The Correlation of Mandibular Ankylosis by Arthroplasty and the Insertion of a Cast Vitallium Glenoid Flap.

A NEW TECHNIQUE

A Preliminary Report of Three Cases

Robert W. Christensen, D.D.S.

The present report will be limited to a discussion of certain technical aspects of the mandible and will concern itself with methods of treating a condition against the occurrence of this problem.

Adaptation of the mandible can be divided into three main classes: (1) Silicone elastomers, (2) metal-on-metal, and (3) metal-on-plastic. Each of these is suitable for a variety of different situations, but the author would emphasize the advantages of the latter. Orthodontic considerations, esthetic considerations, and the need for more rapid and effective treatment are following mandibular joint surgery—especially mandibular surgery, which is the main thrust of the present report. The discussion of the mandibular joint is dependent upon the mandible being a variable factor, and the study of the joint is dependent upon the mandible being a variable factor. The history of the mandible is dependent upon the joint being a variable factor, and the study of the joint being a variable factor is dependent upon the joint being a variable factor. The history of the mandible is dependent upon the joint being a variable factor...

In the case of a young lady who had a condylar process that had been reduced and in which the condylar process was subsequently reduced, it was necessary to reduce the joint. This was done by replacing the condylar process with a new one that had been reduced in the normal way. This method is not dependent upon the joint being a variable factor...

Recently published, the author of an articles on the subject of the mandible reports that this method is not dependent upon the joint being a variable factor...

In conclusion, it would seem that the best method of treating a condition against the occurrence of this problem would be to use the method outlined above and to replace the joint with a new one that had been reduced in the normal way.

In conclusion, it must be stated that the best method of treating a condition against the occurrence of this problem would be to use the method outlined above and to replace the joint with a new one that had been reduced in the normal way.
In the case of the subject under study, the number was 30. The subject was divided into five groups: A, B, C, D, E. Each group had six subjects. The results were as follows:

- Group A: The number of subjects was 12. The subjects were divided into two subgroups: A1 and A2. The subjects in A1 were given a drug treatment, while the subjects in A2 were given a placebo. The results showed a significant improvement in the symptoms of the subjects in A1 compared to those in A2.

- Group B: The number of subjects was 10. The subjects were divided into two subgroups: B1 and B2. The subjects in B1 were given a different drug treatment, while the subjects in B2 were given a placebo. The results showed a significant improvement in the symptoms of the subjects in B1 compared to those in B2.

- Group C: The number of subjects was 8. The subjects were divided into two subgroups: C1 and C2. The subjects in C1 were given a drug treatment, while the subjects in C2 were given a placebo. The results showed a significant improvement in the symptoms of the subjects in C1 compared to those in C2.

- Group D: The number of subjects was 6. The subjects were divided into two subgroups: D1 and D2. The subjects in D1 were given a different drug treatment, while the subjects in D2 were given a placebo. The results showed a significant improvement in the symptoms of the subjects in D1 compared to those in D2.

- Group E: The number of subjects was 2. The subjects were divided into two subgroups: E1 and E2. The subjects in E1 were given a drug treatment, while the subjects in E2 were given a placebo. The results showed a significant improvement in the symptoms of the subjects in E1 compared to those in E2.
and a small piece of Teflon was placed over each wound and pressure was maintained for over 5 minutes.

The patient's condition at the end of surgery was satisfactory and the venous refill in the lower extremities was normal. The patient was up and about the room by 1 p.m. and her condition was good on the first postoperative day. The patient was discharged on the third postoperative day. She was given 300 mg of prednisone daily for two weeks, then tapered off slowly over a period of six weeks, and she was maintained on 10 mg of prednisone daily for one year. The patient was scheduled for a biopsy of the specimen obtained at the time of surgery in order to rule out the possibility of a second primary lesion.

Case 2: H.M., a 46-year-old woman, had developed a verruciform xanthoma on the left side of her neck for the past 15 years. She was referred to my office by her general dentist for consultation regarding her bilateral xanthelasm.

The lesion was removed surgically, and the specimen was sent for histological examination.

Case 3: M.B., a 46-year-old woman, had developed a verruciform xanthoma on the right side of her neck for the past 15 years. She was referred to my office by her general dentist for consultation regarding her bilateral xanthelasm.

The specimen was removed surgically, and the specimen was sent for histological examination.

Bacteriologic Examinations: Both verruciform xanthomas were removed surgically, and the specimens were sent for bacteriologic examination.

There was no evidence of any evidence of infection or inflammation.

The verruciform xanthomas were removed surgically, and the specimens were sent for bacteriologic examination.

Bacteriologic Examinations: Both verruciform xanthomas were removed surgically, and the specimens were sent for bacteriologic examination.

There was no evidence of any evidence of infection or inflammation.
prepares for the method, but the actual extent of the operation was usually not determined in advance. Low field was opened. The skin was incised and the underlying tissue was dissected. The edges were then sutured with absorbable sutures. The wound was closed with a sterile dressing.

The patient was then transferred to the operating room, where the operation was performed. The wound was then closed with a sterile dressing.

On December 3, 1982, the patient was discharged from the hospital. The patient was then transferred to the operating room, where the operation was performed. The wound was then closed with a sterile dressing.

Case B: A 57-year-old male, who had been operated on for a brain tumor on December 3, 1982, was readmitted to the hospital on December 8, 1982. The patient was then transferred to the operating room, where the operation was performed. The wound was then closed with a sterile dressing.

One of the most important factors in determining the success of the operation was the extent of the incision. In this case, the incision was made at the level of the skull, and the underlying tissue was dissected. The edges were then sutured with absorbable sutures. The wound was closed with a sterile dressing.

On December 1, 1982, the patient was discharged from the hospital. The patient was then transferred to the operating room, where the operation was performed. The wound was then closed with a sterile dressing.
In June, 1941, she was able to open 116 inches and had total left internal mandibular right internal mandibular which was 90 inches. The patient was seen again, but showed no signs of improvement. The patient was seen at 96 inches.

In September, 1941, the patient did not seem to be improving any scars and was managed under the care of Dr. Jones. The patient was right compared to the results reported previously to surgery. In October, 1941, the patient was operated on and showed no signs of improvement. The patient was seen in the spring of 1942 and showed no signs of improvement. The patient was seen again in the spring of 1943 and showed no signs of improvement.

I explained to the patient that there were no signs of improvement. The patient was left on her own two feet and was unable to support the left mandible to move and the dotted lines were the dotted lines that the patient was left with.

On the subsequent visit I explained to the patient that there was no improvement and that the dotted lines were the dotted lines that the patient was left with. I explained to the patient that there was no improvement and that the dotted lines were the dotted lines that the patient was left with.
This article presents a discussion of non-articular ankylosis of the mandible and proposes a new method of creating a barrier against the recurrence of this problem.

Ankylosis of the mandible can be stress-induced, inflammatory, or congenital in nature and also be caused by trauma, neoplastic, infectious, traumatic, developmental, or idiopathic etiologies. It can affect healthy bone or occur in the context of fractures, infections, tumors, or other disease processes. The onset of symptoms is often gradual, with patients reporting difficulty in moving their jaw. The condition can lead to significant functional and aesthetic issues, causing discomfort, limitation of mandibular movement, and a potential for psychological distress.

The new method described in the article involves the placement of a cast Vitalium glenoid fossa prosthesis. This prosthesis is designed to mimick the anatomic shape of the glenoid fossa and is placed on the non-ankylosed side of the mandible. The purpose is to provide a barrier against the ankylosis process. The use of Vitalium, a cobalt-chromium alloy, is advantageous due to its biocompatibility and durability. The prosthesis is custom-fitted and secured in place, allowing formandibular movement while preventing the ankylosis process from spreading.

The procedure involves a series of steps: inlaying the implant into the glenoid fossa, ensuring an adequate fit, and securing it with an appropriate mechanism. The patient is monitored for signs of recurrence and adjusted as necessary. The long-term success of the prosthesis is demonstrated through case studies and patient outcomes, indicating a reduction in the recurrence rate of ankylosis.

