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Is in-vivo sensing in a total hip replacement a possibility? A review on past systems and future challenges.

To cite this article before publication: Oliver George Vickers *et al* 2021 *Prog. Biomed. Eng.* in press <https://doi.org/10.1088/2516-1091/ac1b7f>

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Title: Is in-vivo sensing in a total hip replacement a possibility? A review on past systems and future challenges.

Authors: Vickers, O.G., Culmer, P.R., Isaac, G.H., Kay, R.W., Shuttleworth, M.P., Board, T. and Williams, S.

Keywords: Total hip replacement, instrumented orthopaedic implants, smart implantable medical device, wireless technology, sensing

Abstract:

Surgery to implant a total hip replacement (THR) is very successful in reducing pain and restoring function. This procedure has become more prevalent, and projections estimate further increases in demand. However, complications can arise, and current diagnostic techniques often fail to expose underlying issues before they result in a catastrophic failure that requires revision surgery. An instrumented implant, with embedded sensors capable of real time condition monitoring, would be an attractive proposition to incorporate within a THR. Continued advances in the performance and miniaturisation of electronic components, embedded systems, sensing and wireless communications have given the tools and resources medical device manufacturers need to innovate in the field of implantable medical devices. Smart implants are already being widely used in healthcare including pacemakers, cochlear implants, glucose monitors and insulin pumps however, a widely used smart THR has not yet been realised. Since the implantation of the first instrumented hip implant in the 1960s there have been several in-vitro studies monitoring levels of implant loosening. Additionally, significant research has been conducted using instrumented THRs to perform in-vivo measurement of biomechanical metrics, including force and moments. To date less than 100 patients have successfully received an instrumented implant. The results of these studies have aided researchers, designers and surgeons in wider research projects, however, the motivation behind the work was to provide discrete biomechanical data sets and not provide real-time condition monitoring of an implants performance or highlight early indications for revision surgery. If in-vivo sensing within

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3 a THR is to be achieved and adopted in regular clinical practice then the following
4 challenges need to be addressed: choice of the sensing method, biocompatibility and
5 integration within the implant, power supply, communication, and regulatory
6 considerations.
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1. Introduction

Total hip replacement (THR) surgery is a successful intervention and relieves pain and restores function [1]. National joint registries [2]–[4] have all shown consistent increase in the number of THR surgeries performed annually and projections are estimate further growth in the demand for both primary and revision procedures [5], [6]. Furthermore, patient expectations are changing as younger patients are undergoing THR and increasingly demand return to recreational activities [7]. Despite the success of THR surgery, complications can still arise, and current diagnostic techniques often take too long to expose underlying issues before they result in catastrophic failure which may result in revision surgery. Revisions are undesirable because of increased surgery time, complication rates and expense. Equally, unnecessary clinical reviews of well-functioning THRs are routinely carried out because there is no alternative to assess on-going function. The use of in-vivo sensing capable of real time condition monitoring of the implant's performance, occurrence of adverse events and patient health metrics offers a potential solution. Research in this area was first explored in the 1960's, however, despite almost 60 years of continued innovation, there has not been widespread adoption in orthopaedics. Recent advancements in materials, manufacturing and electronics may provide new potential innovations in the field of in-vivo sensing and smart implants thus making it an opportune moment to conduct a review on past systems and applicable technology.

Why is it desirable to have telemetry in an implanted medical device?

An implanted medical device (IMD) with sensing capabilities and telemetric link could provide a means of continuous monitoring as oppose to traditional episodic monitoring [8]. This would enable clinicians to track the post-operative recovery process, better guide personalised postoperative care [9], [10] and empowers patients with the ability to review and manage the health of their implant. Additionally, the system could provide alerts on the occurrence of adverse events to give an early indication of the need for further investigation, or modification in activities.

Increased availability of cheaper, smaller and more powerful integrated circuits and semiconductors has led to huge technological advances in electronics, sensing and communications. These advances and increased adoption of technology in

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3 healthcare has meant that smart IMDs are becoming a reality and are commonly used
4 across healthcare. For example, the Freestyle Libre continuous glucose monitor
5 (Abbott, Ill, US) offers an alternative to traditional finger prick blood glucose tests. The
6 Freestyle Libre offers a pain free method for continuously measuring blood glucose
7 levels and information on the direction blood glucose levels are trending. This
8 demonstrates an example of how the advent of technology has improved both the
9 convenience and quality of the care.

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16 The data gathered by an instrumented implant could inform the healthcare
17 professional during their diagnostic decisions. In the case of a THR this data could
18 include (for example) metrics on the performance of the implant or activity of an
19 individual patient such as daily steps, range of motion, and condition of the bone-
20 implant bond or wear of the bearing surfaces. Furthermore, this data would also be
21 valuable to researchers to gain a better understanding of the overall use and
22 performance of THRs across a patient population. Ultimately this research could be
23 used to refine the design and surgical placement of existing implants to give enhanced
24 performance and increased longevity. If these improvements were achieved, they
25 would be of benefit patients and clinicians; and also providers (healthcare systems)
26 and financiers (governments and insurance companies).

37 38 How do hip implants fail?

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40 The common indications and percentage occurrence for primary revision following
41 primary THR surgery (that occurred in England, Wales, Northern Island, the Isle of
42 Man and the States of Guernsey from 1st April 2003 to 1st March 2020 [2]) are
43 summarised in Figure 1. In the short term (less than one year after primary hip
44 replacement), the most common indications for revision (as measured by failures per
45 1000 prosthesis-years) were dislocation/subluxation (2.50), infection (1.92), peri-
46 prosthetic fracture (1.71), aseptic loosening (1.03), reaction to particulate debris (0.77)
47 and malalignment (0.73). Clearly pain cannot be detected by means of an
48 instrumented implant however there is scope for the other listed indications to be
49 detected in-vivo.
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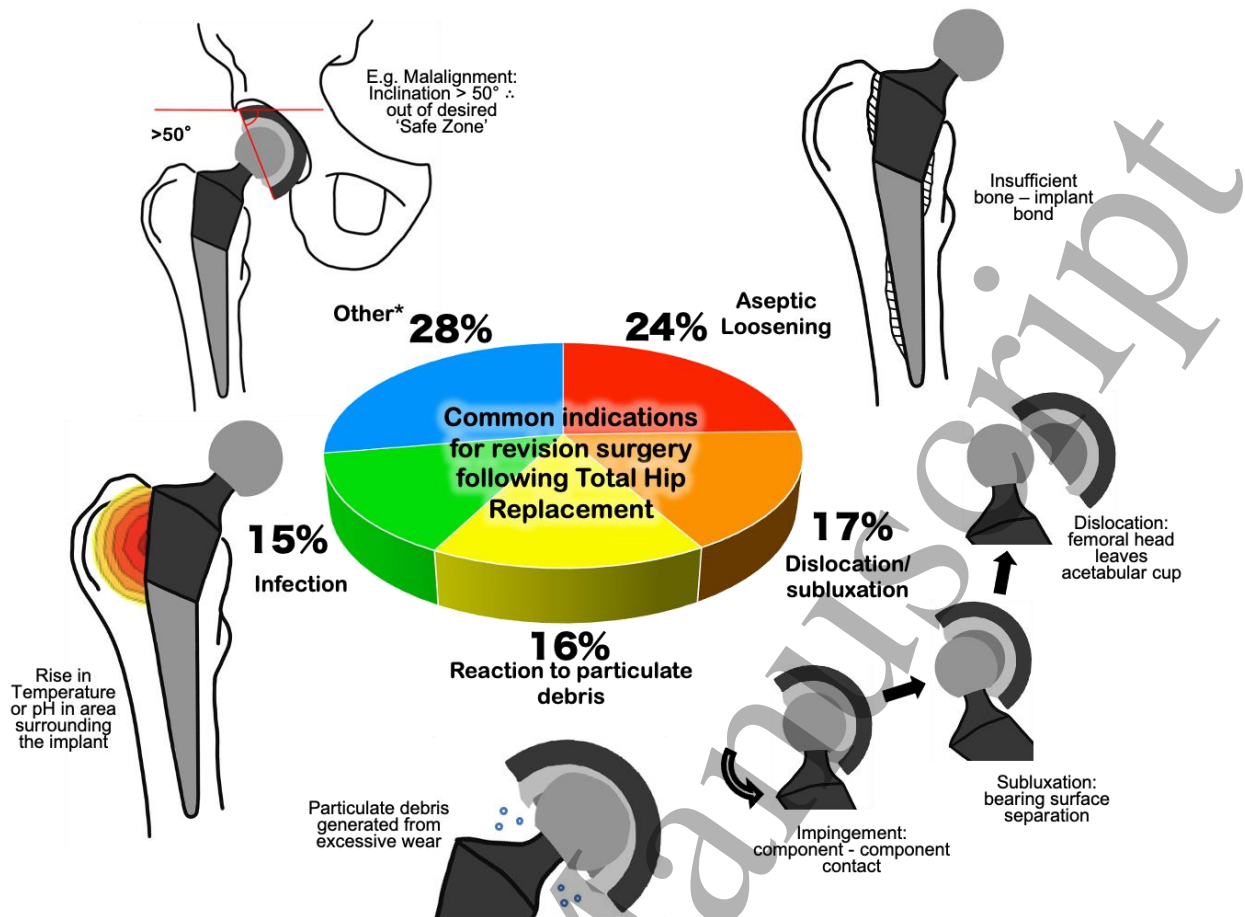


Figure 1 – Common indications for primary revision following primary revision surgery as reported by the 17th Annual Report of the National Joint Registry [2]. *Other indications of note include malalignment, implant wear and implant fracture.

