Surgical Technique

TMJ Prosthetics
- Partial and Total Joint Solutions
- Stock and Patient-Specific Systems
Welcome to TMJ Medical's Partial and Total Reconstructive Prostheses Systems. Our implants offer surgeons several treatment options, from partial joint reconstruction to Patient-Specific Prostheses unique to each individual patient's needs. This informational portion is intended to give you some answers and treatment options for temporomandibular disease (TMD). However, this is not intended to be an exhaustive or comprehensive treatise on this subject of alloplastic joint reconstruction.

Temporomandibular Disease

Temporomandibular disease does not merely suggest problems that are isolated to the joints but includes all disturbances associated with the function of the masticatory system. When establishing a diagnosis and developing an appropriate treatment plan for the patient, it is vital to understand the (1) muscles, (2) the temporomandibular joints, and (3) the dentition. A good, sound occlusal condition is paramount for healthy muscle function during chewing, swallowing, speaking, and mandibular posture. Disturbances in the occlusal condition can lead to increased muscle tonus (hyperactivity) and symptoms. Nocturnal bruxism, however, appears to be relatively unrelated to tooth contacts and is more closely related to changes in levels of emotional stress and sleep stages (CNS activity).

How The TMJ Works

A Healthy TMJ

The temporomandibular joint is formed where the rounded head of the condyle of the lower jaw contacts the fossa-eminence of the temporal bone. The joint has a smooth, soft tissue separating material between the bony surfaces called the meniscus or disc. It covers the ball of the condyle, and muscle tissue moves the meniscus in conjunction with the movement of the condyle. Large muscles for movement, chewing, and swallowing power the jaw. When all of the parts are healthy, a temporomandibular joint should move easily and smoothly (Drawing 1).

Drawing 1: Healthy TMJ

An Unhealthy TMJ

There are symptoms that may indicate a TMJ has a problem. Those symptoms can include pain, clicking or joint sounds, restricted opening, and radiographic evidence (x-rays, MRI, MRAr, tomography, CT Scans, and/or a bone scan) of joint degeneration. Take time to discuss each individual diagnosis and any non-surgical options with your patient.

Figure 1: Ankylosis
THE TREATMENT PLAN

Each patient's diagnosis is the result of his or her history, clinical exam, range of motion, and x-rays (or other imaging modalities) to form a treatment plan. It is important that both signs and symptoms be clearly identified. A sign is an objective clinical finding revealed during examination. A symptom is a description or complaint by the patient. Patients are acutely aware of their symptoms, yet may not be aware of their clinical signs. So that subclinical signs are not overlooked, the examiner must be acutely aware of the common signs and symptoms for the specific disorder.

You are responsible for diagnosing and explaining your patients' disorder to them. Disorders of the temporomandibular joints often follow a path of progressive events, a continuum, from the initial signs of dysfunction to degenerative joint disease.

They are summarized as follows:

1. Normal healthy joint (Drawing 1)
2. Conditions that interfere with the sliding of the disc on the condyle (Figure 1)
3. Muscle hyperactivity creating anteromedial pull on the disc (Figure 2)
4. Thinning of the posterior border of the disc
5. Stretching of the attaching discal tissues
6. Functional displacement of the disc
   a. Single click
   b. Reciprocal click
7. Functional dislocation of the disc
   a. Dislocation with reduction (catching) – Periodic displacement of disc
   b. Dislocation without reduction (closed lock) – Permanent displacement
8. Inflammatory arthritis (rheumatoid arthritis)
9. Degenerative joint disease (osteoarthritis) (Figure 3)

Since the prevalence of TMDs is very high, it is recommended that every patient who comes to the dental office be screened for these problems, regardless of apparent need and lack of need for treatment.

The purpose of the screening history and examination is to identify patients with subclinical signs as well as symptoms that the patient may not relate but are commonly associated with functional disturbances of the masticatory system (i.e., headaches, ear symptoms).

The following are questions the general practitioner should ask:

1. Do you have difficulty opening your mouth?
2. Do you hear noises from your jaw joints?
3. Do you have frequent headaches?
4. Does your jaw get “stuck” or “locked”; does it “go out”?
5. Do you have pain in or about the ears or cheeks?
6. Do you have pain while chewing or yawning?
7. Does your bite feel uncomfortable or unusual?
8. Have you had recent injury to your head or neck?
9. Do you have arthritis?
10. Do you have any muscle or joint problems?
11. Have you ever been treated for temporomandibular disorders?
This is followed by a physical inspection of your patient’s face, bite, musculature, and jaw movement. Several structures will be palpated for pain or tenderness, and should any positive indications be noted, a more thorough history and exam will be completed.

At this point, the TMJs are examined both clinically and radiographically. Any signs or symptoms associated with pain and dysfunction are noted. Diagnosis of temporomandibular disorders becomes an extremely important part of successful treatment.

TREATMENT OPTIONS

Non-Surgical Treatment Options

Upon diagnosing your patient’s current TMD, you may prescribe the following conservative (reversible) therapy: Emotional stress therapy (relaxation, patient awareness, voluntary avoidance), exercise, prescription medications (i.e., anti-inflammatories, muscle relaxers), physical therapy, appliances (i.e., splint, night guard, occlusal guard), TENS unit (Transcutaneous electric nerve stimulation), acupuncture, coolant therapy, thermotherapy, manipulative therapy (i.e., massage, passive muscle stretching, and joint distraction).

