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Strength Evaluation of a Variable Diameter Acetabular Trial Implant under Realistic Loading Conditions

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Abstract—**A variable diameter acetabular trial implant (VDATI) was designed to reduce the costs related to cleaning, sterilisation and storage of surgical instruments used for total hip arthroplasty. The purpose of this study was to evaluate the mechanical strength of a functional prototype of the VDATI. Experimental testing was performed to identify if the VDATI can resist loading conditions similar to the ones occurring during the surgical procedure and to validate a finite element model (FEM) of the VDATI. The results highlighted the potential of the current concept of the VDATI and demonstrated the relevance to continue its development.**

I. Introduction

TOTAL hip arthroplasty is a common orthopaedic surgery for the treatment of osteoarthritis and pain. This surgery improves the functional capabilities and the quality of life of patients [1]-[2]-[3]. The prevalence of hip arthroplasty is continuously increasing in Canada and US. In 2006-2007, the number of hip arthroplasty performed in Canada (24,253) was 59 % higher than in 1996-1997 and 2,6 % higher than in 2005-2006 [1]. By 2030, the demand for primary total hip arthroplasties is estimated to grow in the US by 174% up to 572,000 [4].

The surgical procedure requires the evaluation of the joint range of motion prior to insertion of the final prosthesis to ensure no instability could lead to post-operative joint dislocation. Usually, trial liners similar to the final prosthesis are used as templates. More than 153 trial liners are required to cover all the possible sizes and shape of the final prosthesis. The orthopaedic surgeon must have access to all trial liners during surgery despite the fact that only a few of them will actually be used. This requirement generates high costs related to cleaning, sterilisation and storage of the surgical instruments.

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A variable diameter acetabular trial implant (VDATI) was designed to reduce the number of trial liners used during total hip arthroplasty [5]. In brief, the VDATI consists of a deployment mechanism which can adapt various metallic cup sizes and three exchangeable seats adapting to various femoral head diameters (Fig.1).

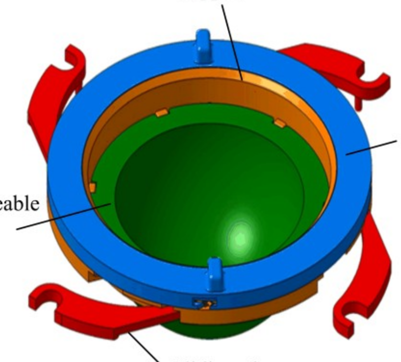

Fig. 1. Assembly of the Variable Diameter Acetabular Trial Implant

A finite element model (FEM) of the VDATI was developed to evaluate its mechanical behavior under loading conditions that are similar to the ones encountered during the surgical procedure [5]. The results suggested the need to improve the mechanical strength of the current concept of the VDATI. Some parts of the VDATI revealed a maximum stress up to 100 MPa over the target yield stress [5]. However, estimation of the stress level was doubtful due to the presence of mathematical singularities in the FEM.

II. Objective

The purpose of this study was to carry out experimental testing to evaluate the mechanical strength of the VDATI under loads approaching surgical conditions. Achievement of mechanical testing will also validate a FEM of the VDATI previously described by the authors [5].

III. Materials and Methods

This study was divided in three steps. The first step was the fabrication of a functional prototype of the VDATI. The VDATI prototype was then submitted to mechanical loading under three different conditions. Finally, the prototype was inspected for potential permanent deformation.

A. *Manufacturing of a functional prototype*

A functional prototype of the VDATI was fabricated using two additive fabrication processes. These free-form processes consisted of depositing the material layer-by-layer onto a platform until the part is fully built. The support, the rotating disk and the sliding plates were fabricated out of stainless steel 17-4 by Direct Metal Laser Sintering (EOS of North America Inc., Novi, MI) while the interchangeable seat was fabricated out of acrylonitrile butadiene styrene by Fused Deposition Modelling (Stratasys, Eden Prairie, MN). The support, the rotating disk and the sliding plates were also sanded to improve the surface finish.

B. *Experimental testing*

The mechanical strength of the VDATI was evaluated using a material testing machine (858 Mini Bionix® II, MTS Systems Corporation, Eden Prairie, MN). Three loading conditions, which may all occur during the surgical procedure were tested. The first loading case (loading case #1) consisted of applying 150 N perpendicular to the VDATI (Fig. 2). This loading case corresponds to the weight of a 95^{th} percentile leg [6]-[7]-[8] positioned vertically above the VDATI. The VDATI was placed on a support block which was maintained in place with a swivel-base vice. A 32 mm femoral head fixed to the actuator was used to load the VDATI at a constant speed of 0.005 mm/s until the 150 N force was reached. The load was maintained for 10 seconds and then removed. The force applied on the VDATI was recorded using a 2.5 kN load cell (662.20D-04, MTS Systems Corporation, Eden Prairie, MN). The same procedure was repeated for the two other loading cases: 150N force oriented in the YZ plane at 55.7 degrees from the Z axis (loading case #2), 150 N force also oriented at 55.7 degree from the Z axis but in the XZ plane (loading case #3) (Fig. 2). This angle corresponds to the tilt of the femoral neck when it comes into contact with the VDATI. Subsequently, the VDATI was loaded to failure using the orientation of loading case #3.

