Vigilance vital to ensure high standards

With effective surgical instrument decontamination critical to ensuring that harmful pathogens are not passed from patient to patient, and, for example, an acknowledged risk that human brain degenerative diseases such as vCJD, Alzheimer's disease, and Parkinson's disease, may be transmitted from person to person via contaminated instruments, an IHEEM seminar in Birmingham recently examined effective device decontamination, and the quality of surgical instruments generally, with some found to be defective even when unpacked straight from the factory. Among leading experts to pass on valuable guidance at the seminar, titled 'Dirty Little Secrets 2', and held at the Hilton Birmingham Metropole Hotel, was Tom Brophy, lead medical engineering technologist at Barts Health NHS Trust. As *HEJ* editor, Jonathan Baillie, reports, he gave an interesting follow-up to a presentation he made on the same topic at an earlier IHEEM 'Dirty Little Secrets' seminar in February 2012.

As with the first IHEEM 'Dirty Little Secrets' seminar, which was held at the same venue three and a half years previously, this year's IHEEM decontamination seminar on 30 June focused on some of the patient risks associated with instruments that have passed through the decontamination process, but have failed to be decontaminated sufficiently to prevent them harbouring blood, body tissue, and other 'debris' which may be passed to a subsequent patient during surgery, with all the attendant infection risk.

When he spoke at the original 'Dirty Little Secrets' seminar in February 2012, which, as with this year' event, was chaired by Graham Stanton, a senior decontamination officer at NHS Wales Shared Services Partnership who also chairs IHEEM's Decontamination Technical Platform, Tom Brophy explained how in 2000 the then Barts and the London NHS Trust had established its own surgical instrument quality assurance section. This was mainly because, as he and his co-authors from the Department of Clinical Physics at St Bartholomew's Hospital, and the Department of Vascular Surgery at The Royal London Hospital, explained – in a 2010 *Hospital Healthcare* article, New surgical; instruments: a question of quality[1] – 'we had no confidence that new instruments were undergoing a real quality control process'.

Photo courtesy of: Jonathan Baillie.

The audience at June's IHEEM Dirty Little Secrets 2 seminar, which focused on some of the patient risks associated with instruments that have passed through the decontamination process, but have failed to be decontaminated sufficiently to prevent them harbouring blood, body tissue, and other 'debris'.

MHRA warnings

In the 2012 presentation, Tom Brophy explained that the UK Medical and Healthcare Products Regulatory Agency (MHRA) had warned in 2010 of the potential infection transmission risks and other dangers associated with contaminated surgical instruments. He also discussed his part in a BBC Television *Panorama* programme, itself titled 'Dirty Little Secrets', broadcast in June 2011, which investigated the surgical instrument industry, and found 'evidence of lax quality control and poor manufacturing practices and conditions'. The programme also highlighted the fact that many surgical instruments used in the UK are produced in developing countries, and particularly in Pakistan, where quality control standards may be low or non-existent.

Tom Brophy's presentation at this June's 'Dirty Little Secrets 2' seminar had the self-explanatory title, 'Quality of Surgical Instruments – Two Years On'. Sub-titled 'Don't accept our rejects', the

presentation covered both quality assurance procedures implemented by the Trust to ensure that poor quality or contaminated instruments are not used on patients, and some of the recent, ongoing research undertaken by the Trust in association with external partners. Tom Brophy said he believed Barts Health was the country's only NHS Trust currently undertaking independent evaluation of its instrument decontamination.

Five-year apprenticeship

Beginning, however, with his own professional background, he explained that he had originally served a five-year apprenticeship, managed by the Worshipful Company of Cutlers – which saw him become a Master Cutler Surgical Instrument Maker – before taking up a position as a research and development instrument maker, making prototypes and pre-production batches. He later worked as a research and development technician, which entailed 'meeting surgeons and bringing their concepts back to HQ'. He explained: "If commercially viable and safe, we would then place the instruments into production."

