

A Delicate Balance:
The Food and Drug Administration and
Reform of the Medical Device Approval
Process

Senate Special Committee on Aging

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Statement Submitted by
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I am Terrie Cowley, President of The TMJ Association, a Wisconsin-based non-profit patient advocacy organization. Our mission is to improve the quality of health care and lives of everyone affected by Temporomandibular Disorders (TMD).

My thanks go to you Chairman Kohl as well as to you, Senator Corker for convening this extremely important hearing focusing on FDA's medical device approval and Postmarket Surveillance processes. These processes determine how the FDA carries out its mission to protect the American public who depend upon the FDA to assess the safety and efficacy of medical devices. I trust the following account provides insight into how government agencies, including the FDA, professionals, and professional organizations continually shirked their responsibility to protect the TMJ implant patients of this country.

What are Temporomandibular Disorders?

Temporomandibular disorders are characterized by pain in the jaw area and/or dysfunction of the temporomandibular (jaw) joints.¹ They represent a family of disorders mediated by genes, age, sex, and environmental triggers.¹ Most patients have pain in the joint area, neck and shoulders, but may show little or no joint pathology. Some patients do exhibit joint pathology, which may be the result of injury or conditions that routinely affect other joints in the body, such as arthritis. However, in addition to the jaw pain, many TMD patients, who are primarily women in their child-bearing years, experience other chronic pain conditions, such as fibromyalgia, chronic fatigue syndrome, chronic headache, and vulvodynia.² Needless to say, the existence of comorbid conditions increases the complexity and difficulty in diagnosing TMD, much less in finding safe and effective treatments in a health care system where these associated conditions lack a medical home. As yet there is little scientific understanding of what causes TMD and why these disorders progress in some patients. Nevertheless, this has not prevented practitioners from proposing over 50 different treatments and a range of medications, with little scientific scrutiny to establish their safety or efficacy. Currently, there are no standards of care applicable to the diagnosis or treatment of TMD patients.³

A 2010 National Institutes of Health publication, *TMJ Disorders*, states, "Surgical treatments are controversial, often irreversible, and should be avoided where possible. There have been no long-term clinical trials to study the safety and effectiveness of surgical treatment for TMJ disorders. Nor are there standards to identify people who would most likely benefit from surgery."⁴ What we at The TMJ Association do know from our patient base is that increasing surgeries typically result in increasing pain and dysfunction, actually, even death. Unfortunately, these increased surgeries often lead to an implant to replace the jaw joint, about which the NIH comments; "Surgical replacement of jaw joints with artificial implants may cause severe pain and permanent jaw damage. Some of these devices may fail to function properly or may break apart in the jaw over time. If you have already had temporomandibular joint surgery, be very cautious about considering additional operations. Persons undergoing multiple surgeries on the jaw joint generally have a poor outlook for normal, pain-free joint function."⁴ This may explain the death of Margaret Rose Hutchison, of South Park, PA, who had multiple TMJ implants and died at the age of 41 after her 62nd jaw surgery.⁵

Why the Jaw Joints are Special

The pair of temporomandibular joints are located at the base of the skull amidst the most sensitive and vulnerable areas of the head, at the convergence of the body's major cardiovascular, neurological, auditory and ocular systems. The joints allow us to talk, eat and swallow and make facial expressions that reflect every emotion. They are the most complex joints in the body, unique in their composition and unique in that they always work as a pair, They are controlled by four sets of chewing muscles that enable three-dimensional movements: up and down, side to side, and forward and back.⁶ When trauma or pathology results in destruction or degeneration of joint tissue, an artificial joint may be implanted in hopes of restoring function.

TMJ Implants: The Recent History

Since the mid-1960s, a variety of materials have been used to replace all or parts of the temporomandibular joint. Sometimes surgeons replace the soft tissue disc, which acts as a shock absorber between the head (condyle) of the lower jaw bone (the mandible) and its insertion into the temporal bone of the skull, allowing the mandible to glide smoothly during movements. The disc replacements are frequently called interpositional implants (IPI). In other instances, a mandibular component with condylar head, the fossa (the depression in the temporal bone of the skull into which the condyle fits) or both, are replaced with prosthetic devices.

