THE CHRISTENSEN TEMPOROMANDIBULAR JOINT PROSTHESIS SYSTEM

An Overview

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Temporomandibular disease (TMD) is one term used to describe a complex group of disorders or problems that affect the temporomandibular joint (TMJ) and the related musculoskeletal, neural, and dental structure.[42] It is estimated that up to 40% of the population have some signs or symptoms of TMD; with most symptoms being seen in women (10:1 women/men).[56] In 1996, the National Institutes of Health estimated that 10 million Americans had painful TMJ dysfunction.[54] Most of these symptoms are self-limiting or respond to nonsurgical treatment.

There is no consensus on treatment for the small number of patients who do not respond to nonsurgical therapies. Impaired function and severe pain are the most common symptoms imported by these patients.[11] Etiology of these symptoms is related to a number of conditions, including severe internal derangement often associated with degenerative joint disease,[71] osteoarthritis,[15,60,65] arthrotic changes,[4,70] osteochondritis dissecans,[62,63] avascular necrosis,[61] rheumatoid arthritis,[55] neoplasm, congenital malformation, and trauma.[47] Surgical treatments for these disorders include disk repair and repositioning,[3] meniscectomy,[7,64,67] total or partial con condyle with either autografts[53,72] or allografts.[11,18,44-46] Autogenous graft materials have been used with some success, especially in primary TMJ reconstruction; however, much of the data on autogenous grafts are preliminary.[17,40,41,57] One study reports on pathologic conditions associated with autogenous grafts. Wolford et al[73] reported that autogenous grafts have a poor success rate in treating multiple surgery patients. One study did show that the use of costochondral rib grafts in conjunction with a temporoparietal fascia flap was successful in total TMJ reconstruction in 11 patients and 13 joints with follow-up to 7 years.[14] Kearns et al[30] describe a protocol for replacement of disk allografts with an autogenous pedicled temporalis muscle/fascia flap after aggressive joint debridement, recontouring of the articulating surfaces. Failure of the allografts was defined as any one or combination of the following symptoms and signs: TMJ pain, jaw hypomobility, occlusal changes, and radiographic evidence of bone pathology related to the implant. It would have been useful to determine the success of the surgical procedure without placement of the autogenous graft while maintaining the allograft.

In 1992, the American Society of Temporomandibular Joint Surgeons and the American Society of Maxillofacial Surgeons[23] stated in their guidelines for diagnosis and management of TMJ disorders that total joint prosthetic replacement maybe required in selected patients with severe TMJ degeneration. The 1993 American Association of Oral and Maxillofacial Surgeons recommendations on management of TMJ implants[59] states

that alloplastic joint replacement is an option for extensive joint disease. This report also points out the need for prospective and retrospective studies on prosthetic joint systems.

In this article the authors give some back ground on alloplastic TMJ treatments and report on work done with the Christensen TMJ prosthesis system, including information on the materials used in the prosthesis, clinical studies performed with the Christensen system, and the current Food and Drug Administration (FDA) status of the system.

BACKGROUND

Eggers[16] reported the first use of allograft material placed into the TMJ. He treated severe ankylosis in a 4-year-old girl by placing tantalum foil over the base of the skull and over the mandibular stump. Christensen[12] was the first person to attempt to cover the fossa eminence with an anatomically correct device to treat ankylosis. He modeled a series of 0.5-mm thick Vitallium prostheses based on molds taken from 20 (later 33, then 44) human skulls. The prosthesis that most closely fit was then attached to the base of the skull with screws.

Christensen[13] reported on total joint replacement with the fossa eminence devices in conjunction with cobalt-chrome (Co-Cr) alloy condylar prosthesis, which had a molded polymethylmethacrylate (PMMA) head.

Morgan[49] used a modification of the Christensen fossa eminence prosthesis as a partial joint replacement. His device covered only the eminence and was used to prevent reoccurrence of osteoarthrosis. Later, he combined this with a condylar prosthesis made of Vitallium with an acrylic head to produce a total joint prosthesis.[69]

Kent et al[31] published a pilot study on the use of a proplast-coated condylar prosthesis. Because of problems with glenoid fossa resorption, a fossa prosthesis of laminated proplast and Teflon was added in 1983, and resulted in the Vitek-Kent (Vitek, Inc., Houston, TX) total joint prosthesis.[32] Serious problems assodated with fragmentation of the teflon/ proplast in a large number of patients caused manufacturing of this device to be stopped in 1990. Van Loon et a1[69] give a review of many of the alloplastic TMJ systems described over the years.

