TMJ
Joint Replacement System

Patient Information

What is the Temporomandibular Joint (TMJ)?

The Temporomandibular Joint is one of the body's most complex joints. It is similar to a ball and socket, but can also slide. It is what allows you to open and close your mouth, as well as chew, talk and swallow.

The ball portion is the mandibular condyle and socket portion is the fossa. There is a disc between the two bone segments which allows the condyle to slide smoothly during a range of motion or while opening your mouth. Muscles keep the joint together and provide the force required to move your jaw.

What is Temporomandibular Joint Disease (TMD)?

Any jaw joint problems are commonly referred to as TMJ but this is simply the joint itself. TMD is the joint that is diseased and needs repair. Various factors can cause TMD which result in restricted jaw movement and pain. Some symptoms include pain in your jaw, headaches, earaches, popping of your jaw, difficulty opening and locking of the jaw (closed or open) or dizziness.

How are the majority of TMD patients treated?

The majority of patients with TMD do not require surgery. They can be treated conservatively with one or a combination of the following:

- Soft diet
- Hot/cold pack applications
- Mouth splints
- Physical therapy
- Anti-inflammatory medications
- Muscle Relaxants
- Analgesics (pain medications)
- Dental treatment including:
    - Bite adjustments
    - Restorations
    - Orthodontics

Only those patients who have a "mechanical" problem inside the joint itself that does not respond to conservative care, may be candidates for surgery.

What types of surgery are performed in the TMJ?

Oral and maxillofacial surgeons basically have these surgical options:

- Arthrocentesis
- Arthroscopy
- Arthroplasty
- Partial joint replacement
- Total joint replacement

In arthrocentesis, the surgeons place two needles around the joint space, then flush and irrigate the joint, getting rid of scar tissue and fibrous matter that is interrupting the joint. Arthroscopy is a procedure where a small endoscope is placed inside the joint for diagnostic purposes and to treat inflammation and discs that are "stuck" in position or displaced. For more serious disorders where the disc is badly displaced an open arthroplasty can be performed to repair, reposition or remove the disc. Only in cases where there is severe late-stage degeneration of the disc and condyle is total joint replacement considered.

What is the Total TMJ Replacement System?

The Total TMJ Replacement System is a "ball and socket" type prosthetic joint similar to a hip implant. The following implants, which make up the Total TMJ Replacement System, are made of biocompatible materials with over 30 years of successful use in orthopedic joint replacement.

- **Condyle (also called mandibular) implant**
  The condyle implant is made of metal Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy or Titanium (Ti-6AL-4V) alloy. Both implants have a roughened titanium porous coating on the implant surface that contacts bone. Co-Cr-Mo alloy contains nickel.
- **Fossa implant**
  The fossa implant is made of a hard, plastic polyethylene. The fossa is made of molded polyethylene that has shown excellent wear resistance during mechanical testing.
- **Screws**
  Both the condyle and fossa implants are attached to bone using titanium alloy screws.

Who is a candidate for the Total TMJ Replacement System?

Candidates are patients who have finished growing and have TMJ problems along with one of the following indications:

- Arthritic conditions: e.g. osteoarthritis, rheumatoid arthritis or traumatic arthritis
- Ankylosis (an abnormal fusion of the joint)
- Revision procedures where other treatments have failed
- Avascular necrosis (death of tissue due to poor blood supply)
- Multiply operated joints
- Fracture
- Functional deformity
- Benign neoplasms (non-malignant abnormal new growth of tissue)
- Malignancy
- Joints with severe bony changes
- Developmental abnormality (birth defect)

What are the contra-indications for the Total TMJ Replacement System?

- Patients with an active infection
- Patients who do not have enough bone and/or deformed bone or good quality bone to support the device
- Patients requiring partial TMJ joint reconstruction only
- Known allergic reaction to any of the materials used in the implants
- Patients with mental or neurologic conditions who are unwilling or unable to follow postoperative care instructions
- Patients who are still growing
- Patients with severe hyper-functional habits (e.g. clenching, grinding, etc.)
- Patients with an active foreign body reaction

What are the possible complications?

