A piezoelectric energy harvesting concept for an energy-autonomous instrumented total hip replacement

Hans-E Lange¹, Dennis Hohlfeld², Rainer Bader¹ and Daniel Kluess¹

¹ Department of Orthopaedics, Rostock University Medical Center, Rostock, Germany
² Institute for Electronic Appliances and Circuits, University of Rostock, Rostock, Germany

E-mail: hans-eckhard.lange@med.uni-rostock.de

Received 16 April 2020, revised 22 August 2020
Accepted for publication 8 September 2020
Published 22 October 2020

Abstract
To improve the clinical outcome of total hip replacements (THRs), instrumented implants with sensory functions for implant monitoring and diagnostics or actuators for therapeutic measures are a promising approach. Therefore, an adequate energy source is needed. Batteries and external power supplies bring shortcomings e.g. limited lifetime or dependency on external equipment. Energy harvesting has the clear benefit of providing continuous and independent power for fully autonomous implants. Our present study evaluates by means of finite element analysis (FEA) the capabilities of a concept of a piezoelectric energy harvesting system (ring shaped multilayer piezoelectric element of 5 mm diameter and 2.5 mm height) integrated in a femoral hip stem. The deformations from a modified load-bearing implant are used to generate electric power for various instrumentation purposes. Besides the expected amount of converted energy, the influence on the stress distribution of the instrumented implant is analysed. The results show that the local stress increase for the modified implant geometry does not exceed the stress of the original reference model. The maximum generated open circuit voltage of 11.9 V can be processed in standard energy harvesting circuitry whereas an average power output amounts up to 8.1 µW. In order to increase the electric power in an upcoming design optimization, a sensitivity analysis is performed to identify the most important influencing parameters with regard to power output and implant safety.

Keywords: energy harvesting, piezoelectric element, instrumented implant, total hip replacement, finite element analysis

(Some figures may appear in colour only in the online journal)

1. Introduction
Osteoarthritis is considered one of the most common disabling diseases in the industrialized countries [1, 2]. For patients suffering from severe hip osteoarthritis, surgical intervention with implantation of a total hip replacement (THR) is the standard therapy if conservative treatments have been exhausted [3]. In the Organisation for Economic Co-operation and Development (OECD) countries with high-income, 166 hip replacement surgeries per 100 000 population where performed in 2015, with a continuous increase over the past 15 years [4]. This rise is projected to proceed for the next decades with regard to a growing and aging world population and increased use of arthroplasties in younger patients, revealing the pertinence of good clinical outcome for THR [5–7]. Albeit the predicted use of joint replacements in the future years illustrates the success of THR, primary joint replacement may fail,
requiring revision surgery. While THR shows an actual low revision burden, as reported in various national arthroplasty registries, the rising number and the longer service life of primary THR is expected to be accompanied by an increased absolute number of failed implantations [6–8]. The caused loss in quality of life, higher risk of complications in revision surgeries and also the economic burden highlight the persistent demand of improvements [9–12].

The development of instrumented implants with sensory and active functions, often called smart implants, is a promising approach to reduce current shortcomings. By passively monitoring implant-related parameters and actively taking therapeutic measures, the clinical outcome can be further improved. Early research on sensory functions in THR has already been reported in 1966, equipping the neck of a femoral endoprosthesis with strain gauges [13]. Moreover, implantable orthopaedic devices measuring pressures, displacements, temperatures, implant loosening etc have been investigated [14–24]. New research towards actuation include e.g. electrical or mechanical stimulation of bone tissue for improved regeneration and implant anchorage [25–28]. Nevertheless, smart implants have not become daily clinical practice [29]. The promising advances in wireless and microelectromechanical systems provide small, reliable and low-power sensors or actuators but a major drawback is still the realisation of an optimal energy source [30]. In early years, percutaneous wires have been used in instrumented implants for transmission of power and data [13, 23, 31]. The danger of infection is an evident disadvantage, which was reduced by telemetric data transfer powered by batteries [20, 21]. Due to the limited life time of batteries, the required space and the risk of leakage, energy transmission by electromagnetic fields was developed [14, 32–34]. The dependency on permanent equipment outside of the human body is still a disadvantage that limits the use to temporary experimental or clinical applications.

