

Mid-term outcomes of first metatarsophalangeal arthroplasty using the Primus FGT double-stemmed silicone implants



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ABSTRACT

Background: Silicone implants for first metatarsophalangeal (MTP-1) arthroplasty are regaining popularity, though most studies have long inclusion periods, or short follow-up. The authors aimed to report mid-term outcomes of a cohort that received a third-generation MTP-1 implant at minimum follow-up of 5 years.

Methods: The authors evaluated 70 MTP-1 arthroplasties performed in 64 patients using the PrimusTM Flexible Great Toe implant. The indications were hallux rigidus of grade II (10%) and grade III (87.1%) or revision surgery (2.9%).

Results: All patients completed clinical and radiographic assessments at 83.5 months (range, 62–114). There were no revisions or reoperations and the AOFAS-HMI score was 88.9 ± 9.1 (median, 90; range, 67–100). Metatarsalgia was 'absent' in 47.1%, 'mild' in 41.1%, 'moderate' in 7.1% and 'severe' in 1.4%.

Conclusion: This study reported excellent mid-term clinical outcomes and survival rates of a third generation MTP-1 arthroplasty design and confirmed findings of recent studies regarding efficacy of silicone double-stemmed implants.

Level of evidence: Level IV case series.

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1. Introduction

Since the 1950s, numerous implants were developed for arthroplasty of the first metatarsophalangeal (MTP-1) joint [1], but none succeeded at granting patient satisfaction and implant survival to the levels established for hip and knee replacements [2–5]. For this reason, arthrodesis remains to many surgeons, the 'gold standard' treatment for severe hallux arthritis or deformity [6–9]. The predictable outcomes of arthrodesis render it a possible alternative for revision of failed MTP-1 implants [10–12] despite associated shortcomings such as loss of mobility and cosmesis [5,13].

Arthroplasty of the MTP-1 joint gained popularity in the 1970s, when Swanson et al. [14,15] demonstrated their successful short-term outcomes of silicone hinged implants. This type of implant was associated with frequent mid- and long-term complications, however, including synovitis, osteolysis, lymphadenopathy, and

fracture [16–18]. The alarming incidence of complications led Vanore et al. to publish a classification system for their diagnosis and management [19,20], and caused some authors to recommend discontinuation of such implants [17,21]. The design of silicone MTP implants was improved in several ways through the 1980s [1]: LaPorta's 'Silastic' implant had stems of rectangular (rather than circular) cross-sections and incorporated 15° of sagittal inclination to replicate the natural metatarsal declination angle [22,23]; Lawrence's 'Silflex' implant had an inclined proximal phalanx to preserve the anatomic insertion of the flexor hallucis brevis [24]; and Swanson shortened the stems and added titanium grommets to shield the silicone collars from abrasive contact against resected bone surfaces [25,26].

In the meantime, various other MTP arthroplasty designs were launched, but none attained adequate patient satisfaction and implant survival [3,5]. A meta-analysis [27] of 47 articles distinguished four generations of MTP implants and classified them into five categories, according to their material (silicone, metal, ceramic) or design (hemi or double-stemmed), and noted that satisfaction was highest for double-stemmed silicone implants and metal hemi implants but poorest for silicone hemi implants. Recent publication of long-term clinical outcomes of third

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generation hinged double-stemmed silicone implants revived interest in MTP arthroplasty, although most studies are flawed due to long inclusion periods (15–23 years) [6,28–30], or high proportions of patients excluded or lost to follow-up (24.5%–77.7%) [28–31].

The goal of the present study was to report mid-term outcomes of a series of patients that received a third generation double-stemmed MTP-1 implant manufactured from high-performance silicone. The authors aimed to evaluate clinical and radiographic outcomes using a validated scoring system, with particular attention to complications described in the literature.

