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Misalignment of Total Ankle Components Can Induce High Joint Contact Pressures

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Background: A major cause of the limited longevity of total ankle replacements is premature polyethylene component wear, which can be induced by high joint contact pressures. We implemented a computational model to parametrically explore the hypothesis that intercomponent positioning deviating from the manufacturer’s recommendations can result in pressure distributions that may predispose to wear of the polyethylene insert. We also investigated the hypothesis that a modern mobile-bearing design may be able to better compensate for imposed misalignments compared with an early two-component design.

Methods: Two finite element models of total ankle replacement prostheses were built to quantify peak and average contact pressures on the polyethylene insert surfaces. Models were validated by biomechanical testing of the two implant designs with use of pressure-sensitive film. The validated models were configured to replicate three potential misalignments with the most clinical relevance: version of the tibial component, version of the talar component, and relative component rotation of the two-component design. The misalignments were simulated with use of the computer model with physiologically relevant boundary loads.

Results: With use of the manufacturer’s guidelines for positioning of the two-component design, the predicted average joint contact pressures exceeded the yield stress of polyethylene (18 to 20 MPa). Pressure magnitudes increased as implant alignment was systematically deviated from this reference position. The three-component design showed lower-magnitude contact pressures in the standard position (<10 MPa) and was generally less sensitive to misalignment. Both implant systems were sensitive to version misalignment.

Conclusions: In the tested implants, a highly congruent mobile-bearing total ankle replacement design yields more evenly distributed and lower-magnitude joint contact pressures than a less congruent design. Although the mobile-bearing implant reduced susceptibility to aberrant joint contact characteristics that were induced by misalignment, predicted average contact stresses reached the yield stress of polyethylene for imposed version misalignments of >5°.

Clinical Relevance: To improve long-term outcome, this study supports the hypothesis that proper positioning of the tested total ankle replacement implants is likely an important requirement, especially in version.

Total ankle replacement for the restoration of normal ankle kinematics and kinetics was first introduced in the 1970s. While the results of the first generation were so poor that replacement was often abandoned in favor of arthrodesis, in the last two decades, total ankle replacement has progressed considerably in terms of design and in our understanding of the factors that influence outcome. However, in addition to wound-healing problems and deep infection, the limited longevity of total ankle replacement implants remains a serious problem in comparison with the other lower-extremity joint replacements. One major cause of limited longevity is premature wear of the polyethylene components.

A wide variety of designs has been introduced and implanted. Modern total ankle replacement designs generally fall into two classes: two and three-component (mobile-bearing) designs. While short to medium-term clinical results of various three-component designs have been favorably reported and several three-component designs are undergoing controlled clinical trials, only two-component designs are currently approved by the U.S. Food and Drug Administration (FDA). One of them, the Agility (DePuy, Warsaw, Indiana), was the only

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FDA-approved total ankle replacement design from 1992 to 2007. This particular implant has been associated with revision rates of up to 35% at nine years of follow-up\textsuperscript{13}. Also, consistent with our own clinical observations (Fig. 1), retrieved Agility implants have been reported to display marked wear of the polyethylene component\textsuperscript{14}. The reduced kinematic constraint imposed by three-component mobile-bearing designs generally allows improved component congruency over a wider range of motion (thus maximizing contact area) and has been hypothesized to lead to more uniform polyethylene contact pressure distributions\textsuperscript{7}. However, few published studies have quantitatively investigated the influence of total ankle replacement geometry on the average and peak contact pressures and distributions on the polyethylene component\textsuperscript{15,16}. While joint contact characteristics for various two and three-component total ankle replacement designs have been investigated, sensitivity to implant misalignment as a potentially important factor in premature wear has not been studied, to our knowledge, until now\textsuperscript{17}. Further, it has not yet been determined whether a three-component design approach can offer better tolerance to misalignment in the relevant anatomical planes. In the present study, we implemented a computational model to explore the hypothesis that intercomponent positioning, deviating from the manufacturer’s recommended positioning, can result in excessive pressure distributions that may predispose to wear of the polyethylene insert. This in vitro study of joint contact pressures in total ankle replacements also investigated the hypothesis that a modern mobile-bearing total ankle replacement design may be able to better compensate for imposed misalignments compared with an early two-component design.