Energy harvesting is thought to bridge the remaining gap for providing continuous and independent power for energy-autonomous instrumented implants [30]. For orthopaedics, a special focus is on energy harvesting from mechanical energy, e.g. motion and deformation energy via electromagnetic or piezoelectric converters. Platt et al were the first reporting a piezoelectric energy harvesting concept within an orthopaedic implant [35]; A modified tibial tray (distal part of a total knee replacement) was equipped with three lead zirconate titanate (PZT) multilayer elements. Almouhied et al further improved the latter concept with regard to implant design and loading [36]. The first prototype was optimized and extended by circuits for power conditioning and telemetry [37]. Other research included different positioning of the piezoelectric elements: While Holmberg et al inserted a piezoelectric transducer in the stem of the tibial tray [38], Wilson et al first presented the idea of placing the piezoelectric elements to the polyethylene insert of a total knee replacement (TKR) [39, 40]. Safaei et al extensively investigated this concept to develop an autonomous, multifunctional TKR [41, 42]. Electromagnetic energy harvesters were presented by Luciano et al (magnets in the femoral condyle of a TKR, moving relatively to a coil in the polyethylene insert pin when the knee is bent) [43]. Morais et al developed a magnet-spring system with translational displacement surrounded by coils inside of a THR [44]. To the authors’ knowledge, this latter is the first energy harvesting concept for THR. An optimized and extended version was presented in 2012 with an additional rotation based electromagnetic harvester in the metal femoral head and the acetabular ultra-high molecular weight polyethylene (UHMW-PE) component and a piezoelectric membrane transducer inside the lower part of the femoral head that can freely deflect as a function of the joint loads [45, 46]. Nevertheless, for the last-mentioned work, no stress analysis or alike was conducted to proof the mechanical implant safety of the presented modified THR.

Therefore, our present study aims to investigate a piezoelectric energy harvesting concept for THR to power an autonomous instrumented implant by means of finite element analysis (FEA). Equally to the above mentioned research for TKR it utilizes the deformations of an implant to transfer forces to the end faces of a multilayer piezoelectric element, rather than excited vibrations of a piezoelectric membrane or cantilever beam. We want to emphasize that our study not only aims for the energy conversion aspects but also takes into account the mechanical safety of the implant by comparing the local stress maxima to those of the unmodified reference geometry.

2. Materials and methods

A reference finite element model of an arbitrary total hip stem (Exeter V40, size 37.5 mm N°3, Stryker, Howmedica Osteonics Corp, Mahwah, New Jersey, USA) implanted within a femur with physiologically based deformation behaviour was set up. This model served also as basis for the modified implant with an integrated piezoelectric energy harvesting system and the related model variations within the scope of a sensitivity analysis. For the sake of clarity, the baseline model is described first, followed by the description of the changes realised for the modifications.

2.1. Geometry and virtual implantation

The femur geometry emanates from previous reconstructions of a body donor’s CT data using AMIRA 5.4 (Thermo Fisher Scientific Inc., Waltham, Massachusetts, USA) and Geomagic Studio 2013 (3D Systems Corporation Rock Hill, South Carolina, USA) [47, 48]. With regard to the virtual implantation and loading, landmarks were defined (femur axis, neck axis, femoral head centre, epicondyles, femoral notch). According to Bergmann et al [49] a femur coordinate system was defined, additionally to the global coordinate system from the CT scan. The implant geometry was 3D-scanned and reconstructed with Geomagic Studio 2013 including the definition of the implant stem axis, the implant neck axis and the virtual centre of rotation pt. C of the femoral head, assuming the maximal allowed offset of 8 mm, which is prescribed by the manufacturer and results in the maximum lever arm of the acting hip contact force.
For the virtual implantation, the femoral head centre and the centre of rotation pt. C were superposed and the stem aligned with the femoral axis, see figure 1. The femoral neck was resected maintaining the whole greater trochanter. Around the implant, a bone cement mantle of 3 mm homogenous thickness was generated. The cavity for the implant was created by a Boolean operation. Two points of muscle insertion (pt. N and pt. C) were selected for the gait cycle. The femoral neck was fractured to align the axis towards the femoral notch. This was realised by rotating the nodal coordinate system of pt. C and distributed to the implant taper’s outer surface. A reduced set of muscles forces was applied on the femoral bone, according to the work of Heller et al [50, 51]. All the forces were transformed to the global coordinate system. For illustration of the points of loads, see figure 1(a).

For the integration of the piezoelectric energy harvesting system, a cavity was excised of the medial stem part. Within the cavity a UHMW-PE housing was placed, containing an off-the-shelf ring shaped PZT multilayer piezoelectric element (PICMA® actuator, provided by PI Ceramic GmbH, Lederhose, Germany, with an outer diameter 5 mm, inner diameter 2.5 mm, height 2.5 mm, capacity 110 nF), see figure 2. To restrict the force transfer from the housing to the piezoelectric element’s top and bottom end faces, a small gap was introduced by oversizing the diameter of the cylindrical cavity in the housing. The multilayer piezoelectric element consists of 43 active, and two additional passive top and bottom layers. The position and size of the energy harvesting system was based on the results for the reference model and a preceding iterative geometry study.