Currently the only system that includes either a partial or total TMJ prosthesis and is marketed as a stock device in the United States is the Christensen prosthesis system. It is estimated that more than 15,000 partial and total Christensen prostheses have been implanted since their introduction in the early 1960s. The system is currently being used by surgeons in the United States, Canada, Great Britain, Sweden, Spain, and Columbia.

DESCRIPTION OF THE CHRISTENSEN TMJ PROSTHESIS SYSTEM

The Christensen TMJ fossa eminence prosthesis (FEP) is designed to be used alone as a partial joint for treatment of severe internal derangement, adhesions, disc perforation, and ankylosis. The condylar prosthesis is always used in conjunction with a FEP and constitutes a total joint replacement (TJR). 1JR is used to correct severe adhesions, condylar destruction, ankylosis, severe arthritic change, and other pathologic conditions with resultant occlusal deficiency.

FEP

This device is fabricated entirely of Co-Cr alloy and is approximately 20 mm to 35 mm across and 0.5 mm thick (Fig. 1). The articulating surface is highly polished. There are 88 different sizes and shapes, 44 for the right side and 44 for the left side. These different configurations cover a range of sizes and shapes to fit most anatomic variations. The system has trial sizing templates that correspond in size and shape to the available prostheses. These sizers are also made of Co-Cr and can be reused after steam sterilization. The sizers have a series of holes on their surface to allow the surgeon to determine the best fit out of the selection of prostheses provided before placement. The standard system also includes Co-Cr bone screws and drill bits sized to the screws. This portion is fixed to the base of the skull with Co-Cr bone screws.

Universal Condylar Prosthesis

This prosthesis has a Co-Cr alloy frame work with a molded PMMA head. The device comes in three lengths of 45, 50, and 55 mm. It designed to replace approximately 13 mm of the natural condylar head and attach to the ramus with Co-Cr bone screws.

Artho-Chrome Universal Condylar Prosthesis

The Arthro-Chrome (TMJ Implants, Inc., Golden, CO) condylar device is identical to the universal condylar prosthesis, except that it is composed entirely of a Co-Cr alloy.

Christensen/Chase Condylar Prosthesis

This device is the same as the universal condylar prosthesis except that it has an angular extension of 28 mm off the distal portion of the flange 30° from perpendicular (Fig. 3). It can have either a PMMA or Co-Cr articulating head. The device comes inconfigurations for the right and left side in 45-, 50-, and 55-mm lengths. This prosthesis is designed for use in patients who have considerable bone loss and allows for greater attachment along the mandible.

Patient-Specific^{TM} Prosthesis

All of the previously mentioned prosthetics can be made patient specific by using a CT scan to generate a stereolithography model of the patient. Stereolithography uses a patient

CT to produce a clear, plastic model of the affected hard tissue showing both external and internal anatomy. The model is accurate to within approximately 1 mm[35] and is used to make prostheses that conform exactly to the patients' anatomy. This is useful to the surgeon who is operating on a patient with an extremely deformed or mutilated TMJ.

STUDIES ON MATERIALS USED FOR THE CHRISTENSEN PROSTHESIS

Co-Cr alloy is the primary material used in the manufacturing of the Christensen TMJ prosthesis system. This material has a long history of use in orthopedic applications.[50] Specifications for this material have been developed and published, and the American Society for Testing and Materials (ASTM) states that this material "has been shown to produce a well characterized level of local biological response following long term clinical use and has been used as controlled material in Practice f981.[37] Extensive biocompatability test ing, in accordance with International Organization for Standardization (ISO) and FDA guidelines, has been conducted on this material.[38] These tests include United States Pharmacopeia (USP) systemic injection, USP intracutaneous injection, guinea pig delayed contact sensitization, Ames mutagenicity, and in vitro cytotoxicity test. All these tests reported no harmful reaction to living tissues.

