ROUNDUP360

Knee

For other Roundups in this issue that cross-reference with Knee see: Research Roundup 5 and Hip & Pelvis Roundups 3 and 6.

Intra-operative sensors for knee balance?

Balancing in total knee arthroplasty (TKA) has been shown to be an important predictor of outcome, both in terms of patient satisfaction and longer-term survivorship outcomes. The precise interplay between the importance of bony balance and soft-tissue balance is not quite sorted out as yet, but it is clear that both are important. Surgeons in **Florida (USA)** reported a novel study examining a potential method for improving intra-operative soft-tissue balance using sensor technology, then attempted to see if this had an effect on the functional outcomes. The study used an intra-operative sensor to establish if the arthroplasties were balanced, and related this to a satisfaction rating one year post-operatively. Of the 135 primary TKAs assessed as part of this study, 113 (87%) were described as 'balanced' using the sensor technology. The outcomes between the balanced and unbalanced cohorts were significantly different by final follow-up, with just 82% of unbalanced patients reporting high satisfaction levels, as opposed to 97% in the balanced group.[1] The authors did not change their intervention based on the results of the sensors, nor randomise patients to one balancing method or another. However, given their results from this comparative series it would seem that this is an intervention in need of a randomised controlled trial.

Mobile bearing no advantage

One of the strongest methodologies in intervention studies is the randomised controlled trial with internal control. There is no better patient selection than randomising patients to one intervention on one side, and the comparative intervention on the other ipsilateral joint. Researchers in **Seoul (South Korea)** present a neat long-term follow-up of such a study which has been previously reported with a shorter-term follow-up. Their study concerned 444 patients undergoing bilateral simultaneous TKAs; one with a mobile-bearing PFC Sigma, and one with a fixed bearing. Both prostheses were cruciate-retaining designs. Outcomes were assessed at a mean of 12.1 years with functional scores (total knee, WOMAC and UCLA activity scores) and radiologically. The authors were unable to find significant differences between any of the scores. In addition, post-operative radiographs did not demonstrate any differences in loosening rates (1.8% vs 1.4%) or ten-year survivorship (98.2% vs 97.5%). In what is one of the largest comparative prospective studies, the authors demonstrate conclusively that certainly by ten years there is no difference in the rates of complication, functional outcome or longevity of mobile-bearing *versus* fixed-bearing total knee arthroplasties of this design.[2] It is tempting to generalise results such as these to all prostheses; however, constraint, type of mobility and fundamental design features vary between different manufacturers. While this currently represents the best comparative evidence there is, it is important to remember the limitations in general.

Death and knee replacement: a falling phenomenon

Although now considered routine by patients and surgeons alike, the risk of mortality following total knee arthroplasty remains, and, more importantly, the trend and associations are not clearly understood. With low event rates, large 'big data' studies are required to establish incidence, trends and associations between death and TKA. Researchers from the **National Joint Registry (UK)** have attempted to understand the changes in mortality and knee replacement in the eight years the joint registry has been collecting data, with an end point of 45-day mortality. The study includes data from nearly half a million knee replacements. The research team focused their efforts on identifying any potential modifiable risk factors in order to establish the potential for improvement. In what is the largest inclusive nationwide study on mortality in knee arthroplasty, the research team identified a substantial decline in post-operative death with rates falling from 0.37% to 0.20% over the observation period of the study. An adjusted mortality analysis for age, comorbidities and sex yielded unicompartmental knee arthroplasty as a clear winner, with a hazard ratio of 0.32 for death within 45 days when compared with traditional THA. There was an established association between several comorbidities including myocardial infarction (HR 3.46), cerebrovascular disease (3.35), liver disease (7.2) and renal disease. The authors were able to state conclusively that several other modifiable operative risk factors, including surgical approach and thromboprophylaxis, were not associated with mortality.[3] This study is heartening in that knee replacement is becoming safer and safer, with the number of post-operative deaths nearly halving over an eight-year period. It is also interesting to find that implant selection (discussed in the next paper) does have an effect on mortality while thromboprophylaxis regime does not. Targeting patients with established medical comorbidities should clearly be next on the agenda of improving risk of death following knee arthroplasty.

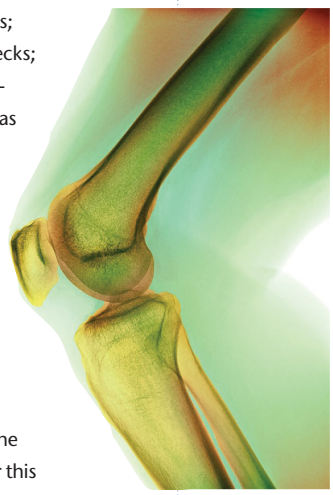
The swings and roundabouts of unicompartmental arthroplasty

The fierce debate on the interplay between functional outcomes, revision rates, death and complications associated with unicompartmental *versus* traditional total joint arthroplasty is revisited in this national joint registry-based paper from the arthroplasty group in **Oxford (UK)**. The group devised a case-matched study design based around a propensity score analysis comparing the outcomes of 25 334 unicompartmental knee arthroplasties (UKAs) with 75 996 total knee replacements (TKAs) – cases from the UK National

Joint Registry (NJR) performed over a nine-year period. The research team used database matching from the National Health Service Hospital Episode Statistics data to try and establish the outcomes of baseline characteristics in a fuller way than just use of the NJR data. Outcomes were compared between the two cohorts of patients with end points of revision arthroplasty, re-operation, complications, mortality and length of stay.
It is well established that overall implant survival is poorer in UKA and, even with propensity matching, the implantation of a UKA had a profound effect on outcome in terms of revision risk (HR 2.12). However, there was a much lower risk of death associated with UKA (HR 0.23), which appeared more marked with propensity matching and 30 days outcome (HR 0.32). As might be expected, the smaller operation is also associated with reduced length of stay and fewer recorded major complications.[4] Interestingly, the authors (who come from the designing unit of the most widely implanted UKA in this dataset) choose to interpret outcomes at four years (rather than the eight-year follow-up of the study). They conclude that there would be one fewer death/100 implantations, but three more revision operations. This in itself is a confusing statement. Reporting mortality at four years for arthroplasty is a very unusual choice. If a shorter period were chosen (say 45 days), around 200 patients would have to be implanted at contemporary death rates to see any difference between the groups. Bias in the reporting? Quite possibly.