Having thus briefly discussed his own training and career – he joined the then Barts and the London NHS Trust in 1988 as a radiation physics technician – Tom Brophy told delegates; "At some point you, you, a family member, or friend, will undergo surgery, so instrument quality is important to us all. We are all potential future patients." At Barts Health, he explained, he also has a 'clinical role' – meeting patients and their families.

First-hand experience

He said: "I thus know first-hand how scared some patients are on coming into hospital. Some of the images of defective or contaminated surgical instruments I will show you illustrate risks that patients should not expect. Patients are, after all, entitled to expect safe and reliable devices, and hospital instruments supplied new, uncontaminated, and manufactured to British or international standards.

Tom Brophy at work at Barts inspecting a tray of surgical instruments.

Hospitals also expect such instruments to have a long working life, and not to have to waste valuable resources replacing faulty devices that have had little or no use."

Tom Brophy went on to explain that this year he and his medical engineering team colleagues at Barts Health have undertaken independent evaluation of the instrument decontamination process. He elaborated: "We take trays out of service in our theatres at our Whipps Cross University Hospital sterilisation department, and inspect them."

Inspecting the wrapping

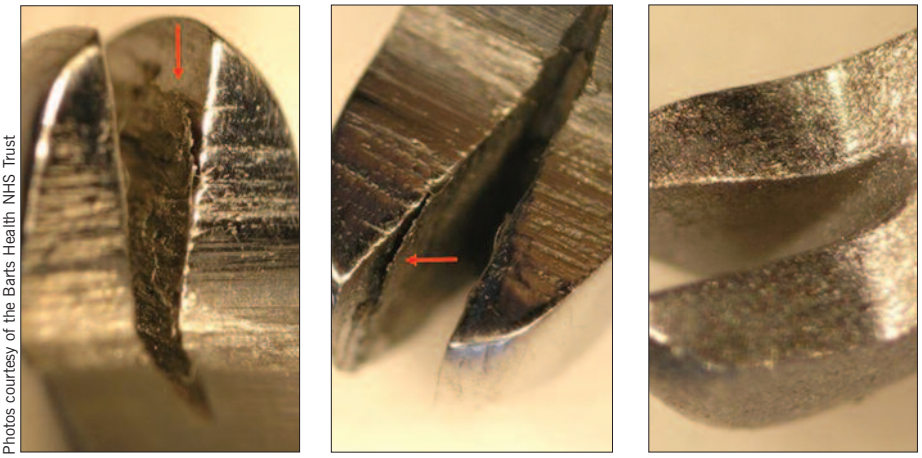
Under now well-established protocols, having gone into a theatre, and removed an instrument tray, Tom Brophy and his colleagues will firstly inspect the 'wrapping' to ensure that it has not been breached, since, if so, the contents will be deemed not to have been decontaminated. He explained: "We then check the tray list, to ensure that the right instruments are in the right tray, before checking the instruments' condition to see if they are fit-for-purpose, or, for example, fractured, damaged, or otherwise defective.

"As we go through this process, we visually inspect how effective decontamination has been, i.e. there should be no blood or other debris present. We use the same magnification as our private decontamination partners, following exactly what our sterile services operatives are doing, before the instruments reach the patient. If we do find a problem with any tray, it is removed from service before it reaches the patient, the issue is reported on our incident reporting system, and to our private partner. Theatre staff see the benefits of this service, and are fully supportive of our in-house tray inspections, and can be actively involved in the process if they wish. They routinely monitor all equipment to ensure that the wrapping is intact, and that there doesn't appear to be any damage to, or 'debris' on, the equipment, so it is natural for them to be supportive of our approach."

A collaborative effort

'Private partners' and the Trust were, he explained, working collaboratively in this area. Tom Brophy said: "I myself am also an ISO auditor. I thus know how the paperwork is all audited, but where many Trusts miss out is that when orders come in, they don't look at the final product."

