Acoustic Emission Monitoring of Total Hip Arthroplasty Implants

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Abstract: Acoustic Emission (AE) monitoring of patients with Total Joint Replacement (TJR) implants uses an array of four passive ultrasonic receivers to undertake *in-vivo* monitoring of the acoustic events created by patients with TJR implants. This manuscript presents and compares the results of *in-vivo* and *in-vitro* measurements of the acoustic signature created by a range of Total Hip Replacement (THR) implants. A major focus of this investigation is in the characterization of squeaking of hard-on-hard bearing surface combinations. The presence of an audible squeak of the bearing surface can cause significant embarrassment and potential discomfort to patients. It has been identified that squeaking is primarily identified at the main bearing interface and the fundamental peak falls in the range of 2-5kHz, with multiple higher harmonics also observed. The frequency of the primary squeak is seen to vary based on bearing surface type of both the acetabular liner and femoral head (ceramic-on-ceramic, metal-on-metal bearing combinations)

Comparison is also drawn between *in-vivo* and *in-vitro* testing through the use of implant components retrieved during revision surgery of patients previously subjected to *in-vivo* testing. In the trials presented within this manuscript, strong correlation was achieved between the two test methods. *In-vivo* signal magnitudes were substantially smaller than those recorded from bench tests directly on the implant. However, characteristic frequencies were very similar in both cases, indicating that tissue attenuation reduces signal magnitude, but the influence of any period shifting of signals through the soft tissue were minimal. These initial results provide an important base for future testing and provide useful insight into the underlying cause of audible squeaking of total hip replacement patients with hard-on-hard bearing surfaces.

Keywords: Biomedical Systems, Vibration Measurement, Vibration Monitoring, Ultrasonic Transducers, Signal Analysis, Bode Plot, Frequency Spectrum, Attenuation Observations, Acoustic Emissions, Orthopaedic Implants, Patient Testing, Tissue Attenuation.

1. INTRODUCTION

The number of total knee replacements performed in the U.S. will leap by 673% - reaching 3.48 million - by the year 2030, and hip replacements will increase by 174% to 572,000 (Kurtz et al., 2003), largely due to demographic ageing (NZOA, 2003). Total joint replacement (TJR) surgery is typically the last resort for people with osteoarthritis (OA), also known as degenerative joint disease. TJR surgery is extremely successful (~90%), but these joints need to be replaced due to wear and/or premature loosening of the implant after 10-15 years (Kurtz et al., 2003; NZOA, 2003). The more primary joint replacements surgeries there are, the more revision TJR surgeries there will be all else equal, thus creating a significant and increasing cost, in both dollars and use, of scarce surgical services.

With an epidemic of degenerative joint disease occurring, there is a huge challenge to find and implement effective screening programmes for detecting early TJR wear or failure, and clear diagnostic indicators for orthopaedic surgeons to properly manage revision surgery (NZOA, 2003; Browne et al., 2005). Early diagnosis of impending failure can save significant time, cost and more serious surgery. Currently, there are no reliable, non-traumatic and noninvasive methods to monitor the healing process or loosening status after TJR.

AE monitoring devices use passive ultrasonic receivers to record high frequency vibrations emitted by the implant and correlate the recorded signal with clinical outcomes. The ultrasonic signals are typically characterised on frequency content or signal characteristics (short-duration high amplitude events/long-duration, lower amplitude events). These AE signals can be correlated with events, such as micro-scale brittle breakages of bone or bone cement, or vibrations due to wear and/or wear debris within the bearing surface between the femoral and acetabular components.

Research over the past 15-20 years has investigated acoustic emission (AE) monitoring to provide insight into implant condition and provide early detection of wear and loosening (Browne et al., 2005). Mavrogordato et al (2011) investigated the use of embedded acoustic emission sensors in the in-vitro testing of a simplified total hip stem construct, subjected to loading in a hydraulic test machine. Davies et al (1996) and Sugiyama et al (1989) have also investigated the use of acoustic emission testing in orthopaedics, looking at micromovements within the surrounding bone and fixation to bone cement.

