Research Journal of Medical Sciences 2 (2): 82-91, 2008
ISSN: 1815-9346

Acoustic Tests on Hip Prosthesis Models Using Frequency Resonance Monitoring (FRM)

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Abstract: In this study with tests A to B3 we now have determined sound patterns in bovine and human cadaver bone. The B3 experiment measured the sound behaviour of prosthesis in cow bone with an intact cement mantel in comparison with a loose-cemented prosthesis (broken cement mantel) in the soft tissue simulator. The frequency measurements were performed with a special microphone, which could accurately detect very low frequencies and minor vibrations. According to our study protocols FRM was used in different sets of experiments (experiments A-B): Experiment A: In this experiment the sound behaviour of cow bone (femur with distal condyles) in a soft tissue simulator was measured as well as the sound behaviour of the combination of a loose prosthesis in cow bone. Experiments B: In this set of experiments the cow bone with different types of prostheses, i.e. the sound behaviour of different types of fixation with different stabilities of the implant were tested. The possible scenarios of loose and secure prostheses were observed. High frequencies of the spectrum were hardly observed. However, a closer look at the more common lower frequencies shows a specific bone pattern.

Key words: Acoustic test, bovine, cadaver bone, feasibility, human, FRM

INTRODUCTION

The conventional investigations for prosthesis loosening are still standard x-rays (for loosening lines, cement fractures or migration of the prosthesis) and Scintigraphy. These investigations have the disadvantage of inter-observer variability and unnecessary x-ray exposure, which are making it difficult and undependable to detect early and late loosening of the components. Very often the micro and macro-movements as well as the bone absorption have led to a loss of bone substance around the weight bearing area of the prosthesis (aseptic loosening). Detection of loosening of implants by sound has so far been unsuccessful (Paech *et al*., 2007; Friberg *et al*., 1999; Natali *et al*., 1997; Meredith *et al*., 1997; Temmerman *et al*., 2004; Davis *et al*., 1996; Qi *et al*., 2003).

In a battery of laboratory tests the possible application of non-invasive monitoring using Resonant Frequency Monitoring (RFM) as a method for hip prosthesis integrity is to be evaluated. The standard method for using this technique in hip prostheses has been established in the first part of the study "Acoustic Properties of Femoral Components of Hip Endoprostheses Analysis Using Frequency-Resonance-Measurement in a Soft Tissue Simulation Model.

In the following study, the application of FRM will be evaluated in different bone models with different types of hip prostheses.

MATERIALS AND METHODS

According to our study protocols RFM was used in different sets of experiments (experiments A-B).

Experiment A: In this experiment, the sound behaviour of cow bone (femur with distal condyles) in a soft tissue

Fig. 1: Set arrangement of soft tissue simulator and microphone

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simulator was measured as well as the sound behaviour of the combination of a loose prosthesis in cow bone.

Experiments B: In this set of experiments the cow bone with different types of prostheses, i.e., the sound behaviour of different types of fixation with different stabilities of the implant were tested. The possible scenarios of loose and secure prostheses were observed.

Experiment B1 tested the sound behaviour when the primary fixation is achieved by press-fit (non-cemented).

Experiment B2 showed the results for the loose hip prosthesis vs. secure hip prosthesis in the soft tissue simulator (Fig. 1).

The B3 experient measured the sound behaviour of prosthesis in cow bone with an intact cement mantel in comparison with a loose-cemented prosthesis (broken cement mantel) in the soft tissue simulator. The frequency measurements were performed with a special microphone, which could accurately detect very low frequencies and minor vibrations.

The results of the frequency monitoring were analysed with acoustic software (Adobe Audition 12.5). In the graphics the x-axis represents the time (seconds), the y-axis represents the frequencies from 0 to 2200Hz. The colour corresponds to the sound intensity at a particular point in the frequency level. In this respect the graphic is tri-dimensional.

The results of the measurements represent intra-individual changes with high dynamics (e.g. 20dB). These variations correspond to a significant change of the factor 100 (10000%). Such highly dynamic changes can be easily detected. The statistic data of the results were performed by means of the correlation analysis of the frequency spectrum.

