TMJ IMPLANTS
INCORPORATED

TMJ Fossa-Eminence Prosthesis System
For Partial Joint (hemiarthroplasty) Reconstruction

Instructions for Use
Products distributed in the United States

Right Side Kit
(Models FER-01 through FER-33)

Left Side Kit
(Models FEL-01 through FEL-33)

Supplemental Kit -- Right/Left
(Models FER-34 through FER-44, FEL-34 through FEL-44)

TMJ Patient-Specific™ Fossa-Eminence Prosthesis
(Models CFER and CFEL)

Store between 10° and 32°C (50° - 90°F) and 20% to 80% relative humidity.

Manufactured by

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Caution: United States Federal Law restricts this device to sale by or on the order of a physician/dentist.

1. DEVICE DESCRIPTION

The TMJ Fossa-Eminence Prosthesis

The TMJ Fossa-Eminence Prosthesis is designed to provide a thin, rigid, well-fitting prosthetic covering for the articulating surface of the temporomandibular joint comprised of the glenoid fossa and articular eminence of the temporal bone. The articular surface of the prosthetic glenoid fossa and articular eminence is highly polished to minimize friction in joint movement.

The prosthesis and the screws, with which it is to be secured to the skull, are manufactured from surgical Co-Cr-Mo alloy (ASTM F75/ASTM F799). These devices are intended for permanent implant and are for single use only.

All components in this Fossa kit, including individual prosthesis, drills and screws are sterilized by gamma-irradiation or e-beam radiation (2.5 Mrads), and are packaged in individual double-peel PETG and Tyvek containers.

Two additional NON-STERILE Fossa kits accompany this TMJ Fossa-Eminence Prosthesis System and are essential for its use. The Fossa-Eminence Trial Sizing System contains trial sizer components for each size of implant. The Instrument Kit contains screwdrivers and Fossa-Eminence holders.

These two accompanying kits must be steam sterilized prior to use in accordance with procedures outlined in Section 9.

2. INTENDED USE/INDICATIONS

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.

3. CONTRAINDICATIONS

The TMJ Fossa-Eminence Prosthesis System should not be used for patients with one or more of the following conditions:

- Infection or malignancy in the head or neck region
- Known allergy to any of the components of the system

- Ability to exert significant post-operative masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and fracture of the device or loosening of the screws

4. WARNINGS

USE OF THE FOSSA-EMINENCE ALONE FOR INTERNAL DERANGEMENT

The medical literature reports:

- that many cases of Internal Derangement, resolve after non-surgical treatment, or, in some cases, with no treatment at all.
- that the complexity of contributing factors in this patient population must be considered in the diagnosis and decision to surgically treat patients.
- that replacement surgery, therefore, should be utilized only as a last resort after other treatment options are exhausted or determined not to be warranted in the medical judgment of the physician/dentist in consultation with the patient.
- that the Wilkes classification is a guide in determining the severity of the disease. This classification should not be relied on as a sole criterion for surgical treatment.

Wilkes Classifications for Internal Derangement[1]

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/prolapse 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.

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[1] Quinn, P. **"Color Atlas of Temporomandibular Joint Surgery"**; Chapter 4: *Surgery for Internal Derangements*, Table 4.1, p 56. Mosby 1998.

- **PERFECT THE TECHNIQUE FOR IMPLANTATION**

It is strongly recommended that the surgeon perfect the technique for implantation of the TMJ Fossa-Eminence Prosthesis System through attendance at surgical demonstration courses, use of an instructional video, and manipulation of replica models. Instructional videos and literature are available from TMJ Implants, Inc. TMJ Implants Inc can provide names of individuals, independent from the company, with extensive experience can be obtained for consultation prior to surgery.

- **READ ALL ACCOMPANYING LABELING**

Prior to use, the surgeon must read the entire Instructions for Use and device labeling.

Dynamic fatigue tests were conducted on the TMJ Implants Inc. Metal-on-Metal Total Joint Replacement System with a force applied vertically to the Fossa-Eminence prosthesis. No failures occurred at 130 lbs. Physicians/Dentists should carefully consider the results of these fatigue tests when patients present with particular anatomical considerations or unusual masticatory forces.

- **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 Implants, Inc. 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.

5. PRECAUTIONS

Prior to Surgery

- All TMJ Fossa-Eminence prostheses, screws, and drills are provided sterile. Inspect sealed sterile package before opening. If seal is broken, do not use. Do not resterilize.
- Prior to use the Fossa-Eminence Sizer kit and the Instrument Kit containing screwdrivers and Fossa-Eminence holders must be sterilized as outlined in Sections 8 and 9.
- 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 Fossa-Eminence Prosthesis System must be secured only through the use of the drills and screws supplied by TMJ Implants, Inc. The screws and drills used with the TMJ Fossa-Eminence 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 Implants, Inc. 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.
- It is strongly recommended that at least four (4) Fossa-Eminence screws be used where practical to achieve firm fixation of the TMJ Fossa-Eminence prosthesis.
- It is recommended that the head of the natural condyle be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence prosthesis with all interposing soft tissue removed. The condyle articulating surface should preferably be centered in the Fossa and should not contact the screws of the Fossa-Eminence prosthesis.

6. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Adverse events observed in the clinical use of the TMJ Implants Inc. Fossa-Eminence prostheses are as follows: (in descending order of frequency)

- Postoperative pain, swelling, jaw muscle spasm
- Facial nerve and muscle weakness or paralysis
- Ankylosis and Fibrosis
- Other: trauma, nausea, condylar dislocation, malocclusion, blurry vision
- Suspected allergic reaction
- Heterotopic bone formation

- Decreased interincisal opening
- Joint locking
- Malocclusion
- Hearing loss/problems
- Degenerative joint changes
- Poor fit of custom prosthesis
- Increased pain

In addition to the adverse events identified above, potential adverse events and complications associated with temporomandibular joint surgery and reconstruction may require further treatment and include but are not limited to:

- Hematoma formation
- Hemorrhage
- Foreign body or allergic reactions to the device materials
- Rejection of the device
- Wear, displacement of the device or implant loosening
- Fracture of the device/Surgical damage to anatomical structures adjacent to the TMJ
- Patient discomfort
- Speech problems
- Facial deformity

7. CLINICAL DATA

There have been two studies conducted that support the safety and effectiveness of the TMJ Fossa-Eminence Prosthesis System. The first is the TMJ Implants, Inc. Registry, a retrospective study; the second, a prospective clinical study, TMJ-96-001.

Pain measurements for both studies were recorded using a 10cm Visual Analog Scale (VAS). The left side of the scale represented no pain while the right side represented the most severe pain imaginable. The patients were instructed to mark a vertical line on the scale to indicate their perceived level of pain. At the point where this vertical line crossed the horizontal scale, a measure was recorded using a ruler graduated in millimeters. Interincisal opening was measured in millimeters using a Therabite™ Scale. The interincisal opening was measured at the point at which the patient cannot open his/her mouth any wider.

TMJ Implants, Inc. Registry

The Registry is a collection of data on patients that receive a TMJ Implants device. The primary purpose of the Registry is for device tracking. Monitoring clinical progress is a secondary function. The operating surgeon is asked to voluntarily submit baseline assessments of pain, and interincisal opening and then is asked to submit clinical reports at 6 months, 1year, 18 months, 2 years, and yearly thereafter.

Demographics

The Registry included 1358 partial joint recipients representing 1909 devices. Nearly two-thirds (860) of the 1358 reports provided a Wilkes Staging Classification for Internal Derangement, of which 98 percent (839) were Wilkes Classifications III, IV, or V. The Registry data was described in two ways:

1. Cross-sectional data where serial data on patients are not available.
2. Cohort data, where serial data are available on patients

Two cohorts were analyzed: one representing 157 patients with Wilkes Classifications, pre-op and 2 year pain and opening data, and one representing 84 patients with Wilkes Classifications, pre-op and 3 year data. The majority of the patients in each group received "stock" devices (i.e. FER, FEL models). The mean age of the cross-section group of patients was 40±12 years and of each cohort was 41±12 years and 42±12 years respectively. There were 90% female in the cross-section and 94% and 91% in each cohort respectively.

Pain: Partial Joint Reconstruction

The cross-sectional data in table 1 has different patient sets and decreasing observations at each successive time point. The samples at various time points are arbitrary and not drawn according to a sampling scheme. From the cross-sectional data set, there is a mean reduction in pain within the first month after surgery, as demonstrated by Figure 1. The cross-section of patients appear to reach their greatest mean pain relief within 6 months of surgery and continue to improve on average through 5 years implant duration. The cohort data with serial measures on one group of patients over two years and another group of patients over three years demonstrated a similar trend (see tables 2 and 3).

