Medical Device Incident Investigations: Recommendations

The IRIS Statistics Report for 01/10– 31/12/2002 is on the TGA website
<www.health.gov.au/tga/docs/html/tganews/news40/tganews40.htm>

Complications related to the use of bone cement in Vertebroplasy and Kyphoplasty procedures

Problem

The FDA has issued a Public Health Notification about reports related to the use of polymethylmethacrylate bone cement to treat osteoporotic compression fractures of the spine. The FDA has received a number of reports describing complications such as soft tissue damage and nerve root pain and compression, which relate specifically to leakage of bone cement. Other reports relate to reactions to the bone cement such as pulmonary embolism, respiratory and cardiac failure and death.

The TGA has also received a report of a death possibly related to the use of bone cement on a patient having a vertebroplasty.

Vertebroplasty and Kyphoplasty are used to treat osteoporotic compression fractures in patients where conservative treatment has failed. These procedures are relatively new with no prospective, randomised, controlled trials to describe its long term safety or effectiveness.

The bone cement used in these procedures was modified by increasing the amount of contrast agent and changing the handling properties. The effects of these modifications on the spine are not well documented.

Recommendations

This article is intended to inform clinicians contemplating these procedures so that they are informed about adverse events associated with the procedure.

The TGA encourages users to report all adverse events related to the use of bone cement to the TGA's Medical Device Incident Report Investigation Scheme (IRIS) and to the supplier of the user's bone cement.

Sourced from: FDA Public Health Web Notification.

Femoral Stem Fractures in Zimmer Modular Revision (ZMR ®) Hip Systems

The ZMR® Hip System is specifically designed for revision hip surgery. The femoral component of the ZMR® system comprises three modular components: the stem, the body and the femoral head. The stem is available in several lengths. The body is available in several geometries (cone, spout, calcar, taper) each with its own size/geometry variations. This provides a great degree of surgical flexibility.

Since the introduction of the system in 1999, Zimmer has sold in excess of 8000 ZMR® units worldwide. However, Zimmer has received 21 reports of stem failure, 19 of these have been with the taper body. To date, 1 failure has been reported in Australia out of 254 units implanted.

	All Bodies	Taper Bodies Only	Other Bodies Only (Calcar, Spout, Cone)
# Fractures reported (global)	21	19	2
Sales (global)	8710	4189	4521
Incidence	0.24%	0.45%	0.044%

Analysis of the failures by Zimmer indicates that the predominant failure mode is fatigue fracture of the stem at the proximal end, which is usually associated with inadequate proximal bone support of the prosthesis. According to Zimmer, some surgeons did not successfully obtain proximal bone support with the taper style of body. As a result higher loads than those the device was designed for may have been applied to the stem/taper body junction resulting in fracture of the proximal stem.

In March 2002, Zimmer issued a safety alert, which highlighted the importance of bone support and surgical technique. As a further precaution, Zimmer has now halted the distribution and sale of the proximal taper body and has withdrawn unimplanted product. The products affected are described below.

009992-075-45 -ZMR 75mm Taper Body Large Junction Extended Neck
009992-085-45 -ZMR 85mm Taper Body Large Junction Extended Neck
009992-095-45 -ZMR 95mm Taper Body Large Junction Extended Neck
009992-075-40 -ZMR 75mm Taper Body Large Junction Standard Neck
009992-085-40 -ZMR 85mm Taper Body Large Junction Standard Neck
009992-095-40 -ZMR 95mm Taper Body Large Junction Standard Neck

According to Zimmer Australia, all unimplanted taper bodies in Australia are accounted for.

Zimmer will continue to sell and distribute other ZMR System components as it is thought that proximal bone support can be more easily provided when bodies of these other geometries are used. Zimmer, the TGA and other regulatory agencies, such as the UK MDA, will continue to monitor the performance of these other components.

Recommendation

1. Even if the ZMR taper body is not used, proximal bone support is extremely important in all Type IV hip revisions (using the Allan Gross Revision Classification System).
2. For patients implanted with products with the catalogue numbers listed in this article, consideration should be given to counselling regarding the risk of implant facture, particularly if proximal bone support was not possible or is being resorbed.

For further information contact Mr Michael Schaffler,
Zimmer Australia, (02) 9950 5400.

Update on High Flow Fluid Warmers

The TGA has received several reports of deaths or serious injury to patients due to intra-vascular air embolisms associated with the use of high-flow fluid infusers/fluid warmers.

