A NEW METHOD FOR DETECTION OF TOTAL HIP REPLACEMENT LOOSENING

Development and First Results of a Novel Mechano-acoustical Sensor

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Abstract: Currently applied diagnostic methods for loosening of total hip replacements often result in imprecise identification of implant fixation and in the worst case unnecessary revision surgery. Developed sensors integrated in implants require adequate energy supply, which in most cases is achieved by inductive coupling and complex data telemetry. In order to avoid a telemetric apparatus, we developed a passive concept of a novel in vivo method to improve diagnostic investigations of total hip replacement loosening. A mechano-acoustical sensor, attached on small membranes inside the femoral hip stem, is proposed and enables osseous anchorage detection. The sensor is excited and detected by extracorporeal coils. First functional models show significant differences between different material layers located at the membrane. The novel in vivo sensor system has a promising potential to detect implant loosening.

1 INTRODUCTION

Prediction of total hip replacement (THR) loosening using ex vivo techniques such as imaging often fails to deliver reliable and localized results (Temmerman, 2005). Moreover, monitoring of implant anchorage is an important factor in determining the longterm success rate of implants (Pastrav, 2009). Currently diagnostic methods used to identify THR loosening do not provide satisfying results. Hence, researchers strive for supporting techniques or even attempt to replace ex vivo techniques by novel in vivo sensors such as accelerometers in vibrometry (Li, 1995), which showed that implant instability can be identified by several harmonics in the output signal of the sensors. However, the low signal-to-noise ratio of presently available accelerometers needs to be addressed (Marschner, 2007).

Besides miniaturized design and biocompatibility, a reliable power supply is a challenge in development of in vivo sensors. The technology of choice for vibrometry is wireless powering and data telemetry (Puers, 1999). With this system, energy can be provided externally and transcutaneous. This is achieved by a primary coil, used outside the human body, and a secondary coil integrated in the implant in vivo.

Inductive powering and passive data telemetry is effective for implants where both coils are positioned with small separation distance and fixed orientation. In many cases this cannot be achieved because of possible changes in the patients´ weight. The influence of variable distances between both coils leads to lower coupling factors and therefore poor signal transmission. Additionally, interferences of the inductive telemetry during patients´ movements could occur. Another problem is the use of only low frequencies, which affect the damping of the signals caused by eddy currents, especially in metals. This is an evident drawback for orthopaedic implants, especially for THR where biocompatible metal alloys are used.

Due to the aforementioned reasons we propose a novel and passive sensor concept without inductive

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coupling of two coils. The concept is characterized by extracorporeal coils and permanent magnets inside the THR acting as loosening sensors. In the present work, we demonstrate the development of a custom trigger circuit as well as first results gained by functional models of a sensor prototype.

2 METHODS

2.1 Principle of the Loosening Sensor

The proposed method is based on the conservation of momentum including impingement of a magnetic body on a membrane placed inside the femoral hip stem (Figure 1). The magnetic body, fixed on a flat spring, is part of the sensor, which is designed as a simple mechanical oscillator for impinging in the middle of a membrane (Ruther, 2010). The magnetic poles allow oscillations using an external magnetic field impulse. Thus, motion of the oscillator is initiated using an external coil.

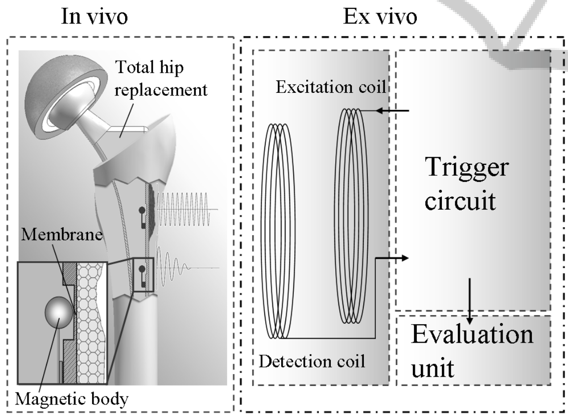

Figure 1: System concept of the novel sensors for excitation of the THR inside the hip stem and wireless detection of implant loosening.

The end velocity of the oscillator after impingement varies depending on the osseointegration of the implant. On the one hand, a well osseous integrated implant leads to lower end velocities of the oscillator after impingement caused by the higher energy transfer of the oscillator due to lower deformation energy. Therefore, the spring back of the sensor will be lower. On the other hand, a loosened THR with soft tissue on the external surface of the membrane results in higher end velocities caused by higher deformation energy.

