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Comparison of Total Joint Replacement With Arthrodesis of the First Metatarsophalangeal Joint

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Abstract

Background: The aim of this study was to compare outcome (clinical, patient-reported outcome measures, radiologic, joint motion and pedographic) of total joint replacement with Roto-Glide (RG) and arthrodesis (A) for severe osteoarthritis of the first metatarsophalangeal joint (MTP1).

Methods: All consecutive patients with arthrodesis and RG from January 23, 2011, until September 18, 2019, at the authors' institution were considered for inclusion in the study. Preoperatively and at follow-up (FU), radiographs, and/or weightbearing computed tomographic imaging were obtained. Standard dynamic pedography was performed. Visual analog scale foot and ankle (VASFA), European Foot and Ankle Society (EFAS) score, MTP1 range of motion for dorsiflexion/plantarflexion (DF/PF) were registered and compared preoperatively and at FU.

Results: Seventy RG and 72 arthrodesis patients were included. Preoperative VASFA and EFAS scores did not differ between the RG and arthrodesis groups (average scores: VASFA, 50.6 and 45.6; EFAS score, 10.7 and 10.6, respectively; each $P > .05$). Wound healing delays without further operative measures were registered in 4 patients (6%) for RG and 5 (7%) for arthrodesis ($P = .67$), and 5 revisions in 5 patients (7%) for RG and 12 in 8 (11%) for arthrodesis ($P = .05$). The longest available FU was higher in RG than in arthrodesis (47 vs 37 months on average, $P < .001$). Pedography showed higher first metatarsal head or sesamoids and lower great toe force percentage from force of entire foot in RG than in arthrodesis ($P = .05$) resulting in physiological pattern in RG only. VASFA and EFAS scores at FU was higher in RG than in arthrodesis (average scores: VASFA, 72.6 and 63.6; EFAS score, 16.1 and 14.1, respectively; each $P < .05$). DF/PF measurement was only possible in RG (average value: DF/PF, 36.1/14.0).

Conclusion: We found marginally lower revision rates and higher patient-reported outcome measures, joint motion (DF/PF), and more physiologic force distribution at slightly longer FU for the RG group than the arthrodesis group. Longer follow-up and broader clinical reporting are needed to identify the potential deficits of RG.

Level of Evidence: Level III, retrospective cohort study.

Keywords: first metatarsophalangeal joint, arthrodesis, total joint replacement, Roto-Glide

Introduction

Total joint replacement of the first metatarsophalangeal (MTP1) joint has been in use for more than 40 years.[10,14] However, it has not become standard treatment like joint-preserving procedures and arthrodesis that is considered as gold standard.[3,4,6,12,13] Stemmed silicone prostheses from hand surgery showed a significant number of failures in MTP1 replacement.[10] This was probably caused by the much higher forces and pressures in MTP1 than in the hand, and missing rotational motion.[10] The typical consequences were implant breakage, severe synovitis, and bone loss.[10] Metal implants as hemi joint replacements and 2-piece metal-on-metal total designs for total joint replacement have been and are still used.[10] Uncemented hemiprosthesis

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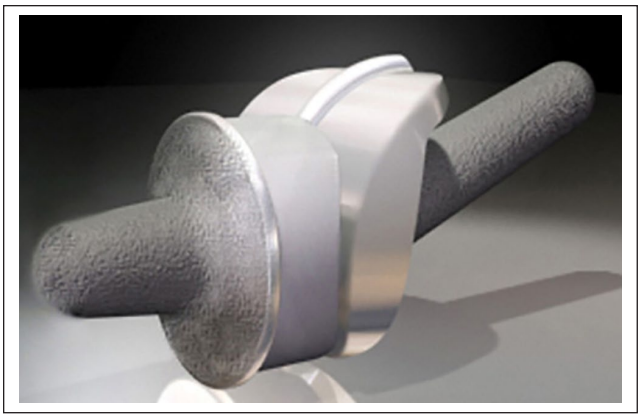

Figure 1. The Roto-Glide. A 3-component noncemented device with a mobile bearing.

