Temporomandibular joint devices: Treatment factors and outcomes

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TMJ devices have been used for many years in reconstruction of the temporomandibular joint (TMJ). The most common endosseous implant currently used in TMJ reconstruction is a mini-anchor that is placed in the posterior head of the condyle to support artificial ligaments to stabilize the articular disk in the proper position. A 2-year follow-up study shows a success rate of 90% in reference to incisal opening, jaw and occlusal stability, and significant reduction in presurgical pain level. Some materials that have been used in TMJ reconstruction, including Proplast-Teflon (PT) and Silastic devices, have caused devastating problems for patients. These materials, particularly the PT, can cause severe foreign-body giant-cell reaction, severe bone and soft-tissue destruction, and migration of particles to other body areas, and may initiate or exacerbate connective tissue and autoimmune disease problems. Christensen joint prosthesis has been reported to have very good success in TMJ reconstruction. The most thoroughly studied TMJ total joint device is the Techmedica custom-made total joint prosthesis, with a 5-year follow-up study on 31 patients and 52 reconstructed joints. All patients have functioning prostheses with good jaw and occlusal stability and an average pain reduction of 4.4 points on a 0-to-10 visual analog pain scale. However, this device currently is unavailable. In complex cases requiring multiple TMJ operations, particularly those with previously failed alloplast, a custom-made total joint prosthesis, using materials with proven safety and efficacy in orthopedic joint reconstruction, may be the only option available to improve predictably the quality of life of these patients. (Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1997;83:143-9)

Temporomandibular joint (TMJ) devices have been used for many years as (1) endosseous implants to stabilize articular disks; (2) articular disk replacements; (3) condylar replacements; (4) fossa replacements or liners; and (5) total joint prostheses. Some of these devices have worked very well in the treatment of TMJ disorders, but other devices have created worse problems, sometimes leaving patients severely debilitated. There are other factors that may affect patient outcomes, including (1) connective tissue and autoimmune disorders; (2) endocrine system dysfunction; (3) biomechanical factors; (4) nutritional deficiencies; and (5) genetic predisposition to diseases or acquired diseases that affect the body's biologic responses. This article presents information on these devices, factors affecting treatment outcomes, and the outcomes of the devices that have been studied.

ENDOSSEOUS IMPLANTS

Endosseous implants can be placed in the condyle to aid in securing the articular disk in position. One approach is to place a mini anchor (Mitek Mini-Anchor, Mitek, Inc., Norwood, Mass.) (Fig. 1) in the posterior head of the condyle with artificial ligaments attached to it that are then secured to the articular disk to stabilize the disk in position.° The mini anchor is composed of a titanium alloy body, 5 mm in length and 1.8 mm in diameter. Two nickel-titanium wings provide the intra bony locking mechanism. An eyelet in the body allows attachment of sutures that will function as artificial ligaments.

Wolford et al. studied 63 patients (59 women and 4 men), designated group 1, for an average follow-up of 12.2 months (range 8 to 16 months), with 12 unilateral and 51 bilateral cases for a total of 114 joints (Wolford LM, Cottrell DA, Karras SC, Cardenas L. Mitek Mini Anchor for TMJ articular disc stabilization. Unpublished data). Group 2 consisted of 32 patients (30 women and 2 men) followed up for an average of 25.5 months (range 18 to 36 months) with 7 unilateral and 25 bilateral cases for a total of 57 joints. In group 1, 57 of 63 patients (90%) had successful outcomes with an incisal opening of 35 mm or greater, jaw and occlusal stability, and a significant reduction of pain, with an average pain decrease of 4.1 points on a 0-to-10 visual analog scale. In group 2, 29 of 32 patients (91%) had successful outcomes based on the same criteria, with an average decrease in pain of 4.0 points on a 0-to-10 visual analog scale. Fields and Wolford demonstrated osseointegration of the anchors in two condyles removed caused by progressive pathology (Fields TR, Wolford LM. Osseointegration of Mitek Mini Anchors in the TMJ condyle: histological analysis [abstract]. Unpublished data). No
Fig. 1. The Mitek mini anchor is used to stabilize the TMJ articular disk. The body, which is composed of titanium alloy, is 5 mm long and 1.8 mm in diameter. The winged arcs are of nickel titanium alloy with shape memory superelasticity.

Fig. 2. The Mitek mini anchor with two strands of 0-Ethibond suture placed through the eyelet, to be used as artificial ligaments to secure the articular disk into proper position after the anchor has been inserted into the posterior head of the condyle.

inflammation or bone resorption was noted around these devices.

