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# Prospective analysis of a first MTP total joint replacement. Evaluation by bone mineral densitometry, pedobarography, and visual analogue score for pain

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ABSTRACT

*Background:* We hypothesized that a total replacement of the first metatarsophalangeal joint (MTP-1) would alter the walking pattern with medialisation of the ground reaction force (GRF) of the foot and subsequently cause an increase in bone mineral density (BMD) in the medial metatarsal bones and a decline of BMD in the lateral metatarsal bones.
*Methods:* Twelve patients receiving total joint replacements (Roto-Glide®) of MTP-1 were enrolled in a prospective cohort. BMD and pedobarography of the heel bone and the metatarsal heads were performed preoperatively and at least 12 months postoperatively.
*Results:* BMD in the lateral metatarsals and GRF under the lateral column of the operated feet decreased significantly on the operated feet.
*Conclusions:* Total joint replacement of MTP-1 tends to reduce GRF under the lateral column of the foot causing a corresponding decline in BMD and pedobarographic measures. Our findings support the further use of the Roto-Glide® prosthesis for osteoarthritis of the first metatarsophalangeal joint.


## 1. Introduction

Hallux rigidus (HR) with osteoarthritis of the first metatarsophalangeal joint (MTP-1) is a progressive and painful disorder [1]. The reduced function and increased pain lead to a skewed function of the forefoot with increased loading on its lateral side [2–4]. Surgical solutions for advanced stages include osteotomies, arthrodesis, or joint replacements – partial or total [1]. Keller's resection arthroplasty was previously frequently used, but is now seldom performed as it changes the loading of the foot radically towards the lateral side giving rise to secondary metatarsalgia [2,5,6]. While osteotomy or arthrodesis may allow for loading over the first ray, they do not lead to normalisation of gait [2,6–8] although pain can be reduced. A well-functioning total joint replacement aims at re-establishing mobility and a normal symmetrical gait pattern. Different designs for total arthroplasty have been tried out, but abandoned due to loosening, breakage, or instability. Newer implants using titanium coated surfaces have shown better osseointegration [9–11]. Such prosthesis (Roto-Glide®, Implants International, Thornaby-On-Tees, UK) has been used since 1999 in the orthopaedic clinic of the senior author. The manufacturing company is CE (Conformité Européenne) marked and FDA (Food and Drug Administration) certified.

The goals of surgery for osteoarthritis of the MTP-1 joint are pain reduction and improvement of function. To quantify pain a visual analogue scale score (VAS score) is frequently used [12]. An aspect of gait can be evaluated by pedobarography (PBG) whereby ground reaction force (GRF) is measured. Bone mineral density (BMD) depends, among other factors, of the impact on the bone; immobilisation or inactivity reduces bone mass while physical activity increases bone mass [13–15]. In general an increased impact on a specific bone will increase the bone mass of that particular bone [14,16–18]. In the present study pain was evaluated by the patients with visual analogue score. Impact on bones in the forefoot has been measured indirectly by pedobarography, and the changes in bone mass in the heel and the metatarsals by means of bone densitometry. We hypothesized that a successful total joint replacement would lead to a decreased GRF of the lateral metatarsals and a corresponding increase of bone mass and GRF of medial metatarsals.

## 2. Patients and methods

### 2.1. Design

The study was set up as a prospective open trial of a single cohort. From January 1st 2000 through December 2005 patients with grade 3 or 4 osteoarthritis (according to radiographs and

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clinical presentation [1]) of the first MTP joint receiving total joint replacement were invited.

Patients with bilateral symptoms were excluded, along with patients with hallux valgus, previous fractures or surgery of the foot, ankle, knee or hip, as well as patients with osteoporosis. Included patients were examined preoperatively and at a minimum of 12 months postoperatively. Initially patients were invited for a randomized controlled trial with arthrodesis as the alternative, however a considerable number of patients were reluctant to participate in randomization and consequently the design was altered to the above described. The protocol for the studies was approved by the local ethical committee (KF 01-251/99 with supplements 2006). Of forty-eight available 24 patients did not wish to participate. Twenty-four patients were examined prior to total joint replacement. Eleven patients were excluded due to either bilateral symptoms (seven patients at the primary examination and two during the follow-up period), interfering surgery on 2nd and 3rd metatarsals (one patient), or removal of excessively large prosthesis component (one patient). One patient withdrew consent due to age related health problems. The remaining 12 patients were examined pre- and postoperatively with a mean follow-up (FU) of 3.1 years (range 1.0–7.2). All of the 24 patients who initially did not wish to participate were offered a postoperative examination, which 21 accepted with a mean FU of 3.6 years (range 1.4–5.6).

