The Correction of Mandibular Ankylosis by Arthroplasty and the Insertion of a Cast Vitallium Glenoid Fossa

A NEW TECHNIQUE

A Preliminary Report of Three Cases

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INTRODUCTION

This article will be limited to a discussion of intra-articular ankylosis of the mandible and will discuss a new method of creating a barrier against the recurrence of this problem.

Ankylosis of the mandible can be fibrous, fibro-osseous, or osseous and can be initiated by a variety of etiologic factors. Such factors are birth trauma, hemarthrosis, infections, fractures of the condyle, tumors, rheumatoid or osteoarthritis, anatomic variation in the condyle or articular eminence, or following mandibular joint surgery—especially menisectomy. It might be well to state my belief that the degenerative changes which occur in some of these joints may occur in jaws with normal occlusion. An imbalance in the neuromuscular activity of some patients is undoubtedly a predisposing factor in the development of the forces which lead to joint degeneration which in turn, may lead to fibrous ankylosis[1]

In the cases to be presented, we have more readily recognized factors which have preceded the ankylosis.

In the first case, we have a young lady who had a unilateral menisectomy for chronic mandibular joint pain and who developed unilateral fibro-osseous ankylosis—which was later relieved by condylectomy but was again followed by ankylosis.

The second case is one in which a 46 year old man had generalized rheumatoid arthritis and slowly developed bilateral osseous ankylosis of the mandible.

The third case is that of a 57 year old woman who had a long history of left mandibular joint degeneration with negligible mobility. The attrition of the disc was such that a high condylectomy did not relieve her pain and immobility of the joint soon recurred.

Generally speaking, the fibrous or osseous ankylosis requires the same type of treatment with, perhaps, slight variations in technique.

Dr. Laszlo Schwartz states, "Ankylosis is highly disabling and when ankylosis has developed any form of conservative treatment is useless. Operation is the only possible way of helping the patient."[2]

Over a period of years, previous authors have advocated either no treatment or high condylectomy for fibrous ankylosis and osteoarthrotomy for osseous ankylosis.

The disability caused by either type of fusion is one of pain and degree of limitation. It would seem that a more uniform approach to both types of ankylosis would be welcome and that every effort should be made to restore a reasonably anatomic joint surface.

In the previously reported articles on osteoarthrotomy of the mandibular joint, the procedures have varied from placing nothing in the new joint space to the use of fascia, muscle, cartilage, plastic, or metal. Good results have been reported with each variety of osteoarthrotomy. In a case I reported in 1955, I placed no new material between the two bone surfaces and the patient has done well for nine years.[3]

Ideally, it would seem, a rigid mechanical barrier of anatomical shape would be most valuable; and for that reason I have attempted to devise a metal prosthesis which is anatomic, creates a permanent barrier and is well tolerated. The problem that has faced oral surgeons who might have wished for an anatomic prosthesis is how does one know the shape of the particular bone prior to surgery? Most attempts have been focused on attempting to restore a lost condyle or to cover the condylar stump with a non-anatomic barrier. The most promising prosthesis from a strictly bio-mechanical point of view would be to place the prosthesis against the base of the skull where unusual lateral pressures would not tend to loosen it.

It occurred to me, that in the case of a fibrous ankylosis, where it is possible to define the glenoid fossa and articular eminence both radiographically and clinically, that we should be able to cover this surface with a thin, anatomic cast vitallium prosthesis. With this premise I decided to make castings to cover the glenoid fossa, articular eminence and adjacent zygomatic process on 20 skulls (Fig. 1). The castings were made .022 inch thick and were perforated on the surface covering the zygoma and lateral articular eminence with numerous holes for the 5 mm. cast Vitallium implant screws, which would

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be used for anchorage (Fig. 2). The articular surface was highly polished, while other surfaces and margins were sandblasted. This thickness of Vitallium had some resiliency and could be formed lightly with pliers to allow for last minute variations in contour. The borders were extended, as shown in the pbotograph, to include most of the glenoid fossa, articular eminence, and lateral surfaces of both on to the lateral aspect of the zygomatic process of the temporal bone.

In the preparation of this type of prosthesis, for any given case, it is important to have accurate X-rays of the joint to give as much information as possible of the anatomic shape of the joint. In cases of osseous ankylosis, the procedure needs to be varied slightly because of the loss of the normal anatomic contour of the joint. In this

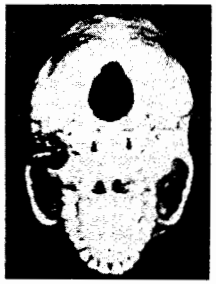

FIG. 1. Inferior view of skull with joint prosthesis in place.

case, it is necessary to create an osteotomy below the normal glenoid fossa and attempt to make it at the level of the articular eminence. In so doing, one can be sure not to perforate the cranial cavity. In the past, the suggestion has been made to remove, if possible, the condyle head or at least a 1 cm segment of bone. This has been necessary, where no mechanical barrier has been placed in the area. In some cases where a large segment of bone has been removed, the powerful elevator muscles have tended to close the bone gap, thus allowing a refusion to occur and at times an open bite.

By using several skulls and filling the glenoid fossa with modeling compound or plasticene, it is possible to make a pattern which will lay on the external surface of the condyle, fossa, eminence and to decide just how the cut should be made. If this small pattern is fixed with screws to the bone, then one can follow the exact curvature of the osteotomy which will be most suited. By making the final prosthesis in the shape of the previously mentioned glenoid fossa and articular eminence (only following the contour of the pattern), one can be sure that it will slide into place following the osteotomy In this case, the condylar head can be left in the fossa and the prosthesis can be attached to it. This then decreases the hazards attached to the removal of the condyle head; and in cases where this would be impossible, it removes the need for doing it. The thickness of the prosthesis can be from .014 to .022 inch so that varying degrees of adaptability can be selected. For this purpose, these thicknesses give ample rigidity and act as a perma-

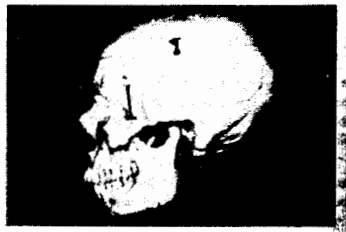

FIG. 2. Lateral view of skull showing condyle resting against joint prosthesis.

nent barrier to reankylosis of the joint. It is conceivable that Tantalum, in about 0.19 inch thickness, could be fabricated at the time of surgery and would also be useful. I have preferred cast Vitallium for its rigidness and also for the fact that the articular surface can be highly polished, thus giving it a smooth surface for the condyle to function against.

In all cases of ankylosis of one or both mandibular joints it is wise to correct the problem surgically since over a period of time, fibrosis may occur in the elevator muscles, thus causing an additional type of restriction which is difficult to relieve.

CASE REPORTS

CASE 1: Sister L., a 35 year old Catholic Nun, was referred to my office on December 5, 1960, for consultation regarding pain in her right mandibular joint, which was intermittant, dull and present for two to three years.

Past History: The patient gave a history of having a left mandibular joint menisectomy in 1948 by a surgeon in another city. She stated she had joint pain, cracking, and periods of trismus prior to 1948, and was advised that the removal of the meniscus would alleviate her problem. The surgery was done through a horizontal incision at the level of the zygomatic arch.

The patient's jaws were immobilized following this treatment. She stated that her mandible functioned more smoothly and with less pain for about one year, and then she began to notice her jaw deviate to the left side, and pain and grating returned.

Over the following few years, she was aware of the pain and restriction of the jaw movements until finally seven years later, the same surgeon suggested a condylectomy to relieve the fibrous ankylosis.

Again, this was done through a horizontal skin incision, and the mandible was immobilized by intermaxi-

FIG. 3. Case I—Pre-operative X-ray view of patient's normal right mandibular joint.

FIG. 4. Case I—Pre-operative X-ray view of ankylosed left mandibular joint.

FIG. 5 (top). Case I—Ankylosis of condyle neck to articular eminence. FIG. 6 (bottom). Vertical osteotomy completed with condyle repositioned in glenoid fossa of prosthesis.

lary traction for five weeks post surgically. Her recovery, again, was uneventful, until several months later, when her mandible began to deviate to the left with an abnormal occlusal relationship developing. She stated her left mandibular second and third molars and left maxillary first, second, and third molars were extracted to assist in closing an anterior open occlusion, which had developed. Her mandible became asymmetrical, and occlusal equilibration followed by gold crown restoration, on virtually all posterior teeth, was accomplished next.

Her mandible remained the same, until two years later, when she began to develop pain and granting in her right mandibular joint. Her course for the past three years had been one of limited motion with pain in her right and at times, left joints.

Clinical Examination: The patient was a very pleasant and calmly disposed Catholic Sister with a noticeable asymmetry of the face.

The left side of her mandible was elevated approximately ¾ inch above the right side. When the patient opened her mouth, the chin deviated to the left 12 mm. Her vertical amount of opening was less than ¾ inch. There was a noticeable pain in her expression as she attempted to open her jaws. The pain apparently eminated more from her right mandibular joint area.

By palpation, the right condyle would move forward more than expected with the degree of opening she could accomplish. In contrast, the left joint could not be discerned during movements. There was tenderness over the right joint and clicking was noted.

The intra-oral examination showed marked attrition of all of the teeth with gold crowns covering most of the bicuspids and molars. She was missing the left maxillary molars and left mandibular second and third molars.

Roentgenographic Examination: *Centric profile roentgenogram:* disclosed a shortening of the condyle area on the patient's left side, so that there was ¾ inch variation between the right and left angles of the mandible.

Mandibular joint films: showed a normal appearing right joint with hypermobility of the right condyle to the point of near dislocation while opening ¾ inch (Fig. 3). The left joint showed severe degenerative changes. The condylar head was missing, and the neck of the condyle had an osteoarthritic contour with much lipping and spurring of its margins. Its position was opposite the crest of the articular eminence and showed fibro-osseous attachment to the poorly defined, flattened eminence (Fig. 4). There was no change in this position during open or occlusal position. The glenoid fossa was empty and appeared flatter and with areas of osteoporsis in its cortical margins.

P-A Mandible roentgenogram: showed an elevation of the left side of the mandible due to the condylectomy and removal of molar teeth.

Treatment Plan: From the history, clinical examination, and X-ray findings it was apparent that the patient had a fibro-osseous ankylosis of the left joint due to the previous meniscetomy and condylectomy (Fig. 5). Because of the unilateral ankylosis, the patient's mandibular movements were accentuated in the right joint causing a constant strain on the capsule and ligaments which was painful. It was apparent that any attempt toward restoring permanent pain-free function in the right mandibular joint would be useless unless normal function could be established in the left joint. To restore this would mean taking three major steps. First, free the ankylosis; second, reconstruct the condyle so it would be in the glenoid fossa; third create a metal barrier to prevent future fusion of the mandible to the skull.

