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In This Issue

TMJ Implants: Lessons for All of Us

Temporomandibular joint disorders (TMD) are conditions that affect as many as 10 million people in the U.S. Women outnumber men sufferers by as much as five or six to one, and most sufferers are less than 40 years old. People with pain in their temporomandibular joints can suffer excruciating headaches and dizziness which limit their work, social activities and enjoyment of day-to-day living. A bad hip, knee, or elbow may result restricted mobility; a bad jaw or painful temporomandibular joints may result in years of excruciating pain, soft diet, altered physical appearance as well as swallowing or even talking difficulties. Patients with long-term debilitating TMJ pain endure bouts of depression, despair, and hopelessness as do many terminally-ill patients.

TMJ disorders can be caused by trauma, but for many patients, there is no known cause. Because so little is known about what causes this disease, there are many providers who offer treatments for TMJ pain. These providers include oral and maxillofacial surgeons, plastic, ENT, and craniofacial surgeons, neurologists, dentists, psychologists, physical therapists, massage therapists, and chiropractors. Patients, desperate with pain, are referred to many of these specialties all with limited success and often end up worse off than when they sought treatment in the first place. According to the Academy of General Dentistry, there are 49 different treatment modalities for TMJ pain. At one extreme is rest and hot and cold packs, and at the other is surgical intervention including total joint implants.

There are two types of surgical procedures involving implants: replacement of the disc, which rides above the mandibular condyle, and replacement of the condyle and/or glenoid fossa. Disc replacements were supplied in the 1980s by Vitek of Houston, Texas, and Dow Corning of Midland, Michigan. Currently only TMJ Implants, Inc. of Golden, Colorado, and the TMJ Research Foundation of La Crescenta, California manufacture joint implants, although Vitek, Osteomed, Techmedica, and others have in the past. Other surgical procedures involve the transplantation of ear cartilage, rib graft, muscle, or fascia into the joint. Surgical repair of the temporomandibular joint reached its peak in the United States in the mid-1980s, according to data supplied by HCIA, a Baltimore-based healthcare information company. In 1985, over 17,000 temporomandibular joint arthroplasty procedures were performed; between 1973 and 1993, over 170,000 procedures were performed. What is not known is how many of which type of procedure were

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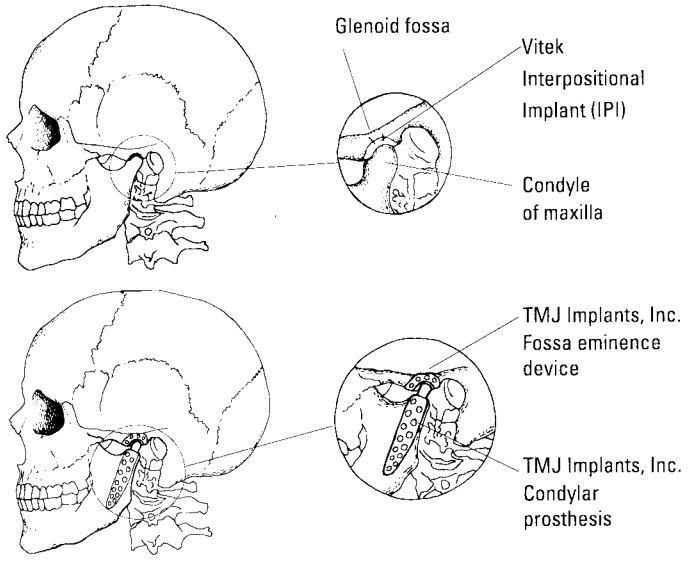
TMJ Implants Manufactured by Vitek and TMJ Implants, Inc.



Organizations of TMJ Practitioners

American Academy of Head, Neck and Facial Pain
International College of Cranio-mandibular Orthopedics (ICCMO)
American Academy of Pain Management
American Association for Functional Orthodontics
American Academy of Gnathologic Orthopedics
American Alliance of TMJ Practitioners
American Academy of Orofacial Pain
Includes the following affiliates:
- European Academy of Craniomandibular Disorders
- Asian Academy of Craniomandibular Disorders
- Australian Academy of Craniomandibular Disorders
- Latin American Academy of Craniomandibular Disorders

American Equilibration Society
Association of University TMD and Orofacial Pain Programs
Neuroscience Group of the International Association of Dental Research
Other organizations whose focus is not just TMJ:
American Academy of Oral and Maxillofacial Surgeons (AAOMS)
American College of Prosthodontics
Academy of Denture Prosthetics
American Pain Society
International Association for the Study of Pain

Editorial

Stan Mendenhall
Editor
Orthopedic Network News

Why TMJ?

Most of you familiar with this publication will wonder why we are writing about TMJ (temporomandibular joints) in an orthopedic newsletter. I was approached last fall by Terrie Cowley, president of the TMJ Association to help them. I was vaguely familiar with TMJ, having had a bite splint recommended by my dentist and having read the Wall Street Journal article about the Vitek implants. Terrie had Dow Corning Silastic® sheeting placed in her temporomandibular joints in 1982. This was recommended to her by her dentist because he didn't want to do dental work on her "loose jaw." Prior to her surgery, she said that she had occasional headaches which she managed with aspirin. She says that immediately after the surgery, she asked the oral surgeon whether "they had dropped me on the floor during the procedure," since she had pain from that moment on. Since 1982, she has not been without pain. After visiting numerous dentists, surgeons, and other specialists who all insisted that there was no reason for her pain, that all other patients were doing just fine, she began a support group for patients who suffer from TMJ.

Now with about 5,000 members, her constituent support group has been instrumental in Congressional hearings on TMJ implants, having the National Institutes of Health allocate funds for TMJ research, and birddogging everyone vaguely involved in the field. She spends most of the day on the phone talking to people much worse off than she. One woman had over five surgeries on her joints and was unable to find a dentist in three states who would treat her and was now suicidal. A 30-year old woman must now be cared for by her parents after 32 surgeries and $300,000 in medical expenses. Another patient received a bill from an oral surgeon in excess of $30,000 for a procedure which was a revision for a previous surgery and will, at best, only provide temporary relief from constant pain. One physician wrote on behalf of one of his patients who has applied for social security disability payments: "As Leigh's physician, I've witnessed her decline throughout 7 of her surgeries and seen her travel all the avenues of TMJ surgery. Instead of improving after each method, she has developed more daily pain. Unfortunately the surgeries that she has had, I feel, have probably left her joint in much worse shape. Her depression has now reached a dangerously high level in which she describes herself as having nothing left, having no hopes, no dreams. She states only that she hopes her life will be short in duration so that she will not have to exist in the constant painful state that she is in."

So what's the lesson for orthopedics? I figure there are a couple of things we can learn from this. First, the distrust that Terrie and members of her association feel for the dental and medical profession is real. While reports in the professional journals claimed 70-90% success rates, they were suffering symptoms similar to autoimmune disorders, osteolysis of the jaw, and constant pain. For them, it is not enough that the doctors say that a procedure will work. They have become assertive in asking questions about procedures, looking for long-term results, and questioning the science behind the research. They have developed more trust in their own collective experience than in medical professionals. At some point the medical, dental, and research communities will need to involve these people in research and patient outcomes evaluation. It may be relevant to ask whether the medical community should report the outcomes of their own procedures. *[See also Lieberman, et. al. page 14—ed.]*

Secondly, a category of patient, the multiply-operated patient, merits review. It is not uncommon to find patients with 15, 20, 30, or more surgeries on their TM joint. Multiply operated patients are also found in patients with trauma, congenital anomalies, or back pain. Treatments which require life-long dependence on medical technology, often with deteriorating results, should become better known to the medical practitioners, payers, and most importantly, the patient population.

A corollary which I have developed is that the existence of independent patient support groups for a specific disease, be it TMJ disorders, rheumatoid arthritis, or fibromyalgia, indicates that conventional medical treatments probably do not work very well. Terrie operates her support group out of her home and has a network of individuals whose every waking moment is consumed with this medical problem.

Finally, the lesson for orthopedics may simply be to reiterate what is already known: an implant is a life-long commitment. Hip implants have been so successful because they generally have been used in patients that are in their later years; they generally die before the implants wear out. There is evidence that the age of the hip and knee patients is getting younger and younger. This means that they will probably need several revisions during their lifetimes. It is also known that each successive hip or knee surgery is generally not as successful as the first. It is important that we are vigilant that we do not sow the seeds of an implant disaster in five or ten years. ◥

Terrie Cowley
TMJ Association
Milwaukee, Wisconsin

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performed during those years. Estimates are that about 26,000 patients received Vitek's implants, and about 20,000 received Dow Corning sheeting or implants between 1983 and 1993.

Vitek's disc replacements, known as interpositional implants (IPIs), were made of Teflon® FEP film laminated to Proplast®. Proplast, developed by Dr. Charles Homsy at DuPont, consisted of Teflon PTFE and vitreous carbon. Subsequently, the carbon was replaced with aluminum oxide, and the resulting structure was known as Proplast® II. These implants were sold by Vitek, a company started by Dr. Homsy, between 1983 until 1988 when they were taken off the market. Other Vitek TMJ implants included the VK-I, and VK-II, which included a condyle and a glenoid fossa component, designed by Dr. John Kent of the Louisiana State University Medical Center. Dow Corning provided Silastic® sheeting and a Silastic TMJ implant based on a design by Dr. Clyde Wilkes, of Minnesota. They were taken off the market in 1993.

