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A Medical Wireless Measurement System for Hip Prosthesis Loosening Detection Based on Vibration Analysis

¹ Sebastian Sauer, ² Sabine Kirsten, ³ Florian Storck, ⁴ Hagen Grätz,

¹ Uwe Marschner, ³ Dietmar Ruwisch and ^{1,4} Wolf-Joachim Fischer

¹Institute of Semiconductors and Microsystems, Technische Universität Dresden,
Dresden, Germany

Tel.: +49 351 463 34939, +49 351 463 37021

² Electronics Packaging Laboratory, Technische Universität Dresden, Dresden, Germany

³ Ruwisch & Kollegen, Berlin, Germany

⁴ Wireless Microsystems, Fraunhofer IPMS, Dresden, Germany

E-mail: sebastian.sauer@tu-dresden.de

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Abstract: Vibration analysis is a promising approach in order to detect early hip prosthesis loosening, with the potential to extend the range of diagnostic tools currently available in clinical routine. Ongoing research efforts and developments in the area of multi-functional implants, which integrate sensors, wireless power supply, communication and signal processing, provide means to obtain valuable in vivo information otherwise not available. In the current work a medical wireless measurement system is presented, which is integrated in the femoral head of a hip prosthesis. The passive miniaturized system includes a 3-axis acceleration sensor and signal pre-processing based on a lock-in amplifier circuit. Bidirectional data communication and power supply is reached through inductive coupling with an operating frequency of 125 kHz in accordance with the ISO 18000-2 protocol standard. The system allows the acquisition of the acceleration frequency response of the femur-prosthesis system between 500 to 2500 Hz. Applied laboratory measurements with system prototypes on artificial bones and integrated prostheses demonstrate the feasibility of the measurement system approach, clearly showing differences in the vibration behavior due to an implant loosening. In addition a possibility to evaluate the non-linear mechanic system behavior is presented. *Copyright © 2013 IFSA.*

Keywords: Hip prosthesis loosening detection, Vibration analysis, Wireless medical system, Lock-in amplifier.

1. Introduction

Established and widely used diagnostic techniques in clinical routine, such as plain radiography, bone scintigraphy or arthrography (subtraction or nuclear), are yet to unreliable in order to determine the fixation

state of a hip prosthesis in the bone as, for example, discussed in [1-3]. Under these circumstances, a reliable predication of the loosening state is still challenging and leaves room for misinterpretation. This leads to either revision of sufficiently osseointegrated endoprostheses (false-positive result)

or a late diagnosis with bone stock destruction and difficulties in implant revision (false-negative result). Therefore, there are continuing efforts to establish new or enhance established diagnosis techniques to increase sensitivity and specificity. In [4], a shaft integrated loosening sensor based on the conservation of momentum theory is described and evaluated with an oversized demonstrator; in [5], an ultrasound based extracorporeal testing method is presented. A promising alternative approach to determine the loosening state is vibration analysis, e.g., frequently used in mechanical structural analysis. A measurement system, capable of delivering amplitude and phase information of a femurs' frequency acceleration response due to a mechanical excitation, is the required base to extract system resonance frequencies. By monitoring the shift of these resonances, predictions about the loosening state are possible. Several early attempts [6, 7] used both, extracorporeal vibration excitation and extracorporeal acceleration measurement, in order to determine the system response in frequency or time domain. Especially for an extracorporeal acceleration measurement the obtained signal amplitude is heavily damped due to the influence of tissue. Is a miniaturized system directly placed in the prosthesis, as, e.g., realized by Puers [8], the negative influences of tissue in the measurement path are minimized. In difference to a previous realization with a prosthesis shaft integrated system [9], a solution with a femoral ball head integrated measurement system is presented in this paper (Fig. 1). Within this work the proposed overall medical system is described, a description of the integrated lock-in amplifier is given and two housing variants of the femoral ball head integrated system are discussed. The developed end-user application is described. Several experimental results of applied measurements on an artificial bone-prosthesis system, demonstrating the influence of loosening, are presented.

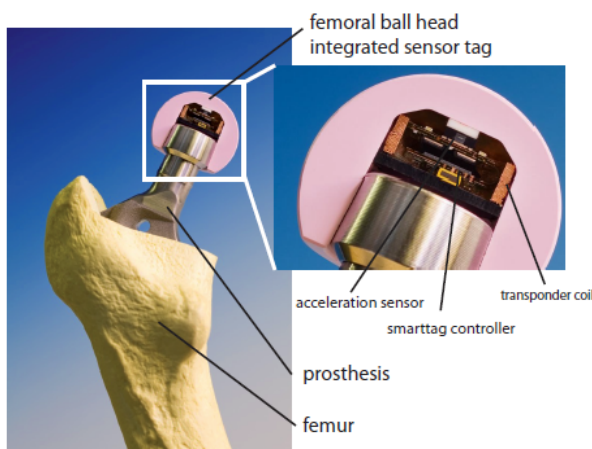


Fig. 1. Medical wireless system (cross sectional cut) integrated in the femoral head of the hip implant (packaging variant).

2. Diagnostic Measurement System

The diagnostic measurement system (Fig. 2) consists of two main components: the prosthesis integrated wireless sensor system (intracorporeal unit) and a reader station combined with a mechanical vibration excitation and measurement system, both connected to a PC (extracorporeal unit).

The wireless sensor tag is placed in the femoral ball head of the hip implant, in difference to the previous placement in the stem [9]. This approach follows the request of the medical industry project partners due to the following reasons: 1) it simplifies the manufacturing process (modifying stems involves higher costs) 2) it permits an unproblematic sterilization process (stems exhibit a special micro porous surface coating supporting osseointegration, which requires a gamma sterilization process with devastating effect on integrated hard- and firmware) and 3) it reduces the required number of system variations (there are less femoral ball head types and embodiments).

