Monitoring Femoral Component Insertion During Uncemented Total Hip Arthroplasty

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ABSTRACT

With emerging minimally invasive surgical techniques in total hip arthroplasty, there has been anecdotal evidence of an increase in periprosthetic fractures associated with the insertion of the prosthesis into the femur. This is likely the result of diminished visibility, auditory and tactile feedback for a surgeon operating through much smaller incisions. This study attempts to identify a means to supplement the surgeon's tactile and auditory senses by using damage identification techniques, typically used in civil and mechanical structures, to determine when a cementless femoral implant is fully seated. A tapered femoral component was instrumented with accelerometers and a PZT patch and data was obtained as the femoral component was being impacted into a third generation replicate femur. Five replicate femurs were prepared for a cementless femoral component by an orthopedic surgeon using standard implant-specific instrumentation. Acceleration measurements were taken in the direction of impaction and in the two transverse directions. Signal processing techniques were applied to the acceleration time histories to determine if features exist that can be used to determine when the implant is fully seated. The PZT patch was used as an actuator, as well as a sensor, and impedance measurements were taken to determine if impedance could be used as a feature. This paper discusses the experimental set-up, the signal processing techniques used, and the subsequent results.

INTRODUCTION

Total hip replacement reliably and reproducibly eliminates pain in patients with end-stage osteoarthritis or osteonecrosis of the hip and is one of the most consistently successful surgical procedures in medicine. Recently, new surgical techniques in total hip arthroplasty, termed "minimally invasive", have been introduced and are reported to offer numerous advantages over standard surgical approaches. These advantages include shorter hospital stays, more rapid rehabilitation and recovery, less blood loss, and diminished postoperative pain, which are purportedly due to the relative lack of muscle and tendon damage via the minimally invasive technique [1-9]. However, there are some potential drawbacks to this newly advancing technique. The smaller incisions may diminish the surgeon's ability to adequately visualize the entire proximal femur and potentially increase the risk of intraoperative periprosthetic femur fractures [10]. This potential decrease in visual ability places additional emphasis on the surgeon's auditory and tactile senses in determining the optimal interference fit of the implant within the geometry of the proximal femur that is required for maximal implant stability. Intraoperative periprosthetic femur fracture may occur if the implant is impacted past the point of maximal interference fit, subjecting the cortical bone of the proximal femur to excessive hoop stresses [11]. Choosing the correct implant size, preparing the femur to accurately match the implant geometry, and accurately assessing maximal implant seating are essential to minimize detrimental hoop stresses during femoral component insertion [12, 13].

The main objective of this research is to determine a method to supplement the surgeon's auditory and tactile senses during surgery by using damage identification techniques, such as monitoring vibration characteristics of the impaction process. Commonly utilized in structural dynamics, these techniques may potentially aid in determining when the prosthesis is fully seated within the femur. An accurate method of determining maximal interference fit and stability of the implant in the proximal femur would most certainly diminish the incidence of intraoperative periprosthetic femur fractures. Intraoperative femur fractures, especially if unrecognized, decrease the mechanical stability of the femoral component and may increase the risk of implant failure [14]. This failure is most likely a result of diminished early bone-ingrowth to the prosthesis due to excessive micromotion that occurs secondary to the fracture-induced instability [13, 15].

Past research concerning this topic monitored vibration of the prosthesis during the impact process using a single shock accelerometer located along the axis of impact [16]. Energy introduced into the system was measured using an impact hammer equipped with a force transducer. A replicate femur was constructed using PVC pipe and a surgical hammer and punch were used to impact the prosthesis. After each hit the impact hammer was used to generate an excitation and measurements were taken. The Holder exponent was then used to track the wavelet transform of the acceleration time history. While the Global Holder exponent showed promise as a seating feature, it was suggested that further testing be completed using different surrogate bone test beds that more closely replicate human bone properties for each impact test [16]. Additional research was undertaken to improve upon the initial testing methods. The PVC pipe was upgraded to a composite replicate femur. The composite replicate femur (Sawbones, Pacific Research Laboratories Inc., Vashon, WA) has similar mechanical properties to human cortical bone and has been validated in mechanical laboratory analysis [17]. The prosthesis was impacted into the replicate femur and measurements were taken during the insertion process. The data received during this process was also analyzed using the Global Holder exponent, however, this analysis technique failed to provide an accurate indication that the prosthesis was fully seated [18, 19]. The data collected was separated into low and high frequency signals and the low frequency signals were observed to increase as the prosthesis neared the fully seated position.

The research discussed in this paper was aimed at further improving upon the previous two attempts. Instead of using a single replicate femur, multiple replicate femurs (five specimens) were used during testing. Three accelerometers were used, one measuring in the impact direction and two measuring the transverse directions, along with an instrumented hammer to monitor the impact process. A PZT patch was attached to the femoral component and impedance measurements were taken. Also, the PZT patch was used as an actuator while the accelerometers monitored acceleration in order to find the frequency response functions. It was the goal of this study to determine features that can indicate when the implant is fully seated and has reached a position of maximal interference fit and mechanical stability within the proximal femur prior to periprosthetic fracture.

