Characterization of Acetabular Cup Insertion Forces in Cancellous Bone Proxy for Validation of an Invasive Sensing Model and Development of Automatic Prosthesis Installation Device: A Preliminary Study

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Total hip replacement is a widespread medical procedure, with over 300,000 surgeries performed each year in the United States alone. The vast majority of total hip replacements utilize press fit fixation. 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. To improve patient outcomes, surgeons need assistive technologies that can guide them as to how much force to apply and when to stop impacting. The development of such technology, however, requires a greater understanding of the forces experienced in bone 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, cup insertion and axial extraction force increase linearly, then nonlinearly, and finally plateau with full insertion. Within the small nonlinear zone, approximately 90% of both cup insertion and extraction force are achieved with only 50% total energy required for full seating, posing the question as to whether full seating is an appropriate goal in press-fit arthroplasty. For repeated impacts of a given energy, cup displacement and force experienced in bone (measured force profile—MFP) increase correspondingly and reach a plateau over a certain number of impacts (number of impacts to seating—NOITS), which represents the rate of insertion. The relationship between MFP and NOITS can be exploited to develop a force feedback mechanism to quantitatively infer optimal primary implant stability. [DOI: 10.1115/1.4049085]

1 Introduction

The initial stability of metal backed acetabular components is an important factor in the ultimate success of cement less hip replacement surgery. Acetabular component stability is obtained by impaction of an oversized component (1–2 mm) into an undersized acetabular cavity, which produces primary stability through cavity deformation and frictional forces at the acetabular rim. Initial interaction of the implant with bone is due to circumferential surface interference transitioning to compression of the cavity with deeper insertion. A compromise must be reached between seating the implants deep enough to obtain sufficient primary stability at the aperture, while avoiding fracture with deep insertion. However, finding the endpoint that corresponds to optimal primary stability remains elusive and is currently achieved qualitatively through surgeon's auditory and tactile senses based on personal experience [1]. Therefore, currently, there is no reliable quantitative method to assess quality of press fit fixation (primary implant stability) in the operatizing room.

In addition to materials and design of the implant, optimal primary implant stability is one of the most important factors necessary for long-term secondary implant stability, which occurs due to bone ingrowth (osseointegration) [2]. Micromotion at the bone implant interface should be less than 50 μm to promote osseointegration and prevent fibrous tissue ingrowth and aseptic loosening [3,4] while exceeding certain levels of circumferential strain and interference leads to fracture and bone necrosis [5]. Despite the success of total hip replacement surgery, a disturbing trend of increasing early failures ranging from 25% to 50% within 5 years after the index surgery has been documented in the last decade [6–8]. Additionally, aseptic loosening is the main cause of surgical failure for orthopedic implants [9,10]. A significant portion of all hip replacement surgeries (10–13%) is done for revisions, and within this group, aseptic loosening is the most common diagnosis [11–13].

From a practical perspective, surgeons are tasked with multiple cognitive demands when impacting the acetabular cup (Fig. 1), but with respect to press-fit fixation, all they need to know is how hard to hit and when to stop impacting. These two fundamental questions are significant as surgeons rely heavily on direct experience with skepticism in methods that tend to rely too much on data postprocessing. Several investigators have noted similar deficiencies in current techniques and developed experimental methods that measure time variations of force in the impacting tool (smart hammer) to asses primary implant stability [14,15].

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However, these methods, despite sophisticated signal processing, which provide information about progressive dampening at the implant/bone interface, do not provide the surgeon with a clear definition of optimal fixation end point. Additionally, while acoustic measurements and vibrational analysis have been used to assess implant stability and insertion endpoints [16–21], these techniques have been difficult to implement in the operative room due to noise and damping issues, which influence modal properties [21]. So far, no device has been developed to allow assessment of acetabular cup implant stability noninvasively and through direct evaluation of the implant/bone interface.

Additionally, current techniques of acetabular cup implantation involve impaction of the acetabular cup with a mallet. Despite the infusion of advanced technologies into multiple aspects of hip replacement surgery, the process of cup impaction with a mallet is primitive. The magnitude of forces utilized in cup impaction during hip replacement surgery is highly nonstandardized, while the resistive forces at the implant/bone interface are poorly quantified. While previous studies have recorded impact forces of 2–3 kN necessary to seat an acetabular cup using visual observation [22,23], some researchers have observed users imparting as high as 8.9 kN of force [24].

Optimal fixation implant fixation is a relative (not absolute) value, and determined by many factors, including bone site preparation, material properties of the bone and implant, implant geometry, coefficient of friction of the implant–bone interface, alignment, and depth of implant insertion. 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.

2 Materials and Methods

Rigid 20 lb polyurethane foam was selected for use as a substitute for the acetabulum due to similar material properties with cancellous bone (Table 1). The foam (BoneSim Laboratories, Cassopolis, MI) was prepared as $70 \times 70 \times 40\,\text{mm}^2$ blocks and reamed using a standard hemispherical 61 mm diameter reamer. A milling machine with custom fixture was used to ensure center alignment of the prepared cavity along with consistent reaming depth between samples.

