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Acoustic Properties of Femoral Components of Hip Endoprostheses Analysis Using Frequency-Resonance-Measurement in a Soft Tissue Simulation Model

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Abstract: Objective of this study is if the technique of Frequency-Resonance Measurement (FRM) can be used to reliably and non-invasively detect the loosening of the femoral component of a metal hip endoprosthesis. As a first step to determine the feasibility of FRM we investigated the own sound property of a full metal body hip endoprosthesis. Four different types of endoprostheses were tested to establish their acoustic properties regarding own frequency and resonance. In the first step the acoustic properties of the implants were determined. In the second step the acoustic properties of these metal specimens under the influence of a soft tissue simulation were investigated. The test results for the investigated prostheses showed typical similarities regarding the pattern of the spectral lines as well as the duration of the oscillations. All spectral lines where sharply marked and were situated between 1-20 kHz. The duration of oscillation was up to 700 ms. In all tested series the correlation in the 6 measurements of each prosthesis model in each mode were >0.95. In a soft tissue simulation model there still was a detectable specific acoustic pattern for each prosthesis model. FRM might be used as a remote and non-invasive tool for monitoring in-growth or loosening of hip endoprostheses. Mutations in this dimension can be easily automated for a computerized evaluation. The soft tissue dampening is a factor of less importance. We have now begun *in vivo* studies of different interface situations, cadaver studies are planned after that.

Key words: Acoustics, fequency-resonance, biomechanics, bone cements, femur pathology ultrastructure, hip prosthesis

INTRODUCTION

In the field of orthopaedic surgery there is no satisfactorily reliable and safe method available yet for the determination of the in growth or loosening of a hip endoprosthesis (Kramhoft *et al*., 1996; Rosenstein *et al*., 1989).

So far, standard procedures in a case of a clinically suspected loosening are conventional radiographs, bone-scans and Digital Subtraction Radiographs (DSA) (Miniaci *et al*., 1990; Qi *et al*., 2003; Simank *et al*., 1998). All of these include exposure to radiation the DSA is also an invasive procedure. All of these methods result in a relatively low sensitivity and specitivity and a poor inter-and intraobserver variability (Kramhoft *et al*., 1996; Rosenstein *et al*., 1989). For these reasons, screening procedures with the described methods are not feasible. It is thereby often problematic to diagnose early- and delayed aseptic loosening in due course. First investigations are mostly undertaken when patients complain about pain on excertion. At this stage often there is already a significant loss of bone stock adjacent to the implant due to macro- and micro-movements. There is so far no reliable non-invasive and radiation-free method available to diagnose the loosening of the prosthesis-bone or prosthesis-bone cement-bone interface in the case of a suspected loosening of a hip endoprosthesis.

Objective of this study is if the technique of Frequency-Resonance Measurement (FRM) can be used to reliably and non-invasively detect the loosening of the femoral component of a metal hip endoprosthesis. As a first step to determine the feasibility of FRM we raised the question if there is an own sound property of a full metal body hip endoprosthesis. If so, is it possible to determine between different models and how would the acoustic properties change by the dampening of the surrounding tissues. The measurement technique and its feasibility for

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the use at the bone-prosthesis interface of different types of hip-endoprostheses shafts are determined. Furthermore the acoustic properties of these in air and simulated soft tissue environment are investigated.

Frequency resonance measurement has been used for many years in the quality- and material control of the automobile- and aerospace industry. Via an acoustic analysis, the material bonding is tested for structural integrity. Sound patterns caused by vibrational tools where tested in the past for the determination of prosthetic loosening (Georgiou and Cunningham, 2001; Li *et al.*, 1995, 1996; Natali *et al.*, 1997) a clinical tool is so far not available. Acoustic measurements have so far failed to distinguish between a loose and a stable prosthesis-bone cement-bone interface (Davies *et al.*, 1996).

MATERIALS AND METHODS

The implants used in this study were (Fig. 1):

Implant A: Type G1, Cementless structured fixation using surface structure Spongiosa Metal® II, ESKA Implants GmbH and Co., Lübeck, Germany.

Implant B: Type GHE for Stem Extension, ESKA Implants.

Implant C: I.S.P.® Endo-Exo-Prothese, ESKA Implants.

Implant D: Long stem prosthesis Standard, ESKA Implants.

In the first step the acoustic properties of solely the implants was determined in the way described below. In the second step the acoustic properties of these metal specimen under the influence of a soft tissue simulation was investigated.