EXPERIMENTAL PROCEDURE

During cementless hip replacement surgery the prosthesis is press-fit into the femur. In this study it was attempted to simulate this process as accurately as possible. First, a practicing surgeon prepared the third-generation composite replicate femurs using the manufacturer’s reamers and broaches. Second, a test structure was used to hold the femurs in a consistent manner, and third, the prosthesis was inserted into a simulated femur using an instrumented hammer and a punch. The main purpose of the test structure was to maintain consistency from bone to bone. Foam padding was placed beneath and around each femur to simulate the compliance associated with the soft-tissue and muscles surrounding the femur in vivo, although no tests were performed to determine if this compliance was realistic. A photo of this test structure can be found in Figure 1.

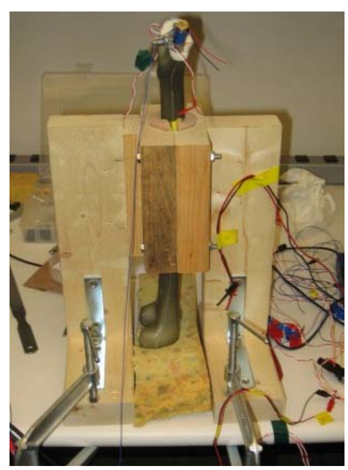

Figure 1. The test setup used during experimentation. C-clamps were used to hold the structure to the table while bolts were used to clamp the two pieces of the structure around the bone.

The prosthesis was instrumented with two transverse accelerometers, an accelerometer in the direction of the impact, and a piezoelectric (PZT) patch as shown in Figure 2. The transverse accelerometers were model number PCB 353B13. They had a nominal sensitivity of about 5 mV/g, a measurement range of ±1,000 g, and a frequency range of about 10 kHz (±5%) or 20 kHz (±10%). The accelerometer used in the direction of impact was a shock accelerometer model PCB 352B01, which had a sensitivity of 1.047 mV/g, a measurement range of ±5,000 g, and a frequency range of about 10 kHz (±5%) or 20 kHz (±10%). It was not possible to use accelerometers with a higher sensitivity due to the shock-loading environment and the decision to leave the transducers on throughout the impacting process. The PZT patch used was a 0.25 inch diameter, 0.01 inch thick, APC 850. The transverse accelerometers were attached to a mounting block that was glued to the prosthesis and the accelerometer in the direction of impact was glued directly to the prosthesis in order to remove any non-repeatable effects associated with remounting. The PZT patch was attached to the prosthesis using M-Bond.

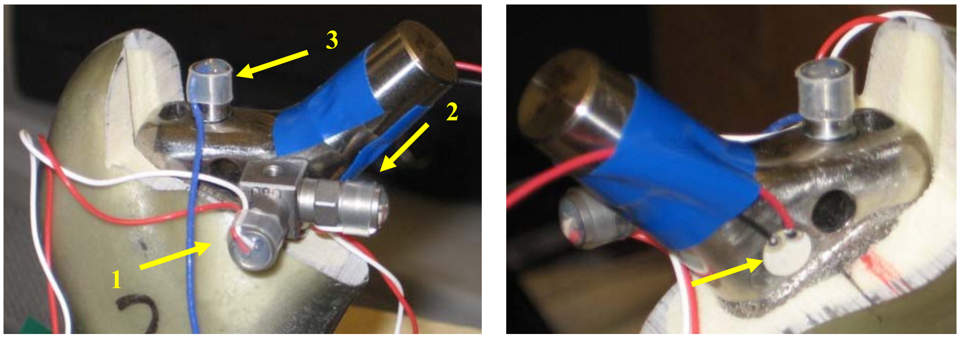

Figure 2. The photo to the left shows the layout of the three accelerometers while the photo to the right shows the position of the PZT. Numbers 1 and 2 are the transverse accelerometers and number 3 is the shock accelerometer.

Two measurements were taken prior to insertion. An impedance measurement was taken using the PZT patch; and frequency response functions (FRFs) between the PZT patch as the input and the three accelerometers as outputs were determined. The impedance measurements were taken using a 24 bit NI-DAQ system from National Instruments, model number PXI-1042. A Gaussian white excitation was used as the input to the PZT patch and 16,384 samples were taken at a sampling rate of 200 kHz. This data was averaged 300 times in order to acquire the best representation of the data. A Hanning window was incorporated. The FRF measurements were performed using a Dactron Photon dynamic signal analyzer and a laptop computer. The software was set to supply a band-limited random input to the PZT patch and to acquire data from the accelerometers at a rate of 18.75 kHz and to record 4,096 points of data. A Hanning window was used and 200 averages were taken.

