

Systemic Health Consequences of Alloplastic Implants of the TMJ: A Pilot Study

Karen G. Raphael, PhD
Assistant Professor of Psychiatry
New Jersey Medical School

Assistant Professor
Department of Oral Biology, Pathology,
and Diagnostic Sciences
New Jersey Dental School

Joseph J. Marbach, DDS
Robert and Susan Carmel Professor of
Algesiology
Department of Oral Biology, Pathology,
and Diagnostic Sciences
New Jersey Dental School

Professor of Psychiatry
New Jersey Medical School

Steven E. Keller, PhD
Professor of Psychiatry

Associate Professor of Neuroscience
New Jersey Medical School

Jacqueline A. Bartlett, MD
Associate Professor of Psychiatry
New Jersey Medical School

University of Medicine and Dentistry of
New Jersey

Correspondence to:
Dr Karen Raphael
New Jersey Medical School
University of Medicine and Dentistry of
New Jersey
30 Bergen Street, ADMC 14
Newark, New Jersey 07107-3000

The aim of this study was to examine the relation between alloplastic temporomandibular joint (TMJ) implants and immune-associated systemic health problems. The authors compared 14 patients who received alloplastic TMJ implants with 31 TMJ patients who had never received surgery on the self-reported occurrence of symptoms and systemic disorders that are associated with problems of immunomodulation. Those with alloplastic jaw implants reported similar or lower rates of surveyed physical disorders than nonsurgical TMJ participants. When the rates were summed across symptom categories and physical disorders, implant participants had significantly fewer symptoms and disorders than nonsurgical participants ($P < 0.01$). This first report on systemic health problems in alloplastic TMJ implant patients found no evidence of elevated rates of systemic disorders that are associated with problems of immunomodulation.

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Alloplastic implants were used to replace the temporomandibular joint (TMJ) disc beginning in the 1970s and peaking through the 1980s.¹ Official criteria for surgical candidacy state that patients should have demonstrated facial pain and/or impaired function and should have been unresponsive to conservative treatment protocols.² Proplast/Teflon (Vitek) and silicone rubber (Silastic, Dow-Corning) materials were most commonly used. One source³ estimates that 60,000 to 80,000 patients in the United States have received alloplastic TMJ implants. These implant materials fragment under functional conditions and require replacement or removal in the majority of patients.⁴⁻⁸ It has been established that the implants accelerate bone destruction.⁹⁻¹⁴ Multiple studies¹⁵⁻¹⁹ have found evidence of a local foreign-body giant cell reaction that has been reported to continue after implant removal and is presumably caused by residual alloplastic material.^{7,20}

In response to increasing complaints of morbidity, the United States Food and Drug Administration (FDA) instituted several actions, including a patient notification program and notifications to oral and maxillofacial surgeons: "We believe these implants present an unreasonable risk of substantial harm to the public health because they may deteriorate, flake and migrate within the body. This process can lead to implant fragmentation, bone degeneration, and/or foreign body response which could cause a local or systemic immunologic response."²¹

The occurrence of a localized immunologic response to alloplastic jaw implants has been well established. Less well established is the foundation for the claim that alloplastic jaw implants lead to systemic health problems. Anecdotal claims of systemic health consequences appear in media reports,²²⁻²⁴ patient testimonials in congressional hearings,²⁵ and many of the more than 2,500 legal proceedings against the manufacturer of Proplast/Teflon Implants.

Case reports and uncontrolled studies that contend that systemic disease is associated with jaw implants are confounded by methodologic problems. First, subjects in studies of implant failures are unlikely to be representative of all implant recipients. For example, patients with systemic disease may be more likely to be seen in treatment settings regardless of any relation between the disease and the implant by virtue of treatment-seeking behavior. It may be more difficult to sustain follow-up on satisfied implant patients who see no need for further contact with the implant surgeon. Second, those who report high rates of disorder in implant patients fail to contrast these rates with rates of disorder in nonimplant TMJ patients. The lack of a comparison group renders it difficult to determine whether systemic disease seen in implant patients is a result of the implants themselves. Alternately, disease may be associated with TMJ status and/or the immunologic consequences of living with a painful disorder.²⁶

