Comparison of 2 Temporomandibular Joint Total Joint Prosthesis Systems

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Purpose: The study goal was to evaluate the comparative outcomes of patients treated with temporomandibular joint (TMJ) total joint prostheses, using either the Christensen prosthesis (TMJ Inc, Golden, CO) (CP) or the TMJ Concepts prosthesis (TMJ Concepts Inc, Camarillo, CA; formerly Techmedica Inc) (TP).

Patients and Methods: Forty-five consecutive patients treated with either CP or TP total joint prostheses were evaluated. The CP group consisted of 23 patients (40 prostheses; average patient age, 38.8 years). The TP group consisted of 22 patients (38 prostheses; average patient age, 38.5 years). The average number of previous operations for the CP group was 3.9, whereas it was 2.6 for the TP group. The CP and TP groups had an average follow-up of 20.8 and 33.0 months, respectively. Patients were evaluated for incisal opening and occlusal and skeletal stability. A visual analog scale was used for subjective assessment of TMJ pain (0 = no pain, 10 = worst pain), jaw function (0 = normal function, 10 = no function), and diet (0 = no limitations, 10 = liquids only). Statistical analysis was performed using an independent *t* test, and a value of $P < .05$ was considered significant.

Results: The average postsurgical incisal opening for the CP group was 30.1 mm (increase of 6.7 mm), and that for the TP group was 37.3 mm (increase of 9.9 mm), indicating significant increase of the TP group ($P = .008$). The average postsurgical pain level for the CP group was 6.0, a decrease of 1.8, and that for the TP group was 4.1, a decrease of 3.1, indicating significant improvement for the TP group ($P = .042$). Postsurgical average jaw function for CP was 5.5, an improvement of 1.2. The postsurgical TP average was 3.9, an improvement of 3.0, showing significant improvement for the TP group ($P = .008$). Average postsurgical diet rating for the CP group was 5.4, an improvement of 1.8. The TP group average was 3.9, an improvement of 2.0, indicating significant improved eating ability for the TP group ($P = .021$). Skeletal and occlusal stability were good in both groups.

Conclusion: The TP group had statistically significant improved outcomes compared with the CP group relative to postsurgical incisal opening, pain, jaw function, and diet. Both groups showed good skeletal and occlusal stability.

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Temporomandibular joint (TMJ) disease is estimated to affect 30 million Americans, with approximately 1 million new patients diagnosed yearly.[1] Although many of these patients can usually be managed with nonsurgical therapies, there remains a group of patients who require surgical intervention. When surgical intervention of the TMJ is required, it can often be repaired or reconstructed with autogenous tissues. However, there are certain specific TMJ conditions and pathology that require reconstruction with a total joint prosthesis for better predictability of treatment outcomes. Some of these conditions are 1) multiply operated TMJs (≥2 previous operations); 2) previous TMJ alloplastic implants containing Proplast/Teflon (PT), Silastic (Dow Corning Inc, Midland, MO), acrylic, or bone cements; 3) inflammatory, infective, reactive, or resorptive TMJ pathology; 4) connective tissue or autoimmune disease (ie, rheumatoid arthritis, psoriatic arthritis, scleroderma, Sjögren's syn-

drome, lupus, ankylosing spondylitis, etc); 5) fibrous or bony ankylosis; 6) absence of TMJ structures due to pathology, trauma, or congenital deformity; and 7) tumors involving the fossa and/or condyle and mandibular ramus region.

Alloplastic total joint prostheses provide a biomechanical rather than a biologic solution for the treatment of severe joint disease.[2,3] The prosthesis provides an efficient and effective means of dealing with distorted and mutilated joint anatomy while not relying on the vascularity of the periarticular tissues, which is essential in autogenous reconstruction. Alloplastic reconstruction eliminates the need for a second surgical site with the associated morbidity and minimizes the effects of connective tissue/autoimmune disease, ankylosis, reactive arthritis, infectious arthritis, etc, which can cause destruction of autogenous tissues used in TMJ reconstruction.[4]

There have been numerous alloplastic materials used in TMJ joint prostheses.[5] Some of these devices, such as the PT containing Vitek-Kent products (Vitek Inc, Houston, TX) and Silastic implants, have been removed from the market due to poor biocompatibility, increased wear, fragmentation, and foreign body giant cell reaction (FBGCR). The failure of most of the prostheses used in the past necessitated the need for improvement in biotechnology and the construction of alloplastic prostheses with proven safe materials, with little to no wear and with long-term stability.

