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Novel Approach to Determine Components Size in A Total Ankle Replacement

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Ankle; Arthritis; CT; X-ray; Total Ankle Replacement; Prosthesis; Digital Template

List of Abbreviations:

TAR**:** Total Ankle Replacement; WBCT: Weight-Bearing Cone Beam Computed Tomography; THR: Total Hip Replacement; TKR: Total Knee Replacement; ICC:Intraclass Correlation Coefficient

1. Abstract

As a total ankle replacement (TAR) prosthesis has been developed and improved into design and surgical technique, it could expect to lead to successful functional outcome in the ankle join. However, several complications of TAR procedure may be often caused by incomplete understanding of abnormal biomechanics in the ankle joint and the prosthesis design of TAR. This study was performed to suggest a novel approach to determine the TAR prosthesis size by using an orthopaedic digital templating software based on the comparison between X-ray and CT images. This study was examined in a novel approach to determine the prosthesis size by using an orthopaedic digital templating software (OrthoviewTM, Florida, USA) based on the comparison between X-ray and CT images. A total 6 kinds of clinical foot and ankle images were obtained from 100% and 115% magnification of X-ray and CT images in the coronal and the sagittal plane from 55 patients who had the ankle arthritis corresponding to stage-3b of the Takakura's ankle arthritis classification. To minimize the analysis variables, the same TAR prosthesis (HINTEGRA, Newdeal, France) was chosen and the tibial and talar component sizes were changed until the prosthesis was appropriately adapted to the tibia and talus according to the osteotomy range. Preoperative prosthesis size between an unskilled surgeon who measured size by using the software and a specialist surgeon who predicted fitting size were statistically compared by the Cohen's Kappa correlation coefficient. In the predicted TAR component size from CT images, the average agreement rate was over 77% between an unskilled and a specialist surgeon. Especially, the tibial part showed highest agreement rate almost 80% in the coronal plane and over 75% in the sagittal plane. In the talar part, the agreement rate showed over 76% in the coronal and sagittal plane, respectively. Overall, the predicted TAR size from CT image indicated more consensus with the specialist surgeon than X-ray image. In conclusion, application of the orthopaedic digital templating software based on CT images may provide more complete and detailed visualization to predict the appropriate size of the TAR components compared with conventional X-rays, which were limited by higher sensitivity, specificity and overlapping the adjacent bones.

2. Introduction

The most of common cause of end-stage ankle arthritis is typically post-traumatic arthritis such as the ankle fracture or ankle instability as a result of the ankle ligament injury[1]. To treat the end-stage of ankle arthritis, although ankle arthrodesis is considered as some standard surgical treatment, it restricts range of motion and may lead to osteoarthritis of adjacent cartilages in the ankle joint[2]. Currently, as total ankle replacement (TAR) prosthesis has been developed and improved into design, material, and surgical technique, it could expect to lead to successful functional outcome in the ankle join, and it could provide smooth motion at the ankle joint. Also it may improve ability in gait and running,

even show low complication rate[3, 4]. However, several previous studies has been reported severe clinical risk factors including component loosening and migration, subsidence, prosthesis-bone interface displacement, prosthesis fracture and osteoarthritis of the adjacent ankle joint so on[2, 5-9].Most complications of TAR procedure may be caused by incomplete understanding of abnormal biomechanics in the ankle joint and the prosthesis design of TAR. These limitation may lead to unexpected abnormal stress at the ankle joint[2]. Thus, accurate radiologic assessment of the foot and ankle alignment and position of components is fundamental during preoperative plan, intra-operative execution, and post-operative analysis[10].Typically, the clinical X-ray and CT examination are widely used to diagnosis lesion in the foot and ankle. These two examination techniques show certain advantages and disadvantages[11]. X-ray has been considered a reference standard for evaluating pre and post-operative alignment of the foot and ankle in anteroposterior, lateral, and hindfoot planes. Also it could provide good diagnostic value by obtained an opaque clinical image and evaluation of bone alignment in pre and post operation. However, it has inherently flaws including unclear tissue image, poor contrast, and inability to identify fine structures. Also it could not measure the dimension of the complex structure of the foot and ankle structure and may lead to measurement error in 20%. And even patients may be exposed to radiation risk especially to children and pregnant women[10, 12, 13]. While CT image examination is able to provide a clear and high-density tissue image and the accuracy of measuring the distance between bone structures but has few disadvantages such as depending on experience level of the technician and the slice interval limit of the scanning image in the anatomical plane.Since introduction of weight-bearing cone beam computed tomography (WBCT), it can provide a 3D foot and ankle image and enable measurement without perspective bias or superimposition on a sing examination. Based on the reliable 3D measurement, WBCT can provide customized treatment by better understanding of individual pathology such as osteotomy guides and total replacement procedure[13]. Reflecting different characteristic between X-ray and CT examination, those techniques often indicate different diagnosis result in the foot and ankle lesion even, in severe case, inaccurate diagnosis may suggest a wrong surgical strategy, clinical accidents and finally cause complications and secondary injuries.Particularly, considering the TAR procedure, it should be necessary to obtain an accurate clinical image and measure dimension in the foot and ankle complex to avoid clinical and biomechanical complications.Thus, the purpose of this study is to suggest a novel approach to determine the prosthesis size by using an orthopaedic digital templating software based on the comparison between X-ray and CT images.

