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CHARACTERIZATION OF ACETABULAR CUP INSERTION FORCES IN CANCELLOUS BONE PROXY FOR VALIDATION OF AN INVASIVE SENSING MODEL AND DEVELOPMENT OF AUTOMATIC INTELLIGENT PROSTHESIS INSTALLATION DEVICE

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ABSTRACT

Total hip replacement is a widespread medical procedure, with over 300,000 surgeries performed each year in the US alone. The vast majority of total hip replacements utilize press fit fixation, where the implant cup is physically impacted into the patient's acetabular cavity. Successful seating of the implant requires a delicate balance between inserting the implant deep enough to obtain sufficient primary stability, while avoiding fracture of bone, which causes pain, complications during recovery, and revision surgery. To improve patient outcomes, this surgical field needs assistive technologies that can measure the forces applied during press fit fixation, and provide real-time feedback to guide how much force to apply, and when to stop applying additional forces. The development of such technology, however, requires a greater understanding of the forces experienced at the implant-acetabular cup interface, and the resulting cup insertion and implant stability. Here, we present a preliminary study of acetabular cup insertion into bone proxy samples. We find that as the magnitude of force on the acetabular cup increases, the cup displacement and axial extraction force increase linearly and then plateau. For repeated impacts of a given force, cup insertion and force experienced in bone increase correspondingly and reach a plateaued value over certain number of impacts, which represents rate of insertion. These finding suggest the plausibility of a feedback mechanism that utilizes measured force patterns in bone, implant/bone interface, and impaction tool in relation to rate of insertion to infer optimal primary implant stability in arthroplasty.

Keywords: Acetabular Implants, Press-fit Implantation, Invasive Sensing, Automatic Intelligent Prosthesis Installation Device, Fixation Algorithm

NOMENCLATURE

THA	total hip arthroplasty
NOITS	number of impacts to seating

1. INTRODUCTION

Total hip arthroplasty (THA) has developed into one of the most successful and widespread orthopedic operations, providing pain relief and restoring function in patients with severe arthritis affecting the hip joint [1-3]. During this operation, a surgeon replaces damaged bone and cartilage with a prosthetic femoral stem and cup. Since the inception of THA, the method has benefitted from improvement in prosthesis materials and design, as well as refinement of surgical techniques [4]. For placement of the prosthesis into the patient, cementless implantation has gained popularity [5,6]. These implants rely on press-fitting of the prosthesis into a slightly undersized hip bone socket (typically, 1 mm). Modern cementless implants feature surface textures and coatings that encourage bone to grow either across or into the matrix of the prosthesis [5,6]. As a result, implants of this type are more resistant to loosening, maintain long-term stability, and limit the entrance of joint fluid and debris that contribute to osteolysis [6-8].

Successful seating of the implant requires a delicate balance between positioning deep enough to obtain sufficient primary stability, while avoiding excessive force leading to fracture. Fracture represents a key risk in cementless implants, with fracture occurring in between 2.95% to 27.8% of operations [9-13]. The implant quality of fixation during patient recovery is determined by many factors, including bone site preparation, material properties of the bone and implant, implant design, alignment of the implant relative to the acetabulum, and depth of implant insertion [14,15]. Despite the numerous advances in technologies and techniques for hip replacement surgery, the process of acetabular cup implantation remains poorly controlled. During the operation, the surgeon uses a mallet to impact the cup into the acetabular cavity, primarily relying on visual, auditory and tactile senses to assess the quality of fixation. As a result, the magnitude of forces applied in press-fit fixation vary widely based on surgeon (1-8.9 kN), and the endpoint seating of the implant during hip replacement surgery lacks standardization [16,17]. This haphazard application of force to the acetabulum can lead to either too loose or tight-fitting implant. The instability of a loose-fitting implant causes micro-scale motions that can lead to fibrous tissue formation, aseptic loosening, and infection [18,19]. These complications may necessitate revision surgery, increasing cost to the patient and extending pain and recovery times. Conversely, an overly-impacted implant contributes to intra-operative fractures, which also can cause aseptic loosening and revision surgery [20-24]. This is a particular concern in older patients and those with osteoporotic bone [22].

