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Sensors and imaging methods for detecting loosening of orthopedic implants - a review

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Abstract **- This paper presents sensors and imaging methods for the detection of orthopedic hip implants loosening. Within orthopedic surgical practice one of the major applications is the reconstructive joint replacement. The hip is used to be the most replaced joint. Although considered an excellent surgical procedure, it can be complicated by implant particle-induced osteolysis (bone resorption) followed by loosening of the implant. Techniques used to assess the loosening of the hip implant involve imaging methods as well as sensors used to characterize the bone-implant interface. Implants with integrated sensors have the potential to raise the specificity and sensitivity of the diagnostics of implant loosening.**

Keywords - orthopedic implants; sensors; total hip replacement; imaging techniques

I. Introduction

An implant by definition is a medical device manufactured to enhance, support or replace a biological structure. Some implants like artificial peacemakers and cochlear implants contain electronics as well. As the implants are intended to function in the biological environment *i.e.* in the living human system, the choice of the constituent materials is crucial. These materials are termed biomaterials or biomedical materials and must be biocompatible. According to the Williams definition, biocompatibility is the ability of the materials to perform with an appropriate host response in a specific application [1].

Orthopedic implants are devices surgically placed into the body to restore function of a damaged structure *i.e.* bone screws and plates for fixation of fractured bone segments or hip and knee prostheses to artificially replace these joints. The orthopedic implant sector is an important part of the biomedical industry with a market value estimated to increase from 29.2 billion USD in 2012 to 41.2 billion USD in 2019 [2]. Geographically, North America dominated the global market for orthopedic devices but Europe was the second largest regional market in 2012. In 2012, knee orthopedic devices accounted for the largest share by revenue of the total orthopedic devices market [2]. The knee is the largest joint of the human body consisting of two articulations permitting flexion and extension. The most important in retaining balance and support the weight of the body in static and dynamic postures is the hip joint. Both joints however are vulnerable to acute injury and the development of osteoarthritis.

Osteoarthritis is characterized by degenerative changes in the joints. These start with the successive loss of articular cartilage and may even lead to the exposure of the bone surface. Determined by disease severity and the site affected, osteoarthritis results in impairments of function, activities of daily living and quality of life [3, 4, 5].

The prevalence of osteoarthritis continues to increase and it will represent the fourth leading cause of disability worldwide by 2020 [6, 7]. This places a globally major burden on individuals, health and social care systems [8, 9]. The prevalence of osteoarthritis in Germany varies between 20 and 25% [10]. Upon data from the German Health Interview and Examination Survey for Adults *("Studie zur Gesundheit Erwachsener in Deutschland"*, DEGS) which is part of the health monitoring system of the Robert Koch Institute (RKI) from a total of 7,988 persons aged 18–79 years 22.3% of women and 18.1% of men were diagnosed with osteoarthritis [11].

Hip osteoarthritis is degeneration and finally the destruction of the cartilage in the hip joint. This leads to a complete failure of the hip joint. A total hip replacement (THR) is a proven therapy to restore the mobility of the hip joint (Figure 1). In this case, both the femoral head and the socket of the hip joint are replaced by ceramic or metal and polyethylene components designed to restore painless mobility. In Europe, yearly 500.000 people undergo hip joint replacement [12]. In Germany there were 210.000 hip prostheses implanted in 2012 [13]. Prosthesis survival depends on several factors such as surgical technique, prosthesis shape, age and activity of the patent. Most often 5-10 years after total hip replacement loosening of the stem component occurs. The most common cause of joint replacement loosening is due to wear of the implant surfaces and the subsequent weakening of surrounding bone. This process is called osteolysis, meaning the active resorption of bone matrix by osteoclasts (bone cells) [14]. As a result, large displacements of the prosthesis relative to the host bone could occur that may result in walking difficulties as well as severe pain and elevated risk of pathological fractures. Currently, patients with loose prostheses undergo open revision surgery, which is a highly demanding procedure. As a consequence, there is a need for methods that detect precisely and accurately the hip implant loosening and help physicians in establishing the right moment for intervention such as revision surgery. In the following we present diagnostic methods to confirm loosening of the hip prostheses. These methods are divided into imaging and implant integrated sensors.

Fig. 1. Examples of orthopedic implants: hip prosthesis (manufactured to replace the femoral head and acetabulum), knee prosthesis (used to replace the diseased joint surfaces of the knee), interlocking nails (used to fix the fractures of long bones) and small fragments (the choise of treatment in case of small fracture fixations of the Humerus, Pelvis or Distal Tibia) [modified from 28].

II. Imaging Techniques of Hip Implant Loosening

Total hip replacement, pioneered by Charnley in the 1960s, is a widely used surgical procedure, which is beneficial to a great number of patients suffering from osteoarthritis [15]. However, a major complication accompanying this procedure is mechanical loosening of the implants. Loosening of the hip implants can be the result of inadequate initial fixation, mechanical loss of fixation over time or a biologic loss of fixation caused by particle-induced osteolysis (bone resorption) around the implant [14].

Poor implant fixation and subsequent motion facilitates release of wear debris (particles) and loosening of implants [16]. This leads to inflammatory responses and bone loss, being apparent from progressive bone resorption. Revision arthroplasty is more costly and associated with a higher complication rate than the primary total hip replacement because patients requiring revision surgery are older than their age at the primary surgery and have decreased physiologic reserve. As a result, early diagnosis can spare many patients increased costs and potential mortality.

