Medical Wireless Vibration Measurement System for Hip Prosthesis Loosening Detection

Sebastian Sauer, Uwe Marschner
Institute of Semiconductor and Microsystems
Dresden University of Technology (TUD)
Dresden, Germany
e-mail: sebastian.sauer@tu-dresden.de
e-mail: uwe.marschner@tu-dresden.de

Hagen Grätz, and Wolf-Joachim Fischer
Wireless Microsystems
Fraunhofer IPMS
Dresden, Germany
e-mail: hagen.graetz@ipms.fraunhofer.de
e-mail: fischer@ipms.fraunhofer.de

***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 smart 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 through 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.**

***Keywords*-hip prosthesis loosening detection; vibration analysis; wireless medical system.**

I. 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],[2],[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

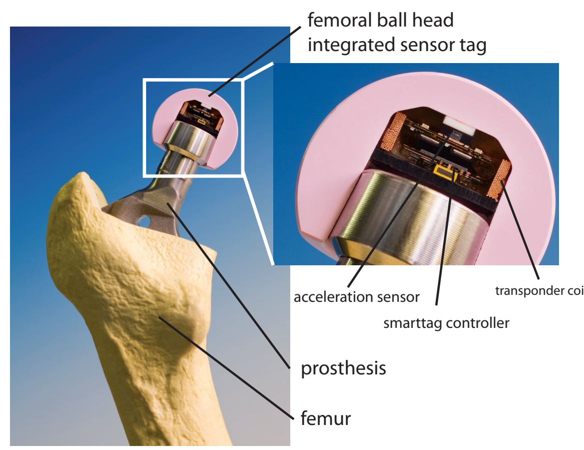

Figure 1. Medical wireless system (cross sectional cut) integrated in the femoral head of the hip implant.

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 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 incorporated into the prosthesis, as, e.g., realized by Puers [6], the negative influences of tissue in the measurement path are minimized. In difference to a previous realization with a prosthesis shaft integrated system [7], a solution with a femoral ball head integrated measurement system is presented (Fig. 1). Within this work the proposed overall medical system is described, a detailed view of the integrated lock-in amplifier is given and experimental results of applied measurements on an artificial bone-prosthesis system, demonstrating the influence of loosening, are presented.

II. 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 [7]. 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). The intracorporeal system is built around a freely programmable transponder unit called Smart Tag 1 (Fraunhofer IPMS ST1). A solution on chip 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, I^2C bus module and an integrated voltage regulator. Wireless energy transmission and bidirectional data communication via inductive coupling and amplitude modulation between tag and reader is 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 mechanic sensitivity of 420 mV/g with a measurement range of $\pm 2.5g$. Since the acceleration sensor output is strongly affected by noise, additional signal preprocessing is required. For this purpose a lock-in amplifier, based on the chopper principle, has been integrated in the sensor tag in order to improve the signal-to-noise ratio.

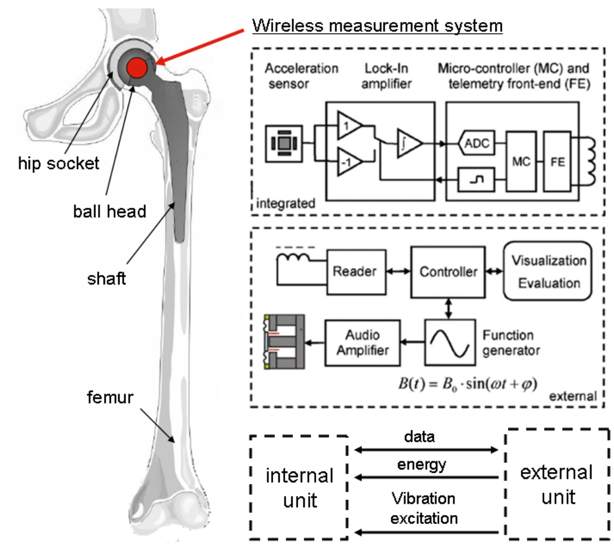

Figure 2. Overview of the diagnostic measurement system.