Fields et al.² studied the pull-out strength of mini anchors inserted in 20 human cadaver condyles, demonstrating an average pull-out load of 16.0 lb (range, 8.5 to 28.4 lb) with the cortical bone failing in 18 of the 20 specimens, the suture failing in two specimens, and no failures (deformation or breakage) of the anchor.
Fig. 3. A, The sagittal view of the condyle shows the anchor placed through the posterior head of the condyle. The wings are compressed against the body until the anchor is positioned beyond the cortical bone, and the wings spring outward to lock the anchor beneath the cortical bone. B, Two sutures are then secured to the posterior band of the articular disk in a mattress-type fashion. One suture is applied medially and one more toward the lateral aspect of the disk.

Cardenas et al. performed a cephalometric study to evaluate long-term positional changes of the anchor within the condyle and the effect of the procedure on the morphologic features of the condyle (Cardenas L, Wolford LM, Gonçalves J. Mitek mini anchor in TMJ surgery: positional changes and condylar effects [abstract]. Unpublished data). The sample consisted of 29 patients (n = 54 joints) with an average age of 31.3 years (range, 15 to 52 years) and an average follow-up of 16.8 months (range, 12 to 29 months). Positional changes were minimal for horizontal and vertical movement with an average change of 0.01 mm (range, \(-1.5 \text{ to } 1.5 \text{ mm}\)). Condylar and ramus height average changes were \(-0.02 \text{ mm}\) (range, \(-1 \text{ to } 1 \text{ mm}\)). These studies support the use of Mitek mini-anchors for TMJ articular disk stabilization.

TMJ ARTICULAR DISK REPLACEMENT

Alloplastic replacement of the TMJ articular disk was a popular technique in the 1970s and 1980s. The two materials most commonly used as interpositional implants to replace the articular disk were Proplast/Teflon (Vitek, Inc., Houston, Tex.), and Silastic (Dow-Corning, Midland, Mo.). It was later recognized that these materials fragment under loading and functional conditions, creating microscopic particles. The human body cannot degrade these polymers, and severe local and systemic reactions can occur. Proplast-Teflon (PT) and Silastic TMJ implants have resulted in numerous complications, including fragmentation, foreign-body giant-cell reaction, particle migration, pain, lymphadenopathy, severe osteoarthritic, bone resorption, perforation into the middle cranial fossa, and immunologic dysfunction.3-8

Henry and Wolford9 evaluated 107 patients with failed PT implants. Reconstruction was performed with use of autogenous tissues, including temporal fascia and muscle grafts, dermal grafts, conchal cartilage grafts, costochondral grafts, and sternoclavicular grafts, with a 4-year follow-up success rate of the various grafts ranging from 8% to 31%. Failures with these autogenous tissues were primarily associated with continued foreign-body giant-cell reaction, pain, and ankylosis that was created by foreign-body giant-cell reaction and reactive bone. Even multiple debridements of the TMJ demonstrated the continued presence of a foreign-body giant-cell reaction, with as many as four or five TMJ surgical debridements. Patients who have had previous PT implants, reconstructed with the Technmedica custom-made total joint prosthesis that used materials proved in orthopedics, had func-
TIONAL AND OCCLUSAL STABILITY WITH SIGNIFICANT DECREASE IN PAIN IN 84% OF THE CASES.

CONDYLE, FOSSA, AND TOTAL JOINT REPLACEMENT

Materials used in partial and total TMJ reconstruction included PT, polymethylmethacrylate (PMMA), dense ultra–high-molecular-weight polyethylene, and various metals. Numerous companies have made TMJ joint prostheses, but FDA regulations in response to the PT failures halted their manufacture, except for two devices that are “grandfathered” because they fall within the Food and Drug Administration (FDA) preamendment for implanted devices, making them available for patients, although they are not FDA approved. The materials used in these two prostheses include chromium–cobalt alloy and PMMA in the articulating condylar surface. PMMA is not used for articulating surfaces in any non-TMJ approved orthopedic devices because of poor wear properties and subsequent particulation. However, one report on 69 patients found decreased pain (95% to 100% of patients), improved eating ability (82% to 96%), and increased incisal opening (77% to 91%). Improvement varied with the use of the fossa implant and retention of the articular disc, only the metal fossa, or the fossa and the PMMA condyle. TMJ Inc. (Golden, Colo.) has recently obtained an FDA preamendment approval (“Grandfathered”) for a metal condyle and fossa joint prosthesis. There are no published studies relative to the use of this device.