Most biomaterials for jaw joint reconstruction were on the market before passage of the 1976 Medical Devices Amendment Act. That act required manufacturers to provide evidence that their devices were safe and effective. However if new TMJ implants to be marketed after 1976 were shown to be "substantially equivalent" to a pre-Amendment device, the law allowed them to be sold without testing. This is known as the 510K process. Two synthetic materials that have been widely used as disc replacements for torn or displaced natural TMJ discs are Dow Corning Silastic (based on Silicone) and the Vitek, Inc. Proplast-Teflon implant.⁷

Dow Corning Products

Silicone implants appeared in several forms. The first, introduced in the mid-sixties, was a block that was carved to disc shape. Another was Silastic H.P. sheeting reinforced with Dacron. In 1983 the FDA approved the Dow Corning Silastic TMJ implant H.P. based on substantial equivalence (510K) to Silastic Sheeting marketed prior to 1976. This implant had been designed by Dr. Clyde Wilkes for temporary use only and was made with "tabs" facilitating removal after several months. He was aware that complications arose from long-term implantation of Silastic in the jaw joint.⁷

The TMJ Association has heard from patients who have had an array of Silicone implants, the most common being the disc made of Silastic H.P. sheeting. However, other Silicone blocks designed to reconstruct toes and testicles have been implanted into patients' jaw joints.

Short-term studies on Silastic in the seventies looked good. However, after one to five years there were reports showing substantial problems including ankylosis, arthritis, and lymph node swelling.⁷ A 1986 article reported "fragmentation, perforation, and deterioration of the Silastic material."⁸ And another stated that, "Silicone may not be a totally inert material and that its biomechanical properties are not ideal for use in the TMJ."⁹ By the end of the 1980's enough

failures had occurred for some researchers to call for strict limits on the use of Silastic.¹⁰ One 1992 study warned surgeons that implant particles could migrate from the disc site and that they should be alerted to possible systemic reactions and foreign body synovitis, which would hasten implant failure.¹¹

Dr. Mark Lappe, Professor of Health Policy and Ethics at the University of Illinois, provided testimony in 1992 at a Congressional hearing, *Are FDA and NIH Ignoring the Dangers of TMJ Implants?* He stated, Dow Corning's public documents and a review of the literature indicated that "as early as the sixties they saw foreign body giant cell reaction and knew it induced fibrosis and calcification.⁷ But, even in the late seventies and early eighties, with the knowledge of the adverse effects of the wear particles, Dow Corning issued no adequate warning in the package insert and continued marketing the implants.¹² Dow Corning knowingly allowed their Silicone sheeting to be used for restoring the damaged TMJ even though it was highly likely that the sheeting, even when reinforced, could not stand up to the stresses typical of a major, pressure-bearing, inflammation-damaged joint."¹³ As late as 1989 there had not been a single long-term study of the use of Silastic in animals or humans.⁷ In 1991 when sheep studies were conducted, severe bony destruction and foreign body giant cell reaction were found. Finally, after twenty years of use in humans, it was decided that Silastic isn't appropriate for long-term use and that even short-term use is highly problematic. In 1993 Dow Corning exited the TMJ business. To date no company has submitted a Premarket Application for the use of Silastic in the Temporomandibular joint, however it is being used off-label by oral surgeons.

Vitek, Inc.: the Proplast-Teflon Disaster

In the seventies, Vitek, Inc. developed and sold Proplast sheeting (Teflon FEP film laminated to a porous composite material made from polytetrafluoroethylene (PTFE) and carbon).⁷ When the carbon blackened the whites of the implant recipient's eyes, the implant was modified and the Teflon film was laminated to PTFE and aluminum oxide.⁷ These implants, like the Silastic IPIs, were usually no larger than a thumbnail and were manufactured individually or custom-cut from sheets in the operating room by the surgeon, and then sutured to the fossa.⁷ Vitek also manufactured a TMJ total joint device coated with PTFE as well as other facial implants.

