Long-Term Study of Temporomandibular Joint Surgery With Alloplastic Implants Compared With Nonimplant Surgery and Nonsurgical Rehabilitation for Painful Temporomandibular Joint Disc Displacement

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Purpose: The purpose of this study was to determine the long-term objective and subjective outcomes of temporomandibular joint (TMJ) implant surgery for the treatment of painful TMJ disc displacement using temporary Silastic (Dow Corning Corporation, Midland, MI), permanent Silastic, or Proplast (Vitek, Houston, TX) implants to replace the disc. These cases were compared with other cases of the same diagnosis treated with either nonsurgical rehabilitation or nonimplant surgery involving discectomy or disc repair procedures.

Materials and Methods: A cross-sectional study was conducted among 466 patients who received treatment for unilateral or bilateral TMJ disc displacement before January 1, 1990. The 5 treatment groups noted above were compared for long-term outcomes. Objective outcome measurements for jaw function were performed using a calibrated examiner and the Craniomandibular Index (CMI). Subjective (self-reported) outcomes were obtained relative to jaw function (Mandibular Function Impairment Questionnaire [MFIQ]), symptom severity (Symptom Severity Index [SSI]), and the impact of pain (Global Pain Impact [GPI] scale).

Results: The results, adjusted for gender, baseline tomogram score, and baseline symptom scores, showed that the nonsurgical rehabilitation group (n = 159) and the group having TMJ surgery without implants (n = 149) had statistically better results than the group who underwent surgery with a Proplast implant (n = 94). These between-group differences included both objective signs (CMI), and subjective reports of jaw function (MFIQ), symptom severity (SSI), and global pain impact (GPI). The MFIQ score associated with the nonsurgical rehabilitation group was also statistically better than for the Silastic implant groups, including both the temporary (n = 31) and permanent (n = 33) implants. Clinical differences between groups were slight.

Conclusion: This study suggests that the use of interpositional disc implants in TMJ surgery is not associated with improved outcomes when compared with nonimplant surgery or nonsurgical rehabilitation.

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Temporomandibular joint (TMJ) disorders are a common cause of persistent facial pain, headaches, jaw clicking, and jaw locking. TMJ disc displacement is the most common type of disorder affecting the TMJ, and is classified by 5 stages of clinical dysfunction involving disc displacement relative to the condyle.1-4 The early stage TMJ disc displacement is quite common, affecting about 40% of the general population. It is characterized by reciprocal clicking of the joint on opening and closing caused by the impaired function of the disc.5-8 Later stages of TMJ disc displacement are less common and are characterized by permanent disc displacement, interference in jaw opening, pain, and degenerative changes in the joint.9-12

Temporomandibular joint surgical procedures including arthroscopic surgery, discectomy, and disc repair have been used to correct structural disc problems in TMJ disc displacements.15-16 Alloplastic materials were often used during discectomy to provide

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interpositional support between the condyle and fossa. Various types of materials were used, including Proplast polytetrafluoroethylene (Vitek, Houston, TX) and Silastic (Dow Corning Corporation, Midland, MI) (silicone).\textsuperscript{15,17-21} In many patients, alloplastic implants initially provided pain relief and improved function of the joint. However, in some patients, these implants were found to gradually break down from the forces placed on them. This resulted in pain, inflammation, and fibrosis due to foreign body giant cell reactions provoked by the breakdown particles.\textsuperscript{22-25} Some patients experienced progressive bone degeneration, intense pain, and severely limited joint function. These symptoms often required further surgery.\textsuperscript{15,26-30} Other patients with the same implants remained asymptomatic, with little or no radiographic evidence of bone degeneration.\textsuperscript{31}

Because of the reported problems, in 1990 the Food and Drug Administration (FDA) recommended “immediate and appropriate radiographic examination” for all patients who had received Proplast implants and who had not received radiographic imaging in the previous 6 months.\textsuperscript{26} On June 4, 1992, a Congressional hearing was convened on the subject, “Are FDA and NIH Ignoring the Dangers of TMJ (Jaw) Implants?” In October 1992, the American Association of Oral and Maxillofacial Surgeons (AAOMS) recommended that all TMJ implants, including Proplast and Silastic, be monitored annually for as long as the implants remained in place. Magnetic resonance imaging (MRI) was recommended as the most efficient method to detect giant cell reactions. Plain film radiography, tomography, and computed tomography were recommended if metal had been placed in the joint, or if MRI was otherwise contraindicated.\textsuperscript{32} A workshop of expert clinicians organized by the AAOMS in November 1992 recommended that the use of Proplast implants be discontinued, and that the permanent placement of Silastic implants be used only for prevention of recurrence of TMJ ankylosis.\textsuperscript{31}

