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ORIGINAL PAPER

Total ankle replacement: is pre-operative varus deformity a predictor of poor survival rate and clinical and radiological outcomes?

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Abstract

Purpose The objective of this study was to compare survival rate and clinical and radiological outcomes of a cementless mobile-bearing total ankle replacement (TAR) between two groups of patients, affected by end-stage ankle arthritis, with or without a pre-operative varus deformity.

Methods A total of 81 patients (81 ankles) were included in the study and divided in two groups. Group A, "varus" group, includes 11 patients with pre-operative varus deformity of more than 10 ° and group B, "neutral" group, includes 70 patients, with a varus/valgus deformity of less than 10 °. American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot score, visual analogue scale (VAS), and Short Form (SF)-12 score were used to compare clinical outcomes. Radiological parameters, complications, and survival rate at last follow-up were also recorded.

Results In both groups, all clinical and radiological parameters improved after surgery ($p < 0.05$) without statistically significant difference. Complications were similar between two groups. Overall in three cases, an implant revision was necessary: 1 in group A (9%) at 3.1 years follow-up and 2 (3%) in group B at 3.8 years, without statistically significant difference ($p > 0.001$).

Conclusions Severe varus malalignment should not be considered a contraindication for a mobile-bearing TAR. Nevertheless, TAR in severe deformity should be performed only by experienced surgeons.

Keywords Total ankle replacement · Varus deformity · Malalignment · Coronal malalignment

Introduction

Improvement in design [1], more knowledge, numerous studies, and scientific publications have made total ankle replacement (TAR) a valid alternative to joint fusion in the treatment of end-stage ankle arthritis [2], severe and very disabling pathology that negatively affects the quality of life and the performance of daily activities [3]. At the same time, there are still disputes and debates regarding definitive indications [4], contraindications, risk factors, premature failures, and long-term outcomes [1, 5, 6]. Despite progress, in fact, TAA revision rates are higher compared with other joint arthroplasty [1, 7], as well as re-operation rates [8], and some authors suggest that inclusion criteria for this procedure should be refined [1, 9]. Moreover, surgeon's learning curve is considered to be an absolute priority [10].

A crucial point in the setting of TAR indications is ankle malalignments on coronal plane [11]. Some authors continue to prefer ankle arthrodesis [11] in case of a severe varus or valgus deformity. On the other hand, there are authors who routinely perform TAR even in more than 30 ° deformity [4]. Even if a severe malalignment has been suggested by the most as relative contraindication to TAR [1], an univocal pre-operative cutoff has not been widely accepted yet. There is, instead, a good agreement about the need to restore a correct coronal alignment after a TAR, to avoid early failure due to imbalances, edge loading, increased polyethylene stress, and wear [9, 12].

Level of Evidence: III.

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Purpose of this study was the comparison of clinical and radiological outcomes, complications, and the correction maintenance at follow-up in patients with pre-operative varus deformity of more than 10 ° versus patients with varus deformity of less than 10 °, all treated with mobile-bearing Hintegra™ (Newdeal SA, Lyon, France) TAR system.

Material and methods

We conducted a prospective observational cohort study. Procedures were conducted according to the Declaration of Helsinki. Prior to participation in the study, all subjects signed an informed consent form. The Ethical Committee approval was received before performing the study. The study was designed according to the STROBE publishing guidelines [13].

Since May 2011, a total of 84 consecutive patients (84 ankles) affected by symptomatic end-stage ankle arthritis have been treated with a cementless, mobile-bearing, Hintegra TAR system.

All total ankle replacements were performed by one of the authors, practicing the technique described by Hintermann [14].

Exclusion criteria for this study were valgus deformity > 10 °, neuropathic arthropathy, neuromuscular disorders, pathologic joint laxity, local or systemic infection, avascular necrosis of the talus, and revision surgery.

