CHRONOLOGY OF NIDR TEMPOROMANDIBULAR DISORDERS-RELATED INITIATIVES*

June 15, 1992

1969 First NIDR grant on a TMD subject awarded to Daniel Laskin, Psychophysiology of the TMJ Dysfunction Syndrome. Dr. Laskin has received active NIDR support for eighteen of the past twenty-three years.

1977 First training grant for clinical research on chronic pain was awarded. From 1980 to the present, NIDR has supported 115 trainees in neuroscience and TMD-related research with funds totalling $4.1 million.

1983 NIDR Long-Range Research Plan: Challenges for the Eighties testified to the uncertainty surrounding the etiology and treatment of TMDs and recognized the importance of non-invasive approaches to therapy and significance of stress and psychological factors in initiating or exacerbating pain problems. The Plan was distributed widely throughout the world to the dental research, education, and practice communities.

1984 Workshop to Develop Diagnostic Criteria of TMD for Use in Epidemiologic Studies was held. Several alternative definitions of a "case" were developed, but it was agreed that current levels of knowledge were not sufficient for consensus.

1985 NIDR Request for Applications, Orofacial Pain Research Centers was announced. A P50 grant (specialized center) was subsequently awarded to UCLA in 1988. Several TMD-related studies were subprojects of this grant.

1986 NIDR published "Pain Research: From Laboratory to Clinic," a booklet describing NIDR research, knowledge gained, and treatment underway. Within the booklet, pain clinic studies and findings on myofascial pain dysfunction syndrome are discussed.

* The chronology does not include all the awards made for TMD research and training. Over the years, the NIDR TMD portfolio has evolved from one grant in 1969 to 20 in FY 1991. A total of 24 million from 1980 to the present ($3 million in FY 1991) has been awarded.

1987 Working group meets to assess whether the state of the science concerning TMD diagnosis is sufficiently advanced to allow oral examiners to ascertain cases in the National Health and Nutrition Examination Survey (NHANES III). It was decided that the current state of knowledge did not justify inclusion of clinical examination items, although data gathering through the HANES was recommended and subsequently implemented in 1989.

1987 Evaluation of Temporomandibular Joint Meniscus Replacements in Primates (Michael Block), a Small Research Grant (R03), awarded to evaluate the advantages and disadvantages of a Proplast material versus dermis graft for surgical correction of internal derangements.

1988 The NIDR Dental Research Programs Advisory Committee (PAC) reviewed NIDR-sponsored pain, neuroscience, and behavior research. Recommendations for TMD research were discussed. Unresolved controversies about TMD research and management were acknowledged, and a cautious expansion of research in the area was suggested in the conclusions.

1988 NIH/NIDR published "Relieving Pain," a booklet for pain sufferers that discusses treatment approaches and research efforts.

1989 NIDR prepared a fact sheet on TMDs for routine distribution to the public and health professionals who have questions about TMDs.

1989 NIDR funded a supplement to the 1989 National Health Interview Survey (NHIS), an annual probability survey of non-institutionalized U.S. civilians conducted by the National Center for Health Statistics, that included an orofacial pain questionnaire. Data collection was completed in 1991, and non-specific indicators of the population at risk for TMDs are being analyzed.

1989 A two-day scientific workshop entitled, New Approaches to Differential Diagnosis of Chronic Orofacial Pain, included discussions of TMDs. The proceedings were published in Anesthesia Progress 37(2/3), 1990.

1989 NIDR/NICHD co-sponsored a Program Announcement, Basic and Clinical Research on Normal and Impaired Oral-Motor Function, specifically highlighting the need for research on the relationship between oral-motor function and the causes or exacerbation of TMD-related conditions. Sixteen applications have been received under this active program announcement; a total of six

have been funded to date.

1990 An NIDR Program Announcement, Pathogenesis of Joint, Muscle, and Inflammatory Pain as Related to Temporomandibular Disorders focused exclusively on the etiologies underlying muscle and joint pain. To date, fourteen applications have been received; 5 have been funded.

1990 The NIDR Long-Range Research Plan for the Nineties: Broadening the Scope has a chapter on pain that addresses chronic orofacial pain, including TMDs. The use of conservative, reversible therapies is stressed, with the comment, "There is no scientific basis for the routine use of irreversible therapies such as occlusal adjustment, restorative dentistry, orthodontics, and surgery." The Plan was distributed widely throughout the world to the dental research, education, and practice communities.

1990 NIDR supported the development of Research Diagnostic Criteria for TMDs: objective somatic and psychosocial measures were developed. A final report will be published (Journal of Craniomandibular Disorders and Oral Facial Pain, October 1992.) The report identifies fundamental research questions that need to be studied to validate these criteria in multisite clinical research and epidemiological field studies.

1991 A symposium for dental practitioners, Scientific Frontiers in Clinical Dentistry was held. At this NIDR-sponsored meeting, "Current Concepts in the Management of Temporomandibular Disorders and Chronic Orofacial Pain" were addressed. Over 500 practitioners were in attendance, representing 40 states. A follow up article was published in the Journal of the American Dental Association, vol. 122, October 1991.

1991 The first surgical clinical trial for TMDs supported by the NIDR, Craniomandibular Disorders: Long Term Outcome Study (Schiffman, Eric L.) is a five-year study that compares surgical vs non-surgical treatments in patients with TMJ internal derangements. The surgical procedures do not call for the placement of implants; they involve removal of adhesions and lavage or adjustments in disc shape. The non-surgical patients will receive splint therapy.

1991 NIDR held a Task Force meeting to explore the feasibility of a technology assessment conference on TMDs. As a first step, NIDR has proceeded with a meta analysis study of treatment-related research appearing in peer-reviewed professional journals. The study, conducted by Dr. Alexia Antczak-Bouckoms, Technology

Assessment Group, Harvard School of Public Health, will:

- assess the state of the science reflected in the scientific literature;
- highlight treatment practices that appear either promising or problematic;
- provide a framework for identifying research needed to improve TMD therapies; and
- provide core information that could be used in developing workshops or conferences on the safety and efficacy of TMD therapies.

1992 A symposium on Frontiers of Pain Research in the Decade of the Brain was held under the auspices of the National Academy of Sciences; TMDs and facial pain were discussed.

Mr. SANDERS. So ordered.

Dr. LÖE. A summary of our major activities and accomplishments would have to include first, a consensus of how to classify TMD's. It is now agreed that TMD's fall into three main areas or classes. The vast majority of cases involve pain in the muscles of mastication—the chewing muscles—associated with the joint, with no direct involvement in the joint. The next most common classification are internal derangements involving the disc and the associate structures of the joint. Last are degenerative joint and bone conditions, such as rheumatoid and osteoarthritis.

A second accomplishment is the development of new research diagnostic criteria. NIDR contracted with experts to design a more objective system of diagnosis of these diseases. The system sets numerical limits for clinical measurements combined with psychosocial indicators to characterize the TMD problems in the individual patient. The description of this two-dimensional classification will be published this fall. NIDR will follow up with clinical studies to validate the approach. Validation will include confirmation of the clinical diagnosis using x rays and magnetic resonance imagery.

A third accomplishment relates to prevalence data. NIDR added a supplement to the 1989 National Health Interview Survey to find out who in the general population has symptoms of TMD's. The criteria used were reports of pain of at least 1 month's duration either in the face, around the joint, or in the joint itself, or in both the face and joint. Estimates from the survey suggest that approximately 10 million adults between 18 and 75 may be at risk. The ratio of females to males was 2 to 1. The NIDR also supported a study in Seattle in which 12 percent of adults enrolled in a large health maintenance organization reported signs and symptoms of TMD, again with a female to male ratio of 2 to 1. However, the ratio of women to men in treatment was 6 to 1.

It appears that many more people report TMD symptoms than come in for treatment. We believe that this is because the symptoms in some may be mild, they may come and go, or the individual may choose to ignore them. The reasons why more women are in treatment may be because American women are generally more health conscious than men and get regular dental and medical checkups. However, there may be underlying gender differences in susceptibility or severity of TMD's that we intend to explore.

The fourth, if I may complete this list of activities, Mr. Chairman, relates to treatment; NIDR is supporting an evaluation of treatment-related scientific papers that have appeared in peer-reviewed professional journals. A technique called meta-analysis is being used to assess the state of the science and highlight treatments that appear either promising or problematic. We will use these results to develop a research agenda targeted to improving the TMD therapies.

In 1991 we initiated funding for a 5-year randomized clinical trial at the University of Minnesota, comparing surgical with nonsurgical treatments in patients with TMJ internal derangements. Other clinical studies will determine if there are biochemical changes in the chewing muscles that may indicate pathology and test a method to improve delivery of steroids or anesthetic drugs to treat TMD's.

In summary, Mr. Chairman, I believe we have made substantial progress in important areas of TMD research and we now are poised to move closer to the point where we can expand the clinical repertoire, hold technology assessments workshops, and publish state-of-the-art information to educate the public and professionals. The committee should also know that we are in touch with a number of investigators who are interested in analyzing joint implant failures and following up with patients who are now experiencing these complications.

This ends my statement, Mr. Chairman. I shall be pleased to answer any questions that you may have.

[The prepared statement of Dr. Löe follows:]

Human Resources and
Intergovernmental Relations Subcommittee
of the
Committee on Government Operations

Hearing on the safety and effectiveness of jaw implants made of silicone, teflon, bone, and other materials

Statement of the Director
National Institute of Dental Research

June 4, 1992
10:00 a.m.
Room 2203
Rayburn Office Building

Mr. Chairman, my name is Harald Lõe, and I am the Director of the National Institute of Dental Research. With me today is Dr. Vivian Pinn, Director of the Office of Research on Women's Health at the NIH and Dr. Dushanka Kleinman, the Deputy Director of NIDR. We are pleased to be here to take part in this hearing and to report on research relevant to temporomandibular disorders. We share the Committee's concerns for the serious situation many of the patients who have had implant surgery now face and we hope that ways can be found to ameliorate their pain and suffering.

When the NIDR was established 44 years ago it was charged with the overall mission of improving the oral health of the American people. At that time dental caries and periodontal diseases were rampant--the cause of much pain, suffering, tooth loss, and high dental care expenses. Oral health research not only established the infectious nature of these diseases, but also paved the way to prevention. The result has been a dramatic decline in prevalence and severity of these diseases that continues to this day. Economists now estimate that savings in the nation's dental care bill caused by these improvements in oral health totalled over $40 billion in the last decade alone.

As NIDR made headway in controlling the two most prevalent dental diseases, our research efforts expanded to other oral health problems. Today, our investigators study a broad range of diseases and disorders of the teeth, the mouth, the jaws, and the face. These include birth defects, oral cancers, AIDS and other infections, autoimmune diseases, and conditions of chronic pain and oral motor dysfunction,

such as those we are talking about today. We also study the normal development, repair, and aging of the oral, facial, and cranial tissues, and how the health or disease of these tissues interacts with general health and systemic disease.

Studies of the temporomandibular disorders (TMDs) largely fall in the area of neuroscience. This area includes research on pain and oral sensory and motor systems conducted by grantees in dental schools and other research institutions across the country, as well as by our staff scientists in the Neurobiology and Anesthesiology Branch of our Intramural Research Program. This Branch also directs the Pain Research Clinic in the NIH Clinical Center, which studies patients with a variety of pain problems, e.g., not restricted to the face or head. Since 1980 we have invested approximately $21 million on TMD issues and NIDR funding for TMD research will be a little over $3 million in FY 92 (Chart 1). That is about a fourth of our total estimated funding in neuroscience ($13 million), and approximately 2 percent of the FY 1992 appropriation of $159 million.

Funding for TMD research is aimed at improving our understanding of these disorders: What are they? What causes them? How do we diagnose them? How prevalent are they? Why do we see more women in treatment? What sorts of treatment are appropriate? None of these questions is trivial; none has been answered to the satisfaction of the scientific community. For these reasons NIDR has consistently advocated a conservative approach to treatment. As stated in our Long-Range

Research Plan for the Nineties: "There is no scientific basis for the routine use of irreversible therapies such as occlusal adjustment, restorative dentistry, orthodontics, and surgery." In essence, we support the ancient advice to healers: "First, do no harm."

Now I would like to review the main research questions and how we approach them.

The temporomandibular joint allows the lower jaw to move in three dimensions--up and down, side to side, and forward and back--and in the many combinations of those movements that we use in speaking, biting, chewing, and swallowing, coughing, sneezing, smiling, and making other facial expressions. The ability of the joint and its associated muscles and bone to function smoothly and efficiently during these complex movements depends on a rich nerve and muscle supply. This enables exquisite control over facial movements and also makes this part of the face and head extremely sensitive to touch, pressure, and pain. Under the circumstances, any symptoms of pain combined with a failure of the joint to perform normally will be highly disturbing. To make matters worse, these problems affect the head and face--the parts of the body that are uniquely tied to our identity and personality. Any compromise, any dysfunction, in this part of our anatomy, can be expected to add to the stress and suffering associated with physical disability.

What kinds of dysfunction are we talking about? What are the temporomandibular disorders? I use the plural because there is consensus in the scientific community

that we are talking about a number of discrete problems, each associated with different causal mechanisms. While there are a variety of ways to classifying the TMDs, there is general agreement that they commonly fall into three areas or classes: The first is restricted to muscle pain affecting the muscles in and around the joint; the second area refers to internal derangements of the joint. This has to do with abnormal positions and motions of the disc--the soft tissue that acts as a shock absorber--and related structures of the joint, including structural changes in the disc itself. The third area refers to degenerative conditions of the joint and bone such as rheumatoid or osteoarthritis.

By far the most prevalent form of TMD relates to the first group--pain in the muscles of mastication--the chewing muscles--associated with the joint. Next are internal derangements, and last, the degenerative conditions. There are other more rare conditions affecting the joint, such as infiltrating tumors, infections of the joint and bone, and trauma. These are generally excluded from consideration as "TMDs," although it is well to remember that a number of patients with these conditions may have been treated surgically with implants.

How prevalent are the more common forms of TMD? This is not an easy question to answer because data collection on who has and who does not have a disease in an epidemiological survey depends on how the disease is defined and how it is diagnosed. And this has been a major problem. For the past 40 or 50 years the

diagnosis of TMD has largely depended on the patient's subjective report of symptoms of pain and limitation in jaw function and a clinical examination. The practitioner measured how wide patients could open their mouths and also listened for clicks, popping noises, or creaking sounds during jaw movements. The clinician would also note any pain or tenderness upon palpation of the jaw muscles. X-rays could detect gross abnormalities of hard tissues, but the position of the joint tucked under the skull and the fact that X-rays provide only two-dimensional views limits their usefulness. In time, electrical tracking of jaw movements, X-ray motion pictures and other methods of capturing jaw movements, were proposed to refine diagnosis, but it was soon obvious that there is wide variation in the normal range of motion of healthy individuals so that these recordings have limited diagnostic value. More detailed X-ray technology such as computerized tomography, arthrograms, as well as direct visualizing of the joint in the surgical procedure of arthroscopy are more informative, but are invasive procedures, expensive, and certainly not routinely available in the dentist's or physician's office. More recently, magnetic resonance imaging has become available and is proving to be an invaluable non-invasive method of visualizing the soft tissues of the joint. This too is expensive and not routinely available. And, like the invasive procedures, would never be used in health surveys of the adult population at large.

Given these limitations we <u>can</u> say the following: In a recent National Health Interview Survey conducted by the National Center for Health Statistics, NIDR arranged to have a set of questions asked relating to facial pain. In particular, adults were asked about

pain they experienced over the last six months either in the jaw only; in the jaw and nearby facial area; or only in the facial area (excluding sinus pain). Clearly, those questions are not specific for TMD, but as a ballpark indicator, we have estimated that in 1989 as many as 10 million Americans 18 to 75 years of age experienced these painful symptoms for at least a month over a six-month time period, with a ratio of females to males of about 2 to 1. More targeted information on TMDs comes from a community-based study of adults enrolled in a large Health Maintenance Organization in Seattle. In a random sample of adults screened for TMD signs and symptoms and later followed up with clinical examinations and interviews, investigators reported that 12 percent of the adult population had signs and symptoms of TMD with a female to male ratio of 2 to 1. However, the female to male ratio among those in treatment was 6 to 1.

Clearly we have to be careful in interpreting self-reports of orofacial pain symptoms. Not only is there uncertainty about whether the responses are specific to the TMDs, but we have to take into consideration that even if a person has the condition, it may be mild, it may come and go, it may resolve over time, or the individual may elect to do nothing about it. Those are among the reasons we see differences in prevalence when we compare community-based studies with clinical populations. Women predominate in clinical populations by ratios as high as 9 or 10 to 1; perhaps even higher. Frankly, we do not know why. We know that women are more health-conscious than men and that in general, they are more likely to seek dental and

medical care and regular check-ups. However, there may also be underlying biological differences in susceptibility or severity of the TMDs. These may be related to female hormones or they may reflect structural differences or perhaps even differing sensitivities to pain. These are important research issues to explore.

Regardless of gender, we have to get on with the problem of getting a better handle on the TMDs and their treatment. With regard to the issue of diagnosis, I am pleased to report that in 1990 NIDR contracted with a group of clinical investigators who are experts in the field to develop Research Diagnostic Criteria. The goals of this effort were to develop an objective set of somatic measurements--numbers setting upper or lower limits for each measurement of a sign or symptom of one or another type of TMD. In addition, these investigators emphasize the importance of collecting information on the psychosocial dimensions of the TMD problem. Chronic pain affects the quality of the patient's life--either by interfering with work, social life, or in the every day routine of living. Chronic pain is also associated with insomnia, fatigue, depression, and other consequences, all of which can exacerbate the TMD problem, and, in fact, create a vicious circle of pain, leading to depression, leading to a further erosion in the quality of life, leading to more pain and more depression, and so on. I believe the expert working group's proposal for a two-dimensional physical and psychosocial approach to the diagnosis of a TMD in the individual patient has much merit. If validated in multicenter sites and epidemiological field tests, it could greatly benefit patients, provide a more rational guide to treatments, and perhaps provide

some real clues as to etiology.

...Because today our understanding of what causes the TMDs is limited. All too often theories have been proposed, and treatments subsequently imposed, that have proved fruitless, and in some cases only made the problem worse. I should add that this situation is by no means unique to TMD. Much the same problem exists in relation to low back pain and other chronic pain problems. Again, in parallel with low back pain, there has been a tendency in recent years to group all patients with similar signs and symptoms as having "TMJ syndrome"--an approach that has highlighted the joint at the center of the problem and blurred any distinctions among different modalities of the TMDs.

A combination of these two phenomena – describing patients as having the TMJ syndrome and then imposing what a particular practitioner believes to be the CAUSE may account for the more invasive treatments and surgeries that have occurred in recent years.

In contrast, NIDR has consistently recommended conservative approaches to treatment. We did this when we reviewed the state of the art in our research plan for the eighties and in the more recent plan for the nineties, documents which have served as blueprints for NIDR research activities for the past 15 years or more. A workshop we held in 1989 again affirmed the need to proceed conservatively as well

as the importance of considering the whole person in diagnosis and treatment, rather than focusing on a diseased organ and what to do with it. Conservative therapies include the use of resting splints--which are something like an orthodontic retainer fitted to the teeth to maintain an appropriate resting position of the jaws and teeth--physical therapy, exercises, techniques to reduce muscle tension, and, as appropriate, pharmaceutical agents for pain relief and adjunctive approaches such as stress reduction. These therapies continue to be employed by many practitioners because they help many patients.

Nevertheless, NIDR continues to support research to develop new or improved diagnostic and treatment approaches. In 1990 we issued a Program Announcement soliciting research on basic and impaired oral motor function. In the next few months we expect that the report of the working group that has been developing the Research Diagnostic Criteria will be published, and, as follow up, we will pursue studies to see if these standardized measures are both valid and reliable when tested in multisite clinical research and epidemiological studies.

With regard to alternative treatments, we have contracted for a study of the scientific literature that will select all treatment-related articles that have appeared in peer-reviewed professional journals. The contractor will use the analytic technique of meta-analysis to evaluate these studies. Such an analysis will 1) assess the state of the science reflected in the scientific literature; 2) highlight treatment practices that appear

either promising or problematic; 3) provide a framework for identifying research needed to improve TMD therapies; and 4) provide core information that could be used in developing workshops or conferences on the safety and efficacy of TMD therapies. This information will serve as a baseline that NIDR will use to determine treatment-related research needs and, we hope, move us closer to the point where we can hold technology assessment workshops and publish state-of-the-art information to educate the public and professionals on the TMDs.

In 1991 we initiated funding for a five-year clinical trial at the University of Minnesota comparing surgical vs non-surgical treatments in patients with TMJ internal derangements. The surgical procedures do not call for the placements of implants, however. Either the disc will be reshaped or the area irrigated to remove debris and treat adhesions. The non-surgical patients will receive splint therapy.

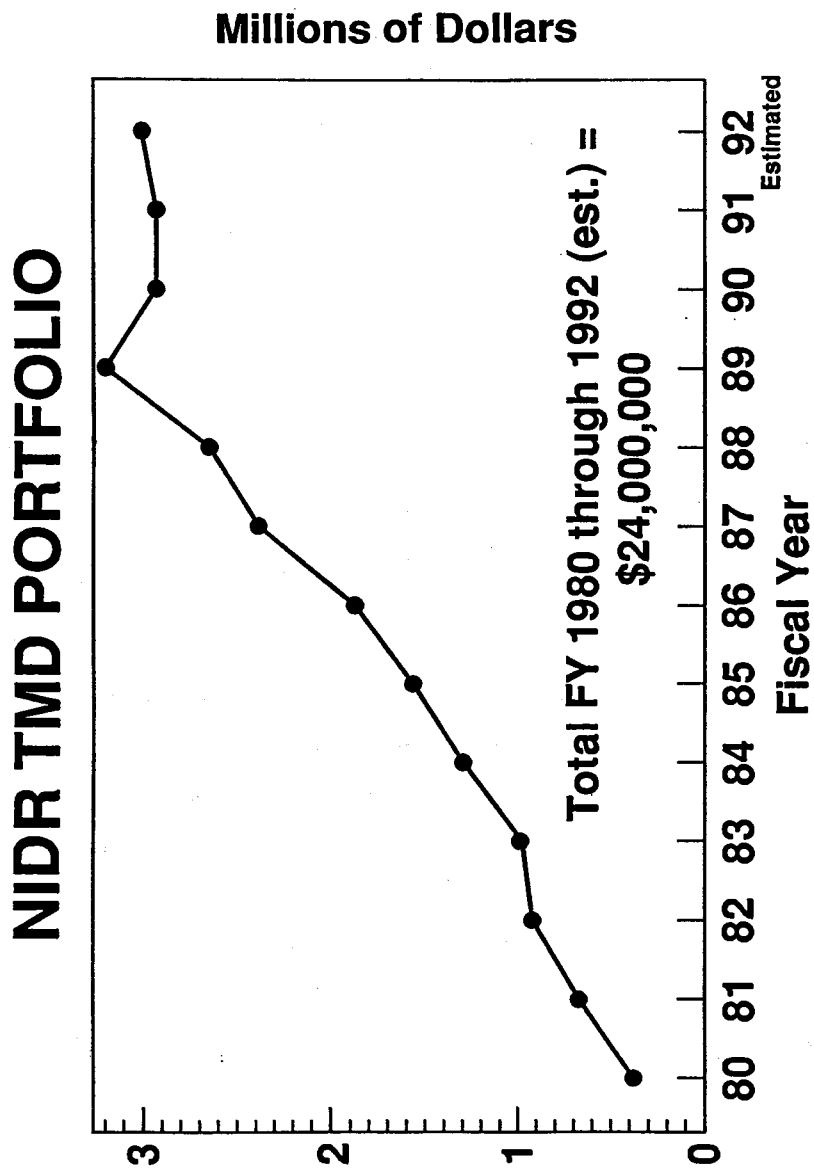
Other clinical research under way includes studies of whether there are biochemical changes in the muscles of mastication that may indicate pathology. This investigator is also looking at referred pain in TMD, in which stimulation to a trigger point at some part of the face results in pain in the TM muscles. A third study involves a method to improve delivery of steroid or anesthetic drugs to treat TMDs by applying electric currents to propel the drugs across the skin in the affected area.

None of these studies directly addresses the plight of women who have had jaw

implants and are suffering long-term consequences. However, more important from the Committee's point of view, we are in touch with a number of investigators who are interested in analyzing jaw implant failures and following up with the patients who are now experiencing complications. Such follow-up should reflect the efforts of teams of professionals who can address not only issues of replacement surgery, but immune responses, pain, and quality of life issues.

NIDR has been aware of the problems of jaw implant surgery for some time through the efforts of concerned individuals and consumer groups. As part of our broadened agenda for oral health research, we are especially mindful of the oral health problems of women or minorities and have targeted for emphasis those diseases or disorders, common or uncommon, that seriously threaten oral and general health.

In addition, the NIDR has worked closely with the FDA. Not only do we maintain informal contacts, but in 1990 the Assistant Secretary for Health established a Public Health Service Oral Health Coordinating Committee which meets regularly to discuss common concerns. Recently, we expanded this kind of collaborative/coordinating activity to specifically address oral health research issues and we have included not only dental representatives from the PHS, but other Federal agencies, including the Department of Veterans Affairs, the Department of Commerce and the Department of Defense. I believe that this kind of collaborative activity, in concert with the scientific community and concerned patients, can serve to resolve this unfortunate situation.



Mr. SANDERS. Thank you very much, Dr. Löe. At this point I want to recognize that we have been joined by my distinguished colleague, Mr. Hobson. Also we would ask for the record, all witnesses who have not yet been identified, please identify themselves for the record.

Dr. KLEINMAN. Dushanka Kleinman, Deputy Director, National Institute of Dental Research.

Dr. PINN. Vivian Pinn, Director, NIH Office of Research on Women's Health.

Mr. LEVITT. Joseph Levitt, Director, Center for Devices and Radiological Health, FDA.

Mr. NIEDELMAN. Steven Niedelman, Deputy Director, Division of Compliance Operations, Office of Compliance and Surveillance at the FDA Center for Devices and Radiological Health.

Mr. SANDS. Barry Sands, biomedical engineer with the Office of Device Evaluation, Center for Devices and Radiological Health, FDA.

Mr. SANDERS. Mr. Benson, this morning we heard testimony that research published in the 1960's showed Teflon joint implants wore down badly and produced small Teflon fragments. The body responded with a giant cell foreign body reaction, which is an immune response.

Given that history, why didn't the FDA require the company to provide safety studies before they were allowed to sell their product in the 1980's?

Mr. BENSON. I think you are referring to the hip—the use of the Teflon in the hip joints.

Mr. SANDERS. Yes, and TMJ implants.

[A copy of a medical review is in app. 2, p. 197.]

Mr. BENSON. I guess it was in 1982 or 1983 when the premarket notification came in for the Teflon joint for Vitek, I think that is what you are asking; the decision that the agency had to make at that time was whether there was a product on the market prior to 1976, when the device amendments were approved, that this new product was equivalent to or, if not equivalent, then safer or more effective.

And at that time, the decision was made that this product was in fact equivalent or at least equivalent or even perhaps even better than the prior product. So this is a function of the law. And at that point, we didn't have the authority or capacity to call for data. There is a vehicle—I don't want to mislead you with that. There is a vehicle that allows us to require data for these products and let me say right now I think that is something we must do.