These devices are generally used in emergency situations. It is believed that, in most of the incidents, the injury has resulted from re-attachment of partially-exhausted fluid bags to the system. The bags contained significant volumes of air as a result of the handling and storage associated with detachment and re-attachment. This large volume of air is generally not present in a correctly handled fresh bag of solution when it is first attached to the infusion device. It is also believed that the likelihood of occurrence is higher when high flow consumables are being used.

In January 2002, after consultation with, and in cooperation with, the TGA, all sponsors of these devices issued a Safety Alert to remind users of the risks of introducing air into these systems and the possible consequence of serious injury to patients connected to these systems. The recommendations read as follows:

- REMOVE ALL AIR from fluid bags and lines before connection to patients;
- FOLLOW appropriate instructions for PRIMING the infusion line and set; and
- MONITOR fluid lines to ensure that they are free of air.
- DO NOT open ports in the infusion system, unless appropriate measures are in place to prevent the entry of air.
- DO NOT reconnect partially emptied fluid bags — significant volumes of air may be sucked into the bag when disconnected.
- DO NOT use auto-transfusion bags with these systems, unless the infuser is clearly indicated for this use.

In response to continuing concern from the TGA regarding air embolism, Level 1 Incorporated has developed a new device: an air detector/clamp. The device stops the flow of fluid when air is detected in the fluid lines from the warmer and is designed to be compatible with all existing Level 1 high flow fluid warmers.

In November 2002 all existing users of Level 1 High-flow fluid warmers were notified of the availability of the new device and the additional safety features that it offers. The notice also provided a reminder of the procedures to be followed when using these devices. While this detector/clamp will assist in the detection of air it is still important to be vigilant and that the manufacturer's instructions for use of the device are followed.

Further information may be obtained from Smiths Medical Australasia on 1800 654 949.

Recommendation

Ensure that you have received the Safety Notice dated November 2002 from Smiths Medical Australasia about the Level 1 warmer and that this has been distributed to all appropriate staff in your facility.

The use of air-in-line detectors is recommended in all rapid infusion situations, particularly when High Flow rate consumables are being used.

Syringes used with the Lieble Flarsheim Angiomat Power Injectors

The TGA received a report of leakage from syringes when they were used in combination with Liebe Flarsheim Angiomat Power Injectors to inject contrast solution. The syringe had been loaded on the injector and then filled with contrast solution. The injector head was tipped vertically to expel any air. The user found that about 5-6mls of solution was leaking around the plunger and contaminating the syringe barrel and injector head. The consequences of this leakage is contamination of the injector head which will require extensive cleaning between uses and contact with the contrast medium by the user.

Closer investigation of this problem revealed that the procedure used to fill and deliver the contrast medium was incorrect. The syringes had been changed from a hard tip to a soft tip. As a result, a slightly different procedure was needed when loading the syringe.

Recommendation

When preparing contrast medium injection it is recommended to take the following precautions.

- The syringe should not be over filled.
- When the contrast medium is removed from the box the syringe should be filled straight away.
- The contrast medium will expand as it is warmed up to room temperature so a small air gap should be left to allow for this expansion.
- The tip cover should not be placed back on the syringe too tightly.

The sponsor is conducting servicing at the hospitals that have been having this problem.

Zimmer Harris Gallante (HG) polyethylene liner dissociation

The Bioengineering Division of Royal Perth Hospital has sent a report to the TGA regarding continuing problems with Zimmer Harris Gallante (HG) acetabular shells and liners. The group is concerned about the large number of retrieved dissociated HG liners that have been referred to their laboratory. They conclude that liner dislocation caused by failure of the locking mechanism of the shell due to bent or broken tines continues to be a major concern.

The problems with HG acetabular components have been known for some time and much has been published about them. The shell is made of titanium alloy and has a layer of titanium fibre mesh for bone ingrowth. The locking mechanism consists of 3 pairs of titanium tines situated on the rim and lock into the circumferential slot in the liner. Later modifications (HG-II) included a thicker shell, larger screw holes, and increased number of locking tines, dependant on the size of the shell. Despite the design modifications, the implant suffers from significant micro-motion compared to other designs, leading to a greater incidence of liner backside wear, slippage and subsidence. Zimmer stopped supplying the HG cups when they introduced the Trilogy series of implants, but HG polyethylene liners continue to be available for revision purposes. The Bioengineering Division at Royal Perth Hospital is still receiving a significant number of dissociated liners, raising concern that new liners are placed in shells with broken or bent tines and this may lead to early re-revision. It may be that thorough examination of the tines *in situ* is not being performed routinely at revision or, alternatively, subtle damage may be difficult to assess.