A custom-made total joint prosthesis (Techmedica, Camarillo, Calif.) uses materials proved in orthopedics for joint replacement: titanium mandibular shaft and fossa liner, chromium–cobalt alloy for the condylar head, and dense ultra–high-molecular-weight polyethylene as the functional fossa surface. A three-dimensional plastic model of the TMJ and associated boney structures is fabricated from computed tomographic data and the joint prosthesis is then constructed to each patient’s specific anatomic morphologic features and interrelations (Fig. 4). These devices have been followed for as long as 6.5 years with very good results. Published data on 100 consecutive custom-made total joint prostheses placed in 56 patients observed 86% success with 16- to 46-month follow-up. In this study, 49% of the joints had previous PT implants. Patient outcomes were affected by the number of previous surgeries. Fourteen patients had one or no previous surgeries and all had significant improvement relative to pain, occlusal stability, and function, whereas eight (19%) of the
remaining 42 patients with two or more previous surgeries had unfavorable outcomes, related primarily to no significant decrease in pain. Anspach, Inc. (Lake Park, Fla.) has recently received full FDA approval for the "Techmedica" total joint prosthesis, but the device will be unavailable for 1 year.

A common problem with total joint prostheses, particularly in patients with previous PT or Silastic implants, is the recurrent development of foreign-body giant-cell reaction and reactive bone, causing pain and limited jaw function as a result of fibrous or bony ankylosis. A recently presented technique involves harvesting abdominal fat and packing it around the custom-made total joint prostheses to prevent these unwanted tissues from developing. This case series compared 15 patients with the custom-made prostheses and fat grafts with 20 patients with the prostheses but without the fat grafts. In the group without the fat grafts 35% of patients required additional TMJ debridement surgeries for heterotopic bone and fibrosis. Since beginning this fat graft procedure 4 years ago, none of the 15 patients with the fat grafts (22 joints) has had to return to surgery for additional joint debridement. A biopsy specimen of the fat graft in one patient, 1 year after surgery, revealed viable fat tissue around the prostheses.

A 5-year follow-up study (Wolford LM, Reiche O, Pitta M. Techmedica custom-made total joint prostheses: 5-year follow-up study. Unpublished data) on the outcomes of the custom-made total joint prostheses (n = 31 patients with 52 joints) reported that all patients had functioning prostheses with acceptable jaw and occlusal stability, with an average reduction in pain of 4.4 points on a 0-to-10 visual analog scale. Incisal opening increased an average of 7 mm.

These observations suggest that in patients with TMJ undergoing multiple operations and those with previously failed alloplasts, a total joint prosthesis with use of materials with proven safety and efficacy in orthopedic use may be the only option available to predictably improve the quality of life for these patients.

HUMAN LEUKOCYTE ANTIGEN (HLA) STUDIES

The possible relationship between certain arthropathies and an increased incidence of specific human leukocyte antigens (HLA) was evaluated in a clinical study by Namey et al.,14 who performed HLA typing on 37 patients (35 women and 2 men) with TMJ dysfunction and failed PT implants. It was hypothesized that an increased incidence of HLA markers is associated with a predisposition to connective tissue and autoimmune diseases. Most of the patients were experiencing chronic pain and dysfunction. In the patient sample 11 of 37 (30%) had HLA-B locus antigens associated with psoriasis or psoriatic arthritis versus 22 (17.6%) of 125 control subjects. Other patients in the sample, 24 of 37 (65%), demonstrated antigens associated with other connective-tissue or autoimmune disorders, including juvenile rheumatoid arthritis, sarcoidosis, ankylosing spondylitis, Rieter's syndrome, Sjögren's syndrome, scleroderma, Still's disease, and systemic lupus erythematosus. These observations suggest that predisposition to connective tissue and autoimmune diseases may predispose these patients to immune dysfunction and treatment failure. Medical histories of the 35 female patients in this study also included a history of: hysterectomy (40%); removal of ovaries (31%); endometriosis or uterine fibroids (26%); fibrocystic breast disease (49%); low-grade fever (35%); and sensitivity to nonprecious metals (51%). The incidence of these findings is much higher than that in the healthy female population.

