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Knee

Re-admission following total knee arthroplasty: are complications to blame?

■ In these days of bundled payments and financial penalties for re-admissions, with some healthcare systems imposing enforced financial implications on hospitals and surgeons where patients are re-admitted within a fixed time period, the surgeon now faces dual burdens. On the one hand, there is significant pressure to reduce hospital admissions and length of stay, and, on the other, there are penalties if the patients are re-admitted (higher re-admission rates seem almost inevitable with day-case or 24-hour stay arthroplasty). Surgeons in the Hospital for Special Surgery in **New York, New York (USA)** are taking a look at the somewhat contentious issue of re-admission after surgery for total knee arthroplasty (TKA).[1] Aiming to clarify what the causes and risk factors are after surgery, they used the Statewide Planning and Research Cooperative System (SPARCS) database from the New York State Department of Health to identify 377 705 patients, all of whom had undergone TKA between 1997 and 2014 in New York State. In total, there were 22 076 re-admissions within 30 days: an overall incidence of 5.8%. The authors extracted the ID-9 codes for re-admission and attributed them as due to complications as a result of the primary procedure (ICD-9 attributable and a wider definition agreed by expert opinion) or unrelated. The authors then undertook a multivariable analysis to examine the incidence, causation and predisposing factors for re-admission following surgery for a TKA. There were differing rates of re-admission between units included in the study, with a median rate of 3.9%. Using the two criteria defined in the study, 11% were ICD-9 attributable to the knee arthroplasty, and 31% were potentially attributable on the expanded expert list. The authors identified older age (> 85 years, odds ratio (OR) = 1.32), male gender (OR = 1.41), Medicaid coverage (OR = 1.40), and various comorbidities as increasing risk factors for knee-related re-admissions. However, although smaller units had a higher re-admission rate, this was not specific to knee-related complications and appeared to be important in units operating on < 90 patients per year. The key take home point of this study is that re-admission for any cause after TKA is much higher than for total knee-specific causes. With this being the case, orthopaedic surgeons and their units should not be punished for every hospital re-admission after surgery. Hospital administrators and healthcare funders should recognise and make the distinction between separate re-admissions that should not be bundled with the index procedure payment, if the complications are different and not related to the index surgery.

Total knee constraint and surgical technique: any effect on survival?

■ Constraint and ligament substitution is an interesting area in total knee arthroplasty (TKA), and there are certainly a number of differing philosophies as to what is best. At one end of the spectrum, there are some surgeons who will undertake rotating hinge knee arthroplasties, even as a primary procedure. On the other, there are those who will do their utmost to retain the ligaments, and preferentially insert posterior cruciate ligament (PCL)-retaining implants – even into valgus knees, which potentially require more constraint. These authors from **Adelaide (Australia)** reason that there are potentially two types of surgeons: those who always undertake posterior-stabilised implants; and those who use cruciate-retaining knees where possible (sometimes known as kinematic and minimally stabilised, respectively).[2] The authors sought to take advantage of these preferences to test the assertion that kinematic knee arthroplasty survival is poorer due to case selection, as those with a preference for minimal stability will undertake kinematic knees in more complex cases. The authors constructed a form of intention-to-treat analysis using the apparent surgical preferences from the Australian Joint Registry. They then went on to compare outcomes between posterior-stabilised and cruciate-retaining TKAs. The study showed interesting results in a large patient population. However, it is important to recognise the drawbacks in this method, in that by comparing surgeons who used one prosthesis exclusively, the study is really a comparison of surgical philosophy and technique as opposed to a comparison of implants. The primary outcome of this study was the hazard ratio (HR) for revision, which was calculated using cumulative percentage revision. The data set follows patients for up to 13 years, where the cumulative percentage revision was 5.0% (95% CI 4.0% to 6.0%) *versus* 6.0% (95% CI 4.2% to 8.5%) for surgeons who preferred minimally stabilised *versus* posterior-stabilised, respectively. Therefore, there were no overall significant differences in the cumulative percentage revision rates between the groups. Slightly confusingly, however, the hazard ratios were significantly different for all causes (HR 1.45, 95% CI 1.30 to 1.63), for loosening or lysis (HR 1.93, 95% CI 1.58 to 2.37), and for infection (HR 1.51, 95% CI 1.25 to 1.82). Further studies using prospective randomised cohorts are clearly needed here to determine

whether these differences are true in all patient populations. Estimation of risks in large cohort studies with variable follow-up and loss to follow-up is always rather difficult, and we are somewhat perturbed by the apparent conflict in overall cumulative revision risk and calculated hazard ratios for revision. Clearly, one would expect causes such as infection not to vary between the two techniques, with a reported HR of 1.45 (which is not, of course, a 45% increased risk of revision, despite the report here).[3] Despite the flaws in the study design, analysis, and reporting, here at 360 we do think that this study is worthy of mention – it does focus on a topical and poorly studied question: what should the inherent position for knee stabilisation be?