What amazes patients and many orthopedic surgeons is that problems with PTFE (i.e. Teflon) implants were reported as far back as 1963 by Sir John Charnley, the acknowledged father of hip implant surgery. "Teflon [PTFE] proved unsuitable not so much because of its low resistance to wear as by the adverse tissue reactions caused by the wear debris. It may seem strange that it took us some 300 operations and between three and four years to arrive at this conclusion [that PTFE was unsuitable]... the results up to three years were so spectacular, that we could not bring ourselves to face the suspicion that the x-rays were showing incipient harmful evidence." [1]

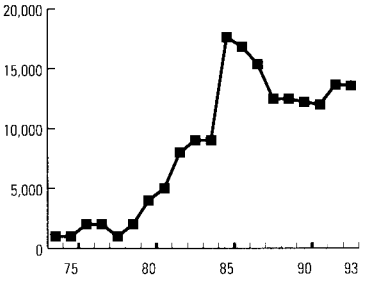
"...resorption of the glenoid fossa [caused by the implant] would expose the brain."

In 1983, Vitek was given approval by the Food and Drug Administration (FDA) to sell their interpositional implant (IPI) to surgeons to treat TMJ disorders. Even while the FDA was approving the IPI for distribution, the main medical advisor to Dr. Homsy, Dr. John Kent from Louisiana State University, was beginning to discover problems with the Teflon-coated device. In a February 14, 1984 letter to Homsy, Kent warned of a "calamity of unbelievable proportions" based on the excessive wear of one of the components in one of his patients. By 1985, the first problems with Proplast were disseminated to a wider professional audience. In a May 1985 newsletter from the Medical College of Wisconsin, Doran Ryan reported that "our experience [over the last five years] of Proplast/Teflon implants has not been favorable. We have encountered degeneration of the condyles." In April 1986, the FDA received their first Medical Device Report concerning Vitek's TMJ devices.

Animal studies, using the implants, which had not been performed prior to FDA approval were now being conducted. The first studies involving dogs were performed in 1984; El Deeb at the University of Minnesota examined the results of Proplast implants in monkeys and reported his findings at the annual American Association of Oral and Maxillofacial Surgeons meeting in October 1986. His conclusion was that the monkeys were experiencing "progressive fragmentation with giant cell reactions." In July 1986, Timmis reported giant cell reactions in rabbits to both Proplast/Teflon as well as silicone.

February 20, 1987, the Air Force surgeons who had been using the IPIs reported problems with patient reactions to both the FDA and Vitek and suspended their use. They reported "severe painful and nonpainful foreign body reaction with resorption of condyle and glenoid fossa." Continued resorption of the glenoid fossa would expose the brain. By May 1, 1987, Vitek had its first patient lawsuit and in June 1988, Vitek had removed the IPI from the market. Under pressure from the FDA, Vitek began to issue advisories to physicians on the potential fragmentation of the implant. Under growing litigation, Vitek filed for Chapter 7 bankruptcy protection on June 7, 1990. Aimed at Vitek, the FDA began a series of actions including a patient notification program warning patients of adverse reactions to the Vitek implants, alerting oral and maxillofacial surgeons, and rescinding Vitek's approval to sell the IPI. In June 1992, all of the implant inventory of Novamed and Oral Surgery Marketing, Inc. (sister companies of Vitek) were seized by the FDA, crushed by a bulldozer, and buried in a Houston, Texas dump.

U.S. Temporomandibular Joint Replacements, 1974-1993



1993 procedures: 13,565

Based on hospital discharges between October 1, 1992 and September 30, 1993. ICD-9-CM procedure code 76.5 Temporomandibular arthroplasty

Source: HCIA Inc.

Demographics of Patients with TMJ Replacements—1993

	% of cases
Age Distribution	
<18 years	5%
18-39 years	70%
40-59 years	23%
>60 years	3%
Sex % Female	**87%**
Payor	
Commercial insurance	50%
Medicaid	4%
Self pay	6%
Workers compensation	6%
Geographic Distribution	
% Northeast	26%
% North Central	15%
% South	44%
% West	15%

Source: HCIA Inc.

Based on ICD-9-CM Procedure code 76.5 Temporomandibular arthroplasty, and estimated from hospital discharges between October, 1992 and September, 1993

The Aftermath

It has been four years since the Vitek implants were pulled from the market, and two years since the intensive media scrutiny. There has been fallout on all parties involved—the manufacturers, physicians, regulators, insurers, and of course, the patients.

The manufacturers: Currently, there are over 2,200 claims against Vitek from patients who are trying to obtain funds to have their implants removed, a course suggested by the FDA. Given the limited funds available from the Vitek bankruptcy court, patients with the Vitek implant have filed a class action lawsuit against DuPont, and those with the Silastic implant have filed against Dow Corning. DuPont provided about five cents' worth of Teflon for the Vitek implant but is being sued for the medical expenses of the tens of thousands of patients with the implants. Dow Corning and other raw materials manufacturers have begun to disassociate themselves from the development of products because of the liability associated with them.

The FDA reclassified TMJ implants as Class III devices, which means new TMJ devices must submit several years of data on patient outcomes before they can be marketed. Scientific data on safety and efficacy may need to be submitted for devices manufactured by TMJ Research Institute and TMJ Implants, even though they have been manufactured prior to the 1976 Medical Device Amendments. The reclassification of these devices has also led both Synthes and Howmedica to withdraw their Ramus joint prostheses from the market. Ramus prostheses are predominately used for patients with cancer.

The physicians: The American Association of Oral and Maxillofacial Surgeons (AAOMS) represents about 4,700 active members in the United States, and many were involved in placing implants in patients in the mid-1980s. While the literature in the mid-1980s discussed options and surgery to deal with TMJ pain, many of these professionals must now deal with the multiply-operated patient and those who suffer the after-effects of failed TMJ implants. Dr. Daniel Laskin, editor of the Journal of Oral and Maxillofacial Surgery, says that "their members were led to believe that the implants were safe because the FDA had approved them. Most oral surgeons don't have the time to investigate the devices and review the literature."

These events have also opened the oral surgeon community to unexpected scrutiny in their practices and profession. Congressional hearings in June 1992 led to a November 1992 AAOMS workshop on management of patients with TMJ implants in which the majority of participants "recommend removal of [Proplast/Teflon] implant and affected soft tissues." In a rare display of self-assessment, one oral surgeon has called for a reduction in the number of residents graduating from oral and maxillofacial surgery programs. "The scope of services provided by our specialty has greatly increased in the past 10 years, especially in the area of cosmetic surgery. Interspecialty rivalries are at an all-time high. Some services are being provided for patients with little justification of their benefit. One could argue that surgical experimentation is being performed on humans...[the] problems we face can be directly related in one way or another to an excess of manpower."[2]

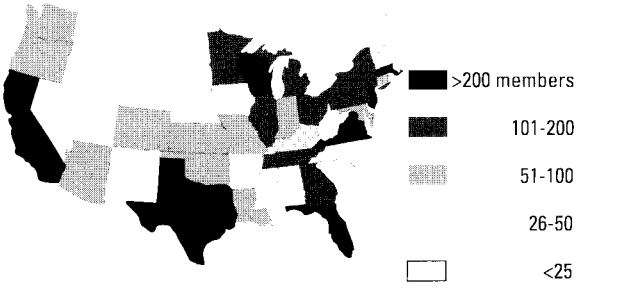
The surgical success of oral surgery is now being compared to other medical specialties. While orthopedic implants are looking at longer time frames for success—decades instead of years—TMJ procedures are considered successful if 75% of patients have pain reduction at five years. Although some patients with TMJ implants have been tracked for over thirty years, many with the Vitek and silicone implants have unknown prognoses as they approach their forties, fifties, and beyond. It is a valid question to determine how many patients in this age group will allow themselves to have a surgery on their jaw every three or four years.

The regulators: In 1992, under pressure from patient constituents, Congressional hearings were held on TMJ implants and whether the FDA and National Institutes of Health (NIH) had been ignoring their dangers. One upshot is that funding of basic research into TMJ disorders will almost double over the next three years.

This episode has also highlighted the separate dental and medical research communities who often independently research similar issues, but seldom share information. Dental researchers have investigated materials used in orthopedics such as hydroxyapatite, titanium, and bone cements; similarly orthopedics and other medical specialties have had experience with PTFE (Teflon), silicones, and other materials which the dental specialties could learn from. This lack of commmunication, at least in the case of the TMJ implants, has harmed patients.

Insurers/payers: The history of TMJ coverage has been intermittent and haphazard since the 1970s. With the advent of TMJ implants in the early 1980s, many insurers offered coverage to patients. When implants were found to be unsuccessful, they began to deny coverage, even for surgery to repair the problems of the first surgery or for the removal of implants which had begun to deteriorate. Insurers in some states cover the surgical management of TMJ disorders, but not the non-surgical care of these patients. Minnesota started providing coverage for non-surgical management of TMJ disorders and found that the number of patients treated increased, the surgical rate decreased, and the overall costs decreased.

Membership in TMJ Association, Ltd



Source: TMJ Association, Ltd; Milwaukee, Wisconsin

Chronology of an Implant Disaster

The following are some of the relevant publications, filings, and correspondences in this episode.