IMMUNE SYSTEM FUNCTION AFTER TMJ IMPLANTATION

A preliminary study evaluated the human immunologic response to PT implants in 12 patients.8 The total lymphocyte count was calculated and immune response assessed by immunophenotyping peripheral blood lymphocytes: IA, CD2, CD3, CD4, CD8, CD4:CD8 ratio, CD20, CD56, and surface immunoglobulin positive cells. The IA subset was below controls in 73% of patients, and the CD4:CD8 ratio was decreased significantly below the normal range. By contrast, the CD56 subset was elevated in 60% of patients. An in vitro lymphocyte activation assay was used with 6 patients to determine the presence of activated T cells. Lymphocytic activation was present in 4 of 6 patients. The activated T-cell response was greater in those patients experiencing more severe symptoms. The immunologic consequences of the activated T-cell response remains to be investigated.

In four patients with PT implants who had a significant decrease in their immunodeficiency panel, removal of the PT implants and reconstruction with a custom-made total joint prosthesis resulted in a significant improvement toward normal values in three of the four patients at 1 year after surgery.

Clinical observations suggest that some patients may have developed connective tissue diseases that have been promoted or exacerbated by TMJ implant materials. Some conditions that have been recorded in patients with TMJ with PT, Silastic, and PMMA...
implants include chronic fatigue syndrome, chronic pain, fibromyalgia, impaired cognition, short-term memory loss, lupus, psoriasis, psoriatic arthritis, sarcoidosis, polyarthritis, human adenovirus disease, scleroderma, Sjögren's syndrome, rheumatoid arthritis, visual disturbances, localized and distant muscular disease, neurologic dysfunction, chronic low-grade fever, generalized synovitis, and significant hormonal imbalances. Undifferentiated or mixed connective tissue disease may be a common finding, or these patients may have an undefined polymeric disease. Problems associated with these conditions, especially chronic pain, physical limitations, and diminished mentation, often render these patients partially or totally disabled. Foreign-body giant-cell granulomas have been reported in the TMJ, masticatory muscles, parotid and submandibular glands, and regional lymph nodes; on the roof of the orbit; within the orbit; in the lung; and in breast biopsy specimens. The extent of systemic involvement with alloplastic materials remains unclear and requires further investigation.

**HISTOPATHOLOGIC DIFFERENCES WITH ALLOPLASTIC TMJ IMPLANTS**

Our series of patients suggests that foreign-body giant-cell reaction to PT implants is proliferative and worsens with time as more PT particles are generated. Cartilage and bone degeneration and resorption occur. Heterotopic bone formation or reactive neossification can develop. It is unknown what effect that aluminum oxide, used in some PT implants, has in the pathologic process, but it may play a major role because clinical observation indicates that patients with Proplast II (Teflon with aluminum oxide) are more severely affected locally and systemically compared with the patients who received Proplast I (Teflon with vitreous carbon).

Silastic particulation appears to create a less proliferative foreign-body giant-cell reaction, probably related to a larger particle size. Cartilage and bone resorption can occur, but heterotopic and reactive bone can also develop. PMMA particle size may be even greater than that of the Silastic particles, resulting in even less foreign-body giant-cell reaction and more fibrosis, sometimes with reactive cartilage, neossification, or heterotopic and reactive bone formation. Local tissues may be affected by direct contact with the material or leaching of monomer from the PMMA. Local reactions to any of these materials may in part be chemically mediated from the polymers, from cells releasing substances in an effort to degrade the polymers, or upon cell death and lysis. Goldblum et al. identified antibodies to silicone. Unidentified antibodies may exist for other polymers.

**CONCLUSIONS**

The mini-anchor system provides a predictable method to stabilize the TMJ articular disk in position. It osseointegrates with adjacent bone and appears to have a minimal effect on morphologic features of the condyle. Longer follow-up studies, however, are indicated for long-term outcome assessments.

The local and systemic effects of PT, Silastic, PMMA and other polymeric implants that undergo fragmentation and formation of particulate debris are not clearly understood. Further studies will be necessary to identify the effects of these materials, particularly in patients who may have a predisposition to connective tissue and autoimmune disease, and to develop treatment modalities that will predictably help patients afflicted with these diseases.

Current research evidence demonstrates that custom-made total joint prostheses, constructed with materials that are proved and are used as the standards for orthopedic joint devices, work very well for TMJ reconstruction. Total joint prostheses with use of appropriate materials are the only predictable alternative for thousands of patients. The current unavailability of these types of devices are rendering thousands of patients to remain in a state of chronic pain, dysfunction, and ill health.

**REFERENCES**

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