

Are You Considering Total Temporomandibular Joint Replacement?

INFORMATION FOR THE PATIENT

WHAT MAKES UP MY TMJ?

The TMJ can be considered a ball-in-socket joint. The ball (condyle) is a part of the lower jaw (mandible). The socket (fossa) is part of the skull (Figure 1). These two parts come together to form the moveable joint that you can feel when you place your fingers over the skin in front of your ears as you open and close your mouth.

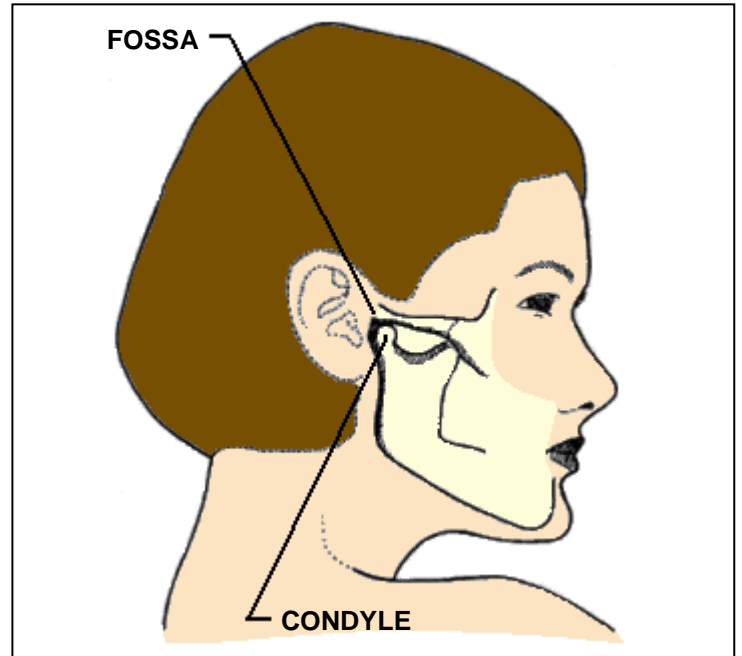
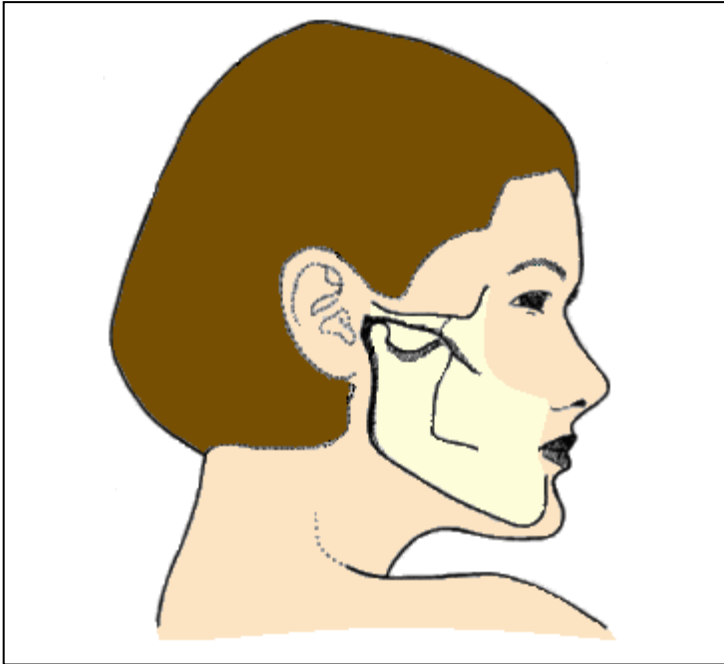


Figure 1

Your surgeon has asked you to consider total temporomandibular joint (TMJ) reconstruction because your TMJ has become compromised or damaged resulting in pain and/or loss of jaw function.

This pamphlet is intended to provide you with information about your TMJ condition, about the risks and potential complications associated with TMJ surgery, and about the *TMJ Concepts* Patient-Fitted TMJ Reconstruction Prosthesis so that you may make an educated decision as to whether or not to undergo treatment with this implant.

Much of the information included in this brochure is general and should only be considered as an aid to your surgeon's explanation of your specific problem. Please address your clinical questions to your surgeon as you make your final decision. Also, *TMJ Concepts* is available to address inquiries related to implant design and manufacture.