The main evaluation was the assessment of the pre-operative coronal deformity of the ankle. Considering the malalignment on coronal plane on AP view X-ray [1], estimating the angle between a line along the superior talar dome relative to a line perpendicular to the axis of the tibial shaft (Fig. 1), 3 patients have been excluded because of having a valgus deformity > 10 °.

Remainder 81 patients have been divided into two groups: group A, “varus” group, including patients having a varus deformity > 10 ° and group B, “neutral” group, including patients with normal alignment or valgus or varus malalignment < 10 °.

The indication for TAR in the selected population was post-traumatic osteoarthritis in 72 ankles (88.9%), rheumatoid arthritis in four cases (4.9%), primitive arthritis in one ankle (1.2%), previous failed matrix-induced autologous chondrocyte implantation (MACI) in one case (1.2%), ankle instability in one case (1.2%), and clubfoot in two cases (2.4%).

Eleven patients were included in group A, and 70 patients were included in group B. In group A, there were seven men (63.6%) and four women; the average age at time of surgery was 66.2 years (range 42.6–79.6 years), and the medium BMI was 29.6 (range 21.2–49.9). In group B, there were 41 men (58.6%) and 29 women; the average age at time of surgery was 54.6 years (range 23.6–75.8), and the medium BMI was 28.1 (range 18.8–40.1). No statistically significant differences were found between the two groups for age ($p = 0.04$), gender ($p = 0.75$), and BMI ($p = 0.53$).

Fig. 1 Patients are assigned at group A or B depending on pre-operative coronal deformity (the angle between a line along the superior talar dome relative to a line perpendicular to the axis of the tibial shaft, yellow angle)

All patients were clinically and radiographically evaluated, before and after surgery, and subsequently at six and 12 months, then annually.

As for survival rate, we considered the necessity to perform a revision surgery. As for revision procedures, the isolated polyethylene replacement has been excluded, and conversely, the replacement of at least one of the two tibial or talar components has been considered.

Clinical evaluation was comprised of pain evaluation, performed by visual analogue scale (VAS), ranging from 0 (no pain) to 10 (maximum pain); American Foot and Ankle Society Score (AOFAS) ranging from 0 (worse) to 100 (better condition); and the Short Form (SF)-12 Quality of Life, in both of its “physical” (PCS) and “mental” (MCS) components [15–17].

Complications and accessory surgical procedures were recorded and compared between the two groups.

Radiological evaluation was based on standardized weight-bearing anteroposterior (AP) and lateral radiographs of the ankle. The tibio-talar surface angle (TTS) [18], the lateral distal tibial angle (LDTA–α), and the anterior distal tibial angle (ADTA-β) [19] were measured before surgery and at each follow-up.

TTS is the angle between the tibial axis and the superior surface of talus (on pre-operative view) or on the superior surface of prosthesis talar component (on post-operative view) evaluated on AP view (Fig. 2a).

LDTA or “α” angle is the angle between the anatomical axis of the tibia and the distal tibial articular surface (on pre-operative view) or the articular surface of the tibial component

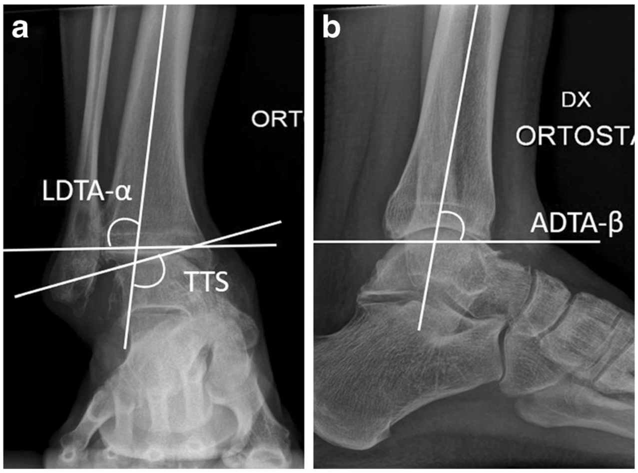

Fig. 2 Weight-bearing measure of TTS an LDTA-α angles on antero-posterior view (Fig. 2a) and of ADTA-β angle on lateral view (Fig. 2b)

(on post-operative view) measured on the AP view (normal value, 92.4 ± 3.1 °) (Fig. 2a).