The indications for revision demonstrate different modes in which an implant can fail, all may be linked to patient reported pain. This can make an initial diagnosis through clinical observations a challenge. An instrumented hip implant could give quantitative data demonstrating an adverse event providing an early indication for the need for clinical review. This could reduce the diagnostic pathway providing a quicker diagnosis thus reducing the impact of time sensitive conditions [8].

This review will look at the current state of the art of instrumented hip implants focusing on their capability to perform in-vivo sensing and translation into routine clinical practice. Following this the challenges that will need to be overcome for in-vivo sensing systems to be viable will be considered. These are as follows: choice of sensor (including author recommendations on potential sensing applications for use within a

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3 THR), biocompatibility and integration within the implant, power, communication, and
4 regulatory considerations.
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2. Review: Instrumented hip implants current state of the art

The review's findings are reported in sections on related to the indication for revision or main phenomena that the study was looking to detect or monitor; (i.e. biomechanics and aseptic loosening).

2.1 Biomechanics

In terms of instrumented hip implants, most of the focus has been on studying the biomechanics of THRs and function in an in-vivo environment. Strain gauges, piezoelectric transducers and temperature sensors have been used to measure forces, pressures, moments and temperatures in-vivo. The data collected in these studies has been important in validating computational and cadaveric models, and inform designers and surgeons thus improving implant design and surgical technique.

2.1.1 Early Work on Measuring Hip Joint Force In-Vivo

The first use of sensors in an instrumented implant, for in-vivo use, was that of Rydell et al [11] who positioned strain gauges within the neck of the femoral prosthesis. The prosthesis was implanted successfully in two patients successfully and six months later a second surgery passed lead wires out of the skin to allow for data collection. After a week these lead wires were designed to be cut free by a sharp edge at the junction with the prosthesis however this method failed, and a separate operation had to be conducted to remove the leads. Results (in terms of measured load) were recorded from two patients were collected (Table 1).

Convenience, improved patient comfort and reduced risk of infection led to the use of wireless connections. An approach, first described by English and Kilvington [12] and later in Kilvington and Goodman [13], was to use battery power and a FM transmitter chip (Sandev SNIO2F) operating at 102.3 MHz. Their implant consisted of a sealed piston with four strain gauges thus forming a load cell capable of measuring the axial compressive load transmitted through the neck of the femoral component. A cable was passed out of the implant stem and led to an implanted Perspex box where the transmitter and accompanying electronics were housed, the cable and box were encapsulated within silicone rubber. The system had an operational battery life of

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3 approx. 70 hours and with the use of sub miniature magnet controlled reed switches,
4 recordings could be made up to 43 days post-op [12]. Results (load from walking and
5 one legged stance) from a single patient were collected (Table 1).
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9 Other early work measured contact pressures at the joint surface, Carlson et al
10 [14] developed a prototype prosthesis to measure the magnitude and distribution of
11 pressure generated over the inner surface of a natural human hip socket. The implant
12 featured 14 pressure transducers covering the outer surface of the femoral head, and
13 a 16-channel telemetry system located within the femoral head. The power and data
14 transfer induction coil were located at the distal end of the implant, allowing the implant
15 to be powered by an external power coil. A similar approach was adopted by Otake et
16 al [15] who developed a modified femoral head with eight sub-miniature pressure
17 sensors embedded over the surface and covered with a spherical ABS plastic surface
18 to reduce friction. The device was limited in that it was only intended to measure
19 intraoperative pressures at the bearing contact surfaces.
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31 2.1.2 3D Force Measurements Acting on the Femoral Stem

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33 In 1979 Georg Bergmann developed a new method for measuring force distributed
34 over a femoral head termed the matrix method [16]. The method required only one
35 sensor for each load component and so meant that 3D force measurements could be
36 made on the femoral head with the use of only three strain gauges positioned within
37 the femoral neck (on the inner surface). Bergmann then developed his own
38 instrumented hip implant that he initially tested in sheep [17]. A functional
39 telemeterised hip for in-vivo human use was first described and implanted in 1988 [18].
40 The implant, (Figure 2a), included three semiconductor strain gauges positioned on
41 the inner wall of the hollow neck. The remaining electronics, including the power coil
42 and RF transmitter, were placed on both sides of a 15mm X 7mm wide substrate and
43 housed in an 8mm X 25mm cylinder. The top plate of the cylinder had two lead
44 throughs that connect to the RF transmitter antenna which was fitted into the cavity of
45 a ceramic head [19]. Two patients received the instrumented hips, firstly in 1988 a
46 bilateral procedure (both hips) was performed on an 82 year-old male with height
47 168cm and bodyweight (BW) 650N, and then in 1990 in the right hip of a 69 year-old
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3 female of height 160cm and BW 470N. Results recorded (peak loads in walking and
4 stumbling) from the two patients are shown in Table 1.
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7 In the 1990s Bergmann's group developed a further endoprosthesis which
8 measured the force components experienced by the head and also the temperature
9 distribution across the full length of the femoral stem [20]. The implant, (Figure 2b)
10 was based on the hollow shaft hip endoprosthesis CENOS (ARTOS, Berlin, Germany)
11 and featured three semiconductor strain gauges and two temperature sensors (TS1 &
12 TS2 Figure 2b) glued to the inner surface of the hollow neck along with an additional
13 six temperature sensors (TS3 - TS8 Figure 2b) positioned along the shaft of the stem.
14 The power coil and two telemetry units were positioned within the hollow shaft, which
15 was sealed by a top plate. The top plate was welded to the top of the implant neck,
16 and featured two lead throughs that allowed connection to the antenna that occupied
17 the cavity of the ceramic head, [20] similar to the previous endoprosthesis [19].
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27 In 2001 Bergmann and colleagues published the results of two studies
28 conducted using these new endoprosthesis [21], [22]. Firstly, contact forces were
29 reported from four patients', age range 51 – 76 years and BW range of 702N – 980N.
30 Hip contact force results collected from these four patients are shown in Table 1. In
31 the second study temperature measurements were made in seven patients', age
32 range 51 – 82 years. Peak temperature of implants with a polyethylene liner was
33 measured at 43.18°C after an hour of walking and was observed in sensor TS1 which
34 was positioned at the top of the neck [22], (Figure 2b).
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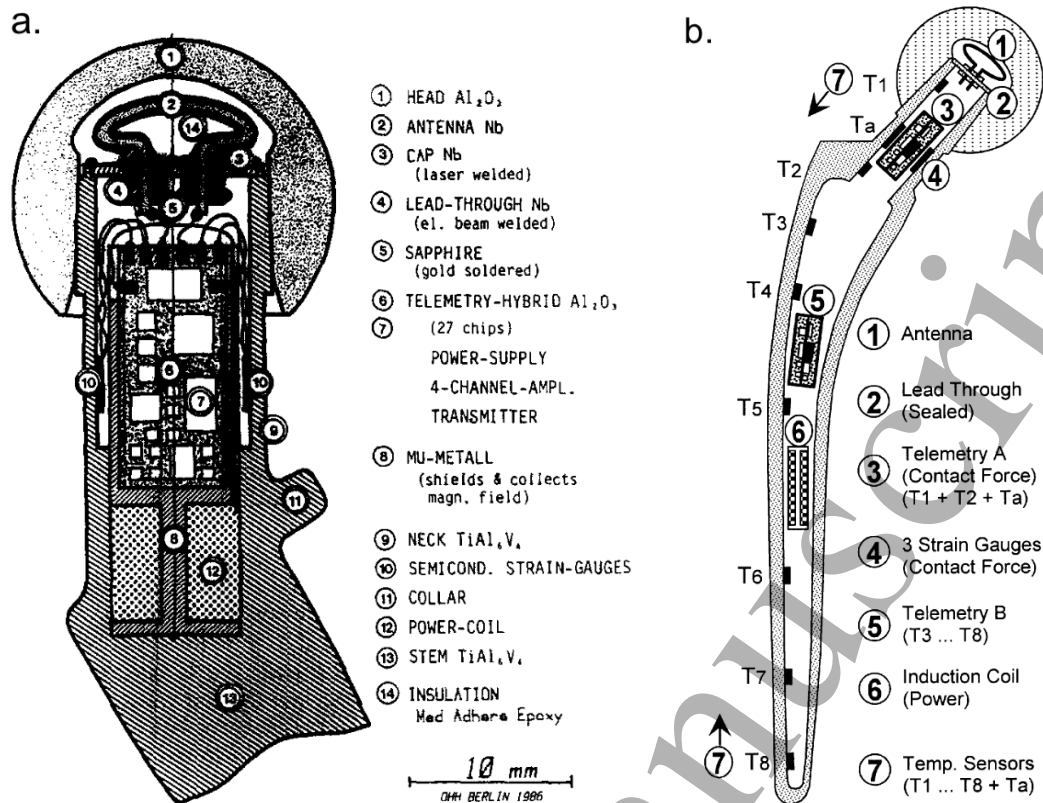


Figure 2a – Cross section of Bergmann's first hip endoprosthesis for force measurements [18]. Figure 2b – Bergmann's hollow shaft smart prosthesis capable of force measurement and temperature measurement along the full length of the stem [22].

