X-ref ***For other Roundups in this issue that cross-reference with Shoulder & Elbow see: Trauma Roundups 1, 2 & 5; Children's orthopaedics Roundup 7; Research Roundups 3 & 6.***

Largest RCT on clavicles to date

■ It is pretty much impossible to open an orthopaedic journal (or this edition of *360*, for that matter) without reading something new about the humble clavicular fracture. An excellent ethos for multicentre studies in both trauma and the upper limb is developing in the UK. This latest nationwide randomised controlled trial (RCT), led from the Royal Free Hospital, **London (UK)**, seeks to gather valuable information in order to address the controversial management of displaced mid-shaft clavicular fractures.[1] The study team designed a prospective RCT to compare conservative management with open reduction and internal fixation (ORIF). Patients were randomised to one of the two interventions in a pragmatic design. The primary outcome measure was the incidence of nonunion at three months. Secondary outcomes included nonunion at nine months, and functional scores (Constant and Disabilities of the Arm, Shoulder and Hand (DASH)) at six weeks, three months and nine months. The multicentre study team recruited 300 patients, and there was no difference in union rates at three months. However, there were some significant differences in some of the secondary outcome measures. At nine months' follow-up there was a significant difference in union rates, with a nonunion rate of 0.8% in the operative group *versus* a cumulative total of 15% in the non-operative group. Functional scores were the opposite, however, with significantly better outcomes in the operated group at six weeks and three months, but no significant difference at nine months. Apart from its obvious benefit of high patient numbers, this study benefited from well-balanced demographics between the screened and randomised patients, including patients from a wide range of hospitals over an extensive geographical area, thus increasing the study's external validity. The rate of complications was surprisingly low, with no wound infections and only two re-operations (one loss of fixation and one plate removal). Overall, patients who go on to unite have a good outcome, regardless of whether they were operated on or not, and this study adds to previous data on the risk of nonunion. Clavicular fracture studies are starting to reach saturation level, and the addition of reliable data is valuable. We can't help wondering exactly how many of these studies are required.

Mid-shaft clavicle meta-analysis

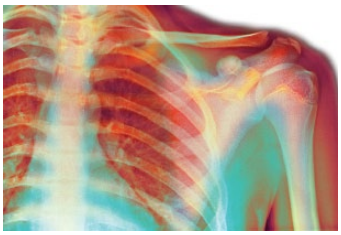
■ In the last issue of *360*, we drew attention to what was then the latest in a series of large clavicle trials.[2] We suggested that a meta-analysis was required and our wishes have been met by the same group from **Leiden (The Netherlands)**.[3] The review team undertook a thorough literature review with the intention of establishing whether open reduction internal fixation (ORIF) or conservative treatments are most effective for mid-shaft clavicle fractures. The review team undertook a comprehensive search of the indexed literature and were able to identify six randomised controlled trials reporting the outcomes of 614 patients. Meta-analysis revealed that the risk of nonunion was, unsurprisingly, significantly lower in the operative group (relative risk 0.14). However, the results were far from a slam dunk in favour of the operative group, with 17.6% of operated patients requiring a further operation, including those requiring plate removal. Despite the relatively high nonunion rate, just 16.6% of the initially non-operated group went on to require an operation. The abstract of this study states that the Constant scores and the Disabilities of the Arm, Shoulder and Hand (DASH) scores were somewhat better after fixation, but the differences are not significant, and nor do they meet the generally accepted minimum clinically important difference. Overall, the authors conclude that there is not enough evidence to support routine operative treatment for all patients with a displaced mid-shaft clavicular fracture. Alas, this paper does not incorporate the more recently published study above, which would have increased the included numbers from 614 patients to over 900. Here at *360*, we would agree with the authors that a blanket recommendation is inappropriate but, certainly in the UK, recent legal cases such as Montgomery *vs* Lanarkshire Health Board and Thefaut *vs* Johnson mean that informed decisions tailored to the individual patient are critical, and this meta-analysis does go a long way towards quantifying the risks and benefits of each approach in the contemporary literature.