PMMA has been used as a prosthetic material in a number of medical applications for more than 50 years. These applications include ocular lens replacement,[28] bone/prosthesis cement,[9,51] and bone replacement/augmentation material in craniofacial and prosthodontic defect repairs.[1,74] Reports have suggested that some individuals may have an allergic reaction to the monomeric methylmethacrylate when PMMA is cured in situ; however, the PMMA used in the Christensen condylar prosthesis is precured, and any residual monomer has been released before placement.

The wear of the prosthetics also has been tested extensively. An independent research laboratory performed a number of wear tests on the all-metal and metal/PMMA prosthetic system. A custom device was made to simulate as closely as possible the in vivo conditions in the laboratory. Wear tests were conducted with the prostheses in bovine calf serum to simulate biologic fluids. Brehnan et a1[6] and Boyd et al[5] directly tested the load placed on the TMJ of primates. Smith[66] adjusted this value to humans. Based on these studies the wear device applied a cyclic load varying from 10 lb to 35 lb for 2 million cycles. The wear zones on the tested devices appeared similar to those seen in retrieved devices. The amount of wear on the Co-Cr head was smaller than that seen on the softer PMMA head. The Co-Cr FEPs that were tested against the PMMA heads showed no wear, and those tested against the Co-Cr condyle showed surface scratches oriented in the direction of the articulation when observed with light microscopy and scanning electron microscopy.[38] The results of the wear testing for the all-metal system are similar to that seen in metal-on-metal hip implants and indi cate that the all-metal system should have a longer functional life in patients.

There is great concern, based on recent information from orthopedic literature, regarding the effect of wear particles in joints with prosthetic devices. There is evidence that these particles may set up an adverse reaction in the tissues surrounding the prosthesis, resulting in inflammation, foreign body reactions, and ultimately in prosthesis failure.[8,29] There is also evidence that these particles could cause systemic problems.[48] For that reason, two animal studies were undertaken to determine the effect of wear particles on the TMJ of rabbits. PMMA and Co-Cr wear particles were injected into one TMJ of New Zealand white rabbits[20,21] The other TMJ of each animal had an equal volume of saline injected into it and served as a control. Animals were sacrificed at 1, 2, 3, 6, 9, and 12 months after injection. Histologic examination of the TMJ and surrounding tissues showed a mild to moderate inflammatory reaction to both the PMMA and the Co-Cr up to 3 months. By 6 months the PMMA injected joints showed no pathologic condition, and by 9 months the Co-Cr injected joints appeared normal. Additionally, blood chemistry and hematology tests were performed on all animals before sacrifice, and were normal for all animals. Antinuclear antibody (ANA) titers for all animals were negative. Histologic examination of the major organs, including the kidney, liver, spleen, lungs, heart, and submandibular lymph nodes showed no sign of any pathologic changes or the presence of any particles. Howie and Vernon-Roberts[27] report similar findings on studies injecting Co-Cr particles into the knee joints of rats, and other studies show similar results.[43,46]

CLINICAL STUDIES

Christensen[12] first reported on placement of a FEP to treat severe ankylosis. He later reported on placement of a TJR.[13] Kiehn et al[33] reported on placement of the Christensen FEP in conjunction with a Cargill-Hahn condyle component in 1974. Both components were made of cast Vitallium (a Co-Cr-Mo alloy). Short-term follow-ups of 27 patients who received this total joint indicated success in reducing pain and increasing range of motion.[34] Chase et al[11] reported on 69 patients who did not respond to nonsurgical or prior surgical treatment. Forty-eight patients received a total of 89 FEP, and 26 patients received a total of 29 TJP. Seventy-seven percent of the patients in this study had undergone at least one previous surgery. Patients ranged in age from 17 to 78; 64 (93%) patients were women and 5 (7%) were men. Data on the patients' ability to eat and level of pain were measured preoperatively and at regular postoperative intervals using a visual analog scale. Interincisal opening was measured at the same times using a Therabite scale. In the patients who received a FEP after menisectomy, 96% showed a significant improvement in their ability to eat and 86% showed a significant decrease in pain 1.2 to 10 years after surgery Interincisal opening improved from a mean value of 27.52 mm to 37.65 mm. Patients who received total joints had previous surgical histories that included failed rib grafts, Vitek allografts, and silastic allografts. Eighty-six percent of the patients who received total joints showed a significant im provement in their ability to eat, and 95% showed a significant decrease in pain 1 to 10 years after surgery. Mean values for interincisal opening improved from 17.6 mm to 31.7 mm. This study suggests that the Christensen TMJ prosthesis system is effective in reducing pain and improving function in patients who suffer from a number of different problems, including patients with multiple previous failed surgeries.