The third iteration of Bergmann's instrumented hip prosthesis [23] was based on a "Cementless Tapered Wedge" (CTW) prosthesis (Merete Medical GmbH, Berlin, Germany). This allowed for the measurement of forces and moments acting in the joint. Three custom-made twin semiconductor strain gauges were positioned inside the hollow neck along with a nine-channel telemetry transmitter and an internal induction coil. A cut-out model of the prosthesis is shown in Figure 3a. The prosthesis had a transmission range of 50cm [23]. In 2013 Damm and colleagues [24] reported in-vivo friction measurements using Bergmann's modified CTW prosthesis. Results at 3 months post-op from eight subjects, age range 50 – 69 years and BW range of 754N – 899N and are shown in Table 1.

Table 1 – Summary of studies reporting in-vivo loads measured through hip joint

Study	Method	Patients	Stance/Activity	Measured load through joint normalised to body weight
Rydell [11](1996)	6 strain gauges in stem	2	One-legged stance	2.3X (peak patient 1) 2.9X (peak patient 2)
			Walking 1.3m/s (patient 1) & 1.4m/s (patient 2)	1.8X (peak patient 1) & 3.3X (peak patient 2)
Kilvington & Goodman [13](1981)	Load cell piston	1	One-legged stance	2.8X (12 days post-op) & 2.2X (40 days post-op)
			Walking	2.0X (12 days post-op) & 1.9X (40 days post-op)
Davy [25] (1988)	3 strain gauges matrix method	1	One-legged stance (31 days post-op)	2.1X
			Walking	2.6X to 2.8X (range)
			Stair climbing	2.6X
Kotzar [26] (1991)	3 strain gauges matrix method	2	One-legged stance (23 days post-op)	2.1X to 2.8X (range)
			Walking	2.8X to 3.6X (range)
Bergmann et al. [27]1993	3 strain gauges matrix method	2	Walking 0.3m/s (patient 1) & 1.4m/s (patient 2)	2.8X (peak patient 1) & 4.8X (peak patient 2)
			Stumbling	7.2X (peak patient 1) & 8.7X (peak patient 2)
Bergmann et al. [21]2001	3 strain gauges matrix method	4	One-legged stance	2.3X (mean from 4 patients)
			Walking (1.1m/s)	2.4X (mean from 4 patients)
Damm et al. [24]	3 strain gauges matrix method	8	Walking (3 months post-op)	2.5X (mean from 8 patients)

Bergmann et al [28] also developed a further prosthesis based on the CTW design solely for in-vivo temperature measurements. This had a 6.2mm diameter X 50mm long bore in the neck for the thermistor and accompanying electronics, (Figure 3b). Bergmann's previous implants had all featured internal power coils and an external niobium antenna. The new prosthesis however, had a combined power and data coil positioned within a hermetically sealed chamber instead of being positioned in the recess of the femoral head and encapsulated in silicone. The justification being that the plastic encapsulation of electronics should only be used for non-permanent

implants [28]. To date no study has been reported from this prosthesis however, Bergmann et al. [28] state that a clinical study on temperature rise in hip implants was planned in 100 patients.

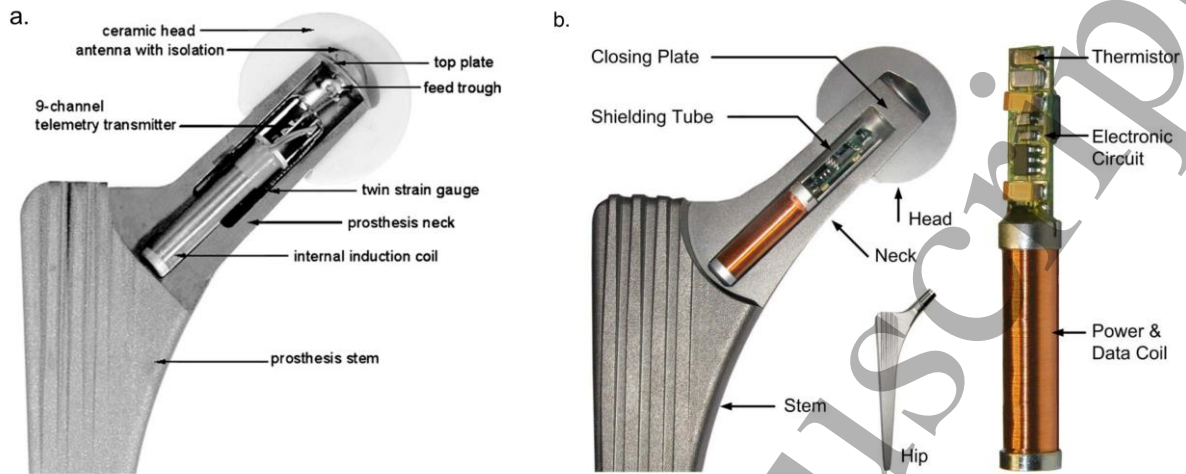


Figure 3a – Bergmann's first CTW implant with three twin semiconductor strain gauges, internal power coils and an external niobium antenna [23]. Figure 3b – The latest of Bergmann's smart implants and the first to feature a combined power and data transfer coil [28].

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2.2 Implant Loosening

Aseptic loosening is failure of the implant – bone bond in the absence of infection. It is the most common reason for orthopaedic implant revision. Aseptic loosening can cause pain and if it is diagnosed too late, can lead to a destruction of bone stock which can create issues when implanting a new revision implant [29]. The initiation and progression of aseptic loosening is multifactorial, this includes: resultant adverse biological reactions to cement, polyethylene, metal or ceramic particles, micromotion at the interface, stress shielding, high fluid pressure, endotoxin or individual and genetic variations [30].

2.2.1 Vibration Analysis

Vibration analysis (VA) relies on measuring the ambient vibrations and frequencies of a system or the vibration response following a mechanical excitation from an external source e.g. a shaker. A structural change or degradation within the system, for example an imbalance, worn and broken components or torque variations, will give rise to distinct features in the output signals. An abnormal vibration response can be more easily identified if an original or typical vibration response is known [31]. The frequency response of a linear system will show the excitation (input) oscillating at the same frequency as the output. Whereas the output of a nonlinear system will contain multiple harmonics. In the case of a THR, a well-fixed prosthesis can be considered as a linear system whereas an unstable or loose implant will behave like a nonlinear system, Figure 4.

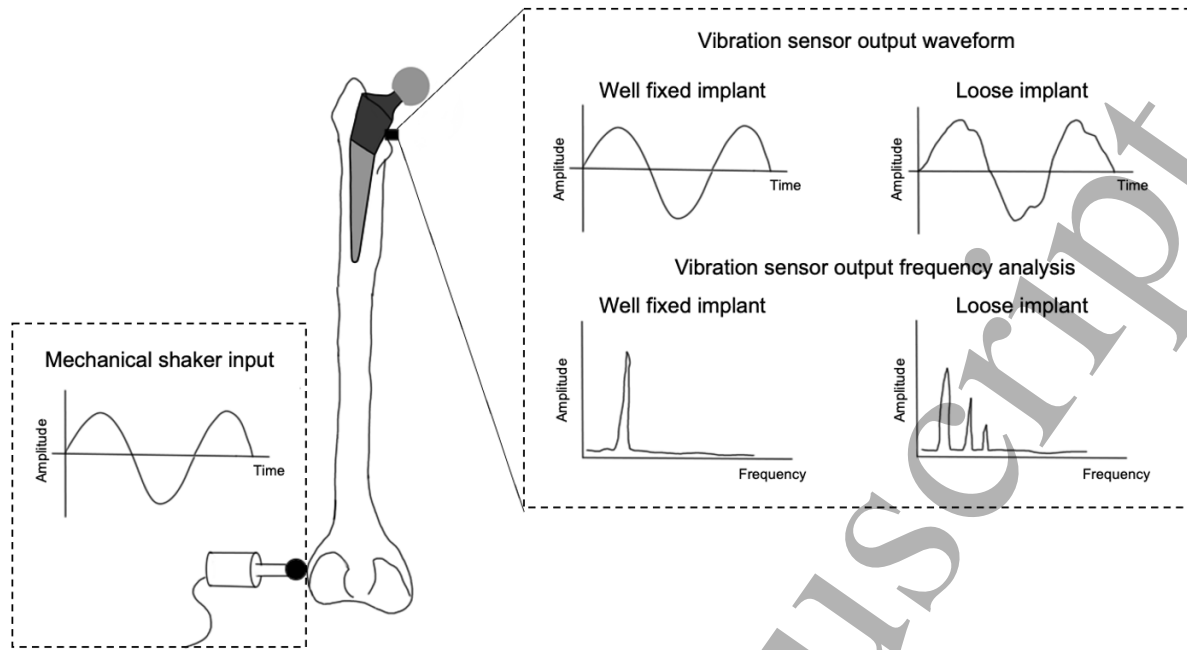


Figure 4 – Conceptual diagram of vibration analysis being performed on a femur and implanted stem. The output waveform of a well-fixed implant will match the sinusoidal nature of the input excitation and frequency analysis will reveal one major frequency. Conversely a loose implant will have a distorted output waveform and multiple harmonics will be present [32].

Chung et al [33] first suggested the use of VA as a diagnostic technique to assess THR fixation. They described the technique as safe and non-invasive because only a small mechanical excitation was required; that the method could be used on pre-existing implant designs and previously implanted prostheses and allow for the real time monitoring of levels of osseointegration. The in-vitro experimental setup included a mechanical shaker applying an excitation to the implant–bone system and accelerometer(s) attached to the bone, measuring the vibration response. Several studies report similar findings to Chung et al [33] using a femoral stem implanted in a femur [32], [34], [35], acetabular cup implanted in a Sawbone block [36] and complete THR system implanted in a Sawbone femur and pelvis [37]. Results demonstrate that an implant–bone interface with a loosened implant, gave a distorted output waveform, increased numbers of resonance peaks and a reduction in the magnitude of the fundamental frequency.