Figure 1: Partial Joint Pain Scores

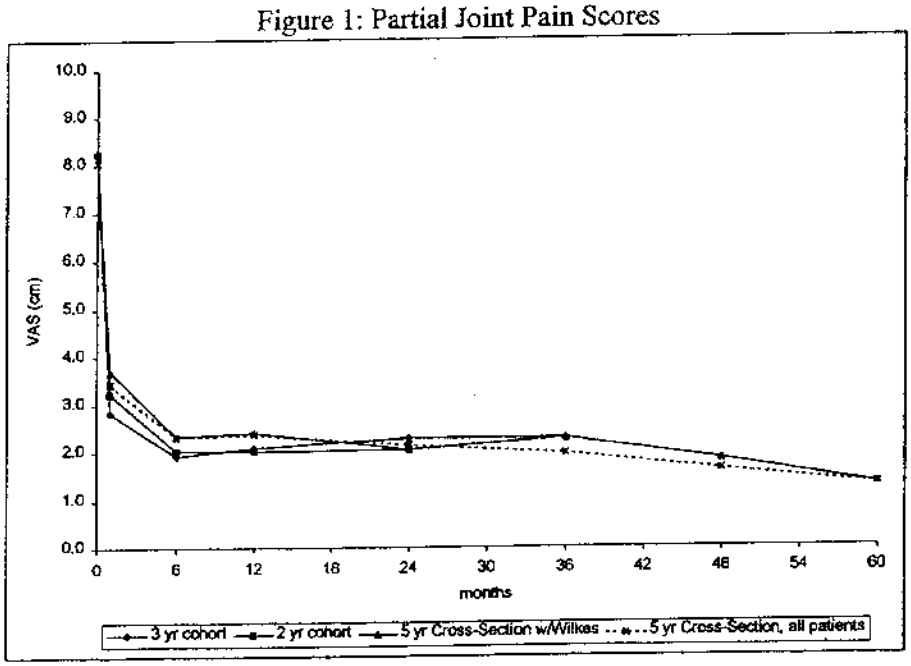

Table 1: Partial Joint, Pain Cross-Section Data

Months	0	1	6	12	24	36	48	60
Mean	8.0	3.4	2.3	2.4	2.1	1.9	1.6	1.3
n	1358	1295	807	555	286	166	80	32
SD	2.0	2.6	2.5	2.7	2.6	2.5	2.2	1.7

Table 2: Pain 3 Yr. Cohort Data

0	1	6	12	24	36
8.2	2.8	1.9	2.1	2.3	2.3
84	80	71	64	65	84
1.7	2.2	2.1	2.5	2.5	2.6

Table 3: Pain 2 Yr. Cohort Data

0	1	6	12	24
8.2	3.2	2.0	2.0	2.0
157	152	124	115	157
1.7	2.4	2.1	2.5	2.5

Interincisal Opening: Partial Joint Reconstruction

From the cross-section data in table 4, there is a mean improvement in the interincisal opening at 6 months after surgery, as demonstrated by Figure 2. Patients appear to reach their greatest mean improvement at 6 months after surgery and maintain that level of improvement on average through 5 years implant duration. A similar trend of improvement in opening is demonstrated with a cohort of 75 patients and 136 patients with complete data at 3 years and 2 years implant duration respectively, Tables 5 and 6.

Figure 2: Partial Joint, Opening Data

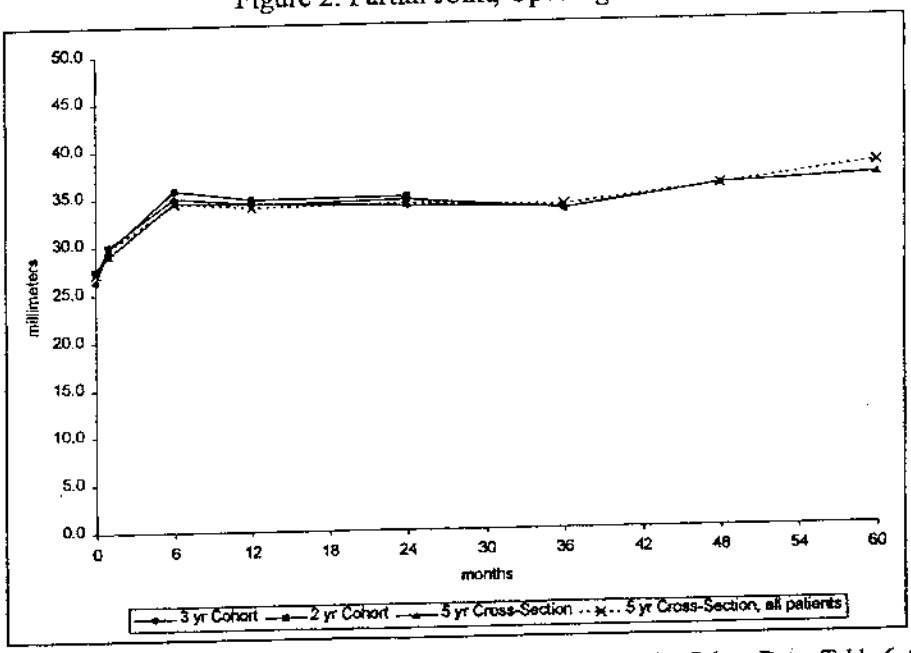

Table 4: Partial Joint, Opening Cross-Section Data

Months	0	1	6	12	24	36	48	60
Mean	27.1	29.7	34.4	33.9	34.2	33.8	35.7	37.8
n	1175	1123	714	491	261	152	76	29
SD	10.2	7.9	7.4	7.9	8.4	9.0	8.7	7.1

Table 5: Opening 3 Yr. Cohort Data

0	1	6	12	24	36
26.2	30.0	35.0	34.4	33.9	33.5
75	74	62	53	57	75
9.4	8.4	7.2	8.3	9.4	8.5

Table 6: Opening 2 Yr. Cohort Data

0	1	6	12	24
27.4	29.7	35.7	34.8	34.9
136	133	111	97	136
9.6	8.2	6.3	7.5	8.5

Prospective Study – TMJ-96-001

The prospective study, TMJ-96-001 was designed to evaluate the ability of the TMJ Fossa-Eminence prosthesis, when used alone (partial joint replacement), to reduce TMJ pain and improve interincisal opening in appropriately selected patients. An additional objective of the prospective study included a review of the incidence of device related adverse events occurring during the study.

