Evidence-Based Fit Assessment of Anatomic Distal Medial Tibia Plates

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Purpose: A good anatomical fit of precontoured plates is ideal to decrease malalignment of fracture fragments, reduce operating room time, and avoid unnecessary soft-tissue prominence. This last point is of great importance when plating the distal medial tibia, since the soft-tissue coverage is very thin. This study quantitatively compares the plate fit of seven different anatomic distal medial tibia plates from four different manufacturers on a large collection of 3-dimensional (3D) tibia models created from high-resolution clinical CT scans.

Methods: We generated 573 3D models of the tibias from CT scans of healthy subjects. 403 models were created from scans of Caucasian patients, and 170 models were created from the Asian population. There were female models (51%) and male models (49%). All models were created by using standard segmentation software (Materialise Mimics and MeVisLab). Automatic fitting software was developed, which quantitatively determines how well a given implant fits to a large collection of varying 3D tibia models. With help of a least-squares approach, the software finds an implant placement for every individual tibia that closely resembles a surgical placement. The software calculates the so-called fitting error (fe) in mm² for every plate-tibia combination. The lower the value for the fitting error, the better the anatomical fit of the implant, and the larger number of patients can be treated without the need to bend the implant. For this study, seven different distal medial tibia plates were optically scanned and imported to the computer software: DePuy ALPS 9-hole (8162-10-009), Synthes LCP 3.5-mm 8-hole (238.705), Stryker AxSOS 10-hole (627410), Smith & Nephew Peri-Loc 3.5-mm 10-hole (7182-1110), Synthes 2.7/3.5-mm LCP 10-hole (439.913), Synthes 2.7/3.5-mm VA-LCP 12-hole (02.118.011), and Stryker AxSOS 16-hole (627416).

Results: The analysis reveals that all plates are fit better on the Asian population tibial models compared to the Caucasian population tibial models. In the group of shorter plates (168-176 mm) the Synthes LCP 3.5-mm shows the worst fit (fe = 3.05), the DePuy ALPS shows an intermediate fit (fe = 2.14), and the Stryker AxSOS shows the best fit (fe = 1.51, $P < 0.001$). In the "long" group (185-254 mm) Smith & Nephew Peri-Loc 3.5-mm (fe = 5.24), Synthes 2.7/3.5-mm LCP (fe = 5.48), and Synthes 2.7/3.5-mm VA-LCP (fe = 5.33) show a highly significant worse fit than the Stryker AxSOS (fe = 1.96, $P < 0.001$). In addition to the highly significant difference in the fitting error for the "average" population, the error margins were also better than the competitive devices in the "outlier" size models.

Conclusion: The analysis reveals that the Stryker distal medial tibia plates show a significantly better anatomical fit to the 573 tibia models than the comparable plates from DePuy, Smith & Nephew, and Synthes. We also demonstrated that the Stryker plates show better results for a larger percentage of the population of tibias. These superior plate-to-bone fitting results suggest an improved anatomical fit with a reduced need for plate-bending when using these plates.

- The FDA has not cleared this drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an "off label" use). For full information, refer to page 600.