

ROUNDUP³⁶⁰

Research

Xref For other Roundups in this issue that cross-reference with Research see: [Knee Roundup 6](#); [Shoulder & Elbow Roundup 5](#); [Spine Roundups 1 and 4](#); [Trauma Roundup 6](#); [Oncology Roundup 3](#).

Scientific writing needed in orthopaedic papers

■ In recent years, more papers are being submitted to scientific journals than ever before, with massive growth in submissions from developing nations. In an interesting paper from **Denver (USA)**, the authors set out to recommend standards for medical writing in orthopaedics in the context of this explosion. In wider academic circles, medical writing has risen to become a discipline in itself with rules and standards. However, significant heterogeneity in the quality of paper submitted still prevails, with large variations in both form and content. The authors recommend a phased approach to improve submission quality, including a preparative phase that includes extensive reading to get new ideas on research and understand how papers that are published are written, meeting and discussing ideas at conferences and possibly discussing with reviewers or editors and planning the manuscript in advance.¹ In what can be a very thorny topic, these authors set out clearly and succinctly how best to go about producing a concise and, most importantly, readable and publishable manuscript. We would echo many of their comments here at 360 and particularly recommend reading draft manuscripts several times, making it

shorter each time it is edited. Often a good deal of patience and politeness with reviewers will be required and overall, as Mauffrey et al suggest, don't lose faith.

Antiseptics and osteoblasts

■ The detrimental effects of antiseptic on chondroblasts are well documented, with surgeons mixed in their opinions as to the relative benefits of the use of antiseptics in and around joints. While there is no doubt the infection rates are lowered with the use of antiseptics, there is plenty of laboratory evidence to suggest they may have a deleterious effect on chondrocyte health. It is curious that there is little evidence surrounding the effects of commonly used antimicrobials such as chlorhexidine and polyhexanide on osteoblastic cell viability. Researchers in **Berlin (Germany)** set out to establish the effects, toxic or otherwise, of polyhexanide and chlorhexidine on human osteoblasts *in vitro*.² Using cultivated osteoblast cell lines *in vitro*, the research team undertook an assay of the toxic effects of chlorhexidine 0.1% and polyhexanide 0.04%. The potential toxic effects were assessed through both histopathology (cell morphological changes) and lactate dehydrogenase activity (evaluated with trypan blue staining). Both antiseptics resulted in morphological changes and increased LDH activity after incubation with osteoblasts. Both antiseptics have a profound effect on viability of osteoblasts. While there is obviously no clinical data presented here, there

is little doubt in our minds here at 360 that in this case, the basic science evidence supports clinical practice.

Thromboembolic management in orthopaedic patients

■ The thromboembolic disease problem continues to cause consternation on both sides of the Atlantic. Surgeons preferring variably aspirin, low molecular weight heparin, extended regimes, or other strategies (such as early mobilisation and calf pumps), seem to struggle to balance the risks and benefits of complications of anticoagulation with the rare (but potentially fatal complication) of pulmonary embolism. Bearing in mind the increasing number of arthroplasties, fractures, and other musculoskeletal surgeries performed each year worldwide, balancing the risks with this potentially fatal complication remains a complex challenge. A review team from **Sofia (Bulgaria)** has undertaken a fairly comprehensive review of the need for, the complication rate of and current standards of compliance for thromboprophylaxis. This review makes essential reading for the practicing orthopaedic surgeon and researchers alike. The study team outline the current state of practice with evidence to suggest that thromboprophylaxis may be inadequate in up to 50% of patients. They trace the evidence for and the efficacy of both low molecular weight heparins (LMWHs) and the direct oral inhibitors of clotting factor Xa.³ Despite newer regimes and awareness of

the problem, thromboembolism continues to occur in up to 10% of our patient population. It is curious that despite millions spent on large randomised controlled trials, widely published health campaigns, and a wealth of scientific literature, experts cannot agree as to the best method for reducing thromboembolic risk, what that risk is, and how best to mitigate it.

Nicotine and obesity in post-operative complications

■ The detrimental effects of both nicotine and obesity, in terms of wound healing and side-effect profiles in fracture and other orthopaedic surgery, are well established but controversial. While there is a wealth of basic science evidence, the clinical evidence is mixed in quality (as are most epidemiological studies due to the nature of the surgery and event rates). Perhaps no area is more controversial than the upper tibial osteotomy, where obesity is said to lead to higher knee pain scores and more complications following surgery, and smokers are felt to have higher rates of complication and nonunion. Despite this relatively widely held view, there are no actual clinical studies proving or disproving the problem. Researchers in **Hanover (Germany)** have set out to establish exactly what the clinical situation is with regards to obesity, smoking and high tibial osteotomy. They designed a retrospective outcome study with prospective follow-up (Level III evidence) using complications (both intra-operatively and post-operatively) as their primary

outcome measure in combination with clinical outcome scores (Oxford Knee Score) for all patients at a single centre undergoing high tibial osteotomy for osteoarthritic knees. The study cohort consisted of 533 patients, of whom 386 were followed up to 3.6 years. Functional scores were excellent, with a mean Oxford Knee Score of 43 points and an overall reported complication rate of 6%. Obesity appeared to have adversely affected outcomes, with significantly poorer functional knee scores in the obese (37.5) when compared with overweight and normal patients. Interestingly, there were no links found between complication rates and obesity or smoking. Patients who were smokers did not have any poorer outcomes than non-smokers.⁴ Based on these clinical results, high tibial osteotomy can be offered to smokers without concern about non-union or an excess of complications. However, care should be taken to ensure obese patients are fully informed as to the likely functional outcomes. It is always with slight caution here at 360 that we interpret functional results in the obese. Patients with poorer outcome scores may not be limited by their knee performance, but by their obesity. It is often better to report improvement in functional scores than raw scores themselves as this can overcome some of these difficulties.