In summarizing the scant research studies on the systemic immunologic consequences of implants, Wolford et al²⁷ reported a high incidence of human leukocyte antigen (HLA) types that are associated with various connective tissue diseases in a sample of failed implant patients. It is unclear, without a control group with which to contrast rates, whether these HLA rates are generally high in TMJ patients who had implantation and/or whether these antigens predispose patients to implant failure. Wolford et al²⁷ also reported elevated T cell responses in a small sample of implant patients. The range of systemic diseases purportedly promoted or exacerbated by TMJ implant materials is diverse, including but

not limited to mixed connective tissue disease, fibromyalgia, scleroderma, rheumatoid arthritis, systemic lupus erythematosus, chronic fatigue syndrome, sarcoidosis, and other conditions that lead to significant disability.^{27,28}

However, to date, no controlled study has examined whether alloplastic jaw implant patients are at increased risk for disorders that are associated with a systemic immunologic response. With the exceptions noted above, scientific studies of implant outcome have focused exclusively on localized immunologic response, bone formation, and symptoms related to TMJ function (eg, pain, dental occlusion, and range of mandibular motion). Existing reports of systemic disease in implant-exposed patients did not determine whether rates of disease exceeded general population rates, whether disease onset predated implant exposure, or whether disease was triggered by a foreign-body response to the implant.²⁸

This paper examines the question of the broad health consequences of alloplastic TMJ implants and addresses these methodologic problems. It reports findings from the first study to examine systemic diseases among TMJ patients, comparing those with and without implants.

Materials and Methods

Subjects

An advertisement was placed on two consecutive days in July 1995 in the largest circulation newspaper in Portland, Maine. It invited self-identified TMJ patients, especially those who had undergone TMJ surgery, to call a toll-free number to complete a brief questionnaire and receive a \$10 payment. Response was intentionally invited from "TMJ" patients, as this lay term was thought to best identify to the public the broad range of conditions that involve the TMJ and masticatory muscles. Those who did not report treatment by a doctor, dentist, or other health professional for a TMJ problem were ineligible. Because the majority of TMJ patients and the overwhelming majority of implant patients are women,²⁹ only women were eligible. Fifty-five women responded, of whom 31 had never had TMJ surgery and 14 had received alloplastic jaw implant surgery. The 10 remaining patients had undergone a heterogeneous group of other surgical procedures, including arthroscopic surgery, discectomy, condylectomy, etc. To permit comparison between an alloplastic implant and nonsurgical group, these 10 patients were removed from the analyses that are reported here. All of the implant

1. TMJ-related symptoms
 Now I'd like to focus on how you're feeling lately. In the past 6 months, have you had any of the following:
 A. Pain in the face? (Y/N)
 B. Pain in the jaw? (Y/N)
 Etc

2. Surgery history
 Have you ever had facial/TMJ surgery? (If yes...)
 Now I have some questions about the different kinds of TMJ surgery you might have had. If you're not sure of the name(s), I'll read you several descriptions and you can tell me which one(s) you've had.
 A. Have you ever had disc replacement with an alloplastic (artificial or plastic) implant?
 Etc

3. Other medical conditions
 Now I'd like to ask you about other health problems you might have had recently. In the past 6 months, which of the following conditions have you experienced for at least 2 weeks?
 A. Fibrocystic breast disease (noncancerous changes/cysts in breast tissue)
 B. Endometriosis (growth of the tissue lining the uterus outside of the uterus)
 Etc
 Other serious medical conditions (specify...)

Fig 1 Sample medical history questions.

patients reported that they had received their implants between 1980 and 1988, with the exception of one procedure that was performed in 1992.