To restore the height and position of the condyle neck to its proper position could best be accomplished by doing a vertical osteotomy of the ramus of the mandible and repositioning the proximal segment of bone so its superior surface would be in the fossa and its inferior-anterior surface would rest against the cut surface of the ramus. The two segments of the ramus would be secured by a transosseous wire suture, while the mandible would be immobilized for nine weeks. The fossa-articular eminence would be covered with a cast Vitallium prosthesis as described above and held securedly by two 5 mm. Vitallium screws (Fig. 6.)

Since the patient taught school, it was decided to wait for summer vacation to perform the surgery. In the interim, the right mandibular joint was injected with hy-

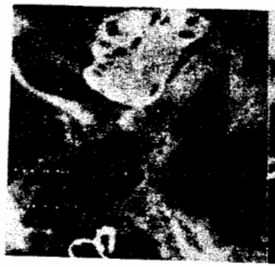

FIG. 7-A. Case I—X-ray of left mandibular joint with prosthesis in place.

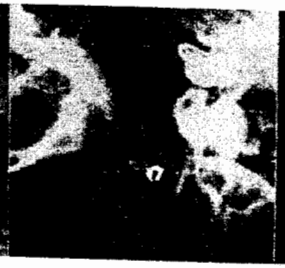

FIG. 7-B. Case I—X-ray of left ramus showing osteotomy with fragments held by transosseous wire suture.

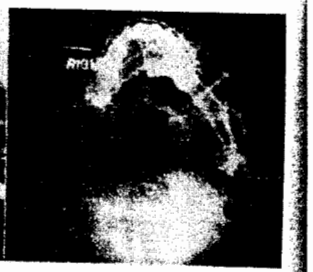

FIG. 8. Case I—Vertex-submental X-ray of skull showing prosthesis in left mandibular joint.

drocortone acetate-zylocaine (25 mg-0.5 cc 2% Zylocaine) on two occasions, and gave temporary relief which lasted two months.

Surgery: On June 19, 1961, the patient was admitted to St. Luke Hospital for surgery the following day. Under intra-venous Sodium Pentothal, with Anectine drip and naso-endotracheal gas-oxygen anesthesia.

The routine application of Winter-arch-fracture-bars was accomplished by placing a circumferential wire around the mandibular arch and symphysis of the mandible. This would prevent the lower arch bar from being pulled superiorly. An acryllic occlusal splint (intra-oral) prepared from previous impressions and models and were constructed to open the left posterior occlusion approximately 2 mm. The jaws could not be immobilized in the splint until after the vertical osteotomy of the ramus.

The vertical osteotomy of the left ramus was performed through a one inch skin incision using the Risdon approach. The osteotomy was made with a specially adapted bone saw (Christensen variation of the Joseph Nasal Saw) and was directed parallel to the posterior surface of the ramus from the mandibular notch to just forward of the angle of the mandible.

When the osteotomy was complete, the mandible could be immobilized in the acryllic splint by intermaxillary elastic traction. A sterile gauze pack was placed over this wound, and the pre-auricular incision was made with a scalpel to facilitate the arthroplasty by freeing the ankylosis. The skin incision ran vertically in the pre-auricular fold from the superior to the inferior attachment of the ear. A skin flap was elevated by sharp dissection and sutured forward with three silk sutures. The dissection to the level of the joint was carried along the cartilage of the ear by sharp dissection. When the lateral rim of the glenoid fossa was exposed, we used sharp and blunt dissection to elevate the attachment of the capsule and masseter muscle until the posterior third of the zygoma and lateral surface of the articular eminence was exposed.

The condyle stump was now fully exposed and found to be attached by very dense fibro-osseous tissue to the crest of the articular eminence. The glenoid fossa was filled with soft tissue; and by blunt dissection with a periosteal elevator, the tissue was reflected until the entire fossa was exposed.

The fibrous and partially bony attachment of the condyle neck to the eminence was severed using a scapel and sharp chisel. When this had been dissected. the assisting surgeon grasped the inferior end of the proximal fragment, with a Kelly forcep, through the Risdon approach and retracted this segment of bone inferiorly.

This made it possible to totally free the condyle neck from the eminence and to totally expose the anterior, inferior and posterior surfaces to the articular eminence, so that a suitable surface of bone would be available for the cast Vitallium prosthesis, which would cover the glenoid fossa and articular eminence.

At this point, the various cast prostheses. 20 in number, were placed against the bone, to check for accuracy of fit. One pattern fit all areas precisely, and was now held in position while a hole was drilled for one of the 5 millimeter cast Vitallium implant screws. The hole was drilled slightly smaller in diameter than one of the screws and the screw was inserted. This held the prosthesis in proper adaption to all the surfaces of bone. (Fig. 7-A) The second screw was now placed in a similar fashion.

The proximal segment of bone was now positioned so the condylar surface was in the most posterior portion of the glenoid fossa of the prosthesis. The inferior margin of this segment of bone was now tilted forward to contact the posterior surface of the osteotomy of the ramus approximately ⅛ of an inch higher than the inferior margin of the mandible. Because the condyle was tilted posteriorly, there was a V shaped space between the two fragments above the point of contact at the lower margin. A single trans-osseous steel wire was placed near the lower margin, where the two bones contacted each other (Fig. 7-B). This was found adequately to immobilize the two fragments, since the jaws were secured by intermaxillary traction (Fig. 8).

The pre-auricular wound was now closed in layers. The Risdon wound was closed in a similar fashion and a small piece of Telfa was placed over each wound and a pressure dressing was used over this.

The patient's condition at the end of surgery was satisfactory and she was taken to the recovery room for observation. The naso-tracheal tube was left in place until she was fully awake. Vistaril 25 I.M. was given 20 minutes prior to the end of surgery and every three hours for three doses to prevent nausea and to keep the patient tranquil.

Her recovery was uneventful and she was discharged on the fourth post-operative day. There was no impairment to any branch of the facial nerve, nor was there and disturbance to the mandibular branch of the trigeminal nerve. The mandible was left immobilized for nine weeks to allow the bone fragments to unite. At that time the intermaxillary elastic and wide traction was removed. The patient was able to open her jaws ⅜ inch and the occlusal splint was removed. One week later, under local anesthesia, the fracture arch bars and circumferential wire were removed.

Over the next few weeks, the patient was able to open her jaws 1¼ inch and was able to create left excursion with ease and excursions to the right to a lesser degree. The pain which she had noticed in the right mandibular joint subsided shortly after surgery and has not returned at six months following surgery. Eighteen months later she was well satisfied; without pain, trismus, and with a serviceable range of motion.

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Case 2: H.S.: a 46 year old man, who had developed generalized rheumatoid arthritis over the past 20 years. He was referred to my office by his general dentist for consultation regarding his total bilateral ankylosis of the mandible. He was an accountant by profession.

FIG. 9. Case II—Pre-operative X-ray of right mandibular joint showing osseous onkylosis.

FIG. 10. Case II—Pre-operative X-ray of left mandibular joint showing osseous onkylosis.

FIG. 11. Case II—Pre-operative cephalometric X-ray of skull with total onkylosis.

Past History: The patient first became aware of his arthritis 20 years before when he noted chronic neck and back pain and over the ensuing period of years developed kyphosis of the cervical and thoracic vertebrae. He had been six feet in height and over a seven year period diminished to only five feet seven inches due to the kyphosis. His weight had been 210 pounds but had dropped to 140 pounds.

Fortunately his limbs were not markedly disturbed by this disease, but over the past 12 to 14 years bilateral arthritic involvement of the mandibular joints occurred, so that for the past eight years he had absolutely no mandibular mobility.

Clinical Examination: The patient was a typically arthritic patient with a severely stooped posture. His head was flexed forward and downward, so that his ability to see what was in front of him was very difficult. He as unable to turn either to the right or left.

Roentgenographic Examination: *Mandibular Joint Films*: The right and left joint areas showed hyperostosis of the condyle areas with lack of normal joint space. There was total osseous ankylosis of both right and left mandibular joint areas. (Figs. 9 and 10).

The other skull films showed no bony ankylosis of the coronoid-zygoma areas.

Roentgenographic Conclusion: Total bilateral articular bony ankylosis of the mandible (Fig. 11).

Treatment Plan: The plan was to do an osteoarthrotomy in the right and left mandibular joint areas and insert a cast Vitallium prosthesis.

Since the actual joint areas would be, for all practical purposes, imperceptive it was decided to plan the osteotomies just inferior to the normal glenoid fossa but level with the normal articular eminence.

Twenty skulls were used as a pattern in the following manner to construct a total of 40 prostheses: The mandibles were removed from the skulls and plasticene was used to fill in the glenoid fossa of the right and left sides of each skull. The plasticene was smoothed to a slow sigmoid curve whose forward curve was even with articular eminence. When this was accomplished, a wax pattern was made to fit the lateral aspect of each glenoid fossa-articular eminence and the lower border corresponded to the sigmoid curve just described. Each template, when cast in Vitallium, was numbered, to right or left, and was given the particular skull number.

The actual wax pattern for the prosthesis was now

prepared just like the template but also extended in a horizontal direction to cover the new glenoid fossa and articular eminence. Each of these was identified with a number to correspond with the template. The prostheses were now cast in .018 inch thick Vitallium.

The plan would be to explore surgically the areas of intra-articular ankylosis, place the template, which best fit the particular area, against the bone surface with its most superior margins along the superior edge of the zygomatic arch adjacent to the joint area. The inferior sigmoid curve would be at the level of the patient's articular eminence.

The template could be secured by screws to the bone, or held in place while a sharp instrument was used to mark the sigmoid curve on the bone.

When this had been done, a #8 or #557 carbide burr would be used in the straight handpiece to accomplish the osteoarthrotomy. Following this, the glenoid fossa-articular eminence prosthesis, which corresponded in number to the template, would be placed and secured with two, three, or four cast Vitallium screws to the lateral surface of the zygoma in the area of the joint.

FIG. 12. Case II—Post-operative X-ray of skull showing prosthesis in place.

FIG. 13. Case II—Post-operative X-ray of left mandibular joint with prosthesis in place.

FIG. 14. Case II—Post-operative profile X-ray with jaw open.

Surgery:

On December 1, 1961, the patient was admitted to Huntington Memorial Hospital for surgery. On the following day this was accomplished under intravenous anesthesia with naso-trachael gas-oxygen anesthesia. Intubation was difficult because of the patient's mandibular and vertebral ankylosis.

The exploration of the right and left mandibular joints was accomplished through the typical pre-auricular approach. Both joint areas showed total bony obliteration and fusion of the mandibular joints. The osteoarthrotomies were accomplished after proper placement of the templates as described in the treatment plan.

Following this the prostheses were placed (Figs. 12 and 13), and the mandible could be forced open ¾-inch in the incisor area. The wounds were closed with sutures and a dressing was placed over the wounds.