In another retrospective study, Chase et al[10] looked at a total of 132 patients with severe unilateral or bilateral TMJ disease. In this study, 94 patients received 171 partial joints, and 38 patients received 60 total joints. Average follow-up was 42 months, with a range of 12 to 84 months. Results of this study indicate that more than 90% of patients snowed a significant increase in function and decrease in pain.

Quinn[58] reported on 42 joint reconstructions using the Christensen TJR with the PMMA condylar head. The average follow-up was 32.2 months. The average preoperative range of motion was 12.3 mm and postoperatively it was 28.1 mm. The average preoperative visual analog scale measure for pain was 9.1 and postoperatively it was 4.2. Complications reported included ankylosis, a fractured condylar prosthesis, and an allergic reaction to the acrylic. The author states that "the total joint prosthesis has been extremely successful in reconstruction of the severely degenerative joint."

Another study reported on 50 patients who had received either unilateral or bilateral Christensen Patient-Specific™ (TMJ Implants, Inc., Golden, CO) all-metal joints.[19] All patients in this study had multiple previous TMJ surgeries. The average follow-up was 36 months, and more than 90% of patients showed a significant improvement in function and decrease in pain. A study that has been submitted for publication[22] examined 64 consecutive patients from a single practice. Forty-six of these patients received 82 FEP, and 17 patients re ceived 26 TJR. Fifty-eight (91%) of the patients were women, and 6 (9%) were men. The average age of the patients at the time of surgery was 39, with a range of 16 to 68 years. Preoperative and postoperative pain and ability to eat were measured on a visual analog scale. Interincisal opening was measured at the same time using a Therabite scale. Average time of follow-up was 50 months, with a range of 12 to 84 months. Forty-one (89%) patients showed significant reduction in pain. Forty (87%) patients showed a significant improvement in function and interincisal opening. One (2%) patient had a significant decrease in interincisal opening from 55 mm to 50 mm. Twenty-eight (61%) patients had previous surgery on the affected joints, and 2 (4%) patients were lost to follow-up. One FEP (1%) had to be removed due to postoperative infection. Of the 17 patients who received TJR, 9 (53%) received bilateral TJR and 8 (47%) received unilateral TJR. Fourteen (82%) of these patients had prior surgeries, including 7 (41%) patients who received Teflon/ Proplast devices. Fourteen (82%) patients showed a significant decrease in pain, and 2 (12%) patients showed no significant change. Fifteen (88%) patients showed significant improvement in function, and 1 (6%) patient showed no significant change. Fourteen (82%) patients showed a significant improvement in interincisal opening, whereas 2 (4%) showed a significant decrease. One (4%) condylar prosthesis required replacement due to iatrogenic placement, and 1 patient had the TJR removed and replaced with a costochondral graft by another surgeon.

Hensher (R. Hensher, MD, personal communication, 1999) evaluated 88 patients, 72 women (82%) and 14 men (16%). Gender in 2 patients was not provided. The mean age was 38. Forty-seven patients received a partial joint, and 41 patients received total joints. In this study, data on diet and pain were collected presurgically and 1, 6, 12, 24, and 36 months postoperatively. Visual analog scale scores for ability to eat showed a dramatic

improvement in the first month and to a lesser degree at 6 months after surgery. This improvement leveled off at 6 months and was maintained to 36 months. Reduction in pain showed a similar pattern in ability to eat, and the improvement was maintained to 3.6 months. Interincisal opening was measured at the same time and showed a similar pattern of early marked improvement that was maintained for 36 months.