### 2.2. Clinical data

Data were recorded on age, sex, height, and weight. Pain was evaluated pre- and postoperatively. Answers were given on a visual analogue scale score (VAS score).

### 2.3. Operative procedure

The Roto-Glide® prosthesis (Implants International, England, www.implantsinternational.com) consists of three parts with titanium and hydroxyapatite coated metatarsal- and phalangeal components and a UHMWPE (Ultra High Molecular Weight Poly Ethylene) meniscus (Fig. 1).

The surgical procedure was performed under spinal or general anaesthesia using a tourniquet. A standard dorsomedial incision was extended distally to the interphalangeal joint of the hallux. The metatarsal head and proximal phalanx were exposed subperiostally. The metatarsal head was cut to the shape of the metatarsal component preserving the distal half of the articulating surface. The entire articulating surface was cut off the proximal phalanx preserving the capsular attachment as well as the short flexor. The metatarsal and phalangeal medullary canals were drilled through guides. The appropriate prosthesis size was measured. After insertion of the uncemented metal components the meniscus was inserted. The mobility was tested. If dorsiflexion was less than 80° fasciotomy of the flexor muscles was performed. The incision was closed anatomically, and capsular reefing to ensure stability was added if needed. A popliteal block was installed for pain relief. Postoperatively patients were instructed to do toe-standing exercises frequently to regain mobility. Sutures were removed 2–3 weeks postoperatively, at which time position of the prosthesis was controlled with radiograms. After surgery the patients were instructed by the surgeon in achieving normal gait, with loading over the great toe rather than the lateral side of the foot.

All surgery and clinical follow-up was performed independently of VAS registration as well as the BMD and PBG measurements.

#### 2.3.1. Bone mineral density

Measuring of bone mineral density (BMD) of the heel bone and metatarsals was done by means of dual X-ray absorptiometry (DXA). All scans were performed on the same scanner, a Norland XP-37, Norland Medical Systems, White Plains, USA and Research software version 5.40 was used. BMD was assessed in regions of interest (ROI) measuring 1 $cm^2$ (resolution 0.5 $mm^2$) on the second to fifth metatarsal heads adjacent to the MTP joints. The first metatarsal was not analyzed due to the presence of the metal implant. A ROI of 1 $cm^2$ (resolution 1.0 $mm^2$) in the heel bone was measured as a point of reference [19]. Repeatability of BMD measurements was performed on dry cadaver metatarsals. Five sets of metatarsals I through V were placed anatomically fixed in a plastic resin basis upon a water filled plastic bag serving as surrogate for soft tissue. The 2nd to 5th metatarsal heads were scanned 10 times each. Interobserver variation was examined on a single patient. The age related bone loss of the metatarsals is not known, but is in accordance with other studies [20–23], assumed to be approximately 5% during the mean follow-up period of 3.1 years. The metatarsal heads were chosen as measurement sites due to their amount of cancellous bone, which has higher turn-over than cortical bone and thus enables detection of changes in bone mass.

*2.3.1.1. Pedobarography (PBG).* Footscan®, single step clinical version (Rsscan international, Olen, Belgium) was used for pedobarographic measurements. Patients were asked to walk barefoot at a comfortable speed and length of stride. During walking one step took place on an 8 mm thick rubber mat containing pressure transducers connected to a computer. The procedure was repeated 10 times for each foot in order to achieve repeatable data. While processing the data the Software system (version 4.41) suggests placing of the following structures of the foot: the middle of the heel, first toe, and metatarsals I through V, these regions were adjusted manually. Corresponding maximal pressure, $p_{max}$ ($N/cm^2$) was recorded for each region. Furthermore the foot was divided in zones: forefoot, midfoot and hindfoot and the forefoot subdivided in medial, central and lateral zones, and the maximum ground reaction forces $F_{max}$ (N) in the latter three zones as well as the hindfoot was recorded. Finally, the duration of