The mean age of subjects was 41.5 years (SD = 11.9). Over 75% were college graduates. The mean "worst pain" level in the past 6 months was 40 (median = 40, mode = 0, SD = 40.8) on a 0 to 100 scale (where 0 = no pain and 100 = pain as bad as it could be). Five (36%) of those in the implant group and 15 (48%) of those in the nonsurgical group reported no pain in the past 6 months. Only two subjects (one in the implant group and one in the surgery group) reported a pain level of 100, representing pain as bad as it could be. The average length of time since symptom onset was 12 years (SD = 7.4). Implant and nonimplant subjects did not differ in age, educational level, or chronicity of disorder.

Procedure

A single interviewer answered calls to the toll-free number and, after ascertaining eligibility, completed a brief medical history with participants. The structured medical history was close-ended, but any details supplied by the respondents were recorded verbatim (see Fig 1 for sample questions). Participants were asked about their history of treatment for TMJ problems (surgical and nonsurgical), about the nature of past and current symptoms,

and about selected health conditions in the past 6 months. Questions about the presence or absence of health conditions were limited to conditions that represented possible problems of immunomodulation and conditions that have been suspected to occur at elevated rates based on previous literature. Respondents were also given an open-ended opportunity to indicate whether they had other serious medical problems; if so, they were asked to describe those problems.

Results

Given the sample size, the *P* values shown in Tables 1 and 2 represent the results of Fisher Exact Tests (two-tailed) of the hypothesis that rates of symptoms or disorders were different in implant versus nonsurgery groups. Table 1 shows rates of self-reported signs and symptoms that occurred in the past 6 months. With the exception of clicking, the two groups were not significantly different in terms of TMJ-related signs and symptoms (implant patients with removed implants and no replacements were less likely to report current clicking). Regarding other nonspecific symptoms, implant patients complained similarly or somewhat less than nonimplant patients. As shown in Table 2, alloplastic jaw implant patients had similar or somewhat lower rates of surveyed physical disorders. The only health

Table 1 Prevalence of Selected Physical Symptoms in the Past 6 Months in Implant Versus Nonsurgical TMJ Patients

Symptom	No surgical procedure (n = 31) (%)	Implant (n = 14) (%)
Pain in the face	48	43
Pain in the jaw	68	79
Pain in the temple	52	50
Pain in the TMJ	74	64
Jaw locks/catches	39	21
*Clicking/popping noise	77	36
Grating/grinding noise	26	29
Difficulty chewing	55	29
Unstable bite	52	36
Facial deformity	16	14
†Swollen glands	35	7
‡Dizziness	42	7
Ringing in ears	45	36
Hearing loss	26	14
Chronic colds	3	0

* $P < 0.05$; † $P < 0.01$.

condition in which implant patients had significantly more reported conditions was for conditions related to thyroid problems. In this small sample, the rates of thyroid problems were 7 times higher in implant patients than in nonimplant patients. However, this represents only one condition in the nonimplant group versus three in the implant group. When summed across all symptom categories and physical disorders as shown in Tables 1 and 2, the mean number of symptoms and disorders was significantly higher in nonimplant patients (mean = 4.45) than in implant patients (mean = 2.43, $t = 2.78$, $P < 0.01$).

Discussion

The alloplastic jaw implant patients in this study appeared to suffer from the same number or fewer immune-related disorders than the nonsurgical TMJ patients. This contrasts with other reports that suggest higher rates of various connective tissue disorders and other disorders that indicate problems of immunomodulation.

The sample size in this study raises several issues. The first is one of statistical power. With a small sample of implant patients, it is more difficult for differences between surgical and nonsurgical groups to reach statistical significance. In a small-sample study, where the risk of missing differences that do exist (Type II error) is considered more of a problem

Table 2 Prevalence of Selected Physical Disorders in Implant Versus Nonsurgical TMJ Patients

Condition/ disorder	No surgical procedure (n = 31) (%)	Implant (n = 14) (%)
*Fibrocystic breast disease	29	7
Endometriosis	19	21
Arthritis	39	29
Environmental sensitivity	19	7
Eczema	16	7
Asthma	16	7
†Thyroid condition (includes thyroiditis and thyroidectomy)	3	21
Other immune system problems	6	0
Other serious medical conditions	23	7
‡Mean number of symptoms and disorders	4.45 (SD = 2.90)	2.43 (SD = 1.91)

* $P < 0.10$; † $P < 0.01$.

than the risk of finding a difference that does not really exist (Type I error), Bonferroni procedures for multiple comparisons were not conducted. However, we exercised care in the interpretation of findings at the $P < 0.05$ but > 0.01 level.

