Does Unilateral Temporomandibular Total Joint Reconstruction Result in Contralateral Joint Pain and Dysfunction?

Daniel E. Perez, DDS, * *Larry M. Wolford, DMD,* † *Emet Schneiderman, PhD,* ‡ *Reza Movahed, DMD,* § *Campbell Bourland, DDS,* ‖ *and Enrique Perez Gutierrez, DVM, MSc, MPVM, PhD* ¶

Purpose: The purpose of this study was to evaluate patients requiring unilateral total temporomandibular joint (TMJ) reconstruction and the risk for development of postsurgical contralateral TMJ pain and dysfunction over time requiring subsequent contralateral total joint reconstruction. Long-term subjective and objective outcomes of unilateral TMJ reconstruction also were evaluated.

Materials and Methods: Seventy patients underwent unilateral total joint reconstruction using a patient-fitted total joint prosthesis from a single private practice from 1990 through 2012. The inclusion criteria were *1)* unilateral TMJ reconstruction with TMJ Concepts or Techmedica patient-fitted total joint prosthesis; *2)* operation performed by 1 surgeon (L.M.W.); *3)* minimum 12-month follow-up; and *4)* adequate records. There were no specific exclusion criteria. The primary outcome variable was to evaluate the effects of unilateral TMJ reconstruction with a total joint prosthesis on the contralateral TMJ relative to development of pain and dysfunction requiring subsequent contralateral reconstruction with a total joint prosthesis. Secondary outcome variables for all patients included TMJ pain, facial pain, headaches, diet, disability, quality of life, maximum incisal opening (MIO), and lateral excursion movements after unilateral TMJ reconstruction with the patient-fitted total joint prosthesis. Student *t* test and Wilcoxon test were used for statistical analyses, with a *P* value less than .01 for statistical significance.

Results: Sixty-one of 70 patients (87%) met the inclusion criteria (47 women [77%] and 14 men [23%]; average age, 38 yr; age range, 11 to 69 yr; average follow-up, 44 months; range, 12 to 215 months). Eight of 61 patients (13%) subsequently required contralateral TMJ reconstruction with a total joint prosthesis related to contralateral pain, dysfunction, and arthritis, but all 8 (8 of 27 [29.6%]) had previous contralateral TMJ disc repositioning surgery. For the secondary outcomes, TMJ pain decreased 63%, jaw function improved 61%, facial pain decreased 59%, headaches decreased 57%, diet improved 52%, disability decreased 58.5%, and MIO increased from 31.4 to 38.8 mm (mean change, 7.4 mm). All subjective factors and MIO showed statistically significant improvements at longest follow-up ($P < .01$).

Conclusions: Patients requiring unilateral TMJ reconstruction with a patient-fitted total joint prosthesis have a strong probability of improving their clinical condition and do not require bilateral reconstruction if

*Assistant Professor, Department of Oral and Maxillofacial Surgery, University of Texas, Health Science Center San Antonio, San Antonio, TX.

†Clinical Professor, Departments of Oral and Maxillofacial Surgery and Orthodontics, Texas A&M University Baylor College of Dentistry; Private Practice, Baylor University Medical Center, Dallas, TX.

‡Professor, Department of Biomedical Sciences, Texas A&M University Baylor College of Dentistry, Dallas, TX.

§Clinical Assistant Professor, Department of Orthodontics, St Louis University, Center for Advanced Dental Education, St Louis, MO.

‖Former Resident, Department of Oral and Maxillofacial Surgery, Texas A&M University Baylor College of Dentistry; Private Practice, Dallas, TX.

¶Senior Adviser, Food Borne Diseases and Zoonosis, World Health Organization, New York, NY.

Address correspondence and reprint requests to Dr Wolford: 3409 Worth Street, Suite 400, Dallas, TX 75246; e-mail: lwolford@swbell.net

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the contralateral TMJ is healthy. Patients with previous or concomitant contralateral TMJ surgery (articular disc repositioning) have an approximately 30% chance of requiring a total joint prosthesis in the future.

