

Available online at www.sciencedirect.com

The Surgeon, Journal of the Royal Colleges of Surgeons of Edinburgh and Ireland

www.thesurgeon.net

Correspondence: Surgical Technique

The use of non-orthopaedic devices for orthopaedic procedures

Dear Sir,

The field of orthopaedics is constantly undergoing development through progress in basic science and clinical investigation.⁶ Being a dynamic specialty, surgeons have continued to develop ways to improve surgical steps in order to become more efficient and effective. This has involved modifying non-orthopaedic devices to suit particular procedures, resulting in relevant regulatory advice.⁷

A study aimed at the review of published technical tips relating to the use of non-orthopaedic devices by surgeons in orthopaedic practice and to address compliance with regulatory advice was undertaken.

A literature review of published technical tips in three leading journals: *Annals of the Royal College of Surgeons England* (2002–2010), *The Surgeon* (2002–2010), and *Acta Orthopaedica Scandinavica* (2005–2010), using the online archives of these journals was carried. Terms including 'technical tips' and 'techniques' were employed for the search.

We divided the reports into those dealing with trauma, elective and general orthopaedic procedures. Letters written in response to the published technical notes were also scrutinised (Table 1).

Thirty-three technical tips were identified in the three journals in which non-orthopaedic devices had been used for orthopaedic procedures. Table 2 shows a summary. Of these,

13(39%) related to trauma procedures, and 10(30%) to both elective and general orthopaedic procedures.

Of the twenty-eight tips written up in the *Annals*, there were 6 letters in response to some of technical tips confirming the use of various new methods and suggestions were made for their improvement. There were three letters, which confirmed the use of some tips but warned of technical flaws. *The Surgeon* and *Acta Orthopaedica* did not have any response from readers on the technical tips published within the above-specified period.

Christensen et al. noted that current surgical practice rewards convenience, accessibility, low cost, and reliability^{3,6} Conventional orthopaedic instruments reflect the parallel evolution of orthopaedics and battlefield medicine, innovation having often been a process of revision and refinement rather than sudden inspiration^{5,10}. Many devices became eponymously named.⁴ Exploring the use of instruments from other surgical specialties can sometimes be of great value²

A report published in 2004 by the Medical Devices Agency (MDA), now part of the Medicines and Healthcare products Regulatory Agency (MHRA) deals with use of medical devices for purposes not intended by the manufacturer, otherwise referred to as 'off-label' use.⁸ Examples include the use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis.⁹ The MDA Alert provides some specific guidance and advises that when there is judged to be no alternative to off-label use or modification of a device, clinicians should 'carry out and document a full risk assessment and ... consider the ethical and legal implications'. This 'risk assessment' ought to be part of the normal thought process of any surgeon in considering use of a modified device. Discussion with colleagues is a sensible part of risk assessment and could perhaps be regarded as a variant of the Bolam test (i.e. a responsible body of colleagues would support use the modified device).^{1,8} Responses by readers to the technical tips published reviewed could be looked on as some form of risk assessment. A twenty percent response rate is probably not sufficient to warrant its widespread acceptance. It would be seem appropriate for the orthopaedic community to be sensitized towards such procedures and devices before they become fully established.

Some hospital trusts have provisions where medications have been used outside their licensed premise for certain conditions, and so a case could be made for using non-orthopaedic devices for certain procedures. The goal of both

Table 1 – Showing journals and number of technical tips published involving the use of non orthopaedic devices in orthopaedic procedures.

	Annals Royal College of Surgeons	The Surgeon	Acta Orthopaedica
Letters	9 ^(a6)	0	0
Technical tips	28	2	3
Classifications of technical tips published			
Trauma	12	0	1
Elective	7	2	1
General orthopaedics	9	0	1

a Letters in response to these tips.

Table 2 – Summary of technical tips published within specified period.