Figure 1. (a) Full reference model of femur with implant, cement mantle and schematic of loading and boundary conditions. Hip contact force $F_{\text{HCF}}$ acting in pt. C and reduced set of muscle forces acting in pt. 1 ($F_{m1}$ to $F_{m4}$) and pt. 2 ($F_{m5}$), constraining of pt. N and restriction of movement of pt. C along axis C-N by constraining two DOF. Suppression of model rotation around the axis C-N by constraining one DOF in pt. E. (b) Exemplary comparison of CT slice (left) and heterogeneous Young’s modulus distribution from 0 GPa to 20 GPa in the femoral bone (right).

Figure 2. Cross section view of the modified total hip stem within the proximal femur.

Table 1. Forces for walking at maximum joint contact and muscle forces in the global coordinate system, scaled for a 75 kg total hip patient, according [50–52].

| Force                     | Force components (N) | Pt. of load |
|---------------------------|----------------------|-------------|
| Hip contact $F_{\text{HCF}}$ | $-464.4$ $-273.6$ $-1663.8$ | pt. C       |
| Abductor ($F_{m1}$)       | 448.3 28.4 621.6     | pt. 1       |
| Tensor fascia prox. part ($F_{m2}$) | 60.7 85.4 92.5 | pt. 1       |
| Tensor fascia dist. part ($F_{m3}$) | $-8.5$ $-9.5$ $-139.4$ | pt. 1       |
| Vastus lateralis ($F_{m4}$) | $-21.5$ 114.1 $-687.2$ | pt. 2       |

2.2. Loads and boundary conditions

Using the finite element software ANSYS Workbench V18.2 (Ansys Inc. Canonsburg, Pennsylvania, USA), the reference model was loaded with forces for walking according to Heller et al [51], derived from in-vivo measurements reported by Bergmann et al [52]. The instance of maximum total hip contact force during the gait cycle was chosen and all values were scaled for an average weight patient of 75 kg, see table 1. The hip contact force $F_{\text{HCF}}$ was acting as a remote force in the center of rotation pt. C and distributed to the implant taper’s outer surface. A reduced set of muscles forces ($F_{m1}$-$F_{m4}$) was applied to the femoral bone, according to the work of Heller et al in pt. 1 and pt. 2 [50, 51]. All the forces were transformed to the global coordinate system. For illustration of the points of loads, see figure 1(a).

The system was constrained according to the physiologically based boundary conditions of Speirs et al [53] (figure 1(a)). One single node (pt. N) at the femoral notch was constrained in all three translational degrees of freedom (DOF). The centre of rotation pt. C was allowed only to move on an axis towards the femoral notch. This was realised by rotating the nodal coordinate system of pt. C and aligning the x-coordinate axis with the above described direction. Constraining all translational DOF but in direction of the x-coordinate axis allows for the specified movement. For a statically determinate system, one node in the distal epicondyly...
Figure 3. Schematic of the electrical design of a ring shaped multilayer piezoelectric element with n layers and the height h. The polarization direction of the single elements is indicated by arrows.

(pt. E) was equally rotated and constrained in the nodal y-direction to prevent rotation of the model around the above described axis. The shared surfaces of the bone and cement mantle were connected by a bonded contact, restraining relative movement. In contrast, between the implant outer surface and the cement mantle a frictional contact definition was chosen with a friction coefficient of $\mu = 0.35$ [54]. All additional contacts for the modified implant were chosen to be frictional ($\mu = 0.15$ [55] for the UHMW-PE housing towards the metallic implant, assumed value of $\mu = 0.3$ between piezoelectric material and housing, respectively housing and cement mantle).

The used multilayer element consisted of 43 layers of piezoelectric material with alternating polarization. The electric interconnection scheme was mimicked by two electrodes formed through coupling the potential degree of freedom on the layer surfaces to either ground potential (GND) or a common floating potential simulating an open circuit. Figure 3 shows the schematics of a piezoelectric energy harvesting system.

2.3. Meshing

The complex femur and implant geometries were meshed with tetrahedral elements (SOLID187). For the cement layer, the effort of a structured hexahedral mesh was accepted to account for a minimum mesh density of three elements over its narrow thickness (SOLID186). All elements were of quadratic order. For the piezoelectric energy harvesting system, the embedding geometry was also meshed with tetrahedrons (SOLID187), whereas the piezoelectric layers were meshed with hexahedrons to control the element number of the thin layer height (SOLID226 for the active piezoelectric element layers and respectively SOLID186 for the passive top and bottom layer).