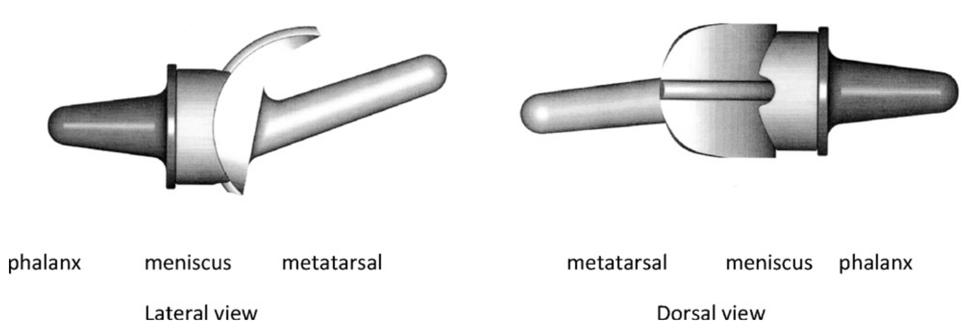


**Fig. 1.** Schematic drawings of the Roto-Glide® prosthesis and its components.

**Table 1**
Demographic data, mean (range).

| N = 12 | |
|---|---|
| Gender (male:female) | 3:9 |
| Age (years) | 56 (49–63) |
| Height (cm) | 171 (162–184) |
| Weight (kg) | 72 (57–90) |
| BMI (kg/m$^2$) | 24.7 (19.2–30.5) |
| Follow-up (years) | 3.1 (1.0–7.2) |

foot contact (time-off) was recorded. Repeatability of PBG measurements was examined on 8 individuals walking 10 sets twice. Interobserver variation was examined on 8 individuals. We hypothesize that maximal ground reaction forces and maximal pressures correspond and choose to use only ground reaction forces as the primary outcome among the pedobarographic variables.

### 2.4. Statistics

Measurements on operated feet were compared to non-operated feet by paired *t*-test, as were pre- and postoperative measurements on both feet. Changes in VAS score were evaluated by use of a Wilcoxon signed rank sum. Level of significance was chosen at $p \leq 0.05$ (SPSS Inc. Chicago, software version 18.0). At a power of 0.80 and a clinically relevant BMD change of 25 g/cm$^2$ in the 2nd metatarsal head and 12 g/cm$^2$ in the 5th metatarsal head and a $p_{max}$ change of 10 N/cm$^2$ under the 1st and 5th metatarsal head 12 patients were sufficient.

## 3. Results

BMD repeatability expressed as the coefficients of variation (CV) ranged from 3.3% to 4.0% and interobserver variation ranged from 0.5% to 3.9%. PBG repeatability had a CV ranging from 2.6% to 15.5% with the best repeatability for time-off and the poorest for $F_{max}$ of the central forefoot. Median interobserver variation was 3.4% (range 0.3–8.9%).

Baseline demography data on patients are shown in Table 1.

BMD results are given in Table 2 and PBG results in Table 3.

Preoperatively there was significantly lower BMD of 2nd metatarsal head ($p < 0.05$). No significant differences of BMD were seen for the lesser metatarsal heads. $F_{max}$ under the medial forefoot of the affected foot was significantly lower preoperatively ($p = 0.04$). No significant differences were seen in central and lateral foot zones. Shorter off-time in the affected compared to the non-affected foot ($p = 0.008$) was seen. Postoperatively no significant differences were seen in the affected compared to the non-affected foot.

Prospectively, there were significant decreases of BMD (5%, $p = 0.02$) of the 5th metatarsal head on the affected foot (Table 2). Maximum ground reaction force of the lateral forefoot decreased significantly (42%, $p = 0.03$), but the maximal force of the medial and central forefoot did not reach significant changes (Table 2).

Self evaluation results are illustrated in Fig. 2. Patients experienced significantly less pain postoperatively (median VAS score changed from 7.9 to 2.1, $p \leq 0.001$).

## 4. Discussion

This study of BMD- and PBG-data of 1st metatarsal joint replacement shows changes compatible with the initiation of normalisation of the load across the forefoot.

Bone mineral density: Preoperatively there was a significantly lower BMD of the 2nd metatarsal head. At the postoperative scan no significant differences were seen. We found a significant decline in BMD of the 5th metatarsal of the affected foot, supporting our hypothesis of a decreased load of the lateral column of the operated foot. There was no increase of BMD of the 2nd metatarsal head. This finding can be explained by the age related bone loss. The bone loss is significantly lower than 5% on the heel of both the non-affected foot ($p = 0.001$) and the affected foot ($p = 0.004$), as well as the non-affected 5th metatarsal ($p = 0.005$). This preservation of bone density may be interpreted as a relative increase of bone mass due to an increase in load. In the heel this may be explained by reduced discomfort causing the patient to walk more and thereby increasing GRF on both heels. The expected bone loss on the lateral side of the affected foot implies that the patient no longer loads excessively on the lateral side, while the preservation of bone mass in the non-affected 5th metatarsal might be explained by the patient having discomfort of the non-operated foot and loading more on the lateral side. In the present study patients operated bilaterally were excluded to avoid bias caused by influence from the contra lateral foot, but since HR has a tendency of bilateral symptoms with time such a bias is practically inevitable.