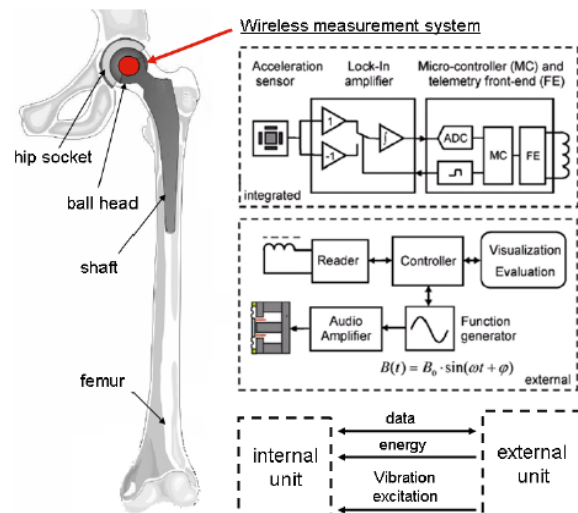


Fig. 2. Overview of the diagnostic measurement system.

The intracorporeal system is built around a freely programmable transponder unit called Smart Tag 1 (Fraunhofer IPMS ST1). It is designed specifically for transponder applications requiring a sensor interface in order to monitor physical quantities besides providing identification information. It includes a 16 bit MSP430 microcontroller core, 16 kByte Flash, 8 kByte RAM and 512 Byte EEPROM memory, 16 digital I/O signals, 2 counter/interval timers, a Real-time clock, RF front end, 10 bit A/D converter with four channels, I2C bus module and an integrated voltage regulator. Wireless energy transmission and bidirectional data communication via inductive coupling and amplitude modulation between tag and reader are in accordance to ISO 18000-2 standard at a carrier frequency of 125 kHz. Transponder coil and a tuning resonance

capacity are connected directly to the chip.

In order to perform vibration analysis, the application specific circuitry incorporates a low power acceleration sensor (ADXL327, Analog Devices) for x, y and z axis measurements with a mechanical resonance frequency of 5.5 kHz. It provides a typical measurement frequency range (3dB cutoff frequency) of 0.5 to 1600 Hz in x, y direction and 0.5 to 550 Hz in z direction and a typical sensitivity of 420 mV/g with a measurement range of ± 2.5 g. Since the acceleration sensor output is strongly affected by noise, additional signal preprocessing is required. For this purpose a single phase lock-in amplifier, based on a switched rectangular reference signal, has been integrated in the sensor tag in order to improve the signal-to-noise ratio. The mechanic excitation system consists of an electro dynamic vibration excitation (S50018, TIRA vib), in short a shaker, with a maximum force of 18 N (unloaded) and a working frequency range from 2 Hz to 18 kHz. It is connected to a power amplifier and measurement unit. Besides amplification of the excitation signal provided by the reader, it is responsible for measurements of excitation current and voltage as well as acceleration and static pressure at the point of force application. For a medical diagnosis system, these additional measurements are necessary in order to detect faults and to ensure reproducibility between different measurements.

The external reader unit generates the magnetic field generation, extracts data and provides the low frequency input signal for the sinusoidal mechanical vibration excitation. Further measurement flow control, processing and visualization of measurement data as well as data storage and maintenance are carried out on a PC connected to the reader.

3. Integrated Lock-in Measurement

The lock-in measurement technique, as an application of cross-correlation in signal processing, has been identified as a very useful approach to reduce the noise influence in the measured acceleration sensor signal [10]. It is integrated in the wireless sensor tag as a discrete circuit. The approach is feasible due to the facts that the mechanical system (prosthesis, femur and surrounding tissue) is excited through the shaker with a signal of known frequency and phase, the acceleration response is time-periodic and shows a fix phase relation for each frequency, and the mechanical excitation signals frequency and phase information is available in the wireless sensor tag in order to generate the lock-in reference signal. The principle behavior of the integrated lock-in can be described through Eq. 1, in which U_L is the voltage after applying the lock-in technique, U_M is the measured signal amplitude, ω_M the measured signal frequency, ω_{ref} the reference signal frequency and ϕ_{ref} the reference signal phase, which are averaged over the time period T. For explanation

purposes, the measured signal is a spectral component of interest, contained in the mechanical system response (besides noise, harmonics, ...).

$$U_L = \frac{1}{T} \int_{t_0}^{t_0+T} \underbrace{U_M \sin(\omega_M t)}_{\text{measured}} \cdot \underbrace{\sin(\omega_{ref} t + \phi_{ref})}_{\text{reference}} dt \quad (1)$$

When the excitation signal has the same frequency as the reference signal ($\omega_M = \omega_{ref}$) and an integration time from $0 \leq t \leq T$ is used, the integral solves to Eq. 2.

$$U_L = \underbrace{\frac{U_M \cos(\phi_{ref})}{2}}_{\text{wanted}} + \underbrace{\frac{U_M [\sin(\phi_{ref}) - \sin(\phi_{ref} + 2T\omega_M)]}{4T\omega_M}}_{\text{unwanted}} \quad (2)$$

The unwanted parts in Eq. 2 are of increasing influence in the case of small integration times and small measurement signal frequencies. If for a given frequency a phase match is reached (phase difference $\phi_{ref} = 0^\circ$) the lock-in amplified signal reaches its maximum signal output (Eq. 3).

$$U_L = \frac{U_M}{2} \quad (3)$$

Due to technical constraints, such as available energy and space in the sensor tag, the generation of a sinusoidal reference can be too costly. In this case a periodic rectangular signal can be used, as reference for the lock-in amplifier, an approach also chosen for the sensor tag. The associated special circumstances (i.e., higher order harmonics) have been discussed in [9].

The acceleration sensor signal is AC coupled and split into two signal paths, which are separately amplified (inverted and non-inverted) and passed through a switch to an integrator (low pass). Therefore the integration time (T) of the lock-in amplifier has a fix value. Switching is controlled with the rectangular reference signal (with ω_{ref} , ϕ_{ref}) by the transponder unit ST1. The base frequency, for both excitation and lock-in reference signal, is the 125 kHz telemetry frequency of an internal oscillator (synchronized with reader station), which is divided by the factor n.