To improve patient outcomes and reduce the risk of fracture, a significant need exists for improved, standardized methods of press-fit fixation. Particularly, assistive instrumentation in applying and measuring the forces during fixation would enable surgeons to minimize intra-operative fractures and achieve a more controlled implant endpoint seating. The development of such tools requires improved understanding of forces generated during acetabular press-fitting. In this study, we investigate the forces generated within a bone proxy during weighted drop testing. The force relations outlined in this work suggest a feedback mechanism could be developed using the inputs of applied force, measured force in bone and tool, and the number of impacts to seating as a proxy for rate of insertion. In the future, the development of such a feedback mechanism into an automatic prosthesis installation machine could guide surgeons as to how to quantitatively determine how much force to apply, and when to stop force application to achieve optimal primary implant stability.

2. MATERIALS AND METHODS

In all testing, we use rigid 20 lb polyurethane foam as a substitute for acetabular bone because it displays similar mechanical properties to cancellous bone [25,26]. The foam (BoneSim Laboratories) is cut into 70x70x40 mm blocks and reamed to produce a 61 mm diameter hemispherical cavity. For each test method, we use a Zimmer Continuum 62 mm diameter hemispherical acetabular cup with 1 mm press fit.

We perform weighted drop tests to imitate the forces generated during a mallet strike. A custom fixture is used to align the implant and sample. A strike rod is threaded into the implant, and a low friction bushing constrains the strike rod's polar and azimuthal angle relative to the pole of the implant. Using a 2 kg steel mass suspended at controlled heights above the strike rod, we generate impact forces on the sample, and measure resulting forces using a 8900N-rated force gauge placed beneath the bone block (+/- 5 N accuracy, sampling frequency of 25 kHz). To determine insertion depth, we measure the height of the implant face relative to the foam block before and after each weighted drop. We test eight drop heights ranging from 10 to 260 mm, and perform five repetitions at each height. The mean impact forces with this technique range from 773 to 7758 N. For each drop height test, we repeat impacts at the respective height until cup displacement between impacts are within the measurement error of 0.05 mm. Once reaching this point, we measure the endpoint cup displacement into the cavity.

To evaluate post-impact cup stability, we measure the axial extraction force using a pull test. Each sample is secured to a test stand outfitted with a Mark-10 M5-100 force gauge with 0.1 N accuracy. We thread a custom adapter into the implant to allow the force gauge to apply axial tension. The test stand force gauge raises at a rate of 1 mm/s until the implant separates from the foam block, and the maximum pull-out force is recorded.

3. RESULTS AND DISCUSSION

Increasing the number of impacts at a constant drop height results both in an increase in measured impact force and the displacement of the implant cup into the cavity. For a 50 mm drop height, we show that the first five impacts result in the greatest change in measured impact force and cup displacement (Figure 1a). Past five impacts, the impact forces and cup displacements continue to increase, but at a decreasing rate, and eventually plateau to a maximum value. Similarly, for a 90 mm drop height, change in cup displacement between impacts is greatest for the first five impacts (Figure 1b). As impact number increases at this drop height, the displacement per impact decreases. For a given drop height, an average force per impact is exerted on the implant over the course of seating. For example, full seating at a 50 mm drop height requires 27 impacts, with an average force per impact of 2438 N. As shown in Figure 1c, as the average insertion force per impact (corresponding to different drop heights) increases, the number of impacts required to achieve seating decreases and the cup insertion plateaus. A proof of principle in Figure 1d demonstrates the plateauing of cup insertion with increases in drop height (indicated by dashed black lines).