Alluding briefly to the 'specialist work' he had undertaken for the 2011 *Panorama* television programme, 'Dirty Little Secrets', he said that the BBC's researchers were 'horrified' by many of the images (of faulty instruments) he had taken. He added: "I am working closely with Visiting Professor of Patient Safety at Brighton and Sussex Medical School, and Emeritus Professor of Patient Safety at Coventry University, Brian Toft, who has been at actively involved in my work, am the NHS Supply Chain consultant on surgical instruments. I also lecture at the University of Bedfordshire to perioperative care students. While I appreciate that they cannot do what I do QA procedure-wise, I can at least reinforce for them the 'quality matters' message."



Photos courtesy of the Barts Health NHS Trust

Toothed forceps – showing both 'good' and 'bad' teeth.

Scottish study work

Tom Brophy is also working with Professor George Corner at the National Surgical Instrument Reference Centre (Reusable Surgical Instruments) at the University of Dundee, which runs a programme to study the quality, management, and care, of reusable surgical instruments, in collaboration with NHS Scotland and NHS Tayside. "This is ground-breaking stuff," he explained. "Dundee University has even been checking the raw materials used for instruments. They have found materials not defined as entirely stainless steel in one of the instruments they have tested, and, for example, have found aluminium particles, which should not be in stainless

steel. We are working closely together to take forward this work."

Tungsten carbide insert 'left' in patient

At this juncture the Barts Health speaker showed a slide supplied by a Dundee University PhD student, Wendy Xu, highlighting a 17% failure rate for 'general' surgical instruments, 'mirroring' what he and his team were seeing. Tom Brophy added: "Wendy Xu is constructing a database similar to the model we have here at Barts. On general instruments, we are seeing, on average, a failure rate of about 20 per cent."

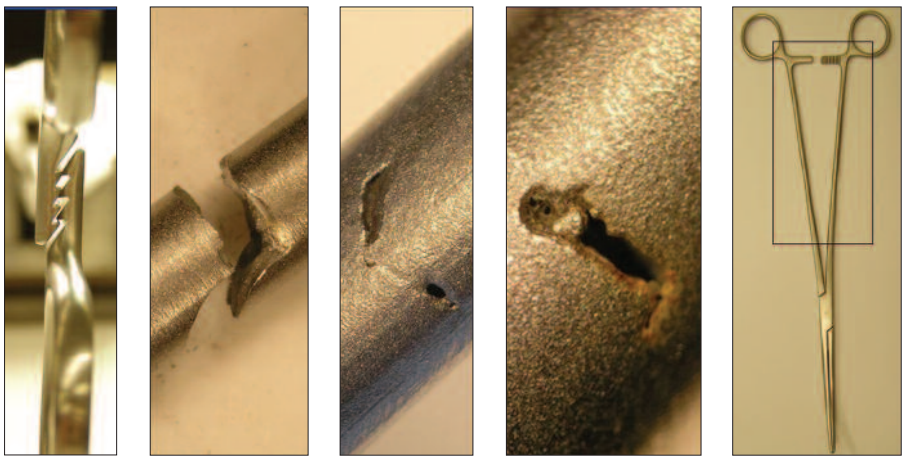
The quality assurance service at Barts Health started in 1998, he went on to explain, when the Trust's Clinical Physics Department was asked by clinical colleagues to investigate the quality of instruments being supplied to the Trust. "We began a quality assurance study of new surgical instruments arriving at the Trust to determine whether they complied with British and international standards," Tom Brophy explained. "This found a large number of poor quality instruments entering the Trust's hospitals; all were discarded immediately before use."