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Temporomandibular joint (TMJ) reconstruction with a total joint prosthesis can be indicated for any of the following TMJ pathologic conditions or situations: *1)* multiply operated TMJs (≥2 previous surgeries); *2)* failed TMJ alloplastic implants, including Proplast/Teflon (P/T; Vitek, Inc, Houston, TX) and Silastic (Dow-Corning, Midland, MO); *3)* failed autogenous TMJ grafts; *4)* osteoarthritis with nonsalvageable articular discs; *5)* inflammatory or reactive TMJ pathology; *6)* connective tissue and autoimmune diseases (eg, juvenile idiopathic arthritis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, scleroderma, Sjögren syndrome, lupus); *7)* fibrous or bony ankylosis; *8)* trauma; *9)* absence of anatomic structures (eg, fractured displaced condyles, absence of condyles and portions of the ramus from previous surgery, pathology, birth defects); and *10)* tumors involving the condyle and glenoid fossa area.[1-11] These TMJ pathologies can occur bilaterally or unilaterally and often are associated with dentofacial deformities, malocclusion, TMJ pain, headaches, myofascial pain, TMJ and jaw functional impairment, and ear symptoms. Autogenous tissues, such as ribs, sternoclavicular, temporal fascia, concha cartilage, dermis, and sliding ramus osteotomy, used for TMJ reconstruction can have a high incidence of failure because many of these TMJ pathologies can adversely affect autogenous grafts. Patients with these conditions can benefit functionally, esthetically, and from a pain standpoint by corrective surgical intervention using TMJ patient-fitted total joint prostheses and orthognathic surgery, if indicated. When the end-stage TMJ pathology occurs unilaterally, a unilateral TMJ total joint prosthesis might be indicated to reconstruct the ipsilateral joint. This can have an adverse effect on the healthy contralateral TMJ, but particularly if the contralateral TMJ has had previous surgery or requires surgery (articular disc repositioning, not a total joint prosthesis) at the same time as the ipsilateral prosthesis is placed.

Although several published studies evaluated the outcomes of patients receiving total joint prostheses,[1-8] bilateral and unilateral cases were evaluated conjointly in the study groups. Only 1 previous study by Franco et al[12] in 1997 evaluated the outcomes specifically of unilateral patient-fitted TMJ total joint prostheses and the effect on the ipsilateral and contralateral TMJs. However, 15 of 20 patients (75%) who underwent reconstruction had previous TMJ P/T devices placed in the ipsilateral TMJ before the TMJ patient-fitted prosthesis and all 15 patients had at least 1 previous TMJ surgery to the contralateral side (non-P/T). Six of these 15 patients (40%) required contralateral TMJ reconstruction with a total joint prosthesis within 2 years of the ipsilateral TMJ reconstruction. The 5 patients with no exposure to P/T and no contralateral TMJ surgery required no additional surgery. Further studies are necessary to evaluate the effects of unilateral TMJ total joint replacement on requirements for subsequent contralateral total joint reconstruction.

The objective of this study was to elucidate further the outcomes of patients receiving unilateral TMJ total joint prosthesis. The primary aim was to evaluate the effects of unilateral TMJ reconstruction with a total joint prosthesis on the contralateral TMJ relative to development of pain and dysfunction requiring subsequent contralateral reconstruction with a total joint prosthesis.

Materials and Methods

This retrospective study evaluated records of 70 patients from a single private practice, from 1990 through 2012, who required unilateral TMJ reconstruction with a total joint prosthesis. Criteria for study inclusion were *1)* unilateral TMJ reconstruction with a patient-fitted TMJ total joint prosthesis (TMJ Concepts Inc, Ventura, CA; Techmedica Inc, Camarillo, CA); *2)* all surgical procedures performed by 1 surgeon (L.M.W.) at Baylor University Medical Center (Dallas, TX); *3)* minimum 12-month postsurgical follow-up; and *4)* adequate records. There were no specific exclusion criteria. Standardized presurgical and postsurgical evaluation forms were used to collect objective and subjective clinical data. The institutional review board at Baylor University Medical Center reviewed and approved this study (reference number, 073646).

Patients were assessed for the primary outcome of determining subsequent requirement for contralateral TMJ total joint reconstruction after the initial ipsilateral total joint reconstruction by chart review. This was correlated to the number of prior contralateral TMJ surgeries or if performed concomitantly with the ipsilateral total joint replacement and if orthognathic surgery was performed concomitantly.

Secondary outcome variables for all patients included facial pain, headaches, diet, disability, quality of life, maximum incisal opening (MIO), and lateral

excursion movements after unilateral TMJ reconstruction with the patient-fitted total joint prosthesis. Patient outcomes also were evaluated according to age, gender, previous TMJ exposure to a P/T device, or other failed alloplastic reconstruction.