The mechanic excitation system consists of an electro dynamic vibration excitation (S50018, TIRAvib) 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 is responsible for magnetic field generation, data extraction 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 is carried out on a PC connected to the reader.

III. 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 [8]. 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

 ISBN: 978-1-61208-208-0

signal. 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.

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

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

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

The unwanted parts in Eq. 2 are of increasing influence in the case of small integration times and signal frequencies. If for a given frequency a phase match is reached (phase difference $\phi_{ref} = 0$) 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 to costly. In this case a periodic rectangular signal can be used, as reference for the lock-in amplifier (chopper principle), an approach also chosen for the sensor tag. The associated special circumstances (i.e., higher order harmonics) have been discussed in [7].

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). 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 chopper principle is the occurrence of harmonics, due to the fact that the reference signal is rectangular. These are damped by the low pass 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 system resonances. If the extrema of a single phase measurement are evaluated a changing phase relation (i.e., change of

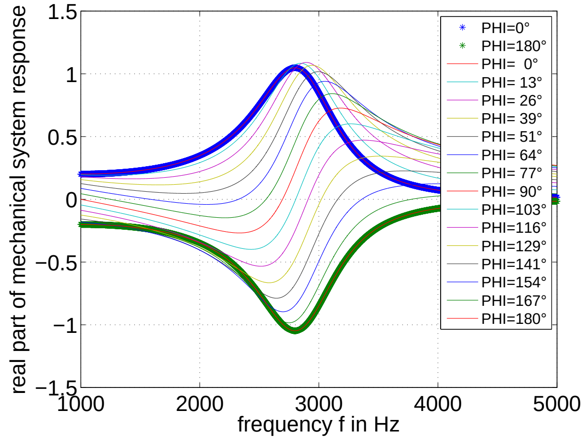

Figure 3. Influence of a varying reference phase onto real part of simulated mechanical system response, leading to falsely interpreted resonance frequency values (extremal value frequency in plot).

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. 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 value has been varied in steps of 10° between 0° and 90°. For each frequency point the two consecutive measurements (ϕ_{ref} =x°, ϕ_{ref} =x°+90°) were made instantly after each other.

IV. EXPERIMENTAL RESULTS

The overall system prototype has been tested in a measurement setup, which allows a varying anchorage of a 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. 6). 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.)

 ISBN: 978-1-61208-208-0

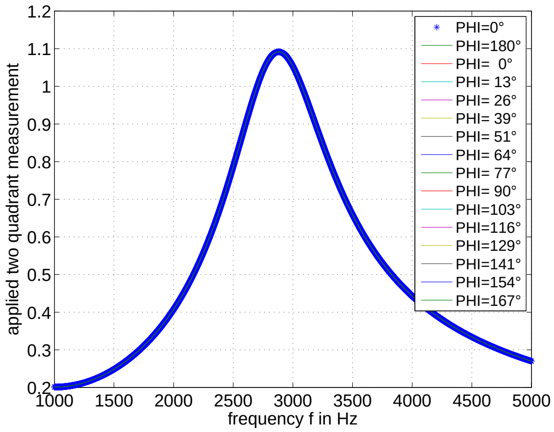

Figure 4. Advantage of combining two measurements with 90° phase difference - the calculated magnitude is independent from an unknown phase angle of excitation and measurement path.

