

# 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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## 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

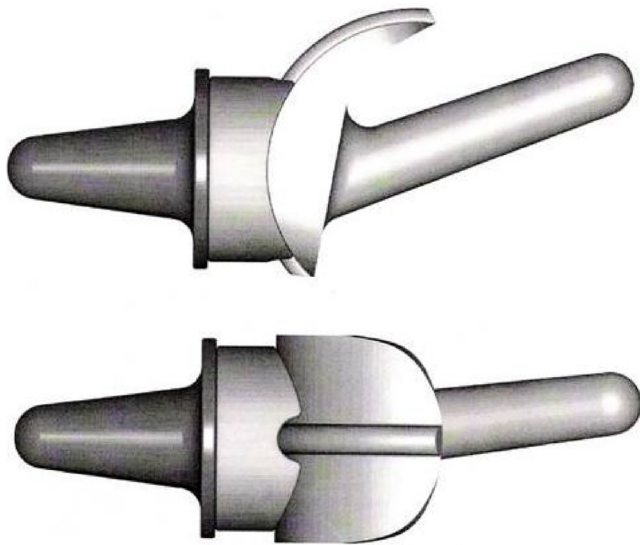
materials – cemented or uncemented – and with varying degree of success [4–6]. Based on these results the orthopedic community considers MTP-1 arthrodesis the gold standard for the condition. It relieves pain, but at the expense of movement in the MTP-1 joint and it frequently gives the same lateralization 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.  $\text{cm}^2$  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%	



Fig. 2. Lines indicating metatarso-hallux angle and intermetatarsal angle.

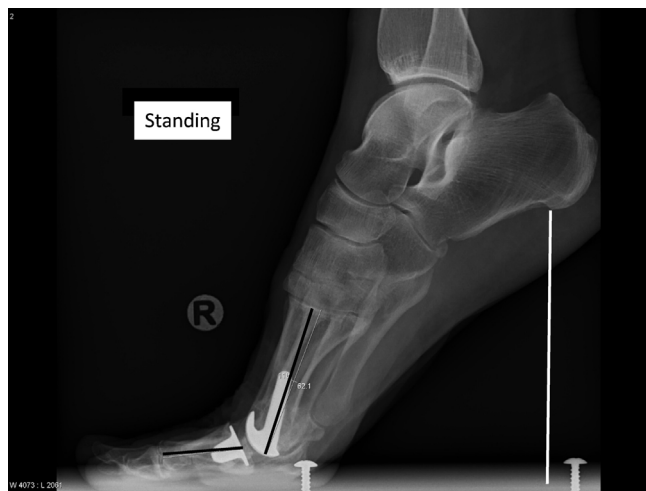


Fig. 3. Standing lateral radiograph. Lines for dorsiflexion and heel raise are indicated.



Fig. 4. The Holly view. Subluxation of the sesamoid bones.

any total replacement in the lower extremity. In spite of that two of our patients were doing half marathon, others were playing tennis and badminton, or jogging with their dogs. One climbed the Andes mountains for three weeks.

Table 1 shows the preoperative and follow-up AOFAS scores (median and range). The AOFAS score had increased significantly. Eighty-four percent of the patients would have the surgery again, and 87.5% of them would recommend the procedure. Those who did not want the procedure again fell in the category of stiffness. Pain was not found in the prosthetic junction at the clinical examination, but was located to especially to the tibial sesamoid junction when trying to dorsiflex the hallux. The clinical measurement of dorsiflexion was median 40° (0–80). The

normal position under the metatarsal head in the standing AP view. In case of doubt the Holly view [11] was used to examine the sesamoid–metatarsal head junction (Fig. 4).

**Dislocation** of the sesamoid was defined as the entire sesamoid outside the cortical border of the metatarsal head.

**Arthrosis of the metatarso-sesamoid junction** was said to exist when the joint line between the metatarsal head and the tibial sesamoid in the standing lateral position was obliterated or, was sagged and with osteophytes.

The measurements and the description of the radiographs were performed by (JG) who was unaware of the clinical results.

## 2. Results

There was one primary infection, and one late infection after 12 years. The reasons for removal of the implant in the 4 cases were: the two infections, one dislocation of the joint, one technical error (metatarsal head too large leading to a “metallic bunion”). During the follow-up four patients had the tibial sesamoid enucleated due to loading pain. We do not recommend running and jumping for

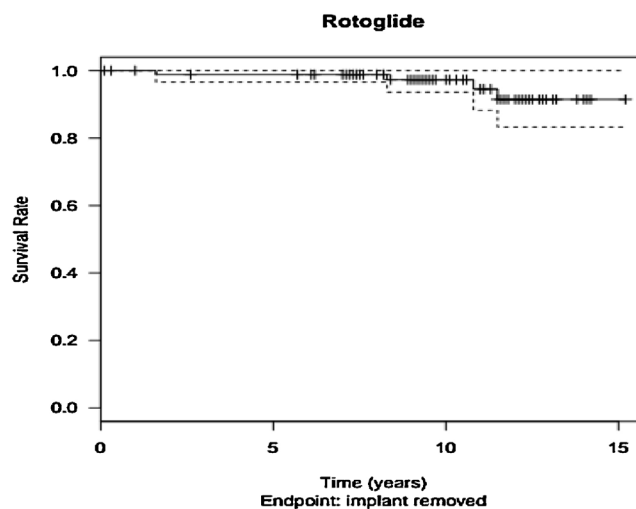


Fig. 5. Kaplan Meyer survival curve. 15 years follow-up. 91.5% (83–100).

**Table 2**

Radiographic results.