Rosenstein et al [32] and Georgiou and Cunningham [38] further developed this concept by conducting in-vivo trials using VA to detect THR loosening in-vivo. In both studies, a single accelerometer was positioned over the greater trochanter and a

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3 vibrator applied excitation to the lateral epicondyle of the femur. Rosenstein et al found
4 that in five patients where the VA test was positive for loosening, it was also observed
5 in revision surgery. Additionally, Georgiou and Cunningham reported their VA method
6 had a sensitivity of 80% and a specificity of 89%, and when compared to the standard
7 radiographic method was 20% more sensitive and able to diagnose 13% more
8 patients. There were however, limitations in the in-vivo method; firstly, the technique
9 is unsuitable for patients who could not lie on their side or who experience pain and
10 discomfort induced by the vibrator, in Georgiou and Cunningham's study this
11 accounted for 10% of the patients. Secondly, although the authors took care to position
12 the sensor and shaker with "good bony contact" variations in patient soft tissue can
13 greatly affect the propagation of the vibrations to the body's surface and so affect the
14 diagnostic capabilities [39].
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25 Using an implant with telemetry presents an alternative method that would allow
26 for ongoing VA assessment of the THR component loosening. Puers et al [40] propose
27 a concept that included a capacitive accelerometer sealed in a titanium can and placed
28 into a recess made in the femoral head (Figure 5). The inductive power and data coils
29 were fed through the lid of the titanium can and coil around the superior portion of the
30 neck stem. Puers et al. [40] state that having the sensing system within the implant
31 will provide far better results when compared to previous VA methods. One limitation
32 of this integration method is that the required recess incurs significant modification to
33 the femoral head which would affect the bearing function at the articulating interface.
34 Additionally, the coils are within the operating space of the ball and socket joint and
35 are thus vulnerable to damage if primary impingement (contact between the cup and
36 stem) occurred.
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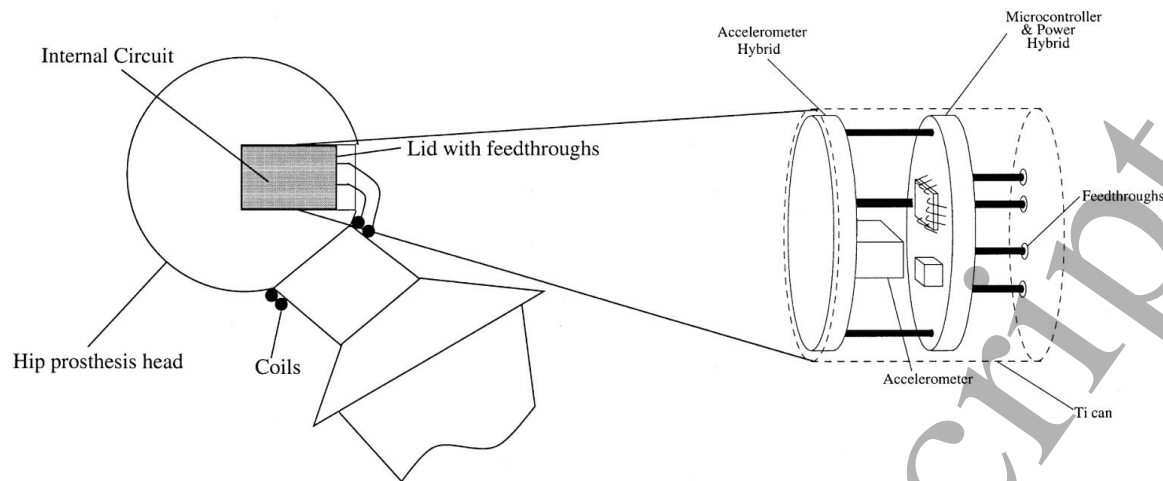


Figure 5 - Method of packaging showing the location of the recess in the femoral head and positioning of the transmission coils [40].

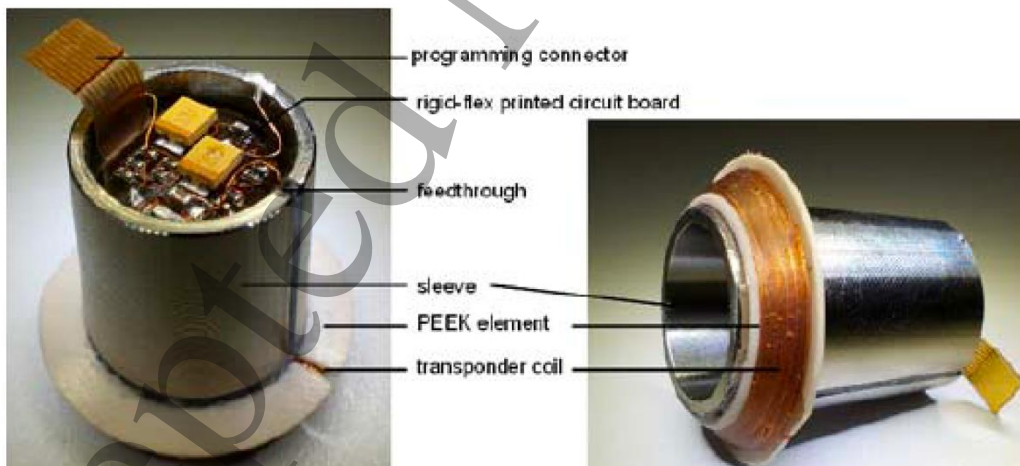
Marschener et al [41] developed a system with a custom transponder chip and an accelerometer complete with a lock-in amplifier, which filtered out signal noise generated by the in-vivo environment. The system also featured onboard storage, that could include patient and prosthesis manufacturer data as well as reference data sets for loosening trend analysis. The chosen integration solution was to screw the coil and electronics housing to the distal end of the prosthesis this ensured vibration coupling to the implant and meant that there was no metal surrounding the transponder coil [41].

Sauer et al [42] positioned a sensor system in the femoral head. The rationale for the approach was that firstly, when compared with the manufacturing process of stem, modifying the femoral head would be far simpler and cheaper. Secondly, the micro-porous surface coating on their stem required a gamma sterilisation process that would have a detrimental effect on integrated hardware. Finally, there were less femoral head design options compared with the number of stem sizes so using the femoral head would reduce the number of required variations. Their system included a 3-axis acceleration sensor, lock-in amplifier and inductively coupled data transmission and power supply working at 125Hz. The first integration concept was to put the sensor system within the cone of a ceramic head, (Figure 6). To secure the sensing apparatus a low consistency silicone was selected to provide a durable fixation and no electromagnetic disturbance or shielding of the telemetry coils. However, it was noted that the titanium acetabular cup would interfere with the

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3 electromagnetic field of the transponder coils and so an alternative approach was
4 devised. In this approach, the sensor system was encapsulated within the titanium
5 sleeve and the coils, connected by lead throughs, were wound on a polyether ether
6 ketone (PEEK) element and mounted on the sleeve (Figure 7).
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33 *Figure 6 - THR sensing system to measure vibration potted in the femoral head [42].*

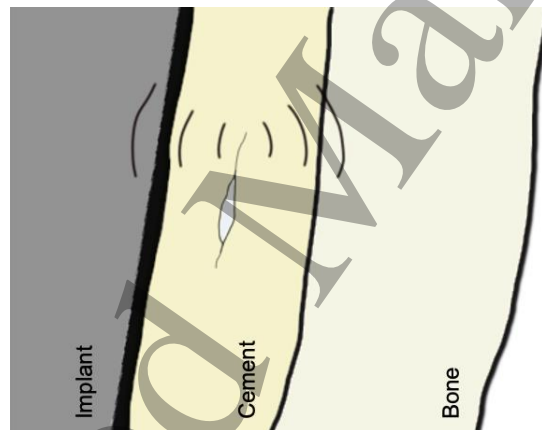


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54 *Figure 7 - THR sensing system to measure vibration showing the sensing system positioned within a*
55 *titanium sleeve and the transponder coil wrapped around a PEEK element [42].*
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3 All three research groups [40]–[42] that investigated telemetric VA were able to
4 verify their sensing systems and produced similar vibrational response data to [32]–
5 [37].
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10 2.2.2 Acoustic Emissions