Patient selection in outcomes?

■ As we become increasingly data-driven across the world, this somewhat tongue-in-cheek article from **Flint, Michigan (USA)** has focused on the effect of patient selection in demonstrating significant outcomes.[4] There are, of course, some critical differences in how outcome measures perform across their range, both as a whole and within the various subscales that make up the constituent score. We were very interested to see this paper, which asks the question: can patient selection play a role in ensuring that 'significant' improvements are seen in Short Form-36 Health Survey (SF-36) scores? These authors evaluated patients' initial (pre-operative) and one-year SF-36 scores to see if there were any trends in achievement of minimally clinically important differences (MCID) in patient-reported outcomes. More specifically, they looked for trends that could be exploited either in patient selection or in order to temper expectations of patients who are less likely to do well. The study revolves around the MCID in the SF-36, and the authors established that, for knee arthroplasty

at least, younger patients, women, and non-diabetic patients have the best outcomes. The slightly unusual approach taken here (chances of achieving an MCID improvement) is one that perhaps should be adopted more often, as, rather than testing mean improvements, it focuses on the chances of an important benefit. Of course, in order for this analysis to be undertaken, the score in question needs to be appropriately validated. The groups identified here that do particularly well can be used to temper patient expectations in certain patient populations, prior to total joint arthroplasty, so that post-operative patient-reported outcomes can reflect these expectations. The cynical among us, however, worry that, in the data age, this kind of data (either formally presented or just from surgical experience) is being used by surgeons and healthcare providers to pick 'winners' as a form of healthcare rationing on the provider's side and to improve apparent outcomes on the surgeon's side.

Fall risk score for predicting re-admission?

■ In the era of bundled payments, understanding patient characteristics that predispose to re-admission after total joint arthroplasty may allow providers to implement systems to reduce the number of such re-admissions. The holy grail of accelerated discharge programmes and reducing re-admissions following joint replacement has been an effective predictive score that might be able to predict the likelihood of re-admission. These authors from the Mayo Clinic in **Phoenix, Arizona (USA)** set out to investigate the potential advantages of using a falls risk score (in this case, the Hendrich Fall Risk Score) to predict the likelihood of re-admission at 30 days following joint arthroplasty at their clinic.[5] The study is based on the results of 2437 Medicare patients who underwent a primary elective total joint arthroplasty of the hip or knee, all for osteoarthritis. The patients were all scored using the

falls assessment score, recorded both pre-operatively and post-operatively, which was evaluated as a predictor of re-admission. Using a relatively arbitrary falls assessment score cut-off of > 6, these authors were able to demonstrate a significantly higher risk of re-admission (odds ratio (OR) 2.84), and show that 9.3% (n = 223) of patients fulfilled this criterion. Not only were these patients more likely to have an unplanned re-admission, but they were also more likely to stay as an inpatient for longer than three days (49.6% *vs* 36.6%) and less likely to be discharged home (20.8% *vs* 35.8%). Obviously, this may just be an effect of patient demographics, with falls scores known to increase in step with comorbidities. However, even when controlling for age, muscle weakness and psychiatric diagnoses, the falls score continued to remain a significant predictor of re-admission (OR 2.44). Clearly, identification of patients likely to be re-admitted following total arthroplasty is critical to reducing the chances of an unsuccessful discharge. Clinicians must weigh the benefits and costs of trying to discharge directly to home and having a potential re-admission, or discharging to respite care, or a physiotherapy-led facility, with the potential to reduce the risks of re-admission. There is much food for thought here and, as bundled payments take hold, clearly there will be more and more focus on this topic.