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Demographics and Indications

Of the 131 subjects enrolled in the study and implanted with a partial joint, there are 109 subjects for which data are currently available. Of this data set 90% of the 109 subjects are female and 90% are Caucasian. The mean age is 39±11 years.

In the data sets 87 subjects included in this protocol were treated with a diagnosis of internal derangement. The subjects that were available for evaluation with the diagnosis of internal derangement were then retrospectively categorized with a Wilkes classification. These patients had all or some of the criteria necessary for a classification of Wilkes class III, IV, or V.

The indications for surgery are as follows:

Table 7: Indications for Surgery

[illegible]	n	Cum. %	Wilkes Classification
Internal Derangement without meniscal perforation	48	44	III, IV
Internal Derangement with meniscal perforation	31	72	V
Internal Derangement and meniscus status unidentified	8	80	III, IV, V
Inflammatory arthritis	10	89	V
Recurrent Fibrosis and/or bony ankylosis	9	97	N/A
Failed alloplastic joint reconstruction	2	99	N/A
Failed tissue graft	1	100	N/A

The mean reduction in pain scores as measured using a VAS and the interincisal opening for all subjects receiving a partial joint replacement are represented in Figures 3 and 4.

Figure 3: Mean Pain levels, all subjects with partial joint replacement

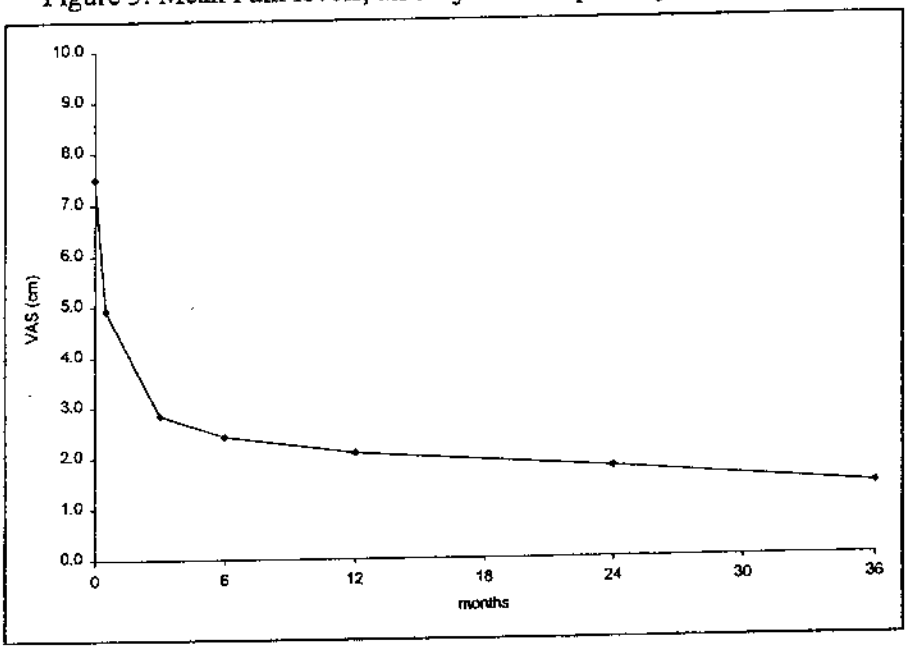
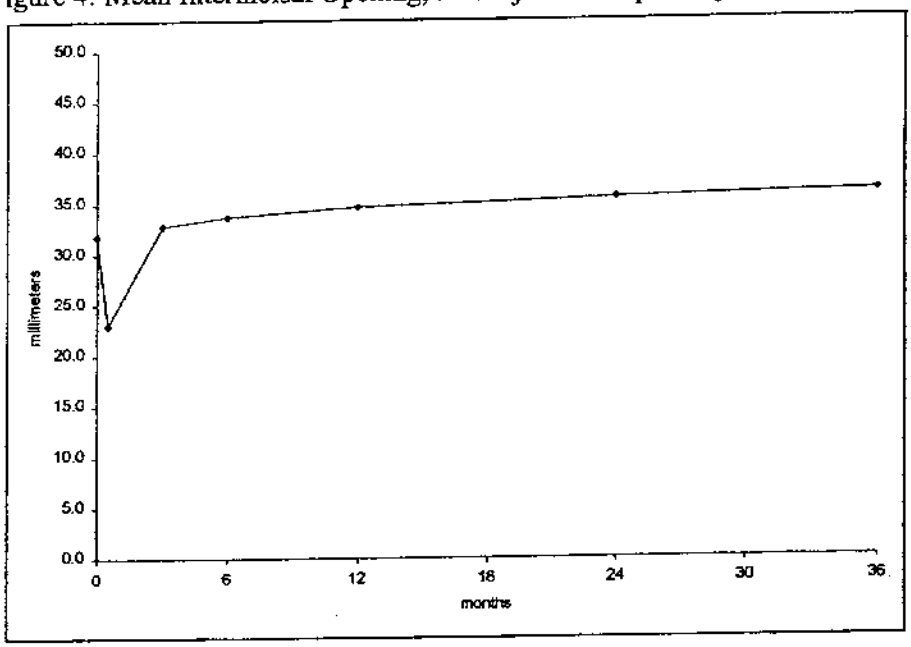


