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Reliability of the Phi angle to assess rotational alignment of the talar component in total ankle replacement

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ABSTRACT

Background: The purpose of this study was to investigate the test–retest reliability of the Phi angle in patients undergoing total ankle replacement (TAR) for end stage ankle osteoarthritis (OA) to assess the rotational alignment of the talar component.

Methods: Retrospective observational cross-sectional study of prospectively collected data. Post-operative anteroposterior radiographs of the foot of 170 patients who underwent TAR for the ankle OA were evaluated. Three physicians measured Phi on the 170 randomly sorted and anonymized radiographs on two occasions, one week apart (test and retest conditions), inter and intra-observer agreement were evaluated.

Results: Test-retest reliability of Phi angle measurement was excellent for patients with Hintegra TAR (ICC = 0.995; $p < 0.001$) and Zimmer TAR (ICC = 0.995; $p < 0.001$) on radiographs of subjects with ankle OA. There were no significant differences in the reliability of the Phi angle measurement between patients with Hintegra vs. Zimmer implants ($p > 0.05$).

Conclusions: Measurement of Phi angle on weight-bearing dorsoplantar radiograph showed an excellent reliability among orthopaedic surgeons in determining the position of the talar component in the axial plane.

Level of evidence: Level II, cross sectional study.

1. Introduction

End stage ankle osteoarthritis (OA) is a chronic disease associated with mental and physical disability at least as severe as that associated with end-stage hip OA [1]. In the last decades, total ankle arthroplasty (TAA) has progressed as a treatment option in patients with ankle OA [2,3]. Total ankle replacement (TAR) has a learning curve [4,5]. The correct positioning of the talar component is one of the most demanding steps, especially in patients with valgus or varus hindfoot deformities. The primary goals when performing a total ankle arthroplasty is to restore a physiologic sagittal and coronal axis for the long-term survival of the implants. Furthermore, proper size and rotation of the components and ligamentous balancing is mandatory to avoid high contact pressures [6]. Coronal and sagittal malalignment result in altered joint mechanics and joint reactive forces that may ultimately result in implant failure [7].

Previous research has described radiological measurements to evaluate the proper position of tibial and talar components in coronal and sagittal planes, but none of them evaluated the rotational alignment [8–12]. Instead, in total knee replacement, the importance of the rotational alignment of the tibial and femoral components has been widely assessed [13,14]. It has been suggested to align the axis of the talar component with the second metatarsal shaft while performing a TAR [15].

However, to our knowledge no previous research has described the measurement of the talar component alignment in the axial plane in TAR.

Good test–retest reliability (both intra- and inter-rater) enables valid comparisons to be made over a period of time and across raters. Reliable results allow the researcher and health care professional to reach conclusions that are minimally affected by external factors, thereby reducing the chances of error. Therefore, the purpose of this study was to investigate the test–retest

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reliability of the radiologic measurements using Phi angle for subjects undergoing TAR.

2. Methods

2.1. Design

Retrospective observational cross-sectional study of prospectively collected data.

2.2. Participants

The postoperative radiographs of 170 adult patients (101 males and 69 females), undergoing primary TAR with at least 12 months of follow up between May 2011 and April 2016 were included in the study.

The indications for TAA included: primary degenerative OA, systemic (rheumatoid) arthritis, and secondary OA (e.g. post-traumatic arthritis, hemophilia, hereditary hemochromatosis, gout, and post-infectious arthritis). Patients were excluded with the presence of any of the following: neuropathic arthropathy, neuromuscular disorders, pathologic joint laxity, acute infectious arthritis, and avascular necrosis of the talus involving greater than 50% of the bone.

All primary TARs between May 2011 and December 2015 were included in this study. The sample was composed of two subgroups. The first group included 72 consecutive patients, 69.5 ± 14.0 years old, that had been treated through an anterior approach by the 3-component, mobile-bearing Hintegra^{TM} implant (Newdeal SA, Lyon, France), were included in the study. The second group consisted of 88 consecutive patients from the same hospital facility between the ages of 53.7 ± 13.9 years to whom the 2-component Zimmer Trabecular Metal Total Ankle prosthesis^{TM} (Zimmer, Warsaw, Indiana, USA) was implanted through a trans-fibular approach. The standard care protocol for these cases included preoperative and postoperative (2, 6 and 12 months) weight bearing plain radiographs, [anteroposterior (AP), mortise, and lateral view of the ankle and AP view of the foot]. Patients underwent subjective and physical examination conducted by 3 orthopaedic surgeons with >4 years of experience in treating musculoskeletal disorders.

Informed consent was obtained from all participants and all procedures were conducted according to the Declaration of Helsinki. The ethical committee approved the protocol of the study.

2.2.1. X-rays measurements

Our standardized protocol included weightbearing AP, mortise, and lateral radiographs of the ankle and AP and later radiographs of the foot.