**Table 2**
Differences between affected foot and non-affected foot preoperatively and postoperatively regarding densitometry using a paired samples *t*-test. Mean (SD), BMD: mg/cm2, index indicates number of metatarsal head.

| N = 12 | Preoperatively | | | | Postoperatively | | |
|---|---|---|---|---|---|---|---|
| | Non-affected | p | Affected foot | p | Affected foot | p | Non-affected |
| BMD heel | 540 (100) | n.s. | 525 (89) | n.s. | 540 (89) | n.s. | 541 (100) |
| BMD2 | 306 (36) | <0.05 | 281 (31) | n.s. | 275 (23) | n.s. | 292 (46) |
| BMD3 | 259 (29) | n.s. | 257 (24) | n.s. | 244 (31) | n.s. | 255 (29) |
| BMD4 | 254 (26) | n.s. | 250 (26) | n.s. | 237 (31) | n.s. | 248 (26) |
| BMD5 | 242 (29) | n.s. | 251 (37) | 0.02 | 238 (41) | n.s. | 244 (35) |

**Table 3**
Differences between pre- and postoperative pedobarographic measurements using a paired samples *t*-test. Mean (SD), off time: ms, $F_{max}$: *N*.

| N = 12 | Preoperatively | | | | Postoperatively | | |
|---|---|---|---|---|---|---|---|
| | Non-affected | p | Affected foot | p | Affected foot | p | Non-affected |
| $F_{max}$ heel | 222 (58) | n.s. | 230 (53) | n.s. | 343 (218) | n.s. | 312 (140) |
| $F_{max}$ medial | 240 (112) | 0.04 | 172 (68) | n.s. | 274 (140) | n.s. | 251 (131) |
| $F_{max}$ central | 410 (106) | n.s. | 395 (138) | n.s. | 496 (304) | n.s. | 466 (229) |
| $F_{max}$ lateral | 193 (82) | n.s. | 239 (113) | 0.03 | 139 (97) | n.s. | 146 (74) |
| Off-time | 655 (81) | 0.008 | 621 (99) | n.s. | 609 (63) | n.s. | 629 (48) |

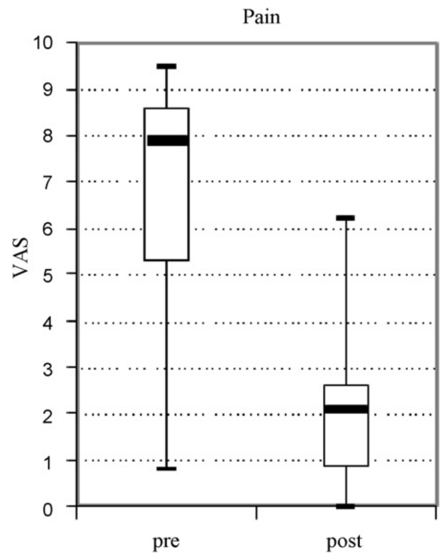


**Fig. 2.** Median, inter quartile range, minimum, and maximum VAS score before surgery (pre) and at follow-up (post).

BMD-measurements of the bones of the foot have to our knowledge only been performed by Commean et al. and Hastings et al. who measured volume and density of the tarsal and metatarsal bones by means of vQCT [16,24]. Coefficients of variation within 0.5–4.0% on BMD-measurements are low considering the small areas of the metatarsals. The spread of metatarsal BMD in the study performed by Commean et al. was comparable to ours despite their obviously more sophisticated technique. Hastings found increased BMD after reloading of a foot that had been non-weight bearing for 6 weeks. The largest increase was recorded in the lateral metatarsals and pedobarography correspondingly showed higher pressures under the lateral column of the foot.

Pedobarography: Preoperative PBG shows significantly lower GRF under the medial forefoot of the affected foot compared to the non-affected foot supporting our hypothesis (Table 3). There were no significant differences postoperatively. The off-time was significantly shorter preoperatively on the affected foot indicating a limp. Postoperatively there was no difference in off-time between affected and non-affected foot indicating that the limp was no longer present. We found a significant decline in $F_{max}$ of the lateral forefoot of the affected foot, supporting our hypothesis of a decreased load of the lateral column of the operated foot. BMD, PBG and VAS data for the 21 patients only examined postoperatively showed results similar to the 12 patients prospectively evaluated patients.

