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A PROTOCOL TO EVALUATE AND VALIDATE IMPLANT INTERNAL FORCES AND MOMENTS

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MISCHA MÜHLING[*†], SABRINA SANDRIESSER[*†] AND PETER AUGAT[*†]

[*] Institute for Biomechanics, BG Unfallklinik Murnau
Prof.-Küntscher-Straße 8, D-82418 Murnau
biomechanik@bgu-murnau.de, https://www.bg-kliniken.de/unfallklinik-murnau

[†] Institute for Biomechanics, Paracelsus Medical University Salzburg
Strubergasse 21, AUT-5020 Salzburg
https://www.pmu.ac.at/

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ABSTRACT

A wide variety of implant types are used to address several challenges of fracture fixation. Manufacturers develop new models in order to face different fracture scenarios or improve the existing implants. There is limited knowledge about the internal forces and moments acting on the implants while implanted in the human body. Therefore, new implants are commonly tested and approved with respect to their corresponding predecessor products, because the mechanical requirements are unclear. The aim of this study is to evaluate and validate implant internal forces and moments and translate the complex physiological loading case into a simplified 3 or 4 point bending loading case of the implant. A finite elements model for a transverse femur shaft fracture (AO/OTA type 32-B2) treated with a locked plate system (AxSOS 3 Ti Waisted Compression Plate Broad, Stryker, Kalamazoo, USA) was developed and experimentally validated. The fractured construct was physiologically loaded by resulting forces on the hip joint from previously measured in-vivo loading experiments (Bergmann et. al). The forces were reduced to a level where the material response in the construct remained linear elastic. Resulting forces, moments and stresses in the implant of the fractured model were analysed and compared to the manufacturers' approval data. The FE-model accurately predicted the behaviour of the whole construct and the micro motion of the working length of the osteosynthesis. The resulting moment reaction in the working length was 24 Nm at a load of 400 N on the hip. The maximum principle strains on the locking plate were predicted well and did not exceed 1 %. In this study we presented a protocol by the example of locked plated femur shaft fracture to evaluate and validate implant internal forces and moments. It included calculation of implant internal loading using finite element analysis and validation of the internal loading. The presented protocol can be used to identify the internal loads of several different implants. The obtained information about the physiological situation of implants can be used to optimize the design of the implants.