The following risks are associated with the use of a Total TMJ Replacement System:

- Removal of component(s) including, but not limited to the following:
  - Implant changes caused by loading and/or wear
  - Degenerative changes within the joint surfaces from disease or previous implants
  - Implant materials producing particles or corroding
- Loosening or displacement with or without removal of the implant
- Infection
- Foreign body or allergic reaction to implant components
- Wearing through of the fossa material
- Facial swelling and/or pain
- Facial nerve problems
- Removal of tissue
- Heterotopic bone formation (bone found in an abnormal place)
- Neuroma formation (abnormal growth of nerve tissue)
- Ear problems
- Dislocation
- Placement of an implant in one side joint may result in harmful effects to the joint on the opposite side
- Placement of an implant may produce an improper relationship between teeth surfaces that should contact during biting

What have been the results with the use of the Total TMJ Replacement System?

Clinical Study Summary

A clinical study began in the United States in 1995 and was designed to document patient outcome after implantation of the Total TMJ Replacement System. 119 unilateral (one side) and 105 bilateral (both sides) cases were included only after appropriate non-surgical treatment and/or previous implant failure. The average patient follow-up was 28.7 months (range: 0.4-91.7 months) with 85 patients having follow-up data at the 3 years study endpoint.

A total of 224 cases received 329 total joints. Overall, patients improved by having a decrease in pain, increase of function, increase in maximal incisal opening (MIO) and satisfaction with their outcome.

The Total TMJ Replacement System has not been studied in pregnant women or children, therefore, the safety and effectiveness for these patients is not known. The safety and effectiveness of revision surgery using a second set of Total TMJ Replacement System implants is not known.

What should I expect after surgery?

"Reasonable expectations" after TMJ implant surgery as stated can include:

- An increased mouth opening
- Pain reduction
- Improved chewing ability

Outcomes are dependent upon the severity of the disease, the number and type of previous treatments, the condition of the patient and patient compliance with postoperative instructions.

What precautions should I take after TMJ Surgery?

1. Follow your surgeon's postoperative instructions, especially those related to physical therapy, diet and medication. See your surgeon for scheduled follow-up visits including annual visits after the first year.

2. Avoid the following:
   - Hard, crunchy or tacky food
   - Contact sports
   - Activities which may damage your implants
3. If you have to have other surgeries, not related to your TMJ surgery, please tell your doctor that you had a TMJ surgery. Your doctor will need to know this to prescribe an antibiotic to prevent infection from the new surgery. An infection can cause a problem with your TMJ implants

What rehabilitation do I need after surgery?

Rehabilitation regimens can vary among physicians and generally include a home-based regimen of jaw stretching with a plastic, hand-held device within 48 hours of surgery. You may require more or less rehabilitation, depending on the seriousness of your TMJ disease. The length of time for your rehabilitation will depend on how much jaw movement you had before surgery. Rehabilitation may last from about 6 weeks to 6 months following implant surgery.

Call your doctor if you experience any of the following:

- Excessive swelling
- Sudden pain
- Sudden less opening of your mouth and/or locking
- Impact to your face and/or head such as from an automobile accident

Surgeon Training

All surgeons are required to have prior training with the use of this device by hands-on and educational course instruction.

Patient and manufacturer responsibilities

Request that your implants be returned to Biomet Microfixation at the address on the back of this brochure, if all or part of the implants are removed for any reason. Notify Biomet Microfixation and your surgeon if you change your mailing address so that you can be contacted if necessary with information regarding your implants. The FDA requires Biomet Microfixation to have your current address on file to be able to contact you at any time after your surgery.

This patient information brochure is for general information on TMJ surgery. Biomet Microfixation, as the manufacturer of implants, does not practice medicine. The contents of this brochure, including your condition, treatment, prognosis, and potential risks associated with this device should be discussed thoroughly with your surgeon.

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