Materials and Methods

For the purpose of this study, we evaluated two different total ankle replacement designs: (1) the Agility two-component prosthesis (size 4; DePuy) and (2) the Mobility three-component prosthesis (size 3; 3 × 7-mm mobile-bearing; DePuy) (Fig. 2). Both implants were comparable in size (anterior-to-posterior length of the tibial component) and had similar thickness of the polyethylene inserts. A single implant of each type was used for all tests. Finite element models of each implant were established, the models were validated by means of biomechanical experiments, and they were used within a parametric study to explore joint contact pressure sensitivity to misalignment.

Finite Element Model Construction

A light holography measuring system (Rev. 01, ATOS II; GOM, Braunschweig, Germany) was used to scan and generate numerical three-dimensional representations of the implant surfaces within a tolerance of 0.1 mm. The geometry was smoothed and imperfections were removed by means of geometric manipulation software (Raindrop Geomagic, Research Triangle Park, North Carolina). These surfaces were then imported into ANSYS software (ANSYS, Canonsburg, Pennsylvania) for finite element meshing. All components were modeled as three-dimensional solid hex elements. After a meshing sensitivity analysis, the polyethylene insert of the two-component Agility total ankle replacement was modeled with use of approximately 80,000 elements and the insert from the three-component Mobility total ankle replacement was modeled with 55,000 elements. The three-dimensional finite element meshes were finally exported to MSC.Marc Mentat for analysis (MSC Software, Santa Ana, California). The material properties used for the finite element model were retrieved from the literature\textsuperscript{18}. Given the relatively low component stresses with respect to material yield, the titanium (Agility tibial component) and cobalt-chromium-molybdenum components (all other metal components) were defined to be linearly elastic (an elastic modulus of 100 GPa and a Poisson ratio of 0.35 for titanium and an elastic modulus of 200 GPa and a Poisson ratio of 0.3 for cobalt-chromium). The ultra-high molecular weight polyethylene components were modeled as an elastic-plastic material with properties derived according to published material curves for implant-grade polyethylene\textsuperscript{18}. Accordingly, an elastic mo-
dulus of 1.05 GPa was used, with material yield of >18 MPa, and a nonlinear post-yield modulus that reached an asymptotic value of 45 MPa at >22 MPa of applied stress.

**Model Boundary Conditions: Implant Loading and Standard Component Alignment**

The implants were investigated by simulating their positions at four distinct phases of gait: heel-strike, midstance, heel-off, and toe-off (Fig. 3, A1 through B2). Standard relative component position was established according to the manufacturer’s recommendations, and imposed misalignments deviated from this reference position. The talar component was rigidly fixed in a specific phase of gait by appropriate transverse translation and rotation relative to the sagittal axis. All tibial component degrees of freedom were constrained except for a single translational degree of freedom along the tibial axis. The joints were loaded along the tibial axis according to the simulated phase of gait with use of in vivo loads for a patient one year after a total ankle replacement as described in the literature (Fig. 3, C)\(^1\) and assuming a body weight of 80 kg (a heel-strike of 800 N, midstance of 2000 N, heel-off of 2800 N, and toe-off of 800 N).

**Model Validation**

Computational models of both total ankle replacement systems were experimentally validated. The positions in each phase of gait (heel-strike, midstance, heel-off, and toe-off) were tested with use of standard implant alignment as well as imposed misalignments spanning the investigated range described above. Experiments were performed on a universal materials testing machine (model 1456; Zwick, Ulm, Germany). The tibial and talar prosthetic components were rigidly fixed in custom-designed clamps to mimic the boundary conditions defined for the finite element model. A hinge joint at the talar component fixation allowed variable degrees of plantar flexion and dorsiflexion to simulate the various chosen gait phases. Two linear bearing sleds allowed relative dorsal-ventral and anterior-posterior centering of the components. The lower parts of this construction holding the talar component could be positioned in either inversion or eversion. The upper part (where the force was applied) held the tibial component, and an angulated wedge could be used to impose variable degrees of inversion and eversion.