But at that time, back in 1983, the program called for an equivalence decision, not for a call for data decision.

Mr. LEVITT. I would also like to add please, Mr. Chairman, during the review of the application in 1983, the information on Teflon that you referred to was not part of that review. It is important to know that in today's review process we have significantly upgraded the scope of the review of 510(k)'s so we take into account an engineering point of view, a toxicology point of view, a clinical point of view, and so forth, to be sure that we get the information that we need on the characterization of the product and of all the product's components.

Mr. SANDERS. Mr. Benson, the Teflon Proplast TMJ implants were allowed to be sold because the FDA determined they were "substantially equivalent" to a pre-1976 device, the silicone sheeting made by Dow Corning used for the TMJ implant material.

First of all, Teflon Proplast is not the same as silicone.

Second, sheeting material was originally approved for reconstructing facial contours, not for use in a joint.

On what basis did the FDA decide these two very different products were substantially equivalent?

[A memo describing this decision follows:]

MEMORANDUM

Date: February 1, 1990

To: The Record
Through: Lillian Yin, Ph.D., Director, Division of OB-GYN, ENT, Dental Devices (DOED), Office of Device Evaluation HFZ-470
Louis Hlavinka, Chief, ENT and Dental Devices Branch, DOED HFZ-470

Subject: Procode Designation for Vitek 510(k) K823549/Proplast TMJ Interpositional Implant

From: Jane Yurawecz, Chemist, DOED HFZ-470

The Vitek Proplast TMJ Interpositional Implant was found substantially equivalent to rubber sheeting laminated to polyester cloth. The predicate device is an unclassified pre-Amendments device, and when K823549 was reviewed, had not had a procode assigned. The procode ELE, assigned to subperiosteal implants, was used for K823549 because at the time it seemed to be the most appropriate procode assignment available.

The Dental Products Panel met April 21, 1989 for the purpose of making classification recommendations for TMJ implants. Prior to this meeting, a procode assignment for TMJ implants was established. The procode for TMJ implants is LZD.

Jane Yurawecz

Mr. LEVITT. I would ask Mr. Barry Sands to respond to that, please.

Mr. SANDS. The basis for equivalence, the Vitek IPI in that 510(k), was based on the use of Silastic sheeting for the treatment of what they refer to as "trismus." That indication interpreted at that time, and the manner in which the literature reflected how that pathology was treated, demonstrated that Silastic sheeting could be used in the TMJ joint.

So in the 510(k) for the Vitek IPI, there was a published article comparing Silastic sheeting to that of the Vitek IPI device, with the conclusions that the results were equal or better than the Silastic device.

Mr. SANDERS. Mr. Benson, at the FDA panel meeting on TMJ implants in 1989, an FDA official suggested any manufacturer that made a TMJ implant of any material could market their device as substantially equivalent to preamendment devices. Is that still the position of FDA today?

Mr. SANDS. At present, if a manufacturer intends to market a device, they do have the avenue of premarket notification. In today's review of the 510(k), as Mr. Levitt referred to, the battery of information is much more intensive in what we require and would also include lengthy clinical studies to demonstrate equivalence.

Mr. SANDERS. Mr. Benson, given the disaster with Teflon TMJ implants, I would hope at least FDA has learned something about the dangers of Teflon from this experience. How has the information from the Vitek implants influenced FDA's regulation of other Teflon implants?

Mr. BENSON. I think that is a very good question and I think that we need to continue to emphasize internally what we learn from one set of products to another. I think this lesson has been going out in the last year or so, vividly, at least it has in my mind. I think that we have a number of strategies in place. I will just mention one concept. If you would like to go into more detail, I would ask Mr. Levitt to do that.

Simply put, I think what we have learned is that Teflon, silicone, same principle, when it is in a load-bearing situation, it may break down into particles. Those particles are likely to cause foreign body reaction. This is not a good thing.

Therefore, we have to systematically look at the performance characteristics of products that are made of these materials or these kinds of materials. It doesn't mean if they are in nonload bearing for other uses that they would be inappropriate. They may well be appropriate. But where there is clear information, then we will act to remove those products from the market with whatever vehicle is appropriate.

We can go further with this if you like.

Mr. SANDERS. Mr. Levitt.

Mr. LEVITT. If I could add one additional point, speaking specifically to the TMJ use. At the panel meeting that you referred to, the panel recommended that these kinds of products for TMJ, IPI, interpositional use, and so forth, be put in class III, which would require full extensive premarket testing under investigational device exemption and premarket approval application.

We need to act on that recommendation and move that process forward.

Mr. SANDERS. Mr. Benson, the FDA is currently considering approval of Polytef, an injectable Teflon product for use in the bladder to correct incontinence and related problems. Polytef is already on the market for the treatment of vocal cords.

When the FDA advisory panel met to discuss this product, were they given information about the dangers of other Teflon products, such as the TMJ implants?

Mr. BENSON. I don't know the answer. Perhaps Barry does. He is saying he doesn't either.

Mr. SANDS. As far as specific to the TMJ use, no, they were not.

Mr. SANDERS. They were not given that.

Mr. SANDS. No.

Mr. SANDERS. Given this history of problems with the Vitek implants, Mr. Benson, why isn't the FDA reconsidering the use of Teflon injections for any purpose and why would you consider a new kind of treatment that could potentially harm millions of people?

Mr. BENSON. The answer to the first question is that I think it fits under the answer I gave you a few minutes ago, that we are going to look—I didn't want to get into great detail, but we need to look at, in the case of the vocal cords, what would not be a load-bearing use. The potential problem with this use of Teflon is that the particles are already there to start with. It is a paste and they have very small particles embedded in the paste.

The concern that is being shown is those particles can drift off and cause the foreign body reaction that we have been talking about. We have to look at that and we have to see if there are foreign body reactions in that case. Let me make it hypothetical: The vocal cord case—if there is a better way of solving the problem, if the benefit of that use outweighs the risk of those foreign bodies, we will look at that.

In the case of load bearing, as I said, with load-bearing use, we already know, I think, that it is inappropriate.

In the case of the bladder use, I would only say that it really is inappropriate for us to discuss an open application publicly, but we are obviously considering what to do about that.

Mr. SANDERS. Mr. Benson, Polytef is currently available for treating vocal cords which means it can be used for "off label" treatments that are not approved by the FDA. According to Dr. Nir Kossovsky, a professor at UCLA, several years ago a 2-year-old girl had half her bladder removed as a result of problems of Teflon injections with this product.

Since that is not an approved use, would such adverse reactions be likely to come to the attention of the FDA?

Mr. BENSON. We would hope they would. It is the only vehicle really that we have to warn people. We take that information and we have really taken it upon ourselves to get out and issue alerts or issue warnings of one kind or another when that happens.

There is an obligation now, as a result of the new amendments, the law passed in November for users—that if such a procedure were done in a hospital, that hospital must report that reaction to the manufacturer and in certain cases, report it to us.

We have a longstanding voluntary program where we encourage physicians, and Dr. Kessler is presently trying to beef up that program, agencywide, to get more adverse reactions reported to the agency.

At the same time, I am very anxious within our center to do a better job of focusing in on problems when things like that come to our attention so we can take action.

Mr. SANDERS. Would it be fair to say most adverse reactions really are not reported? Would that be a fair statement?

Mr. BENSON. We have a saying—not a saying, but an observation, that it is hard for us to know what the denominator is to things. That is the answer I would have to give you. We don't know how many adverse reactions occur, so it is hard to know what the percentage is.

Mr. SANDERS. Dr. Nir Kossovsky has published an article describing the severe persistent chronic inflammation, swelling, and pus resulting from Teflon injections. I know Dr. Kossovsky is on an FDA advisory panel for other devices, so I assume you are familiar with his work.

How has this article influenced FDA's position on Polytef Teflon injections?

Mr. BENSON. I am not familiar with that work. I am afraid—I have to check, maybe some of our people are.

Mr. SANDERS. Is there anybody on the panel who is familiar with that article?

[A summary of that article follows:]

In vivo characterization of the inflammatory properties of poly(tetrafluoroethylene) particulates

Nir Kossovsky,* David Millett, Saad Juma,[‡] Nancy Little,[§] Preston C. Briggs, Schlomo Raz,[†] and Eric Berg[#]

Biomaterials Bioreactivity Characterization Laboratory, Department of Pathology and Laboratory Medicine, and [†]Division of Urology, Department of Surgery, UCLA Medical Center, Los Angeles, California, and [#]American Medical Systems, Minnetonka, Minnesota

Suburothelial injections of particulate poly(tetrafluoroethylene) (PTFE) is becoming a widely accepted treatment for a number of urological disorders. Because little is known about the long-term histologic morphology of the injection site, this animal study was performed. Three populations, each consisting of two mongrel dogs, five New Zealand White rabbits, and 10 BALB/c mice, were injected with poly(tetrafluoroethylene) particulate in a glycerine carrier (Polytef Paste) and were followed for a period of 1 week, 3 months, 6 months, and 1 year. Mice received one subcutaneous dorsal injection each, rabbits received two subareolar injections each, and dogs received three subareolar injections each in addition to two periurethral injections. Histologic examination of the biopsy sites revealed a persistent chronic inflammatory reaction with progressive growth of the involved tissue volume. In addition to giant cells and macrophages, lymphocytes became apparent at 3 months and constituted up to 40% of the cellular infiltrate by 1 year. Plasma cells were also noted at the 1-year period in the rabbit model. The progressive growth of the inflammatory pseudotumors evoked by injected PTFE may compromise the long-term safety of certain urological procedures involving particulate PTFE.

INTRODUCTION

Periurethral injections of materials have been used to treat urinary incontinence since the 1930s. Over the last 20 years, dispersed particulate poly(tetrafluoroethylene) under the trade name of Polytef** has become a material of choice for this procedure. Although this product generates a grossly satisfactory suburothelial mound, little is known about the long-term histologic

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**Mentor O&O, Hingham, MA, presently distributed by Mentor Corp., Goleta, CA.

Journal of Biomedical Materials Research, Vol. 25, 1287–1301 (1991)

CCC 0021-9304/91/101287-15$4.00

Mr. BENSON. No. We will collect and get back to you if you will like.

Mr. SANDERS. You will provide us with that information?

Mr. BENSON. Yes, we will.

[The information requested had not been provided at the time of printing.]

Mr. SANDERS. Mr. Hobson.

Mr. HOBSON. I would like to ask one question. Some years ago as a young businessman, I realized I was having great pain. I didn't know why. My oral surgeon told me—and my jaw drops out, still does. I won't do it for you here.

I went to a couple of oral surgeons and they told me that somehow—now, the best I can remember, the explanation was that somehow my jaw, one side is off from the other side—and they could do certain things but they weren't sure that would be effective and alleviate the pain; or I could live with it.

I could live with it dropping out and I have always been able to get it back in except for a couple times it scared the hell out of me when it didn't go back in—especially one time when the dentist couldn't get it in and I got it back in. It is rather frightening. I didn't have anything done.

My pain, either I live with it and I don't know it is there or it went away, but I didn't have anything done because he told me at the time what was going to happen, and they weren't sure that it would do any good.

We talk about the materials, but do we talk about who does the protocols? I am looking through some of the data. Fifteen to twenty percent, they are going to use, whatever, in this one position here. Where is the protocol and who says to the patient—who designs that? Is this something that comes out periodically?

FDA obviously has some stuff—these are the things you use when you decide that you are going to do it. But does the dental society? The dental schools? Who makes this decision and how does the patient know? When you are in pain, you will do almost anything to get rid of that pain or even if you think it will, because you—there is an excruciating pain that you just want to stop—it just drives you—it is really difficult.

I guess what I am concerned about is making sure that the patient gets the information and that the physician—the oral surgeon or whoever, or even the general practitioner looking at these people—where do they get the data that says, hey, these things are only used in extreme cases.

Who does that and whose responsibility is that for the ordinary patient?

Mr. BENSON. I—let me try to address at least part of it.

Mr. HOBSON. If you can't answer it, who should we ask?

Mr. BENSON. Let me address part of it and perhaps Dr. Löe or someone from NIH would like to pick it up. I think what doesn't exist here and what we want to push are the proper experiments and clinical trials that will give us information about the appropriate use of these devices. That information hasn't been collected and hasn't been evaluated by the FDA. We need to do that.

That is what Mr. Levitt was referring to a few minutes ago when he said we have to get on with the classification and call for data

processing. That hasn't happened. It needs to happen. I want to make it happen. That is part of getting the answers to specific practitioners and, in turn, to specific patients so that they will know when a given therapy is appropriate and when it isn't.

That experimentation hasn't been done, at least not in a way that has been presented to the FDA. I should make that caveat. I would defer to Dr. Löe.

Dr. LÖE. What you are talking about, Congressman, are standards of care. I believe there are many channels of communication for the concept of standard of care in various areas of therapy. However, when it comes to questions of practice or malpractice, decisions remain with the States and licensing boards.

In terms of communicating to professionals the optimal care for various diseases and disorders, that comes through the dental schools, through the curricula and the teaching and education program. Graduates learn new concepts and standards through continuing education courses, and through the professional societies. I believe that the American Association of Oral and Maxillofacial Surgeons have criteria for standard of care.

We at NIDR or NIH do not have the authority and do not try to encompass expertise in every area of dentistry. In the case of TMD's, we have recommended conservative approaches and reversible procedures whenever possible.

Mr. HOBSON. Let me ask you this. I was chairman of health for 4 years in the State of Ohio. I was on the Health Committee for the full 8 years I was in the legislature. I can tell you from my experience, the dental boards and medical boards are not truly effective, in my opinion, at getting at this type of issue, because peer review, in my opinion, is very lax and it is not the best result.

Do you have any dialog with—and do you need assistance through legislative authority or through other types of things, to talk to the people that are making the curriculums, that are making the protocols that go across these countries to various States and say, "Hey, we don't have enough data on this or we don't have the authority to talk to these people."

Is there not a dialog?

Dr. LÖE. Sir, I think there is a dialog. I think the NIDR and the American Association of Dental Schools, for instance, have excellent communications, so that dental schools are very much aware of the current frontiers in oral health research and science. That information is incorporated into both the predoctoral and postdoctoral curricula.

With regard to the practicing profession, there is a less structured and probably a less controlled type of information that flows from us and from others into the professional societies and the specialties and into continuing education channels.

Mr. HOBSON. Let me ask you one other question. This was some data I had trouble getting when I was in the State legislature, not in just this particular field. And so I am not just picking on this area.

But you can't find out very readily in a State, for example, how many of these procedures are being done—you may find out where there is public money involved, how many are being done. But in the private sector where there are private funds, it is very difficult

to find out the number of these procedures that are being done, whether it be this procedure or some other procedure.

I don't care if it is an OB/GYN or whatever you are talking about. The data that comes back doesn't tell you how many in Cleveland, OH, are being done, or how many in Cincinnati, or wherever. And you try to get that data to find out who is utilizing this, who may be overutilizing. You can't find that stuff out.

Dr. LÖE. There is no complete system. There are other areas probably more important than the ones we are talking about, like genetic diseases.

Mr. HOBSON. That to me is something our Chair here ought to be, in my opinion, looking at—the collection of data, not just on this issue, but other issues so we know where there is overutilization. You can't find out who is improperly doing things very well.

Mr. SANDERS. Mr. Hobson, if I could jump in.

Dr. LÖE. Mr. Hobson, could I add one more source. It could at least get a partial solution to these problems of reporting.

We can obtain data from the National Center for Health Statistics on hospital discharges. Most of these procedures are done in hospitals, so at least we get a sense of how many open surgeries of the TMJ have been done in a particular hospital. What is happening out in the practices, in the outpatient environment, there is no systematic way of knowing.

Mr. HOBSON. OK.

Mr. SANDERS. I think Mr. Hobson raises perhaps one of the crucial issues of this whole discussion. Perhaps if you had gone to another oral surgeon, you might have been treated very, very differently and there is a not a base of information for those physicians to make a decision.

Mr. HOBSON. That is not only true in this area. To me, that is one of the basic difficulties we have in the whole health care arena in looking at data and looking at utilization and trying to know what works and what doesn't work. What particular groups of specialties are effective—I mean, I happened to get into some of this stuff in the State.

In one part of Ohio, if you appeared to look like a woman, there was a certain procedure you were going to get in that part of Ohio. There was tremendous overutilization in that part of the State where it appeared. Again it was only where public money was involved and we could get the data. To me, that is a real health care problem in this country. We don't know enough about what is happening and who is establishing the protocols.

When you go into some physicians' offices, they are so inundated with papers that come in the door on not only procedures, but on types of medications and other stuff to use, that you don't know—they don't know many times to keep up. It is very difficult.

Mr. SANDERS. I would agree with you. I don't know if you remember, but last week, in approving the NIH authorization, we passed a national cancer registry effort which, in fact, I introduced into the House just for that reason. We don't have the national statistics. I think you are exactly right.

Mr. Benson, let's continue if we might.

The FDA first heard reports with problems with Teflon TMJ implants through medical device reporting [MDR] systems in 1986, but according to FDA memos, the first reports were ignored. It took 2 years for the FDA to take these reports seriously. Meanwhile, thousands of patients had these devices implanted.

Why did it take so long?

[A memo describing the MDR's follows:]

Mr. BENSON. I am not aware when the first MDR reports came in. Maybe Mr. Niedelman is. As I looked over the background for this hearing, what hit me was that it was a study that was done, I think in Ohio—Iowa, I am sorry—that really brought it to our attention and caused us to focus on the problem.

Do you have any information on the MDR reports, Steve?

Mr. NIEDELMAN. The MDR reports you are referring to were received in April 1986 and we understood them to be malfunctions at that time of the device. They were not high priority problems, although a directed inspection at the firm did follow, several months thereafter, that captured MDR as well as other issues at the plant.

Mr. SANDERS. Is it fair to say this information was quite public?

Mr. NIEDELMAN. MDR reports are, yes.

Mr. BENSON. If I may make a further point on that. In retrospect, I wish we would have acted more swiftly, but you can say that, you know, for just about any problem that emerges. As it first comes to your attention, you only see limited data and that data has to be reinforced for you to realize you have a problem. Retrospectively, I wish we had acted more swiftly.

Mr. SANDERS. In November 1986, the company acknowledged problems when they sent a "Dear Doctor" letter regarding bone loss caused by the implants. Moreover, in November 1987, the company revised their failure rate from 8 percent to 17 percent. Do you agree with that?

Mr. LEVITT. That is correct.

Mr. SANDERS. Eventually, Vitek's Teflon implants were removed from the market, primarily because of an avalanche of lawsuits. Last fall, the FDA finally published a public health notice warning about the problems with Teflon implants, and yet we have heard testimony that many patients and doctors still know little about the dangers. This is the point Mr. Hobson was making.

In some cases, people with these implants may not realize that an immune reaction might be creating a hole in their skulls, leaving the brain unprotected. What is FDA planning to do to help notify patients?

Mr. LEVITT. First, it is important to point out that the FDA has made a number of attempts and very good faith attempts to try to notify as many patients as possible. This includes a safety alert to health professionals that was issued near the end of 1990, followed by a press release which would go to lay press, as well, in January 1991.

We initiated, as has been acknowledged, a widespread patient notification program, and without belaboring it, let me say in that program, in the fall of 1991, we used publications that reached over 50,000 health care practitioners. We utilized 40 professional organizations, 8 TMJ support groups, and over 500 consumer groups to try to reach as many patients as possible.

We tried to use this multiplier effect which we felt was the most advantageous way to reach people. Clearly, it has not been enough. We are undertaking additional steps as well. We are going to be sending notifications to dentists across the country and are developing a strategy to deal with that.

Mr. SANDERS. Would it be fair to say at this point, despite all your efforts, they have not worked?

Mr. LEVITT. They have not worked as much as we would like.

Mr. SANDERS. Do you want to be more specific on exactly what you will be doing to make sure they do work?

Mr. LEVITT. The specifics we are preparing to undertake are still in the final stages of development but they include, for example, a direct mailing to over 100,000 dentists in the country.

Mr. SANDERS. These, presumably, are all the dentists that would be performing these procedures.

Mr. LEVITT. All the dentists in the country, so we don't have to try to figure out which ones are using it and which ones are not.

Mr. HOBSON. What about hospitals?

Mr. LEVITT. Yes, hospitals have been part of that already.

It has been, I think, frustrating for us also that the response has not been as great. As I said, we have tried to utilize a number of mechanisms and are going to keep upgrading that until we achieve an acceptable level.

Mr. SANDERS. Can we agree we have a serious problem, that efforts up to now have not yet succeeded, and our goal is to make sure every patient has all available information to understand the risks involved?

Mr. LEVITT. I think we can certainly agree the efforts taken so far have not achieved the degree of success we need to. We need to do much more—we can have a goal to reach every single patient. I am not sure, realistically, that will ever be achieved. We will make every effort possible toward that goal.

Mr. SANDERS. Patients have to pay to enroll in the TMJ implant registry and very few have done so. I think we can all agree this registry has not been a success thus far. If the FDA wants to provide information to implant patients in the future, there is no way to contact them directly; isn't that correct?

[An FDA document describing TMJ implants and the registry follows:]

Sample Questions and Answers about TMJ Implants

How can I find out what kind of implant I have?

Contact your implanting surgeon and/or hospital for the name of the implant. If you were reimbursed by your health insurance company, they should also have the information.

What should I do if I have a Vitek TMJ implant?

Contact your implanting surgeon or another oral maxillofacial surgeon to schedule a clinical examination and have an MRI or CT examination if you have not had one within the last six months.

What is the problem with the Vitek TMJ implants?

Vitek implants are composed of Proplast and other materials. These materials have been shown to either break apart or fail to function because of the forces caused by chewing.

Because the materials break apart (fragment), it may be very difficult to remove all particles and some symptoms may persist after surgical removal of the implant. Additional medical treatment may be required.

What are the common symptoms associated with the Vitek TMJ implants?

Symptoms may vary widely, and in some cases, may mimic sinus infections, ear infections, and/or loss of hearing. ***In some cases there are no symptoms even though the implant is failing.***

The most common symptoms are:

- pains near the ear on the side where the implant has been placed and/or headaches;
- limited lower jaw movement along with a change in the bite or the way the teeth meet;
- joint noise in the jaw;
- nausea, dizziness, or ringing in the ear; and,
- increased sensitivity in the head, neck and shoulder.

If I don't have any problems with the implant, should I still make an appointment?

Yes. Changes, such as bone loss, can occur even without symptoms. These changes can only be found through careful medical evaluation.

What should I do if I have the symptoms described earlier?

Contact your implanting surgeon or the surgeon who now treats you. Schedule an appointment for a clinical examination and a CT or MRI examination. Screening radiography (limited skull radiography and tomograms) may be needed to determine if metal was used with some of the implants. For nonmetallic implants (those without metal), MRI will help to discover if there are signs of foreign body giant cell tumor response, implant break down, and/or destruction in bone and/or soft tissue. A CT scan may be used under special circumstances or when an MRI is not advisable. Depending on the results of these examinations, it may be necessary to remove the implant as soon as possible. ***Speedy removal will prevent further damage.***

What if I'm not having symptoms, should I have the implant removed now to avoid future problems?

Not necessarily, but you should be followed routinely. However, if there is evidence that the implant is breaking up, the implant should be removed if possible, even if you have no symptoms. If you are experiencing pain or a change in your bite, this may be a sign that the implant is breaking up and removal should be considered. Contact your implanting surgeon or the surgeon who now treats you.

What alternatives to the Vitek TMJ implants are currently available?

The use of the patient's own bone grafts have shown success in certain cases. There are other options available, but for the best option for you, please consult with your implanting or oral maxillofacial surgeon.

If I've had my implant removed, should I still make an appointment with my physician?

No, but if you experience any of the symptoms, make an appointment.

If I've had my implant removed, do I need to enroll in the registry?

Yes, enroll in the registry. There may be situations where because of the difficulty in removing all the particles, soft or bone tissue changes may still occur. The registry will allow you to receive additional information should it become available.

What is the cost of joining the registry?

There is an enrollment fee of $20. On your enrollment anniversary date (12 months after you first join the registry), there an a $10 renewal charge to maintain your records.

Why do I have to pay the registry fee?

Ordinarily, Vitek, the manufacturer of these TMJ devices, would be responsible for the patient notification program. However, the company has declared bankruptcy and has been unable to finance this program.

How can I find an oral surgeon for consultation?

Call your local or State dental society or a major medical or dental school in your area.

Where do I sign on the enrollment form?

There are two places for your signature on the form:

- To grant permission to Medic Alert to release your name to the FDA, sign in the box at the bottom of the registry form.
- To enroll in the International Implant Registry (IIR), sign in the space under item number 7.

You should know that granting permission to Medic Alert to provide the FDA with your name and address does not automatically enroll you in the International Implant Registry (IIR).

Mr. LEVITT. That is correct.

Mr. SANDERS. In April 1989, an FDA advisory panel recommended that TMJ disc replacements should be a class III device, which would require manufacturers to submit proof that their implants are safe and effective. The panel was unanimous that the FDA consider this a high priority, because of the damage that patients were experiencing. This would have applied to all TMJ disc replacements made of silicone, Teflon, or other materials.

How is it that more than 3 years later, the FDA has not yet published a proposed rule in the Federal Register?

Mr. LEVITT. First let me say, as you referenced earlier, that we fully recognize the need to move forward and move forward swiftly on that.

I think that in retrospect there are a number of factors that have gone into the time. One is that, of course, the particular Vitek IV(a) product was withdrawn from the market by the company.

Second, we have undertaken a large number of regulatory steps vis-a-vis the company involving multiple inspections, multiple seizures, the patient notification programs that we have talked about briefly, and so on. We also, of course, in addition to this particular product within the center, deal with, of course, a wide variety of products. We receive over 10,000—between 10,000 and 16,000 applications per year that all need to be dealt with.

And we need to balance all the different functions, and responsibilities that we have. We try to balance them as best we can. Often, in retrospect, it is clear that some actions should have been readjusted on the priority list.

Mr. SANDERS. The fact remains, 3 years have come and gone and we still do not have a proposal for the Federal Register.

Mr. BENSON. I think this hearing has focused attention on this issue. It certainly has focused my attention. We will get that out as rapidly as we can. I can't control it once it gets out of the center, but we will have it out of the center by the end of this month.

Mr. SANDERS. Thank you. I have a copy of the draft of this proposed rule, which is apparently not ready for publication in the Federal Register. For at least 5 years, FDA has known how badly some patients have suffered from the Vitek implants and there have also been similar concerns about the Dow Corning silicone implants, about titanium implants, and other implants for many years.

Why is it taking so long to publish a proposed rule?

Mr. LEVITT. I am sorry. Is that a different one than the one you just referenced?

Mr. SANDERS. It broadened the question a little bit.

Mr. LEVITT. I believe it was the same document, the same answer would apply.

Mr. SANDERS. I guess the point is, there is concern about all these implants.

Mr. BENSON. It may be worth it, for the record, just to reference the classification process itself. The FDA faces roughly 70,000 manufactured products, 70,000. Back when the device amendments were passed, there were roughly 1,700 or 1,800 product types, individual product types. Each of those needed to be classified, going

through a rather rigorous and drawn out classification process that included panel discussions, proposals, final regulations, and so on.

That process has taken us a long time. I think that we are in the final stages now of collecting, if you will, some of the products that were not earlier classified. I think your question refers to a collection of those.