This leads to a large step width with increasing frequencies. The controller can adjust the phase shift to obtain measurements with an arbitrary phase angle. A disadvantage of the switched rectangular reference signal is the occurrence of odd harmonics. These are partly damped by the low pass (integrator) before digitized through the 10 bit A/D converter in the sensor tag. The magnitude information, in general, is easier to interpret in order to identify the initially unknown or estimated system resonances in a frequency spectrum. If the extrema of a single phase measurement are evaluated a changing phase relation (i.e., change of excitation or measurement

equipment) can influence a determined extrema frequency value (Fig. 3). By performing two measurements for each examined frequency ($U_{L,A}$, $U_{L,B}$), with a 90° phase difference, the magnitude can be calculated. The result is independent from an unknown reference phase angle (Eq. 4) and the behavior of a dual phase lock-in amplifier can be reproduced (regarding the magnitude).

$$|U_L| = \sqrt{U_{L,A}^2 + U_{L,B}^2} = \frac{U_M}{2} \sqrt{\cos(\phi_{ref})^2 + \sin(\phi_{ref})^2} \quad (4)$$

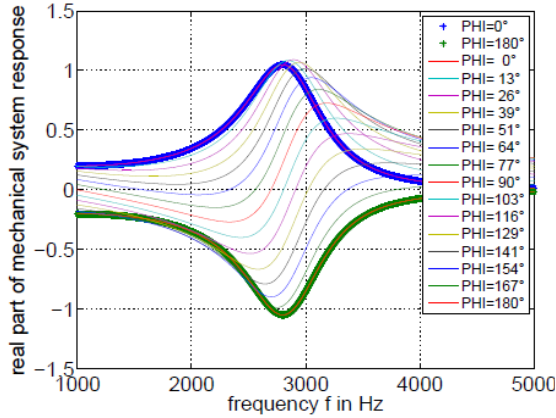


Fig. 3. Influence of a varying reference phase onto the real part of simulated mechanical system response, possibly leading to falsely interpreted resonance frequency values.

Fig. 4 and Fig. 5 demonstrate the feasibility of the approach with both numerically simulated and experimentally obtained data from the measurement system. For the applied measurements with the measurement system, the reference phase has been varied in steps of 10° between 0° and 90° . For each frequency point the two consecutive measurements ($\phi_{ref} = x^\circ$, $\phi_{ref} = x^\circ + 90^\circ$) were performed instantly after each other. When evaluating a system response, it's behavior must not necessarily be of linear nature. Especially in case of a loosening of prosthesis, a non-linear behavior is likely. This has been demonstrated in [8]. Therefore measurement techniques targeting the non-linear system should be considered. Since the presented lock-in amplifier works in the frequency domain, additional harmonics (2,3,4) besides the fundamental frequency (1. harmonic) could be present in the acceleration sensor signal output. These could be generated by the bone-prosthesis system, e.g., due to the prosthesis hitting the bone in a loose case, or also due to a nonlinear behavior of the bone-prosthesis interface. There are numerous possibilities and so far there is no complete understanding, of what the actual reasons are.

As Fig. 6 depicts a non-linear system responds to a sinusoidal excitation with additional spectral components.

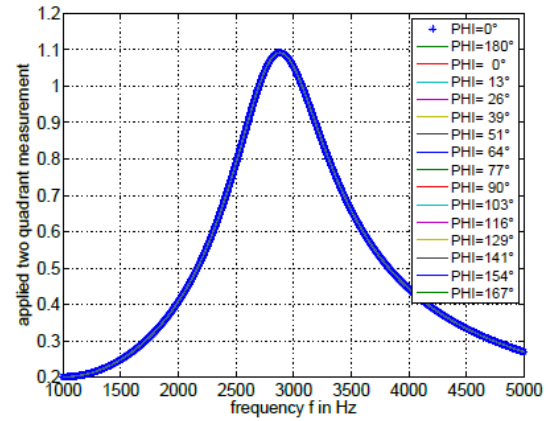


Fig. 4. Advantage of combining two measurements with 90° phase difference - the calculated magnitude is independent from an unknown phase angle of excitation and measurement path.

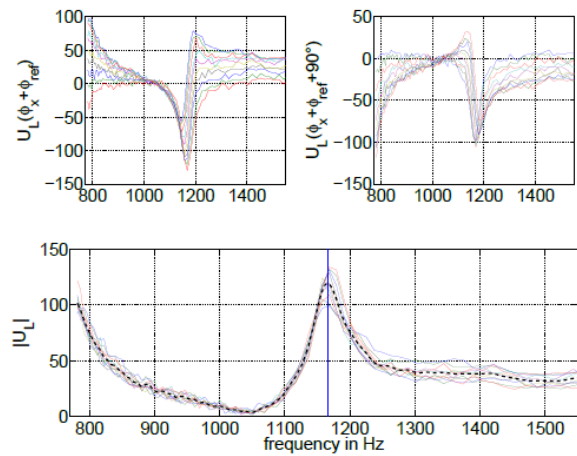


Fig. 5. Applied measurement with the INHUEPRO system on a mechanical resonator around a resonance frequency with varied reference phase ($\phi_{ref} = 0^\circ \dots 90^\circ$) of the lock-in amplifier. The top-left plot shows the measurement in the first quadrant ($\phi_{ref} = x^\circ$), the top-right plot shows the measurement in the second quadrant ($\phi_{ref} = x^\circ + 90^\circ$), the bottom plot shows the calculated magnitude (the dashed line is averaged and additionally interpolated to increase the frequency resolution, since frequency step width increases with increasing frequency). The magnitude response maxima frequency is almost independent from the reference phase angle (ϕ_{ref}).

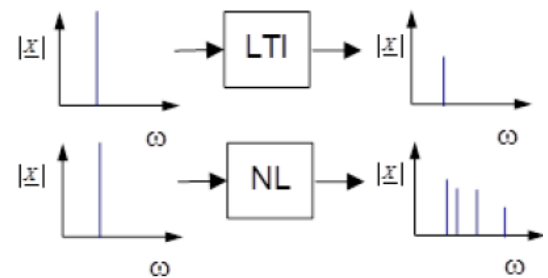


Fig. 6. The spectral response of a non-linear system (NL) compared to a linear system (LTI).