As with the Silastic implants, early reports claimed success, and in 1983, the FDA notified Vitek president and founder Dr. Charles Homsey, that the IPI was deemed equivalent (510K) to a device marketed prior to May 28, 1976. Three years later, however, at the 1986 meeting of the American Association of Oral and Maxillofacial Surgeons (AAOMS), several surgeons reported catastrophic biomechanical failure of the Vitek IPI causing a giant cell reaction that led to bone resorption and pain. A summary of the literature from 1986 to 1991 reported a failure rate of 10 to 25 percent and by 1992 a success rate of less than 20 percent was being reported.¹⁴

As early as 1963, Sir John Charnley, the acknowledged father of hip implant surgery, reported in the orthopedic literature on the failure of Teflon when used in hip prostheses, citing fragmentation, giant cell reaction and bony changes.¹⁵ Certainly, "the orthopedic experience could have predicted the long-term results described in the oral and maxillofacial surgery literature decades later."⁷

Nor is that all. Only after reports of the Teflon implant failure began appearing in 1984, were animal studies conducted on dogs. The results were “essentially catastrophic,” according to a 1990 deposition that Dr. Jack Kent, a Vitek consultant, who also owned 21,000 shares in the company, gave in an Arizona court case against Vitek.⁷ After just a few months, the Teflon layer was “completely worn” and Teflon particles had triggered bone erosion in the dogs.⁷ Dr. Kent wrote a letter to Dr. Homsy in early 1984 expressing his concern that, based on what he found when he explanted an IPI from one of his patients, Vitek might have a “calamity of unbelievable proportions on our hands.”¹⁶ This did not deter Dr. Kent from continuing to write articles praising the Vitek implants or stop him from collecting royalties.

Though the FDA had been hearing about adverse problems related to the Vitek implant at least by 1986, because of a mix-up with their Medical Device Report (MDR) Program, the reports had been dismissed.¹⁷ By 1988 they “had received information from experts that the Vitek implants were failing and needed to be explanted, and that the patients with explanted devices were worse off than they had been before treatment. Problems included excruciating pain and the degeneration of parts of the skull,”¹⁷

In August 1990 FDA finally took action and rescinded the 510K for Vitek’s TMJ devices and on January 7, 1991 the FDA issued a Class I recall. However, in June 1990 Vitek declared bankruptcy, Charles Homsy moved patents off shore, and in March 1992 fled the country for Switzerland, leaving the FDA to handle the recall.

FDA and the Recall

The Class I recall of the Vitek products was the first time it fell to the FDA to conduct the recall of a device since passage of the 1976 Medical Devices Amendment Act. Not only was this because the manufacturer had declared bankruptcy, but also because he had left the country leaving inadequate records of sales behind. Considering the gravity of the situation the possibility of what FDA called “open communication to the brain,” one would have hoped that the FDA would pursue every option to reach out to potentially affected patients. Instead, the agency turned to the professional oral surgery organizations. Members of AAOMS received a copy of the FDA “Safety Alert” concerning these implants.⁷ Later, in a “Public Health Advisory,” surgeons were asked to notify their patients, discuss the risks of device failure, and continue to monitor them.⁷ In addition, they were told to encourage their patients to enroll in Medic Alert’s International Implant Registry.⁷ The surgeons were given 30 days to complete Patient Notification Confirmation forms regarding the action they had taken.⁷ A year later, only 312 patients had been registered with Medic Alert and the registry was discontinued. Less than 200 notification forms had been received from surgeons.⁷ This, in spite of an estimated 26,000 Vitek IPI’s had been sold and that some 87,000 sheets and blocks had been marketed, which oral surgeons could use instead of individual IPIs.

At the time of the Vitek FDA recall the FDA initiated a media blitz, not about the Vitek devices, but about misbranded orange juice—not orange juice that would harm anyone, just that the labeling misrepresented the ingredients. The TMJ Association begged the FDA to do the same for a device that could enter one’s brain but to no avail.

