U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

"Getting More Information"

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)
1350 Piccard Drive
Rockville, MD 20850

FAX: 240-276-3356

Phone: 240-276-3357

Email: mailto:phann@cdrh.fda.gov

PUBLIC HEALTH ADVISORY
ON
VITEK PROPLAST TEMPOROMANDIBULAR JOINT IMPLANTS

September 1991

Dear Doctor:

This letter contains important health information for your patients who have the temporomandibular joint (TMJ) implants manufactured by Vitek, Inc., Houston, Texas. These include the IPI, VK (glenoid fossa), and VK-I (condylar head, glenoid fossa). For detailed explanation see the clinical information enclosure. The Food and Drug Administration (FDA) is sending you this information in response to your recent call to Vitek TMJ Patient Notification toll-free 800 telephone number.

As you may be aware, severe problems have been experienced by patients with the TMJ implants manufactured by Vitek. A high percentage of these implants have failed because the materials fragment. Because these failures may occur without symptoms, FDA believes that all persons with the Vitek TMJ implants should be notified about the risks associated with these implants and receive regular, appropriate medical examination.

Here is what we are asking you to do at this time:

- If you have **not** had patients with the Vitek TMJ/IPI, VK, VK-I, or VK-II:

  Respond on the enclosed form within 30 days of receipt of this letter informing us that you have not had such patients. Receipt of the form will obviate further follow up with you.

- If you **have** had patients with the Vitek TMJ/IPI, VK, VK-I, VK-II:

  1. **Discuss the risk of device failure and the alternative therapies with your patients.** The enclosures may help in your discussions.

  2. **Conduct clinical followup of your Vitek TMJ patients.** Screening radiography (limited skull radiography and tomograms) may be needed to detect the presence of metal associated with some of the implants. For non-metallic implants, MRI is the most efficient method to detect signs of the foreign body giant-cell tumor response, implant deterioration, and destruction in bone and/or soft tissue. A CT scan may be used under special circumstances or when an MRI is contraindicated. The patient should be re-examined annually for as long as the implant remains in place.

     If the evaluation demonstrates progressive bone degeneration, implant disruption or loss of integrity, or if the patient demonstrates pain or occlusal changes for a period of six months or longer, the implant should be removed.

  3. **Encourage your patients with the implant to enroll in the Medic Alert Foundation International Implant Registry.** Medic Alert is a nonprofit organization that has set up this registry at FDA's request. It will allow the FDA to easily contact patients and their surgeons or dentists with any new information about this implant as it becomes available. Patients will be requested to pay a one-time enrollment fee of $20.00. An additional $10.00 renewal fee will be charged annually on the anniversary date of patient enrollment. This fee will cover the cost of routinely updating the information in the registry file. Information about the registry and how to enroll is enclosed in the sample patient packet. All information about registry members is kept confidential. **For further information about the registry, you can call Medic Alert at 1-800-554-5297, 7 days a week, 24 hours a day.**

  4. **Respond on the enclosed form within 30 days of receipt of this letter informing FDA, through Medic Alert, of what actions you have taken to notify your patients.**

5. **Complete the enclosed form** with information for each of the Vitek/OSMI implant patients you have or may have had.

You may decide that for medical reasons some patients should not be provided with this information. You should nonetheless be prepared for questions from these patients since anyone is free to call the toll-free number and obtain the information.

Whether or not you have patients with Vitek TMJ implants, we request that you share this information with other health care professionals, including primary care physicians or dentists who may now be treating these patients.

I would also like to alert you to the problems associated with the VK-II implant. This device was marketed initially by Vitek in 1988 and subsequently by Oral Surgery Marketing, Inc., (OSMI), the successor corporation of Vitek. The VK-II has not been cleared by the FDA for commercial distribution. Safety and effectiveness have not been demonstrated for this device. Because of the history of problems associated with the other implants containing Proplast, I am advising you to closely monitor symptomatic or asymptomatic patients with this implant. Despite past safety alerts and recalls, the FDA is aware that a number of the Vitek TMJ implants are still available for implantation. You should not implant any of these devices.