Despite this controversy over TMJ alloplastic implants, there have been few studies designed to assess the long-term outcome of patients who underwent TMJ implant surgery and to compare these results with those from patients with nonsurgical treatment or TMJ surgery without an implant. This paper presents the results of a cross-sectional study involving 466 patients who received treatment for unilateral or bilateral TMJ disc displacement prior to January 1, 1990. Five treatment groups were evaluated: group I patients underwent nonsurgical rehabilitation; group II patients underwent either disectomy or disc repair procedures, but did not receive an alloplastic implant; group III patients had discectomies and received temporary Silastic alloplastic implants; group IV patients had discectomies and received permanent Silastic alloplastic implants; and group V patients underwent discectomies and received Proplast alloplastic implants. Long-term outcomes for these 5 treatment groups were evaluated as objectively assessed jaw function (Craniomandibular Index [CMI]), subjectively assessed jaw function (Mandibular Function Impairment Questionnaire [MFIQ]), symptom severity (Symptom Severity Index [SSI]), and the impact of pain (Global Pain Impact [GPI] scale).

**Experimental Design and Methods**

**OVERVIEW**

Potential subjects for this cross-sectional study were identified through past records in charts or databases of multiple clinics and hospitals. The Current Procedural Terminology (CPT) and International Classification of Diseases (ICD) codes of patients who were treated for TMJ disc displacement were used to identify all possible patients. Selection of subjects was based on their fulfillment of inclusion and exclusion criteria for 1 of the 5 treatments noted above, and with the requirement that treatment for painful TMJ disc displacement was performed prior to 1990. All eligible subjects who could be contacted were invited to undergo a battery of tests and examinations. Identical examination, questionnaire, radiographic, and laboratory data regarding outcome and risk measures were collected for consenting subjects in each treatment group.

The primary measures in this study included a clinical examination that measured jaw dysfunction signs, the CMI, and a self-report measure of symptoms, the SSI. A single blinded examiner calibrated to a gold standard (trained and tested for acceptable reliability compared to a gold standard examination) collected the CMI examination data. The radiographic examination included MRI, tomography, and cephalometric radiographs to detect structural abnormalities in the joint and the jaw, as well as abnormal maxillomandibular relationships. One blinded examiner using a gold standard scored the MRI and tomography reports, and another blinded and calibrated orthodontist performed the cephalometric measures. Several secondary self-reported anamnestic outcome measures that had previously undergone reliability and validity testing, were also used in this study. This study was reviewed and approved by the Institutional Review Board, Human Subjects Committee, University of Minnesota.

**TREATMENT GROUPS**

Group I received nonsurgical rehabilitation treatment, provided in most cases by an interdisciplinary team that included a dentist, a physical therapist, and
a health care psychologist. The dentist placed a full-coverage stabilization splint and prescribed or monitored medication, including nonsteroidal anti-inflammatory analgesics or muscle relaxants. The physical therapist provided an exercise program designed to improve jaw and cervical range of motion, function, and posture. This was supplemented with ultrasound, heat/cold therapy, and other modalities as needed. The psychologist, when needed, provided management and support for behavioral and psychosocial problems, and offered a cognitive behavioral program designed to change maladaptive behaviors such as clenching, bruxism, and sleep and dietary factors. Patients who had any surgery or arthrocentesis of the TMJ were excluded from group I.

Group II had undergone an open TMJ surgical procedure without implant. This was limited to discectomy, discal repositioning, or discectomy via a preauricular incision. The goal of the procedure was to reduce mechanical interference, pain, and clicking due to the disc displacement. This was accomplished by removing or repairing the disc, as well as by breaking adhesions and performing joint lavage.

Group III had a discectomy with a temporary Silastic implant. This involved removing the disc and placing a temporary interpositional Silastic implant between the condyle and fossa. In all cases, this implant was removed after a few weeks. The rationale for its temporary use was to create a natural disc replacement with fibrous connective tissue that develops around the synthetic material. When the implant is then removed, the connective tissue is expected to remain and replace the disc tissue, thus allowing the condyle to stabilize in its natural position.

Group IV had a discectomy with a permanent Silastic implant, and group V had a discectomy with a permanent Proplast implant. Both treatments involved removing the disc and securing the interpositional alloplastic implant between the condyle and fossa as a permanent replacement for the articular disc. However, the majority of these patients (82% with Proplast and 78% with Silastic) had their implants removed before our follow-up evaluation, based on the recommendation of their surgeons. After the evaluation, all of the patients with implants, with 1 or 2 exceptions, were advised to have the implants removed. In addition, most patients in the surgical groups also had nonsurgical rehabilitation treatment, including physical therapy, splints, and behavioral therapy after surgery.

