Combined Computational and Experimental Protocol for Assessing the Biomechanical Efficacy of Femoral Augmentation for Preventing Hip Fractures

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I. INTRODUCTION

Prophylactic femoral augmentation devices are used increasingly for various clinical indications and may be an improved alternative to conventional hip fracture prevention strategies for the elderly. To test the biomechanical efficacy of such devices, the authors have developed an inertia-driven sideways fall simulator, which incorporates both proximal femurs and the entire pelvis, considers subject-specific loading, and allows for fracture outcomes to be identified directly (Fig. 1) [1]. A corresponding finite element model (FEM) of the test setup has been developed and validated [2]. In an *in silico* study using the FEM, prophylactic femoral augmentation using a fracture fixation implant was found to increase the load tolerance of a specimen relative to its corresponding unaugmented FEM [3]. A limitation of running the same test *ex vivo* is that the same specimen cannot be tested in both an unaugmented and augmented state. Therefore, the purpose of this study was to develop a protocol to test the mechanical efficacy of a fracture fixation nail *ex vivo* using our recently-published FEMs [2] as unaugmented control specimens.

II. METHODS

Experimental Testing

CT scans were taken of specimens S1 (81y f, 152.4 cm, 61.2 kg) and S2 (63y f, 172.7 cm, 44.0 kg) with a pelvis-femur construct before and after implantation with a fracture fixation nail. The specimens were then embedded in ballistics gel soft tissue surrogates. Afterwards, the specimens were placed on a test setup which includes metallic lower limbs with subject-specific masses (Fig. 1). The specimens were subjected to an inverted pendulum fall motion resulting in an impact velocity of 3.1 m/s at the greater trochanter [1]. Fractures were identified by a fellowship-trained trauma surgeon (PG) after testing.

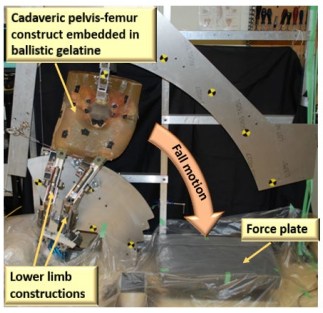

Fig. 1. Fall simulator (reprinted from [1]).

Computational Modelling

Unaugmented FEMs (Fig. 2) of the specimens were generated using an automated pipeline which uses the pre-implantation CT scans as input and positions the specimens into the appropriate fall configuration. Element failure was defined using a strain-based criteria [4], and the experimental impact velocity was used. Commercial software (LS-Dyna, Livermore, USA) was used to solve the FEM.

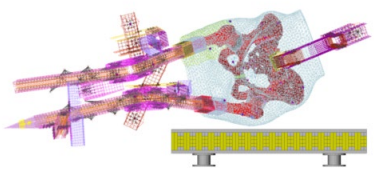

Fig. 2. FEM of specimen. [2]

III. INITIAL FINDINGS

S1 sustained damage to the left ramus from the drop experiment (Fig. 3A). No fractures were found on the femurs. The FEM for S1 also showed damage to both rami but no damage to the femurs (Fig. 3B). For S2, no damage was observed in the experiment for either the pelvis or femurs, but the unaugmented FEM predicted

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fractures to both the impacted femur and pelvis (Fig. 3C).

