Journal Club: 14 December 2011.
Organiser: Mr Barry Ferris/Mr A Goldberg
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Keating, J. F., Will, E. M. **Operative *versus* non-operative treatment of acute rupture of tendo Achillis: A PROSPECTIVE RANDOMISED EVALUATION OF FUNCTIONAL OUTCOME**. J Bone Joint Surg Br 2011; 93-B: 1071-1078

Reviewer: Mr Matthew Welck

Introduction

The 2010 Cochrane review (Khan RJK, Carey Smith RL. Surgical interventions for treating acute Achilles tendon ruptures) found that there was generally a poor level of methodological rigour in many studies comparing the operative and non-operative management of tendo-achilles rupture, particularly with respect to assessor blinding. They included 6 trials (536 participants) and concluded that, with regard to complications, there is a statistically significant lower risk of re-rupture in the operative group (risk ratio (RR) 0.41, 95% confidence interval (CI) 0.21 to 0.77). On the reverse side, there is a higher risk of other complications including infection (RR 4.89, 95%CI 1.09 to 21.91), adhesions and disturbed skin sensibility. On the functional outcomes, they concluded that these are often incompletely reported, including the frequent use of non standardised outcome measures. The difference in functional outcome is therefore inconclusive.

On this background, the authors of this study state that it is often assumed that an open repair will lead to a more rapid rehabilitation, with improved muscle function and earlier return to sport and occupation.

The aim of the study was therefore, 'to investigate whether surgery offers any functional benefit'.

Methods

This was a single centre, randomised trial, All patients with an acute rupture of the tendo-achilles between 2000-2004 were included. The exclusion criteria were: Age over 60 years, presentation over 10 days post injury and systemic disease (e.g. Rheumatoid arthritis, chronic renal failure, steroid or chemotherapy usage). The patients were randomised using a blind envelope technique to operative or non-operative treatment.

The surgical group had their surgery within 7 days of presentation, by a consultant or senior trainee under consultant supervision. The procedure involved a longitudinal posteromedial incision, with a core PDS Kessler suture, vicryl to the outside of the tendon and nylon mattress sutures to skin. The post operative regime involved 4 weeks in full equinus, non weight bearing, then 2 weeks in semi equinus non weight bearing. The cast was removed with full weight bearing at 6 weeks. In the non-operative group, they spent 4 weeks in full equinus; then 4 weeks in semi equinus, non weight bearing. Then 2 weeks at neutral with partial weight bearing. They were out of cast and fully weight bearing by 10 weeks. After cast removal, both groups had twice weekly physiotherapy according to guidelines. The first 2 weeks were non weight bearing stretches, then after that weight bearing, strength and proprioceptive exercise were added.

The data collection was by a research physiotherapist, on admission and at 3,4,6 and 12 months. The functional outcome measures were: muscle dynamometry (primary measure), short

musculoskeletal function assessment questionnaire (SMFA), time to return to work and sport, and range of movement by a goniometer. Other outcomes included the rate of rerupture and any other complications. Their power study was done to give then a 90-95% power to detect a 10% difference in muscle dynamometry. This required 80 patients. They used a range of statistical tests, to include a paired sample t-test, one sample t-test, fishers exact test, Mann whitney U test and students t test. The justifications for using these tests are listed in the paper.

Results

80 patients were included. 76 were excluded, predominantly as they were over age, partial Achilles rupture, unwilling to take part or a delayed presentation. The baseline characteristics of the 2 groups were similar. They had 39 patients in the surgical arm, and 41 in the non-operative arm. One patient from each group withdrew as they wanted the alternative treatment modality. A further patient from each group was lost to follow up after 4 months.

The pain scores showed a median VAS score of 4/10 at 2 weeks for the operative group, compared with 2/10 for the non-operative group. This did not reach statistical significance ($p<0.07$).

The range of movement was compared to the normal side. There was better dorsi and plantar flexion in the operative group at 3 months, and better dorsiflexion at 4 and 6 months in the non-operative group. Neither of these reached statistical significance, therefore there was no significant difference in the range of dorsi or plantar flexion between either group at any time point.

The muscle power of plantarflexion was significantly stronger in the operative group at 3 months ($p<0.005$). There was no significant difference of plantar flexion power at any other time point. At 1 year post-op, there was still approximately 20% less strength of plantar flexion compared to the normal side. As would be expected, there was much less difference compared to normal side with dorsiflexion. There was no difference in dorsiflexion strength between either group at any time point.

The SMFA was significantly better at 3 months in the operative group ($p<0.03$). It was also better at 4 and 6 months although that didn't reach statistical significance/.