These previous *in-vitro* and *in-vivo* studies demonstrate the potential AE frequency range of interest varies significantly (up to 1MHz *in-vitro*, but only up to 50kHz for *in-vivo* tests on the skin surface) due to attenuation of vibrations through tissue (Browne et al., 2005). More recently, Mustafa et al (2012) have examined the use of acoustic emission technology in the field of Orthopeadics. However, there is only limited research that has looked more explicitly at the attenuation characteristics of soft tissue. Moreover, AE monitoring devices have typically utilised a single sensor located near the greater trochanter to determine joint condition.

Recent research has developed an AE prototype diagnostic tool to assess implant designs and materials. The prototype includes four ultrasonic sensors placed against the skin, between the greater trochanter and the mid femur. The additional information from the multiple sensors and relative signal strength at each location can determine likely vibration sources (acetabular cup, bearing surface or femoral stem) and lead to clinical diagnosis. The technology can be applied to cemented versus uncemented components, and the performance of metal-on-plastic, metal-on-metal, and ceramic-on-ceramic bearing surfaces, and combinations thereof. This manuscript aims to investigate the range of frequencies observed on the skin surface during patient testing.

2. METHODS

An AE prototype was used to undertake in-vivo monitoring of patients with Total Hip Replacement (THR) implants. The prototype consisted of four passive ultrasonic receivers, each with a resonant frequency of 32.8kHz. The ultrasonic sensors were placed against the skin, between the greater trochanter and the mid femur. The data from each sensor was simultaneously recorded at 100kHz as the patients undertook a range of standard orthopaedic test motions. These motions included squatting from standing, standing from sitting in a chair, dropping from standing to crouching, walking up stairs, heel strikes and baseline walking. Patients were also given the option of undertaking any additional movements that they felt would produce specific implant noises. Patient testing was given ethical approval from the New Zealand Upper South A regional ethics committee under approval number URA/10/11/075.

The use of four ultrasonic sensors was included to allow the use of relative signal magnitude and arrival time at the four sensors to provide insight into the likely source of the recorded vibrations. Previous methods have relied on a single ultrasonic sensor to record vibrations, which limits the amount of data available for analysis and restricts analysis primarily to the frequency domain. The recording system utilised a National Instruments CompacDAQ and NI-9222 analog module. Data was recorded simultaneously at 100 kS/s per channel, giving a Nyquist frequency of 50kHz. A total of 52 patients have been tested using this prototype, with a total of 58 hip implants monitored as some patients had bilateral implants where both were monitored independently. The physical data acquisition system used for both in-vivo and in-vitro testing is shown in Figure 1.

While the focus of this research is to investigate a range of possible acoustic events and indicators or wear, loosening or other early failure modes, audible squeaking provides the clearest, most definable acoustic signature. Therefore, the preliminary results presented here focus on this squeaking mode. Primary data analysis is undertaken in the frequency domain through Fourier transform analysis to quantify the different modes present within the recorded results.



Fig. 1. Data acquisition system, showing the set of four ultrasonic sensors (32.8kHz resonant frequency), signal processing/breakout box and NI CompacDAQ.

3. RESULTS AND DISCUSSION

3.1 In-vitro implant measurements

Figure 2 presents the *in-vitro* bench testing of a range of different implant combinations. The combinations of ceramic and metal bearing components all exhibited audible squeaking. The combination of a metal cup and ceramic head was seen to produce an extremely repeatable frequency of approximately 1.2kHz. The other bearing articulations were seen to exhibit a much larger variability, with repeated trails producing squeaks of different frequencies. It should be noted that two different ceramic-on-ceramic implants exhibited

overlapping frequencies, whereas the squeaks recorded from the articulations involving a metal bearing component exhibited distinctly different frequencies.

Implant testing was undertaken in two different *in-vitro* test set-ups. The first method used manual manipulation of the implants, which had limited ability to control the range of motion and inaccurate position control. However, this method has the notable advantage that it does not induce additional vibrations into the system and reduces the chance of contaminating the signal with unwanted noise from the actuation method. Despite the limitations of this method, repeatability of the squeaks was clearly identified, as shown in Figure 2.