2. Methods

2.1. Study design

The authors retrieved the records of all 116 patients (149 ft) that underwent MTP-1 arthroplasty between November 2003 and December 2008 by the same surgeon (SF). All patients received a Primus™ Flexible Great Toe double-stemmed MTP implant manufactured from high-performance silicone (UltraSIL™). Conservative treatment was attempted in most patients prior to considering surgery. An evaluation protocol was established and approved by the local ethical committee in April 2013 (National Health Service—Veneto Region: protocol #1202-T-FGTI-M) and patients were recalled for clinical and radiographic examination between September 2013 and April 2014. The inclusion criteria were: indication of hallux rigidus, minimum follow-up of five years, and informed consent for participation in this study. The exclusion criteria were: indication other than hallux rigidus (hallux valgus, geriatric bunions, rheumatoid arthritis), and patients that underwent further surgery on the ipsilateral foot.

From the original cohort of 116 patients, 31 met the exclusion criteria (29 different indications and 2 reoperations due to ankle fractures), leaving the records of 85 patients for evaluation. A further 21 patients (24.7%) were lost to follow-up (9 moved to distant towns, 5 could not be contacted, 4 were unwilling to participate, and 3 died). The data of the remaining 64 patients (75.3%), corresponding to 70 MTP-1 arthroplasties were evaluated. The patients included 46 women (3 bilateral) and 18 men (3 bilateral) with mean age 59.8 years (range, 45–77) at the time of surgery (Table 1). Of the 70 operated feet, 3 (4.3%) were from diabetics, 9 (12.9%) were from smokers, and 13 (18.6%) had previous surgery on the ipsilateral MTP-1 joint.

Table 1
Patient demographics.

	MTP-1 arthroplasties n = 70
Age	59.8 ± 7.2 (45.0–77.0)
BMI	24.7 ± 3.3 (19.4–33.5)
Women (feet) ^a	49 (70%)
Indications	
Hallux rigidus of grade II	7 (10%)
Hallux rigidus of grade III	61 (87%)
Revision of previous MTP-1 surgery	2 (3%)
Preop subjective activity level	
High	6 (9%)
Moderate	48 (69%)
Low	12 (17%)
Sedentary	4 (6%)

^a 3 women and 3 men had bilateral procedures.

2.2. Operative technique

All patients were operated by the same surgeon (SF) following the same surgical technique. First, dorsomedial longitudinal incision and capsulotomy were made over the MTP-1 joint with special care to avoid injury to the chondral surface. Second, peripheral osteophytes were removed using a rongeur and an oscillating saw to obtain flat and orthogonal surfaces on the dorsal and medial aspects of the metatarsal head and phalangeal base. The preparation of flat and orthogonal surfaces is essential for accurate and stable positioning of the cutting jig which guides the subsequent bone resections, and in turn influences the choice of implant size, positioning and fixation. Third, the medullary canals were reamed to accommodate the implant stems and grommets. The following step was the insertion of the trial implant of the correct size and verification of the range of motion. Finally, the trial spacer was removed and the titanium grommets were press-fitted into the medullary canals before the final implant was inserted (Fig. 1).