70% of the operative group, and 64% of non-operative group returned to pre-injury sporting level. The mean return to work time was 12 weeks in both groups. The mean return to driving time was 12 weeks in the operative group and 14 weeks in the non operative group. There were 2 reruptures in the operative group, and 4 in the non operative group, 2 of which happened on dynamometer testing. This did not reach statistical significance. There were 3 infections in the operative group and 2 DVT's in the non-operative group.

Summary

The main findings were no significant difference in range of motion at any time point between the 2 groups, significantly stronger plantar flexion and better SMFA scores in the operative group at 3 months (but not thereafter).

Conclusion

They were unable to show a convincing functional benefit from surgery for tendo-achilles rupture. Their discussion shows this is in keeping with several other papers.

Discussion.
A discussion followed about the relative merits of the paper. We found the subject area to be relevant, as was highlighted by the lack of functional studies in the Cochrane review. It does add something new, as there have been very few trials with a temporal objective measure of muscle function recovery. The study was well designed, being single centre, randomised and prospective. The exclusion criteria were reasonable. The operations were not performed by a single surgeon and the merits of this were discussed. On one hand, it gives a more realistic picture, but it makes the operative group less homogenous. To the same effect, there was not a single physiotherapist, and they were not blind to the treatment modality. We discussed their protocols. They did justify their choice of protocol. There is a trend toward functional rehabilitation after Achilles tendon rupture, and recent evidence shows early weight bearing and range of motion may be beneficial to tendon healing. We discussed whether it would have been more current to have had a more functional rehabilitation programme for both groups. Furthermore, both groups had a different rehabilitation regime (6 weeks in plaster against 10 weeks) which makes comparison more difficult. It is hard to say whether the increased plantar flexion strength at 3 weeks in the operative group was due to the surgery, or the fact they had been in plaster for a shorter time. The outcome scores were validated (SMFA) and objective, quantitative and reproducible (dynamometer). The comparison with the normal limb was good, to avoid the range of absolute values that would have occurred due to patient variation. It was discussed whether a newer outcome measure (The Achilles tendon rupture score) would have given a better indication of outcome, compared to the more generalised SMFA score. Furthermore, it is hard to equate a difference in muscle strength to functional outcome. With regard to the results, the groups were comparable at baseline, and the statistical tests used were well chosen. There was minimal loss to follow up. The possibility for type II error was discussed as there may not have been enough numbers to detect a significant difference. One would expect a significant difference in rerupture rate and pain score at 2 weeks, however neither of these reached statistical significance.
Overall, it was considered to be an excellent paper, with robust methodology. We concluded that we would continue to tell our patients that surgery leads to a lower rate of rerupture and a higher level of complications. This study adds to the evidence that difference in functional outcome is equivocal.

Rippstein, P.F., Huber, M., Coetzee, C., Naal, F.D. Total ankle replacement with use of a new three-component implant. J Bone Joint Surg Am 2011; 93: 1426-35.

Reviewer: Mr Anand Patel

Introduction
The last decade has seen growing interest in the development of total ankle arthroplasty, as an alternative to ankle arthrodesis, for the treatment of end-stage ankle arthritis. Modern three-component implants have demonstrated favourable clinical results and survivorship, and modern unconstrained designs allow a better range of motion, thus reducing tensile and shear forces at the bone-prosthesis interface. With this in mind, the authors have focused their interest on the Mobility total ankle replacement (DuPuy International, Leeds, United Kingdom). They state that although it is not a revolutionary design, minimal bone resection is required and instrumentation is better developed to permit more accurate and reproducible implantation. The aim of this study

is to highlight the design rationale, explain the surgical technique, and to determine the clinical and radiographic results of the first 240 total ankle arthroplasties performed by the authors with the Mobility implant.

