

Monitoring Femoral Component Insertion In Cementless Total Hip Arthroplasty

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Abstract

With emerging minimally invasive surgical techniques in total hip arthroplasty, there has been an increase in fractures associated with the insertion of the prosthesis into the femur. Diminished visibility necessitates a greater emphasis on the surgeon's tactile and auditory senses to ascertain the femoral component position, ensuring maximum stability and interference fit and prevention of further component impaction and subsequent fracture of the femur. Because of the smaller incision, it is not possible to take measurements directly on the bone. Measurements must therefore be taken proximally on the femoral component. The work described in this study attempts to identify a means to supplement the surgeon's tactile and auditory senses by using damage identification techniques normally used in civil and mechanical structures to monitor the insertion process of the prosthesis. It is hypothesized that vibration characteristics of the impact process may be used intra-operatively to determine at what position the femoral component has reached maximal interference fit and stability in the femur, referred to as "seating." Such information can be used to prevent further impacts and potential fracture. An ICP accelerometer was used to monitor the impact process. This paper summarizes features derived from the measured data that will be used to develop a dynamic seating indicator.

Nomenclature

M_n n^{th} spectral moment
 ω Frequency
 $f(\omega)$ Magnitude of FRF
 α Holder Exponent
 K Y axis intercept

Cancellous - bone located in the center of long bones having a porous structure

Intramedullary canal - central portion of long bones that contains soft, cancellous bone

Proximal - nearer to center of body

Arthroplasty - process of reshaping or reconstituting a diseased joint

Femur - thighbone

Prosthesis - implant or implants that comprise the components of an artificial joint

Introduction

The medical community has highlighted the importance of less invasive surgery because benefits include: smaller drug doses, increased post-surgery mobility, reduced muscle atrophy, decreased hospital stays, and increased

patient morale [1]. However, as surgeons use smaller incisions in total hip arthroplasty (artificial hip replacement) to decrease patient recovery time, they are causing an increased number of femur fractures [2].

The fractures incurred during surgery result from the bone failing in the circumference. Jasty, et al. [3] report the occurrence of femur fractures to be as high as 20% for uncemented total hip arthroplasty with a standard incision length of 25.4 cm (10 inch). The uncertainty in this clinical study is due to the variability of both surgeon skill and bone properties among patients. It is understood that the femur will fracture if it is subjected to an excessive hoop stress generally caused by over-insertion of the femoral component. Furthermore, striking the wedged shaped implant after it has been correctly seated can raise the hoop stress, thereby increasing the risk of femur fracture. The fracture length can vary along the length of the femur.

Unfortunately, many fractures are not visible to the surgeon. This problem can be exacerbated when surgeons use smaller incisions, as is becoming common with less invasive techniques. Choosing the proper prosthesis size, creating recesses of appropriate size into which the prosthesis will mate, and knowing when the prosthesis is properly aligned are important components to avoiding high hoop stress situations [3]. Diminished visibility resulting from smaller incisions necessitates a greater emphasis on the arthroplasty surgeon's tactile and auditory senses to ascertain the femoral component position in the operating theater.

This research is essential because femoral fractures during surgery may cause movement of the prosthesis relative to the femur during normal post-operative activities. This movement can inhibit bone growth into the porous coating on the device, increasing the probability of loosening. As a result, the benefits of less invasive techniques can be negated if a second surgery is required to correct the loosened prosthesis.

Many cadaver studies have been done to characterize the hoop stress created during impaction [3-6]. Significant instrumentation on the femur, such as photoelastic coatings and strain gauges, were allowed for these studies. Use of these techniques, however, is not appropriate in the operating theater, and non-invasive methods characterizing the femoral component position are lacking. The motivation of this paper is to begin defining such a non-invasive technique. In this research, the insertion of a hip prosthesis in surrogate bone has been dynamically monitored using fully removable sensing hardware. Dynamic features that indicate seating were found that show promise for real world application. It was hypothesized that a feature could be found that fully describes when the system has been completely assembled. Impact response tests were performed on the prosthesis in a surrogate bone test bed at varying levels of insertion. Frequency response functions (FRFs) were analyzed for features indicating the placement of the prosthetic device. Additionally, MATLAB (The Mathworks, Natick, MA) was employed to create analytical tools to quantify the identified features. These techniques were compared to determine which feature gave the best indication of proper seating of the prosthesis. A commercially available hip prosthesis was used in this study.