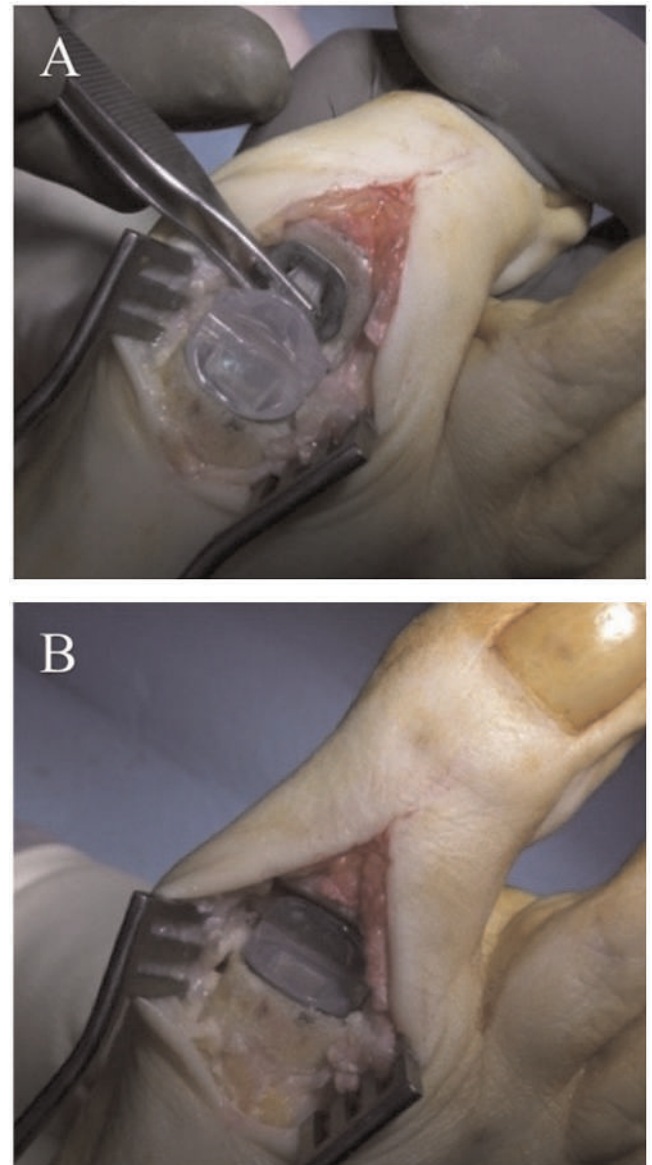


Fig. 1. Intraoperative photographs illustrating (A) insertion of the stem through the grommet into the phalanx and (B) implant in final position before closure.

The implant used is available in 4 different sizes (20, 30, 40, and 50 mm). The 30 mm implant was used in 55 ft (79%), followed by the 20 mm implant in 14 ft (20%), and the 40 mm in only 1 foot (1.4%). Adjunctive procedures were performed in 11 ft (15.7%) to optimise alignment of the joint in cases of considerable valgus deformity or abnormal elevation that could not be corrected using the standard cutting guides of the implant: a first phalanx osteotomy using staples in 6 ft (8.6%) (Fig. 2), and a first metatarsus osteotomy of the base using screws in 5 ft (7.2%). Grommets were used on both metatarsal and phalangeal sides in 60 ft (85.7%) where bone quality was sufficient to grant press-fit of the titanium. In 9 ft (12.9%) of 4 women and 5 men aged 63.1 years (range 51–74), grommets were not used at all, and in 1 foot (1.4%) of woman aged 60 years, a single grommet was used solely on the metatarsal side.

2.3. Postoperative care and follow-up

Patients were immediately allowed to walk without crutches but using postoperative shoes. They were advised to exercise passive dorsiflexion and plantarflexion for 5–10 min every hour, to the extent tolerated, during the first postoperative month. All patients returned for routine visits at 3 weeks, 6 weeks, and 4 months and their operative reports as well as clinic notes were reviewed, noting all evaluations and complications. They were also assessed clinically and radiographically at a minimum follow-up of 5 years. The American Orthopaedic Foot & Ankle Society-Hallux Metatarsophalangeal-Interphalangeal (AOFAS-HMI) scoring system [32] was used. In addition, the following outcomes were rated on a three-point scale (absent, moderate, severe): pain at passive motion, pain at pressure on the MTP-1 joint and dorsal swelling. Subjective patient satisfaction was assessed and pain was evaluated during walking and at rest. Radiographic evaluation was performed by the senior author (AF) who was not involved in surgical intervention, based on weight-bearing frontal and sagittal x-ray films analyzed for presence of osteolysis and/or bone

resorption and to assess alignment. Failure and revision rates were analyzed, the end-point being implant replacement for any reason.

2.4. Statistical analysis

Statistical analyses were performed using R version 3.1.3 (R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics were used to summarize the data. Data were not normally distributed. A multivariable analysis was performed to determine whether postoperative outcomes were influenced by any preoperative factors. Between group differences were evaluated using Wilcoxon rank sum tests (Mann Whitney U test). When 3 or more groups were compared Kruskal–Wallis tests were used followed by Wilcoxon rank sum tests for pairwise comparisons. Categorical data were analyzed using Pearson chi-square tests or Fisher's exact tests. The level of statistical significance was set to $P < 0.05$.