Date(s)	Source	Event
The Background Research		
1963, 12/28	Lancet	Charnley warns against the use of Teflon in joints because of intense foreign-body reactions. Describes unfavorable results of injecting Teflon into his own thigh.
1967	WSJ	Dupont sends Homsy warning about complications caused by implanted Teflon.
1968	WSJ	Proplast developed by Homsy at DuPont.
1970's	ONN	Homsy starts Vitek.
1974	WSJ	Kent started collaboration with Homsy.
1976, 5/28	FDA	Medical Device Amendments: Premarket notification is not required for devices developed prior to 5/28/76.
1978, 3/1	TMJ	Earliest known recipient of Vitek Proplast/Teflon implant.
1982, 3/30	FOI	Kent writes Homsy that procedures to rise to 10,000 per year for TMJ implants.
1982, Oct	JOMS	Wolford compares Silastic to Proplast in twelve patients. Follow-up ranged from one to four years. No differences in comfort, mobility. Proplast had better long-term stability than Silastic.
1982, 11/23	FOI	Vitek files intent to market Interpositional Implant (IPI) with FDA.
Distribution Begins		
1983, 3/23	FOI	FDA notifies Homsy that IPI is equivalent to device marketed prior to May 28, 1976.
1983		Commercial distribution of IPI implants begins.
1983, 12/9	FOI	510(k) approval for Dow Corning Silastic TMJ implant H.P. based on substantial equivalence to Silastic sheeting marketed prior to 5/28/76.
1984, 2/14	FOI	Kent concerned about safety of Vitek implants warns Homsy of "calamity of unbelievable proportions."
1984	WSJ	First animal dog studies done on IPI.
1984, July	JBJS	Tullos, et. al. report thirty-six percent of forty-seven hips coated with Proplast failed after an average of thirty-seven months. Concluded that coating had insufficient strength to withstand normal weight-bearing loads.
Growing Concerns		
1985, May	TMJI	First problems with Proplast reported by Ryan. ("degeneration of condyles")
1986, Apr	CONG	First Vitek Proplast Medical Device Report.
1986, Apr	DCNA	Moriconi et. al. "The TMJ IPI's should be singled out as having provided a new and more predictable mode of TMJ reconstruction."
1986, Jul	JOMS	Timmis et. al. report giant cell reactions by rabbits to Proplast/Teflon and silicone implants. "Indicate a need for further evaluation of these materials as disc replacements in humans."
1986, Oct	AAOMSm	El Deeb reports 6 monkeys showed Proplast fragmentation with giant cell reactions after 3-12 months.
1986, Oct	WSJ	Vitek's survey of oral surgeons 91.5% of 5,070 satisfactory results. Vitek says prognosis for IPI's success beyond 3 years was unknown in package insert.
1987, 2/20	FOI	U.S. Air Force reports problems with Proplast to Vitek, FDA ("severe painful and nonpainful foreign body reaction with resorption of condyle and glenoid fossa").
1987, Spring	HC	First lawsuit against Vitek.
1987	DC	Wilkes design TMJ implant marketed by Dow Corning.
Shutdown—The Bureaucracy Swings into Action		
1988, June	WSJ	Distribution of IPI suspended by Vitek.
1988, July	WSJ	FDA conducts first inspection of Vitek's plant.
1989, Mar	HC	FDA cites Vitek for not reporting patient complaints through Medical Device Reports (MDRs).
1989, May	JOMS	El Deeb publishes 1986 findings on monkeys.
1990, 3/23	FOI	Vitek issues letter advising docs that IPIs could fragment.
1989, Jul	JOMS	Valentine et. al. Nine patients (14 joints) showed deteriorations, foreign-body giant cell reaction in all joints.
1989, Dec	OMSC	Yih/Merrill report "both silicone rubber and Teflon-Proplast are not biologically acceptable implant materials in the functional TMJ."
1990, 6/7	HC	Vitek files for Chapter 7 bankruptcy.
1990, June		Oral Surgery Marketing, Inc (OSMI) takes over Vitek products.
1990, 8/30	FDA	FDA rescinds 510(k) for Vitek's IPI implant.
1990, Sept	OSOMOP	Estabrooks reports 88.7% surgical success with Proplast/Teflon implants with average follow-up of 33 months. Only 10% resulted in removal.
1990, Oct	HC	FDA seized all implants manufactured by Vitek, NovaMed Inc. and OSMI. (NovaMed, a sister company of Vitek, manufactured hip implants.)
1990, 12/28	FDA	FDA safety alert to oral and maxillofacial surgeons warning of complications associated with Proplast-Teflon.
1991, 1/7	FDA	FDA recalls Vitek IPI (Class I recall).
1991, 10/2	FDA	FDA issues medical alert to patients with Vitek implant.
1991, Fall	ONN	Bankruptcy court appoints JAMS to referee Vitek lawsuits.
1992, Feb	JOMS	Fontenot reports that laboratory tests of IPIs show that they have a service life of about three years. Intermediate and long-term survival of implant is uncertain.
1992, Mar	HC	Homsy moves to Switzerland.
1992, Jun	HC	Implant inventory of NovaMed and OSMI crushed with a bulldozer, buried in Houston dump.
The Aftermath		
1992, 6/4	CONG	Congressional hearings on TMJ implants.
1992, Oct	OSOMOP	Spagnoli/Kent report that of 465 patients with IPI, 86% of implants were still in place after an average of 32 months. 92.4% were asymptomatic, however 249 showed some degree of condyle resorption. Project that 54% may fail.
1992, Nov	AAOMS	AAOMS workshop on TMJ implants. "Recommend removal of Teflon/Proplast implant and affected soft tissues."
1993, 1/26	ONN	Dow Corning exits the TMJ business.
1993, April	JOMS	Wolford reports revision surgery after Proplast-Teflon failure. 88% of 163 joints showed significant osseous changes after two to 126 months.
1993, 4/26	ONN	Class action lawsuit filed against Dow Corning and Dupont on behalf of both Vitek and Dow Corning Silastic TMJ recipients.
1993, 8/31	WSJ	WSJ article about TMJ patients.
1993, Sept-Oct		20/20, American Journal, Current Affair segments aired on ABC TV.
1994, 12/20	FR	FDA reclassifies TMJ implants as Class III.
1995, 4/1	ONN	Claims against Vitek exceed 2,200, excluding about 500 patients who received $1,000 total reimbursement.

Sources: *AAOMSm=Annual meeting of American Association of Oral and Maxillofacial Surgeons; CONG=Proceedings of Congressional Hearings on TMJ implants, June 4, 1992; DC=Dow Corning; DCNA=Dental Clinics of North America; FDA=Food and Drug Administration public releases; FOI=Food and Drug Administration Documents obtained under Freedom of Information Act; FR=Federal Register, December 20, 1994; HC=Houston Chronicle articles of September 10, 1990, April 1, 1991, and June 23, 1992; JBJS=Journal of Bone and Joint Surgery (American); JOMS=Journal of Oral and Maxillofacial Surgery; ONN=Orthopedic Network News sources; OSOMOP=Oral Surgery Oral Medicine Oral Pathology; TMJ=TMJ Association, Ltd., Milwaukee, Wisconsin; TMJI=TMJ Institute Newsletter, Medical College of Wisconsin; WSJ=Wall Street Journal article of August 31*

The patients: By 1986, Terrie Cowley had had a Silastic implant in her jaw for four years. After her surgeon told her, "I don't know why you are having pain," she embarked on a mission to see if other people had had as bad a reaction as she had. She now heads a not-for-profit organization whose mission is to help those with TMJ disorders or TMJ implants, and to provide advocacy to those who need it. The Association has been instrumental in obtaining Congressional hearings on TMJ implants, and having research money allocated to basic TMJ research within the National Institutes of Health.

Of the 5,000 members in the TMJ Association, 257 are known to have a Vitek implant, and 189 are known to have a Silastic implant. Of the Vitek implant patients, the average age in which they received their surgery was 34 years old, and the average number of surgeries they have received is 6.0. There were two patients who had more than 30 surgeries on their jaw, and five who had 20 or more surgeries. Several indicated that their medical expenses exceeded hundreds of thousands of dollars. For example, one patient's bill obtained by *ONN* for the surgeon fees for the removal of a Vitek implant and the implantation of another was $37,500. This did not include the cost of the hospitalization, implant, or anesthesiologist.

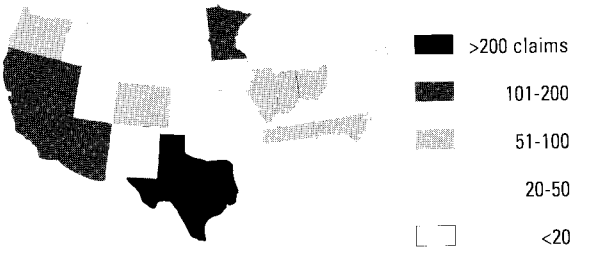
"One patient's bill for surgeon fees for the removal of a Vitek implant and the implantation of another was $37,500. This did not include the cost of the hospitalization, implant, or anesthesiologist"

For those with implants who are suffering in pain, the future can be a devastating prospect both physically and financially. Multiple surgeries as well as devastation of careers, marriages, and finances are not uncommon. For the many implant patients who have had relief from their TMJ pain, the studies on Proplast and Silastic can raise many doubts in their minds. Should they live with their pain and their degenerating condition or should they risk getting worse by having their implants removed? The worst part of this problem is that even after the implants are removed, the deterioration of the bones in the skull will continue.

Insurance relief for medical expenses, even the removal of the implant, is generally not available even though this has been recommended by the FDA. The insurers for Vitek have made a pool of $22 million available for these patients. Patients receive between $1,000 and $8,000 depending on their degree of disability, number of surgeries, age, and other factors. Thus far, approximately 2,700 patients have been paid from this fund.

One of the most hopeful signs for patients is the recognition by many of the providers that their pain is not all caused by stress. Much of the research in the past has examined the "TMJ personality," and sources of stress which can lead to their pain. Patients have argued for years that their underlying pain can lead to the stresses which the researchers were examining. What they hope for is more research into the root causes of TMJ disorders.