Method

In surgical practice, the installation of the uncemented hip prosthesis requires an interference fit into the proximal femur. The prosthesis can be seen in Figure 1. First, the neck and ball of the femur are removed and the intramedullary canal is reamed. Then, a rasp (broach) is used to create the geometry necessary for the proper interference fit of the hip prosthesis. Specialized impact tools are used to hammer the prosthesis into the cavity until it is correctly seated in the proximal femur. Proper seating occurs when the flange makes contact with proximal surface of the femur. The surgical tools commonly used during clinical installation were made available by the prosthesis manufacturer for this study to create a tapered hole with dimensions necessary for a proper press fit.

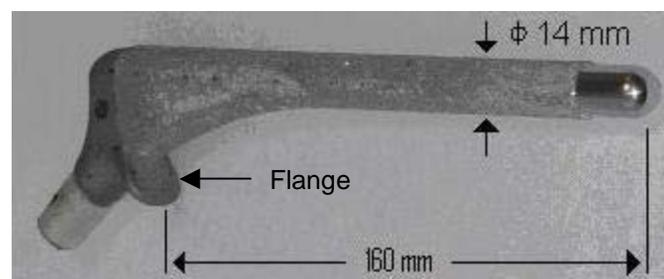


Figure 1: Hip Prosthesis

The 19.1 cm (7.5-inch) test bed of surrogate bone, identified Figure 2, was constructed from a 5.08 cm (2-inch) polyvinyl chloride (PVC) pipe filled with SG200 vacuum cast polyurethane (Huntsman Advanced Materials, East Lansing, MI). A 14-mm (0.551 inch) through cavity was created to simulate the intramedullary canal. Using the broaches, a surgically accurate hole was created in the test bed to accommodate a press fit of the femoral implant.

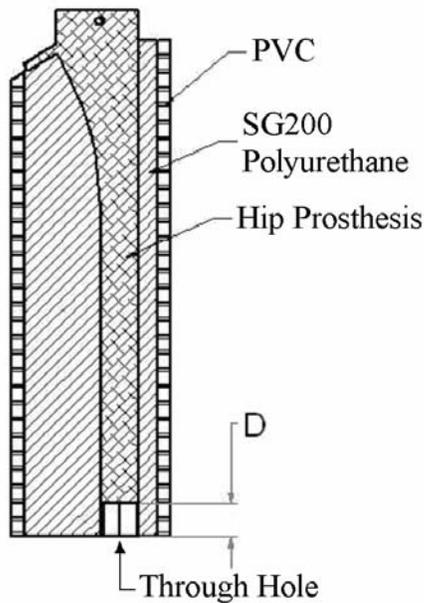


Figure 2: Section view of test bed with illustration of measured depth

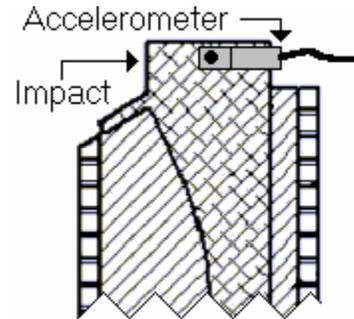


Figure 3: Impact and Accelerometer Location

With the surgical hammer and punch provided, the prosthesis was driven into the test bed to multiple depth levels. A depth gauge was used to measure the distance, D , between the bottom of the prosthesis and the bottom of the test fixture via a through hole. Impact response tests were then performed with the prosthesis at the different depths. A removable shock accelerometer (PCB Piezotronics, Inc., Depew, NY, Model 350B04) was used to measure the vibration characteristics of the hip prosthesis, and an impact hammer (PCB Piezotronics, Inc., Depew, New York Model 086C05) provided the force input to the prosthesis. At each depth, the impact hammer provided an excitation in the direction of the accelerometer's measurement axis. This is depicted in Figure 3. During the excitation and measurement, the test bed and femoral component were placed on foam between two pieces of board at the most proximal and distal points. The experimental setup can be seen in Figure 4.