3. Results

The 64 patients (70 ft) were evaluated at mean follow-up of 83.5 months (range, 62–114). There were no intraoperative complications and only one postoperative complication, which was a superficial skin infection that occurred one month after surgery, successfully treated with a systemic antibiotic and local wound care.

The mean overall AOFAS-HMI score improved from 51.6 ± 11.6 (median, 59; range, 29–72) preoperatively to 88.9 ± 9.1 (median, 90; range, 67–100) at final follow-up (Table 2). Hallux pain was 'absent' in 38 ft (54.3%), 'mild' in 32 ft (45.7%) and 'severe' in none (0%). Activity level was 'without limitation' for 47 ft (67.1%), 'with limitation of recreational activities' for 21 ft (30.0%), and 'with limitation of both daily and recreational activities' for 2 ft (2.9%). Fashionable or conventional shoes were worn for 33 ft (47.1%) while comfort footwear or shoe inserts were required for 37 ft (52.9%). Stability was satisfactory in all feet (100%) and symptomatic callous formation was observed in only one patient (1.4%) at the medial side of the distal phalanx.

The radiographic evaluation revealed signs of osteolysis around 13 implants (18.6%) and of bone resorption around 25 implants (36%). Alignment was 'good, hallux well aligned' in 61 ft (87.1%), 'fair, some degree of hallux malalignment, asymptomatic' in 9 ft (12.9%) and 'poor, obvious symptomatic malalignment' in none (0%). The outcomes for feet that underwent adjuvant osteotomies ($n = 11$) to optimise alignment were compared to the remaining feet ($n = 59$) and there were no significant differences in neither postoperative AOFAS-HMI score (90.8 and 88.5, respectively) nor radiographic alignment ('good' in 91% and 86%, respectively).

There were no revisions, or reoperations at a minimum follow-up of five years. The additional clinical observations noted



Fig. 2. Antero-posterior x-ray of a foot that required a first phalanx osteotomy using staples.

Table 2
AOFAS-HMI score at final follow-up.

	Mean $\pm$ SD	Median	(Range)
Pain (40 pts)	35.4 $\pm$ 5.0	40	(30.0–40.0)
Function (45 pts)			
Activity limitations (10 pts)	8.9 $\pm$ 1.6	10	(4.0–10.0)
Footwear requirements (10 pts)	7.4 $\pm$ 2.5	5	(5.0–10.0)
MTP joint motion (10 pts)	8.1 $\pm$ 2.6	10	(0.0–10.0)
IP joint motion (5 pts)	5.0 $\pm$ 0.0	5	(5.0–5.0)
MTP-IP stability in all directions (5 pts)	5.0 $\pm$ 0.0	5	(5.0–5.0)
Callus related to hallux MTP-IP (5 pts)	4.9 $\pm$ 0.6	5	(0.0–5.0)
Alignment (15 pts)	14.1 $\pm$ 2.4	15	(8.0–15.0)
Total (100 pts)	88.9 $\pm$ 9.1	90	(67.0–100.0)

Table 3

Clinical observations in addition to the AOFAS-HMI score.

	Preoperative	Postoperative
Pain at passive motion		
Severe	64	2
Moderate	6	3
Absent	0	65
Pain at pressure on MTP-1		
Severe	54	1
Moderate	16	8
Absent	0	61
Swelling		
Severe	45	2
Moderate	25	14
Absent	0	54