A 'dynamic' management team

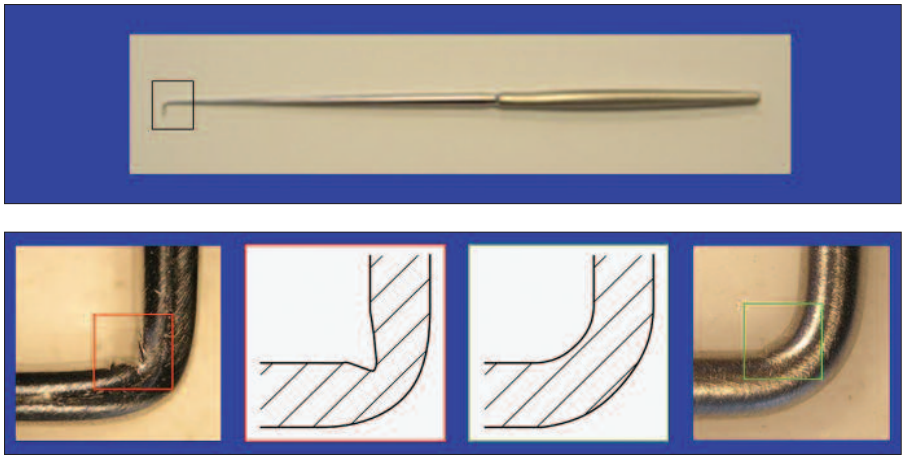
Fortunately, he explained, the management team was 'very dynamic', and asked him to establish a Trust quality assurance service for surgical instruments. Here he referred to a research paper, 'Quality of surgical instruments', co-authored in 2006 by he and a number of surgeons, and published in the *Annals of the Royal College of Surgeons of England*,[2] which reported on 'a local quality control exercise for new surgical instruments supplied to the Barts and the London NHS Trust between January and June 2004'. This showed that, of 4,800 instruments examined, 15% had 'potential problems', including 116 with machining burrs and debris in the teeth of the tissue-holding regions, 71 defects of ratcheted instruments, 34 scissors with a deficient cutting action, and 35 tissue forceps with protruding guide pins. Additionally, 254 instruments had no visible manufacturer's mark.

Unretrieved fragments

Turning next to another paper, 'Unretrieved Device Fragments – the clinical risk of using poor quality surgical instruments', written by a combination of clinical scientists and surgeons (Tom Brophy also contributed), and published in the February-April 2010 edition of *Medical Device Decontamination*,[3] he said: "This reported on the potential consequences when fragments of surgical instruments get inserted into patients in error. Prior to that, several suppliers had told me that such occurrences 'didn't matter', since



12 inch Crafoord forceps – 'a bodged job', and thus 'fundamentally weakened'.



'Good' and 'bad' examples of a Blalock hook.

'the body can deal with it'. In reality, the body does 'deal' with it, but in a negative way. A lot of the information gathered for this piece was from US soldiers who had fought in Korea, and explained how, later on in their lives, fragments had moved around their bodies, causing foreign body embolisms or granuloma.

"Basically," Tom Brophy continued, "foreign body granuloma, depending on their location, can result in serious consequences for the patient – especially if they change position – and may also weaken the immune system." The speaker next referred to an article titled 'Call for Trusts to review instrument quality', that appeared in the October 2010 issue of *HEJ's* sister publication, *The Clinical Services Journal*,[4] which examined how experts at Barts and The London NHS Trust were 'campaigning to raise awareness of the risk of unretrieved device fragments posed by poor quality surgical instruments'.

Latest paper

The last paper Tom Brophy had written, 'New surgical instruments: a question of quality', published in *Hospital Healthcare Europe* in 2012,[5] 'brought together all the information we had at that time'.

At this point, the speaker showed slides of pages from instrument manufacturers' catalogues, in which they cited, as examples of 'extensive quality control', for example, 'microscopic examination', and 'Rockwell' hardness testing etc. Pointing to one catalogue, Tom Brophy said: "This particular image must have been produced purely for marketing purposes, because the woman examining an instrument with a microscope hasn't even got the light on. She is also examining new scissors with a microscope, and, unless she is looking at screws, there is no reason to do that."

Key standards set out

He next showed slides setting out the key standards that surgical instrument manufacturers should abide by. These include BS 5194, parts 1-4 (governing the specification for stainless steel, instruments with pivot joints, dissecting forceps, scissors, shears, and 'other jointed instruments', respectively); International Standard 7740-1985 'Instruments for surgery – Scalpels with detachable blades – Fitting dimensions'; International standard 8319-1: 1996 'Orthopaedic instruments – Drive connectors – Part 1: Keys for use with hexagon socket heads', and International Standard 8319/2 – 1986 'Orthopaedic instruments – Drive connectors – Part 2: Screws for single slot heads, screws with cruciate slot and cross-recessed head screws'.

