

Unretrieved Device Fragments - the clinical risk of using poor quality surgical instruments

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Abstract

The US Food and Drug Administration (FDA) has published a Public Health Notification advising on serious adverse events arising from fragments of medical devices left behind after surgical procedures, known as unretrieved device fragments (UDFs). There are many risks from UDFs including local tissue reaction, infection, perforation and obstruction of blood vessels and death.

One major source of UDFs is from surgical instrument failure. At Barts and The London NHS Trust, we receive a large number of poor quality newly purchased surgical instruments, with 10% of instruments failing Quality Assurance (QA) in the first 6 months of 2009. Many surgical instruments have manufacturing faults which can result in fragments becoming detached and entering the patient during surgery.

It is assumed that all hospitals in the UK receive the same quality of instruments as Barts and The London NHS Trust. However, it is unknown whether QA of surgical instruments is being carried out widely. Every hospital needs to ensure that they use good quality surgical instruments to minimise the risk to patients when undergoing surgical procedures.

This paper reviews clinical risks from the use of poor quality surgical instruments, examines how instruments fail and proposes how these risks can be minimised.

Introduction

In January 2008, the US Food and Drug Administration (FDA) published a Public Health Notification advising on serious adverse events arising from fragments of medical devices left behind after surgical procedures, known as unretrieved device fragments (UDFs). The FDA's Centre for Devices and Radiological Health receives nearly 1000 adverse event reports each year related to UDFs.^{1,2}

One major source of UDFs is from surgical instrument failure.³ The following are reported examples of surgical instruments breaking and leaving behind fragments in patients:

- A 56-year-old woman had surgery on the temporomandibular joint. In the 10-year period after surgery she suffered pain, tinnitus and restricted mouth opening and a 4mm metallic foreign body was subsequently removed. The foreign body was most probably a fractured tip of a surgical awl which had been left behind in the original surgery.⁴
- A small metal fragment disassociated from an arthroscopic instrument and remained inside a patient's knee joint for 14 months, causing recurrent swelling and pain.⁵
- Conway *et al.* (1999) report that it is a well known complication of oral surgery that surgical instruments may fracture. Fragments can subsequently be lost with the possibility of ingestion, inhalation or embedding into adjacent soft tissues.⁶

In this paper we will review clinical risks from UDFs, examine how poor quality causes surgical instruments to fail and propose how these risks can be minimised.

Clinical Risks from Unretrieved Device Fragments

There are many risks from UDFs. The FDA state: "The adverse events reported include local tissue reaction, infection, perforation and obstruction of blood vessels, and death. Contributing factors may include biocompatibility of the device materials, location of the fragment, potential migration of the fragment, and patient anatomy. During MRI procedures, magnetic fields may cause metallic fragments to migrate, and radiofrequency fields may cause them to heat, causing internal tissue damage and/or burns."¹

If fragments of surgical instruments are left in the body, they have the potential to cause an embolism. A foreign body embolism occurs when an object travels through the bloodstream and obstructs a blood vessel in another part of the body. This restricts the flow of vital oxygen and nutrients to the tissue and can result in a number of clinical problems including pulmonary embolism, stroke or death.⁷⁻¹¹ In addition, it has been known for foreign bodies to migrate through soft tissue into the venous system.⁹

A foreign body granuloma is an inflammatory mass of tissue that accumulates around the embedded fragment as the immune system attempts to engulf the foreign body.¹² If this enters the bloodstream, an embolism can occur with serious consequences to the patient.¹³ Even small particles have the potential to block critical vessels.

Foreign bodies can also lead to a wide range of clinical problems including peritendinitis, acute nerve lesions, post-traumatic neuromas and neuropathies. Long term retention of foreign bodies has also led to the onset of tumours.⁷ In addition foreign bodies may give rise to adhesion formation,

hypersensitivity, abscesses, carbuncles, cysts,¹² the formation of gallstones,¹⁴ fibrosis⁹ and metal allergy.^{4,15} Particles in surgical wounds can disrupt the immune system's defences, increasing the likelihood of infection.¹² There is also evidence that embolic metal particles in the brain may cause epileptic seizures.¹⁶ Ferromagnetic material present in the body during MRI scans has resulted in instances of fatality¹⁷ and blindness.¹⁸

Metallic implant material needs to be biocompatible, i.e., not exhibiting any toxicity to the surrounding biological system.¹⁹ Steel that is designed to be implanted in patients is made out of austenitic steel, however most surgical equipment is made out of martensitic steel. Surgical instrument steel is therefore not intended to be implanted in the human body.

