

The TMJ Association, Ltd.  
Milwaukee, Wisconsin

Temporomandibular disorder (TMD), commonly referred to as "TMJ," is a term used to describe a variety of disorders of the jaw joint. It affects one in five Americans, 80 percent of whom are women. Symptoms range from clicking and popping sounds in the joint to severe, debilitating pain and biomechanical dysfunction. Although 80 percent of people with TMD get better with no treatment or with conservative therapy such as moist heat and over-the-counter painkillers, others spend years of their lives and thousands of dollars on unproven and unscientifically based treatments that generally make them worse and are not covered by insurance. For many, the result is a lifetime of chronic, unrelenting pain and disability. Every day we hear stories of failed marriages, lost careers, bankruptcy, and families torn apart.

Despite the pervasiveness of this disorder and its ability to totally devastate lives, the state of the art of TMD is best characterized as follows:

1. There is no consensus among professionals as to definition, cause, diagnosis, or treatment, leading to many diverse "standards of care."
2. Few treatments are supported by valid scientific evidence because little research has been conducted to determine the cause of TMD or the safety and efficacy of current treatment modalities. Only two percent of the National Institute of Dental Research (NIDR) or .07 percent of the total NIH 1992 budget, was directed toward TMD research. The majority of funding over the years has been to study the psychosocial aspects to the neglect of basic science.
3. In contrast to the number of dollars allocated to research, approximately \$32 billion is spent annually on the treatment of craniofacial pain.

The absence of basic research has permitted what one researcher calls "the Great American Medical Disaster" -- the iatroepidemic of temporomandibular joint implants. TMJ implants date back almost thirty years, when surgeons first began using various materials and devices to replace all or part of the jaw joint. Most of these implants were approved by the FDA without adequate animal or clinical studies.

The Proplast-Teflon implants manufactured by Vitek, Inc. were recalled in December 1990 due to their high failure rate. However, efforts by the FDA have failed to locate even one-fifth of the estimated 26,000 people who received the interpositional implants, or discs. To date, only 312 people with the Vitek implants are registered with Medic Alert's International Implant Registry, and less than 200 patient notification confirmation forms have been received by Medic Alert from oral and maxillofacial surgeons. Needless to say, many doctors have not told their patients about the recall or potential dangers of these implants.

According to studies, the implants are deteriorating -- often without any clinical symptoms. By the time symptoms *do* appear, the damage can be well advanced and irreparable. Some people have experienced progressive bone degeneration in as little as one or two years, resulting in chronic, excruciating pain, reduced jaw mobility, permanent loss of masticatory function, permanent hearing damage, a broad range of immune system effects, and what the FDA says is "open communication to the brain" -- meaning holes in the skull, exposing the brain to infection and migration of the particles of material into the brain. The damage and autoimmune response brought about by the body's giant cell reaction can continue long after explantation and require further

medical treatment. We hear reports of dementia, paralysis, tumors, and always the excruciating, intractable pain. All the effects of these implants are not yet known, and there is no evidence that the damage can be reversed.

The concern over TMJ devices resulted in the hearing held in June of 1992 by the Subcommittee on Human Resources and Intergovernmental Relations. According to the late Ted Weiss, chairman of the committee, "there is evidence that the overwhelming majority of the grafts and implants that have been used so far will eventually fail, if they haven't already."

These implant failures have resulted in an ever-growing medical disaster. Because of the bone destruction and tissue damage caused by the implants, implant recipients will eventually need multiple revision surgeries. Presently, there is no FDA-approved, safe, or functional implant on the market to replace the ones that have failed. Many implant victims have inadequate insurance coverage or no coverage at all, and cannot afford to have their implants removed, or to pay for follow-up care, complications, and pain management. Reconstructive surgeries often cost between \$35,000 and \$85,000, and we know one patient whose pain medication alone costs \$1,000 a month. This woman, like many others, is unable to function on a day-to-day basis, let alone work and lead a normal, productive life. An equally distressing problem is that many people with TMJ implants are not aware of the potentially serious risks posed by their implants. Some of these people are seriously ill and may not even know that their implants have already failed, shattered in their heads, and are migrating throughout their bodies. The bottom line is that these people's lives have been destroyed, and little, if anything, is being done to address the numerous medical needs they will face for the rest of their lives.