ADTA or "β angle" is the angle between the anatomical axis of the tibia and the distal tibial articular surface (in pre-operative view) or the tibial component (on post-operative view) on lateral view (normal value, 85 ± 2 °) (Fig. 2b).

Statistical analysis

The mean and the minimum and maximum of clinical and radiological parameters are computed for pre-operative measurements and for post-operative measurements at six months and one and two years after surgery and at last follow-up. To compare the measurements over time or between group A and group B, linear regression models were fitted. For each model, the response was the measurement of interest and the covariates were time (pre-operative and 1-year post-operative) and group (A or B). In order to take into account the correlation of measurements performed on the same subject, a random effect for patients was considered. The results are reported in terms of mean differences with pertinent 95% confidence intervals (CI) and p values. Differences showing a p value < 0.05 are considered statistically significant. The rate of complications was computed in the two groups, and they were compared between groups using the binomial exact test for proportion differences. All statistical analyses were performed using R software, version 3.4.2 with package *lmerTest*, version 2.0-36 and package *exact2x2*, version 1.5.2, added.

Results

Mean follow-up was 3.2 years in group A (range 2–5.2 years) and 3.9 years in group B (range 2–7 years). Mean surgical time was 113 minutes in group A (range 100–210 minutes) and 116 minutes in group B (range 65–210).

Clinical and radiological parameters were recorded for each patient before surgery and after surgery at six months, one year, two years, and at last follow-up. In group B, last follow-up included three patients at seven years, four patients at six years, 11 patients at five years, 15 patients at four years, and 18 patients at three years follow-up. In group A, last follow-up included one patient at five years, three patients at four years, and four patients at three years. Two years follow-up was obtained for each patient of both groups.

VAS, AOFAS, and SF-12 (MCS and PCS) scores are summarized in Table 1. Difference estimated between pre- and 1 year postoperative values showed a significant improvement ($p < 0.001$) for each parameter in both groups and maintained till the last follow-up (Table 1).

Clinical pre-operative and post-operative data were similar between the groups, and their difference was not statistically significant ($p > 0.05$).

As expected, different radiographic parameters showed an improvement after surgery ($p < 0.05$). In group A, a significant improvement has been showed by TTS and ADTA-β angle. In group B, ADTA-β angle showed the best improvement. Detailed data are listed in Table 2, upper part.

Pre-operative TTS and LDTA-α showed significant difference between the two groups. At 1 year after surgery, no differences were found. Results are summarized in Table 2, lower part.

Particularly, the difference in post-operative TTS between group A and group B is not statistically significant at 2, 6, and 12 months comparison. Conversely, the difference in pre-operative TTS between group A and group B is statistically significant ($p < 0{,}001$), as reported in Table 2 and better illustrated in box-plot models (Figs. 3 and 4).

Survival rate and complications

In one case in group A (9%), the revision consisting in both talar and tibial components and polyethylene replacement, at a mean follow-up of 3.1 years, and two revision procedures (3%) in group B were executed at 3.8 years, particularly in one patient, both talar and tibial components and polyethylene replacement were performed, and in one patient, the talar component and polyethylene replacement.

One complication (9.11%) in group A and ten complications (14.28%) in group B were reported. Difference as regards number and type of complications of two groups was not statistically significant ($p > 0.001$) (Table 3).