Legal Claims against Vitek by Patients and Attorneys

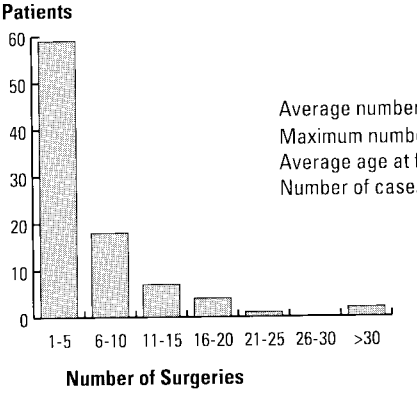


Total Claimants:	2,217[1]
Maximum settlement:	About $8,000
States with highest number of claimants[2]	
Texas	458
Minnesota	183
California	149
Nevada	130
Percentage of claimants represented by attorneys:	74%

[1] Excludes over 500 who accepted $1,000 settlement as total compensation
[2] State represented is location of claimant, not necessarily location of patient. Patients represented by attorneys in other states will be counted in the state of the attorney, not of the patient, although most patients have attorneys in their own state.

Source: JAMS (Judicial Arbitration and Mediation Service/ Endispute) Houston, Texas

Number of Surgeries of Patients with Vitek Proplast/Teflon Implants



Average number of surgeries/patient:	6.0
Maximum number of surgeries/patient:	30
Average age at first surgery:	34.3 years
Number of cases:	114

Source: TMJ Association, Ltd.

Sources cited
[1] Waugh W; John Charnley: The Man and the Hip; page 120 Springer-Verlag, 1990.
[2] Ellis Edward; Manpower Excess: One Source of Our Problems, J Oral Maxillofac Surg 51:1135-1138, 1993.

External Fixation Shows Procedure Growth

While manufacturer sales of total joint prostheses may be languishing due to market penetration, a segment of the orthopedic market, external fixation, is showing double-digit increases in sales to hospitals. The use of external fixation has increased for a number of reasons including improved technology and greater physician awareness for its applicability.

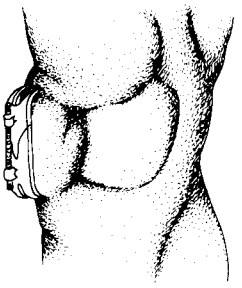
External fixation is usually associated with severe fractures involving extensive soft tissue damage and/or with numerous segmented bone fragments. There are no absolute indications for external fixation; each case must be individually reviewed by the surgeon. It can be utilized for fractures of the tibia femur, pelvis, humerus, and small bone fractures although most are used for the tibia/fibula and the wrist. New materials and instrumentation have also expanded the use of unilateral external fixation into new areas which involve limb lengthening procedures, joint fusion (arthrodesis), and angular and rotational correction of joints, such as club foot.

The technology

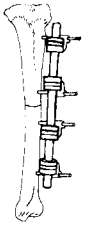
The technology for external fixation has undergone several evolutions over the last 150 years. There have been two problems with external fixation: (1) infections in the pin tracts, and (2) instability in the bar and pin mechanism which causes the fracture to displace and not heal properly. The problems have led to stronger materials for the bars, and better designed pin and clamp systems attaching to the rods. One approach to improving stability has been to provide fixation in two or more planes; that is, in order to stabilize a complicated fracture, a rod may be used on the front of the bone, and another on the side, which is designated as a delta or bilateral device. The most recent trend has been pre-assembled fixators which take less time to construct than the older component fixators. These packaged fixators also include half pins and the necessary instrumentation. Currently all-in-one fixators are available for unilateral, bilateral, and pelvic frames and include the Ace-Unifix, EBI-Orthofix, Smith & Nephew Richards Hex-Fix, Synthes trauma fixation, and OrthoLogic Orthoframe. While these devices may be more expensive than their equivalent component systems, they require no sterilization and take less time to construct during an operative procedure.

Another patient concern is the fact that many of these devices can be complicated, bulky, and heavy. Manufacturers have recently made composite (carbon-fiber) rods available as an alternative to stainless steel. This has reduced the weight of the fixator for the patient and is radiolucent allowing for unobstructed x-rays. The drawback to this has been that hospitals have traditionally reused the external fixation devices for other

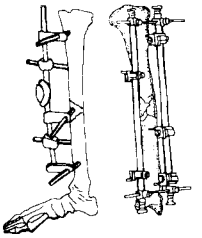
text continued on page 10



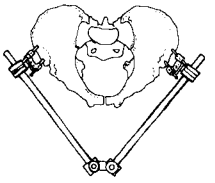
External fixation has a long history. It was noted by Hippocrates over 2,500 years ago. In 1843 a French surgeon, Joseph Francisco Malgaigne developed a claw-like clamp with four prongs inserted under the skin to reduce fractures of the patella. It is no longer in use.



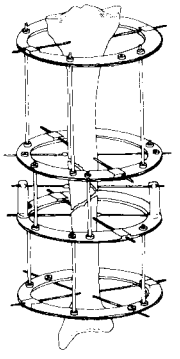
Unilateral: Unilateral fixation devices are used for relatively uncomplicated fractures of the tibia/fibula, and occasionally the femur or humerus.

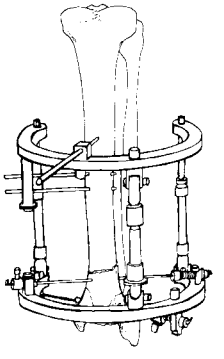


Bilateral/Delta: These devices are used if the fracture would require support in two different geometric planes, eg. side and front. These are usually fractures of the tibia/fibula which are located close to a joint.

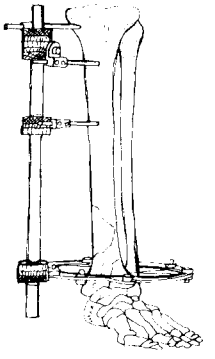


Pelvic: Pelvic fractures, also called "open-book," are very difficult to treat because of the odd shape of the pelvis, and the high risk associated with performing open surgical procedures to repair them. The devices used to treat them avoid the need for an open surgical procedure.

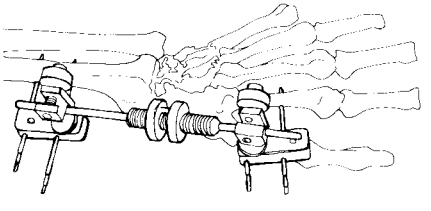




Circular: Circular external fixation devices, such as Lizarov, are most often associated with limb lengthening procedures, sometimes used for young patients with congenital short stature. They are also used in complex fractures with many segmented bones.

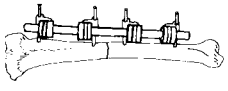
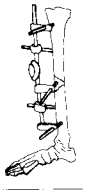
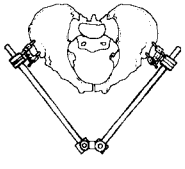
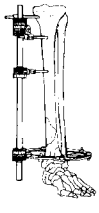
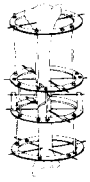
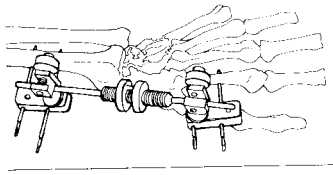


Hybrid: Hybrid devices combine a circular external fixation device with a bilateral or unilateral frame, generally for complicated fractures involving the upper or lower tibia.



Colles Devices: These devices are specifically designed for fractures of the wrist, known as Colles' fractures.

