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Original Articles

Early results of Roto-glide joint arthroplasty for treatment of hallux rigidus

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ABSTRACT

Background: Traditionally severe hallux rigidus is treated with arthrodesis. Recently arthroplasty has been used in order to retain motion at the metatarsophalangeal joint.

Aim: To assess the early to mid-term functional and radiological outcomes in patients undergoing first metatarsophalangeal arthroplasty using the Rotoglide implant.

Materials and methods: A prospective review was undertaken to assess functional and radiological outcomes of all patients undergoing an un-cemented three-component first metatarsophalangeal arthroplasty for hallux rigidus. Thirty four implants were performed in 28 patients over a 2-year period. Mean age was 60.5 years (range 45–77 years). Mean follow-up was 27.7 months (range 7–44 months).

Results: Mean AOFAS score improved from 41.2 pre-operatively to 89.1 at final follow-up (47.9; 95% CI = 43.6–54.3; $p < 0.0001$). The mean metatarsophalangeal (MTP) range of motion improved from 29.5° pre-operatively to 68.2° post-operatively (38.7; 95% CI = 35.1–42.2; $p < 0.0001$). The mean AOFAS pain scores improved from 8.8 preoperatively to 35.0 postoperatively (26.2; 95% CI = 22.4–29.9; $p < 0.0001$).

Three patients required revision surgery. No radiological complications were observed in any other patients.

Conclusions: This un-cemented prosthesis provides pain relief, while maintaining range of motion of the joint. The authors have observed clinically and statistically significant improvement in functional outcomes, with a low early complication rate and high patient satisfaction levels.

1. Introduction

Hallux rigidus is a degenerative condition of the first metatarsophalangeal (MTP) joint of the great toe, characterised by progressive loss of motion, particularly dorsiflexion. This combined with the formation of dorsal osteophytes, results in pain and stiffness of the joint.

An estimated 2% to 10% of the general population has varying degrees of hallux rigidus [1–3] and it is the second most common forefoot presentation after hallux valgus.

Coughlin and Shurnas developed a classification system for hallux rigidus, using a combination of clinical and radiological findings [1]. This is a commonly used tool for grading severity of disease (Table 1). In addition, the presence and extent of any associated deformity, patients' age and activity level should also be considered when deciding on surgical treatment.

Traditionally, mild to moderate disease has been treated with cheilectomy or osteotomy, with more severe cases being treated with arthrodesis [3]. Arthrodesis is the accepted surgical options for advanced arthritis providing long-term pain relief [1]. However, all patients do not accept this option due to concerns about loss of motion. There are concerns about potential limitations to involvement in physical activity and alteration of gait. More recently, arthroplasty of the MTP joint is becoming an increasingly used surgical treatment for patients with advanced disease. This gives the option of providing pain relief, while maintaining range of motion [1,4,5].

There are numerous implants available for use in hallux rigidus of varying designs, including hemiarthroplasty and total joint arthroplasty, each with their own benefits and limitations. However, long term outcomes and large series evaluating the use of such implants is lacking in the literature.

Roto-Glide™ (Implants International, UK) is an uncemented three part, non-constrained titanium-on-ultra-high molecular weight polyethylene implant which incorporates a rotating meniscus and was first introduced into the UK in 2002.

The aim of the present study was to assess the early to mid-term functional and radiological outcomes in patients undergoing first metatarsophalangeal arthroplasty using this implant for the treatment of severe hallux rigidus.

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Table 1
Grading of hallux rigidus, by Coughlin and Shurnas [1].