In case of the excited femur-prosthesis system, not only the waveform of the sinusoidal excitation is changed, but in addition resonances of the femur-prosthesis system are excited. Due to the dispersive nature of the mechanical waves in the system, the higher eigenfrequencies are not integer multiples of the first eigenfrequency. Therefore harmonics of the excitation signal are generated, as well as standing waves in the femur-prosthesis system. For the presented system approach multiplying the frequency of the lock-in amplifier was not favorable due to the fact, that it relies on the fixed base frequency of 125 kHz which is divided by an integer value (1 byte) in order to create the lock-in reference frequency. The frequency step width for measuring the higher order harmonics would be too large. Instead of varying the frequency ω_{ref} of the lock-in amplifier, the excitation signal frequency (ω_{exc}), the mechanical system is excited with, and therefore ω_m is varied. In addition, this approach also allows to shift the start frequency to lower values (e.g. $\omega_{ref}/1 = 490$ Hz, $\omega_{ref}/2 = 245$ Hz, $\omega_{ref}/4 = 122$ Hz, ...). In the following this is called a subharmonic excitation. In the technical realization only an even division of the fundamental reference frequency is possible by the vibration excitation subsystem. But one has to keep in mind, that the generated signal amplitudes are much smaller for the harmonics than for the fundamental frequency. When carrying out measurements under laboratory conditions, analyzable signals from an artificial bone prosthesis system could be obtained for the 2nd and 4th subharmonic.

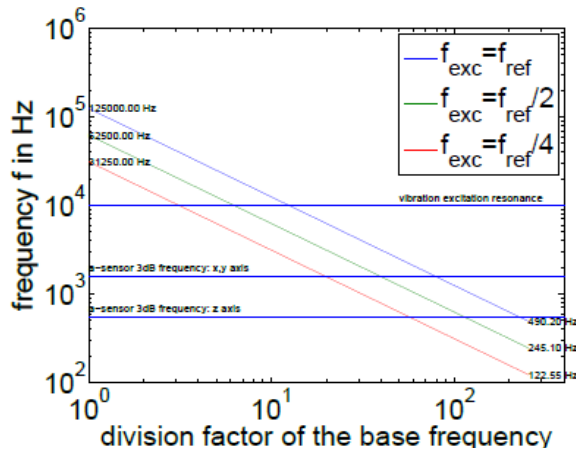


Fig. 7. Possible frequencies, which can be evaluated by dividing the mechanic excitation signal. For the presented system a division by even divisors is possible, which allows the evaluation of the 2nd/4th/nth harmonic. Each division lowers the starting frequency.

But hereby damping played only a minor role. The approach by a division of the harmonic excitation signal in order to detect system harmonics can be expressed with following representation:

$$\begin{pmatrix} \underbrace{U_{M1} \sin(1\omega_M t)}_{\omega_{exc}=\omega_M=\omega_{ref}} + \underbrace{U_{M2} \sin(2\omega_M t)}_{2.harmonic} + \underbrace{U_{M4} \sin(4\omega_M t)}_{4.harmonic} \\ \underbrace{U_{M1} \sin(1\omega_M t)}_{1.harmonic} + \underbrace{U_{M2} \sin(2\omega_M t)}_{\omega_{exc}=\omega_M=\omega_{ref}/2} + \underbrace{U_{M4} \sin(4\omega_M t)}_{4.harmonic} \\ \underbrace{U_{M1} \sin(1\omega_M t)}_{1.harmonic} + \underbrace{U_{M2} \sin(2\omega_M t)}_{2.harmonic} + \underbrace{U_{M4} \sin(4\omega_M t)}_{\omega_{exc}=\omega_M=\omega_{ref}/4} \end{pmatrix}$$

Under the assumption that the measured system response is of analytic nature the Hilbert transform can be used to calculate the imaginary part instead of measuring it. This could lead to a decrease in measurement time. A demonstration based on measured data is presented in Fig. 8. Applying the Hilbert transform introduces additional errors (start and end of measurement range). Otherwise spectral characteristics and their associated frequencies seem to stay consistent. The approach requires further investigations and is hereby only demonstrated as a possible solution to reduce the overall measurement time.

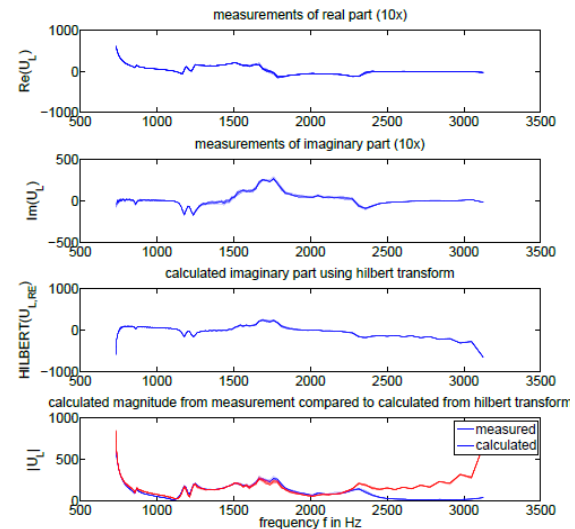


Fig. 8. Feasibility of the application of the Hilbert transform (12 individual measurements of real and imaginary part). The first (top) plot shows a measured real part of the system response, the second plot shows a measured imaginary part of the same system. The third plot shows the calculated system response based on the Hilbert transform and the 4th plot shows a comparison of the calculated magnitudes based on the measured data (blue) and partially calculated data (red) using the Hilbert transform. Additional errors are introduced in the beginning and at the end of the measurement range. Otherwise spectral characteristics and their associated frequencies seem to stay consistent. The approach requires a further investigation and is hereby only demonstrated as a possible solution to reduce the measurement time.