1995 External Fixation Price Comparisons

	Manufacturer Location Price List Date	**EBI (Biomet)** *Parsippany, New Jersey* *November 1, 1994*	**Synthes** *Paoli, Pennsylvania* *January 1, 1995*	**Smith & Nephew Richards** *Memphis, Tennessee* *July 1, 1994*
Unilateral *Includes: 1-2 medium bars* *2-4 pin clamps* *4 half pins* *(5mm x 50mm)* 		**Orthofix Dynamic Axial Fixator** **Standard model** **$2,105** Standard model 10000A $1,825 Includes: Standard body, straight clamps (2) Ti tapered pins(4) 10-10102 $280 **Standard kit** **$2,220** Standard kit 10000 $1,940 Includes: Standard body, straight clamps(2), allen wrench, compression/distraction unit Ti tapered pins(4) 10-10102 $280	**AO (dynamized)** **$1,617** Bar 343.56 $92 Clamps(4) 393.64 $620 Pins(4) 294.74 $140 Bar 393.52 $80 Universal joint 393.71 $375 Clamps (2) 393.64 $310 **AO Trauma Kit 199.951S $760** Includes: bar and 4 clamps	**Hex - Fix** **$1,147** Bar 11-2702 $117 Spools(2) 11-2706 $360 Clamps(2) 11-2735 $550 Pins(4) 12-2753 $120 **Hex-In-A-Box** **$1,800** Sterile kit w/ instrmts 11-2750 **Hex Universal-In-A-Box** **$1,800** Sterile Kit w/ instrmts 7111-2760
Bi-Lateral (Delta) *Includes: 1-2 medium bars* *2-6 pin clamp assem.* *2 connecting bars* *4 half pins* *(5mm x 50mm)* 		**Orthofix Dynamic Axial Fixator** **Standard model** **$2,445** Standard model 10000A $1,825 (see above for components) Ti tapered pins (4) 10-10102 $280 Screw holder clamps(2) 10-0039 $331 Bar (150mm) 10039 $30	**AO** **$2,244** Bars(2) 393.56 $184 Clamps(12) 393.64 $1,860 Connect. bar (2) 393.91 $60 Pins(4) 294.74 $140	**Hex Fix** **$1,147** *same as above* **Hex-In-A-Box** **$1,800** *same as above* **Hex Universal-In-A-Box** **$1,800** *same as above*
Pelvic *Includes: 2-3 medium bars* *2-8 pin clamps* *2-4 stainless half pins* 		**Orthofix** **$2,710** Iowa pelvic fixator kit 10075	**AO Pelvic Frame** **$1,349** Bars(2) 393.56 $184 Clamps(2) 393.75 $670 Universal joint 393.71 $375 Pins(4) 283.69 $120	**Hex-Fix 2 Bar** **$1,748** Bar(2) 11-2702 $234 Bar clamp 11-2731 $154 Sgl. spools(4) 11-2706 $720 Dbl. swivels(2) 11-2710 $520 Pins(4) 12-2781 $120 **Hex-Fix 3 Bar** **$3,180** Short bar(2) 11-2701 $336 Bar clamps(2) 11-2731 $308 Sgl. spools(8) 11-2706 $1,440 Sgl. swivels(4) 11-2730 $976 Pins(4) 12-2761 $120
Hybrid *Includes: 1 bar, nuts, bolts* *2-4 pin clamps* *2-4 stainless half pins* *1 ring* *2 K-wires* 				**Hex-Fix/Lizarov** **$2,122** Bar 11-2702 $117 Spools(2) 11-2706 $360 Double spool 11-2707 $202 Pin clamps(3) 11-2711 $510 Half rings(2) 10-1307 $702 K-wires(2) 10-2102 $56 Bolts(2) 10-3203 $3 Fixation bolts(4) 10-0600 $72 Nuts(12) 10-3300 $10 Pins (3) 12-2761 $90
Circular *Includes: 2-4 complete rings* *2-4 threaded rods* *3-48 nuts, 0-16 bolts* *6-8 K-wires* 				**Lizarov** **$3,424** Half rings180 mm(8) 10-1307 $2,808 Thread rods 250 mm(3) 10-2311 $53 Nuts 10 mm(48) 10-3300 $43 Bolts(8) 10-3203 $10 Wire fixation bolts(16) 10-0600 $286 K-wires(8) 10-2102 $222
Colles *Includes: 1 Bar, 4 Pins* *2-8 Pin Clamp Assem.* 		**Penning Dynamic Wrist Fixator** **$1,490** Complete kit 35000 $1,490	**AO Small Fixator** **$753** Bar 395.74 $17 Clamps(4) 395.57 $600 Pins(4) 294.30 $136	**Richards Colles** **$776** Frame 11-0096 $631 Pins(4) 12-4828 $145 **Complete kit w/instrmt 11-0097 $1,393**

Howmedica
Rutherford, New Jersey
October 1994

Hoffman		**$1011**
Rod	5029-8-250	$22
Ball joint clamps(2)	5029-2-110	$660
Stopclips (4)	5029-4-110	$15
Pins (6)	5018-5-150	$314
Monotube (medium)		**$1,409**
Tube	5150-2-420	$100
Clamp (2)	5150-3-020	$1,100
Pins (4) pkg of 3	5018-5-150	$209

Hoffman		**$2,255**
Rod 300mm (2)	5029-8-300	$44
Rod 200mm (2)	5029-8-200	$44
Couplings (4)	5029-5-013	$596
5-hole ball joint (4)	5029-1-210	$1,152
Pins (8) pkg of 3	5018-5-150	$419

Hoffman		**$1,791**
Rod 250mm	5029-8-250	$22
Rod 300mm	5029-8-300	$22
Rod 350mm (2)	5029-8-350	$50
Connecting rod	5029-7-016	$166
5-hole ball joint (2)	5029-1-210	$576
Artic. couplings(4)	5029-5-013	$596
Stop clips (12)	5029-4-110	$46
Pins (6) pkg of 3	5020-7-250	$313

Hoffman/Monticelli-Spinelli		**$2,636**
Medium 3/4 ring	5181-1-301	$281
70 degree ball joint (2)	5102-1-330	$517
Thread rods w/nuts(2)	5102-8-395	$74
K-wire holders(4)	5102-1-245	$556
w/spacers(2)	5102-1-246	$284
K-wires(3)	5101-2-450	$101
10-hole ball joint (2)	5029-2-110	$666
Pins (3) pkg of 3	5018-5-150	$157

Monticelli-Spinelli		**$4,193**
Medium 3/4 rings(2)	5181-1-301	$281
1/4 rings (2)	5118-1-304	$368
Thread rods w/nuts(3)	5102-8-395	$111
70-degree ball joint (6)	5102-1-330	$1,551
K-wire holders(8)	5102-1-245	$1,112
w/spacers(4)	5102-1-246	$568
K-wires(6)	5101-2-450	$202

Dynamic Wrist Fixator		**$1,629**
Frame	5049-2-100	$1,491
Pins(4)pkg of 3	5038-5-080	$138
Monotube (small)		**$1,038**
Monotube	5150-2-380	$100
Clamps (2)	5150-3-015	$800
Pins(4)pkg of 3	5038-5-080	$138
Hoffman		**$794**
Rod	5049-4-031	$142
4-hold ball joints (2)	5049-1-310	$514
Pins(4)pkg of 3	5038-5-080	$138

ACE Medical
Los Angeles, California
June 1, 1994

Ace Unifix		**$1,240**
Bar	10800	$260
Clamps(4)	10801	$760
Pins(4)	FS-10190	$220

Ace Unifix		**$1,240**
same as above		

Ace Pelvic Stabilizer		**$3,872**
Bar	6081	$3,500
Threaded holders(2)	10801	$192
Pins(2)	6075-1.0	$800

Ace-Fisher		**$3,262**
Distract. assembly w/bolts	10480	$262
Med. connect. rods(3)	FA-10000-2	$1,635
Anchor assembly	FF-10023	$148
Pins(4)	FS-10175.3	$192
2/3 rings(2)	FA-10029	$564
K-wires(2)	10489	$25
Single pin holders (2)	FA-10355	$242
Double pin holder	FA-10360	$194

Ace-Colles		**$987**
Frame	AC11095	$875
Pins(4)	SC/90.16	$112
C-Series Hoffman		**$701**
Connecting rod	AC-16	$139
Universal ball joints(2)	AC-10	$450
Pins(4)	SC/90.16	$112

Zimmer [1]
Warsaw, Indiana
September 1, 1994

Torus		**$1,719**
Bar	2613-01-04	$111
Clamps (4)	2613-05	$680
Ti pins(4)	2613-05-50	$260
Pin caps (4)	2613-08	$104
Pin collets (4)	2613-03-60	$216
Rod caps (4)	2613-07	$112
Rod collets (4)	2613-03	$236

Torus		**$1,719**
Bar	2613-01-04	$111
Clamps(2): right	2613-05	$340
left	2613-04	$340
Ti pins(4)	2613-05-50	$260
Pin caps (4)	2613-08	$112
Pin collets (4)	2613-03-60	$216
Rod caps (4)	2613-07	$112
Rod collets (4)	2613-03	$236

Torus		**$3,070**
Rods (2-12")	2613-01-04	$222
Rod (14")	2613-01-05	$130
Rods (2-4")	2613-01-02	$110
Rod clamps(4)	2613-31	$1,340
Pin clamps(2)	2613-06	$340
Pin caps (4)	2613-08	$104
Pin collets (4)	2613-03-60	$216
Rod caps (4)	2613-07	$112
Ti pins(4)	2613-05-75	$260
Rod collets (4)	2613-03	$236

Torus Hybrid		**$3,378**
Rod	2613-01-04	$111
Ring to rod clamp	2613-24	$240
150 degree ring	2613-21-15	$198
Transfixation wire (2)	2613-22-01	$174
Tensioning bolts (2)	2613-23	$154
Tensioning collet (2)	2613-35	$114
Transmitter clamps (2)	2613-36	$546
Receiver clamps (2)	2613-37	$820
Wire retainer (2)	2613-34	$300
Pin caps (2)	2613-08	$56
Pin collets (2)	2613-03-60	$108
Rod caps (3)	2613-07	$84
Ti pins(2)	2613-05-25	$130
Rod collets (3)	2613-03	$177
Double clamp	2613-06	$170

Clyburn Dynamic Colles Fixator		**$1,105**
Frame	6013-01	$886
Pins (4)	6014-33	$219

OrthoLogic
Phoenix, Arizona
January 1, 1995

OrthoFrame		**$2,500**
Sterile kit w/ instrmts	01-03-0001	$2,500
Ti Pins		

OrthoFrame		**$2,995**
Sterile Kit w/instrmts	01-03-000	$2,500
Includes:		
Ti Pins		
Pin clamp kit	09-03-000	$495

OrthoFrame		**$2,500**
Sterile Kit w/instrmts	01-03-0001	$2,500
Includes:		
Ti Pins		

OrthoFrame		**$4,445 ***
Sterile kit	01-03-0001	$2,500
Lizarov ring adaptor kit	09-13-0012	$950
Monticelli-Spinelli ring adaptor kit	09-13-0011	$995

** Excludes:*
Lizarov components will add approximately $850; Monticelli-Spinelli components will add a similar amount.

OrthoLogic Mayo wrist fixator		**$1,395**
Sterile kit	01-03-0008	$1,395

Hand Biomechanics
Sacramento, California
January 1, 1995

Agee Wrist Jack		**$1,200**
Complete Kit	CFD-47	

[1] *Prices provided by Zimmer were promotional prices and generally lower than those in 9/1/94 price list.*

text continued from page 7

patients after appropriate sterilization. However, carbon materials shows wear and tear much more readily than stainless steel rods. This has made some physicians and patients reluctant to reuse them, which in turn, increases the cost to the hospital. One manufacturer source indicated that after moving to carbon materials, their sales increased significantly.