preoperatively and postoperatively (Table 3) revealed a reduction of pain at passive motion and at pressure as well as swelling. It was not clear why 2 cases had severe residual pain and swelling postoperatively, though both cases had moderate metatarsalgia which may be the underlying cause. The data also showed an improvement of walking distance for 59 ft (84.3%) and no change for 11 ft (15.7%), as well as a reduction of pain during walking which diminished for 15 ft (21.4%) and disappeared in 55 ft (78.6%). Metatarsalgia was noted as 'mild' in 29 ft (41.4%), 'moderate' in 5 ft (7.1%) and 'severe' in 1 ft (1.4%). The patient with severe metatarsalgia was a woman aged 74 years at the index operation and had excess weight (BMI of 26.2). She was operated for grade III hallux rigidus with severe metatarsalgia pre-operatively, and had previously undergone proximal interphalangeal (PIP) arthrodesis of the second ray. The postoperative antero-posterior x-rays were qualitatively reviewed to discern whether metatarsalgia was associated with shortening of the first metatarsal but 6 ft with moderate or severe metatarsalgia had no noticeable shortening (Fig. 3), and conversely, cases with considerable shortening that were asymptomatic (Fig. 4).

Statistical analysis revealed significant correlations of overall AOFAS-HMI score with age at index operation and with incidences of metatarsalgia, osteolysis and bone resorption. The overall score reduced significantly with age (Spearman's $r = -0.43$; $P < 0.01$). The overall score was also lower in feet with any degree of metatarsalgia (median, 82; range 67–100) than in feet with no metatarsalgia (median, 92; range, 77–100) and the difference was statistically significant ($P < 0.01$). It is noteworthy that the AOFAS-

HMI score accounts for pain in the first ray whereas metatarsalgia indicates pain under the lesser rays. Finally, the overall score was lower in cases with osteolysis (median, 80; range, 67–100; $P < 0.01$) and in cases of bone resorption (median 82; range, 67–100; $P < 0.01$). Patients with osteolysis were older (median, 66 years; range, 46–77) than patients with no osteolysis (median, 58 years; range, 45–74), though the age difference was not statistically significant ($P = 0.078$).

Statistical analysis also revealed significant associations between the use of grommets and both metatarsalgia and bone resorption. Metatarsalgia was more frequent in feet that received two grommets (53.3%) than in feet that received no grommets (33.3%) ($P = 0.11$). Bone resorption was observed in 6 of the 9 ft (67%) that received no grommets and in 19 of the 60 ft (31.7%) that received two grommets ($P = 0.06$). It is noteworthy that grommets were not used if bone quality was insufficient to grant enough titanium press-fit, mainly in patients with pre-existent bone resorption.

4. Discussion

The aim of the present study was to report mid-term outcomes of a series of 64 patients (70 ft) that received a third generation double-stemmed MTP-1 arthroplasty manufactured from high-performance silicone. At a minimum follow-up of five years the mean AOFAS-HMI score was 89. The overall clinical outcomes of the present series are therefore comparable to those published over the past five years using similar implants (Table 4) [6,28–31]. The findings of the present series thus provide a reliable confirmation of the recent retrospective studies that demonstrated safety and efficacy of this type of silicone double-stemmed implants for MTP-1 arthroplasty [6,28–31].

The principal cause of concern is metatarsalgia which was not always associated with shortening of the first metatarsal (Fig. 3). Nevertheless, all 35 ft with metatarsalgia had good AOFAS scores (median, 82; range 67–100) and 12 of them wore fashionable or conventional footwear. Metatarsalgia was the most frequent complication reported in the recent series of Lawrence and Thuen [31] using the same implant model. Metatarsalgia is one of the most common complications of surgical procedures of the MTP joint in general, including arthrodesis, Keller resection arthroplasty, and other hemi or total arthroplasty procedures [3,33–35]. In a recent review article, Espinosa et al. [36] distinguished



Fig. 3. (A) Antero-posterior and (B) lateral weight-bearing x-rays of a foot at a follow-up of 7.0 years, from a man aged 58 years at index operation. The image reveals signs of osteolysis and bone resorption. The patient reported 'moderate' metatarsalgia on the Likert five-point scale (AOFAS = 67), but had no noticeable shortening of the first metatarsal.



Fig. 4. Antero-posterior weight-bearing x-ray of both feet at follow-up of 9.4 years and 7.5 years, from a woman aged 49 years at revision operation on her left foot, operated on her right foot two years later. Both feet exhibit considerable shortening of the first metatarsal but the patient reported 'mild' metatarsalgia on the Likert five-point scale only in her right foot (AOFAS = 100) but no metatarsalgia in his left foot (AOFAS = 95).

between primary, secondary and iatrogenic metatarsalgia, outlining the causes and various treatment options [37–40].