Femoral nerve block *versus* periarticular infiltration following knee arthroplasty

■ Contemporary publications in total knee arthroplasty (TKA) cannot resist mentioning its increasing numbers and ballooning demand. Despite this, though, management of early post-operative pain continues to be a problem, and modern arthroplasty practice includes one of a number of post-operative analgesic strategies. Femoral nerve blocks can be very effective and have been shown to reduce the need for systemic analgesia, including opiates. A femoral nerve block in isolation,

however, does not address pain from the posterior aspect of the knee joint (supplied by the sciatic nerve). Aside from iatrogenic injury, femoral nerve blocks also have the downside of temporarily impairing quadriceps function, leading to difficulties in extending the knee and delayed mobilisation post-operatively. Other options have been suggested, including the adductor canal block, but this can be difficult to perform even in skilled hands, and does not provide any analgesia to the back of the knee. Alternatives to these techniques include periarticular infiltration with local anaesthetics, opiates, and non-steroidal anti-inflammatories. With the increasing numbers of TKAs being performed, and enhanced recovery programmes becoming the norm in elective knee arthroplasty surgery, we were delighted to see this report from **Coventry (UK)**, one of the first adequately powered comprehensive randomised controlled trials comparing the use of a femoral nerve block with periarticular infiltration.[6] This pragmatic study included a standard care regime of gabapentin, spinal or general anaesthetic and usual post-operative analgesia. The patients were randomised either to a femoral nerve block, using a nerve stimulator and ultrasound guidance as appropriate, or to a periarticular infiltration infiltrated into the medial, lateral, suprapatellar, and posterior soft tissues, as well as the skin. Patients received regular analgesia post-operatively but not in the form of a 'patient-controlled analgesia' (PCA) delivery system. In all, a total of 262 patients were recruited to the study and randomised (131 in each group). There was little difference in pain scores post-operatively with either technique. There was a small difference in the ability of patients to transfer from bed to chair independently on the first day post-operatively and a small difference in the Timed Up and Go test, both favouring the periarticular infiltration group. This was coupled with a

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reduced requirement for morphine in the periarticular group in the first 24 hours, and better mean flexion post-operatively. This study essentially established that these two interventions are equivalent in providing sufficient analgesia for patients following TKA. However, there were secondary advantages associated with the periarticular infiltration technique, such as lower opiate requirement and potentially better early mobilisation. There is nothing here to recommend conclusively one intervention over another; however, with some benefits and no apparent drawbacks, the local infiltration group seem to do better.

Periprosthetic joint infection: the main cause of failure for TKA

■ There is significant morbidity, as well as cost, associated with revision total knee arthroplasty (TKA), and with the plethora of publically available data at a hospital and surgeon level, we are in the best position we have ever been as a scientific community to understand the causes of failure in TKA. National joint registries, while an extremely important step forward, are not without their weaknesses, and data entry accuracy is one of them. On the other hand, outcomes from tertiary referral centres provide more accurate information but often lack data linkage to the original TKA.

The aim of this study was to review the combined data from the New Zealand Joint Registry (NZJR) and an individual patient chart review. This was a multicentre retrospective study from **Westlake (New Zealand)** of 11 134 primary TKAs at three tertiary referral centres, of which 357 patients underwent subsequent revision surgery, giving a 15-year cumulative incidence of 6%.[7] The five most common reasons for revision in this series were infection, aseptic loosening, patellofemoral arthrosis, instability, and stiffness. Somewhat unexpectedly, the majority (n = 169 of 357) were revisions or re-operations for periprosthetic joint infection (PJI). Aseptic loosening and polyethylene wear were unsurprisingly seen later in the follow-up, on average at eight years after the index surgery, whereas the annual incidence of PJI was highest during the first four years after the index operation. The most important findings of this study are that PJI is more than likely under-reported in the national joint registries, and that it is more of a problem than has been generally recognised. PJI is a costly complication to treat, not only to the patient in terms of pain and time off work, but also for the health economy. The strength of this study in combining data from a national joint registry with patient records enabled a comprehensive review of the true incidence of revision TKA. At present, the national joint registries of Australia, UK, Sweden, and New Zealand all show that aseptic loosening is the most common failure mechanism after primary TKA. The results of this study would challenge this assertion and they highlight that the capture of revision surgery by national joint registries, particularly after infection, is poor. For us to improve the outcomes for our patients, we need an accurate picture of the outcomes following TKA. There is clearly a need to improve the accuracy of data collection.

