

The Rotoglide™ total replacement of the first metatarso-phalangeal joint. A prospective series with 7–15 years clinico-radiological follow-up with survival analysis



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ARTICLE INFO

Article history:

Received 8 September 2016

Received in revised form 30 March 2017

Accepted 4 April 2017

Keywords:

Rotoglide™ MTP-1 implant

Prospective study

Long-term results

Survival analysis at 15 years

Multiple variance analysis

ABSTRACT

Background: The Rotoglide total replacement of the MTP-1 joint. 15 years survival analysis. **The purpose** of this prospective study was to evaluate the long-term performance clinico-radiographically of an uncemented three-component total replacement for the first metatarso-phalangeal joint (MTP-1) used for hallux rigidus (primary osteoarthritis grades 3 and 4). The follow-up was median 11.5 years (7–15). **Methods:** The AOFAS forefoot score was used preoperatively and at follow-up. Radiographs were taken weight-bearing in the AP-projection and in tip-toe standing in the lateral view. Arthrosis in the sesamoid junction, prosthetic loosening, subsidence (of prosthesis as well as sesamoids), and dorsiflexion were measured, recorded and subjected to multiple variance analysis. Survival analysis was performed for 15 years.

Material: Ninety implants in 80 patients (53 women and 27 men); median age 58 (41–76) were evaluated. **Results:** Six patients representing seven prostheses in situ had died from unrelated reason. The median preoperative AOFAS increased significantly from 40 to 95. The median gain was 45. Four replacements (4.4%) were extracted for other reasons than loosening. No aseptic loosening were recorded. The survival rate at 15 years was 91.5% (83–100). Multiple variance analysis showed that arthrosis in the metatarso-sesamoid junction correlated with reduced AOFAS score.

Conclusion: The prosthesis has stood the test of time; the results justify its further use.

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1. Introduction

Primary osteoarthritis of the first metatarso-phalangeal joint (MTP-1) is common and gives clinical symptoms already in the fourth and fifth decade of life. Definition of the clinical entity is a painful dorsal collision phenomenon, a dorsal bunion, pain from shoe wear, and severely diminished dorsiflexion in the MTP-1 joint. Lateralization of the loading pattern over the lateral side of the foot and off loading of the great toe is typical and often leads to metatarsalgia. Depending on the radiographic grade of osteoarthritis (1–4) [1], the options for surgical treatment are cheilectomy or osteotomy (grades 1–2) and for grades 3–4 either resection arthroplasty (Keller), arthrodesis or replacement (hemi or total). Replacements have been tried for 50 years [2,3] using different

materials – cemented or uncemented – and with varying degree of success [4–6]. Based on these results the orthopedic community considers MTP-1 arthrodesis the gold standard for the condition. It relieves pain, but at the expense of movement in the MTP-1 joint and it frequently gives the same lateralization of foot pressure as preoperatively and with results not different from those of osteotomy and cheilectomy [7–9]. Special shoe wear, MBT shoes or inlay soles are often required. To overcome these shortcomings we have used a three component uncemented total MTP-1 prosthesis for 15 years (Rotoglide™, Implants International, UK) for grade 3 and 4 primary arthrosis, and hereby presents the clinico-radiographic long-term results.

1.1. The prosthesis

The Rotoglide™ implant (Implants International, Thornaby, Stockton-on-Tees, UK) is a three component device Fig. 1. The prosthesis comes in three interchangeable sizes and with resection

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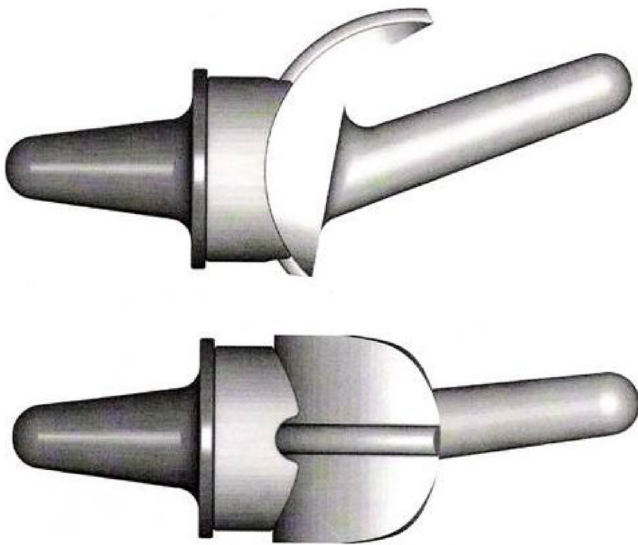