At the time of completion of this study, 2 total joint prostheses were commercially available in the United States: The Christensen prosthesis (TMJ Inc, Golden, CO) (Fig 1) (CP) and the TMJ Concepts prosthesis (TMJ Concepts Inc, Camarillo, CA; formerly Techmedica Inc) (Fig 2) (TP). The manufacturers of both of these prostheses have claimed good success rates and have shown improvement for the multiply operated TMJ patients.[4,6,7] This retrospective study was undertaken to evaluate and present our treatment outcomes and experience in using these 2 prostheses for total joint reconstruction in similar groups of patients.

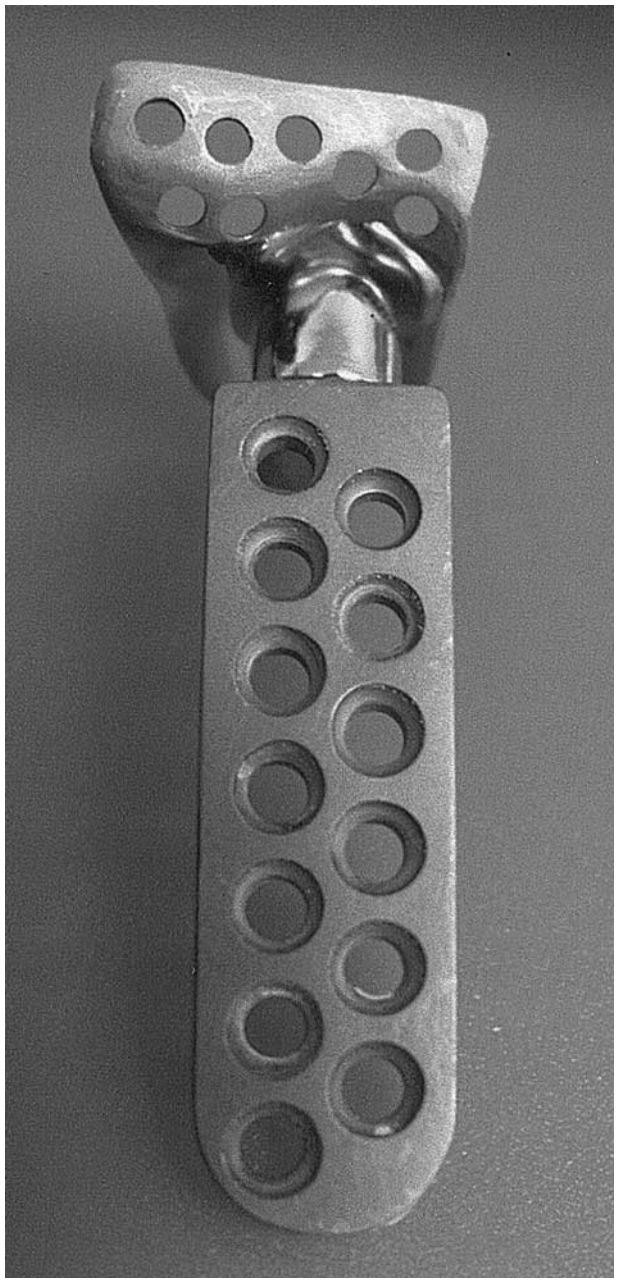

FIGURE 1. The Christensen (TMJ Inc, Golden, CO) total joint prosthesis is an off-the-shelf device made of cast chromium-cobalt alloy. The devices used in this study had a metal condylar head functioning against a metal fossa.

Patients and Methods

In this retrospective study, we analyzed the treatment records of 45 patients (40 females and 5 males) who underwent TMJ reconstruction (78 joints) with total joint prostheses. Criteria for inclusion in the study were 1) unilateral or bilateral TMJ reconstruction with total joint prostheses, 2) minimum of 1-year postsurgical follow-up, 3) absence of postsurgical trauma, and 4) placement of fat grafts around the TMJ prostheses at the time of surgery. All operations were performed by one surgeon. The patient population was divided into 2 groups: Group 1 consisted of 23 patients (22 females and 1 male) who were reconstructed with the CPs (17 bilateral and 6 unilateral), and group 2 consisted of 22 patients (18 females and 4 males) who were reconstructed with the TPs (16 bilateral and 6 unilateral).