Mesh independence studies have been conducted for the reference and the modified model. At first, the global model stiffness characteristics have been evaluated by means of the deformation behavior (displacement between center of rotation pt. C where the hip contact force is applied) and the global fix point at the femoral notch pt. N). Based on these results, a local mesh refinement has been performed within all regions of interest where results are reported from.

| Table 2. Material properties. |
|-------------------------------|
| Component | Young’s modulus E (GPa) | Poisson’s ratio |
|-----------|-------------------------|----------------|
| Metallic implant (Orthinox®) | 195 [62] | 0.3 |
| Bone cement | 2.3 [63] | 0.3 |
| UHMW-PE | 0.83 [64] | 0.46 [64] |
| PZT | 52.4 [65] | 0.35 [65] |
| Femoral bone | $6850^7 \rho_{app}^{\text{exp}}$ [59] | 0.3 |
| $\rho_{app}$ in g/cm$^3$ (E max.: 20 GPa) | 60, 61 |

| Table 3. Piezoelectric properties [65] ($\varepsilon_0=8.854 \times 10^{-12}$ As/(Vm)). |
|---------------------------------------------|
| Parameter (Unit) | Value |
| $\varepsilon_{33}^S/\varepsilon_0$ (-) | 936 |
| $\varepsilon_{33}^A/\varepsilon_0$ (-) | 759 |
| $\varepsilon_{33}/\varepsilon_0$ (-) | 1751 |
| $d_{33}$ (m/V) | $3.996 \times 10^{-10}$ |
| $e_{31}$ (N/Vm) | $-6.730$ |
| $e_{33}$ (N/Vm) | $15.680$ |
| $g_{15}$ (Vm/N) | $13.140$ |
| $g_{33}$ (Vm/N) | $0.02579$ |

2.4. Material properties

Every material behaviour was assumed linear-elastic. The mechanical material properties are listed in table 2. The heterogeneous stiffness distribution in the femoral bone was taken into account by application of material mapping on basis of the CT data (figure 1(b)). The CT scan of the bone was performed together with an bone density phantom to determine the ash density $\rho_{ash}$ [48]. The apparent density $\rho_{app}$ was calculated from the ash density $\rho_{ash}$ by $\rho_{app} = \rho_{ash}$ [56, 57]. For material mapping, the freeware Bonemat V3.2 was used [58], assuming the density–elasticity relationship of Morgan et al [59] with a maximum limited Young’s modulus of 20 GPa [60, 61]. By definition of a minimum gap of 50 MPa between two subsequent material cards for the bone compartment, the heterogeneous stiffness distribution was approximated by around 400 different Young’s modulus values.

The piezoelectric properties provided from the manufacturer are listed in table 3. These are in very good agreement with the according literature data from Berlincourt et al [66]. For the realization of the alternating polarization of the active layers (figure 3), the cylinder axis of the piezoelectric element was used to define the two opposite polarization directions.

2.5. Analysis settings and hardware

The numerical problem was solved with a sparse direct solver. The initial substep size was set to 10% of the total applied load for reasons of convergence. Non-linear behaviour was taken into account. The computation was accomplished on a high performance computing Linux cluster (each node equipped...
with an Intel® Xeon® CPU E5-2640 v3 processor (2.60 GHz) and 64 GB RAM).

2.6. Approximation of generated voltage and energy output

For plausibility check of the immediate simulation, the open circuit voltage $U_{OC}$ of the piezoelectric element was analytically approximated as a function of the simulated contact force $F_{33}$, acting on the element’s end faces in direction of its cylinder axis. With the voltage constant $g_{33}$ (see table 3), the total height $h$ of the active piezoelectric element, the number of layers $n$ and the base area $A$, $U_{OC}$ under static compression is given by:

$$U_{OC} = \frac{g_{33} F_{33} h}{n A} \quad (1)$$

To evaluate the energy output, the simulated contact force $F_{33}$ for the instance of maximum total hip contact force was used to approximate a full loading cycle of the piezoelectric element based on the work of Wilson [40] and Safaei [67, 68]. Therefore, the data from in-vivo measurements from Bergmann et al for normal walking for an average weight patient [52] was scaled so that the maximum equals $F_{33}$. The force profile is used as input to calculate the generated voltage $v(t)$ by solving the governing differential equation for a piezoelectric multilayer element (the piezoelectric properties are listed in table 3, for the derivation of the equation we refer to the work of Safaei [67, 68]):

$$\frac{n_{layer} c_{15} T A}{n_{layer}} \frac{dv(t)}{dt} + \frac{v(t)}{R} = n_{layer} d_{33} F_{33}(t) \quad (2)$$

The power output for one gait cycle of the duration $T$ can be calculated by:

$$P = \frac{1}{T} \int_0^T v^2(t) dt \quad (3)$$

The calculation of the generated voltage $v(t)$ and the power was done in MATLAB 8.4 R2014b (MathWorks Inc., Natick, Massachusetts, USA).

2.7. Sensitivity analysis

To evaluate the influence of input variations on the output parameters, a sensitivity analysis was performed with regard to the main uncertainties, considered to be the bone’s Young’s modulus ($\pm 10\%$), the acting forces ($\pm 10\%$) and the position of the center of rotation $pt. C$ along the neck axis ($\pm 0.5\, \text{mm}$). Furthermore, the influence of the energy harvesting system’s position to the embedding level was analysed ($\pm 0.5\, , \, -1.0\, , \, -10.0\, \text{mm}$) and the energy harvesting configuration itself, by altering the piezoelectric element, assuming a double stacked multilayer piezoelectric element and a different and stiffer polymer (polyether ether ketone (PEEK), Young’s modulus: 4 GPa, Poisson’s ratio: 0.36 [69]).