In conclusion, the article presents a novel approach to treating mandibular ankylosis, offering a promising solution for patients facing this challenging condition. Further research and clinical trials are recommended to validate the effectiveness and durability of the Vitalium glenoid fossa prosthesis as a treatment option for mandibular ankylosis.
Surgery

The patient was a 46-year-old man, who had developed generalised rheumatoid arthritis over the past 20 years. He was referred to his dentist for consultation regarding oral bilateral ankylosis of the mandible.

Volume 27, Number 1, 1984

Figure 10—Photographs of left maxillary bar prosthesis in place. Arrows indicate movement of the maxillary bar and bending from the closed to open position.

Figure 11—Radiographs of left maxillary bar prosthesis showing structures and ankylosis of the mandible.

Figure 12—Postoperative view showing position of implants.

Each of the 23 maxillary prosthesis was placed against the bone to check for accuracy of fit. One prosthesis filled all areas present, and was secured with 3 Vicryl implant screws (Figure 1D). The distal segment of the maxillary bar was positioned so that the maxillary bar was in the prosthetic facial fossa and the lower section was tilted forward so that the lower sympyphysis contacted the maxilla approximately 1 inch above the anterior border of the maxilla. A single transverse metal wire was placed near the maxilla where the two bones were in contact (Figures C, right, and E). This was found adequate to immobilize the two bone segments, since the jaw was secured by the splint and intermaxillary traction (Figure F). The prosthesis and Rintons were closed in the routine manner, and prosthesis adjustments were applied. Recovery was uneventful.

The patient was discharged on the fourth post-operative day.

Postoperative care

The mandible was kept immobilized for nine weeks. At that time the occlusal splint was removed, and the patient was able to open her jaw by 1 inch. One week later under local anesthesia, the fractured arch bars and circumferential wires were removed. During the next few weeks, the patient was able to open her jaw 1.5 inches, and was able to maintain left dental occlusion with maxilla and right occlusion to a lesser degree. The pain in the right mandibular joint subsided shortly after surgery. Two years have elapsed since the left joint prosthesis was placed, and no pain or irritation of function has occurred.

Case 2

The patient, a 65-year-old man, had developed generalised rheumatoid arthritis over the past 20 years. He was referred to his dentist for consultation regarding oral bilateral ankylosis of the mandible.

Volume 27, Number 1, 1984

Figure 1—Preoperative radiographs showing maxillary right mandible.

Figure 2—Preoperative radiographs showing maxillary right mandible.

Figure 3—Postoperative radiographs showing maxillary right mandible.

Figure 4—Postoperative radiographs showing maxillary right mandible.

Figure 5—Postoperative radiographs showing maxillary right mandible.

Figure 6—Postoperative radiographs showing maxillary right mandible.

Figure 7—Postoperative radiographs showing maxillary right mandible.

Figure 8—Postoperative radiographs showing maxillary right mandible.

Figure 9—Postoperative radiographs showing maxillary right mandible.

Figure 10—Postoperative radiographs showing maxillary right mandible.

Figure 11—Postoperative radiographs showing maxillary right mandible.

Figure 12—Postoperative radiographs showing maxillary right mandible.

Figure 13—Postoperative radiographs showing maxillary right mandible.

Figure 14—Postoperative radiographs showing maxillary right mandible.

Figure 15—Postoperative radiographs showing maxillary right mandible.

Figure 16—Postoperative radiographs showing maxillary right mandible.

Figure 17—Postoperative radiographs showing maxillary right mandible.

Figure 18—Postoperative radiographs showing maxillary right mandible.

Figure 19—Postoperative radiographs showing maxillary right mandible.

Figure 20—Postoperative radiographs showing maxillary right mandible.

Figure 21—Postoperative radiographs showing maxillary right mandible.

Figure 22—Postoperative radiographs showing maxillary right mandible.

Figure 23—Postoperative radiographs showing maxillary right mandible.

Figure 24—Postoperative radiographs showing maxillary right mandible.

Figure 25—Postoperative radiographs showing maxillary right mandible.

Figure 26—Postoperative radiographs showing maxillary right mandible.

Figure 27—Postoperative radiographs showing maxillary right mandible.

Figure 28—Postoperative radiographs showing maxillary right mandible.

Figure 29—Postoperative radiographs showing maxillary right mandible.

Figure 30—Postoperative radiographs showing maxillary right mandible.

Figure 31—Postoperative radiographs showing maxillary right mandible.

Figure 32—Postoperative radiographs showing maxillary right mandible.

Figure 33—Postoperative radiographs showing maxillary right mandible.

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Figure 110—Postoperative radiographs showing maxillary right mandible.

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Figure 128—Postoperative radiographs showing maxillary right mandible.

Figure 129—Postoperative radiographs showing maxillary right mandible.

Figure 130—Postoperative radiographs showing maxillary right mandible.

Figure 131—Postoperative radiographs showing maxillary right mandible.
This study demonstrates the relative frequency of tooth space infections in maxillary, mandibular, and maxillary tooth spaces. It is shown, however, that the number of tooth space infections is higher in maxillary tooth spaces than in mandibular tooth spaces and that the majority of these infections occur in the anterior portion of the mandible.

Reference


dental implant placement, including the tooth space infection, and results. It is shown that dental implant placement is a common site for tooth space infections, and that these infections are often accompanied by pain, discomfort, and swelling. The study also highlights the importance of proper oral hygiene and the role of antibiotics in the treatment of these infections.


dentistry, and surgery. It is shown that dental implant placement is an effective treatment for tooth space infections, and that the use of antibiotics and proper oral hygiene can significantly reduce the risk of infection.


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DATE: 1992-06-04
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To: Subcommittee on Human Resources and Intergovernmental Relations
Congress of the United States
Honorable Ted Weiss, Chairman; ATT: Ms. Diana Zuckerinan, Staff Person
Re: Hearing June 4, 1992, FDA regulation of TMI Implants

Honorable Congressmen Weiss:

I have only learned of the subject hearing a few days ago. As the former President of Vithek Inc., I believe the attached information should be a part of the deliberations of your Subcommittee. My comments reference the destruction of uniquely successful medical devices and human resources by FDA regulatory activities.

1. In 1984 the American Association of Oral and Maxillofacial Surgeons published that a failure of between 10-20% is the expected surgical experience for any surgery of the TM joint. (Snipada added). Lawsuits and claims relative to the Vithek interpositional implant have been well below 10%.

2. The mode of procedure failure with the Vithek implant was described for the first time solely in connection with silicone rubber interpositional implants in one of the two main oral surgery journals in May 1985. The procedure failure was related to "excessive loading of the joint surface" either because the 'implant was too large' or because of 'excessive loading secondary to bruxism'. I.e., to teeth grinding and jaw clenching. A condition that splits, fissures, and/or psychological counseling may alleviate. These are not conditions that any implant can treat. This paper also reported the replacement of the silicone implants with Vithek interpositional implants by surgeons apparently convinced of their superiority. To my knowledge FDA did not conduct any investigation of the silicone rubber procedure failures.

3. When, as in 1985 and 1986, Vithek learned that a few surgeons were reporting that its implant could be abused by the above patient condition it immediately added correspoding "Caution" to labelling, sent corresponding "Dear Doctor" letters to all oral surgeons, convened a scientific meeting of surgeons reporting disparity cases and reported their deliberations to all oral surgeons. Vithek also ceased advertising the implant because of the disparate results being reported for interpositional implant surgery.

I believe FDA can and should conduct an examination of the Vithek implant in the same manner as it pursuing examination of the silicone implant.

FDA has unjustly called jaw- the question the OSMI VHI total TMJ implant replacement implant and made it un-available to US citizens and ignored Vithek's and its successor company OSMI's request to document the almost 100% success of this implant in several hundred patients over the past 5-6 years. It has ignored detailed written reports to this effort from oral surgeons highly experienced in the use of this implant.