WHEN MIGHT I BENEFIT FROM THIS IMPLANT?

You may benefit from this implant if you suffer from one of the following conditions.

- Inflammatory arthritis (such as rheumatoid arthritis) of the TMJs not responsive to other treatment
- Immobility of the joints (fibrous and/or bony ankylosis) not responsive to other treatment
- Failed TMJ reconstructions using body tissue such as bone, muscle, or cartilage
- Failed TMJ reconstructions using joints or other implants made from man-made materials
- Loss of correct jaw position due to bone loss (resorption), trauma, developmental abnormality, or tumor

WHEN SHOULD THIS IMPLANT NOT BE USED?

This implant should not be used if you have one of the following conditions.

- Active or suspected infections in or near the TMJs
- Uncontrolled clenching or grinding of teeth which may lead to overload or loosening of attachment screws
- Any mental or neuromuscular disorder that may cause the limitations and precautions for the use of this implant to be ignored
- Known allergy to any of the implant materials

If any of these conditions apply to you, speak to your surgeon.

WHAT MATERIALS ARE IN THIS IMPLANT?

The components of this implant (Figure 2) are made with the same types of materials used for decades in orthopedic surgery to successfully reconstruct knees, hips, shoulders, elbows, and other joints of the body.

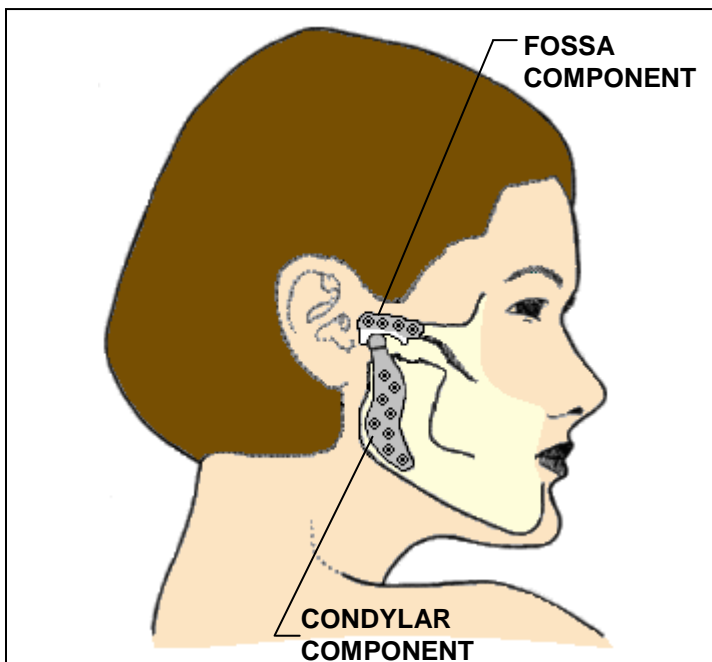


Figure 2

The condylar component has a metal condyle made from cobalt-chromium-molybdenum. This is attached to a metal implant body made from titanium alloy. This component is anchored to the lower jaw with titanium alloy screws.

The fossa component has a durable medical-grade plastic surface made from ultra-high-molecular-weight polyethylene (also known as UHMWPE). This is attached to a metal backing made from pure titanium. This component is anchored to the skull with titanium alloy screws.

HOW ARE THESE IMPLANTS MADE?

Each set of components is made to fit the unique shapes of your skull and lower jaw and to address your surgeon's specific plans for your TMJ surgery. This is done using an anatomical bone model of your TMJ anatomy.

The following steps are required to make these implants:

- The surgeon orders implants from *TMJ Concepts*.
- The patient undergoes a CT scan of their TMJs.
- The scan is used to make an anatomical bone model.
- The model is forwarded to the surgeon for evaluation and surgical planning modifications.
- The model is returned to *TMJ Concepts* for design of the patient-fitted TMJ implant components.
- The model and implant designs are sent to the surgeon for review and approval.
- Once approved, the implant components are made and sent to the surgeon's hospital for implantation.

Patients having failed metal implants in place may need to have them removed before the CT scan is performed. This is because metal often interferes with the scanning process. If existing implants are removed, your talking, eating, jaw opening, or other functioning may become temporarily impaired until your new implants are designed and implanted. Ask your surgeon what to expect in your particular case.