Testing was performed using a Zimmer Continuum 62 mm diameter hemispherical acetabular cup (Ti-6A1-4V with Tantalum coating) with 1 mm press-fit. Selection of implant hardware and circumferential press-fit interference was performed based on clinical prevalence.

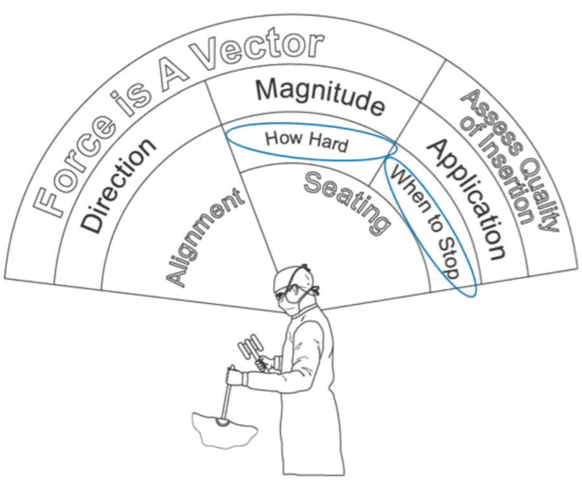

Fig. 1 Cognitive process during implant impaction: how hard to hit and when to stop

A test stand was utilized to perform weighted drop tests mimicking mallet strikes to imitate the range of forces generated in clinical setting. A custom fixture was used to align the sample and implant. A strike rod was threaded into the implant, and a low friction bushing was used to constrain the strike rod's polar and azimuthal angle relative to the pole of the implant. Impacts were generated by means of a 2 kg steel mass suspended at controlled heights above the strike rod. An 8900 N rated force gauge (± 5 N accuracy) was placed beneath the cup within the polyurethane sample, with a sampling frequency of 25 kHz. Insertion depth was determined by measuring the height of the implant face relative to the foam block before and after performing each strike (Fig. 2).

Eight drop heights were tested with a range of impact forces from 773 N to 7758 N. Five replications were performed for each height, with a total sample population of 40 units. For each sample, impacts were repeated at a selected drop height until implant displacement between impacts were within the measurement error of 0.05 mm, indicating the full seating for given impact energy. The number of impacts to seating was recorded and termed (NOITS). Once reaching this point, we measured the endpoint of cup displacement as final cup displacement. For each impact energy repeated over time, incremental cup displacement was measured and collectively referred to as cup insertion profile (CIP). Each CIP corresponded with a range of forces measured in bone, which in aggregate is referred to as measured force profile (MFP).

3 Results

Drop height attributes including impact energy, mean impact force, NOITS, cup insertion, and extraction force are shown in (Table 2). 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 (Fig. 3(*a*)). Past five impacts, the measured 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 (Fig. 3(*b*)). As the number of impacts increase at this drop height, the displacement per impact decreases. For a given drop height, the same impact force is repeatedly exerted on the implant over the course of seating. For example, for the 50 mm drop height, an average force of 2438 N was repeatedly exerted on the cup, requiring 27 impacts to fully seat the cup (NOITS of 27). Higher drop heights resulted in lower NOITS. As shown in Fig. 3(*c*), as the insertion force (corresponding to different drop heights) increases, the number of impacts required to achieve seating (NOITS) decreases. A proof of principle in Fig. 3(*d*) demonstrates the plateauing of cup insertion with increases in drop height (indicated by dashed black lines).

Figure 4 demonstrates that both the cup displacement and axial extraction force increase with insertion force; initially linearly, then nonlinearly, and finally plateau. Note that the insertion forces in Fig. 4 represent the average measured insertion forces required to achieve final seating (maximum seating after a given number of impacts, as seen in Fig. 3(*c*)). The cup displacement and extraction force both begin to plateau around 4000 N, producing approximately 5.6 mm of cup displacement and 765 N of extraction force. This region represents approximately 89% cup insertion and 88% extraction force.

4 Discussion

Figure 3(*a*) demonstrates that a given impact force, repeated over time, results in a given range of cup insertion depths CIP, which produces a corresponding measured force pattern in bone MFP. CIP and MFP are produced over certain number of impacts NOITS when a given impact energy is repeated over time. NOITS

Table 1 Comparison of material properties between rigid polyurethane foam with cancellous and cortical bone [25]

	Polyurethane foam, 20 lb	Cancellous bone	Cortical bone
Density (g/cc)	0.32	0.3–1.2	1.4–1.9
Hardness (Shore D)	35	35–80	85–95
Compressive strength (MPa)	8.4	2–20	100–182
Elastic modulus (GPa)	0.6	7–11	7–30

is inversely related to rate of insertion, where a high value for NOITS represents slow rate of insertion, and a low value for NOITS represents rapid rate of insertion. The first- and second-order relationships of MFP with respect to NOITS, characterized by *when* ΔMFP approaches zero and *how fast* ΔMFP approaches zero, provide two distinct metrics that can be utilized to assess optimal implant stability.