In 1993, TMJ Implants, Inc. (Golden, CO) began an implant registry. One of the primary functions of this registry is to track every prosthesis sold. A record is maintained on which surgeon placed the prosthesis and which patient received the prosthesis. In addition, enclosed with every prosthesis is a patient evaluation form that includes assessment on preoperative and postoperative pain, diet restriction, and intericisal opening. Every month after the surgery, TMJ Implants, Inc. sends a patient evaluation form to the operating surgeon requesting postoperative data on pain, function, and intericisal opening. Although return of this information is voluntary, this registry is a source of valuable information about patient outcome and satisfaction of operating surgeons. More than 350 surgeons have returned these forms to the company since the registry program begun. Since its inception in 1993 to June, 1998, 3544 patients have been entered into the registry.

Demographic information from the registry gives a valuable overview of patients who receive partial and total TMJ prostheses. The average age of patients entering the registry is 40.5 years, with a standard deviation of 12 years. Three percent of patients were aged 11 to 20, 16% of patients were aged 21 to 30, 36% of patients were aged 31 to 40, 28% of patients were aged 41 to 50, 10% of patients were aged 51 to 60 years old, 5% of patients were aged 61 to 70, and 2% of patients were aged 70 or older. One patient was younger than 10 years. This registry indicates that 55% of the patients who receive either partial or total TMJ prostheses are under the age of 40, and 83% are under the age of 50. Because most patients who receive either FEP or TJR are relatively young, this strongly suggests that clinicians must do a better job of accurately diagnosing and effectively treating TMD. The number of women in tne registry (3081, 87%) compared with men (434, 12%) closely mirrors the ratio of patients reported in many studies who seek treatment for disorders of the TMJ. Partial joint prostheses were placed in 2053 patients (58%), whereas 1491 patients received TJR (42%).

A multicenter, open label, prospective clinical trial was begun in November, 1996. The study will enroll a minimum of 138 patients. As of November, 1998, 103 patients had been enrolled. The mean age is 41, with a range of 19 to 74. Ninety-three percent of the patients are women. Sixty-eight percent of patients have received FEP, and 31% have received TJR. The type of prosthesis has not yet been reported for 2 patients. Data on 28 patient; are available up to 12 months, and the result are similar to th'e studies described previously. There is a significant improvement in function and reduction in pain early after surgery, and these values are maintained up to 12 months.

PATIENT EVALUATION AND EXPECTATIONS

Patients who are candidates for either a FEP or a TJR are among the most challenging and difficult patients seen by the clinican. Most of these patients have had previous TMJ surgery. It is essential that the surgeon use all of his or her skills in evaluating these patients. Patients should have a thorough medical evaluation that includes a complete medical history. The condition of the effected joint(s) should be well documented using modern imaging techniques such as CT and MR imaging.

It has been reported that patients who suffer from TMJ disorders have a higher incidence of symptoms associated with chronic pain disorders.[48] It may be important for a number of these patients to be encouraged to seek treatment for chronic pain as part of their overall treatment. Halpern et al[25] suggest that surgical failure of the TMJ may be associated with autoimmune dysfunction and a predisposition to multisystemic disease. This study also lists a series of previous medical and surgical problems of patients who may be at higher risk for TMJ surgical failure. Serologic testing along with evaluation of a complete medical and surgical history of patients aids the surgeon in identifying patients who are at higher risk for surgical failure. Namey et al[52] evaluated 37 patients with failed proplast/teflon implants and found an increased incidence of human leukocyte antigen (HLA) markers in these patients compared with the general population. Most patients in this study (65%) showed antigens associated with autoimmune disorders. A predisposition to connective tissue or autoimmune disease may increase the likelihood that treatment of these patients may not be successful. Patients with this profile may also be more likely to demonstrate allergic reactions to some of the materials used in these prostheses. If there is any indication that patients are allergic to certain materials contained in these devices, a sensitivity test should be performed as part of the patient evaluation.

It is important that the surgeon and patient have realistic expectations for recovery from placement of a FEP or TJR. Although some patients who receive a FEP report that they are restored to normal pain-free function, they are the minority. In the case of a TJR, return to normal function is virtually impossible because of the loss of muscle attachments. Patients who have had previous surgeries or who have significant joint pathologic conditions may never be pain free. The level of postsurgical recovery is different for each patient and is difficult to predict. In many cases the best that can be hoped for is a significant improvement in function and reduction in pain. It is critical for the surgeon and the patient to realize that the level of success of the surgery is affected greatly by continued support of the patient after surgery. This support varies from patient to patient but in every case should include a complete regimen of physical therapy and regular evaluation by the surgeon. Also, the patient should be trained in the reasonable use of the prosthesis. In some cases, treatment for chronic pain by people trained in this area may be helpful in maintaining patients. Many patients may need to remain on long-term medication therapy for pain under careful supervision.