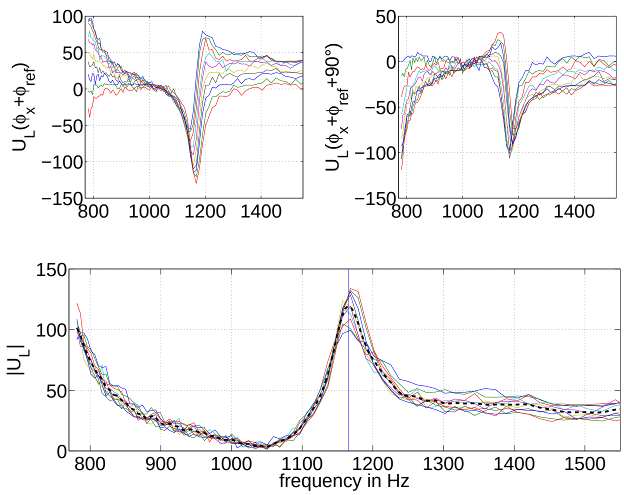

Figure 5. Applied measurement with the INHUEPRO system on a mechanical resonator around a resonance frequency with varied reference phase (ϕ_{ref} =0°..90°) of the lock-in amplifier. The top-left plot shows the measurement in the first quadrant (ϕ_{ref} =x°), the top-right plot shows the measurement in the second quadrant (ϕ_{ref} =x°+90°), the bottom plot shows the calculated magnitude (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}).

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

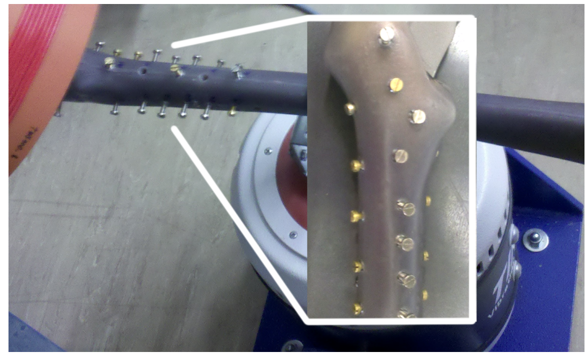

Figure 6. Measurement example with a prosthesis integrated in an artificial bone allowing an adjustable state of anchorage.

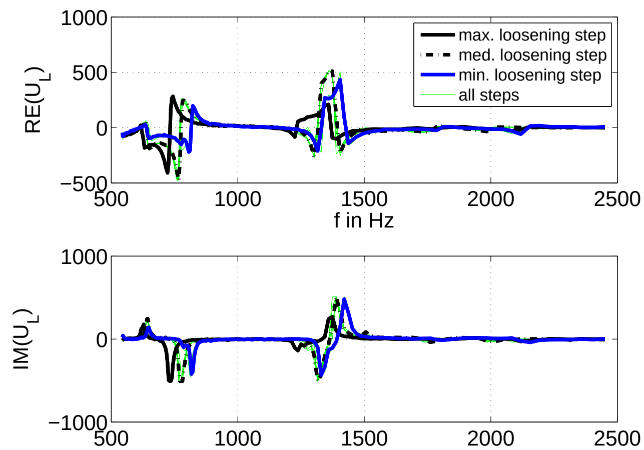

Figure 7. Measurement example with an artificial bone and an artificial prosthesis showing I. quadrant (0°, referenced as real part, top) and II. quadrant measurement (90°, referenced as imaginary part, bottom).

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. 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. 7. For each frequency value the magnitude is calculated, which leads to the results in Fig. 8. The first four magnitude resonance frequencies where evaluated. The absolute values for each loosening case as well as the frequency difference to the initial loose case are presented in Fig. 9.

V. Conclusion and Future Work

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

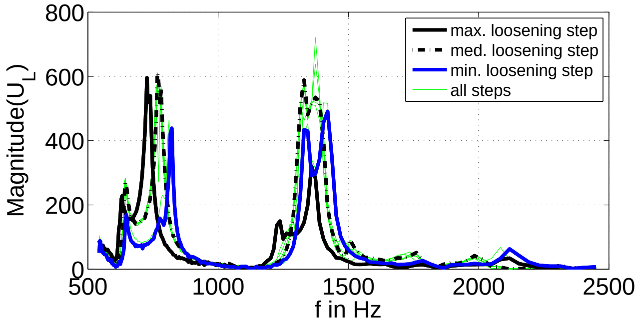

Figure 8. Calculated magnitude of several measurements on the same mechanic system with varied prosthesis anchorage state.