The FDA has some concerns about other load-bearing devices composed of Proplast, e.g., material used for alveolar ridge augmentation, the ulnar ridge head, and the trapezium. If you encounter problems related to this material used in these circumstances, I encourage you to report them to the FDA's Problem Reporting Program by calling the toll-free number 1-800-638-6725. The data provided in these reports allow the FDA to identify problems and take needed corrective actions.

If you wish to contact the Food and Drug Administration for additional clinical information about the TMJ implants, call Dr. Greg Singleton at 301-427-1180 between 8 a.m. and 4:30 p.m. Eastern Time, Monday through Friday.

Sincerely yours,

James S. Benson
Director
Center for Devices and
Radiological Health

Enclosures

Clinical Information
on the Vitek TMJ Interpositional (IPI) Implant
and the Vitek-Kent (VK) and Vitek-Kent I (VK-I)
TMJ Implants

The Interpositional Implant

The Vitek Interpositional Implant (IPI) has been demonstrated to significantly wear, migrate, tear, fragment, delaminate, and perforate. When this type of failure occurs, a significant amount of wear particles are produced. These particles have been reported to migrate to regional lymph nodes, as well as the adjacent tissue. In the immediate anatomical area of the TMJ, the particulate, including the failed prosthesis itself, initiates a foreign body response that cause progressive bone degeneration (including the glenoid fossa and the mandibular condyle). This degeneration can result in permanent hearing damage, chronic pain, permanent loss of functional masticatory function, and reduced range of motion of the mandible. An additional report has described bone erosion into the cranial space resulting in an open communication to the brain.

Due to the uncertainty of the actual number of implants placed in the TMJ, failure rates on the total patient population cannot be calculated. However, retrospective studies (1-7) have been conducted that provide the respective failure rates and failure modes experienced. In addition, numerous case studies have been published that demonstrate individual experiences with the IPI.

The Department of Oral and Maxillofacial Surgery at the University of Iowa retrospectively evaluated patients who had the IPI implanted at its medical center from 1983-86. The study demonstrated that of the 51 IPI's available for followup examination, 73% had been removed due to fragmentation (the sheeting material separated into small particles due to wear), perforation (the sheeting material developed holes), and/or foreign body reaction that resulted in progressive bone degeneration.

In addition, 19 implants in 15 patients were initially determined to be successful, that is, there was no clinical evidence of temporomandibular disease or symptoms. However, radiographic analysis demonstrated that 65% of these implants had been displaced, 50% had fractured or been perforated, and that significant progressive bone degeneration was occurring around all implants. The studies demonstrate that patients with symptoms and, more importantly, patients without symptoms are extremely likely to experience failure of the IPI.

September 1991

Route to:
OR
Medical Records
Purchasing
Risk Manager

PUBLIC HEALTH ADVISORY
FROM
THE U.S. FOOD AND DRUG ADMINISTRATION
ON
VITEK PROPLAST TEMPOROMANDIBULAR JOINT IMPLANTS

Dear Health Professional:

In December 1990, the Food and Drug Administration (FDA) issued a special Safety Alert letter to oral and maxillofacial surgeons (copy enclosed), urging that they contact patients implanted with Vitek temporomandibular joint interpositional implants (TMJ/IPI). FDA is now expanding this public health advisory to include the VK and VK-I implants which are also used in the TMJ joint. These implants may pose a significant health risk, and we ask that patients be notified and then examined to monitor the condition of the implant.

Despite FDA's Safety Alert, investigation has shown that many patients were not notified about problems with the TMJ/IPI. **We are again requesting that you contact these patients if you have not already done so.** In addition, we are asking you to contact patients with the VK, VK-I and VK-II implants.