The mouth was then entered and when the mandible could not be forced open more than ¾ inch, it was decided that an intra-oral, bilateral, coronoidectomy should be done to relieve the fibrous adhesion in the temporal muscle which undoubtedly was preventing proper mobility of the mandible.

The coronoidectomies were accomplished with burrs and chisels, and the oral wounds were closed with sutures. The mandible could now be open 1½ inches (Fig. 14). While forcing the mandible to open with a mouth gag, the left maxillary lateral incisor, which had cervical caries, was fractured and the mandibular centrals were displaced labially and extracted.

The pre-auricular areas were now covered with pressure bandages and the patient was taken to the recovery room.

His post-operative course was uneventful, and he was discharged from the hospital on the fifth day and started on a regular diet at once. Because of the adhesions in the temporal muscles it was decided to use ultra-sound therapy over these areas, daily, for the following month.

The patient five months following surgery was able to open 1½ inches and chew hard and soft foods with ease. He is most pleased to be able to eat hamburgers. He still continues to improve two years later.

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Case 3: A. W., a 57 year old lady, was referred October 25, 1960, to another oral surgeon for a chronic left mandibular joint problem by an orthopedist.

History: This patient gave a history of left joint pain and trismus which occurred about 10 years earlier. She consulted another oral surgeon at that time who told her the pain in her left joint was caused by the removal of her impacted third molars some years earlier. The oral surgeon referred her to an orthopedic surgeon for treatment of her joint problem. This physician had mandibular joint films taken which showed lack of mobility of the left joint. He advised diathermy to the area. The physiotherapist gave two or three courses of diathermy to the area over a two month period.

FIG. 15. Case III—Pre-operative X-ray of right mandibular joint showing normal joint.

FIG. 16. Case III—Pre-operative X-ray of left mandibular joint showing loss of articular space, and steep articular eminence.

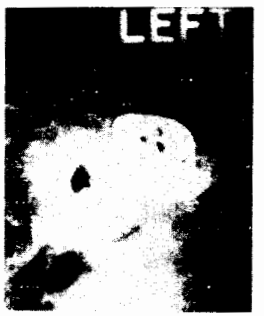

FIG. 17. Case III—Post-operative X-ray of left mandibular joint with prosthesis in place.

Much of the acute pain subsided and function "clinically" seemed to improve. The patient had intermittant intervals of tenderness and limited motion over the next ten years but was not given any definite therapy.

In October, 1960, she developed acute mandibular joint pain and trismus sought the advice of another orthopedic surgeon who then referred the patient to this oral surgeon.

Clinical Examination: The patient in October, 1960, had acute pain in the left mandibular joint with trismus which had become acute ten days earlier. Her ability to open was limited to 1 cm in the incisor area.

There was marked tenderness to palpation directly over the left joint. Her occlusion appeared normal.

Roentgenographic Examination: The mandibular joint films were taken in November, 1960, and showed a normal right mandibular joint (Fig. 15) with normal motion considering the limited mandibular opening.

The left joint gave a different appearance in that all of the bony surfaces appeared less well defined. The condyle's articular surface appeared to be less well defined with areas of radiolucency within the condyle. The glenoid fossa appeared more radiopaque and yet less well defined. The articular eminence was very steep with an appearance of osteoporosis within its crest (Fig. 16).

The condyle was in close approximation to the posterior surface of the articular eminence giving the impression the disc was either missing, perforated, macerated, or thinned.

The left condyle moved only slightly during opening of the jaws. Appreciably less motion was noted in the left joint as compared to the right joint.

Roentgenographic Conclusion: Chronic degenerative changes of left mandibular joint with possible early fibrous ankylosis.

Treatment Plan: The joint changes visualized in the X-rays were thoroughly explained to the patient. I advised her to continue the pain and muscle relaxing medication and I felt that the injection of Hydrocortone Acetate 25mg mixed with 0.5cc of Xylocaine into the joint might give some temporary relief. On November 11, 1960, the left joint was injected and November 29, it was reinjected.

Pain and trismus subsided although function of this joint, as evidenced by right lateral and protusive excursions, was minimal. In January, 1961, the patient noticed a slow return of pain and trismus. I explained to the patient that I felt a high condylectomy should be considered to reduce attrition to the already degenerated articular disc. I felt that the remnant of this disc should be left in place, and that the left molar occlusion should be opened by placing an acryllic occlusal splint and by immobilizing the jaw in the splint following condylectomy. She agreed to this so the necessary impressions were taken to prepare the splint. On February 10, 1961, the surgery was performed in the hospital.

First Surgery: The fracture arch bars were placed and the mandible was immobilized in the acryllic splint. Through a pre-auricular incision the high condylectomy of the left joint was carried out. A 7 mm. section of the crest of the condyle was removed. The articular disc appeared very thinned, if not perforated, in the center. The articular surface of the condyle was roughened. The articular eminence was now explored from above the disc and found very steep. With careful hand pressured chisels, the articular eminence was recontoured to give a more suitable surface for the condyle to glide upon. The mandible was moved manually to observe the freedom of the new condylar surface. The incised capsule was carefully closed with 3-0 gut sutures. The wound was closed in layers.

The patient's post-operative course was uneventful. She was discharged from the hospital on the fifth day. Her jaws were mobilized after four weeks. Masticatory function became normal over the following few weeks.

FIG. 18. Case III—Post-operative transorbital view X-ray of mandibular joint area with prosthesis in place.

FIG. 19. Case III—Post-operative cephalometric X-ray of skull with prosthesis in place.

FIG. 20. Case III—Post-operative cephalometric X-ray of skull with jaws open.

In June, 1961, she was able to open 1½ inches and had total left lateral moderate right lateral excursions which I hoped would continue to improve. Her occlusion was, at that time, normal.

In September, 1961, the patient did not seem to be improving her excursions, and some tenderness returned in the left joint. The pain was slight compared to that experienced prior to surgery. In October, 1961, her excursions to the right were negligible and new joint roentgenograms were ordered. These showed normal motion in the right joint and lack of movement of the left condyle and joint.

I explained to the patient that apparently the degenerated left mandibular joint disc was apparently not sufficient to prevent fibrous ankylosis of this joint. It was suggested, for diagnostic purpose, that she be given general anesthesia to determine if the left condyle could be forcibly moved by finger pressure on the mandible. On October 27, 1961, in the office surgery, the patient was anesthestized, and it was impossible to cause the left condyle to move out of the glenoid fossa by brisement force.

On the subsequent visit I explained to the patient that she distinctly had a fibrous ankylosis of the left mandibular joint. I explained that apparently the perforated meniscus was not sufficient to prevent the ankylosis which had formed.

I explained, in detail, my recent experience in placing a metal barrier between the two bone surfaces as a hopeful means of preventing future ankylosis. It was explained that this method could not be guaranteed to give the desired results; but I felt that surgical revision of the ankylosis was the logical treatment and that the placement of the prosthesis, in my opinion, was indicated. I advised continued observation until the patient felt that some future treatment was imperative.

In March, 1962, the patient requested further treatment in hopes of relieving the pain in the left joint and trismus. New joint films were taken which showed loss of left mandibular joint function.

Second Surgery: On March 24, 1962, the patient was admitted to Huntington Memorial Hospital for revision of the fibrous ankylosis and insertion of a cast Vitallium glenoid fossa.

The operation was performed through the preauricular incision in a fashion similar to the previous cases. The disc was present but a dense, fibrous attachment was noted from the anterior condylar surface to the posterior surface of the articular eminence. It was impossible to force the condyle to move by manipulating the mandible. By sharp dissection the entire disc and interposed tissue was removed in one piece and submitted to the pathologist for miscroscopic examination. The glenoid fossa, articular eminence and condyle were now free of any attached tissues, and the mandible could now be moved freely in all directions to a maximum degree.

The cast Vitallium prosthesis was selected from 60 which had been prepared. The fit of the prosthesis was as precise as a crown on a tooth and was immobilized by four 5mm. cast Vitallium screws (Figs. 17 and 18). Again the mandible was moved manually as the condyle glided smoothly over the polished articular surface of the prosthesis.

The patient was encouraged to use her jaws the next day (Figs. 19 and 20). She was discharged from the hospital on the third post-operative day. On the fourth day the patient was free of pain and able to chew nuts, celery and apples. She was delighted at her apparent speedy recovery.

She is now 12 months post-surgery and a recent follow-up indicates that she is very pleased, has no pain, and has a useful range of motion.

The pathologist's report is interesting especially in view of an article by Chireson and Robinson in which

they state, "In 16 necropsies at Los Angeles County General Hospital it was found that the discs is only fibrous connective tissue."[4]

The pathologist's report is as follows: "The specimen is a strip of dense, pink white tissue, and in one piece cartilage is present. One edge of the cartilaginous tissue is frayed and irregular. There also is a synovial lining here, with numerous chronic inflammatory cells present close beneath it. No specific type of inflammation is in evidence and there is no malignancy. Diagnosis: Nonspecific chronic inflammation and scarring in tissue from left temporomandibular joint (Figs. 21, 22 and 23)."

FIG. 21. Case III—Low power photomicrograph of articular disc showing synovial layer.

FIG. 22. Case III—Low power photomicrograph of articular disc showing fibro-cartilage.

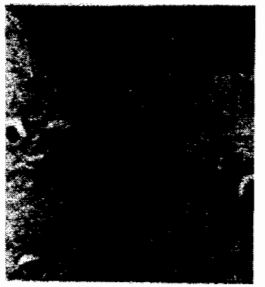

FIG. 23. Case III—High power photomicrograph of articular disc showing cartilage cells.

SUMMARY

This paper describes a new technique for creating an anatomic, prefabricated, well tolerated prosthesis to accurately cover the patient's glenoid fossa and articular eminence in the correction of ankylosis of the mandible. Three cases have been described.

Several more cases have been operated in which the cast Vitallium glenoid fossa prosthesis has been placed to correct unilateral or bilateral mandibular joint arthrosis, since this paper was submitted. The results evidenced in all cases thus far show relief of symptoms and restoration of function.

It is too early to totally evaluate this new technique for the correction of unilateral or bilateral ankylosis of the mandible. Certainly the results thus far are most encouraging. Color motion picture films have been taken of each of these cases which will be useful in making a comprehensive review of the success of this operation at a later time.

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ACKNOWLEDGMENT

I wish to thank Mr. Robert F. Chapin for the photographic reproductions used in this article, and Dennis Shillam, M.D. and Alvin Foord, M.D. of the Pathology Department of Huntington Memorial Hospital, Pasadena, for the microscopic examination and photomicrographs.

Surgical treatment of mandibular ankylosis

Use of a cast Vitallium glenoid fossa

ROBERT W. CHRISTENSEN, D.D.S.

Secretary of the Southern California Association of Oral Surgeons, Pasadena, California.