A Finding of Fact of a Federal Court in Houston in an unrelated matter was:

"Uncontroverted evidence was presented by plaintiff's counsel of the devices in question that the products (VHI Total TMJ Implant) manufactured by OSMI were above average products which failed at a lower rate than other similar products".

Congressman Weiss, Documentation of the foregoing is being forwarded to your office.

I am now employed by a European company using the technology developed by us and my associate over the past twenty-five years. The technology will not be pursued in the country of its birth nor by the employees of Vithek and OSMI who have lost their jobs. I hope the tragic Vithek story will be studied by your Committee so that the laws regarding surgical implants will not be roadblocks to inventors and entrepreneurs dedicated to improving US health care.

I must appear before your Committee in the near future because of an injury recently sustained in a fall.

Sincerely,

Charles A. HOMSY Sc.D.

Members of the Subcommittee: attachments FED-X and/or separate cover.
SUMMARY FROM RCTS

1. Randomized controlled trials have been performed for several treatments for temporomandibular disorders.

2. Generally these RCTs have a poor definition of criteria for patient selection or diagnosis.

3. There is great variability in the outcomes used to measure treatment effectiveness.

4. Important treatment areas have not been assessed using RCTs. The most obvious areas were RCTs are lacking are in surgical therapy for TMD, and the use of non-steroidal anti-inflammatory agents and other pharmacologic agents that might influence pain and muscle relaxation.

5. An initial investigation into practice patterns indicates that a wide range of therapies are being used to treatment TMD and that RCTs are lacking for many treatment modalities that are frequently applied.

Meta-analysis of Therapy for Temporomandibular Disorders: IV. Discussion and Conclusions

Alessia Antczak-Bouckoms DMD, MPH, MS, ScD

November 16, 1992

Technology Assessment Group
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115
SUGGESTIONS

1. Further examination of practice patterns to identify what treatments are being applied to patients so that priorities can be determined for future clinical investigations.
2. Develop consensus about disease classification.
3. Develop consensus about outcomes to be used to assess efficacy.
4. Encourage further research using generally accepted scientific methods of clinical research design.
5. Hold a Technology Assessment Conference as a forum for the development of a consensus regarding diagnosis and outcomes, and the encouragement of appropriate clinical research.

BASIC AND CLINICAL RESEARCH ON NORMAL AND IMPAIRED ORAL-MOTOR FUNCTION

P. T. Ba, W. S. 07/03/64, 07/04/64, 07/05/64, 10/02/64, 07/04/65

National Institute of Dental Research
National Institute of Dental Research and Other Communicable Diseases
Clinical Research Branch, National Institute of Dental Research
Application Receipt Date: June 1, 1964

The National Institute of Dental Research and Other Communicable Diseases of the National Institutes of Health and other government agencies support research in the sciences dealing with the oral cavity and diseases that may involve the oral cavity in order to study oral health.

The NIH and NIDR seek to accelerate research progress in this area by initiating research on disease processes, either with fundamental processes involving the structures of development and growth, or with clinically relevant aspects of oral-motor function.

BACKGROUND

Considerable scientific progress has been made over the past decade toward elucidating neurobiological processes controlling jaw movements and the oral function associated with speech, swallowing, and mastication. The field of research encompasses a number of interrelated areas of interest, including the elucidation of the mechanisms of sensory and motor control of jaw movements and oral function. These areas of interest include the role of the brain in the control of jaw movements and oral function, the neural and muscular basis of jaw movements and oral function, the role of the peripheral nervous system in the control of jaw movements and oral function, and the role of the central nervous system in the control of jaw movements and oral function.

Stationary and moving jaw movements are essential for normal speech, swallowing, and mastication. The normal function of these movements is achieved by the coordinated action of the muscles of the oral cavity, pharynx, and larynx. The muscles of the oral cavity are responsible for the production of speech sounds, the production of oral sounds, and the production of oral noises. The muscles of the pharynx and larynx are responsible for the production of vocal sounds and the production of oral sounds. The muscles of the larynx are responsible for the production of vocal sounds and the production of oral noises.

The normal function of jaw movements is achieved by the coordinated action of the muscles of the oral cavity, pharynx, and larynx. The muscles of the oral cavity are responsible for the production of speech sounds, the production of oral sounds, and the production of oral noises. The muscles of the pharynx and larynx are responsible for the production of vocal sounds and the production of oral sounds. The muscles of the larynx are responsible for the production of vocal sounds and the production of oral noises.

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ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

OSF/PAIN RESEARCH CENTERS

NATIONAL INSTITUTE OF DENTAL RESEARCH

Application Receipt Date: June 15, 1985

The National Institute of Dental Research (NIDR) invites applications for one or more multidisciplinary research centers studying orofacial pain. The NIDR is initiating support for centers of research excellence in this area in an effort to accelerate scientific progress related to acute and chronic orofacial pain.

The overall purpose of these Centers will be to conduct basic and clinical research expanding knowledge concerning the mechanisms underlying orofacial pain and developing methods of diagnosis, treatment, or prevention of orofacial pain conditions. The ultimate goal of such research is to establish a scientific foundation permitting optimally safe and effective prevention and control of orofacial pain.

In pursuit of the intent of this RFA, the proposal for center activity must include both basic and clinical research. It is anticipated that each center will direct some research effort toward studies relevant to chronic orofacial pain.

Research objectives to be addressed in the Orofacial Pain Research Centers may include, but are not limited to the following:

1. Studies to identify and elucidate the biological mechanisms involved in orofacial pain transmission and modulation.
2. Research on CNS mechanisms involved in pathological pain.
3. Neuropharmacological studies of agents for use in the control of chronic orofacial or acute dental pain.
4. Small scale epidemiological studies assisting toward the identification of the incidence and distribution of chronic orofacial pain.

This program is described in the Catalog of Federal Domestic Assistance No. 13.444, Pain Control and Behavioral Studies. Awards will be made under the authority of the Public Health Service Act, Title II, Section 301 (Public Law 78-500), as amended; 42 USC 281 and administered under the PHS grant policies and Federal Regulations 42 CFR Part 2 and 46 CFR Part 34. This program is not subject to Health Systems Agency review.

5. Studies of factors influencing human pain perception, as well as studies developing improved behavioral and psychophysiological means of pain assessment.
6. Studies of the basic and clinical aspects of acute dental pain, including post-surgical pain.
7. Basic and clinical studies of chronic pain associated with the temporomandibular joint or orofacial pain, or orofacial pain syndromes such as fibromyalgia, trigeminal neuralgia, and postherpetic neuralgia.
8. Experimental or clinical studies that clarify the association between orofacial motor dysfunction and orofacial pain.
9. Studies to develop improved, effective diagnostic and treatment procedures applicable to acute dental pain and to chronic orofacial pain conditions.

The substance of each research program may vary according to local expertise, interest, resources, and recruitment possibilities. Applicants should attempt to develop a unique program which is complementary to, rather than substitutive of, ongoing research. The institution must be willing to make a commitment of resources and staff to ensure the development, operation, and function of the proposed center. Applicants may request up to $300,000 in direct costs for the first year, with appropriate increases in subsequent years. Funding is anticipated for a five year project period with a possibility of renewal.

Copies of the complete RFA and additional information may be obtained from:

Dr. Patricia Bryant
Cancer Control Branch, Pain Control, and Behavioral Research Branch
National Institutes of Health
Westwood Building - Room 3059
Bethesda, Maryland 20205

Telephone: (301) 496-7607
REQUEST FOR APPLICATIONS FOR OROFACIAL PAIN RESEARCH CENTERS

NATIONAL INSTITUTE OF DENTAL RESEARCH

Application Receipt Date: June 15, 1985

The National Institute of Dental Research (NIDR) invites applications for the support of one or more Orofacial Pain Research Centers. The overall purpose of the centers is to support both basic and clinical research to expand our understanding of orofacial pain. The ultimate aim of such research will be to establish a sound scientific foundation permitting improved diagnosis, treatment, and prevention of orofacial pain.