The recorded signal chain can be studied according to the well-known theory of telecommunications. There is a chain of signal transmitters transducing signals applied to the wall of the soft tissue simulator. Each one is linked to the chain and can be analysed with a so-called transducer function. The transducer function can be described as frequencies A (f) as well as time A (t). When having a closer look at the description of the frequencies the out-going signal (measured signal) of the complete signal chain can be formed from the product of the transducer function of each single link through this formula.

$$Y(f)=A(f)*B(f)*C(f)\ldots\ldots*X(f)$$

Y(f) : Outgoing spectral function
A(f) : Transmitter function of the links
X(f) : Incoming spectral function

The outgoing signal Y (f) corresponds to the electric signal. The incoming signal X (F) corresponds to the spectral function of the hit. The objects transmitting sound are the soft tissue simulator, microphone, PE-cylinder, bone, bone gap (when existing), cement (when applied) and prosthesis.

The dynamic scale of the measurements in study 2 were observed around 48 dB corresponding to a signal contrast of 1:60 000.

RESULTS AND DISCUSSION

Experiment B

FRM on cow bone (distal femur with condyles): In this experiment the long cow bone in the soft tissue simulator was tested (Fig. 2).

High frequencies of the spectrum were hardly observed. However, a closer look at the more common lower frequencies shows a specific bone pattern (Fig. 3).

At around 1000 Hz an increase in the spectrum was found. The specific spectral image gives the same result. Around 1000 Hz a maximum can be seen. After this a decrease of the higher frequencies follows (Fig. 4).

The combination of a loose prosthesis in the soft tissue simulator shows a mixture of spectral characteristics (Fig. 5). Higher frequency patterns as well as low bone signals were found.

When analysing the frequencies around the 2000 Hz a specific resonance pattern of prosthesis 1 is found (compare prosthesis 1 air, Fig. 6).