The oral surgeons practiced damage control. In 1993, with a 20/20 segment on TMJ implants imminent, AAOMS hired one of the country's top public relations firms to run interference for them. In an urgent and confidential memo AAOMS discussed how fortunate that the 20/20 broadcast would air opposite game three of the American League Championship Series.¹⁸

Almost all of the implant patients who contacted The TMJ Association said that they had never heard about the Vitek recall from their implanting surgeons. It appears that many dentists denied that the implants could cause the problems experienced by the patients, often blaming them and recommending that they get psychological help. Patients' records were lost and in one case, every piece of evidence of the procedure, including hospital and insurance records, were erased. It was only when this patient moved to another state and had imaging studies done that her implant was confirmed. The patients had been lied to and abandoned, left without care, and in many cases, were unable to find another surgeon to care for them. We have photos of patients who had a total joint device that had broken through their skin and had been exposed for up to four years before they were able to find a surgeon to help them. Last year, twenty years after the recall, we heard from several patients who had Vitek implants, subsequent surgical procedures, and increasing health problems and were never told the Vitek devices had been recalled.

Total Jaw Joint Devices

Considering the harm associated with the Vitek and Silastic implants of the eighties and nineties, one would have thought that the FDA would be hyper vigilant in reviewing TMJ total joint devices for approval. That was not to be.

In 1999 FDA called for Premarket Approval Applications (PMAs) from companies manufacturing devices for implantation into the jaw joint. Two companies submitted applications: TMJ Concepts and TMJ Implants, Inc. In 2002 Lorenz Surgical, a subsidiary of Biomet Inc., submitted a PMA.

In 2006 the General Accountability Office (GAO) was asked by members of the US Senate to investigate the FDA approval process of TMJ devices. Their report, published in 2007: *FDA's Approval of Four Temporomandibular Joint Implants*, noted that the FDA looked at study protocols, patient follow-up, engineering testing, and other issues, such as device labeling, and found that all implant PMAs had similar deficiencies, such as inadequate patient follow-up, making it difficult to determine outcomes over time.¹⁹

Nevertheless the FDA "conditionally" approved all the devices, requiring sponsors to comply with specific FDA conditions to obtain full approval.¹⁹ These included conducting Post Market Surveillance and collecting data on patients for at least three years. To determine how FDA monitored compliance, the GAO reviewed the annual reports that the FDA required from the companies. These reports were to include information on their Post Market Surveillance Studies and other requested data. Although a total of 18 annual reports should have been submitted to FDA by 2006, only 13 had been received by the agency and of those 13 seven lacked sufficient information for the FDA to judge compliance.¹⁹ In detail, here is how each company complied with FDA demands:

TMJ Concepts

- The PMA found the clinical study to be observational without a protocol. From a statistical perspective, the study was seriously flawed. From a bioengineering perspective, the device should not pose problems.
- Though many annual reports were missing from TMJ Concepts,¹⁹ FDA was able to review the two annual reports submitted by the sponsor in 2000 and 2004. For both reports, TMJ Concepts included information related to a number of conditions of approval, such as providing data on its Postmarket study and including a patient quality of life question in that study. In 2000, the sponsor did not comply with the condition of approval to separate data by patients' clinical histories, but did complete this in its 2004 annual report. Therefore, in 2004, TMJ Concepts addressed all conditions of approval except one – submitting annual reports each year. Although all conditions of approval were not met and FDA was not able to review 5 years of annual reports, FDA found that the 2000 and 2004 annual reports provided adequate data and no additional information was required of the sponsor for those two reports.

TMJ Implants, Inc.