Regulation, implants and innovation

■ In the wake of the ASR crisis there has been more of a spotlight on the introduction of new and amended technology than perhaps there has ever been before. There is a careful balance to be struck between the introduction of new technology and the stifling of innovation. Most, however, would agree that all new implants should be supported by peer-reviewed scientific literature. The scale of the problem has been investigated in a number of articles recently supporting implanted prostheses. However, surgeons in **New York (USA)** have looked at things from a different perspective, examining if there is evidence on the safe introduction of new implants (rather than evidence of longevity for established implants). The research team undertook a systematic review with the intention of establishing where we are with evidence for the safe introduction of five device innovations. The study team reviewed indexed literature, reference lists of articles, registry reports, pre-market safety data and post-market studies. The innovations evaluated were from hip arthroplasty (ceramic-on-ceramic bearings; modular femoral necks; uncemented monoblock cups) as well as knee arthroplasty (high flexion knee; gender-specific knee). The authors took the interesting approach of evaluating design features rather than specific implants. The inclusion criteria for this study included studies featuring the results of primary hip or knee replacement that reported at least a single outcome measure of interest (either PROMs or complications). A stonking 10 557 searched articles were reviewed by the authors, with only 118 of these eligible for inclusion in the study, recording data on 15 384 implants. While there were no improvements in complication rates or PROMs found in this review, there were some differences in the evidence to support this statement for each innovation. Modular femoral necks were the most poorly supported innovation, with just four low- or moderate-quality studies describing their outcomes, while the introduction of high flexion knees was supported by 56 studies, including seven randomised controlled trials.[5] The reviewed national registries reported the outcome of 1 200 000 well-established devices, and comparisons with the 200 000 'innovative' new devices suggested that there was little in the way of improved implant survival. The research team concluded that they had failed to find any high-quality convincing data to support the use of these new implants and that some devices have been introduced without appropriate pre- and post-introduction surveillance. The arguments made in this paper support the 'Beyond Compliance' system promoted by the BOA in the UK – we hope that other nations will follow suit.



The weight of arthroplasty responsibility!

■ On a somewhat lighter note, surgeons in **Paris (France)** have answered a burning question on the lips of surgeons and patients alike: "Doctor, how much heavier will I be with my new knee?" While we have to confess to it never having occurred to us at 360 HQ, the authors of this study feel "local weight gained after TKA is a new parameter that should be taken into account for further studies and when creating new implants". In this unusual study only a relatively simple design was required. The study patients having primary total knee replacements had the 'bits' that went in, and the 'bits' that came out, weighed. They established that average weight gain is in fact a surprising 270-odd grams for an arthroplasty.[6] We are not sure this is as devastating a finding as the authors of this unusual study seem to feel – after all, metal is heavier than bone!

BMI in arthroplasty

x-ref Hip

■ In an interesting but likely underpowered and certainly flawed study, researchers in **Devon (UK)** set out to re-examine the effects of BMI during arthroplasty. The research team recorded patient factors (age, sex, BMI), and evaluated the effects of BMI and comorbidities on both length of stay and operative time.[7] Their retrospective study evaluated 589 patients, all of whom underwent lower-limb arthroplasty procedures in their institution. Although they performed a relatively rudimentary analysis, their results are interesting in that each single BMI point increase results in a 2.9% increase in length of stay, and 1.5 minutes of surgical time. While seemingly small numbers, given the usual range of patients BMIs, otherwise identical patients may have a vastly different resource utilisation.

REFERENCES

1. **Gustke KA, Golladay GJ, Roche MW, et al.** Increased satisfaction after total knee replacement using sensor-guided technology. *Bone Joint J* 2014;96-B:1333-1338.
2. **Kim YH, Park JW, Kim JS, Kulkarni SS, Kim YH.** Long-term clinical outcomes and survivorship of press-fit condylar sigma fixed-bearing and mobile-bearing total knee prostheses in the same patients. *J Bone Joint Surg [Am]* 2014;96-A:e168.
3. **Hunt LP, Ben-Shlomo Y, Clark EM, et al.** 45-day mortality after 467,779 knee replacements for osteoarthritis from the National Joint Registry for England and Wales: an observational study. *Lancet* 2014;384:1429-1436.
4. **Liddle AD, Judge A, Pandit H, Murray DW.** Adverse outcomes after total and unicompartmental knee replacement in 101,330 matched patients: a study of data from the National Joint Registry for England and Wales. *Lancet* 2014;384:1437-1445.
5. **Nieuwenhuijse MJ, Nelissen RG, Schoones JW, Sedrakyan A.** Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies. *BMJ* 2014;349:g5133.
6. **Gibon E, Mouton A, Passeron D, et al.** Doctor, What Does my Knee Arthroplasty Weigh? *J Arthroplasty* 2014;29:2091-2094.
7. **Bradley BM, Griffiths SN, Stewart KJ, et al.** The effect of obesity and increasing age on operative time and length of stay in primary hip and knee arthroplasty. *J Arthroplasty* 2014;29:1906-1910.