may be useful in grade 1 and 2 osteoarthritis, but did not show acceptable results in grade 3 and 4 osteoarthritis.[10] The 2-piece metal devices were initially cemented.[10] Still, the device's short pegs loosened.[10] The same has been reported about the uncemented devices.[1,8] Modern 2-piece devices have used metal on polyethylene.[7] Fuhrmann et al[7] found radiographic loosening at 3-year follow-up (FU) in one-third of their cases. In a later study, Bartak et al[1] found 16% failures after 24 months, which confirms the results of Kundert and Zollinger-Kies.[12] Ceramic-on-ceramic devices showed poor short-term results with loosening 12.5% to 18% after 26 months and 3 years.[2,5] The only attempt of a randomized prospective study comparing arthrodesis vs total replacement had serious flaws.[8,10] The procedure was change in the replacement group during the study from uncemented to cemented implantation because of loosening of the uncemented devices.[8,10] Osteoarthritis stages 1 to 3, bilateral cases, and cases that got both arthrodesis on one side and replacement on the other side were included.[8,10] The authors claimed that the arthrodesis group got normal loading of the great toe.[8,10] This is contradictory to all previous and later studies, and at the same time the replacement group did not get any loading on the great toe.[10,14] Earlier results of the Roto-Glide (RG, Implants International, Cleveland, United Kingdom) have been very promising.[9,11,14,19,20] The aim of the current study was to compare the outcomes (clinical, patient-reported outcome measures [PROMs], radiologic, joint motion and pedographic) of RG with arthrodesis. In addition, the surgical techniques are described.

Material and Methods

Roto-Glide[10]

The Roto-Glide (Implants International, Cleveland, United Kingdom) is a noncemented TiCaP-coated 3-component device for total replacement of MTP1 (Figure 1).[10] The design was intended to allow for physiological joint motion.[10] The metatarsal component has a long intramedullary stem, and the upper part of the metatarsal head has an anatomical flange.[10] It has a crest in the center that corresponds to the natural crest in the lower part of the head.[10] The phalangeal component has a shorter hollow stem.[10] The polyethylene component has a peg corresponding to the hollow phalangeal component stem.[10] The proximal surface of the meniscus is congruent with the metatarsal component's surface corresponding to the crest for sideboard stability.[10] Dorsi-/plantarflexion takes place between polyethlene and metatarsal components, and rotation between polyethylene and phalangeal components.[10] Available interchargable component sizes are 3 metatarsal, 4 phalangeal, and 3 polyethylene.[10] RG is not intended to be used in hallux valgus deformity corresponding to the local guideline-based definition of first-second intermetatarsal angle (IMA) $\leq$11 degrees and hallux valgus angle (HVA) $\leq$20 degrees.[10,14] RG is also not recommended with simultaneous lesser ray corrective osteotomies.[10,14]

Preoperative Diagnostics, Surgical Technique, and Postoperative Care[14]

- Dorsoplantar and lateral weightbearing radiographs are obtained showing osteoarthritis stage 3 in this case (Figure 2A and B).[18]
- Pedography shows unloading under the MTP1 with decreased contact area and decreased force percentage. Lateral shift of the course of the center of gravity especially during the second half of the gait stance phase (Figure 2C).
- Positioning includes supine position, thigh tourniquet, leg elevated, and surgeon position medial side.
- Medial approach with straight incision is recommended.[10,14]
- The medial joint capsule is incised. The entire joint including the sesamoids is exposed. The flexor hallucis tendon is tenolysed and integrity confirmed. Synovectomy follows.
- Osteophytes at the metatarsal head are removed dorsally, medially, and laterally (Figure 3B). The osteophytes at the base phalanx do not need to be removed because of the following osteotomy. Osteophytes at the sesamoids should also be removed if present.
- Metatarsal and phalangeal component sizes are measured with templates.
- The metatarsal jig is attached with correct length, rotation, and dorsi-/plantarflexion (Figure 3B). The cut removes the upper part of the metatarsal head.
- The phalangeal jig is applied for the cutting of the phalangeal joint surface, that is, 2 to 3 mm of the upper phalanx is resected perpendicular to the phalanx's axis