According to data compiled by HCIA, there were approximately 27,000 external fixation procedures performed between October 1992 and September 1993. This represents an increase of over 15% in 1992. About two-thirds of the external fixation procedures are for either the tibia/fibula or the radius/ulna. The demographics of patients receiving these procedures are entirely different. The external fixation of the radius/ulna are basically for Colles' fractures, which often happens when people fall down and stick out their hand to break their fall. Over 67% of these patients were over 40 years of age, and 18% of them had Medicare as primary insurance. Average length of stay was three days, and average hospital charges were $8,465. In contrast, external fixation of the tibia/fibula, often associated with motor vehicle accidents, showed 64% of the patients under the age of 40 years, and only 9.3% having Medicare as primary payer. Twenty-two percent of these patients were under the age of 18, the prime age for motor vehicle crashes. The average hospitalized length of stay was 10.1 days, and hospital charges were $18,303, again reflecting the greater trauma associated with these patients.

Although external fixation procedures have increased, internal fixation devices such as rods, nails, or plating are used much more frequently in the treatment of either tibial or radius/ulna fractures. According to HCIA data, 3.9% of tibia/fibula fractures were treated with external fixation compared to 73% with internal fixation; hospitalized Colles' fractures were treated 8.8% of the time with external fixation, and 43% of the time with internal fixation.

In general, there are large differences in prices of preassembled external fixation devices versus component systems. For example, a component-based Hoffman unilateral external fixation device manufactured by Howmedica is $1,011, while a prepackaged Orthroframe manufactured by OrthoLogic is $2,500. Some systems can also be converted relatively easily from a unilateral to a bilateral frame. For instance, the ACE Medical Unifix and Smith & Nephew Richards Hex-Fix systems use the same types of components for unilateral as well as bilateral constructs. By comparison, converting a Howmedica Hoffman system from unilateral to bilateral in a delta configuration requires the addition of ball joints and couplings, which increases the cost to $2,255.

The market

According to IMS America of Plymouth Meeting, Pennsylvania, sales of external fixation devices to U.S. hospitals were about $66 million in 1994, a 17% increase over the 1993. This is relatively small compared to the overall orthopedic market of $2.5 billion, and even quite small within the trauma market of $643 million. IMS lists 18 different manufacturers of external fixation devices, and there are doubtless many other manufacturers with relatively small market shares. EBI, Synthes, Smith & Nephew Richards, Howmedica, and ACE Medical account for over 90% of the external fixation market. Between 1993 and 1994, gains were registered by EBI Medical Systems, Hand Biomechanics, and ACE Medical.

Hospital cost issues

Two predominate issues regarding external fixation appear to be inventory and the re-use of external fixation components. Older component systems have numerous parts. Their benefit is that

External Fixation Procedures, 1993—Key Facts

External Fixation Procedures	Procedures	% of all external fixation procedures
All sites	27,140	100%
Tibia/Fibula	**9,000**	**33%**
Radius/Ulna	**9,189**	**34%**
Femur	3,826	14%
All other	5,125	19%

How fractures are treated	Tibia/Fibula	Radius/Ulna
Open reduction, internal fixation	73%	43%
Closed reduction, no fixation	17%	38%
Closed reduction, internal fixation	5%	8%
Open reduction, no fixation	2%	2%
External fixation	**4%**	**9%**

External Fixation procedures statistics	Tibia/Fibula	Radius/Ulna
Length of stay	10.1 days	3.0 days
Hospital charge per case	$18,303	$8,465
Payer mix of patients		
Medicare	9%	18%
Commercial insurance	35%	32%
Age Distribution of patients		
<18 years	22%	4%
18-39 years	42%	29%
40-64 years	27%	45%
65 years and older	9%	23%
% Male patients	73%	48%

DRGs assigned to external fixation

DRG 442[1]—Other OR Procedures for Injuries with CC	
DRG weight	2.0135
Approximate Medicare payment	$7,640

[1] *Note: Other DRGs may be assigned for external fixation such as DRG 218 (Lower Extremity Procedures) or DRG 223 (Major Shoulder/Elbow Procedures); however, many of the patients presenting with trauma will be assigned to DRG 442.*

Source: HCIA Inc., St. Anthony's Publishing, Federal Register, September 1, 1994

they can treat any bone or bone fracture pattern; the pitfall is extensive inventory. Large hospitals, such as level one trauma centers, need a complex fixation system to treat the problems which they are likely to encounter. However, there is some evidence that a large trauma hospital may find use for a prepackaged external fixation device for the multiply-injured patient. For patients who have multiple injuries, the time required to assemble an external fixation device may be less important than dealing with their other life-threatening injuries. A smaller rural hospital may be able to utilize a pre-packaged fixator for the commonly seen fractures. However, many rural hospitals may refer all patients requiring external fixation to larger hospitals.

Re-use of external fixation components is the question being repeatedly raised by hospitals. The half pins are the only implanted portion of external fixation; the remaining portion of the fixator remains external. Reusing an external fixation system could save a hospital several thousand dollars per case. One hospital, contacted by *ONN*, indicated that they have been using the same Colles' fracture external fixation device for "over ten years" with good patient results. Since it has not been manufactured for a number of years, worn-out stainless steel pins are made by a local instrument manufacturer, and cost about "$10-$30." The cost advantage when compared to purchasing a new Colles' system is over $1,000.

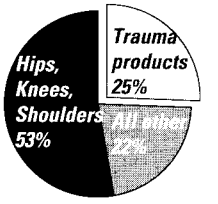
Manufacturers are reluctant to promote reuse for a number of reasons, including their concern for liability as well as the fact that reused items decrease potential sales. The average patient can wear an external fixation device for six months or more. Since fixators are most commonly used for tibial fractures, one should realize these patients are usually weight bearing within four to six weeks. Therefore, it is difficult to determine whether some structural damage has occurred to the device during this time, which could affect the care of the next patient using the system. Since there are no means of checking the fixators for compromising structural damage such as micro fractures, hospitals would have to accept the liability of problems arising from the reuse of components. None of the companies contacted by *ONN* have written re-use policies with the exception of Synthes who stated: "Provided the clamps are disassembled, cleaned, visually inspected (for pitting, corrosion, wear, and abuse), properly reassembled, found to be in proper working order, and autoclaved properly, we have no disagreement with the reuse of clamps, tubes, or rods."

Issues for hospital review

The hospital should determine the types of fractures treated and the types of systems used. As mentioned before, the two philosophies of pre-assembled versus component systems could result in substantial cost and inventory differences. In general, the Level I trauma centers which see all types of fractures will always need the more complex component-based systems. Hospitals with physicians who do not have lots of experience working with component systems may benefit from the pre-assembled systems. The hospital should also determine the reuse policies of their institution, as well as their manufacturers, to determine whether there are any savings potential. ■

Orthopedic, Trauma, and External Fixation Market

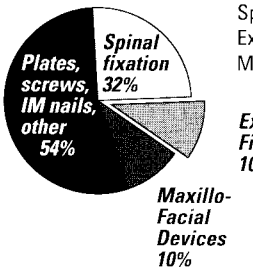
All Orthopedic Devices



Segment	94 sales ($000's)	% change 1993-1994
Hip and knee implants	$1,308	+ 7.0%
Trauma devices	$643	+ 12.0%

U.S. 1994 Market $2.528 Billion

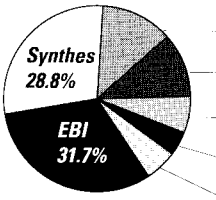
Trauma Devices



Internal fixation	$349	+ 15.9%
Spine	$164	+ 0.7%
External fixation	$66	+ 19.9%
Maxillofacial	$63	+ 16.8%

U.S. 1994 Market $643 million

External Fixation Devices



Manufacturer	1994 market share	Change 93-94
EBI	31.7	+ 3.2
Synthes	28.8	– 0.2
Smith & Nephew	12.5	– 3.0
Howmedica	11.1	– 0.7
ACE Medical	6.5	+ 1.3
Hand Biomechanics	4.2	+ 1.9
All other	5.3	– 2.4

U.S. 1994 Market $66 million

Source: IMS America

Yvonne Camper, formerly of Smith & Nephew Richards and Wright Medical Technology, Inc. served as technical advisor for this article

Meeting Highlights: Polyethylene, Outcomes, Costs

The 62nd annual AAOS meeting, held in Orlando in February this year, had over 26,000 participants. Mt. Sinai Medical Center of Cleveland and the Case Western Reserve University School of Medicine also sponsored a meeting entitled "Current Concepts in Joint Replacement" which provided a focused forum to discuss issues related to total joint implants. This year's December meeting was attended by over 700 participants. It is impossible to review, much less attend the thousands of papers, posters, scientific, and technical exhibits presented in both of these meetings. The main areas of interest reviewed by *ONN* this year included discussions of improving the wear and durability of polyethylene, measuring patient outcomes, and managing and measuring costs.

Improving Polyethylene

The wear of ultrahigh molecular weight polyethylene (UHMWPE) has been associated with implant loosening and failure. Failure of a polyethylene component means, at a minimum, that very small UHMWPE debris is released in the joint, initiating a biological cascade which can lead to bone resorption and implant loosening. Pain associated with loosening may require revision surgery. At worst, it means that the polyethylene component will break and will require a revision surgery, usually less successful than the initial surgery.