5. Implant Specific Packaging Concepts

Materials typically used for electronic devices are neither resistant against the reactive biological

environment nor biocompatible [11, 12]. Therefore, a reliable encapsulation of the medical wireless system is necessary, to enable the system function within its default life time (usually more than 10 years). Several requirements must be fulfilled. First of all, interface materials have to be biocompatible according to USP Class VI or ISO 10993 standard. Furthermore the material properties should be stable and resistant during a chosen sterilization process (preferred is an ethylene oxide sterilization), the implantation and the system lifetime. In this regard the encapsulation complies with demands on tissue protection against toxic materials used in electronic devices and device protection against harsh biological environment simultaneously. And finally, electrical insulation and mechanical protection of the device are required. For a first packaging variant, combining the microsystem with the prosthesis should not cause any alteration of the femoral ball head. For this purpose the microsystem was miniaturized and placed in the cone of the ceramic ball head (Fig. 1 and Fig. 9). Other known approaches, for example described in [8], would have led to significant constructional modifications impeding a marketing approval procedure. In the first integration concept an encapsulation with suitable electromagnetic screening properties was required, as the telemetry unit (coil) is not separated from the printed circuit board (Fig. 9). As an additional requirement, the microsystem has to be durable connected to the femoral ball head for transmitting the femur's

mechanical excitation to the acceleration sensor. Therefore potting the sensor system in the cone of the ceramic head, has been identified as an easy to realize and cost-efficient approach. Pourable polymers like epoxy resin, silicone and polyurethane, which comply with USP Class VI or ISO 10993 standards, are promising candidates. In general, polymers are more advantageous due to their weight, space, processing, advantageous chemical as well as mechanical properties and electromagnetic permeability compared to an inflexible titanium package. Since polymers interact with their environment and change their properties over time [13], these materials have not yet been used for packaging of long-term-implanted microsystems [14]. For this reason, chemical, mechanical and electrical properties of three epoxy resins (Epoxy Technology, Inc., two silicones from NuSil Silicone Technology and polyurethane from AdvanSource Biomaterials) were investigated, in order to determine their stability during sterilization and implantation. None of the characterized polymers fulfill requirements equally well, but low-consistency silicone seems to be the most reliable and suitable encapsulation material, as demonstrated in earlier work in [15].

Because of the electromagnetic screening effect of the titanium acetabular fossa on the telemetry transmission, in a second housing concept the coil was placed beneath the ceramic head (shown in Fig. 10), where it was mounted on the titanium sleeve.

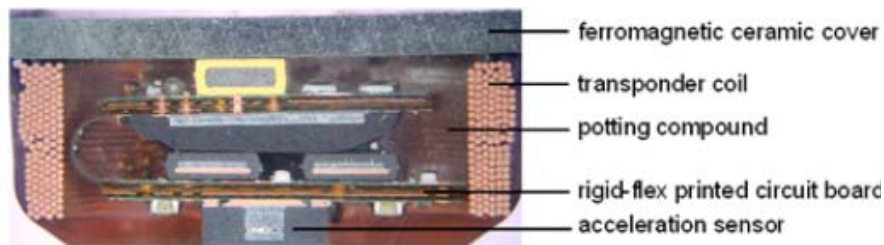


Fig. 9. Microsection of potted sensor system integrated in the femoral ball head and covered with a ferromagnetic ceramic to suppress electromagnetic screening effects caused by prosthesis stem.

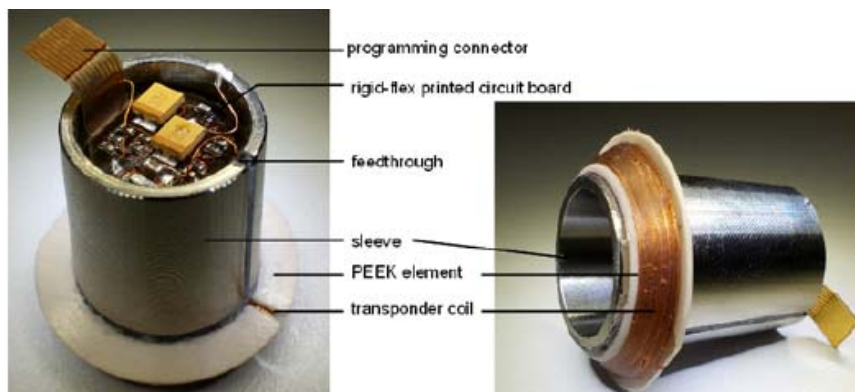


Fig. 10. A second realized sensor system housing concept, with electronics integrated in the titanium sleeve and the transponder coil (with triangular cross section) wound on a PEEK element.

The second integration concept provides a hermetic packaging of the printed circuit board in the upper part of the sleeve. The electronic is potted in a special designed recess, and protected by a welded titanium plate. As a drawback, this approach requires leadthroughs to connect the transponder coil with remaining electronic components. Also unfavorable is the much more elaborate encapsulation and mounting technology of the transponder coil, due to the unprotected position outside of the ceramic ball head. The whole assembly should not extend the round shape of the ball head, to maintain the original prosthesis geometry. Therefore, the coil was designed with a triangular cross section, and was wound on a polyether ether ketone (PEEK) element and mounted on the sleeve. In a final step the coil will be covered with glass.

6. Developed End-user Application

The software of a medical product must be in agreement to the ISO 62304 standard, which implicates a classification as 'Class B' component. The usage of the software and its components could cause 'nonserious' injury. Since the development of a market ready solution was not the project goal, these requirements are only partially discussed. In favor of a proof of concept, passing the medical approval at this early state was not a subject of highest priority during the software development. However, from the software perspective, no roadblocks are expected, which would prevent a medical approval.

The main component of the developed end-user application is a measurement loop, which gathers up to four acceleration values for each frequency step, as shown in Fig. 11. In addition, the excitation system is constantly monitored to ensure equal measurement conditions during each measurement run. Is a threshold violation of one of the monitored parameters detected (so far voltage, current, pressure, acceleration) the measurement process is stopped, until the limits are again met or the measurement is aborted.