Fig. 1. The Rotoglide prosthesis. Lateral view (upper). Dorsal view (lower). The phalangeal and metatarsal components consist of cobalt-chrome-molybdenum as the core material, and the non-articular surfaces are covered by titanium beads and calcium phosphate. The head of the stemmed metatarsal component covers the upper half of the obliquely resected metatarsal head including the dorsal bunion. The plantar aspect of the head is left intact to allow the sesamoids to glide freely. The phalangeal component is also stemmed, but hollow allowing for a polyethylene peg from the polyethylene meniscus to accommodate free rotation between the flat basis of the phalangeal component and the meniscus. The meniscus has a central groove corresponding to a ridge on the metatarsal component for sideboard stability. This ridge is a continuation of the natural crest on the lower part of the metatarsal head. The entire construction allows for free flexion/extension and rotation.

and drilling guides. It is at present used in several European countries.

1.2. Patients

During the period 2000 through 2008 eighty patients with primary arthrosis grade 3 or 4 without hallux valgus or metatarsus primus varus representing 90 Rotoglide implants were operated upon in Fredriksberg Hospital, University of Copenhagen, Denmark. The patients mean age at the index surgery was 58 years (41–76). There were 53 females and 27 males. Six patients representing seven implants in situ had died from unrelated reasons during the follow-up period. Four replacements were extracted (4.4%).

1.3. Statistics

The level of significance was set at 0.05. For comparison of preoperative and follow-up AOFAS scores the Wilcoxon signed rank sum test was used. Multiple variance analysis of the AOFAS score and radiographic findings used the ANOVA test for patients alive with the prosthesis in situ. Visual analog score for pain (VAS) used the same method. For survival analysis the Kaplan–Meier plot was used with the end points deaths with intact prosthesis or prosthetic extraction. The Statistical analyses were performed by an independent investigator (SM)

The study was approved by the local ethical committee (KF 01-251/99)

1.4. Index operative procedure

This has been described in detail elsewhere [12], but it is appropriate to mention that no more than 4–5 mm should be

removed from the length of the upper half of the metatarsal head in order not to damage the collateral ligaments. The attachments of the plantar structures on the proximal phalanx should be protected in order to retain joint stability. The resected base of the phalangeal bone is given by the resection guide. During the index surgery the metatarso–sesamoid junction should be checked and if sesamoid bones are not correctly positioned measures should be taken to realign them in the grooves under the metatarsal head. In case of sesamoid arthrosis, fracture or chondromalacia enucleation of the sesamoids could be considered. We did not remove any sesamoids intraoperatively, but nipped off spurs and osteophytes.

1.5. Clinical follow-up examination

The clinical scoring used the AOFAS score [10] preoperatively and at follow-up. The clinical scoring was performed by one of the investigators (LD) who was unaware of the results of the radiographic investigation. All patients with surviving prostheses attended the follow-up. The patients were also asked whether they would have the procedure again and whether they would recommend it or not. Table 1 shows the demographics of the material (gender, age at surgery, time of follow, extraction of prostheses), as well as the clinical results.

1.6. Radiographic follow-up examination

A weight-bearing AP projection as well as a tip-toe standing for the lateral view was performed in all available patients. The tip-toe projection is new and allows one to see whether the sesamoids glide or not, and also gives a good judgement of whether sesamoid pathologies are present. In the AP view the **inter-metatarsal angle** (center lines between metatars 1 and metatars 2 was measured, as well as the **hallux angle** (center lines between the first metatarsal shaft and the center line of the proximal phalanx (Fig. 2).

The center of the metatarsal head and the midline of the metatarsal shaft in the lateral view constituted one leg. The other leg was the midline of the upper phalanx. The angle between the two lines constituted the **dorsiflexion of the joint** (Fig. 3). The **heel raise** was measured as the distance between the lowest point of the calcaneus bone and the ground surface (Fig. 3).

Loosening was defined as more than 2 mm of radiolucency in both planes somewhere around the prosthetic components.

Periprosthetic cysts were measured when found. cm^2 was calculated as $A = ((d_1 + d_2)/4)^2 \cdot \pi$, where d_1 and d_2 are length and height of the cyst.

Subluxation of the prosthesis was defined as more than a 2 mm shift from the center of the metatarsal prosthetic components and the meniscus.

Subluxation of the sesamoids was defined as ad latus dislocation of the sesamoid bones of more than 25% from the

Table 1
Demographics.

Female/male	53/27	
Age	58 (41–76)	
Prostheses	90	
Follow-up years	11.5 (7–15)	
Implants extracted	4.4%	
Clinical results		
Preop. AOFAS	40 (22–65)	$p < 2.2 \times 10^{-16}$
Follow-up AOFAS	95 (55–100)	
Gain	45 (23–65)	
VAS (pain)	0 (0–6)	74% scored zero
Would recommend to others	87.5%	
Would have the procedure again	84%	

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