Patients were assessed immediately before surgery (T1) and at the longest available follow-up (T2). The same examiner administered the standardized subjective questionnaire and recorded the objective ranges of jaw movement in all patients at all follow-up intervals. Patients self-rated TMJ pain, headache, facial pain, jaw function, diet, disability, and quality of life. MIO (unassisted) and excursive movements were recorded.

Subjective ratings used a numeric analog scale ranging from 0 to 10 (pain, 0 = no pain to 10 = worst pain imaginable; jaw function, 0 = normal to 10 = no function; diet, 0 = no restriction to 10 = liquids only; disability, 0 = no disability to 10 = totally disabled). At longest follow-up, patients were asked to rate their quality of life as improved, the same, or worse.

Objective functional assessments measured MIO and lateral excursion movements at T1 and T2. MIO measurements between the lower and upper incisor tips used a ruler with the jaws at maximum opening without assistance. For anterior open bite, the amount of open bite was subtracted from the maximal opening. For anterior deep bite, the amount of vertical dental overlap was added to the opening to record the actual result. Lateral excursion was the average measurement between left and right maximum excursions without assistance using a ruler to measure the shift between the upper dental midline and the alignment of the lower arch starting from a centric relation.

The number of prior TMJ surgeries was recorded, with patients dichotomized as those with 0 to 1 previous surgery and those with at least 2 previous surgeries. Consideration of this variable was based on previous studies that documented patients with at least 2 previous TMJ surgeries having poorer outcomes than those with 0 to 1 previous surgery.[2-4,6-8] Whether patients had previous or concomitant surgery on the contralateral TMJ also was assessed. Patients with 1 failed prior contralateral TMJ surgery received bilateral total joint replacement and were excluded from this study.

Two groups were established based on postsurgical follow-up intervals. Short-term results (<35 months) were compared with long-term results (36 to 212 months) to determine whether there were statistically relevant differences.

STATISTICAL ANALYSIS

The paired *t* test and Wilcoxon test were used to evaluate changes from T1 to T2 for objective and subjective variables, respectively; *t* test was used to compare the groups. The conservative significance level ($P < .01$) was used to defend against the inflated type I error rate that occurs with multiple related tests. *P* values of at least .01 but less than .05 were characterized as marginally significant. Risk was calculated for previous surgical procedures and the need for a future prosthesis on the contralateral side.

SURGICAL TECHNIQUE

Before surgery, a computed tomogram was obtained to construct a 3-dimensional (3D) stereolithographic polymer model of the patient's jaws and jaw joints (Fig 1). Surgery was performed on the 3D model based on the clinical analysis and prediction tracing, including condylectomy and ramus and fossa recontouring, if indicated. If simultaneous orthognathic surgery was planned, then the mandible on the 3D model was placed in the final predetermined position and secured to the maxillary teeth with quick-cure acrylic. A patient-fitted total joint prosthesis was manufactured on the model to meet the patient's specific anatomic requirements. Then, the mandibular movement was duplicated on articulator mounted dental models for construction of an intermediate splint. Maxillary model surgery was performed and the final palatal splint was constructed.

Surgical procedures were performed under general anesthesia with nasal endotracheal intubation. The face and mouth were prepped and the mouth and nose were isolated with a Tegaderm dressing (3M, St Paul, MN) for the first stage of surgery. The ipsilateral TMJ was approached through an endaural or preauricular incision and the TMJ was exposed, a condylectomy was performed, and the fossa was debrided. A coronoidotomy or coronoidectomy was performed through this incision if the mandible was to be markedly advanced or vertically lengthened as required for counterclockwise rotation of the mandible. A submandibular or Risdon incision was used to expose the mandibular angle and ramus with detachment of the masseter muscle. For cases requiring marked mandibular advancement or counterclockwise rotation of the mandible, the medial pterygoid muscle also was detached. A subperiosteal tunnel was created on the ramus to connect to the glenoid fossa. The mandible was mobilized and bony modifications to the fossa or ramus or angle of the mandible were completed as determined from the 3D model preparation. If the contralateral TMJ required disc repositioning, then an endaural incision provided access for mobilization of the disc and stabilization with a Mitek anchor (DePuy Synthes, West Chester, PA) and artificial ligaments.[13-15]

In some patients, double-jaw orthognathic surgery was indicated to correct a coexisting dentofacial