Fig. 2: Bovine bone in soft tissue simulator

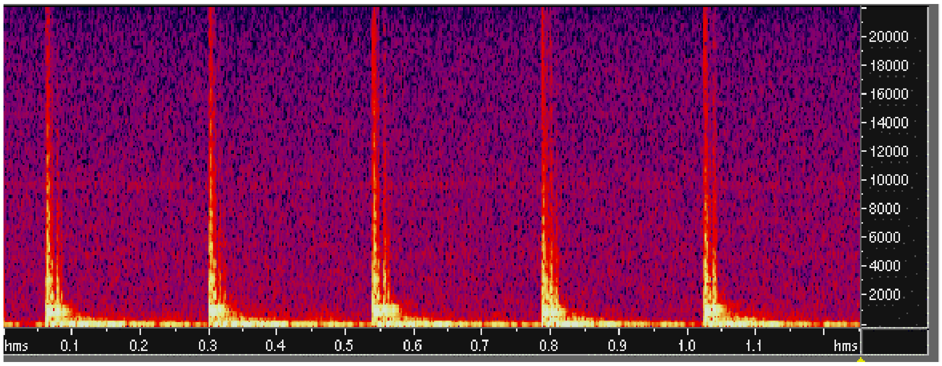

Fig. 3: Frequency spectrum, bone-water

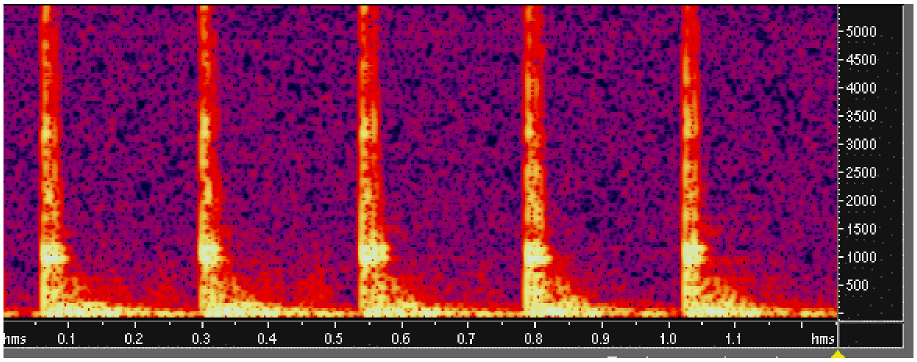

Fig. 4: Representation of lower frequencies, bone-water

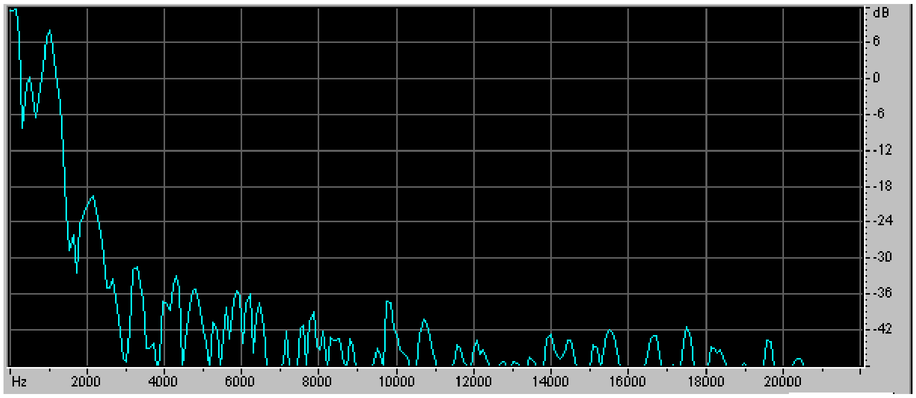

Fig. 5: Spectral image, bone-water

The same counts for prosthesis 2 (Fig. 7), but as expected the spectrum lacks the "fingerprint" at around 2000 Hz.

Experiment B: Three sets of experiments B1 to B3 were carried out (B1 press-fit, B2 loose prosthesis bone- water vs. firm prosthesis bone-water, B3 to be cemented).

In the set of tests B1 (press-fit 1-4) the prosthesis was hammered into the bone (Fig. 8).

As well as the fast disappearance of the prosthesis resonances (as the prosthesis becomes more and more secure) an increasingly clear structure of low frequencies of the bone are found and visible (Fig. 9-12).

