A Novel Method to Determine Ankle Flexion Range of Motion in Total Ankle Arthroplasty

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INTRODUCTION: Ankle range of motion (ROM) is critical for performing daily activities such as walking. Total ankle arthroplasty (TAA) is a surgical intervention for end-stage osteoarthritis aimed at improving the patient's ROM. Ankle flexion (plantarflexion and dorsiflexion) is the primary motion required for natural gait making it an important consideration when choosing a TAA system. Clinically, ankle flexion is measured radiographically or using a goniometer. While clinical ROM measurements are beneficial for tracking patient post-operative improvement, specific patient conditions and anatomy may limit the full post-operative ankle flexion. Multiple studies report the clinical flexion of various total ankle prostheses in the post-operative setting; however, research has not been conducted on methods for measuring the total flexion capability of the ankle prostheses without confounding factors such as ligament tension, variations in anatomy, or other patient-specific conditions. While minimum values for plantarflexion/dorsiflexion in TAA are mandated by regulatory bodies, these minimums are often exceeded in day-to-day activities in healthy individuals. Moreover, flexion ROM values for specific TAA systems are not often made publicly available. The primary objective of this study was to propose a novel method to measure ankle prosthesis flexion and determine the method's accuracy by comparing this method to flexion values from 3D-scanned explants.

METHODS: Multiple users performed two methods for measuring ROM of various TAA systems. Method 1 included 3D implant models analyzed using computer-aided design (CAD) software and serves as the gold standard for this study. Six TAA explants were scanned using a Comet 3D scanner. Coordinate systems and surface geometries were reverse-engineered to approximate the correct anatomic alignments and joint articulations. Tibiotalar flexion was determined by establishing the arc of motion between the ankle liner and talus for each ankle system. Maximum plantarflexion and dorsiflexion angles were defined as the largest angles in the sagittal plane in which the liner could arc until either its articular surface extended beyond the talus articular surface, or the edge of the liner interfered with the talus implant (Figure 1). Method 2 used publicly available 2D images of the ankle prostheses in the sagittal perspective. Observers used ImageJ, an image-based measurement tool, to create a best-fit circle to match the articulating curvature of the talus, with the circle center representing the center of rotation (COR) of the talus. Observers established vectors originating at the COR of the talus and terminating at the second point of each vector drawn to the furthest anterior and posterior point on the articular surface of the liner and talus (Figure 1). Angles corresponding to plantarflexion and dorsiflexion were then determined. Results were statistically compared to assess accuracy.

RESULTS: The CAD program analysis yielded mean total ROM values between 44° to 65°, whereas the ImageJ analysis yielded mean ROM values between 40° to 62°, excluding the outlier (Figure 2). Inter-rater reliability between the users resulted in an intraclass correlation coefficient (ICC) of 0.995 for ICC(3,1), and reliability of their average ratings yielded an ICC(3,k) of 0.998, indicating excellent consistency. The paired t-test comparing these datasets resulted in $p > 0.05$ for both plantarflexion and dorsiflexion ($p=0.39$ and $p=0.88$), indicating no significant difference between the two methods. Notably, values for Inbone II were confirmed to be an outlier and were not included in the statistical analyses. When tested with the Shapiro-Wilk test, the data, excluding the outlier, was found to be normally distributed ($p=0.14$ for plantarflexion, and $p=0.81$ for dorsiflexion) . The two one-sided tests (TOST) for equivalence yielded statistically significant results for both plantarflexion ($t = 4.55$, $p = 0.0052$; $t = –2.61$, $p = 0.030$) and dorsiflexion ($t = 3.74$, $p = 0.010$; $t = –3.42$, $p = 0.013$). Equivalence bounds were set to +/- 1.6° based on an allowance of five percent total deviation from the largest system ROM identified in this study. This provides evidence that Method 1 and Method 2 yield statistically equivalent measurements.

DISCUSSION: The results of the study show that across users, the ImageJ method is highly consistent, and calculating ROM via this method is statistically equivalent to using 3D models. Most clinical studies that measured flexion radiographically for various ankle systems showed that the average total ROM of patients post-TAA is around 30°. This corresponds with the minimum ROM established by international standards that require at least 15° of both plantarflexion and dorsiflexion in TAA systems**.** The ImageJ analysis method was applied to seven additional competitor systems, and it was discovered that most systems exceed 30° of total ROM (Figure 3). Some TAA systems far exceeded this value, such as the STAR and Vantage Curved systems which allow for at least 50° of total ROM. Regarding limitations, 100% congruency between the liner and talus, neutral alignment of the components in the analyzed images, symmetry across the sagittal plane, production-level implants in images, and available explant sizes and images representing the system were all assumed. Additionally, the accuracy of the fitted circle may be affected by liner congruency partially obscuring the true condylar radius. Upon further investigation of the outlier, it is possible that this, or a non-production-level assembly in the image analyzed may have contributed to the large differences between ImageJ and NX measurements. Future work should consider looking at the smallest and largest sizes of implant constructs for all systems, finding additional images per system for the ImageJ analysis, and increasing the number of raters to enhance statistical power. In conclusion, the novel ImageJ method showed promising results considering the consistency of measurements between engineers, and equivalence to the scanned model values.

SIGNIFICANCE/CLINICAL RELEVANCE: The novel application of ImageJ to quantify the total flexion ROM capable by ankle prostheses independent of patient factors, offers a valuable tool for engineers in prosthesis design, and assists surgeons in selecting implant systems that align with patient-specific requirements.

IMAGES AND TABLES:

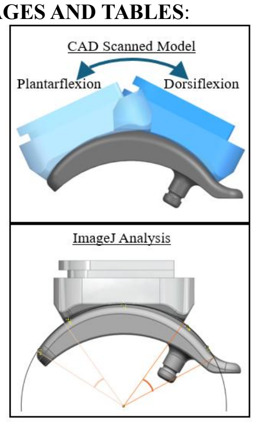

Figure 1: ROM measurement using the scanned CAD model vs ImageJ analysis

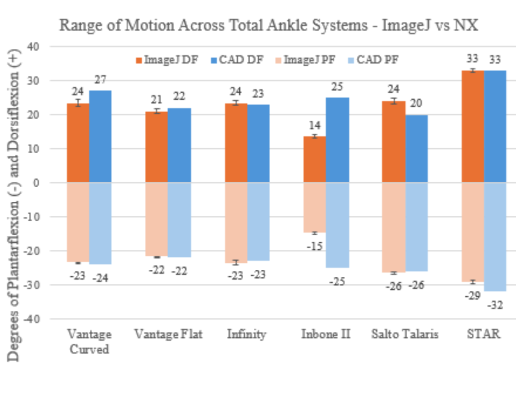

Figure 2: TAA system ROM values comparing the ImageJ method (orange) and CAD method (blue) with standard error bars.

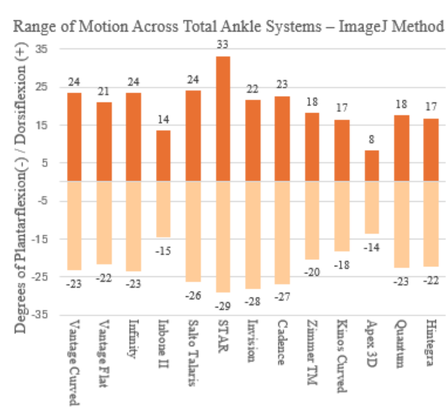

Figure 3: Comparison of ROM values between various TAA systems using the ImageJ method.