The two relevant measurement modes are either a frequency or phase sweep, of which the frequency sweep is preferred. The initial phase relationship between the mechanical system and the lock-in amplifier is unknown. It is possible, to implement a calibration procedure, which can be used to determine and set this initial phase relationship. During a standard frequency sweep measurement run, the lock-in measurement is carried out with a reference phase of $\varphi_{ref} = \varphi_0 + 0^\circ, 90^\circ, 180^\circ, 270^\circ$ relative to the set reference phase angle φ_0 , resulting in a four quadrant measurement (Q_1, Q_2, Q_3, Q_4). This measurement carries redundant information, which is used to assess the quality of a taken measurement. Due to the fact, that the lock-in amplifier output is overlayed with a constant offset, an additional offset correction is required for each taken data point. This offset can be either determined by a direct

measurement with the vibration excitation turned off or indirectly by a calculation from the acquired four quadrant measurement data. Besides the collection of measurement data, one of the goals of the developed software, was an automatic determination of frequency response characteristics (markers), as a criteria to detect a prosthesis loosening. These markers are determined by an intersection of the frequency response functions of the second (90°) and the fourth (270°) quadrant measurement. To avoid false-positive results additional criteria were introduced, such that the Q_2 and Q_4 measurements show a minimum and the complementary Q_1 and Q_3 measurements show a maximum. In addition, a minimum threshold (MTH) value must be exceeded, so that $|U_{M,Q1} - U_{M,Q3}| \geq MTH$. The identified markers are internally rated from 0 to 1 in order to provide a validity level. Fig. 12 is an example of the visualization of the collected measurement data with the developed software GUI, with all visualization options activated. Multiple measurements can be compared with each other using the developed 'marker view' representation shown in Fig. 13. Hereby identified markers for individual measurements are filled into a grid, in which the x-axis represents the frequency and the y-axis the time of a measurement. This allows the comparison of a time series of taken measurements and provides a tool to determine and compare any shifts of identified marker frequencies.

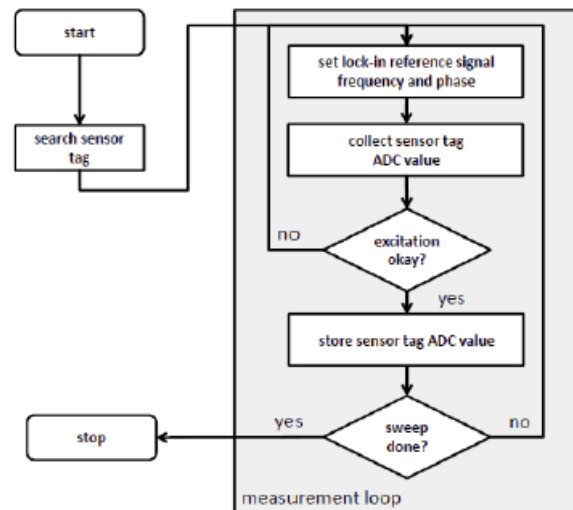


Fig. 11. Measurement process program flow chart.

7. Experimental Results

The overall system prototype has been tested in a measurement setup, which allows a varying anchorage of prosthesis (Bicontact S, Aesculap) in an artificial femur (Sawbone). The housed sensor tag prototype is placed at the proximal end of the prosthesis stem and pressed onto the stem (Fig. 14).

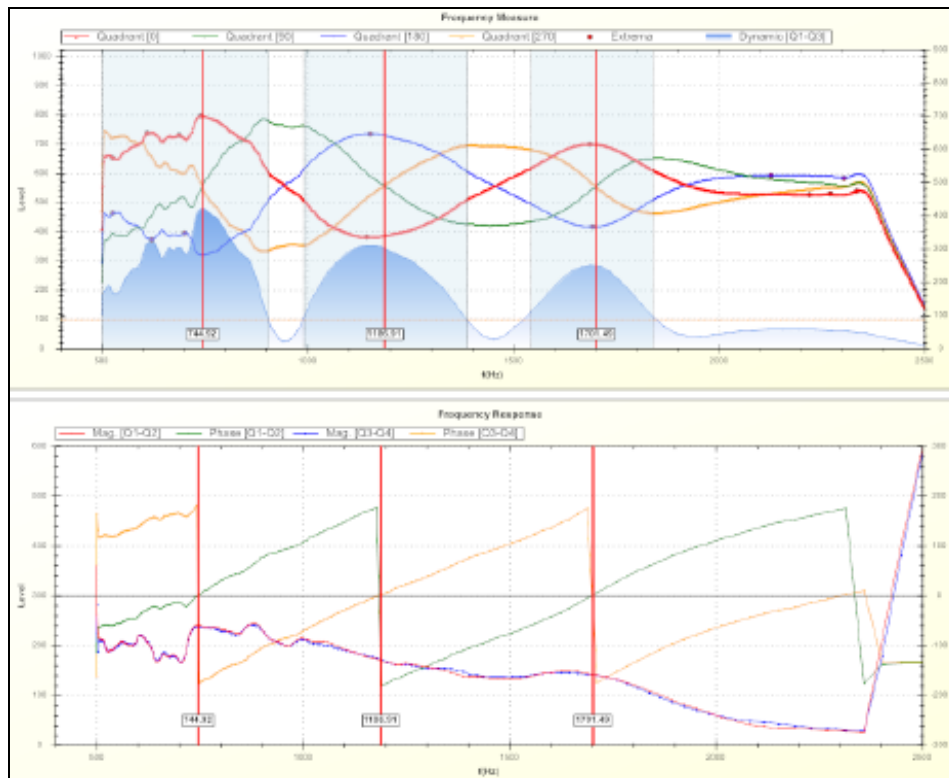


Fig. 12. Example of the visualization of the acquired measurement during a single measurement run. The top plot shows the acceleration responses of the 4 quadrant measurement versus frequency. The bottom plot shows the calculated magnitudes, as well as a phase relationships from the 4 quadrant measurement. In addition algorithmically identified resonances are visualized.