Fig. 2. Distribution of primary squeak frequency for a range of bearing surface combinations.



a) Manual manipulation of in-vitro implant testing



b) Automated robot manipulation of in-vitro implant testing

Fig. 3. Manual and robot manipulation of *in-vitro* implant testing, showing the location of ultrasonic sensors.

Robot manipulation of the implants was also undertaken to increase the accuracy of the range of implant motion. While this method substantially reduced variability, it also introduced vibrations from the robot itself. Therefore, an isolation system was designed to allow force transfer but limit the vibration transfer path. This isolation system consisted of layers of high density foam and orthotic material, which provided good isolation of the implant from the robot-based actuation method. The manual manipulation method is presented in Figure 3a, while the robot manipulation is presented in Figure 3b.

3.2 In-vivo Patient Testing

Testing was undertaken on total hip replacement patients. The recruitment criteria included patients that exhibited audible squeaking, patients identified by surgeons as being of interest to monitor during regular post-operative clinics and those that were due for revision surgery. A group of 12 control patients were also tested that had natural hips with no history of osteoarthritis or trauma to the joint. These patients were included to provide a benchmark and provide an indication of the ambient noise threshold.

In these control trials, the participants had the device attached to them in the same manner as the standard patients. The control participants also underwent the same range of exercises and movements as the standard patients to replicate the same trial conditions. Ambient noise tests were also undertaken, where data was captured with the sensor array placed on a bench in the test room with no motion of the array. These tests were used to establish the baseline noise values of the test environment and enable comparisons to be made to the noise floor.

A typical time-domain response of an *in-vivo* patient trial that exhibits an audible squeak is presented in Figure 4. Each of the four sensors has a nominal voltage offset to represent the relative position on the patient. The highest sensor is located near the top of the pelvis, near the greater trochanter, while the lowest sensor is located at mid-femur height. The sensor pad is a fixed size for all patients, so there is some variation in position for patients of different height.



Fig. 4. Time-domain response of an audible squeak in *in-vivo* patient testing.

The time-domain profile of a squeak is significantly different to other implant sounds, such as "clicking", "graunching" or "shuddering". These different sounds can often be measured by the ultrasonic sensors, are sometime audible and often reported as being felt by the test subjects.

It is evident in Figure 4 that the largest magnitude is displayed in the second highest sensor. The onset of the signal is typically earlier at this location as well. These aspects indicate that the likely source of this squeak is at the primary bearing interface between the acetabular linear and femoral stem.





Fig. 5. Frequency domain magnitude of *in-vivo* signals showing patients, control participants and ambient noise data.

Figure 5 presents a comparison of four different types of recordings: 1) a total hip replacement patient exhibiting audible squeaking; 2) a total hip replacement not exhibiting squeaking; 3) a control patient with a healthy, natural hip; and 4) ambient noise data.

It is evident in Figure 5 that patients exhibiting audible squeaking produce the highest acoustic emission throughout the audible range (up to about 15kHz) and right up to the 50kHz Nyquist frequency. The non-squeaking patient produces similar or lower emissions across most of the spectrum compared to the control participants. It should be noted that while these trends are relatively typical, they do represent only single patient trials and there is inherent variability. Moreover, the ambient noise floor is relatively low across the entire spectrum, indicating that background noise in the test room is not significant.

The frequency spectra presented in Figure 5 represent an average frequency magnitude across entire recordings. Spectrograms can provide significant additional insight into the noise profile and indicate which regions are consistent unwanted noise and which signal are time-varying. Figure 6 presented a typical spectrogram of a patient trial. Figure 6 represents a repeated lunging motion of the patient and the corresponding frequency content of the recorded signal.



Fig. 6. Spectrogram of the in-vivo patient data.

The spectrogram in Figure 6 represents a range of Fourier transform results, calculated at 0.01s data frames, each with 1000 data points. These frequency domain results are plotted against time, showing the variation in frequency content throughout a patient trial

It is evident in Figure 6 that there is consistent ambient noise in the 38-40kHz range that is present throughout the record. As the patient undergoes the range of motion (a repeated lunging action), a range of additional time-varying frequencies are displayed. Plotting the measured patient data in this manner allows for much clearer delineation of the erroneous ambient components and those components which occur in response to patient motion.

