead to a foreign body giant cell reaction (FBGCR) that not only adversely affects the surrounding host bone and soft tissues, but also can affect the sustainability of any autogenous graft reconstruction.

Henry and Wolford[2] reported on a study of 107 patients in whom autogenous tissue grafts were placed to reconstruct the TMJ whose architecture was damaged by failed PT and resultant FBGCR. A 4-year follow-up subjective and objective evaluation of pain, occlusal stability, and JawFn after TMJ reconstruction in such cases reported the percentages of acceptable outcomes for each autogenous tissue graft (costochondral, 12%; sternoclavicular, 21%; dermal, 8%; temporal fascia, 13%; temporal fascia with mandibular sagittal split osteotomies, 31%; auricular cartilage, 25%). This study also reported a major increase in failure rates for all autogenous tissue groups as the number of prior TMJ surgeries increased. After 2 previous TMJ surgeries, the long-term success rate for autogenous tissue grafts approached 0. Ankylosis, decreased mandibular function, and pain were the most common causes of failure with autogenous tissue grafting after exposure to failed PT. Further, this study found that the Techmedica patient-fitted CAD and CAM TMJ devices had an 86% success rate relative to jaw and occlusal stability, improved JawFn, and decrease in pain. These results were confirmed in further studies by Mercuri[15] and Mercuri and Giobbe-Hurder.[16]

Wolford et al[4] published a study of 56 patients (55 women and 1 man) who underwent reconstruction with 100 Techmedica patient-fitted TMJ TJR devices. The average age at implantation was 39 years and the average follow-up was 30 months. The outcomes were categorized as good, fair, or poor based on clinical and radiographic assessments for pain, incisal opening, and occlusal stability. The study reported

that 35 patients (63%) had good outcomes, 13 patients (23%) had fair outcomes, and 8 patients (14%) had poor outcomes. Patients with 0 to 1 previous TMJ surgery had success rates of 84% in the good group, 16% in the fair group, and 0% in the poor group. In patients who had undergone at least 2 previous TMJ surgeries, the success rates decreased to 55% in the good group, 26% in the fair group, and 19% in the poor group. Continued pain was the major factor that placed patients in the poor result group, which could be related to problems such as cervical neuropathy, residual inflammatory disease or FBGCR, immunologic reaction to alloplastic particles, fibrosis, calcification, heterotopic or reactive bone formation, sympathetic mediated pain, autoimmune polyneuropathy, multiple chemical sensitivity, bacterial or viral contamination, or other unidentified factors.[13,14]

Autoimmune, connective tissue, and inflammatory diseases also can adversely affect autogenous TMJ grafts, especially when the TMJs are involved in the primary disease process. Wolford et al[3] reported outcomes after using sternoclavicular grafts to reconstruct the TMJ in 3 different patient types: *1)* those with previous TMJ PT or SR implants; *2)* those with autoimmune or connective tissue or inflammatory disease processes (ie, rheumatoid arthritis, psoriatic arthritis, lupus, Sjögren syndrome, reactive arthritis, or spondyloarthropathies); and *3)* those with noninflammatory TMJ pathology (ie, previous fractures, congenital deformities). The outcomes showed success rates of 29% in the PT or SR joints, 50% in inflammatory disease processes, and 93% in joints with noninflammatory pathology. Similar results could occur with other autogenous grafts when used in joints with previous failed alloplasts or inflammatory, connective tissue, or autoimmune diseases. After autogenous tissue TMJ reconstruction for fibrous or bony ankylosis, the potential for redevelopment of heterotopic bone, reactive bone, or fibrosis with subsequent re-ankylosis is considerable.[2] The use of a patient-fitted TMJ TJR could improve the results in these conditions.