During our investigation, the TGA considered recommending that Zimmer cease supply of the HG liners also. However, orthopaedic experts have advised against this measure, as this would prevent surgeons using liner-only replacement in situations when there is no better clinical choice. The issue is that removal of both the liner and the acetabular shell causes considerably more trauma than simply replacing the liner alone.

Recommendation

Where at all possible it is recommended that, for HG revisions, both the shell and the liner be replaced. Zimmer has designed a special tool to remove HG shells while minimising trauma. If removal of the shell even with the use of this tool is undesirable, then Zimmer recommends considering cementing the new liner into place.

For further information contact Mr Michael Schaffler,
Zimmer Australia, on (02) 9950 5400.

General References: Implant Technology and Biomaterials Bulletin Nos 1&2 (2002) – Bioengineering Division, Royal Perth Hospital.

Handles on Siemens SC 900 XL Patient Monitors

The Victorian Coroner asked the TGA to investigate a device-related death in one the State's hospitals. "A Siemens SC 900 XL Patient Monitor was being removed from a patient's bed over the patient's head, when the monitor's handle broke. The monitor hit the patient's head which caused serious head injuries leading to the death".

The TGA examined this monitor's handle and the pattern of fracture of the handle appears to be a stress fracture. Independent examination by NSW University confirmed this opinion.

As a result of this investigation the manufacturer issued a Safety Alert with the following warning:

> "When the weakened handle is used to transport or move the monitor, the handles may break resulting in possible dropping of the monitor. Always use caution when carrying monitors to ensure no damage or injury is done should the handle material be weakened under normal carrying mode**. Do not carry the monitor directly over patients.**
>
> New SC7000 and SC9000XL monitor handles have been developed and released as a spare part, number 7264406E539U and 7264422E53U. These handles have hooks built in and are made of a more durable polymer (polyamide glass fiber filled).
>
> To verify whether your monitor handles are of the old or newer type of polymer there are two observable differences:
>
> i. The struts of the old handles are grey with a slight marbled appearance. The struts of the new handles are of a solid grey.
> ii. The raised surfaces at the top of the struts along the sides near the handles have been removed from the new handles.
>
> If uncertain, contact your Siemens Service Representative. If it is confirmed that the handles are of the original version you will receive replacement handles at no charge."

Recommendations

- Check that your Siemens patient monitor is fitted with the upgraded handles.
- Never carry anything over the top of a patient.

Update on Gemstar Infusion Pump Sets

There have been a number of reports to the TGA relating to free flow of Gemstar pump sets. The sets feature free flow protection, but this can be disabled if one of several steps in the set up procedure is performed incorrectly. The TGA has noted that some of the steps that users have performed incorrectly are:

1. The anti-syphon valve is removed to prime the set and this valve is not replaced once the set is primed. This problem only occurs with the Gemstar general purpose set. The Gemstar patient controlled analgesia (PCA) and epidural sets do not have a removable anti-syphon valve.
2. The PCA set has a Y-extension which has the anti-syphon valve on one arm and an anti-reflux valve on the other arm. Some users have connected the distal tube on the cassette to the arm that has the anti-reflux valve, not the anti-syphon valve.
3. The cassette was not placed into the pump correctly and the flow control switch was not set to "stop" or "off" after priming.

Future enhancements to the pump and set

Abbott will be improving the pump and sets in an attempt to alleviate the problem of free flow. The PCA set is being redesigned so that it is physically impossible to connect the cassette to the wrong side of the Y. These sets will be available by about May 2003.

The pump software is also being revised. This revision will enable the pump to check for the presence and correct placement of the cassette when the pump is switched on. The pump will alarm and will not be able to be programmed until the cassette is correctly placed.

Recommendations

1. Do not remove the anti-syphon valve unless it is unavoidable. If the valve is removed, other checks should be used to prevent free flow, such as correctly seating the cassette into the pump, setting the flow control to stop or off and ensuring that the slide clamp on the distal tube is open while a check of the connections is carried out prior to connecting the set to the patient. Leaving the slide clamp open will ensure that any free flow will be detected prior to connection to the patient.
2. When setting up the PCA set check that the cassette is connected to the correct arm of the set.

Look out for product upgrades in the near future. Abbott will advise when these are available directly.