3. Results

3.1. Deformation and stress distribution of the reference model

The hip contact force is transmitted through the implant to the bone, shifting the proximal part of the model towards the distal end of the femur. The deflection of the centre of rotation $pt. C$ in the reference to the model’s fix point $pt. N$ amounts up to 1.58 mm. This movement forces bending of the stem in lateral direction with slight flexion towards anterior, see figure 4(a).

The bearing of the implant within the bone results in a comparable deformation of the metallic component, leading to a nearly load-free region that well coincides with the stem and neck axis (figures 4(b) and (c)). Towards the implant surface, the stress rises. The maximum von Mises stress of 290.9 MPa is found at the lower neck region at the margin to the taper.

In the lateral and upper neck regions tensile loads dominate, whereas the medial and lower neck regions are predominantly under compression. This is also reflected by the minimum principle stress distribution along a path at the medial implant surface (figure 5), showing high minimum principle stress (compression) in the neck region that decreases towards the embedding level of the stem, and is then followed by a renewed rise. This region is suitable for the integration of the energy harvesting system, since piezoelectric ceramics are strong in compression but prone to damage under tensile loads [70]. The maximum von Mises stress along the path in the region where the implant modification is introduced (see marked area in figure 5) amounts up to 108.5 MPa.

3.2. Results of modified implant geometry with energy harvesting system

The deflection of the centre of rotation $pt. C$ rises for the modified implant by 0.07 mm (4.4%) to 1.65 mm. The stress distribution in the implant globally equals the initial situation.
Figure 5. Minimum principal stress (compression) along path (from (1) to (2)) on the medial implant surface for the reference geometry. The embedding level and the area where the cavity is introduced, which contains the energy harvesting system, are marked.

At the cavity base a new local maximum of 269.4 MPa von Mises stress forms, which is 21.5 MPa lower than the global maximum for the unmodified reference geometry (figure 6(a)) and 160.9 MPa higher compared to the maximum von Mises stress in the according region along the path on the medial implant side (more than double).

The von Mises stress distribution within the piezoelectric element shows a strong influence of the contact situation at the top and bottom end faces (figure 6(b)). The local effects fade after few elements towards the midplane. As representative value for the unaffected volume, the maximum von Mises stress in the undisturbed midplane cross section is given with 14.1 MPa. The contact forces acting on the piezoelectric element’s end faces in direction of the element’s axis amount up to 141.6 N.

The directly simulated open circuit voltage \( U_{OC} \) is 11.9 V. The distribution of the electrical potential in the layers of the piezoelectric element is shown in figure 6(c). It reflects the applied electrical boundary conditions and opposed polarization directions. Comparing to the analytically approximated value of 12.4 V, using the simulated contact forces and equation (1), the difference is only 4.2%.

The scaled load profile for the simulated force \( F_{33} \), acting on the piezoelectric element’s end face, is shown in figure 7(a). The according generated voltage for the load resistor resulting in the maximum power output is pictured in figure 7(b).

Figure 8 displays the power output as a function of the load resistor. Peak power output is 8.10 \( \mu \)W for 1027 kΩ.

3.3. Results of the sensitivity analysis

The main results of the sensitivity analysis are shown in figure 9. The influence of the bone’s Young’s modulus, considered as major uncertainty in the model, is relatively low (<2%) for all parameters regarding the energy harvesting system. Only the deflection of the centre of rotation \( pt. \ C \) is notably altered (±0.15 mm, not shown in figure 9). The sensitivity of the model to small changes of the energy harvesting system’s position to the embedding level of around ±0.5 to −1.0 mm is equally low (<2.5%). All other changes have stronger influence on various parameters. Regarding the von Mises stress concentration at the cavity base, a strong increase of over 20% is related to a 10 mm distally displaced energy harvesting system to an amount of 328.8 MPa. This value exceeds the maximum stress in the reference model by 37.9 MPa. Further important influence is exerted by the forces in a comparable effect as their scaling factor. At the high force level, the von Mises stress maximum is 6.1 MPa higher compared to the
Figure 9. Results of the sensitivity analysis with absolute values (blue) and percentage deviation (red) relative to the original value of the reference model, note that for convenience the moduli of the percentages are shown. The reference values are pictured as dashed line. (a) von Mises stress maximum at the implant’s cavity base (MPa), (b) von Mises stress maximum in piezoelectric element (undisturbed plane, MPa), (c) contact force $F_{33}$ acting on the piezoelectric element (N) and (d) peak power output for an ideal load resistor ($\mu W$). Model configurations described according to the changed parameters: Young’s modulus bone—‘E bone’, Force values—‘Forces’, Displacement of the energy harvesting system (EHS) towards or away from the embedding level—‘Position EHS’, Displacement of the centre of rotation along the neck axis—‘Position pt. C’, double stacked piezoelectric element—‘piezo stack’ and stiffer polymer for housing assuming PEEK—‘E housing PEEK’.

unmodified geometry. All further stress maximums are below the reference value. Increase of the distance of the centre of rotation $pt. C$ to the taper frontal surface slightly increases the loading of the cavity (1.7%) and vice versa. A stiffer housing material considerably reduces the stress ($-6.7\%$).

