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Entwicklung und Validierung eines Models zur Primarstabilität von Schulterschäften für in silico klinische Studien

In silico clinical trials (ISCT) can contribute to demonstrating a device's performance via credible computational models applied on virtual cohorts. Our purpose was to establish the credibility of a model for assessing the risk of humeral stem loosening in total shoulder arthroplasty, based on a twofold validation scheme involving both benchtop and clinical validation activities, for ISCT applications. A finite element model computing bone-implant micromotion (benchtop model) was quantitatively compared to a bone foam micromotion test (benchtop comparator) to ensure that the physics of the system was captured correctly. The model was expanded to a population-based approach (clinical model) and qualitatively evaluated based on its ability to replicate findings from a published clinical study (clinical comparator), namely that grit-blasted stems are at a significantly higher risk of loosening than porous-coated stems, to ensure that clinical performance of the stem can be predicted appropriately. Model form sensitivities pertaining to surgical variation and implant design were evaluated. The model replicated benchtop micromotion measurements (52.1 ± 4.3 µm), without a significant impact of the press-fit ("Pressfit":54.0 ± 8.5 µm, "No press-fit": 56.0 ± 12.0 µm). Applied to a virtual population, the grit-blasted stems (227 ± 78µm) experienced significantly larger micromotions than porous-coated stems (162 ± 69µm), in accordance with the findings of the clinical comparator. This work provides a concrete example for evaluating the credibility of an ISCT study. By validating the modeling approach against both benchtop and clinical data, model credibility is established for an ISCT application aiming to enrich clinical data in a regulatory submission.

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