11 Acoustic emission (AE) is the phenomenon of energy release, in the form of acoustic
12 (elastic) waves, as a result of a solid material undergoing irreversible changes in its
13 internal structure such as crack propagation, phase changes and dislocations within
14 the material [43]. The stress waves generated propagate to the materials surface
15 (Figure 8) where they can be recorded by sensors, typically piezoelectric. Key
16 parameters can then be derived including rise time, maximum signal amplitude, signal
17 duration, signal energy and peak counts. If multiple sensors are present the timings of
18 the waves arrival at the materials surface can be used to triangulate the point of origin
19 and hence the location of the defect.
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43 *Figure 8 – Crack propagation in the bone cement will release acoustic waves which will travel to the*
44 *surface of the bone or implant and can then be detected.*
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47 One of the earliest examples of using AE to determine the occurrence of implant
48 loosening was conducted in 1989 by Sugiyama et al [44]. They used an AE technique
49 to investigate the effect torsional load has on femoral stem loosening and compared
50 three cementing techniques including combinations of canal irrigation, manual
51 insertion, and vacuum mixing combined with pressure injection. They concluded that
52 the most successful cementing technique (as measured by reduced AEs) was
53 pressure injection and vacuum mixing of the cement, however some AEs were still
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3 detected suggesting that even the best cementing technique was prone to failure when
4 torsional loading was applied [44].
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7 Other studies [45]–[47] have also assessed whether AE can be related to
8 cement-bone debonding. These studies used a similar approach; placing piezoelectric
9 transducers positioned on the surface of, or embedded into, the femoral stem. All
10 noted the discontinuous nature of the cumulative AE events and attributed this to the
11 propagation of a crack or coalescence between a main crack and a microcrack.
12 Additionally, AE waveforms related to cement cracking have higher energy, longer
13 signal duration and shorter rise times. Furthermore, work conducted by Rowland et al.
14 [48] demonstrated that AE monitoring could be used for the detection of excessive
15 wear. They had two AE sensors positioned on the top and bottom fixtures of a five-
16 station wear rig and noted that one of the stations showed two repeating signals of
17 57dB and 66dB amplitude. This was associated with higher volumetric wear and a
18 subsequent inspection of the implant components showed evidence of wear that was
19 not seen in the other stations.
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30 Ruther et al [49] developed a novel detection technique they termed magnetic
31 oscillator, that uses elements of AE sensing. The sensing process begins with an
32 external coil exciting the ferrous head of the oscillator. The oscillator then hits the
33 membrane inside the implant and the impulse generated by this contact is dependent
34 on the material adjacent to the membrane. For example, close bone contact, indicative
35 of successful osseointegration, would mean there would be a lower deformation
36 energy and reduced spring dampening. This could be measured by a second external
37 detection coil measuring the velocity of the oscillator or by recording the resulting AE
38 generated by the oscillator contacting the membrane. A mock-up of how the system
39 could be used clinically, a cross section of an instrumented implant and magnified
40 views of the oscillator, is shown in Figure 9.
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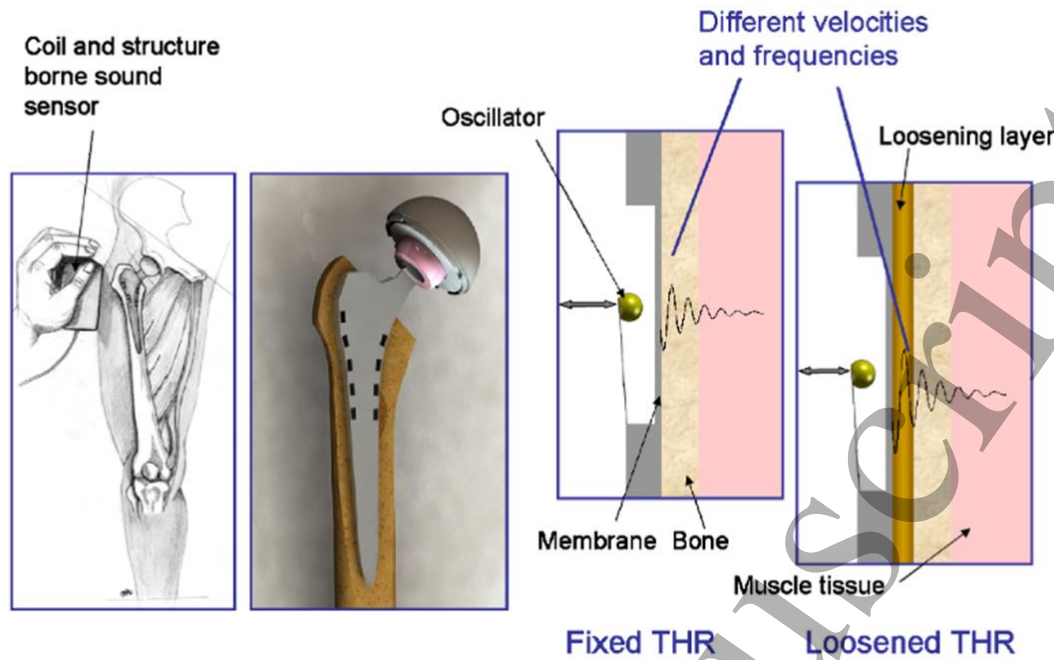


Figure 9 - Mock-up of how the novel magnetic oscillator system could be used clinically, a cross section of an instrumented implant and magnified views of the oscillator [29].

Ruther et al [50] assessed this concept in an in-vivo rabbit model. Three different implant surfaces were used to induce various levels of osseointegration. Over the 4 weeks of implantation the AE changed with loosening of the implants (defined by the low axial pull-out strength of the implant) showing a continuous increase in central frequency. Ruther et al propose a novel solution for a non-destructive in-vivo assessment of implant loosening, this required no embedded electronics or telemetry systems and has the potential to provide localised measurement of osseointegration. However, to cover the full surface of the implant the concept would likely require extensive modification to the prosthesis and the addition of the oscillators would potentially complicate the manufacturing process.

2.2.3 Eddy Current

An Eddy current sensor uses a sensing coil supplied with an alternating current to create a magnetic field (primary field). If a conductive material intersects the primary field, a magnetic field will then be induced within the conductive material (secondary field), causing a change in the impedance of the coil. This change in impedance can then be detected and related to the distance between the sensing coil and conductive material.

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3 Khoke et al [51] examined the efficacy of implanting Eddy current sensors within
4 the positioning holes left after total knee arthroplasty with the aim of detecting tibial
5 component micromotions. Mohammadbagherpoor et al [52] assessed the use of an
6 Eddy current proximity sensor with a 10mm diameter solenoid coil. Their simulated
7 and experimental work showed that they were able to detect the micromotions of a
8 10mm CoCr rod with a 100 μ m resolution at a distance of 20mm. Although, an Eddy
9 current sensing coil would enable noncontact sensing of micromotions, it remains
10 relatively under-developed and there are potential concerns of factors such as sensor
11 migration over time with any changes in bone morphology.
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22 2.3 Summary

23 Since 1966 less than 100 patients have been reported in literature to have received
24 an instrumented hip implant and had in-vivo measurements recorded. Biomechanical
25 and thermodynamic measurements, and the assessment of implant fixation have been
26 the predominant focus in the field of instrumented hip implants. The first instrumented
27 prosthesis to successfully obtain in-vivo measurements was implanted in 1966 (Rydell
28 1966). From then to the present there have been several successful attempts at using
29 smart hip implants to record measurements in-vivo with the most noteworthy being the
30 work conducted by the Orthoload group led by Bergmann. Bergmann's work improved
31 on previous efforts as they were able to measure the 3D load components acting on
32 the stem with minimal changes to the external geometry or features of the implant
33 components. The packaging of the sensing system within a cavity in the stem meant
34 that the components were shielded from the in-vivo environment. However, the
35 modifications made to the internal structure to make the hollow shaft (Figure 2b) will
36 have involved removal of substantial volumes of material which bring significant risks
37 of compromising the integrity of the stem and increased the complexity of the
38 manufacturing process. This is likely why the cavity housing the sensing system was
39 reduced in the later iterations (Figure 3a & 3b).
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54 Vibration analysis and tracking the acoustic emissions of the components has
55 shown promising results as a method for measuring implant loosening. However, the
56 limitations of this technique may be that pre-existing data of a well-fixed implant would
57 be required as a reference dataset and that excitation from an external shaker is
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3 required. Although, there could be potential for a far wider range of indications or
4 phenomena to be detected from examining the vibration response of an implant
5 system for example wear [48]. These techniques are also vulnerable or sensitive to
6 background noise from the environment for example generated by an experimental
7 hip simulator or when in an in-vivo environment. However, improvements in data
8 acquisition and processing techniques and advancements in artificial intelligence and
9 machine learning could address these challenges. More recent developments by
10 Sauer et al [42] demonstrate that potting a sensor system within the head of the
11 implant can address many concerns over sensing performance and implant
12 robustness and therefore represent good candidates for clinical use. Furthermore,
13 non-ferrous metals are no longer being used for implant components, and so there
14 won't be electromagnetic distortion caused by the acetabular cup disrupting the
15 wireless communications.
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3. Challenges in developing a telemetry system for an instrumented hip implant