Radiography is the first method used to confirm loosening of the hip prosthesis. Conventional radiographs can be effective in the diagnosis of mechanical loosening in case of both, cemented and non-cemented femoral prosthesis and acetabular components [17]. Lucencys at the cement-bone or at the metal-cement interface or fracture of the cement mantle represent radiographic appearances of loosening. Additional radiographic features of loosening are: migration, fracture, change of position or movement of the hip components [18]. Radiographs remain, however, a 2-dimensional assessment of a 3-dimensional disease process and studies have shown that they are not sensitive to the depiction of osteolysis [19]. Although computed tomography (CT) more precisely quantifies osteolysis as compared with radiographs, in detecting the loosening of the prosthesis CT and magnetic resonance imaging (MRI) are mostly useful in the evaluation of periprosthetic tissues [20, 21].

Fluoro-deoxy-glucose positron emission tomography (FDG-PET) is a potential useful modality in diagnosing loosening in hip endoprostheses, but it would be more accurate when investigated in combination with other diagnostic tools [22]. Positron emission tomography based on 2-fluoro-2-deoxy-D-glucose could be an option if researchers will be able to find specific uptake pattern for septic and aseptic loosening. In addition, FDG-PET is cost-intensive.

III. Sensors for Detecting Hip Implant Loosening

Currently, signs and symptoms of loosening may not be clinically apparent until late stages of failure due to the lack of accurate and sensitive early diagnosis methods. All the imaging techniques listed above detect advanced pathologic conditions. First trials to apply sensors to detect loosening were based on the measuring of the resonance frequency and dampening [23]. This method is called vibrometry and relies on the detection of acoustic properties using *in vivo* sensors. In a resonance frequency analysis the changing eigenfrequencies of the implant-femur system due to loosening can be measured as vibrations or structure-borne sound [24]. Upon analysis of resonance frequencies involving accelerometers, Li et al. suggest that a well fixed implant shows linear while a loosened a non-linear acoustic behavior [23]. However, one problem of using accelerometers is the low-signal-to-noise ratio. Rowlands et al. have replaced the accelerometer with a blood flow ultrasound probe for detecting vibrations of anchored and loosened implants [25]. This led to increased amplitudes of the output vibrations when compared to accelerometer signals. The specificity and sensitivity of vibration analysis is estimated to be only 20 % higher than with radiographs [26].

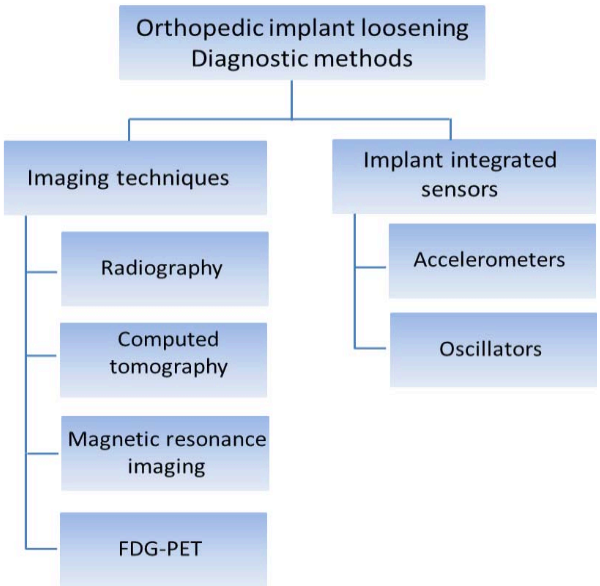

Fig. 2. Methods for the characterization of the loosened status of orthopedic implants with a special focus on total hip replacements.

A novel method to detect implant loosening proposes the application of mechanical magnetic sensors (oscillators) [27]. These sensors impinge on small membranes inside the hip prosthesis component *e.g.* the femoral stem. The maximum velocity of the oscillator after impingement depends on the osseous anchorage of the implant. The oscillator is excited by a coil placed outside the body. The velocity is detected by another external coil. Close contact to the bone is indicated by a lower back spring of the oscillator.

Currently researchers are striving to develop novel *in vivo* sensors in order to improve diagnostic investigations of hip implant loosening. Any electronics integrated into the hip prostheses including sensors are subject to stringent clinical requirements such as sterilization, stability and life time at least as long as the total hip replacement. Miniaturized design, biocompatibility, wireless powering and telemetry pave the way towards the realization of intelligent implants.

IV. Conclusions

Hip replacement is the most common orthopedic surgery. During the total hip replacement procedure, the degenerated or fractured hip is treated by implanting an artificial joint consisting of a stem cemented or impacted into the femur and a cup placed into the cavity after reaming the acetabulum. Despite more than forty years of clinical experience there are still complications occurring which require the revision of the artificial hip or its components. Most often the reason for the implant failure is loosening of the stem or the cup. Revision surgery is a highly demanding procedure and especially in patients with poor general health, the complication rate is very high. Currently most techniques used to identify the loosening status are based on imaging methods such as radiography, computed tomography, magnetic resonance imaging and fluoro-deoxy-glucose positron emission tomography. Other diagnostic methods for loosening include implant integrated sensors such as accelerometers and mechanical magnetic sensors.

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