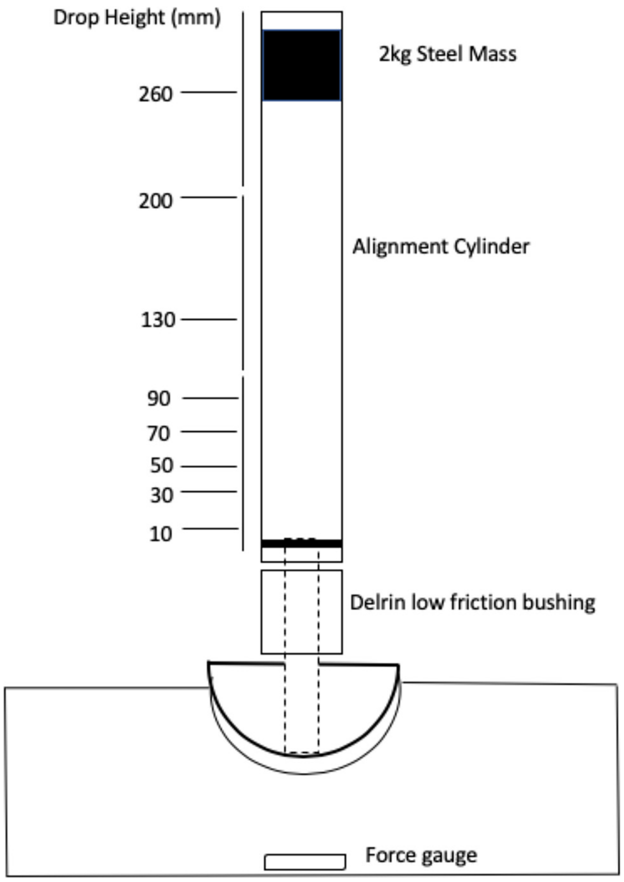

Fig. 2 Test stand

Measured force profile results from the change in the 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 in bone for each impact. The maximum force measurement 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 change either the insertion of the cup or the measured force in bone.

The variety of drop heights tested correspond to different average insertion forces per impact. Figure 3(*c*) shows that as the average force per impact increases, the number of impacts required to seat the implant (NOITS) 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 resulting in a large polar gap. Additional impacts at this 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, where the cup is observed to be fully seated. This range of impact forces reflects a realistic force range that surgeons exert during hip replacement surgery [23]. Figure 4(*a*) represents the endpoint result of the plot shown in Fig. 3(*a*), but for a range of drop heights. Figure 4(*a*) shows that for the weighted drop test producing progressively increasing impact forces, the extraction force and cup displacement initially increase linearly with insertion force, then nonlinearly at an inflection point, and finally plateau. This plateau suggests maximum (full) seating of the implant, where additional cumulative applied forces do not further contribute to axial implant stability or final insertion depth.

Notably, approximately 90% of cup insertion and 90% extraction force were achieved within the nonlinear zone, with only 50% of total energy required for full insertion. This phenomenon, if replicated in the clinical setting, would beg the question as to why one should apply an additional 4000 N of force and risk fracture, just to obtain the final 10% insertion and pullout force? We contemplated that if this “nonlinear zone” could be attained reliably and consistently, it can be considered a better and safer endpoint than the current standard of full seating. We termed this concept best fixation short of fracture (BFSF). A theoretical

Table 2 Drop height attributes: impact energy (J), mean impact force in bone (N), number of impacts to seating (NOITS), cup insertion (mm), extraction force (N)

Drop height (mm)	Impact energy (J)	Mean impact force (N)/SD		Number of impacts to seating (NOITS)/SD		Cup insertion (mm)	Extraction force (N)/SD	
10	0.2	774	(178)	52	(5.9)	1.4	71	(23.6)
30	0.6	1641	(93)	47	(4.0)	3.5	258	(33.1)
50	1.0	2437	(66)	27	(6.1)	4.7	480	(36.2)
70	1.4	3104	(156)	23	(2.1)	6.0	676	(26.9)
90	1.8	3927	(151)	16	(2.9)	5.6	765	(35.7)
130	2.5	4870	(472)	9	(0.8)	6.1	827	(47.7)
200	3.9	6818	(340)	6	(0.4)	6.2	849	(31.8)
260	5.1	7757	(593)	3	(0.5)	6.3	867	(51.3)