Figure 4: System suspended on each end between wood planks by foam

A Dactron Photon (LDS Test and Measurement LLC, Charlotte, NC) dynamic signal analyzer and a laptop computer were used for data acquisition. RT Pro Analyze Anywhere 3.31 software was used to set the measurement parameters and to calculate spectral quantities. The software was set to a range of 0 to 4000 Hz (97.7 μ s) taking 2048 points of data. The hammer input served as a trigger for both input and output measurement channels. No windowing was used. After an impact with the hammer, the time history of each input channel was taken and the frequency response function, power spectra, and coherence were calculated. Five data sets were measured at each depth, D , with each data set consisting of the averaged spectra from ten impacts. The prosthetic device was extracted and this process was repeated on the same test bed. Because the fully seated condition requires the flange to be in complete contact with the bone surrogate, the final hit required a

negligible change in depth to satisfy this state. The change in depth between the last two depth intervals could be visibly determined when a light was shone between the flange and test bed, but not measurable with the depth gauge used. A list of the measurement depths can be seen in Table 1. MATLAB was then used for further data analysis and manipulation.

Table 1: Depth Intervals		
Depth Interval	Data Set 1	Data Set 2
1	3.18 cm (1.25 inch)	3.25 cm (1.28 inch)
2	3.10 cm (1.22 inch)	3.02 cm (1.19 inch)
3	2.94 cm (1.16 inch)	2.94 cm (1.16 inch)
4	2.78 cm (1.09 inch)	2.86 cm (1.13 inch)
5	2.70 cm (1.06 inch)	2.778 cm (1.09 inch)
6	2.62 cm (1.03 inch)	2.70 cm (1.06 inch)
7	~2.62 cm (1.03 inch)	2.62 cm (1.03 inch)
8	N/A	~2.62 cm (1.03 inch)

Results

The most prominent feature in the FRFs is a peak growing larger and shifting in the 1200-1500 Hz band as the femoral component is inserted deeper into the surrogate bone, seen in Figure 5. The peak that evolves suddenly changes shape at a depth of 2.70 cm and then returns to the shape of the original data. Once the data was extracted from the frequency band of interest, three methods of data analysis were performed using MATLAB. The methods included analyzing the locations of the maximum magnitude resonance and anti-resonance, spectral moments, and global Holder exponents. Then, the results of each of these analyses were compared to determine which approach best described the placement of the hip prosthesis.

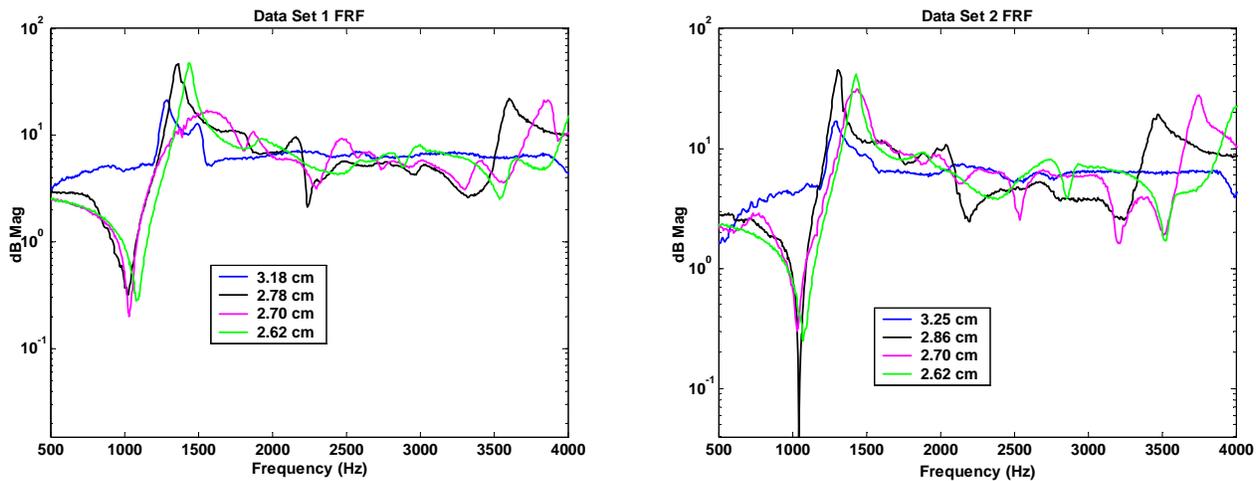


Figure 5: Frequency Response Functions of selected data over a selected range for each data set