The von Mises stress in the piezoelectric element is sensitive to almost the same parameters as the cavity base is, albeit in different manifestation. The stiffer housing nearly doubles the stress up to 27.6 MPa, followed by the piezoelectric stack configuration with a 21% increase. For both models, the maximum stress in the representative volume switches from the inner to the outer cylinder face of the piezoelectric element. The influences of forces and the position of the centre of rotation $pt. C$ are comparable to the values for the cavity base, whereas the 10 mm more distal position of the energy harvesting system decreases the stress by 9.5%.

The contact forces on the piezoelectric element’s end faces are sensitive to the same parameters as the von Mises stress in the piezoelectric element. Small but not negligible is the influence of the position of the centre of rotation $pt. C$ and the 10 mm displaced position of the energy harvesting system, whereby the latter reduces the contact forces. Of higher importance are the scaled forces that increase $F_{33}$ by 10.2% when rising. A piezoelectric stack leads to an increase of +38.7% compared to the single multilayer piezoelectric element and the stiffer housing more than doubles the reference value up to 289.0 N.

The generated power for an ideal load resistor has the maximum percentage deviation in this study and is therefore most sensitive. A stiffer housing, resulting in higher contact forces and thereby generating more voltage leads to a power increase of 316.4% to up to $33.7 \mu W$. For a piezoelectric stack, the harvested power is still more than 2.75 times higher (31.1 $\mu W$). For all other parameters, the sensitivity is nearly double compared to that of the contact forces $F_{33}$. With 10% higher forces, the harvested power can be increased by around 20% and vice versa. Shifting the energy harvesting system 1 mm distally increases the harvested power by 1.8% whereas a shift of 10 mm results in a decrease of 14.3%. The position of the centre of rotation $pt. C$ has an influence of around 3% when shifting by 0.5 mm.
4. Discussion

The reference model of the femur with implanted total hip stem shows typical deformation characteristics, as also reported by Speirs et al. [53] which is consistent with the applied boundary conditions that force the body of the femur to slightly bend laterally. The displacement of the centre of rotation pt. C is in a realistic physiological range [53, 71, 72]. Small deviations can be explained by different bone geometry and different material models. The increase of the femoral head’s displacement for the modified implant is due to the reduced structural stiffness by the introduced cavity. Filled with polymer with a lower Young’s modulus, the cavity deforms which results in higher displacement of the centre of rotation pt. C.

The loading of the implant can be explained by comparing with the stress distribution in a simple beam. While on the lateral and upper neck side tensile stress dominates and the medial and lower neck part is in compression, in between a neutral axis must develop. The medial implant stem region below the embedding level is ideal for the integration of the piezoelectric energy harvesting system: The piezoelectric ceramic material can only withstand large compressive loads and, compared to the neck region, the implant cross section here is large enough to introduce the needed cavity. With regard to further electronics for power management, sensors etc. the relatively unloaded regions along the stem and neck axis are favourable locations for safe placement of additional components that need to be considered in further research.

The maximum von Mises stress in the reference model concentrates in the lower neck. This region is more critical than the area just above the embedding level, due to the decreased cross section. The small and decreasing profile distal to the embedding level is less affected, being supported by the surrounding material. The maximum value served as a reference limit in the iterative geometry study for the energy harvesting system placement. The challenging requirement is to align the implant safety with creating enough space for the piezoelectric element, being aware that the introduced cavity acts as notch and highly reduces the remaining cross sectional area. The here presented design fulfills this criterion with a small safety margin of 20 MPa. Hence, the integration of the energy harvesting system was possible while preserving the implants maximum stress level. Compared to data from literature, the acting maximum stress is 200 MPa below the fatigue limit of the used high nitrogen stainless steel (Orthinox®) which is in the range of 470 MPa (maximum stress at 10^7 cycles, 10 Hz, R = 0.1, in Eagle’s medium at 37 °C) [73]. Such comparisons must be handled with caution because other parameters e.g. manufacturing, heat treatment, surface roughness, notching effects, component size etc. have strong influence on the fatigue safety. The use of the reference value in the same model as well as literature data are reasonable starting points for this study. In further evaluations we will experimentally and numerically evaluate the mechanical implant safety considering a worst case scenario of proximal loosening as ISO 7206-4 specifies, which all THRs have to withstand [74, 75].

