Pre-clinical test to discriminate shoulder performance

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ABSTRACT
A pre-clinical test to discriminate shoulder performance is purposed. It consists of a finite element model (FEM) of the implanted glenohumeral joint. Strain distribution inside the bone structures agree with the clinical observations present in literature, suggesting that the FEM predicts bone behaviour in the presence of a prosthesis and may be considered a pre-clinical test to evaluate shoulder implants performance.

Key-words: pre-clinical test, glenohumeral joint, anatomical prosthesis, finite element model

INTRODUCTION
Joint prosthesis are largely used and thousands are implanted in the most developed countries every year [1]. With the popularity of hip and knee replacements, shoulder arthroplasty has been gaining space and many prosthesis concepts and designs have appeared, assuring better success rates. However, the reality shows that there continue to exist prostheses withdrawn from the medical market due to high failure rates. According to Prendergast and Maher [2], the European regulations for medical devices does not evaluate prostheses efficacy, not detecting problems leading to an unsuccessful surgery. Thus, the main goal of this study was to develop a pre-clinical test to predict shoulder prosthesis performance after implantation.

MATERIALS AND METHODS
A FEM of the implanted shoulder joint, previously developed and validated by the authors, was used. The FEM considers fourth generation composite left humerus and scapula (Sawbones®), and a Comprehensive® Total Shoulder System (Biomet®), comprising a humeral implant and a glenoid implant (two distinct designs). The muscles considered in the analysis were the subscapularis, supraspinatus and the deltoid, and the joint was analysed in a 90° abduction. The CAD model of the prosthesis and the implanted glenohumeral joint are depicted in Figure 1, with mesh representation.

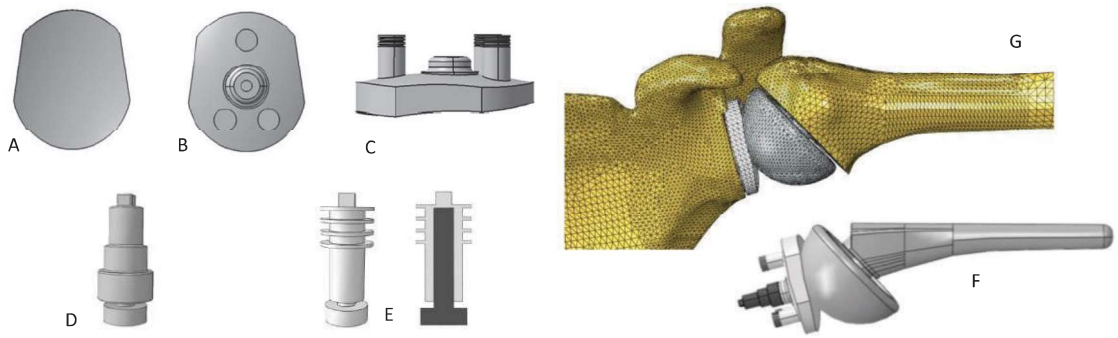

Figure 1. A, B, C: Modular Hybrid® Glenoid Base; D: Porous titanium post; E: polyethylene post, with evidence of the titanium core; F: Comprehensive® Shoulder System, BIOMET®; G: FE mesh of the implanted shoulder model.

The FEM simulated a short-term condition considering a Coulomb friction between the prosthesis components and the surrounding bone structure. The humeral shaft was constraint on all translational degrees of freedom. The humerus was modelled with isotropic linear elastic properties [3], as well as the cortical bone of the scapula [4]. Its trabecular bone was assumed as an anisotropic linear elastic material [5].

RESULTS AND DISCUSSION

The clinical outcomes of the Comprehensive® Total Shoulder System available in literature [6], were evaluated, showing evidence of new bone next to the central titanium post in nearly all regions. The clinical outcomes of the Anchor Peg Glenoid Component (DePuy) (polyethylene post) [7] were also evaluated, where signs of bone ingrowth were identified around and between the flanges of the central fixation post.
The computed tomography scans (CT-scans) of both clinical outcomes were compared with FEM results (see Figure 2). On the titanium-fixation-post, regions of bone ingrowth ((2500, 4000) με) and of bone collapse ((4000, 25000) με) are found around the entire structure. On the contrary, those are mainly at the flanges of the polyethylene-fixation-post (see regions 2, 3, 6 and 7 in Figure 2 (E and F)). These results are in accordance with clinical observations, suggesting that the titanium-fixation-post is a better option, as it allows new bone to grow around its entire porous surface, promoting better implant fixation.
The FEM also allowed comparison with humeral prosthesis component, not shown in this abstract.

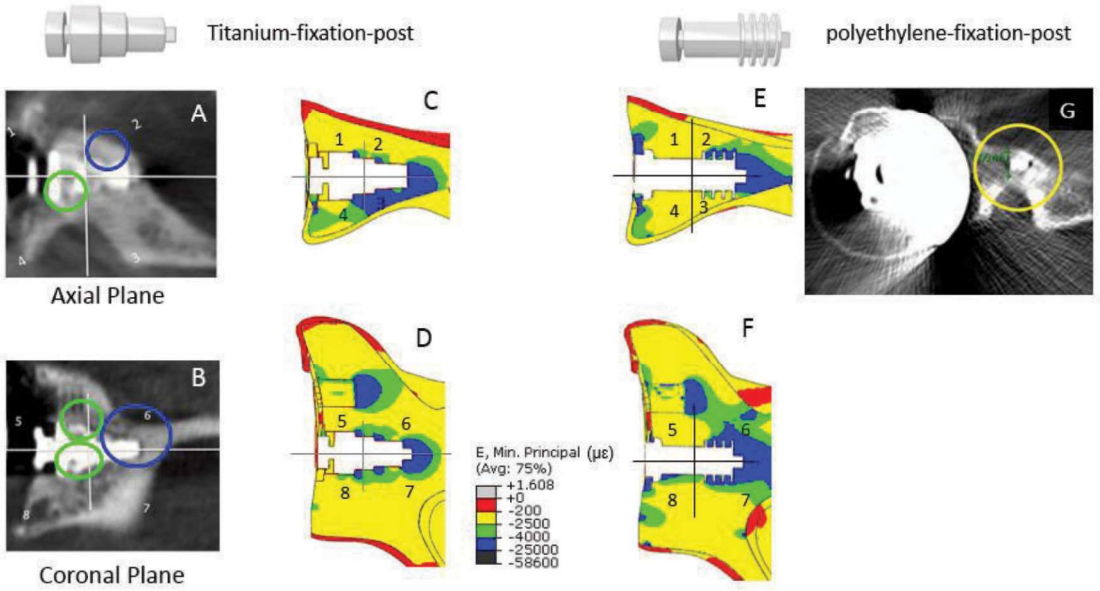

Figure 2. Titanium and polyethylene fixation post vs clinical results.

CONCLUSIONS

From the comparison between the clinical predictions available in literature and the numerical results obtained, it is concluded that the developed FEM allows the prediction of short-term prosthetic behaviour.

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