Tom Brophy - Lead Technician

Quality Assurance of New Surgical Instruments

Paul Srodon - Surgeon
Phil Daly - Scientist
Malcolm Birch - Clinical Physics Director
Specialist Work Undertaken

- NHS Patient Safety Action Team London
- Medicines and Healthcare products Regulatory Agency
- NHS Supply Chain
- University of Bedfordshire
  Peri-operative Critical Care Team
The Beginning - Mayo Needle Holder
Quality of surgical instruments

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ABSTRACT

INTRODUCTION Many surgeons will have encountered the scissors that would not cut, and the artery clip that comes off in a deep difficult location, but it would be reasonable to assume that new instruments should be of assured quality. This study reports the surprising findings of a local quality control exercise for new instruments supplied to a single trust.

MATERIALS AND METHODS Between January 2004 and June 2004, all batches of new surgical instruments ordered by the Central Sterile Supplies Department of St Bartholomew’s and The Royal London Hospitals were assessed by three clinical engineers, with reference to British Standards (BS) requirements.

RESULTS Of 4800 instruments examined, 15% had potential problems. These included 116 with machining burrs and debris in the teeth of the tissue-holding regions, 71 defects of ratcheted instruments, 34 scissors with deficient cutting action, and 35 tissue forceps protruding guide pins. In addition, 254 instruments did not have a visible manufacturer’s mark.

CONCLUSIONS This study demonstrates the value of local quality control for surgical instruments. This is of importance in an increasingly hazard-conscious environment, where there are concerns over instrument sterilisation, surgical glove puncture and the potential for transmission of blood-borne and prion diseases.
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.

One major source of UDFs is from surgical instrument failure. 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 15-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.

- 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.

- Conway et al. (1999) report that it is a well
Call for Trusts to review instrument quality

Experts at Barts and The London NHS Trust are campaigning to raise awareness of the risk of unretrieved device fragments posed by poor quality surgical instruments, which can lead to infection, perforation or obstruction of blood vessels, and even death.

Phil Daly and Tom Brophy from the department of clinical physics, Barts and The London NHS Trust, are urging other Trusts to follow their lead in implementing stringent quality assurance processes to ensure newly purchased instruments are fit for purpose, following research which identified quality issues in a significant number of devices.

‘The latest reported figures show that some suppliers are continuing to sell substandard instruments, with 10% of instruments failing quality assurance tests in the first six months of 2009.’

unretrieved device fragments are reported to the FDA’s Centre for Devices and Radiological Health, each year – many of which are caused by surgical instrument failure.

Head technician, Tom Brophy, who has over 30 year’s experience of mechanical engineering, revealed that he had observed inadequate quality control procedures during visits to a significant number of manufacturing sites. However, he added that there is very little pressure on suppliers to improve performance, as so few Trusts employ dedicated expertise to perform systematic inspection of newly purchased instruments.
Standards to which Manufacturers or Suppliers of Surgical Instruments must comply

**Medical Device Directive 93/42/EEC**


International Standards 7740-1985 Instruments for surgery - Scalpels with detachable blades - Fitting dimensions.


Instruments must comply with all the relevant British Standards or International Standards.

Note: Tungsten Carbide needle holders inserts, if soldered should have no blow holes in the solder.  
In the result of no formal standards instruments must fulfil the requirements of their intended use.
Quality Assurance Procedures applied to Surgical Instruments at Barts and The London (1)

Instruments will be inspected in accordance with British and International Standards

- All Instruments will be inspected by normal vision.

- Devices that include teeth, serrations and prongs will be inspected to ensure sharp edges, burrs and manufacturing debris have been removed with the aid of a \textit{x15} Eye Glass.

- If a problem is discovered, further evaluation may be required using a \textit{x60} Microscope.

- Any medical device that is a risk to patient safety must comply with the above requirements.
Quality Assurance Procedures applied to Surgical Instruments at Barts and The London (2)

- Instruments that include Tungsten Carbide Inserts, will be inspected using a Microscope with a magnification up to $\times60$ to ensure the inserts are soldered correctly, and free from fractures.

- Batch inspection is carried out:
  
  $1-24 = 100\%$  $25-50 = 50\%$  $50-75 = 30\%$  $75-99 = 20\%$  $100-up = 15\%$

- If any failures occur during inspection, a 100% inspection will be carried out.
Defective Instruments

- No manufacturer’s mark - no traceability.
- Fracture material may be inserted into patients.
- Soldering faults may provide niches for retention of blood and tissue.
- Forceps guide pins protruding on jaw closure - may cause glove puncture.
- Artery forceps with deficient ratchets and scissors not cutting properly.
- Visible corrosion.
- Previously used and contaminated.
Roberts Artery Forceps  Ratchet not holding

Bad

Good
Sellors Rib Spreader  Blade not secure
12 inch Crafoord Forceps  Bodge
Potts Smith Dissecting Forceps  Jaws not meshing
Blalock Hook Right Angle

Bad Example

Good Example
Cooley Clamps  Rust
Lockhart Mummery Probes  Rust - Pitting
Scissors  Joint screw fracture
Needle Holders  Fractures
Castroviejo Needle Holder Good Example
Sterilisation Containers

Bad

Good
Burrs, Fractures, Voids, Rough Surface Finishes

• All trap potentially infectious tissue debris.

• Most of this would be removed by sterilization but there is a danger that new types of infection transmitted by protein ‘Prion disease’ might survive this.

  e.g. CJD (Creutzfeldt-Jakob disease).
Burrs

- Burrs may become detached - debris provides a focus for infection.
  - Foreign body granuloma.
  - Foreign body embolism.
  - Weaken patient immune system.
  - MRI burns.

- The majority of instruments are manufactured from martensitic stainless steel which is not an implant grade.
Officer Tissue Forceps Fracture – Burrs
Infant Retractor  Burr
Barraquer Iris Forceps  Burrs - Void
Dennis Browne Tonsil Forceps  Surface finish
McCulloch Muscle Retractor Blades

Burrs
Toothed Forceps  Burrs

Bad Examples  Good Example
**Russian Dissecting Forceps**  Burrs - Debris

Bad Example

Good Example
Fibrillator Lead - Clips  Burrs - Shredding - Debris
Debakey Dissecting Forceps

Burrs
Debakey Coarctation Clamp

Bad Example

Good Example

Burrs
Infiltration Cannula
Ross Ventricular Vent Adult  

Bad Examples  

Good Example  

Burrs
Angled Artery Forceps  Blood - in service
Spencer-Wells Artery Forceps

Blood - in service
Spencer-Wells Artery Forceps  Blood - in service
Inspection Failure

Year 2001 13%  Year 2002 18%  Year 2003 16%

Year 2008 17%  Year 2009 13%

In 2004 the following action was taken:

1) We supplied manufacturers/suppliers with our QA procedures.
2) Photographs taken to support written documentation.
3) Trust talks to manufacturers/suppliers.
4) Only purchasing from companies that met our QA procedures.
5) Involved in clinical trials.
Advantage of the QA Service

• Protects patients, surgeons and SSD staff.

• Protects Trust from legal action.

• Instruments are being supplied to British Standards.

• Saves money on unnecessary replacement.
Barts and The London NHS Trust is supplied with the best quality instruments in the NHS, if not the world!

What is the quality of your instruments?

I hope you don’t accept our rejects!
Tom Brophy

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