Post-operatively, the rotational alignment of the talar component was determined by measuring the Phi angle on the standard dorsoplantar radiographs. The radiographs were obtained with patient standing upright on the image receptor (IR) placed on the floor. To avoid distortion of the images, the focus of the radiograph was centered exactly in the ankle. Patients were asked to distribute their body weight equally on each foot. The central ray (CR) was pointed at the base of third metatarsal. Optimal orientation of the CR was ten degrees from anterior to posterior towards the heel. The Phi angle is the angle between the medial edge of the talar component and the anatomic axis of the second metatarsal shaft. The Phi angle was defined as negative when the talar component was aligned in an abducted position to the second metatarsal axis; similarly, the angle was defined as positive when the talar component was aligned in an adducted position, Fig. 1.

Fig. 1. Anteroposterior (AP) radiograph of the foot showing the Phi angle.

3. Measurements

The outcome measures were collected at 12 months follow-up. All radiological evaluations were made using the standard tools in our Picture Archiving and Communication System (PACS). Patient identifiers were blinded in all radiographs. All the radiographs were evaluated by three orthopaedic surgeons, who were not directly involved in the surgical procedure.

On the first test session, all raters tested all radiographs. The order in which raters measured the Phi angle on all radiographs was randomly assigned. On the second test session, one week later, all raters measured all radiographs with a different random order.

4. Data analysis

Data were analyzed using SPSS version 21.0 (SPSS Inc, Chicago, IL, USA). The results were expressed as means, standard deviations (SD), and/or 95% confidence intervals. Intra-rater and inter-rater reliability were analyzed using the Intraclass Correlation Coefficient (ICC). ICC values that are equal or greater than 0.80 are considered high [16]. We calculated ICC for single measures using a two-way random effect model of absolute agreement for the computation of ICC. In order to assess the absolute reliability, the standard error of measurement (SEM) and the 95% limits of agreement (LOA) were calculated by means of the following equations: $SEM = SD \times \sqrt{(1\text{-}ICC)}$ and LOA = inter-trials mean difference ± 1.96 SD of the between trials difference. The SEM expresses measurement error in the same units as the original measurement, and it is not influenced by variability among patients. The agreement was also examined graphically by plotting the difference between test and retest against their mean, according to the Bland and Altman approach to calculate LOA [17]. A one-way analysis of variance (ANOVA) with repeated measurements and Bonferroni correction of the *p*-value threshold for repeated measurements was used as post-hoc test to evaluate statistical significance. The statistical analysis was conducted at a 95% confidence level and a $p < 0.05$ was considered statistically significant.

5. Results

5.1. Demographic and clinical data of participants

One hundred and seventy patients (56.6 ± 14.3 years old) had a complete set of valid test and immediate re-test (less than 1 week) AP radiographs of the foot, (Table 1**)**. The average age at the time of operation was 54.3 ($\pm$14.2) years (range 21–88). The main indications for ankle replacement was post-traumatic arthritis (147 patients, 83.5%) and rheumatoid arthritis (8 patients, 4.5%). 77 patients were treated on the left side and 93 on the right side; 101 were males and 69 females.

5.2. The Phi angle

5.2.1. Test-retest reliability

The relative reliability between test and retest was very high. Test-retest reliability was excellent for Hintegra (ICC = 0.995; $p < 0.001$) and Zimmer (ICC = 0.995; $p < 0.001$). The absolute reliability (SEM and LOA) was good. For both the Hintegra and Zimmer implant, the mean absolute difference between test and retest reliability was 0.02° and 0.04°, respectively. The 95% LOA ranged from −0.59° to 0.38° for the Hintegra implant and from −0.22° to 0.18° for Zimmer implant the postoperative measurement of Phi (Fig. 2**a–b**) and (Table 2). The ANOVA found no statistically significant differences between the raters (Table 3).

5.2.2. Interobserver reproducibility

ICC indicated very good interobserver reproducibility for measurement of Phi on test (ICC = 0.995 vs. 0.995; $p = 0.001$) and (ICC = 0.995 vs. 0.995 re-test $p = 0.001$) radiographs, (Hintegra and Zimmer implant, respectively).

5.2.3. Intraobserver repeatability

The ICC for intra-examiner reliability of Phi measurements ranged from 0.992 to 0.997 for the Hintegra and from 0.985 to 0.997 for the Zimmer implant. The SEM ranged from 0.43° to 0.95 °for both groups.

Table 1
Baseline demographics for both groups.*

	Hintegra (n = 72)	Zimmer (n = 98)
Age (years)	60.6 ± 14.0	53.7 ± 13.9
Male gender [n (%)]	41 (56.9%)	60 (61.2%)
Height (cm)	167.2 ± 9.5	170.3 ± 10.1
Weight (kg)	79.5 ± 14.9	78.73 ± 16.6
BMI	28.5 ± 5.2	27.2 ± 5.7
Side of surgery, [Right, n (%)]	40 (55.6%)	53 (54.1%)

Abbreviations: BMI: Body Mass Index ($kg\,m^{-2}$).
* Data are expressed as means ± standard deviations (SD).