Or the following nonconservative (irreversible) therapy: selective grinding (occlusal adjustment), restorative and/or fixed dentistry (i.e., crowns and bridge), orthodontic treatment, orthognathic surgery.

Surgical Treatment Options

Surgery is considered only after supportive therapy has failed to eliminate or reduce the problem to an acceptable level. Depending on age and the amount of damage to the temporomandibular joint, surgery may be the best answer to the patient’s problem. The AAOMS Parameters of Care-95 states “temporomandibular joint surgery is indicated for the treatment of pathologic conditions, including developmental and acquired deformities, internal derangements, arthritis, functional abnormalities, ankylosis, and infection. The parameters that are being used for temporomandibular joint surgery were based on the descriptions of pathologic entities and modalities for their treatment which have appeared in peer reviewed medical literature.”

Keep in mind that different patients have varying degrees of joint deterioration, requiring: arthroplasty (primary or revision), arthroscopic surgery, high condylectomy, condylectomy with or without replacement with autogenous (e.g., costochondral rib graft), allogenic or alloplastic material (e.g., partial or total joint replacement prosthesis), gap arthroplasty with or without interpositional autogenous, synovectomy, partial joint replacement or total joint replacement for severe joint deterioration (e.g., Wilkes Stages III, IV, V).

A joint replacement can last for years, and it can often be successfully repeated if the first prosthesis is damaged due to trauma (e.g., automobile accident), or ongoing disease process. For certain situations, there are times when the anatomy and joint condition of a patient does not conform to the stock prosthesis system. You may recommend a customized model Patient-Specific Prosthesis, designed and manufactured for a single patient utilizing a model of their bony anatomy.

INTENDED USES / INDICATIONS

When Temporomandibular Joint Replacement Is Indicated

The TMJ Fossa-Eminence Prosthesis System is intended for use in treatment of severe temporomandibular joint disease due to:

- Inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment
- Recurrent fibrosis and/or bony ankylosis not responsive to other modalities of treatment
- Failed tissue graft
- Failed alloplastic joint reconstruction
- Internal Derangement confirmed to be pathological in origin by both clinical observation and radiographic findings, where the patient has moderate to severe pain and/or disabling dysfunction and has not responded to less invasive, conventional therapy

The TMJ Fossa-Eminence and Condylar Prosthesis System is intended for use in treatment of severe temporomandibular joint disease. The TMJ Condylar Prosthesis is intended for use in conjunction with the TMJ Fossa-Eminence Prosthesis whenever total joint replacement is necessary due to:

- Inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment
• Recurrent fibrous and or bony ankylosis not responsive to other modalities of treatment
• Failed tissue graft
• Failed alloplastic joint reconstruction
• Loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality or pathologic lesion

Wilkes Classifications for Internal Derangement

(Quinn, P. “Color Atlas of Temporomandibular Joint Surgery”; Chapter 4: Surgery for Internal Derangements, Table 4.1, p 56. Mosby 1998.)

Class I: Painless clicking. No restricted motion.
Slight forward displacement of disk.

Class II: Occasional painful clicking, intermittent locking, headaches. Slight forward displacement of disk, beginning deformity, and slight thickening of posterior edge.

Class III: Frequent pain, joint tenderness, headaches, locking, restricted motion, and painful chewing. Anterior disk displacement with significant deformity/prolapase of disk.

Class IV: Chronic pain, headaches, and restricted motion. Increase in severity from III with early to moderate degenerative changes, flattening of eminence, deformed condylar head, sclerosis.

Class V: Variable pain, joint crepitus, and painful function. Disk perforation, filling defects, gross anatomic deformity of disk and hard tissues with degenerative arthritic changes.

The long-term effects of the TMJ Fossa-Eminence Prosthesis System on the natural mandibular condyle are unknown. Remodeling of the natural mandibular condyle has been observed. Other degenerative changes may be attributable to the TMJ Fossa-Eminence Prosthesis. Therefore, the physician/dentist should periodically monitor the condition of the natural mandibular condyle.

Dynamic fatigue tests were conducted on the TMJ Fossa-Eminence and Condylar Prosthesis System with a force applied vertically to the device. Fatigue run-out strength to 10 million cycles was found to be 130 lbf. Physicians should carefully consider the results of these fatigue tests when patients present with particular anatomical considerations or unusual masticatory forces.

PERFECT THE TECHNIQUE FOR IMPLANTATION

It is strongly recommended that the surgeon perfect the technique for implantation of the TMJ prostheses through attendance at surgical demonstration courses, use of an instructional materials, and manipulation of replica models. Instructional materials are available from TMJ Medical. Also, TMJ Medical can provide names of individuals, independent from the company, with extensive experience for consultation prior to surgery.
READ ALL ACCOMPANYING LABELING
Prior to use, the surgeon must read the entire Instructions for Use and device labeling.

TEST FOR ANY SUSPECTED SENSITIVITY TO MATERIALS
Patients with suspected sensitivity to metals, such as nickel, should undergo appropriate testing for sensitivity to Co-Cr-Mo alloy. Upon request, TMJ Medical will supply a sample of this alloy and/or the chemical composition for pre-operative allergy testing. The device should not be used in patients who test positive for Co-Cr-Mo alloy sensitivity.