3.3 Testing of retrieved implant components

The patient recruitment procedure included patients scheduled for revision surgery. Patients which have progressed onto revision surgery since their *in-vivo* testing have has their retrieved implant components examined and tested *in-vitro*. The *in-vitro* testing has aimed to investigate the relationship to the prior *in-vivo* measurements and further investigate tissue attenuation characteristics. The correlation of a particular frequency signature between these two test methods can be used to help determine the root cause of measured vibrations, as significantly more information about implant response can be obtained *in-vitro*.



Fig. 7. Spectrogram of the *in-vivo* patient data and the subsequent *in-vitro* testing of the implant bearing surfaces after removal during revision surgery.

Figure 7 presents a comparison of *in-vivo* and *in-vitro* measurements of a retrieved implant. The *in-vivo* measurements are recorded from the patient before the revision surgery. During the revision surgery only the bearing surfaces were replaced by the surgeon, with the acetabular shell and femoral stem remaining in the patient. Therefore, these bearing surfaces were mated to closely matching implant components (acetabular shell and femoral stem) to allow manipulation during subsequent *in-vitro* testing.

Figure 7 shows that while there is a significant different in signal magnitude, the inherent frequency characteristics of the squeak do not change notably between *in-vivo* and *in-vitro* testing. Importantly, this represents an important initial result that begins to validate the approach of undertaking *in-vitro* implant testing to further examine the mechanics of implant failure modes *in-vivo*. However, it should be noted that this particular study is only presented for a single patient and this result alone is not statistically significant. Additional testing is being undertaken to further investigate the relationship between recorded *in-vivo* and subsequent *in-vitro* implant testing.

It should be noted that initial patient recruitment placed a primary focus on patients that were identified to have audible squeaking of hard-on-hard bearing surfaces. This clinical outcome is one of many areas to investigate. Testing of patients with loosening of the acetabular shell or femoral stem would also be of particular interest. This loosening and the corresponding implant movement may exhibit its own characteristic emissions. Moreover, those patients that are suffering loosening of cemented implants are likely to exhibit different emission signatures due to small-scale breakages of bone or bone cement as the implant components move. These additional investigations are key aspects of future work to develop a large database of clinical data and aid in the development of a diagnostic clinical tool.

Attention should also be drawn to the fact that *in-vitro* implant testing was undertaken with dry implants. No lubrication film was provided at the bearing interface. Future research seeks to undertake simulated biological lubrication, such as synthetic substitutes for synovial fluid or through the use or recovered human synovial fluid. While human synovial fluid is obtainable through orthopaedic practices, current ethics approval does not cover the use of these biological materials. Synthetic substitutes have been considered for future research.

The development of an Acoustic Emission monitoring device has the potential to be a very useful diagnostic tool for orthopaedic surgeons. The underlying premise of the AE monitoring device is that different wear and failure modes of the implant will produce unique frequency signatures, which can be identified during *in-vitro* testing of the implants.

It should be noted that the source of vibration from the implants is not restricted to just the bearing interface. Any loosening of the femoral head on the morse taper, loosening of the femoral stem within the femur, or loosening of the acetabular components will all produce a vibration response.

These aspects have not been well investigated in the study to date, but are the focus of ongoing research.

It should also be noted that these results are specific to hip replacement implants, but that a similar approach could be used for knee replacements. However, certain aspects such as characteristic implant frequencies and soft tissue attenuation properties will likely be quite different due to difference in implant design and the proximity of the boney landmarks to the skin surface respectively.

5. CONCLUSIONS

This manuscript presents comparison between *in-vivo* patient testing and corresponding *in-vitro* bench testing results on total hip replacement implants. Comparisons are drawn between these two test methods through the use of implant components retrieved during revision surgery. Strong correlation between the two methods was seen, validating the ability to relate bench test results to implant performance and degradation within a patient. However, care should be taken to avoid extensive extrapolation from the limited results presented here and further research is required.

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