Contact pressures between the polyethylene and cobalt-chromium components were measured with use of sensors (Prescale; Fujifilm, Tokyo, Japan) with two different sensitivities (a high-sensitivity sensor range from 2.5 to 10 MPa and a medium-sensitivity sensor range from 10 to 50 MPa). The two sensors were stacked to simultaneously measure a full range of pressures from 2.5 to 50 MPa with a manufacturer-specified accuracy of ±10%. A custom MATLAB algorithm (MATLAB...
version 7.5, 2007; The MathWorks, Natick, Massachusetts) converted the results of the Fujifilm sensors into contact pressure distribution images and allowed calculation of absolute pressure values. The accuracy of the Fujifilm sensors and conversion algorithm was verified through validation experiments with use of a stainless-steel cube of known dimensions mounted to the testing machine and allowed to freely rotate by means of a ball-and-socket joint, thus facilitating a uniform pressure distribution. The cube was pressed against a polyethylene substrate over a range of forces, with the Fujifilm in between. The calibration confirmed that the accuracy of the films combined with the conversion algorithm was generally better (approximately ±5%) than the 10% specified by the manufacturer.

After positioning and instrumentation, the total ankle replacement components were brought into light contact and allowed to self-center on the linear sleds. To permit repeated testing and to avoid experimental damage to components (permanent polyethylene deformation), only low-force quasistatic loads were applied through an axial tibial component load of 800 N at all tested phases of gait and applied for all imposed misalignments as described above. The prostheses were loaded for two minutes, as recommended by the Fujifilm manufacturer. Then the force and the prosthetic components were gently released and the Fujifilm removed for further analysis. Validation experiments were performed at four phases of gait (heel-strike, midstance, heel-off, and toe-off) under the following conditions: the manufacturer’s recommended implant position, ±10° of both the tibial and talar components, and external rotation of 5° of the Agility tibial component. In each experimental configuration, two repeat measurements were performed.

**Experimental and Finite-Element-Simulation Data Reduction**

Contact pressure distributions from both the experimental contact pressure films and finite element simulations were

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**Fig. 3**

Simulated implant configurations in the investigated phases of gait (A1, A2, B1, and B2). Heel-off (HO) and midstance (MS) have identical relative positions but with different axial force. Axial force through the tibia of patients one year after total ankle replacement (TAR) was adapted from Stauffer et al.19 (C). HS = heel-strike, and TO = toe-off.

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**Fig. 4**

Finite-element-simulated evolution of the polyethylene contact pressure distributions over the gait cycle demonstrated with the Agility total ankle replacement (top panel) in the standard alignment and the Mobility total ankle replacement (bottom panel) in the standard alignment. Pressures are shown in MPa. The bar graph (right) shows the average values of these distributions. A = anterior, P = posterior, L = lateral, and M = medial direction.
reduced to peak and average pressures and joint contact area. The Fujiﬁlms were analyzed with ImageJ software (version 1.410; National Institutes of Health, Bethesda, Maryland). They were ﬁrst scanned at 300 dpi resolution (CanoScan LiDE 60; Canon, Tokyo, Japan), converted to 8-bit gray-scale images, and smoothed by Gaussian ﬁltering ($\sigma = 3$). The high-sensitivity ﬁlms were analyzed to quantify joint contact area (pixel dimensions were converted to square millimeters). Then both high-sensitivity (2.5 to 10-MPa) and medium-sensitivity (10 to 50-MPa) ﬁlms were analyzed to calculate average pressures (the mean intensity of pixels indicating contact, multiplied by the linear calibration factor). This was done with use of carefully applied thresholding of the pressure ﬁlms to preclude “double counting” of areas that appeared in both sensitivity ﬁlms. Peak pressures were averaged according to the highest measured values with use of the medium-sensitivity ﬁlms.

In the ﬁnite element analysis, total contact area was automatically determined by the software. Average contact pressures were calculated by dividing the cumulative normal force (element contact stress multiplied by element area) for elements in contact by the total contact area as described above. Peak pressures were calculated from elements sharing the node with highest normal contact force (the cumulative normal force divided by the cumulative area of the elements$^2$).

**Source of Funding**
Implants were provided by the manufacturer (DePuy) without cost. This study was funded internally, and no external funding was obtained or employed.