IF LONGER SCREWS ARE NECESSARY
Occasionally, longer screws will be necessary to engage bone. It is important that the surgeon exercise great care to prevent injury to deeper vital structures. Care must be exercised not to penetrate or impinge any auditory structure, middle cranial fossa, or any neuro/vascular structures.

IF EXCISING BONE
When performing an excision of bone in the area of the normal glenoid fossa and condyle, especially in cases of bony ankylosis, the surgeon must exercise great care to avoid penetration into the middle cranial fossa, the auditory canal, or other vital structures.

TEMPOROMANDIBULAR JOINT RECONSTRUCTION SURGERY
Always refer to the labeling included at the beginning of the manual before you begin any surgical procedure.

PRECAUTIONS

Prior to Surgery
- Special attention should be paid to patient selection. Careful evaluation should be made of patients with disorders that might interfere with their ability to comply with the limitations and precautions necessary to achieve beneficial outcome from this implant.
- All TMJ prostheses, screws, drills, burs, and the TMJ Condylar Trial Sizers are provided sterile.
- Inspect sealed sterile package before opening. If seal is broken, do not use. Do not re-sterilize.

- Prior to use, the TMJ Fossa-Eminence Trial Sizers and Instruments must be sterilized as outlined in provided Instructions for Use and device labeling.
- The surface of the device must remain clean and free of debris prior to implantation.
- The implant must be handled only with talc-free gloves to avoid introduction of talc into the implantation site.
- The prostheses must be protected from scratching or bending prior to and during surgical implantation, as such damage may cause weakening or fatigue of the metal or fracture of the part.

During Surgery
- The TMJ Prosthesis System must be secured only through the use of the drills and screws supplied by TMJ Medical. The screws and drills used with the TMJ Prosthesis System have been specifically selected by size to ensure correct fixation of each prosthesis when used as directed. Any use of substitute drill bits or screws not supplied by TMJ Medical in the TMJ Prosthesis System may result in less than optimal long-term results and may adversely affect the performance of the prosthetic device.
- It is strongly recommended that at least four (4) screws be used where practical to achieve firm fixation of the TMJ Fossa-Eminence Prosthesis. NOTE: Use only the supplied 2.0mm or 2.3mm screws to ensure correct fixation, and to ensure compatibility of the metals.
- It is strongly recommended that at least six (6) screws for the TMJ Condylar Prosthesis be used, where practical, to achieve firm fixation. Care must be taken to secure at least 3 screws in the topmost holes, where practical. NOTE: Use only the supplied 2.7mm or 3.0mm screws to ensure correct fixation, and to ensure compatibility of the metals.
- It is recommended that the head of the TMJ Condylar Prosthesis be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence Prosthesis with all interposing soft tissue removed. The TMJ Condylar Prosthesis articulating surface should preferably be centered in the fossa and should not contact the screws of the TMJ Fossa-Eminence Prosthesis.
PREPARATION OF THE PATIENT FOR SURGERY

1. The patient should be directed to thoroughly wash and rinse their hair the night before the surgery with a mild shampoo and avoid the use of hair spray or styling gels the day of surgery.

2. Patients are started pre-incision and kept on a broad spectrum IV antibiotic (e.g., Ancef 1 g) during the hospital course followed by one week of oral antibiotic (e.g., Cephradine 500 mg) therapy. Anti-inflammatory steroid therapy to minimize edema may be started pre-incision and continued postoperatively as with other reconstruction or orthognathic surgery.

3. Arch bars may be applied prior to draping, if desired.

4. After the patient is anesthetized and the airway secured, any hair that could become involved in the surgical field should be carefully arranged and/or parted to facilitate the incision of the skin. If the hair is to be shaved, care should be taken to avoid cutting or nicking of the skin in the area of the surgical incision.

5. The auditory canal(s) and tympanic membrane(s) should be inspected with an otoscope to ensure there is no preoperative infection and to document any pre-surgical pathology.

6. Occlude the external auditory canal on the surgical side. A cotton pledget moistened with sterile mineral oil can be utilized.

7. The surgical incision sites should be prepared and isolated so that there is no loose hair appearing in the surgical field. Sterile lubricant can be useful to assist in keeping the parted hair out of the field.

8. In unilateral cases, a plastic adhesive isolation drape (e.g., 1010) should be applied from the contralateral submental area to the ipsilateral temporal area to isolate the mouth from the surgical fields. This drape allows access to the oral cavity while providing for sterility of the implantation sites.

9. In bilateral cases, a plastic adhesive occlusive dressing (e.g., Tegaderm or Opsite) can be placed over the mouth to isolate it and its contents from the implantation sites. This dressing can be removed to verify occlusion or to place the IMF wires if needed.

10. The anesthesiologist should be sure the eye(s) are moist and protected throughout the surgery.

THE SURGERY

PREAURICULAR APPROACH

The Preauricular Incision

1. Find the crease between the helix and the preauricular skin and mark a line from the top of the helix to the lobe. In previously operated patients, use the scar to make this incision. In patients with multiple scars, excise the scarred tissue with the initial incision and revise the scar at closure. The superior aspect of the incision should extend from the superior attachment of the ear and progress inferiorly to the level of the ear lobe. In some cases the superior margin of the incision may be extended 2-4 cm on a 45° line angled anterosuperiorly. The incision was made following the previous line of incision, just in front of the right ear. This incision was designed to increase cosmetics and to allow for a good dissection and exposure of the temporomandibular joint.