Computer-navigated *versus* conventional knee arthroplasty

■ Computer navigation of total knee arthroplasties (TKA) is not new; however, it is a technology that, despite a lack of significant evidence in its favour, is continuing to persist. There are two possible reasons for this: either there are not enough good-quality studies to detect the effect size or there really isn't any impact on patient outcomes. The authors of this excellent paper designed a prospective randomised double-blind, long-term study comparing computer navigation with conventional TKA. Not only that, but the 162 patients identified in the study required bilateral TKAs that were performed sequentially. For each patient, navigation was randomised either to the right or to the left. These authors from **Seoul (South Korea)** designed a study with clinical performance, revision incidence, and radiological outcomes.[8] At a mean follow-up of 12.3 years, there was no significant difference in the Knee Society Scores between the two groups. In addition, the alignment of the limb, positions of the components, level of the joint line, posterior condylar offset, and rotational alignment were not significantly different. There was also no difference in terms of survivorship analysis, with revision or aseptic loosening defined as the endpoint. However, there was one complication associated with the navigation group, and that was of anterior femoral notching, with an incidence of 5% compared with an incidence of 0.6% in the conventional group. This may be one of the more significant studies to dissuade surgeons from using navigation for every TKA. However, it did not identify certain patient subgroups who may benefit from this technique. The morbidly obese and patients with complex bone deformities, such as those following trauma or those with femoral nails preventing a conventional TKA, may benefit from

computer navigation. This study also highlighted a troubling complication in the navigation group of anterior femoral notching. For those enthusiasts of computer navigation, the software should be a guide and the experienced surgeon needs to know when to intervene and recognise when an error is being made before it is too late. As more technologies come onto the scene, such as robotically assisted joint arthroplasty, these adjuncts should be exactly that – adjuncts, not a replacement for an experienced surgeon.

Expectations predict PROMS, but not satisfaction, in total knee arthroplasty

■ Total knee arthroplasty (TKA) is one of the most successful and effective surgical interventions available. Used primarily for end-stage osteoarthritis of the knee, effect sizes are large and pain relief is reported to be good. Despite this, patient satisfaction following the surgery is somewhere between 70% and 90%. With today's heavier focus on value-based medicine, using Patient-Reported Outcome Measures (PROMs) as a measure of success is very important. While it is generally understood that fulfilment of expectations predicts higher patient satisfaction, the link between patient expectations prior to surgery, PROMs and patient satisfaction remains unclear. Investigators from **San Francisco, California (USA)** report their own multicentre prospective observational study with the expectation of exploring any apparent link between pre- and post-operative PROMs, expectations and satisfaction.[9] The authors present the results of a total of 83 patients, all undergoing primary TKA, who were enrolled in the study. Pre-operatively, patients were administered a variety of PROMs (Short-Form, 12-item, version 2 (SF-12), the University of California Los Angeles (UCLA) Activity Score, the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the Hospital for Special Surgery Knee Replacement Expectations Survey (HSS-KRES)). Follow-up was

at six and 12 months post-operatively with PROMs measures, and a short satisfaction survey completed at both time points. The authors were unable to establish a link between pre-operative PROMs and the cohort's relatively high pre-operative expectation scores. Pre-operative American Society of Anesthesiologists (ASA) scores and HSS-KRES were both predictive of one-year post-operative HSS-KRES scores in both the univariate and multivariate models. Higher pre-operative HSS-KRES scores also predicted more improvement in UCLA activity scores at six months and one year, and in SF-12 and KOOS at six months, suggesting that perhaps the level of optimism and positivity going into the surgery is beneficial. The authors of the study have demonstrated that higher pre-operative expectations predict greater improvement in PROMs and greater fulfilment of expectations, and that greater fulfilment of expectations predicted greater satisfaction. The missing link between pre-operative expectations and satisfaction may be as a result of a mixed bag of patient personalities. While optimistic patients may have high expectations, meet those expectations, and be satisfied, pessimistic patients may have lower expectations and may meet or exceed those expectations, but will still be dissatisfied whatever their outcomes. This is an important study as there is a concept of 'expectation management' in orthopaedic surgery, with those patients with high expectations being thought of as unrealistic. It appears from the work presented here that if you expect to do well, then in fact you will do well.