This article presents a discussion of intra-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 fibrous, fibro-osseous, or osseous in nature and can be initiated by numerous etiologic factors. Such factors are birth trauma, hemarthrosis, infections, fractures of the condyle, tumors, rheumatoid arthritis, osteoarthritis, anatomic variation in the condyle or articular eminence, and following mandibular joint surgery especially meniscectomy. The degenerative changes which occur in some of these joints may occur in jaws with normal occlusion. An imbalance in the neuromuscular activity is undoubtedly a predisposing factor in the development of the forces that lead to articular degeneration which in turn may lead to fibrous ankylosis.[1] The disabilities caused by any type of ankylosis are pain and limitation of function.

Dr. Laszlo Schwartz stated,[2] "Ankylosis . . . is in itself highly disabling, and when ankylosis has developed, any form of conservative treatment is useless. Operation is the only possible way of helping the patient."

For many years several authors have advocated either no treatment or high condylectomy for fibrous ankylosis and osteoarthrotomy for osseous ankylosis. Generally speaking, both fibrous and osseous ankyloses require the same treatment, with perhaps slight variations in technic. The procedures for osteoarthrotomy of the mandibular joint have varied from placing nothing in the new joint space to using fascia, muscle, cartilage, plastic, or metal, with good results being reported for all. In a case that the author reported[3] in 1955, no new material was placed between the two bone surfaces, and the patient has done well for nine years.

Knowing the shape of the particular bone prior to surgery presents a problem to the oral surgeon who wants an anatomic prosthesis. Most attempts have been focused on restoring a lost condyle or covering the condylar stump with a nonanatomic barrier. The most promising prosthesis from a strictly biomechanical point of view is one placed against the base of the skull where unusual lateral pressures would not tend to loosen it. Ideally the prosthesis should be a rigid mechanical permanent barrier that conforms to the anatomy, is well tolerated, and can be polished. A cast Vitallium prosthesis provides these characteristics. The thickness of Vitallium can vary from .014 to .022 inch and have ample rigidity and still be resilient enough to allow slight variations in the contour with pliers during the surgical procedure.

In fibrous ankylosis the glenoid fossa and articular eminence can be defined radiographically, and also clinically during surgery; therefore, it should be possible to cover the surfaces with a thin, anatomic, cast Vitallium prosthesis. It is important to have good quality radiographs of the joint to assure accurate visualization of its anatomic shape. With this premise, 20 skulls were used as models, and castings were made to cover the glenoid fossa, articular eminence, and adjacent zygomatic process. The castings were perforated on the surface covering the zygoma and lateral articular eminence to accept the cast Vitallium 5-millimeter screws used for anchorage. The prostheses have numerous perforations to allow for variations in anatomy. The articular surface was highly polished, and the other surfaces and margins were sandblasted. Reproductions of the

Open 1 inch | Relaxed | Closed

Figure 1A—Preoperative radiographs showing normal right mandibular joint.

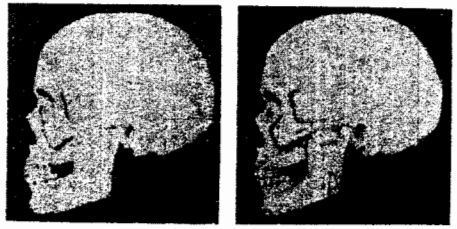
Figure 1B—Preoperative radiographs of ankylosed left mandibular joint.

Closed | Relaxed | Open 1 inch

ing the ankylosis, 2) placing a metal barrier to prevent future fusion of the mandible to the skull, and 3) repositioning the condyle neck so that it would be in the glenoid fossa.

The condyle neck could be substituted for the head of the condyle by performing a vertical osteotomy on the ramus of the mandible and raising the distal segment so that the condyle neck would be in the glenoid fossa. A transosseous wire suture would maintain this relationship (Figure 1C).

Figure 1C—Left: Drawing depicting ankylosis of the condyle neck to the articular eminence. Right: Vertical osteotomy with condyle neck repositioned in prosthetic glenoid fossa.



Surgery

On June 20, 1960, under intravenous Sodium Pentothal with Anectine drip and nasotracheal gas-oxygen anesthesia, the surgery was accomplished.

Winter fracture arch bars were applied with a circumferential wire around the mandibular arch bar and symphysis of the mandible. The circumferential wire would prevent superior displacement of the bar. An acrylic occlusal splint was prepared to open the left posterior occlusion approximately 2 millimeters. The jaws could not be immobilized in the splint until the vertical osteotomy of the ramus was done.

The vertical osteotomy of the ramus was accomplished through a 1-inch skin incision in the Risdon approach. When the osteotomy was complete, sterile gauze pack was placed over the wound. The preauricular incision was made with a scalpel to facilitate the arthroplasty and to free the ankylosis.

Surgical access was gained to the area of the glenoid fossa and condyle. The condyle neck which was attached to the articular eminence by dense fibro-osseous tissue was severed by a scalpel and sharp chisel. Soft tissue filled the glenoid fossa and was removed by blunt dissection with a periosteal elevator. The articular eminence and glenoid fossa were fully exposed in preparation for placement of the Vitallium prosthesis.

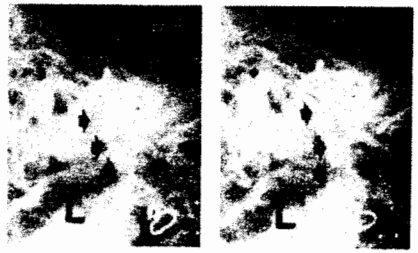


Figure 1D—Radiographs of the left mandibular joint with prosthesis in place. Arrows indicate the movement of the condyle neck and stump from the closed to open position.

Each of the 20 cast prostheses was placed against the bone to check for accuracy of fit. One prosthesis fitted all areas precisely, and was secured with 2 Vitallium implant screws (Figure 1D). The distal segment of the ramus was positioned so that the condyle neck was in the prosthetic glenoid fossa and the lower section was tilted forward so that the lower margin contacted the osteotomy approximately ⅝ inch above the inferior border of the mandible. A single transosseous steel wire was placed near the lower margin where the two bones came in contact (Figures 1C, right, and 1E). This was found adequate to immobilize the two bone segments, since the jaws were secured by the splint and intermaxillary traction (Figure 1F). The preauricular and Risdon wounds were closed in the routine manner, and pressure dressings were applied. Recovery was uneventful. The patient was discharged on the fourth postoperative day.

Postoperative care

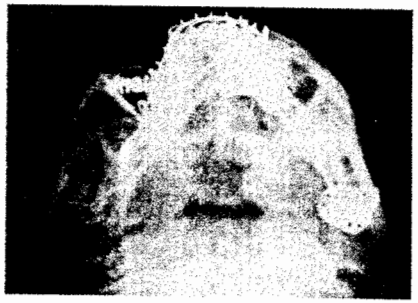
The mandible was kept immobilized for nine weeks. At that time the occlusal splint was removed, and the patient was able to open her jaws ⅜ inch. One week later under local anesthesia, the fracture arch bars and circumferential wire were removed. During the next few weeks, the patient was able to open her jaws 1¼ inches, and was able to execute left lateral excursions with ease and right excursions 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 limitation of function has recurred.

Case 2

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

Figure 1E—Radiograph of left ramus showing the osteotomy and the transosseous wire suture that retains the bone segments in proper position.

Figure 1F—Vertico-submental view showing prosthesis for left mandibular joint and Winter fracture arch bar.



History

The patient first became aware of his arthritis 20 years before when he developed chronic neck and back pains, and subsequently he developed kyphosis of the cervical and thoracic vertebrae. Fortunately, his limbs were not markedly disturbed by this disease. During the past 12 to 14 years, the bilateral arthritic involvement of the mandibular joints occurred, with no mobility for the past 8 years.

Clinical examination

The patient had a severely stooped posture. He was unable to stand erect or turn his head either to the right or left. His mandible could not be moved for a thorough intraoral examination.

Radiographic examination

Radiographs of the right and left mandibular joints showed hyperostosis of the condyle areas with lack of a normal joint space. There was total osseous ankylosis of both right and (*Continued on page 22*)

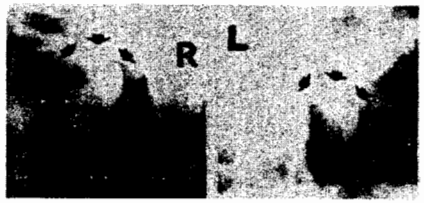


Figure 2A—Preoperative radiographs of the right and left mandibular joints showing osseous ankylosis.

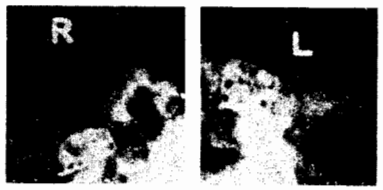


Figure 2B—Above: Postoperative radiographs of right and left mandibular joints with prostheses in place. Maximum opening is ¾ inch. Below: Lateral radiograph made after coronoidectomies were performed shows the maximum opening of 1½ inches.

Mandibular ankylosis

(*Continued from page 7*) left mandibular joint areas (Figure 2A).

Other radiographs of the skull showed no bony ankylosis of the coronoid-zygoma areas.

Diagnosis

Total bilateral ankylosis of the mandible.

Treatment plan

To restore functioning of the mandible, bilateral osteoarthrotomies would be performed and cast Vitallium prostheses inserted. Each osteotomy would be made level with the normal articular eminence.

The previously constructed templates were used as guides for the osteotomies. For each side, the template would be placed against the bone surface with the lower border at the level of the patient's articular eminence. The template could be secured by screws to the bone or held in place while a sharp instrument was used to mark the lower border. Then a No. 8 or No. 557 carbide bur would be used in the straight handpiece for the osteoarthrotomy. Following this, the matching prosthesis would be secured with Vitallium screws to the lateral surface of the zygoma.

Surgery

On December 2, 1961, the surgery was accomplished under intravenous anesthesia with nasotracheal gas-oxygen anesthesia. The right and left mandibular joints were explored through the routine preauricular approach. The osteoarthrotomies were performed after proper placement of the templates. Following this, the prostheses were placed (Figure 2B, above). The mandible could now be forced open ¾ inch in the incisor area. The wounds were closed with sutures, and dressings were applied.

When the mandible could not be forced open more than ¾ inch, it was decided that intraoral bilateral coronoidectomies should be done to relieve the fibrous adhesions in the temporal muscles, which undoubtedly were preventing proper mobility of the mandible. The coronoidectomies were accomplished with burs and chisels, and the oral wounds were closed with sutures. The mandible could now be opened 1½ inches (Figure 2B, below). The preauricular areas were covered with pressure bandages.

Postoperative care

Recovery was uneventful. The patient was discharged from the hospital on the fifth day, and started on a regular diet at once. Eighteen months following surgery, the patient was able to open his mouth 1½ inches and eat a normal diet.