BACKGROUND

Preventing and controlling orofacial pain remains a central concern of the dental profession, and a major concern of the public which dentistry seeks to serve. The significance of orofacial pain, both to the health profession and the public, stems in part from a simple biological fact. The face and mouth possess a dense, rich supply of nerves, which makes them exquisitely sensitive and responsive to painful stimuli.

Both acute and chronic orofacial pain constitute major clinical problems which can challenge the limits of our current scientific knowledge. Acute dental pain may occur as a manifestation of oral disease or pathology, as, for example, in the case of an infection exposing the dental pulp or nerve in the case of certain dental procedures. In such cases, pain serves a protective, adaptive function through signaling the existence of tissue damage or injury and impelling the individual to seek treatment. Acute post-surgical pain can occur following procedures such as tooth extraction or periodontal surgery. Chronic, iatrogenic pain may occur following dental treatments, but is also caused by the fact that various technological innovations in dentistry (such as the high speed drill) have substantially reduced post-operative aspects of many dental procedures. Nevertheless, the expectation of acute dental pain associated with dental care still deters many Americans from seeking needed dental care. An estimated 20 million Americans admit to being too highly fearful of dental care to seek or delay needed care. Only approximately half of the American public seeks regular dental care. While many factors contribute to dental fear and the level of dental utilization, concerns regarding the effectiveness and safety of dental pain management clearly constitute one barrier to the appropriate utilization of preventive and therapeutic dental services.

Chronic orofacial pain disorders also present a difficult and urgent area for study. Chronic pain problems by definition persist over a long period of time, usually a minimum of several months. In contrast with acute pain, chronic pain often appears to serve no adaptive or protective function. It can have devastating effects on the individual and the individual's family, including depression, impotence in males or response in females, and even in some cases, all chronic pain problems have been estimated to total over $50 billion per year in the United States. Pain clinic surveys suggest that as many as 20-25% of chronic pain problems involve the orofacial region.

Major advances in pain research have occurred over the past decade. These advances have emerged from the efforts of investigators representing a variety of disciplines, including biology, endocrinology, pharmacology, psychology, psychophysiology, anesthesiology, neurology, psychiatry, psychosomatic medicine, and the social sciences. Understanding how pain signals are encoded and transmitted within the nervous system is now emerging. Neurotransmitters in the brain and spinal cord have been isolated and used to operate as pain-blocking agents in pain-irritated pathways. New insights on anatomical, physiological, and behavioral dimensions of pain modulation have led to new pain treatment procedures such as transcutaneous electrical nerve stimulation and stimulation-produced analgesia. Improved measures of both the sensory and affective dimensions of pain have been developed. Nevertheless, many questions remain to be answered regarding the role of descending activity, and regarding many aspects of orofacial pain diagnosis and treatment.

In recent years, there has been a great surge of clinical interest within dentistry for the temporomandibular joint (TMJ), an interest resulting from increased numbers of individuals seeking treatment for a variety of pain and dysfunction problems associated with this joint. Such individuals commonly report a combination of symptoms which include muscle pain or tenderness, localized aches or pain, and various types of sounds or 'clicking' in the TMJ joints. Epidemiologic studies suggest that 10-25% of the population now one or more of these findings. Because of controversies about diagnostic methods and critical outcomes, it is not surprising that the diagnosis is not yet fully understood. Nevertheless, the TMJ and pain constitute important problems for many Americans.

NIDR recognizes the need for an improved and expanded interdisciplinary orofacial pain research effort. It is both scientifically feasible and necessary to stimulate additional efforts to this area of demonstrable research need. The Center mechanism is well suited to fostering an expanded orofacial pain research effort. Integration of basic and clinical orofacial pain research is an effort to help stimulate the translation of basic research findings into clinically-relevant hypotheses and improve, innovative approaches to orofacial pain diagnosis or treatment. Such Centers are also expected to provide an environment fostering basic orofacial pain research.

ACTIONS

The overall objective of the Orofacial Pain Research Centers will be to accelerate the development and synthesis of knowledge concerning acute dental and chronic orofacial pain, with the ultimate aim of developing an scientifically-founded framework for optimally safe and effective prevention and control of orofacial pain.

The research emphasis of specific Orofacial Center proposals may vary depending on the expertise, resources, and interests represented within the applicant institution. However, in order to be responsive to the intent of this RFA, the research proposal for Center activity must include both basic
and clinical research. Studies related to the basic biological mechanisms involved in orofacial pain are expected to comprise a significant proportion of the research effort. A Center application comprised mostly of basic neurological studies without direct relevance to orofacial pain is beyond the scope of this RFA and would be more appropriate to the interests of the NIHCO.

It is anticipated that each Center will direct some research effort toward studies relevant to chronic orofacial pain. The increasing clinical demands for interdisciplinary research in this area, as well as the growing clinical status of patients suffering from chronic orofacial pain disorders and the scarcity of relevant basic or clinical information provide the impetus for this program component. Determining the specific proportion of research effort devoted to chronic orofacial pain studies remains the applicant's prerogative.

Research objectives to be addressed in the orofacial pain research centers may include, but are not limited to the following:

1. Studies to identify and elucidate the biological mechanisms involved in orofacial pain transmission and modulation.
2. Research on ONS mechanisms involved in pathological pain.
3. Neurpharmacological studies of agents for use in the control of chronic orofacial or acute dental pain.
4. Small scale epidemiological studies assisting toward the identification of the incidence and distribution of chronic orofacial pain.
5. Studies of factors influencing human pain perception, as well as studies developing improved behavioral and psychophysiological means of pain assessment.
6. Studies of the basic and clinical aspects of acute dental pain, including post-surgical pain.
7. Basic and clinical studies of chronic pain associated with the temporomandibular joint or myofacial pain, or orofacial pain syndromes such as tic douloureux, atypical facial pain, and post-herpetic neuralgia.
8. Experimental or clinical studies that clarify the association between orofacial motor dysfunction and orofacial pain.
9. Studies to develop improved, effective diagnostic and treatment procedures applicable to acute dental pain and to chronic orofacial pain conditions.

MECHANISM AND LENGTH OF SUPPORT

The Centers will be supported by the research grant mechanism for a period of five years, with funding projected to start on or before July 1, 1988. Subsequent support will be contingent upon program needs and the Center's performance, as determined by peer review. While funds have been allocated for this purpose in the NIH plan for FY '86 and subsequent years, awards are contingent upon the availability of funds. All policies and requirements which govern the research grant programs of the NIH, including cost sharing, will apply to grants made as a result of responses to this invitation.

REVIEW PROCEDURES AND CRITERIA

The applications will be reviewed by a Special Review Committee to be convened by NIH's Scientific Review Branch. Scientific review may include a site visit. Secondary review will be by the National Advisory Dental Council.

Major factors to be considered in the evaluation of applications will include:

1. The scientific merit of each project including its originality and feasibility, the soundness of the methodology proposed, and the competence of the investigators.
2. The extent to which the Center will promote advances in orofacial pain research which could not be achieved or which would be achieved more slowly, if the component projects were funded separately.
3. The availability of basic and clinical researchers qualified to conduct the proposed research.
4. The adequacy of laboratory and clinical facilities and the availability of appropriate patient populations.
5. The scientific and administrative qualifications and experience of the director and his/her availability to provide effective leadership.
6. Adequacy of plans for establishing and maintaining the Center, for monitoring research for encouraging scientifically productive interactions between basic and clinical researchers, and for reviewing changes in research directions.
7. Institutional commitment to the Center both in terms of financial and related resource allocations.
8. The technical merit and justification for core resources requested.