What do patients expect from total knee arthroplasty?

■ In light of the current focus on value-based medicine, which relies heavily on the patient's perception of the intervention they may undergo, and going hand in hand with the previous paper, this interesting exercise from **Dresden (Germany)** has set out to investigate patient expectations, reported outcomes, and satisfaction.[10] There remains a disconnect between expectations, outcomes, and satisfaction that we are all struggling to understand. It is unusual to use patients in a Delphi-type study; however, this is exactly what these investigators have achieved with the aim of determining the specific expectations, or treatment goals, of 108 patients, all with advanced osteoarthritis of the knee considering total knee arthroplasty (TKA). The Delphi method is an iterative consensus-building approach that, in this study, was used to determine which treatment goals were considered the group's principal, most important goals for TKA. From the patients' perception, treatment goals fell into one of three main categories: symptom reduction; functional improvements; and prevention and safety concerns. The patients identified the major goals of TKA as: increasing physical function and range of movement; decreasing pain; preventing secondary impairments; increasing walking distance; long-term implant survival; improving ability to navigate stairs; increasing the level of physical activity; increasing knee stability; and improving quality of life. Correlations between treatment goals and patient or disease characteristics were low, suggesting that patient treatment goals are not governed by disease or patient-specific symptomatology. Unfortunately, patients often have higher expectations than surgeons. Interestingly, more specific goals such as dependency on medical aids, use of medication, dependence on others, and sleep disturbance were unimportant to over 25% of patients. This consensus study identified ten main goals of treatment. However, it is important to help our patients formulate realistic goals and expectations prior to undergoing TKA in accordance with their current level of impairment, and this study should also be useful in guiding both service evaluation and research into new treatments.

Does pre-operative mobility predict post-operative function?

■ Patients making a slow functional recovery during their hospital stay following total knee arthroplasty (TKA) are more often discharged to rehabilitation facilities or home with additional support. It has been suggested that a prolonged stay in these post-acute facilities increases the risk of complications. We almost always assess our patients pre-operatively for risk factors such as BMI, smoking status, and history of deep vein thrombosis (DVT), but what about functional mobility? To investigate whether objective measures of pre-operative functional mobility may be a factor in delayed inpatient recovery, investigators from **Maastricht (The Netherlands)** enrolled 682 patients undergoing TKA, who were recruited during changes in the clinical pathway.[11] Over the six-year period of the study, 682 patients were administered the Timed Up and Go (TUG) test and the de Morton Mobility Index questionnaire (DEMMI) pre-operatively. Following surgery, inpatient recovery was measured using the Modified Iowa Levels of Assistance Scale (MILAS), which assesses a patient's ability to change posture and ambulate (supine to sitting, sitting to supine, sitting to standing, walking, and stair-climbing). A reference model was developed to determine the predictors of recovery, including known risk factors such as BMI, age, gender, American Society of Anesthesiologists (ASA) score, Charnley score, and Identification of Seniors at Risk (ISAR) score (a self-reported measure of frailty), as well as the TUG test and the DEMMI. Patients were considered to have delayed recovery when they were slower than 70% of their peers based on MILAS scores. Both the TUG test and DEMMI offered some predictive value to the model independently, and, when combined, predicted 22% of the variability in delayed inpatient recovery of activities. It appears that these pre-operative measures of functional mobility may be associated with a risk of delayed inpatient functional recovery. This article certainly offers a starting point for research into the association between pre-operative functional mobility and post-operative time to recovery. However, further work is clearly needed on establishing which variables do contribute and which measures can be used to predict post-operative functional recovery – just 22% of observed variation was explained by these two scores.

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Foot & Ankle

Platelet-rich plasma for ankle arthritis: is there any benefit?