Grade	Clinical findings	Range of motion	Radiographic findings
0	No significant pain Stiffness, loss of passive motion	Dorsiflexion: 40–60° ± 10–20% loss compared to normal side	Normal or minimal changes
1	Mild or occasional pain and stiffness Pain at extremes of motion	Dorsiflexion: 30–40° ± 20–50% loss compared to normal side	Dorsal osteophyte main finding
2	Moderate to severe pain, constant stiffness Pain before maximal dorsi- or plantar-flexion	Dorsiflexion: 10–30° ± 50–70% loss compared to normal side	Dorsal, lateral ± medial osteophytes Flattened appearance of metatarsal head Mild-moderate joint space narrowing ≤1/4 dorsal joint space involvement on lateral radiograph
3	Constant pain, significant stiffness Pain throughout motion, except for mid-range	Dorsiflexion: ≤10° ± 75–100% loss compared to normal Notable loss of plantar-flexion (usually ≤10°)	As grade 2, and: Substantial joint space narrowing Periarticular cystic changes ≥1/4 of dorsal joint surface involved on lateral view Sesamoids enlarged, cystic or irregular
4	As for grade 3, with additional pain at mid-range of motion	As for grade 3	As for grade 3

2. Materials and methods

Thirty four toes in 28 patients (6 patients were bilateral) were included in a prospective review of all patients undergoing first MTP joint arthroplasty for the primary treatment of hallux rigidus under the care of the senior author between February 2013 and July 2015. All patients were operated using the same 3 component total arthroplasty system (Roto-glide™ Implants International, UK) and surgical technique.

Pre-operative assessment included clinical examination with documentation of range of motion at the first MTP joint using a goniometer, completion of American Orthopaedic Foot and Ankle Society Hallux Metatarsophalangeal Interphalangeal (AOFAS-HMI) scores [6] and standing AP and lateral radiographs of the foot to confirm the diagnosis.

Patients with advanced disease (Coughlin and Shurnas stage 3 or 4) with good bone stock and normal MTP joint alignment were eligible for inclusion. All patients had a trial of non-operative measures for at least 6 months prior to surgery.

Patients with inflammatory arthritis, associated hallux valgus (of more than 15°) and managed with arthrodesis. Those with neurovascular compromise, metal allergy or poor local tissue condition were also excluded from this study.

Informed consent for the procedure was gained from all participants during their pre-operative visit. In accordance with published guidelines on MTPJ arthroplasty from the National Institute for Health and Care Excellence (NICE) [7], all included patients were also given the option of arthrodesis, but declined as the loss of range of motion was unacceptable.

Radiological and clinical outcomes were assessed at 3, 6, 12, and 24 months post-operatively by an independent assessor. Patients were clinically assessed for the occurrence of any complications and range of motion at the first MTP joint. At each visit, AOFAS and visual analogue (VAS) pain questionnaires were completed. Patient satisfaction questionnaires were completed at 12 months post-operatively.

Radiographs were assessed for any evidence of subsidence, loosening or malalignment at each clinic visit. Loosening was defined as more than 2 mm of lucency around the bone-implant interface.

3. Experimental

All patients were operated on as a day-case procedure under a combination of general or spinal anaesthesia and ankle block; intravenous antibiotics were given at induction and a tourniquet was used in all patients. A dorsomedial approach was used to expose the joint.

A dorsal cheilectomy of the metatarsal was performed at 60° using the manufacturers jig and any osteophytes were excised from the proximal phalanx. The phalangeal jig is then used to resect 2–3 mm of the joint surface perpendicular to the axis of the bone.

The medullary canals of the metatarsal and proximal phalanx are prepared with a drill and the trial implant components are inserted.

Further soft tissue release was performed as necessary, to include the sesamoid sleeve and flexor hallucis brevis tendon. A small periosteal elevator was inserted under the metatarsal head to relieve any contractures. Any osteophytes from the dorsal surface of sesamoids were excised

The definitive components were implanted and intra-operative range of motion was checked and deemed to be satisfactory if dorsiflexion was more than 70–80°. An image intensifier was used to ensure adequate placement of the prosthesis, and active radiological screening was performed during range of motion.

The wound was closed with non-absorbable sutures and patients were placed into a soft dressing.

On the operating table a rough assessment of the dorsiflexion was checked. At follow-up, a goniometer was used.

All patients undertook the same post-operative rehabilitation protocol. Patients were encouraged to fully weight bear and perform active range of motion of the first MTP joint immediately post-operatively.