Accessory procedures, all performed at the same time of TAR implantation, were the following: percutaneous Achilles lengthening (executed in 15 patients of group B); fibular osteotomy (in 2 patients of group A and in 7 of group B); tibial medial malleolus osteotomy (in 4 patients of group A and in 7 of group B); subtalar arthrodesis (in 3 patients of group A and in 10 of group B); calcaneal medial displacing or Z osteotomy (in 1 patient of group A and in 3 of group B); tendon transfer

Table 1 Clinical pre-and postoperative parameters

	Pre-operative	Post-op. 6 months	Post-op. 12 months	Post-op. 24 months	Last follow-up
Group B, "neutral" ankles					
AOFAS	32.63 (11–55)	56.84 (23–94)	73.36 (42–93)*	75.72 (20–100)*	80.94 (3–98)*
VAS	8.66 (4–10)	4.09 (0–8)	2.19 (0–6)*	2.34 (0–7)*	2.18 (0–7)*
SF12_PCS	34.57 (26–44.7)	42.1 (28–51.5)	46.2 (32.5–56.7)*	45.07 (23.7–56.6)*	44.37 (27.4–57.4)*
SF12_MCS	39.24 (17.6–56.2)	50.99 (38.1–65.7)	51.26 (34–63.5)*	51.6 (28.3–63.5)*	49.85 (37.9–61.6)*
Group A, "varus" ankles					
AOFAS	33.64 (18–61)	58.45 (33–87)	74.91 (50–93)*	74.27 (20–100)*	84.67 (79–90)*
VAS	8.18 (4–10)	4.36 (2–6)	2.27 (0–5)*	2.82 (1–10)*	1.9 (0–6)
SF12_PCS	32.03 (30.7–36.9)	39.65 (27.1–44.2)	42.84 (30.2–56.7)*	46.12 (28–56.7)*	44.6 (37.7–51.5)*
SF12_MCS	42.21 (38.2–64.5)	52.15 (40.6–61.6)	53.45 (40.6–60.5)*	52.52 (37.3–57.6)	60.4 (58.5–62.3)

VAS, visual analogue scale for pain; *AOFAS*, American Foot and Ankle Society Score ranging; *SF-12*, Short Form-12 Quality of Life; *PCS*, physical component; *MCS*, mental component. **p* value postoperative versus preoperative < 0.001

(extensor hallucis longus pro tibial anterior, tibial posterior pro tibial anterior, longus peroneum pro brevis) (in 1 patient of group A and in 2 of group B); medial release (in 1 patient of group B); extensor osteotomy of first metatarsal (executed in 4 patients of group B); subtalar and talonavicular arthrodesis (in 1 patient of group B); and subtalar disarthrodesis and arthrodesis (executed in 3 patients of group B).

Discussion

Despite the undoubted progress achieved in total ankle replacement scope, many authors in the literature report high rates of re-intervention [8] and revision [1, 7] in patients with TAR.

The aim of our study was to compare clinical and radiological outcomes, complications, survival rate, and correction maintenance of a mobile-bearing Hintegra™ TAR system in patients with pre-operative varus deformity of more than 10 ° versus patients with none or mild varus deformity (less than 10 °).

The two groups differed pre-operatively only for the TTS angle value ($p < 0.05$). No statistical difference was found between the two groups for any parameter evaluated.

Literature is scarce regarding clinical and radiological studies in consecutive patients who underwent total ankle replacement with severe deformity, particularly treated by the same surgeon with the same prosthetic model [20].

Currently in literature, there is not a widely accepted definition of varus or valgus misalignment. We decided to follow