AUTHOR'S NOTE: Acknowledgment is made to Mr. Robert F. Chapin for the drawings reproduced in Figure 1C. The Vitallium prostheses were manufactured and supplied by the Austenal Company, New York City.

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This survey demonstrates the relative frequency of facial space infections by anatomic location, and bacteria. It also shows that the typical patient at our institution with a deep facial space infection secondary to odontogenic origin most likely is a 30-year-old white male with a buccal space infection having alpha strep as the infectious bacteria.

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POSTER 14

Total Joint Reconstruction Utilizing the Christensen Prosthesis: A Preliminary Report

Bradford S. Jungles, DMD,
Hospital of the University of Pennsylvania,
3400 Spruce St., 5 Silverstein, Philadelphia,
PA 19104 (Quinn, P.D.)

Temporomandibular joint reconstruction utilizing the Christensen prosthesis was first reported in 1964. Since November 1988 we have used the Christensen prosthesis in cases of severe degenerative joint disease where conservative surgical management is precluded. The purpose of this abstract is to present initial clinical follow-up for 57 cases where the Christensen prosthesis was used. These include total joint reconstruction utilizing the vitalium condylar prosthesis in concert with a vitalium glenoid fossa, as well as use of the alloplastic fossa against a natural condyle. The prosthesis, related instrumentation and surgical technique will be presented. Complications and contrast with the Vitek-Kent, Synthes and Ti-Mesh Delran systems will also be covered.

A total of 57 surgeries were performed on 49 patients, over a period of 17 months beginning in November 1988. Forty-five patients were female, four were male. Most patients suffered from severe degenerative joint disease secondary to trauma or previous surgery with alloplastic implants. Some patients had fibrous or bony anklosis of the TMJ. A few patients had apertognatia and/or mandibular hypoplasia secondary to previous trauma.

A total of 77 joints were entered at separate surgeries. Forty-six (59.7%) were treated with placement of alloplastic fossa only. Twenty-one (27.3%) joints were totally reconstructed with a prosthesis. Seven joints (9%) were treated with a prosthetic condyle only. Of these, five were reoperations on patients who had a previously placed fossa. Three (3.9%) joints were operated for miscellaneous reasons.

Preliminary follow-up indicates that temporomandibular joint reconstruction utilizing the Christensen prosthesis is an acceptable surgical technique. The majority of patients have better postoperative function and decreased pain after the surgery. Thus far we have seen only one fractured prosthesis. This prosthesis functioned normally for 320 days. Seven joints (12.3%) treated with only partial joint reconstruction required a second surgery and conversion to a total joint prosthesis.

Severe degenearative joint disease presents a treatment challenge to the TMJ surgeon. The Christensen prosthesis should prove to be a valuable treatment modality for this disease. In our hands this prosthesis has been the most successful. As compared to other prostheses, we have seen decreased failure and complication rates. Many surgeons advocate total joint reconstruction utilizing autogenous costocondral. grafts. The main advantages we see to utilizing an alloplastic prosthesis are: (1) decreased operative time secondary to ease of placement; (2) eliminates surgical morbidity and complications associated with rib harvest; and (3) decreased rates of post-operative infection and other complications. Further controlled study of post-operative function and pain indices remains to be done. As further data is amassed the Christensen prosthesis will likely survive as a viable treatment option in temporomandibular joint reconstruction.

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POSTER 15

Arthroscopic Traction Suture for Clicking and Hypermobility of the Temporomandibular Joint

Toshirou Kondoh, First Dept. of OMS, Tsurumi Univ. School of Dentistry, Tsurumi-ku, Yokohama Japan (Seto, K.)

In many cases of clicking jaw, the first choice of treatment procedure has been conservative splint therapy. However, this treatment was not always effective. Especially, in late opening click with severe noise or clicking in the laterotrusive jaw movement and/or clicking with hypermobility of the mandible were difficult to treat.

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DATE: 1992-06-01

FAX: 001 202 225 2382

TO: Subcommittee for Human Resources and Intergovernmental Relations
Congress of the United States
Honorable Ted Weiss, Chairman; ATT: Ms. Diana Zuckerman, Staff Person

RE: Hearing June 4, 1992, FDA regulation of TMJ Implants

Honorable Congressman Weiss:

I have only learned of the subject hearing a few days ago. As the former President of Vitek 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. (Emphasis added). Lawsuits and claims relative to the Vitek interpositional implant have been well below 10%.

2. The mode of procedure failure with the Vitek 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 surfaces" 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 splint-, physical-, and/or psychological counselling may alleviate. These are not conditions that any implant can treat. This paper also reported the replacement of the silicone implants with Vitek interpositional implants by surgeons apparently convinced of the their superiority. To my knowledge FDA did not conduct any investigation of the silicone rubber procedure failures.

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

Subcommittee on Human Resources and Intergovernmental Relations 2.
Congress of the United States

4. Clearly, since the oral surgery profession did not recognize a significant frequency of interpositional implant procedure failures in 1982 and 1983 when the Vitek implant was reviewed and approved for sale by FDA, neither FDA nor Vitek could have anticipated procedure failures with the predicate silicone rubber interpositional implant nor Vitek's implant. At this time the majority of patients who do not have continuing clenching and bruxing behavior have been denied access to Vitek's device, the best of its kind.

5. I believe FDA has confused *patient caused failure* with implant failure and, thereby, has damaged the reputation of Proplast implant material; this is the *only* material developed exclusively for implantation in a medical center setting and consequent to exhaustive laboratory, animal, and pre-commercial clinical studies which were recognized by three separate FDA expert review panels as valid and confirmed by FDA publication in the Federal Register of its decision to grant Class 2 device status (Standards category) to implants of the material.

6. FDA has unscientifically called into question the OSMI V-II total TM joint replacement implant and made it unavailable to US citizens and ignored Vitek'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 effect from oral surgeons highly experienced in the use of this implant.

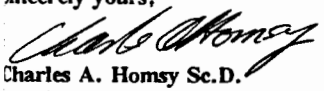
7. A Finding of Fact of a Federal Court in Houston in an unrelated matter was:

> **"Uncontroverted evidence was presented by physician consumers of the devices in question that the products (V-II 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 via Federal Express today. I am now employed by a European company using the technology developed by me and my associates over the past twenty-six years. The technology will not be pursued in the country of its birth nor by the employees of Vitek, and OSMI who have lost their jobs. I hope the tragic Vitek 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 cannot appear before your Committee in the near future because of an injury recently sustained in a fall.

Sincerely yours,



Charles A. Homsy Sc.D.
cc: Members of the Subcommittee; attachments FED-X under separate cover.

APPENDIX 5.—SUMMARY OF META-ANALYSIS AND NIDR REQUESTS FOR PROPOSALS FOR STUDIES OF JAW IMPLANTS

Not for quotation

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

Alexia Antczak-Bouckoms DMD, MPH, MS, ScD

November 16, 1992

Technology Assessment Group
Harvard School of Public Health
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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

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 consensus regarding diagnosis and outcomes, and the encouragement of appropriate clinical research.

Vol. 18, No. 13, April 14, 1989

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

P.T. 34; K.W. 0715148, 0715050, 0715055, 1002034, 0785045

National Institute of Dental Research
National Institute on Deafness and Other Communicative Disorders

Application Receipt Dates: June 1, October 1, February 1

The Craniofacial Anomalies, Pain Control and Behavioral Research Branch of the National Institute of Dental Research (NIDR) invites research grant applications to study neurobiological and physiological processes controlling coordinated oral movements (such as mastication) and to expand knowledge concerning relationships between oral-motor function and dental procedures or abnormal oral conditions. In addition, the Division of Communication and Neurosensory Diseases of the National Institute on Deafness and Other Communicative Disorders (NIDCD) invites research grant applications to study processes involved in normal and disordered speech production and/or swallowing.

The NIDR and NIDCD seek to accelerate research progress in this area by inviting meritorious applications dealing either with fundamental processes underlying the control of coordinated oral movements, or with clinically relevant aspects of oral-motor function.

BACKGROUND

Considerable scientific progress has been made over the past decade toward delineating neurobiological processes controlling limb movements and locomotion, respiratory movements, and eye movements. In contrast, relatively little attention has been directed toward understanding neurobiological and physiological processes involved in coordinated oral movement, except as they directly affect speech production. Yet oral motor behaviors-- including those involved in mastication, drinking, and suckling-- have important biological significance and remain among the most fundamental behaviors required for survival. Movements of the jaw and the surrounding musculature are integrally involved, in animals and in humans, in tasks as diverse as manipulating objects, attack and defense, communicating through facial expressions, and producing vocalizations.

Oral-motor function is of particular interest to dentistry because oral behaviors affect oral conditions or dental treatments. For example, proper motor control of the jaw and tongue is required for successful use of dental prostheses. Habitual, persistent movements of the jaw and tongue can produce morphological malformations requiring orthodontic treatment. Impaired chewing can limit food intake and nutrition, and can also prompt interventions to improve masticatory efficiency, such as functional appliances, orthodontic treatment, or orthognathic surgery. Chronic hyperactivity (jaw clenching) in masseter muscles appears to be an important causal factor in development of temporomandibular joint (TMJ) pain--a sometimes disabling condition which may afflict as many as one in every ten adults. Bruxism (i.e., tooth-grinding) and dyskinesias involving the jaw and tongue (seen in tardive dyskinesia, senility, stroke, and comas for example) all involve oral-motor behaviors and remain poorly understood. Through an enhanced understanding of how the oral-motor system operates, more effective prevention and management of many of these clinical conditions should become possible.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-DE-01

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 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 dental 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 the etiology, diagnosis, and treatment of various dental and orofacial pain conditions. The ultimate aim of such research is to establish a scientific foundation permitting optimally safe and effective prevention and control of orofacial pain.

In order to be responsive to 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. 13.844, Pain Control and Behavioral Studies. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under the PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. 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 myofascial pain, or orofacial pain syndromes such as tic douloureux, atypical facial pain, 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 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. 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
Craniofacial Anomalies, Pain Control,
and Behavioral Research Branch
Extramural Programs
National Institute of Dental Research
Westwood Building - Room 506
Bethesda, Maryland 20205

Telephone: (301) 496-7807

REQUEST FOR APPLICATIONS FOR OROFACIAL PAIN RESEARCH CENTERS

RFA-85-DE-01

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 these Centers will be to support both basic and clinical research to expand knowledge concerning the etiology, treatment and mechanisms underlying 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 professions 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, when deep carious lesions expose the dental pulp or when infection occurs in oral soft tissues. In such cases, pain serves a protective, adaptive funtion 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. Acute dental pain can also be associated with other dental procedures, despite the fact that various technological innovations in dentistry (such as the high speed drill) have substantially reduced pain-eliciting 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 so highly fearful of dental treatment that they forgo or delay needed care. Only approximately half of the American public seeks regular dental care. While many factors combine to produce this low level of dental utilization, concerns regarding the effectiveness and safety of dental pain management clearly constitute one barrier to 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 negative effects on the individual and the individual's family, including depression, impairments in social or vocational functioning and even in some cases suicide. Direct and indirect costs associated with 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 neuroanatomy, neurochemistry, neurophysiology, pharmacology, psychology, psychophysiology, anesthesiology, neurology, neurosurgery, psychiatry, and pathophysiology. An understanding concerning how pain signals are encoded and transmitted within the nervous system is now emerging. Neurochemicals in the brain and spinal cord have been isolated and found to operate as pain-blocking agents in pain-inhibited 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 human pain have been developed. Nevertheless, many questions remain to be answered both regarding the mechanisms underlying the transmission and modulation of acute and chronic pain, and regarding many aspects of orofacial pain diagnosis and treatment.