Patients who have undergone multiple (≥2) TMJ surgical procedures report poorer subjective variable outcomes (pain, function, diet) compared with those with 0 to 1 previous surgery, particularly when using autogenous tissues for TMJ reconstruction.[11,12,15,16] Multiple TMJ operations create scar tissue and interrupt normal blood flow and normal physiologic nutritional distribution to the anatomic structures. This results in degradation of the fibrocartilage, bony structures, articular disc, capsular ligaments, neurogenic components, and associated musculature that can lead to joint dysfunction, TMJ pain, headaches, myofascial pain, and jaw deformities. Multiple surgeries can establish an environment conducive to a bacterial or viral reactive arthritis, sympathetic mediated pain, autoimmune polyneuropathy, chronic joint inflammatory disease, etc.[13,14]

The biology of successful autogenous tissue grafting requires that the host site have a rich vascular bed. Unfortunately, the scar tissue always encountered in the multiply operated patient does not provide an environment conducive to the predictable success of free or vascularized autogenous tissue grafts. Marx[17] reported that capillaries can penetrate a maximum thickness of 180 to 220 μm of tissue, whereas scar tissue surrounding previously operated bone averages 440 μm in thickness. This could account for the clinical observation that free autogenous tissue grafts, such as cartilage, costochondral, and sternoclavicular grafts, often fail in cases of multiply operated patients or those with extreme anatomic architectural discrepancies resulting from pathology (eg, failed autogenous materials). Reitzik[18] reported that, in an analogous situation to autogenous costochondral grafting, cortex-to-cortex healing after vertical ramus osteotomy in monkeys required 20 weeks and probably 25 weeks in humans. Typically in patients who undergo reconstruction with costochondral grafts, intermaxillary fixation is maintained for only 4 to 6 weeks to return the mandible to function and prevent ankylosis.

Despite screw and plate fixation, micromotion of these free grafts will invariably occur. Early mandibular function can result in shearing movement forces of the graft, leading to poor vascularization, nonunion, or potential failure.[19] This fact and the compromise in vascularity discussed earlier undoubtedly account for autogenous costochondral graft failures seen in these cases. Therefore, in light of the fundamental biologic issues discussed and reported, TMJ cases involving multiply operated patients with failed alloplastic materials or anatomically distorted and severe intra-articular pathology should undergo reconstruction with a total alloplastic device to achieve optimal outcomes.

In 1995, Mercuri et al[12] published a prospective multicenter study on 215 patients (202 women and 13 men) who underwent reconstruction with the Techmedica CAD and CAM patient-fitted TMJ TJR device. The average age at implantation was 40.9 years. There were 363 total joints placed (296 bilaterally in 148 patients and 67 unilaterally). The patients had TMJ problems for an average of 10.7 years before surgery and had undergone a mean of 5.4 prior unsuccessful TMJ surgeries. Preoperative and postoperative data were collected for up to 48 months using a standardized collection format. Subjective data indicated a 58% decrease in pain, a 51% increase in mandibular function, a 55% increase in diet consistency, and a 27% increase in incisal opening. As discussed earlier

and confirmed in further reports, the number of previous surgeries was a strong predictor of postoperative pain, function, and diet scores, as was MIO, with an increased number of previous surgeries resulting in poorer outcomes. This study showed that the Techmedica CAD and CAM patient-fitted TMJ TJR device was useful in the treatment of multiply operated patients with anatomically mutilated TMJs. However, it also showed that those patients with the largest number of prior surgeries had the least favorable pain and jaw-opening outcomes and that this association was significant ($P \leq .004$).

Mercuri et al[20] in 2002 published the results of outcomes after Techmedica and TMJ Concepts TJR. Analysis of the subjective data at 10 years showed a 76% decrease in mean pain scores and a 68% increase in mean mandibular function and diet consistency scores ($P < .0001$). Objective data analysis showed a 30% improvement in mandibular range of motion ($P = .0009$). Long-term QoL improvement scores were statistically related to the number of prior TMJ operations the patients had undergone.

Wolford et al[11] in 2003 published a prospective study with 5- to 8-year follow-up on 38 patients who had TMJ reconstruction using the Techmedica patient-fitted TMJ TJR device. There was statistically significant improvement in incisal opening, JawFn, and pain levels. Histologic evaluation of intracapsular tissues sampled from patients with no previous exposure to PT or SR TMJ implants showed no evidence of wear debris or FBGCR.

Mercuri et al[21] in 2007 published a 14-year follow-up study of outcomes after TMJ Concepts TJR. Analysis of the subjective data showed a significant decrease in pain scores and an increase in mandibular function and diet consistency scores ($P < .001$). Analysis of objective data showed an improvement in mandibular range of motion after 14 years ($P = .02$). Eight-five percent of respondents reported QoL scores indicating improvement above the baseline. Long-term QoL improvement scores also were statistically related to the number of prior TMJ operations the patient had undergone.