Both prostheses consisted of a fossa and a mandibular component. The CP components were off-the-shelf products, and all components were made of cast chromium-cobalt alloy (chromium 28%, cobalt 64%, molybdenum 7%, and nickel 1%). The fossa compo-

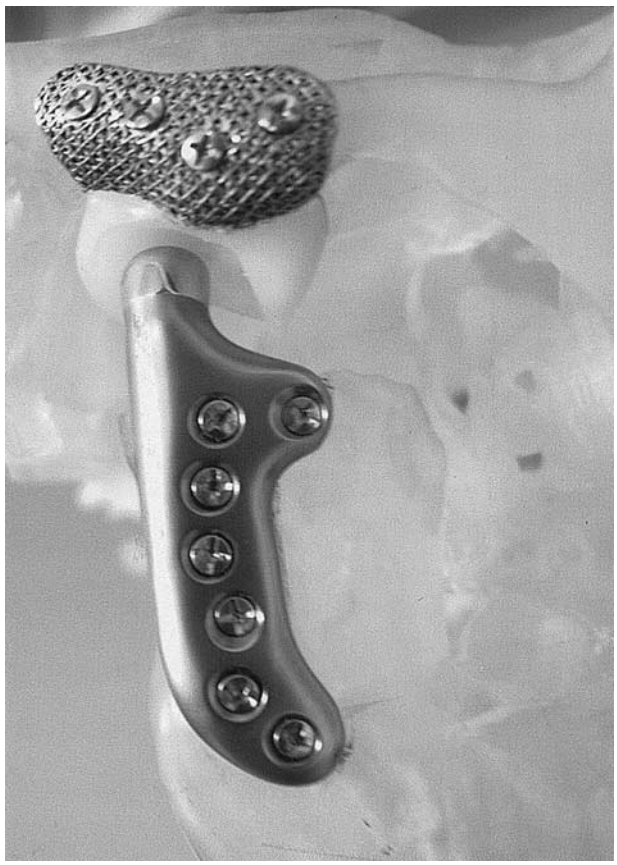

FIGURE 2. The TMJ Concepts (TMJ Concepts Inc, Camarillo, CA; formerly Techmedica Inc) total joint prosthesis is a custom-made device constructed from wrought metals of titanium, titanium alloy, chromium-cobalt alloy (for condylar head only), and ultrahigh–molecular weight polyethylene. The chromium-cobalt alloy head functions against the ultrahigh–molecular weight polyethylene.

nent had more than 30 choices of size and shape. The surgeon selected the best fit intraoperatively. The fossa was stabilized with 3 or 4 screws of 2.0-mm diameter. The ramus/condyle component had 3 standard sizes from which to select, which was stabilized with 6 to 8 screws of 2.7-mm diameter.

The TP was a custom-made and custom-fitted device derived from computed tomography (CT) data using computer-aided design/computer-aided manufacture stereolithography technology, fabricating an accurate anatomic plastic model of the patient's jaws and TMJs. The prosthesis was constructed on this model. The TP metal components were wrought, and all parts were machined. The fossa was made of a commercially pure titanium shell and 4 layers of commercially pure titanium mesh bonded to the shell, which allows bone growth into the mesh to maximize stabilization of the fossa component. Dense ultrahigh–molecular weight polyethylene (UHMWPE) was bonded to the titanium mesh as the articulating surface. The fossa component was secured to the zygomatic arch with 4 screws of 2.0-mm diameter. The mandibular ramus component was made of wrought titanium alloy (titanium 90%, aluminum 6%, and vanadium 4%). The condylar head was wrought chromium-cobalt alloy (chromium 28%, cobalt 64%, molybdenum 6%, and nickel 1%). The ramus component was stabilized with 7 to 10 screws of 2.0-mm diameter.

Presurgery (T1) and longest follow-up (T3) clinical evaluations were performed by one clinician and included 1) subjective evaluation using visual analog scales (VASs) for TMJ pain (0 = no pain, 10 = worst pain), jaw function (0 = normal function, 10 = no function), and diet (0 = no restrictions, 10 = liquids only); 2) objective evaluation of maximal incisal opening (MIO); and 3) skeletal and occlusal stability. Acetate tracings of standardized lateral cephalometric radiographs taken immediate after surgery (T2) and at T3 intervals were superimposed for each patient to assess skeletal and occlusal stability. Tracings for each patient were superimposed on the stable cranial base

Table 1. COMPARISON OF CHRISTENSEN PROSTHESES (CP) WITH TMJ CONCEPTS PROSTHESES (TP)