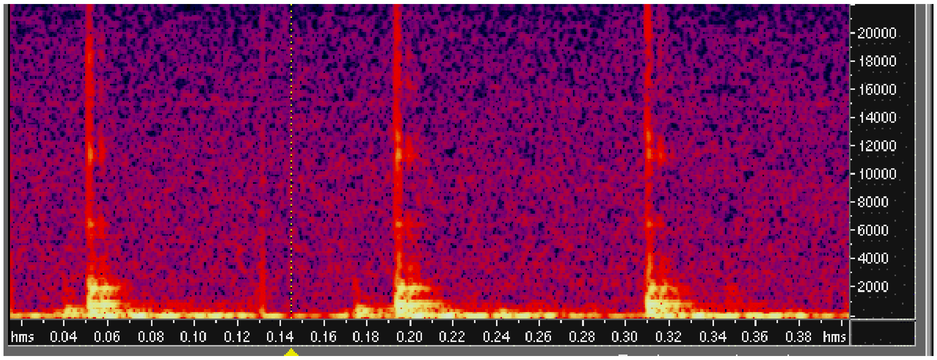

Fig. 6: Loose prosthesis 1 bone-water

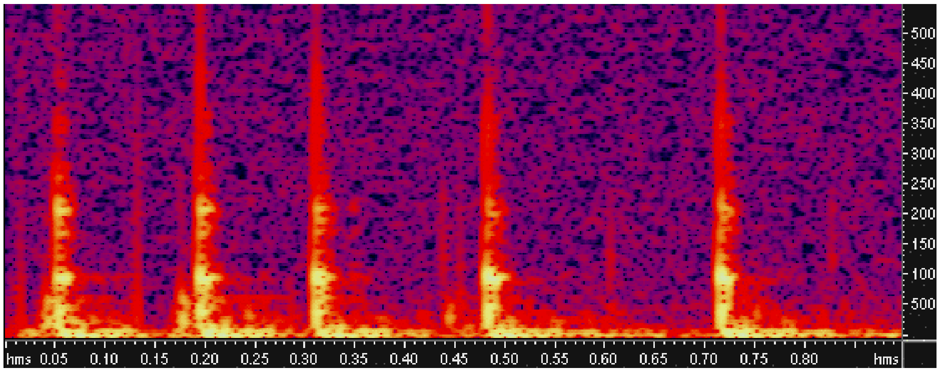

Fig. 7: Loose prosthesis bone-water

Fig. 8: Prosthesis in bone

It must be taken into consideration that during the experiment only a limited contact between bone and the press-fit prosthesis could be achieved. This is because of the contact area between trabecular bone and metal surface. The contact areas hadn't increased from the test of one hit to the test of press-fit. Here also the resonance of the firm prosthesis disappears and the low frequencies of the bone become visible.

The comparison of the tests between a loose prosthesis and a secure prosthesis in water was highly informative.

The effects correspond to the results of the set of experiments B1 (press-fit 1-4). The prosthesis resonances in a secure condition disappear and the low frequencies of the bone become apparent (Fig. 13-16).

In the set of tests B3 the prosthesis was fully cemented and was loosened afterwards by hammer hits. This means that the cement mantel was broken in-situ but the prosthesis was still embedded in the long bone.