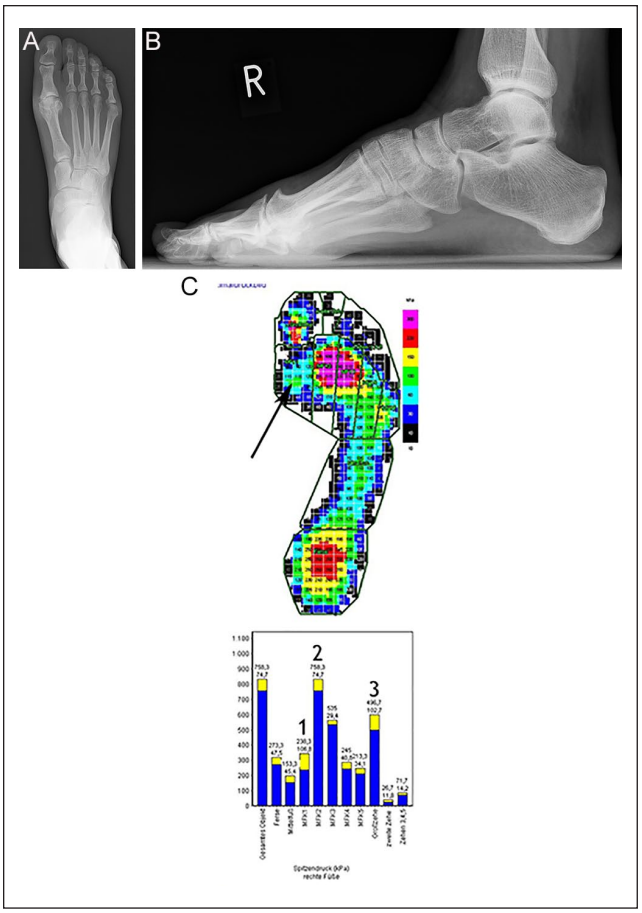

Figure 2. Preoperative radiographs and pedography. (A) Dorsoplantar and (B) lateral radiographs with weightbearing showing a hallux rigidus grade 3. Pedography shows increased pressure under first toe (3) and decreased pressure under metatarsal head/sesamoids (arrow and 1). Lateral shift of the course of the center of gravity especially during the second half of the gait stance phase, and consequently increased pressure under second and third metatarsal heads (2).

(Figure 3C). Care must be taken to secure the plantar structures (especially flexor tendons).

- Figure 3D shows metatarsal and phalangeal cuts.
- Instruments for drill guides to the medullary canals are used to ensure central position. The correct position at the metatarsal is above the crest (Figure 3E and F). The drilled canals are reamed to fit desired component sizes.
- Trial metatarsal and phalangeal components are inserted, and the best fitting polyethylene component, and checked fluoroscopically.
- The definite prosthesis is coated and the stems are minimally thicker than that from the trial prosthesis.[10,14] This allows for press-fit fixation (Figure 3G). The joint should be sideboard stable (no subluxation during varus or valgus stress), and 80 degrees dorsiflexion is desired.
- Intraoperative fluoroscopic imaging includes dorsoplantar (Figure 4A) and lateral (Figure 4B) views, and lateral view with dorsiflexion to confirm adequate dorsiflexion and missing dorsal (sub)luxation during dorsiflexion (Figure 4C).
- A drainage and pain control catheter are inserted and fixed with tape. The wound is closed in anatomical layers (joint capsule, subcutaneous, skin) following the local standard. A dressing and an orthosis unloading the forefoot (Forefoot Relief Shoe; Bort, Weinstadt-Benzach, Germany) are applied.
- Postoperative care. Full weightbearing is allowed in cases with normal bone situations, that is, normal or moderately decreased bone density. Partial weightbearing is safer and recommended in cases with significantly decreased bone density.[14] The same strategy is recommended for postoperative physiotherapy.[14] The patient is instructed to load on the medial side of the foot over the hallux as walking on the lateral side of the foot should be abandoned from day 1.[14] Skin staples are removed 18 days postoperatively. In less stable situations, motion could be limited until osseous integration at 6 weeks. Radiographs are taken at 6 weeks to confirm adequate position without signs of loosening (Figure 5A and B). Pedography at 3 months is recommended to confirm adequate loading of the first ray.

Arthrodesis. Arthrodesis was performed in similar fashion as RG regarding preoperative diagnostics, positioning, approach, joint preparation, osteophyte removal, closure, and postoperative care. The preparation of the joint surfaces of metatarsal and phalanx have been performed with cup and cone reamers (Halluream, Normed, Tuttlingen, Germany). Two fully threaded, cortical thread, noncannulated, titanium alloy, small fragment screws were used for osteosynthesis: one running retrograde from the plantar aspect of the base of the base phalanx into the intramedullary canal of the metatarsal and the other running antegrade bicortical from the distal dorsomedial part of the metatarsal toward the plantar lateral part of the base of the phalanx.