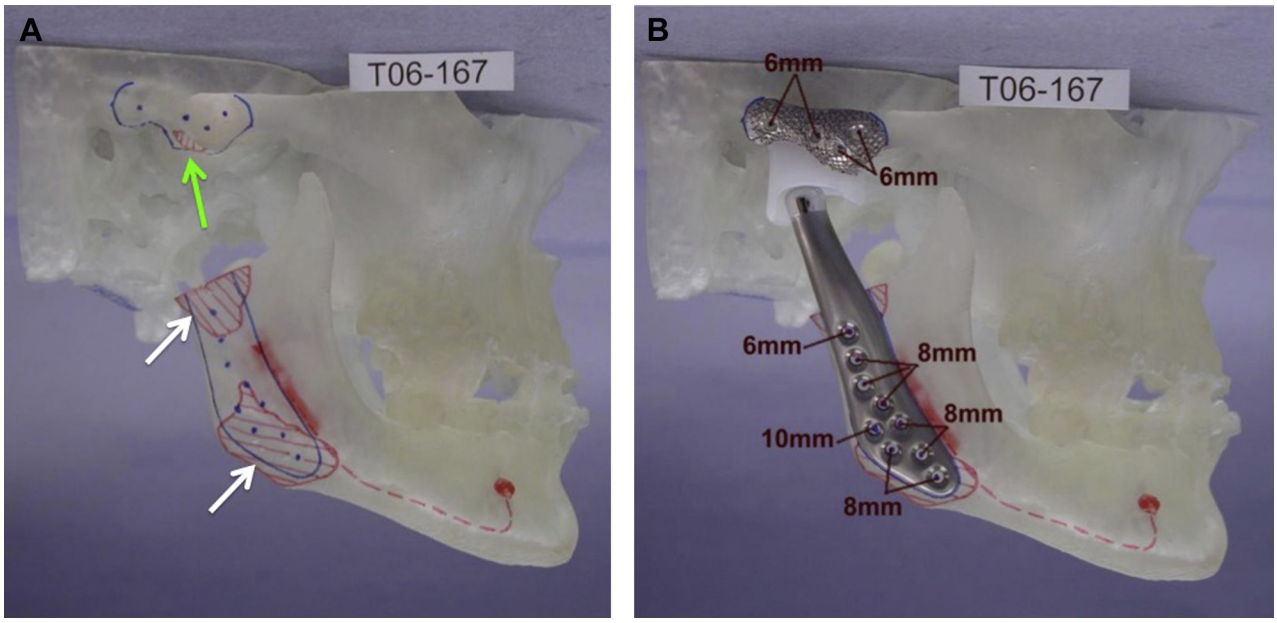

FIGURE 1. *A,* Preparation of stereolithographic model for prosthesis construction. Hash marks on the ramus (*white arrows*) indicate areas of bone recontouring to facilitate manufacture and placement of the prosthesis. *Green arrow* points to the fossa that occasionally requires recontouring. Twenty millimeters of space is required between the fossa and ramus to accommodate the prosthesis. *B,* TMJ Concepts patient-fitted prosthesis manufactured and positioned on the model. Numbers represent recommended screw lengths for bicortical screw placement.

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deformity. After the preparatory surgery on the ipsilateral and contralateral TMJs, the face was draped exposing only the mouth, the Tegaderm dressing covering the mouth was incised between the lips for oral access, a contralateral mandibular ramus sagittal split osteotomy was completed, the mandible was mobilized, an intermediate occlusal splint was inserted, and intermaxillary fixation (IMF) was applied. The contralateral mandibular sagittal split osteotomy was rigidly stabilized with a bone plate and screws, the incision was closed, and the oral cavity was isolated with a Tegaderm dressing.

With clean sterile instruments and technique, the fossa component of the TMJ Concepts prosthesis was placed through the ipsilateral endaural incision and secured to the lateral rim of the fossa with 4 2-mm-diameter 6- to 8-mm-long screws. The mandibular component was inserted through the submandibular incision with the condyle seated in the depth of the fossa component against the posterior stop and secured to the ramus with 7 to 9 2-mm-diameter bicortical screws. The surgical areas were thoroughly irrigated, the masseter muscle was approximated to the angle of the ramus, and the submandibular incision was closed.