As a first feature to analyze, the frequency of the resonant peaks and anti-resonant valleys were analyzed. The resonances and anti-resonances were tracked within the frequency band to observe, in a very simple way, which modes had the most energy in the measurement direction of the accelerometer. If the frequencies are examined over the entire band, it can be seen that there is a definite shift in the dominant mode from around 1200 Hz to around 4000 Hz for the peaks as the prosthesis is implanted, and then the maximum peak shifts back. There is no corresponding shift in the antiresonances (See Figure 6). The shift in the peak with the maximum magnitude indicates a significant change in the system; perhaps the prosthesis has been implanted to some critical depth where the geometry changes the dynamics of the significantly; perhaps at this point some part of the surrogate bone yields, etc. The depth at which this occurs is at about 2.70 cm for data set 1 and at about 2.62 cm for data set 2, an indication that seating of the prosthesis is imminent.

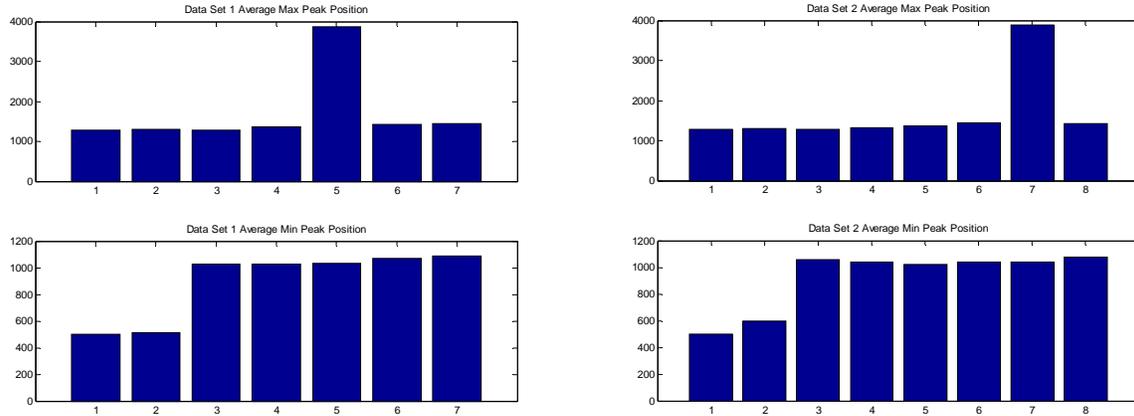


Figure 6: Frequency of the maximum magnitude resonance and antiresonance

The next features examined were spectral moments. The moment concept was first applied in transient dynamics for signal characterization [7] and has since been used successfully in other structural dynamics applications [8,9]. Spectral moments applied to impedance signals have been successfully used to identify damage by Rutherford, et al [9]. Spectral moments may be calculated as

$$M_n = \int_{\omega_l}^{\omega_r} \omega^n f(\omega) d\omega \quad (1)$$

where M_n is the n^{th} moment (starting with zero), the interval $[\omega_l, \omega_r]$ is the frequency band of interest, $f(\omega)$ in this case, is the magnitude of the FRF. All moments are typically normalized to the zeroth moment. The zeroth moment may be thought of as the energy contained in the bandwidth of interest. The first moment may be thought of as the centroid, or the frequency that divides the energy content of the bandwidth in half.

For the application of inserting the hip implant into the surrogate bone, the moments were calculated for each data set taken at each impact depth in the frequency band of 500-4000 Hz (moment features were also examined over the range of 500-2000 Hz, but results were less conclusive). Also, a statistical normalization procedure was applied. Moments calculated at the first impact depth were normalized by subtracting the mean and dividing by the standard deviation of the five datasets taken at that depth. Then for each successive depth, the moments were normalized in the same manner to the previous depth. This gives an idea of how each impact depth differs from another.