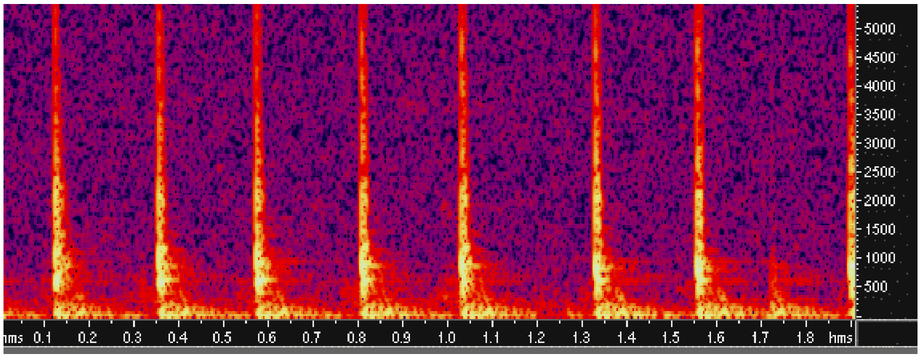

Fig. 9: Secure

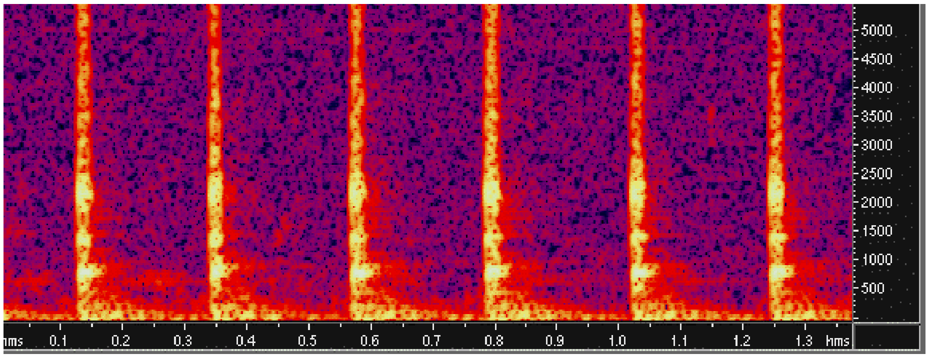

Fig. 10: One hit

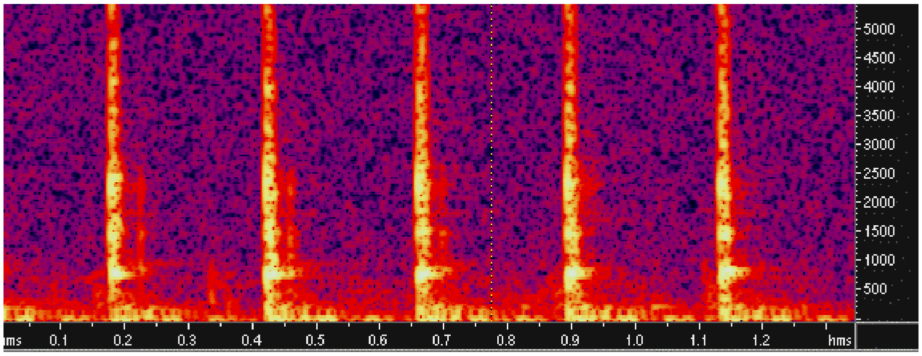

Fig. 11: Two hits

Intact cement coat

Broken cement coat: This set of experiments shows the transition from a sharp and clear spectral structure (intact cementl) to an unclear and diffuse structure especially around the low frequencies of the bone (broken cement).

The spectral image of the cemented prosthesis 1 in water seems to be more structured than the spectral image obtained during the hammering in the set of tests B1 (press-fit 1-4). Regarding prosthesis 2 bone-water, it is important to mention that the prosthesis is press-fit and 100% of bone contact cannot be achieved (because of metal-cancellous bone surface) (Fig. 17-21).

In previous studies (Li *et al*., 1996; Georgiou and Cunningham, 2001; Roder *et al*., 2003; Rosenstein *et al*., 1989). It has not been possible to reliably determine if a hip endoprosthesis is loose. The tested prostheses are