Should further investigation show that patients have not been notified, we may invoke Section 518 of the Food, Drug and Cosmetic Act. **Under this provision, health professionals may be required to notify patients.**

Here is what we are asking you to do at this time:

- If you have **not** had patients with the Vitek TMJ/IPI, VK, VK-I, or VK-II:

  Respond on the enclosed form within 30 days of receipt of this letter informing us that you have not had such patients in your practice or institution.

- If you **have** had patients with the Vitek TMJ/IPI, VK, VK-I or VK-II:

  1. **Conduct clinical followup of your Vitek TMJ patients.** Screening radiography (limited skull radiography and tomograms) may be needed to detect the presence of metal associated with some of the implants. For nonmetallic

An inability to open the mouth fully, joint clicking, and pain immediate to the TMJ are common symptoms associated with a failed IPI. However, it is extremely important to recognize that an asymptomatic patient may still be undergoing progressive bone degeneration.

The Vitek Interpositional Implant (IPI) was distributed between 1973 and 1988. The actual number of IPI's implanted has not been confirmed; however, at least 26,000 were distributed between 1983 and 1988 in the United States.

The Vitek-Kent and Vitek-Kent I

The Vitek-Kent I (VK-I) has been demonstrated to wear significantly, fragment, and perforate. When this type of failure occurs, a significant amount of wear particles are produced. This failure mode is very similar to that of the IPI failure mode. Many of the same complications that lead to failure in the IPI have also been observed. In the immediate anatomical area of the TMJ, the particulate, including the failed prosthesis itself, initiates a foreign body response that causes progressive bone degeneration. These particles, when produced in IPI failure, have been reported to migrate to regional lymph nodes, as well as the adjacent tissue. This degeneration can result in chronic pain, permanent loss of functional masticatory function, and reduced range of motion of the mandible.

Due to the ever changing design of the VK TMJ implant system and the lack of FDA clearance for the implant (thus not having reliable sources of when each design was marketed), it is impossible to determine the actual number of implants that were marketed. Therefore, failure rates on the total patient population cannot be calculated. However, a retrospective study (9,10) has been conducted that provides the failure rates and failure modes experienced at an individual clinical site. In addition, reports have been provided to the FDA that convey individual experiences with the Vitek-Kent (VK) and VK-I.

The Department of Oral and Maxillofacial Surgery at Louisiana State University (LSU) Medical School has reported its experience with the VK-I (10). The retrospective study evaluated patients who had the VK-I used for both partial and total TMJ reconstruction. These implants were placed between 1982-1986. The study demonstrated that of 39 implants used in partial TMJ reconstruction 16 (41.03%) had failed. The resulting cumulative success rate was 42.4%. In total TMJ reconstruction, 29 of 85 implants failed (34.12%). The resulting cumulative success rate was 57.95%. In this study, similar physiological and anatomical effects were observed (e.g., pain, progressive bone resorption, etc.). An inability to open the mouth fully, joint clicking, and pain immediate to the TMJ are common symptoms associated with a failed VK-I. Although, the LSU study did not look at asymptomatic patients in particular, the lessons learned with the IPI warrant monitoring all patients with the VK or VK-I.

The history of the development of VK and VK-I glenoid fossa and condylar implants is not well known. The first indication of clinical use of the V-K glenoid fossa) is in 1981 (8). This device was composed of Proplast I (interfacing the glenoid fossa), a middle layer of Teflon/FEP embedded with a polyamid or metallic mesh, and an articulating surface of Teflon reinforced with graphite. This device was used alone or with condylar prosthesis until 1982. From 1982 through 1984, numerous changes were made to the implant resulting in a bilaminate structure for the glenoid fossa prosthesis. The resulting material composition of this implant is Proplast II (interfacing the glenoid fossa) and a Teflon/FEP (articulating with a condylar prosthesis) articulating surface with a polyamid mesh embedded in the Teflon/FEP. Later in the development of additional TMJ implants (e.g., VK-II), it appears that the VK was renamed VK-I. Oral Surgery Marketing Inc. (OSMI) is the manufacturer that currently markets the V-II (formerly known as the VK-II) implant. The VK, VK-I and VK-II (V-II) have not been cleared for marketing in the United States or for exportation to foreign countries.