Elderly olecranon fixation RCT

■ Following up on their 2014 paper documenting the longer-term outcomes of non-operative management of Mayo type II olecranon fractures in the elderly, this trauma group study team from **Edinburgh (UK)** sought to add randomised controlled trial (RCT) data to the evidence base.[4] The group designed a RCT of displaced olecranon fractures in patients over the age of 75 to determine whether operative or non-operative management was superior. Patients were randomised to one of the groups and operative management could consist of either tension-band wiring or plate fixation as appropriate, but the rest of the management was essentially pragmatic. Outcomes were reviewed at six weeks, three months, six months and one year after the injury. The primary outcome measure was the Disabilities of the Arm, Shoulder and Hand (DASH) score at one year. However, despite worthy intentions, the group were able to recruit just 19 patients aged over 75 years with displaced olecranon fractures who were randomised before the trial was prematurely halted. This was due to an observed complication rate of 9 out of 11 in the operative group. This is obviously a huge shame as the trial becomes underpowered and the non-inferiority of operative management cannot be proven. The complications were mainly loss of fixation and removal of prominent metalwork. This study may therefore come in for a bit of criticism from the sector of the elbow community who advocate plate fixation in osteoporotic bone, even for type IIA fractures. The authors allowed the individual surgeon to make a pragmatic choice between wires and plate, and nine of 11 patients underwent wiring. There was no difference in outcome scores between the groups at any stage and the authors take this as further supportive evidence for non-operative management while acknowledging the lack of power.

Tension band wiring *versus* plate fixation for olecranon fractures

■ This same group from **Edinburgh (UK)** have reported another randomised controlled trial (RCT) in the olecranon, this time aimed at answering the question for those undergoing an olecranon fracture fixation: should one use a tension band wire construct or plate?[5] The study team designed and undertook their own prospective RCT in an attempt to answer the question of best implant for fixation in those patients with an isolated displaced



olecranon fracture. The RCT included adult patients aged 16 to 75 years, all with isolated olecranon fractures. Outcomes were assessed at regular intervals up to a year following surgery, with a primary outcome measure of the Disabilities of the Arm, Shoulder and Hand (DASH) score at a year following surgery. In all, 67 patients were recruited to the study and randomised to tension band wire (n = 34) or plate fixation (n = 33). There was a moderate rate of attrition, and 85% of patients were available for follow-up, with an even split between the groups. In terms of take home messages, the DASH score, Mayo elbow score, and range of movement were not significantly different between the groups at any timepoint. However, there were some differences in the secondary outcomes. The metalwork removal rate following tension band wiring was significantly higher and, interestingly, infections only occurred in the plate group in this study, perhaps due to the more extensive approach. The authors should be commended in their efforts with this study. Although single-centre and underpowered, it is tricky to recruit to this kind of intervention study. It appears that, with regard to the metalwork, there is not much to choose between the plate and wiring option; however, there are newer techniques such as tension band suturing that are starting to gain traction in some quarters.

High BMI a risk for shoulder arthroplasty complication

Obesity is a well-documented risk factor for complications in a multitude of orthopaedic interventions, being implicated as a risk for complications in pretty much any surgical procedure one cares to name, from cancer surgery through to hip arthroplasty. Nonetheless, the evidence behind this widely held belief is often little better than circumstantial. With case series failing to account for other associated comorbidities such as diabetes and hypertension, it is far from clear in many surgical disciplines what exactly is the scale of the problem is with obesity (if indeed there is one). The lack of quality evidence is a particular problem in the upper limb, and we were delighted to see this paper from **Rochester, Minnesota (USA)**, which examines the potential association between obesity and complications following shoulder arthroplasty.[6] There are few places in the world that are able to draw on their own experience of their past 4500 cases to answer a simple question such as 'does increasing body mass index (BMI) have an adverse effect on outcomes?' However, the Mayo clinic is one of those places. Their series is formed from the institutional experience of 4567 consecutive shoulder arthroplasties of various designs, undertaken over four decades, from 1970 to 2013. Patients had a mean BMI of 29.7 kg/m² (14 to 66). In this series at least, increasing BMI was associated with an increased risk of a revision surgical procedure, re-operation, revision for mechanical failure, and superficial infection. Interestingly, the risk of a revision procedure rose by 5% for every single unit increase in BMI, and this effect was seen even when a multivariable model was used to account for potential confounders. It is somewhat difficult to quantify exactly how large an increase in BMI presents an unacceptable risk. Clearly, increased BMI does have an adverse effect on outcomes, and, when taking other risk factors into consideration on an individual level, this study should inform patient counselling. However, the more profound question of who is too obese to receive a shoulder arthroplasty is more a philosophical than a scientific one, given the data presented here.