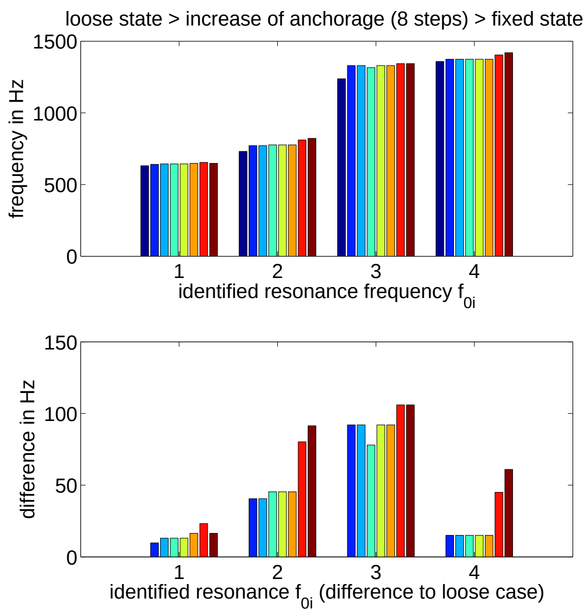

Figure 9. First four extracted resonances as identified with the diagnosis system under the influence of a step-by-step increase of prosthesis fixation (individual bars). The top plot shows the absolute frequency value for each fixation step. The bottom plot shows the absolute difference to the initial loose state.

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. 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 meaningful data visualization strategies supporting the diagnostic system.

ACKNOWLEDGEMENTS

This Work was supported by the 'German Bundesministerium für Bildung und Forschung (BMBF)', project 'IN-HUEPRO', program grant No. 16SV3916.

REFERENCES

[1] D. O'Neill and W. Harris, "Failed total hip replacement: assessment by plain radiographs, arthograms, and aspiration of the hip joint," *The Journal of Bone and Joint Surgery*, vol. 66, pp. 540–546, 1984.

[2] G. Qi, W. P. Mouchon, and T. E. Tan, "How much can a vibrational diagnostic tool reveal in total hip arthroplasty loosening?" *Clinical Biomechanics*, vol. 18, pp. 444–458, 2003.

[3] O. Temmerman, P. Raijmakers, J. Berkhof, E. David, R. Pijpers, Marinus, Molenaar, O. Hoekstra, G. Teule, and I. Heyligers, "Diagnostic accuracy and interobserver variability of plain radiography, subtraction arthrography, nuclear arthrography, and bone scintigraphy in the assessment of aseptic femoral component loosening," *Archives of the Orthopaedic and Trauma Surgery*, vol. 126, pp. 316–323, 2006.

[4] C. Ruther, H. Ewald, W. Mittelmeier, A. Fritsche, R. Bader, and D. Kluess, "A novel sensor concept for optimization of loosening diagnostics in total hip replacement," *Journal of Biomechanical Engineering*, vol. 133, 2011.

[5] A. Rowlands, F. Duck, and J. Cunningham, "Bone vibration measurement using ultrasound: Application to detection of hip prosthesis loosening," *Medical Engineering and Physics*, vol. 30, p. 278284, 2008.

[6] R. Puers, M. Catrysse, G. Vandevoorde, R. Collier, E. Louridas, F. Burny, M. Donkerwolcke, and F. Moulart, "A telemetry system for the detection of hip prosthesis loosening by vibration analysis," *Sensors and Actuators*, vol. 85, pp. 42–47, 2000.

[7] U. Marschner, H. Grätz, B. Jettkant, D. Ruwisch, G. Woldt, W.-J. Fischer, and B. Clasbrummel, "Integration of a wireless lock-in measurement of hip prosthesis vibrations for loosening detection," *Sensors and Actuators A: Physical*, vol. 156, pp. 145–154, 2009.

[8] J. H. Scofield, "A frequency-domain description of a lock-in amplifier," *American Journal of Physics*, vol. 62, pp. 129–133, 1994.