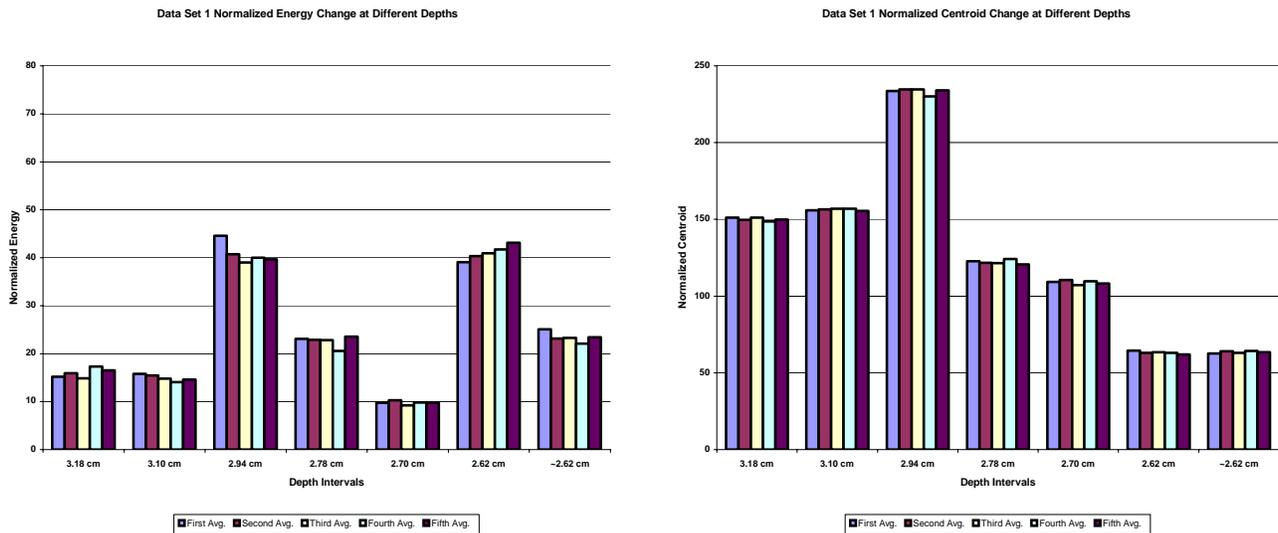


Figure 7: Spectral moments for Data Set 1 calculated to in the frequency band of 500-4000 Hz

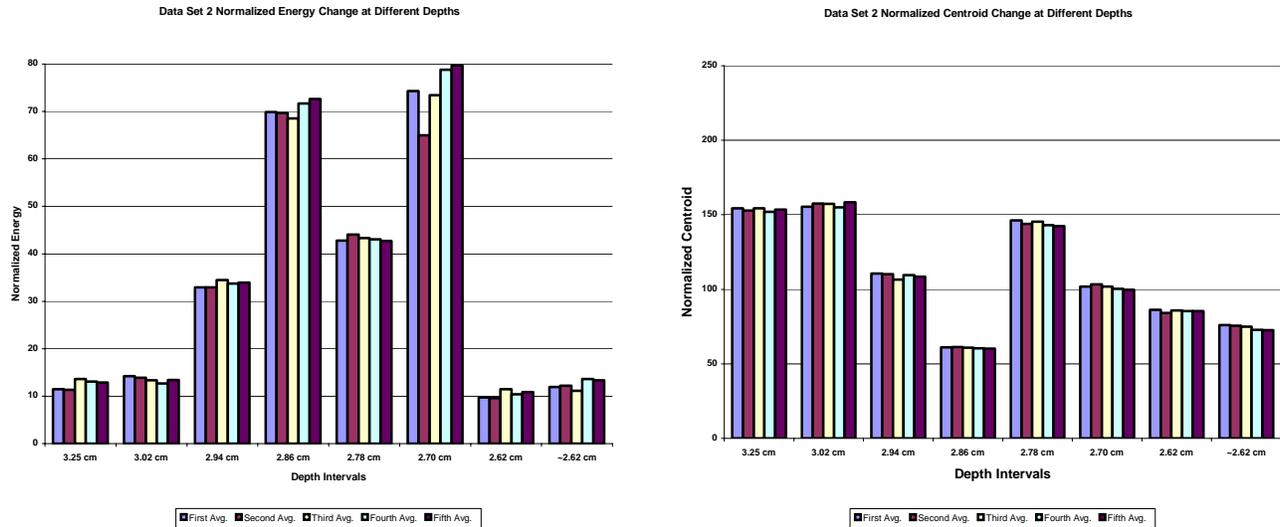


Figure 8: Spectral moments for Data Set 2 calculated to in the frequency band of 500-4000 Hz

Unfortunately, these plots show that the spectral moments are not definitive indicators of seating in the system. Examining the spectral energy, data set 1 shows significant change at a depth of 2.94 cm and 2.70 cm, indicating a change earlier than the resonance tracking method revealed. Data set 2 also shows two depth positions at which change system occurs in the system, 2.86 cm and 2.70 cm. While it is encouraging that large changes occur at the depth of 2.70 cm again, when seating is imminent, the changes at 2.94 cm and 2.86 cm are more difficult to explain. Results from examining the spectral centroid are less conclusive; for data set 1, the change occurs early on, and for data set 2, there are no definitive changes at all.