Fulfilling their 'intended use'

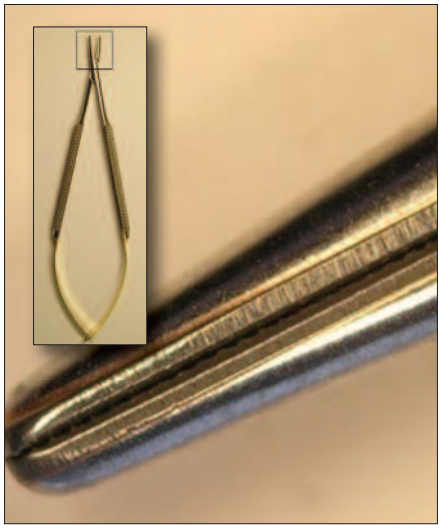
Where no particular standards applied, he said instruments must 'fulfil their intended use'. "We also," he added, "insist that 'associated equipment be marked with a registered trademark, as stipulated in British and international standards for surgical instruments. What this means is that we really want to know where all our equipment comes from."

Tom Brophy moved on here to describe the quality assurance procedures applied to surgical instruments at Barts Health, explaining that not only must all instruments be 'inspected by normal vision', but also that devices that include teeth, serrations, and prongs 'must be inspected to ensure that sharp edges, burrs, and manufacturing debris, have been removed, with the aid of a x15 eye glass'. Where a problem was discovered, further evaluation might then be required using a x60 microscope, while it was a Trust 'absolute' that any medical device that might be considered 'a risk to patient safety' must comply with all these requirements.

He told delegates: "Instruments that include tungsten carbide inserts are inspected using a microscope with a x60 magnification to ensure that they are soldered correctly, and free from fractures." The batch inspection currently being employed by the Trust was, he said, 'proving really effective'. "Currently," he explained, "we are going through the biggest procurement drive we've ever had. In the past six months we have quality assessed over 6,000 instruments, and the QA process now encompasses all our hospitals. We are seeing hundreds of scissors, forceps, and other instruments arrive, and will run a detailed QA check on 15%. If we find a failure, we will then undertake a 100% check."

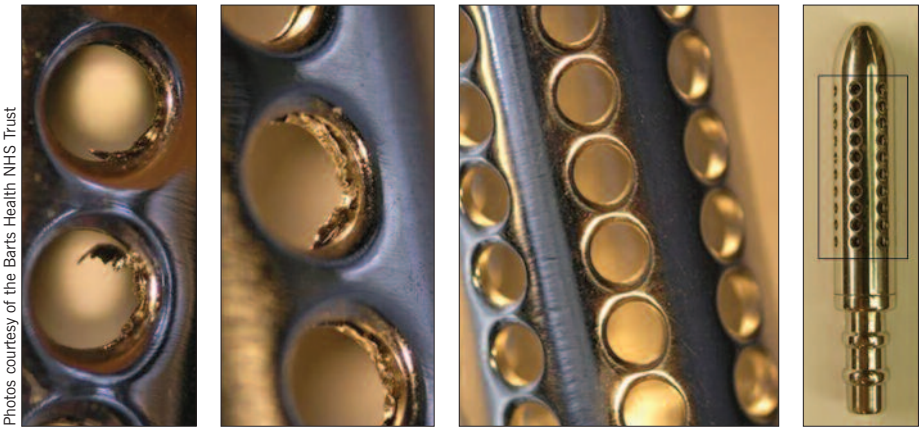
Typical defects found

Describing some of the typical defects commonly found, Tom Brophy said these included instruments with no 'maker's mark' or trademark. He elaborated: "If you accept instruments with no trademark, there is no traceability, so in the case of an issue or a fault, you are liable for all costs. If a problem occurs with that instrument, you also can't get back to the manufacturer to warn them, and they can't rectify the defect.