Figure 4: Mean Interincisal Opening, all subjects with partial joint replacement



Tables A and B, describe the current status of the 97 patients diagnosed with internal derangement classified into Wilkes III-V, and/or inflammatory arthritis in the ongoing trial.

Table A: Pain

months	0	0.5	3	6	12	18	24	30	36
mean pain	7.5	5.0	2.9	2.3	1.9	2.5	1.8	0.8	1.4
completed visits	97	95	82	71	43	29	29	11	12
SD	2.1	3.0	2.8	2.4	2.4	3.2	2.0	1.5	2.4
Expected # of subjects	97	97	95	91	83	70	59	52	40
Actual or potential lost to follow-up	0	2	13	20	40	41	30	41	28
% completed visits	100%	98%	86%	78%	52%	41%	49%	21%	30%

Table B: Interincisal Opening

months	0	0.5	3	6	12	18	24	30	36
mean opening measurement	33	23	33	34	35	34	36	36	36
completed visits	97	95	82	71	43	29	29	11	12
SD	11.0	6.8	4.8	4.5	5.4	5.6	5.4	3.6	5.9
Expected # of subjects	97	97	95	91	83	70	59	52	40
Actual or potential lost to follow-up	0	2	13	20	40	41	30	41	28
% completed visits	100%	98%	86%	78%	52%	41%	49%	21%	30%

Mean pain and interincisal opening for the group of subjects with internal derangement and/or inflammatory arthritis correlating to Wilkes class III-V are represented in Figures 5 and 6 respectively.

Figure 5: Mean Pain Reduction, subjects with Wilkes III-V

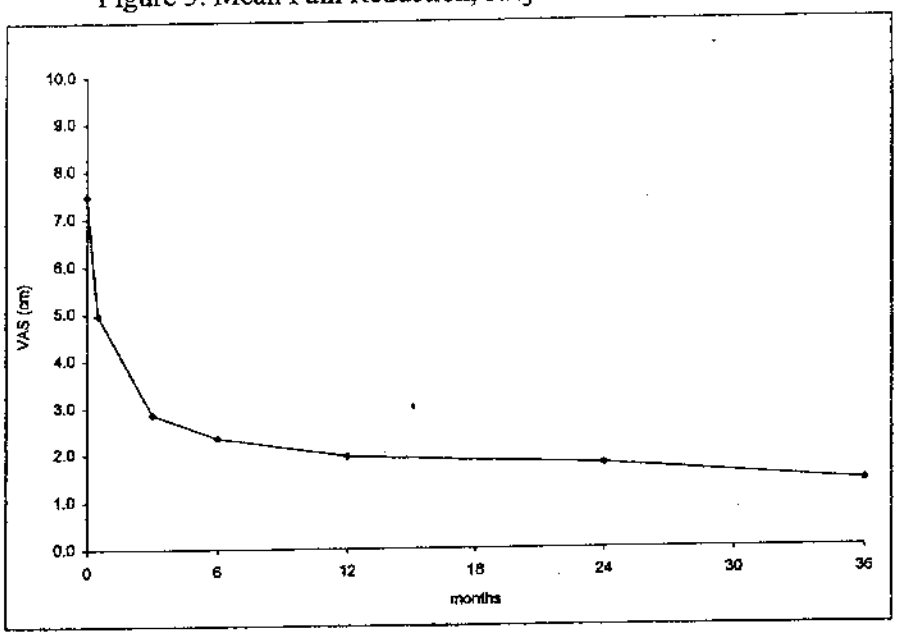
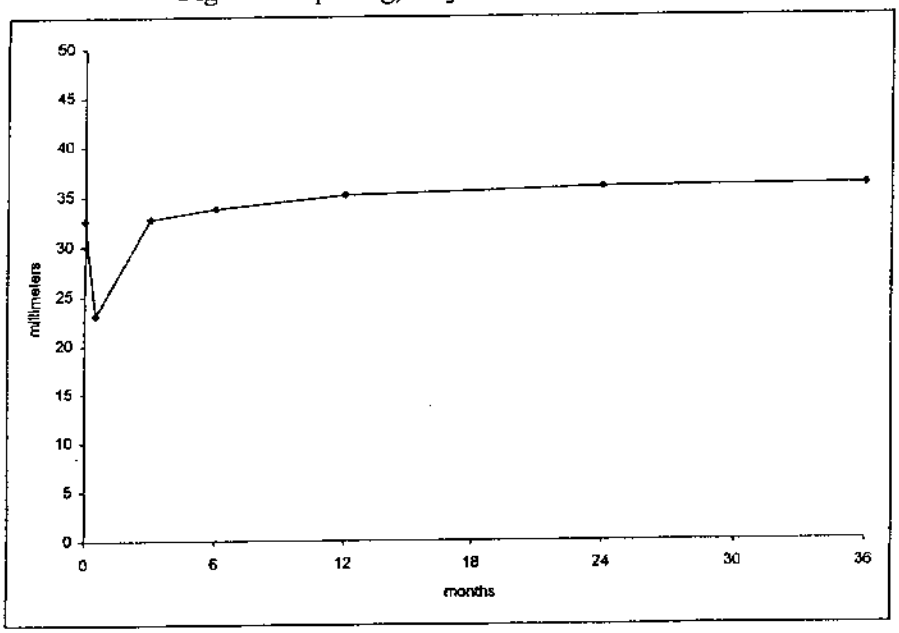