2. Inject a vasoconstrictor (e.g., Xylocaine with epinephrine 1:100,000) along the line to be incised to decrease bleeding. Wait for its effect (3 minutes).

3. Apply traction to each end of the incision line with single-ended skin hooks.

4. With a #15 blade, incise the skin and subcutaneous tissue along the incision line.

5. At the superior aspect of the incision, spread the tissue with a curved mosquito hemostat to find the superficial layer of the temporalis fascia. This is the very obvious tough, shiny, white, sinewy appearing dense tissue.

6. Once this layer has been found, slide the hemostat inferiorly along the top of this fascia to the area of the zygomatic arch.

7. Deepen the remainder of the incision to this plane using dissecting scissors remembering to stay close to the auricular cartilage posteriorly in the avascular plane. In the multiply operated patient, this is more difficult due to the scar tissue. Care must be
taken to avoid cutting or nicking the auricular cartilage to avoid a postoperative chondritis.

8. Using blunt retractors, retract the skin flaps. Care must be taken to avoid penetration of the parotid capsule at the inferior aspect of the incision as this may lead to persistent bleeding.

9. At the tragus, in previously unoperated patients, just above the parotidomasseteric fascia is the tragal ligament beneath which are found the auriculotemporal nerve and the transverse facial artery, both of which can be sacrificed.

10. Once the parotidomasseteric fascia has been divided down to the level of the joint capsule attaching along the zygomatic arch, make a 2-3 cm horizontal incision along the crest of the zygomatic arch's horizontal incision. With the periosteal elevator reflect the capsule inferiorly to expose the superior joint space. A vertical incision can be made through the capsule to expose the condyle. The deep temporal vein crosses the zygomatic process of the temporal bone and can be cauterized at this point to avoid persistent bleeding. Extend this fascial incision across the posterior aspect of the temporal bone inferiorly along the posterior aspect of the condylar process.

11. Reflect this fascial flap anteriorly along the zygomatic process of the temporal bone exposing the lateral aspect of the fossa and the articular tubercle. Care must be taken not to tear this tissue as branches of the facial nerve course through it in this area. Electrocautery and retraction should also be done in a judicious manner to avoid injury to these nerves as well. In the multiply operated patient, this step is made more difficult due to scar tissue. This flap may have to be elevated with the assistance of dissecting scissors cutting the scar tissue away from the temporalis muscle above the zygomatic process of the temporal bone as the flap is elevated. To assist in determining the anterior extent of dissection in patient-specific cases, refer to the anatomical bone model that should be available in the operating room. It is recommended to keep these models out of the sterile field. They are merely a three-dimensional film (so to speak) of your patient’s anatomy, and are to be used as a diagnostic tool.

12. The fossa can be entered through the superior aspect of the capsule if present. If there is an articular disc, it can be seen as the fossa is entered.

13. With a Freer periosteal elevator, separate the capsular tissue from the lateral aspect of the condyle and make a vertical incision through that tissue directly over the instrument, opening this tissue to expose the lateral aspect of the condyle and condylar neck. This step is also made more difficult in the multiply operated patient due to scar tissue.

14. The condylar resection can be performed at this point if a TMJ Condylar Prosthesis is to be placed. If the remnant of the condyle or condyloid process is too small to be seen, felt, or reached from the preauricular incision, proceed to the submandibular incision and dissect up to the fossa area from below along the posterior mandibular ramus to find the bone for resection.

15. Control all bleeding, irrigate, and pack the area with moist gauze, and direct attention to the submandibular incision if a TMJ Condylar Prosthesis is to be placed. If not, please skip to the Fossa Preparation section.

**SUBMANDIBULAR (RETROMANDIBULAR) APPROACH**

**The Submandibular Incision**

1. Mark a 6 cm line along one of the skin creases, one finger-breadth below the earlobe along the inferior and posterior aspect of the mandible.

2. Inject a vasoconstrictor (e.g., Xylocaine with epinephrine 1:100,000 solution) along the line to be incised to decrease bleeding. Wait for its effect (3 minutes).

3. Apply traction to each end of the incision line with single-ended skin hooks.

4. With a #15 blade, incise the skin and subcutaneous tissue along the incision line down to the playtsma.

5. Incise through this muscle, carefully testing for the marginal mandibular branch of the facial nerve.

6. The next layer encountered in the previously unoperated patient will be the superficial layer of the deep cervical fascia. Dissect carefully through this layer, testing for the marginal mandibular branch of the facial nerve.

7. Carefully dissect out the facial vein and artery, isolate them, and clamp, cut, and tie these vessels.
8. Identify and incise the pterygomasseteric sling and the periosteum at the inferior border of the mandible along the length of the incision, then using a periosteal elevator expose the whole lateral aspect of the ramus of the mandible, the coronoid process, and the sigmoid notch. Connect the preauricular dissection with this one by following the posterior border of the mandible up to the condyloid process resection. Passing the blunt end of a periosteal elevator from below up into the area of the resection will allow it to be seen in the fossa through the preauricular incision.