Table 2 Radiological pre- and post-operative data

	Pre-operative	2 months	6 months	12 months	24 months	Last follow-up
Group B, "neutral" ankles						
TTS	89.63 (82–98)	88.79 (80–99)	88.8 (81–97)	88.03(76–97)^	88.3(77–95)	88.8 (81.4–99.3)
LDTA–α	91.37 (80–102)	91.68 (81–100)	91.56 (81–101)	91.91 (84–103)	91.54(85–100)	91.45 (85–99.5)
ADTA-β	83.78 (67–98)	86.01 (79–93)	86 (78–98)	86.61 (78–97)*	86.62(77–94)*	85.98 (79.9–90.3)
Group A, "varus" ankles						
TTS	73.54 (56–80)	86.58 (71–94)	88.38 (78–93)	88.14(86–90)*	88.6 (85–92)*	89.29 (86.9–91.2)*
LDTA–α	96.55 (69–117)	91.45 (85–100)	94.22 (84–119)	90.74 (86–98)	91.64 (87–100)	90.76 (87.6–93.1)
ADTA-β	82.09 (73–95)	87.59 (84–91)	87 (83–90)	87.83 (85–91)^	87.52(83–91)	87.76 (84.9–91.7)
Radiological parameters	Radiological preoperative difference in group A versus group B radiological parameters (95% CI)		p value	Radiological difference in group A versus group B 1 year after surgery parameters (95% CI)		p value
TTS	−16.09 (−18.98–13.27)		<0.001**	0.70 (−3.35–4.76)		0.728
LDTA–α	5.18 (1.26–9.09)		0.010**	−1.17 (−3.82–1.47)		0.381
ADTA-β	−1.68 (−5.60–2.23)		0.394	1.21 (−1.04–3.47)		0.288

Radiographic parameters before and after surgery are shown in the upper part. In lower part of the table, it shows the comparison between pre-operative and 1 year after surgery radiological parameters between group A and group B. *TTS*, tibiotalar surface angle; *alpha*, lateral distal tibial angle (LDTA–α); *beta*, the anterior distal tibial angle (ADTA-β). **p* value post-operative versus pre-operative < 0.001; ^*p* value post-operative versus pre-operative < 0.05; ***p* value post-operative versus pre-operative < 0.001

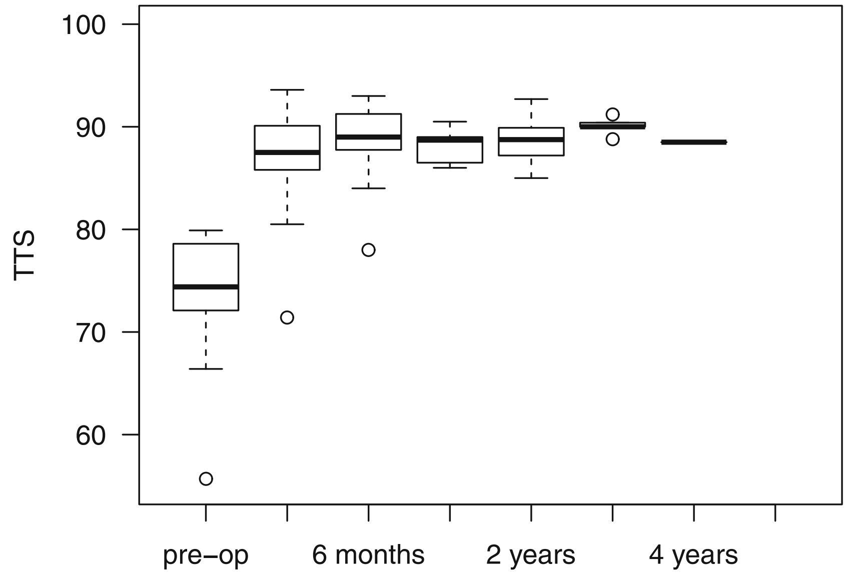

Fig. 3 Box-plot illustration of TTS values before and after surgery in group A (varus group)

some authors' statements [1, 4, 9, 11] and to set 10 ° as cutoff to create the two groups of our study.

Varus or valgus deformity greater than 10 ° is very common in patients with post-traumatic ankle osteoarthritis with an incidence ranging from 10 to 40% [12, 21–25]. Several studies have advocated against TAR in patients with significant coronal plane deformity, and an arbitrary cutoff of 15–20 ° has been defined by most. With such limitation, an important proportion of patients with ankle arthritis should not be eligible for TAR [24–29]. Recently, other authors have shown that TAR can be performed with excellent results even in ankle deformities up to 30 ° [1, 22, 24].