Figure 6: Opening, subjects with Wilkes III-V



Of the 97 subjects, 40 subjects have had the TMJ Fossa-Eminence Prostheses implanted for at least 3 years.

Not all 40 subjects have long-term follow-up data at 3 years. The periods of follow-up have been divided into the following groups based on the currently available long-term follow-up data:

Group A: 12 subjects with follow-up data for 3 or more years

Group B: 16 subjects with follow-up data for 2 - 3 years

Group C: 4 subjects with follow-up data for 1 - 2 years

Group D: 9 subjects with follow-up data for less than 1 year

Results for the subjects in each group are presented below:

Pain (measured using a 10 cm Visual Analog Scale)

Group A. Of the 12 subjects in Group A, 7 had a baseline pain score ranging from 5.5 to 9.1. These 7 subjects had 3-year pain scores ranging from 0.0 to 0.3. Of the remaining 4 subjects, one had a baseline pain score of 10.0 and a 3-year pain score of 1.7, 2 subjects declined in pain scores at 3-years from 6.0 to 5.0 and 8.9 to 6.6 respectively, and one subject had a baseline pain score of 5.0 and reported "no pain" at 3-years. These 12 subjects represent 30% of the subjects expected at this time point. The remaining 70% are either lost to follow-up, withdrawn, or potentially lost to follow-up

Group B. Of the 16 subjects in Group B, 6 subjects had baseline pain scores ranging from 5.0 to 9.8, and had a 2½-year pain score of 1.0 or less. Five subjects had baseline pain scores ranging from 5.0 to 9.3, and had a 2-year pain score of 1.1 or less. Four subjects

had a change from baseline ranging from 5.9 to 9.9 and a 2-year pain score of 1.9 to 4.1. One subject had a baseline score of 4.9 and a 2-year pain score of 7.2.

Group C. Of the 4 subjects in Group C, one subject had a baseline pain score of 8.1 and a 1-year pain score of 4.4; the second had a decline in pain score 10.0 to 4.2 at 1-year; the third subject had a decline in pain score from 2.2 to 0.1 at 1-year; and the fourth had a decline in pain score from 9.0 to 5.3 at 18 months.

Group D. Of the 9 subjects in Group D, 4 subjects had baseline pain scores ranging from 5.5 to 8.2 and 6-month pain score ranging from 1.0 to 1.8. One subject declined in pain score from 8.0 to 6.0 at 6 months; another subject declined in pain score from 7.4 to 4.0 at 6 months. One subject had a baseline pain score of 3.1 and a 6 month score of 5.0. Two subjects with 3 month follow up data declined in pain from 8.6 to 2.8 and from 10.0 to 0.5, respectively.

Interincisal Opening (measured in millimeters)

The 40 forty subjects having had the TMJ Fossa-Eminence Prostheses implanted for at least three (3) years were being treated primarily for significant TMJ pain. As can be expected with the placing of an alloplastic implant, there was a decrease in interincisal opening at two weeks post-surgery. However, at the three month follow-up visit, opening had increased from the two week measurement in all but 1 patient. The last available opening score for 36 subjects (follow-up ranging from 6 months to three years) was 30 mm or greater. Of the remaining four subjects one had an opening score of 26mm at 3 months, the other 3 subjects had opening scores of 27, 28, and 29mm, respectively at 2 years. On average patients interincisal opening decreased by 2 millimeters from their preoperative opening measurements.

Adverse Events

50 adverse events were reported from 22 different patients in the prospective study. The adverse events that were reported may be associated with the implantation of the TMJ Implants Inc. Fossa-Eminence Prosthesis.