The Modified Risdon Incision

An incision can be made into the lines of Langer in what is known as a modified Risdon incision, approximately 2 cm below the angle of the mandible. A nerve stimulator should be used throughout the procedure to avoid any nerve trauma. A sharp incision is then made after careful dissection through the playtsma muscle and deeper fascia up to the inferior border of the mandible. A Molt instrument can be used to release fibers of the masseter and the internal pterygoid muscles. This allowed for a rather expeditious removal of tissues from the lateral border of the ascending vertical ramus.

CONDYLAR RESECTION

1. Once the wound has been opened to expose the remaining natural condyle and the occlusion has been fixedated, then remove enough condyle height to allow a TMJ Condylar Trial Sizer with its 13mm head to be placed in position. The trial sizer will allow you to determine which length of the TMJ Condylar Prosthesis will most accurately fit the patient’s mandible.

2. Mark the position of the ramus cut and using a short-blade oscillating saw with copious irrigation separate the proximal segment containing the condyloid process from the ramus.

3. Once the proximal condyloid process segment is separated, bring it lateral to the ramus with a Seldin elevator and remove.

4. Using a similar technique, the coronoid process may be resected at this time if desired. It is wise to remove a resected coronoid process.

5. Obtain hemostasis.

6. When the correct condylar length has been determined by use of the condylar sizer, you are now ready to place the actual TMJ Condylar Prosthesis. It is important to place the TMJ Fossa-Eminence Prosthesis first.

FOSSA PREPARATION

1. Exposure of the entire zygomatic process of the temporal bone lateral to the joint is necessary to facilitate placement of the TMJ Fossa-Eminence Prosthesis. The residual fossa must be thoroughly debrided of all soft tissue posteriorly to the tympanic plate, anteriorly along the surface of the articular eminence of the temporal fossa, and medially to the medial ridge of the fossa where the medial capsule attaches superiorly to the temporal bone.

2. In patient-specific prosthesis cases the surgeon must reproduce any contouring that was pre-operatively performed on the anatomical bone model.

VERIFICATION OF IMPLANT FIT

1. When the joint is fully exposed try the TMJ Fossa-Eminence Trial Sizer for fit. Take your time at this point. Find the trial sizer that fits the bone most accurately with at least 3-point contact and allows the condyle to function smoothly, without dislocation of the joint and provides suitable stability. Seat the fossa component superiorly and medially with the TMJ Fossa-Eminence Holder. The component must fit snugly without any rocking and the lateral flange should engage the zygomatic arch securely.

2. If there is any resistance or rocking noted, determine the impinging hard or soft tissue and relieve or remove it. The fossa component must fit passively in its intended position. In patient-specific cases, this can be verified on the anatomical bone model.

3. At this stage with the assisting surgeon holding the trial sizers firmly in place, check the occlusion very carefully. Ensure the occlusion remains as seen pre-operatively or as desired post-operatively. If not, determine why. Also, manually move the mandible to be sure the natural condyle, if retained, does not get hung up on the anterior rim of the fossa.

4. After selecting the proper trial sizer, check the laser-marked number on the sizer and have the nurse or anesthesiologist record it for future reference.
5. Noting the marked number from the correct-fitting sizer, select the same numbered TMJ Fossa-Eminence Prosthesis, which has been packaged sterile. Try it for accuracy of fit, proper occlusion, and mobility of the condyle.

6. Place the mandibular component on the ramus without the fossa component in position to ensure its independent fit. In patient-specific cases, the mandibular component should fit passively in its intended position as indicated on the anatomical bone model if no pre-operative contouring of the ramus was performed. Verify occlusion before final seating of any prosthesis.

7. There are some cases where the lateral ramus bone remodels in an unusual manner after a first-stage surgery, particularly after failed alloplasts and bone grafts. This trial placement will determine the amount of remodeled lateral bone that may have to be removed to allow the mandibular component to have maximal bone contact with the residual ramus. **Bone contouring should not be performed, however, until the patient is placed in proper occlusion.**

8. For a bilateral case, irrigate and pack the incisions with moist gauze, and perform the incisions and implant trial reduction on the contralateral side.

**FINAL IMPLANT FIXATION**

**PLACING THE TMJ FOSSA-EMINENCE PROSTHESIS COMPONENT OF THE TMJ FOSSA-EMINENCE AND CONDYLAN PROSTHESIS SYSTEM**

1. Place the patient in the planned occlusion bilaterally posteriorly and anteriorly. Care must be taken not to contaminate the surgical sites during this procedure. If an IMF is placed, it is recommended that the individual applying the IMF change their gown and gloves before returning to the sterile field. Care must also be taken that none of the instruments used intraorally find their way back to the sterile field. Having a separate Mayo stand with dedicated IMF instrumentation and suction precludes such problems.

2. Perform any pre-operatively planned mandibular contouring. **Remove bone conservatively with repeated trial placement of components to prevent unnecessary bone removal.**

3. Insert the fossa component and place into proper position using the TMJ Fossa-Eminence Prosthesis Holder.

4. Again, confirm the fit of the fossa component. It is strongly recommended that at least four (4) screws are used where practical to achieve firm fixation of the TMJ Fossa-Eminence prosthesis. NOTE: Use only the supplied 2.0mm or 2.3mm screws to ensure correct fixation, and to ensure compatibility of the metals. Caution should be used so as not to force the screw in place with too much pressure as the screw head could fracture. Always drill the hole slightly deeper than the length of the screw.