Study Design

All consecutive patients with arthrodesis and RG from January 23, 2011, until September 18, 2019, at the authors' institution were considered for inclusion in the study. The study specifics were not formulated before the first patient was enrolled (evidence level III).

Inclusion criterion. The inclusion criterion for the study was the operative procedure (RG, n=83; arthrodesis, n=264).

Exclusion criteria. Exclusion criteria were bilateral treatment (RG, n=8; arthrodesis, n=21), additional lesser ray corrective osteotomies (RG, n=0; arthrodesis, n=95), RG revision and/

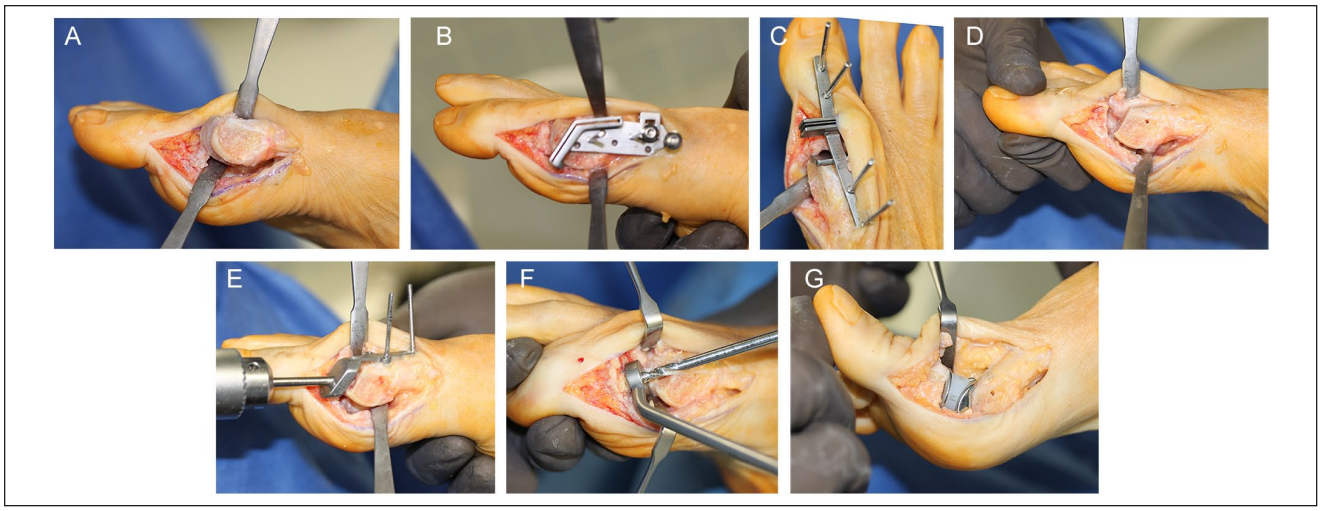

Figure 3. (A-G) Operative technique.