Mr. SANDERS. Just out of curiosity, do you feel you have the staffing to respond as rapidly as you should be responding?

Mr. BENSON. That is always a difficult question to answer. I think that when you think about having—and I feel overwhelmed sometimes—70,000 products out there, each of which has potential for doing harm, and our job is clearly to protect the public and that is what we want to do—we have got to sharpen our ability to be able to collect information as it comes to us, as we were talking about earlier.

We have to be able to focus attention on that information, analyze it, figure out whether there is a problem, that there is some kind of corrective action that can work. We get it out there. Is it enforcement action? Do we need to take a product off the market? Do we need to warn physicians or patients? If we had more resources, we could do better at that. There is no question in my mind. We are trying to do the best we can within the constraints we have.

Mr. SANDERS. The problem here is that new technology is exploding. For somebody suffering who is in pain, it doesn't do them any good to hear you have 70,000 devices to look at. The question is, we, as the U.S. Government, have a responsibility to deal with these problems. I am not sure I have gotten a clear answer other than we all know there are a lot of devices out there.

Can we respond as rapidly as we should be responding to protect the public?

Mr. BENSON. I think we constantly try to improve what we do within the resource constraints that we have. If we had more resources, we could do more, there is no question about that.

Mr. SANDERS. Even if the proposed rule that we were talking about was published tomorrow, it would take months for that rule to be final; and then, by law, the FDA would have to wait at least 30 months to require the manufacturers to submit their safety data. So we will have to wait at least 4 to 5 years before the FDA actually reviews safety data; isn't that correct?

Mr. BENSON. If we follow the procedure—you have accurately portrayed, the law requires us to go through from classification to calling for data for class III preamendments devices.

For some of the products contained in that recommendation, it might be possible to go more swiftly. If we determine that a product was not on the market prior to 1976, then we could make a determination that a PMA [premarket approval application] was required right away. But if a manufacturer, the sponsor, hasn't collected the data on that product, they are not going to be able to submit it to us. It is going to be, at best, many months.

Mr. SANDERS. In the meantime, the most commonly used TMJ implants are probably the ones made of silicone by Dow Corning. These are grandfathered devices as well. Has the company ever

provided research evidence to FDA that these devices are safe and effective?

Mr. BENSON. Mr. Sands should answer that.

Mr. SANDS. Since the Silastic implant was out there prior to 1976, and demonstration of that device was out there prior to 1976, it has legal status to be marketed. Subsequently, we did receive premarket notification for a modification of that device, but the only modification of that device was a small geometrical change in that device and, thus, did not require extensive clinical studies to demonstrate the safety and effectiveness.

Mr. SANDERS. Just for the record, then, what we are saying is that the company has never provided research evidence to the FDA that the most commonly used TMJ implants are safe and effective. Is that a fair statement?

Mr. SANDS. Within the context of the applications I have seen, they have not.

Mr. BENSON. In fairness, they have never been required to.

Mr. SANDERS. We understand that. In fairness, also, I think for most lay people, this would indicate a real problem.

We heard this morning that during the 1980's there were many published studies showing these silicone TMJ devices cause many of the same problems as breast implants and Teflon TMJ implants, especially the giant cell foreign body immune response.

Dow Corning responded by recommending their Wilkes implant as a temporary device for only 1 to 2 months; is that correct?

Mr. SANDS. In the 510(k), is that what you are referring to within the application?

Mr. SANDERS. In general.

Mr. SANDS. In the application, they notified us that it was limited to 4 months of implantation. Currently, it is 1 to 2 months.

Mr. SANDERS. Currently, they are recommending 1 to 2 months?

Mr. SANDS. Yes.

Mr. SANDERS. However, their silicone sheeting, which is sometimes also used for TMJ implants, has no such warning and may still be used permanently; isn't that correct?

[The instructions for the Wilkes TMJ implant and the silicone sheeting follow:]

SILASTIC®
BRAND

Temporomandibular Joint Implant H.P.

(WILKES DESIGN)

INSTRUCTIONS FOR USE

Description

The SILASTIC® Temporomandibular Joint Implant H.P. (Wilkes* Design) is a temporary implant developed for use in treating internal derangements of the temporomandibular joint. The implant was designed to be used in disc removal procedures. Its principal purpose is to prevent formation of postoperative adhesions by maintaining joint recesses. Additionally, it can be used to protect exposed bearing surface cartilage and encodrage resurfacing of eroded cartilage. In such procedures, the implant is placed interpositionally in the joint. A small stem on the implant is allowed to extend through the joint capsule and is secured just beneath the skin to facilitate easy removal. The implant should be removed about one to two months postoperatively in meniscectomy procedures. Removal is accomplished during a simple out patient procedure under local anesthesia.

The SILASTIC® Temporomandibular Joint Implant H.P. (Wilkes Design) is fabricated from implant-grade high performance silicone elastomer and is available in three sizes to adequately meet various operative requirements.

HP

The letters HP in the product nomenclature indicate that the implant is fabricated from implant-grade, high performance silicone elastomer. This elastomer shows greater resistance to tear propagation than conventional silicone elastomer. In addition, this elastomer has excellent biodurability and biocompatibility.

Diagnosis and Staging

Experience has shown that most cases of internal derangement can be categorized into five groups according to disease stage. Moreover, the categories are equally applicable from the standpoint of clinical, arthrographic and surgical/pathological diagnoses. The descriptions of each stage are as follows:

1. *Early Stage*
   a. Clinical: No significant mechanical symptoms other than reciprocal clicking (early in opening movement); no pain or limitation of motion.
   b. Arthrographic: Slight forward displacement, good anatomical

* *Clyde H. Wilkes, M.D., Minneapolis, Minnesota*

SILASTIC® H.P. SHEETING

DESCRIPTION

SILASTIC® H.P. Sheeting (Reinforced, Radiopaque) is a flexible, medical-grade H.P. silicone elastomer sheeting designed for implant applications, surgical repair procedures and laboratory uses. SILASTIC® H.P. Sheeting is fabricated from a Dacron* reinforced, medium durometer** H.P. silicone elastomer, that is visible upon X-ray evaluation.

ADVANTAGES

- Made from medical grade H.P. silicone elastomer, a material highly resistant to tearing and suture pull-out.
- Dacron-reinforced sheet eliminates stretch and permits suture attachment.
- Easily cut to modified shape.
- Adaptable to combined use with autogenous, homogenous and preserved tissue.
- Highly permeable to gases.
- Will not adhere to adjacent tissue, permitting easy removal if desired, with minimal trauma.
- Autoclavable without change in consistency, softness or other inherent properties.
- Excellent biocompatibility.

HOW SUPPLIED

SILASTIC® H.P. Sheeting (Reinforced, Radiopaque) is supplied ***non-sterile*** and individually packaged as follows:

Cat. No.	Description
2403-0020	One ea. 6"x 8"x .020" Thick (non-sterile)
2403-0030	One ea. 6"x 8"x .030" Thick (non-sterile)
2403-0040	One ea. 6"x 8"x .040" Thick (non-sterile)
2403-0080	One ea. 6"x 8"x .080" Thick (non-sterile)

* Dacron is a registered trademark of E.I. DuPont De Nemours Co.

** Shore A durometer of approximately 50.

SILASTIC® - This registered trademark is the brand name for Dow Corning's silicone elastomer products and materials. Only Dow Corning may identify its products with the trademark SILASTIC®. The word is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's material. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

APPLICATIONS

- For surgical repair of fractured orbital floors.
- As a protective sheathing to help facilitate neural-regeneration and tendon healing.
- As an anchoring device for hemodialysis shunts.
- For various laboratory uses (e.g., gaskets and stoppers for microbiological closures and septa in gas-liquid chromatography).
- As a protective sheathing to help facilitate osteogenesis.
- For surgical repair of urethral strictures and duramater.
- To prevent synostosis following corrective surgery for cranial fusions and forearm fractures.
- To prevent soft tissue fibrosis or bony ankylosis following surgical correction of trismus or related TMJ dysfunctions such as meniscus displacement. (Note: It is recommended that SILASTIC® H.P. Sheeting not be used as a permanent interface in the presence of degenerative bone changes or chronic bruxism.)
- For fabricating components in artificial hearts.

DOW CORNING
WRIGHT

5677 Airline Road • Arlington, TN 38002
(901) 867-9971

SILASTIC® H.P. SHEETING

Radiopaque Implant Material

SILASTIC® H.P. Sheeting is fabricated from medical-grade high performance silicone elastomer and contains $BaSO_4$ to provide radio-opacity. This material is one of the most inert implant materials available. However, dust, lint, talc, skin oil deposited in handling, and other surface contaminants can evoke foreign body reactions. Extreme care must, therefore, be taken to prevent recontamination once these deposits are removed.

High Performance Silicone Elastomer

The letters H.P. in the product nomenclature indicate the implant material is fabricated from medical-grade high performance silicone elastomer. This elastomer shows greater resistance to tear propagation than conventional silicone elastomer.

STERILIZATION

The SILASTIC® H.P. Sheeting is supplied ***non-sterile.***

The following sequential steps are recommended to clean and sterilize.

1. Scrub thoroughly with a clean, soft-bristled brush in hot water-soap solution to remove possible surface contaminants. Use a non-oily mild soap such as Ivory Flakes or Ivory bar soap. Do not use synthetic detergents or oil based soaps, as these may be absorbed and subsequently leached out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave by one of the following methods:
   a. High speed instrument sterilization 10 minutes at 270°F (132°C).
   b. Standard gravity sterilization—30 minutes at 250°F (121°C).
   c. Prevacuum high temperature sterilization—either 10 minutes at 270°F (132°C), or 30 minutes at 250°F (121°C).

NOTE:

Gas sterilization is not recommended for silicone elastomers. Should this be the only available method of sterilization, it is essential to avoid inserting the implant material within 10 days of the gas sterilization; otherwise severe tissue reaction might ensue from the in vivo release of the ethylene oxide and validation of safety is the user's responsibility.

CAUTION

Federal (United States) law limits this device to sale by or on the order of a physician.

NOTE:

The purchaser should thoroughly test products made in part or otherwise incorporating SILASTIC® H.P. Sheeting to determine the acceptability of the product's performance in a specific application.

CAUTION—WEAR PARTICLES

In some patients, wear particles from silicone elastomer implants used in bone and joint reconstruction may participate in, or exacerbate, synovitis or bone cyst complications in contiguous bone. These complications have been reported to occur more frequently with scaphoid and lunate replacement implants, and to a lesser degree with trapezium or other spacer implants. Contributing factors have been reported to include the use of implants in physically overactive patients, associated preoperative pathology such as cysts and degenerative changes, intraoperative temporary stabilization with K-wires, uncorrected associated carpal collapse or instability, subluxated implants, implant over or undersizing and uncorrected or recurrent deformity. Synovitis and bone cyst complications seldom occur with flexible hinge implants such as the finger, wrist, hammertoe, and flexible hinge toe implants.

WARNING

Potential for Complications

A thorough discussion of all potential complications that may be associated with implant reconstructive procedures is not possible in product labeling. It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedures and the potential complications that may occur in each specific case.

Implants are mechanical devices that can be worn away, fatigued, or broken. An implant site may become infected, painful, swollen, or inflamed. Strenuous implant loading, excessive mobility, the presence of articular instability, implant oversizing, and patient over-activity or misuse increase the potential for complications including wear or fracture of the implant and particle formation. Excessively mobile joints are generally less stable and an implant alone cannot provide long-term stability in a joint that lacks functional stability; complications necessitating revision surgeries are thus more frequent in unstable joints. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate in time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon. Therefore, surgeons must balance many considerations to achieve the best result in individual patients. Providing each patient scheduled for implant surgery with documented counseling of potential complications is required.

Adverse Reactions

There have been reports in the literature suggesting a relationship between silicone implants and a broad spectrum of connective tissue disease, systemic illness, and autoimmune phenomena, suggesting immunological responses to silicone implants. If any of these possible reactions are suspected and the response persists, removal of the implant should be considered.

Dow Corning
Medical

SILASTIC® Medical Grade Sheeting (Cat. #500, 501, 502)

DESCRIPTION

SILASTIC® Medical Grade Sheeting is a flexible, translucent, silicone elastomer sheeting material designed for medical and laboratory applications.

Three types of sheeting are available in a variety of thicknesses and flexibilities, including:

- Nonreinforced – made from a medium-durometer (50 Shore A) silicone elastomer in five thicknesses (0.005, 0.010, 0.020, 0.040, and 0.060 inch)
- Reinforced – made from a medium-durometer (50 Shore A) silicone elastomer in four thicknesses – reinforced with Dacron®[1] plain weave fabric (0.007-inch sheeting thickness), and Dacron tricot fabric (0.020-, 0.030-, and 0.040-inch sheeting thickness)
- Nonreinforced extra firm – made from a high-durometer (70 Shore A) silicone elastomer in three thicknesses (0.050, 0.080, and 0.120 inch)

Advantages of SILASTIC Medical Grade Sheeting include:

- Body tissue and fluids are minimally reactive to sheeting
- Dacron-reinforced sheet minimizes stretch and permits suture attachment
- Easily cut to size and shape
- May be bonded to itself or synthetics (Dacron, tricot) with silicone adhesive (SILASTIC® Medical Adhesive Type A)
- Highly permeable to gases
- Will not adhere to adjacent tissue, permitting easy removal with minimal trauma
- Autoclavable without significant change in physical properties

APPLICATIONS

The purchaser should thoroughly test products made in part or otherwise incorporating SILASTIC Rx Medical Grade Sheeting to determine the acceptability of the product's performance in a specific application.

SILASTIC Medical Grade Sheeting has been used for the following applications:

- Protective sheathing to help facilitate neutral regeneration and tendon healing
- Anchoring device for hemodialysis shunts
- Various laboratory uses, such as gaskets and stoppers for microbiological closures and septa in gas liquid chromatography
- To prevent soft tissue fibrosis or bony ankylosis following surgical correction of trismus
- Insulating material for electrostimulation devices
- Temporary covering for a prenatally ruptured omphalocele during staged repair

CAUTION

There have been case reports of thickened neomembrane encapsulation of silicone sheeting used in dural repair, with delayed subdural hemorrhage and brain and spinal cord compression[2].

INSTRUCTIONS FOR USE

Cleaning

Scrub thoroughly with a clean, soft sponge or soft-bristled brush in a hot water and soap solution to remove sodium bicarbonate (which is dusted on the sheeting surface to facilitate handling), skin oils deposited in handling and other possible surface contaminants. *Use a nonoily cleaner or mild soap. Do not use synthetic detergents or oil-based soaps, as these soaps may be absorbed and may subsequently leach out to cause tissue reaction.* Rinse copiously in hot water and follow with a thorough rinse in distilled water.

STERILIZATION

Steam

Wrap in nonlinting material or place in a clean, open tray. Autoclave by one of the following methods:

- High-speed instrument (flash) sterilizer – 10 minutes at 132°C (270°F) and 30 psi (2 kg/cm²)
- Standard gravity sterilizer – 30 minutes at 121°C (250°F) and 15 psi (1 kg/cm²)

[1]Registered trademark of E.I. du Pont de Nemours & Co.

[2]Reference: Ng, T.H.K., et al., An Unusual Complication of SILASTIC® Dural Substitute: Case Report. 1990. Neurosurgery 27(3):491-493.

Radiation

Post-radiation testing of sheeting and elastomer reveals minimal physical property changes at 2.5 megarads exposure level, with tensile strength and elongation essentially unchanged. Minimal but measurable increases were seen in durometer and tensile modules at 200 percent elongation. Such property changes are similar to those seen when the sheeting is subjected to additional oven post-curing.

Ethylene Oxide

Ethylene oxide (ETO) will not deteriorate SILASTIC® Medical Grade Sheeting. However, sterilization by ethylene oxide is not recommended unless sufficient data is available regarding the time required for complete outgassing of residual ethylene oxide and other ETO by-products from the specific system employed.

BIOCOMPATIBILITY

Biocompatibility tests, which meet or exceed USP Class VI Plastics Tests, have been performed on the elastomer from which SILASTIC Medical Grade Sheeting is made and are shown in Table I.

Every production lot of elastomer is tested for levels of trace metals and for absence of cytopathic effects using a tissue cell culture test (direct contact method).

TABLE 1: Biocompatibility of SILASTIC Medical Grade Sheeting

Test	*Results*
Hemolysis, percent	<1
Pyrogenicity	Nonpyrogenic[1]
Intracutaneous Injection	Nonirritating[1]
Systemic Injection	Nontoxic[1]
Skin Sensitization	Nonsensitizing[1]
Intramuscular Implant,	
10 days	Nonreactive[1]
30 days	Nonreactive[1]
90 days	Nonreactive[1]
Cell Tissue Culture	No Cytopathic Effect

[1]Based on comparison with defined USP negative controls.

SHIPPING LIMITATIONS

None.

Certification No. FM 10734

STORAGE AND SHELF LIFE

When stored at room temperature, SILASTIC Medical Grade Sheeting has a shelf life of 60 months from date of shipment.

PACKAGING

Each piece of SILASTIC Medical Grade Sheeting measures 6 inches by 8 inches and is individually packaged in a resealable, nonsterile plastic bag.

Description	*Catalog Number*
Nonreinforced	
0.005-inch-thick sheet	500-1
0.010-inch-thick sheet	500-3
0.020-inch-thick sheet	500-5
0.040-inch-thick sheet	500-7
0.060-inch-thick sheet	500-9
Reinforced	
0.007-inch-thick-sheet (with Dacron plain weave)	501-1
0.020-inch-thick sheet (with Dacron tricot)	501-3
0.030-inch-thick sheet (with Dacron tricot)	501-5
0.040-inch-thick sheet (with Dacron tricot)	501-7
Nonreinforced (extra-firm grade)	
0.040-inch-thick sheet	502-1
0.080-inch-thick sheet	502-3
0.120-inch-thick sheet	502-5

ORDERING

These products are sold only through distributors. To obtain the telephone number of a Dow Corning authorized distributor in your area, call a Medical Products customer service representative at 1-800-248-2481.

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MEDICAL MATERIALS
DOW CORNING CORPORATION
MIDLAND, MICHIGAN 48686-0994

Printed in U.S.A. Form No. 51-048E-91

Dow Corning
Medical

Mr. SANDS. With labeling that has been provided to us recently, that is correct.

Mr. SANDERS. In addition, Dow Corning changed their silicone TMJ implant in several ways, including adding a material that would make it show up in x rays. However, Dow did not ask for FDA approval for that change as required by law. What has the FDA done about that?

Mr. SANDS. We have recently become aware of some of the changes that you are outlining and that has been passed on to our Office of Compliance and Surveillance for followup.

Mr. NIEDELMAN. An inspection request has been initiated to follow up.

Mr. SANDERS. Do you think we should have moved earlier, faster?

[An undated draft memorandum regarding these changes follows:]

DRAFT

TO: William Damaska, Division Director, DCO, OCS HFZ-320

FROM: Biomedical Engineer, DEDB, DGRD, ODE

Through: Philip Phillips, Division Director, DGRD, ODE, HFZ-410 ____
Thomas Callahan, Associate Director, ADRD, DGRD HFZ-410____
Louis Hlavinka, Branch Chief, DEDB, ADRD, DGRD HFZ-410____

SUBJECT: Significant Changes to TMJ Interpositional Implant Manufactured by Dow Corning

It has come to our attention that significant changes have occurred to the material composition and labeling of the Wilkes Interpositional Implant (marketed by Dow Corning. In addition, significant concerns exist with respect to the mechanical integrity and performance of the preamendment Silastic TMJ implant (Silastic sheeting).

Dow Corning has or is marketing two types of TMJ Interpositional Implants. The first type is considered to be a preamendments device (marketed prior to 1976). The second TMJ implant is referred to as the Wilkes design. The material composition and intended use of these devices are listed below.

Silastic sheeting (preamendments TMJ implant)	elastomer not specified (radioopaque material not included) three grades available - nonreinforced extra firm grade - reinforced medium grade - nonreinforced medium grade	To prevent soft tissue fibrosis or bony ankylosis following surgical correction of trismus (No restriction on length of implantation)
Wilkes design (K834379)	same material composition as above	Same as above (However, the actual labeling section of 510(k) states that implant is for temporary use only - 4 months)

Three sets of labeling are attached to this memo. Attachment one represents the 1973 labeling for the Silastic sheeting implant. Attachment two represents 1991 labeling for the Silastic sheeting implant. Attachment three represents April 1985 labeling for the Silastic HP sheeting implant. Attachment four represents September 1985 labeling for the Silastic HP sheeting implant. Lastly, attachment

five represents labeling for the Wilkes design that I believe is current (no date on labeling).

Several changes have occurred to the Wilkes version of the TMJ implant. The implant now contains a radiopaque substance (Barium Sulphate). This was not described in the 1983 510(k). The labeling has also significantly changed. The implant was originally intended to be implanted for no longer than four months. Today, labeling states that the implantation period should not exceed one to two months. During this labeling evolution, Dow Corning significantly strengthened the warning of implantation fragmentation, wear particulate production, and other significant adverse events that occur with this type of implant.

The Silastic HP sheeting does not have a 510(k) for use in the treatment of trismus. In addition, the labeling associated with this sheeting does not provide any limitation on the length of implantation in the TMJ. They do caution the reader that significant wear particulate and implant failure can occur.

Although Silastic sheeting does not appear to have changed in material composition, significant concerns still exist. This material is still indicated to be used in the treatment of trismus. However, there is no limitation on the length of implantation, nor is there the significant caution statements that relate to the wear and mechanical breakdown of the implant itself.

The final point to make is that silastic sheeting (all of the above configurations) has very poor wear properties. It has been estimated that silastic sheeting wears 100 times faster than teflon. A article published in the Journal of Biomedical Materials Research (Vol. 22, 475-484, 1988) entitled "Silicone rubber temporomandibular joint (TMJ) meniscal replacements: Postimplant histopathologic and material evaluation" documents the poor wear properties experienced in-vivo. Other articles exist that document silastic TMJ implant failures. In addition, the MDR database contains four MDRs that relate to Silastic TMJ implant failures.

Due to the above concerns, we request that you inspect Dow Corning to document the device changes, including labeling, that have occurred to Silastic sheeting and the Wilkes design over the past 16 years. The complaint files of Dow Corning relating to these devices should also be investigated to determine if all complaints that meet the MDR requirements have been reported to the Center. Lastly, Dow Corning should be informed that the Silastic HP sheeting does not appear to have clearance for marketing, the Wilkes design implant has changed significantly such that a premarket notification is necessary, and that the labeling for the preamendments Silastic sheeting indicated for TMJ use does not have adequate labeling reflecting the recognized (recognized by Dow Corning in the other TMJ implant labeling) device failures that occur when this implant is placed beyond one to two months.

Barry E. Sands

Mr. NIEDELMAN. We just became aware of it in the center.

Mr. HOBSON. Do you know when those changes were made? Six months, a year?

Mr. SANDS. As far as can be seen from the labeling that we have presently, I would say it has been more than 6 months or 1 year. I could not give you, today, the exact time period. I would have to go back and review that labeling.

Mr. HOBSON. But you received no documentation until you saw the labeling?

Mr. SANDS. That is correct.

Mr. HOBSON. When did you receive the labeling?

Mr. SANDS. We received this labeling approximately 2 months ago, I believe.

Mr. HOBSON. May I ask how you received it? Do you have a protocol for receiving it?

Mr. SANDS. What—I won't say commonly—happened, out of concern or just out of advice from the surgeon, someone will sometimes send labeling to us and ask is this current labeling, is this approved? And that is basically——

Mr. HOBSON. It came from the company?

Mr. SANDS. No, it did not. It came from a public citizen.

Mr. HOBSON. Did it come from the company?

Mr. SANDS. No, from a public citizen.

Mr. HOBSON. Has anyone asked the company why they didn't send it to you?

Mr. LEVITT. That is what part of our investigation will look at. The company is supposed to send in what I will call an "amended application" if there are changes in the materials, in the labeling, and so on and so forth. One of the things we are looking at with this product, as well as other products, and letters were just sent out recently, is whether companies involved in these kinds of products submitted the kind of updated applications with new information justifying any changes that they needed.

Mr. HOBSON. Could I ask one more question?

Mr. SANDERS. Sure.

Mr. HOBSON. This brings me to a general statement. Is there a flaw in the reporting procedures that does not get this information to you, or in your surveillance ability to get this kind of information on this product or any other product out there that you are 6 months—I am not suggesting that you are at fault for this, don't get me wrong.

Is there a problem in the system, either from the private sector or from your own sector, that doesn't get you this information in a more timely fashion on various types of changes that may occur in the marketplace?

Mr. LEVITT. There is, I believe, a clear requirement that manufacturers of products update or amend a 510(k) application when they have changes that affect safety and effectiveness.

Sometimes there is a little room for interpretation and some of that may be going on here, but we believe that the system is in place and we are constantly involved in trying to enforce that system and make sure it is working as it is supposed to. It clearly appears here it has perhaps not worked and we are notifying companies and following up to make sure.

Mr. HOBSON. Can I ask you a practical question?

When this happens, does anybody pick up the phone or do you have to write an official letter signed by six people and approved by seven? Can you call up on the phone and say, "Hey, what are you guys doing? Has anyone looked at this? Come down and talk to me about this." There may be a logical reason, or what happens?

Does it have to be so documented it never gets done for 4 months?

Mr. BENSON. I would like to take a shot at that. I think you are referring to the bureaucracy and is there a simpler way to do things. We have tried to streamline the process in a lot of different ways. We give exemptions to people when we feel information isn't needed for safety reasons or effectiveness reasons.

We take a lot of potential information off the table to prevent that. If a company we have—I don't know, 7,000 manufacturers that report to us, many—you know, 70,000 products, you get a sense of the magnitude here. I have no objection to asking people to report in a situation where there is a genuine oversight or it didn't come to their attention.

I think a very difficult issue the FDA faces constantly is a little bit analogous to how you deal with speeders on the street. If we set a precedent of being too lax about our requirements, then I think we are going to encourage speeding, if you will.

I think what we have to do in this case, is with our 17 district offices, about 150 resident posts throughout the country, something like this will trigger an inspection so we will get the data. We will get the information necessary.

If there is a violation of the law that we think was an oversight, the agency will give the company the chance to make a correction. But if it looks like it is a pattern or something intentional, we will bring the full pressure of the law on them. Sometimes we make the phone call, but not always.

Mr. HOBSON. Can I ask you, in this case, has anybody made a phone call?

Mr. BENSON. My guess with the history of Dow Corning, we would not use that approach, appropriately so.

Mr. HOBSON. OK.

Mr. SANDERS. Thank you. Some of us don't quite understand why the FDA has ignored the changes in Dow's implants and the mounting scientific evidence against them. Even today, your testimony does not accurately describe concerns of TMJ researchers regarding the dangers of solid silicone in joint implants.

The bottom line is: The FDA has done nothing in the more than 3 years since the FDA advisory panel recommended that the FDA require safety data. How do you explain that?

Mr. BENSON. This is the third time you have addressed this question.

Mr. SANDERS. It is an important question.

Mr. BENSON. I agree it is an important question. We are going to act on it as swiftly as we can. I can say that again. We are going to act on it as swiftly as we can.