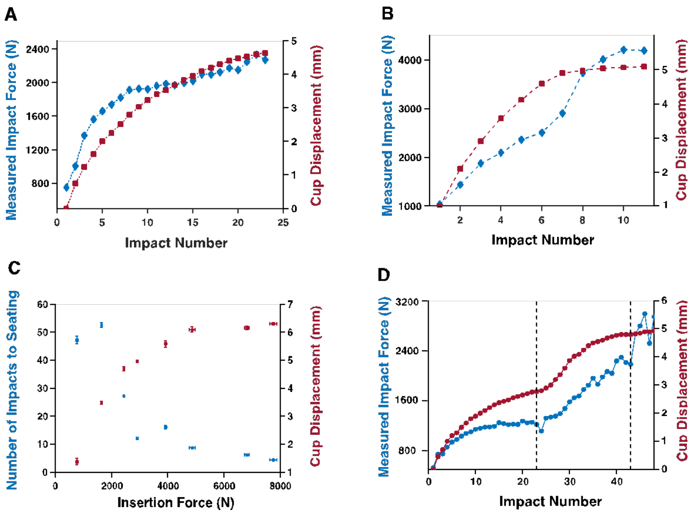

FIGURE 1: (A) THE RELATIONSHIP OF IMPACT FORCE EXPERIENCED IN THE CAVITY VERSUS CUP INSERTION FOR A 50 MM WEIGHTED DROP TEST. (B) THE RELATIONSHIP OF IMPACT FORCE EXPERIENCED IN THE CAVITY VERSUS CUP INSERTION FOR A 90 MM WEIGHTED DROP TEST. (C) NUMBER OF IMPACTS TO ACHIEVE PLATEAUED CUP INSERTION (NOITS) VERSUS INSERTION FORCE PER IMPACT. (D) PROOF OF PRINCIPLE WITH THREE GRADUATED APPLICATIONS OF DROP HEIGHT FORCES (INDICATED BY BLACK DASHED LINES).

Figure 2 demonstrates that both the cup displacement and axial extraction force increase with insertion force, then plateau. Note that the insertion forces in Figure 2 represent the average measured insertion forces required to achieve fixation (after a given number of impacts to achieve seating, as seen in Figure 1c). The cup displacement and extraction force both begin to plateau around 4000 N, producing approximately 5.6mm of cup displacement and 765 N of extraction force. This region represents approximately 89% cup insertion and 88% extraction force. Above this level, an additional 4000 N of force was required for cup displacement and extraction forces to reach average values of 6.3mm (at which the implant is fully seated) and 867 N, respectively.

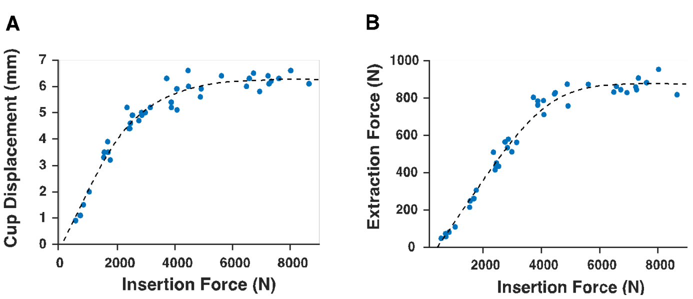

FIGURE 2: (A) INSERTION FORCE VERSUS CUP DISPLACEMENT FOR DROP TESTING (SMOOTHING SPLINE FIT, R^2 = 0.957). (B) INSERTION FORCE VERSUS AXIAL EXTRACTION FORCE FOR DROP TESTING (SMOOTHING SPLINE FIT, R^2 = 0.981).

During the process of implantation of the acetabular cup, surgeons apply forces without any quantitative guidance regarding applied and resulting forces. Instead, they assess depth of cup insertion visually or optically while simultaneously assessing quality of fixation qualitatively through human tactile and auditory senses. When the goal of full seating is not achieved and faced with a polar gap, surgeons cannot determine if they have achieved adequate fixation. In this situation, the surgeon can choose from a few primary decisions. First, they can increase impact energy and either fully seat the cup or fracture the acetabulum. Alternatively, they can ream line to line (insert with minimal force), and lose interference fit fixation – resorting to screws to impose stability. Finally, the surgeon may accept the fit offered by the polar gap, and not pursue further insertion. A better understanding of the implant-bone interface and the resulting force patterns during insertion would allow modeling and calibration of the interface such that surgeons gain a quantitative sense of the level of primary cup stability achieved, and whether or not full seating has been accomplished.