Recommendations

On the basis of the clinical information described in the LSU and Iowa studies and the experience derived from the IPI failures, the following actions are recommended:

- All patients (symptomatic or asymptomatic) should undergo routine radiographic evaluation. This evaluation must include CT or MRI scans to evaluate the implant, as well as the adjacent anatomical structures.

- If progressive bone degeneration or implant disruption is demonstrated in these evaluations, the IPI, VK, or VK-I should be removed.

- If pain or occlusal changes persists six months or longer, the IPI, VK or VK-I should be removed.

- If bone degeneration is not revealed, the patient should still undergo routine (annual) radiographic evaluations (CT or MRI) for the life of the IPI, and radiographic evaluations for the life of the VK or VK-I implants.

- Further implantation of the IPI, VK, VK-I, and VK-II should not occur.

Please contact Barry E. Sands at 301-427-1230 for further information pertaining to this clinical risk paper.

Sample Consultation Questions and Answers

What should I do if I have patients that have been implanted with the Vitek TMJ implants?

You should make every effort to notify these patients. They should have a clinical MRI or CT evaluation as soon as possible if that has not been done within the last six months.

What is the problem with the Vitek TMJ Implants?

The Vitek implants are composed of Proplast and other materials. These materials have been shown to either fragment or fail to function because of masticatory forces.

What types of clinical symptoms should I expect to find in these patients?

The predominant clinical symptoms are:

- pain often associated with a limited range of jaw motion;
- malocclusions, such as dysfunctional occlusal relationship;
- swelling and changes in joint noise;
- nausea;
- vertigo, tinnitus, hearing loss; and
- increased sensitivity in the head, neck and shoulder.

In some cases there are no symptoms while the implant is failing.

What are the anatomical changes associated with the TMJ Implants?

Bone degeneration or resorption of the mandibular condyle occurs with the formation of foreign body giant cell tumor response as a result of the fragmentation of the implant. Some bone degeneration has also been observed in the glenoid fossa of these patients.

Why is a normal radiograph often inadequate to evaluate the anatomical problems associated with the TMJ implants?

The superimposition of bone over giant cell granulomatous material necessitates the use of magnetic resonance imaging (MRI) or Computerized Tomography (CT) scans in order to visualize the soft tissue changes.

Screening radiography (limited skull radiography and tomograms) may be needed to detect the presence of metal associated with some of the implants. For nonmetallic implants, MRI is the most efficient method to detect signs of foreign body giant cell tumor response, implant deterioration, and/or destruction in bone and/or soft tissue. A CT scan may be used under special circumstances or when MRI is contraindicated.

What is the best course of action To take for patients exhibiting pain, bone degeneration or resorption or loss of mobility?

It is strongly recommended that all of these patients have the TMJ implants removed as soon as possible. Currently asymptomatic patients may have bone degeneration or resorption and should be considered as likely candidates for explantation.

If implant is removed, what is an appropriate alternative procedure?

Alternatives are non-Proplast coated implants, autologous bone graft or management without replacement.

Should I remove the implant?

Not necessarily, but the patient should be followed. However, if there is evidence that the implant is fragmenting, the implant should be removed if possible, even if the patient is asymptomatic. If the patient is experiencing pain or a change in bite, this may be a sign that the implant is fragmenting and explantation should be strongly considered.

What is the VK-II?

The VK-II is identical to the VK-I, with the following exceptions: the material interfacing with the fossa is Proplast hydroxylapatite (Proplast-HA), and the material on the articulating side is ultra high molecular weight polyethylene. In other devices containing Proplast material, the incidence of problems begins to appear within 24 to 36 months.

What should I do with any implants that I have in inventory?

The manufacturer is not accepting any implants nor refunding any monies for implants as they are bankrupt. You may either destroy or send the implant(s) to the FDA; however, there is no reimbursement by the FDA for implants.