Applicants should attempt to develop a unique program which is complimentary to, rather than duplicative of, ongoing research. The institution must be willing to make a commitment of resources and staff to ensure the development, operation, and function of the proposed Center. Should no application meeting these criteria and judged to show a high level of scientific merit be received, no award will be made and this RFA may be reconsidered.
CENTER CHARACTERISTICS

The Orofacial Pain Research Centers will be identified in units within a larger institution; eligibility is limited to domestic institutions. The Centers will focus on two related project areas: (1) types of research projects, (2) investigator projects, and (3) related programmatic areas. Each investigator project will involve some level of collaboration with specialists from other research units conducting research relevant to orofacial pain. The investigators will provide a training environment for young and new investigators. Funds may be used to support pilot or exploratory studies.

ADMINISTRATIVE ITEMS AND COST

Core resources such as computer services and equipment to be shared by the investigators can be provided. Funds can be used for equipment, supplies, consultation services, travel, publications costs and for salaries of professional, technical, or administrative support staffs. Funds will not be used for supplies, travel, publications, major renovations or facilities or costs associated with delivering oral health services other than those directly related to the research.

Each investigator is expected to obtain independent research support from sources other than the Center during the year period, thereby releasing funds to attract other scientists to enter the Center's interdisciplinary research environment. The investigators are expected to receive a 10% increase in their annual salary the second year, with appropriate increases in subsequent years. Funding is anticipated for a five year period with a possibility of renewal. This proposed duration should provide a more stable environment than is often encountered when investigators are supported entirely by individual research project grants. Site visits to review the performance at the Center and provide guidance will be conducted periodically by the NIH and consultants.

METHOD OF APPLICATION

It is suggested that prospective applicants submit a letter of intent to Dr. Bryant by April 30, 1985. Those applicants that meet the eligibility criteria will be notified by early May 1985 of the review process. Selections will be announced in June 1985. Applicants are also encouraged to contact Dr. Bryant for additional information.

The suggested letter of intent should summarize the Center's objectives, a list of armament component research projects and a summary of relevant ongoing research. This is expected to assist respondents assure that their applications are responsive. It will also assist staff in planning for timely review of applications. The letter of intent is not binding nor is it a prerequisite for acceptance of applications. Applications which are judged nonresponsive to this RFA will be returned to the applicant, as will applications received after June 30, 1985.
APPENDIX E.—FEDERAL REGISTER ANNOUNCEMENT FOR TMJ IMPLANTS

Federal Register / Vol. 87, No. 192 / Friday, September 16, 2002 / Proposed Rules

The Federal Food and Drug Administration (FD&A) is proposing to amend the classification of TMJ (temporomandibular joint) implants to Class III. This action is being taken because since the last time the classification was reviewed in 1966, the TMJ implant industry has matured and many new materials and designs have become available.

This revision is being proposed at the request of the manufacturers who have expressed interest in the evolution of the classification to allow for more advanced design features. The proposed changes to the classification are based on the latest available data, and the reclassification is intended to provide a more accurate representation of the current state of the art in the field of TMJ implants.

The proposed changes are intended to provide a more comprehensive classification that better reflects the diversity of materials and designs currently available. The proposed classification will also be more consistent with the classification of other medical device implants, such as dental implants.

The proposed changes will also facilitate the development of new technologies and the introduction of innovative designs. The proposed classification will be more flexible and allow for the rapid incorporation of new designs and materials into the market.

The proposed changes will also facilitate the implementation of a new testing and evaluation program for TMJ implants. The new program will be more comprehensive and will include new performance criteria that are more relevant to the current state of the art in the field.
The Federal Register is a daily publication by the National Archives and Records Administration. It contains federal notices and regulations. The text below is a sample of the content typically found in the Federal Register.
APPENDIX 7—SUMMARY OF NIH MEETING ON JAW IMPLANTS

OFFICE OF RESEARCH ON WOMEN'S HEALTH

Temporomandibular Disorders and Implant Devices

Meeting Summary

Overview

On July 14, 1992, the Office of Research on Women's Health (ORWH) arranged a meeting with Terrie Cokley and Jennifer Kihlstrom of the Temporomandibular Joint Association (TMJ) and representatives of the Food and Drug Administration (FDA) and National Institutes of Health (NIH) to discuss the current studies related to temporomandibular disorders (TMD) and implant devices. The goal of the meeting was to identify patient concerns and research opportunities, to review current and future activities related to TMDs, and to obtain recommendations for improving the health status of TMD patients.

Issues Discussed

A. Patient Concerns

Officials of TMJ have become increasingly aware of patient concerns related to musculoskeletal, neurological, dermatological, and psychological symptoms. A greater number of patients are reporting constant and severe orofacial pain, fibromyalgia, visual and auditory impairment, dysaesthesia, and mental health disorders.

Abnormal bone resorption, a physiological response to a foreign body, such as certain TMJ implant materials, may require removal of the implant device. As a result of bone resorption, an open bite can develop which contributes to orofacial pain of varying degrees.

Fear that future implant device availability may be severely limited or restricted results in patient anxiety, frustration, and anger. Insufficient follow-up of TMJ implant patients occurs which contributes to inaccurate assumptions regarding post-implant status. According to TMJ officials, greater attention is being given to the high incidence of "iatro-epidemic" diseases.

B. Current and Future Activities Related to TMDs

Major NIH and FDA activities include:

- Ongoing basic and clinical research on orofacial pain and TMDs

(S1)
- Development of TMD research diagnostic criteria (to be published in the December issue of the Journal of Craniofacial Disorders, Facial, and Oral Pain)

- MIR Meta-analysis study

The National Institute of Dental Research (NIDR) is conducting a comprehensive review of current literature on TMD treatment in peer-reviewed journals. By using criteria and statistical techniques to reveal patterns of data, new treatment protocols and modalities will be identified.

The results of the meta-analysis study will serve as a model in planning a 1995 World Workshop on Chronic Orofacial Pain and TMD sponsored by the National Institute of Dental Research.

- Sponsorship of TMD International conference

The World Workshop will review the state of science in the area of chronic orofacial pain and TMD. Basic research on the joint and muscular pain, as well as appropriate treatment modalities will be highlighted. Studies involving materials and load-bearing joints will be reviewed. The conference will serve as catalyst for the development of education and resource materials for patients and practitioners.

- Inter-agency and Intra-agency collaboration

The National Institute of Dental Research, the National Institute on Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Allergy and Infectious Diseases (NIAID), and the Food and Drug Administration are collaborating in TMD activities.

C. Research Opportunities

- Biomaterials and immunological responses

Greater research on biomaterials used in implant devices, including silicon, is needed to ascertain the risks and benefits to implant recipients and to develop new devices. The NIAID has issued a Request for Applications for research to study the effects of silicon, a common product used in the manufacture of various types of implant devices, on the immune system.

- Data collection

There is a need for accurate determination of the incidence and prevalence of TMDs. Partnerships with patients, clinicians, researchers, and academicians are viable mechanisms for obtaining better epidemiological data and increasing the scientific knowledge base.

Recommendations

- Data Collection Tools: Records and Surveys

Develop patient registries that enhance data collection efforts and facilitate documentation and research on disease onset, intervention, treatment, and prevention.

- Create and implement questionnaires, such as the recent NCES National Health Interview Survey on chronic pain, or other surveys of the National Center for Health Statistics, as necessary for increasing the amount and depth of scientific knowledge.

- Collaboration

- Continue joint dialogue with multidisciplinary experts, intra-agency and inter-agency representatives, clinicians, academicians, patients, and public advocates.

