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Validated computational framework for efficient systematic evaluation of osteoporotic fracture fixation in the proximal humerus

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ABSTRACT

The high rate of fixation failure in osteoporotic proximal humerus fractures indicate the need for improved solutions. Computer simulations may help to overcome the limitations of the gold standard biomechanical testing in evaluating the performance of new implants and enhance the effectivity and outcome of the design process. This study presents a framework for automated computational analysis that facilitates efficient and systematic evaluation of proximal humerus fracture plating under a variety of conditions including bone quality, fracture pattern, implant configuration and loading regime. The underlying finite element methodology was previously validated. The capabilities of the software tool are demonstrated by virtually reproducing a previously published biomechanical study on the effect of screw augmentation and showing that the models capture the essence of the experimental results. Due to the modular design of the framework, the currently available set of angle-stable plate implants can be readily expanded to include other fixations such as intramedullary nails. Besides the capability to compare already existing solutions, the tool can provide rapid feedback on novel ideas. Therefore, it is expected to efficiently complement and partially replace expensive experimental tests and aid development and optimization of implant designs for improved fixation of osteoporotic proximal humerus fractures.

1. Introduction

Proximal humerus fractures represent the third most frequent osteoporosis-related injury in the elderly with expected increasing incidence due to the ageing population and prevalence of osteoporosis [1–4]. Management of unstable fractures requires surgical treatment to achieve and maintain anatomical reduction, enable early functional recovery and ensure rapid healing. Joint-preserving treatment options include intramedullary nailing and plating. The introduction of locking plates revolutionized fracture treatment at this anatomical site [5,6]. However, the rate of fixation-related complications in osteoporotic bone, including intra-articular screw perforation and loss of reduction, still remain high, ranging up to 36% in general and up to 86% for the most endangered patient collective [5–11]. Fixation of osteoporotic proximal humerus fractures is particularly challenging due to absence of bony support, complex loading conditions in the shoulder, comminution, and limited surgical access [9]. This challenge combined with the high incidence of complications demand advanced strategies for preoperative planning and osteosynthesis through more robust and comprehensive design techniques.

Implant development is traditionally based on surgical experience combined with engineering expertise. The state-of-the-art for evaluating the biomechanical competence of implant designs is in vitro testing of bone-implant constructs on cadaveric bones [12–19]. However, such laboratory experiments are time consuming, expensive and require valuable human specimens. Moreover, the methodology is limited to non-physiological loading and boundary conditions that are not well standardized for the proximal humerus. Experimental evaluation is typically restricted to one or two simplified load situations and a single simulated fracture pattern. Additionally, the time and costs usually limit the sample size and statistical power. Ideally, various surgical solutions would be tested on the same specimens, but cadaveric testing is limited to contralateral pairing that only enables comparison of two strategies on bones that can still be dissimilar in anatomy and bone density [20]. These limitations of in vitro biomechanical experimentation compound to limit the robustness of each study and, in turn, the design process.

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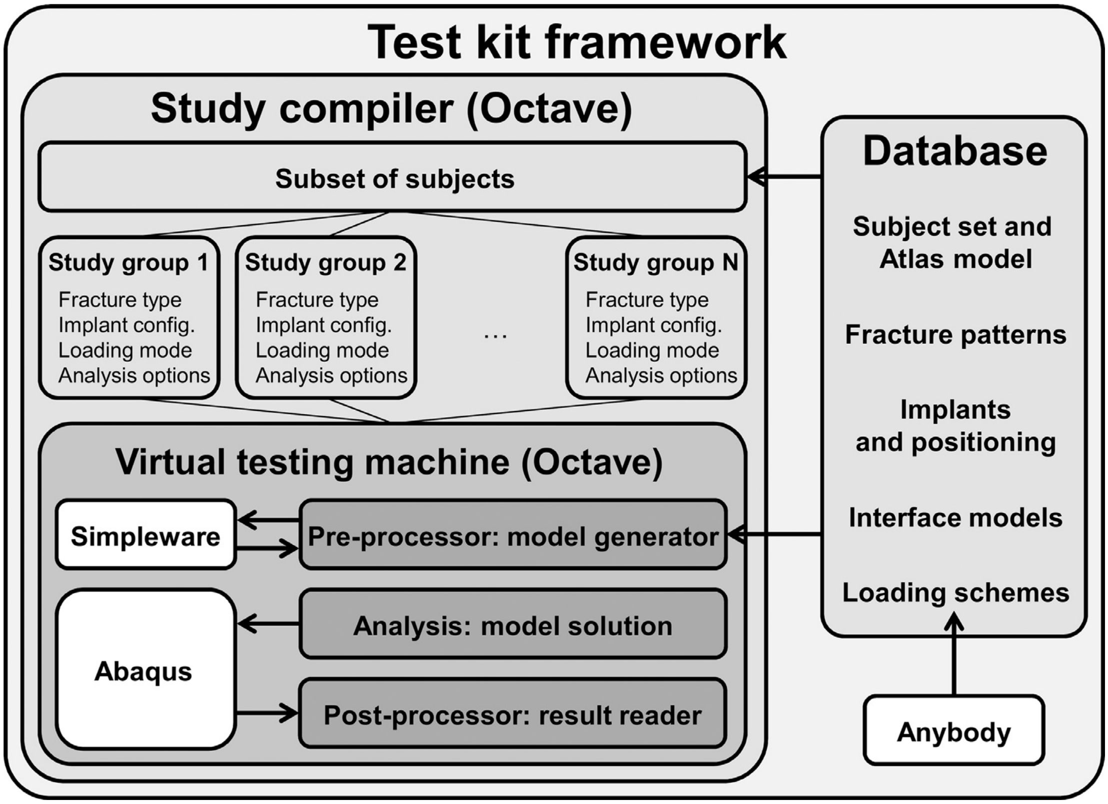