The principal improvement reported from the present series is the sensation of hallux pain during walking – disappeared in 78.6% and reduced in 21.4% – which resulted in improved function and allowed fashionable or conventional footwear for 47.1% of cases.

The present study has some limitations, such as the portion of patients lost to follow-up, and the inability to compare preoperative and postoperative AOFAS-HMI scores [41,42]. But the study also has several strengths, such as the reduction of bias by virtue of a continuous series operated by the same surgeon, following a pre-established evaluation protocol, the restriction of indications to hallux rigidus, the limited inclusion period which ensured consistency of implant design, material and surgical techniques, and finally, the sufficiently large cohort that allowed robust statistical analysis.

The high overall AOFAS-HMI score and survival rate observed in the present series are consistent with the recent literature on similar implants [6,28–31]. Equivalent survival rates were reported

over the past decade for other MTP-1 arthroplasty designs, most of them metallic hemi or total systems [43–45], but the associated follow-up tends to be shorter (1.8–3 years), the AOFAS scores tend to be lower (82.5–86.5) and the indications for surgery are generally more heterogeneous. The authors believe that the good outcomes obtained with the present series could be attributed to four key features, though it was not possible to investigate their influence in this study. First, the use of grommets in most feet prevented abrasive friction and damage to the double-stemmed silicone component [6,26,28–30]. Second, the high-performance silicone (UltraSIL™) material prevented reactive synovitis and lymphadenopathy typically associated with hinged silicone components [3,5,27]. Third, the angulation of the silicone collars and adjustment of surgical technique to avoid damaging the flexor hallucis brevis tendon grants superior joint mobility and more natural gait [3,31,46]. Fourth, the sagittal angulation of the metatarsal and phalangeal stems reproduces the alignment of the toe in neutral position and therefore maintains natural muscle and tendon tensions at rest and while walking. And last, the

Table 4
Clinical outcomes of double-hinged silicone implants published over the past 5 years.

Authors	Year	Inclusion period (Years)	Follow-up period (Years)	Patients [feet]	Lost to follow-up (%)	Manufacturer	Model	AOFAS (Mean score)	Survival (%)
This Study	2015	5	7.0	64 [70]	44.8%	Tornier	Primus	88.9	100.0%
Lawrence et al.	2013	5	5.5	54 [70]	62.5%	Tornier	Primus	87.4	94.9%
Morgan et al.	2012	15	8.5	83 [108]	24.5%	Unspecified ^a		77.5	97.1%
Van Duijvenbode et al.	2012	18	19.0	36 [42]	57.1%	Dow Corning	Swanson	n.a. ^b	97.2%
Sung et al.	2011	23	7.2	63 [92]	77.7%	Unspecified ^a		82.4	95.2%
Ter Keurs et al.	2010	16	9.0	48 [59]	18.6%	Dow Corning	Swanson	83.0	85.9%

^a Possibly Dow Corning Swanson considering bibliography cited by the authors.

^b FOAS median score = 99; AOFAS score not measured.

combination of accurate metatarsal and phalangeal osteotomies ensured accurate alignment of the first ray, and prevented exacerbation of shear forces at the implant hinge. The impact of the aforementioned features on outcomes is only hypothetical, as direct comparisons were not possible, but they seem consistent with the recent literature.

5. Conclusion

The present study reported excellent mid-term clinical outcomes and survival rates of a third generation double-stemmed MTP-1 arthroplasty design at a minimum follow-up of five years. The only concern is the incidence of 'mild' metatarsalgia which did not affect functional outcomes. The overall clinical outcomes corroborate the results of recent retrospective studies, that demonstrated efficacy of this type of silicone double-stemmed implants for MTP-1 arthroplasty, though longer-term follow-up is necessary to confirm its safety and performance.

Conflict of interest

None.

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