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Loosening detection of the femoral component of hip prostheses with extracorporeal shockwaves: A pilot study

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ABSTRACT

The diagnosis of aseptic loosening of hip implants is often challenging. A vibrational analysis of the bone-implant interface could be an alternative method to analyze the fixation of endoprostheses. We assessed an innovative and new approach for excitation by using extracorporeal shockwaves in this study.

In three cadaver specimens total hip arthroplasty was performed bilaterally. Four different states of implant loosening were simulated. Three accelerometers were fixed at the medial condyle, the greater trochanter, and the crest of the ilium. The bone-implant compound was excited with highly standardized extracorporeal shock waves. Resonance spectra between 100 Hz and 5000 Hz were recorded.

This technique permitted a good adaptation to varying soft tissue conditions. The main resonance frequency of the hip joints occurred at about 2000 Hz. The analysis of the measured spectra showed an interrelation between the state of loosening and the frequency values of the resonances. In case of a stem loosening, there were significant shifts of the resonance into the lower frequency area between 386 Hz and 847 Hz.

With this novel technique the degree of stem loosening could be assessed in a soft tissue considering configuration. This study forms a first step for future establishment of a non-invasive, non-radiological and fast applicable diagnostic procedure for early detection of endoprostheses loosening before manifest presence of clinical signs.

1. Introduction

The number of performed total hip arthroplasties has rapidly increased in the last decades. This trend is expected to continue. Simultaneously the average long term clinical outcome after implantation of hip endoprostheses improved steadily [1]. In practice, revision rates of less than 5% are realistic [2,3].

Despite these positive results, the increasing absolute number of primary hip arthroplasties results in a higher number of revision surgeries. The main cause of revisions is (aseptic) loosening with rates of 54.1% in the Australian register [3] and 69.8% in the Swedish register [2]. Enabling a valid and early detection of such implant loosening is important to avoid bone loss around the implant and to ascertain an appropriate therapy for the patient. However, the loosening detection remains a challenge of modern medical technology. Conventional diagnostic procedures, such as the analysis of plain film radiographs, arthrography and scintigraphy do not fully suffice the demands with respect to sensitivity and specificity [4–7].

New approaches are necessary to show clinicians early signs of loosening or give a higher certainty of diagnosis to guide the appropriate therapies for the patient. Moreover an early loosening detection will help to avoid complicated surgeries. One attempt to detect loosening of endoprostheses is the use of vibration techniques. Several research groups assessed the vibration behavior of bone-endoprosthesis-systems and the influence of loosening and implant stability. Rosenstein et al. [6], Li et al. [5,8] and Jacques et al. [9] revealed in studies with artificial human femurs and in cadaver studies that the frequency-response characteristics of well fixated implant varies significantly from a loosened implant. The differences appear in form of distorted harmonic signals and displacements of the resonance frequencies. These results were confirmed numerically with the finite element method [10–12] as well as in clinical studies [4,6,13,14]. Hereby, the analysis of the resonances of the bone-implant-system is most promising. The frequencies of the resonances are dependent on the vibration modes of the system that are directly influenced by boundary conditions and fixation of the implant. However, in clinical studies the assessment of the bone-implant-compound poses technical difficulties because of the surrounding soft tissue [15].

Accelerometer based systems are commonly used for tactile measurements of vibrations. The dynamics of hip components needs to be

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Table 1
Donor data of the assessed specimen.

Specimen	Sex	Age	Height (m)	Weight (kg)	Stem (right/left)	Cup (right/left)
# 1	Male	70	1.73	86.2	8/8	54/52
# 2	Male	80	1.75	55.5	10/9	52/52
# 3	Male	76	1.63	55.8	11.25/11.25	52/52

measured non-invasively, though. In this case, certain soft tissue limitations are imposed on the accelerometers. To ensure the feasibility of vibration techniques for clinical use, a couple of groups improved this sensory concept: To ensure an accurate acquisition of the vibrations they developed telemetric systems [16,17] or they made successfully use of the Doppler Effect in ultrasonic measurements [7,18].

Basic requirement for a vibrational analysis is a reliable excitation of the system. The mentioned studies used either an impact hammer or an electro-magnetic shaker without one method gaining unreserved approval [19]. Only one research group worked on an alternative approach combining excitation and measurement [20,21]. They aimed for an actuator-sensory-element, which is intended to be implemented into the prosthesis itself. This concept provides the possibility to excite and measure the system from the internal of the prostheses. However, the main drawback of this concept is the change of the biomechanical properties of the implant introduced by the space needed for the integration of the electronics.