The spread on PBG-data is considerable, but nonetheless comparable to similar studies [6,25,26]. Jacob proposes after studying 84 normal feet by means of the Novel-Emed system that it is caused by intraindividual differences [27]. PBG-data are difficult to reproduce since each step is an intricate act of balance with large intraindividual variations. This has lead to recommendations of up to 15–20 measurements per persona. We had to make do with 10 repeated measurements due to preoperative pain in several patients.

### *4.1. Review of the literature*

No previous studies of the Roto-Glide® prosthesis have been published, and there are only few studies of the newer implants with coated surfaces [8–11,28–30]. Gibson and Thomson [8] conducted the only randomized clinical intervention study in osteoarthritis grade 2–4 looking at the Biomet prosthesis with arthrodesis as alternative. Sixty-three patients had 77 toes randomized, of which 49 had a unilateral procedure, while the remaining 14 patients received either the same or both procedures causing a considerable bias. Within a follow-up of 2 years 15% of patients in the Biomet group had a secondary arthrodesis due to implant loosening and a further 20% had radiolucent lines adjacent to the prosthesis. Significant pain relief was found in both groups, however significantly better in the arthrodesis group (VAS change 6.0–2.7 and 6.2–1.1 respectively). The writers suggest poor osseointegration as the reason for the many loosenings and after the operative procedure was modified and implants were cemented (on the last 9 patients) no more loosenings occurred. By means of in-shoe PBG Gibson and Thomson found increased pressure underneath the 5th metatarsal of patients receiving total joint replacement ($p = 0.003$), a result that differs from our results but is in accordance with the clinical results of the study. Ess et al. [9] followed 10 patients prospectively after insertion of the Re-Flexion prosthesis (FU 2 years), and found pain measured by VAS improved from 7.6 to 1.1, which is in good accordance with our findings. Ramanathan et al. [30] followed 6 patients prospectively after ceramic press-fit implant arthroplasty with a FU ranging from 23 to 40 months and found satisfactory subjective results but were unable to show normalization of pressures underneath the metatarsal heads.

Pedobarographic analyses of various surgical treatments of HR have been published [5–8,25,26,30,31]. Mulier et al. [25] also used in-shoe PBG in their prospective study of 20 patients having received cheilectomy. With a 5.1 year FU moderate changes consistent with a lower degree of lateralisation were found. DeFrino et al. [7] found increased pressure under the hallux in their prospective PBG study of 9 patients having received arthrodesis, but no change under the metatarsals, that means no normalisation of the gait. Nawoczensky et al. [31] also failed to find significant changes in a prospective PBG study of 15 patients 1.7 years after cheilectomy.

Samnegard et al. [26] found in a retrospective PBG study of 10 patients receiving resection arthroplasty and 10 patients receiving arthrodesis and a 5 year FU increased pressure underneath the1st metatarsal head in the arthrodesis group compared to a normal population–contrasting to other studies of arthrodesis [6–8]. Southgate and Urry [6] in a retrospective PBG study following osteotomy (8 pts) and arthrodesis (16 pts) give examples of typical centre of pressure lines showing lateral loading and deviation of the axis of the foot associated with HR as well as arthrodesis. There was significantly longer duration of floor contact underneath the 5th metatarsal after arthrodesis. Lau and Daniels' [5] retrospective study of 19 patients treated by cheilectomy combined with osteotomy and 11 patients treated by interposition arthroplasty (IAP) revealed a high frequency of metatarsalgia, lack of hallux purchase, one stress fracture of the 2nd metatarsal and one secondary arthrodesis in the group of IAP-operated patients. VAS was reduced from 8.1 to 2.9 by cheilectomy and from 8.2 to 3.9 by IAP. Changes consistent with lateral loading were found in both groups. Considering the generally large variation in PBG studies, retrospective studies should be interpreted with caution.

The large number of variables (12 BMD-measurements and 24 PBG-measurements) increases the risk of type 1 error. However, all significant changes are in support of our hypothesis, although the small number of patients examined also increases the risk of a type 2 error.

The present study is – like the vast majority of other studies on the issue – limited by a modest size. On the other hand it provides the so far only material with simultaneous PBG- and BMD-data.

In conclusion, we found changes in BMD- and PBG-data after 1st metatarsal joint replacement compatible with the initiation of normalisation of the load across the forefoot. The achieved pain reduction and normalisation of ground reaction forces is in favour of the Roto-Glide® prosthesis as a possible solution for severe MTP-1 osteoarthritis. Long-term clinical results, however, must be awaited.

## Conflict of interest statement

The senior author has since 2008 acted as consultant for the distributing company (Small Bone Innovations, USA). He has, however, not been involved in neither recording nor analysis of PBG and BMD. None of the other authors has conflicts of interest.

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