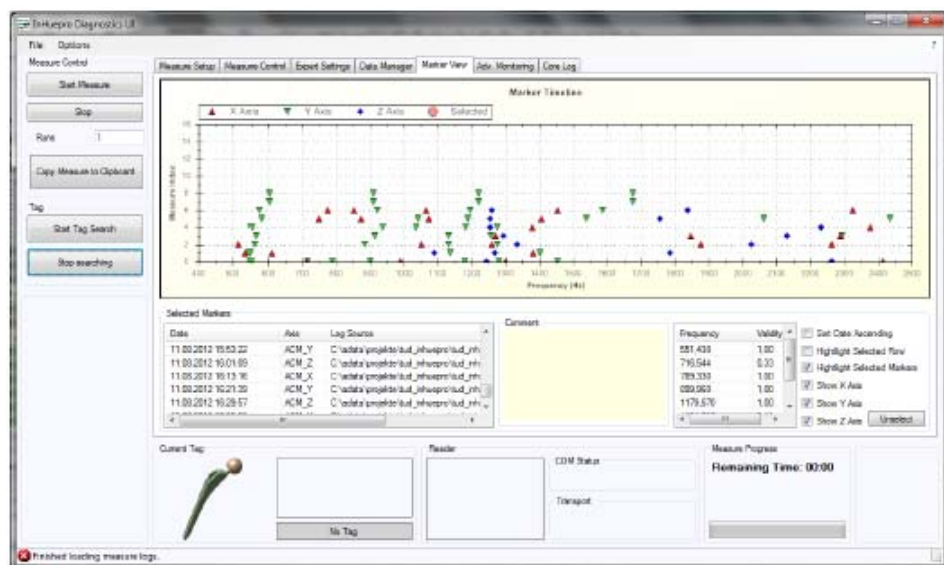


Fig. 13. Example of the 'marker view' representation, used to visualize the shift of resonances due to loosening over time.

The horizontal axis represents the measurement frequency range, the vertical axis represents the time the individual measurement was taken. Identified frequencies for the spatial x, y and z directions are visualized with individual symbols.

This representation allows the visualization of trends and should be useable during clinical routine.

A reproducible anchorage variation is realized through threaded sleeves, placed in the artificial femur, which are distributed evenly around the prosthesis. In order to verify the feasibility of the measurement approach, the influence of loosening (decreasing prosthesis anchorage) on the resonance

frequencies in the frequency spectrum is of interest. Therefore, the mechanical setup focuses on this behavior. Other influencing mechanical factors (i.e., surrounding tissue, hip and knee boundary conditions, etc.) are not in the scope of this work. The femur-prosthesis system is attached to an electro-

dynamic vibration exciter (TIRAvib S522). The mechanic connection is realized via a clamp, placed at the central part of the femur, and a thread bar attached to the shaker. The reader station (with attached coil establishing communication and energy supply) is connected to a PC running the user application. It also provides the mechanic excitation signal for the shaker, which is amplified by a power amplifier (TIRA BAA 60). During the experiment the state of anchorage has been gradually increased. For each measurement run, screws were fixed step-by-step starting from the distal end, until the well-fixed case was reached.



Fig. 14. Measurement setup focusing on a variation of the loosening state. Hereby prosthesis is integrated in an artificial bone. An adjustable anchorage is reached by fastening or loosening off screws evenly distributed around the prosthesis.

The obtained measurement results for a measurement with an initially unknown phase (1. quadrant measurement - claimed real part) and a measurement with a 90° degree offset (2. quadrant measurement – claimed imaginary part) are presented in Fig. 15. For each frequency value the magnitude is calculated, which leads to the results in Fig. 16. The first four magnitude resonance frequencies have been evaluated. The absolute values for each loosening case as well as the frequency difference to the initial loose case are presented in Fig. 17. In Fig. 18 measurements results for the non-linear system behavior are presented. For these measurements the prosthesis was excited with half of the reference frequency of the lock-in amplifier circuit ($\omega_{exc} = \omega_{ref}/2$). Therefore the second harmonic of the mechanic system has been evaluated. Starting from an initial fix case, screws were unfastened at the proximal end of the prosthesis. The obtained maximum shifts to lower values. In order to quantify the precision of the developed measurement system, 14 measurements were repeated and the standard deviation (SD) for each frequency point has been calculated (Fig. 19). For larger amplitude values, the standard deviation increases. In general the averaged precision over all frequencies is tolerable, showing a variation below 1 % over the full measurement scale.

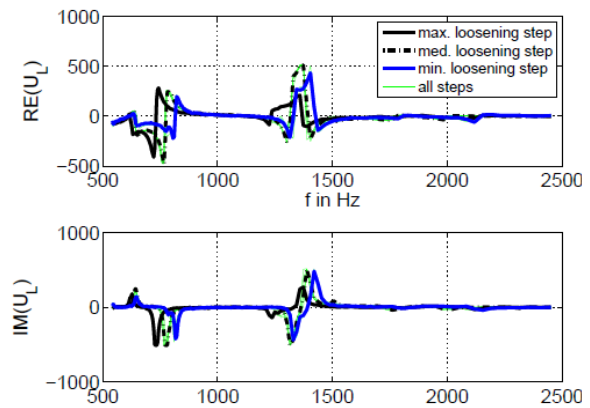


Fig. 15. Measurement example with an artificial bone and an artificial prosthesis showing I. quadrant (0°, referenced as real part, top) and II. quadrant measurement (90°, referenced as imaginary part, bottom).

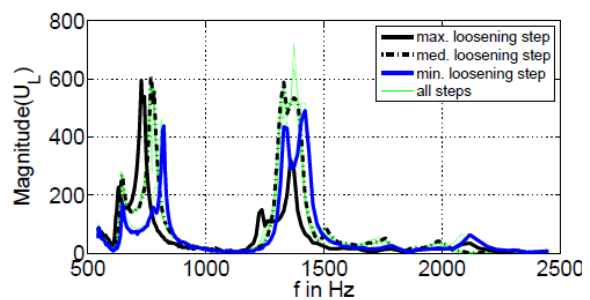


Fig. 16. Calculated magnitude of several measurements on the same mechanic system with varied prosthesis anchorage state.

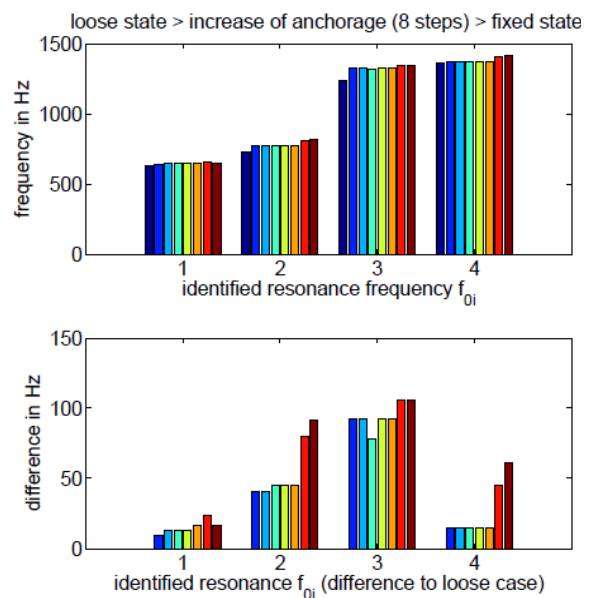


Fig. 17. First four extracted resonances as identified with the diagnosis system under the influence of a step-by-step increase of prosthesis fixation (individual bars). The top plot shows the absolute frequency value for each fixation step. The bottom plot shows the absolute difference to the initial loose state.