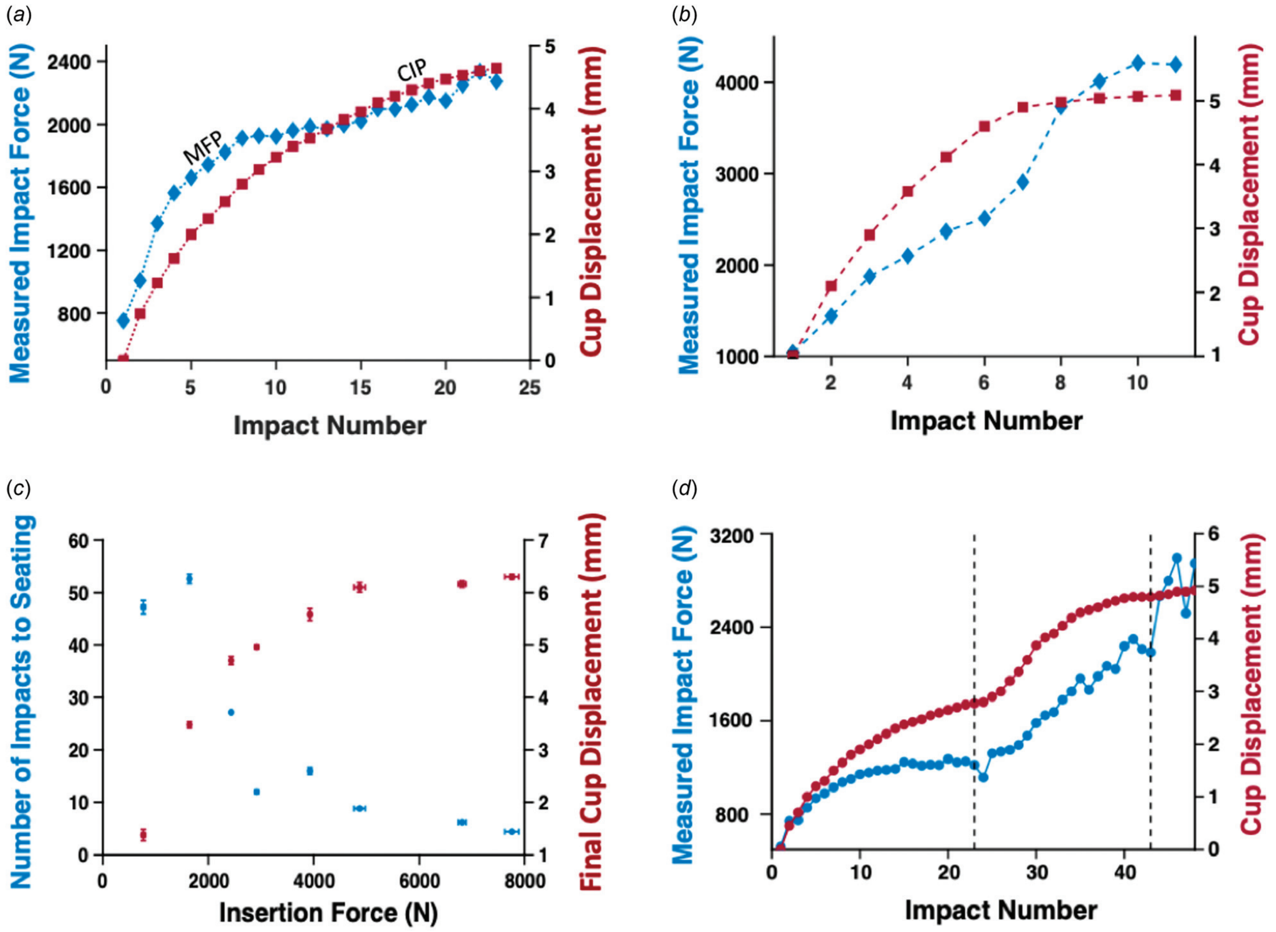

Fig. 3 **(*a*) The relationship of measured impact force experienced in the cavity (MFP) versus cup insertion (CIP) for a 50 mm weighted drop test. (*b*) The relationship of measured impact force experienced in the cavity (MFP) versus cup insertion (CIP) for a 90 mm weighted drop test. (*c*) The relationship of NOITS and final cup displacement with insertion force. (*d*) Proof of principle with three graduated applications of drop height forces (indicated by black dashed lines).**