For patients treated from 1992 through 2012, fat grafts were harvested from the abdomen at the suprapubic or umbilicus region or from the buttock, packed around the articulation area of the fossa and condyle components, and the incision was closed.[16,17]

For double-jaw cases, the mouth was entered, the IMF and intermediate splint were removed, the maxillary osteotomies were performed, the maxilla was mobilized and segmented if necessary, the palatal splint was applied, and turbinectomies and septoplasty were performed if indicated. IMF was applied, rigid fixation with 4 bone plates was used, bone gaps were grafted with autogenous or synthetic bone (Interpore 200, Interpore Inc, Irvine, CA), IMF was removed, the incision was closed and followed by any other indicated procedures, such as genioplasty, rhinoplasty, etc. Light elastics were placed to guide the occlusion and decrease stress on the muscles of mastication immediately after surgery.

Results

Sixty-one of the 70 patients (87%) met the criteria for inclusion (47 women [77%] and 14 men [23%]). Nine patients were excluded from the study because of inadequate records (some of the earliest patients) or failed to meet the 12-month minimum follow-up. The average age at surgery was 38.6 years (range, 11 to 69 yr) and average follow-up was 44 months (range, 12 to 215 months). Left and right TMJs were equally affected. When patients with only short-term results (<36 months) were compared with those with long-term results (≥36 months) for change in subjective and objective parameters, there were no significant differences ($P \geq .082$). Therefore, T2 outcomes for

all patients were combined. The number of patients per TMJ diagnosis included 24 (39.3%) with osteoarthritis and nonsalvageable articular disc, 13 (21.3%) with failed TMJ alloplastic reconstruction, 7 (11.5%) with hemifacial microsomia, 7 (11.5%) with trauma, 5 (8.2%) with ankylosis, 3 (4.9%) with reactive arthritis, and 2 (3.3%) with tumor (Table 1).

The average number of previous ipsilateral TMJ surgeries was 2.1 procedures per patient; 35 patients (57.4%) had 0 to 1 previous ipsilateral TMJ surgery, whereas 26 patients (42.6%) had at least 2 previous TMJ surgeries. On the contralateral side, 27 patients (44.3%) had 1 previous TMJ surgery or surgery was performed at the same time as the ipsilateral total joint prosthesis placement, usually consisting of articular disc repositioning with a Mitek anchor,[13-15] whereas 34 patients (55.7%) had no surgery on the contralateral side (Table 1).

Eight of the 61 patients (13%) subsequently required a contralateral total joint replacement secondary to pain, decreased function, and arthritis; all these patients had previous contralateral surgery (8 of 27 patients [29.6%]). Twenty-four of 61 patients (39.3%) had concomitant orthognathic surgery at the initial operation, with 4 of 24 (16.7%) requiring contralateral TMJ reconstruction, and 4 of 37 (10.8%) without orthognathic surgery required contralateral TMJ surgery. The observed difference between those with and without concomitant orthognathic surgery was not statistically significant ($P = .210$).

Table 1. PATIENT DEMOGRAPHICS (N = 61)

Women/men, n (%)	47 (77)/14 (23)
Age at surgery (yr), mean (SD)	38.6 (10)
Follow-up (mo), average (range)	44 (12-215)
Unilateral prostheses, right/left	31/30
Prior ipsilateral surgeries, average (range)	2.1 (0-15)
Patients with 0-1 surgery, n (%)	35 (57.4)
Patients with ≥2 surgeries, n (%)	26 (42.6)
Patients with prior contralateral surgery, n (%)	27 (44.3)
Patients with no prior contralateral surgery, n (%)	34 (55.7)
Patients with concomitant orthognathic surgery, n (%)	24 (39.3)
Patients with no concomitant orthognathic surgery, n (%)	37 (60.7)
Ipsilateral TMJ diagnosis, n (%)	
Ankylosis	5 (8.2)
Tumor	2 (3.3)
Trauma	7 (11.5)
Reactive arthritis	3 (4.9)
Osteoarthritis	24 (39.3)
Failed alloplastic devices	13 (21.3)
Hemifacial microsomia	7 (11.5)
Patients requiring contralateral TMJ prosthesis, n (%)	8/61 (13)
Prior TMJ surgery	8/27 (29.6)
No prior TMJ surgery	0/34 (0)

Abbreviations: SD, standard deviation; TMJ, temporomandibular joint.

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All subjective and objective criteria evaluated showed significant changes ($P < .01$) from T1 to T2 (Table 2) except lateral excursions, for which the change was minor. TMJ pain decreased 4.1 points, representing an improvement percentage (IP) of 63.08%; jaw function improved 3.8 points (IP, 61.29%), facial pain decreased 3.7 points (IP, 58.73%), headaches decreased 2.2 points (IP, 57.14%), diet improved 2.8 points (IP, 51.85%), and disability improved 3.1 points (IP, 58.49%). MIO increased 7.4 mm (IP, 23.57%), from 31.4 mm at T1 to 38.8 mm at T2, but right excursion decreased 0.8 mm (IP, −16.0%) and left excursion decreased 0.6 mm (IP, −13.33%; Table 2).