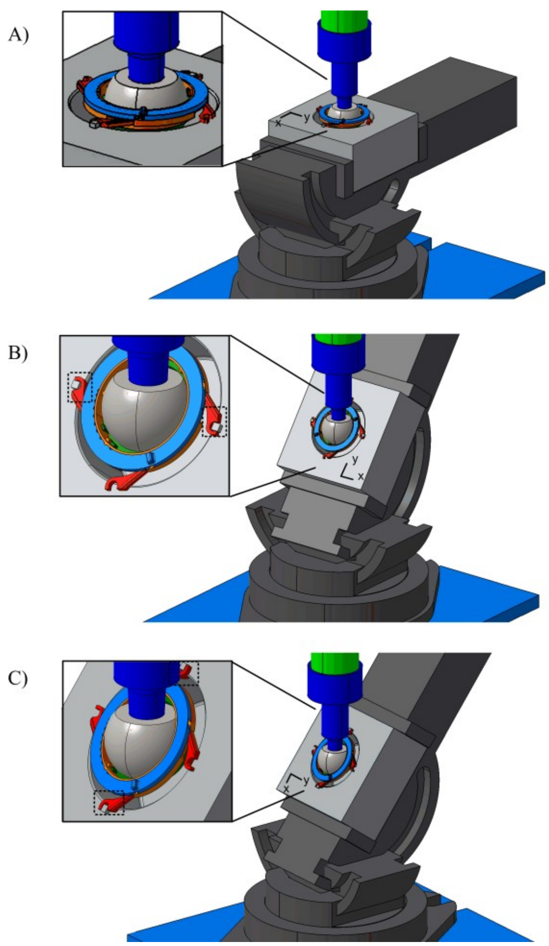

Fig. 2. Experimental set up configuration used to determine the mechanical strength of the VDATI under three loading conditions. Illustration A, B and C represent the loading case #1, #2 and #3 respectively.

At every step of the experiments, residual deformation of the VDATI was measured with a coordinate measuring machine (Bright-STRATO 7106, Mitutoyo, Aurora, IL). Six regions of interest (ROI) of $1mm^2$ each were identified on the sliding plates (4) and the support (2) (Fig.3). The 3D coordinates of 36 points distributed in each ROI were recorded three times before and after the mechanical loading. The mean deviation calculated before and after loading was compared to the deformation threshold of 94 µm for the sliding plates and 13 µm for the support. The deformation was considered permanent if the deviation exceeded these values.

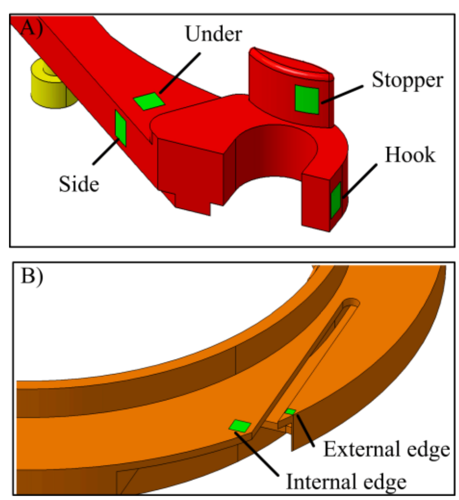

Fig. 3. Regions of interest identified on the sliding plate and the support.

IV. RESULTS

A. Defined loading conditions

No movement of the sliding plates or the support was perceived when a 150 N load was applied perpendicular to the VDATI (loading case #1). A bending of the sliding plate #2 was reported when a 150 N load oriented at 55.7 degree was applied in the YZ plane (loading condition #2) (Fig. 4A). The sliding plate #3 was compressed towards the VDATI and the sliding plate # 1 moved away (Fig. 4A). Bending of the sliding plate #1-2-3 was observed (Fig. 4B) when the load was oriented in the XZ plane. Sliding plate #2 was compressed towards the VDATI while sliding plate #1 and #3 also tend to slide along the Y axis (Fig. 4B). The behavior of sliding plate #4 cannot be analyzed in any case because it was hidden by the piston during loading.