Another damage feature extracted from the two trials was the global Holder exponent. Robertson, et al. [10] showed that singularities in a structure (such as a rattle, or in this case the seating of the implant) could be found by tracking the Holder exponent of the wavelet transform of the acceleration time history. Qualitatively, the holder exponent is a measure of how continuous or regular the signal is. The signal is only of importance at very particular times, such as, after each impact of the implant. Therefore, calculation of the global Holder exponent, which may be derived from the magnitude of the FRF (as opposed to calculating it from the wavelet transform, which would be for many time points) was performed.

For each data set, the FRF is transformed to log-log space. Then, over the bandwidth of interest (500-4000 Hz) a line was fit to the FRF. The resulting slope of the line is the Holder exponent, that is

$$\text{Log}(Mag) = \alpha \text{Log}(\omega) + K \quad (2)$$

where α is the Holder Exponent, ω is the frequency and K is the intercept. The Holder exponent was calculated for each of the 5 datasets taken at different depths and the mean and standard deviation calculated. It can be seen in Figure 9 that for both trials, the Holder exponent starts near zero. This is not a surprising result. At the beginning of the test, when the implant has not been impacted, it can be expected to be “loose” in the reamed hole of the surrogate bone and, as a result of the increased damping and noise introduced by the “looseness,” the peaks in the FRF are poorly defined. This is evident in Figure 9 at depths 3.18 cm and 3.25 cm on Data Set 1 and 2, respectively. This causes the fitted line to become flatter and hence we calculate a lower Holder exponent value. As the implant is further inserted, however, the bone and implant act more as a system and the resonances and antiresonances are more clearly defined. The fitted line begins to have a small positive slope resulting in a steadily increasing Holder exponent value. This is illustrated in Figure 10. Seating of the implant flange (again causing damping/high frequency noise content) may be marked by the drop in the Holder value at a depth measurement of between 2.7 cm and 2.6 cm. Variation in seating depth could be caused by the surrogate bone being used twice causing the hole to become larger. Of the three, feature extraction methods examined, the global Holder exponent holds the most promise for developing a definitive assembly identification technique.