Recent years have brought a great surge of clinical interest within dentistry in 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 show a combination of findings which include muscle pain or tenderness, localized pain, limitations in jaw opening, and various types of sounds or "clicking" in the TM joint. Epidemiologic studies suggest that 10-20% of the population show one or more of these findings. Because of controversies over diagnostic criteria, however, the exact prevalence of TMJ disorders remain unclear. It seems likely, however, that TMJ dysfunction and pain constitute important problems for many Americans.

The NIDR recognizes the need for an improved and expanded interdisciplinary orofacial pain research effort. It is both scientifically feasible and necessary to stimulate additional effort in 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 within the Centers is expected to help stimulate the translation of new basic research findings into clinically-relevant hypotheses and improved, innovative approaches to orofacial pain diagnosis or treatment. Such Centers are also expected to provide an environment fostering basic orofacial pain research.

OBJECTIVES

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 a scientific foundation 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 NINCDS.

It is anticipated that each Center will direct some research effort toward studies relevant to chronic orofacial pain. The increasing clinical demands placed upon dentistry for diagnosis and treatment of chronic orofacial pain disorders and the paucity of relevant basic or clinical information provide the context for this requirement. 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 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.

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 myofascial 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, 1986.

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 NIDR plans 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 PHS, 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 NIDR'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.

9. Appropriateness of budget justifications.

Applicants should attempt to develop a unique program which is complementary 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 readvertised.

CENTER CHARACTERISTICS

The Orofacial Pain Research Centers will be identifiable units within a larger institution; eligibility is limited to domestic institutions. The Centers will consist of a cluster of related projects, some of which may be single investigator projects, while others will involve interdisciplinary team approaches.

The Center director will be responsible for scientific and administrative leadership. A committee, consisting of staff members and other expert consultants, who are not members of the Center staff, would be expected to advise the director on the merits of new projects as well as review the progress of existing studies. It is anticipated that the Center will encourage collaboration with researchers from other departments or research units conducting research relevant to orofacial pain. It is also anticipated that the Center 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 staff. Funds will not be used for new construction, major renovations of facilities or costs associated with delivering oral health services other than those directly related to the research program.

Each scientist is expected to obtain independent research support from sources other than the Center grant during the award period, thereby releasing funds to attract other scientist to enter the Center's interdisciplinary research program. 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. 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 NIDR staff and consultants.

METHOD OF APPLICATION

It is suggested that prospective applicants submit a letter of intent (limited to two pages) by April 30, 1985 to Dr. Patricia S. Bryant at the address indicated below. 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 proposed 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 15, 1985.

Applications should be prepared on Form PHS 398, (Rev. 5/82), Application for PHS Grant, which can be obtained from the Division of Research Grants, NIH, or from the institution's application control office. The first (face) page of the application and the outside of the mailing package should be labeled RESPONSE TO RFA-85-DE-1. The instructions accompanying Form 398 should be followed as far as possible but some modifications will be necessary. For example, a new Table of Contents should be prepared giving page numbers for all items in the application. Each component project should be identified by number and investigator. Separate detailed budgets for the first 12 month period for the entire Center, core resources and component projects should be prepared. Consolidated budgets for all years of support should be included for the entire Center and for the separate component projects. Funds may be requested for professional technical, and administrative personnel, core resources, equipment, supplies, minor renovations, consultant services, travel, publication costs, and patient costs directly related to the research. Detailed justification of the budget requests will be required. Under Section 2, Research Plans, describe the goals of the Center and explain how the core resources and each component project will contribute to achieving those goals. Describe the administrative structure and define the responsibilities of the Director, advisory groups, and individual investigators. Describe the relationship of all existing institutional research projects to the Center. Describe the core unit and explain how it will relate to the projects that will utilize its resources. Each component project should be presented as if it were a research project grant application, that is, the instruction pages 15-18 of Form 398 should be followed. A page (Abstract) Form 398 should be completed for the core resources, each component project and the entire application. The receipt date for an original and four copies of the complete application is on or before June 15, 1985. Applications should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

In addition, two copies should be sent under separate cover to:

Patricia S. Bryant, Ph.D.
Health Scientist Administrator
Craniofacial Anomalies, Pain Control and Behavioral
Research Program
National Institute of Dental Research
Westwood Building, Room 506
5333 Westbard Avenue
Bethesda, MD 20205
301 - 496-7807

APPENDIX 6.—FEDERAL REGISTER ANNOUNCEMENT FOR TMJ IMPLANTS

Federal Register / Vol. 57, No. 182 / Friday, September 18, 1992 / Proposed Rules

above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the name of the device and the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 864 be amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 864.5620 is amended by revising paragraph (b) to read as follows:

§ 864.5620 Automated heparin analyzer.

* * * * *

(b) *Classification.* Class II (special controls).

* * * * *

Dated: August 6, 1992.

Micahel R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-22620 Filed 9-17-92; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 872

[Docket No. 92N-0391]

Medical Devices; Classification of Temporomandibular Joint Implants

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify certain temporomandibular joint (TMJ) implants into class III (premarket approval). Based upon the recommendations of FDA's Dental Device Classification Panel, the agency published a final regulation classifying 110 preamendments dental device on August 12, 1987 (52 FR 30662 at 30667). The TMJ prostheses were inadvertently omitted from the dental devices considered for classification by the Dental Device Classification Panel and the agency. Based upon the recommendations of the Dental Products Panel, FDA is now proposing to classify certain TMJ prostheses, including the interarticular disc prosthesis (the interpositional implant), the mandibular condyle prosthesis, and the glenoid fossa prosthesis into class III. After considering public comments on the proposed classification, FDA will publish a final regulation classifying the devices. These actions are being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the amendments) and the Safe Medical Devices Act of 1990 (the SMDA).

DATES: Written comments by November 17, 1992. The Commissioner of Food and Drugs proposes that any final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 12720 Twinbrook Pkwy., Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

I. Background

The act, as amended by the amendments (Pub. L. 94-295) and the SMDA (Pub. L. 101-629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are as follows: Class I, general controls; class II, special controls; and class III, premarket approval.

Devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments) are classified under 21 U.S.C. 360c after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. A device that is first offered in commercial distribution after May 28, 1976, and is substantially equivalent to device classified under this scheme, is also classified into the same class as the device to which it is substantially equivalent.

A device that was not in commercial distribution prior to May 28, 1976, and that is not substantially equivalent to a preamendments device, is classified by statute into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Based upon the recommendations of FDA's Dental Device Classification Panel, the agency published a final regulation classifying 110 preamendments dental devices on August 12, 1987 (52 FR 30662 at 30667). The TMJ implants were inadvertently omitted from the dental devices considered for classification by the Dental Device Classification Panel and the agency. Based upon the recommendations of the Dental Products Panel, following its April 21, 1988, meeting, FDA is now proposing to classify the interarticular disc prosthesis (the interpositional implant), the mandibular condyle prosthesis, and the glenoid fossa prosthesis into class III.

The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application (PMA) by a date to be set in a future regulation under section 515(b) of the act (21 U.S.C. 360e(b)). Each application must include sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective under the conditions of use prescribed, recommended, or suggested in its proposed labeling. PMA's for class III preamendments devices must be submitted within 30 months after their final classification, or 90 days after the agency publishes a final regulation under 21 U.S.C. 360e(b) requiring PMA's for the device, whichever is later.

FDA is also advising interested persons that the agency lacks evidence that the total TMJ prosthesis was legally in commercial distribution in the United States on or before May 28, 1976. FDA invites comment on this issue. If the agency concludes that the total temporomandibular prosthesis is not a preamendments device, it is automatically classified into class III, and would require an approved PMA before it could be marketed. In accordance with section 501(f)(1)(B)(i) of the act (21 U.S.C. 351(f)(1)(B)(i)), the device would therefore be adulterated if its commercial distribution were to continue without such approval in effect. Rather than delay classification of this device, however, in the event FDA concludes that it is, in fact, a preamendments device, the agency is now proposing to classify the device into class III, based upon the recommendations of the Dental Products Panel.

FDA advises manufacturers of the devices being classified that, if the devices are classified into class III, the agency intends to require PMA's to be filed for these devices at the earliest date allowed under the statute. Therefore, PMA's (or approved investigational device exemptions) would be required for these devices on the last day of the 30th month following final classification into class III.

It is the agency's position that the SMDA does not require the agency to obtain new classification recommendations from a panel that had made classification recommendations under the previous standards. In addition, the agency believes that, in light of the reasons for which the Dental Products Panel recommended that the TMJ devices be classified into class III, its recommendation of class III would be the same under the new standards. FDA's decision concerning classification of these devices will be made under the standards set forth in the act as amended by the SMDA.

II. The Dental Products Panel Recommendations

A. Total TMJ Prosthesis

The Dental Products Panel, an FDA advisory committee, made the following recommendation regarding the classification of the total TMJ prosthesis:

1. *Identification:* A total TMJ prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.

2. *Recommended classification:* Class III (premarket approval). The Panel recommended that premarket approval of the total TMJ prosthesis be low priority.

3. *Summary of reasons for recommendation:* The Dental Products Panel recommended that the total TMJ prosthesis be classified into class III because the Panel believed that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. The Dental Products Panel also believed that the device presents a potential unreasonable risk to health and that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Dental Products Panel believed that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish such a standard. Therefore, the device should be subject to premarket approval to ensure that each manufacturer of this device develops sufficient information to provide reasonable assurance that it is safe and effective.

4. *Summary of data on which the recommendation is based:* The Dental Products Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and presentations by Panel members and interested parties (Ref. 1).