■ There has been a noticeable increase in interest in using platelet-rich plasma (PRP) injections for pathology around the foot and ankle (possibly due to its failure to show efficacy elsewhere in the musculoskeletal system). Its reported use now extends to a wide range of conditions including tendinopathies, plantar fasciitis and osteochondral pathology. We were delighted, here at *360*, to read a report from a group in **Chiba (Japan)** who have examined the effects of PRP injection into the ankle for symptomatic treatment of ankle osteoarthritis, an area of relatively common use without much in the way of quality evidence.[1] This interesting article provides some literature in an area in which there are very few studies. These authors recruited 20 patients, all with proven varus ankle arthritis, after performing a power analysis for minimal clinically significant difference, based around the expected effect size of the PRP. Patients were included only if they had not responded to at least six months of conservative therapy and no patients with post-traumatic ankle arthritis were included. There were 15 women and five men, with a mean age of 59 years (37 to 76). Pre-operative clinical evaluations were performed at one week before the first injection, followed by four, 12 and 24 weeks after the last injection. The primary outcome measure was the visual analogue scale (VAS) score for pain. An independent orthopaedic surgeon who was not part of the patient evaluation performed all of the PRP injections, and a single injection of 2 ml of PRP was injected into the ankle using an anteromedial approach under ultrasound guidance. Patients received a total of three injections spaced at two-week intervals. First, there were no significant adverse effects noted, although a single patient experienced pain and swelling at the injection site that resolved after two days. When evaluating the primary outcome measure, overall, the VAS score significantly decreased over time from baseline. This remained statistically significant at each clinical assessment interval, but was lowest at 12 weeks. The patients in this study experienced a significant reduction in their ankle pain for four weeks following intra-articular injection of PRP. However, with no control group, this study has a serious limitation when interpreting these results, and it is not clear what the treatment effect for the PRP would be if judged against placebo or steroid. Although this study does add to the global picture, for us at *360* it effectively establishes that there are no adverse events. However, there remains insufficient evidence to make a sound judgement on the value of PRP injection for ankle arthritis based on this small study.

Vitamin D and bone marrow oedema

■ Bone marrow oedema syndrome (BMOS) is a poorly understood condition for which the aetiology remains largely unknown. There has, however, been rampant interest in vitamin D deficiency in all branches of orthopaedics and, given that there is known to be an increase in bone turnover associated with BMOS, it does seem logical that, despite the potential 'me too' nature of vitamin D studies at the moment, it may well play an important role in the cause of this condition. A group from **Würzburg (Germany)** studied 31 patients, all with a diagnosis of BMOS of the foot and ankle diagnosed with an MRI scan, in what is quite a sizeable cohort study given the rarity of the diagnosis.[2] The investigators measured serum 25-hydroxyvitamin D (25(OH)D) levels in all patients on the day of their outpatient consultation. The guidelines of the Endocrine Society were used in the definition of vitamin D deficiency as 25(OH)D of 20 ng/ml or less, and insufficiency as 25(OH)D levels between 21 and 29 ng/ml. In this cohort of 31 patients, 61% (n = 19) of patients were found to be vitamin D deficient and 23% (n = 7) were vitamin D insufficient, with just 16% (n = 5) of patients having essentially normal vitamin D levels. There was no significant difference in vitamin D levels in samples from different ages or genders and, despite the small sample, the authors attempted to establish if there was a significant difference between vitamin D levels taken during different seasons of the year, but there was not. This is the largest study of this kind, with the only other study to look at vitamin D levels in BMOS including only ten patients and showing a similar result. Although more information is needed about this condition, this study, especially when considered in the context of the previous, suggests a significantly low vitamin D level in patients with bone marrow oedema syndrome. Vitamin D has been associated with many orthopaedic pathologies and it is possible that it has a role to play in this condition too. What we have here, of course, is an association study, not a causation study. It would be ideal to establish what, if any, the potential efficacy is of treatment.

Evaluating the learning curve for total ankle arthroplasty

■ There is undoubtedly a learning curve for every procedure that we carry out, and this has particularly come into focus in the arthroplasty world, where outcomes are increasingly being shown to be affected by volume. Increased experience has been shown to be associated with a decrease in peri-operative and post-operative complications and, in hip arthroplasty surgery at least, to be associated with longevity. The exact number of cases required in total ankle arthroplasty for this learning curve to stabilise remains unclear. In this paper from **Milan (Italy)**, an analysis was performed of the learning curve for a single fellowship-trained foot and ankle surgeon who was not an implant designer.[3] The first 46 cases of primary total ankle arthroplasty performed were included in the study; however, patients undergoing any additional procedures were excluded from the study, leaving a final study population of 31 patients. These patients underwent isolated primary total ankle arthroplasty for ankle arthritis using the HINTEGRA total ankle prosthesis. Outcome evaluation took place at six, 12 and 24