2003	Use of Shirodkar sutures in shoulder surgery The use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis
2004	Protection of soft tissues during K-wiring Arthroscopy toast rack Knee stabilizing device for lower limb orthopaedic procedures An easy method of passing a cerclage wire around a fractured patella Wound Irrigation: A simple delivery of the litre
2005	A Technique of nail avulsion using cleaner found in hand scrubbing pack Use of aortic restrictor in intramedullary nailing. Intramedullary nailing of the femur; syringe to avoid soft tissue interposition while reaming
2006	A simple adjunct to lavage of open fractures Removal of broken drill bits and locking screws from an intramedullary nail Obtaining an optimal bone cement interface in total knee arthroplasty A technique to remove cannulated screws Knee Arthroscopy; 1ml syringe as an outflow cannula Use of dental instrument in paediatric hip surgery A simple and cheap method for vacuum-assisted wound closure
2007	A novel technique for wound irrigation Level determination in Anterior cervical decompression and fusion surgery Removal of broken tibial nail fragments with sigmoidoscopy biopsy forceps
2008	A makeshift mallet splint A pulsed lavage pouch A simple technique for introducing bone graft during revision ACL surgery
2009	Orthopaedic use of ophthalmic drapes A novel splash guard for use in wound irrigation Use of a dental tool to remove excess cement in Unicomp. knee arthroplasty An alternative crossbar for controlling postoperative hip rotation An alternative use of Foley's catheter in Ilizarov external fixation A radiolucent retractor for locking screws No hands technique for arthroscopic washout of septic arthritis of the knee The "glove" technique: a modified method for femoral fixation of antibiotic-loaded hip spacers The "glove" technique: a modified method for femoral fixation of antibiotic-loaded hip spacers
2010	A 20ml syringe bung as a economical and practical Ilizarov pin site dressing An innovative technique for long bone biopsy (Use Of oesophageal biopsy forceps) Pulsed lavage in the orthopaedic theatre (use of adapted plastic light handle)

The MDA Alert emphasizes consent, stating that 'the patient must be fully informed ... and a note made in their records' when an off-label device is to be used. How much this is actually done in practice is unknown.

From the study it is clear that peer review by letters in response to these technical tips is limited. Setting up local committees made up of relevant surgeons who have tried or witnessed the device is a possibility. They could authorize or perhaps giving peer support in writing prior to publication. Such mechanisms would satisfy Bolam's test & allow introduction and trial of such innovations.

REFERENCES

- Campbell B. Home-made, adapted and modified devices in surgical practice. *Ann R Coll Surg Engl* 2008 April;**90**(3):251–2.
- Mueller M, Bintcliffe WL. Use of aortic restrictor in intramedullary nailing. *Ann R Coll Surg Engl* 2005 March;**87**(2): 140–1.
- Hing CB, Back DL. A review of intellectual property rights in biotechnology. *Surgeon* 2009 August;**7**(4):228–31.
- Meals C, Wang J. Origins of eponymous orthopaedic equipment. *Clin Ortho Relat Res* 2010;**468**(6):1682–92.
- (1877–1958) Porro and Lorusso, Pellegrini Augusto. Contributions to surgery and prosthetic orthopaedics. *J Med Biogr* 2007;**15**:68–74.
- Hansen E, Bozic KJ. Impact of disruptive innovations in orthopaedics. *Clin Ortho Relat Res* 2009;**467**:2512–20.
- Willis-Owen CA. Innovations in surgery. *Ann R Coll Surg Engl* 2009 January;**91**(1):90.
- Medicines and Healthcare products Regulatory Agency. Medical devices in general and non-medical products. Medical Device Alert. MDA/2004/006, <http://www.mhra.gov.uk>.
- Mehra A, Zaman T, Jenkin AI. The use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis. *Surgeon* 2003 Oct;**1**(5):290–2.
- Harold SL. Economic incentives to promote innovation in healthcare delivery. *Clin Ortho Relat Res* 2009;**467**:2497–505.

Akintunde George*
Department of Orthopaedics,
Princess Elizabeth Orthopaedic Centre,
Royal Devon and Exeter Hospital,
Exeter EX2 5DW, UK

Imran Abdulkareem, Michael Bould, Robert Spencer
Department of Trauma and Orthopaedics,
Weston General Hospital, Grange Road,
Weston Super Mare BS23 4TQ, UK

* Corresponding author. Tel.: +44 7877096062.

Available online 18 June 2012

clinicians and regulators should be 'first, do no harm', but slavish adherence to any blanket ban on adaptation or off-label use would be a significant disincentive to innovation and technical flexibility in the eyes of most surgeons.^{1,2}

1479-666X/\$ – see front matter
© 2012 Royal College of Surgeons of Edinburgh (Scottish charity number SC005317) and Royal College of Surgeons in Ireland.
Published by Elsevier Ltd. All rights reserved.
doi:10.1016/j.surge.2012.02.004