- The GAO found the sponsor combined data on five different device components, making it impossible to judge the safety or efficacy of several of its devices under review. Compounding the inadequacy of the company's application were disagreements within FDA between staff reviewers of the data and agency managers who decide on approval. In the end, management conceded that staff had raised legitimate concerns, but determined that the need for the devices outweighed the concerns. A senior FDA manager broke the logjam and intervened with a new policy review standard declaring surgeons and their patients share FDA's risk responsibility. Ultimately, all TMJ Implants, Inc. devices were approved.¹⁹
- The GAO investigation further found that TMJ Implants, Inc. had submitted several annual reports for both of its devices under review that lacked sufficient information regarding patient follow-up. FDA said the sponsor also underreported problems experienced by patients—known as adverse events—associated with the devices. FDA issued letters to the sponsor asking it to resolve these concerns, yet the sponsor repeatedly provided inadequate responses. This situation ultimately led FDA to file an administrative complaint for civil monetary penalties against the sponsor, which resulted in a decision from an administrative law judge in favor of FDA on July 6, 2007.”¹⁹ In October 2009 the United States Court of Appeals Tenth Circuit ruled in favor of the FDA in a civil money penalties case against TMJ implant device manufacturer, TMJ Implants, Inc. and President, Dr. Robert W. Christensen, for failure to submit 17 medical device reports and was ordered to pay \$340,000 in civil penalties.²⁰ TMJ Implants Inc. declared bankruptcy in 2010 and the company was subsequently sold to Croker Ventures. TMJ Implants, Inc. devices will now be marketed under the name TMJ Medical.
- Information revealed during the 1999 Dental Products Panel meeting indicated that TMJ Implants, Inc. received 361 MDR reports, but determined that only four were device-related and reportable to the FDA.²¹ Surgeons and patients were blamed for the remaining failures.
- In its approval of TMJ Implants, Inc. devices, FDA management acknowledged that there were concerns about the quality and quantity of clinical data provided by the sponsor.

However, FDA management dismissed this stating that the clinical data were not to be expected of high quality because the sponsor was a small manufacturer. It then decided that either good engineering data or good clinical data was acceptable to approve a device—not necessarily both—and that it deemed the engineering data for the TMJ Implants, Inc. total joint implant to be satisfactory though even some engineering concerns had not been addressed.¹⁹

- Upon approval of the TMJ Implants, Inc. partial implant, two FDA staff wrote “respectful disagreement” memos. One indicated that the conditions of approval did not mitigate the concerns she highlighted in her memo.¹⁹
- The TMJ Association twice filed petitions with the FDA to hold an open hearing on its decision to approve the TMJ Implants, Inc. Fossa-Eminence Prosthesis after a Dental Products Panel concluded that not only were scientifically valid clinical studies to support the use of the device lacking, but also there were no clear indications for use. Further, clinical and/or testing data demonstrating the effect of the metal eminence on the natural mandibular condyle was not presented. The TMJ Association’s petitions were denied - twice.

The Biomet-Walter Lorenz Implant

- A Dental Products Panel meeting was held on August 22, 2002 to evaluate the Lorenz Surgical TMJ implant now being marketed as Biomet Microfixation. The Panel reviewed the data submitted from Biomet’s clinical study and unanimously approved the device. Two and one half weeks later, the FDA conducted an inspection at one of the two implanting surgeons’ institutions and found serious violations including:²²
 - Failure to obtain signed and dated informed consent documents from all study subjects prior to participation in the study.
 - Failure to conduct the study in accordance with the investigational plan.
 - Failure to maintain accurate, complete, and current subject records.
 - Failure to use the Institutional Review Board (IRB) approved informed consent form for all study subjects.

The result was that 40 of 180 cases had to be dropped from the study. When Dane Miller, President of Biomet was asked during the Dental Products Panel meeting why he brought the device to panel before the company reached their designated case number, he responded that the FDA had recently approved a device without data so he felt his company deserved equal treatment.

"There were a million red flags," said Mark Patters, DDS, who, between 1999 and 2002, served as an FDA advisory panel member for all four of the device hearings and who voted to approve three of them. "You don't have to know the particulars to know the science wasn't there."⁵

FDA Mechanisms for Oversight of Medical Devices

TMJ device history at the FDA can be reduced to two words—no science. Every TMJ device was approved with blatant lack of scientific evidence of safety and efficacy. Indeed, at the very outset when a manufacturer submits a PMA for a medical device, the FDA should evaluate the quality of the scientific and bioengineering data and reject the application if the data are flawed. It is advisable that prior to approving a device, FDA should inspect facilities to ensure that clinical studies are carried out according to established rules and regulations.

What follows is an account of the mechanisms FDA employs in conducting device oversight: The Association describes what went wrong in the past with TMJ devices and what we recommend for remedying the situation in the future.