SUBJECTS

The goal for this study was to enroll 150 nonsurgical rehabilitation subjects (group I), 150 subjects who had undergone TMJ surgery without an implant (group II), and 150 subjects who had undergone TMJ surgery with a TMJ implant (groups III, IV, and V). The final study sample consisted of 466 subjects who were consecutively recruited (in the order they were treated before 1990) both from within and outside of the University of Minnesota clinics. Group I patients (n = 159) were identified and recruited from the following 3 clinics: the University of Minnesota TMJ and Craniofacial Pain Clinic, the Hennepin County Medical Center TMJ Clinic, and the Minnesota Head and Neck Pain Clinic. These clinics were chosen because they represented a broad sample of patients from the Twin Cities (Minneapolis and St Paul) areas. The 4 TMJ surgery groups, group II patients (n = 149), group III patients (n = 31), group IV patients (n = 33), and group V patients (n = 94), were identified through the surgical registries and CPT codes of 6 hospitals in the Twin Cities. These hospitals are where most of the TMJ procedures were performed before 1990. These care centers included the University of Minnesota Hospitals and Clinics, Fairview Riverside Medical Center, Fairview Southdale Hospital, Methodist Hospital, Unity Hospital, and Hennepin County Medical Center.

The inclusion criteria were simply that the patient had undergone 1 of the 5 study treatments for TMJ disc displacement before 1990. The exclusion criteria for all 5 treatment groups included: 1) the current presence of infection (such as, mumps, measles, or infectious mononucleosis), tumor, or any other disease unrelated to a TMJ disorder that could cause jaw symptoms or dysfunction; 2) an inability to provide informed consent; 3) an age greater than 75 or less than 18 at the time of follow-up; 4) a primary TMJ diagnosis other than TMJ disc displacement; 5) a surgical treatment not directed at the joint (such as orthognathic surgery); 6) treatment consisting of a total joint surgical implant; 7) treatment consisting of only TMJ arthroscopic surgery or arthrocentesis; 8) no treatment for TMJ disc displacement; and 9) pregnancy at the time of follow-up.

Because the currently accepted research diagnostic criteria for TMJ disorders had not yet been developed when these patients were originally treated, the presumed baseline diagnosis in each case was based on the care provider’s expert opinion using the clinical and imaging data. These diagnoses were corroborated using a combination of symptoms, signs, and radiographic evidence retrieved from the patient records.

RECRUITMENT PROCEDURES AND INITIAL DATA COLLECTION

Subjects who met inclusion and exclusion criteria were first contacted by a representative of their primary TMJ surgeon or care provider. They were then sent a written description of the study and were requested to return a card indicating their willingness
to be contacted by study personnel. Patients whose
address or phone number had changed were tracked
through standard epidemiological procedures, includ-
ing social security number and forwarding address
information. For subjects willing to be contacted by
study personnel, a research assistant conducted a tele-
phone inquiry using a standard script and explained
the study and the benefits of participation. These
benefits included the opportunity for the subject to
determine the current status of her/his TMJ disorder.
Patients were also offered $100 for their participation.
Subjects who could be contacted but indicated an
unwillingness to participate were classified as nonre-
sponders. However, information was requested from
them to evaluate potential differences between re-
sponders and nonresponders: current age, age at time
of treatment for TMJ disc displacement, number of
years since treatment, gender, and probable treat-
ment group classification.
Eligible and consenting subjects were consecu-
tively scheduled for follow-up examination in the or-
der they were treated according to the records of the
participating clinics and hospitals. Figure 1 shows
that 548 eligible patients consented to participate.
However, 80 of these subjects could not be scheduled
due to their inability to commit the time required for
TMJ imaging. Most of these patients were nonsurgical
patients. Thus, only 468 of 548 consenting subjects
were examined. As group I sample size approached
150, scheduling was continued on a restricted basis to
allow more subjects in groups II through V to be
scheduled. During the entire study, all 5 groups were
scheduled concurrently to circumvent differential
bias that might arise if a clinical examiner were to
systematically deviate from the examination protocol.
As the reliability assessment presented later shows,
such examiner drift was not a problem.
All study subjects were scheduled for a 2-hour ap-
pointment at the Clinical Dental Research Center,
University of Minnesota School of Dentistry, where
the study was explained again and each subject was
asked to read and sign a consent form. A clinical
examination was then performed, blood and urine
samples were collected for specified laboratory tests,
and all study questionnaires were completed. If no
TMJ imaging had been done in the past year, the
subjects were asked to consent to imaging including
MRI, TMJ tomography, and a cephalometric radi-
ograph. In addition, patients were asked to sign a
release form for past medical records, including all
past imaging studies. All of the follow-up imaging
studies were performed in the Department of Radiol-
ogy, Hennepin County Medical Center, Minneapolis,
Minnesota.