5. *Risks to health:* The following risks are associated with the total TMJ prosthesis: (a) Implant loosening or displacement. The screws used to anchor the implant may loosen, resulting in implant loosening or displacement, causing changes in bite, difficulty in chewing, limited joint function and unpredictable wear on implant components (Refs. 2 through 5); (b) Erosion or resorption of the glenoid fossa. Implant breakdown may result in erosion or resorption of the glenoid fossa. The erosion or resorption may result in intense pain, changes in bite, difficulty in chewing and limited joint function (Refs. 2 through 5); (c) Foreign body reaction. Implant deterioration and migration may result in a foreign body reaction characterized by multinucleated giant cells (Refs. 2 through 5); (d) Infection. If the implant cannot be properly sterilized, infection may result; (e) Loss of implant integrity. If the implant materials are unable to withstand mechanical loading, the implant can be torn, worn, perforated, delaminated, fragmented, fatigued, or fractured, resulting in failure of the device to function properly (Refs. 2 through 5); (f) Chronic pain. Degenerative changes within the articular surfaces and components of the temporomandibular joint due to implant breakdown may result in chronic pain (Refs. 2 through 5); (g) Corrosion. If the implant materials are subject to corrosion, toxic elements may migrate to various parts of the body; (h) Changes to the contralateral joint. Unilateral placement of the implant may result in deleterious effects to the contralateral joint; and (i) Malocclusion. Placement of the device may produce an improper occlusal relationship.

FDA agrees with the Dental Products Panel's classification recommendation and is proposing that the total TMJ prosthesis be classified into class III (premarket approval). FDA does not concur with the Dental Products Panel's recommendation that premarket approval of the total TMJ prostheses be low priority. FDA believes that insufficient information exists to identify the proper materials or design for the total TMJ prosthesis. Therefore, FDA is proposing that premarket approval of the total TMJ prosthesis be high priority.

The act requires the agency to classify into class III a device that presents a potential unreasonable risk of illness or injury unless it determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary for this device. FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to ensure the safe and effective use of the device. The agency believes that general controls, either alone or in combination with the special controls applicable to class II devices, are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

B. Glenoid Fossa Prosthesis

The Dental Products Panel did not make a recommendation respecting classification of the glenoid fossa prosthesis, but noted that the implanted glenoid fossa should not be used with a naturally occurring mandibular condyle. FDA has determined, however, that the implanted glenoid fossa has been used to replace a naturally occurring glenoid fossa. Therefore, FDA makes the following proposal regarding the glenoid fossa prosthesis:

1. *Identification:* A glenoid fossa prosthesis is a device that is intended to be implanted in the temporomandibular joint to augment a glenoid fossa and provide an articulation surface for the head of a naturally occurring mandibular condyle.

2. *Recommended classification:* Class III (premarket approval). FDA proposes that premarket approval of the glenoid fossa prosthesis be high priority.

3. *Summary of reasons for proposal:* FDA proposes that the glenoid fossa prosthesis be classified into class III.

The act requires the agency to classify into class III a device that presents a

potential unreasonable risk of illness or injury unless it determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary for this device. FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to ensure the safe and effective use of the device. The agency believes that general controls, either alone or in combination with the special controls applicable to class II devices, are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device should be subject to premarket approval to ensure that each manufacturer of this device develops sufficient information to provide reasonable assurance that it is safe and effective.

4. *Summary of data on which the proposal is based:* FDA is basing its proposal on the Dental Products Panel members' personal knowledge of, and clinical experience with, the device and presentations by Panel members and interested parties (Ref. 1).

5. *Risks to health:* The following risks are associated with the glenoid fossa prosthesis: (a) Implant loosening or displacement. The screws used to anchor the implant may loosen, resulting in implant loosening or displacement causing changes in bite, difficulty in chewing, limited joint function, and unpredictable wear on implant components (Refs. 2 through 5); (b) Degenerative changes to the natural articulating surfaces. Implant breakdown may result in erosion or resorption of the head of the mandibular condyle or the glenoid fossa. The erosion or resorption may result in intense pain, changes in bite, difficulty in chewing, limited joint function, and perforation into the middle cranial fossa (Refs. 2 through 5); (c) Foreign body reaction. Implant deterioration and migration may result in a foreign body reaction characterized by multinucleated giant cells (Refs. 2 through 5); (d) Infection. If the implant cannot be properly sterilized, infection may result; (e) Loss of implant integrity. If the implant materials are unable to withstand mechanical loading, the implant can be torn, worn, perforated, delaminated, fragmented, fatigued, or fractured, resulting in failure of the device to function properly (Refs. 2 through 5); (f) Corrosion. If the implant materials are subject to corrosion, toxic elements may migrate to various parts of the body; (g) Chronic pain. Degenerative changes within the articular surfaces and components of the temporomandibular joint due to implant breakdown may result in chronic pain (Refs. 2 through 5); (h) Changes to the contralateral joint. Unilateral placement of the implant may result in deleterious effects to the contralateral joint; (i) Malocclusion. Placement of the device may produce an improper occlusal relationship.

C. Mandibular Condyle Prosthesis

The Dental Products Panel did not make a recommendation regarding the classification of the mandibular condyle prosthesis, but noted that the implanted mandibular condyle should not be used with a naturally occurring glenoid fossa. FDA has determined, however, that the implanted mandibular condyle has been used to replace a naturally occurring mandibular condyle. Therefore, FDA makes the following proposal regarding the mandibular condyle prosthesis:

1. *Identification:* A mandibular condyle prothesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a naturally occurring glenoid fossa.

2. *Recommended classification:* Class III (premarket approval). FDA proposes that premarket approval of the mandibular condyle joint prosthesis be high priority.

3. *Summary of reasons for proposal:* FDA proposes that the mandibular condyle posthesis be classified into class III.

The act requires the agency to classify into class III a device that presents a potential unreasonable risk of illness or injury unless it determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary for this device. FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to ensure the safe and effective use of the device. The agency believes that general controls, either alone or in combination with the special controls applicable to class II devices, are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device should be subject to premarket approval to ensure that each manufacturer of this device develops sufficient information to provide reasonable assurance that it is safe and effective.

4. *Summary of data on which the proposal is based:* FDA is basing its proposal on the Dental Products Panel members' personal knowledge of, and clinical experience with, the device and presentations by Panel members and interested parties (Ref. 1).

5. *Risks to health:* The following risks are associated with the mandibular condyle prothesis: (a) Implant loosening or displacement. The screws used to anchor the implant may loosen, resulting in implant loosening or displacement causing changes in bite, difficulty in chewing, limited joint function and unpredictable wear on implant components; (b) Degenerative changes to the natural articulating surfaces. Implant breakdown may result in erosion or resorption of the glenoid fossa. The erosion or resorption may result in intense pain, changes in bite, difficulty in chewing and limited joint function; (c) Foreign body reaction. Implant deterioration and migration may result in a foreign body reaction characterized by multinucleated giant cells; (d) Infection. If the implant cannot be properly sterilized, infection may result. (e) Loss of implant integrity. If the implant materials are unable to withstand mechanical loading, the implant can be torn, worn, perforated, delaminated, fragmented, fractured, or fatigued, resulting in failure of the device to function properly; (f) Corrosion. If the implant materials are subject to corrosion, toxic elements may migrate to various parts of the body; (g) Chronic pain. Degenerative changes within the articular surfaces and components of the temporomandibular joint due to implant breakdown may result in chronic pain; (h) Changes to the contralateral joint. Unilateral placement of the implant may result in deleterious effects to the contralateral joint; and (i) Malocclusion. Placement of the device may produce an improper occlusal relationship.

D. Interarticular Disc Prosthesis (Interpositional Implant)

The Dental Products Panel made the following recommendation regarding the classification of the interarticular disc prosthesis (interpositional implant):

1. *Identification:* An interarticular disc prosthesis (interpositional implant) is a device that is intended to be implanted in the human jaw to replace the natural disc and act as an interface between the natural articulating surface of the mandibular condyle and the glenoid fossa.

2. *Recommended classification:* Class III (premarket approval). The Panel recommends that premarket approval of the interarticular disc prothesis (interpositional implant) be high priority.

3. *Summary of reasons for recommendation:* The Dental Products Panel recommends that the interarticular disc prothesis be classified into class III because the Panel believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. The Dental Products Panel also believes that the device presents a potential unreasonable risk to health and that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device. The Dental Products Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish such a standard. Therefore, the device should be subject to premarket approval to ensure that each manufacturer of this device develops sufficient information to provide reasonable assurance that it is safe and effective.

4. *Summary of data on which the recommendation is based:* The Dental Products Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and presentations by Panel members and interested parties (Ref. 1).

5. *Risks to health:* The following risks are associated with the interarticular disk prothesis (interpositional implant): (a) Loss of implant integrity. If the implant materials are unable to withstand mechanical loading, the implant materials can be torn, perforated, delaminated, or fragmented, resulting in failure of the device to function properly (Refs. 4, 6 through 10, and 12 through 15); (b) Implant migration. Torn, worn, perforated, delaminated, and fragmented implant materials are capable of migrating to surrounding tissues, including the lymph nodes (Refs. 4 and 13); (c) Foreign body reaction. Implant deterioration and migration may result in a foreign body reaction characterized by multinucleated giant cells (Refs. 4 and 6 through 15); (d) Degenerative changes within the articular surfaces and components of the joint. Implant breakdown may result in severe resorption of the head of the mandibular condyle and glenoid fossa. The degenerative changes may result in joint noise, changes in bite, difficulty in chewing, severely limited joint function, erosion or perforation into the middle cranial fossa, crepitus, avascular necrosis and fibrous ankylosis (Refs. 4 and 6 through 14); (e) Implant displacement. Displacement of the implant may result in changes in bite, difficulty in chewing and limited joint function (Refs. 6 through 9, 11, and 12); (f) Infection. If the implant cannot be properly sterilized, infection may result.

FDA agrees with the Dental Products Panel's recommendation and is proposing that the interarticular disc prosthesis (interpositional implant) be classified into class III (premarket approval).

The act requires the agency to classify into class III a device that presents a potential unreasonable risk of illness or injury unless it determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary for this device. FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to ensure the safe and effective use of the device. The agency believes that general controls, either alone or in combination with the special controls applicable to class II devices, are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

The agency notes that, in addition to the risks to health identified by the Dental Products Panel, the following risks to health also are associated with the device: (g) Chronic pain. Degenerative changes within the articular surfaces and components of the joint due to implant breakdown may result in chronic pain (Refs. 6 through 8 and 11); (h) Calcification. Implant breakdown may result in the formation of scar tissue, leading to calcification (Refs. 10 and 15); (i) Granulomatous reaction. Implant particulate may produce a mass or nodule of chronically inflamed tissue with granulation (Refs. 12 through 15); (j) Leaching of elements. Toxic elements may be leached from the implant materials and migrate to various parts of the body.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Transcripts of the Dental Products Panel meeting, April 21, 1988.

2. Fontenot, M.G. and J.N. Kent, "In-vitro and In-Vivo Wear Performance of TMJ Implants," abstract, International Association of Dental Research, 1991.