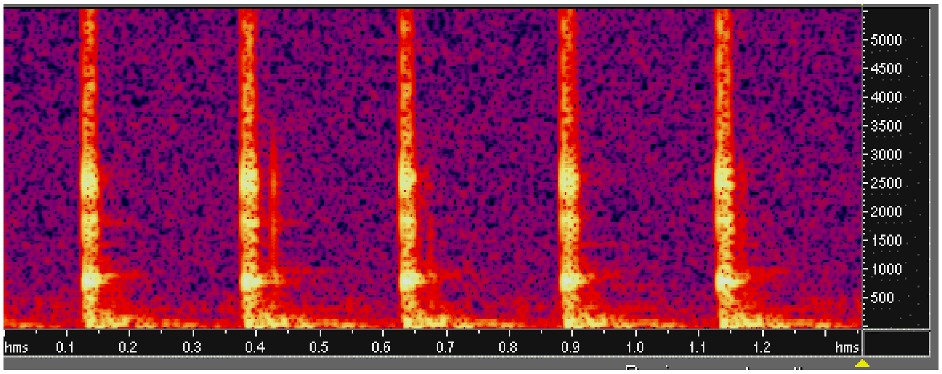

Fig. 12: Firm/press-fit

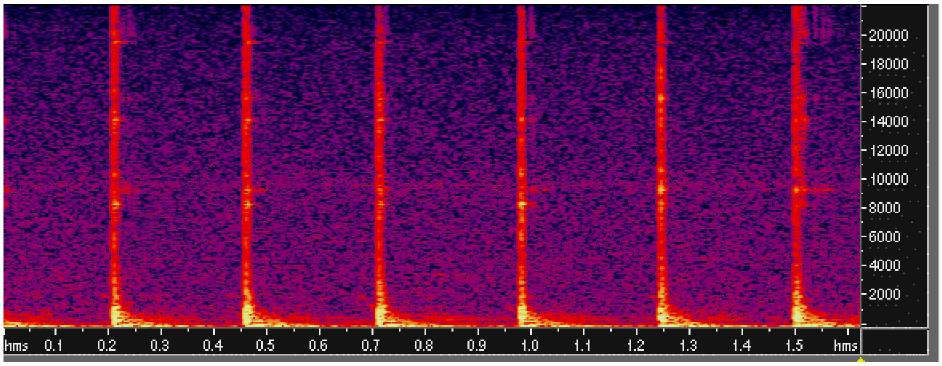

Fig. 13: Loose prosthesis 2 bone-water

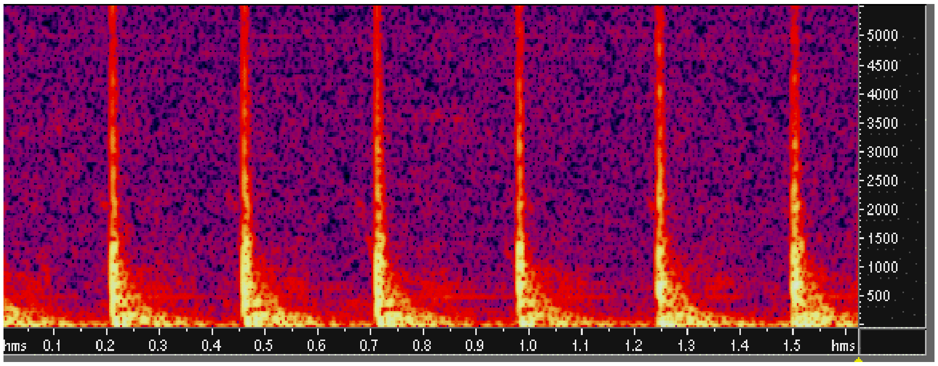

Fig. 14: Loose prosthesis 2 bone-water

able to vibrate well even in a muffled environment (soft tissue simulator) and keep their unique vibration signature. Typical frequencies are stretched in the area around 20 KHz. An observation of very high frequencies is not necessary according to our study.

Weak signals or decreased sensibility do not play an important role but in some cases over-modulation-phenomena can be found (harmonics). There is a more intensive dampening of prosthesis vibrations with increased bone contact. A tight fit bone contact with the prosthesis erases almost completely the prosthesis vibration signature. However, the bone structure gives significant spectral information. In all experiments the frequencies around 1 KHz show significant changes

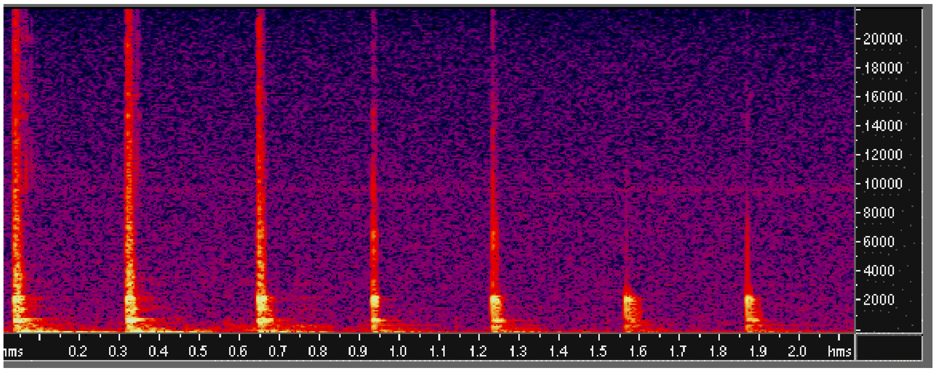

Fig. 15: Firm prosthesis 2 bone-water

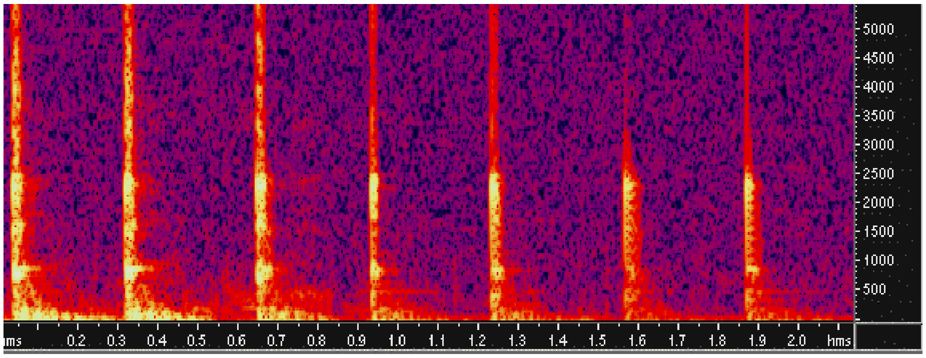

Fig. 16: Firm prosthesis 2 bone-water

Fig. 17: Prosthesis with bone cement (Pallacos with Gentamicin)