In 2011, Trincat was one of the first authors to consider a coronal deformity greater than 10 ° as a good indication for TAR [11]. Twenty-one TARs with coronal plane deformities greater than 10 ° were included in the study with a mean follow-up of 38 months. At final follow-up, deformity ranged from 16.5 to 2.5 ° of varus, and from 16.7 to 1.4 ° of valgus. Six varus TARs required revision surgery for a further correction. Three incongruent ankles failed.

In literature, other studies have shown that TAR should be considered the gold standard in ankle osteoarthritis, even in severe deformities: in 2009, Hobson et al. evaluated 123 (111 patients) consecutive TAR using STAR system with a mean follow-up of four years [1]. Patients were divided in two groups depending on neutral or varus alignment. There were 18 failures (14.6%), with no significant difference in survival, range of movement, and complications between the two groups.

In the same year, Kim et al. reported the clinical outcome of TAR, using Hintegra system, performed in 23 patients with

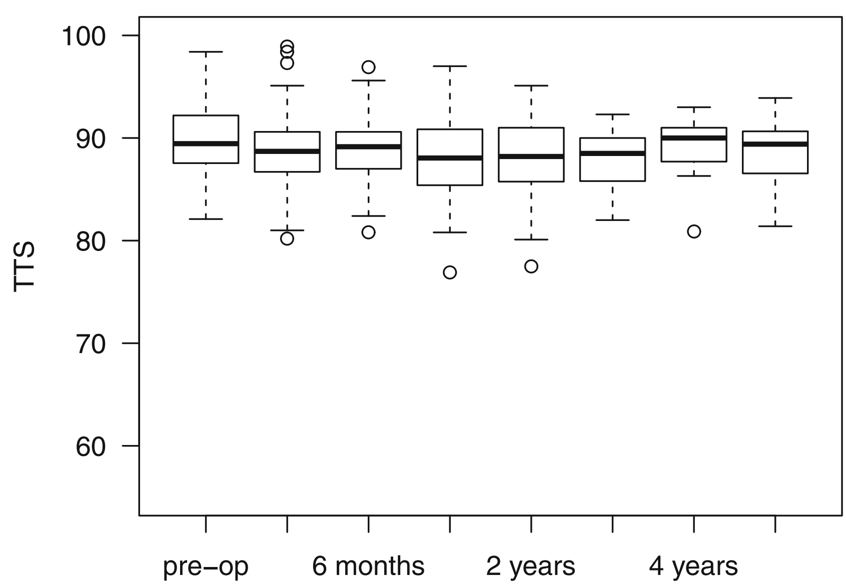

Fig. 4 Box-plot illustration of TTS values before and after surgery in group B (normal group)

Table 3 Post-operative complications

Complications	Group A	Group B	Difference A vs. B (95% CI)	p value
Superficial infection	0/11	4/70	5.71(−18.02–12.15)	0.512
Deep infection	0/11	3/70	4.29(−19.33–10.21)	0.596
Talar necrosis	0/11	1/70	1.43 (−21.92–5.96)	0.805
Revision	1/11	2/70	−6.23(−34.12–4.83)	0.374

moderate to severe varus deformity [12]. After a mean follow-up of 27 months, the varus ankles improved significantly in all clinical measures showing that clinical outcome of TAR performed in ankles with pre-operative varus alignment ≥ 10 ° is comparable with that of neutrally aligned ankles.

Shock et al. evaluated the correction of large frontal plane varus deformities with TAR using two different replacement systems, Inbone and Salto Talaris [4]. Also, a stepwise operative approach for consistent correction was determined. TAR was performed on 26 patients with varus ankle deformity and a mean age of 63.85 years. Duration of follow-up was 16.69 months. The difference between the immediate post-operative frontal plane radiographic alignments was compared with the pre-operative deformity and re-evaluated after at least one year of weight-bearing function. On the pre-operative mortise view, varus deformity was 16.8 °, whereas at final follow-up, it was 0 ° on the anteroposterior view and 0.5 ° on the mortise view. All but one patient were corrected within 4 ° of frontal plane to neutral.