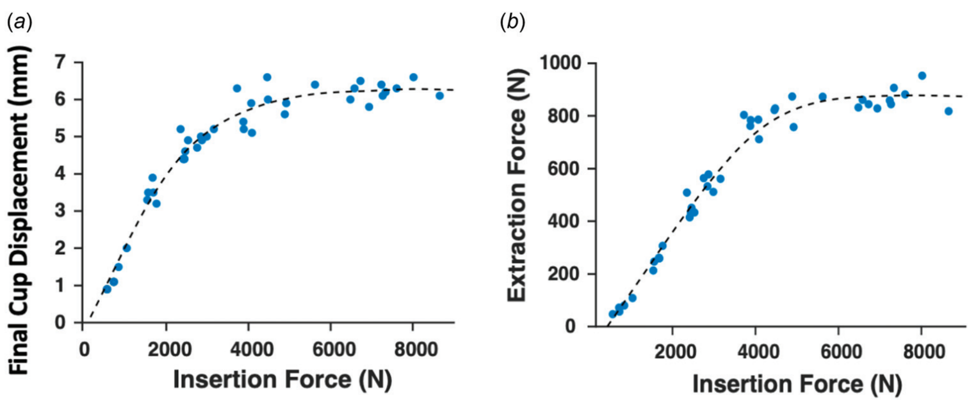

Fig. 4 **(*a*) Insertion force versus final cup displacement for drop testing (smoothing spline fit, $R^2 = 0.957$). (*b*) Insertion force versus axial extraction force for drop testing (smoothing spline fit, $R^2 = 0.981$).**

abstraction of this concept is shown in Fig. 5. Similar situations are frequently experienced by clinicians in the operating room where significant increase in impaction force is typically required to overcome the final 1 or 2 mm polar gap.

Figure 6 demonstrates the CIP and MFP for a constant repeated impact energy of 1 J, where it took an NOITS of 27 to seat the cup a maximum of 4.7 mm for an extraction force of 480 N. The first- and second-order relationships of MFP with respect to NOITS, characterized by when ΔMFP approaches zero and how fast ΔMFP approaches zero, provide two distinct metrics that can be considered the *force footprint* and the *rate of insertion footprint* for a given impact energy. When ΔMFP approaches zero, additional impacts at 1 J do not increase cup displacement or extraction force, no matter how many times this level of impact energy is repeated. The surgeon can increase impact energy to the next level. Therefore, monitoring the force footprint provides an answer to the first question posed at the outset, “how hard should I hit?” How fast ΔMFP approaches zero provides an indication of