Fig. 1. Illustration of the components and organization of the virtual osteosynthesis test kit. The white boxes indicate external commercial software tools.

The power of computer simulations has been demonstrated in predicting the biomechanical competence of bones [21] and evaluating the performance of bone-implant systems [22]. Only a few computational studies targeted the problem of proximal humerus fracture fixations, comparing the biomechanical performance of different implants [23–26] and investigating the effect of screw configuration [27], cement augmentation [28] and fracture gap geometry [29]. However, these models were usually based on a single sample, used simplified material properties and applied only a few and/or simple loading conditions. The analyses were restricted to the evaluation of elastic stiffness, interfragmentary motion, or stress distribution in the bone and in the implant, but did not include the prediction of fixation failure. None of these models were validated experimentally. We have recently demonstrated that finite element (FE) analysis can predict experimental cyclic construct failure of plated proximal humerus fractures [30]. However, preparation of these models and extraction of the relevant results time-consuming and traditionally require extensive user interaction. Automating these modeling steps could efficiently support the implant development process by providing rapid feedback on the biomechanical performance. Furthermore, none of the previous studies considered the variety of complex conditions including the variations in bone quality, fracture pattern, implant configuration and loading regimes. Therefore, there is a need for virtual testing via automated simulations that consider the range of complex conditions and would allow systematic evaluations related to repeated measures and enable study designs capable of elucidating the mechanisms of success through factorial analysis.

The aim of this study was to develop and validate a computational test kit for efficient and systematic biomechanical evaluation and optimization of surgical strategies for treatment of refractory osteoporotic proximal humerus fractures.

2. Materials and methods

The test kit developed in this study is a collection of data and computational algorithms designed to facilitate efficient and systematic finite element simulations of the biomechanical behavior of proximal humerus fracture fixations. This software tool can be used to compare various implant configurations under the same conditions, or to investigate the effect of a given parameter, e.g. loading mode, on the performance of a selected implant configuration. Each set of simulations used to answer a specific question is referred to as a "Study". A given Study is composed of at least two Study groups that are based on the same set of subjects, but impose different user-defined conditions, such as the fracture type, implant configuration, loading mode and analysis options.

The test kit is composed of three main modules: the database, the Study compiler, and the virtual testing machine (Fig. 1). The database consists of five components: (i) a collection of processed medical image data of the proximal humerus from 47 subjects, (ii) a set of osteotomy models to simulate clinically relevant fracture patterns, (iii) implant geometries and an automated implant positioning tool, (iv) interface types to control the interaction of the different model components, and (v) loading schemes replicating experimental test setups or corresponding to physiological loading conditions. The Study compiler is the module responsible for running a given Study. Based on the input specified by the user, this module loads the selected set of subjects, configures the Study groups by utilizing components from the database, calls the virtual biomechanical testing machine to simulate each subject of each Study group and collects the results for the entire Study. The virtual testing machine is an automated modeling and simulation framework, designed to allow systematic generation of FE models. This tool consists of three main components: a pre-processor generating the FE models of the selected subjects according to the