Figures 1a and 1b demonstrate that an impact force, repeated over time, results in a given range of cup insertion depths. This produces a corresponding force pattern in bone associated with rate of insertion (termed number of impacts to seating, or "NOITS"). These two values produced during cup insertion can be viewed as foot prints of force and rate of insertion for that depth of cup insertion. The change in force measured in bone results from frictional forces between the cup and the surrounding cavity material. The initial impact has a slow deceleration of the cup due to its relatively large displacement, resulting in a low force measurement. The displacement decreases for subsequent impacts due to the increasing frictional forces between the cup and cavity, which results in faster deceleration of the cup. This causes an increase in force measurement for each impact. The maximum force for a given impact energy occurs when the cup can no longer overcome the static friction forces from the surrounding material. This results in a plateau region, where any subsequent impact will not greatly impact either the insertion of the cup or the force measured.

The variety of drop heights tested correspond to different average insertion forces per impact. Figure 1c shows that as the average force per impact increases, the number of impacts required to fully seat the implant decrease. For example, a drop height of 10 mm results in a maximum impact force of 774 N, requiring 52 impacts to insert the cup to a plateaued value of 1.4 mm. Additional impacts at the drop height result in no further cup displacement. Conversely, the maximum drop height of 260 mm causes a maximum impact force of 7757 N, and requires only 4 impacts to insert the cup to 6.3 mm. At 6.3 mm, the cup is observed to be fully seated. This range of impact forces reflects a realistic force range that surgeons exert during this operation[16]. Figure 2a represents the endpoint result of the plot shown in Figure 1a, but for a range of drop heights. Once the acetabular cup displacement per impact falls below 0.05 mm, we assume the implant has achieved maximal implantation for that impact force. We present this data point as maximum cup displacement for the corresponding impact force at that drop height (Figure 2a). For the weighted drop test producing progressively increasing impact forces, the extraction force and cup displacement initially increase linearly with insertion force, increase non-linearly at an inflection point, and then plateau. This plateau suggests the maximum seating of the implant, where additional cumulative applied forces do not further contribute to axial implant stability or final insertion depth. Notably, within the non-linear zone, approximately half of the total drop testing insertion force range produced ~90% of insertion depth and axial implant stability. Thus, the inflection point (or small range) between the linear increase in extraction force and cup insertion, and the plateau phase are of interest for identifying the region where best fixation short of fracture may be achieved. Past the inflection point, additional force applied results in negligible cup displacement and stability, and may contribute to fracture.

Using this information, it may be possible to determine the relative movement of the cup for repeated impacts of a given energy by measuring the change in force between blows. Successive impacts of a given energy could be made until the measured force is no longer increasing (i.e. the first-order difference quotient of the measured force approaches zero). At this point, the impact energy could be increased by a constant amount and the process repeated. Assuming an appropriately-sized increase in impact energy, this system may enable quantification of when resistive force is no longer linear, as an increase in energy would result in an immediate plateau in measured force. We visualize this concept below in Figure 3 with a hypothetical plot of measured impact force as a function of impact number. In Figure 3, we outline the hypothetical relationship between insertion force, cup displacement, extraction force and number of impacts to seating (NOITS). During the linear phase, as cup displacement and extraction force increase, NOITS, is generally high but decreases with increase in cup displacement and extraction force. During the non-linear phase, NOITS reduces. (NOITS) therefore appears to provide a scale of elasticity of the cavity, where high NOITS indicates large residual elasticity in the cavity and low NOTIS warns of low residual elasticity in the cavity. To provide a proof of principle, we perform drop testing on a sample until the measured cup displacement was within 0.05 mm measurement error, and then increase the impact energy to a larger drop height (Figure 1d). A plateauing relationship appears between the difference quotient of the measured impact force and the resulting cup displacement. We believe that determining the quality of cup insertion by means of impact force measurement holds high promise due to its simplicity and ability to provide real-time information relevant to optimal primary implant stability while avoiding acetabulum fracture.