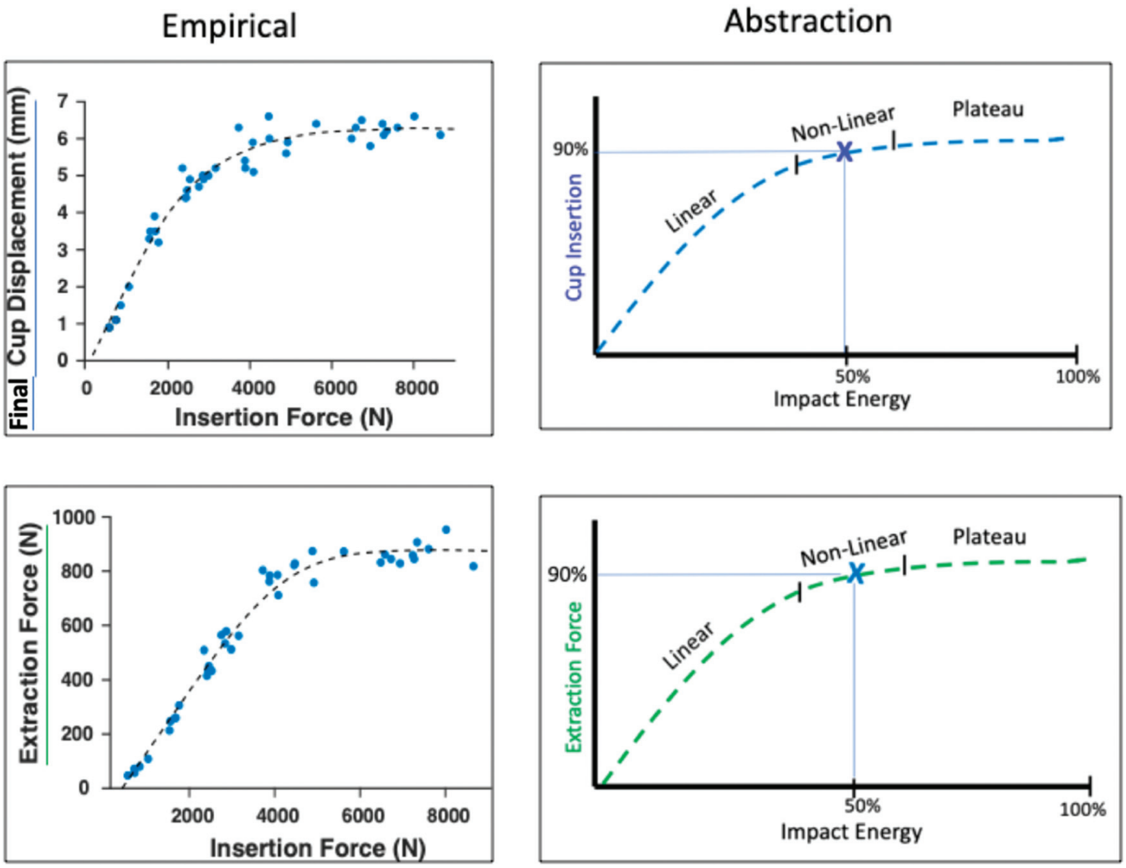

Fig. 5 Theoretical abstraction of BFSF at the nonlinear zone

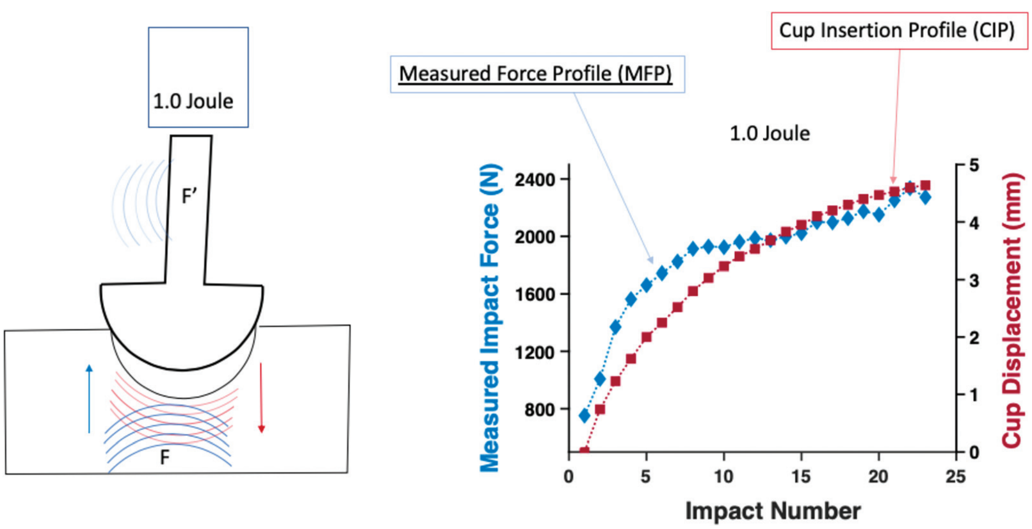

Fig. 6 CIP and MFP at 1 (J) impact energy repeated over time, producing 4.7 mm of cup insertion over NOITS of 27 for an extraction force of 480 N

the residual elastic capacity at the rim, for when an increase in impact energy results in a step cut increase in MFP, the elastic capacity of the cavity is likely exhausted, suggesting that impaction should not continue beyond this level. Monitoring the rate of insertion footprint answers the second question, "when should I stop impacting?" Impaction should stop at low levels of NOITS (high rates of insertion).

Therefore, the two metrics, referred to as force and rate of insertion footprints, represented by the first- and second-order relationships of MFP as a function of NOITS, can be tracked to provide two simultaneous binary decisions: (i) increase force or not and (ii) continue to impact or not, which allow the surgeon to monitor incremental cup insertion in order to reach the nonlinear zone. We termed this endpoint BFSF, which is distinctly different from the endpoint of full seating. In other words, if impact energy can be controlled, modulated, and delivered incrementally, the two metrics obtained through simple computations can be utilized to quantitatively determine the best possible end point for press fit

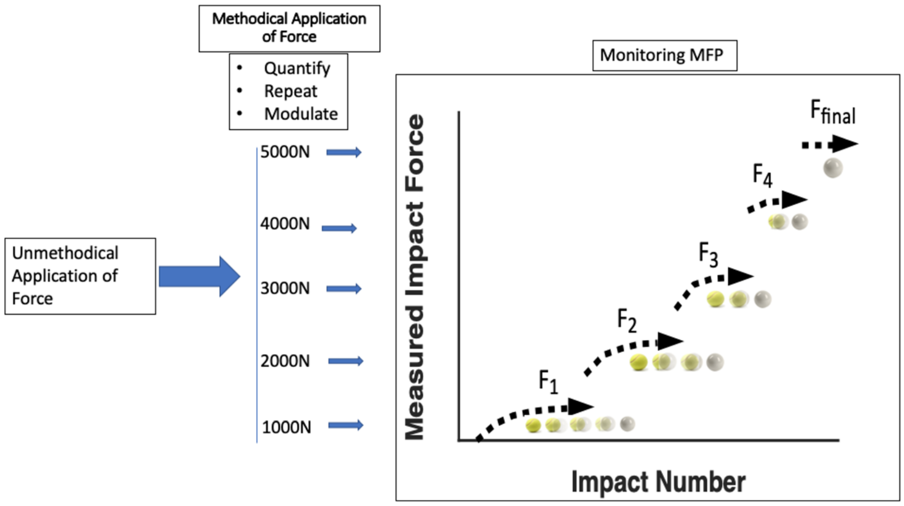

Fig. 7 Hypothetical plot of series of MFPs as a function of impact number, produced as a result of methodical incremental application force

arthroplasty. This method has the promise of achieving optimal primary stability for each individual implant/bone interface regardless of the patient's age, sex, skeletal health, and the implant used.

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 Fig. 7 with a hypothetical plot of series of MFPs as a function of impact number, produced as a result of methodical (quantified, repeated, and modulated) application of force.