After these two preliminary measurements, the prosthesis was placed in the simulated femur and the impedance and FRF measurements were repeated. These results were used as baselines for subsequent measurements. At this point the prosthesis was impacted into the simulated femur using an instrumented hammer (PCB model 086D20) and a punch. Three different types of measurements were taken. During the impact, acceleration time history data was taken from the three accelerometers and the force transducer on the instrumented hammer was used to measure the force input. This data was taken using the 24 bit NI-DAQ system described above. For this measurement there was no window and 2,048 samples were taken at a sampling rate of 40 kHz. The data acquisition was triggered using the force input and 10 pre-data points were used. Therefore, when the force crossed a predetermined threshold, the data acquisition equipment recorded the signals as well as 10 points before the event took place which allowed for recording of the signals in their entirety. After the impact, an impedance measurement and FRF measurements were taken using the same hardware and measurement parameters used in the preliminary tests. The distance from a line on the prosthesis to the simulated bone was measured using a digital caliper. Following these measurements another impact was applied and the process was repeated. These tests were continued until the prosthesis no longer moved with a subsequent impact. The number of hits generally ranged from 7 to 15 although the amount of movement for the last number of hits was often much less than a millimeter. After the data was collected it was analyzed in MATLAB.

RESULTS

The PZT excitation data, impedance data, and impact test data were all analyzed in order to identify features in the data that indicated when the prosthesis was fully seated in the bone. Since the bones were unable to be driven to the point of fracture, features which would be indicative of impending fracture were unidentifiable. Instead, features that showed dependence upon the degree of insertion of the prosthesis were sought after. Potential features that are indicative of seating were found in all three types of data.

PZT EXCITATION DATA

Representative FRFs from the y-direction accelerometer with excitation from the PZT are shown in Figure 3 at various stages of insertion and the associated coherences are shown in Figure 4. The most salient features of these FRFs are the increasing frequencies of both the resonance and the anti-resonance near 10 kHz and the decreasing magnitude of the resonance. Several different methods of quantifying these observations were devised such as measuring the widths of peaks, the frequencies of resonances and anti-resonances, and the peak values over certain frequency bands. The two most promising of these metrics are the frequency of the anti-resonance in the 10.5 to 12 kHz band and the peak magnitude in the 9 to 11 kHz band. Figure 5 shows the frequency of the anti-resonance in the 10.5 to 12 kHz band as a function of number of hits for the five bones tested and Figure 6 shows the peak magnitude in the 9 to 11 kHz band as a function of number of hits for the five bones tested. As can be seen from these figures, both features appear to converge as the prosthesis is inserted. It may therefore be possible to determine whether seating has occurred by finding the change in one of these metrics due to the impact and determining whether or not it is significant. Both metrics proposed here exhibit good convergence as the prosthesis is inserted but it is clear that the peak value in the 9 to 11 kHz band converges much more quickly than the anti-resonant frequency. The manner in which these metrics (and others) converge as the prosthesis is inserted will be compared with the manner in which the distance of the prosthesis to its final position converges later in this paper.

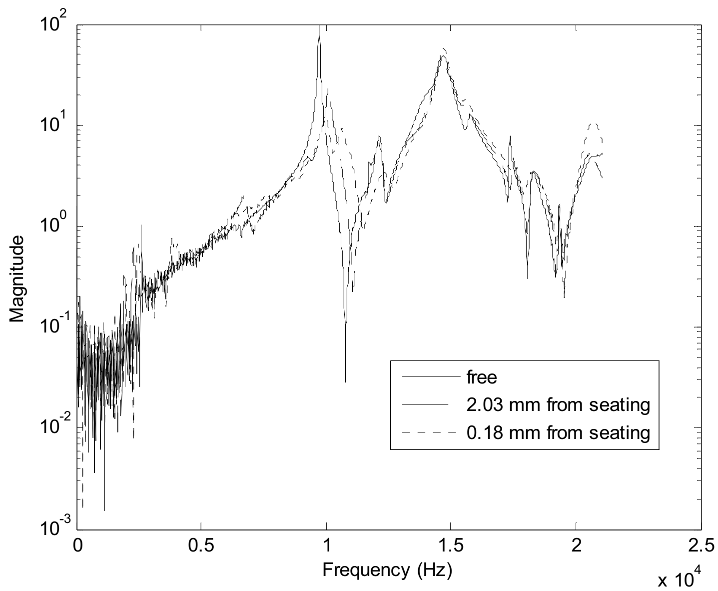

Figure 3. Typical y-direction FRFs for three different degrees of insertion. The resonance and anti-resonance near 10 kHz increase in frequency as the prosthesis is inserted.

