FDA Public Health Web Notification*:
Complications Related to the Use of Bone Cement and Bone Void Fillers in Treating Compression Fractures of the Spine

Updated: May 7, 2004

Original Publication: October 31, 2002

Purpose of this update

This notification originally advised the health care community that there had been serious complications from the use of acrylic bone cements in treating compression fractures of the spine, an indication for which these products had not been cleared. The notification has now been expanded to include all forms of bone cements and bone void fillers. Surgeons should also note that on April 1, 2004 a bone cement was cleared by the FDA for the treatment of pathological fractures of the vertebral body due to osteoporosis using a kyphoplasty procedure. There may be other products cleared for this purpose in the future. To check for bone cements and bone void fillers cleared for such use, go to the FDA 510(k) database search at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Enter Product Code NDN. The database is updated as new products are cleared.

The information in the remainder of this notification applies to all bone cements (polymethylmethacrylate and calcium phosphate) and bone void fillers that are not specifically cleared and labeled for vertebroplasty or kyphoplasty, two techniques used to treat spinal compression fractures. These products will still require clearance before they can be marketed for this use.

Complications with bone cements and bone void fillers

Leakage of bone cements can result in soft tissue damage as well as nerve root pain and compression. Other reported complications generally associated with the use of bone cements in the spine include pulmonary embolism, respiratory and cardiac failure, abdominal intrusions/ileus, and death. Each of these types of complications has been reported in conjunction with use of these products in both vertebroplasty and kyphoplasty procedures.

Reported complications associated with the use of bone void fillers in the spine include pulmonary embolism, respiratory and cardiac failure, and death. Bone void fillers are cleared for use only in non load bearing applications. Under ideal conditions, these bone void fillers resorb over time and are replaced with new bone growth. Bone growth in osteoporotic patients or in load bearing applications (e.g. a vertebral compression fracture) has not been adequately studied to support marketing applications.

Advice for physicians

Physicians should follow the labeling when using bone cement cleared by FDA for

vertebroplasty or kyphoplasty. Physicians who are considering vertebroplasty or kyphoplasty using bone cements and bone void fillers that are not cleared by FDA for this purpose should be especially attentive to patient selection, treatment techniques, potential complications, and patient monitoring. They should also be aware of the literature in this area, as well as recommendations from professional organizations.

Because more study would be beneficial, we are currently working with professional organizations and manufacturers of orthopedic devices to develop a basis for evaluating the safety and effectiveness to support equivalence of different or new formulations of bone cements and different or new bone void fillers used to treat compression fractures of the spine.

Historical background

According to the National Osteoporosis Foundation, about 700,000 vertebral fractures occur annually; approximately 270,000 of these fractures are painful and clinically diagnosed. Most patients are treated non-operatively, but some do not respond to conservative treatment and are left with persistent pain and limited mobility. These patients are potential candidates for vertebroplasty or kyphoplasty procedures, two invasive procedures that use bone cement or bone void fillers to treat spinal compression fractures.

Vertebroplasty and kyphoplasty procedures mainly differ based on surgical technique. The differences in surgical technique, along with surgeon preferences, can affect the selection, modification, and application of bone cements and bone void fillers.

Vertebroplasty, developed in the 1980s, involves the percutaneous injection of a mixture of bone cement and a contrast agent, typically barium sulfate, into the vertebral bodies using fluoroscopic or computed tomography guidance, or both. Early vertebroplasty procedures were primarily performed to alleviate pain and to stabilize fractured bone in patients with hemangiomas, malignant metastases, or other types of tumors of the spine.

Kyphoplasty, developed in the 1990s, involves introducing a surgical instrument into the compressed vertebral body, with the intent to elevate or expand the fractured vertebra to its original shape. Once this instrument is withdrawn, the space created is then filled with bone cement or a bone void filler mixture. By reducing and fixing the fracture in this way, kyphoplasty procedures may correct deformity, restore body height, or both.

Bone cements have been used for many years for the fixation of metal and plastic prostheses in joint replacement and less frequently in the fixation of pathological fractures. Existing bone cements and bone void fillers designed for uses other than the treatment of spinal compression fractures are generally modified for this use. Modifications to bone cements and bone void fillers may vary from physician to physician and among procedures. These types of modifications may include increasing the amount of contrast agent to improve x-ray visualization and changing the consistency and handling properties to address procedural goals (including changing the method of preparing the cement without altering its ingredients). To date, there are no standardized

formulations, biomechanical standards or safety guidelines for methods of preparing or modifying bone cement or bone void filler for use in the spine.

Reporting Adverse Events to FDA

The FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices, including bone cements and bone void fillers. We request that you follow the procedures established by your facility for such mandatory reporting.

We also encourage you to report any malfunctions of the bone cements, bone void fillers, or their ancillary equipment. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch one of four ways: online at http://www.accessdata.fda.gov/scripts/medwatch/; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

FDA Contact

Nancy Pressly
Issues Management Staff
Office of Surveillance and Biometrics (HFZ-510)
1350 Piccard Drive, Rockville, Maryland, 20850
Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov.

Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html.

Sincerely yours,

Daniel G. Schultz, MD
Acting Director
Center for Devices and Radiological Health
Food and Drug Administration

[*] CDRH Web Notifications are intended to augment the existing Safety Notification program by providing a mechanism to quickly disseminate device–related safety information that may be beneficial to healthcare providers. Unlike other forms of Notifications, such as Safety Alerts or Public Health Advisories, Web Notifications usually do not make specific recommendations and are typically used in situations where the available information and our understanding of an issue are still evolving.