It is important to note that the mean total number of reported physical symptoms and conditions was significantly lower in implant TMJ patients than in nonsurgical TMJ patients. Thus, low statistical power cannot be the reason that our conclusions differ from earlier speculations²¹⁻²⁸ about systemic problems in implant patients. Subsequent power analysis with the Number Cruncher Statistical System (NCSS, Hintze) revealed that power was adequate (power = 0.78) to detect a difference in the mean number of conditions of the magnitude actually found in the contrary direction.

The one significant disorder-specific finding in the predicted direction was that there were relatively high rates of self-reported thyroid conditions in implant patients compared to nonimplant patients. Given the possibility that this elevated rate was an artifact of inaccuracies in self-report, we carefully examined the interviews of those subjects who reported "thyroid problems." We discovered that two of the three "thyroid conditions" in the implant group were actually secondary to thyroidectomies that had occurred prior to the implant surgery. Thus, these respondents' thyroid conditions could not logically have been a consequence of the

implant surgery. After adjusting rates to exclude these two conditions, the rate of thyroid conditions did not differ between groups. Nevertheless, this examination illustrates the limitations of relying on self-reported health status. Future studies should record, ideally through medical records, whether the onset of any health problems occurred prior to, concurrent with, or subsequent to implant placement.

Another potential limitation of this study is the lack of access to medical records to identify the specific implant composition and design employed in the 14 patients with implants. Our limited sample size and our inability to definitively determine implant material and design limits the possibility of detecting differences in health effects as a function of material.

Our findings may differ from the other limited studies on this topic because of our sampling method. In contrast to others,²⁷ we did not explicitly select patients who were identified as "implant failures," as the aim was to examine the systemic health effects of implant exposure, not of local implant failure. Only 5 of the 14 implant patients in our study reported that their implants had been removed. Moreover, other studies²⁷ failed to include control groups with which to contrast rates of disorder. For example, nearly one third (29%) of the patients in our implant sample reported that they suffered from arthritis. This may seem elevated until one notes that even more of the nonimplant sample (39%) reported the same problems.

One remaining problem is that the surgical versus nonsurgical patients could represent patients with essentially different disorders. The acronym "TMJ" is a lay term for *temporomandibular disorder(s)* (TMD),³⁰ a group of heterogeneous disorders that have potentially different courses, treatment responsiveness, and risk factors. The heterogeneity of the category and label renders it possible that the comorbidity of specific TMD subtypes and other physical disorders is more common for some TMD subtypes than for others, regardless of implant status. However, the fact that patients in both groups were similar in terms of current signs and symptoms argues against this possibility.

It is possible that, given the selectivity of sampling by newspaper advertisement, we garnered a nonrepresentative sample of nonsurgical TMJ patients. The representativeness of the small sample of TMJ implant cases can also be questioned. Variability in success rates and implant removal rates across surgeons have been reported.³¹

Despite these limitations, our data provide a partial response to Milam's³² comment that "the long term health risk of chronic exposure to

particular implant debris is currently unknown." This study indicates that poor health is far from ubiquitous among alloplastic jaw implant patients. A history that includes an alloplastic jaw implant is not a sufficient condition for the occurrence of the immunologically related disorders that were surveyed in this study. The state of knowledge concerning systemic diseases caused by these implants parallels an earlier state of knowledge about silicone breast implants. Until recently, case reports and uncontrolled studies^{33,34} suggested that patients with silicone breast implants were at an increased risk for connective tissue diseases. Later case-control³⁵⁻³⁷ and population-based historic cohort studies, which use matched control samples followed forward in time,^{38,39} did not generally confirm this pattern. Nevertheless, the personal, social, and legal/economic harm that was generated by earlier reports of systemic disease could not be eradicated by later reports that failed to substantiate such problems.