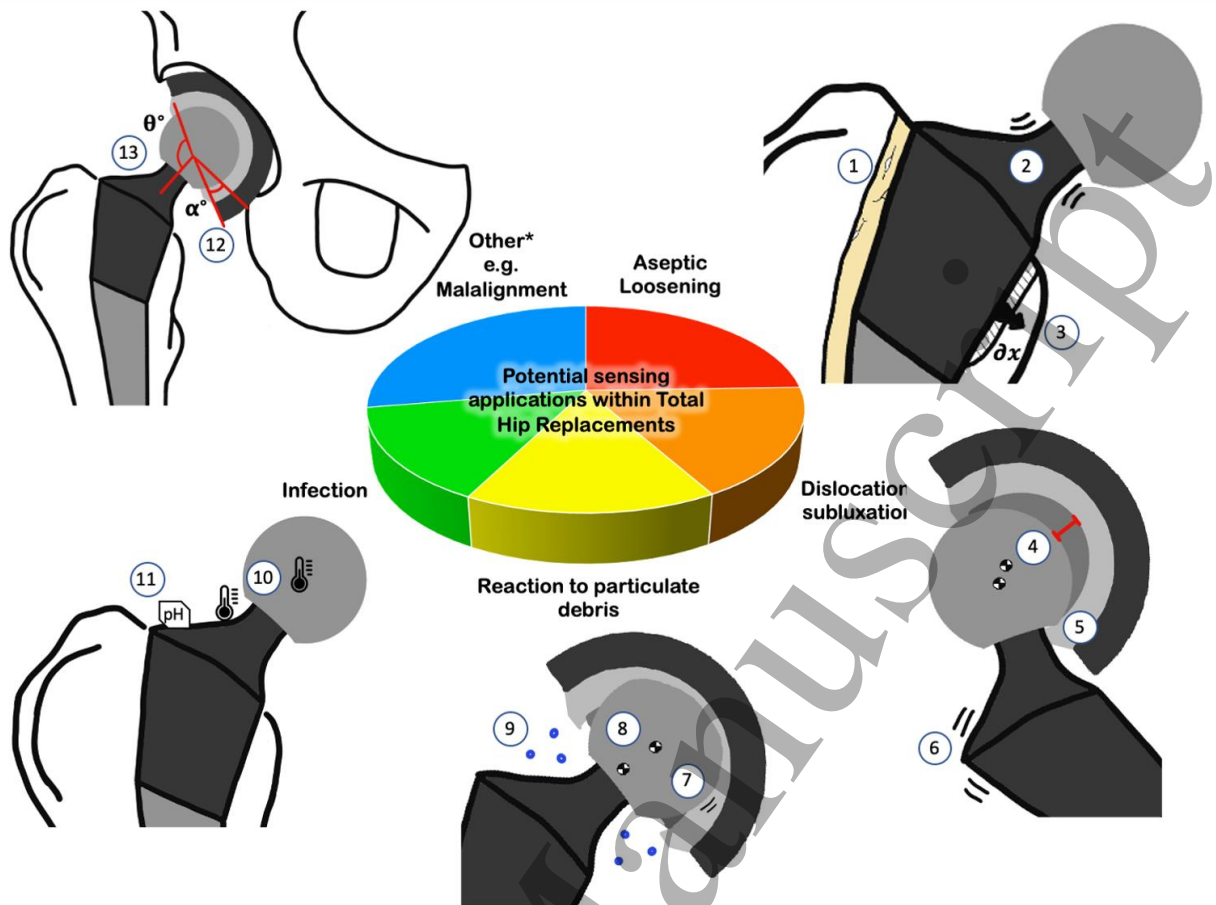
The following section will discuss the challenges that need to be overcome to enable an effective in-vivo sensing system for use within a THR. These include choice of sensor, biocompatibility and integration within the implant, power, communication, and regulatory considerations.

3.1 Choice of Sensor

The choice of sensor is a key challenge in developing a telemetry system for an instrumented implant. The potential sensing applications that have been formulated around the common indications for revision surgery of a THR (as shown Figure 1), are summarised in Figure 10. The aim being to develop a system that could continuously provide useful data on the performance of the implant and occurrence or progression of the phenomena associated with the indications for revision surgery.

Sensor choice is clearly a complex challenge, but most simply should primarily be driven by the cause or causes of revision for which data is being collected and accordingly the type and complexity of the system required. There are however several additional considerations. Firstly, the implant is likely to be in situ and functional for over ten years. . So, the information collected upon implantation may well be needed to address questions formulated 10-15 years in the future. So wherever possible the system needs to be future-proofed. Secondly as more data is collected on implant performance it may be that hitherto unknown associations or 'surrogate' measures may be found to link a data output with impending revision. For example, could reduction in activity be a pre-cursor to failure caused by loosening?

Thirdly, the outcomes outlined in Figures 1 and 10 are binary in that they focus on revision as an endpoint. It is likely that as more data is collected there will be a more nuanced measure of failure such as degradation of activity or reduced range of motion. These additional factors may modify the primary driver for sensor choice to what sensors or combination of sensors would give the most comprehensive output data.



Aseptic Loosening	
1.	Acoustic Emission sensing to monitor the integrity of the bone cement
2.	Vibration sensing can be used to compare vibrational response of well fixed and loose implant – bone system
3.	Measuring the displacement of the implant components relative to the bone and so the magnitude of the Micromotions (dx)
Dislocation/Subluxation	
4.	Measuring relative displacement of components to show if bearing surfaces separate
5.	Force or pressure sensors at the cup's rim to sense force from femoral stem contact
6.	Vibration sensing could detect torque generated when components contact
Reaction to particulate debris	
7.	Vibration sensing could show changes in friction as bearing surfaces become worn/rough
8.	Measuring relative displacement of components to show if head position in cup has changed due to excessive wear
9.	Directly measure wear particle concentration at the implant sight or in patients' blood
Infection	
10.	Measuring the temperature of components or the tissue surrounding the components
11.	pH sensing the tissue surrounding the components
Malalignment	
12.	Measuring the relative angles of the components relative to the bones to show if they are positioned in "Gold Standard" range intra or post-op
13.	Measuring the relative angles of the components to show if they are positioned in "Gold Standard" range intra or post-op

Figure 10 – Graphical representations of potential sensing methods within a THR addressing the common indications for THR revision surgery

Accepted Article

3.2 Biocompatibility and integration within the implant

Integration of sensing system within an IMD such as a total hip replacement has the potential to be beneficial however, it is important that the system does not impede the normal function of the implant nor cause an adverse biological response. This will require miniaturisation of the components to fit the size constraints of the implants as well as careful selection of materials and the mounting, embedding or encapsulation method. The assessment of biocompatibility should require biological evaluation including cytotoxicity testing, examination of the immunological and pathological effect on surrounding tissue and characterisation of the expected degradation of the implant's material over the lifetime of the implant as per the recommendations of ISO 10993 or other such standards. Furthermore, conventional consumer electronics are designed for a lifetime of 2 – 5 years whereas the lifetime of an orthopaedic implant is longer 10-15 years and so this is a factor that will need to be considered by medical device manufacturers (MDMs).

Typically, electronic components require protection and shielding from dust, debris, moisture, temperature and salinity that could interrupt their function or cause a degradation in their performance. Electronics implanted in humans must be protected from inner body elements such as cells, proteins, platelets, and chemical gases [53]. Furthermore, electronic components and the substances for the building up of integrated circuits, circuit boards, packaging materials and communication cables are not suitable for implantation. Printed circuit boards (PCB) consist predominantly of fiberglass and copper foil which are not biocompatible [54], [55], additionally PCB manufacture requires toxic chemical treatments.

Conventional electronics can be used within IMDs but will require encapsulation within a polymer or in a hermetically sealed chamber. Low consistency silicone has been shown to have favourable water absorption, water solubility and surface characteristics for long term implantation when compared to epoxy resin or polyurethane [56]. Chambers or recesses can be manufactured within the bulk material of the implant be it metal, polymer, glass or ceramic and welded or bonded to create a hermetic seal [53]. The hermeticity of the device would need to be assessed before medical device approval.

3.3 Power delivery system

Power supply is vital for the telemetry system of an IMD and the selection affects the proper function of the circuitry and the longevity of the working system. To date, only batteries and inductive power coupling have been used in untethered instrumented hip implants. Power supply still remains one of the most limiting factors of IMDs with the most significant constraints being size and demands of high capacity/lifespan [53], [57].

Sensing systems can be classified as active or passive; active systems require an internal power supply to drive active components such as a microcontroller unit and transducers. Conversely, passive systems don't receive power internally but instead by an external interrogator, whereby, a signal is generated by the interrogator's excitation circuit and sent at radiofrequency to the sensor [58]. A sensing system can include active sensors but have a passive power supply unit such as an inductive charging link.

Batteries can supply consistent levels of electrical energy that is stored in the form of chemical energy. The first use of a battery within an instrumented hip implant was English and Kilvington [59] and then Davy [25]. Many widely accepted IMDs use batteries. Examples are drug pumps, cochlear implants and pacemakers which can have a lifespan of 8 – 10 years [60].

Lithium ion batteries are preferred owing to their high energy density which can range from 210 mWh/g to 440 mWh/g [57], [61]. A rechargeable system would satisfy the requirements of an IMD including longevity and power supplied. However, during the process of recharging battery cells temperature can increase significantly and energy capacity is decreased with every recharge cycle. Recharging options are limited, one option would be an ultrasonic source. Ultrasonic transcutaneous power transfer begins with an external transmitter converting electrical energy into acoustic or vibration waves which propagate through the tissue gap to the internal receiver. The piezoelectric receiver then converts the acoustic or vibration energy back to electrical energy [62]. Awal et al. [63] conducted an empirical review on the use of acoustic energy transfer for IMDs and found that the efficiency of such systems can reach an efficiency of 45% over a range of 400mm and typically operated over a frequency range of 35kHz to 30MHz with a maximum power level being found to be 5.4W.