**Results**
**Model Validation**

Good agreement was obtained for all conﬁgurations (both standard and misaligned) of the computational models and the experimental testing under nondestructive loads (800 N along the tibial axis). Simulated peak and average pressures were all within 15% of experimental values for the Agility implant (with a median error for peak and average pressure of 4% and 8%, respectively), and pressure distributions appeared qualitatively similar by visual inspection (see Appendix). For the Mobility implant, experiments and simulations were also qualitatively similar by visual inspection (see Appendix), and the majority of average pressure values were within 20% (median error, 18%; range, 3% to 32%). Divergent peak pressure measurements (median error, 22%; range, 3% to 53%) were attributed to unavoidable experimental artifacts associated with cutting and ﬁtting the pressure ﬁlms to the highly contoured talar joint surface. Edge effects due to the thickness of the inserted ﬁlms induced stress concentrations in certain implant conﬁgura-

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**Fig. 5**

Finite-element-simulated alignment and corresponding pressure distributions for the Agility implant. These data represent a subset of tested or imposed misalignments. Similar trends that reﬂected system symmetry, e.g., inﬂuence of rotation or version of the tibial component in contrast to rotation or version of the talar component, were observed. A = anterior, P = posterior, L = lateral, and M = medial direction.
tions for which contact forces were located near the margins of the films (see Appendix).

**Finite Element Simulation**

Between twofold and threefold differences in average contact pressures were found in a comparison of the Agility total ankle replacement and Mobility total ankle replacement in their standard alignments, depending on the tested phase of gait (Fig. 4 and Appendix). All evaluated cases for the Agility design showed average contact pressure distributions of >10 MPa in the standard alignment and average pressures above the yield stress for polyethylene (18 MPa) at heel-off.

In the Agility total ankle replacement, deviation from the standard position by adjusting version of the upper or lower component increased contact pressure magnitudes but resulted in a generally similar stress distribution (see Appendix). Conversely, external rotation showed pressure distributions similar to those in the standard implant configuration (comparable peak and average pressures) but reoriented in the transverse plane according to the imposed rotational misalignment. Resulting contact pressure distributions were similar for mirrored misalignments; because of the approximate implant symmetry, the effect of misalignment was very similar in eversion compared with inversion and in external compared with internal rotation (Fig. 5).

The three-component Mobility mobile-bearing prosthesis was generally characterized by contact pressures of <10 MPa. The implant was sensitive to versions of >2°, for which contact pressure distributions shifted markedly to the outer edge of the polyethylene component (Fig. 6), and average contact pressure magnitudes increased to >10 MPa (Fig. 7). As in the Agility total ankle replacement, the distributions were similar regardless of whether the misalignment was imposed at the tibial or the talar component, and distributions were similar in eversion and inversion. Since external rotational misalignments were fully compensated at the freely rotating

![Fig. 6](image_url)

Finite-element-simulated alignment and corresponding pressure distributions for the Mobility implant. These data represent a subset of tested or imposed misalignments. Similar trends that reflected system symmetry, e.g., influence of version of the tibial component in contrast to version of the talar component, were observed. A = anterior, P = posterior, L = lateral, and M = medial direction.
bearing surface, there was no appreciable change in joint contact stress distribution (data not reported).

**Discussion**

In the standard position (as recommended by the manufacturer), the three-component Mobility total ankle replacement generally demonstrated more evenly distributed and nearly threefold lower average contact pressures compared with the Agility total ankle replacement. Agility implant peak pressures exceeded the yield stress of polyethylene (18 to 20 MPa)\(^{18}\) for all tested configurations. The less kinematically constrained Mobility design exhibited contact pressures that were less than the yield stress for polyethylene. This finding supports earlier studies indicating that a congruent total ankle replacement design can result in lower contact pressures and, by extension, may result in longer service life of the implant.\(^7\)

The Mobility implant was generally less sensitive to deviation from the standard position. By its design, the mobile-bearing total ankle replacement effectively eliminates the possibility of misalignment through transverse translation or axial rotation, the latter of which was seen to adversely affect pressure distributions in the Agility implant. Relative version between the Agility bearing surfaces also noticeably increased average contact pressures. In the Mobility prosthesis, the effects of relative component version were similar, showing an increase in magnitude of peak and average pressures if relative version was >5°. Thus, on the basis of the data in the present study, care should be taken to ensure appropriate inversion-eversion when implanting either prosthesis.