If corroded metal enters the patient there are a number of biological reactions. Corroded stainless steel releases iron, chromium and nickel ions which are powerful allergens and carcinogens.¹⁹ Other effects include neurological symptoms and cellular toxicity²⁰.

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Causes of Surgical Instrument Failure

There are various reasons why surgical instruments fail. Brophy *et al.* (2006) carried out a study of 4800 instruments between January and June 2004 and 15% were found to have problems.²¹ Typical faults found were gaps left from poor soldering, burrs, corrosion & poor surface finish.

Corrosion can result in fragments of the instrument becoming detached and entering the patient during surgery.²¹ Stainless steel surgical instruments are made from corrosion resistant high-grade steel. The manufacturer forms a 'passive oxide layer' on the surface through the process of passivation, which protects them against corrosion. However this layer doesn't make the instruments corrosion proof and the passivating oxide film can break down under unfavourable conditions.¹⁹

All surgical instruments go through a decontamination process which removes blood and tissue. However, decontamination is only effective on good quality instruments with smooth surfaces. Blood and tissue will be more difficult to remove from rough surfaces, burrs or crevices. In these cases, blood may remain on the instrument after the decontamination process.²¹ **Figure 1** shows artery forceps which have been through the decontamination process. Dried blood can clearly be seen trapped by burrs on the jaws. Blood contains chloride ions, which are highly reactive and cause corrosion if allowed to remain on the instrument.^{19,22,23}



Figure 1: Artery forceps with dried blood remaining on jaws after decontamination

Figure 2 shows a new pair of surgical scissors with a fractured screw head. Blood can get trapped in the fracture which may not be removed by the decontamination process. The retained blood may corrode the instrument and there is a risk that a screw fragment may become detached and enter the patient during surgery. Instruments with missing screw heads are sometimes found in theatres and an investigation has to be carried out to try and locate the missing metal fragments. This can result in unnecessary X-rays and surgery for the patient.

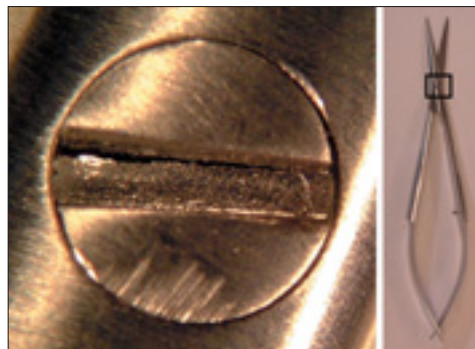


Figure 2: Newly purchased scissors with fractured screw head

Another cause of surgical instrument failure is poor soldering of tungsten-carbide inserts. **Figure 3** shows a pair of wire holding forceps with a poorly soldered insert. The lack of solder reduces the support for the insert and could result in it fracturing when used in surgery. Alternatively the whole of the insert may become detached from the main body of the forceps.



Figure 3: Wire holding forceps with poorly soldered insert

Burrs are a hidden danger and are commonly found on various surgical instruments.²¹ These occur when the manufacturer's machining process has not smoothed off rough edges. They may become detached through mechanical wear and be deposited in a surgical wound. British Standards require surfaces of surgical instruments to be smooth.²⁵⁻²⁷ A long burr measuring 15mm can be seen quite clearly on the infant retractor in **Figure 4** and there is a risk that this will shear off.

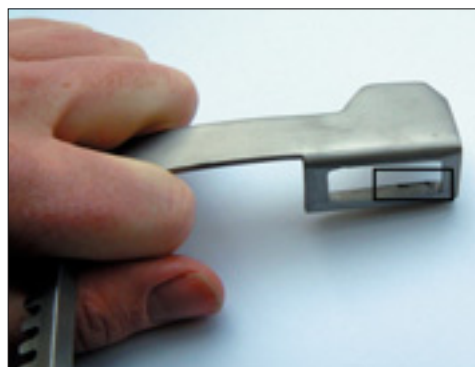


Figure 4: Infant retractor with burr

Figure 5 shows an adult Ross ventricular vent which is used for perfusion. The vent is attached to a heart/lung bypass machine which drains the blood from the chambers of the heart, filters it and feeds it back into the bloodstream. Burrs are clearly visible to the naked eye and these could become dislodged and end up in the bloodstream.