A clinical review of the wound was undertaken at 2 weeks when the sutures were removed. Formal physiotherapy was commenced at this time.

4. Statistical analysis

Statistics were obtained using SPSS for Windows statistical program (SPSS Inc., Chicago, USA). Before applying parametric methods (paired student's t-test), the data was checked for normality. Statistical significance was designated at $p < 0.05$. All student's t-tests were two-tailed. Confidence intervals are reported at 95%. Bilateral patients ($n = 6$) were analysed as though the measurements on each foot were independent.

5. Results

The mean age of patients in this series was 60.5 years (range 45–77). Fourteen males and 15 females were included. One patient underwent a simultaneous hammer correction of the second toe at the time of MTP joint replacement. Mean follow-up was 27.7 months, (range 7–44 months).

5.1. Functional outcomes

There was a statistically significant improvement in mean AOFAS score from 41.2 preoperatively to 89.1 postoperatively (47.9; 95% CI = 43.6–54.3; $p < 0.0001$).

Fig. 1. Bilateral pre and post operative X-rays.

There was a statistically significant improvement in mean AOFAS pain score from 8.8 preoperatively to 35.0 postoperatively (26.2; 95% CI = 22.4–29.9; $p < 0.0001$).

There was a statistically significant improvement in mean MTP range of motion from 29.5° preoperatively to 68.2 postoperatively (38.7; 95% CI = 35.1–42.2; $p < 0.0001$).

At their most recent follow up, 13 patients were very satisfied, 13 were satisfied and 2 were not satisfied with the outcome of their surgery.

5.2. Radiological outcomes (Fig. 1a and b)

Radiographic evaluation did not reveal any subsidence or disengagement of implants. Two of the 34 prostheses demonstrated minor osteolysis below the metatarsal head, though this did not correlate with the onset of new symptoms and both patients remain satisfied with the outcome of surgery. The osteolysis developed 12 months post-op. This was under the dorsal side of the MT under the flange of the prosthesis.

Figs. 1–3 show X-rays for bilateral and unilateral patients.

No other radiological complications were observed.

5.3. Complications

One patient with diabetes developed a superficial infection in the early post-operative period, which fully resolved following a short course of oral antibiotics.

Two patients required revision to fusion due to severe on going pain and stiffness at 11 and 12 months post-operatively. One fused with allograft but the second patient still had not fused until 18 months postoperatively. A third patient had a superficial infection that resolved with oral antibiotics. In another patient hallux valgus occurred post-operatively requiring a second corrective surgery.

6. Discussion

Hallux rigidus is a common condition, with management dependent on the stage of disease, the presence of any associated deformity, patients' age and activity level.

Traditionally, the mainstay of treatment for significant disease was arthrodesis of the first MTP joint; a surgical option which is still widely used [1]. First MTP arthrodesis leads to effective pain relief [8–12] and is considered the gold standard for end stage hallux rigidus with union rates ranging between 90 to 100% [13]. However, arthrodesis has problems of its own. It leads to loss of motion especially kneeling and squatting and restriction in wearing high heel shoes [14,15]. There is also a 10% chance of nonunion that may need further revision procedures [13]. The alteration in forces across the joint following fusion makes activity more difficult and can lead to degenerative arthritis of the neighbouring joint [16].

MTP joint replacement is gaining popularity as it provides pain relief while maintaining range of motion. It eliminates the problems associated with other procedures such as metatarsal osteotomy, resection arthroplasty or joint fusion [17–21]. The authors do acknowledge though that revision to fusion when the Rotoglide implant fails, is not simple and straightforward.

The ideal MTP implant is one that improves pain, maintains alignment and length of the first ray, restores normal ROM and has ease of revision. Arthroplasty of the first MTP joint was initially developed in the 1950s as an alternative surgical option to arthrodesis. Initial optimism for this new surgery led to its increased use, without adequate understanding of implant designs or choice of materials, and lack of appreciation for the importance of patient selection [22]. The complex demands however of the first MTP implants resulted in poor medium and long term results [22–25].