Polyethylene wear cannot be predicted by the contact pressure alone, and other parameters (such as gamma ray sterilization) also play an important role.\(^{24}\) Nonetheless, examination of retrieved Agility total ankle replacements has indicated that polyethylene wear is a potentially important causative factor affecting their high long-term revision rates. In contrast, in a review of twenty-six studies comprising 1318 mobile-bearing total ankle replacements, Hoffmann and Fink recently reported that only 3% of retrievals were associated with complications of the mobile-bearing polyethylene insert.\(^{25}\) On the basis of those data, they concluded that the cause of complications associated with mobile-bearing total ankle replacement is not readily linked to a three-component design. They stated that causes of failure of the mobile bearing rather were attributed to incorrect indications, incorrect soft-tissue balancing, incorrect positioning of the components, and implantation in ankles with hindfoot misalignment and ankle instability. However, the interpretation of these clinical results and conclusions is limited by a paucity of biomechanical data that could support any direct associations between prosthetic design, surgical positioning, joint contact pressure characteristics of the total ankle replacement, and implant survival.
A few biomechanical studies have attempted to bridge this gap. The first of these was in a cadaver model to assess contact characteristics (average contact area, average contact pressure, and peak contact pressure) for the Agility total ankle replacement. The mean peak contact pressures exceeded recommended contact pressures (10 MPa)\(^\text{15}\) as well as the compressive yield point for polyethylene (18 to 20 MPa)\(^\text{16}\). A more recent computational study used the finite element method to simulate a three-component mobile-bearing total ankle replacement (BOX; Finsbury Orthopaedics, Surrey, United Kingdom) over a complete gait cycle\(^\text{16}\). For this implant, a peak contact pressure of 17 MPa was predicted, but with a majority of contact pressures of <10 MPa. This model was unique in that it explicitly incorporated the contribution of ankle ligaments to ankle joint kinematics (which accorded well with the experimental baselines) and was introduced as a potentially useful computational platform to quantitatively evaluate total ankle replacement designs. While providing useful insight, the model was not apparently used to explore the implications of the design parameters or component positioning of the total ankle replacement on joint contact characteristics.

Our investigation shows that such factors may be important, and it tends to support clinical studies suggesting that a highly congruent, three-component total ankle replacement design can provide a distribution of joint force over a greater area of contact, resulting in lower peak and average contact pressures. Except for imposed versions of >5\(^\circ\) joint contact pressures in the investigated three-component design were below the yield stress for polyethylene\(^\text{18}\).

To perform a straightforward comparison between the two total ankle replacement designs, some underlying assumptions and simplifications were adopted in both the experimental and finite element analyses. The first was that the implants were mounted on a rigid representation of the tibia and talus. The rigidly fixed talar component was perhaps the most problematic, as the ankle ligaments permit relative movement of the talus over the stance phase of gait\(^\text{16}\). Thus, any imposed misalignment between the two components must be considered to be a worst case, in which relative talar movement does not act to reorient the joint bearing surface to minimize contact stresses. The relative movement of the talus is likely to have some effect on the resultant distributions; however, assuming the implants to be rigidly fixed allowed for a comparison of the two total ankle replacement designs.

The study also did not incorporate potential long-term plastic deformation and wear of the polyethylene components. This may be important, since associated changes in implant geometry may effectively alter (and even reduce) joint contact stresses. However, previous “evolutionary” models predicting polyethylene wear in total knee replacements\(^\text{26}\) that dynamically incorporate implant geometry changes have indicated that these changes tend to increase peak and average contact pressures, leading to increased rates of wear rather than reducing them. Nevertheless, the investigation of long-term implications of plastic deformation on wear characteristics remains ground for future work.

Finally, caution must be exercised in extrapolating the findings of this study to total ankle replacement systems that were not explicitly investigated. The Mobility total ankle replacement design incorporates a high degree of congruency and constraint at the talar component-insert interface that is compensated at the tibial component-insert interface through a mobile bearing. While this design principle has clearly emerged as a preferred concept for the latest generation of three-component total ankle replacement systems\(^\text{15}\), one cannot fully predict the functional differences that can accompany subtle differences in total ankle replacement design. As for two-component total ankle replacement designs, modern designs are likely to have unique functional characteristics that depend on the degree of implant congruency and the effective bearing surface.

In summary, our in vitro study indicates that the highly congruent mobile-bearing design of the DePuy Mobility total ankle replacement may result in more evenly distributed and lower-magnitude joint contact pressures than the less congruent two-component DePuy Agility design. Further, the reduced kinematic constraints of the mobile bearing may mitigate potential susceptibility to misalignment-induced wear. Nonetheless, both tested mobile-bearing designs remained vulnerable to increased contact pressures induced by certain misalignments and, to improve long-term results, proper positioning of the investigated implants in version is likely an important requirement.

**Appendix**

Data supporting the validation of the finite element models and a table presenting the joint contact pressures are available with the electronic version of this article on our web site at jbjs.org (go to the article citation and click on “Supporting Data”).

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