Setup for the measurement of acoustic properties of endoprostheses: Fixation of the prostheses was in all tests with a thin nylon rope around the neck of the prosthesis. This was to assure the least dampening possible. Fixation of the microphone was 10 cm away of the midpoint of the prosthesis. The activating impact for sound emission was performed with an acoustically neutral steel ball (120 g). After impact at the prosthesis-neck the sound was recorded. The hard impact results in a broad band impulse generation with excitation of a wide range of frequencies.

Setup for the acoustic measurement in the soft tissue simulator: Fixation of the prosthesis, the activating impact and the microphone placement was exactly as described above. The simulator was developed to mimic the situation of the soft tissue envelope of a human hip joint. It consisted of a Polyethylene (PE) sheath formed like a cylinder with a volume of approximately 5000 mL (Fig. 2). This PE-cylinder was mounted erect on a frame system and kept open on the top side. The cylinder was filled with water containing 0.9% Natrium-Saline. The object under investigation (hip endoprosthesis shaft) was immersed in the cylinder so that just the tip of the conus of the prosthesis was above water level. A sinusoidal force was applied on the prosthesis shaft. For the determination of the frequencies that would be expected a testing with a 125 kHz Oscilloscope (PC-Based Digital-Oscilloscope 2130, FFT, Fourier transpormation) was performed under the later test conditions. This showed no relevant spectrals above 20 kHz (Fig. 3).

Fig. 1: The four full metal endoprostheses used in this study (A-D from left to right)

Fig. 2: The soft tissue simulation setup

The frequency measurements were therefore performed with an electronic microphone (0-25 kHz, Cardio-Signal GmbH, Hamburg, Germany) which can reliably detect very low frequencies. It is a wide-range frequency microphone which detects contact waves in solid or liquid substances rather than air waves. The acoustic properties of the apparatus itself were determined with the same activating impact onto the water surface (Fig. 4) as used on the prostheses.

Characteristic frequencies of the acoustic probes (in this case hip endoprosthesis shafts) as the own frequency of the probe or resonance where then determined in the data analysis. This data was then processed with an analyser-software (Adobe Audition Version 12.5, Adobe Systems Incorporated, San Jose, California, USA) for the frequency analysis. The graphical output shows the time axis (in seconds) on the x-coordinate whilst the y-coordinate displays the frequency-axis (from 0 to 22,000 hertz (Hz)). Colour coded is the sound intensity at the given point in the time-frequency level. This thereby provides a three-dimensional pattern.

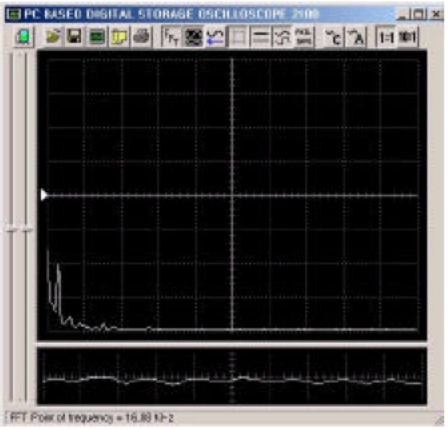

Fig. 3: Spectral analysis of test body up to 125 kHz. Under 20 kHz some resonancy peaks, above that no significant energy is detectable

Intra-individual spectral changes were measured with a high dynamicity of 20 decibel (dB). This means a change in sound intensity by the factor of 100 (10,000%). Such changes in intensity can reliably be detected and measured. The statistical analysis of the data was performed with a correlational analysis (SPSS 11.0, SPSS Inc., Chicago, Illinois, USA).

Technical aspects and interpretation of the transmitted signals: The evaluated signal chain has been computed in accordance to the theories of telecommunication and communication engineering. It is composed of a chain of different signal conveyors or converters. Every single chain link can be described with a so called transmission-function. The signal transmission can be described equally in the frequency range A (f) and the time frame A (t). The advantage of the description of frequency is the fact that the output signal (which equals the measured signal) of the complete chain can be described as the product of the transmission function of the chain links:

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

Y (f):	Spectral function output signal
A (f), B (f),..:	Transmission function of the chain links
X (f):	Spectral function input signal

The output signal Y (f) equals the measured electrical signal, the input signal X (f) equals the spectral function of the activating impact. Transfer elements in this case are PE cylinder, bone, gap between prosthesis and bone, bone cement, prostheses, soft tissue simulation and microphone.