5. When the implant has been secured in place, check again for proper occlusion. Be sure to use the drill bits provided for preparing screw holes. Be diligent in this surgery to avoid injury to important adjacent structures i.e. middle cranial fossa, ear structures, facial nerve, and middle meningeal artery. **Copiously irrigate to remove any bone or metal residuals that might occur in securing the metal components.**

6. The TMJ Fossa-Eminence Prosthesis must be secured only through the use of the drills and screws supplied by TMJ Medical. The screws and drills used with the TMJ Fossa-Eminence Prosthesis have been specifically selected by size to ensure correct fixation of each prosthesis when used as directed. Any use of substitute drill bits or screws not supplied by TMJ Medical in the TMJ Fossa-Eminence Prosthesis System may result in less than optimal long-term results and may adversely affect the performance of the prosthetic device.

7. If this patient requires only a hemiarthroplasty, again check that the condyle moves freely over all parts of the TMJ Fossa-Eminence Prosthesis.

**PLACING THE TMJ CONDYLAN PROSTHESIS COMPONENT OF THE TMJ FOSSA-EMINENCE AND CONDYLAN PROSTHESIS SYSTEM**

1. Once the fossa component has been placed, place the mandibular component through the submandibular incision. Articulate it with the fossa component and align it with the lateral surface of the mandible, and place parallel the posterior border of the ramus.

2. It is recommended that the head of the TMJ Condylar Prosthesis be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence Prosthesis with all interposing tissue removed. The TMJ Condylar Prosthesis articulating surface should preferably be centered in the fossa and should not contact the screws of the TMJ Fossa-Eminence prosthesis. The mandibular component may be
held flush against the ramus with the mandibular forceps.

3. Once the fit of both components and their articulating relationship have been confirmed, hold the mandibular component in position with the mandibular forceps, and fixate using the predetermined size and length of screws. The proper placement of the condylar head into the TMJ Fossa-Eminence Prosthesis assures that the head does not contact any screw heads during function.

4. It is important to fix the TMJ Condylar Prosthesis to the ramus of the mandible with as many screws as possible. It is strongly recommended that at least six (6) screws for the TMJ Condylar Prosthesis be used, where practical, to achieve firm fixation. Care must be taken to secure at least 3 screws in the topmost holes, where practical. NOTE: Use only the supplied 2.7mm or 3.0mm screws to ensure correct fixation, and to ensure the compatibility of the metals. The flange direction of the TMJ Condylar Prosthesis is generally ideal when it parallels the posterior margin of the mandibular ramus. Copiously irrigate to remove any bone or metal residuals that might occur in securing the metal components.

5. The TMJ Condylar Prosthesis must be secured only through the use of the drills and screws supplied by TMJ Medical. The screws and drills used with the TMJ Condylar Prosthesis have been specifically selected by size to ensure correct fixation of each prosthesis when used as directed. Any use of substitute drill bits or screws not supplied by TMJ Medical in the TMJ Condylar Prosthesis System may result in less than optimal long-term results and may adversely affect the performance of the prosthetic device.

6. If both sides of the mandible are to be reconstructed, the contralateral side is operated in a similar fashion.

7. The mandible should now be mobilized and forced open, observing the maximum range of opening and occlusal competence. Should mobility be limited, the surgeon should assess the possible need for coronoidectomies and/or relief of adhesions to the medial side of the ramus. Observe the movement of the condylar head(s) to be sure that dislocation does not occur.

8. Always verify occlusion.

9. Once both wounds are copiously irrigated and closed carefully in layers. A pressure dressing is applied and kept in place for 48 hours. Some surgeons may wish to place a vacuum catheter type drain in the surgical area for the first 24–48 hours.

**ADDITIONAL CONSIDERATIONS**

1. The placement of an abdominal fat graft around the condylar head of the implants at surgery may reduce the occurrence of subsequent adhesion or even ankylosis and is therefore recommended. For those patients susceptible to heterotopic bone formation, appropriate fat grafts and radiation therapy should be considered.

2. Occasionally, longer screws will be necessary to engage bone. It is important that the surgeon exercise great care to prevent injury to deeper vital structures. Care must be exercised not to penetrate or impinge any auditory structure, middle cranial fossa, or any neuro/vascular structures.

3. When performing an excision of bone in the area of the normal glenoid fossa and condyle, especially in cases of bony ankylosis, the surgeon must exercise great care to avoid penetration into the middle cranial fossa, the auditory canal, or other vital structures.

**POST-OPERATIVE MANAGEMENT**

1. Post-operative radiographs, panoramic and PA skull or cephalometric films, are made to confirm position and alignment of the components and screws.