When the subjective data were analyzed relative to postsurgical patient outcomes, all values showed statistically relevant improvement (Table 3). Relative to quality of life subjective changes for all 6 parameters, 56 to 90% of patients improved, 3 to 37% stayed the same, and 7 to 10% became worse (Table 3). The best results for outcome were for decreased TMJ pain (79%), decreased facial pain (80%), improved jaw function (90%), and improved dietary function (80%). In the group that remained unchanged, many patients did not have that particular symptom before surgery. For example, before surgery, 5 of 8 patients did not have TMJ pain, 5 of 8 had no facial pain, 20 of 23 had no headaches, and 5 of 11 had no disability. Most patients who reported worsening had multiple operations or had P/T implants.

Patients previously exposed to TMJ P/T devices (n = 13; Table 4) showed improvement after reconstruction with TMJ Concepts total joint prostheses, but the level of improvement was not as good as for patients without previous exposure to P/T devices (n = 48). The only variables to improve significantly ($P < .01$) for the P/T group were TMJ pain, jaw function, and headaches. The results were only marginally statistically relevant for facial pain, diet, disability, and MIO (Table 4). More previous TMJ surgeries (with or without P/T) indicated less improvement. No statistically relevant differences were found when analyzing patients according to age or gender.

There were 56 patients (91.8%) who received fat grafts around the periarticular area of the prostheses and 5 patients (8.2%) who did not. The non-grafted group was too small to make a meaningful comparison

Table 2. SUBJECTIVE AND OBJECTIVE EVALUATIONS (N = 61)

Subjective and Objective Evaluations	T1, Mean (SD)	T2, Mean (SD)	Improvement, %	*P* Value
TMJ pain*†	6.5 (3.0)	2.4 (3.1)	63.08↓	<.0001
Jaw function*‡	6.2 (2.1)	2.4 (2.0)	61.29↑	<.0001
Facial pain†	6.3 (2.8)	2.6 (2.9)	58.73↓	<.0001
Headaches†	3.8 (3.4)	1.6 (2.7)	57.14↓	<.0001
Diet§	5.4 (2.4)	2.6 (2.4)	51.85↑	<.0001
Disability‖	5.3 (2.7)	2.2 (2.7)	58.49↓	<.0001
MIO (mm)	31.4 (13.4)	38.8 (8.8)	23.57↑	<.0001
Right lateral excursion	5.0 (3.2)	4.2 (2.9)	16.00↓	.0300
Left lateral excursion	4.5 (3.0)	3.9 (2.3)	13.33↓	.0930

Abbreviations: MIO, maximum incisal opening; SD, standard deviation; T1, immediately before surgery; T2, at longest available follow-up; TMJ, temporomandibular joint.
* Primary variables.
† Numerical analog scale, 0 = no pain to 10 = worst pain.
‡ Numerical analog scale, 0 = normal to 10 = no function.
§ Numerical analog scale, 0 = no restriction to 10 = liquids only.
‖ Numerical analog scale, 0 = no disability to 10 = totally disabled.

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with the fat-grafted group. All 5 patients were treated before 1992, before the development of the fat graft technique.

Discussion

The primary purpose of this study was to evaluate patients requiring unilateral TMJ total joint reconstruction and the risk for development of postsurgical contralateral TMJ pain and dysfunction over time requiring subsequent contralateral total joint reconstruction. The ipsilateral TMJ reconstruction showed no meaningful adverse effect on the healthy unoperated contralateral TMJ, but previous or simultaneous contralateral TMJ surgery (articular disc repositioning) resulted in an increased risk of approximately 30% for requiring subsequent contralateral total joint prosthesis related to pain, dysfunction, and arthritis. There was no statistically significant increased risk of requiring a subsequent contralateral TMJ total joint reconstruction when orthognathic surgery was concomitantly performed ($P = .210$). There is a theoretical increased risk related to the counterclockwise rotation of the intermaxillary complex often required for these patients that could increase the load to the TMJs until the muscles, periosteum, skin, and other soft tissue structures can equilibrate to the new position of the skeletal and dental structures. This did not appear to be a relevant risk factor for this series of patients.