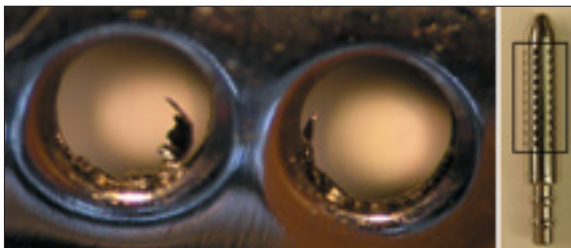


Figure 5: Ross ventricular vent with burrs

The quality of the surgical steel is also of importance. Surgical instruments are manufactured through ‘cold working’, i.e. shaping of the stainless steel which adds strength and hardness. However, this causes internal stresses and instruments should subsequently undergo stress relief through heat treatment. If this doesn’t happen, corrosion can instigate stress corrosion cracking.^{22,23} An example of this on Spencer-Wells artery forceps is shown in **Figure 6**. Trapped blood is visible within the fracture and this is likely to accelerate the corrosion further.

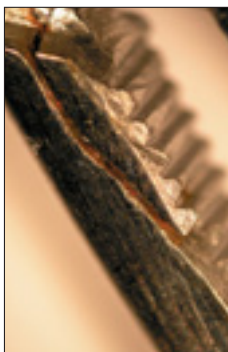


Figure 6: Spencer-Wells artery forceps with stress corrosion cracking

Some surgical instruments suffer from poor surface finish. As stated earlier, surgical instruments are protected against corrosion through the process of passivation. However, if this process is not carried out to a sufficient degree, corrosion will result. For example, **Figure 7** shows a brand new Desmarres corneal knife where corrosion is clearly visible. This will undoubtedly lead to additional corrosion.



Figure 7: Newly purchased Desmarres corneal knife with corrosion

Reducing the Risk

In 1998, a needle holder was discovered in a Barts and The London NHS Trust theatre with a missing insert. The insert was located in a patient following an X-ray scan and further surgery was needed to remove it. The hospital’s Clinical Physics department was asked to investigate and faults were found with a number of newly procured needle holders. Subsequently the Surgical Instruments Service was developed which carries out Quality Assurance (QA) checks on newly purchased surgical instruments. Recent figures indicate that some manufacturers are continuing to sell substandard instruments, with 10% of instruments failing the QA in the first 6 months of 2009.

Newly purchased surgical instruments are tested to ensure they meet International and British Standards.²⁴⁻³⁰ Instruments are subjected to a range of tests, for example **Figure 8** shows a Mayo needle holder undergoing a suture test. All instruments are visually inspected with the naked eye and an eye glass – see **Figure 9**. For instruments with a tungsten carbide insert, inspections are carried out using an Olympus SZ61 microscope – see **Figure 10**. An Olympus C-5060 digital camera is used to capture images as appropriate.



Figure 8: Mayo needle holder undergoing suture test



Figure 9: Dissecting forceps inspected using eye glass



Figure 10: Mayo needle holder viewed through a microscope

A database has been developed which is used to store all surgical instrument data. Statistics are collated enabling performance comparison between suppliers. This has enabled Barts and The London NHS Trust to analyse the QA data and to differentiate between good and under performing suppliers.

Conclusion

The FDA report that every year there are many serious incidents arising from fragments of medical devices left behind after surgical procedures. At Barts and The London NHS Trust we receive a high percentage of poor quality surgical instruments with manufacturing faults and believe that these are a significant contributing factor in such incidents.

At the present time, not all manufacturers are providing good quality instruments. Manufacturers need to ensure that the instruments they sell meet British and International Standards and do not needlessly endanger patients.

It is assumed that all hospitals in the UK receive the same quality of surgical instruments as Barts and The London NHS Trust. However, it is unknown to the authors whether Quality Assurance of surgical instruments is being carried out widely. The FDA recommends inspection of devices prior to use.¹ Every hospital needs to ensure that they use good quality surgical instruments to minimise the risk to patients when undergoing surgical procedures. ■