Classification

The FDA classifies devices according to level of control necessary to assure the device's safety and effectiveness and the degree of risk to the patient or user. Class I devices pose the least risk; Class III the most. Class III devices impose the most stringent regulations on the manufacturer. When The TMJ Association spoke with FDA staff in 1992, the Association was told that TMJ implants "fell through the cracks" and had been omitted from dental devices considered for classification during Dental Products Panel Meetings in 1987 and again in 1989. According to Public Citizen, "At the very least, it would have been prudent for FDA to call for safety and effectiveness data from all TMJ implant manufacturers" when problems first surfaced with the Vitek devices and at least by 1987.²³ During the June 1992 Congressional Hearing, *Are FDA and NIH Ignoring the Dangers of TMJ (Jaw) Implants?*, Mr. Benson, then Director of the Center for Devices and Radiological Health (CDRH) was asked when the FDA was going to classify TMJ devices. Mr. Benson replied, as soon as possible.²⁴ At a February 1993 meeting, the FDA Dental Products Panel did finally recommend that TMJ devices be placed in Class III but there were errors in filing. The result was that PMAs from the manufacturers were not requested until 1999 – six years later. TMJ devices are now classified as Class III. Given this dilatory performance, it is essential **that FDA address future classifications of all medical devices according to the appropriate level of control and in a timely manner.**

Device Tracking

The FDA requires manufacturers to track certain devices upon order from the agency. Tracking is intended to facilitate notification and recall in the event a device presents a serious risk to health that requires prompt attention. Temporomandibular Joint (TMJ) prostheses, glenoid fossa prostheses, and mandibular condyle prostheses are among devices that the FDA has ordered manufacturers to track. But many patients have told The TMJ Association that they had never been contacted by the manufacturer of their device in an attempt to keep the patients' contact information current. Moreover, when the TMJ Association asked FDA staff if assessing compliance of the tracking system was part of the FDA inspection process, the reply was no. **The FDA should include in their inspection process evidence that the manufacturer is complying with a device-tracking order.**

MedWatch

MedWatch is a voluntarily reporting system in which either professionals or the public can report a serious adverse event from a medical device, drug, biologic, dietary supplement or cosmetic. In 1986, the FDA was informed of adverse problems related to the Vitek implant, but due to problems with their Medical Device Report (MDR) program, the reports were dismissed. Over the years MedWatch reports have been filed on all TMJ devices. In July 2010 The TMJ Association asked FDA officials how many reports had to be filed before FDA took action, since in addition to those submitted by the association there were many others submitted by individual patients. We asked the FDA to review all MedWatch reports on TMJ devices over the years. Responding to The TMJ Association's request, FDA analyzed TMJ implant-related adverse

event reports submitted between April 30, 2004 and Aug. 17, 2010. The analysis found 52 percent of TMJ patients had implants replaced within three years or less after implantation because of extreme pain. This is considerably shorter than the expected minimum five-year life span of the device, based on premarket mechanical testing. What is important to note is that this analysis was conducted only after The TMJ Association pointed out the problems it was hearing from patients to the FDA. **The current ineffective MedWatch and Medical Device Reporting systems must be drastically improved if the agency is to respond to a medical device problem effectively and promptly to save lives. Further the agency should conduct an awareness campaign directed toward health professionals and the public to alert them to the importance of these systems and their role in reporting device-related problems.**

Recalls

The FDA became the responsible party to conduct the Class I Recall of the TMJ Vitek implant. The FDA was ill prepared to carry out that recall. **If a company does not take the responsibility to carry out an FDA recall, a system should be in place so that the FDA can respond in an efficient and timely manner.**

The Plight of the Patient: The Economic Cost

When a patient receives an implant, there is no warranty comparable to those accompanying the purchase of consumer goods or appliances. If the device needs to be explanted within a short period of time (as happened recently in the case of 52 percent of TMJ implant patients whose devices had to be removed in under three years' time), the patient does not get a replacement implant free of charge, nor will the surgeon or hospital provide free services. Further, no one will compensate the patient for time lost from work. Responsibility rests solely with the patient to pay for the next, or 8th or 32nd procedure.