5.3. Variation of Phi angle Hintegra versus Zimmer implant

A non-significant interaction for time (from test vs. re-test) in the Phi angle was found, ($F = 0.175$; $p = 0.68$). In addition, there were no significant differences between Hintegra and Zimmer implant ($F = 1.0$; $p = 0.32$), (Table 4). The optimal cutoff point reliability of the radiologic measurements was approximately −1.5° of Phi angle (52.8% sensitivity; 12.2% specificity; +LR = 1.4). The area under the ROC curve relating to the reliability of the radiologic measurements of Phi angle requiring that subjects underwent TAR for end-stage ankle OA was 0.711 (95% CI 0.631–0.791), Fig. 2.

6. Discussion

This study shows that the measurement of Phi has an excellent test-retest reliability and ability to discriminate 170 patients that underwent TAR for ankle OA.

Our findings demonstrate that TAR using the Hintegra prosthesis and Zimmer prosthesis allows for good positioning of the talar component in the axial plane. Furthermore, the measurement of the phi angle showed an excellent reliability among orthopaedic surgeons. To the best of our knowledge, this is the first study to describe an angle to measure the position of the talar component in the axial plane in patients undergoing TAR.

When performing a TAR, restoration of the anatomical position of the tibial and talar component is mandatory to provide good clinical outcomes and ensure long-term survival of TAR [18–21]. Sagittal and coronal malalignment in total ankle arthroplasty are possible causes of premature implant failure, and unfavorable mechanical effects of implant malpositioning have been described [7,22]. Many authors described angles to measure the alignment of the tibial and talar component in the sagittal plane and in the coronal plane in patients undergoing TAA [23–25].

Furthermore, patients with ankle OA often show a sagittal malalignment with an anterior translation of the talus relative to the tibia [9,10,26]. The anterior talar shifting in ankle osteoarthritis and in patients with TAA implant was assessed with different measurements. The most reliable are the tibiotalar ratio (TT ratio) [9,10] the AP offset ratio [21], the contact point ratio [24] and the lateral talar station.

Radiographic evaluation of the ankles were performed using weight-bearing radiographs, including AP views of the foot and ankle and a lateral view of the foot. Weight-bearing radiographs are helpful for evaluation of foot and ankle alignment because nonweight-bearing radiographs are often misleading [27–29]. Furthermore, weight-bearing standardizes the radiograph technique, allowing more reliable comparison among different surgeons and different follow-ups.

Causes of failure for TAR include infection, biomechanic failure due to malposition, stiffness. There is evidence that TAA has a long learning curve, regardless of the prosthesis [30]. Pain relief in patients who underwent total ankle arthroplasty may not be absolute. Medial ankle pain is a complication of many prostheses [21,31]. This may be caused by the shape of the talar component. Newer prosthesis have been designed to improve the anatomical design of bearing surfaces, especially the talus, which is broader anteriorly and has a larger radius laterally than medially [24,32]. However, despite novel systems with more anatomic talar components, the incidence of medial pain syndrome remains high [21]. In our opinion, this might be due to talar malposition in axial plane. Many TAR methods suggest aligning the talar component with the second metatarsal shaft while performing