3. Material and Method

This study was based on the high quality clinical images of 55 patients (male: 31; female: 24; mean age: 65.8 years) between December 2016 and March 2020 who had been suffered from severe ankle arthritis corresponding to over 3b-stage of the modified Takakura's ankle arthritis classification, including a patient in 2-stage (severe pain)[14] (Table 1 and Figure 1). A total 6 kinds of clinical images in the foot and ankle were obtained in the coronal and the sagittal plane from X-ray(Digital X-ray system, DK Medical systems Co. Ltd., Korea) at 100% and 115% magnification and CT(Planmed Verity®, Helsinki, Finland), respectively. All of pre-operative ankle arthritis images were paired with X-ray and CT images for each patient. In addition, unsuitable clinical images were excluded including not matched both types of images and low quality resolutions, bone fracture and other foot and ankle diseases. The study was approved by the institutional review board (2020-05-036) from the Keimyung University Hospital in Korea. Pre-operatively, the templating sizes of the tibial and talar TAR components were measured basing on the clinical images by using an orthopaedic digital templating software (Orthoview™, Florida, USA) which is possible to plan joint replacement and osteotomy procedure and is customizable for each patient. Also, to minimize the analysis variables, same TAR prosthesis (HINTEGRA®, Newdeal, France) basically provided from the software was applied. The prosthesis is typically used to treat the ankle arthritis and may be developed to guarantee requirements of minimal bone resection, extended bone support, proper ligament balance and minimal contact pressure around the post-operative prosthesis[15]. Each clinical image was imported into the digital templating software and then a mechanical axis and guide lines were embedded at the tibia and the talus in each images in the AP view or coronal plane and lateral view or sagittal plane. In the coronal plane, the mechanical axis of the tibia was defined as the line that was drawn as the line drawn perpendicularly from the center point of the tibial stem to the center of the ankle joint. In the distal part of the tibia, an additional axis was horizontally drawn from distal medial and lateral gutter following the tibial joint.

In the sagittal plane, the distal tibial guide line was perpendicularly drawn to the tibial mechanical axis and the talar guide line was connected to the above tibial line at the anteroposterior end-point of the talar articular surface.

This software includes templates from Hintegra total ankle implant and provide various sizes of the tibia and talar components from size 0 to size 6. The templating process was conducted from selecting the size of prosthesis and positioning at to distal tibia and talus. The tibial and talar component sizes were changed until the prosthesis was appropriately adapted to the tibial and talus according to the osteotomy range. In each CT plane, the most ideal image was selected that included both the talar dome and tibial axis. Those templating process was equally applied to all of the X-ray and CT image (Figure 2).Preoperative prosthesis size was predicted for all types of the clinical images by using the OrthoView templating software by a resident who has practiced in the

foot and ankle surgeon. In addition, to assess the predicted TAR component size by the unskilled surgeons, a blind test was conducted as the specialist surgeon selected the appropriate TAR size to patients during a surgical procedure. In order to provide the most ideal fitting size of the TAR components including the tibia and the talus, the fitting accuracy was compared between the predicted templating size based on each x-ray and CT clinical image at 100% and 115% magnification in the AP and lateral view measurement and the component size selected by the specialist surgeon.