In 2013, Trajkovski et al. determined whether clinical outcomes of total ankle replacement in patients with ankle arthritis and pre-operative talar varus deformity of ≥ 10 ° were comparable with those of patients with varus deformity of < 10 ° [9]. Thirty-six patients with varus deformity (≥ 10 °) and 36 ankles with varus deformity of < 10 ("neutral" group) underwent total ankle replacement using HINTEGRA, S.T.A.R., and MOBILITY system. The mean follow-up was 34.7 months. Eighteen (50%) of the ankles in the varus group had a pre-operative varus deformity of ≥ 20 °. Patients in the varus group underwent more ancillary procedures during the index surgery to achieve a plantigrade foot. The AOFAS score improved by a mean of 57.2 points in the varus group and 51.5 points in the neutral group. The improvement in AOS and SF-36 scores did not differ significantly between the groups at final follow-up. Tibiotalar deformity improved significantly toward a normal weight-bearing axis in the varus group. Thirteen ankles in the varus group and six in the neutral group underwent additional procedures at a later stage.

Comparing the results from literature is difficult. The mentioned authors used different prosthetic implants and different operative procedures; in our study, all cases were performed by the same operator using the same prosthetic implant. In the presence of significant deformities (> 10 °), surgeon's experience is known to be essential [10].

A key point, emerged also from our study, is how to maintain the correction. A recent study has highlighted how TAR, performed with an anterior approach, may often result in a significant movement of the talus, in antero-posterior direction, specifically within the first six months post-operatively [30]. This movement of the talus, however, did not affect the coronal correction of deformity in our study.

In the presence of a severe deformity, the biggest challenge is to correct the axis. With current prosthetic designs, this is not always possible, and in many cases, it is necessary to perform an accessory surgery. In our cohort of varus ankles, 11 accessory surgical procedures in eight patients (72.7%) have been performed. Furthermore, two procedures were needed in one patient and three in another one. In the neutral group, 53 additional procedures have been performed in a total of 27 patients (38.5%; 2 in 20 patients, 3 in 3 patients, and 4 in one patient). Our results are in line with the literature. Patients with a higher deformity are subjected to a higher number of additional procedures [1, 4, 11].

We used AOFAS scale to evaluate ankle function although not yet completely validated. But literature confirms that AOFAS is the most used scale in articles dealing with foot and ankle pathology [31].

Limitations of this study are the relatively small number of patients with a varus deformity and the short follow-up. As regards the small sample of patients with varus deformity, our data are still representative because they reflect the percentage of the deformities of greater than 10 °, which Dodd reports to be from 10 to 40% of patients with end-stage ankle arthritis [32].

The strengths are its prospective comparative design and the use of multiple clinical outcomes and radiographic parameters, a single prosthetic implant used by the same performing surgeon.

Conclusions

Total ankle arthroplasty is an effective treatment in patients, with symptomatic end-stage ankle arthritis regardless of deformity. The outcomes in two groups were comparable confirming that total ankle replacement is achieving to be the new gold standard for the treatment of ankle arthritis. Larger studies with longer follow-up are necessary to confirm our results. Total ankle replacement in severe deformity should be performed only by trained foot and ankle surgeons.

Compliance with ethical standards

Conflict of interest Dr. Federico G. Usuelli reports personal fees from Geistlich and grants and personal fees from Zimmer, outside the submitted work.

Dr. Claudia A. Di Silvestri reports grants from Zimmer, outside the submitted work.

Dr. Riccardo D'Ambrosi, Dr. Annalisa Orenti, and Dr. Filippo Randelli declare that they have no conflict of interest.

Ethical approval and informed consent All procedures were conducted according to the 1964 Declaration of Helsinki. Prior to participation in the study, all subjects signed an informed consent form. The Institutional Ethical Committee approval was received before performing the study.

This article does not contain any studies with animals performed by any of the authors.

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