Mr. SANDERS. Let me ask about another manufacturer called TMJ Implants, Inc. A few months ago, the FDA notified TMJ Implants, Inc., that they have made changes in their total joint replacement, called the Christensen device, that required a 510(k) application. The company has protested, saying that the FDA was wrong. A few days ago FDA sent the company a warning letter.

What is the next step?

[Warning letters to several manufacturers are in app. 3, p. 224.]

Mr. NIEDELMAN. Denver district was, in fact, to meet with the firm regarding this letter that they issued to TMJ Implants, Inc. The firm was given 15 days to respond to the letter demanding the submission of a new 510(k) and was being requested they discontinue further distribution of the device until such time as a 510(k) is found substantially equivalent, if that is possible, in contrast to going through the investigational device PMA approval process.

Mr. SANDERS. Dr. Christensen, the president of TMJ Implants, Inc., has contacted this subcommittee to inform us about the quality of his implants, and he has asked several surgeons to do so as well. I appreciate their providing this information. However, when the subcommittee requested research data indicating the safety and effectiveness of the implants, Dr. Christensen sent 30-year-old articles describing short-term success in a handful of patients.

Don't you think it is time that the FDA asked for research data regarding this device?

[Documents provided by several implant manufacturers are in app. 4, p. 243.]

Mr. BENSON. It is included in the panel, is it not?

Mr. SANDERS. Yes.

Mr. BENSON. It will be part of that classification procedure we were just talking about. The answer is yes.

Mr. SANDERS. Do you think we will get better information than 30-year-old articles?

Mr. BENSON. Ultimately, if we don't, the product won't be on the market.

Mr. SANDERS. You appreciate the problem here is that this is a widely disseminated device and what this subcommittee has received is short-term success stories of 30 years ago, which some might think is a little bit out of date and not quite up to par.

Are we in agreement on that?

Mr. BENSON. That is—yes, we are in agreement.

Mr. SANDERS. The FDA has also contacted another manufacturer, Techmedica, regarding their TMJ devices. We had witnesses this morning who are optimistic that this device will succeed where others have failed, but unfortunately, again, there are no long-term studies. If FDA classified TMJ implants as class III devices, companies like Techmedica would have to conduct safety studies and submit them to FDA. What are you waiting for?

Mr. BENSON. For the fifth time, sir, we are going to get the classification regulation out as swiftly as we can. I want to get that done, and that will resolve those issues.

Mr. SANDERS. Will you forgive the impatience of the subcommittee, but you have heard this morning about the pain and suffering that exists. There is a widespread feeling that the FDA has not moved as swiftly as it could.

The subcommittee invited the manufacturers to provide written testimony and copies of research data for inclusion in the hearing record. Based on their responses, none have any long-term studies.

In addition, Dr. Homsy, the former president of Vitek, who wrote from Switzerland, is still claiming he has research evidence showing his products are safe. He is apparently still selling them despite the overwhelming evidence that they are dangerous. This is a good example of how biased manufacturers' safety claims can be.

What can the FDA do to ensure that the research provided to the FDA is less biased and of better quality than some of the research evidence you have received in the past?

Mr. BENSON. One thing that we are doing is beefing up our bioresearch monitoring group within the center. This has not functioned in as strong a way in the past as it should.

Ultimately, I think the way to assure that we get good data is to make sure that manufacturers understand the importance of that. We need to be very clear that we can't allow fraudulent data, poor data, inadequate data, in support of approval for a product.

That is a step that I think we are doing our best to make clear. As far as this particular example is concerned, we have an import alert on those products, we have notified foreign governments about the problem, and so we are trying to make sure that others, as we heard this morning from the first panel, are not subject to the same problems.

Mr. SANDERS. Mr. Hobson.

Mr. HOBSON. I want to ask something for the record here. Is it fair to say that this Homsy Vitek IPI is not an effective product, that it is not sold in this country currently, but that it is sold in other parts of the world, and people might be going outside the country to get this product, and do we have the ability—I want to get this on the record—do we have the ability to protect our citizens from this type of product?

Mr. BENSON. All the systems that the FDA has at its disposal are in place to prevent your concerns from reaching a realization. We work with the Customs Department, we have an import alert out, which means that in conjunction with customs, we will prevent or attempt to prevent any shipments into this country.

We have warned, again, as I mentioned, other countries about the problem. As far as your first question goes, we certainly have enough evidence that has caused us to act against the product and rescind the 510(k) for the product. That doesn't preclude additional studies or additional proof. We have reached the conclusion that the product is not functioning properly.

Mr. LEVITT. If I might add for the record, we do not have any information that they are selling or distributing the IPI product anywhere, although we do believe he is selling a hip product to other countries. But there is no evidence that we know of that he is distributing the IPI product anywhere in the world.

Mr. HOBSON. Thank you.

Mr. SANDERS. Dr. Löe, we will address the next question to you. Dr. Löe, this year the NIDR plans to spend about $3 million on TMJ. That amounts to 30 cents per year per patient using your estimate of 10 million patients who experience relatively serious pain.

Why do we have so little funding available to study a problem that affects so many millions of Americans and costs the Federal Government billions of dollars in medical bills, lost productivity, et cetera?

Dr. LÖE. First of all, I am not sure the mathematics you are giving me here has any relevance to the operation of the NIDR. We spend approximately 2 percent of our budget for TMJ research. That is very comparable with some of the other diseases that we study.

Paget's disease, diabetes, cleft palate, they are all in the same category of $3 to $4 million per year.

We have a budget of about $159 million in fiscal year 1992. We have commitments to study an array of problems, from dental materials to genetic diseases. And so there are plenty of diseases and disorders to go around.

I should add that I don't think that we are funding less quality research in the area of TMD's. You have to realize that over these 10 or 15 years, we have built up some capability in this area, and we are funding quality research. We have been very conservative in trying to establish diagnostic criteria and good classifications of these diseases, so that we know what we are doing. But we are not haphazardly funding any kind of treatment approach that may develop here or there.

Investigators have to submit applications for peer review, and we try to fund them in due course relative to the quality of their application. That is the process we use at the NIH.

Mr. SANDERS. Do you think serious and worthwhile applications being submitted to you are not being acted on because of inadequate funding?

Dr. LÖE. I can tell you that over the last 10 years we have had seven applications in the area of joint implants. We have funded four of them. Now, that is higher than we usually are able to fund in an area. Typically, we fund only one out of five applications. So in this particular area, I think we have been generous.

Mr. SANDERS. Is that response because of lack of funding or because you felt that the applications were not of high enough quality?

Dr. LÖE. No, we funded them because they were quality applications.

Mr. SANDERS. The NIDR has not funded any clinical studies of the effectiveness of TMJ implants or their short-term or long-term dangers. It has funded very few studies of treatment of any kind for TMJ. However, after this hearing was announced, the NIDR apparently decided it would fund a meta-analysis of treatment studies.

Dr. LÖE. That is not true. That is a strong statement from me, but that is the truth. We have been in negotiation with the individual who is going to do the meta-analysis for a long time, and it has absolutely nothing to do with this hearing. The contract was negotiated prior to my knowledge of any hearing coming up in this particular area.

Mr. SANDERS. Dr. Löe, a meta-analysis is a statistical analysis of previously conducted studies. It is a good way to consolidate information from lots of well-conducted small studies. Unfortunately, in

The subcommittee invited the manufacturers to provide written testimony and copies of research data for inclusion in the hearing record. Based on their responses, none have any long-term studies.

In addition, Dr. Homsy, the former president of Vitek, who wrote from Switzerland, is still claiming he has research evidence showing his products are safe. He is apparently still selling them despite the overwhelming evidence that they are dangerous. This is a good example of how biased manufacturers' safety claims can be.

What can the FDA do to ensure that the research provided to the FDA is less biased and of better quality than some of the research evidence you have received in the past?

Mr. BENSON. One thing that we are doing is beefing up our bioresearch monitoring group within the center. This has not functioned in as strong a way in the past as it should.

Ultimately, I think the way to assure that we get good data is to make sure that manufacturers understand the importance of that. We need to be very clear that we can't allow fraudulent data, poor data, inadequate data, in support of approval for a product.

That is a step that I think we are doing our best to make clear. As far as this particular example is concerned, we have an import alert on those products, we have notified foreign governments about the problem, and so we are trying to make sure that others, as we heard this morning from the first panel, are not subject to the same problems.

Mr. SANDERS. Mr. Hobson.

Mr. HOBSON. I want to ask something for the record here. Is it fair to say that this Homsy Vitek IPI is not an effective product, that it is not sold in this country currently, but that it is sold in other parts of the world, and people might be going outside the country to get this product, and do we have the ability—I want to get this on the record—do we have the ability to protect our citizens from this type of product?

Mr. BENSON. All the systems that the FDA has at its disposal are in place to prevent your concerns from reaching a realization. We work with the Customs Department, we have an import alert out, which means that in conjunction with customs, we will prevent or attempt to prevent any shipments into this country.

We have warned, again, as I mentioned, other countries about the problem. As far as your first question goes, we certainly have enough evidence that has caused us to act against the product and rescind the 510(k) for the product. That doesn't preclude additional studies or additional proof. We have reached the conclusion that the product is not functioning properly.

Mr. LEVITT. If I might add for the record, we do not have any information that they are selling or distributing the IPI product anywhere, although we do believe he is selling a hip product to other countries. But there is no evidence that we know of that he is distributing the IPI product anywhere in the world.

Mr. HOBSON. Thank you.

Mr. SANDERS. Dr. Löe, we will address the next question to you. Dr. Löe, this year the NIDR plans to spend about $3 million on TMJ. That amounts to 30 cents per year per patient using your estimate of 10 million patients who experience relatively serious pain.

Why do we have so little funding available to study a problem that affects so many millions of Americans and costs the Federal Government billions of dollars in medical bills, lost productivity, et cetera?

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Mr. SANDERS. Dr. Löe, a meta-analysis is a statistical analysis of previously conducted studies. It is a good way to consolidate information from lots of well-conducted small studies. Unfortunately, in

this case experts have advised our staff that there are very few well-conducted studies to consolidate.

Why hasn't the NIDR been willing to support any studies of implants and why have you supported so few studies of treatment outcome?

Dr. LÖE. I don't agree with the assessment of meta-analysis as a deficient method for studying the problem we are talking about. I think there is published material that is worth looking at; these are scientific papers published in peer-reviewed journals. We expect that something will come out of this type of analysis and that it will guide us to where we should be going next. Meta-analysis is a legitimate approach to the problem, as far as I am concerned.

In response to the second part of your question: Why have we funded so few grants in this area? The answer is simply that we haven't had any grant applications. We have taken several steps to try to inspire researchers out there, both in terms of workshops and symposia, and also requests for applications.

I mentioned in my opening statement that I have a chronology of some of these activities, and I am going to submit it for the record. It will show that we have been trying to push this area for a long time.

[The chronology is presented on p. 100.]

Mr. SANDERS. So you have been active in requesting studies on implants?

[Requests for proposals and a summary of the Meta-analysis are in app. 5, p. 334.]

Dr. LÖE. That is right.

Mr. HOBSON. This hearing may serve a function, too, to encourage some people to come forward.

Dr. LÖE. Absolutely.

Mr. HOBSON. I know these things are laborious to go through, but sometimes this can help.

Dr. LÖE. The other part of the problem, though, Congressman, is that there is only so much money to go around; 20 to 25 percent of the applications can be funded, and 75 percent cannot.

Mr. HOBSON. Maybe this will get you some good quality ones.

Mr. SANDERS. Dr. Pinn, this is the second hearing that the subcommittee has held regarding implants that are widely used without any safety data. The other hearing, of course, was on breast implants.

In both cases, the FDA did not require the manufacturers to conduct safety research and NIH did not either.

What is NIH's position on research on medical devices?

Dr. PINN. NIH believes that it does have an obligation to look at the scientific data surrounding anything affecting health. I should tell you, I cannot give you too many specifics because it is under development.

But at the present time there is consideration being given to establishing a medical and biological engineering center at NIH which would have as its major function to look at both the basic and applied research as well as clinical evaluation of the new technologies, including bio—I just lost my word. Thank you, biomaterials.

So that is under consideration right now. I cannot say more about that, but just to let you know we are thinking about that. The second thing is that at the present time, as you are probably aware, there is a Public Health Servicewide task force that has been appointed by Dr. Mason which includes both—which is cochaired by the FDA as well as the NIH and requires the participants throughout the Public Health Service to take another look, for example, at the breast implant issue, and we are progressing with that right now.

The first meeting was held on March 23. We just held another meeting this week at which we had consumer advocacy groups speak to us and present us with their concerns.

And I think this may serve as a model as to how we can in the future address some of the concerns jointly about implants.

Mr. SANDERS. Dr. Löe, if I might, NIDR also hasn't funded studies of bone grafts or other tissue grafts used for TMJ disorders. Why is that?

Dr. LÖE. As I said in my opening statement, the one big problem in this area has been to define the different aspects of this disease and classify the subclasses, so that we know which can be approached through conservative treatment and which can be approached by a surgical method. May I also correct any misunderstanding about whether we are not funding anything in the clinical area. As you heard this morning, several of the scientists who testified have been funded by us. There are others who are also conducting clinical studies. There is one at Minnesota, for instance, comparing surgical versus nonsurgical treatments.

What I am trying to say is that we have worked hard and long over the past years to arrive at a point where we are ready to go forward. This is an important change that has taken place. We now have enough data to pursue clinical trials in the various areas we are talking about, and also to advise the profession and the public. So I think that things are now developing rapidly.

Mr. SANDERS. Would it be true to say that grafts and implant studies are not funded?

Dr. LÖE. Yes, I think that is probably true. I can't categorically say that we might not have funded some of these over the past few years, but we have not—we have thought that that would be somewhat peripheral to the priorities of the institute.

We have had long-range research plans for these issues published in the 1980's and in the 1990's. We have described in very fine detail what we would like to do in the next few years in order to arrive at certain endpoints, and we are acting according to that plan.

Mr. SANDERS. The bells going off means there is a vote, but I think we can finish up the questions and still have enough time on the vote.

Dr. Pinn, we heard testimony this morning that these grafts and implants might be worse than nothing at all. In cases where products are widely used and apparently harming patients, don't you think NIH has some responsibility to conduct research comparing what happens to patients who have implants to what happens to those who don't?

Dr. PINN. The answer to that is yes, with qualification. Dr. Löe has addressed part of that question, and that is all I want to say to that at this point.

Mr. SANDERS. We have documents indicating that one of the major researchers who was a proponent of Vitek's Teflon TMJ implants, Dr. John Kent, owned 21,000 shares of stock in the company. He published medical journal articles praising the implants until the evidence against the implants was overwhelming.

Even if FDA did require manufacturers to conduct research, NIH could still play an important role by funding researchers who do not have a financial interest in the outcome of the research.

Dr. Pinn, does NIH have a policy regarding the need for such unbiased research for medical devices, drugs, and other products?

Dr. PINN. We certainly do, and it certainly applies to my office, the Office of Research on Women's Health. Although TMD's are not conditions that affect only women, it is women who predominate among those who are receiving therapy or who are exposed to the procedures, and therefore it does become a women's health issue.

As a result of testimony that NIH sponsored several years ago, we have developed a research agenda on women's health for the next decade. I have suggested in testimony before this hearing, and certainly following what we have heard this morning, that my office, working with the National Institute of Dental Research and the National Institute of Arthritis and Musculoskeletal and Skin Diseases, intends to meet with concerned individuals, especially some of those you have heard this morning, to see what we can do to generate the research needed to address the kinds of problems you have heard presented today. We are committed to doing that.

Mr. SANDERS. Dr. Pinn, it seems to me this is another example where women may be getting unnecessary surgery and even dangerous surgery. And research on women is getting shortchanged. I know that Chairman Ted Weiss is very concerned that the National Cancer Institute is planning to conduct a major study for breast implants that completely excludes cancer patients, a decision that the Congressional Women's Caucus, Representative Henry Waxman, and Mr. Weiss have written to Dr. Healy about, to no avail.

So my question is, what is your office planning to do to remedy this situation regarding implants generally and TMJ and breast implants specifically?

Dr. PINN. In terms of breast implants, we are working as part of a Public Health Service task force to look at the issue and get more information to guide us. We need scientific data as well as input from women who have breast cancer and who are concerned about how all the studies that NIH conducts will affect them or others with similar conditions.

I have also stated to you what we plan to do to help address and redress the concerns of those who are suffering from TMJ disorders. Our office is concerned about how women are treated medically and how applications of scientific knowledge are applied to women.

You heard this morning that it is primarily men who are treating TMD's and that their patients are mostly women. Let me tell you

that our office is working to increase participation of women in biomedical careers.

We certainly appreciate the cooperation and efforts of our male colleagues, but we feel that if we can increase the number of women participating in biomedical careers, we can increase the sensitivity of those who hear the concerns of women and address them seriously and scientifically.

Mr. SANDERS. Chairman Weiss has returned. Let me give the Chair back to him.

Mr. WEISS [presiding]. Thank you very much, Mr. Sanders, and my apologies. The Foreign Affairs Committee took longer than I expected.

I know that you have gone through your testimony and oral response to the questions, and I simply want to express my appreciation to you for the commitments that I understand you have made regarding how the situation is going to be improved.

I think that for whatever reason, between NIH and FDA, there has been sort of a juggling act, and the people who have been hurt by that are those who have this very serious problem, and find that there has been no real research done on some aspects of it. For reasons which really are very hard to follow, it seems that research on implants isn't being done because it seems that by doing the research, NIH has believed they would be encouraging their use.

But I think that is illogical, since these implants are already being used on thousands and thousands of patients. And I hope that the situation changes, because the research just got lost between the cracks, and neither FDA nor NIH did it. As a result, there is limited knowledge.

We will be following it closely. I am very appreciative of your participation here today, and I look forward to some positive actions from the agencies in the near future.

Thank you very, very much. The hearing is adjourned subject to the call of the Chair.

[Whereupon, at 1:25 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIXES

APPENDIX 1.—LETTERS FROM TMJ PATIENTS AND RELATED INFORMATION

Thu 21-May-1992

Newspaper:pb Reporter:wire Category:cri Illustration:p Location:ia

Family: Man who took hostage killed himself to end pain
CUTLINE: Members of the Fillmore County SWAT team break open a door to a dentist's office Wednesday in Caledonia. Police said Randy Otterness of Mabel took a dentist hostage but released him unharmed before fatally shooting himself.
CALEDONIA, Minn. (AP) -- The family of a man who shot and killed himself after taking his dentist hostage says he wanted to end the excruciating cluster headaches that had tormented him for the last five years.
The family members said Randy L. Otterness had talked about committing suicide for several months.
The 37-year-old Mabel electrician killed himself shortly after noon Wednesday after a 3-hour police standoff in this southeastern Minnesota town. He earlier freed the dentist, Mark Zard, unharmed.
Houston County Sheriff Dennis Swedberg said Otterness brought a suicide note with him and gave it to Zard.
''I am going to terminate myself today, based on years of thought and agony,'' said the note, written on a legal pad. ''I WILL die today, as a result of a cure for my illness.''
''He was getting headaches three times a day and at night,'' said Orvin Otterness, Randy's father, who was at the scene when he died. ''He couldn't even touch the hair on the side where it hurt him, because just touching the hair hurt like everything. He tried a lot of different doctors, and they couldn't do anything with him. Sometimes the headaches were so bad he couldn' see hardly more than a couple of feet ahead of him.''
Otterness' sister, Diane Otterness, said her brother had visited Zard, Mayo Clinic and several neurological experts many times in recent years seeking a remedy for the headaches, but he was unable to find a cure.
''There is just no relief for it. That's basically why he shot himself in the head,'' she said.
Otterness' body was found in one of Zard's exam rooms, where Otterness believed his pain had begun five years ago.
But Diane Otterness and Daryl Jensen, chief investigator for the Fillmore County Sheriff's Department, said Otterness never blamed Zard for the headaches, which occur when blood vessels in the brain swell. They said he merely wanted the dentist there when he died:
''I don't think he disliked Zard. I think he actually kind of respected him he kind of befriended him,'' Jensen said. ''He tried to get Zard to help him with his cluster headaches. He never blamed Zard for anything he did.''
Diane Otterness said it was probably a coincidence that her brother began suffering the headaches after Zard performed extensive dental work on his mouth five years ago.
No one answered the phone at Zard's offices in Caledonia and Mabel, and his home phone was busy Wednesday.
Mabel Police Chief Leroy Kreager said the incident began Wednesday morning when Otterness took Zard hostage at Zard's Mabel office.
Kreager said Otterness, who was armed with two shotguns and a handgun, fire a shot outside the Mabel office that hit a man who was picking up trash nearby. Authorities said the garbage hauler, Doug DeWall of Caledonia, was no seriously hurt.
''It was meant to be a warning shot, but one of the pellets apparently

wounded the individual in the arm,'' Kreager said.
Otterness and Zard then left town in Zard's car and drove to Zard's branch office in Caledonia, about 10 miles east of Mabel.
Zard was released within five minutes of their arrival, and Otterness staye in the dental office for the next three hours, authorities said. About 25 officers surrounded the clinic and about six blocks in the town of 2,850 were evacuated, Swedberg said.
''We tried to talk to him. The hostage negotiating team talked to him an hour and a half off and on, almost had talked him out at one point. but he went back in,'' Swedberg said. ''From the beginning he was threatening suicide.''

My name is Jennifer Hutchinson. I am founder and director of the TMJ Information and Resource Center, located in Winchester, Virginia, and editor and publisher of *The TMJ Report,* a newsletter for TMJ sufferers across the country.

When I was asked to provide testimony, I was told to briefly relate my experience with TMJ and tell what it has done to my life. My first thought was, "How in the world can I even begin to condense seven and a half years of pain and frustration into a brief summary?" My initial inclination was to run through my entire history, starting with my first symptoms, bouncing back and forth among half a dozen doctors, going through an endless number of splints, orthodontics, drug withdrawal, and, worst of all, five surgeries, which, by the way, cost some $60,000 and only made me worse than ever before.

As I read through my rough draft, however, I realized that it all sounded very factual and even clinical. And although I could use words such as "painful" and "frightening" to describe my life for the last few years, they just don't cut it. I really can't tell someone who has not been through it, what it is like to spend literally years of your life in pain -- every day -- and what it does to you and your family. How it wears you out, beats you down, takes control, and robs you of your life, changing it forever.

As I prepared my testimony, so many memories came to mind. I remember times when I was at my worst and completely bedridden, sometimes for days at a time. And I can remember my husband and two children hovering over me, trying in some way -- perhaps by gently rubbing my back, getting my Tylenol, or simply putting my hot pack in the microwave for the hundredth time -- trying to cheer me up and make me forget my pain, even just for a few moments. I remember leaving my children -- not once, but five times -- as my husband and I went out of town for surgery. And I can still see them fighting back their tears, trying to be strong for me. This has been going on for years. This kind of life has to leave permanent scars. I know that it strains even the best of marriages and leaves people in virtual financial ruin.

I am one of the lucky ones. I have been fortunate enough to have unrelenting support from my husband, who has willingly assumed many of my responsibilities; my two children for whom pain and fear has become a way of life; and my mother and grandmother, who, at age 86 and 70, still drop everything when I need them. But what about the people who have no support? No understanding? Nobody to comfort them? I will never forget the telephone conversation I had with one patient. Right in the middle of a sentence, she broke off sobbing, and said to me, "Oh my God, the pain is so bad. I just wish somebody was here to hold me." What about the patients who have lost everything -- spouse, job, every penny, all hope?

It would be wonderful if, because of this hearing today, a change would begin that would stop this senseless devastation of lives. But even this, while it may keep others from going through what this panel of patients and so many others have endured, can do nothing to help those whose lives have already been devastated. For them, it is too late. There is no turning back.

My mother has often said that the saddest words in the world are "if only." If only this had never happened to me. If only I could do all the things I used to do. If only I knew seven and a half years ago what I know now ... I wouldn't be writing this. And what is so tragic, so sad, about it all, is it should never have happened to me. It should never have happened to anybody. And most of all, it should not *still* be happening.

They say hindsight is always 20/20. Looking back, it is so clear now why this *did* happen to me. Like thousands of other sufferers, I was desperate. It's that simple. I was in agony and I was desperate. Not only that, I was ignorant. I don't mean stupid -- just uneducated. I didn't know that the medical community virtually agrees on nothing when it comes to TMJ. I didn't realize that, with no standards of care, doctors are free to try just about anything they want. I didn't know that most available treatments have never been proven to be safe, let alone effective. I didn't even know that TMJ was a controversial field. And I had no idea how much money doctors are making on a disorder that is not even being studied. I knew next to nothing except that I was in a lot of pain and my quality of life was diminishing rapidly. And when you're in a lot of pain and you see your life slipping away little by little, day by day, it's so easy to get caught up in the "medical merry-go-round" of going from doctor to doctor, each one telling you they don't know what's wrong with you and, by the way, here's a referral to a psychiatrist because you *are* just a little bit crazy. All of this only makes it easier to believe the first doctor who looks at you and says, "I know what's wrong with you and I can help you." I know I didn't need a whole lot of convincing. I was desperate for some kind of relief. And I think the biggest tragedy of all is I cannot go back. My life will never be the same.

What frightens me more than anything is knowing that I am not one of the worst cases. I know a patient whose pain became so severe about a year ago that she began seeing a psychologist. She was suicidal. She told him she just wanted to die so she wouldn't have to suffer anymore. The psychologist told her that she must tell the orthodontist who was treating her at the time (thank God she's no longer seeing him) how bad her pain was. And she did. She said she couldn't go on any longer. At first, he turned around and walked away. Then he returned, looked at her, and said, "I know what you need to do. You need to go home, have a couple of drinks, make love to your husband, and forget about your problems." This is what we have to listen to. Is it because we are women? I don't know. But I don't know of a single doctor who would treat a male patient in this way. I am appalled and shocked by what I am hearing from TMJ sufferers.

And I'm not talking only about implant patients or, for that matter, patients who have had surgery, because you don't have to have an implant or surgery to have been mutilated and left with chronic, intractable pain. Many other current treatments are extremely damaging and also have the ability to leave lives in ruin. The implants are, of course, the most deplorable part of this entire TMJ issue. When the breast implant issue was front-page news every day, I kept asking myself, "Why doesn't somebody address the jaw joint implants?" I know there is nothing particularly glamorous or sexy about the jaw joints, but articles began to appear which mentioned chin, hip, knee, and even penile implants. Yet, nobody even acknowledged the jaw joint implants. Why? Statistically, 80 percent of women who get silicone breast implants do so for cosmetic purposes. Eighty percent. I personally know few -- if any -- TMJ patients who receive jaw joint implants for their looks. No. They do so because some doctor has convinced them that this is the answer to their pain. Again, we're talking about desperate people. They will try anything.

I believe very strongly that somebody must take a stand and do something about the state-of-the-art of TMJ. Because right now, it stinks. I honestly don't know how some of the patients on this panel made it today. But the very fact that we are here tells me that we are desperate people living desperate lives, and we are asking the people -- perhaps the only people -- who have the ability to do something about it, to do it. Thank you.

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June 2, 1992

Honorable Ted Weiss
Chairman
Subcomittee on Human Resources
#372 Rayburn Building
U.S. House of Representatives
Washington, D.C. 20515

RE: TEFLON-PROPLAST TMJ IMPLANTS

Dear Congressman Weiss:

Dr. Zuckerman requested that I write a summary letter to you regarding my experience with Teflon/Proplast TMJ implants.