Method

This was a prospective cohort study carried out at a Foot and Ankle Centre (Schulthess Clinic) in Zurich. Between November 2003 and October 2007, 240 consecutive primary total ankle arthroplasties performed by two of the authors (P. F. R. and M. H.) were recruited in the study. This comprised 233 patients (115 women and 118 men) with a mean age of 61.6 +/- 13.1 years. The diagnosis was post-traumatic arthritis in 123 ankles (51.3%), primary osteoarthritis in 74 ankles (30.8%), rheumatoid arthritis in 36 ankles (15.0%) and haemochromatosis in 7 ankles (2.9%). Exclusion criteria were those with insulin-dependant diabetes mellitus, peripheral arterial disease and severe hindfoot deformity. Concomitant procedures such as tendon procedures, corrective osteotomies and arthrodesis were performed in 124 patients (51.7%). Clinical and radiographic follow-up were arranged at 6 weeks, 6 months, 1 year and yearly thereafter. 233 patients (97.1%) were available for follow-up at 1 year- 1 patient died of an unrelated cause, and 6 patients moved abroad. The latter group were contacted by telephone and reported the ankle was functioning well and a re-operation was not needed. This data was not included in the study. The mean follow-up was 32.8 +/- 15.3 months. Post-operative management involved 2-3 weeks in a cast, followed by a removable walker boot. Passive and active mobilisation was encouraged under the supervision of a physiotherapist. Patients were kept partially-weightbearing till clinical and radiographic evaluation at 6 weeks, then fully-weightbearing in the walker boot alongside strengthening exercises and training involving proprioception and co-ordination. Patients that underwent concomitant corrective osteotomy or fusion underwent the same post-operative protocol except a step-wise return to fully-weightbearing during the 2 weeks following removal of the walker boot. Pre-operative data was based on the entire series of 240 ankles. Post-operative data was based on the 233 ankles available for follow-up at 1 year. Kaplan-Meier survival curves with 95% confidence intervals were calculated with censoring of the ankles at their latest follow-up. Data was tested for normal distribution using the Shapiro-Wilk W test. Pre and post-operative data were compared using paired t tests. Comparisons between groups were performed sing unpaired t tests. All data was presented as a mean and the standard deviation. Clinical outcomes were measured using the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score, a mean Visual Analogue Score (VAS) for "overall average pain" and a Patient Satisfaction Questionnaire that asked if patients were satisfied with the outcome of surgery; if patients would undergo the same surgery again; if patients have difficulties climbing stairs. All intraoperative and postoperative complications, reoperations and implant failures (exchanged, pending exchange, or removed and arthrodesis) were also noted. Radiographic evaluation took place pre-operatively and at each follow-up visit using weight-bearing AP and lateral radiographs, as well as functional radiographs (weight-bearing lateral views with the ankle in maximum plantar-flexion and in maximum dorsiflexion). The following parameters were measured: range of motion of ankle; combined range of motion (hindfoot and midfoot); ankle alignment (angle between the talar and tibial component on the AP radiograph); alpha angle (the angle between the axis of the tibial component and the axis of the tibia- >5 degrees was defined as valgus or varus); beta angle (the posterior slope of the tibial component with respect to the tibial axis, on the lateral radiograph);

centering of the talar and tibial components with respect to each other on both AP and lateral radiographs; tibial radiolucencies >1mm in the 5 zones on the AP radiograph and the 5 zones on the lateral radiograph; talar radiolucencies in the 3 zones of the lateral radiograph; migration of tibial component (change in alpha or beta angle >3 degrees); migration of the talar component (>2mm subsidence into the talus); cysts; osteophytes.

Results

The AOFAS hindfoot scores demonstrated a significant improvement at 1 year ($p<0.001$) from 48.2 +/- 17.5 pre-operatively to 84.3 +/- 12.1 points. No further improvement was seen after the first year, with a score of 84.1 +/- 13.6 points at the latest follow-up. Mean pre and post-operative scores were lower in patients with rheumatoid arthritis, however rheumatoid patients showed a greater mean improvement than patients with posttraumatic arthritis- 44.9 points compared with 29.3 points ($p=0.014$). The mean Visual Analogue Score (VAS) had decreased at the time of latest follow-up, from 7.7 +/- 1.4 to 1.7 +/- 2.0 points ($p<0.001$). The mean pain level at the latest follow-up was lower in patients with rheumatoid arthritis than primary osteoarthritis or posttraumatic arthritis. 73.6% of patients were very satisfied and 4.2% unsatisfied with the outcome of surgery; 97.3% would undergo the surgery again; 90.4% had no difficulty climbing stairs and 1.4% had severe difficulty. There were 10 intraoperative complications (4.2%), of which four were a fracture of the medial malleolus and 5 were accidental osteotomies of the lateral malleolus. 8 of these 10 complications occurred within the first 100 cases operated on. There were 20 postoperative complications (8.6%) of which 50% had a fracture of the medial malleolus. 18 patients (7.7%) underwent a reoperation, most commonly (in 8 patients) to remove a painful osteophyte at the tip of the lateral or medial malleolus. Postoperative complications and reoperations were significantly less frequent in patients with rheumatoid arthritis. 5 arthroplasties failed at a mean of 27 mths. There were 4 cases of tibial loosening, of which 2 were associated with a low-grade infection. 3 patients were treated with a tibial component exchange and 1 patient underwent a tibiotalar arthrodesis. 1 patient had an oversized talar component that was replaced to treat persistent pain. Mean ankle plantar flexion improved only slightly from 12.5 +/- 7.0 degrees pre-operatively to 13.6 +/- 6.4 degrees at latest follow-up ($p = 0.049$). Mean ankle dorsiflexion only slightly improved from 7.3 +/- 5.9 degrees to 8.3 +/- 5.3 degrees ($p = 0.021$). However, the mean total range of ankle motion improved from 19.8 +/- 9.8 degrees to 21.9 +/- 8.7 degrees ($p<0.001$). No further improvement was seen after the first post-operative year. The mean combined range of motion improved from 29.3 +/- 14.1 degrees to 34.6 +/- 11.0 degrees ($p<0.001$). 9 pts (3.9%) had a malalignment, of which 7 patients had rheumatoid arthritis. Only 1 of these patients reported severe pain. The mean alpha angle was 2.1 +/- 2.9 degrees varus which was deemed acceptable. The mean beta angle was 6.0 +/- 3.8 degrees. 93% patients had correct centering in the frontal plane and 97.4% in the sagittal plane. Radiolucency around the tibial component in the AP view (zones 1 and 5) was difficult to assess in 44% of patients as the projections were not perfectly parallel to the tibial plafond. Tibial zones 6 and 10 were difficult to assess in only 8% as 3 different views were available for evaluation (Lateral and 2 functional radiographs). Tibial radiolucency ranged from 1.8% in zone 7 to 37.3% in zone 6. Talar zones were easy to assess for radiolucency. Radiolucency ranged from 0% in zone 2 to 2.2% in zones 1 and 3. Appeareances were non-progressive and <2mm in width, and there was no tibial component migration. There was a non-