The first MTP implants are divided into four generations, largely based on their evolution [22]. The first generation implants made of silicon were used either for a partial or total replacement. These however led to synovitis and lymphadenopathy and hence went into disrepute. The second generation were better quality silicone implants with grommets to the surfaces [26]. Despite this, wear, osteolysis, foreign body reaction, fracture and displacement of implants lead to poor long term outcomes [27].

The third generation of implants were metallic prostheses designed for partial and total arthroplasty, with a "press-fit" type clamping system [28]. Although the material had improved, the cortical bearing mechanism led to loosening due to high dorsally directed pressures

Fig. 2. Unilateral pre and post operative X-rays.

Fig. 3. Intraoperative X-ray.

across the metatarsal component of the prosthesis during the toe-off phase of gait [27,29].

The fourth generation implants were also metallic prostheses designed for partial and total arthroplasty with a medullar threaded rod fixing system. This was created to reduce the overall incidence of loosening by creating a stem to counteract shear forces across the implant.

In contrast to other designs, the Roto-glide™ implant is a stemmed three part system with a rotating meniscus and a dorsal extension on the metatarsal component, allowing increased dorsiflexion, gliding and free rotation. It is relatively bone preserving with a resection of 2–3 mm from the metatarsal and 2–3 mm from the proximal phalanx; the tangential nature of the bone cuts do not interfere with the metatarsal–sesamoid articulation. These features aim to overcome the problems encountered with earlier implant designs. A 2011 study undertook pedobarographic analysis of the Roto-glide™ implant in 12 patients. It demonstrated some degree of normalisation of the load across the forefoot following surgery, emphasising the biomechanical advantage over arthrodesis. The same study described a significant reduction in VAS scoring post-operatively [30].

In the present study, the authors have demonstrated similar significant improvements in AOFAS post-operatively, as well as a marked increase in ROM at a mean follow up of 27.7 months.

Following the occurrence of hallux valgus in one patient post-operatively, requiring a second corrective surgery, the senior author now considers even minor degrees of deformity as a relative contra-indication to arthroplasty and would favour arthrodesis for such patients.

Despite design features aiming to increase range of motion, 2 patients in this cohort with normal appearances on post-operative radiographs, required revision for significant stiffness and pain, Poor pre-operative range of motion is often a good indication of the occurrence of stiffness post-operatively and following on from experience with such cases, the senior author will favour arthrodesis in patients with significantly reduced pre-operative range of motion.

A weakness of this study is that being a case series the authors had no control group for comparison. A randomized controlled trial (RCT) comparing arthroplasty with arthrodesis would provide conclusive evidence of the superior efficacy of arthroplasty. Furthermore, the authors did not use a patient reported outcome measure. Although the AOFAS was used, there is controversy about the use of other questionnaires such as the SF-36 that have not been not validated for use in foot and ankle surgery.

Although complications led to additional surgery in 3 patients, the majority of patients had excellent outcomes with this prosthesis. Five patients came in for a similar procedure on the other foot after having a satisfactory outcome with the first surgery. Hopefully, with increased experience and revised indications for this procedure, complication rates will continue to decrease.

7. Conclusions

First MTP joint arthroplasty using the 3 component Roto-glide™ arthroplasty system provides excellent functional outcome in the short to medium term for patients with advanced hallux rigidus. It provides pain relief, while maintaining or improving range of motion of the joint. Along with improving implant design, patient selection is paramount to a successful outcome.

Longer-term follow-up and higher-level evidence in the form of a RCT will be required to determine whether arthroplasty is a superior treatment to the well-established first MTP joint arthrodesis.

What is already known

- Severe hallux rigidus is usually treated with arthrodesis.
- Arthrodesis reduces range of motion and patient satisfaction.
- Arthroplasty is an alternative that maintains range of motion.

What this study adds

- In this series, arthroplasty with the Roto-glide implant results in clinically and statistically significant improvement in functional outcomes in most cases.
- Roto-glide arthroplasty maintains range of motion of the joint.
- Arthroplasty results in low complication rate and high patient satisfaction.

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