**OUTCOME MEASURES**

The 2 primary outcome measures were the CMI
and the SSI. Two secondary measures were the MFIQ
and the GPI scale. Each scale has reported adequate
reliability and validity. Analyses of other outcome
measures and risk factors will be reported in future
manuscripts.
The CMI has a 0 to 1 scale that measures tenderness
dysfunction in the stomatognathic system and
includes all currently recognized signs of TMJ disor-
ders. There are 2 subscales: the Dysfunction In-
dex (DI) and the Muscle Index (MI). The DI is de-
digned to measure limitation in mandibular
movement, pain and deviation in movement, TMJ
noise, and TMJ tenderness. The MI measures the prev-
alence of muscle tenderness in the stomatognathic
system.
The SSI has a 0 to 1 scale that was designed to
measure multidimensional symptom severity in pa-
tients with chronic pain and was chosen because it
includes the symptom domains that are most likely to
change with time or treatment. It is composed of 5
single-item scales: 2 Likert rating scales for pain fre-
cuency and duration and 3 visual analog scales for
sensory intensity, affective intensity, and intolerability
of pain.
The MFIQ (with a 0 to 5 scale) was designed to
measure the impairment in the function and chewing
ability of the stomatognathic system. The index in-

**FIGURE 1.** Subjects treated for TMJ disc displacement (DD) before
1990 were consecutively recruited from clinic and hospital registries to
receive a follow-up evaluation. The numbers of patients unable to be
located, ineligible, declining participation, and unable to be sched-
uled are noted.
cludes measures of limitations and pain while chewing various foods, as well as general questions on chewing ability. This self-report was chosen based on the need for a subjective outcome measure of stomatognathic function to compare with the objective findings of the CMI.\textsuperscript{36}

The GPI (with a 0 to 5 scale) is a 6-point scale that was designed to categorize the severity of pain, along with its disabling impact on life.\textsuperscript{37} The impact of pain is characterized as no pain (0), persistent but nondisturbing pain with no impairment (1), disturbing pain but no impairment (2), impairment (3), disability (4), or handicap (5). Impairment, disability, and handicap are all defined in accordance with standards set by the World Health Organization.\textsuperscript{38}

FIVE ADJUSTMENT VARIABLES

The TMJ literature suggests that significant gender and age differences exist relative to the severity of symptoms and signs of TMJ disorders.\textsuperscript{1} For these reasons, gender, and age at the time of treatment, and age disorders at the follow-up examination were used as adjustment variables. Data were also collected for 2 additional potential confounders: the baseline tomogram and anamnestic scores. All 5 adjustment variables were used to evaluate baseline differences between the study groups and to control for these imbalances in the analysis of outcomes.

The tomogram score at baseline was chosen as an objective measure to control for baseline differences between the treatment groups relative to the disease severity of their TMJ disc displacement. Because primary record holders had destroyed many of the baseline tomograms, it was necessary to employ the radiologist reports. For purposes of statistical analysis, these reports were scored based on the following observations by the radiologists: degenerative changes in the fossa (0 = none, 1 = mild, 2 = moderate, 3 = severe); degenerative changes of the condyle (0 = none, 1 = mild, 2 = moderate, 3 = severe); limited range of motion (0 = none, 1 = present); soft tissue calcifications in the joint (0 = none, 1 = present); bone density of the joint (0 = normal, 1 = abnormal); and condyle deformity (0 = none, 1 = present). Therefore, the range for tomogram scores was potentially 0 to 10.

Helkimo’s anamnestic symptom score at baseline was based on information retrieved from past medical record data and was obtained to control for symptom differences between treatment groups at baseline.\textsuperscript{8} The range of scores was 0 to 2, with a score of 0 indicating that no temporomandibular pain, fatigue, or stiffness was reported by the patient or noted by the care provider in the records. A score of 1 indicated a report of 1 or more of the following: noise in the TMJ, feelings of jaw fatigue, stiffness of the jaw on awakening, or stiffness when moving the mandible. A score of 2 indicated more severe signs or symptoms based on a positive response to 1 or more of the following: difficulty in opening the mouth, reduced range of jaw motion, locking or subluxation of the jaw, pain on mandibular movement, pain in the jaw joint, or pain in the masticatory muscles.

RELIABILITY ASSESSMENT

Baseline calibration and periodic reliability testing were performed at the beginning, during, and at the end of the study. The calibration procedure established inter-rater reliability between the examiner who performed all the CMI clinical examinations and a “gold-standard” examiner. The gold-standard examiner (E.S.) has also served in this role for previous studies to ensure consistency in measures between studies. The follow-up reliability tests evaluated the maintenance of inter-rater reliability to estimate the extent of examiner drift. The intraclass correlation coefficient (ICC) was computed as the measure of reproducibility between the paired scores of the clinical examiner and the gold-standard. The ICC for the reliability of the CMI examination varied only slightly from 0.94 during the study to 0.93 after the study. The intra-rater reliability of the tomography scorer was also assessed using blinded re-scoring of a random 10% of the tomogram interpretations. The results indicated excellent reliability, with ICCs of 0.96 for both right and left joint interpretations. Random re-measurement of the mandibular plane angle on the cephalometric films yielded in an ICC of 0.98.