Meeting Attendees

- Vivian W. Pinn, M.D.
- Judith B. Lebow, Ph.D.
- Patricia Bryant, Ph.D.
- Terrie Arpin, President NIDR
- Stephen L. Gordon, Ph.D.
- Jennifer Brumberg, Vice President NIDR
- Elizabeth D. Jakobson, Ph.D.
- Liliana K. Joseph, D.P.H.
- Dushanka V. Klinkman, D.D.S., M.S.O.
- Ruth Barkat, Ph.D.
- Chukk Sabates
- Barry Z. Saude
- David H. Scher
- Susan K. Stein, M.D.
- Joan Wilb
- Susan Win

- NIH
- NIAID
- CO/SCA
- CO/SEA
- CO/CCA
- CO/SCA
- CO/SEA
- CO/CCA
- CO/SCA
- CO/SEA
- CO/CCA

APPENDIX B.—FOLLOWUP MEMORANDUM ON THE JUNE 4, 1992, SUBCOMMITTEE HEARING ON JAW IMPLANTS

December 23, 1992

TO: Donald M. Payne

FROM: Diana M. Zuckerman

RE: Followup Memorandum on the June 4, 1992 Subcommittee Hearing on Jaw Implants

The subcommittee on Human Resources and Intergovernmental Relations held a hearing on research and regulations regarding temporomandibular (jaw) implants on June 4, 1992.

The hearing focused on the pain and problems associated with various types of TMJ implants, and with the failure of the FDA and NIH to ensure that research was conducted on their safety and effectiveness.

This memorandum summarizes the issues raised at the hearing and new developments that have occurred since then.

BACKGROUND

Temporomandibular disorder (TMD) is a common but vaguely defined disorder involving pain and other symptoms in the area near the temporomandibular joints (TMJ) that attach the jaw to the skull. (You can feel the joints by putting your fingers in front of your ears, while opening and shutting your mouth.) Between 500,000 and 1 million new patients seek treatment each year. These patients suffer from facial pain, limited range of motion in terms of opening the mouth, and other problems. Most are treated with physical therapy, drugs, or splints rather than surgery; however, there are approximately 750,000 patients in the United States who have had at least one TMJ surgery.

TMD is the more current term, but essentially means the same thing as TMJ. The main parts of the joint are the condyle, the fossa, and the disc.

Between 80-90 percent of TMJ patients are women, and most are 20-40 years old. Women are apparently more likely to develop TMJ problems naturally; men tend to develop them after an accident. The most famous TMJ patient is Burt Reynolds, who was bedridden and unable to work for 2 years. He had severe pain and vertigo but did not get implants. As is frequently the case, his pain was treated with painkillers, halocon, and other drugs; according to articles about Reynolds, the drugs may have caused at least as many problems as the disorder itself.

In the most severe cases, implants are used to replace one or all of the parts that make up the TMJ. Experts estimate that 75,000 to 100,000 patients have received artificial implants. Three or four times as many have had autogenous bone grafts from their own ribs or other bones, or implants made of cadaver bone or tissue. However, bone grafts and implants usually last only a few years, and will usually be replaced with synthetic implants.

The American Association of Oral and Maxillofacial Surgeons has 6,000 members; approximately 70 percent perform TMJ surgery. There is considerable concern within the profession that TMJ problems are difficult to treat and have been overreated in the past. The American Dental Association states that 80 percent of
TMJ patients get better with or without treatment. However, the pain of TMJ can be debilitating, and patients do not always want to wait to see if they will get better without surgery.

There are several types of jaw implants, replacing different parts of the jaw, made of different substances, by different manufacturers.

Bone and Other "Natural" Implants

The most commonly used implants have been made of bones, cartilage, muscle flaps, dermis (the layer of skin just below the outside skin layer), or dura (a membrane covering the brain and spinal cord), usually from the patient (such as a piece of rib) or from a cadaver. The experts acknowledge that these implants will dissolve after a few years, and can cause foreign body giant cells to secrete enzymes, which can cause tissue destruction and other problems. If they are replaced with another bone graft or implant, subsequent replacements tend to last an even shorter time than the first. For that reason, bone grafts and implants tend to be replaced with synthetic implants. Cadaver implants are more likely to be rejected by the "host" but autogenous bone grafts have the disadvantage of requiring two surgeries: One to remove the bone from the rib or wherever, and the second to implant it in the jaw.

Grafts made from bone, cartilage, and other tissue are not regulated by the FDA. However, implants made from cadaver bones or tissues are supposed to be regulated by the FDA; they rarely are.

Dow Corning's Silastic TMJ Implant

The FDA's authority to regulate jaw implants is based on the 1976 Medical Devices Amendments to the Food, Drug, and Cosmetic Act. Prior to 1976, device manufacturers were not required to prove that their products were safe or effective. After 1976, silicone sheeting implants intended for the face and jaw made by Dow Corning were "grandfathered" onto the market because they had been sold before the law passed. This sheeting (sold in pieces 6 x 8 inches in size) could be cut into pieces that were used by surgeons to reconstruct the face, to protect nerves in the face, or to create a space to help damaged TMJ joints. The sheeting does not replace the joint itself.

In 1983, Dow Corning submitted a premarket notification (510(k)) to FDA regarding a modification of their implant from permanent sheeting to a temporary TMJ implant (called the Wilkes implant) pre-cut from sheeting; this was cleared by the FDA in 1984. The company told the FDA that the TMJ implant was "substantially equivalent" to the sheeting that was already on the market, since it was just a pre-cut version of the same material. Although the sheeting had been used for TMJ surgery, it had been cleared for marketing for other uses that did not involve as much friction. The FDA apparently ignored the fact that the friction and stress on a TMJ implant would be much greater than for other uses of sheeting, making the implant much more likely to fragment.

The company implicitly admitted the problems that patients were having with their TMJ sheeting implants by recommending that the pre-cut Wilkes implant be used only for temporary use.
surgeons believe that they can be used to create a space near a
missing TMJ disc, since the implants are not safe for long-term
implantation. The hope is that, when implanted for only 1–2
months, the body will form scar tissue around the implant (as it
does with breast implants and most other implants), and that the
implant can be carefully removed, leaving the scar tissue capsule
to take the place of the missing pieces of jaw. However, there are
apparently no long-term studies to determine the safety or
effectiveness of this technique. Moreover, both the sheeting and
the Wilkes implant have sometimes been used as a permanent implant.

Meanwhile, the company continued to change the type of
silicone used, as they had with breast implants, without filing an
additional 510(k) with the FDA. Most notably, they added barium
sulfate so that the implant would show up on X-rays, without ever
filing a 510(k). That implant is called the Wilkes Silastic MP.
According to FDA documents, there is now a general recognition
within the FDA that a 510(k) should have been filed for that
change. In fact, FDA might have rejected the 510(k) if it had been
submitted, because the company could provide no evidence that the
implants would function similarly.

Dow Corning did not conduct animal studies or clinical studies
to test silicone’s safety or effectiveness for the TMJ, according
to company documents. Data published in dental journals in the
1980’s indicated that TMJ implants made from silicone were
deteriorating, breaking and cracking, with fragments of the
silicone causing foreign body giant cell reactions. There was
clear microscopic evidence of foreign body reactions to the
silicone in the TMJ implants. This fragmentation has been found to
cause destructive lesions, bone degeneration, and other serious
problems.

Dow Corning provides package inserts for the surgeons
regarding the risks and benefits of their Wilkes implants, but does
not provide a package insert for the sheeting. Instead, upon
request, they will provide what they call ‘data sheets.’ No
written information about risks and benefits is made available to
the patients, since the surgeon is the user of the product (as was
the case with breast implants, until the FDA required information

VITREK IMPLANTS

The synthetic TMJ implants with the most obvious problems were
made by Vitrek and later by Oral Surgery Marketing, Inc. (OSMI), a
successor corporation of Vitrek. Vitrek implants were made from
tetron and propelit (a tetron composite product).

After the 1976 FDA device law, some types of Vitrek TMJ
implants were ‘grandfathered,’ based on ‘substantial equivalence’
to the silicone sheeting material described previously in this
memorandum. In other words, the FDA agreed with the company that
implants used to replace or reconstruct a jaw joint were
essentially the same as an implant that replaces a broken cheekbone
(which is subject to much less friction and pressure), even one
made of a completely different material. The company did not even
file a 510(k) for each type of jaw implant that they were selling.
During the 1980's, Vitex implants became more popular than the previously used silicone TMJ implants, because dental journal articles indicated that the Vitex implants were safer and more effective during the first 2 years after surgery. In addition, Vitex made a TMJ implant that could replace the joint, whereas the silicone implants could only be used to cushion the joint.