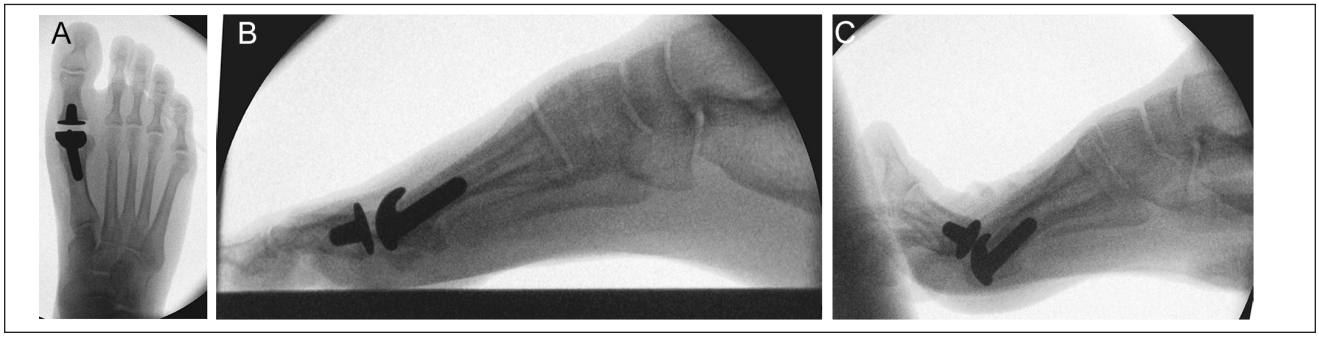

Figure 4. Intraoperative imaging included (A) dorsoplantar and (B) lateral views, and (C) lateral view with dorsiflexion to confirm adequate range of motion and missing dorsal (sub)luxation during dorsiflexion. Same patient as in Figures 2 and 3.

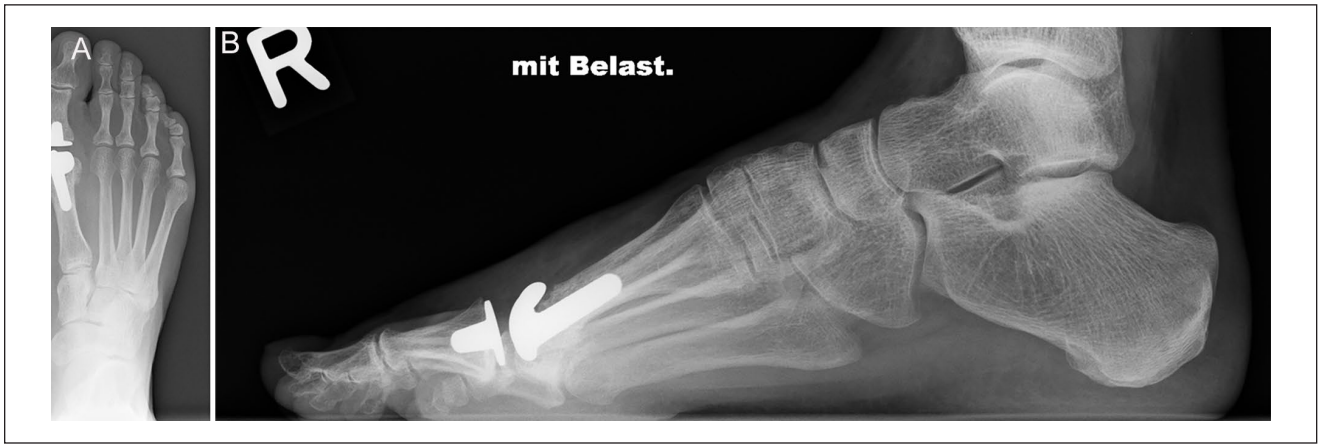

Figure 5. Postoperative radiographs and pedography. (A) Dorsoplantar and (B) lateral views with weightbearing. Same patient as in Figures 2–4.

or exchange (n=5), arthrodesis after removal of total joint replacement (not RG, n=14), IMA > 11 degrees and/or HVA > 20 degrees (RG, n=0; arthrodesis, n=62), and incomplete minimum follow-up of 24 months (RG, n=0; arthrodesis, n=0).

Assessment. Preoperatively and at FUs (except 3 months), weightbearing radiographs (before February 15, 2013) or weightbearing computed tomographs (WBCTs, from February 15, 2013) were obtained preoperatively and at all FUs. Degenerative changes were preoperatively classified in 4 degrees.[18] Standard dynamic pedography (3 trials, walking, third step, midstance force pattern) was performed preoperatively and at all FUs as described before at the authors' institution by independent staff.[16] A standard platform (Emed AT1; Novel Inc, Munich, Germany) and software (Emed ST1, version 12.3.18) was used.[16] Both sides were measured.[16] Computerized mapping to create a distribution into the following foot regions was performed with the standard software (Automask, version 12.3.18; Novel Inc): hindfoot, midfoot, first metatarsal head, second metatarsal head, third metatarsal head, fourth metatarsal head, fifth metatarsal head, first toe, second toe, third to fifth toe.[16] This mapping process does not include manual determination of landmarks.[16] Visual analog scale foot and ankle (VASFA), European Foot and Ankle Society score (EFAS score) and MTP1 range of motion for dorsiflexion/plantarflexion (DF/PF) were registered.[15-17] The EFAS score was available at the authors' institution since 2016, that is, before official publication, because the institution was included in the development and validation of the score.[15] FUs were performed at 3, 12, and 24 months in all patients, and at 36 months in the so-called longest FU in subcohorts. Preoperative assessment and FUs were performed in the outpatient clinic of the author's institution with the patient present. Range of motion was personally measured by the author or coauthors (orthopaedic foot and ankle surgeons) using a goniometer (Goniometer; Seahan Industries, Eschborn, Germany). PROMs were gathered by study nurses. The score forms including instructions were handed to the patient, and the patient completed the forms in the waiting area without supervision of the research team; that is, the patient filled out the PROMs independently.