In order to minimize the deterioration of the polyethylene, implants have undergone a number of design changes. For example, the thickness of polyethylene has been increased in both the tibial inserts of knees and in acetabular liners. While at one point the philosophy was to minimize the amount of tibial bone removed which resulted in thin (ie. 5mm or less) tibial inserts, the current philosophy is to use thicker (at least 6mm) components to reduce the risk of fracture. Most manufacturers are also designing more congruent surfaces in which the roundness of the femoral component of the knee is matched more evenly with the tibial insert. Unfortunately, greater congruence may predispose the tibia to loosening as well.

Other patient related factors can also contribute to the deterioration of polyethylene such as patient weight and activity level. Patients who provide greater stresses on the polyethylene components are likely to have components which fail earlier.

Slab molded vs. Ram Extruded

There are several grades of UHMWPE resin in use in the US and a number of manufacturers convert the resin by either slab molding or ram extrusion. Thus, not all UHMWPE is initially the same, adding to the confusion. Nicholas Alexander, MD of the Johns Hopkins University School of Medicine presented "The Correlation of Acetabular Failure to Polyethylene Manufacturing Techniques in Total Hip Arthoroplasty." In it, he compared the clinical results of slab molded polyethylene to ram extruded polyethylene. Five times as many revisions were found with slab molded polyethylene, although the number of cases in each (68 ram and 21 slab) may preclude generalized conclusions.

The Great Sterilization Debate

A number of papers and exhibits dealt with the sterilization of UHMWPE. One paper which received significant attention was presented by Lauren Sutula, a member of Dr. John Collier's research group at Dartmouth, New Hampshire. She and her colleagues researched a "white band" below the surface of the polyethylene which was "significantly lower strength and ductility than the surrounding material in the component." The white band also "correlates significantly with clinical wear modes of cracking and delamination and can affect clinical performance." The white band only appeared after gamma sterilization of polyethylene components in air, and only after three years.

The conclusion that some manufacturers and physicians have made is that the gamma sterilization of polyethylene components should be discontinued and ethylene oxide sterilization should be used instead. Among the manufacturers at the AAOS meeting, both Wright Medical Technology, and Smith & Nephew Richards had begun to convert from gamma sterilization to ethylene oxide sterilization, and were actively promoting this feature. Joint Medical Products, after years of using ethylene oxide, had converted to gamma sterilization, and is now in the process of converting back to ethylene oxide.

Most sources contacted by *ONN* indicated that the sterilization problem is greatest for tibial inserts of knee implants, since there is greater stresses on this component than on others.

Before hospitals, physicians, or patients become overly concerned with the gamma sterilization issue, it should be realized that patients have had gamma sterilized implants for dozens of years. Many of the devices implanted by Charnley in the early 1960s were doubtlessly gamma sterilized, and many have had success over a considerable number of years. According to Seth Greenwald of Mt. Sinai Medical Center in Cleveland, "we have known for a long time that gamma sterilization of polyethylene components began a series of chemical processes which would deteriorate the polyethylene. Gamma sterilization has been used in the past since it is inexpensive and convenient from a manufacturing point of view. It should also be stated that gamma sterilization is one of several factors which will contribute to polyethylene implant failure. Others include voids in the polyethylene, its physical characteristics, the conformity of the materials, raw materials, and other factors." However, other researchers take a more cautious view, pointing out that, except in cases of extreme damage, there is no established correlation between measures of UHMWPE "quality" generated in a laboratory and clinical prognosis.

Some manufacturers have stated that an abrupt reaction to this issue may not be appropriate. According to one industry source, there have been concerns about residual ethylene oxide in packages and the fact that ethylene oxide is a suspected human carcinogenic agent. According to another source, "ethylene oxide may not be effective when sterilizing assemblies, since the gas may not be able to touch all of the parts." In addition to gamma irradiation and ethylene oxide expores, there are other sterilization alternatives, including reducing the amount of radiation in the gamma dose, solution sterilization, e-beam irradiation, plasma glow discharge, to name a few. Each has potential advantages and disadvantages but all share in common an absence of long-term patient outcome data.

Biomet researchers have demonstrated through laboratory studies that the way to reduce wear in polyethylene is to use compression molded polyethylene rather than extruded polyethylene, and sterilize it in an inert gas rather than in air. These are their Arcom™ components. DePuy has marketed their Hylamer™ polyethylene as a different type of raw material which should reduce wear as well. Many manufacturers contacted by ONN indicated that they were looking at alternatives to gamma radiation, but were not sure that they were going to ethylene oxide sterilization.

"...although gamma sterilization may cause some problems, it is unknown what problems may surface with ethylene oxide sterilization in the future."

The difficult issue for physicians, manufacturers, hospitals, and patients to deal with is that although gamma sterilization may cause some problems, it is unknown what problems may surface with ethylene oxide sterilization in the future. Since the research paper only identified white bands three years after the sterilization, it may take five or ten years to find out whether the switch to ethylene oxide has made any difference. Although there appears to be consensus that UHMWPE properties are altered by gamma radiation, no consensus has emerged as to whether this is good or bad, or whether the alternative, ethylene oxide, will improve patient outcomes. Furthermore the overwhelming excellent performance of gamma irradiated components in a wide range of hip and knee designs, with survivorship in some series exceeding 95% at 10 years, suggests the need for caution in making such global changes as adopting a new method of sterilization.

Nevertheless, it is likely that hospitals, physicians, and manufacturers will see more discussion, papers, research, products, and debate of this issue.

Outcomes Research

The topic of patient outcomes and outcomes research was prevalent both at the Mt. Sinai Medical Center's "Current Concepts in Joint Replacement" as well as the national meeting of AAOS. Many orthopedic manufacturers, surgeons, and software vendors have begun to offer products and services which are designed to help orthopedic surgeons and hospitals assess outcomes of patients.

Long-term Follow-up Studies

Two papers presented at the AAOS meeting were pushing the envelop as to long-term patient follow-up after hip implant surgery. Since hip implant surgery was in its infancy in the early 1970s, it is relatively rare to find studies of 20-year results. Augusto Sarmiento, Edward Ebramzadeh, Harry McKellop, Patricia Normand, Adolfo Llinas, and Stephanie Elkins reported on "Twenty-two Year Follow-up of Charnley Total Hip Replacements." They studied how 420 patients, originally implanted between 1970 and 1977 with a stainless steel Charnley hip, have fared since their implantation. They found that the cumulative risk of revision of the femoral stem at 18 years was between 3% and 11%. The risk of radiographic loosening of the acetabular cup was 54% at 18 years, although many were asymptomatic. Their conclusion is that the long-term radiographic and clinical performance of the cemented stainless steel Charnley prosthesis is as good or better than that of may modern designs, although they were disappointed that they did not achieve similar results with the Charnley cup.

Similarly, Steven Madey, John Callaghan, Jason Olejniczak, Devon Geotz, and Richard Johnston reported 320 patients who had total hips between July 1976 and June 1978 with a Charnley hip prosthesis and an all polyethylene cup ["Fifteen Year Follow-up of Charnley Total Hip Arthroplasty Using Second Generation Cementing Technique"]. Greater than 90% of all patients undergoing a total hip arthroplasty using a Charnley prosthesis and second generation cementing techniques retained their original prosthesis at the time of death or at a minimum of 15 years after their index procedure. It should be noted that the original Charnley hips, reported in this study, would be regarded as "low demand" prostheses, although, as has been demonstrated, their long-term survivorship is good.

Types of Outcome Measurements

In one paper, delivered by Cecil Rorabeck at the "Current Concepts in Joint Replacement" meeting, an analysis of different outcome instruments was presented. He discussed the difference between disease-specific outcome measures such as the Hospital for Special Surgery rating system or the Knee Society clinical and functional rating scores. Others which have been developed include the WOMAC which measures 23 dimensions in which the patient of patient activities.

Patient-specific outcome measures include the MACTAR. This instrument, which has been validated for hip implants but not for knee implants, allows the patient choose the disabilities most affected by his/her arthritis. Each patient chooses five activiites which are impaired by their arthritic knee. For example, a patient may state his reasons for having an artificial knee implanted include severe pain with walking, night pain, inability to go up or down stairs, difficulty with shoes and socks, and an inability to play golf. Those five parameters

would be studied at each follow-up visit at an attempt to assess how total knee arthroplasty has affected that outcome for that particular patient.

Global outcome measures such as the SF36 (Short-form 36) may be used to compare the outcomes of one type of disease intervention compared to another. For example, these instruments are used to see how patient general health is changed after total joint replacement compared to coronary bypass, for example.

Functional outcome measures such as the Six-Minute-Walk are useful as well. Each patient is asked to walk down a corridor of known length for a period of six minutes and the distance walked is recorded. This is a useful method of measuring functional improvement following total knee replacement. Similar functional measurements can also be designed using stair climbing, and other related activites.

Comparing Surgeons' and Patients' Evaluations of Surgical Procedures

In "Differences in Patient and Physician Evaluation after Total Hip Arthroplasty," Jay Lieberman, Frederick Dorey, Paul Shekelle, Lana Schumacher, Bert Thomas, Douglas Kilgus, and Gerald Finerman evaluated 147 total hip patients. Patients and physicians independently evaluated pain and satisfaction with the results of the surgery using a 10 cm analog scale. Of the 147 patients, 77% thought their surgery had substantially improved their quality of life, When comparing the mean pain rating (0 being no pain, 10 being severe pain) was 1.9 for patients, and 1.2 for physicians. The analog rating for the overall results (0 being poor and 10 being excellent) was 8.6 for the patients and 8.8 for the physicians. There were marked differences between patient's and physician's evaluations when patients noted moderate to severe pain, or when patients were dissatisfied or only somewhat satisfied with their result. For the forty-two patients with a pain rating greater than 2.0, the average pain rating for patients was 5.6 versus 3.0 for the physicians. The study suggests that physicians and patients may disagree with regard to the degree of pain and overall outcome, especially when the patient is not completely satisfied with the results.