Facial nerve and muscle weakness, paralysis, hearing problems	8/16	7%
Postoperative pain, swelling, jaw muscle spasm and hematoma formation	11/15	10%
Degenerative joint changes, development of joint arthritis	8/10	7%
Foreign body or allergic reactions, implant rejections	1/1	1%
Jaw dysfunction	1/1	1%
Limited range of motion	1/1	1%
Other	5/6	5%

Two of the 109 subjects required additional surgery during their participation in the study. Note: these 2 subjects were not part of the 40 subjects with the device implanted for at least 3 years reported above. Both events occurred within 1½ years of the original surgery. One subject progressed from a unilateral Fossa-Eminence prosthesis to a bilateral prosthesis due to progressive internal derangement in the contralateral joint. The other subject progressed

from a unilateral Fossa-Eminence prosthesis to a bilateral total joint replacement due to progressive, bilateral degenerative joint disease and heterotopic bone formation.

8. INFORMATION FOR USE

This Instructions for Use is intended to give you some answers for the use of TMJ Implants, Inc.'s TMJ Fossa-Eminence Prosthesis System. However, this is not intended to be an exhaustive, or comprehensive treatise on this subject of alloplastic joint reconstruction.

Prior to Surgery

Patients with suspected sensitivity to metals, such as Nickel, should undergo appropriate testing for sensitivity to Co-Cr-Mo alloy. Upon request, TMJ Implants, Inc. 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.

There are instances where this technique is not recommended due to prior surgical procedures and the need to place prostheses in less than optimal angles and positions, or in cases where systemic medical disease would contraindicate this implant procedure in the view of the operating surgeon. The operating surgeon must make this evaluation. It is the surgeon's responsibility to determine the need for patient specific implants given anatomical considerations or unusual masticatory forces in a given patient.

Patients undergoing local or general anesthesia, prolonged dental therapy, extraction of teeth, or those patients using mechanical devices which create abnormal forces within the joint need to be alerted to possible injury to the joint or prosthesis due to those unusual forces.

The TMJ Fossa-Eminence Prosthesis System is intended for partial joint replacement.

All TMJ Fossa-Eminence prostheses, screws, and drills, are provided sterile.

Prior to use, the Fossa sizer, and the screwdrivers and holders must be sterilized in their respective containers in accordance with hospital standards for steam sterilization. Steam sterilization should be accomplished at or above 121° C for 30 minutes (See Section 9).

Caution - The surface of the device must remain clean and free of debris prior to implantation.

Caution - The implant must be handled only with talc-free gloves to avoid introduction of talc into the implantation site.

Caution - The prostheses must be protected from scratching or bending prior to and during surgical implantation, as such damage in certain circumstances may cause weakening or fatigue of the metal or fracture of the part.

PLACING THE TMJ FOSSA-EMINENCE PROSTHESIS

The location of each component included in the TMJ Fossa-Eminence Prosthesis System is shown on a diagram on the inside lid of the respective package.

A detailed Patient-Specific Manual is available which provides instructions for CT scanning patients, and describes how to prepare the Anatomical Bone Model prior to implant design.

It is the responsibility of the surgeon to become familiar with the surgical techniques for implantation of these devices through attendance at surgical demonstration courses, use of instructional video, consultation with experienced associates and manipulation of replica models.

During Surgery

The normal preauricular or endaural incision and approach to the joint is accomplished. Exposure of the entire zygomatic process of temporal bone lateral to the joint is necessary to facilitate placement of the TMJ Fossa-Eminence prosthesis.

When the joint is fully exposed try the sizer for fit. Take your time at this point. Find the 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. At this stage check the occlusion very carefully. Ensure the occlusion remains as seen pre-operatively or as desired post-operatively. If not, determine why.

After selecting the proper sizer, check the laser-etched number on the sizer and have the nurse or anesthesiologist record it for future reference.

Noting the etched 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.

It is strongly recommended that at least four (4) Fossa-Eminence screws be used where practical to achieve firm fixation of the TMJ Fossa-Eminence prosthesis. Be sure to use the screws provided to insure 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. When the implant has been secured in place, check again for proper jaw function and proper occlusion. Be sure to use the drill bits provided for preparing the 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.

The TMJ Fossa-Eminence prosthesis must be secured only through the use of the drills and screws supplied by TMJ Implants, Inc. 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 Implants, Inc. 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.

Additional Considerations

The placement of a fat graft around the implant at surgery may reduce the occurrence of subsequent adhesion or even ankylosis. For those patients susceptible to heterotopic bone formation, appropriate fat grafts and radiation therapy should be considered.

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.

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 Surgery

Accepted surgical practice should be followed in post-operative care.

After the partial joint replacement is completed, all instruments must be thoroughly cleaned, decontaminated, and sterilized in accordance with the following procedures outlined below.

9. CLEANING AND STERILIZATION

Contents must be stored between 10° and 32° C (50° - 90° F) and 20% to 80% relative humidity.

The Fossa-Eminence prostheses screws and drills are packaged sterile. Care must be taken to assure packaging remains undamaged to ensure sterility.