Regarding the fatigue properties of the piezoelectric element, to the authors’ knowledge, no data on comparable PZT multilayer element structure under equal cyclic mechanical loading for the sake of energy harvesting has been reported. The manufacture of the used elements specifies a maximum of 30 MPa preload for constant force [76]. Fatigue data with 20 MPa preload of PZT multilayer stack actuators are available [77]. Therefore, the maximum von Mises stress in the representative cross section of the piezoelectric element of 14.1 MPa is considered uncritical. This is strengthened regarding the specified blocking forces for the piezoelectric element > 400 N [76] in relation to the acting forces of only 141.6 N. In this design, the polymer housing is also aimed as an environmental sealing that can be increased by further encapsulation techniques. As this study focuses on the feasibility of energy harvesting system integration into a THR issues concerning stability and biocompatibility of the piezoelectric element will be addressed in future studies.

The simulated open circuit voltage $U_{OC}$ is in very good agreement with the analytical approximation on basis of the contact forces, confirming the results of the simulation. The voltage level is processible by standard circuitry, for example the power harvesting IC LTC3588-1 (Linear Technology, Milpitas, California, USA) which is optimized for piezoelectric power harvesting applications, with a maximum input voltage of 20 V [78]. This also favours the use of multilayer elements, taking into account that the generated voltage level for a single-layer (monolithic) element would be higher than 500 V, using equation (1). However, with regard to a maximum of harvested energy, advantage of the full possible voltage level should be taken when optimising the current design.

The calculated power output in this study is in the lower range of other reported energy harvesting concepts for orthopaedic implants. Recent research by Safaei et al. has documented average power output while walking of 5.5 µW to 12 µW for single or multiple piezoelectric multilayer stacks integrated in a tibial insert of a total knee replacement [41, 68, 79]. This energy serves a self-powered implant to detect acting forces and centre of pressure tracking [68]. In the latest work, the amount of harvested power was increased to 269.1 µW for four piezoelectric elements (67 µW for a single-piece piezoelectric element) [42]. Due to the size of the tibial insert and in contrast to our work, multiple piezoelectric elements and elements of larger cross-sectional areas could be integrated in the implant. Nevertheless, caution in design development and monitoring is demanded, seen cases of high tibial insert wear and the resulting danger of piezoelectric element baring and damage [80].

The high impact of available space on the amount of harvested power is also apparent in the earliest work on energy harvesting in total knee replacements by Platt et al. [35, 81]. Using piezoelectric elements of up to 20 mm height, 4.8 mW raw power and 840 µW regulated power could be generated. Almouahed et al. improved this latter concept and reduced the tibial tray’s height to a regular thickness, using smaller and more piezoelectric elements [82]. A further, electromagnetic approach was able to produce 92 µW [43]. To the authors’ knowledge, only one group worked on energy harvesting for
TMRs. A multi-source approach combined two electromagnetic generators (translation and rotation movement-based) and a piezoelectric membrane with experimentally measured output of 53.7 μW, 0.77 μW, and 0.7 μW, respectively [45]. In further studies, power of more than 1 mW was experimentally generated by the translation movement-based electromagnetic generator [44, 83]. Issues and solutions concerning permanent magnets in magnetic resonance imaging (artefacts and damage of implant or risk for patient by torque) were not addressed, but kept us from conducting research in that direction.

To evaluate the amount of harvested energy, the relevant power requirements need to be defined. For passive low power applications, e.g. monitoring forces, it was shown that 45 or 92 μW may be sufficient for an intermittent sensing and data transmission circuitry [43, 84]. Of importance is in any case the working cycle that divides in time for energy harvesting, data acquisition and transmission. With regard to active therapeutic measures, e.g. electric stimulation of bone tissue, a continuous operation is not required and harvested energy can be accumulated over the day and delivered during defined periods [27, 85]. The energy output of the here presented conceptual design needs to be increased for application in a completely autonomous instrumented implant. Nevertheless, the feasibility of energy harvesting is shown and the below discussed results of the sensitivity analysis provide promising potential for optimisation without decreasing the mechanical safety. It should be noted that the power approximation in this study is based on a static FEA of the instance of maximum total hip contact force, which is appropriate for first evaluations. To overcome this limitation, further investigation should consider transient FEA to extract the full loading profile on the piezoelectric element for the gait cycle. Before moving to design optimisation, we have to experimentally confirm the full energy harvesting system capabilities. Therefore, a simplified testing set-up is required that allows the reproduction of the implantation in a femur. With such a set-up, we will be able to not only analyse sinusoidal forces but also more complex loadings from in-vivo measurements, resembling the physiological loading situation. Also, an exemplary circuitry for energy conditioning will be considered to evaluate the overall efficiency of power conversion.