DATA MANAGEMENT AND QUALITY CONTROL PROCEDURES

All examination and questionnaire data were collected on optically scannable standardized forms. These forms were scanned into an electronic database to allow data to be stored in a specific order, with associated descriptors, and with specific allowable alphanumeric characters and ranges. The use of the scannable forms facilitated identification of missing data or inaccurately scored data, thus enabling systematic data quality control procedures to be performed. All forms with missing data or data outside a specified range were identified by the software and then reviewed again for any required correction. In addition, the quality of the data recording procedures was routinely evaluated at monthly intervals.

STATISTICAL PROCEDURES

Pairwise contrasts for mean differences in outcome between groups were performed with the Proc T Test procedure (SAS Institute Inc, Cary, NC). Frequency distributions were evaluated by means of the Proc Freq procedure (SAS Institute). Adjusted analyses
were performed with the Proc GLM procedure (SAS Institute). The $P$ value for statistical significance was set at less than .01 to reduce the probability of a type I error. A trend toward statistical significance was specified as .01 is less than or equal to $P$, which is less than .05.

**Results**

The sampling frame of 1,249 patients was provided by the participating hospitals and clinics. These people were listed as having undergone treatment for a primary diagnosis of TMJ disc displacement, reportedly before 1990. Figure 1 indicates that 468 subjects, representing 37.5% of the total sampling frame, were located, met criteria, and were scheduled for examination. Of these, 52 were men (10.7%) and 416 were women (89.3%). Two of the 468, both women, were subsequently found, after examination, to be ineligible for inclusion in any of the treatment groups. As determined by hospital records, 1 subject had undergone the initial treatment of total joint prosthesis; the other had undergone surgery of the masseter muscles that was not related to TMJ disc displacement. There were also 118 subjects who were eligible for the study but declined to participate. Thus, among the 666 eligible subjects who were contacted, the nonresponse rate was 17.7%. There were an additional 80 consenting subjects, representing 12% of all of those eligible, who were unable to be scheduled before study closure.

**INELIGIBLE SUBJECTS**

The sampling frame included a total of 105 ineligible subjects, of whom 67 were in the nonsurgical group, 5 in the surgery-without-implant group, 7 in the combined surgery with TMJ implant groups, and 26 with the treatment group undetermined. Seventy-five percent of the patients ineligible for surgery had an age greater than 75 or an initial treatment date after 1990. Of the 67 ineligible patients in the nonsurgical group, 60% had been diagnosed with TMJ disc displacement but had not received treatment. Thirty percent had been diagnosed with myofascial pain syndrome and not with TMJ disc displacement. Ninety-six percent in the indeterminate treatment group were ineligible because they had had no documented treatment for TMJ disorders (27%), had an ineligible diagnosis (38%), or were older than 75 years at the time of follow-up (31%).

**NONRESPONDERS**

There were 65 nonresponders among the eligible nonsurgical subjects and 53 nonresponders in the surgical groups combined. The latter figure was divided nearly equally between the surgery-without-implant group (n = 26) and the surgery-with-implant group (n = 27). The nonresponders represented 21.4% of the eligible nonsurgical subjects, including those who were examined and those who were not. Nonresponders made up 14.9% of the surgery-without-implant subjects and 14.6% of the surgery-with-implant subjects. The difference between these 2 groups (groups II vs III, IV, and V) relative to these proportions was not significant ($P > .08$). There was also no statistical difference among groups ($P > .5$) regarding the reasons indicated by the 118 nonresponders for their refusal to participate in the follow-up examination. The following reasons were given: 25% were uninterested, 26% had no time to participate, 15% had too great a distance to travel, and 14% were experiencing no symptoms and thus did not believe they had a problem worth evaluating. The remaining 20% had miscellaneous reasons such as no funds to travel, other concurrent medical problems, fear of having their jaw manipulated or of undergoing radiography, inability to leave work, and advice of legal counsel. Of the nonresponders, 100% indicated their probable treatment group; 100% indicated gender; 71%, current age; 66%, age at the time of treatment; and 63%, the elapsed time since treatment.