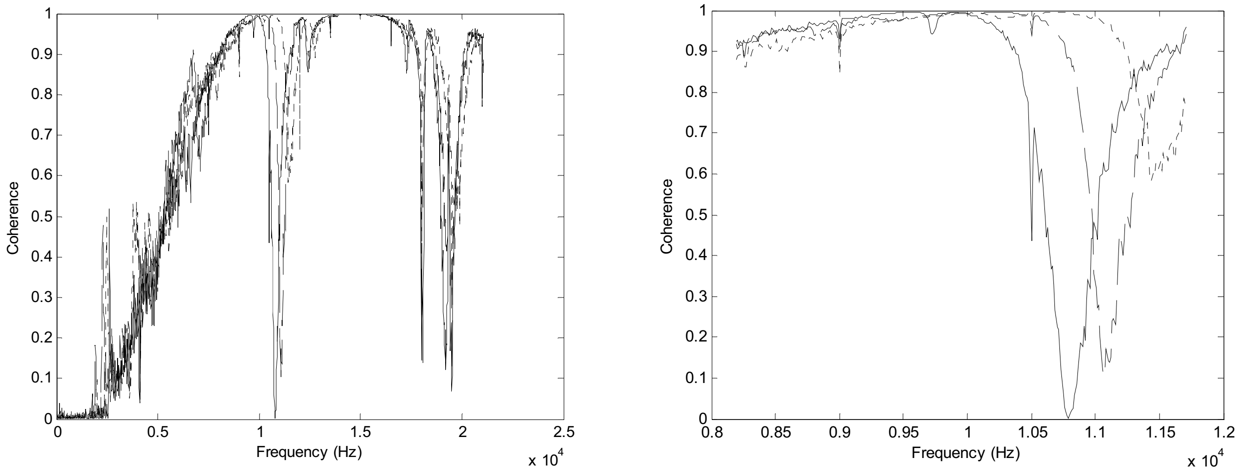

Figure 4. Coherences of the y-direction FRFs shown in Figure 3. The coherence looks good except at low frequencies (less than 8 kHz) and at anti-resonances. A close-up of the 9 to 11 kHz band is shown at right. The legend for both plots is the same as the legend from Figure 3.

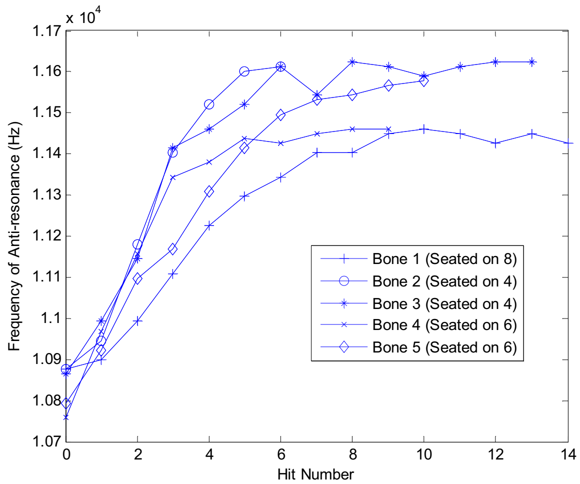

Figure 5. The frequency of the anti-resonance in the 10.5 to 12 kHz band as a function of hit number for all five bones. The frequency increases initially and then levels off. The number of hits it takes to “seat” the prosthesis (drive it to within 0.5 mm of its final position) is shown on the legend.

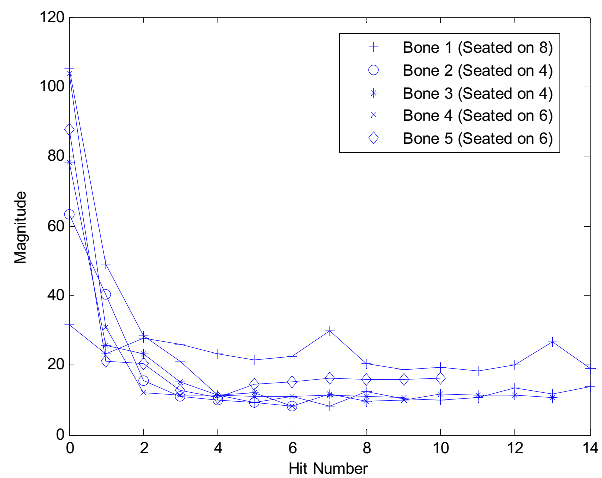

Figure 6. The peak magnitude in the 9 to 11 kHz band as a function of hit number for all five bones. This metric decreases and then levels off rather quickly as the resonance shifts. The number of hits it takes to “seat” the prosthesis (drive it to within 0.5 mm of its final position) is shown on the legend.

IMPEDANCE DATA

The impedance data taken by the PZT originally showed a strong downward trend, as shown in Figure 7, due to the fact that the PZT had decreasing capacitance over the frequency range of interest (30 to 50 kHz). A larger PZT patch would have had relatively constant capacitance in this frequency range, but a larger patch would not fit on the prosthesis. Due to the downward trend of the impedance data, it was necessary to detrend it by subtracting a linear function from it over the entire frequency band. This operation only removes the effect of the PZT's varying capacitance and does not alter any structural information. Additionally, the recorded impedance data was somewhat noisy and was therefore smoothed using a running average over 10 points.