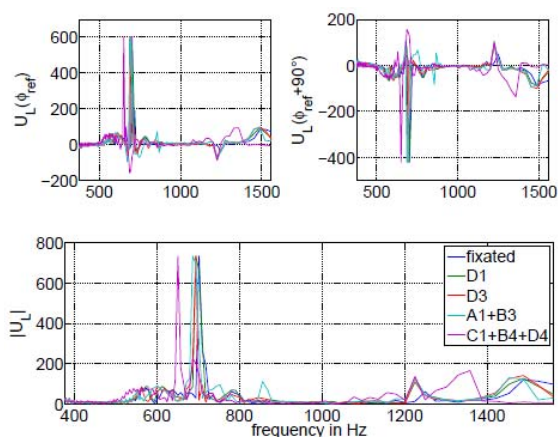


Fig. 18. Non-linear vibration behavior can provide additional frequency domain characteristics, which might aid the detection of a loosening. The plot shows the system response, when mechanically exciting the system with the half reference frequency ($\omega_{exc} = \omega_{ref}$). In the top left (real part) and top right (imaginary) plot measurements of the second subharmonic around a resonance frequency are presented. In the lower plot the magnitude is presented. Starting from an initial fix case, screws were unfastened step-by-step at the proximal end of the prosthesis.

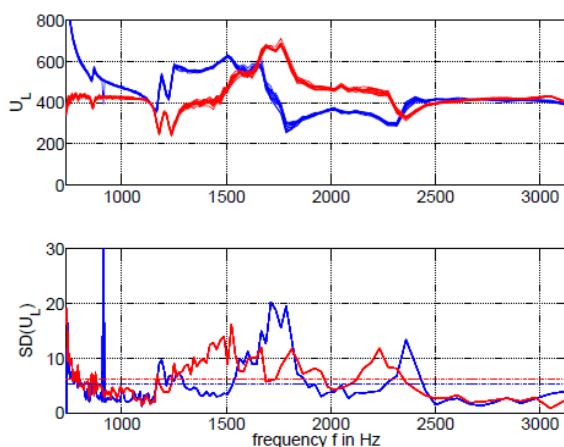


Fig. 19. Calculated standard deviation (bottom plot) of the digitized lock-in amplifier output signal from 14 repeated measurements of the real (blue) and imaginary (red) part of the mechanic demonstration system response. In addition, the bottom plot shows also the averaged standard deviation for real and imaginary part over the full frequency range.

6. Conclusions

Vibration analysis can be a valuable extension in the range of diagnostic measurement techniques and has the potential to detect hip prosthesis loosening. Through integration of a miniaturized vibration measurement system directly into the implant, the damping effects of tissue in the measurement path can be overcome. Different loosening states of the implant can be distinguished in the mechanic frequency response of the bone-prosthesis system as demonstrated in the experimental section. In general, resonance frequencies are shifted to lower values if

the loosening increases. When later on performing measurements with real patients, the obtained frequency spectra will be very different between patients (bone and tissue mass/stiffness, muscle tension, etc.). Therefore, a reference data set, obtained from a measurement after the hip replacement and finished prosthesis osseointegration, is needed for each patient. It can serve as a reference for long term patient monitoring and can be part of a medical case database. Additional experiments, not in the scope of this paper, indicate that mechanic cross-sensitivities, such as static load or mass of surrounding tissue, also influence the detected resonances and need further analysis. Only evaluating a single resonance in order to determine a loosening seems not very favorable, multiple resonances should be evaluated. Current work focuses on the identification of additional affecting factors and their impact (e.g., influence of lubrication) onto resonance shifts, the improvement of the wireless data transmission within the challenging metal environment (stem and backing), an improved bio-compatible housing and the preparation of the medical approval as well as the development of additional meaningful data visualization strategies, besides the shown examples, supporting the diagnostic system. Favorable for the measurement system would be an increase in the frequency resolution, as well as a constant frequency step over the full measurement range.

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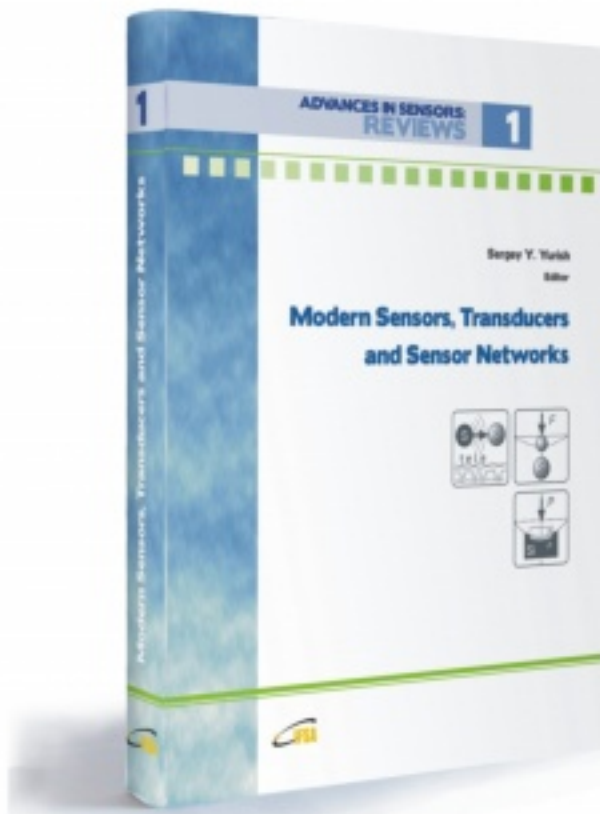
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