3. Kent, J.N. and M.S. Block, "Comparison of FEP and UPE Glenoid Fossa Prosthesis," abstract, International Association of Dental Research, 1991.

4. "Clinical Information on the Vitek TMJ Interpositional (IPI) Implant and the Vitek-Kent (VK) and Vitek-Kent 1 (VK-1) TMJ Implants," and in "Vitek Patient Notification Program," an FDA publication, 1991.

5. Kent, J.N., "VK Partial and Total Joint Reconstruction," Current Concepts of TMJ Total Joint Replacement, University of Medicine and Dentistry of New Jersey, pp. 1-8, March 1992.

6. Primely, D., Jr., "Histological and Radiological Evaluation of the Proplast-Teflon interpositional Implant in Temporomandibular Joint Reconstruction Following Meniscectomy," thesis, Masters Degree in Oral Maxillofacial Surgery, University of Iowa, May 1987.

7. Westhund, K.J., "An Evaluation Using Computerized Tomography of Clinically Asymptomatic Patients Following Meniscectomy and Temporomandibular Joint Reconstruction Using the Proplast-Teflon Interpositional Implant," thesis, Masters Degree in Oral and Maxillofacial Surgery, University of Iowa, May 1989.

8. Wagner, J.D. and E.L. Mosby, "Assessment of Proplast-Teflon Disc Replacements," Journal of Oral and Maxillofacial Surgery, 48:1140-1144, 1990.

9. Florine, B.L. et al., "Tomographic Evaluation of Temporomandibular Joints Following Discoplasty or Placement of Polytetrafluoroethylene Implants," Journal of Oral and Maxillofacial Surgery, 46:183-188, 1988.

10. Heffez, L. et al., "CT Evaluation of TMJ Disc Replacement with a Propiast Teflon Laminate," Journal of Oral and Maxillofacial Surgery, 45:857-865, 1987.

11. Ryan, D.E., "Alloplastic Impants in the Temporomandibular Joint," Oral and Maxillofacial Surgery Clinics of North America, 1:427, 1989.

12. Valentine, J.D., "Light and Electron Microscopic Evaluation of Proplast II TMJ Disc Implants," Journal of Oral and Maxillofacial Surgery, 47:880-896, 1989.

13. Logrotteria, L. et. al., "Patient with Lymphadenopathy Following Temporomandibular Joint Arthroplasty with Proplast," The Hour of Craniomandibular Practice, vol. 4, No. 2:173-178, 1986.

14. Berardoci, J.P. et al., "Perforation into Middle Cranial Fossa as a Sequel to Use of a Proplast-Teflon Implant for Temporomandibular Joint Reconstruction," Journal of Oral and Maxillofacial Surgery, 46:495-498, 1988.

15. Berman, D.N. and S.L. Pronstein, "Osteo Phytic Reaction to a Polytetrafluoroethylene Temporomandibular Joint Implant," Oral Surgery, Oral Medicine, Oral Pathology (continues the Oral Surgery Section of the American Journal of Orthodontics and Oral Surgery), 69:20-23, 1990.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

The agency has examined the economic impact of this proposed rule and has determined that it does not require a regulatory impact analysis, as specified in Executive Order 12291, because the proposed rule would not impose any new requirements. Therefore, the agency concludes that the proposed rule is not a major rule as defined in Executive Order 12291. The proposed rule does not impose any paperwork requirements.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR Part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New §§ 872.3940, 872.3950, 872.3960, and 872.3970 are added to subpart D to read as follows:

§ 872.3940 Total temporomandibular joint prosthesis.

(a) *Identification.* A total temporomandibular joint prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* (Insert date 90 days after date of publication of the final rule in the **Federal Register**.)

§ 872.3960 Glenoid fossa prosthesis.

(a) *Identification.* A glenoid fossa prosthesis is a device that is intended to be implanted in the temporomandibular joint to augment a glenoid fossa and to provide an articulation surface for the head of a naturally occurring mandibular condyle.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* The effective date of the requirement for premarket approval has not been established. See § 872.3.

§ 872.3960 Mandibular condyle prosthesis.

(a) *Identification.* A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a naturally occurring glenoid fossa.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* The effective date of the requirement for premarket approval has not been established. See § 872.3.

§ 872.3970 Interarticular disc prosthesis (interpositional implant).

(a) *Identification.* An interarticular disc prosthesis (interpositional implant) is a device that is intended to be implanted in the human jaw to replace the natural disc and act as an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* The effective date of the requirement for premarket approval has not been established. See § 872.3.

Dated: August 9, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-22821 Filed 9-17-92; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 89

[CGD 91-050]

RIN 2115-AE09

Waters on Which Certain Inland Navigation Rules Apply

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the Inland Navigation Rules by defining certain portions of the Gulf Intracoastal-Coastal Waterway as waters "specified by the Secretary". This will allow towboat operators on designated portions of the Gulf Intracoastal Waterway to use a rule designed for certain rivers and narrow waterways, exempting them from using white masthead lights, thus improving navigation safety.

DATES: Comments must be received on or before November 17, 1992.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council (G-LRA/3406) (CGD 91-050), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001, or may be delivered to room 3406 at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477.

The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room 3406, U.S. Coast Guard Headquarters.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Epstein, Navigation Rules and Information Branch, Office of Navigation Safety and Waterway Services, (202) 267-0352 or (202) 267-0357.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their name and address, identify this rulemaking (CGD 91-050) and the specific section of this proposal to which each comment applies, and give a reason for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Marine Safety Council at the address under **"ADDRESSES."** If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Drafting Information

The principal persons involved in drafting this document are Jonathan Epstein, Project Manager, Office of Navigation Safety and Waterway Services, and Donald W. Faleris, Project Counsel, Office of the Chief Counsel.

Background and Purpose

The Inland Navigation Rules Act of 1980 (Pub. L. 96-591, 33 U.S.C. 2001 *et seq.*) consolidated numerous regional navigation rule systems into one document. These rules apply to all vessels operating on the inland waters of the United States, and to vessels of the United States on the Canadian waters of the Great Lakes to the extent

APPENDIX 7.—SUMMARY OF NIH MEETING ON JAW IMPLANTS

OFFICE OF RESEARCH ON WOMEN'S HEALTH
National Institutes of 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 Cowley and Jennifer Hutchinson of the Temporomandibular Joint Association (TMJA) and representatives of the Food and Drug Administration (FDA) and National Institutes of Health (NIH) to discuss issues related to temporomandibular disorders (TMDs) 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 TMJA have become increasingly aware of patient concerns related to musculoskeletal, immunological, neurological, dermatological, and psychological symptoms. A greater number of patients are reporting constant and severe orofacial pain, fibroid tumors, visual and auditory impairment, dyslexia, rashes, 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 followup of TMD implant patients occurs which contributes to inaccurate assumptions regarding post-implant status. According to TMJA 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

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

- NIDR 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 procedures that permit pooling of data, new treatment protocols and modalities can be identified.

  The results of the meta-analysis study will serve as a tool in planning a 1993 World Workshop on Chronic Orofacial Pain and TMDs 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 TMDs. Basic research on joint and muscular pain, diagnostics, and treatment modalities will be highlighted. Studies involving biomaterials utilized in implants 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 silicone, 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 silicone, 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: Registries 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 NCHS National Health Interview Survey on chronic pain, or other surveys of the National Center for Health Statistics, as mechanisms 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.	ORWH
Judith H. LaRosa, Ph.D.	ORWH
Patricia Bryant, Ph.D.	NIDR
Terrie Cowley, President	TMJ Association
Stephen L. Gordon, Ph.D.	NIAMS
Jennifer Hutchinson, Vice President	TMJ Association
Elizabeth D. Jacobson, Ph.D.	FDA/CDRH
Lireka P. Joseph, Dr.P.H.	FDA/DCRH
Dushanka V. Kleinman, D.D.S., M.Sc.D.	NIDR
Ruth Merkatz, Ph.D.	OD/FDA
Chuck Sabatos	OD/DLA
Barry E. Sands	FDA/CDRH
Tracy Summers	FDA/CDRH
Susana A. Sztein, M.D.	NIAID
Joan Wilentz	NIDR
Susan Wise	NIDR

APPENDIX 8.—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, halcion, 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 overtreated in the past. The American Dental Association states that 80 percent of

TMD patients get better with or without treatment. However, the pain of TMD 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. Some

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 HP. 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 for consumers in September 1991).

VITEK IMPLANTS

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

After the 1976 FDA device law, some types of Vitek 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 <u>each type</u> of jaw implant that they were selling.

7

During the 1980's, Vitek implants became more popular than the previously used silicone TMJ implants, because dental journal articles indicated that the Vitek implants were safer and more effective during the first 2 years after surgery. In addition, Vitek 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 Vitek implants. However, a February 14, 1984, letter from Dr. Kent to the president of Vitek, Dr. Charles Homsy, shows that Dr. Kent was concerned about the safety of Vitek 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 Vitek 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 Vitek stock at the same time he was publishing articles praising Vitek TMJ implants.

According to a 1988 FDA memorandum, serious safety problems regarding Vitek implants first came to the FDA's attention in an Medical Device Report (MDR) in April 1986, but "the report

8

contained no details and was dismissed." The problems caused by Vitek 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 Vitek 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 Vitek for the last 3 years, and the FDA determined that Vitek had not reported those problems to the FDA. In November 1988, the FDA sent a "Notice of Adverse Findings" to Vitek, 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 Vitek'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.

9

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.

10

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 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 26,000 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 Vitek 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 Vitek and OSMI, Charles Homsy, 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 Homsy or the company. Dr. Homsy 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 devices 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. Techmedica 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.

Techmedica 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 Techmedica'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 TMD 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.

TMD 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.

General Concerns

Currently, there are no TMJ implants that are proven to be safe for long-term use. The Vitek 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 Techmedica implants apparently have reasonable track records for the last 2 years, Vitek and Silastic implants also were considered safe for the first 2 years of use. The problems tended to arise after 3-5 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,[1] 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

[1] Yih, W.Y. and Merrill, R.G. (1989). Pathology of alloplastic interpositional implants in the temporomandibular joint. Oral and Maxillofacial Surgery Clinics of North America, vol. 1, No. 2, pp. 415-426. Dr. Ralph Merrill is a well respected oral and maxillofacial surgeon in this country.

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 1992 hearing, Rep. 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.

FDA. Shortly before the hearing, the FDA sent warning letters to all the manufacturers of TMJ 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 FDA 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 can not sell their pre-sterilized device until they have a 510(k) approved by FDA.

On September 18, 1992, 3 months after the Subcommittee hearing, the FDA 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 FDA 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 FDA's Center for Devices and Radiological Health, and other FDA 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, FDA 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 FDA 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 FDA. At my December 1992 briefing, the FDA 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 FDA 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 FDA 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 TMD 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

with the surgeons directly has not reached a sufficient number of patients.

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