Wolford and Karras,[22] Wolford et al,[23] Wolford and Cassano,[24] and Mercuri et al[25] found improved treatment results relative to function and pain by packing autogenous fat grafts (usually harvested from the abdomen) around the articulating area of the prostheses. The fat grafts considerably decreased the occurrence of heterotopic or reactive bone and fibrosis development around the prostheses. Some patients in this study received the periarticular fat grafts, but the number was too small to acquire any meaningful data. However, based on data from their published studies,[22-25] the authors recommend packing fat grafts around the articulation area of the prostheses as a routine step in the implantation of total joint prostheses for improved outcomes.

Coleta et al[26] evaluated 47 female patients for surgical stability after bilateral TMJ reconstruction using TMJ Concepts patient-fitted TMJ total joint prostheses, TMJ fat grafts (for most patients), and counterclockwise rotation of the maxillomandibular complex with Menton (most inferior point on the symphysis) advancing an average of 18.4 mm and the occlusal plane decreasing an average of 14.9°. The average follow-up was 40.6 months. Results showed minor maxillary horizontal changes and the mandibular measurements remained very stable.

Pinto et al[27] evaluated the same 47 female patients for pain and dysfunctional outcomes. Patients were divided into 2 groups based on the number of previous surgeries: group 1 had 0 to 1 previous surgery, whereas group 2 had at least 2 previous surgeries. Meaningful improvements (37 to 52%) were observed for TMJ pain, headaches, JawFn, diet, and disability. MIO increased 14%. Group 1 patients had better pain and JawFn results than group 2 patients. For patients who did not receive fat grafts around the prostheses and had previous failure of PT or SR TMJ implants, more than half required secondary surgery, including TMJ debridement for removal of FBGCR, fibrosis, or heterotopic bone formation. These 2 studies showed that patients with end-stage TMJ pathology could be treated in 1 operation with TMJ Concepts patient-fitted TMJ total joint prostheses, fat grafts, and maxillomandibular counterclockwise rotation for correction of an associated dentofacial deformity with good stability and improvement in pain and TMJ function.

Although not part of this study, potential unfavorable surgical sequelae can occur. Neurologic injuries can include sensory alteration of the maxillary and mandibular trigeminal nerve branches, resulting in paresthesia, dysesthesia, or anesthesia. The multiply operated patient can have major residual pain problems related to such conditions as cervical neuropathy, residual inflammatory disease or FBGCR, immunologic reaction to alloplastic particles, fibrosis, calcification, heterotopic or reactive bone formation, sympathetic mediated pain, autoimmune polyneuropathy, multiple chemical sensitivity, bacterial or viral contamination, or other unidentified factors.[13,14]

Facial nerve injuries can result in partial or complete paralysis of any or all branches unilaterally or bilaterally. Development of heterotopic or reactive bone, fibrosis, or FBGCR can create pain, swelling, and loss of mobility requiring further surgery and debridement. Although relatively unusual, hypersensitivity to the materials in the prosthesis can occur. Malpositioning of the device could result in malocclusion and dysfunction. Infection can occur, but with careful and sterile

techniques, antibiotics, and patients without severe immune dysfunction, infections have a low occurrence rate. If an infection does occur, protocols have been established for management with good prognosis to salvage the device.[28,29]

Although the life expectancy of Techmedica and TMJ Concepts TMJ TJR devices is still unknown, based on the CAD and CAM plan, the biomaterials involved in the manufacture, patient specificity, the lower functional loading forces applied to the TMJ complex compared with the knee and hip, and the relative ease and speed of implantation, these devices should have a lifespan longer than their orthopedic joint counterparts.

This prospective cohort study shows that at approximately 21 years after placement, *1)* the Techmedica CAD and CAM patient-fitted TMJ TJR device continues to function well; *2)* patients show sustained improvement in TMJ pain, JawFn, ability to eat solid food, and QoL; *3)* the degree of long-term improvement of all subjective measurements (except mandibular function and QoL) decreases with the increase of previous TMJ surgeries; and *4)* this prosthesis is not likely to fail because of material wear.

A properly designed and tested total alloplastic TMJ replacement device that is manufactured with biologically compatible materials and is implanted correctly is a safe and effective long-term management option for patients with severe and debilitating end-stage TMJ disease. Continued monitoring of all patients with TMJ TJR over time should be encouraged to provide continued support for their use in management of these TMJ pathologies.

Press Release

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