Since the oscillator is magnetic, the read out of the measured data can also be achieved by an external coil.

2.2 Experimental Setup

In order to demonstrate the functional principle of our loosening detection approach, a cylindrical setup composed of non magnetic aluminium was built. A 0.25 mm thick titanium membrane was mounted to the test device and tightened by screws to ensure symmetrical oscillations of the membrane (Figure 2). The oscillator was made of a steel spring and an attached magnetic neodymium body (1.3T).

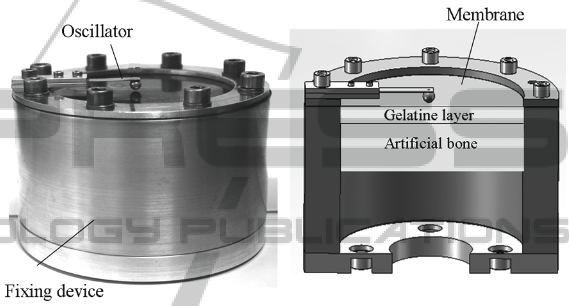

Figure 2: Experimental setup for the new loosening sensor. Left: Fixing device with oscillator, which impinge on a titanium membrane. Right: Cross section of the setup with different material layers attached to the membrane.

The influence of different material layers on the impingement behaviour of the oscillator was also tested. Thus, artificial bone substitute material (20 pcf, Sawbones, Malmö, Sweden) with a thickness of 50 mm was used to simulate full osseous implant integration. A further setup with additional gelatine layers of 10 mm and 5 mm thickness, simulating a loose implant was investigated (Figure 2). Gelatine was used to represent collagen and fluid outside the membrane as in the case of implant loosening. In a final setup, small gaps were included in the artificial bone in order to simulate bone defects adjacent to the membrane (partial osteolysis). Measurements for each material setup were repeated 20 times.

2.3 Power Supply and Detection

2.3.1 Inductive Unit

The inductive unit is composed of two coils and shall be placed outside the patients` leg in defined distances to the oscillators.

In the experimental setup (Figure 3) the excitation coil made of a ferrite core to concentrate the streamlines of the magnetic field on the oscillator inside the implant. Ferrite cores allow faster reduction of the magnetic field than iron cores. The detection coil included an iron core with a diameter of 2.3 mm for precise detection of the oscillator signal.

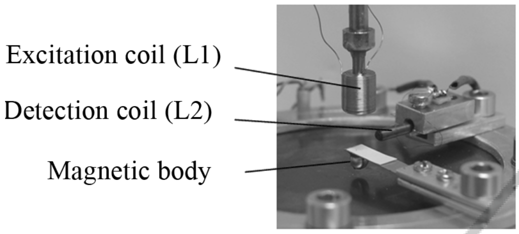

Figure 3: Arrangement of the excitation and detection coils around the oscillator.

2.3.2 Trigger circuit

For adequate configuration of the trigger circuit (Figure 4), it was important that the magnetic field of the excitation coil (L1) reduces very fast. Otherwise, the signal of L1 overlaps the signal of the oscillator. Therefore the external hardware included a central processing unit (CPU) where the sequence control could be achieved by different counters, configured by a custom Labview program (NI 9.0, TX, USA). Counter 0 defined past which time counter 1 was closed. Counter 1 determined the time how long switch 1 was closed. An overflow of counter 0 resulted in an increasing edge (CTR 0 OUT), thus signalizing that switch 1 could be closed due to the excitation time and displacement of the oscillator. Simultaneously, the release of counter 1 was introduced (CTR 1 GATE). The signal for the overflow of counter 1 was CTR 1 OUT.

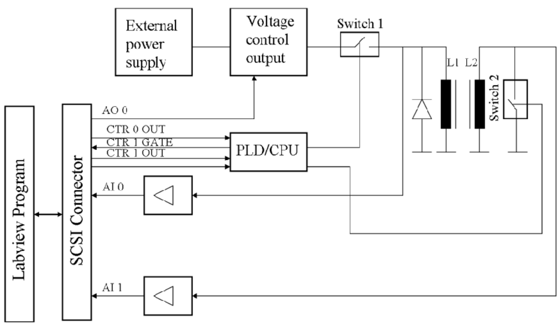

Figure 4: Block diagram of the external hardware.

A recovery diode enabled the fast decrease of the excitation magnetic field. Switch 2 was controlled by a digital signal defining the time when the detection coil (L2) could monitor the oscillator signal without detection of the excitation magnetic field. The signal of L2 was amplified and evaluated in the Labview program. Parameters such as the highest amplitude after impingement and amplitudes in a frequency spectrum were evaluated.