Dr. John Kent, an oral surgeon and well-respected TMJ researcher at Louisiana State University Medical Center, published studies in the 1980's indicating the safety of Vitex implants. However, a February 14, 1984, letter from Dr. Kent to the president of Vitex, Dr. Charles Honsy, shows that Dr. Kent was concerned about the safety of Vitex implants at the same time he was praising the product in articles in oral surgery journals. The letter indicated that one of his patients had to have the implant removed after a year and a half because of pain and swelling. When he performed surgery on that patient, Dr. Kent found that the implant was badly worn and the capsule was covered in a "heavy black pigment." Based on that experience, Dr. Kent expressed his concern that Vitex might have "a calamity of unbelievable proportions on our hands."

Dr. Kent's concern about such a calamity was apparently at least partly financial; according to legal documents, Dr. Kent had 21,000 shares of Vitex stock at the time he was publishing articles praising Vitex TMJ implants.

According to a 1988 FDA memorandum, serious safety problems regarding Vitex implants first came to the FDA's attention in an Medical Device Report (MDR) in April 1986, but "the report contained no details and was dismissed." The problems caused by Vitex implants were not a secret; at the 1986 annual meeting of the American Association of Oral and Maxillofacial Surgeons, several clinicians reported that fragments of proplast were breaking off the implants, causing giant cell reactions, pain, and bone loss. In 1988, there were published reports from previously enthusiastic surgeons that 21-35 percent of the proplast implants were failing over a 5-year period.

Subsequent reports to FDA's MDR system provided evidence of serious problems, and by late 1988, the FDA had received information from experts that the Vitex implants were failing and needed to be explanted, and that 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. An oral surgeon notified the FDA that he had been reporting problems to Vitex for the last 3 years, and the FDA determined that Vitex had not reported those problems to the FDA. In November 1988, the FDA sent a "Notice of Adverse Findings" to Vitex, complaining about their MDR procedures.

In April 1989, an FDA panel voted unanimously to classify all TMJ implants as Class III, requiring proof of safety and efficacy. The panel rejected Vitex's claim that clinical experience was sufficient to prove the implants were safe and should therefore be classified as Class II. (These claims were similar to those made by other companies for breast implants in the 1980's.) However, at the time of our June 1992 hearing, the FDA had not yet announced the classification of TMJ implants in the Federal Register, and safety data had never been required.
IPI’s. At the FDA’s insistence, Vitek issued a letter dated March 23, 1990, advising doctors that Vitek’s interpositional implants (IPI’s) could fragment, delaminate, or otherwise be damaged while in normal use. In the summer of 1990, the FDA determined that Vitek’s devices were misbranded and adulterated, based on “new clinical data that demonstrate new adverse effects.” The information was based on two masters theses conducted at the Department of Oral Surgery at the University of Iowa.

Graduate students conducted a retrospective study of 51 patients who received the Vitek TMJ IPI between 1983-86, and found that 73 percent of the implants had been removed due to fragmentation, perforation, or foreign body reaction that resulted in progressive bone degeneration. When the implants of asymptomatic patients were evaluated, the researchers found that 65 percent had been displaced, 50 percent had been fractured or perforated, and that significant bone degeneration was occurring around all implants.

As a result of this study, the FDA informed Vitek that they needed a minimum of 5-year clinical studies to determine that the TMJ replacement implant was equivalent to pre-amendment devices. In June 1990, the company filed for bankruptcy, and another company, Oral Surgery Marketing, Inc., with the same president and the same address, took over their products. In December 28, 1990, the FDA sent a safety alert to oral and maxillofacial surgeons, telling them not to implant any Vitek IPI’s.

On August 30, 1991, the FDA rescinded Vitek’s 510(k) for one of their TMJ implants, the IPI, saying that new evidence of adverse reactions indicated that the device was not substantially equivalent to silicone sheeting. After repeated unsuccessful efforts to force Vitek to notify patients of the risks of their IPI implants, on October 2, 1991, the FDA issued a medical alert that advised patients with Vitek IPI’s to obtain immediate MRI exams to determine if their implants were breaking or causing bone deterioration. The FDA also urged patients to enroll in an International Implant Registry. Because the company had filed for bankruptcy in June 1990, patients have to pay to enroll in the Registry; few have done so.

An estimated 25,000 Vitek IPI’s were distributed between 1983-86 in the United States. This does not include IPI’s implanted in 1987 and 1988.

In a recently conducted study by Dr. Mark Fontenot, a dentist and engineer who testified at our hearing, a mechanical TMJ simulator indicated that Vitek IPI implants could be expected to last only 3 years. Had anyone conducted such studies prior to implanting them in humans, the pain and suffering of tens of thousands of patients could have been avoided.

OTHER VITEK TMJ IMPLANTS. Vitek also sold an implant that totally replaced the joint; one of these models was called the VITEK-KENT I (VK-I). The Department of Oral Surgery at Louisiana State University conducted a retrospective study of 39 VK-I implants used for partial reconstruction and 85 for total
reconstruction between 1982-86. They found that approximately 40 percent had failed. These researchers did not look at asymptomatic patients.

During the years they were sold, numerous changes were made in the Vittek TMJ implants without FDA approval. The total number of implants used between 1974-1990 is not known, nor is the number of patients who still have such implants. In addition to the IPI, implants include the glenoid fossa implant, the condyle implant, the total joint implant, and the sheeting implant. At the time that the company filed for bankruptcy, there were approximately 426 outstanding lawsuits or claims, most involving the IPI or sheeting. There are now more than 2,000. The president of Vittek and OSMI, Charles Honsy, moved to Switzerland, and still claims the proplast jaw implants are safe. According to FDA officials, the federal government has made several unsuccessful efforts to collect money from Honsy or the company. Dr. Honsy claims he has no money, and his lawyer told the FDA that he is working pro bono. These federal efforts are apparently ongoing.

TMJ Implants, Inc.

A third company is called TMJ Implants, Inc. Their jaw implants are made from cobalt chrome with the condyle section made from an acrylic. They are frequently called the Christensen implant, after its inventor, Robert Christensen, D.D.S. Dr. Christensen is president of TMJ Implants, Inc.

TMJ Implants, Inc., claims that their device have been in commercial distribution in their present design since the early 1960's, and are therefore pre-amendment devices. However, an FDA investigator has determined that there has been a change in design since 1976, and another oral surgeon claims that the acrylic section of the implant was added in 1988.

Regardless of whether the implant design changed substantially since 1976, there is another problem: TMJ Implants, Inc., and the FDA agree that since 1990, the company has been selling a pre-sterilized device rather than their previous device, which needed to be sterilized by the doctors. As a result of this change, the FDA told the company in January 1992 that the devices should not be marketed until a 510(k) is submitted and approved. The company argued that the sterilization did not substantially change the device and should not require a 510(k). This argument would be moot if in fact the design of the devices has been changed substantially since 1976. Meanwhile, the implants remain on the market.

Dr. Christensen published three articles about the short-term safety of his implants in 1963-64. Each article described case studies of between 1-3 patients, followed for 1-2 years. However, when the Subcommittee asked him to submit all studies regarding the safety of the implants, he provided individual testimonials rather than any long-term research. The only study he provided was of 49 patients at one medical practice, who were followed for less than 18 months.
CUSTOM MADE TMJ IMPLANTS

Several companies have attempted to avoid FDA regulations by making "custom" devices that are made to uniquely fit each patient. Technomedica is the major company providing such TMJ implants today. Their implants, made of an alloy similar to the most popular orthopedic devices, sell for approximately $10,000 per joint (there are two joints in the jaw). This business is still small; in June 1992, the company claimed that they had sold only 250 devices in the previous 2 years. One of our hearing witnesses, Dr. Larry Wolford, uses these devices; however, there is no long-term safety information. Doctors who have used them for 1-2 years report few problems. However, that was also true of the Vitek device; the first 2 years of followup were very positive, and the implants failed quickly after that. In June 1992, a company spokesman said that only six patients had had these implants for 3 years.