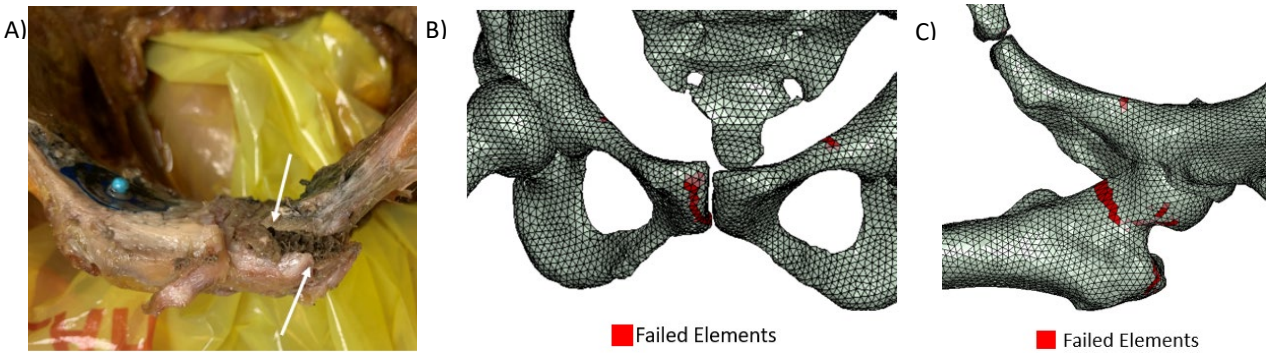

Fig. 3 A) Damage sustained by S1 is indicated by the arrows. B) Strain plot from the FEM for S1 at 2 ms after peak impact force. C) Strain plot from the FEM for S2 at 2 ms after peak impact force.

Impact force measurements from the specimen in the experiment and FEM for S1 are shown in Fig. 4A. The experiment reached a peak force of 4.00 kN for the augmented specimen, while the unaugmented FEM reached a peak force of 4.40 kN. Fig. 4B shows the impact force comparison for S2. In the experiment, the pelvis roller attached to the sacrum became detached and impacted the force plate 41 ms after the peak force was reached. Therefore, unaugmented FEMs both with and without the pelvis roller were simulated. The peak force reached by the augmented specimen in the experiment was 3.58 kN. The unaugmented FEMs reached a peak force of 4.24 kN with the pelvis roller and 4.21 kN without the pelvis roller.

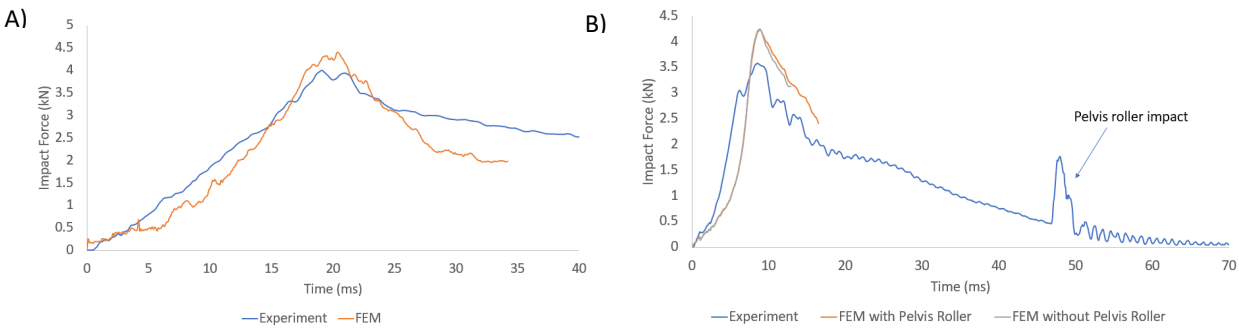

Fig. 4 A) Impact force curve for specimen S1. B) Impact force curve for specimen S2.

IV. DISCUSSION

In this study, *in silico* models of two unaugmented specimens were used as controls to provide baselines for the assessment of the mechanical efficacy of a prophylactic augmentation device. For S1, both the FEM and experiment had pelvis fractures in similar areas, but no femoral fractures. This suggests that even for a specimen that is not at risk of femur fracture in a sideways fall, the implantation of a femoral augmentation device will not increase the risk of femoral fracture. The FEM for specimen S2 indicated that a femoral and pelvic fracture would occur in the event of a sideways fall. From the experiment, the implant appeared to prevent both fractures.

For both specimens, the peak impact force in the experiment occurred at approximately the same time as the FEM but was lower in magnitude. This is in contrast to the results in the *in silico* study [3], which showed that the presence of the implant increased the peak force. However, the previous study did not take into account damage to the pelvis, which may have dissipated energy in the *ex vivo* experiment. Running FEMs with both linear and non-linear material properties in the pelvis could potentially uncover the source of the force discrepancies. Nevertheless, the results show that the combined use of computational and experimental methods could be a feasible method for determining the biomechanical efficacy of prophylactic femoral implants.

V. References

[1] Fleps et al., PLoS ONE, 2018.
[2] Fleps et al., J Bone Miner Res, 2019.
[3] Fung et al., J Mech Behav Biomed Mater, 2022.
[4] Grassi et al., Bone, 2021.