Functionally, patients who receive a FEP often return to close to normal function; however, it has been reported that their bite force is significantly less than individuals who have never undergone TMJ surgery. Patients who receive a TJR have even less biting force than those who receive a FEP.[36] Also, because of the loss of muscle

attachment, lateral movement of the joint is greatly restricted, as is translational movement; however, analysis of wear on retrieved prostheses indicates that patients do retain some lateral movement of their jaw.

Generally, the life expectancy of orthopedic prostheses is 10 to 15 years[39] With most patients who receive either FEP or TJR being younger than 50, it is reasonable to conclude that many of these devices will not last a lifetime in function. The patient must be made aware of this possibility and that there are currently no long-term survival data on TMJ prostheses.

SURGICAL PROCEDURE

Placement of either a FEP or a TJP is performed under general anesthesia in a hospital operating room. In placing a FEP a preauricular incision is made and the joint capsule is opened. Often debridement of the joint is necessary and removal of adhesions is performed. Sizers are used to select the FEP that most closely fits the existing anatomy, and placement of the suitable FEP is maintained with three to four Co-Cr screws.

When performing a TJR, a second incision is made along the inner margin of the lower mandible. The condylar portion of the prosthesis is placed through this incision. Usually the coronoid process is removed during placement, and the connection of the lateral ptergoid muscle is lost. Atrophy and fibrosis of the temporalis muscle are often seen in these patients and are removed. Vertical dimension, anteroposterior occlusal discrepancies, and open bites are corrected by producing centric occlusion with maxillomandibular fixation during condylar prosthesis placement. The condylar portion of the TJR is attached rigidly to the lateral ramus with a minimum of five Co-Cr screws.

POSTSURGICAL COMPLICATIONS

Mercuri[45] lists a number of complications that may occur after total TMJ replacement. As part of the TMJ Implants, Inc registry, a retrospective study was performed on the number and type of adverse events that occurred in conjunction with the placement of TMJ prostheses. Adverse events were categorized as follows: (1) mild: aware of a sign or symptom but easily tolerated; (2) moderate: discomfort sufficient to cause interference with usual activity or to affect clinical status; (3) serious: incapacitating, with inability to do usual activity or to affect clinical status significantly; (4) life threatening: presents a definite hazard with potential for causing death.

The medical records of 249 patients in the registry were evaluated carefully for any record of adverse events. Thirty percent of the events recorded were classified as mild, and the remaining 70% were classified as either moderate or serious. No life-threatening or unanticipated events were recorded. The most common events involved postoperative pain and swelling, and 69% of those events were resolved with drug treatment, physical therapy, or no treatment. Twenty-three percent of the events required additional surgery to resolve the problem. Other events recorded included facial nerve and muscle

weakness, paralysis, hearing problems, degenerative joint changes, and limited range of motion.

Three adverse events were considered to be device related. One involved poor fit of a FEP and was corrected by placement of a properly fitting FEP, and the patient recovered without sequelae. The second involved a loose screw on a FEP that was corrected by an additional surgery. The patient recovered without complications. The third event involved removal of a loose FEP that was causing serious pain. There was insufficient bone to place another FEP, and the patient recovered without sequelae.

SUMMARY

Accurate diagnosis and effective treatment of the complex constellation of problems that make up what some clinicians refer to as TMD is an extremely challenging and complex problem. There is a small but significant population of patients for whom treatment options are quite limited, including patient with severe degenerative joint disease that encompasses a host of underlying pathologic conditions. Another segment of this population includes patients who have received multiple operations to the TMJ. There is increasing evidence that partial or TJR with prosthetic devices offers a safe and effective treatment option for most of these patients. Extensive patient evaluation and postsurgical support are essential components of effective treatment for these patients. Although return to normal function in most cases is not feasible, significant improvement in function and reduction in pain is achievable in most of these severely disabled patients using the Christensen TMJ partial or total joint prosthesis.

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