There was no statistical difference ($P > .2$) between groups relative to any of the 4 comparison variables selected to detect possible differences between responders and nonresponders. Percentage of female subjects differed by 5% between responders and nonresponders for the nonsurgical group ($P > .2$), and less for the other groups. Age at the time of treatment differed by less than 3 years between responders and nonresponders for the nonsurgical group ($P > .2$) and, again, was less for the other groups. Age at follow-up differed by 5 years for the implant groups, with the nonresponders having an average age of 45.9 years versus 40.2 years for the responders. This difference was not significant ($P > .5$), and the other groups showed less than 3 years difference ($P > .2$). Years since treatment were virtually identical ($P > .5$) between responders and nonresponders in all groups.

**TREATMENT GROUP DEMOGRAPHICS AND ADJUSTMENT VARIABLES**

For those subjects who were examined, Table 1 indicates for each of the 5 study groups their means and standard error of the means (SEM) relative to the specified adjustment variables for this study. The adjustment variables included age at follow-up, age at treatment baseline, baseline TMJ tomography score, baseline anamnestic symptom score, and gender distribution. A statistically significant difference ($P < .008$) in age at treatment was observed between the nonsurgical group I (33.20 ± 0.92 years) and the
surgery-without-implant group II (29.83 ± 0.83 years). In addition, there was a difference among groups relative to baseline severity of TMJ disc displacement. The baseline tomogram score of 1.56 ± 0.14 for group II was significantly lower (P < .02) and therefore, better than for groups I (2.12 ± 0.16), III (2.79 ± 0.44), IV (2.90 ± 0.41) and V (2.41 ± 0.19). Finally, the baseline anamnestic symptom score differed (P < .05) between group I (1.86 ± 0.03) and groups II (1.96 ± 0.02) and III (2.00 ± 0.0). There was no statistical difference in anamnestic scores among groups I, IV, and V, or between groups II and III. Although the other between-group differences at baseline lacked statistical significance, all these variables were taken into consideration for the adjustment of outcome estimates at follow-up.

**STUDY OUTCOMES**

Table 2 presents the observed (unadjusted) group means, and Table 3 presents the group means after adjustment for the baseline differences. For the CMI (0-1), groups I, II, and III showed no statistical difference between each other. Group IV also did not differ from group V. However, statistically significant differences (P < .01) were detected among groups I and V, II and IV, and II and V (Table 2). When the mean outcomes were adjusted for baseline differences among groups, just the 2 contrasts of I versus V and II versus V remained statistically significant (Table 3).

For the MFIQ (0-5), statistically significant differences were observed between group I and groups IV and V, and group II versus groups IV and V. When the means were adjusted for baseline differences, the least-squares mean estimate for group I became statistically lower than those for groups III, IV, and V, and group II retained its statistical difference with only group V (Table 3).

For the SSI (0-1) of the TMJ, statistical differences were observed between group I and group V and between group II and groups IV and V. Prior to adjustment, the lowest level of symptoms was observed for group II. However, after adjustment for baseline differences, group I showed the least estimated level of symptoms, and both groups I and II were statistically different from group V (Table 3).

For the GPI (0-5), statistical differences were observed between group I and group V, and between group II and groups I, IV, and V. Prior to adjustment, the lowest level of symptoms was observed for group II, and this was maintained after adjustment. However, after adjustment for baseline differences, only groups I and II remained statistically different from group V (Table 3).

**Discussion**

The results for the adjusted group means showed that the nonsurgical rehabilitation group I and the TMJ-surgery-without-implant group II were statistically better in all measures than group V, the surgery-with-Proplast implant group. In addition, the MFIQ outcome associated with nonsurgical rehabilitation (group I) was significantly better than that for all implant groups, including both Silastic implant groups (temporary and planned permanent) and the Proplast group. The adjusted mean outcomes illustrated in Figure 2 demonstrate that placement of any implant material was associated on the average with a
Contrasts tending toward I, Nonsurgical n differential bias relative to examiner drift. Interexaminer reliability was evaluated 3 times over the course of the study, and agreement was found to be excellent. The final sample size of 468 of a sampling frame of 1,249 (less than half of the number of cases identified) was due to difficulty in locating patients, some of whom had not been seen in more than a decade. However, 82.3% of the patients who were contacted during the study period agreed to participate in the study. The target of 80% participation rate was surpassed due to encouragement from the primary care provider, repeated contacts from our recruiter, and adequate incentives to participate. The percent of nonconsenting subjects (nonresponders) ranged from 14.6% to 20.4% within groups and averaged 17.7% overall. There was no statistical difference among groups relative to the proportion of nonresponders (P > .08), nor was there an overall difference among groups for the reasons given for nonparticipation (P > .5). It is of note that the nonsurgical patients in this study had more severe disease at baseline than the surgery-without-implant group (Table 1).