A well-made Castroviejo needle-holder.

"We also look out for instruments where there is a risk that fractured material might be inserted into patients, and for forcep guide pins protruding on the jaw closure, which may cause a glove puncture. We can show several examples of faulty instruments which would rip through gloves pretty easily, and trays which will cut through them quickly." Other commonly found defects included artery forceps with deficient ratchets, and scissors not cutting properly, as well as visible corrosion on instruments before they were even removed from the pack. The Trust's team had also seen previously used and contaminated instruments arrive. Tom Brophy said: "We see instruments name marked incorrectly; so, for instance if you want a spanner, you have scissors. That will cause problems once the instrument goes into service, because people may not realise, and still put the instrument into the system.



Photos courtesy of the Barts Health NHS Trust

Burrs on a Ross ventricular vent used in perfusions in heart surgery; if the fragments detached, this could result in stroke, amputation of a limb, or death. The instrument also incorporated no name mark.

Ratchets not holding

"We have also found ratchets not holding on some Roberts artery forceps, and rib spreaders with gaps underneath the blades, which will mean endless replacement of nuts. The British Standard says the serrations should mesh accurately, but they are not doing so, and are thus non-compliant."

Tom Brophy next spent several minutes showing slides of both some of the defective surgical instruments his team had encountered, and examples of how 'good quality' such instruments should look.

Looking first at a slide of a faulty Blalock hook right angle, he explained how the manufacturer had 'cut away the natural curve'. He said: "I think the instrument had probably fractured, so the manufacturer decided to hide the fault by cutting away the curve, and has thus fundamentally weakened the instrument; on taking a knock it will almost certainly fracture. What we are after is strong, robust, surgical instruments that will last and do the job in hand."

'Caught' under batch inspection

His next slide showed a pair of faulty 12 inch Crafoord forceps, 'caught' under batch inspection. Tom Brophy said: "The manufacturer had put extension rods into the instruments, but had welded them so badly that they burred the material. When I removed these from the pack, one after the other snapped. Had these gone into service unnoticed by the theatre team, they would have been a risk to the patient, because if the ratchets had held and been used in deep location surgery, had there been a bleed, the surgeon would not have known the source, since, as far he or she was concerned, the ratchets were holding, and the vessel was clamped. The surgeon would not have been able to see the source of the bleed under the mass of material."

Tom Brophy next showed visible corrosion, with material 'failing away' on a Cooley clamp, typically used in cardiac surgery. "When I took this faulty instrument to the supplier," he explained, "he replaced it, and then rang me two weeks later to say he had sold the corroded cardiac clamp to another hospital."

Pitting present

Looking at a Lockhart mummery probe, used as guide for the scalpel in breast surgery, Tom Brophy pointed to pitting, which could attract contamination. He explained: "There is a high risk that once blood and debris is in there, any corrosion will accelerate, and it is highly likely that the instrument will fracture in use." Showing next a slide of a corneal knife used in eye surgery, he pointed to rust and fragments. He said: "In the manufacturing process instrument producers sometimes

do not remove the flux before packing the instruments. Flux is toxic, and very acidic, and, if left on, will start eating into the material, as has happened here. If the corrosion and fragmentation is not removed during the SSD checks, the toxic debris could be inserted into the patient."

His team at Barts Health also checked all screwheads exhibiting signs of fracture. Showing first a fractured screwhead on a pair of scissors, Tom Brophy said: "Some suppliers I talk to see no issue with the screwhead being fractured, since the screw is still there. However, I point out that if blood goes inside there, quite quickly that screwhead will detach. If that happens I will be the one asked by the Trust to investigate. Prior to that, however, if the clinical team knows the screwhead has detached, the patient will need to undergo another X-ray, and potentially another procedure, to identity whether it has been inserted into them. This is another of the type of risks patients and hospitals simply should not accept."