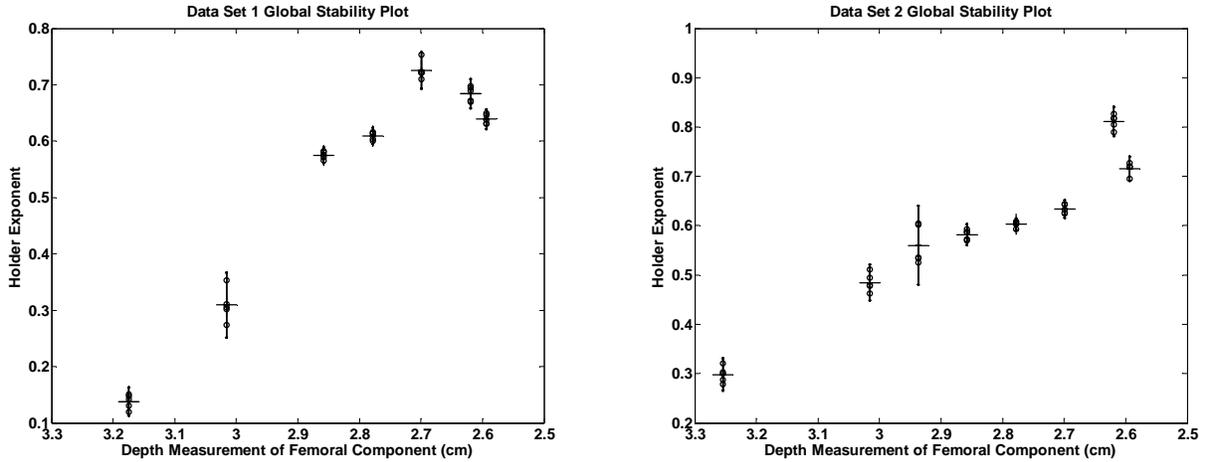


Figure 9: Global Holder Exponent for each data set

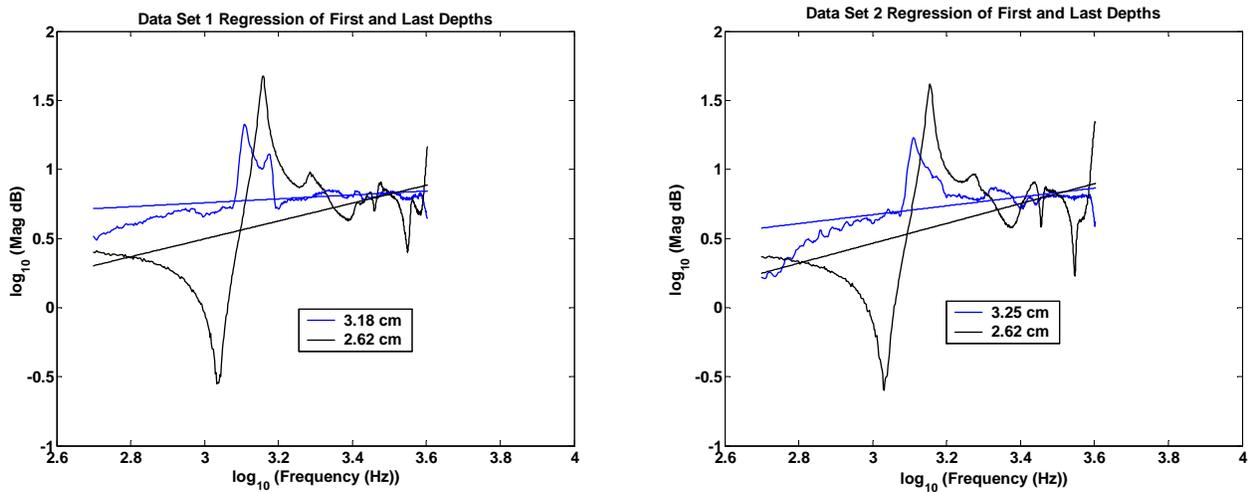


Figure 10: Holder Exponents for First and Last Depths of Each Data Set

Future Work

Novel methods used in this study have indicated that it may be possible to solve the unique problem of seating of the femoral component during insertion. It must be emphasized that while the methods presented, especially the Global Holder exponent, show promise as seating features, further testing must be done. Different surrogate bone test beds should be utilized so that the prosthesis is freshly implanted each time. In the current set of experiments, it is likely that the seating depth was affected by the reuse of the surrogate bone in data set 2, causing the implant to seat at a slightly deeper depth. Additionally boundary conditions could be more rigorously controlled, as there was no way to gage if the test article was being placed on the foam in exactly the same configuration each time. Eventually, surrogates that have a higher fidelity to real bone material should be utilized. Closely matching the anisotropic properties of bone and developing techniques to simulate the patient bone quality variability will be an essential step in qualifying any technique in the orthopedic field of study.

Analyzing and taking the data in future efforts could be refined. Methods of data analysis not explored by the authors could be employed to better characterize the data. Gathering data during implant impaction, instead of between hits would be more useful in the operation theater. This would allow for two important goals to be met. First, the operation could proceed without requiring the surgeon to test the placement of the device between hits.

Second, the time histories can be analyzed with the Holder exponent of the wavelet transform. Because the global Holder Exponent proved to be the most effective method of analysis, data gathered during implant impaction, specifically time histories, may prove to be a more effective method of analysis. This would allow for use of the Holder Exponent of the wavelet transform, thus depicting the singularities of the flange hitting the bone.

Finally, the ultimate solution to this problem cannot impede activity or break federal guidelines within the operating theater. The surgeon must be able to use the tools effectively without hindrance of precision movement from the operating staff. Using techniques written into a computer program would expedite the surgery by allowing the surgeon and operating room technicians to concentrate on the surgery, instead of the new technology created to increase precision. The final product must be able to withstand repeated sterilization to satisfy the rules and regulations of the Food and Drug Administration. Because the sensors have not been approved for long term use within the body, they must be removed once the device has been properly installed.

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