I first became aware of the TMJ Teflon/Proplast implants in 1982. Several patients came to my office for pain management following placement of the implants in their jaw joints. Because I limit my practice to the diagnosis and treatment of TMJ dysfunction symptoms, patients with chronic TMJ pain are referred to my office for evaluation and treatment. I have treated between 3,000 and 4,000 TMJ dysfunction patients to date. What is unique about the patients who received the Teflon/Proplast implants, is that they all appeared to have severe degeneration of their jaw joints following placement of the implants. In most cases there was moderate to severe pain associated with the degenerative breakdown of the jaw joints. The degenerative changes appeared to be rapid and progressive since the implant surgery. This is just the opposite of what we would expect to see following surgery of the jaw joints. The surgery is done primarily to relieve pain and slow down or halt the progression of arthritic changes in the joints.

On numerous occasions I discussed the problem with the local oral surgeons, Ted Kiersch, D.D.S. and Ed Schneider, D.D.S. They stated they either did not know what was going on with the TMJ implants or felt that the arthritic changes were not significant. I also expressed my concerns with Dr. Jack Kent, D.D.S. of Louisiana State University and several other oral surgeons in the United States. Several patients had the proplast material removed from the TMJs because of severe pain and degenerative arthritic changes in the joints. Pathology reports following removal of the implant material indicated that there was a significant foreign body giant cell reaction occurring in the TMJs which could be attributed to the implant material. In spite of the pathology reports, the local oral surgeons continued using the material and even reimplanting it in patients that had a previous reaction to the material. I found this surprising and somewhat deplorable. I was assured by the surgeons that they knew what they were doing. I was also assured by the surgeons that they had been in contact with the manufacturer of the material, Vitek, and other researchers associated with the implant material.

In 1985 a study was completed the University of Texas in San Antonio in which the implant material was inserted in the joints of rabbits. The study demonstrated that the material caused significant foreign body giant cell reaction with significant arthritic changes. The authors of the research publication questioned the use of the Teflon implant material in humans as it appeared to be unsafe in animals. What is ironic about this whole scenario is that the animal studies had not been performed using this implant material prior to using it on humans! It is my opinion that the surgeons in Tucson were doing a human study with this material and not informing the patients.

Since I first became aware of the Teflon/Proplast implant material in 1982, I have treated 50 and 100 patients that are in chronic severe pain because of this material. I am aware of 3 patients that have committed suicide in Tucson related to severe chronic pain that could not be controlled following the use of this material. Even though the material can be removed from the jaw joints, microscopic particles of the material can diffuse into the lymphatic system and into the bone surrounding the jaw joints. A study currently being done at Baylor University in Dallas, Texas under the supervision of Larry Wolford, D.D.S., Ph.D, demonstrates that the microscopic granules of Teflon/Proplast get into the deep layers of the bones, into the marrow spaces, and causes chronic severe inflammation. In order to remove all of the particles, huge sections of facial bone, muscle and lymphatic tissue would need to be resected which is not possible in most cases.

I currently have 15-20 patients that are severely depressed from the chronic pain, uninsurable because of their chronic pain situation and suicidal. The majority of these patients are taking narcotic medication on a daily basis to live with the chronic pain.

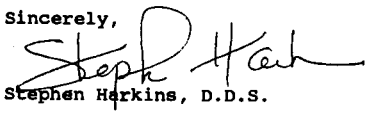
There is currently litigation against the manufacturer of the material, (Vitek) for product liability. There are also several malpractice suits against the local oral surgeons.

I find it amazing that the Food and Drug Administration allowed this material to be utilized on a routine basis without proper animal studies or testing. It is also my understanding that the FDA approval was at least in part based on the research performed in Tucson, Arizona by private practice oral surgeons. It is my opinion that the research performed by these individuals is grossly inaccurate and possibly bogus. I am aware of several patients that I believe were included in this study that had significant complications since the time of insertion of this material into their jaw joints. There is no mention of serious complications or foreign body response in their study. I find this quite ironic. This study is usually cited in most of the articles relating to Teflon/Proplast implant materials.

In addition to the misinformation that was published and circulated regarding Teflon/Proplast being an acceptable biomaterial for use in joint surgery, I feel that the majority of TMJ patients that received the implant material were not properly informed or were misinformed regarding the prognosis with this material prior to surgery. Several clinical evaluation studies have been performed in the last 5-6 years on humans which indicate consistent degenerative changes in the jaw joints related to foreign body giant cell formations around the implant material.

In summary, I find it incredible that this could happen under the nose of the FDA. I find that the conduct and actions of individuals at DuPont, Vitek and several oral surgeons to be reprehensible.

Sincerely,



Stephen Harkins, D.D.S.

SH/bw

J Oral Maxillofac Surg
44:541–554, 1986

Comparative Study of Alloplastic Materials for Temporomandibular Joint Disc Replacement in Rabbits

DAVID P. TIMMIS, DDS,* STEVEN B. ARAGON, DDS,†
JOSEPH E. VAN SICKELS, DDS,* AND THOMAS B. AUFDEMORTE, DDS‡

Young adult, white New Zealand rabbits underwent either sham surgical procedures or discectomy. In the animals that underwent discectomy, either reinforced silicone or polytetrafluoroethylene–aluminum oxide (PTFE–Al_2O_3) implants were placed in the glenoid fossa. During gross sectioning, the silicone implants could be easily displaced from the specimen, while the PTFE–Al_2O_3 implants were firmly anchored. Histologically, fragmentation of the implants was seen in the silicone group; 21.4% of the implants placed were torn. Foreign body giant cell reactions reached a peak after eight weeks. Associated fibrosis and foreign body giant cell reactions were seen, resulting in a thickened capsule and resorption of the condyle and articular fossa. In the PTFE–Al_2O_3 group there was marked osteoclastic activity, with resorption and severe degenerative changes in both the condyle and glenoid fossa. The foreign body giant cell reaction was severe at all time intervals and increased with time. Tearing of the implant was observed in 46.2% of the joints. These results indicate a need for further evaluation of these materials as disc replacements in humans.

Although discectomy yields early postoperative relief, symptoms often recur, in conjunction with persistent or recurrent pain.[1] Additionally, in both clinical[2] and animal studies, osteoarthritic degenerative changes and fibrous ankylosis have been observed in both the condylar and the temporal articular surfaces of the joint following this procedure. Maintenance of an interpositional material between the articular surfaces of the temporomandibular joint (TMJ) appears to be necessary to prevent these adverse osseous changes.[3–7] Silicon elastomers and polytetrafluoroethylene–carbon (PTFE–C) or –aluminum oxide (PTFE–Al_2O_3) are the most commonly used alloplastic materials for this purpose. A number of investigators maintain that porous PTFE–Al_2O_3 offers more stability than do nonporous silicone polymers and, hence, that it is more clinically useful.[8–11] However, there is a paucity of experimental data to document host tolerance and the attendant histologic changes that occur in the periarticular and articular tissues of the TMJ in response to these interpositional alloplastic materials. The purpose of this study was to delineate the morphologic and histologic changes seen in the TMJ and surrounding tissues of rabbits following discectomy and insertion of silicone elastomer or PTFE–Al_2O_3 implants to line the glenoid fossa.

* Department of Oral and Maxillofacial Surgery, University of Texas Health Science Center at San Antonio, Texas.
† In private practice, San Antonio, Texas.
‡ Department of Pathology, University of Texas Health Science Center at San Antonio, Texas.
Supported by The University of Texas Health Science Center at San Antonio, research grant protocol no. 84103.
Address correspondence and reprint requests to Dr. Timmis: University of Texas Health Science Center, Department of Oral and Maxillofacial Surgery, 7703 Floyd Curl Drive, San Antonio, TX 78284.

Materials and Methods

Forty young adult, white New Zealand rabbits with an average weight of 2.7 kg were used as experimental subjects. Eight animals served as controls, while 32 animals underwent discectomy, with

J Oral Maxillofac Surg
50:133–139, 1992

In Vitro Wear Performance of Proplast TMJ Disc Implants

MARK G. FONTENOT, DDS, MEng,* AND JOHN N. KENT, DDS†

This study investigates the in vitro wear performance of Proplast-Teflon interpositional implants (PTIPI; Vitek, Inc, Houston, TX), employing a mechanical TMJ simulator. Predictions of in vivo service life of PTIPIs are presented based on the in vitro wear testing data. Commonly employed laboratory testing methodologies are discussed in the development of alloplastic TMJ devices. Penetrative wear rates of the PTIPI at a 20-lb (9.1 kg) load were calculated to be 2.29 mm/100,000 cycles, yielding a predicted in vivo service life of PTIPIs of approximately 3 years. These results combined with reported clinical fate of this implant indicate that the intermediate- and long-term survival of this implant are uncertain.

In the early 1970s, Teflon FEP (fluorinated ethylene propylene; E. I. Dupont de Nemours & Co, Wilmington, DE) film was laminated to porous Proplast I (Teflon polytetrafluoroethylene [PTFE] and carbon; Vitek Inc, Houston, TX) (Fig 1A) and short-term success was subsequently reported using this sheeting as a temporomandibular joint (TMJ) condylar cap without disc removal.[1–3] Based on these early successes, Teflon FEP film was laminated to porous Proplast II (Teflon PTFE and aluminum oxide; Vitek, Inc, Houston, TX) in the early 1980s (Fig 1B). This Proplast-Teflon interpositional implant (PTIPI; Vitek, Inc, Houston, TX) was used as a TMJ disc replacement and Kiersch was the first to report on its successful use.[3]

In the United States, the use of interpositional TMJ implants for disc replacement, primarily silicone rubber (Silastic; Dow Corning, Midland, MI) and PTIPIs, escalated from hundreds annually in 1983 to thousands by 1986. However, reports began describing biomechanical failure of the PTIPI that caused adverse tissue reaction and bone resorption in both animals and humans.[4–7] At the 1986 Annual Meeting of the American Association of Oral and Maxillofacial Surgeons (AAOMS), several clinicians reported biomechanical failure of both Proplast I and II laminated to Teflon FEP used as disc replacement in patients and animals.[8–12] These reports stated that polymer debris from biomechanical failure and wear had produced progressive macrophage and giant-cell reaction leading to pain, bone resorption, and malocclusion.

Because there is no information regarding in vitro wear testing or statistics on life expectancy of the PTIPI,[13,14] a study of these factors was undertaken. This article reports on 1) in vitro wear performance of PTIPIs by wear testing these implants on a mechanical TMJ simulator; 2) in vivo PTIPI service life predictions based on accelerated in vitro wear testing in combination with reported masticatory loads and the resultant TMJ loading; and 3) a discussion of the PTIPI with respect to evaluation phases that lead to development and use of alloplastic devices for the TMJ.

Materials and Methods

A mechanical TMJ simulator was employed to evaluate the wear performance of 1.3-mm PTIPIs used for in vivo TMJ disc replacement of the TMJ in humans (Fig 2). The loading fixture consisted of a VK-II mandibular condyle (Vitek, Inc) fixed to a piston, which in turn was fitted into a cylinder. Sterilized PTIPIs were placed on a concave parabolic polycarbonate platen and fixed to it by cementing the Proplast side to the platen with cyanoacrylate. The Teflon FEP surface articulated with the VK-II condyle of the loading fixture.

The articulating components were immersed in a circulating distilled water bath open to the atmosphere and maintained at ambient room temperature. Initially, a static 20-lb (9.1 kg) load was placed on the

Received from the Department of Oral and Maxillofacial Surgery, School of Dentistry, Louisiana State University Medical Center, New Orleans.
* Doctoral Candidate in Biomedical Engineering, School of Engineering, Tulane University, New Orleans, LA.
† Boyd Professor and Head.
Address correspondence and reprint requests to Dr Kent: Department of Oral and Maxillofacial Surgery, Louisiana State University Medical Center, School of Dentistry, 1100 Florida Ave, New Orleans, LA 70119.

0278-2391/92/5002-0012$3.00/0

Marcie Grossberg
5413 Poplar Avenue #1
Memphis, Tennessee
38119

(901) 767-2556

May 30, 1992

Congressman Ted Weiss
Rayborn House Office Building
Room 2467
Washington, D.C.
20515

Re: VITEK TEFLON-PROPLAST MAXILLOFACIAL IMPLANT SCANDAL

Congressman Weiss:

I have heard that you will be conducting a hearing concerning the serious problems connected with jaw implants and the FDA's negligence relating to these devices. Since receiving my teflon-proplast implants in July 1987,-my life has been a living hell. The very fact that you are finally going to investigate this national tragedy has given me and many other VITEK VICTIMS much needed encouragement. Please don't let those responsible for our pain and suffering off the hook. What has happened to us did not have to happen.
I am not presently well enough to be in Washington on 6-4-92. I want to be included in some way. I am enclosing pertinent medical data concerning my case. Please advise if anything else is needed.

Thank You,
Marcie Grossberg
Marcie Grossberg

68-249 107

G. TRENT WILSON, D.D.S.
ORAL AND MAXILLOFACIAL SURGERY
5965 MURRAY ROAD
MEMPHIS, TENNESSEE 38119
TELEPHONE (901) 767-0068

Dr. Trent Wilson Surgery 10-12-88 $6213.00 Total

September 2, 1988

Blue Cross-Blue Shield of Memphis
PO Box 30
Memphis, TN 38101

Subscriber: Marcie Grossberg
Patient: Same
654 Spottswood Manor Ln
Memphis, TN 38111
Group #1011
ID #E122-46-0023

To Whom It May Concern:

I have recently examined Ms. Marcie Grossberg in my office. She came to me complaining of moderate to severe pain in the right and left temporomandibular joints. She also complains of an an inability to close her front teeth together. Ms. Grossberg has related a history of previous temporomandibular joint surgery that included removal of the TMJ meniscus bilaterally and placement of bilateral teflon-proplast implants.

My exam has included both clinical inspection and radiographic examination. Radiographs used in the evaluation of Ms. Grossberg were a panoramic view of the jaws, lateral cephametric skull film and CT of the TMJ bilaterally.

Ms. Grossberg is suffering from severe resorption of the temporomandibular joint condyles bilaterally. This irregular condylar resorption is causing damage to the inferior surface of the teflon-coated implants. This damage can be seen on CT scan. There has also been a significant loss in vertical dimension of the vertical ramus of the mandible. This in turn is causing the development of the skeletal anterior open bite. These teflon-proplast implants have been implicated throughout the literature as causing similar problems as we have seen in Ms. Grossberg.

Due to the serious damage caused by the proplast-teflon implants, I plan to remove the implants and place dermal grafts in the glenoid fossa regions bilaterally. This procedure will require a general anesthetic and approximately three days of post surgical hospitalization. There will be a second surgical procedure a minimum of six months following the primary surgery. The purpose of this procedure will be to correct the skeletal jaw discrepency caused by this damage to the mendibular condyles previously described. Please advise me if Ms. Grossberg has coverage for these procedures.

Sincerely,

G. Trent Wilson, D.D.S.

MAYERSON, MUNSING, CORCHIN, ROSATO & OSTROFF, P.C.

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* ALSO MEMBER OF DISTRICT OF COLUMBIA, CONNECTICUT AND DELAWARE AND MARYLAND BAR
** ALSO MEMBER OF NEW JERSEY BAR

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Leslie C White

LITIGATION PARALEGALS
Maria B. Keller
Christina M. D'Emilio
Erica Fiore
Linda Hamilton
Jill Kaufher

June 3, 1992

Representative Ted Weis
Rayburn House Office Building
Room 2467
Washington, DC 20515

Dear Mr. Weis:

I understand that there are hearings planned on Vitek. There are some points that Committee may want to address, in addition to the obvious:

1. The likelihood that this problem may extend beyond oral implants. Proplast, the substance out of which the Vitek implants were made, was marketed by Dow-Corning as being useful for all types of implants. Thus, there may be other implants on the market that may well be causing similar problems which go undiagnosed because the implant may cause auto immune problems had, hither to, been only recently linked to silicone breast implants. Thus, in my client's case, her auto immune problems were not fully explored because neither she nor her internists were sufficiently aware of the potential problem so that she would relate to her internist that she had an implant - because the potential relevance was not aware to her - and the internist never asked her if she had one - because they were not aware.

   Consequently, the "epidemiology" is skewed because the internists aren't asking the right questions and patients aren't volunteering the right information.

2. The manner in which defective products are exported - as you are doubtless aware, the Department of Justice moved to cease remaining stock of Vitek which the company resisted on the basis that they wanted to sell them overseas. In fact, the company is selling them overseas. Not only does this harm our foreign relations, but one may well question the morality of continuing to sell a product that is known to be dangerous wherever one thinks one can get away with it.

3. The manner in which bankruptcy affects victims. Questions have been raised regarding the amount of the bankruptcy proceeds that are available for victims - how much is chewed up in overhead, and why. In addition to these questions, the Committee may wish to look at whether or not the system has needless complexity. Would it not be possible for the very highly paid and well compensated administrators of the system to design fairly easy pamphlet-form forms that a lay person could fill out with their doctor to obviate the need for an attorney. This is crucial in these situations where the amount now available to Vitek claimants may be very low - perhaps $20,000 or less, and every dollar is needed to cover their future medical expenses.

4. The manner in which corporations may transfer assets to avoid liability. In this case, shortly before they declared bankruptcy the owners of Vitek transferred their assets to several successor corporations and to overseas corporations.

5. The effect on servicemen. Many of these implants were placed into service families who now need follow-up care which they cannot afford. Why so many implants were placed in the mouths of service people, why they were not tracked is a question that the Committee may well wish to address. One physician with knowledge of this is Dr. Michael Lessin, Dental and Surgery, Geissinger Medical Center, 100 N. Academy Avenue, Danville, PA 17822.

6. The notice given to doctors - the notice does not alert doctors of the suspected systemic effect. Consequently, this is not followed up with patients with two potential losses - the epidemiologic basis remains small and the patient does not get the type of follow-up care that they need.

7. Tracking within an institution - many of these devices were placed in the mouths of patients at medical facilities. While a national registry may be expensive, there is no reason why an individual physician or institution cannot keep a record, in one file, of these people in which they place a certain device. What occurred with my client was that a notice was sent to the institution. Had not a physician taken it upon himself to review the entire medical records for those who had received surgery to determine which patients had received implants, those patients would never have received notice.

   To add insult to injury, most patients were never notified of the bar dates of the bankruptcy court, nor were they given a phone number with the notification so they could keep abreast of what went on with bankruptcy. Consequently, there are many, many victims who may not receive compensation because of the early bar date set by the bankruptcy court.

As with many systemic disorders, there is an unfortunate tendency to sex sterotype the victims in that many of the implants were placed in women, and women who comiplaint of system disorders are suspected of being either menopausal, premenopausal, or having a bolt loose. There's also an aspect of double victimization, in that many of the women needed the implants because of jaw trauma suffered as a result of abuse, and the manufacturer then tries to claim the problem with their jaw is caused by the abuse and has nothing to do with the fact that the plastic in proplast eats away at the bone, to the extent that it can lead to canals throughout the skull with potentially fatal implications.

A victim who has been very active in compiling information on this subject is Lucille Rinardo. Her phone number is 716-594-0132. I believe she would be a very valuable source.

Please don't hesitate to call if you have any questions.

Very truly yours,

Peter N. Munsing

PNM/mrk
Fax: 202-225-6923

JAW JOINTS & ALLIED MUSCULO-SKELETAL DISORDERS FOUNDATION, INC.

• JJAMD • FORSYTH RESEARCH INSTITUTE • 140 THE FENWAY • BOSTON, MA 02115 • (617) 266-2550

AUG ' 92

August 3, 1992

Congressman Ted Weiss, Chairman
Human Resources and Intergovernmental Relations Subcommittee
Committee on Government Operations
Rayburn House Office Building, Room 8-372
Washington D.C. 20515-6148

Dear Congressman Weiss,

I attended the June 4th TMJ Proplast Implant Hearings and I want to compliment and to thank you for the splendid work that you, your staff, and your committee accomplished.

I was at once mesmerized, horrified, gratified, and a whole host of other emotions were released for me. For, you see, I am a TMJ Patient. I am also the Co-founder and Co-President with my husband, Milton, of the organization named above, which we founded in 1982. We work very hard to bring appropriate awareness and help to this baffling health disorder. This Hearing helped greatly in that awareness.

While the Hearings were appropriate and excellent, we would like to bring to your attention and ask for your continued support in investigating *other facets* of this multifaceted health disorder. As you acknowledged in your opening remarks, there are "millions of Americans" already diagnosed, being treated and maltreated, suffering disenfranchised misspent lives physically, emotionally, and financially. Many among these millions you identified, are living *equally* shattered lives as the TMJ Proplast Patients, although they arrived there from *different* etiologies and treatment modalities.

We would respectfully ask that there be a continuum of your superb efforts that were rightfully focused at this time on the compromised TMJ Proplast patients. The time has come, however, to focus on the

remainder of those millions of TMJ patients who have been similarly compromised by the health care system, the NIH-NIDR lack of research attention and the failure of the health insurers to come to grips with what is one of the most pervasive and shameful health problems in America today.

Our Foundation is currently working on independent research, which we hope will shed new light on the entire subject, and which could serve as a model for future research by "untainted" investigators. Enclosed is a brief description of JJAMD's study, which is being done pro bono by E.D.S. Federal, Blue Cross Blue Shield of Massachusetts, University of Massachusetts, Forsyth Research Institution Biostatistics Department, and with the more recent participation by the Massachusetts Department of Public Health.

JJAMD is now also in the process of compiling its own TMJ Library database and reference library, to be headquartered at JJAMD's location within Forsyth. In this way, future researchers and other interested parties will be able to access data that is not routinely included in the current juried journals inputted only by the professions.

Enclosed is some information about JJAMD and the credentials of the Co-Founders. We ask that you contact us in the very near future for further discussion and networking of the TMJ Dilemma. We plan to follow up on this correspondence to arrange a meeting with you.

Again thank you so very much for your sensitive, compassionate, and effective handling of this very complex, controversial, and largely unnecessary human tragedy! Our conviction continues to be that "TMJ is largely preventable through education." We truly believe this, and working with you towards this end will help prove this axiom in the long term. It will also serve to help alleviate the TMJ Dilemma in the short term and lower the cost of healthcare in the process.

We sincerely look forward to hearing from you and working with you. Thank you for your quick attention and prompt response to this letter.

Sincerely yours,
Renée and Milton Glass
Renée & Milton Glass
Co-Founders & Co-Presidents of JJAMD

Encls.

STUDY OF TEMPOROMANDIBULAR JOINT DISORDERS

SPONSORED BY: JAW JOINTS & ALLIED MUSCULO-SKELETAL DISORDERS FOUNDATION, INC.
IN COLLABORATION WITH THE UNIVERSITY OF MASSACHUSETTS
WITH EDS FEDERAL, BLUE CROSS BLUE SHIELD OF MASS.
THE DEPARTMENT OF PUBLIC HEALTH, THE COMMONWEALTH OF MASS.,
AND
FORSYTH RESEARCH INSTITUTE

SUMMARY -- AS OF MARCH 1992

GOALS:

Using the Blue Cross Blue Shield of Massachusetts Statistical Claims database:

1. To determine the relationship between TMJ disorders and the overall health of patients
2. To measure the financial impact of TMJ disorders on health insurers
3. To investigate the treatments used for TMJ disorders
4. To determine linkages between TMJ and other disorders
5. To disseminate the results of this and other TMJ studies through workshops involving the leading researchers in the field
6. To use the results of this study as the basis for seeking future funding support for continued TMJ research from state, federal (NIH) or private foundations

OUTPUT:

Previous studies of TMJ disorders have often been criticized because they involved small numbers of patients providing anecdotal evidence or large numbers of subclinical cases, i.e., patients who have relatively minor signs and symptoms of the disorders. This study will use a large sample of TMJ patients to investigate the impact of TMJ disorders on both the patients and their health insurer. It is intended for the results of this research project to be published in leading health care journals, presented and discussed at symposiums and conferences on TMJ, and used as the basis for future research and grant proposals. The JJAMD Foundation, as sponsor, is in a position to develop research efforts from among university-based, clinical and research institutional sources in the future.

METHODOLOGY:

The basis for investigation will be the statistical claims data base of Blue Cross Blue Shield of Massachusetts and the EDS Federal Company, which contracts with the Blues. Members covered under the Master Health Plus Plan will serve as the sample of patients to be studied in this project.

This study will investigate the treatments of TMJ disorders and their impact on both patients and health insurers. If TMJ disorders affect the total health of patients, then that portion of the population who require treatment for these disorders should be "sicker" and, therefore, "costlier" than those not requiring treatment. In order to test this hypothesis, an experimental group of Blue Cross Blue Shield of Massachusetts enrollees who were treated for TMJ disorders will be compared to a control group comprised of enrollees who did not require treatment. The control group will be carefully defined so as to avoid inappropriate comparison. All enrollees must be continuously enrolled in Master Health Plus. This control group will be matched with the experimental group on the basis of age, sex and employer group.

REPORT:

This study will result in a report based on the research conducted by Daniel G. Shimshak under sponsorship of the Jaw Joints & Allied Musculo-Skeletal Disorders Foundation (JJAMD) and under contract with the Department of Public Health. This report will include an update survey of the literature on TMJ disorders and a discussion of existing findings and data. There will be a description of the methodology and presentation and discussion of the results of this study. The conclusion will consider areas of future TMJ research. An extensive list of references will be part of the report.

For more information, please send a business-size SASE to Renee Glass, JJAMD, c/o Forsyth Research Institute, 140 the Fenway, Boston, MA 02115

# # #

STATEMENT REGARDING OTHER TREATMENT, COMPLICATIONS, PAIN AND SUFFERING

Since January, 1985, I have suffered tremendously from the pain of bone degeneration caused by the Teflon Proplast Implant. I suffer excruciating headaches, joint pain, and limited range of motion of my temporomandibular joints. I have had braces and retainers; multiple intermaxillary fixations; multiple splints; and many physical therapy treatments. I have had five teeth to die and be removed because of all the times my jaws were wired and all the surgeries I've had. I have developed iron deficiency anemia and B-12 deficiency due to surgery.

My immune system has been depleted, making me susceptible to many viruses influenza, and other illnesses including meningitis.

Two Groshong central catheters have been implanted in my chest because I no longer have even fair peripheral venous access. The 24+ surgeries I've had and the many I.V.'s have ruined my veins.

Nerve damage has caused numbness in my face and neck. My mouth droops due to the damage.

Severe pain fills my days and nights. TENS units, physical therapy, treatments for depression, iontopheresis treatments, etc. have not eased the situation. I am on strong pain medication, muscle relaxants, and Plaquenil, yet the pain continues. It hurts to laugh and smile.

At the present time I am on sick leave without pay due to this condition and recent surgery. I have had to give up my independent life and return to my parents' home. I am unable to concentrate or to fulfill my job responsibilities. This only increased the mental aspect of my surgery.

My entire life has been affected by the pain and limitations I suffer daily because of a VITEK, Inc., Teflon Proplast Implant.

(OVER)

(SIGNED) Carol Ann Waterhouse

(TYPED) Carol Ann Waterhouse

Subscribed and sworn to before me this the 24th day of December, 1991.