Statistical Analysis

All parameters were compared between RG and arthrodesis in FU and between preoperatively and FUs. The data were analyzed with SPSS software (IBM SPSS Statistics 25, IBM, Armonk, NY, USA). An unpaired *t* test was used for comparison between RG and arthrodesis of age, height, weight, IMA, HVA, hallux rigidus or osteoarthritis stadium preoperatively, longest FU time, and DF, PF, and VASFA and EFAS score preoperatively and at FUs. A paired *t* test was used for comparison of VASFA and EFAS score preoperatively and FUs within RG and arthrodesis. Chi-square test was used for comparison between RG and arthrodesis of force percentage of pedography, wound healing delay incidence, and revision incidence. Mann-Whitney *U* test was used for comparison between RG and arthrodesis of gender distribution. Before using the *t* tests, the data were investigated regarding the distribution and the data were proven to be normally distributed. The significance level was defined as $P < .05$. A power analysis that was carried out before *t* tests indicated sufficient power (>0.8). The calculated minimum sample size ranged from n = 10 for range of motion to n = 50 for PROMs (all other parameters in between).

Results

Patients

No patients lost to FU; 100% completed the in-person minimum 2-year FU. Seventy RG and 72 arthrodesis patients were eligible. Patients with RG were younger than patients with arthrodesis (Table 1). Gender distribution, height, weight, IMA, hallux rigidus or osteoarthritis stadium, PF, and pedography force percentage (first metatarsal head/sesamoids/great toe) did not differ between RG and arthrodesis cohorts (Table 1). DF was lower in RG than in the arthrodesis cohort (Table 1).

Adverse Events and Revisions

Wound healing delays without further operative measures were registered in 4 (6%) for RG and 5 (7%) for arthrodesis, and revisions in 5 (7%) for RG and 12 (17%) for arthrodesis (Table 1). Revisions for RG were arthrolysis for stiffness in 3 patients and removal and arthrodesis for subluxation in 2 patients (5 patients [7%] in total). The 2 patients with removal and arthrodesis were not excluded from further FU. Twelve revisions in 8 (11%) patients for arthrodesis were implant removal for local irritation in 5 patients and rearthrodesis for pseudarthrosis in 3 patients. In the 3 patients with rearthrodesis, a second rearthrodesis for symptomatic pseudarthrosis was performed in 1 patient, and 1 of 2 revisions for infection in the other 2 patients.

Follow-up

The latest FU was later in the RG group (47 months on average) than in the arthrodesis group (37 months on average) (Table 1). Fifty-six patients (80%) completed 36 months' or longer FU in RG and 36 (50%) in arthrodesis. At the last FU, no loosening, subluxation, cyst formation for RG, or pseudarthrosis for arthrodesis were registered. DF and PF were only possible in RG. Pedography force percentage (first

Table 1. Clinical Study Results: Roto-Glide vs Arthrodesis Preoperatively and at Longest Available Follow-Up.