Subluxation components	13	
Subluxation sesamoid bones	6	
Metarso-sesamoid arthrosis	22	
Dorsiflexion MTP-1	38° (9–74)	
Hallux angle	11° (1–34)	
Intermetatarsal angle	8° (3–21)	
Radiolucency > 2 mm anywhere	1	
Prosthetic loosening	0	
Periprosthetic cysts metatarsus	2	0.51 cm <sup>2</sup> (0.41–0.61)
Periprosthetic cysts phalangeal	13	0.1 cm <sup>2</sup> (0.05–1.1)
Heel raise		11.3 cm (6.3–14.8)

**Table 3**

Multiple variance analysis (ANOVA test).

	Response AOFAS p-Value	Response VAS p-Value
Radiol. Sublux. Implant	0.99	0.48
Radiol. Sublux. Sesamoids	0.90	0.93
Radiol. Sesamoid junction	0.0045*	0.055
Radiol. Dorsiflex. MTP-1	0.12	0.72

radiological measurement of dorsiflexion was median 38° (9–74). There was no significant difference between these measurement ( $p < 0.82$ ). The heel elevation was median 11.3 cm (6.3–14.8). [Table 2](#) shows the demographics of the radiographic examinations. A comparison of AOFAS score and the VAS score respectively, was conducted toward prosthetic subluxation, sesamoid subluxation, metatarso-sesamoid arthrosis and dorsiflexion in order to judge which parameter that influenced the clinical results. The multiple variance analysis ([Table 3](#)) showed that only metatarso-sesamoid arthrosis correlated with reduced AOFAS score, but also that the VAS score for pain showed a strong tendency for correlation with sesamoid arthrosis ([Fig. 5](#)).

### 3. Discussion

The results of the prosthesis has been reported continuously at international meetings (IFFAS San Francisco 2002, EFAS Copenhagen 2005, AOFAS Boston 2005, First Russian F&A Congress Moscow 2006, DAF Congress Coburg 2008, DAF Congress Berlin 2010, APSFAS Chongqing 2011, COA-EFAS Beijing 2013). These have shown as significant increase in both AOFAS score and dorsiflexion. The current investigation is the first report of long-term results of a three component uncemented mobile bearing total prosthesis for the MTP-1 joint used for a well defined entity of primary arthrosis grades 3 and 4.

We have previously shown that this prosthesis can revert the lateral loading of the foot and normalize the forefoot load as well as redistribute the bone mineral density [12]. There is only one prospective series comparing arthrodesis and a total two-piece implant [13]. This showed better results for the arthrodesis group (less pain, no non-unions and loading over the great toe). In the prosthetic group there was off-loading of the great toe, and several cases with prosthetic loosening. However, as the authors themselves stated, the study had serious flaws. Among them were that the prosthesis was used for grades 1–3 arthrosis, and during the cause of the study the use of the prosthesis was shifted from uncemented use to cemented use because of loosening of the uncemented implant. Other metal polyethylene two-piece devices – cemented or uncemented – have shown significant numbers of early failures [4–6,14,15] ranging 16–30% at 2–3 years follow-up both clinically and radiographically. This has not been the case for the Rotoglide™ prosthesis. During our long-term follow-up four

prostheses (4.4%) were extracted, and radiographically no aseptic loosening were found. There were only two periprosthetic cysts in connection to the metatarsal implant, but 13 adjacent to the phalangeal implant. The size of the cysts were rather small, and there was no significant difference in the numbers from 7 to 10 years follow-up and 11 to 15 year follow-up (7 and 8 respectively), and there was no specific pattern in their localization. It could be claimed that CT scans would give more accurate measurements. However, this was not considered in the original protocol, and it would not in those days have passed an ethical committee. The findings did not seem to influence the clinical results which were excellent or good, and the median AOFAS score increased significantly from median 40 points to 95 points with a median gain of 45 points. The AOFAS score is not validated, and may not be the best solution for a clinical scoring system, but when the study was initiated this was the available scoring system for the forefoot. Seventy-four per cent of cases had a VAS score for pain of zero. Dorsiflexion increased significantly from median 0° to median 40°. There was no significant difference between radiographic and clinical measurements at follow-up. The cases showed good functional mobility and a great heel elevation when standing tip-toe. A vast majority of the patients would have the procedure again and would recommend it to others. Less good results were related to the metatarso-sesamoid junction as a multiple variance analysis showed a correlation between reduced AOFAS score and arthrosis in the metatarso-sesamoid junction. Whether the arthrosis was a result of increased pressure following the increased dorsiflexion after surgery, or it was the natural development of a pre existing arthrosis is unclear. Radiographically slight subluxation in the metatarso-meniscal junction, and subluxation of the sesamoids did not have significant influence on the clinical results. While the prosthetic replacement as such worked excellently, clinically and radiographically, the lesson learned was that particular attention should be paid to the metatarso-sesamoid junction during the index surgery. Subluxation/dislocation of the sesamoids should be corrected, and with signs of arthrosis, fracture or chondromalacia, enucleation of the sesamoids could be considered, as this could seriously impair the gliding of the sesamoids giving raise to pain and reduced dorsiflexion. However, even if abnormalities in the metatarso-sesamoid junction is a common phenomenon including fractures, chondromalacia, and arthrosis in about 1/3 of “normal” cases [16] it is unclear whether such abnormalities will lead to symptoms. All in all this prosthesis has stood the test of time. The radiographic results with no aseptic loosening are so far the best shown for total MTP-1 prostheses. Clinically the results seem at least to match the best results of arthrodesis [17–19].

### Conflict of interest

HK originally designed the prosthesis 1994. All rights were transferred to Implants International 1999 without any payment. None of the authors are consultants for Implants International.

There were no conflicts of interest in the preparation of this paper.

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