2. If IMF elastics are used, release them when the pressure dressing is removed, and the patient is started on a jaw-exercising device (e.g., Therabite or EZ Flex). Arch bars or orthodontic appliances should be removed once occlusion has been confirmed and surgery complete. The patient should utilize the assistance of a physical therapist to increase and maintain mandibular range of motion postoperatively. Two to three visits per week for a minimum of 3 months is appropriate.
THE COMPLICATIONS OR SIDE EFFECTS THAT CAN OCCUR FROM THIS SURGERY

Some complications may result from the surgery or the placement of the device. Like all joint reconstruction, jaw reconstruction with implants is serious and complex. It is not without risk. It is important to evaluate the possible benefits to patient as well as the risks of surgery as you help your patient make their decision regarding whether or not to have surgery. There are a number of possible complications. These may require treatment. The possibility of complications is related to the patient’s condition at the time of the surgery, the surgery itself, and their medical history, especially past surgeries related to TMJ.

ADVERSE EVENTS

TMJ Fossa-Eminence Prosthesis System

Potential adverse events and complications associated with temporomandibular joint surgery and reconstruction may require further treatment and include but are not limited to the following. These adverse events are categorized in descending order by frequency and severity observed in the prospective clinical study. A statistical comparison of the rates of events was made for those that occurred for at least 10% of the subjects in either the partial joint or total joint reconstruction groups.

While the findings of the study indicate that proper use of this device reduces patient pain and improves patient quality-of-life, the number of patients lost to follow-up prior to study completion was sufficient to limit the study’s ability to offer conclusive scientific information about the device’s long-term performance.

Moderate Adverse Event (meaning discomfort sufficient to cause interference with usual activity or to affect clinical status)
- Pain (14.5%)
- Neurological deficit/dysfunction (.7%)

Mild Adverse Event (meaning awareness of a sign or symptom but easily tolerated)
- Pain (64.1%)
- Soreness (31.0%)
- Edema (29.7%)
- Neurological deficit/dysfunction (29.7%)
- Headache (28.3)
- Decrease/Loss of Range of Motion (20.0%)
- Joint Disorder (18.6%)
- Muscle spasm (18.6%)
- Myalgia (17.2%)
- Surgical procedure (12.4%)
- Numbness (10.3%)
- Muscle rigidity 7.6%)
- Nausea (6.2%)
- Infection (3.4%)
- Swelling (3.4%)
- Weakness (3.4%)

Other adverse events could occur following placement of this prosthesis system. The incidence of the adverse events may be related to the patient’s previous surgical history, prior medical conditions, or their on-going temporomandibular joint disease.

- Implant loosening due to poor bone quality and/or ankylosis.
- Foreign body reaction due to metal sensitivity
- Allergic reaction to implant materials
- Infection due to the patient’s challenged immune system
- Device fracture due to unauthorized implant modification, trauma, and/or excessive load (i.e. extreme clenching)
- Chronic pain due to disease progression
- Subsequent fibrosis due to multiple joint surgeries and/or disorders on the TM joint.
- Subsequent adhesions or ankylosis due to multiple joint surgeries and/or disorders on the TM joint.

TMJ Fossa-Eminence and Condylar Prosthesis System

Potential adverse events and complications associated with temporomandibular joint surgery and reconstruction may require further treatment and include but are not limited to the following. These adverse events are categorized in descending order by frequency and severity observed in the prospective clinical study. A statistical comparison of the rates of events was made for those that occurred for at least 10% of the subjects in either the partial joint or total joint reconstruction groups.

Moderate Adverse Event (meaning discomfort sufficient to cause interference with usual activity or to affect clinical status)
- Pain (30.8%)
- Neurological deficit/dysfunction (11.5%)
- Swelling (11.5%)

Mild Adverse Event (meaning awareness of a sign or symptom but easily tolerated)
- Pain (57.7%)
- Edema (43.6%)
- Soreness (26.9%)
- Neurological deficit/dysfunction (29.5%)
• Muscle spasm (21.8%)
• Decrease/Loss of Range of Motion (20.5%)
• Myalgia (20.5%)
• Headache (18.0%)
• Weakness (17.9%)
• Muscle rigidity (17.9%)
• Numbness (12.8%)
• Nausea (11.5%)
• Infection (11.5%)
• Swelling (10.3%)
• Surgical procedure (10.3%)
• Joint disorder (3.8%)

Other adverse events could occur following placement of this prosthesis system. The incidence of the adverse events may be related to the patient’s previous surgical history, prior medical conditions, or their on-going temporomandibular joint disease.
• Implant loosening due to poor bone quality and/or ankylosis.
• Foreign body reaction due to metal sensitivity.
• Allergic reaction to implant materials.
• Infection due to the patient’s challenged immune system.
• Device fracture due to unauthorized implant modification, trauma, and/or excessive load (i.e. extreme clenching).
• Chronic pain due to disease progression.
• Subsequent Fibrosis due to multiple joint surgeries and/or disorders on the TM joint.
• Subsequent adhesions or ankylosis due to multiple joint surgeries and/or disorders on the TM joint.