Cleaning Instructions for Reusable Instruments

For your safety, be familiar with the procedures for handling contaminated materials at your facility prior to utilizing these instructions.

Clean instruments in the provided autoclave trays as soon as possible after use. Avoid allowing soiled instruments to dry. Immerse into or use towels dampened with deionized or distilled water to keep soiled instruments moist prior to cleaning.

Manually wash the templates and instrumentation with mild detergent following the detergent manufacturer's instructions for use. pH neutral cleaners are recommended. Follow the detergent manufacturer's recommendations for use dilution. Enzyme cleaners (e.g. Enzol™) prepared as recommended by the manufacturer may be used to aid in cleaning. Avoid exposure to acidic or alkaline solutions and solutions containing chlorides, bromides, or iodine.

Allow the devices to soak for one minute. Use a soft bristle brush to manually clean the devices while immersed in the cleaning solution, paying particular attention to crevices and other hard-to-clean areas. Clean the devices until all adherent visible soil is removed.

After washing, thoroughly rinse instruments for one minute under lukewarm, clean, deionized or distilled water.

Sterilization Instructions for Reusable Instruments

Visually inspect for cleanliness, especially in recesses. Check instruments thoroughly for damage, (i.e. chips, cracks, corrosion, surface wear, etc.) especially instruments with moving parts or interfits such as a quick–connect mechanism. Do not use instruments that have been damaged. Damaged instruments should be replaced.

Dry completely with a clean, soft cloth before sterilization.

Reusable instruments, e.g., the Fossa sizer, and the screwdrivers and holders for both prostheses must be sterilized in their respective containers.

The recommended prevacuum sterilization cycle parameters are wrapped at 132°C for 4 minutes with a 20 minute drying time. The recommended gravity flash sterilization parameters are unwrapped at 121°C for 10 minutes with no drying time.

It is recommended not to exceed 5 stacked trays per sterilization run.

Should you have any questions, please feel free to call us at:

(303) 277-1338 or (800) 825-4865.

TMJ IMPLANTS, INC. ANATOMICAL MODEL CT SCANNING PROTOCOL

Please take the time to read this entire protocol. The quality of anatomical model we can generate depends on the quality of scan we receive. Please have the CT Technologist call one of our technicians toll-free at 1-800-825-4865 prior to using this protocol for the first time.

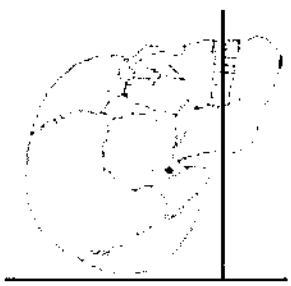
SCANNING GUIDELINES

1. If using this protocol for the first time, please archive the original data to your files until TMJ Implants confirms the transfer.
2. Patient must remain completely still through the entire scan. If patient motion occurs the scan must be restarted.
3. Please scan from bottom of mandible to 1.0 cm above joints (usually midorbit).
4. Please archive entire exam.
5. Please archive uncompressed image data (NOT raw data) onto appropriate media accepted for your scanner.
6. The magnetic tape or optical disk should be sent via express shipment to TMJ Implants.

SCANNING PARAMETERS (Axial or Helical)

FOV:	25 cm
Gantry Tilt:	0
Scan Spacing:	1 mm
Slice Thickness:	1 mm
Algorithm:	Standard (Not Bone or Detail)
MA/KVP:	120-150 MA / 120 KVP
Pitch:	1:1

PATIENT POSITIONING



AREA OF INTEREST

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17301 W. Colfax Ave.
Suite 135
Golden, CO 80401 USA
Phone: (303) 277-1338 Fax: (303) 277-1424
www.tmj.com

SUPPORTED SCANNERS

Models	Media Type(s)
GENERAL ELECTRIC	
Lightspeed	2
CT/i	1,2
Hispeed Advantage	1,3
Hilight Advantage	1,3
Prospeed	1,3
SIEMENS	
Volume Zoom*	2
Somatom Plus 4*	1
Somatom HiQ*	1
Somatom DRH*	1
Somatom AR*	1
*uncompressed data only!	
PICKER	
MX 8000 (Marconi)	2*
PQ 6000	4
PQ 5000	4
PQ 2000	4
*Archive through Omni Pro workstation only! Call for archiving instructions.	
ELSCINT	
Excel / Elect*	2,5
Elite*	2,5
*Archive through Omni Pro workstation only! Call for archiving instructions.	
PHILIPS	
Tomoscan TX, CX, LX, SR	1
TOSHIBA	
Xpress SX / Aspire*	2
*ISG-C format only	

MEDIA TYPES

1 - 5.25" Optical Disk (Pioneer, etc.)
2 - 5.25" Optical Disk (Maxoptix, etc.)
3 - 4mm DAT Tape
4 - 8mm DAT Tape
5 - 3.5" Floppy Disks

Please call regarding other scanners not listed. Internet transfer may be possible, please call for more information.