3 RESULTS

The detection of the oscillation signal of the loosening sensor resulted in a good differentiation of the varying material layers at the external side of the membrane. For evaluation the first amplitude in the time signal proportional to the highest velocity of the oscillator after impingement was considered (Figure 5). The results are presented as mean values ± standard deviation in Figure 6.

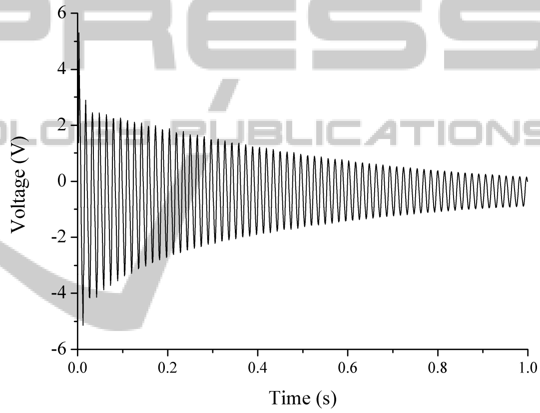

Figure 5: Time signal of the oscillation of the loosening sensor for artificial bone with partial osteolysis.

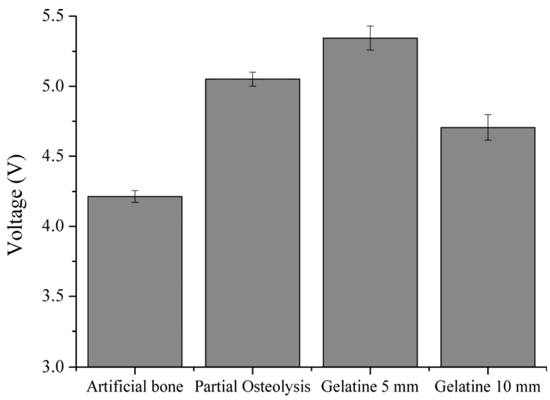

Figure 6: Results of the amplitude measurements with different material layers attached to the external side of the membrane.

Furthermore, the signal in the frequency domain as spectral analysis with a Fast Fourier Transformation was investigated (Figure 7). The first eigen frequency of the oscillator was identified at 67 Hz. The peak of the second harmonic was at 134 Hz. Comparison of different material layers revealed decreased amplitudes with a thicker gelatine layer.

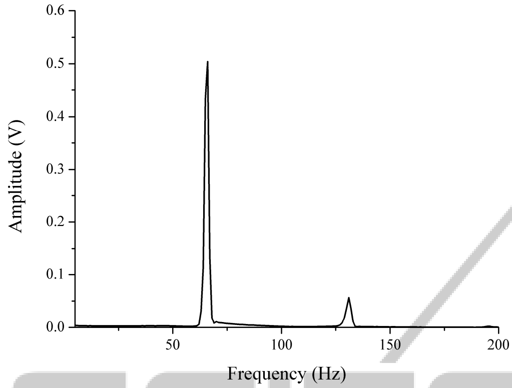

Figure 7: Frequency spectrum of the oscillations of the loosening sensor.

4 DISCUSSION

With respect to the standard application of total hip replacements, unsatisfying results in loosening diagnosis increase the demand for more precise in vivo techniques. Inductive coupling based on radio frequency powering to provide energy supply of in vivo sensors causes problems, especially with regard to the coupling factor between the two coils. To circumvent this problem, our approach was to show the capability of a novel sensor principle using basic research models.

The trigger circuit to control the excitation and detection coils allows the identification of the highest velocity after impingement of the oscillator on the membrane. This leads to promising experimental results, which show the usability of the described in vivo method for detecting total hip replacement loosening with extracorporeal coils and a passive internal sensor.

The robustness of the oscillators due to the simplicity of the assembly guarantees functionality during intraoperative impaction and sterilization of the implant. Moreover, the oscillators can be used in experimental applications to determine the quality of osseointegration of new coated implant materials.

5 CONCLUSIONS

In the present study, a new measurement method for in vivo diagnosis of total hip replacement loosening without inductive coupling based radio frequency powering was demonstrated. The described loosening sensors with two coils and a custom trigger circuit shows results with good prospects in preliminary tests.

Future work will include the implementation of the loosening sensor in real implants. Furthermore, solutions for continuous excitation and therefore the optimization of the trigger circuit are aspired.

Enhancements of the inductive unit are designated with respect to air-core coils as detection coils, which are switched as differential coils for better erasure of the excitation field during detection.

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