In light of the observed relationships between measured 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 Fig. 8). After each application of a known impact energy, the force is measured until it reaches a constant value. When the change in measured force approaches zero, the selected impact energy produces no further cup insertion (or extraction force), and the measured force in bone plateaus over NOITS. This would enable a decision as to whether impact energy should increase or not. Monitoring NOITS for impact energy 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 energy to the next level, whereas low NOITS warns of low residual elasticity in the cavity. With respect to actuation, simple devices utilizing a strike object accelerated by mechanical springs, magnetic fields, or gravity could be developed to apply controlled impact energies.

Several researchers have described alternative methods of assessing optimal stability including vibration analysis (acoustics and modal frequency) and impact analysis (smart hammer-time variation of force). Even though these advanced technologies hold high promise, they are most significantly limited by their reliance on mallet-based techniques, and are considered open loop systems, where the output is not feedback for comparison with the input. Figure 9 shows a shows schematic of open loop systems used to assess implant stability.

The BFSF method is a closed-loop system analogous to active sonar where the output is feedback for comparison to allow adjustments of energy for a desired fixation outcome. In contrast, the current mallet-based systems are analogous to passive sonar

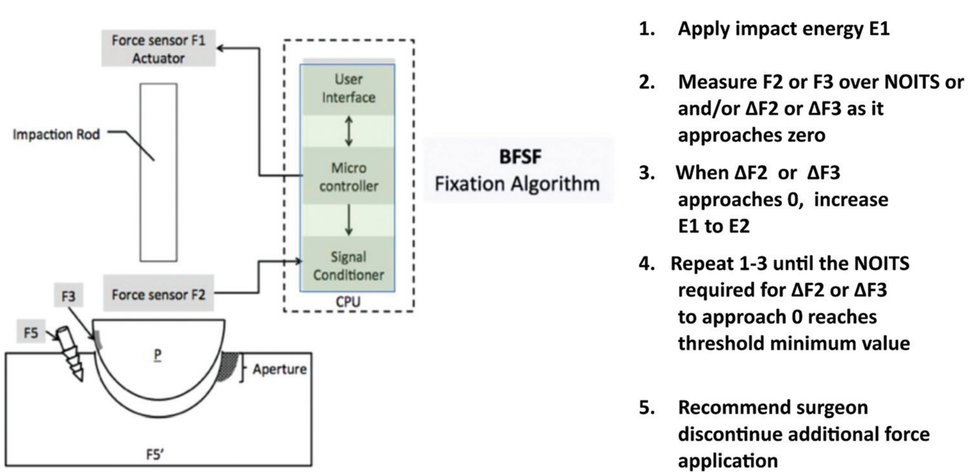

Fig. 8 Conceptual layout of fixation algorithm: BFSF, and automatic prosthesis installation device

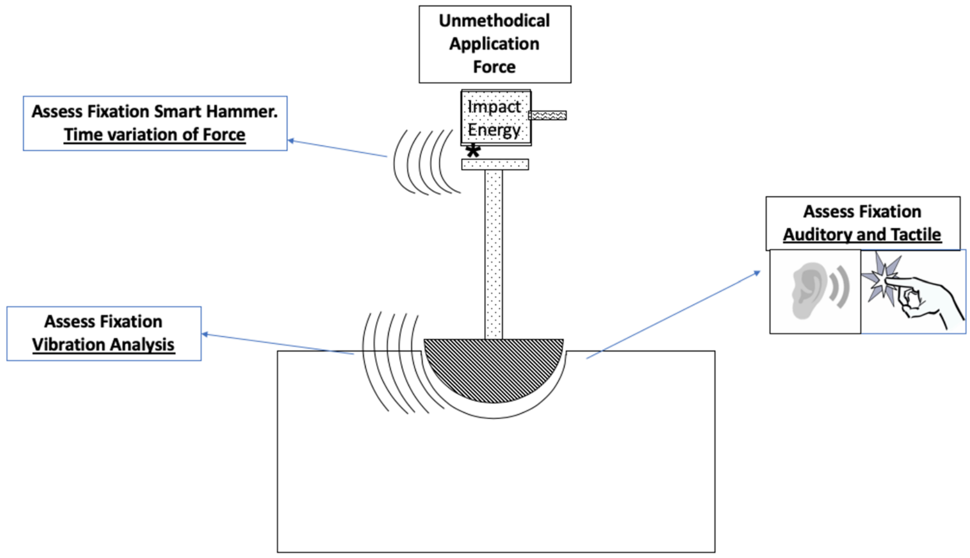

Fig. 9 Open loop systems used to assess implant stability, where output is not feedback for comparison to the input