	Roto-Glide (n = 70)	Arthrodesis (n = 72)	*P* Value
Preoperatively			
Age, y, mean (range)	54 (19-79)	61 (19-85)	<.001[a]
Male, n (%)	33 (47)	32 (44)	.75[b]
Height, cm, mean (range)	171 (153-190)	169 (150-188)	.06 [a]
Weight, kg, mean (range)	74 (49-107)	80 (53-110)	.45 [a]
IMA, mean (range)	8.4 (7-10)	8.2 (1-11)	.54 [a]
HVA, mean (range)	11.6 (5-19)	12.8 (1-20)	.06 [a]
HR, mean (range)	3.4 (2-4)	3.1 (2-4)	.26 [a]
DF, degrees, mean (range)	19.4 (0-60)	30.9 (0-50)	.003 [a]
PF, degrees, mean (range)	7.6 (0-30)	8.4 (0-30)	.71 [a]
Force[c], %, mean	7.9/14.6	8.5/15.3	.82 [d]
Follow-up (longest available)			
Wound healing delay, n (%)	4 (6)	5 (7)	.67 [d]
Revisions, n in n patients (%)	5 in 5 (7)	12 in 8 (11)	.05 [d]
FU time, mo, mean, range	47.3 (24-99)	37.2 (24-95)	<.001 [a]
DF, degrees, mean (range)	36.1 (0-60)	–	
PF, degrees, mean (range)	14.0 (0-30)	–	
Force[c], % (mean)	15.8/5.8	12.3/10.8	.05 [d]

Abbreviations: DF, dorsiflexion; FU, follow-up; HR, hallux rigidus or osteoarthritis stadium; HVA, hallux valgus angle; IMA, first-second intermetatarsal angle; PF, plantarflexion.
[a]*t* test.
[b]Mann-Whitney *U* test.
[c]Force percentage measured by pedography (first metatarsal head, sesamoids, or great toe from force of entire foot).
[d]χ^2 test.

Table 2. PROMs for Roto-Glide vs Arthrodesis.

	Roto-Glide	Arthrodesis	*t* Test *P* value
VASFA			
Preoperative	50.6±16.1	45.6±18.6	.09
3-mo FU	64.7±20.4	64.6±23.9	.97
12-mo FU	65.9±20.8	64.1±22.0	.62
24-mo FU	71.9±17.4	62.9±22.5	.008
36-mo FU[a]	72.8±17.3	60.8±23.0	.001
Longest FU	72.6±14.5	63.6±22.5	.006
EFAS score[a]			
Preoperative	10.7±5.5	10.6±4.4	.90
3-mo FU	14.2±5.3	13.4±3.7	.34
12-mo FU	15.6±2.9	14.2±3.8	.03
24-mo FU	15.7±3.8	13.9±4.2	.009
36-mo FU	16.0±3.8	13.9±4.1	.003
Longest FU	16.1±4.4	14.1±4.0	.007

Abbreviations: EFAS Score, European Foot and Ankle Society Score; FU, follow-up; PROMs, patient-reported outcome measures; VASFA, visual analog scale foot and ankle.
[a]Not available in all patients.

metatarsal head, sesamoids, or great toe) differed between RG and arthrodesis cohorts (Table 1). 1st metatarsal head/sesamoids force percentage from force of entire foot was higher and great toe lower in RG than in arthrodesis. The VASFA score did not differ between RG and arthrodesis preoperatively and at 3 and 12 months FUs, and was higher in RG than arthrodesis at 24 and 36 months and at last FUs (Table 2). The EFAS score did not differ between RG and arthrodesis preoperatively and at the 3-month FU, and was higher in RG than arthrodesis at 12, 24, and 36 months and at last FUs (Table 2). The VASFA and EFAS score in RG and arthrodesis were higher at all FUs than preoperatively (Table 3). In RG, VASFA was higher at 24 and 36 months and at last FU than at the 12-month FU, and higher at the 36-month FU than at the 24-month FU (Table 3). In arthrodesis, the VASFA score was higher at the 36-month FU than at the 24-month FU (Table 3). In case of improvement as described above, EFAS scores improved on average in each single question, and VASFA in all subscales (pain, function, and other symptoms). The VASFA score did not differ between the other FU times as described above (Table 3). The EFAS scores did not differ between the 12-, 24-, and 36-month FU or at the last FU except higher EFAS score at the 36-month FU than at the 24-month FU in arthrodesis (Table 3).

Discussion

RG was compared with arthrodesis in an earlier study with 25 RG and 49 arthrodesis patients.[14] The results were

Table 3. PROMs: Preoperative vs Follow-ups (Paired *t* Test).