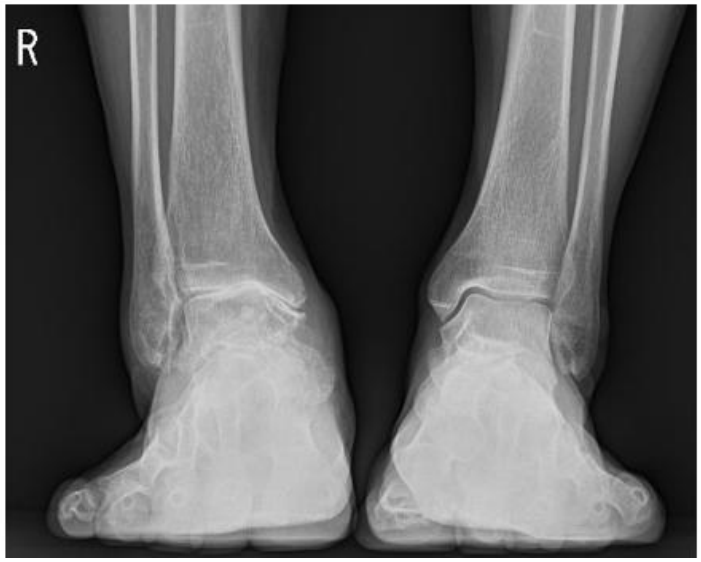

Figure 1: Diagnosis of the ankle osteoarthritis corresponding to stage-3b in the modified Takakura's classification of the ankle arthritis.

The fitting accuracy of the TAR prosthesis was evaluated by the Cohen's Kappa correlation coefficient (SPSS 24, IBM. Co., Ltd., USA). The statistical evaluation is used to quantify the level of agreement between two or more dependent categories is useful to decide subjectivity. Also it provide a guideline to interpret results by 6 grades: values ≤ 0 as indicating no agreement and 0.01–0.20 as none to slight, 0.21 – 0.40 as fair, 0.41 – 0.60 as moderate, 0.61 – 0.80 as substantial, and 0.81 – 1.00 as almost perfect agreement. Generally, Cohen's Kappa coefficient of 0.44 indicates moderate reliability or agreement (Table 2).

Table 1: The characteristic of the patients.

Characteristic	Value
Age (mean±SD years) Sex (male / female)	64.1±8.7 31 / 24
Takakura's classification	Grade
2–stage (severe pain) - 3b–stage - 4–stage -	1 16 37

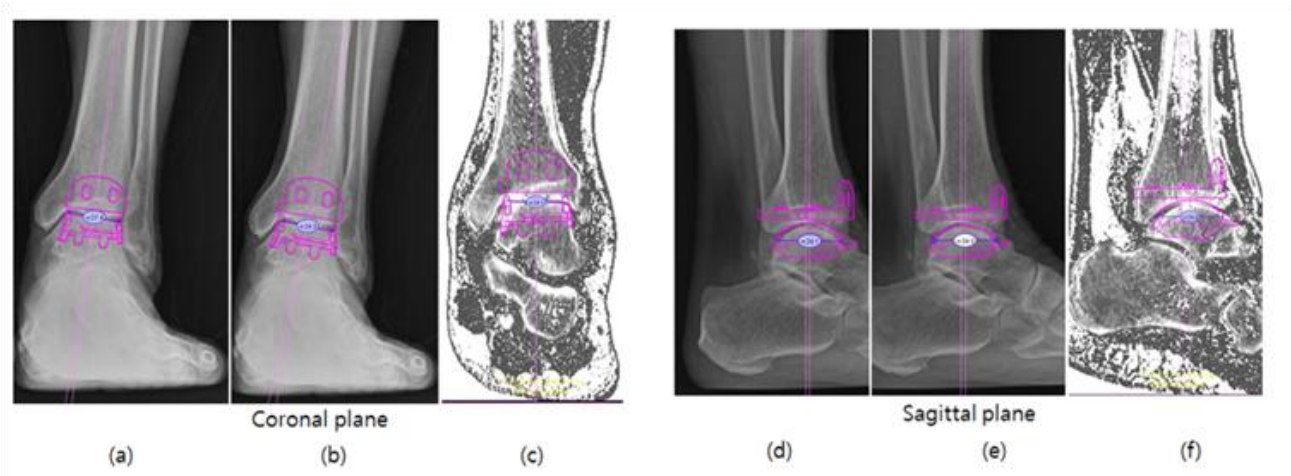

Figure 2: Comparison of the different templating sizes in the TAR components measured by using OrthoviewTM software based on x-ray and CT images on the coronal plane (a) 100% magnification x-ray image; (b) 115% magnification x-ray image; (c) CT image and the sagittal plane (d) 100% magnification x-ray image; (e) 115% magnification x-ray image; (f) CT image.