(experiments A and B). Here the bone frequencies are lower than the prosthesis frequencies. It is striking that a cemented prosthesis with an intact cement mantel shows a different bone sound signature when compared with a press-fit cementless prosthesis or a loose-cemented prosthesis.

The performed correlation analysis of the spectral frequencies shows a very good reproducibility of the measured spectral information within each test. With an average of six measurements per test the correlation in all sets (A- D) was >0.95.

Our experiments indicate that in order to achieve the objective of osteointegration surveillance and identification of interface loosening the observation of changes in bone frequencies is more suitable than the prosthesis sound signature changes alone. There are significant clues for a correlation between prosthesis position and bone spectrums. There are well identifiable patterns between total contact of the prosthesis (intact cement mantel), partial contact (press-fit in sets B1-B4) and loose contact.

For the construction of acoustic models in the future less attention should be paid to the soft tissue simulation

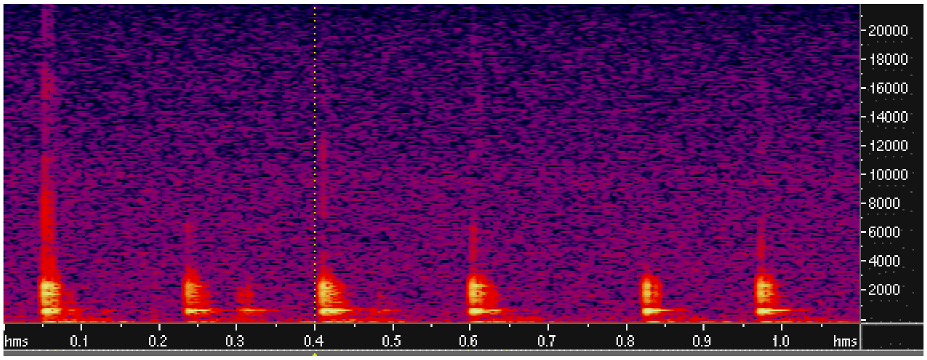

Fig. 18: Cemented prosthesis 1 water

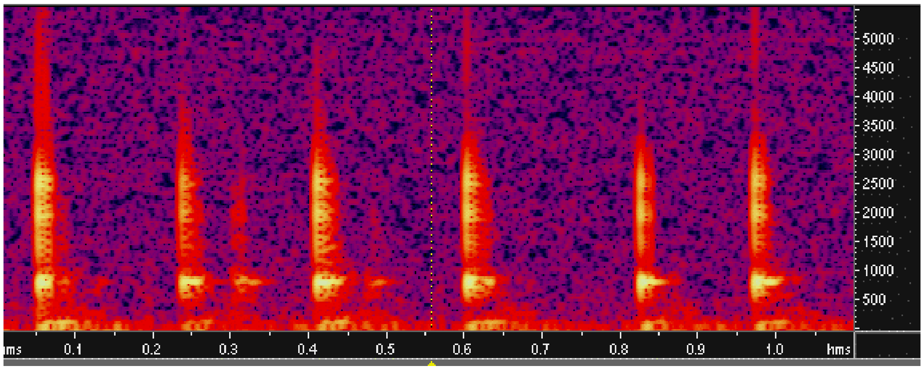

Fig. 19: Cemented prosthesis 1 water

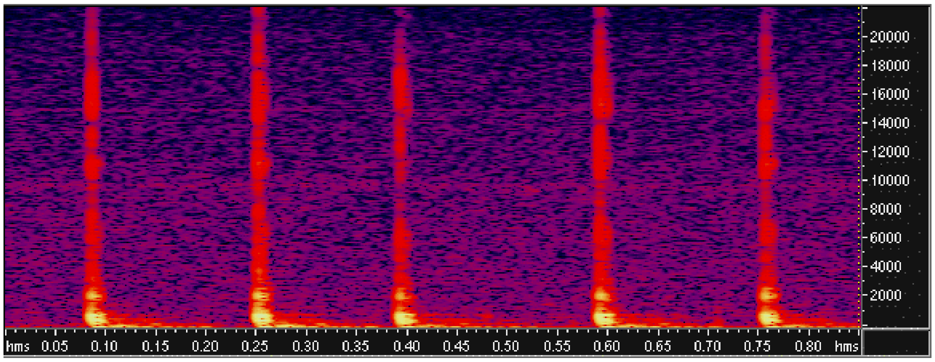

Fig. 20: Loose Cement prosthesis 1 water

and rather to perform the tests in more anatomical and realistic model (cadaver tests).

Low bone frequencies have the advantage of a possible external measurement and good transmission of sound energy, for example trough the knee and hip joints. In order to achieve an optimal reproducibility of all experiments it is important to keep all the geometries of the acoustic environment as constant as possible. If this is the case very good spectral correlations >0.95 within the tests can be achieved.

The results of the acoustic tests in the different prosthesis models show that FRM has the potential to

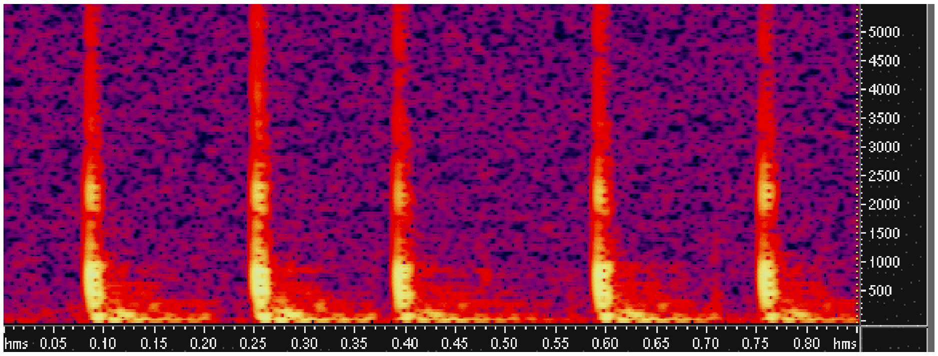

Fig. 21: Loose cement prosthesis 1 water