The real part of the detrended and smoothed impedance data for a typical bone is shown at various stages of insertion in Figure 8. It is clear from this plot that as the prosthesis is inserted into the bone, the peaks of the real part of the impedance decrease in height and increase in width. Both these characteristics were experimented with as measures of insertion and it was found that the most promising measure is the euclidean norm of the vector whose entries are the real parts of the detrended and smoothed impedance data over the entire 30 to 50 kHz band. This metric is plotted as a function of the number of hits for the five bones tested in Figure 9. It exhibits fairly good convergence for bones 2, 4, and 5, but appears more erratic for bones 1 and 3, and consequently does not seem to be as promising as the FRF metrics discussed earlier. It should be noted that the impedance data from bones 3, 4, and 5 was taken using a different data acquisition system that scaled the data differently and so the data from these bones in Figure 9 was multiplied by a scaling factor to make it comparable to the data from bones 1 and 2.

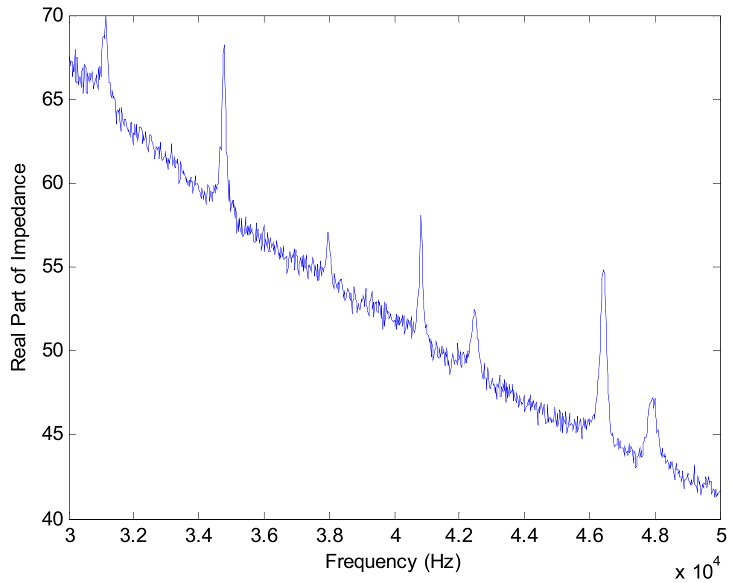

Figure 7. Real part of impedance as a function of frequency prior to detrending. The varying capacitance of the PZT patch accounts for the downward trend.

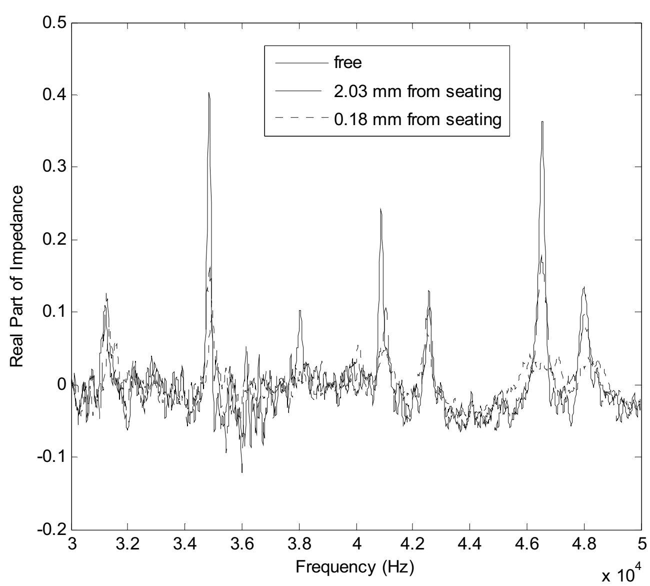

Figure 8. Typical detrended and smoothed impedance results for three levels of insertion. The peaks of the real part of the impedance become shorter and wider as the prosthesis is inserted further into the bone.

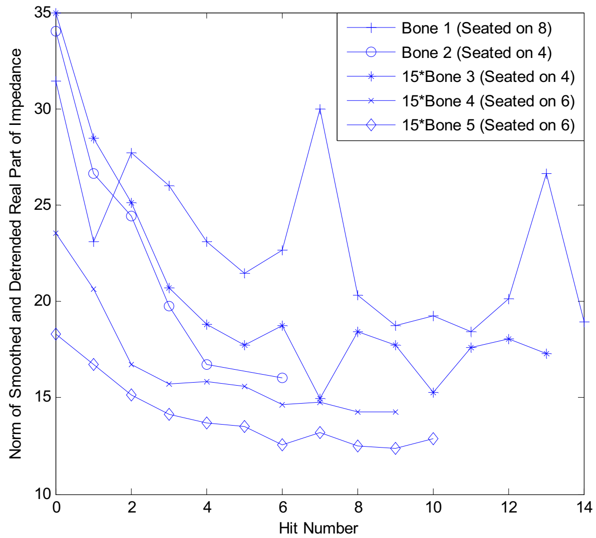

Figure 9. The norm of the smoothed and detrended impedance data as a function of the number of hits for all five bones. This metric shows a fairly regular downward trend for bones 2, 4, and 5, but appears more erratic for bones 1 and 3.