	CP Presurgery (average)	TP Presurgery (average)	*t* Test*	CP Postsurgery (average)	TP Postsurgery (average)	*t* Test*
No. of patients	23	22		23	22	
Incisal opening (mm)	23.4 (7-40)	27.4 (13-41)	$P = .194$	30.1 (5-58)	37.3 (28-53)	$P = .008$
TMJ pain (0 = no pain, 10 = worst pain)	7.8 (2-10)	7.2 (0-10)	$P = .397$	6.0 (0-10)	4.1 (0-10)	$P = .042$
Jaw function (0 = normal function, 10 = no function)	6.7 (0-10)	6.9 (0-9)	$P = .874$	5.5 (1-9)	3.9 (0-7)	$P = .008$
Diet function (0 = no restriction, 10 = liquids only)	7.2 (2-10)	5.9 (0-9)	$P = .073$	5.4 (1-8)	3.9 (0-8)	$P = .021$

*$P < .05$ significant.

landmarks. Changes in position of point A and point B were analyzed for evidence of spatial changes. An independent Student's t test was used for statistical analysis of results, and a value of $P < .05$ was considered to be statistically significant.

Results

The average age was 38.8 years (range, 15 to 61 years) for group 1 patients and 38.5 years (range, 26 to 55 years) for group 2 patients. The average postsurgical follow-up was 20.8 months (range, 12 to 37 months) in group 1 and 33.0 months (range, 12 to 58 months) in group 2. The average number of previous open TMJ operations per patient was 3.9 (range, 0 to 9) in group 1 and 2.6 (range, 0 to 9) in group 2. In groups 1 and 2, 61% and 68% of the patients had a history of previous PT TMJ implants, respectively.

SUBJECTIVE ASSESSMENT

TMJ Pain

The average score on assessment of TMJ pain (0 = no pain, 10 = worst pain) in group 1 was 7.8 (range, 2 to 10) at T1 and 6.0 (range, 0 to 10) at T3, with an improvement of 1.8. The group 2 average score was 7.2 (range, 0 to 10) at T1 and 4.1 (range, 0 to 10) at T3, with an improvement of 3.1. The T1 comparison showed no statistical significance ($P = .397$), whereas at T3, group 2 had a statistically significant improvement over group 1 ($P = .042$).

Jaw Function

The average score on assessment of jaw function (0 = normal function, 10 = no function) for group 1 was 6.7 (range, 0 to 10) at T1 and 5.5 (range, 1 to 9) at T3, with an improvement of 1.2. The group 2 average score was 6.9 (range, 0 to 9) at T1 and 3.9 (range, 0 to 7) at T3, with an improvement of 3.0. The T1 comparison showed no statistical significance ($P = .874$), whereas at T3, group 2 had a statistically significant improvement over group 1 ($P = .008$).

Diet Function

The average score on assessment of diet function (0 = no restrictions, 10 = liquids only) for group 1 was 7.2 (range, 2 to 10) at T1 and 5.4 (range, 1 to 8) at T3, with an improvement of 1.8. The group 2 average score was 5.9 (range, 0 to 9) at T1 and 3.9 (range, 0 to 8) at T3, with an improvement of 2.0. The T1 comparison ($P = .073$) and the T3 comparison ($P = .021$) showed a significant improvement in dietary function for the TP group at long-term follow-up.

OBJECTIVE ASSESSMENT

The average MIO for group 1 was 23.4 mm (range, 7 to 40 mm) at T1 and 30.1 mm (range, 5 to 58 mm) at T3, with an improvement of 6.7 mm. The group 2 average was 27.4 mm (range, 13 to 41 mm) at T1 and 37.3 mm (range, 28 to 53 mm) at T3, an improvement of 9.9 mm. Group 2 showed a statistically significant greater improvement in MIO compared with group 1 ($P = .008$).

Good skeletal and occlusal stability was present from T2 to T3 in the radiographic and clinical examinations for all patients, with minimal detectable changes.