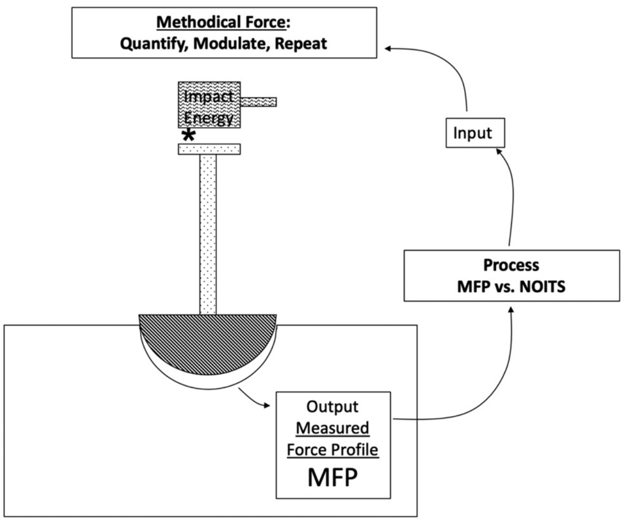

Fig. 10 Closed loop system used to assess implant stability, where output is feedback for comparison to the input to allow adjustment of energy for desired fixation outcome

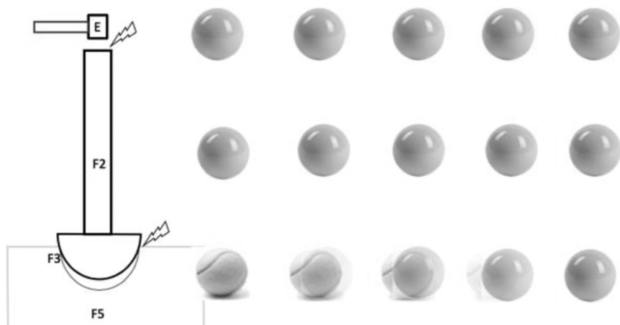

Fig. 11 Distal collision always moves from inelastic to elastic (compliance to noncompliance) producing CIP, MFP, force and rate of insertion footprints. The force fields around the distal collision: F2 (force measured in impacted tool), F3 (force measured at interface), F5 (force measured in bone).

where no feedback mechanism exists to allow for adjustment of energy. We believe the BFSF method holds promise for standardization of assembly parameters for press-fit fixation in joint arthroplasty Fig. 10.

Furthermore, with respect to alternative methods, certain challenges still remain due to basic assumptions inherent within the technologies, most significant of which is the supposition that progressive stiffness and firmness of the implant/bone construct signifies deep seating, firm contact, and therefore good fixation. From a clinical perspective, this assumption has clear limitations, as surgeons will attest that a cup that is too oversized in a young healthy bone (i.e., oversized by 2 or 3 mm) will partially insert, become very firm and stiff with excellent fixation, but be far from seated with a large polar gap. Similarly, a cup that is minimally oversized (i.e., 0.5 mm) in osteoporotic bone may seat deeply become firm with full contact but have extremely poor fixation. Progressive stiffness, rigidity, and firmness of an implant–bone interface, therefore, do not necessarily translate into adequate seating or optimal fixation. This phenomenon may be at least one explanation for the lack of success of vibration techniques in assessing implant stability in cadaveric bones [16]. Additionally, while the smart hammer has the advantage of measuring an aspect of the implant/bone interface live and in real-time during the insertion process, vibration, and acoustic analysis measure fixation “after the fact” (pre-and poststrike). Finally, both techniques appear to provide information about the absolute stiffness of the press-fit implant, whereas optimal stability of an implant for any particular patient is a relative value and is significantly different for each implant/patient interaction. A certain level of implant/bone stiffness maybe good for a 50-year-old large male but be detrimental for an 80-year-old small female.

5 Conclusion

We note the process of press fit arthroplasty involves proximal and distal collisions. The proximal collision is always elastic, while the distal collision is always inelastic and becoming elastic with decreasing NOITS. In other words, the distal collision always progresses from compliance to noncompliance, which produces CIP, MFP, the force and rate of insertion foot prints Fig. 11. We hypothesize that the progression from compliance to noncompliance in the distal collision produces force patterns in the tool and at the interface similar to those observed in this work (MFP) 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. The most valuable information gleaned from this work was related to the force relationships between the "impacting" object, the "impacted" object and bone, during the implantation process.

Our study had significant limitations. It is believed that majority of the grasping force of the acetabular cup occurs at the rim, where the bone is more compact, cortical and more homogeneous in nature. Our bone proxy was a 20 lb polyurethane foam with similar characteristics to cancellous bone, which has significantly lower modulus and compressive strength than the cortical rim. It would be of great interest to see if the same relationships discovered in this study are reproduced with different density bone proxies. The sample sizes were limited, and adequate resources were not available for higher quality sensing equipment. Future studies are recommended with larger sample sizes, using artificial bone blocks or hemipelvis with higher densities, as well as cadaveric bone. Of significant interest would be a comparison of the two endpoints of BFSF and full seating through mallet-based techniques in relation to extraction force and fracture incidence.

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- Kambiz Behzadi MD (Behzadi Medical Device LLC).

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