Table 2: The interpretation of the Cohen's kappa coefficient.

$\kappa = \frac{p_o - p_e}{1 - p_e}$ Cohen's Kappa interpretation	
>0.8	Almost perfect
>0.6	Substantial
>0.4	Moderate
>0.2	Fair
$0 \geq 0.2$	Slight
<0	Poor

4. Results

The results were calculated the agreement rate among the each templating in the tibial and talar component sizes obtained from the different clinical images and the selected sizes assigned to the TAR procedure (Table 3 and Figure 2). The CT image of 100% magnification showed the highest agreement rate comparing to the TAR prosthesis size selected by the surgeon in regard to the coronal (79.6%) and sagittal (75.9%) plane in the tibial component size and also the agreement rate of talar component size similarly indicated in the both anatomical planes (coronal: 75.9% and sagittal: 77.8%) (Figure 3).However, the x-ray images reported a relatively low rate of template agreement. In the 115% magnification image, the agreement rate of the talar component showed about 65% in the both anatomical planes and, in the tibial component, the agreement rate showed under 50%. The template with 100% magnification x-ray image indicated the lowest agreement rate as under 10% in the coronal and sagittal plane for the tibial and talus component excepting the sagittal plane in regard to the tibial component.

Additionally, to statistically examine, the predicted and the selected TAR component size were compared by using the Cohen's Kappa coefficient. As following the results, the TAR component size based on the CT images showed the highest agreement at over 0.6, especially, the tibial component indicated by 0.68 of the agreement in the coronal plane (Figure 3). The predicted TAR size based on the CT image indicated a substantial agreement with the size selected by the surgeon. However, x-ray image of 115% magnification showed a lower Cohen's Kappa coefficient than the CT image. In the talus component, agreement value was moderate as about 0.45, but the tibia component indicated a slight agreement value of around 1.5.Unfortunately, the templating size based on the x-ray image of 100% magnification resulted in a remarkably low agreement value of overall -0.1 comparing to the size selected by the surgeon in regard to the tibial and talar component.

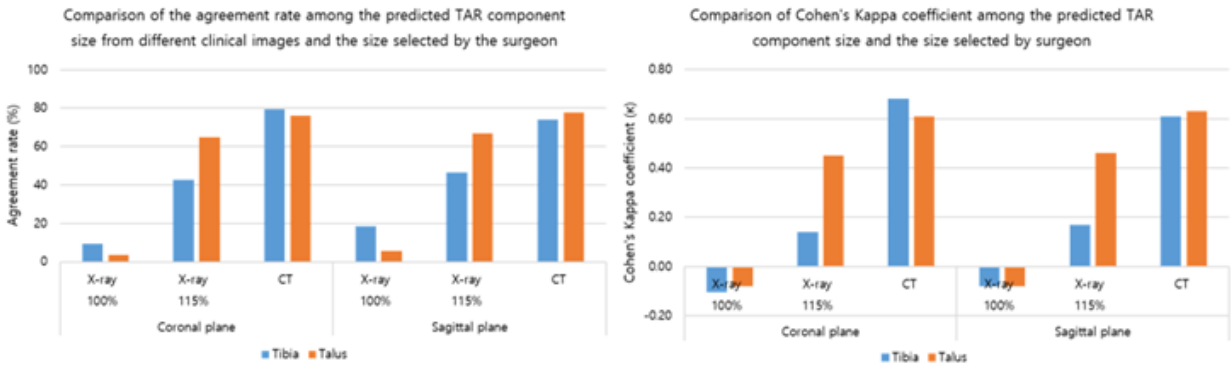

Figure 3: Statistical comparison of the templating size of the TAR between different groups: (a) the agreement rate of the prosthesis size; comparison of Cohen's kappa coefficient.

5. Discussion

The TAR is well known as some standard surgical treatment in the end-stage of ankle arthritis, although post-operative promising results would remain limited by the difficulty of perfecting the surgical technique and the troublesome complications[2,16,17]. In particular, biomechanical complications would be caused by the selection of an inappropriate size and non-anatomical shape of the TAR component such as subsidence of the component into the cancellous bone because the residual bone is too weak to support the load[18,19]. Moreover, malalignment and instability of the TAR components would lead to misbalance of the replaced ankle joint, causing unnecessary stress at between the bone and TAR component and wear of the PE component and even severe pain[17, 20-22].Therefore, in order to minimize the complications due to the biomechanical limitation, it is pre-operatively necessary to select appropriate size of the TAR components to guarantee adequate mechanical support and bonding between the residual tibial and talar bone and the components, which may be fundamental to the success of total ankle replacement.Thus, this study performed comparison of the predicted size from the different clinical images and the selected size by the surgeon in the TAR components. The most appropriate size of the TAR components was predicted based on the CT image than the other X-ray images. The average agreement rate was over 75% and the tibial component showed