Table 3. SUBJECTIVE EVALUATION RESULTS FOR QUALITY OF LIFE (N = 61)

	Patients, n (%)		
Subjective Evaluation	Improved	Unchanged	Worse
TMJ pain*	48 (79)	8 (13)†	5 (8)
Jaw function*	55 (90)	2 (3)	4 (7)
Facial pain	49 (80)	8 (13)‡	4 (7)
Headaches	34 (56)	23 (37)§	4 (7)
Diet	49 (80)	6 (10)	6 (10)
Disability	45 (74)	11 (18)‖	5 (8)

Abbreviation: TMJ, temporomandibular joint.
* Primary variables.
† Five patients had no pre- or postsurgical TMJ pain.
‡ Five patients had no pre- or postsurgical facial pain.
§ Twenty patients had no pre- or postsurgical headaches.
‖ Five patients had no pre- or postsurgical disability.

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Patients who required contralateral TMJ disc repositioning might have had presurgical reactive arthritis, connective tissue or autoimmune disease, or other systemic polyarthritis factors affecting the joint, but not with the destructive factors associated with the ipsilateral TMJ at the time of the initial surgery. In addition, there might be increased loading of the contralateral joint with function because the total joint prosthesis articulation is absent an interpositional disc structure to cushion the load, thus transferring an increased load to the repaired contralateral joint. These conditions can lead to progressive arthritic changes, pain, and dysfunction in the contralateral TMJ, resulting in the requirement for later reconstruction with a total joint prosthesis.

One of the confounding factors in this study is the discrepancy in follow-up times (range,

Table 4. EVALUATION OF CHANGES FROM T1 TO T2 USING WILCOXON TESTS. GROUP 1 (N = 13) WITH PREVIOUS FAILED ALLOPLASTIC TMJ IMPLANTS. GROUP 2 (N = 48) WITH NO PREVIOUS TMJ ALLOPLASTIC IMPLANTS

	Group 1 (n = 13)		Group 2 (n = 48)	
Subjective Evaluation	T2−T1	*P* Value	T2−T1	*P* Value
TMJ pain	−2.446*	.00714	−5.385*	.00001
Jaw Function	−2.725*	.00317	−5.791*	.00001
Facial Pain	−2.236†	.01246	−5.334*	.00001
Headaches (R−L)	−2.374*	.00889	−5.934*	.00001
Diet	−1.216†	.01112	−5.253*	.00001
Disability	−2.157†	.01539	−5.062*	.00001
MIO (mm)	−2.306†	.01044	−3.392*	.00035

Bold Type: Primary Variables

* Statistically significant changes at $P < .01$.

† Marginally significant, where $.01 \leq P < .05$.

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12 to 215 months). It would be ideal if all patients had the same long-term follow-up time, but this is impossible with such a large group of patients from many different areas of the country and added to the study over a 22-year time span (1990 through 2012). Most patients requiring contralateral TMJ reconstruction developed considerable contralateral pain and dysfunction symptoms within a few months to 2 years of the initial surgery, but the contralateral surgery might not have occurred until later related to nonsurgical management, a patient selectively delaying surgery, or insurance and financial reasons. However, this creates concern that some patients with shorter follow-up could still require reconstruction of the contralateral TMJ in the future, particularly those with previous contralateral TMJ surgery, and that prediction is unknown. Even if the outcomes are slightly inflated, the success and improvement rates in the present study suggest that experienced surgeons can expect good, if not excellent, results after performing unilateral TMJ reconstruction when the contralateral TMJ is healthy.

The TMJ Concepts patient-fitted total joint prosthesis was originally developed and marketed by Techmedica from November 1989 through June 1993. In July 1993, the Food and Drug Administration (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 P/T devices for the TMJ. Based on clinical trial outcome data contained in a 5-year follow-up study by Wolford et al,[7] a multicenter study by Mercuri et al,[3] and the technical merit of the prosthesis design and material content, the Techmedica computer-assisted designed and computer-assisted manufactured patient-fitted TMJ total joint replacement 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.

These prostheses use design principles and materials that are proved highly successful and are the gold standard in orthopedic joint reconstruction for hip and knee replacements. The prosthesis consists of a fossa component with a commercially pure titanium framework covered with a mesh and an ultra–high-molecular-weight polyethylene functional component fused to the mesh on the bottom side of the framework. The fossa component is attached to the lateral rim of the fossa with 4 2-mm-diameter screws. The mandibular component is composed of a titanium alloy shaft with a cobalt and chromium alloy head with the prosthesis secured to the mandibular ramus with 7 to 9 2-mm-diameter bicortical screws. The fossa and mandibular components become osseointegrated with the fossa and ramus, respectively.