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References

- (1) FDA Public Health Notification: Unretrieved Device Fragments. 2008 (www.fda.gov/MedicalDevices)
- (2) Fischer R. Danger: Beware of Unretrieved Device Fragments. *Nursing* 2007; 37: 17
- (3) Top 10 Health Technology Hazards. Health Devices November 2008 (www.ecri.org)
- (4) Persson S, Gjerdet R and Tornes K. Metal fragment in the temporomandibular joint: a case report. *Int. J. Oral Maxillofac. Surg.* 2003; 32: 653-655
- (5) Oldenburg M and Mueller R. Intra-articular foreign body after arthroscopy. *J. Arthr. Rel. Surg.* 2003; 19: 1012-1014
- (6) Conway D and Fyfe E. Fractured surgical instruments located using radiographs of the suction bottle. *Brit. J. Oral Max. Surg.* 1999; 37: 113-114
- (7) Callegari L et al. Ultrasound-guided removal of foreign bodies: personal experience. *Eur. Radiol.* 2009; 19: 1273-1279
- (8) Ammann K et al. Embolism of a Metallic Clip: An Unusual Complication following Laparoscopic Cholecystectomy. *Dig. Surg.* 2000; 17: 542-544
- (9) Kones R and Phillips J. Foreign Body of the Heart Complicated by Papillary Muscle Necrosis Located by Echocardiology. *Chest* 1972; 62: 52-57
- (10) Mohr J, Lazar R, Marshall R and Hier D 2004 *Middle Cerebral Artery Disease Stroke: Pathophysiology, Diagnosis and Management* ed J Mohr et al (Churchill Livingstone) pp 123-66
- (11) Caplan L 2006 *Embolism Materials Brain Embolism* ed L Caplan (Informa Healthcare USA, Inc.) pp 259-88
- (12) Truscott W. Patients, Particles, Pathology & Pathogens: The Infection Connection. *Managing Infection Control* March 2009: 94-97
- (13) Truscott W. Lint and Particle Contamination during Diagnostic and Interventional Procedures in the Cardiac Catheterization Lab. *Cath. Lab. Digest* 2006; 14: 10-19
- (14) Atwell A and Hawes R. Surgical clip migration and choledocholithiasis: a late, abrupt complication of laparoscopic cholecystectomy. *Dig. Dis. Sci.* 2007; 52: 2254-2256
- (15) Takazawa K et al. Metal allergy to stainless steel wire after coronary artery bypass grafting. *J. Art. Org.* 2003; 6: 71-72
- (16) Naumann M, Hofmann E and Toyka K. Multifocal brain MRI hypointensities secondary to embolic metal fragments from a mechanical heart valve prosthesis: A possible source of epileptic seizures. *Amer. Acad. Neur.* 1998; 51: 1766-1767
- (17) Klucznik R, Carrier D, Pyka R and Haid R. Placement of a ferromagnetic intracerebral clip in a magnetic field with a fatal outcome. *Radiology* 1993; 187: 855-856
- (18) Kelly W et al. Ferromagnetism of intraocular foreign body causes unilateral blindness after MR study. *Am. J. Neuroradiol.* 1986; 7: 243-245
- (19) Hansen D. Metal Corrosion in the Human Body: The Ultimate Bio-Corrosion Scenario. *The Electrochemical Society Interface*. Summer 2008: 31-34
- (20) del Rio J, Beguiristain and Duart J. Metal levels in corrosion of spinal implants. *Eur. Spine J.* 2007; 16: 1055-1061
- (21) Brophy T et al. Quality of Surgical Instruments. *Ann. R. Coll. Surg. Engl.* 2006; 88: 390-393
- (22) Proper Maintenance of Instruments. 8th Edition. Morfelden-Waldorf:AKI, 2004 (www.aki.org)
- (23) Braun: A Guide to Surgical Instruments 1996
- (24) BS EN ISO 7153-1:2001, BS 5194-1:1991 Surgical Instruments. Metallic materials. Stainless steel.
- (25) BS 5194-2:1989 Surgical Instruments. Specification for instruments with pivot joints (excluding cutting instruments)
- (26) BS 5194-3:1985 Surgical Instruments. Specification for dissecting forceps
- (27) BS 5194-4:1985 Surgical Instruments. Specification for scissors, shears & other jointed cutting instruments
- (28) BS EN 27740:1992, ISO 7740:1985 Specification for dimensions of surgical scalpels with detachable blades
- (29) BS 3531-5.1:1997, ISO 8319-1:1996 Implants for osteosynthesis. Bone screws and auxiliary equipment. Specification for keys for use with screws having heads with hexagon socket
- (30) BS 3531-5.2:1990, ISO 8319-2:1986 Implants for osteosynthesis. Bone screws and auxiliary equipment. Specification for screwdrivers for screws having heads with single slot, cruciate slot or cross-recess

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