become a non-invasive and non-traumatic method suitable for hip prosthesis integrity monitoring and interface analysis. This possibility will have to be investigated further in clinical trials.

CONCLUSION

The difficulties to diagnose loosening in hip arthroplasty using conventional methods or vibration analysis have been shown to be unreliable in the past. The Resonance Frequency Monitoring (FRM) is a non-invasive and non-traumatic method of vibration and sound analysis. In a series of tests in vitro the possible application of FRM as a method for hip prosthesis integrity and surface analysis was investigated.

The experiments were conducted on different cow bone models with different types of hip implants in a soft tissue simulator. Three different types of bone-prostheses were used. The first model was of a secure prosthesis with an intact cement mantel, the second model was of a loose prosthesis with a broken cement mantel and the third model was a press-fit cementless prosthesis.

The results show that the more contact between prosthesis and bone the more dampening of the prosthesis vibration is found. A secure prosthesis with an intact cement mantel erases almost completely the prosthesis vibration and sound signature. However, the bone structure gives significant spectral information. The bone frequencies are lower than the prosthesis frequencies. We found that a secure cemented prosthesis with an intact cement mantel showed a different bone vibration and sound signature when compared with a press-fit cementless prosthesis or a loose prosthesis with a broken cement mantel.

Our experiment results suggest that for the objective of hip prosthesis integrity monitoring and surface analysis the changes in bone frequencies are more suitable than the observation of changes in prosthesis frequencies alone.

The results also show the potential for RFM to become a non-invasive and non-traumatic method suitable for hip prosthesis integrity monitoring. This will have to be evaluated further in clinical trials.

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