Although the life expectancy of this device is unknown, Wolford et al[18] recently published a 20-year follow-up study of 56 patients who had received Techmedica total joint prostheses from 1989 through 1993. There were statistically relevant improvements in all parameters, including incisal opening, jaw function, TMJ pain, and diet, with 85.7% of patients reporting considerable improvement in their quality of life. Patients with more previous TMJ surgeries reported a lower degree of subjective improvement, but they did report increased objective mandibular function and improved quality of life. There were no reports of device removal because of material wear or failure.

Henry and Wolford,[1] Wolford et al,[2,7,18-21] Mercuri et al,[3,6,8,22] and others[23-29] have published numerous

studies in reference to outcome data using TMJ Concepts or Techmedica patient-fitted total joint prostheses. In all these previous studies, bilateral and unilateral cases were evaluated conjointly. A summary of these publications has produced the following facts in reference to the TMJ Concepts total joint prostheses: *1)* TMJ Concepts prostheses are superior to autogenous tissues for end-stage TMJ reconstruction based on subjective and objective outcomes[1,2,4,5,10]; *2)* after 2 previous TMJ surgeries, autogenous tissues have a very high failure rate, whereas patient-fitted total joint prostheses have a high success rate[1,2,9,10]; *3)* no donor site morbidity; *4)* more previous TMJ surgeries produce a lower level of improvement related to pain and function outcomes compared with patients with 0 to 1 previous TMJ surgery[1-11,18,20,22,25]; *5)* failed TMJ alloplastic reconstruction (ie, P/T, Silastic, metal-on-metal articulation, etc) can create a foreign-body giant cell reaction or metallosis that is best treated by joint debridement and reconstruction with patient-fitted total joint prostheses[1-12,21,22]; *6)* packing fat grafts around the articulating area of the prostheses improves outcomes, such as decreased pain, improved jaw function, decreased risk of heterotopic bone formation around the prosthesis, and decreased requirement for repeat surgery[16,17,30]; *7)* osseointegration of the fossa and mandibular components occur and is important for long-term stability[2-11,18-20,23,24]; *8)* posterior stop on the fossa component is important to stabilize the joint, jaw position, and occlusion[2,7,19,20,23-25]; *9)* concomitant orthognathic surgery can be performed at the same time as the TMJs are reconstructed[2,3,19,20,23-25]; and *10)* a 20-year follow-up study reported improvements in pain, jaw function, diet, incisal opening, and quality of life.[18]

In 1992, Wolford[16] developed a technique to place fat grafts (harvested from the abdomen or buttock) around the articulating area of the total joint prosthesis to eliminate the dead space. This prevents blood clot formation in the space around the prosthesis that could provide a matrix for fibrous ingrowth and pluripotential cells migrating into the area that could develop heterotopic bone and dense fibrotic tissues. Also, in patients with previous failed alloplastic implants, the fat graft blocks out a large area in which the foreign-body giant cell reaction might otherwise redevelop. Wolford and Karras[16] and Wolford et al[17] reported improved outcomes for patients using fat grafts packed around the prostheses compared with patients who did not receive fat grafts. Mercuri et al[30] also reported the efficacy of fat grafts packed around the prostheses in TMJ ankylosis cases. Autologous fat grafting is a useful adjunct to prosthetic TMJ reconstruction to minimize the occurrence of excessive joint fibrosis and heterotopic bone formation, thus providing improved range of motion, jaw function, and decreased pain.

Unilateral TMJ reconstruction with a TMJ Concepts total joint prosthesis is a predictable procedure that does not require bilateral reconstruction if the contralateral TMJ is healthy. Patients requiring unilateral TMJ reconstruction with a TMJ Concepts patient-fitted total joint prosthesis have a strong probability of improving their clinical condition. The unilateral devices behave the same as bilateral devices and are affected by the same variables. Patients with unilateral failed alloplastic devices or autogenous grafts and those with multiple operations should show improvement, but will not have the quality of outcome as patients not exposed to those materials or with 0 to 1 previous TMJ operation. Previous or concomitant surgery on the contralateral side creates a risk (30%) for a later need of TMJ total joint replacement.

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