"The study suggests that physicians and patients may disagree with regard to the degree of pain and overall outcome, especially when the patient is not completely satisfied with the results."

Cost Management

A number of papers dealing with cost issues in orthopedics were presented at this years AAOS meeting. This indicates a growing sensitivity on the part of orthopedic surgeons as to their vulnerability in a more competitive market place where managed care has made increasing inroads.

Do We Save Money by Decreasing Length of Stay?

Two papers dealt specifically with length of stay and total costs. "Does Early Hospital Discharge (Decreased Length of Stay) vs. Early Transfer to a Transitional Care Unit or Nursing Home Result in a Decrease in Direct Cost for Total Joint Arthroplasty," presented by Kathleen Killeen and Jack Bert, MD examined 971 primary total hip and knee arthroplasties performed in three hospitals in St. Paul, Minnesota between September 1992 and December 1993. Those patients who were discharged directly home with or without home health care had lower direct costs than those transferred to a transitional care unit or nursing home. Despite the emphasis on decreased length of stay for achieving cost containment, keeping the patient hospitalized for up to 7 days can result in lower total direct costs for total joint replacement compared to an early transfer to a transitional care unit or nursing home.

Another paper, "Analysis of Hospital Cost in Total Joint Arthroplasty: Does Decreasing Length of Stay Really Matter" presented by Steven Stern, MD, Lynn Singer, and Susan Weissman of Chicago, analyzed 30 hospital bills from 1992 through 1994. They found that the average length of stay for hip implants during this time decreased 31% (9.1 days to 6.3 days), and knee implants had a similar reduction. However, expenditures for total hips decreased only 7%. The reduction in length of stay was mainly attributable to decreased hospital room and nursing care costs, with the majority of the reduction coming from reduced fixed costs. Their conclusion was that it is necessary to decrease variable costs (i.e. implant and supply costs) to significantly cutback hospital expenditures.

Are Radiologists Needed for Orthopedic Xrays?

"Cost Burden of Radiologists' Interpretation of Orthopaedic X-rays in Total Joint Replacement," presented by Drs. Nayak, Rorabeck, Bourne, Mulliken, and Robinson of the University of Western Ontario, discussed a sensitive topic, both here in the U.S. as well as in Canada. They questioned the necessity and cost-effectiveness of the routine practice of radiologists interpreting x-rays of orthopedic patients undergoing total hip and knee replacements. They followed five hundred and sixteen consecutive cases of patients undergoing total joint replacement for one year. The pre-operative and post-operative interpretation of x-rays by the orthopedic and radiology departments were compared. The radiologists' interpretation of x-rays did not change the orthopedic management of any patient. The practice of double interpretation of the same x-rays did add to the overall hospital cost of patient management. The radiologists' interpretation of x-rays of those patients coming to revision surgery was less accurate than patients undergoing primary hip or knee replacement. The study concluded that the routine interpretation of orthopedic total joint x-rays by radiologists was redundant and not cost-effective.

Spinal Implant Costs

In "Lumbar Spine Arthrodesis: A Comparison of Hospital Costs Between 1986 and 1993," Drs. Thomas Parfenchuck, John Chambers, and Jacob Goodrich compare the costs of hospitalization of a two level lumbar fusion in 1986 and 1993 at Medical College of Georgia. Twenty patients were evaluated in both years; in 1986, average patient bills were $7,457, and in 1993, average patient bills were $19,712. Average length of stay decreased from 12 days in 1986 to 8 days in 1993. The most significant changes in the bills were that in 1986, the spinal implant was $300, but in 1986, the average implant was $2,967, operating room charges were $1,300 in 1986 and $6,765 in 1993, and surgeon fees in 1986 were $7,503 in 1986 and $8,338 in 1993.

Knee Implant Demand Matching

"Knee Implant Standardization: An Implant Selection and Cost Reduction Program," was presented by William Healy, Felix Kirven, Richard Iorio, Douglas Patch, and Bernard Pfeifer from the Lahey Clinic in Burlington, Massachusetts. They demonstrated the results of their approach to selecting implants for knee implant patients based on objective criteria. [The results of the Lahey Clinic's work on hip implants was reported in the April, 1993 issue of *ONN*]. They developed a patient scoring system for patient demand levels of I (highest demand) through IV (lowest demand). Patients are scored based on five variables of age, weight, activity, general health, and bone stock. Implants are classified based on cementless, cemented, and all polyethylene components. If the knee implant standardization program had been in place during 1992, the clinic would have saved 8.4% ($36,320) on knee implant purchases. The greatest potential savings were noted in Demand Category IV (i.e. the patients in the lowest demand category). If all patients in this category had received all polyethylene tibial components, the hospital would have saved 27% over what they actually spent in 1992.

Amendments and Corrections

The January 1995 issue of Orthopedic Network News described the added cost of polyethylene components designed to reduce wear of tibial, acetabular, and patellar components. In that issue, we state that in the case of Biomet, "Like Depuy, these components add several hundred dollars to the price of a prosthesis." Currently DePuy and Biomet offer both two types of polyethylene materials for their implant systems. DePuy offers Enduron™ as their standard product and enhanced Hylamer™ for higher demand applications . Biomet provides regular polyethylene and "premium" polyethylene products termed Arcom™.

	"Regular" Polyethylene	"Premium" Polyethylene	Difference
Cup liner			
Biomet	Ringloc part 105861 $538	Arcom Ringloc part 11-105861 $624	$86
DePuy	Duroloc® Enduron part 1241-08 $395	Duroloc® Hylamer part 1251-08 $735	$340
Tibial insert			
Biomet	AGC part 155608 $442	Maxim Arcom part 146110 $545	$103
DePuy	AMK Enduron part 1488-30 $550	AMK Hylamer part 1485-31 $920	$370

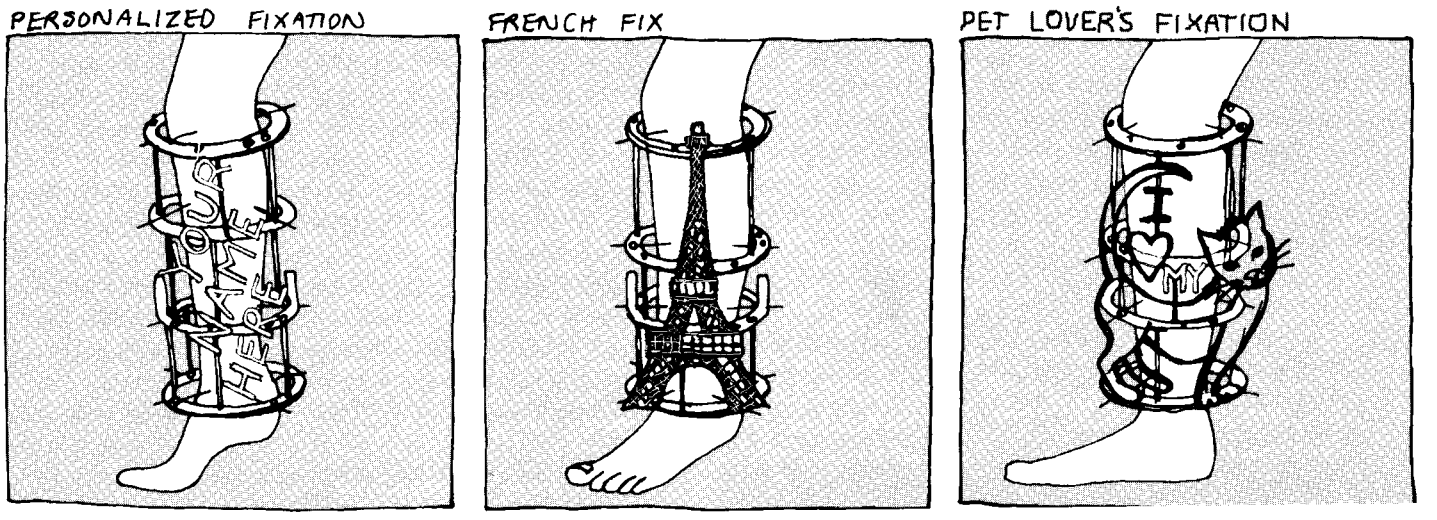
In DePuy's case, the Hylamer is a different molecular structure whereas with Biomet, the Arcom represents a different method of sterilization. In summary, the use of a DePuy hylamer polyethylene tibial insert or cup liner will add between $340 and $370 per case, while the use of a Biomet Arcom component will add $86 or $103 per case.

Network News Briefs

Zee Robertson, formerly senior market research analyst at Intermedics Orthopedics, has taken a position with VHA in Irving, Texas, as Therapeutic Market Manager, Orthopedics. She will be a member of the team which has responsibility for developing a national contract for hip and knee implants for the 800-hospital chain.

Approvals for the marketing of pedicle screws were obtained by both Sofamor Danek and Advanced Spinal Fixation. Sofamor Danek received 510(k) clearance on January 20 for pedicle screw attachment for severe spondylolisthesis or instability of the lumbar spine. Advanced Spine Fixation Systems received their 510(k) approval on February 14 to market their PLSA Titanium System. This clearance included pedicle screw attachment to the L3/L4/L5 vertebrae and is only "intended for patients having severe spondylolisthesis of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine; and who are having the device removed after development of a solid fusion mass."

External Fixation as Fashion Statement



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