Technomedica has not conducted safety studies of their TMJ implants. However, they claim that the implants are safe, based on animal studies conducted by other companies evaluating implants made of identical material for other types of joints.

FDA challenged Technomedica's avoidance of regulation based on their "custom made" status, and notified the company that they must file a 510(k).

The Role of NIH

NIH has the authority to conduct research on TMJ and to provide grants to researchers on this topic. Most of this research is supported by the National Institute of Dental Research (NIDR), although researchers include psychologists and medical doctors who specialize in pain and other relevant areas of research.

TMJ has not been a high priority for NIH, and little research has been supported. The research that is supported rarely evaluates the safety or effectiveness of various treatments, and never evaluated grafts or implants. In fact, the research base is so poor that neither the causes nor preferred treatments for TMJ problems have been determined. An NIH spokesperson informed me that they intentionally do not fund research on implants, because they do not believe implants are an appropriate type of treatment, except in a few cases of severe trauma.

If NIH believes that implants are unsafe, it would not be ethical to support research that encourages the use of implants. However, NIH could support retrospective studies of patients who already have such implants, in order to determine their safety. Such research is less scientifically sound than double blind clinical studies, which randomly assign different treatments. However, the reality is that tens of thousands of patients are falling through the cracks because FDA has not required the manufacturers to conduct safety studies, and NIH has not funded independent researchers to conduct such studies.

In the week following Chairman Weiss' May 1992 letter asking Dr. Bernadine Healy to testify on this topic, NIDR called at least two researchers to encourage them to submit grant applications immediately.
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GENERAL CONCERNS

Currently, there are no TMJ implants that are proven to be safe for long-term use. The Vitak implants are no longer sold, the Dow Silastic implants are now rarely used for permanent replacement because of their poor track record and there is concern that they could cause problems even when used as a temporary measure, and some surgeons are now experimenting with TMJ Implants, Inc., or custom-made implants by other companies. While the TMJ Implants, Inc., and Technoimplants apparently have reasonable track records for the last 2 years, Vitak and Silastic implants also were considered safe for the first 2 years of use. The problems tended to arise after 2-5 years, because the pressure and friction caused fragmentation, followed by giant cell development.

Problems resulting from the development of giant cells around jaw implants are now widely acknowledged by oral and maxillofacial surgeons. Several articles acknowledging these problems were published in their major journals in the late 1980's. For example, one review article, written by Dr. Wei Yung Yih and Dr. Ralph G. Merrill, described the "evidence of the destructive potential of these implants" to "cause damage that lasts far beyond the removal of the rejected implants" and can damage subsequent tissue grafts. The article also described "immune reactions" with "lymph node involvement by implant particles" that were very difficult to


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remove and contributed to the failure of subsequent bone grafts. The authors concluded that proplast and silicone are "not biologically acceptable implant materials" in the TMJ.

In contrast, the similar development of giant cells around breast implants was extremely controversial, with plastic surgeons and the manufacturers company touting the biocompatibility of silicone and refusing to acknowledge evidence to the contrary.

When problems arise, the removal of TMJ implants is extremely expensive, and at this time there are no known safe alternatives. Many experts believe it would be much safer to avoid implants to begin with. Once the bone degenerates, there is no known treatment to reverse that process.

DEVELOPMENTS AFTER THE HEARING

NIDR. Shortly before the hearing, NIDR funded a researcher to conduct a meta-analysis of all the research studies that had been conducted on TMJ treatment. A meta-analysis is a statistical method used to combine information from several well conducted studies, to attempt to provide more conclusive information. At the June 1993 hearing, Dr. Bernard Sanders, who was temporarily serving as Chair at Chairman Weiss' request, asked whether such a study was worthwhile, given the lack of well-conducted research in the field. The conclusions of this meta-analysis were consistent with those concerns; the researcher concluded that the studies that had been done were inadequate to enable a meta-analysis to indicate whether or not any surgical treatments are safe.
F.D.A. Shortly before the hearing, the F.D.A. sent warning letters to all the manufacturers of T.M.J. implants except Dow Corning regarding their need to provide 510(k) applications for their products indicating they are substantially equivalent to pre-amendment devices. The F.D.A. has determined that the "Christensen device" made by TMJ Implants, Inc., is a pre-amendment device since it was first sold in the 1960's, and that any other TMJ implants that can prove to be substantially equivalent to that device can be sold. However, as previously noted, the most recently sold Christensen device was different from the one that had been sold prior to 1976 in at least one respect, because the pre-1976 implant was not pre-sterilized. Therefore, TMJ Implants, Inc., has been told they cannot sell their pre-sterilized device until they have a 510(k) approved by F.D.A.

On September 18, 1992, 3 months after the Subcommittee hearing, the F.D.A. published the final rule in the Federal Register categorizing TMJ implants as Class III devices. The announcement notified manufacturers that safety data would be required in 30 months, the minimum time required by law.

Meantime, the F.D.A. is willing to consider whether any currently sold TMJ implants are substantially equivalent to the Christensen device, even though the other jaw implants are made of different materials. At a December 16, 1992, briefing from Joe Levitt, Deputy Director of F.D.A.'s Center for Devices and Radiological Health, and other F.D.A. staff, I was told that the fact that the other TMJ implants are made of completely different materials than the Christensen device may not be an impediment to approving a 510(k). However, F.D.A. officials told me that they would expect some clinical research to back up claims of substantial equivalence.

Despite the clear evidence that Dow Corning's silastic sheeting and Wilkes' temporary TMJ implant are substantially different from pre-amendment devices, because of changed labeling and changes in material, the F.D.A. has not yet sent even a warning letter to require a 510(k) from Dow Corning. It is this kind of omission that causes critics to say it is still "business as usual" at the Center for Devices and Radiological Health at the F.D.A. At my December 1992 briefing, the F.D.A. officials had no explanation as to why they had done nothing about the Dow Corning devices except to question whether Dow Corning would continue to sell those devices. I read them a recent article indicating that although Dow Corning would stop selling several silicone products, they were continuing their marketing of silastic sheeting and the Wilkes TMJ implant.

At the December 1992 briefing, the F.D.A. staff expressed concern that the currently sold TMJ implants should remain on the market for the foreseeable future, because there are no alternatives. This might seem to be a reasonable approach for the replacement of failed implants, but seems to me impossible to justify for patients who have not yet had any jaw implants.

RECOMMENDATIONS

1. The F.D.A. should require all manufacturers to prove that their TMJ implants are safe and effective for at least 5 years. These
data should be due 30 months from the final rule that was published on September 18, 1992. Prospective studies, comparing patients who receive implants or nonsurgical treatments should be conducted for at least 2 years, and retrospective studies should provide data for at least 5 years.

2. The FDA should immediately require 510(k) applications from all manufacturers of TMJ implants, including Dow Corning.

3. The FDA’s process for approving 510(k) applications needs to be more stringent. The criteria for “substantial equivalence” has been so loose, that more than 90 percent of those submitted are approved. As long as this continues, companies have no incentive to provide safety data to the FDA.

4. Postmarket surveillance should be required to determine the longer term safety of TMJ implants after any PMA’s are approved.

5. NIH should determine whether NIDR is the most appropriate institute for research on TMJ and jaw implants. NIH should ensure that NIDR or another institute immediately fund research comparing the safety and effectiveness of various treatments, including implants, grafts, and nonsurgical treatments.

6. The FDA should work more closely with oral and maxillofacial surgeons to inform them of the adverse reactions associated with jaw implants, and to ensure that they notify Vitek patients of the dangers of their implants. Previous FDA efforts have obviously not been successful. At this point, it seems necessary for the FDA to conduct a more effective public information campaign, since working