Linda D. Gamble
Notary Public

11-26-94

COMPLETE THE REMAINDER OF THIS FORM ONLY IF YOU WISH TO CLAIM MORE THAN $1,000.00

2. Surgeries (maximum of 250 points).

	A. Date	B. Left/Right	C. Purpose (e.g. implant, removal, total joint, rib graft, debridement)
i.	1/11/85	R	Remove disc; insert Teflon Proplast (Vitek)
ii.	6/6/85	R	Remove Teflon Proplast
iii.	10/23/85		Arthroplasty
iv.	11/24/86	R	Arthroscopy
v.	12/22/86	R	Arthroplasty - dermal graft
vi.	2/12/87	R leg	Debridement ofdermal graft site
vii.	3/13/87	R leg	Re-do skin graft site #1
viii.	4/20/87	R leg	Re-do skin graft site #2
ix.	7/31/87	R TMJ	Arthroscopy
x.	6/15/88	R ribs	Thoracotomy for rib graft
xi.	6/15/88	R TMJ	Rib graft
xii.	1/20/89	L TMJ	Arthroscopy
xiii.	6/12/89	L TMJ	Silastic in (Dow Corning)
xiv.	6/23/89	L TMJ	Silastic out
xv.	12/20/89	L TMJ	Conchal Chondial Autograft
xvi.	12/20/89	R TMJ	Conchal Chondial Autograft
xvii.	12/20/89	L TMJ	Arthrotomy
xviii.	12/20/89	R TMJ	Arthrotomy
xix.	3/7/90	L TMJ	Coronoidectomy/muscle biopsies
xx.	3/7/90	R TMJ	Coronoidectomy/muscle biopsies
xxi.	4/4/90	R TMJ	Silastic in Arthroscopy (Dow Corning)
xxii.	4/4/90	L TMJ	Silastic in Arthroscopy " "
xxiii.	4/4/90		Groshong catheter in
xxiv.	5/30/90	R TMJ	Arthroscopy - silastic out (Dow Corning)
xxv.	5/30/90	L TMJ	Arthroscopy - silastic out
xxvi.	6/28/90	R TMJ	Arthroplasty - gold implants in
xxvii.	6/28/90	L TMJ	Arthroplasty - gold implants in
xxviii.	8/6/90		New Groshong catheter in
xxix.	11/21/90	R TMJ	Gold implants removed
xxx.	11/21/90	L TMJ	Gold implants removed
	8/28/91	R & L	Total joints

d) Attach copies of operation reports and hospital

9/5/91	L	Total joint redone
11/19/91	2	Removal of imbedded wires/arch bars
8-92		Removal of infected Groshong catheter
9-17-92		Replacement of Groshong catheter

STATEMENT REGARDING LOST WAGES, INCOME, VALUE OF HOUSEHOLD SERVICES

LOST INCOME

School Years Beginning	Days Missed Due To Implant		Daily Rate Of Pay		Lost Wages
1985	27	x	$ 98.96	=	$ 2,671.92
1986	12	x	106.83	=	1,281.96
1987	8-1/2	x	113.43	=	964.15
1988	12	x	117.48	=	1,409.76
1989	12	x	125.12	=	1,501.44
1990	37	x	131.89	=	4,879.93
1991 (Disability leave without pay)	190	x	135.69	=	25,781.10

TOTAL LOST WAGES	$38,490.26
Value of Lost Houshold Services: 3 hour per day at $5.00 an hour x 2,525 days =	37,875.00
Value of Future Wages (Estimated Minimum)	25,781.10
Value of Future Lost Household Services (Estimated Minimum)	50,000.00

LOST FRINGE BENEFITS:
1991-1992 School Year

Teachers Retirement System	1,177.52
Social Security	1,660.41
Health Insurance - State Merit	484.32
Disability Insurance - Washington National	372.15
Dental Insurance - Great American Reserve	220.80
LIfe Insurance - Lincoln National	127.20
NTA Specified Diseases/Intensive Care	312.60

ESTIMATED LOST FUTURE FRINGE BENEFITS:

Teachers Retirement System	1,177.52
Social Security	1,660.41
Health Insurance - State Merit	484.32
Disability Insurance - Washington National	372.15
Dental Insurance - Great American Reserve	220.80
Life Insurance - Lincoln National	127.20
NTA Specified Diseases/Intensive Care	312.60
TOTAL LOST INCOME, VALUE OF HOUSEHOLD SERVICES	$160,856.36

(SIGNED) Carol Ann Waterhouse

(TYPED) Carol Ann Waterhouse

Subscribed and sworn to before me this the 24th day of December, 1991.

Linda D. Gamble
Notary Public
11-26-94

STATEMENT REGARDING UNREIMBURSED OUT-OF-POCKET EXPENSES

TRANSPORTATION AND LODGING:	
1985	$ 32.00
1986	206.00
1987 - did not itemize	
1988 - did not itemize	
1989	
1990	7,645.00
1991	
1989 - 1991 Parking - UT - average $2.00 x .75 =	150.00
Gas - $10.00 per trip x 75 =	750.00
TOTAL TRANSPORTATION AND LODGING	$ 8,783.00
MOVING EXPENSES:	
To return to parents' home for care:	
Hyde Moving	225.00
JEPCO	60.00 per m
Uninsured Medical Expenses do Date	27,321.45
TOTAL	$36,389.45

(SIGNED) Carol Ann Waterhouse

(TYPED) Carol Ann Waterhouse

Subscribed and sworn to before me this the 24th day of December, 1991.

Linda D. Gamble
Notary Public 11-26-94

JUNE 01, 1992

ROBLYN E. RUGGLES

2486 14TH STREET

CUYAHOGA FALLS, OHIO 44223

CONGRESS OF THE UNITED STATES

HOUSE OF REPRESENTATIVES

HUMAN RESOURCES & INTERGOVERNMENTAL

RELATIONS SUBCOMMITTEE

CONGRESSIONAL HEARING ON THE DANGERS OF JAW IMPLANTS

PLEASE ACCEPT THE FOLLOWING TESTIMONY TO BE INCLUDED IN YOUR HEARING, 6-4-92.

" I AM A MULTI-SURGICAL PATIENT." IT IS NOT BY CHOICE, IT IS TEFLON-PROPLAST THAT HAS DEVASTATED ME. I HAVE HAD 10 SURGERIES ON MY JAW SINCE THE IMPLANTING OF VITEK'S TEFLON-PROPLAST INTERPOSITIONAL IMPLANTS IN JUNE OF 1987. THESE SURGERIES INCLUDE MAXILLARY OSTEOTOMY, REMOVAL OF A FLANGE AND SCREW FROM AN I.P.I THAT DID NOT ADHERE, REMOVAL OF I.P.I'S BECAUSE OF BREAKDOWN OF THE IMPLANT AND FOREIGN BODY REACTION, IMPLANTS OF DERMIS GRAFT

ROBLYN RUGGLES

AND TEMPORARY SILASTIC SPACER, TEMPORALIS MUSCLE STRIPPING, CORONOIDECTOMIES, SILASTIC SPACER REVISION, VITEK-KENT II TOTAL JOINT PROSTHESIS BILATERALLY IN FEBRUARY 1990, AND FINALLY REMOVAL OF THESE FAILED DISPLACED TOTAL JOINTS WITH THE IMPLANTING OF **NOTHING**.

I AM THE END RESULT OF TEFLON-PROPLAST IMPLANTS, I HAVE NOTHING LEFT. THE FOREIGN BODY REACTION TO THE DEBRIS OF THESE LIFE-THREATENING IMPLANTS HAS ERODED MY MANDIBLES AND ZYGOMAS, CAUSED ME GROSS SEVERE DEBILITATING PAIN, MUSCLE SPASMS, NERVE NEURALGIAS, FACIAL DEFORMITIES AND HAS CAUSED SEVERE WEIGHT LOSS WITH MALNUTRITION DUE TO THE INABILITY TO CHEW. **THESE IMPLANTS HAVE LEFT ME AN ORAL CRIPPLE**.

THE FACT THAT THE REACTION AND MATERIAL WAS FOUND IN MY LYMPH NODES, LEADS ME TO BELIEVE THAT OTHER SYSTEMIC PROBLEMS I HAVE HAD ARE ALSO RELATED TO TEFLON-PROPLAST DEBRIS. THESE INCLUDE PERITONITIS FROM BURSTING PELVIC CYST CAUSED BY "AN UNKNOWN DRAMATIC INFLAMATION", (APPENDIX WAS INFLAMED BUT DID NOT BURST), AND 9 MONTHS LATER A TOTAL HYSTERECTOMY BECAUSE OF CYSTS FORMI AND BURSTING THAT WERE UNRELATED TO ENDOMITRIOSIS AND UNRESPONSIVE TO NORM MEDICATIONS. AGAIN AN UNKNOWN CAUSE OF INFLAMATION. IS TEFLON-PROPLAST TRAVELING THROUGH-OUT THE LYMPHATIC SYSTEM ??? IS IT CAUSING SYSTEMIC PROBLEMS IN THE ENTIRE BODY AND NOT JUST THE HEAD AND NECK???

ROBLYN RUGGLES

I HAVE NO JAW JOINTS NOW. THE REACTION AND DAMAGE IS CONTINUING EVEN AFTER EXPLANTATION. I HAVE AN OPEN BITE OF ABOUT 10mm. I NEED FURTHER SURGERIES TO GIVE ME A LIVABLE BITE. I LIVE IN CHRONIC PAIN AND HAVE NO QUALITY OF LIFE. EVEN THE PROSPECTS OF MY HAVING CHILDREN WAS TAKEN AWAY BY TEFLON-PROPLAST AND WHO WILL SAY IT WASN'T.....AND WHO WILL FIND OUT THAT IT WAS ?

I TALK TO OTHER VICTIMS EVERYDAY. THOSE WITH HISTORIES AS SAD AS MINE... AND WE NEED ANSWERS.....WE NEED TESTING.....WE NEED FINANCIAL SUPPORT.....WE WILL NOT JUST DISAPPEAR, WE NEED DEDICATED HEALTH PROFESSIONALS WILLING TO TREAT US, NOT FOR ECONOMIC GAIN BUT BECAUSE THEY TRUELY CARE AND THEY WANT TO DO THEIR JOB !!! WE ARE NOT JUST FREAKS OR JUNK SCIENCE PATIENTS, WE ARE HUMAN BEINGS JUST LIKE YOU, WHO WERE MADE INTO UNKNOWING GUINIE PIGS AT THE HANDS OF WILLING SURGEONS ACROSS THIS COUNTRY.

HELP US.

ROBLYN E. RUGGLES

P.O. Box 560515
Orlando, FL 32856-0515

June 3, 1992

Dr. Diana Zuckerman
Human Resources Subcommittee
U.S. House of Representatives
B-372 Rayburn Office Building
Washington, D.C. 20515

RE: TMJ silicone implant medical devices

Dear Dr. Zuckerman:

"Reported complications of silicone implantation include infection, loosening, breakage, foreign body giant cell reactions, 'detritic' synovitis, and lymphadenopathy...the contention...that the foreign body giant cell response to this implant material is insignificant is not a tenable thesis ...", according to the May 1985 journal Oral Surgery, Oral Medicine and Oral Pathology. The quote is from the article entitled "Silicone-induced foreign body reaction and lymphadenopathy after temporomandibular joint arthroplasty." The article's lead author is M. Franklin Dolwick, D.M.D., Ph.D., chair of the department of oral surgery at the University of Florida in Gainesville.

In 1985, I was unaware of such article which I only found by chance years later. Prior to my first TMJ surgeries involving temporary silastic implants, my employment as an attorney by a major private university included some work for its medical center. After all offered conservative treatments failed to relieve pain from my right joint which had been symptomatic since childhood, I sought several surgical opinions before choosing a surgeon trained at my employer's medical center.

In November 1985, I underwent surgeries of both my right and left TM joints involving repairs of the disks with temporary silastic implants which were intended to remain for about six months before removal. Aside from the risks of the surgeries, I was advised that the only risk unique to the silastic implants was outright "rejection" that should be readily recognizable soon after implantation. I was not informed of the other possible complications described in Dr. Dolwick's article published six months prior.

Immediately following surgery, I began experiencing such complications. I also suffered from severe sinus infections repeatedly, fatigue, fibromyalgia, and unrelenting pain in my previously less symptomatic left joint. In April 1985, the surgical removal of the temporary silastic implants was complicated by the tearing of the implant in my left joint, which resulted in my hospitalization for surgery under general anesthesia to retrieve the remainder.

My condition continued to deteriorate until I became totally disabled in December 1986, at which time my original surgeon recommended further surgery of my left joint. I sought a "second opinion" through a consultation from the Facial Pain Clinic at the University of Florida, where I obtained the opinion of an oral surgery faculty member whose departmental chair was Dr. Dolwick. That oral surgeon did not tell me about Dr. Dolwick's published article and provided only equivocal advice. When I expressed my personal experience of increased pain, joint damage, and other symptoms

associated with my two previous silicone implants, I was told by that surgeon that he personally would not use them in treating me; but, that he would not advise against their use by my original treating surgeon. Then, I was advised that I should return to my original treating surgeon for further surgery.

In January 1987, I underwent another surgery by my original oral surgeon which involved another silicone temporary implant in my left joint. Prior to surgery, my surgeon assured me that he would try to avoid using another silicone implant unless he deemed it absolutely necessary, in which case he would leave it in place for only two or three weeks. During surgery he discovered that my left joint was more damaged than expected from the pre-op arthrogram; so, he decided that the silicone implant should remain for several months until its removal in April 1986. Although removal of the implant relieved some of the pressure and inflammation locally in my left joint, my joint-related jaw, face, head and neck pain remained totally disabling and medically unmanageable with physical therapy treatments, NSAIDs and muscle relaxants such as Robaxin or Flexeril. I also continued to suffer from various physical ailments and multiple symptoms treated by internal medicine and rheumatology physicians.

Later in 1987, my original surgeon suggested another possible surgical procedure for my left joint, which I declined until I could obtain other opinions. In May 1988, I obtained an appointment with Dr. Dolwick during the same week as two other patients of my original surgeon who were treated unsuccessfully with silicone temporary implants. I was accompanied by a physician-friend, yet Dr. Dolwick dismissed my complaints and concerns about my untoward experiences with three silicone temporary implants. He did not even mention to me his clinical observations published three years earlier, about which I still knew nothing at that time. He only referred me back to my original treating surgeon.

When MRI technology became available to me locally in September 1988, I underwent scans showing significant continuing arthritic degenerative changes, adhesions/scar tissue, displaced disks indicating total failure of the earlier disk repairs in both joints, etc. I continued to suffer from increasing and intractable pain and symptoms of systemic immune dysfunction affecting multiple organs and joints.

Because of continuing financial hardship resulting from underpayment of benefits by my total disability insurance company and my instinct to avoid more silicone implants, I underwent a conservative (but ultimately unsuccessful) surgery (leaving the dislocated disk remaining) by another oral surgeon at the University of Florida then in January 1989.

Under threat of imminant termination of my private disability and medical insurance benefits, in December 1990 in Nashville, TN (where I was then residing), I underwent a temporalis muscle and fascia graft upon removal of my disk in the left joint by yet another surgeon. Although the procedure was recommended by surgeons from Johns Hopkins, the University of Maryland, and the University of Alabama, I later learned that surgeons in Florida consider it to be medically unacceptable. (So far, that is the only procedure about which several "leading" surgeons trained at different places have agreed.) Not only did the graft of my own tissue fail immediately after surgery, there were complications with the surgical procedure and anesthesia which caused more damage to my jaw, face, head, neck and shoulder.

Because of history of surgical failures and financial hardship, it was extremely difficult to find a surgeon who would attempt removal of the failed/displaced and avascular graft. After two prior refusals, a surgeon who is a junior faculty member under Dr. Dolwick at the University of Florida reluctantly agreed to perform surgery only to attempt removal of the failed graft. Unfortunately, the surgical removal was incomplete and the surgical procedure resulted in new damage to my facial nerve, among other complications. Ironically, the surgeon and the department chair, Dr. Dolwick, refused to consult with the other physicians and surgeons treating me for systemic immune problems. (Neither that surgeon nor Dr. Dolwick have M.D. degrees.)

I am now again under the care of my original treating surgeon who is trying to assist me with documentation to ensure continuation of my private total disability benefits and medical insurance. He has agreed to perform surgical procedures without any silicone implants in attempt to relieve some portion(s) of my pain and slow down the arthritic degenerative process and re-ankylosis of my jaw joint(s). He is willing to consult and cooperate with the other physicians and surgeons treating me for systemic immune dysfunction problems. (As of December 1991, I had developed a positive ANA result, yet I have no family history of rheumatological/auto-immune disease.)

My original surgeon's education, clinical experience, attention to details, communication skills, and compassionate comprehension of the severity of his patients' pain are unique, as I have sadly discovered from consultations with and treatments by other oral and maxillo-facial surgeons since 1984. The FDA's approval of (and inadequate subsequent regulation of) the use of silicone for human implantation was relied upon by both my original surgeon and me with the resulting tragic consequences of my total and presumed permanent disability.

Not until the December 1990 televised Congressional hearings concerning silicone breast implants did I learn of the non-surgeons, such as Frank Vasey, M.D.(who is now one of my consulting physicians), who were publishing medical journal articles documenting silicone-induced localized and systemic medical complications. The medical journal articles given to me by Dr. Vasey led to my discovery of the existence of other articles noting complications associated with silicone used for various medical purposes.

Information about FDA approved medical devices, including from pre-market testing, clinical trials and experience, AND patient-consumer comments or complaints, must be more readily available and disseminated to physicians and surgeons AND their patients for actual "informed consent". Neither surgeons nor especially patients who are ill or in pain can (or should) be expected to obtain independently medical literature searches for published journal articles to confirm the safety and efficacy of medical devices approved and regulated by the FDA. Moreover, the existing medical device complaint reporting system designed by and for manufacturers and medical professionals affords no relief for patient-consumers who have already been harmed by medical devices.

I would urge Congress to allocate financial support to the FDA necessary for approval and regulation of medical devices which are implanted, even "temporarily", which may result in permanent injuries.

Mrs. Patricia O. Miller
1515 Grainger Avenue
Knoxville, TN 37917
615/524-4172

4 June 1992

Congressman Ted Weiss, Chairman
Human Resources Subcommittee
Rayburn House Office Building
Room B-372
Washington, DC 20515

RE: "Congressional Hearing on the Dangers of Jaw Implants"

Dear Mr. Chairman:

In 08/69, I was originally diagnosed as having "Poly Auricular Juvenile Rheumatoid Arthritis." This is a mild form of the disease. It was originally thought that only the knees, hands, and back was affected. I was treated with NSAIDs, and eventually started on a regime of gold salts therapy. My condition was controlled and I lived fairly normally with the exception of severe headaches and a loss of the envelope of movement normally associated with the TMJs. I developed severe discomfort. I stand 5'8½" and went from a post-parturition weight of 178 lbs to 90 lbs from October 1974 to August 1975.

In 9/76, I was referred to Dr. Don Chase at University of Tennessee, Knoxville. Subsequent radiological studies showed an erosion of the disks, bilaterally. A silastic implant was done 11/76 on the right side and 9/77 on the left. I developed osteomyelitis on the left side which precipitated removal of the silastics. It was already apparent at that time that the silastics were not going to withstand the movement needed in the jaw. I had an early proplast prosthesis installed bilaterally in 3/78. I continued to have the chronic pain and restriction of jaw movement. A problem subsequently developed with this prothesis being coated with bone and almost piercing the cranial fossa. Dr. Chase consulted by phone and sent my X-rays to Dr. Jack Kent at LSU; Dr. Kent advised him that it would be necessary to remove the implants and he supplied the replacement prothesis which have thus been identified as the Vitek I. The surgery was performed bilaterally in June 1982. I immediately began to collapse and by December of '82 it was necessary to put braces on my teeth and band my mouth tightly together as the mandible was in severe retrognathia. I developed an anterior open bite with only about 15 mm of movement. I remained in the fixations for the next year with almost daily trips to the doctor to reattach the braces as the pressure exerted by the backward pull of the mandible was so strong the braces were pulled off my teeth. This backward shift has created numerous problems of the neck, back and shoulders which are still being treated today. This situation was very hard to understand as my arthritis was under complete control in all parts of my body except my head. Little did I know that the problems I developed with my head had nothing to do with the initial health problem.

As my condition worsened, there was nothing that could be done by Dr. Chase. I wrote the Mayo Clinic, Duke University, University of Texas, the American Academy of Craniomandibular Disorders and others seeking answers. I received replies from Dr. Bruce Lund at Mayo telling me there was nothing to be done, the answers from the others were, nonexistent or offered no help. I developed stranger and stranger symptoms. Although from a rheumatology standpiont, my disease appeared to be in complete remission, and at that time it was discovered at the Rheumatology Dept. of the University of Tennessee that I really didn't have JRA afterall. Subsequent studies show that I do have Sarcoidosis, which affects only the Lacrimal glands at this time. The blood studies done in 2/92 by Dr. Thomas Namey show the Sarcoidosis is in complete remission. I also had the tissue rebiopsied, that Dr. Michael McCoy of UT has on file; sarcoidosis is not present. However, there is strong presence of proplast in all my tissue studies. I am bringing you up-to-date on my health as this is very important in light of the fact that the only "disease" that I am afflicted with is a severe reaction to proplast. To put this in its proper perspective, it is very important to see what Dr. Kent found when I travelled to New Orleans, in January 1990 to have the Vitek II prosthesis installed. (Please remember that I was not aware of any problems with any joints nor with proplast.) Dr. Kent did a work up and assured me that he would be able to solve my problems. I would like to now quote from Dr. Kent's letter dated 1/22/90, as to his findings: ". . . proplast teflon sheen of a very old type with carbon was observed and was found to be fragmented and displaced. After removal of that, several perforations were observed int he middle cranial fossa and the arch of the zygoma forward to the suture line was gone. In addition, resorption of the lateral half of the glenoid fossa and all the articular eminence was gone bilaterally. This left

a very thin sheet of bone covering the middle cranial fossa forward to the infratemporal fossa with multiple perforations." Dr. Kent excised the entire iliac crest from my left side to "patch me up". I am again quoting from his letter: "The superior cortical aspect of the iliac crest then became a replacement for the roof of the zygomatic arch. this is a large slab of bone on each side which is literally laying in position since there was nothing to secure the wires to. I say this because there was even some resorption of the posterior glenoid tubercle, and as mentioned above, resorption of the zygomatic arch two thirds of the way out to orbital rim." Please note his reference to the proplast teflon sheen and subsequent perforations. I returned to Knoxville after 8½ hours of surgery that resulted in my being told to wait 6-8 months for the grafts to take since there was nothing to attach a prosthesis to. Even at this time I knew nothing of the implications of the words VITEK I and II or even proplast. Dr. Kent called me several times to set up the surgery, but strangely called me to tell me not to come because a company called Vitek had declared Chapter 7. I wrote asking what this had to do with me but my inquiry went unanswered. He did call me to ask me to return for extremely experimental surgery which I declined. To quote my letter of 6/22/90, "Please be aware that I am not closing the door to all future surgeries; just the ones that result if "companies go bankrupt", models fail and we've got nothing better to work with surgery." He had suggested that I have a CT done, that would have meant that all the metal (including the fillings of my teeth) would have had to be removed to make a model; and if the model failed, he would do rib grafts. I declined and due to the restriction of my airways, costochondral rib grafts were tried in July 1990. I developed infection and lost the left graft. Banked bone grafts were necessitated at this surgery since I continue to erode. Due to the excruciating nature of the pain and the fact that I became unable to breathe if I laid down or even looked at my feet, the Christensen prothesis was installed bilaterally in 6/91. Again, "banked" bone grafts were necessary. These prosthesis became loosened due to the eroded nature of the mandible and the bite has again collapsed with the airways becoming again restricted. Dr. Chase states in his letter to Dr. Robert Christensen dated 4/8/92 (copy enclosed), "I have several patients who due to the failure of the Vitek Condylar Prothesis and Proplast foreign body reaction, who have in place Christensen Prothesis which are becoming loose due to failure of the cortical bone to withstand the loading of the screws in the ramus area." He modified the Christensen prothesis by elongating the mandibular portion so that it would extend beyond the diseased mandible and hopefully form new bone if a tight bond was secured in the stronger bone. He ordered these prototypes for me and two (2) others. However, due to the deterioration of my condition, it has been discovered that my prosthesis has also loosened at the glenoid fossa. This has caused a hopeless situation for me. My skull is so damaged that I can no longer hold the screws in place. My grafts have also been destroyed, so they will not do any further. I lost the 4th and 6th rib on the left side and my hip, and I have run out of spare parts. Dr. Christensen has a program in the works for 8/92 and the top doctors in the field will be present. However, with all due respect to the Oral Maxillofacial Surgeons, new joints will not help those of us who no longer have enough skull to secure these to. My only option to keep from dying from the closing of my airways is now a tracheotomy.

These concerns must be met by treatment of the whole body. Our needs go much further than the field of Oral Surgery. As long as the immune systems are thusly affected, we will never be able to sustain any normalcy in the head area.

I have deteriorated to the point that I can no longer consistently drive myself to my doctors' appointments. I am also unable to carry on any type of social activity due to the excruciating pain and the dizziness, nausea and general malaise. I have always trusted in my God, Jehovah, to sustain me and am very well aware that my handling of this can only be attributed to His strength.

If only one thing is accomplished by all of this, I hope it is that patients' concerns must be met by the medical profession and all of us, no matter our malady, need to be treated with compassion and dignity. Due to the failure of the Vitek joints and my reaction to the proplast, I have been robbed of my health, my family has been robbed of me a wife and mother. I hold no bitterness towards anyone, the truth is my precious strength cannot be wasted on such a futile emotion.

I appreciate your listening to my story and hope that something will be done before it is too late for others.

With utmost sincerity,

Patricia O. Miller

Patricia O. Miller

Copies of all medical records are readily available for verification of the facts of this letter.

Listing of surgeries regarding my cese are as follows:

11/76 -	TMJ arthroplasty with condylectomy (right side)
9/77 -	same procedure on left side; subsequent osteomyletis on left side
12/77 -	removal of implent and debridement
3/78 -	John Kent prosthesis on left side; same procedure on right side
7/82 -	preauricular approach removal of osteophytes ankylosing right and left proplast processes; insertion of Vitek proplast glenoid fossa implants right side (same procedure on left side)

The following surgeries were required due to failure of bone surface to sustain prosthesis:

2/87 -	bone graft cadaver bone left side; same procedure on right side
12/87 -	sagittal split ramus osteotomy right and left sides
8/88 -	Leforte I osteotomy and genioplasty
1/90 -	iliac bone graft right and left sides; and break through of glenoid fossa, cranial fossa, infratemporal fossa, mandivular fossa erosion present, all sides dura exposed
7/90 -	harvest of 4th and 6th ribs on left side; costochondral rib grift on right side; osteomyelitis left side
8/90 -	removal of left graft and debridement
6/91 -	Christensen implants on right and left sides; subsequent loosening of implants bilaterally.
Present -	Christensen implants modified to correct mandivular failure. Cranial failure yet to be addressed.

Sept. 2, 1992
Update

The joints on the R side literally broke, this pulled the screws out of the glenoid fossae bilaterally. On 7-8-92 I had the modified Christensen inserted due to loss of airway, esophagal restriction and excruciating pain. I'm also enclosing the Path report. I'm almost 6 years post removal of the joint w/proplast and still severe some severe giant cell reaction with immunio consequences. The immune problem and pain still are unaddressed.