Fundamentally weakened

The focus of his next slide was a fractured needle-holder. Tom, Brophy said: "As the manufacturer has soldered the inserts in, the soldering has run along the crack. The whole jaw has been fundamentally weakened, and will not withstand the pressure of a needle being clamped all the time. These are all new instruments."

> Foreign body granuloma, depending on their location, can result in serious consequences for the patient – especially if they change position – and may also weaken the immune system

He next showed a slide of a new surgical instrument demonstrating the excellent quality manufacture the Trust seeks – a Castroviejo needle holder, where there were no fractures, and the inserts meshed.

Moving next to sterilisation containers, Tom Brophy showed both 'good' and 'bad' examples. One case, for example, was designed in such a way that one of the instruments did not fit into it, while another container, with a wire basket, which contained 'really expensive' instruments for cardiac surgery, incorporated a tray that did not fit the case. He said: "Our instruments travel by road. The tray has not been designed as a crash barrier, and the wire can detach, placing theatre and SSD staff at risk. We test by turning the cases upside down and then returning them upright; with a good design all the instruments should remain in the same position."

Lack of a name mark

When asked recently by a colleague why his team was testing trays of surgical instruments, Tom Brophy explained that he had found a number with no name mark. He said: "It just happened that at the same time we received a batch of wire basket trays coming in with no name mark. On returning them, I was sent a further batch, also missing a name mark. When I tried opening one, I cut my hand; it had razor-sharp edges. I explained to the SSD personnel that my ultimate aim was to protect them from such faulty items. In any event, the faulty containers went back and I noted the fault on the Trust's incident reporting system, which would have escalated to the MHRA. In a theatre, such a fault could be catastrophic."

The speaker's next slides focused on 'Burrs, fractures, voids, and rough surface finishes'. Tom Brophy said: "All these defects trap potentially infectious tissue debris. While most would be removed by sterilisation, there is a danger that 'new' types of infection transmitted by protein Prion disease, such as vCJD, might survive the process." He added: "Burrs may become detached from instruments, and provide a focus for infection, particularly as you cannot clean

underneath. If the burr does detach, it may cause foreign body granuloma, or a foreign body embolism, weakening the patient's immune system. It can also cause MRI burns. If you have fragment in your eye, for instance, and have an MRI scan, it could potentially blind you."

'Never intended to be left behind'

The majority of instruments were, the Barts Health speaker explained, made of martensitic stainless steel – 'not an implant grade, and never designed to be left behind'. Here Tom Brophy showed a slide of fractured tissue forceps, where there was a high likelihood that the whole tooth would be inserted into a patient. Looking next at an infant retractor with a 15 mm burr, Tom Brophy said this would present a high risk of a foreign body being inserted into an already frail baby.

He went on, in his next dozen or so slides, to outline some of the dangers and considerable potential patient risks of burrs on surgical instruments including Kilner skin retractors, McCulloch muscle retractor blades, Barraquer iris forceps, Dennis Browne tonsil forceps, and monopolar diathermy dissecting forceps. Many of these faults were, he believed, 'attributable to a complete lack of quality control'. To give a clearer idea of the potential risk from poor instrument design, he took as an example Barraquer iris forceps exhibiting clear burrs. He said: "You should never make an eye instrument with a trench or a tunnel in it, because it will capture body tissue. Eye surgery carries high risks of vCJD, but here, as you can see, the manufacturer has designed an instrument which would be able to transfer body debris from one patient to the next. The metal fragments are all ready to be inserted into the eye. If the fragments detach, it is highly likely they will remain there."

> In the manufacturing process instrument producers sometimes do not remove the flux before packing the instruments

Discomfort for many years

One of his latest photographs was of a vaginal speculum, which exhibited burrs and fragments on the smoke tube, 'barely hanging on'. He said: "This instrument will go directly into the vagina. If the fragments are left behind, it will cause considerable discomfort for the lady in question for many years. Here, the supplier has also supplied instruments of the wrong size, which, if used surgically, could cause considerable post-operative discomfort."