IMPACT TEST DATA

The data collected by the accelerometers during the hammer hit was difficult to analyze in the frequency domain because the system changed during the test as the prosthesis was inserted deeper into the bone, and because no averaging could be done due to the fact that the act of testing the system changed it. These factors caused the frequency domain data to look extremely noisy and obscured any useful features that might have been observed. In order to observe how the frequency content varied with time during the impact, wavelet transforms of the time domain signals from the accelerometers were examined, but did not provide any consistent information that was useful in predicting seating of the prosthesis. One useful metric based upon the impact test data was the sum of the acceleration data in the direction of impact divided by the sum of the impact force. This measures how much acceleration is induced per unit of impact force, so one would expect this metric to decrease as the prosthesis seats in the bone. This metric is plotted as a function of the number of hits in Figure 10 and shows fairly good convergence as the prosthesis is inserted.

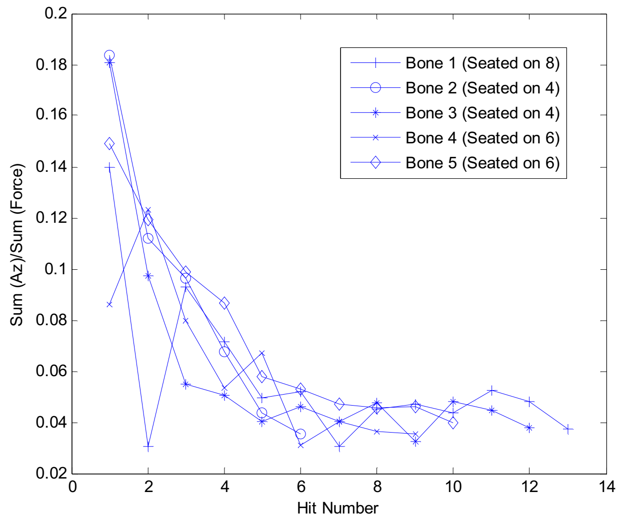

Figure 10. The sum of the acceleration in the direction of impact divided by the sum of the impact force as a function of the number of hits for all five bones. This metric shows good convergence as the prosthesis is inserted.

COMPARISON OF METRICS

In this paper several features of the experimental data that show dependence upon the degree of the prosthesis' insertion into the femur as well as multiple metrics based upon these features have been presented. In order to determine the relative merit of these metrics it is helpful to compare their convergence with that of the prosthesis into the femur. Shown in Figure 11 is the distance of the prosthesis to its final position as a function of hit number. Because there is no clear definition of when the prosthesis is fully seated, it will arbitrarily be declared to be "seated" when it comes within 0.5 mm of its final position. The value to which each of the metrics converges will, in general, be a function of both the prosthesis and the femur, so it is impossible to gauge whether or not a metric has converged based upon its value. However, as long as the metrics converge, the difference between its value after a given hit and its value after the previous hit should decrease as the prosthesis seats and by monitoring this, it may be possible to detect seating. Shown in Figures 12 to 15 is the difference between the value of the given metric on the given hit and its value on the previous hit as a percentage of the initial value of the metric. Again, arbitrary definitions of convergence are adopted as demonstrated by the dashed lines in these figures. Although these definitions are arbitrary, as long as they are chosen reasonably, they match one's intuitive notion of when a given metric has "converged". It can be seen in Figure 12 that the peak magnitude in the 9 to 11 kHz band converges much more quickly than the distance of the prosthesis from its final position. On the other hand, the norm of the impedance, shown in Figure 13, converges much more slowly than the prosthesis and, in the case of bone 1, does not seem to converge at all. Finally, the frequency of the anti-resonance, and the sum of the acceleration in the direction of impact divided by the sum of the force, shown in Figures 14 and 15 respectively, both show convergence that is similar to that of the prosthesis, leading one to believe these may be better metrics. The preceding observations are summarized in Table 1, which lists the number of hits required for the prosthesis and each of the metrics to "converge" according to their arbitrary definitions of convergence. This table shows that the acceleration in the direction of impact divided by force metric does the best job of predicting seating for the five test bones considered here. Additionally, this metric is easy to compute and uses excitation from the actual impact of the prosthesis into the femur, so it would not require the surgeon to stop and wait between hits as would be required by the other metrics. For these reasons, it seems that this metric is the most promising of the four considered.