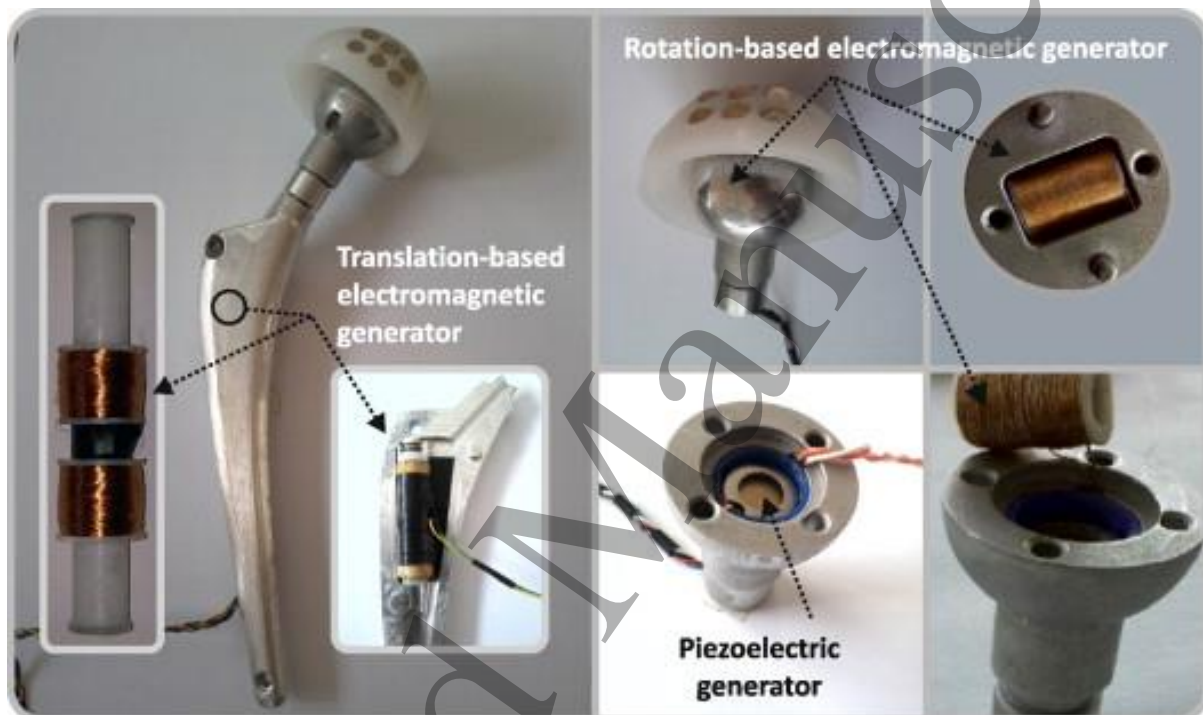
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3 Although, charging capabilities require additional circuitry [64] thus straining the size
4 constraints of IMDs.
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7 Another option for powering an instrumented hip implant is inductive charging
8 which was first used by Carlson et al. [14] and later by other groups [18], [20], [23], [28],
9 [40]–[42]. An inductive coupling system has been the preferred method of power
10 transfer likely since data can also be transferred inductively.
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15 In the early 1830s, Michael Faraday first discovered the concept of
16 electromagnetic induction, the theory behind the wireless transfer of electrical energy.
17 Inductive power transfer works by passing an alternating current through an “external”
18 transmitter coil which generates an electromagnetic field which induces a voltage
19 within an “internal” receiver coil [57], [65]. The voltage can then be converted to direct
20 current through a voltage rectifier and then be used to power a circuit or charge an
21 inbuilt battery or storage capacitor for use at a later time. Factors that can affect
22 wireless inductive power efficiency include resonance/operating frequency, distance,
23 coil alignment, size and number of turns [65], [66]. Inductive power can satisfy the size
24 and energy requirements for an instrumented implant. Theoretically an inductive link
25 power system can be used for an infinite amount of time after surgery thus making
26 them an attractive option for a long term IMD. However, exposure to high levels of
27 electromagnetic fields can be dangerous for patients [64] and if the coils are not
28 properly aligned power transfer efficiency is significantly reduced [67]. Wearing the
29 transmitter coil system can be uncomfortable for patients, possibly limiting their ability
30 to complete activities of daily living and limits the acquisition of data over prolonged
31 periods of time [64], [68].
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45 A promising alternative technology is the use of energy harvesting to convert
46 the mechanical energy from joint motion into electrical energy for powering implants.
47 The concern is whether the joints low frequency movement (typically <1Hz whilst
48 walking) would be sufficient to generate the required power. Unlike conventional
49 sources of mechanical energy, movements can be infrequent and inconsistent and so
50 traditional power management and battery charging systems will be unsuitable. Silva
51 et al. [69] developed a hip prosthesis with three separate power generators including
52 a translation and rotation based electromagnetic generator and a piezoelectric
53 generator powered by a ceramic diaphragm located in the hollow femoral head, shown
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3 in Figure 11. Each generator had an individual power conditioning circuit that fed into
4 the main ultracapacitor energy reservoir, so the implant could function once the
5 generators begin to produce enough energy, or the energy can be stored. Once a
6 predetermined voltage had been reached within the ultracapacitor the energy stored
7 within was delivered to the IMDs telemetry circuit. Other attempts at developing energy
8 harvesting systems for a THR have similarly used a linear electromagnetic generator
9 [70] and piezoelectric transducers [71].
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Figure 11 – Hip prosthesis with three independent power generating systems [69]

3.4 Data transfer system

Wireless communication would be a necessity for the telemetry system of an implantable medical device, particularly in a deeply implanted orthopaedic implant. Wired communications were used in the first iterations of instrumented implants but are not a viable option as they would induce unnecessary pain or discomfort to the patient and pose an infection risk. A wireless connection would also better enable continuous data collection without causing inconvenience to patients. In which case

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3 designers will have to consider data transfer rate, range, permittivity through human
4 tissue and the additional size and power consumption constraints.
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7 The choice of the wireless communication system will depend on what data
8 needs to be transferred to or from the implant, and when. If the system's output only
9 involves small amounts of data (e.g. ID of the patient and implant or single
10 measurement of blood glucose or temperature) or if the frequency of measurement is
11 low (e.g. 1 sample per hour) this places lower demands on a real time data transfer
12 system. Similarly, if the collected data can be stored or processed locally (in the
13 implant), it can be uploaded at the convenience of the user, without requiring a
14 continuous telemetry system in place. One such low capacity yet versatile data
15 transfer method could be radio frequency identification (RFID), which is being seen in
16 warehouse inventory tracking, pet identification, contactless payments and tracking
17 marathon runner times.
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27 A RFID system consists of a transponder or tag, a reader or interrogator,
28 accompanying antennas to enable communication through radio frequency and
29 software that controls the system and manages the data [72]. The tags will have a chip
30 that stores the identification data or electronic product code (EPC). Tags can be active,
31 powered by a battery and favoured for their increased range, or passive, powered by
32 the reader's signal and favoured for their low cost (<10 cents) [73].
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38 RFID technology is used to track items and store low levels of data so, could
39 be used to identify medical devices once they have been implanted and include data
40 on the make and model of the implant, reasons for the intervention, the surgeon who
41 completed the procedure and details of the surgical approach. One such company
42 addressing this is Ortho-tag in collaboration with the University of Pittsburgh. Ortho-
43 tag was developed to provide a non-invasive, battery less and wireless method of
44 identifying an implanted orthopaedic device. The system consists of a RFID chip
45 embedded within an implantable tag and a 'touch probe' that uses transcutaneous
46 near field communication to power and communicate with the tag from outside the
47 body [74]. Orthotag claim their system is capable of storing information on an
48 implanted medical device, information which could include X-rays and patient medical
49 records [75].
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3 An enhancement to a RFID system, that could be beneficial in orthopaedic
4 devices, is passive or battery-less sensing capabilities, such systems are known as
5 computational RFIDs (CRFID) [73]. Sample et al. [76] achieved this with their wireless
6 identification and sensing platform (WISP) which could both receive power and
7 communicate data to a wireless RFID reader. They showed the efficacy of their WISP
8 by integrating sensors such as temperature, ambient light, rectified voltage, and
9 orientation. Other groups have looked at the possibility of using CRFID systems within
10 IMDs including pressure sensors for orthopaedic implants [77] and blood glucose
11 sensors for continuous blood glucose monitoring [78]. Ortho-tag suggest that their
12 system can feature sensors for the in-vivo measurement of pH and temperature to
13 indicate infection in the tissue surrounding an implant [75].
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23 However, past in-vivo sensing systems have been used to record real time load
24 and vibration data at frequencies $>1\text{Hz}$ which required data transfer systems with
25 higher data transfer rates. The predominant method used in the majority of past
26 instrumented hip implants has been inductive data transfer with [28], [40]–[42] all using
27 inductive coupling data transfer and Bergmann [28] having a combined power and
28 data coil. Nikola Tesla was the first to realise that electrical energy, and so data, could
29 be transmitted wirelessly between two inductively resonant coils [79]. Inductive power
30 transfer can reach a data transfer rate of up to 100 Mbps at a range of 6cm outside
31 the body [80]. However, as well as the aforementioned limitations of using inductive
32 coupling for power transfer, when being used for data transfer an inductively coupled
33 system is susceptible to interference from nearby electromagnetic fields [53], [80].
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43 These limitations lead many medical device companies to use, antenna based,
44 radio frequency (RF) transceivers for wireless communications between an IMD and
45 external unit. The IMD is equipped with an antenna that when fed with a signal radiates
46 electromagnetic waves through the body to an external receiver [81]. The radio
47 frequency spectrum ranges from 3KHz to 300GHz; between 30MHz and 400MHz is
48 the human body's resonance range where specific absorption rate is at its highest [82]
49 meaning that RF waves can penetrate the furthest into the body. Therefore, a
50 transceiver operating around this frequency range would be desirable for a deeply
51 implanted medical device.
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3 In 1999, the increased use of RF systems in IMDs lead the Federal
4 Communications Commission (FCC) standardising the Medical Implant
5 Communication Service (MICS), to the RF band 402 – 405 MHz. In 2009 the FCC
6 upgraded the MICS to the Medradio service which included two additional “wing
7 bands” thus extending the band to 401 – 406 MHz [80], [81], [83]. Global medical
8 device companies have manufactured their own remote monitoring systems using
9 MICS: Biotronik Home Monitoring® (FDA approval 2001), Medtronic Carelink®
10 Network (FDA approval 2005) and Merlin.net® Patient Care Network (FDA approval
11 2007) [84].