Another slide showed serrations on a pair of monopolar diathermy dissecting forceps, which Tom Brophy said would trap body tissue and transfer it, while burrs on a Ross Ventricular Vent used in perfusion for heart surgery, could, if the fragments detached, result in stroke, amputation of a limb, or death. The instrument also incorporated no name mark.

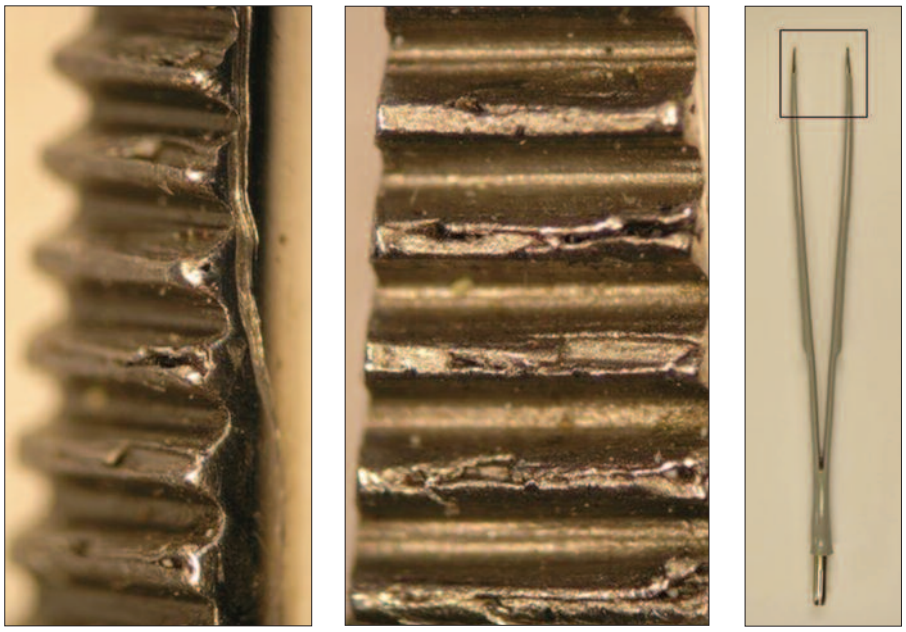
Inspection failure rates

Having by now clearly demonstrated the poor condition of a number of mainly 'new' surgical instruments that, fortunately, his team's vigilance had prevented reaching patients, Tom Brophy moved next to discuss inspection failure rates on surgical instruments at Barts Health in the period from 2002 to 2014. He said: "While in 2002 we saw a failure rate at Barts Health of 18%, this had fallen to 8% in 2013, and then, in 2013, we had a real dip – to just 2%. However, 2013 was a year when we didn't procure many instruments, and also had a high level of orthopaedic and endoscopic instruments, on which we experience few problems.

"Last year we saw a rise in overall surgical instrument failure to 7%, and are currently seeing about a 9 per cent failure rate, no doubt because we are procuring many instruments. The Trust is realising that the only way we will deal with faulty instruments is to use proven tactics – including penalty clauses. We thus tender out for our instruments, get the tenders in, and tell suppliers; 'If you don't comply with our quality standards, you will be penalised financially.'"

Protecting patients, surgeons, and other staff

In concluding, Tom Brophy said that the Barts Health NHS Trust surgical instrument 'QA service', via its independent instrument validation – not only protected patients, surgeons, and staff, but also the Trust and its partners, against potential legal action. He added: "Instruments are being supplied to us produced to British Standards, which saves money in unnecessary replacement, and ensures a long working life from instruments that we know are fit for purpose. We believe Barts Health is now supplied with the best quality surgical instruments in the NHS, if not the world. My question to you all, however is: 'What is the quality of your instruments?' I also hope you do not accept our rejects, because the reality is that a supplier has told me on at least one occasion that an instrument we have rejected has gone to another healthcare provider. Surprisingly, they are quite open about this." With that Tom Brophy closed a fascinating presentation.



Monopolar diathermy dissecting forceps, exhibiting serrations, shredding, and burrs.

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