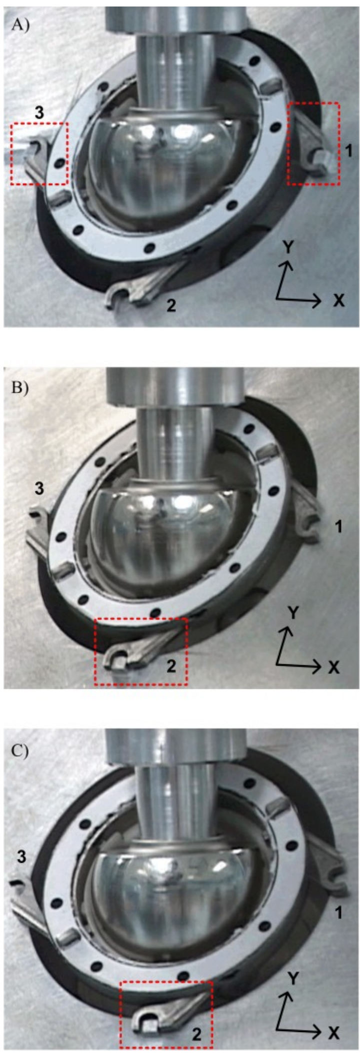

Fig. 4. Behavior of the VDTL observed during mechanical testing. Illustration A and B represent the loading case #2 and #3 while illustration C represents the load to failure.

No deformation superior to the target threshold of 94 µm (sliding plates) and 13 µm (support) was observed for all three loading conditions (Table I). The maximal deformation measured for the sliding plate was 44.0 µm ± 1.1, 29.4 µm ± 4.9 and 20.1 µm ± 0.9 in loading #1, #2 and #3 respectively. It was located on the stopper of sliding plate #2, on the stopper of sliding plate #3 and under the sliding plate #2. The maximal deformation measured for the support was 9.1 µm ± 0.6, 4.2 µm ± 1.8 and 9.9 µm ± 4.3 for the loading case #1, #2 and #3. It was located on the inner edge of groove #3 for the loading case #1 and on the external edge of groove #3 for the loading case #2 and #3.

TABLE I
MAXIMUM DEFORMATION (µm)

	Loading case #1	Loading case #2	Loading case #3	Failure
Sliding plate #1	21.3	13.6	12.6	20.0
Support groove #1	3.7	2.6	6.7	8.9
Sliding plate #2	44.0	27.2	20.1	339.6
Support groove #2	7.4	1.3	8.6	15.1
Sliding plate #3	8.0	29.4	9.2	16.9
Support groove #3	9.1	4.2	9.9	8.9
Sliding plate #4	34.7	19.5	11.0	73.7
Support groove #4	2.6	1.6	8.9	7.2

B. Failure load

The mechanical behavior of the VDATI loaded to failure was similar to the one observed during loading case #3. The major difference was a higher compression of sliding plate #2 toward the VDATI (Fig. 4C).

The interchangeable seat broke at a force of 345 N. Delamination of the seat of approximately one third of the circumference was observed (Fig. 5). No rupture of the sliding plates or the support was reported. However, three ROI located on sliding plate #2 revealed a deformation superior to the target threshold (94 µm), suggesting that plastic deformation occurred. It reached 339.6 µm ± 5.6, 192.6 µm ± 5.5 and 165.4 µm ± 45.5 on the stopper, on the side of the sliding plate and the hook. The external edge of groove #2 was the most deformed part of the support. It reached a deformation of 15.1 µm ± 1.1, which is higher than the threshold of 13 µm.

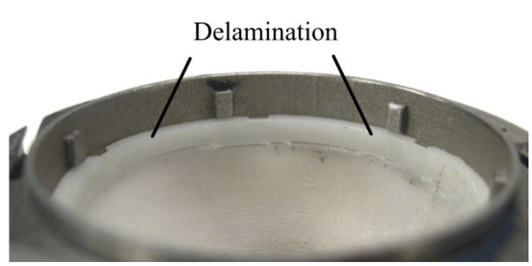

Fig. 5. Rupture of the interchangeable seat by delamination.

V. DISCUSSION

The present study allowed the evaluation of the mechanical behavior of the VDATI under loading conditions similar to the ones encountered during hip replacement procedure. It also permitted the validation of a FEM of the VDATI previously described by authors [5].

The experimental results indicated no permanent deformation of the sliding plates and the support for all three loading conditions, while FE analysis reported maximum stress up to 100 MPa over the target yield stress [4]. The capacity of the VDATI prototype to maintain higher load without deformation can be explained in part by the gap between the components. A higher gap between the components of the prototype allowed the movement of the sliding plate inside the support groove which reduced the stress level.

The VDATI prototype was capable of supporting more than two times the weight of a leg before rupture. The failure mode of the interchangeable seat during ultimate loading may to be due to fabrication technique. The layered structure of FDM parts is subjected to delamination. A different manufacturing process will be used in the future.

VI. CONCLUSION

The aim of this study was to conduct mechanical testing to validate if the VDATI could withstand loading conditions met during hip replacement surgery. The results demonstrate that the prototype can withstand such realistic loading conditions. The results also suggest the need to improve the previously developed FEM because it predicted insufficient strength of the VDATI. However, the experiment related specifically to the weight loading demonstrated the potential of the current concept of VDATI and the relevance to continue its development. Further studies shall include FEM and experimental analyses to test the VDATI fatigue behaviour.

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