progressive subsidence of the talar component in 8 ankles (3.5%)- all within the 1st post-operative year with no further change. Periprosthetic cysts were seen in 20 ankles (8.8%)- half in the medial malleolus. This was less common in patients with post-traumatic arthritis. A posterior overhanging osteophyte was seen in 61 pts (26.8%),with resulting in reduced ankle plantar flexion at the latest follow-up- 11.8 c/w 14.9 degrees (p = 0.0014). All other clinical and radiographic outcomes were similar. Osteophyte formation was most prevalent in primary OA and least prevalent in RA.

Conclusion

The clinical outcome measures showed significantly favourable results particularly in patients with rheumatoid arthritis which may be related to differences in functional demands and expectations. The study showed that the talar component of the Mobility implant was not at high risk of loosening. Previous studies have shown this to be a problem with other component designs. The clinical importance of the variable tibial radiolucency remains unclear. There were 10 intraoperative and 20 postoperative complications, largely malleoli related. Longer follow-up and biomechanical investigations have been recommended. The failure rate, reoperation rate and complication rate were all considered to be relatively low in comparison to other previous studies examining alternative implant designs. The authors also stressed the importance of functional radiographs to assess ankle range of motion as they feel the true ankle range of motion cannot be accurately differentiated from the combined range of motion (hindfoot and midfoot) by clinical assessment alone. Despite using functional radiographs, the authors were disappointed with the postoperative range of ankle motion in this series. They concluded that the range of ankle motion after total ankle arthroplasty is largely determined within the first weeks after surgery and have subsequently changed their postoperative protocol to reduce the period of immobilisation. They also speculated that ankle range of motion may be underestimated as functional radiographs are largely dependent upon the ability of the technician and compliance of the patient. The limitations of this study include: the short length of follow-up; the loss of 7 patients to follow-up; the use of an un-validated patient satisfaction survey. The authors conclude that the short-term clinical and radiographic outcomes of the Mobility implant, including the estimated arthroplasty survival rate of 97.7% at 4 years, are encouraging and comparable with the short-term results associated with other modern 3-component total ankle arthroplasty designs, and that total ankle arthroplasty is a technically demanding surgical procedure as highlighted by the fact that concomitant procedures were performed in over half of the ankles in the series. A discussion followed about the merits and limitations of this paper. This is a relevant study that tackles a condition this still has no universally agreed gold-standard surgical treatment. The introduction provides a good overview of the design rationale and surgical technique. This is a large series and the study has been conducted in a single centre with a special interest in Foot and Ankle surgery. The methodology has been robust and a wide range of clinical and radiographic outcome measures have been used, however both the AOFAS hindfoot score and the patient satisfaction score are not validated tools. The use of functional radiographs to assess ankle range of motion was clearly justified and statistical tests were used appropriately. A longer length of clinical and radiographic follow-up of these patients would be necessary to establish whether the Mobility implant is a suitable choice of surgical intervention for end-stage ankle arthritis and further studies are required to investigate the reasons behind the rate of malleoli complications and posterior osteophyte formation.