Metrological objectives:

- The changes of certain internal transfer functions e.g., C (f) affect directly proportionally the output signal Y (f) when the transfer elements X (f), A (f), B (f) are constant. Therefore generally changes in Y(f) are sufficient for a comparative evaluation of C (f).
- If C (f) has a clearly distinguishable structure

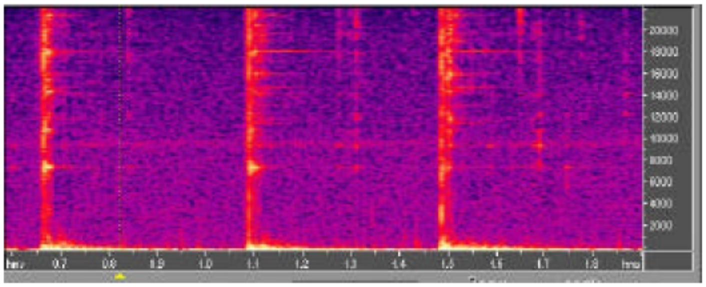

Fig. 4: FRM of the soft tissue simulator without endoprosthesis (zero-testing)

compared to the other signals X (f), A (f), B (f) (e.g., high resonance peaks) and X (f), A (f), B (f) express a generally plain and structure-less signal, then the signal of Y (f) alone allows a conclusion regarding C (f) without the reference signals. Y (f) by that is an absolute criterion, in the ideal case the signal of the output function X (f) should be flat.

The decibel-scale was used for the resulting arrays. The dB equals the 10th logarithm of the difference of two signal energies. The dynamic scale used in this study encompassed 48 dB, equalling a signal contrast of 1: 60,000.

RESULTS

Resonance-frequency determination of different prostheses models: The test results fort he investigated prostheses showed typical similarities regarding the pattern of the spectral lines as well as the duration of the oscillations. All spectral lines where sharply marked and were situated between 1-20 kHz. The duration of oscillation was relatively long, up to 700 ms. These sharp and clearly marked patterns where on the other hand very individual, an identification of the prosthesis model by this pattern easily possible. In all tested series (A-D) the correlation in the six measurements of each prosthesis model in each mode were >0.95.

Figure 5 shows the oscillating spectrum of prosthesis number 1 with its typical energy- and frequency maximum. This pattern is so unique and reproducible for this specific prosthesis that it could be termed a spectral fingerprint. All prosthesis models display typical individual and sharply marked spectral lines with a certain longetivity in the different testing modes.

Acoustic properties of the metallic test bodies under the influence of a standardized soft tissue simulation: Already the fixation of the prosthesis by hand whilst setup of the test series (Fig. 6) changed the acoustic properties of the tested endoprostheses. There was a marked progressive decay with time in the amplitude of the free oscillations (damping). Nevertheless was the specific pattern of each prosthesis type clearly detectable. In the soft tissue simulation model tested without prosthesis there were previously undetected new acoustic patterns detectable. These were clearly the own acoustics of the testing apparatus. Under the soft tissue simulator there was a dampening effect similar to the testing with a fixated prosthesis (Fig. 7). In a soft tissue simulation model there still was a detectable specific acoustic pattern for each prosthesis model. The acoustic patterns of the prosthesis models were overlaid by the own pattern of the soft tissue simulator but each specific fingerprint was still detectable. Each prosthesis was tested six times and there was a correlation of <0.95 between the patterns of each prosthesis.

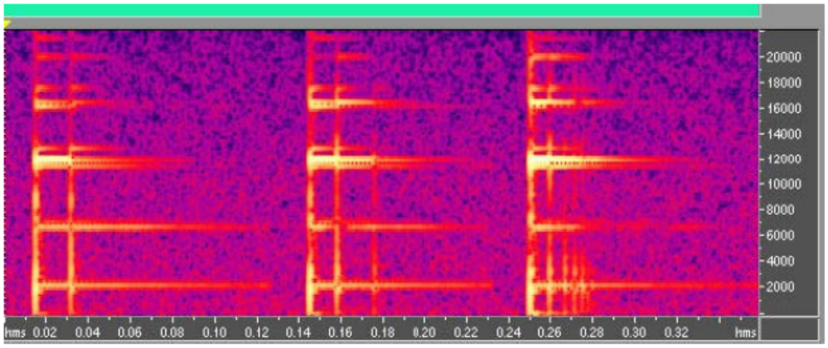

Fig. 5: Prosthesis A tested in air, the specific acoustic pattern clearly visible

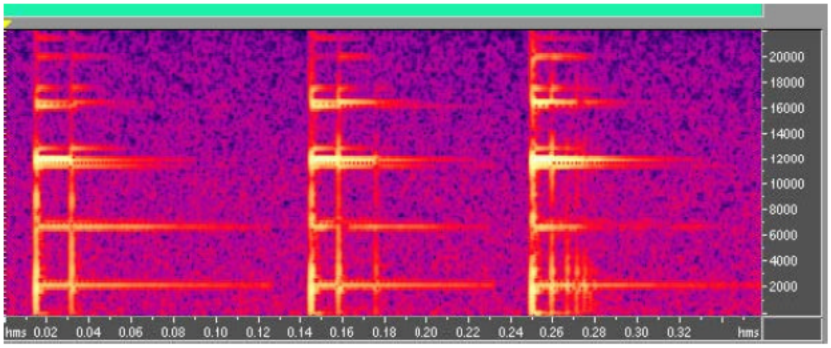

Fig. 6: Prosthesis C when tested with a tight grip around the shaft of the prosthesis