Future studies should readdress the issue of the health status of implant patients through the following design improvements. First, larger samples of implant patients should be acquired and compared to a sample of clinically and demographically similar TMJ patients without implants. If feasible (ie, if clinically and demographically equivalent to implant patients), an ideal contrast group would be composed of TMJ surgical candidates who did not receive implants. Representativeness of patients would be maximized by selecting patients from the practice records of surgeons who have performed implants. The type of implant placed should be recorded to permit the detection of any differences in response because of material type. Patients should be followed forward in time from the point of surgery, or, in the case of nonimplant patients, matched to implant patients and followed for a similar length of time. Self-reported current disorders and symptoms may be ascertained at the time of study participation. Confirmatory physical examinations should be conducted, and state of the art diagnostic methods should be used whenever possible. However, the advantage of the retrospective cohort approach is that it allows a comprehensive and less biased examination of the medical records of patients in both groups.

These data raise doubts about the accuracy of earlier conjectures that TMJ alloplastic implant patients are at an increased risk for a variety of systemic diseases. They point to the need to conduct further research using improved epidemiologic methods to ascertain the long-term health impact of alloplastic implants of the TMJ.

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Resumen

Estudio Piloto Sobre los Efectos de los Implantes Aloplásticos de la Articulación Temporomandibular en la Salud Sistémica

El propósito de este estudio fue el de examinar la relación entre los implantes aloplásticos de la articulación temporomandibular (ATM) y las condiciones de salud sistémica asociadas a problemas inmunológicos. En este artículo, los autores compararon 14 pacientes que habían recibido implantes aloplásticos en la ATM, con 31 pacientes con problemas en la ATM, y que no habían tenido cirugía de acuerdo a los incidentes auto-reportados de síntomas y desórdenes sistémicos que están asociados con problemas de inmunomodulación. Aquellos con implantes aloplásticos mandibulares reportaron proporciones similares o menores, en cuanto a los desórdenes físicos examinados, en comparación con los participantes con problemas de la ATM que no habían sido intervenidos quirúrgicamente. Cuando se utilizaron los resultados a través de las categorías de síntomas y de desórdenes físicos, las personas con implantes presentaron menos síntomas y desórdenes que las personas que no habían tenido cirugía ($P < 0,01$). En este reporte inicial sobre los problemas de salud sistémica en pacientes con implantes aloplásticos en la ATM, no se encontró ninguna evidencia de desórdenes sistémicos de proporciones elevadas que estén asociados con problemas de inmunomodulación.

Zusammenfassung

Systemische Gesundheitskonsequenzen von Alloplastischen Implantaten des Kiefergelenkes: Eine Pilotstudie

Das Ziel dieser Studie war es, die Beziehung zwischen alloplastischen Kiefergelenk (TMJ)-Implantaten und immun-assoziierten systemischen Gesundheitsproblemen zu untersuchen. Die Autoren verglichen 14 Patienten, die alloplastische TMJ-Implantate erhielten mit 31 TMJ-Patienten, welche nie Chirurgie erhielten in Bezug auf selbstberichtetem Vorkommen von Symptomen und systemischen Störungen, die verbunden sind mit Problemen der Immunomodulation. Diejenigen mit alloplastischen Kieferimplantaten berichteten ähnliche oder niedrigere Raten von beobachteten physikalischen Störungen als die nichtchirurgischen TMJ-Teilnehmer. Wenn die Resultate innerhalb der Symptomkategorien und der physikalischen Störungen zusammengerechnet wurden, hatten die Implantatteilnehmer signifikant weniger Symptome und Störungen als die nichtchirurgischen Teilnehmer ($P < 0,01$). Dieser erste Bericht über systemische Gesundheitsprobleme bei Patienten mit alloplastischen TMJ-Implantaten entdeckte keinen Beweis für erhöhte Raten von systemischen Erkrankungen, welche verbunden sind mit Problemen der Immunomodulation.

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