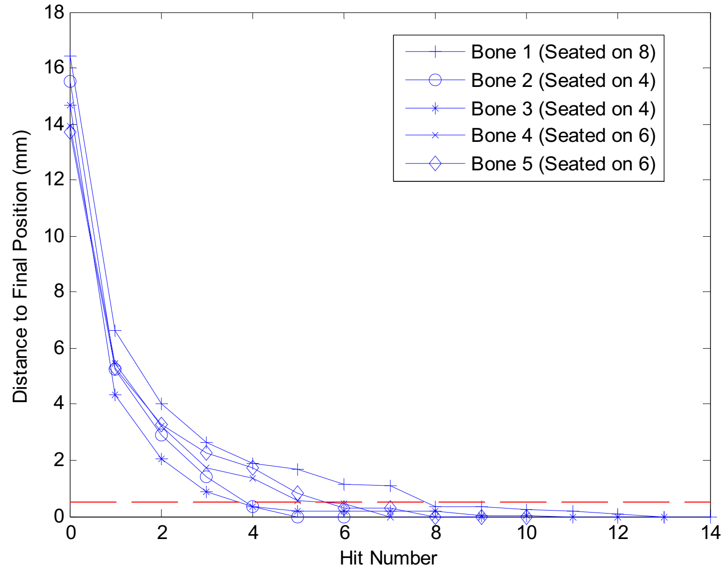

Figure 11. Seating of the prosthesis into the femur occurs as it is hit. The dashed line denotes the arbitrary "seated depth" of 0.5 mm to the final position.

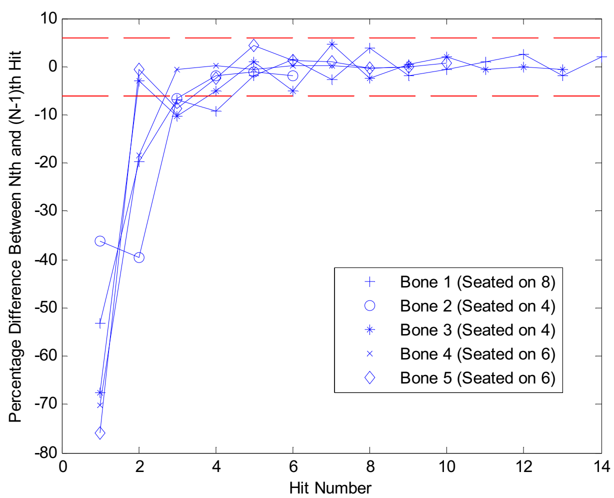

Figure 12 – Change in the peak magnitude in the 9-11 kHz band as a percentage of its initial value as a function of hit number. The dashed lines denote the arbitrary region of convergence of less than a 5% change.

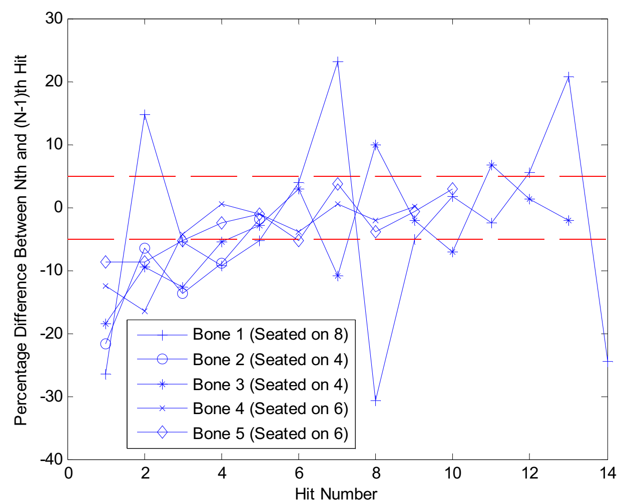

Figure 13 – Change in the norm of the impedance as a percentage of its initial value as a function of hit number. The dashed lines denote the arbitrary region of convergence of less than a 5% change.

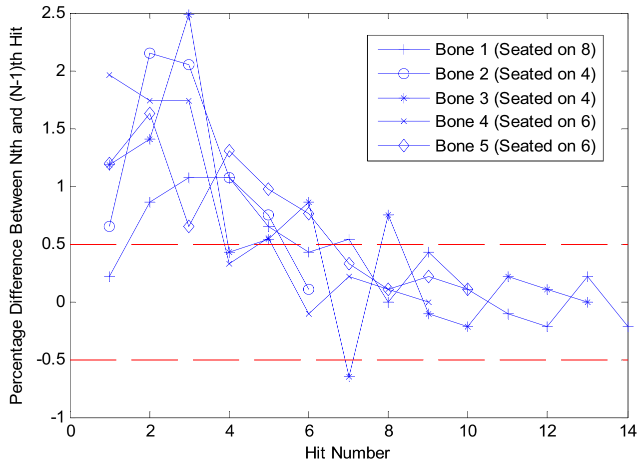

Figure 14 – Change in the anti-resonance frequency as a percentage of the initial anti-resonant frequency as a function of hit number. The dashed lines denote the arbitrary region of convergence of less than of 0.5% change.