Psychological status and shoulder arthroplasty

Another oft-studied part of the outcomes picture has been given another look by the team in **Boston, Massachusetts (USA)**: that of psychological well being.[7] There is again a large volume of data pertaining to other areas of orthopaedics (most notably hands and spines) that essentially establishes that outcomes are, to a great extent, dependent on the psychological well being of the patient. However, despite the significant amount of work published, little concerns outcomes in upper limb orthopaedic surgery. Given that the effect on psychological and physical well being is an often-overlooked dimension when measuring the results of orthopaedic interventions, we were delighted to come across this prospective evaluation of the impact that total shoulder arthroplasty has on a range of psychological outcome metrics. This prospective cohort study focuses on the outcomes of 46 patients who underwent total shoulder arthroplasty and reports measures of depression, anxiety and Health-Related Quality of Life (HRQoL) scores for osteoarthritis. The authors hypothesise that, given the impact pain can have on psychological well being and quality of life, both would improve as a result of the shoulder arthroplasty. There were significant improvements seen from three months post-surgery in the Hospital Anxiety and Depression Scale (HADS), along with the World Health Organization Quality of Life (WHOQOL-bref) measure. As would be expected, these were accompanied by improvements in pain scores and the American Shoulder and Elbow Surgeons Shoulder (ASES) functional scores. Perhaps most interestingly, not only did surgery improve the patients' psychological well being, but pre-operative depression and anxiety scores did not appear to predict poor post-operative outcome.

Tranexamic acid in shoulder arthroplasty

The use of tranexamic acid (TXA) in lower limb arthroplasty is well documented; its use in upper limb arthroplasty less so. This prospective randomised placebo-controlled study from **Vienna (Austria)** set out to evaluate the effect that TXA has on blood loss following total shoulder arthroplasty.[8] The team randomised 54 patients undergoing primary unilateral total shoulder arthroplasty to either standard care with placebo or a 1000 mg TXA infusion prior to skin incision. Outcomes assessed included drain-measured blood loss, post-operative Visual Analogue Scale (VAS) pain scores and adverse events. The infusion of TXA in this setting resulted in a reduction in peri-operative blood loss, post-operative pain and haematoma formation. The authors examined both anatomic total and reverse polarity prostheses and, unusually for shoulder arthroplasty, a drain was placed in the deltopectoral interval. There were no transfusions required in either group, nor were there any adverse events. Given the lower propensity to deep vein thrombosis in upper limb surgery, this is an intervention that should be routine in the absence of contra-indications.

REFERENCES

1. Ahrens PM, Garlick NI, Barber J, Tims EM, Clavicle Trial Collaborative Group. The clavicle trial: a multicenter randomized controlled trial comparing operative with nonoperative treatment of displaced midshaft clavicle fractures. *J Bone Joint Surg [Am]* 2017;99-A:1345-1354.

2. Woltz S, Stegeman SA, Krijnen P, et al. Plate fixation compared with nonoperative treatment for displaced midshaft clavicular fractures: a multicenter randomized controlled trial. *J Bone Joint Surg [Am]* 2017;99-A:106-112.

3. Woltz S, Krijnen P, Schipper IB. Plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a meta-analysis of

randomized controlled trials. *J Bone Joint Surg [Am]* 2017;99-A:1051-1057.

4. Duckworth AD, Clement ND, McEachan JE, et al. Prospective randomised trial of non-operative versus operative management of olecranon fractures in the elderly. *Bone Joint J* 2017;99-B:964-972.

5. Duckworth AD, Clement ND, White TO, Court-Brown CM, McQueen MM. Plate versus tension-band wire fixation for olecranon fractures: a prospective randomized trial. *J Bone Joint Surg [Am]* 2017;99-A:1261-1273.

6. Wagner ER, Houdek MT, Schleck C, et al. Increasing body mass index is associated with worse outcomes after shoulder arthroplasty. *J Bone Joint Surg [Am]* 2017;99-A:929-937.

7. Cho CH, Song KS, Hwang I, Coats-Thomas MS, Warner JJP. Changes in psychological status and health-related quality of life following total shoulder arthroplasty. *J Bone Joint Surg [Am]* 2017;99-A:1030-1035.

8. Pauzenberger L, Domej MA, Heuberer PR, et al. The effect of intravenous tranexamic acid on blood loss and early post-operative pain in total shoulder arthroplasty. *Bone Joint J* 2017;99-B:1073-1079.