This pilot study implemented for the first time an innovative, non-invasive approach based on vibrational excitation with extracorporeal shockwaves. In contrast to pressure waves produced by a hammer, extracorporeal shockwaves can be focused inside the tissue. It was our aim to refine vibrational analysis for diagnostic purposes in combination with the non-invasive sensory solutions described in literature [7,18,22]. The following hypothesis was clarified: With extracorporeal shockwaves an appropriate excitation of the bone implant system for detection of hip prostheses loosening through soft tissue is possible. Furthermore, two sub-hypotheses were tested. First, that a loosened hip implant causes shifts in the resonance spectra of the bone-implant-system and second that a stem loosening can be differentiated from an acetabular cup loosening.

2. Material and method

2.1. Specimen

The dynamic behaviors of artificial hip joints were assessed under consideration of the damping influences of soft tissue. Therefore three fresh-frozen human specimens with intact soft tissue were prepared for examination (Table 1). Each one was a half body from the pelvis to toe tip. Hip replacement surgeries were performed bilaterally and the appropriate CLS™ Spotorno™ stems (Zimmer, Inc., Warsaw, IN, USA) in combination with Allofit™ Cups (Zimmer, Inc., Warsaw, IN, USA) were implanted. A ceramic head with a diameter of 28 mm was paired with a polyethylene inlay. All operations were performed by one experienced orthopedist. Consequently all six hip joints could be vibratory assessed with intact surrounding soft tissue ($n = 6$).

To simulate different states of loose implants, the different components of the total hip endoprostheses were successively loosened. To realize a loosened femoral component, a one size smaller stem was used and the fins of the anterior and posterior side of the implant were removed. The macrostructure of the exterior side of the cup was abraded completely to obtain a plain surface. Like this, any interlocking of the implants with the bone was avoided and by this a cup loosening was simulated.

Four states of severe loosening were simulated for all six hip joints (early loosening was not considered in the study):

- Stem and cup stable fixated, this state was used as reference
- Stem loosened and cup fixated

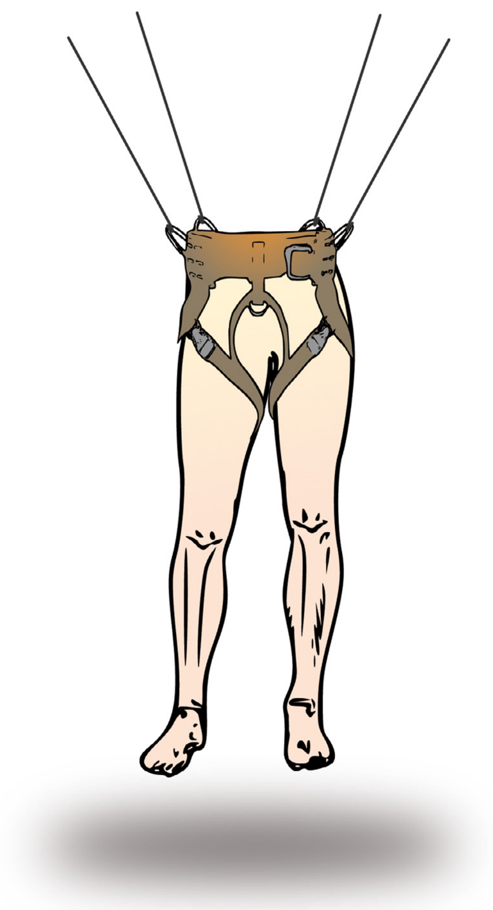

Fig. 1. Three specimens were subjected to a vibration assessment. They were freely hanged.

- Stem and cup loosened
- Stem refixated and cup loosened

The specimens were positioned in an identical way for the measurements, they were freely hanged using a climbing harness (Vario Speed Harness, Black Diamond Equipment, Ltd., Salt Lake City, UT, USA) (Fig. 1).

2.2. Vibrational excitation

The bone-prosthesis-systems were excited with a new method using extracorporeal shockwaves (PiezoWave, Richard Wolf GmbH, Knittlingen, Germany). These shockwaves were generated by an array of expanding piezoelectric-elements arranged on a spherical cap. By this arrangement the shockwaves were mechanically focused in a geometrically fixed and defined point (Fig. 2).

Referenced on the tissue surface, the position of the focus could be varied by using waterless, gel-filled pads of different sizes. In this way the depth of penetration could be adapted to individual soft tissue conditions and varied from 5 mm to 40 mm tissue penetration. The penetration was determined by the height of the pads and defined by