In the case of failure of a TMJ total joint implant, it is all but guaranteed that another implant will be needed to provide jaw function, albeit that function may be limited because of pain and muscle atrophy. Two surgical procedures will be necessary: one to remove the failed implant and a second to implant a customized new device. Following the explantation of the failed device a CT scan is necessary so that the custom device will accommodate the jaw anatomy. The typical costs, based on 2010 figures, are \$30,000 for a pair of devices, \$50,000 for surgical fees and \$75,000 for hospital costs: a total between \$150,000 and \$175,000. Insurance coverage for TMJ disorders is uncertain and surgeons typically expect a sizable amount of their fee to be paid in advance. We don't have data on the out-of-pocket costs, such as, for medications; travel to and from treatment facilities, lost time from work, childcare, surgical and medical complications, an implant patient absorbs. If the life span of a TMJ device is five years and a patient is 30 years old, he or she can expect to have 10 more device procedures by the age of 70. The financial impact on the patient and their loved ones is enormous. Obviously, many patients lose their jobs and are no longer able to work. Their spouses may also lose their jobs because of the impact on the employed person's company insurance. In order to continue TMJ care, treatment and future surgeries, many families declare bankruptcy, patients and their spouses divorce so that the patient can receive Medicaid or Medicare, parents deplete their retirement investments paying for their child's care and parents deplete the college funds of their children. These are just some of the ways patients are affected and deal with the financial strains of an implant gone awry.

What is obvious is that the financial costs are borne not just by the patient and their loved ones but by society at large.

The Plight of the Patient: The Physical and Medical Costs

At a time when the miracles of medical devices are touted to the public, it is important that the problems patients face when implants fail are also reported. The following lists are compiled from information contained in The TMJ Association's implant patient files —information that patients relayed to us in letters, e-mails, phone calls or in person.

Device-Related Problems

- Broken screws
- Device slipping, squeaking, popping or bulging out the side of the face
- Device material particulated and/or splintered becoming embedded into surrounding tissue and migrated.
- Fractured fossa component
- Fractured mandibular/condylar component
- Harvested material necrosed, particulated and migrated
- Implant perforated the skull, ear or face
- Screws loose

Adverse Surgical Events

- Cardiovascular events
- Death
- Paralysis (facial)
- Stroke
- Transient Ischemic attack
- Traumatic Brain Injury
- Trigeminal Nerve damage

Post-Implant Complications

- Allergic reactions – hives, rashes, itching, asthma
- Bone degeneration
- Burning, ice-pick like pain in joint area
- Change in bite, necessitating orthodontics or other dental procedures.
- Decreased Range of jaw motion
- Device material leached into surrounding tissues or into the blood stream
- Facial deformity
- Foreign body giant cell reaction
- Harvest site (buttocks, abdomen, rib, ear cartilage, muscle, rib) complications and pain at harvest site.
- Heterotopic bone growth – ankylosis necessitating a surgical procedure to debrid the area.
- Infections that were not responsive to antibiotics and necessitated explantation, flap back face skin and “power wash” the skull with antibiotics
- Lymphadenopathy
- Metal toxicity

- Metallic taste in the mouth
- Metallosis
- Micro-particles of material migrated throughout tissues.
- Skin discoloration, frostbite on skin over implant in cold weather
- Swelling that does not subside
- Teeth broken during surgical procedure

Systemic Problems/Other Medical Conditions Following Implant Surgery

- Abnormal thyroid function
- Bladder dysfunction
- Chronic Fatigue Syndrome
- Chronic respiratory, urinary tract, pelvic, or gastrointestinal infections
- Chronic headaches
- Cognitive dysfunction
- Cold extremities
- Constant low-grade fever
- Dizziness, balance issues
- Drooling
- Dystonic tremor
- Ear pain, diminished or hearing loss, hyperacusis
- Eye lid paralysis necessitating gold leaf implant or suturing eye lids together
- Face unrecognizable after surgery
- Fibromyalgia, Myofascial Pain Dysfunction
- Facial Paralysis
- Flu-like symptoms
- Headaches
- Hoarseness
- Intolerance to heat and/or cold
- Memory problems
- Muscle atrophy
- Muscle spasms
- Night sweats
- Numbness
- Parotid Gland Cysts, stones
- Post-traumatic Stress Syndrome
- Seizures
- Sjogren's Syndrome
- Sleep apnea or sleep disorders
- Snow blindness, blurred vision, dyslexia
- Speech difficulty
- Stroke
- Swallowing Difficulties
- Teeth breaking gradually following procedure