These results are consistent with other reports of long-term changes associated with patients whose TMJ implants failed. Kearns et al performed a follow-up study on 27 patients with 42 treated joints (24

Table 2. OBSERVED (UNADJUSTED) MEANS AND STANDARD ERROR OF THE MEAN FOR 5 OUTCOME MEASURES BY TREATMENT GROUP

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Craniomandibular Index,* Mean (SEM)</th>
<th>Mandibular Function Impairment Questionnaire,‡ Mean (SEM)</th>
<th>Symptom Severity Index,§ Mean (SEM)</th>
<th>Global Pain Impact,¶ Mean (SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I, Nonsurgical n = 159</td>
<td>0.315 (0.013)</td>
<td>0.975 (0.092)</td>
<td>0.522 (0.019)</td>
<td>1.563 (0.103)</td>
</tr>
<tr>
<td>II, Surgical, no implant n = 149</td>
<td>0.288 (0.014)</td>
<td>1.055 (0.103)</td>
<td>0.273 (0.022)</td>
<td>1.161 (0.100)</td>
</tr>
<tr>
<td>III, Surgical, Silastic temporary implant n = 31</td>
<td>0.325 (0.037)</td>
<td>1.839 (0.338)</td>
<td>0.395 (0.059)</td>
<td>1.774 (0.277)</td>
</tr>
<tr>
<td>IV, Surgical, Silastic permanent implant n = 53</td>
<td>0.375 (0.031)</td>
<td>1.818 (0.248)</td>
<td>0.422 (0.049)</td>
<td>1.909 (0.244)</td>
</tr>
<tr>
<td>V, Surgical, Proplast implant n = 94</td>
<td>0.390 (0.018)</td>
<td>2.140 (0.158)</td>
<td>0.479 (0.027)</td>
<td>2.247 (0.147)</td>
</tr>
</tbody>
</table>

*Craniomandibular Index: 0 = no signs; 1 = all signs present.
‡Mandibular Function Impairment Questionnaire: 0-1 = low impact; 2-5 = moderate impact; 6-8 = severe impact.
§Symptom Severity Index (TMJ): 0 = no symptoms; 1 = some pain but no impairment; 2 = disturbing pain but no impairment; 3 = disturbing pain and some impairment; 4 = disturbing pain and disability; 5 = disturbing pain and handicap.
¶Global Pain Impact: 0 = no pain or impairment; 1 = some pain but no impairment; 2 = disturbing pain but no impairment; 3 = disturbing pain and some impairment; 4 = disturbing pain and disability; 5 = disturbing pain and handicap.
Proplast, 11 Silastic, and 7 Christensen Fossa implants [TMJ Implants Inc, Boulder, CO], all of whom met criteria for removal of the alloplastic implant and surgical debridement. After 38.3 months postoperatively, these patients were reported to be doing well with a mean incisal opening of 39.8 mm and a reduction of pain in 88.9% of patients. Schliephake et al\textsuperscript{41} conducted a 10-year follow-up of 33 of 48 patients who had silicone TMJ implants. They found that 8 of the patients had continuing problems that required removal of the implant. For the group as a whole, there were statistically significant improvements in tenderness, range of motion, and pain, but not in joint function.\textsuperscript{41} However, these studies had no control groups with which to compare results. An extensive clinical and radiographic follow-up study was performed by Eriksson and Westesson.\textsuperscript{42} They examined 22 patients who underwent discectomy with a temporary silicone TMJ implant and compared results with those from 21 patients who received only a discectomy. They found that 10 of the patients with silicone had bad to acceptable results, while all but 3 patients with discectomy had good results.\textsuperscript{42} The authors concluded that there was no positive clinical or radiographic effects associated with the use of the implant.

Although there were statistically significant differences among groups for all 4 outcome measures in this study, the clinical relevance of these differences are minimal. For example, a change of 0.10 in the CMI means that there is a difference of about 2 clinical signs such as pain in range of motion or limitation of range of motion. Concurrent validity studies done at our research facility comparing the GPI to the CMI suggest that a change greater than 0.11 for the CMI is necessary for the improvement to be minimally significant to the patient. Comparison of the GPI to the SSI suggests that a change greater than 0.25 for the SSI would be appreciable to the patient. There is a mean difference of only 0.10 for the CMI between the best and worst groups would be appreciable to the patient. There is a mean difference of only 0.10 for the CMI between the best groups (nonsurgical group and TMJ surgery-without-implant group) and the worst group (Proplast implant), suggesting that the difference in the number of signs is minimal among all 5 groups. Similarly, the difference in SSI between the best and worst groups is only 0.19, again suggesting that average symptom levels were just mildly different among these groups.

It is important to note that most of the TMJ implants have been removed. This has probably minimized the potential for continuing foreign body reactions in the permanent implant patients, resulting in an improved clinical status. This may also explain the relatively small observed differences in signs and symptoms among the study groups. The potential long-term outcomes that might have occurred if these implants had not been removed cannot be determined from this study.