HOW ARE THESE COMPONENTS IMPLANTED?

The surgery used to implant these components is performed under general anesthesia in a hospital operating room. Two incisions are made. The condylar component is implanted through an incision below and behind the lower jaw. The fossa component is implanted through an incision in front of the ear (broken lines in Figure 3).

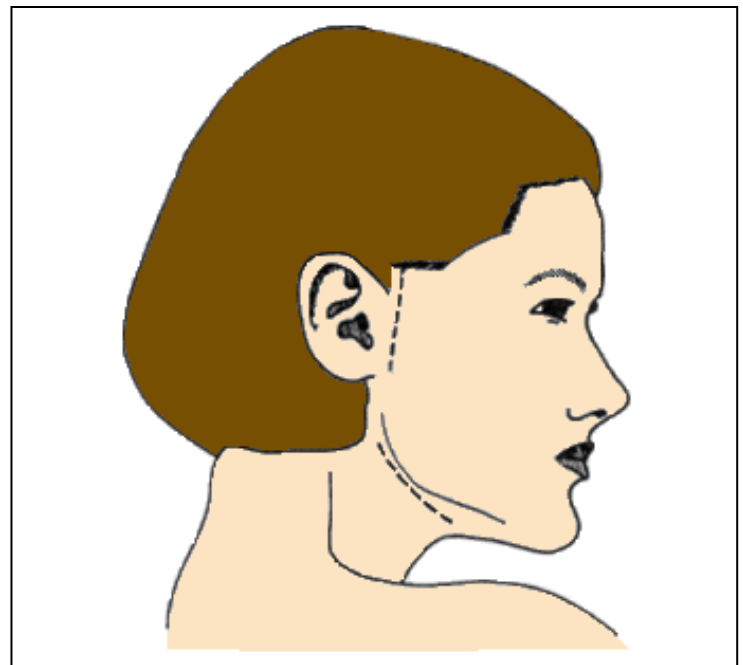


Figure 3

WHAT ARE POSSIBLE COMPLICATIONS?

Complications may occur following placement of these implants and may require further treatment. The occurrence of a complication may be related to or influenced by previous surgical history or prior medical conditions. These complications include but are not limited to:

- Continued or increased pain levels or worsening of other present TMJ symptoms
- Infection
- Facial and jaw swelling after surgery usually lasting several days
- Bruising and discoloration of the skin around the eyes, ears, and jaw
- Temporary or chronic jaw muscle spasm
- Temporary or permanent facial muscle weakness resulting from motor nerve injury during surgery (The most common problems are an inability to wrinkle the brow, raise the eyebrow, or fully close the eyelids.)
- Temporary or permanent numbness of certain areas of the skin in the region of the joint and sometimes in more remote areas of the face and scalp
- Ear problems, including inflammation of the ear canal, middle or inner ear infections, perforation of the ear drum, temporary or permanent hearing loss, ringing in the ears, and equilibrium or eustachian tube problems
- Loss of joint mobility due to the development of scar tissue (adhesions), heterotopic bone, or ankylosis
- Dental malocclusion (improper bite) requiring bite adjustment, orthodontia, or reoperation
- Resorption or erosion of the glenoid fossa, mandible, or surrounding tissues
- Foreign body reaction or allergic reaction to implant components
- Wear, displacement, breakage, or loosening of implant components
- Functional compromise of the opposite TMJ when only one joint is being reconstructed
- Allergic reaction to any of the medications given during or after the surgery
- Objectionable scarring of the incisions

WHAT OTHER TREATMENTS MIGHT I NEED?

Due to the complex nature of your TMJ problem or to the occurrence of a complication, you may require additional treatments including but not limited to:

- Extended physical therapy
- Bite splint therapy
- Restorative or reconstructive dentistry
- Orthodontia (dental braces)
- Orthognathic surgery (jaw repositioning surgery)
- Further reconstructive TMJ surgery

WHAT CAN I EXPECT FOLLOWING SURGERY?

In the immediate post-operative period, your surgeon will provide you with the appropriate medication and care required for your recovery.

In order to establish the proper relationship between the upper and lower jaws, your teeth are wired together during surgery. Depending on your specific circumstances, these fixation wires may temporarily be left in place following surgery.