We offer the following recommendations:

That Congress direct the Department of Health and Human Services to establish a task force composed of scientists who can determine which institutes are best able to utilize existing intellectual expertise and scientific protocols and apply them to the study of TMD. Although the NIDR could assess the pain component of TMD, it is evident that several other important areas of expertise are lacking within this institute, and it would seem redundant and costly to attempt to duplicate resources. For example, the Allergy and Infectious Disease Institute could study the problems associated with systemic immune responses to TMJ implant materials. The Arthritis Institute could study the biomechanics and biochemistry of the temporomandibular joint and related musculature. To enhance research efforts, the FDA could provide scientists with information they have obtained through their investigation of TMJ implants over the last few years.

We then recommend that special funding be allocated for controlled scientific studies in the following areas: a) epidemiology of non-patient population base as well as patient population; and b) etiology -- from the molecular, biomechanical, neuroendocrine, as well as physiological and clinical perspectives.

2. That the Department of Health and Human Services be directed to conduct a national public health media notice -- both in print and on television -- of the recall on Proplast-Teflon implants to inform patients of possible risks associated with their implants.
3. That NIH initiate an immediate, intensive informational campaign to educate both the public and professionals on the realities of this disorder and the efficacy of current treatments.
4. That a national database of TMJ implant recipients is funded so that scientists can remain apprised of new symptoms of disease processes occurring in implant

recipients. A registry will serve as an effective method for tracking these people, as well as a database from which surveys can be conducted to obtain epidemiological and etiological information. This information will allow for outcome assessment of the physical, psychological, financial, and social damage of implant recipients.

I would like to share with you a letter written by the wife of a TMD sufferer.

My husband has been suffering with TMJ dysfunction for ten years. Although he has not had an implant, we are still going around in circles with different treatments. I think maybe over time the mouthpieces he has been wearing have probably made things worse. Now the doctors are talking about braces. Do you have the latest information on this disorder and maybe a list of doctors that really know what they're doing? My husband has no life. He's in pain all the time and, as a result, has trouble at home, trouble at work, just plain trouble with everything. We've been to dentists, oral surgeons, psychiatrists, you name it ... some relief for awhile, and it's back. I hope you can help in some way. Our family is falling apart.

Unfortunately, we have no answers for this woman -- or the countless number of people we hear from daily -- because there *are* no answers. Even worse is the tragedy experienced by TMJ implant victims, as evidenced by the following excerpts from testimony presented at the congressional hearing held last summer.

My life hasn't changed. It's gone. I feel like a big blob of pain, with big, burning-hot screws constantly twisting into my skull bone in front of my ears. This pain *never goes away*. It hurts to walk, it hurts to talk ... sometimes it hurts just to see. And it never stops. I feel useless, completely unproductive, and trapped in my body of pain. Every day of my life begins with thoughts of suicide. I honestly don't believe I can stand the pain much longer. Unfortunately, no doctor wants the responsibility of treating me. They all seem scared of my complex case and unwilling to accept what little insurance I have left.

The financial burden has been almost as devastating as the pain. I have creditors calling daily to collect on bills the insurance doesn't cover. I am 36 years old, and I've been unable to work for years. My parents are using up their retirement money. My family loves me, and the money could be tolerated if we didn't feel we were throwing it into a black hole of empty lies and broken promises.

Another patient writes:

I have bad days and worse days. I have no pain-free days. I've had fifteen surgeries, and each time I kissed my children good-bye, I knew I might never see them again. There have been times when I prayed I wouldn't wake up.

These are not isolated cases. It is almost impossible to believe that this has been allowed to happen. But it will continue to happen without research. A deplorable lack of science has left implant victims desperate and all TMD victims in "no-win" situations.

We appreciate the opportunity to speak to you today, and ask that you seriously consider our recommendations. We desperately need help. Thank you.