POST-OPERATIVE OUTCOMES

Every surgical procedure is different, but based on experience the patient may need to continue various forms of treatment after the surgery. These could include physical therapy, additional dental work, braces, or surgery to correct problems with the position of their jaw or revisions of the implant. Patients can expect a maintenance of a level of pain that is of little or no concern. They may not experience total elimination of pain, but a significant moderation of pain is a reasonable expectation for many patients. The amount of relief will vary by patient, and patients who have had a number of prior TMJ surgeries may not get the same relief as patients who have had no surgeries or only one or two. The same thing can be said for improvement in opening and/or jaw function as evidenced by an acceptable vertical opening, functional bite (occlusion) and the ability to chew solid foods. The range of motion, which may be dependent on the preoperative condition, is generally considered to be:

a. Intercisal opening of 30 mm (20 mm for joint replacement procedures)
b. Lateral excursive movements of 4-6 mm (absent in joint replacement procedures)
c. Protrusive excursive movements of 4-6 mm (absent in joint replacement procedures)

Patients will most likely be able to feel their implant as well, since there is not much soft tissue between the skin and the implant. Most patients are satisfied, however, with the restoration/maintenance of facial aesthetics and jaw function. The relief from pain and restoration of function experienced will be affected by the way in which they follow their surgeon’s instructions after the surgery is completed.

You may give your patient medication, and prescribe a course of physical therapy. You may give them a jaw-exercising device. It is important that you stress to your patient the importance of postoperative instructions so they can get the full benefit from their surgery. Also that they follow the postoperative physical therapy instructions to attain the optimum amount of jaw movement, mouth opening and decrease in muscular pain.

The best surgery is only as good as the therapy that is performed afterwards. Lack of compliance with their therapy can lead to an unsuccessful outcome. If they cannot commit to the postoperative therapy regimen, then they need to reconsider which treatment option other than TMJ reconstruction best suits their needs.

Depending on the results of the surgery, you may start your patient on a special diet. Even if that does not happen, have them avoid hard, crunchy or sticky foods, which could damage the implants or cause them pain and discomfort. For the same reason, patients should not chew gum. Patients should avoid contact sports and dangerous situations that could strain or injure their jaw. Cold weather may elicit pain in the jaw region. This frequently subsides after 1-2 years.

ADDITIONAL POST-OPERATIVE INSTRUCTIONS FOR PATIENTS

Instruct patients to:
• Contact their physician or surgeon if they experience any problems or have any questions
• Keep follow-up visits and do the therapy recommended
• Notify the TMJ Medical if they move. TMJ Medical needs to know how to contact implant recipients in case we need to give them information concerning their implants.
In addition, there may be a difficult types of irreversible resulting from permanent Tissue Disease. Eventually, the blood supply to the bone and injury of chemical imbalance can cause secondary the erosion of articular Bone function permanently. Bone may restricted motion and can fuse to the opposing Adhes. Pain. If left untreated, bone can cause when a disease condition causes the tissues to erode and/or when mechanically, the joint damages itself. Both situations can contribute to deterioration of tissues, which can lead to loss of function and increased pain.

Trauma. A car accident or a blow to the jaw may damage bones and tissues in the TMJ.

Stress. Constant bruxism (grinding teeth), clenching jaw and overloading the joint may cause spasms in the muscles, and expose nerves to severe pain.

Chemical Imbalance. Deterioration of tissues, which can lead to loss of function and increased pain.

Adhesions / Ankylosis. Connective tissues, which can fuse to the opposing bone, can cause restricted motion and pain. If left untreated, bone may actually replace the tissue, impairing the joint function permanently.

Bone. (Osteoarthritis) Arthritis characterized by the erosion of articular cartilage, either primary or secondary to trauma or other condition. A severe injury of chemical imbalance can cause reduced blood supply to the bone and surrounding tissues. Eventually, the bone can die and the joint deteriorates.

Tissue Disease. (Necrosis) The death of the tissue, resulting from permanent (referred to as irreversible) damage (i.e. infection, trauma).

Multiply-Operated Joint. This is one of the most difficult types of symptomatic TMJs to treat. This type of joint has been operated on two or more times and continues to have significant problems. In addition, there may be a history of alloplastic implants for the TMJ which have a significant failure history (Vitek-Proplast/Teflon, and Silastic) and which may continue to cause problems even after removal of the prosthesis. The multiply-operated joint has a predisposed tendency to reject the effectiveness of any surgical treatment.

Glossary

**Internal Derangement / Damaged Meniscus.** Displaced / perforated meniscus can occur due to chemical imbalances which affect the TMJ compartment. A damaged meniscus can occur when a disease condition causes the tissues to erode and/or when mechanically, the joint damages itself. Both situations can contribute to deterioration of tissues, which can lead to loss of function and increased pain.

**Trauma.** A car accident or a blow to the jaw may damage bones and tissues in the TMJ.

**Stress.** Constant bruxism (grinding teeth), clenching jaw and overloading the joint may cause spasms in the muscles, and expose nerves to severe pain.

**Chemical Imbalance.** Deterioration of tissues, which can lead to loss of function and increased pain.

**Adhesions / Ankylosis.** Connective tissues, which can fuse to the opposing bone, can cause restricted motion and pain. If left untreated, bone may actually replace the tissue, impairing the joint function permanently.

**Bone.** (Osteoarthritis) Arthritis characterized by the erosion of articular cartilage, either primary or secondary to trauma or other condition. A severe injury of chemical imbalance can cause reduced blood supply to the bone and surrounding tissues. Eventually, the bone can die and the joint deteriorates.

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Selected References

This list of selected references is intended only to acknowledge some of the sources of information drawn upon in the preparation of this document. Citation of the reference material is not meant to imply endorsement of any statement contained in the reference material. This list is not an exhaustive compilation of information on the topic. Readers should consult other sources to obtain a complete bibliography.