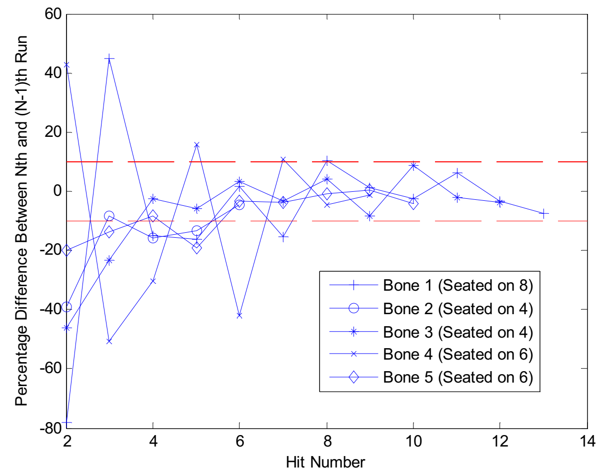

Figure 15 – Change in the acceleration metric as a percentage of its initial value as a function of hit number. The dashed lines denote the arbitrary region of convergence of less than of 10% change.

Table 1. The number of hits it takes for each metric to converge in comparison to the number of hits it takes for the prosthesis to seat, which indicates how useful each metric is in predicting seating.

		Definition of Convergence	Number of Hits to Convergence				
			Bone 1	**Bone 2**	**Bone 3**	**Bone 4**	**Bone 5**
Prosthesis		within 0.5 mm	8	4	4	6	6
Metric	**Anti-resonance**	change less than 0.5 %	8	6	9	6	7
	Max Value in 9-11kHz Band	change less than 6.0 %	5	4	4	3	4
	Norm of Impedance	change less than 5.0 %	Never	5	12	3	7
	Sum(Accel)/ Sum(Force)	change less than 10.0 %	9	6	4	8	6

CONCLUSION

The data analysis techniques implemented in this study showed varying degrees of usefulness in determining when the prosthesis was fully seated. The three analysis methods explored during testing included acceleration time histories taken upon impact, frequency response functions generated from PZT actuation, and impedance measurements. Four metrics were used to analyze the data recorded during testing. A metric generated from accelerations in the axial direction and force input appeared to provide the best indication of when the prosthesis reached the fully seated position due to the fact that its convergence most closely matched the convergence of the depth of insertion. From the FRF produced by the PZT actuation, the largest magnitude within the 9 to 11 kHz range as well as the frequency of the anti-resonance was tracked. The anti-resonance converged similarly to the change in prosthesis depth, however, this convergence did not agree as closely with the change in depth as the acceleration metric did. The largest magnitude within the 9 to 11 kHz range converged much faster than the prosthesis depth, thus making this feature not as reliable as the aforementioned features. The impedance data generated during testing proved to be the least consistent of all four metrics. One of the disadvantages of the FRF and impedance methods was that many averages needed to be taken after each hit, which required excessive time to elapse between hits.

Upon completion of the data analysis, it was noticed that inconsistencies existed in some of the bones. In particular, the data collected for bone 3 was inconsistent with the data taken from the other four bones tested. Based on the impedance data, bone 5 did not show smooth convergence as depth increased. These inconsistencies could be attributed to the natural variability that existed in the preparation of these bones for this study by the orthopedic surgeon. Any metric, however, will need to be insensitive to such variability.

An overlying factor in our testing was determining the point at which to stop impacting the prosthesis and declare it fully seated. The goal of the depth measurement was to maintain consistency and to consider the prosthesis fully seated after three consecutive, unchanged depth measurements were recorded. Variabilities could exist between what was considered to be the fully seated position in this study and what an orthopedic surgeon would have considered to be fully seated, if one had been present during testing. Since this is one of the biggest problems associated with this study, several modifications should be made to the test in order to more closely model actual surgical parameters. For example, an actual orthopedic surgeon could carry out the impaction process so that a better assessment of when the prosthesis is fully seated could be made.

Although the simulated bones have the same bulk properties as human bones, it is unlikely that they have the correct transverse characteristics which are important when looking at fractures associated with over insertion of the prosthesis. Similarly, the simulated femurs have the properties of a healthy male in his twenties rather than the properties of the typical recipient of a hip implant. Therefore, human bones could replace the sawbones used during testing in order to better simulate surgical conditions. Additionally, the boundary conditions of the replicate bone could be more closely matched to actual human characteristics. For example, additional research could be done on how to best support the bone during impaction, specifically, how to better model the compliance of soft tissue found within a human limb.

Analyzing and recording data should also be refined further in future work. The data analysis techniques used in this study should be modified so that the signal processing can take place in real time. This would allow for immediate interpretation of the data during the testing process. The eventual goal would be to provide the surgeon with a red light or green light setup to indicate when the prosthesis is fully seated.

It may also be possible to use PZT-based wave propagation and acoustic emission techniques as alternative data acquisition methods. By relying on much higher frequency ranges than those used in this study, these techniques may serve as more effective methods of seating detection and may be less sensitive to the natural variability expected from one patient to another. It may also be possible to eliminate the need for accelerometers entirely by using one PZT patch as the input and another PZT patch to measure the output.

Finally, the ultimate solution to this problem must be operable within federal guidelines. The tools, techniques, and software should enhance the surgical procedure and not cause any interference of movement from the operating staff. The final product must be able to withstand repeated sterilization, thereby satisfying the rules and regulations of the Food and Drug Administration.

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