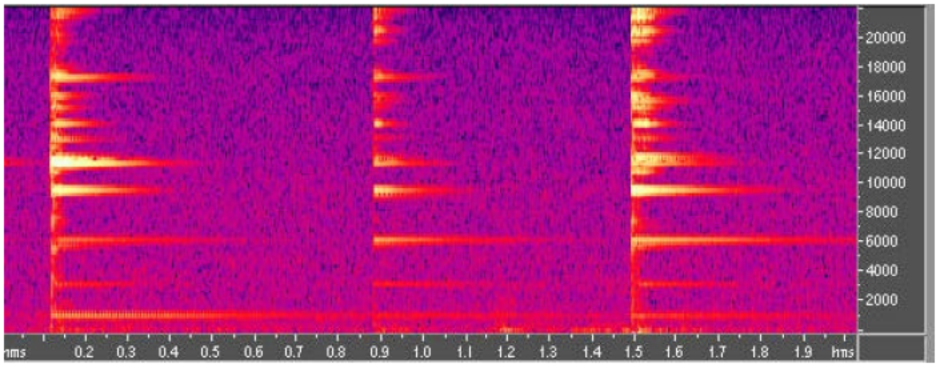

Fig. 7: Prosthesis D in the soft tissue simulator. Some dampening and overlay by soft tissue simulators own acoustics but prosthesis-specific pattern still clearly detectable

DISCUSSION

In the past many study groups have investigated the possibility to detect the loosening of hip implants by sound or vibration (Davies *et al*., 1996; Georgiou and Cunningham, 2001; Li *et al*., 1995, 1996; Natali *et al*., 1997; Roder *et al*., 2003) with mixed results already in the in vitro setting. No standardized testing method is available for clinical use yet. It has been investigated in the past if the debonding of the cement-metal interface of cemented femoral components of total hip arthroplasty could be determined using ultrasound and acoustic emission (Davies *et al*., 1996) in a study using a vibrational analysis it was not possible to reliably differentiate between a loose and a stable prosthesis (Li *et al*., 1995).

So far this is the first study to investigate the acoustic properties of different hip endoprosthesis models and the interferences of their acoustic surrondings in an *in vitro* study. The tested hip endoprosthesis showed, in a defined setting, acoustic properties that made differentiation possible by visualisation. Frequencies of up to 20 kHz are sufficient for acoustic studies involving the tested hip endoprostheses, testing of higher frequencies is not required.

There where no problems regarding weak signals or sensitivity, in some prostheses models there was even slight oversteering in the measurements detectable. Also dampening still made measuring of the acoustic properties possible. This prosthesis type specific acoustic pattern (Fingerprint) can also be visualized after dampening by a soft tissue model. By interference analysis it is also possible to determine this acoustic fingerprint despite of interference acoustic emissions by the soft tissue simulation model. The soft tissue simulation model has its own acoustic properties. These are different from the prosthesis properties regarding the frequencies and duration. It is possible to distinguish between the prosthetic acoustics and the artefacts caused by the soft tissue component once an *in vitro* testing of a specific model has been performed. The correlation analysis of the frequency spectrals showed with >0.95 in all tested series a satisfactory reproducibility.

CONCLUSION

Hip endoprostheses showed acoustic properties that can be readily detected by resonance frequency analysis. We could show that a differentiation of models is possible by visualisation. The observed spectral-variances are in their magnitude considerable, up to 20 dB. Mutations in this dimension can be easily automated for a computerized evaluation.

This feature of the method of FRM could allow its use in the quality and material control in the process of manufacturing of hip endoprostheses. The prosthesis type specific acoustic pattern (Fingerprint) can also be visualized after dampening. By interference analysis it is also possible to determine this acoustic fingerprint in a soft tissue simulation model. The acoustic pattern of the prostheses is so specific that an automated processing with subtraction of the interference should be possible even after implantation in the human body. We are investigating this at the moment. We have now begun *in vivo* studies of different interface situations, cadaver studies are planned after that. These studies will focus on the setup of the prosthesis-(bone cement)-bone interface, with the question how the dampening effect of a tight interface changes the acoustic pattern of bone and prosthesis. For an optimal reproducibility the geometries of the acoustic surroundings should be kept as constant as possible. If so, a correlation of >0.95 can be achieved.

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