Regards,

Pat Miller

Knoxville Oral & Maxillofacial Surgeons, P.C.
1924 Alcoa Highway U-63
Knoxville, Tennessee 37920
(615) 544-9021

Oral-Maxillofacial Surgery
D. C. CHASE, D.D.S.
J. W. HUDSON, D.D.S.

April
~~March~~ 8, 1992

Robert W. Christensen, D.D.S.
TMJ Implants, Inc.
17301 West Colfax Avenue, Suite 275
Golden, Colorado 80401

Dear Bob:

I appreciate the recent information regarding the wear resistant character of the Christensen Condylar Head. I have enclosed copies of several cephalometric tracings and prototype of a "Chase modification of a Christensen Prostheses." I have several patients who due to failure of the Vitek Condylar Prosthesis and Proplast foreign body reaction, who have in place Christensen Prosthesis which are becoming loose due to failure of the cortical bone to withstand the loading of the screws in the ramus area. To that end, several modifications are proposed in your current prostheses which will unable me to take advantage of the strong cortical bone along the horizontal ramus.

If you and your company find it feasible to make this modification, I ought to have these cases operated with follow-up by the time of our August meeting.

I have also taken the liberty of receiving the date of your August 1992 Program. I would appreciate more information with regard to the content of the program in order for me to prepare my lecture material.

Respectfully,

Donald C. Chase, D.D.S.

DCC/la

THE UNIVERSITY OF TENNESSEE MEDICAL CENTER AT KNOXVILLE

Drawer U-108
1924 Alcoa Highway
Knoxville, Tennessee 37920
(615) 544-9080

UNIVERSITY PATHOLOGISTS, PC
Francis S. Jones, MD
Anthony A. Katine, MD
Frances K. Patterson, MD
D. Douglas Wilson, MD

J. Michael McCoy, DDS
Oral Pathology

Paul B. Googe, MD
Dermatopathology
Elizabeth W. Hubbard, MD
Stuart Van Meter, MD

ROOM #: ICU 3
HOSP #: 372709
PATH #: S-309417

NAME: MILLER, PATRICIA BD/AGE: 39 SEX: F DATE: 7-8-92
SOCIAL SECURITY #: 414-88-4530 DOCTOR: Chase

OPERATION PERFORMED: Total Christiansen joint prosthesis replace. R/L Christiansen

SPECIMEN(S) SUBMITTED: A) Capsule L TMJ B) Scar tissue L C) Lymph node L
D) Pericondylar tissue L E) R capsule peri-implant tissue
F) Scar tissue R G) Reactive condylar tissue R TMJ
H) Granulation tissue around neck of R condylar implant
I) Granulation tissue, interface R condyle
J) Tissue R glenoid fossa area
K) Tissue R mandibular condyle

PERTINENT HISTORY AND OPERATIVE FINDINGS: Bil TMJ dysfunction

PREVIOUS SURGICALS: S-205098, 217123, 242134, 262598, 264849, 279092, 283417

GROSS:

A) The specimen is labeled "left capsule" and consists of a single piece of blue-gray to gray-white, irregularly shaped soft tissue measuring 0.8 cm in greatest dimension. The specimen is bisected longitudinally and submitted in its entirety for histologic exam.

B) The specimen is labeled "scar tissue, left" and consists of a gray-white excisional biopsy measuring 4.5 x 0.5 cm, and extending to a maximum depth of 0.4 cm. The specimen is inked, serially sectioned in a transverse manner, and representative cross-sections are submitted in one cassette.

C) The specimen is labeled "lymph node, left" and consists of a light grayish-tan to dark reddish-purple, irregularly shaped lymph node with a small amount of yellowish adipose tissue attached, measuring 1.8 x 0.7 x 0.6 cm. The specimen is serially sectioned in a transverse manner and submitted in its entirety for histological exam.

D) The specimen is labeled "pericondylar tissue" and consists of two pieces of blue-gray, irregularly shaped soft tissue. The largest is elongated and measures 1.2 cm in greatest dimensions, the small measures 0.7 cm in greatest dimensions. The specimens are submitted in their entirety for histological exam.

Continued on Page Two

DATE SIGNED: _____ PHONE REPORT: _____ DATE/TIME CHARTED _____
INTRADEPARTMENTAL: ____ EXTRADEPARTMENTAL: ____ RETROSPECTIVE: ____

THE UNIVERSITY OF TENNESSEE
MEDICAL CENTER AT KNOXVILLE
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ROOM #: ICU 3
HOSP #: 372709
PATH #: S-309417

NAME: MILLER, PATRICIA BD/AGE: 39 SEX: F DATE: 7-8-92

Page Two

E) The specimen is labeled "right capsule" and consists of a single piece of light blue-gray, irregularly shaped soft tissue measuring 0.8 cm in greatest dimensions. Specimen submitted in its entirety for histological exam.

F) The specimen is labeled "scar tissue, right TMJ" and consists of a gray-white excisional biopsy measuring 4.1 x 0.2 cm, and extending to a maximum depth of 0.25 cm. The specimen is inked, serially sectioned in a transverse manner, and representative cross-sections are submitted in one cassette.

G) The specimen is labeled "reactive condylar tissue, right TMJ" and consists of a single piece of light grayish-tan to dark grayish-tan, irregularly shaped, soft tissue, measuring 1.3 x 1.0 x 0.6 cm. The specimen is bisected and submitted in its entirety for histological exam.

H) The specimen is labeled "granulation tissue around neck of right condylar implant" and consists of four pieces of grayish-tan tissue. The largest measures 0.6 cm in greatest dimensions, the smallest measures 0.15 cm in greatest dimensions. Specimen is submitted in its entirety for histological exam.

I) The specimen is labeled "granulation tissue interface right condyle" and consists of five pieces of dull gray-white, dark blue-gray, irregularly shaped, soft tissue. The largest measures 1.4 x 0.7 x 0.6 cm, the smallest 0.3 cm. in greatest dimensions. Specimen submitted in its entirety for histological exam.

J) The specimen is labeled "tissue right glenoid fossa" and consists of two pieces of light grayish-tan to blue-gray, irregularly shaped soft tissue. The largest measures 0.8 cm in greatest dimensions, the smallest 0.5 cm in greatest dimensions. Specimens submitted in their entirety for histological exam.

K) The specimen is labeled "tissue right mandibular condyle" and consists of a single piece of pale yellow to blue-gray, irregular shaped soft tissue measuring 1.5 x 0.9 x 0.8 cm. The specimen is bisected longitudinally and submitted in its entirety for histological exam.

DH/gbs

Continued on Page Three

DATE SIGNED: _____ PHONE REPORT: _____ DATE/TIME CHARTED _____
BOSW REVIEW: ____ INTRADEPARTMENTAL: ____ EXTRADEPARTMENTAL: ____ RETROSPECTIVE: ____

THE UNIVERSITY OF TENNESSEE
MEDICAL CENTER AT KNOXVILLE
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Elizabeth W. Hubbard, MD
Stuart Van Meter, MD

ROOM #: ICU 3
HOSP #: 372709
PATH #: S-309417

NAME: MILLER, PATRICIA BD/AGE: 39 SEX: F DATE: 7-8-92

Page Three

MICROSCOPIC:

Specimen A consists of connective tissue which is quite hyalinized in areas. Portions of it is quite hypercellular with numerous darkly stained foreign bodies surrounded by foreign body type giant cells encountered.

Specimen B consists of hyalinized fibrous tissue and hair bearing skin without atypia.

Specimen C consists of multiple fragments of salivary gland. The gland shows mostly serous acinar structures and significant infiltration by fat. There are also numerous mucous acini identified.

Specimen D consists of fibrous connective tissue within which are found a few darkly pigmented foreign bodies showing very little in way of reaction.

Specimen E is fibrous connective tissue with only a few scattered foreign bodies surrounded by giant cells.

Specimen F is hair bearing skin which shows no abnormalities.

Specimen G is a lymph node within which are found numerous foreign body giant cells surrounding engulfed fragments of darkly pigment foreign material.

Specimen H is connective tissue showing small particulate foreign body surrounded by giant cells.

Specimen I is consistent with connective tissue showing an intense infiltration by darkly pigmented foreign material much of which is surrounded by foreign body giant cells.

Specimen J is hypercellular connective tissue within which are found numerous histiocytes and giant cells. There is also significant synovial hyperplasia identified in these sections.

Continued on Page Four

DATE SIGNED: _____ PHONE REPORT: _____ DATE/TIME CHARTED _____
BOSW REVIEW: ____ INTRADEPARTMENTAL: ____ EXTRADEPARTMENTAL: ____ RETROSPECTIVE: ____

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Page Four

Specimen K demonstrates a diffuse histiocytic proliferation and scattered giant cells.

DIAGNOSES:

A) "Left capsule": Intense foreign body reaction
B) "Scar tissue, left": Unremarkable skin, no foreign bodies seen
C) "Lymph node, left": Submandibular salivary gland, unremarkable
D) "Pericondylar tissue": Scar tissue with minimal foreign body reaction
E) "Right capsule": Scar tissue with minimal foreign body reaction
F) "Scar tissue, right": Skin, no foreign bodies seen
G) "Right TMJ tissue": Lymph node with discrete foreign body granulomas
H) "Right granulation tissue": Foreign body reaction
I) "Right condyle granulation tissue": Foreign body reaction
J) "Right glenoid fossa": Synovial hyperplasia with foreign body reaction
K) "Right mandibular condyle": Diffuse foreign body reaction

JMM:adj
07/13/92

J. Michael McCoy, D.D.S.
Pathologist

DATE SIGNED: 7/13 PHONE REPORT: _____ DATE/TIME CHARTED _____
INTRADEPARTMENTAL: ____ EXTRADEPARTMENTAL: ____ RETROSPECTIVE: ____

Disorders of the TMJ II: Arthrotomy 1042-3699/89 $0.00 + .20

Alloplastic Implants in the Temporomandibular Joint

*Doran E. Ryan, DDS, MS**

The generally accepted indications for removal of the articular disk from the temporomandibular joint (TMJ) include intermediate- to late-stage anterior and medial displacement where the disk demonstrates loss of normal morphology with shortening of the anteroposterior dimension, central perforation, or fragmentation beyond repair. The histologic morphology of the disk in these advanced stages of disease was described by Grote and coworkers.[80] Loss of collagen fiber orientation and the presence of chondrocytes, cartilage, and vascularity were noted. Synovitis, synovial hyperplasia, and fibrous adhesions have been seen by arthroscopy in these late-stage cases. Alteration of the articular surfaces with fibrillation, exposed subchondral bone, and degeneration can follow.[41] As the dysfunction progresses, myofascial pain and parafunctional habits tend to increase.

These are the difficult surgical cases! These are the cases in which alloplasts have been recommended and utilized. In this situation, should alloplastic interpositional materials be abandoned, or are our expectations for success with these materials too high? In trying to answer this question, it is important to review carefully the use of interpositional implants, not only in the TMJ but also in other joints of the body. Microscopic analysis can be performed on removed clinical specimens, arthroscopic biopsy material, and animal tissues. Success can best be evaluated by long-term clinical and radiographic follow-up of the various TMJ alloplasts. This article presents such information, from which the reader can reach his or her own conclusions regarding the efficacy of these products.

PROPLAST-TEFLON

Proplast is the porous form of Teflon (polytetrafluoroethylene; PTFE) and has been fused with either vitrous carbon (Proplast I), aluminum oxide (Proplast II), or synthetic hydroxyapatite (Proplast HA). The interpositional implant is a laminate of either Proplast I or Proplast II and Teflon. The Proplast portion, placed against the temporal bone or periosteum, is designed to encourage ingrowth of tissue to stabilize the implant. The smooth Teflon functions against the condyle. As of this writing, the Proplast-Teflon interpositional implant can no longer be purchased, but it has been used in more 20,000 surgical cases since 1983. Success rates have been reported to range from 93 to less than 50 per cent.[17, 87]

Early Use of Teflon

Calnan,[6] in 1963, attempted to establish standards of quality for the use of foreign materials in reconstructive surgery. He pointed out that movement can be a problem and ultimately leads to failure. This important finding was a factor in the development of the Proplast-Teflon laminate. He also evaluated the tissue reaction to different materials, looking at round cells, macrophages, and giant cells and the fibrous reaction, including capsule formation around

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the implant. The PTFE was the least reactive; in fact, the smooth form was without giant-cell reaction. Although PTFE produced less fibrous reaction than the other materials, a complete capsule was formed. Calnan concluded that the "tissue reaction to PTFE is less than with any other material and for this reason it is recommended that the use of all less satisfactory material should be discontinued." The PTFE used in this study was not medical grade; it was obtained from the Crain Packing Company.

In 1960, Charnley[8] described the use of PTFE as "synthetic cartilage" in total and partial hip replacements. He measured the coefficient of friction between bone and substances commonly used in arthroplasty and concluded that the only solid that remotely approached articular cartilage was PTFE (another important factor in the development of the Proplast-Teflon laminate). Experiments on dogs having hip prostheses with Teflon parts were conducted by Leidholt and Gorman.[30] The Teflon cup showed wear and deformation after an average of 8.7 months. The surrounding capsule and synovium were grossly thickened, and all animals showed acute and chronic inflammation of the joint tissues, in which were found Teflon particles. Giant cells were frequent, indicating a foreign-body reaction. Those investigators could not determine whether the particle size or some characteristic of the local tissue was the principal factor in the reaction. Similar results were observed in an implant taken from the patient of one of those authors. Leidholt and Gorman felt Teflon should not be used in weight-bearing joints.

Charnley and Kamangar stopped using Teflon for hip sockets in 1963 and reported on the results in 1969.[9] They stated that the most serious aspects of the failure of PTFE was the production of tissue reaction by wear debris, which caused loosening of the socket by erosion of the bone. They believed the particles were produced too fast for the tissues to dispose of them.

Oral and Maxillofacial Surgical Experience

The first published use of Proplast-Teflon interpositional implants in the TMJ was in 1982. Gallagher and Wolford[16] had placed 10 implants in the TMJ over the previous 4 years with good results. These implants were placed between the condyle and the meniscus after condylectomy and wired to the condyle. Silastic was used in the same manner in nine joints with three failures secondary to breakage of the ligature wire and herniation of the implant through the capsule. Those authors felt the Proplast-Teflon was a better implant because ingrowth of fibrous tissue led to better stability.

Earlier, Homsy and associates[25] had demonstrated the ingrowth of fibrous tissue into PTFE-pyrolytic graphite with porosity between 70 and 80 per cent and pore size between 100 and 500 μm. Interbridging between pores of greater than 200 μm would allow for bone growth, which was deemed important to prevent movement. Homsy and coworkers[25] noted the presence of giant cells around the implants but did not know the significance, suggesting that it might be secondary to mechanical stimulation. In a presentation to the US Food and Drug Administration in 1989,[30] Homsy again recognized the presence of macrophages and macrophage polykaryons around the implants but felt such "findings are nonmorbid" and, in fact, may contribute to normal healing. He pointed out that fragmentation and motion will increase the number of foreign-body giant cells. Secretory products of macrophages and their functions were reviewed in 1984 by Takemura and Zena,[48] who pointed out that if the macrophages are able to control the foreign material, they become central in tissue repair. When they are unable to control the foreign material, macrophages may inadvertently participate in excessive tissue destruction by secreting neutral proteinases and acid hydrolases.

The clinical success of Proplast-Teflon interpositional implants was highly touted in the early 1980s. Kiersch[27] reported a 93 per cent success rate over 9 years for 250 implants used for both disk repair and replacement. Carter,[7] at the 1983 national meeting of the American Academy of Oral and Maxillofacial Surgeons, reported an 87 per cent success rate on 52 patients over a 3-year period using Proplast-Teflon as a meniscus replacement. Merrill,[32] in a 1985 survey of 37 TMJ surgeons as to their selection of surgical procedures for meniscectomy and interpositional implants, found that 34 felt there was an indication for disk removal and 15 of those favored Proplast-Teflon implants because of the lesser likelihood of displacement. In 1986, Vitek, Inc. conducted a written survey among oral and maxillofacial surgeons who performed TMJ surgery to compare techniques and results. Of these, 259 surgeons had used Proplast-Teflon implants in 5070 cases with a 91.5 per cent rate of satisfactory results. No guidelines for defining success were discussed. Moriconi and colleagues[34] identified Proplast implants as "a more predictable mode of temporomandibular joint reconstruction." Again, ingrowth of tissue into the Proplast was felt to be of utmost importance. Close follow-up was called for to "adequately assess the performance" of these implants. No results were presented.

Problems with Proplast-Teflon interpositioned implants were first identified in writing by this author in a *Temporomandibular Joint Newsletter* from The Medical College of Wisconsin in 1985. On recall examination, development of an anterior open bite was noted in 20 per cent of the patients, as was occasional continued degeneration of the condyles. The etiology of this problem was not identified. Using New Zealand rabbits, Timmis and coworkers[49] replaced the meniscus with either silicone or PTFE-Al_2O_3 implants. The Proplast-Teflon group demonstrated marked osteoclastic activity with resorption and severe degenerative changes in both the condyles and glenoid fossa, and implant tearing was seen in 46 per cent of the joints. Lymph node involvement with collections of Teflon particles, multinucleated giant cells, histiocytes, and granulation tissue was described by Lagrotteria and colleagues.[29] Breakdown of a Proplast I implant with perforation and extensive giant-cell reaction was found in the ipsilateral TMJ. The largest particle found in the node was a carbon fiber of 42 μm. The Proplast-Teflon fragments were only a few micrometers in diameter. An implant examined via arthroscopy by Bronstein[5] "was seen to be in good condition and not fragmented or damaged; however it was not covered with soft tissue." The implant had been in place for 3 months, and the patient's complaint was increased noise. In the same paper, 38 patients with 20 silicone and 18 Proplast II implants were evaluated with tomographic studies. The Proplast-Teflon implants produced more severe bony responses with erosion of both condyle and fossa. Florini and coworkers[17] followed 55 PTFE- and 18 diskoplasty-treated joints for 20 months and 48 months, respectively. More than 60 per cent of the joints with Proplast-Teflon implants showed severe, destructive osseous changes, whereas none of the joints managed by diskoplasty showed such changes. The authors speculated that if the size and number of particles exceeded the capacity of the lymphatic system to remove them, the reaction in the joints themselves would be one of destructive arthritis. In 1989, El-Deeb and associates[15] investigated Proplast implants in non–weight-bearing areas. Fragmentation and giant-cell formation were shown, along with collapse of the Proplast and loss of the interbridging fibrous tissue connections. No bone growth was demonstrated. This lack would tend to decrease stability, which may account for the increased giant-cell reaction. Speculation would suggest a similar phenomenon when Proplast is used in a weight-bearing area such as the TMJ.

Medical College of Wisconsin Experience with Proplast II

Over a 25-month period, 105 TMJ procedures on 67 patients were performed at the Medical College of Wisconsin. In the retrospective clinical and radiographic analysis, 13 patients with 19 TMJ procedures were excluded from this survey because of incomplete medical records. The sample group was divided into subgroups: a primary group of 36 patients with no previous surgery, and a secondary group of 18 patients who had had previous Silastic implants (Table 1). All 54 patients met the criteria for surgical treatment. Similar to other reports, 90 per cent of the patients were women, and the average age was 30 years.

All operative procedures were performed through a standard preauricular approach. In the primary group, a diskectomy was performed because it was deemed technically impossible to repair the disk. Additionally, eminoplasties were performed in all cases to reduce the height and change the slope of the eminence in the hope of reducing the pressure against the implant during function. After diskectomy, a 1.3-mm PTFE–aluminum oxide fossa implant was sized to cover the fossa and the articulating surface of the eminence. The implant was fixed to the lateral rim with either 2-0 Mersilene suture or multiple lateral stainless steel wires. Both prior to and following fixation of the implants, simulated articulation and function of the joints was performed to ensure that the implants did not displace.

Table 1. *Study Groups Receiving Proplast II (PTFE-Al_2O_3) Implants, October 1983 to November 1985*

	NO. OF PATIENTS		TOTAL JOINTS
	Unilateral	*Bilateral*	
Primary group (diskectomy + Proplast II)	17	19	55
Secondary group (Proplast II after Silastic failure)	5	13	31

Table 2. *Number of Joints with Radiographic and Surgical Evidence of Arthrosis Preoperatively and at Exploration*

	NONE	MILD	MARKED	SEVERE
Primary group				
Preoperatively (N = 55)	31	24	–	–
Proplast II failure* (N = 44)	–	3	22	19
Proplast II in situ				
Stable (N = 9)	–	6	3	0
Unstable† (N = 2)	–	–	–	2
Secondary group				
Preoperatively (N = 31)	–	24	5	2
Proplast II failure (N = 26)	–	–	11	15
Proplast II in situ				
Stable (N = 3)	–	1	2	–
Unstable (N = 2)	–	–	–	2

*Implant removed.
†Implant should be removed.

In the secondary group, 31 reoperations were performed because of failure of previously placed Dacron-reinforced Silastic fossa implants after diskectomies. The surgical procedures in all cases consisted of removal of the fossa implants, debridement of the soft tissue including all reactive tissue in the joint space, and, when necessary, minimal bone plasty to smooth areas of degeneration on either the condyle head or the eminence. After debridement and bone plasty, PTFE–aluminum oxide implants were placed as described.

Preoperatively, 68 per cent of the patients exhibited a class I occlusion, 26 per cent a class II malocclusion, and 3 per cent a class III malocclusion. The other 3 per cent were edentulous. In the primary group, 38 per cent of the patients exhibited no symptoms or physical findings of myofascial pain, and 62 per cent did exhibit either symptoms or physical findings of pain in the muscles of mastication. Of the patients who did have symptoms and physical findings of myofascial pain, 92 per cent had splinting preoperatively and postoperatively. In the secondary group, all except one patient presented with signs and symptoms of myofascial pain, and all of these patients had splinting both preoperatively and postoperatively.

Finally, an assessment was made for radiographic or surgical evidence of arthrosis preoperatively or at the time of exploration of the joint. In the primary group, 56 per cent of the joints exhibited no evidence of arthrosis, and the remainder had only mild degenerative changes, that is, minor flattening or a localized loss of articular surface at the site of perforation (Table 2). In the secondary group, 77 per cent of the joints showed mild degenerative changes, 16 per cent proved to have marked changes, and 7 per cent showed severe changes (Table 2).

All patients were recalled via certified mail with follow-up mailing if no response was received. In the primary group, 28 of the 36 patients met the criteria for implant failure (discussed later in this article) and had their implants removed, a 77 per cent failure rate (Table 3). In the secondary group, 15 of 17 patients met the criteria for failure, and, again, the implants were removed. The average time from placement to removal of PTFE implant was 30 months in the primary group and 25 months in the secondary group (Table 4).

Regarding occlusion and rate of failure, patients in class I had greater success with the implants, but the failure rate was so high in all groups that statistically, there was no difference. This held true for both the primary and the secondary groups. In the primary group there was a lower failure rate when myofascial pain was absent preoperatively. The use of splints postoperatively also seem to improve the success rate. Unfortunately, the failure rate was high with all combinations of symptoms and adjunctive measures. The lowest failure rate, 66 per cent, was in those patients without preoperative myofascial pain who utilized splints after surgery. In the secondary group, all but one patient had signs or symptoms of myofascial pain before surgery, so no comparison could be made in this group.

Comparison of the radiographic and surgical appearance of the joints preoperatively with that at the time of the last implant evaluation showed a significant change (see Table 2). All 31 of the joints in the primary group that demonstrated no arthrosis before surgery had evidence of advanced arthrosis, with 84 per cent classified as having marked to severe changes. All the original mild arthroses had become marked or severe. In the secondary

Table 3. *Failure Rates of Proplast II Implants*

	NUMBER (PER CENT) OF FAILURES			
	Unilateral	*Bilateral*	*Total Joints*	*Total Patients*
Primary group	12/17 (70)	16/19 (84)	44/55 (80)	28/36 (77)
Secondary group	4/5 (80)	11/13 (84)	26/31 (83)	15/18 (83)

Table 4. *Number of Proplast II Implants Removed at Various Times after Placement*

MONTHS AFTER PLACEMENT	PRIMARY GROUP	SECONDARY GROUP
4–12	–	3
8–12	5	–
13–24	10	5
25–36	14	8
37–48	13	10
49–51	2	–

group, there was a shift of the arthrosis from the mild and marked category preoperatively to the marked and severe category at the last evaluation.

Magnetic resonance imaging (MRI) was used to evaluate many of the implants before removal. In the cases with severe arthrosis, loss of signal in the condyle, loss of temporal bone, presence of large soft-tissue masses, and fragmentation of the implants (PTIPI) were often identified (Fig. 1). At surgery, all implants were found to be perforated (Fig. 2), 50 per cent exhibited folding, and 17 per cent were fragmented or separated into their two components. Perforation through the temporal bone with exposure of the dura of the middle cranial fossa was found in four cases (Fig. 3).

Histologic studies of the peri-implant tissue consistently showed a fibrous background with exuberant foreign-body giant-cell reactions. Numerous darkly staining foreign-body fragments were always seen, with giant cells surrounding the foreign material (Fig. 4). Secondary characteristics included focal areas of chronic inflammatory cells such as lymphocytes, plasma cells, and occasional histocytes.

SILICONE

Early Use

Silicone in various forms has been used by many surgeons for prevention of ankylosis.[4, 11, 16, 23, 31, 37, 43, 81] The long-term results or complications of the use of this material were seldom discussed. The first mention of the use of silicone as a disk substitute was in 1969, when Henny[24] recommended Silastic sheeting be used after condylectomy if the perforation of the meniscus was extensive. The success rate of the procedure and long-term follow-up findings were not discussed. The first documented clinical and radiographic follow-up of interpositional silicone implants also appeared in 1969.[58] Four patients, one with bilateral procedures, were followed after the implantation of a silicone sponge, 3 to 4 mm thick, which was sewn to the capsular soft-tissue structures. At 3 years, all patients demonstrated normal joint space with a slight decrease in the motion of the condyle and no pain. In 1970, Habbi and associates[41] described the creation of surgical fractures below the condyle in rabbits and placement of either Silastic or Supramid (sulfa-

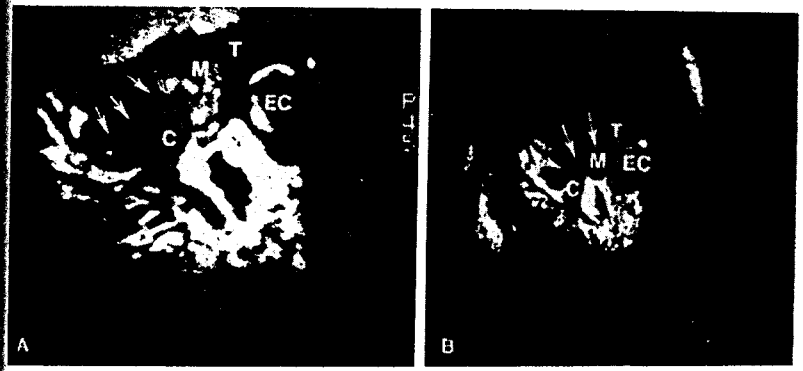

Figure 1. MRI images of PTIPI implants. *A*, Scan of left TMJ showing decreased signal of condyle (C), fragments of PTIPI (*small arrows*), soft-tissue mass surrounding the implant (M), and loss of temporal bone (T) with mass against the dura (*large arrow*). The mass does not involve the ear canal (EC). *B*, Scan of the TMJ with fragmentation of the PTIPI implant (*arrows*), severe degenerative changes and decreased signal of the condyle (C), and a large mass surrounding the implant (M). The temporal bone (T) is intact, and the mass is not affecting the ear canal (EC).