The Need for More Research

Temporomandibular Disorders are still a poorly understood condition. However, recent studies confirm that co-morbidities exist with TMD and research has stimulated investigation into what may be the common underlying mechanisms for these conditions. Some of these conditions are included among the above. However, it may be the case that implant procedures or the materials used in TMJ devices trigger or increase the risk of these other conditions and patients might not develop them in the absence of surgery and/or implants. It is also possible that some of these symptoms are totally unrelated to TMJ implants, and are either a component of the TMJ complex disorder, or a manifestation of an entirely different disease. But, we will not know the answers until studies are conducted. Another area of interest is the sex difference. Ninety percent of the most severely affected are women of childbearing age. The FDA has an interest in whether men and women may respond differently to certain medical devices and the procedures in which they are used. Several FDA studies have focused on identifying some of these differences. Studies in collaboration with the NIH would no doubt yield valuable information on Temporomandibular Disorders as well as differential systemic effects of TMJ implants depending on the sex of the patient.

The Quagmire

TMJ implant patients live in a world of emotional blackmail. If they complain to the FDA, their surgeon will no longer provide pain medication or support their disability claims. If they complain about their device to the surgeon, their concerns may be dismissed, the patient blamed and they may be told to see another surgeon. It is not unusual for patients either to be abandoned because of attitudes or to abandon their surgeon because of insensitivity or denial of their problems. So the patient may find another surgeon who will explant the failing device and implant another. Meanwhile, the original surgeon believes that the patient is doing well and calls the surgery a success because the patient never returned. The second surgeon will not report the explantation of the original device either to the manufacturer or the FDA. In many instances the problems the patients are having are not brought to the attention of the manufacturers by the surgeons. What we have witnessed over a half century is a quagmire. The manufacturer blames the surgeons and patients for the device failure. The FDA says it did its job. The surgeons blame the FDA and the patients, saying they thought the FDA had the data or the patient must have done something wrong to cause the problems. And this “whose on first” continues and it is tragic, not funny. It is clear that in the silo system we have now no one has to accept responsibility or be accountable to the patient.²⁵

The Future of TMJ Devices: A Paradigm Shift

On February 7, 2011 the FDA ordered the manufacturers of TMJ implant devices to conduct Post-market Surveillance studies and to submit protocols within 30 days. A few days after the order was issued, The TMJ Association received a question from a TMJ patient, “Why should we believe the data the manufacturers will present when we were led to believe they had scientific data 10 years ago?” That question provoked much thought and discussion within The TMJ Association, which led us to the conclusion that we could no longer accept the status quo for TMJ patients.

A TMJ Device Round Table

As a patient advocacy organization a frustration over the years has been the lack of cooperation and collaboration among the major interested parties. As we viewed the recent directive from the FDA we saw an opportunity for a major paradigm shift. We would propose a formal agreement to work together to ensure that the best clinical and bioengineering science, based upon robust scientific principles and good manufacturing practices, will be directed toward the implant patients and their devices. Collaboration would take the form of a TMJ Device Round Table where all stakeholders could come together to discuss how to build a body of data on implant performance, patient satisfaction, side effects and complications—data which could better guide patients’ health care decisions as well as future device designs to yield optimal patient outcomes.”²⁶ The Round Table will include manufacturers, bioengineers, clinical, basic, and bioengineering scientists, representatives from FDA and NIH, surgeons, registry experts, and The TMJ Association. On March 9, 2011 we presented our concept to the CDRH Director, Dr. Jeffrey Shuren and staff. They responded with enthusiastic support and intent to participate. The manufacturers have also been positive in their response. We look forward to the challenges of this new approach and are optimistic that results will benefit all stakeholders, especially TMJ patients.

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