Discussion

There are many known factors that contribute to the success or failure of the total joint prostheses. The difficulty comes when trying to minimize these factors. These factors include 1) metal hypersensitivity[8]; 2) prosthesis micromovement[2,3,9]; 3) loosening of the prosthetic components[2,3,9]; 4) material wear, breakdown, and corrosion[2,3,9]; 5) biocompatible and functionally compatible materials[1-3]; 6) FBGCR[9,10]; 7) prosthesis failure[5]; 8) bacterial contamination[11,12]; and 9) development of heterotopic/reactive bone around the prostheses.[13]

A previous history of PT implants is an important factor in determining the success of TMJ surgery.[4,7,9] PT implants have been shown to fragment, particularize, and promote a FBGCR, which continues to increase with time, in both mechanically loaded and unloaded animal models.[14] This FBGCR may continue despite removal of the implant and meticulous surgical debridement.[10,15] Mercuri et al[4] found PT-related FBGCR within intra-articular soft tissue taken from between the condyle and fossa elements of a TP prosthesis functioning for 3 years in a patient with previous PT TMJ implants. In comparing these 2 groups, the TP group (68%) had a higher percentage of patients with previously placed PT implants than the CP group (61%), but this difference was not statistically significant.

The average number of previous TMJ operations is also an important factor when assessing TMJ patients. The success rate of TMJ reconstruction using autologous tissue deteriorates rapidly after 2 previous operations.[7,9,16] Therefore, in the complex, multiply operated TMJ patient or those with previously failed alloplasts, a total joint prosthesis using materials with proved safety and efficacy in orthopedic use may be the best option available for a more predictable improvement in quality of life.[17] In comparing both groups, group 1 had an average number of 3.9 (range, 0 to 9) prior operations per joint, and group 2 had an

average of 2.6 (range, 0 to 9). Both groups had an overall average of more than 2 operations per joint.

An important, but usually overlooked, factor contributing to implant failure is metallic sensitivity.[8] Metal allergies or hypersensitivity may be present before surgery or develop after implant placement. People in the general population are known to have hypersensitivity or allergies to various metals. This hypersensitivity (type IV, delayed hypersensitivity) can lead to alterations in surgical outcomes. The most common metal allergies are to nickel and chromium, which is a probable contradiction to the use of stainless steel or chromium-cobalt–based alloy in hypersensitive patients.[8] The CP contains 1% nickel and 28% chromium throughout the entire prosthesis, whereas the TP has 1% nickel and 28% chromium in the condylar head. There are some patients who are hypersensitive to cobalt and molybdenum, which are contained throughout the CP and in the condylar head of the TP.[8] Hypersensitivity to titanium has been documented but is rare. Placement of fat grafts around the head of the prostheses[13] may be effective in decreasing tissue exposure to the metals in the condylar head.

All of the patients in this study had autologous fat grafts (harvested from the abdomen) packed around the articulating aspect of the prostheses. Wolford and Karras[13] conducted a comparative study on patients who had Techmedica total joint prostheses placed. A total of 22 joints had fat grafts placed and were compared with 37 joints without fat grafts. Statistically significant improvement was found for MIO and excursive movements in the fat-grafted joints compared with the nongrafted joints. In addition, 35% of the nongrafted joints required additional surgery for the removal of heterotopic/reactive bone or severe fibrosis, whereas none of the fat-grafted joints required secondary joint surgery. The fat grafts appear to minimize the occurrence of excessive joint fibrosis and heterotopic calcification, consequently providing improved range of motion.

The CP device used from 1993 to 1997 has a metal condylar head against a metal fossa, which can increase metal wear debris; create stress loading of the fossa component; cause metalosis and corrosion; and increase exposure of elements in hypersensitive patients.

The TP fossa component becomes osseointegrated to the fossa, whereas the CP fossa is mechanically stabilized to the zygomatic arch with bone screws. Osseointegration can contribute to improved patient function and decreased micromovement, which limits overall prosthesis wear and stress.[18] Micromovement of the prostheses can lead to screw loosening, increased wear debris, bone osteolysis, stress fracture of the device, and prosthesis failure.[18] This may lead to an increase in pain and a decrease in function and diet.

The breakdown or wear of the prosthesis material can lead to treatment failure. The orthopedic literature refers to a *hard surface that is wet by physiologic fluids* as probably the best surface against which to articulate. UHMWPE provides this type of surface, and chromium-cobalt alloy is a suitable material to articulate with UHMWPE.[3] The materials that compose the TP prostheses have been used as components of orthopedic total joint systems for decades. These materials have been the subject of much research during that time. Stress and wear studies under loads much greater than those that can be developed in the TMJ have shown limited particulation of the UHMWPE. The biocompatability of TP titanium, titanium alloy, UHMWPE, and chromium-cobalt-molybdeum are well documented in the orthopedic literature.[3]

As a result of our study, it appears that TP provides a more biologically accepted and functional prosthesis than the CP for the complex TMJ patient.

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