	VASFA		EFAS Score[a]	
	RG	A	RG	A
Preoperative vs 3-mo FU	<.001	<.001	<.001	.001
Preoperative vs 12-mo FU	<.001	<.001	<.001	<.001
Preoperative vs 24-mo FU	<.001	<.001	<.001	<.001
Preoperative vs 36-mo FU[a]	<.001	<.001	<.001	.001
Preoperative vs last FU	<.001	<.001	<.001	<.001
12-mo FU vs 24-mo FU	.004	.16	.95	.61
12-mo FU vs 36-mo FU[a]	.001	.009	.61	.08
12-mo FU vs last FU	.006	.14	.46	.66
24-mo FU vs 36-mo FU[a]	.07	.18	.20	.87
24-mo FU vs last FU	.63	.38	.57	.26

Abbreviations: A, arthrodesis; EFAS Score, European Foot and Ankle Society Score; FU, follow-up; PROMs, patient-reported outcome measures; RG, Roto-Glide; VASFA, Visual Analogue Scale Foot and Ankle.
[a]Not available in all patients.

comparable for both groups.[14] The study was proceeded to increase the case numbers to 70 RG and 134 arthrodesis. For this study, hallux valgus deformities (HVA > 20 degrees and IMA > 11 degrees) were excluded from arthrodesis (by exclusion criteria) to better match the RG cohort in which hallux valgus was excluded by indication. Our results show lower revision rate and higher PROMs, joint motion (DF/PF), and more physiologic force distribution at longer FU for RG than for arthrodesis. When considering "simple" implant removal after arthrodesis (n=5), the remaining "major" revision rate (rearthrodesis for pseudarthrosis) in 3 patients would be more similar to RG with 2 removals and arthrodesis. Fusion and implant removal rates in arthrodesis were found to be adequate with the performed 2-screw fixation technique.[14] Better joint motion after RG than after arthrodesis is an expected result, which is the basis for more physiologic force distribution pattern during pedography after RG than after arthrodesis.[16] The typical pedographic pathologic pattern for hallux rigidus or osteoarthritis MTP1 is decreased force at first metatarsal head or sesamoids and increased force at great toe in comparison with physiological patterns (Table 1).[16] In RG, the pattern did improve with increased force at first metatarsal head or sesamoids and decreased force at great toe in comparison with preoperative and with arthrodesis at FU (Table 1).[16] RG showed force distribution as comparative physiologic standard pattern, whereas arthrodesis differed.[16] PROMs improved for both RG and arthrodesis at all FUs. The early FUs (3 months, VASFA and EFAS score; 12 months, VASFA) did not show different scores. The later FU showed increasing scores in RG but not in arthrodesis, resulting in better scores in RG than in arthrodesis at FU 24 months and longer. Considering PROMs as the actual most important outcome parameters, this is the principal result.[15,17] Comparison with other results from the literature is not possible because no other results of RG in comparison with arthrodesis have been published except the earlier results from our institution.[14] One potential disadvantage of RG is bone loss or defect after removal. The bone loss regarding length is less than 1 cm in total. The intramedullary bone loss is also limited. In the 2 cases of the study, autologous cancellous bone transplantation was performed to fill the voids. The bone loss and bone transplantation were not relevant for the study results.

Limitations

Shortcomings are missing randomization and unequal cohorts, including different FU times for RG and arthrodesis. Missing randomization is a shortcoming that cannot be invalidated. The decision was made by the patient after explanation of the 2 treatment options by the surgeons. All data have been collected prospectively and continuously. However, the specifics of the study were not defined before data acquisition (prospective study design). Consequently, this is not a prospective study but a retrospective study with prospective data acquisition. The cohorts differed with lower age and range of joint motion, and longer FU for RG than for arthrodesis. One could argue that patients of the RG group with lower preoperative age and DF and longer FU would have lower expectations as selection bias. However, facing the better outcome of RG including range of motion and pedographic parameters in addition to PROMs, this was not considered as bias as it would have been vice versa. Learning curve might have impact on the result but was not investigated in this study.

In conclusion, we found marginally lower revision rates and higher PROMs, joint motion (DF/PF), and more physiologic force distribution at slightly longer FU for the RG subgroup than the arthrodesis subgroup.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

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Ethical Approval

Ethical approval for this study waived for this study by the Ethical Committee of University Erlangen, Germany because data was collected anonymously, and no extra questionnaires were collected or assessments, diagnostics, treatments or follow-ups performed for the study.

Supplemental Material

A supplemental video for this article is available online.

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