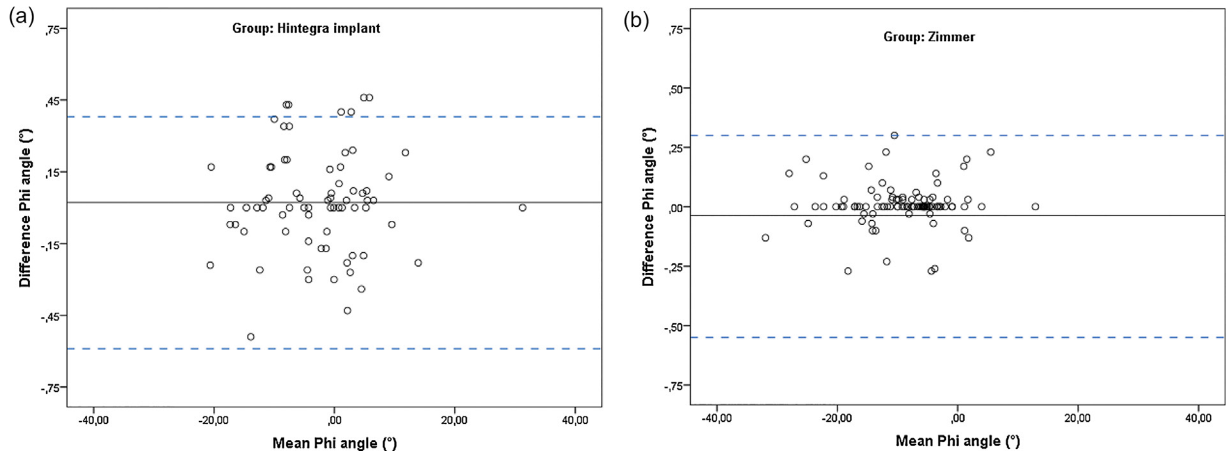

Fig. 2. (a) Bland–Altman plots of the Phi angle for Hintegra in subjects with TAR for end-stage ankle osteoarthritis. The central line characterizes the mean difference between test and retest values; the upper and lower lines characterize the upper and lower 95% limits of agreement (LOA = inter-trials mean difference ± 1.96SD of the inter-trials difference), respectively. (b) Bland–Altman plots of the Phi angle for Zimmer in subjects with TAR. The central line characterizes the mean difference between test and retest values; the upper and lower lines characterize the upper and lower 95% limits of agreement (LOA = inter-trials mean difference ± 1.96SD of the inter-trials difference), respectively.

Table 2
Test and retest values and index of relative and absolute reliability of Phi angle in patients with ankle arthrodesis and total ankle replacement (TAR) of the ankle osteoarthritis.*

Phi angle	Test (°)	Retest (°)	Bias (°)	ICC (95% CI)	95% LOA (°)		SEM (°)
					Lower	upper	
Hintegra	−2.65 ± 8.78	−2.67 ± 8.77	0.02	0.995 (0.993; 0.997)	−0.59	0.38	0.55
Zimmer	−9.23 ± 7.79	−9.19 ± 7.87	0.04	0.995 (0.993; 0.996)	−0.22	0.18	0.55

Bias, difference between test and retest; **ICC**, intraclass correlation coefficient; **95% CI**, 95**%** confidence interval; **95% LOA**, 95% limits of agreement; **SEM**, standard error of measurement.
* Data are expressed as means ± standard deviation.

Table 3
Intraclass correlation coefficient of Phi measurement for each rater on Hintegra and Zimmer radiographs.

		Hintegra			Zimmer		
		Rater A	Rater B	Rater C	Rater A	Rater B	Rater C
Single measures 95% confidence interval	Intraclass correlation	0.997* (0.996;0.998)	0.996* (0.994;0.998)	0.995* (0.992;0.997)	0.985* (0.977;0.990)	0.992* (0.989;0.995)	0.998* (0.997;0.999)
Average measures 95% confidence interval	Intraclass correlation	0.999 (0.998;0.999)	0.998 (0.997;0.99)	0.997 (0.996;0.998)	0.992 (0.989;0.995)	0.996 (0.994;0.997)	0.999 (0.998;0.999)

* $p < 0.001$.

Table 4
Mean (SD) for outcomes at all study visits for each group, mean (SD) difference within groups, and mean (95% CI) difference between groups.

Outcome	Groups				Difference within groups		Difference between groups	
	Hintegra (n = 72)		Zimmer (n = 88)		Hintegra group	Zimmer group	Test	Re-test
	Test	Retest	Test	Retest	(n = 72)	(n = 88)	(n = 170)	(n = 170)
Phi angle	−2.65 ± 8.78	−2.67 ± 8.77	−9.23 ± 7.79	−9.19 ± 7.87	−0.02 (−0.1 to 0.1)	0.04 (−0.0 to 0.1)	−6.57* (−9.1 to −4.1)	−6.52* (−9.1 to −4.0)

Data are expressed as means ± Standard deviation (±SD).
* $p < 0.01$.

a TAR [15]. The use of the medial corner of the tibial plafond and the second metatarsal shaft as reference might not be reproducible. More reliable references for correct alignment are needed. Phi angle may be helpful in determining the most physiological position of the talar component in the axial plane and to compare the reliability of the talar position with anterior and lateral approach. This study provided a method to measure the position of the talar component in the axial plane on dorsoplantar radiographs of the foot and tested the reliability of Phi angle.

It is important to recognize the inherent limitations of this study including its retrospective design and limited and heterogeneous sample size.

In conclusion we described an easily accessible measure on dorsoplantar weight-bearing radiograph of the hindfoot and found it to be reliable to evaluate the position of the talar component in the axial plane. This reference can be used to evaluate the importance of rotation of the talar component when performing a TAR through an anterior or a lateral approach. Furthermore, the Phi angle shows an excellent reproducibility among orthopaedic surgeons.

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No funding sources or conflicts of interest were reported for this study.

Author contributions

1. Conception and design, acquisition of data, analysis and interpretation of data: All authors.
2. Drafting the article or revising it critically for important intellectual content: All authors.
3. Final approval of the version to be published: All authors.

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