Defining the “Patient Acceptable Symptom State”

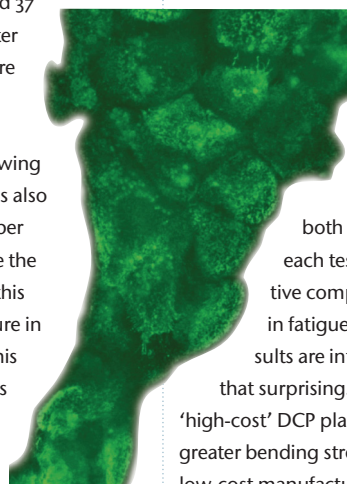
■ One of the difficulties with all outcome measures is working out what really matters to the patient. This isn't just the art of asking the right question, it's asking the right question at the right time for the correct disease - something we are slowly getting better at in orthopaedics. What makes matters worse is the difficulties associated with understanding the result. While the minimally clinically important change defines the smallest change on any given scoring system that is clinically relevant, the Patient Acceptable Symptom State (PASS) is a more defined entity that essentially denotes what an acceptable result

is from the patient's perspective. The PASS has not previously been defined for the Oxford Hip or Knee Scores. Researchers in **Leiden (the Netherlands)** set out to define what an acceptable symptom state was in a prospective multicentre cohort study. The researchers collated the Oxford Hip Score (OHS) and Oxford Knee Score (OKS) at a mean follow-up of three years (1.5 to 6.0). These scores were combined with measures of satisfaction (numeric rating scale) and the external validation question assessing the patient's willingness to undergo surgery again. Data were collected on a total of 550 patients undergoing total hip replacement (THR) and 367 undergoing total knee replacement (TKR).⁵ Using ROC statistics, the investigators were able to establish PASS threshold values. These were calculated at 42 points for the OHS after THR and 37 points on the OKS after a TKR. These values are crucial in the evaluation of acceptable symptom states following surgery. Of course it is also important to remember that these figures, like the MCIC, only relate to this score for this procedure in this patient group. This study really highlights the intricacies of adequately assessing outcomes following orthopaedic surgery. It is not good enough simply to select the correct score.

Cheap and nasty implants of poor quality

■ The impetus to cut costs in health care continues apace. With most nations spending more and more of their GDP on provision of health care, one obvious place to save money has often been thought to be implants. While the latest implants are covered by patents, some older staples (polished taper hips, the venerable DHS, and many others) are so far out of patent that many cheaper alternatives are being pushed by device

companies the world over. There is little evidence to support the efficacy of these cheaper ‘alternate’ implants which may not have undergone the extensive biomechanical testing and rigorous clinical and pre-clinical trials most new (and patent protected) implants undergo. Biomechanists in **San Francisco (USA)** used the humble dynamic compression plate to compare the biomechanical properties of top drawer and ‘lookalike’ implants from leading developed and developing world manufacturers. The research team utilised a standard ten-hole DCP from eight manufacturers (six developing-world and two western manufacturers). Each manufacturer supplied nine plates that were tested in a range of standard biomechanical tests. The study team used a four-point monotonic bending model to assess strength and stiffness



(six tests) and four-point bending fatigue (three tests). Outcomes were assessed using both group means for each test and a qualitative comparison of failure in fatigue testing. The results are interesting, but not that surprising. Manufacturers of ‘high-cost’ DCP plates demonstrated greater bending strength than any low-cost manufacturer. Low-cost manufacturers with manufacturing quality standards could match the high-cost manufacturers in terms of stiffness and fatigue failure and outperformed those with no manufacturing standards in all measures.⁶ This is (to our knowledge here at 360) the only biomechanical comparison of any manufacturers ‘off patent’ products. It is interesting that, although sold as ‘comparable’ products, the mechanical properties of these implants do not match those of western suppliers, even from manufacturers who comply with quality standards. It appears that in orthopaedic implants, like so many other things

in life, you simply get what you pay for. We congratulate the authors on a paper which may go some little way to stemming the cost-cutting policy in implant procurement.

And finally....

■ We would draw our readers' attention to two papers of significant general interest, both for their unusual study design and as part of orthopaedic heritage.⁷ Monsieur Hernigou from **Créteil (France)** does a wonderful job of tracing the development of orthopaedic conditions and the orthotics used to treat them, tracing conditions such as leprosy, poliomyelitis and ‘cripples’ throughout the middle ages and the works of art that record the evolution of their crutches.⁸

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