Post-implantation physical therapy is very important to achieving and maintaining optimum joint function. Your surgeon may recommend a jaw-exercising device for you. You must follow his instructions with regard to the use of that device in order to attain the maximum benefit from your surgery.

Your surgeon may also recommend that you work with a physical therapist for a period of time post-operatively. Each case may have a different regimen in this regard, but most important is the continuous motion of the new joint to attain and maintain motion and function.

WHAT ELSE CAN I EXPECT?

Your diet will start as liquid, pureed, or even solid foods. This will depend on what your surgeon recommends for your particular circumstances.

You may experience "noises" from your new implants that include squishing, squeaking, clicking, and popping. These noises are not usual but may occur in some cases. You may also notice stuffiness and/or a ringing sensation in your ears for a few weeks after surgery. This should subside over time.

In order to implant these devices, certain muscles which assist in jaw function will have to be removed if they have not already been removed from a previous surgery. This removal will reduce your ability to move your jaw from side to side and forward and down. Some of this motion may be regained, however, with aggressive physical therapy.

This implant will not allow you to have "normal" jaw function. A patient with a hip or a knee reconstruction can not expect to be able to run in a race or participate in other sports that are strenuous on the legs. Similarly, a patient with a TMJ reconstruction should not expect to be able to eat hard, crunchy, or tacky foods without discomfort and risk of implant damage.

Long-term success with these joint prostheses may also be dependent on the physical demands placed on them. Excessive joint forces from grinding or "bruxing" teeth can lead to accelerated wear and fatigue resulting in early failure of this TMJ implant.

WILL MY PAIN BE REDUCED?

Unfortunately, the complete elimination of pain is not possible. Some patients may even experience more pain due to the additional surgery required to implant the devices. Even though many patients have experienced some relief from their symptoms, the amount of pain reduction will vary from patient to patient over time.

Patient data collected to date indicates that patients having undergone two or fewer previous surgeries experience less pain post-operatively than those patients having undergone larger numbers of prior operations.

HOW LONG WILL THIS RECONSTRUCTION LAST?

Despite the fact that these implants are fitted specifically to your anatomy, you should not expect them to last for a lifetime. While the expected life of a TMJ implant is difficult to estimate, it is finite and may significantly differ for each patient due to the diversity of conditions seen in TMJ reconstruction.

These components are made from man-made materials which are placed within the body for the potential restoration of jaw function and reduction of pain. However, due to the many biological, mechanical, and physiochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Scar tissue or unwanted bone may develop around the implant components over time and may cause a decrease in motion and function. If this occurs, additional surgery may become necessary to remove this scar tissue or bone. This does not usually require replacement of the implant components.

WHAT ARE THE ALTERNATIVES TO THIS TYPE OF RECONSTRUCTION?

Alternatives to this type of reconstruction include grafts of bone, soft tissue, or cartilage. The suitability of alternative treatments will depend on the condition of the bones, cartilage, disc, ligaments, muscles, nerves, and blood vessels in and around your TMJs. Your surgeon can discuss this aspect of your particular case with you.

HOW DO I CARE FOR AND PROTECT MY TMJ IMPLANTS?

- Inform your surgeon about other types of surgeries or dental procedures you intend to have after your TMJ reconstruction. He may want to prescribe antibiotics to decrease the possibility of infection that could jeopardize the success of your implants.
- Contact your surgeon if you have any problems related to your surgery or your TMJ implants.
- See your surgeon for prescribed follow-up visits. After the first year, it is important that you visit your surgeon for annual check-ups.
- Follow your surgeon's post-operative instructions, especially those related to physical therapy.
- Continue to take medications and to follow the diet as prescribed by your surgeon.
- Avoid hard, crunchy, or tacky foods.
- Refrain from chewing gum.
- Avoid contact sports.
- Never place yourself at physical risk that may result in damage to your TMJ implants.
- Refrain from water sports and general strenuous physical activity for six weeks following surgery.

WHAT OTHER RESPONSIBILITIES DO I HAVE?

- Request that your implants be returned to *TMJ Concepts* for analysis should they be removed for any reason.
- Notify *TMJ Concepts* if you change your address so that you can be contacted if necessary with information regarding your TMJ implant. *TMJ Concepts* is required by the FDA to be able to locate you should the need arise.

For more information contact:



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