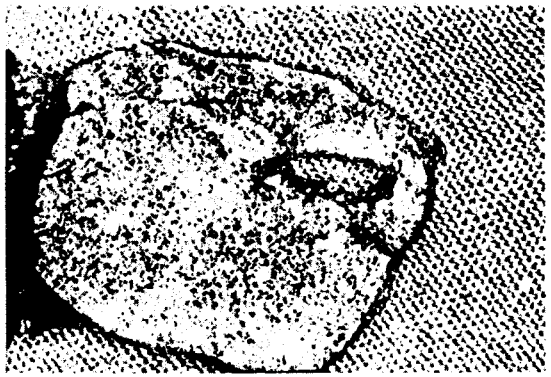

Figure 2. Perforated PTIPI with a soft-tissue mass still attached to the lateral aspect around three stainless steel wires (*left*).

meter) as interpositional materials. The materials produced similar histologic results, with chronic inflammation the first week and then diminution with time such that minimal reaction was noted at 6 weeks. A fibrous connective tissue lining was observed around the pseudoarticulation. Detailed histologic information was not available. A follow-up study by Murname and Doku[38] of the same rabbit population found capsular formation around the pseudoarticulation lined with synovial-type tissue and the presence of synovial-type fluid. A slight foreign-body giant-cell reaction was also noted.

Orthopedic Experience

Silicone has been used as a spacer between joint surfaces by the orthopedic community since the early 1960s. Evaluation of these im-

Figure 3. Looking into the glenoid fossa, the dura (*arrow*) of the medial cranial fossa is seen through a temporal bone perforation.

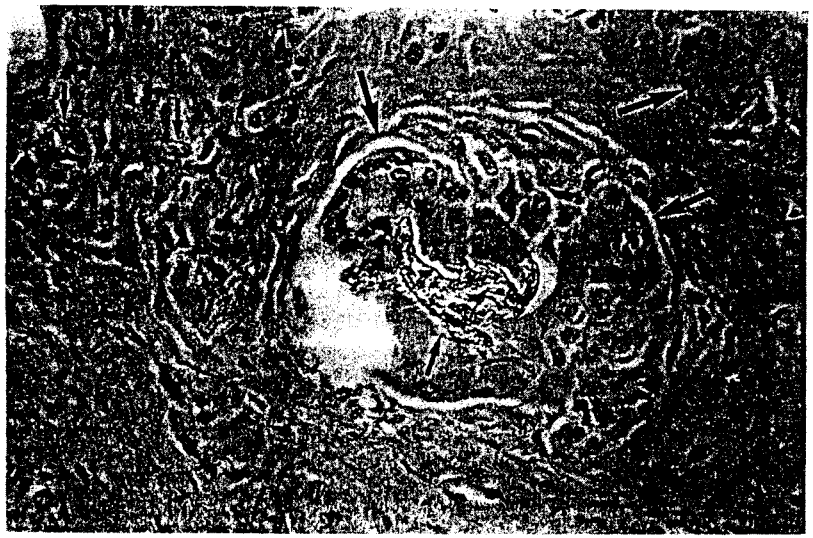

Figure 4. Particles of the PTIPI (*small arrows*) surrounded by giant cells (*large arrows*) and other phagocytic cells.

plants, the complications that can follow, and the controversy surrounding their use thus precedes our experience by about 10 years. In 1962, Swanson[45] introduced a metacarpophalangeal and interphalangeal joint prosthesis made of silicone. Since that time, silicone has been used in almost every joint of the body, including the big toe. Complications such as infections, dislocations, fractures, and dentritic synovitis have been reported. Fracture rates of the implants range from 1 per cent[46] to 25 per cent.[5]

The first report of silicone lymphadenopathy secondary to fractured implants in the hand was published in 1977.[10] The mean maximum diameter of the silicone particles in the nodes was 24.5 μm. Benjamin and associates[3] in 1982 reported on two cases of silicone lymphadenopathy, one with a concomitant malignant lymphoma. Fracture of the implants on the ipsilateral side was not always found in these cases. The occurrence of lymphoma in a patient with Silastic arthroplasty was probably fortuitous, considering that patients with rheumatoid disease have an increased instance of malignant lymphoma. In 1983, Smahel and Meyer[44] examined the capsules around Silastic implants used in hand surgery. They found a collagen structure that matured in 2 months at the latest and thereafter changed little as time passed. The capsule from around joint prostheses had a slightly less closely packed inner layer of connective tissue containing numerous foreign particles surrounded by macrophages and multinucleated giant cells. At times, a pseudoepithelium containing multinucleated giant cells accumulated at the inner margin. Autopsy tissue from three dogs and one patient who had silicone implants in place for 12 and 10 years, respectively, was examined by Nalbandian and coworkers.[36] Again, the uninflamed capsule contained scattered areas of lymphocytes, macrophages, and multinucleated giant cells in a connective tissue stroma. Macrophages and giant cells were adjacent to silicone particles. All organs of the dogs were examined for silicone, and none was found. The human tissue was similar histologically except that silicone was found in one axillary node and in the subsynovial connective tissue. No acute inflammation was noted in any specimen. Those authors noted that Dacron suture provoked a reaction both quantitatively and qualitatively similar to that induced by the silicone particles. Swanson,[46] in a clinical experience of 3000 pa-

tients, found silicone foreign-body synovitis in less than 1 per cent and lymphadenopathy in 0.01 per cent of such cases. In 1984, Swanson and coworkers[47] reported that in a 4-year follow-up of 175 wrist silicone implants, 12 per cent had required replacement and 16 per cent had fractured. Radiographic remodeling was found, but no evidence of tissue intolerance to the silicone elastomer was noted.

Since 1984, many articles have discussed the advantages and disadvantages of silicone in joint arthroplastic procedures. Bone resorption and cystic osteolysis secondary to fragments of silicone have been reported.[14, 38] Introduction of high-performance medical-grade silicone has decreased the complications, but they still occur.[42] In general, the orthopedic community understands the advantages and disadvantages of silicone and uses the product when and if they feel it is appropriate.

Oral and Maxillofacial Surgical Experience with Silicone Interpositional Implants

In 1981, Sanders[40] presented a large series of silicone implants wired to the glenoid fossa. The early results were excellent. In 1983, Bessette[4] reported the results of Silastic block implants sutured to the soft tissues of the TMJ after partial meniscectomy in both monkeys and humans. Of the 62 patients treated, 87 per cent obtained relief of symptoms, and 62 per cent had increased range of motion. In 4 of the 10 animals only a mild tissue reaction was demonstrated. In the other 6 animals, mild to moderate chronic inflammation was seen only immediately adjacent to the implants. No adverse effects on condylar growth were noted. Ryan,[39] at the 1984 Clinical Congress, reported an 89 per cent success rate in 150 patients (185 joints) after meniscectomy and replacement with Dacron-reinforced Silastic wired or sutured to the glenoid fossa and eminence. The average follow-up was 1.5 years. This retrospective study included range of motion of the mandible, a comparison of preoperative and postoperative pain, ability to eat, and determination of the success rate based on specific guidelines (Table 5). Merrill, in 1986,[33] reviewed 69 patients who had meniscectomy and Dacron-reinforced Silastic sutured to the fossa eminence and reported a 91 per cent success rate. In a histologic evaluation of the TMJ soft tissues after removal of failed Silastic implants, Dolwick and coworkers[13] found a foreign-body giant-cell reaction around fragments of Silastic dispersed throughout the tissue. The following year, two of the same investigators[12] reported the presence of cervical lymphadenopathy on the side of a Silastic implant in the TMJ. A biopsy specimen showed a silicone-induced foreign-body giant-cell reaction in the node.

By 1985, many surgeons had given up using permanent Silastic and had gone to Proplast-Teflon laminates, as reported by Merrill in his survey.[32] Only five surgeons were using permanent Silastic implants; two others were using thin Silastic sheets as a temporary implant, removing them 2 to 5 months after placement. In 1986, Timmis and coworkers[49] compared Silastic with Proplast-Teflon implants in the TMJ of rabbits. Many of the Silastic implants became displaced, and wear particles were found throughout the soft tissue of the joint. The bone reaction was mild to moderate compared with the moderate to severe reaction secondary to the Proplast-Teflon implant. Clinical and radiographic evaluation of 20 Silastic implants was discussed by Bronstein.[5] Patients were generally pleased with the function, although in many cases, his criteria for success were not satisfied. Radiographic examination showed less disturbing bone erosion responses than those seen with the Proplast-Teflon implants. He also pointed out that bony apposition and osteophyte formation may be seen in joints in which Silastic implants have been placed.

Table 5. *Minimum Criteria for Implant Success*

Vertical movement	36 mm
Lateral movement	5 mm
Protrusive movement	End to end
Pain relief	85 per cent

Medical College of Wisconsin Experience with Silastic Implants

A survey with 14 questions was sent to all patients treated by meniscectomy and interpositional Dacron-reinforced Silastic implants at the Medical College of Wisconsin since 1981. The criteria for initial surgery were pain in the joints, dysfunction with radiographic evidence of internal joint derangement, and unwillingness of the patient to live with his or her present quality of life. Nonsurgical therapy was made available to all patients. Occasionally, when mechanical dysfunction of the joint was severe, a patient would elect not to pursue nonsurgical therapy. The total number of patients surveyed was 215, of whom 98 responded to the survey,

42 had not responded at the time of this writing, 69 had moved with no forwarding address, three were deceased, and two returned the survey without a name. Adequate records were not available for one respondent. The average follow-up was 5 years, 3 months (range 1 year, 6 months to 8 years).

Because 40 per cent of the patients have had their implants removed, the 98 evaluable patients were divided into two groups: group 1 with the implants still in the joint and group 2 with the implants removed.

Of the 62 patients in group 1, 33 (53 per cent) reported no pain. The remaining 29 patients graded their pain from 1 (no pain) to 10 (most intense pain imaginable). Their present pain average was 2.7, and their usual pain was 2.6 (Table 6). All 62 patients also rated how they felt now compared with the time they were treated using a scale of −7 to +7, with 0 being the original condition. The average score was +4.1, with 13 per cent being worse after treatment (Table 6).

Two questions related to chewing ability. In these, patients graded their chewing from 1 (no difficulty) to 10 (unable to chew). The average in group 1 was 2.2, with 42 per cent having no difficulty at all (Table 7). Patients were also asked to rate how they chewed now compared with when they were treated. The scale was from −7 to +7, with original ability to chew being 0. The group 1 average was +4.5, with 11 per cent worse, 6 per cent the same, and 82 per cent better (Table 7). Seven yes or no questions also were asked (Table 8).

In Group 2, those with implants removed, the results were not quite as good. Only 7 patients (19 per cent) had no pain, and the remaining 26 patients graded their present pain at an average of 3.8 and their usual pain at an average of 4.3 (Table 6). Almost one fourth (21 per cent) were worse since treatment; 44 per cent graded their condition +5 to +7 (Table 6). The average chewing ability was graded 3.5, with 17 per cent having more difficulty chewing since treatment and 71 being better off. Half graded their chewing +5 or better (Table 7). On the other measures of outcome, again, group 2 did not fare as well as group 1 (Table 8).

If the two groups are combined, 40 of 89 patients (40 per cent) were pain free and 60 patients (61 per cent) had little or no pain at the time of the survey. Almost 83 per cent were improved by surgery, whereas 16 per cent were worse off and one patient was unchanged. Ability to chew was improved in 78 per cent of the patients and made worse in 13 per cent.

The patients in both groups also were asked to mark the area of pain on line drawings of the left and right sides of the face. These data have not yet been analyzed; in a future publication, we will try to separate the myofascial pain from the joint pain.

Table 6. *Patient Assessment of Results of Silastic Implants*

	GROUP 1	GROUP 2
Pain (scale 1–10)		
Present	2.7 (N = 29)	3.8 (N = 26)*
Usual	2.6	4.3
Perceived condition relative to preoperative state: number (%)		
Feel better	53 (87)	26 (76)
≥ +5†	45 (74)	15 (44)
Feel worse	8 (13)	7 (21)
≤ −5	3 (5)	4 (12)
Same	0	1 (3)

*Averages were calculated from scores only from those patients reporting pain.
†Scale +7 to −7, with 0 being condition at time of treatment.

Table 7. *Patient Assessment of Postoperative Chewing Ability*

	GROUP 1 (%)	GROUP 2 (%)
Average ability to chew*	2.2	3.5
No difficulty	26/61 (42)	9/34 (26)
Unable to chew	0	(3)
Perceived ability relative to preoperative condition		
Better	51/62 (82)	25/35 (71)
≥ + 5†	46 (74)	19 (54)
Worse	7 (11)	6 (17)
≤ −5	1 (2)	3 (9)
Same	4 (6)	4 (11)

*Scale 1–10.
†Scale +7 to −7, with 0 being condition at time of operation.

Table 8. *General Function in Patients Receiving Silastic Implants*

	PER CENT REPORTING PROBLEM	
	Group 1 (N = 62)	*Group 2 (N = 36)*
Awakened by pain	11	34
Clenching or grinding	40	63
Pain worse on functioning	37	71
Limited opening	41	49
Dietary limitations	31	61
Joint noises	60	89
Locking	8	28

ANIMAL STUDIES

From October 1982 to June 1984, the TMJ disks of 15 *Macaca mulatta* monkeys were removed bilaterally and either not replaced or replaced with Dacron-reinforced Silastic or Proplast II. On one side, a condylar shave was accomplished, and on the other side, every attempt was made to avoid the articular surfaces. All monkeys survived the operation without adverse incident and were started on normal diets within 48 hours. Masticatory function was noted to be unhindered in all animals.

Before euthanasia of the animals, a clinical examination utilizing general anesthesia tested for mandibular range of motion. One monkey with bilateral diskectomies without implants demonstrated restricted opening; three others had limited range of motion in lateral and excursive movements; two of these had Silastic and one a Proplast-Teflon implant. Joint noises were present in all animals except one with Silastic implants.

On histologic examination, a well-defined connective tissue capsule was found surrounding all implants. The functional load-bearing area at the center of the implant showed various degrees of wear (Fig. 5). All of the implants but one Silastic were torn. Microscopic fragments of the implants were found throughout the fibrous tissue capsule and in the marrow of the condyles of two animals with Silastic implants and the one with a Proplast-Teflon implant. The fragments were surrounded by giant cells. In the two monkeys in which no alloplastic replacement was used, a florid growth of fibrous tissue was noted within the joint spaces. This tissue displayed a less organized pattern than was seen in animals with alloplastic replacement. On the condylar shaved side of these specimens, fibrous ankylosis was seen. In the animals with implants and a condylar shave, a cap of the interpositional fibrous tissue had scarred to the condyle (Fig. 5*B*). The contralateral joint displayed a more distinct separation of periosteum and fibrous tissue (Fig. 5*A*). In the 1-year, 3-month specimen in which Proplast-Teflon was used, a large giant-cell mass accumulated anteromedial to the condyle (Fig. 6*A*). Particles of the Proplast-Teflon were contained within this mass (Fig. 6*B*). The results of this study (GE Clark, ET Rippert, GE Nieusma, DE Ryan, unpublished) were consistent with the findings of the other animal studies previously discussed.

DIAGNOSIS OF FAILING ALLOPLASTIC IMPLANTS

Clinical follow-up is paramountl Swelling around the joint, increasing pain in the joint with function, decreasing range of motion, and increasing noise suggest a breakdown of the implant. Occlusal changes, especially development of an open bite, mandate further evaluation. Changes in joint noises, especially crunching or grinding sounds, may signal fragmentation of the alloplast. Panoramic radiographs will document any bony changes in the joint and many times will verify implant position or displacement. Remodeling of the bone is not unusual and in fact is expected, but irregular changes with loss of cortical margins are pathologic and warrant further investigation. Magnetic resonance imaging[88] is the only technique that evaluates both the soft tissues surrounding the implants and the condition of the implants (Fig. 7*A*). Wear of the implant (Fig. 7*B*), increased soft-tissue formation (see Fig. 1*B*), and fracture of the alloplast (Fig. 7*C*) can be identified. Increased soft-tissue reaction around the Silastic noted by MRI is rare, whereas such a reaction around Proplast-Teflon is not unusual and may preclude the clinical sign of occlusal changes. If the implant has fractured, the patient should be informed and, if he or she concurs, the implant should be removed.

Silastic, which will not bind to the tissues of the joint, is easier to remove than Proplast-Teflon. In our experience, Proplast-Teflon has always demonstrated some degree of soft-tissue adherence. Any inflammatory tissue, which usually appears brown or yellowish and granulomatous, should be removed. Unless a concerted effort is made to remove all of the abnormal tissue containing fragments of the implants, the foreign-body reaction may continue (D Chase, personal communication). Reconstruction of the joint following removal of the implant is discussed elsewhere in this issue.

SUMMARY

Although Proplast-Teflon interpositional implants are no longer available for use, many patients still have them in place. All such patients must be contacted and thoroughly evaluated. In our experience, 80 per cent of the implants were removed, and all were found to be damaged. Unused implants should be returned to the manufacturer.

In our study, 40 per cent of the Silastic

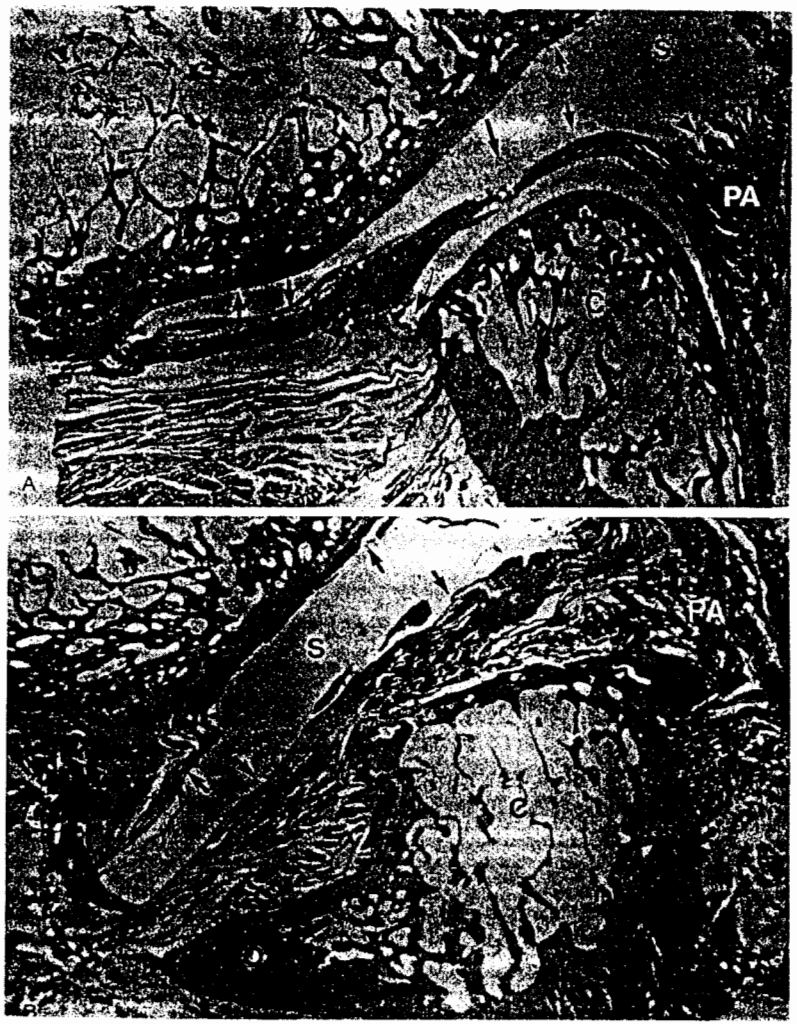

Figure 5. Sagittal sections through the left TMJ of a monkey 15 months after Silastic implant. *A*, Animal without a condylar shave. Both joint spaces are preserved, along with a synovial lining (*curved arrows*). The implant space (S) is surrounded by a connective tissue capsule (*short arrows*) with a small perforation (*long arrow*). Minimal bony changes of the condyle (C) or temporal bone (T) are seen. The posterior attachment (PA) and lateral pterygoid (P) are also identified. *B*, Animal with a condylar shave. The inferior joint space has been lost, an osteophyte formed (O), and the condyle remodeled. A connective tissue capsule (*short arrows*) surrounds the space occupied by the Silastic implant (S). The posterior attachment (PA) and temporal bone (T) are also identified.

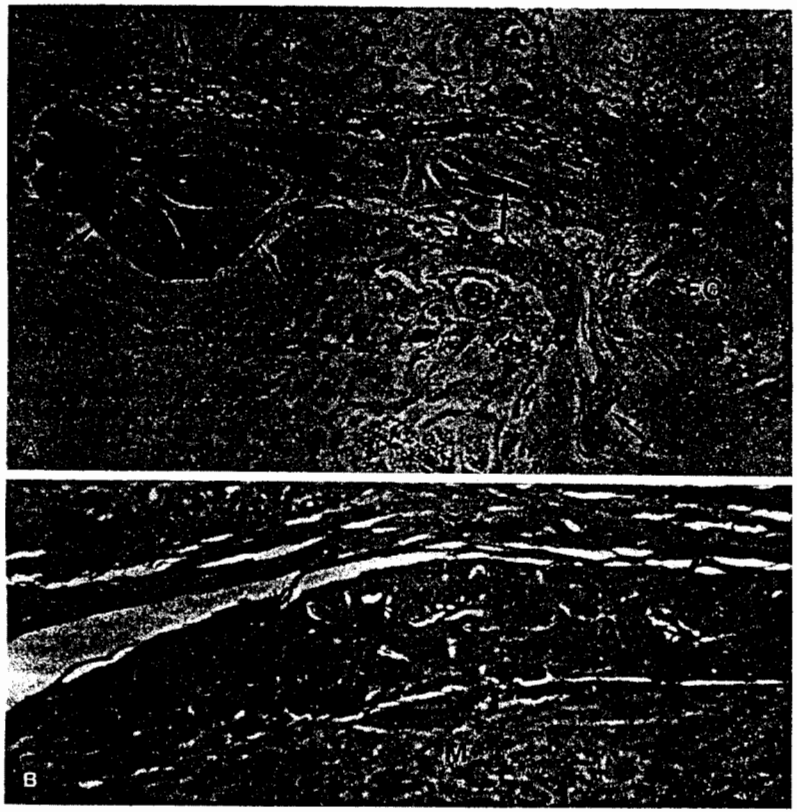

Figure 6. Sagittal section through the left TMJ of a monkey with a PTIPI without a condylar shave 15 months after placement. *A*, Teflon (*curved arrow*) is perforated above the center portion of the condyle (C). Soft-tissue masses (*straight arrows*) are seen anterior to the condyle, above the Proplast (P), infiltrating the temporal bone (T) posterior to the condyle and next to the ear canal (EC). *B*, Higher magnification of the anterior soft-tissue mass (M). The mass consists of particles of Proplast and Teflon surrounded by phagocytic cells and a minimal fibrous tissue stroma. The arrows mark two of the larger particles of the implant.

implants needed to be removed over an 8-year period and were found to be fractured. The presence of noise in the remaining patients may indicate fracture of the implant. The group in which the Silastic implants were removed tended to have more pain, noise, and difficulty with chewing than the group in which the implants were maintained. In our evaluation of the patient's perception of the surgical procedure, 83 per cent of the patients with Silastic implants improved, whereas 16 per cent were made worse. Whether this was myofascial pain, joint pain, or a combination was not determined.

Wear particles and fragmentation take place when condylar surfaces are functioning against Silastic and Proplast-Teflon. The degree of wear depends on the shape of the condyle and the

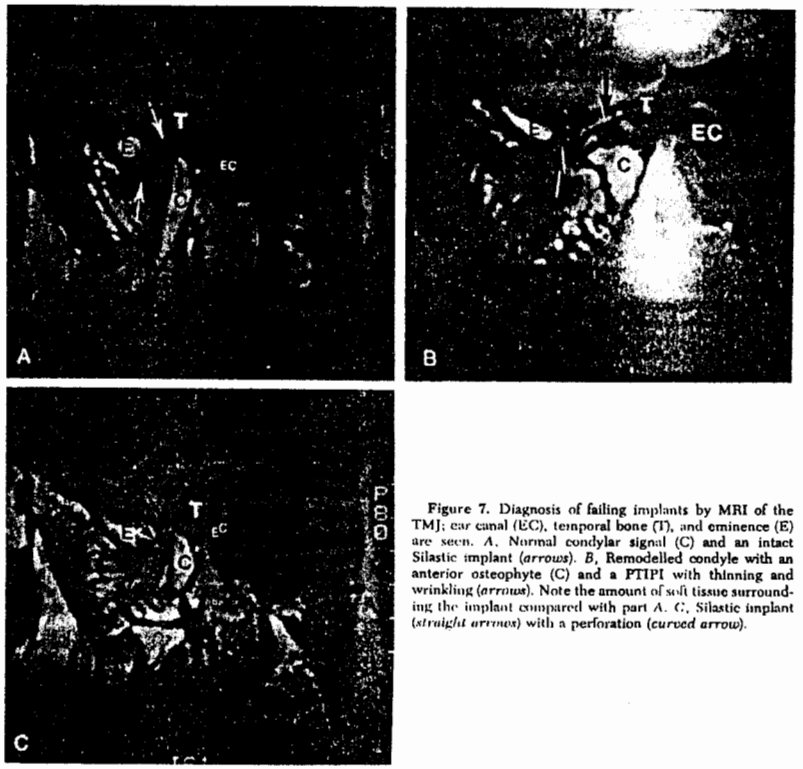

Figure 7. Diagnosis of failing implants by MRI of the TMJ; ear canal (EC), temporal bone (T), and eminence (E) are seen. *A*, Normal condylar signal (C) and an intact Silastic implant (*arrows*). *B*, Remodelled condyle with an anterior osteophyte (C) and a PTIPI with thinning and wrinkling (*arrows*). Note the amount of soft tissue surrounding the implant compared with part *A*. *C*, Silastic implant (*straight arrows*) with a perforation (*curved arrow*).

load produced by muscle tension and parafunctional habits. Particle formation leads to a foreign-body giant-cell reaction, which may cause breakdown of the bony structures of the joint. The reaction to Proplast-Teflon is more severe and includes damage to the temporal bone with possible perforation into the middle cranial fossa. The body appears to cope better with the particles of Silastic by a mechanism not well understood. Particles from both products may cause damage to the joint and its surrounding structures. Particle size or the body's response to the physical structure of the particles may be a factor.

Cervical lymphadenopathy with fragments of the implant in the node tissue can occur. This is more common with silicone, which produces smaller particles more easily transported through the lymphatic system. Tenderness and an increase in the size of the nodes are the only ill effects noted to date.

Magnetic resonance imaging is the best way to evaluate interpositional implants and the surrounding tissues. Close follow-up of patients with interpositional implants is necessary to prevent the long-term effects of fragmentation, including lymphadenopathy, bone destruction, occlusal changes, and continued chronic pain.

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