### Table 3. ADJUSTED MEANS AND STANDARD ERROR OF THE MEAN FOR 5 OUTCOME MEASURES BY TREATMENT GROUP

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Craniomandibular Index, Mean (SEM)</th>
<th>Mandibular Function Impairment Questionnaire, Mean (SEM)</th>
<th>Symptom Severity Index (TMJ), Mean (SEM)</th>
<th>Global Pain Impact, Mean (SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I, Nonsurgical</td>
<td>0.302 (0.020)</td>
<td>0.848 (0.160)</td>
<td>0.289 (0.031)</td>
<td>1.596 (0.158)</td>
</tr>
<tr>
<td>II, Surgical, no implant</td>
<td>0.300 (0.018)</td>
<td>1.149 (0.139)</td>
<td>0.298 (0.027)</td>
<td>1.280 (0.136)</td>
</tr>
<tr>
<td>III, Surgical, Silastic temporary implant</td>
<td>0.324 (0.038)</td>
<td>1.891 (0.294)</td>
<td>0.342 (0.057)</td>
<td>1.679 (0.292)</td>
</tr>
<tr>
<td>IV, Surgical, Silastic permanent implant</td>
<td>0.359 (0.038)</td>
<td>1.771 (0.296)</td>
<td>0.417 (0.057)</td>
<td>1.833 (0.294)</td>
</tr>
<tr>
<td>V, Surgical, Proplast implant</td>
<td>0.389 (0.023)</td>
<td>2.215 (0.176)</td>
<td>0.482 (0.034)</td>
<td>2.224 (0.175)</td>
</tr>
<tr>
<td>Statistically significant contrasts</td>
<td>I vs V: ( P &lt; 0.006 )</td>
<td>I vs III: ( P &lt; 0.002 )</td>
<td>I vs V: ( P &lt; .001 )</td>
<td>I vs V: ( P &lt; .001 )</td>
</tr>
<tr>
<td>(( P &lt; .01 ))</td>
<td>II vs V: ( P &lt; 0.003 )</td>
<td>II vs IV: ( P &lt; .008 )</td>
<td>II vs V: ( P &lt; .001 )</td>
<td>II vs V: ( P &lt; .001 )</td>
</tr>
</tbody>
</table>

**NOTE.** Adjustments (Proc GLM procedure, SAS Institute) were made for age at treatment, age at follow-up, baseline tomogram score, baseline anamnestic symptom score, and gender.
Because this study is a cross-sectional follow-up study, we also do not know whether these TMJ implant patients are now stable following their explanation procedures, or if they are progressing either to a more or less severe problem. Given also that this study did not include a control group, no estimate can be made as to long-term outcome associated with no treatment.

In all 5 groups, including the permanent Proplast group, several patients had excellent jaw function and no pain. This observation should in no manner undermine the FDA safety alert of December 28, 1990, recommending that patients with TMJ implants have the implants evaluated via imaging every 6 months as long as the implants remain in place. If symptoms persist or if imaging changes occur, the patient should be advised and the implant removed as part of an overall rehabilitation treatment plan.

A second important observation is that there is no evidence to suggest that any of the surgical interventions were superior to nonsurgical treatment for this group of patients with painful TMJ disc displacement. Rather, the evidence points to the contrary. Therefore, it is recommended to carefully evaluate all surgical criteria prior to considering TMJ surgery. Based on the recommendations of the American Academy of Orofacial Pain and AAOMS, these criteria include: 1) documented TMJ internal derangement or other structural disorder with appropriate imaging; 2) positive evidence to suggest that the symptoms and objective findings are a result of a structural disorder; 3) pain or dysfunction of such magnitude as to constitute a disability to the patient; 4) previous unsuccessful nonsurgical treatment; 5) previous management, to the extent possible, of bruxism, oral parafunctional habits, concurrent active medical or dental problems, and other contributing factors that may affect the surgical outcome; and 6) patient consent after a discussion of potential complications, goals, suc-
cess rate, timing, postoperative management, and alternative approaches, including no treatment.

Conclusions

The primary conclusion derived from this study is that when a surgical interpositional disc implant was placed in a TMJ, it did not improve long-term outcome relative to pain, dysfunction, and impairment as compared with nonimplant surgery or nonsurgical treatment. To the contrary, the levels of pain, dysfunction, and impairment were statistically higher for the implant groups, although these differences were not clinically significant. The second conclusion is that the nonsurgical intervention described in this study for painful TMJ disc displacement was as beneficial in the long term as any of the surgical interventions. This finding supports the importance of considering rehabilitation treatments before considering surgical intervention for TMJ disc displacements.

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References