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Another option for wireless communication is Bluetooth or Bluetooth low energy (BLE). Bluetooth is a standard for wireless exchange of data operating at a radio frequency of 2.45GHz. At this frequency the radio waves will have a penetration depth of approx. <4cm in fat and <2cm in skin and muscle [85], [86] however, the higher frequency means that BLE has a far higher data transfer rate, up to 2Mbps [87].

To date Bluetooth has not been used in an instrumented hip implant but has seen use in other IMDs. The Confirm Rx ICM (Abbott, Ill, US) is the first Bluetooth enabled and smartphone compatible implantable cardiac monitor to have received FDA approval in Oct 2017 [88]. In July 2018 the world’s first pacemaker with Bluetooth technology (Azure Bluesync pacemaker, Medtronic, Db, Ireland) was implanted [89]. Bluetooth is widely used within consumer electronics with many personal devices being Bluetooth enabled. Based on the early adoption of Bluetooth enabled IMDs it is reasonable to assume that devices of a similar nature will become more widespread throughout the medical sector. However, for application within the hip joint the low penetration of 2.4GHz RF waves will make Bluetooth an unfeasible option. An alternate solution to this is a dual band radio repeater that can receive radio signals at one frequency and retransmit at another. Kiourti et al. [90] configured an on-body antenna to receive transmissions from an IMD in the MedRadio band 401 – 406 MHz and retransmit the received data to an external device in the ISM band, 2400 – 2480 MHz. This approach would also improve energy efficiency as transmitting low frequency waves is far more energy efficient therefore reducing the power consumption of the IMD’s telemetry system.

3.5 Regulatory considerations – Medical device approval

Europe and the US are the largest global markets for medical devices. To market their devices within these territories MDMs need to comply with the regulations laid out by the European Commission in their Medical Devices Regulation (MDR) to achieve a CE mark or be approved by the U.S. Food and Drug Administration (FDA), respectively.

An in-vivo sensing system for use within a THR will be a class III (implanted) medical device and so will require extensive pre-clinical and clinical testing to provide evidence of its efficacy and safety before it can be approved. The same will be required when following the FDA's pre-market approval (PMA) pathway for new medical devices when entering the US market.

If integration of the telemetry system has required modification of the implant, then new approval will be required for the implant. If a pre-existing implant has been used, then the FDA's 510(k) pathway would provide a shorter route to approval. Nevertheless, these additional regulatory hurdles will mean further costs, risks and inconvenience for the MDM. Whereas, if the sensing system is able to integrate with the implant without changing function or geometry then approval requirements may be more easily met. Furthermore, the safety of the in-vivo sensing system, and accompanying telemetry, should not be considered in isolation and interactions with the implant should also be considered. Attaching or embedding the sensing system could lead to corrosion, generation of wear particles and there is the risk that the system will move from the intended position or become separated from the implant. These implications should also be considered for the entire lifetime of the implant even if the telemetry system becomes inactive or stops working.

In a 2018 FDA public workshop [8] it was highlighted that care should be taken to go beyond physical characteristics associated with pre-clinical testing, such as biocompatibility, sterilisation, electrical and mechanical performance, and sensor accuracy and repeatability. For in-vivo sensing systems, regulatory considerations should also encompass validation of the metrics produced and the level of evidence required should be dependent on how the data will be used, for example if the sensor is delivering a treatment or providing a diagnosis of a potentially life-threatening

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3 condition. In either scenario the wrong result would cause harm to the patient or be
4 life threatening.
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10 3.6 Regulatory considerations - Cybersecurity

11 In 2017, the global WannaCry cyber-attack was estimated to have cost the NHS £92m,
12 £19m lost output and £73m in IT costs the majority being spent in the aftermath [91].
13 A study conducted by Clearswift revealed that in the UK, 67% of healthcare
14 organisations suffered a cybersecurity incident in 2019 [92]. The risk of cybersecurity
15 related incidents within healthcare are increasing as more medical devices have
16 wireless connectivity and are joining the internet of things.
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23 In the past there was concern over malicious cyberhackers gaining unlawful
24 access to a patient's implanted medical device (IMD) and causing harm to the patient.
25 In a 2013 interview, Former Vice President Dick Cheney revealed that in 2007 he had
26 the wireless connectivity of his pacemaker disabled to avoid the possibility of an
27 assassination attempt [93]. Halperin et al. [94] were the first research group to show
28 that an IMD could be infiltrated and patient data and safety put at risk. In 2011, amateur
29 hacker Barnaby Jack demonstrated live on stage, at the Hacker Halted conference in
30 Miami, how he could hack into an insulin pump and deliver a fatal dose to the user
31 [95], [96]. The following year Jack performed a similar live demonstration in which he
32 hacked into a pacemaker and commanded the device to deliver a deadly voltage surge
33 of 830V [96], [97]. Although theoretically possible it is highly unlikely that attacks like
34 these would ever occur. Dick Cheney's unique public figure status meant that he was
35 at a high risk and so every precaution was taken to guard him against possible attacks.
36 Additionally, hacking into a user's pacemaker would require the attacker holding
37 'suspicious' specialised electronic equipment close to the user for an extended period
38 of time therefore making it hard for the attack process to be scaled and in general
39 there are far easier, more effective and profitable ways to cause harm or steal a
40 person's data [98]. To-date there is no evidence of cases where a patient's IMD has
41 been hacked with malicious intent. Though there have been device recalls [99], [100]
42 and safety communications issued by the FDA [101]–[104] where cybersecurity
43 vulnerabilities were cited.
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3 Cardiac and drug delivery devices, such as pacemakers and insulin pumps,
4 carry higher levels of risk whereas, a non-active in-vivo sensing system will carry less
5 risk as it only provides diagnostic capabilities so cannot have a 'physical effect' on the
6 patient or user. However, if a smart implant capable of in-vivo sensing is realised, and
7 intended to be used clinically, it is likely that the device would include or even require
8 functionality to store data on the patient and their medical history. This data could be
9 a potential target for malicious cyber hackers as medical records are worth more than
10 a credit card number or bank details when sold on the dark web [105], [106]. Although
11 there will be an inherent risk of an IMD being hacked, this is not the only component
12 of cybersecurity that should concern MDMs and regulatory bodies instead, the majority
13 of medical device cybersecurity should be preventing accidental cyber harm and,
14 making sure the system is robust to the unknown and unexpected [107].
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25 In 2013, the FDA released a safety communication that warned MDMs,
26 hospitals and users that cybersecurity breaches could affect the proper function of an
27 IMD [108]. Building upon this the FDA issued the "Content of Premarket Submissions
28 for Management of Cybersecurity in Medical Devices" guidance document [109], and
29 updated in 2018 [110]. The guidance encourages MDMs to consider cybersecurity
30 measures during the entire lifecycle of the device and provides details on the
31 documentation required for the PMA submission with regards to cybersecurity.
32 Additionally, in 2019, the Medical Device Coordination Group (MDCG) released
33 "Guidance on Cybersecurity for medical devices" [111] which provides
34 recommendations to MDMs on how to satisfy the requirements laid out in the MDD
35 that relate to cybersecurity.
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5. Conclusion

The number of total hip replacements are increasing, complication and revision rates whilst low are still at undesirable levels. An in-vivo sensing system with telemetric capabilities would be beneficial as a means of gathering valuable data on the implant's function and the condition of the surrounding tissue. This data could be used to verify in-silico and in-vitro studies, inform improvements in implant design and surgical technique, and guide postoperative care. If real time condition monitoring is achieved along with intelligent recognition of adverse events and deviations from a patient's normal function, then such systems could provide advantages including remote patient monitoring, improved accessibility to healthcare and continuous as oppose to episodic and largely unnecessary assessment and early detect of problems.

Since the implantation of the first instrumented hip implant in the 1960s less than 100 patients have received an instrumented implant capable of in-vivo sensing. These implants have measured biomechanical metrics, including force and moments and temperature. The data gathered has helped progress understanding of how a THR functions in-vivo and so informed improvements in implant design and surgical technique. However, force, moments and temperature measurements are currently not sufficient to deduce early indications for revision surgery. However, they are important metrics and may still be required in a sensing system for use in a smart THR capable of condition monitoring and intelligent feature recognition. Other experimental work has looked at measuring levels of implant loosening presumably because loosening is the most common indication for revision surgery in THR and indeed other orthopaedic implants. This work has shown potential but until it can be shown that the diagnostic accuracy and reliability is matched to standard radiographic methods then, clinical translation will not be a possibility.

Widespread adoption of smart instrumented THRs and IMDs will not be realised until several key challenges have been overcome these include: what sensing method is used, biocompatibility and integration within the implant, power delivery, communication, and regulatory considerations. Additionally, product liability is also a limiting factor within the field of IMDs as MDMs will not want to take on the additional risks associated with developing and marketing such technology without measurable benefits either in improved outcomes or reduced costs but also to the wider healthcare system. Also, the expected lifetime of a THR is >15 years whereas the lifetime of

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3 common consumer electronics such as a smartphone is <5 years (whilst also receiving
4 regular software updates). This will need to be considered by MDMs when designing
5 the hardware and software of the IMD. Smart implantable medical devices, such as
6 pacemakers and insulin pumps, are becoming more accepted and widely used as
7 clinical interventions. Furthermore, advances in technology such as wireless power
8 and telemetry systems, suggests that the development and eventual adoption of an
9 instrumented hip implant, capable of real time condition monitoring, is imminent.
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16 The successful introduction of technology outlined in this review would not only
17 benefit the patient, but it would also enable clinicians to base decisions on more
18 objective quantitative data This would potentially obviate the need for follow-up clinics
19 for all patients thereby reducing hospital workload and hence costs which would
20 benefit the payer whether they are a government or an insurance company.
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