the agreement rate of almost 80%. Moreover, in the statistical analysis, Cohen's Kappa coefficient resulted a substantial agreement with the size selected by the surgeon. However, the predicted component size based on x-ray images overall tended to have a lower agreement rate at the all of the magnifications. Although the 115% magnification x-ray image showed a slight agreement, 100% magnification image even less indicated a negative agreement rate as poor value.Above the high agreement rate in CT image, compared to x-ray, CT image has higher sensitivity and specificity and is able to type the orthopaedic lesions and assumes a crucial role in the study of complex anatomical structure such as the foot and ankle. Whereas, x-ray image is as two-dimensional image due to the summation effect, which would tend to overlap the adjacent bones and not be properly carried out even by completing of oblique projections[23].Especially, in the predicted size based on the CT image, the agreement rate for the tibial component was a good result, it is important that the appropriate component size would fully support the body weight so that prosthesis should cover the rim of the cortical bone osteotomized tibial residual bone to avoid subsidence of the undersizing component into the soft cancellous bone[18,24]. The orthopaedic digital templating software not only predicts the appropriate prosthesis size but also guides the determination of the osteotomy area in the tibia and talus bone. The tibial and talar bone are osteotomized up to 17mm and 7mm, respectively, to provide adequate support and combine between the osteotomize host bone and the TAR components[24].The determination of the osteotomizing range is closely related to the selection of the TAR prosthesis size. It would offer to increase the successful post-operative result and to provide a guideline to unskilled surgeons. Although the previous study is rare to predict the TAR component by using the digital templating software, several studies reported high accurate, predicting correct implant size in the total hip replacement (THR) and the total knee replacement (TKR). THR and TKR preoperative templating were accurate up to 98.5 and 93.0%, respectively[25]. Especially, in THR, calibrating the image using the metallic sphere marker was found to be highly accurate, predicting the correct femoral head size within 1.5 mm. Additionally, a recent study compared between the standard acetate and the digital templating in THA and found an 11% improvement in predicted acetabular component size and 8% improvement in femoral stem size with digital templating[26].Also, Interobserver reliability for templating THAs and TKAs showed good reliability as measured by intraclass correlation coefficient (ICC) (ICCTHA5.70; ICCTKA5.86). Intraobserver reliability for templating THAs had excellent reliability between the resident group and specialist surgeon gruop, with a kappa coefficient (k) of 0.92, and good reliability for the medical student (k50.78). Intraobserver reliability for templating TKAs showed excellent reliability among all examiners (k50.90)[27].The primary limitations of the current study is the small number of preoperative clinical images and examiners in the simulated TAR templating. However, the purpose of this study was to establish that digital templating software could help to predict the appropriate size of TAR component for the unskilled surgeon and easily train them by the level of the specialist surgeon. Another limitation is that although the digital templating software provides various types of TAR prosthesis templates, other types of TAR except HINTEGRA®(Newdeal, France) have not been applied domestic orthopedic procedure. Therefore, we could consider to only compare its agreement rate. However, templating with a single prosthesis minimized inter-rater measuring bias.Overall, the digital template based on CT image could help reduce errors associated with miss-matching prosthesis size by scaling templates to the actual radiograph magnification and may decrease possibility of the post-operative complication. It could be also considered to the attractive orthopedic training tool with relative ease, accuracy, and reproducibility.

6. Conclusion

CT images allowed for more complete and detailed visualization to predict the appropriate size of the TAR components compared with conventional X-rays, which were limited by higher sensitivity, specificity and overlapping the adjacent bones. Also, quantitatively, the agreement rate showed good between the predicted and the selected size. The CT image would be considered some advantages over conventional X-rays in the pre-operative establishment TAR procedure strategy.Furthermore, the digital templating software enables the flexibility of digitized films to be used for pre-operative templating. It is reasonably accurate in prediction of the component size of the orthopedic total replacement. However, surgeons would consider variability of the predicted templating size in mind until more accurate systems are available.The further study will conduct to increase the number of the subjects and to follow up prognosis of post-operative subjects with and without component size prediction.

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