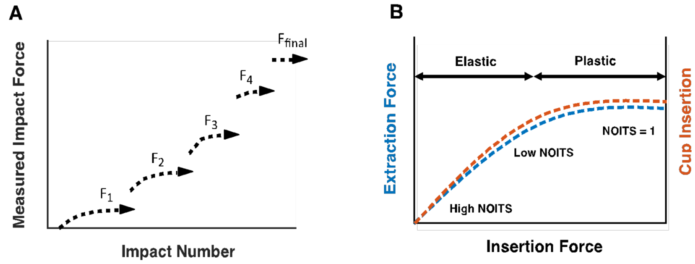

FIGURE 3: CONCEPTUAL REPRESENTATION OF: (A) THE RELATIONSHIP BETWEEN IMPACT NUMBER AND PLATEAUING VALUES OF MEASURED IMPACT FORCE FOR A GRADUATED SET OF APPLIED FORCES AND (B) THE RELATION BETWEEN NUMBER OF IMPACTS TO SEATING (NOITS) AND CUP INSERTION, EXTRACTION FORCE.

4. CONCLUSION

In light of the observed relationships between impact force, cup displacement, number of impacts, and extraction force, we propose a feedback control mechanism where incremental cup displacement can be monitored through measured force at the bone interface, or within the impaction tool (outlined in Figure 4). After each application of a known impact energy, the force is measured until it reaches a constant value. When the change in impact force approaches zero, the selected impact force produces no further cup insertion, and the measured force in bone plateaus over NOITS. This would enable a decision as to whether impact energy should increase or not. Monitoring of NOITS for each impact force can provide a relative sense of the residual elastic capacity of the cavity. High NOITS suggests significant residual elasticity is present and that it is safe to increase impact force to the next level.

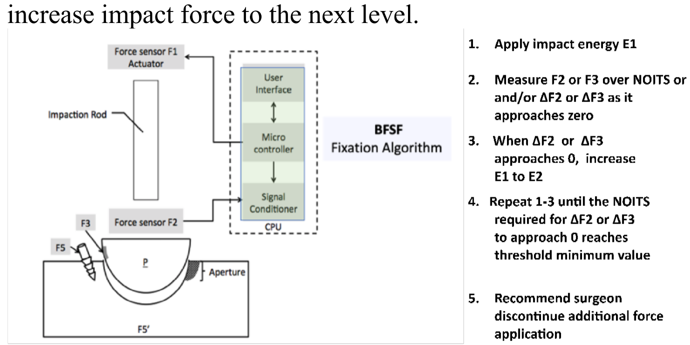

FIGURE 4: CONCEPTUAL LAYOUT OF FIXATION ALGORITHM: BEST FIXATION SHORT OF FRACTURE (BFSF), AND AUTOMATIC INTELLIGENT PROSTHESIS INSTALLATION DEVICE.

We note the process of press fit arthroplasty involves proximal and distal collisions. The proximal collision is always elastic, while the distal collision is inelastic and becomes elastic with decreasing NOITS. Force measured in bone F5, impaction tool F2 and at the implant bone interface F3 all measure force fields around a distal collision. We hypothesize that the progression from compliance to non-compliance produces force patterns in the tool and at the interface similar to those observed in this work over NOITS in bone. Thus, the impacting tool and the implant-bone interface can be exploited to configure a fixation algorithm which can be used within a tool to enhance press fit arthroplasty to obtain optimum primary implant stability without risk of fracture or loosening. Ultimately, the force relations presented in this study provide fundamental knowledge about implant insertion into bone proxy. In the future, we propose further study and validation of this feedback control concept with implants of varying mechanical and surface properties, and the use of wider range of bone substitute densities, as well as cadaver acetabula.

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