Spine

X-ref ***For other Roundups in this issue that cross-reference with Spine see: Children's orthopaedics Roundups 5 & 6.***

Failure in retrieved magnetically controlled spinal rods

Magnetically controlled growing rods offer a high tech, mechanical alternative to repeated rod-lengthening operations, and are gaining traction in the treatment of the growing spine. The potential benefits are clear: fewer operations and thus reduced surgical costs in the long term, reduced morbidity from surgical site infections and a reduced psychological impact on young patients. These promised benefits, however, may not be materialising, with sporadic reports of rods failing to elongate or fracture. These authors from **London (UK)** have retrieved and analysed nine magnetic rods that were explanted for differing reasons – a fractured actuator pin, skin discoloration, scoliosis progression, and in preparation for final fusion.[1] The explanted rods were all investigated with radiographs and, in two cases, the implants were sectioned and analysed with micro-CT. The key findings were that a third of the rods had failed due to pin fracture and this was associated with significant corrosion of the internal mechanism. The authors propose a mechanism of failure that involves fluid ingress between the rod and the external shell, as well as a build-up of corrosive debris that increases friction within the device, reducing its capacity to distract, and leading to fracture of the actuator pin. Although this explant study involves very small numbers, the authors suggest that debris build-up should be considered when rods fail to distract. Several questions remain unanswered: do certain patient factors or distraction techniques increase the risk of pin fracture and does this metal debris have a long-term deleterious effect?

Re-operation following instrumented lumbar spinal fusion

A recent NHS initiative entitled Getting It Right First Time (GIRFT) is aimed at improving patient outcomes by standardising care and optimising treatment pathways and, in part, by avoiding unnecessary re-operations. However, unlike hip and knee arthroplasty where early revision surgery is considered a failure of initial treatment, further spinal surgery can be inevitable and does not necessarily represent poor initial care. The authors of this study from **Tampere (Finland)** have examined the re-operation rate and indications for re-operation following lumbar spinal fusion specifically, which is becoming increasingly relevant to all concerned with the GIRFT initiative, bundled payments and loss of income from re-admissions.[2] The authors report the outcomes of a total of 433 consecutive patients who underwent lumbar spinal fusion in their unit. The most common indication was degenerative spondylolisthesis and mean follow-up was 3.9 years. Within this timeframe, 81 patients had undergone at least one re-operation and there was a cumulative re-operation rate of 12.5% at two years, rising to 19.5% at four years. The most common indication for re-operation was adjacent segment pathology (8.7% at four years), while other indications included early (< one year) and late (> one year) instrumentation failure at 4.4% and 2.9%, respectively. The rate of other acute complications (such as haematoma/deep wound infection/new neurological deficit or implant malposition) that required re-operation was low at 2.5%. These sorts of studies are becoming more and more important as they underline the mixed causes of re-admission and failure. For the clinician, this study provides a useful guide when informing patients of the risks of surgery during the consenting process and a reasonable standard against which to audit outcomes. For healthcare commissioners, it demonstrates that re-operation in spinal surgery needs to be factored in to funding formulas and that re-operation following fusion is a predictable sequela for a number of patients and not always a sign of failure.

Proximal junctional kyphosis

Proximal junctional kyphosis (PJK) is the most common mechanism of adjacent spinal segment failure following instrumented spinal surgery, and is a source of great frustration for the deformity surgeon, and disappointment for the patient. It occurs when the sagittal Cobb angle is > 10° above an instrumented fusion and is therefore an iatrogenic complication often associated with large deformity corrections. Two studies worthy of comment in this edition of *360* have attempted to quantify the risk factors of PJK so that it can be avoided. The first of the two articles, a multicentre study from **Lyon (France)**,[3] set out to investigate the factors predictive of PJK, by undertaking a thorough analysis of radiological parameters present in 250 patients following adult deformity surgery. They compared four different formulas of recognised geometric relationships involving spinal parameters, such as lumbar lordosis (LL), thoracic kyphosis (TK) and pelvic incidence (PI). They used pre-operative and immediate post-operative films in order to establish the potential predictive value of each for PJK. Patients were followed up clinically and the prediction was then compared with actual occurrence of PJK. There was a 25.5% incidence of PJK within the follow-up period. Essentially, only two of the examined methods actually predicted PJK: first, if the global sagittal alignment (GSA = LL + PI +TK) was > 45° (19.9% *vs* 29.9% when > 45°); and second, if the theoretical and actual apex of lordosis did not match up (13.5% *vs* 38.9%). The latter method was based on Roussouly's curve types and the theoretical apex was L3 if PI > 55°, and L4 if PI < 55°. In the second paper on the same topic, originating from several centres in the **USA**, the investigators focused on a number of previously identified risk factors.[4] Their study reported the results of 252 patients, all with adult spinal deformity (ASD), with two years of clinical follow-up available. The