Address to send implants:

Greg Singleton, D.D.S.
Food and Drug Administration (HFZ-470)
1390 Piccard Drive
Rockville, MD 20850

Why should I encourage patients to enroll in the Medic Alert International Implant Registry (IIR)?

The benefits of having patients join the registry are:

- to receive the latest medical information about their implant as soon as it becomes available;
- to receive future information about symptoms that may persist and their treatment after the implant has been removed;
- to inform you and your patient of news about alternative devices that may become available;

- to ensure that your patient receives continuing information if he/she can no longer continue under your care; and,
- to assist the FDA in locating you and your patient should we need to contact you in the future. Neither the FDA nor the manufacturer know the number of implants or the identity of the patients.

References:

1. Primely, Donald, Jr., "Histological and Radiographic Evaluation of the Proplast-Teflon Interpositional Implant in Temporomandibular Joint Reconstruction Following Meniscectomy," Thesis, Masters Degree in Oral Maxillofacial Surgery, May 1987. University of Iowa.

2. Westlund, Kurt 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, May 1989. University of Iowa.

3. Wagner J.D., and Mosby, E.L., "Assessment of Proplast-Telfon Disc Replacements," J. Oral Max. Surg., 48:1140-1144 (1990).

4. Florine, B.L., et. al., "Tomographic Evaluation of Temporomandibular Joints Following Discoplasty or Placement of Polytetrafluoroethylene Implants. "J. Oral Max. Surg., 48:183-188 (1988).

5. Heffez, L., et.al., "CT Evaluation of TMJ Disc Replacement with a Proplast Telfon Laminate," J. Oral Max. Surg., 45:657-665 (1987).

6. Ryan, D.E., "Alloplastic Implants in the Temporomandibular Joint," Oral and Maxillofacial Clin N Am, 1:427 (1989).

7. Valentine, J.D., "Light and Electron Microscopic Evaluation of Proplast II TMJ Disc Implants," J. Oral Max. Surg., 47:689-696 (1989).

8. Kent, J.N., et.al., "Experience with the Polymer Glenoid Fossa Prosthesis for Partial or Total Temporomandibular Joint Reconstruction," J Oral Max. Surg, 44:520-533, (1986).

9. Fontenot, M.G., and Kent, J.N., "In-Vitro and In-Vivo Wear Performance of TMJ Implants," Abstract, International Association of Dental Research, 1991.

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

VITEK/OSMI PATIENT NOTIFICATION CONFIRMATION

Medic Alert Foundation is conducting the Vitek/OSMI (Oral Surgery Marketing, Inc.) implant Registry enrollment program at the request of the Food and Drug Administration (FDA).

In order to monitor this effort, we request that you provide the information contained on this form. Medic Alert maintains strict confidentiality of patient and health care provider data. All information is sent directly to Medic Alert, not to the FDA.

If you have questions about the Registry, Medic Alert can be reached at 1-800-554-5297. FDA will be informing patients about the program through a media campaign that will begin in September.

Thank you for your cooperation in this important public health program.

Please respond on this form within 30 days of receipt.

(If additional space is needed, please copy this form.)

1. Name of Doctor: _____
   Address: _____
   _____
   _____
   Office Phone No._(_____)_____

2. Number of patients with Vitek/OSMI implants: None_____ OR Number_____

3. Please provide the following information for each of the Vitek/OSMI implant patients:

Name:_____	Name:_____
Address:_____ _____ _____	Address:_____ _____ _____
Telephone #: (_____)_____	Telephone # (_____)_____
Social Security No._____	Social Security No._____
Circle Type of Implant: IPI VK VK-I(V-I) VK-II(V-II)	Circle Type of Implant: IPI VK VK-I(V-I) VK-II(V-II)
Hospital (where implanted):_____ _____ _____	Hospital (where implanted):_____ _____ _____
Date of Implant: _____/_____/_____	Date of Implant: _____/_____/_____
Patient Notified: Yes No	Patient Notified: Yes No