The model discussed so far was the basis for the sensitivity analysis, which will be the starting point for upcoming design optimisations. For example, a large influence of the bone’s Young’s modulus distribution (by different material laws or patient individuality) was expected, in view of corresponding studies [86]. Nevertheless, changes only affected the total femoral deformation but had no relevant effect regarding any of the energy harvesting system related output parameters. This applies also to the small changes in the energy harvesting system’s position. Both results militate in favour of a design that works appropriately also for slight changes in the bony surrounding or in the implant positioning.

The displacement of the centre of rotation pt. C is for every configuration in the physiological range, even at the highest force level. Along with the high sensitivity of all other output parameters to the forces, the necessity of exact defined loading patterns for design optimisation is demonstrated. This includes knowledge of the body weight and daily routine activity. Additionally, the potential for power output increases when considering apart from walking also more dynamic activities with higher peak forces [87]. The minor influence of the position of the centre of rotation pt. C is based on the small variations that cover uncertainties in the model set-up. For larger differences of several millimetres (when evaluating different implant sizes or head offsets) the influence will be several percent—alike for the forces, since the distance from the taper to pt. C defines their lever arm.

With regard to the mechanical implant safety no configuration exceeds the referenced fatigue level [73]. The highest stress value occurs for positioning the energy harvesting system 10 mm more distally. This has to be considered as major design change instead of a variation. It shows no advantages, highly increasing the stress level in the implant while not having positive effects on the power output. The stress raise here is due to the reduced cross section of the stem. This result supports the placement of the energy harvesting system directly below the embedding level, where a larger cross section exists. Nevertheless, experimental fatigue testing of the finally chosen configuration is important. A positive result may provide further possibilities in geometric adaptations of the cavity geometry and piezoelectric element size.

Evaluation of the fatigue safety of the piezoelectric element is difficult due to few publications on fatigue date for comparable systems. While the referenced stress level is exceeded for the piezoelectric stack configuration [77], the contact forces are still considerably lower than the specified blocking forces [76]. More reliable fatigue data from the manufacturers is therefore desirable, experimental fatigue testing of the full system can also provide crucial insights.

The contact forces on the piezoelectric element act for all configurations almost only in the direction of the piezoelectric element’s cylindrical axis and generate thereby a maximum possible voltage. Since the generated power increases with the applied contact forces, maximising the contact forces as high as endurable should be the goal of a design optimisation. It is advantageous that configurations that increase the force transfer on the piezoelectric element by a stiffer housing material or a stiffer energy harvesting system by a larger piezoelectric element will also reduce the stress in the cavity base by thus supporting the overall structure.

A combination of these aspects, a stiffer housing or a stiffer energy harvesting system (by additional components like end pieces) together with a larger or higher piezoelectric element may increase the harvested energy by an order of magnitude compared to the basic model. Since a larger force transfer increases the load of the piezoelectric element, the resulting higher stress level has to be checked against fatigue data to ensure safety. Additionally, the use of customised piezoelectric elements has a high potential. For this dimensions, unfortunately no off-the-shelf piezoelectric multilayer elements with circular cross-section where available, which would provide higher capacitance than a ring shape. Moreover, completely free shapes could perfectly match the available space in the cavity, combining higher cross-sectional areas and more layers.
At this point we want to mention the importance of the mediating function of the housing material which is crucial for the design concept and all optimizations. By decoupling the metallic implant component and the piezoelectric element, the design space is broadened and allows flexibility in choice of geometric parameters while retaining a cavity radius large enough to reduce notching effects.

5. Conclusion

This work aims to provide an innovative energy source to power instrumented THRs that can improve the clinical outcome by passive or active measures. To overcome the insufficiencies of batteries or external energy sources the piezoelectric energy harvesting system concept, integrated into a hip stem, was evaluated by means of FEA in a physiologically based loading situation. A modified design feasible for the integration of a multilayer piezoelectric element was presented, preserving the implant’s maximum stress level (compared to the unmodified reference situation). The simulated output voltage is processible in energy harvesting circuitry. As a first application, the generated voltage data can be related to the daily life loading history, thereby functioning as self-powered sensor. The approximated power output for a sinusoidal loading amounts up to 8.1 μW. This is in the lower range of referenced research and needs to be increased. Within a sensitivity analysis configurations with power output of more than 30 μW were found and important influencing factors could be determined that will be used for design optimization in further work with regard to mechanical implant safety and power output. In the next steps we will experimentally confirm the fatigue safety of the modified total hip stem and the energy conversion properties of the developed system.

Acknowledgments

The authors would like to thank Ehsan Soodmand and Maeruan Kebbach for providing the CT-, calibration and geometry data of the femoral bone. Further thanks to Fraunhofer-Institut für Produktions-technik und Automatisierung IPA Rostock for the support with 3D-scan of the implant.

This research is funded by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) - SFB 1270/1–299150580.

ORCID ID

Hans-E Lange https://orcid.org/0000-0003-4926-769X

References

[1] Murray C J L (ed) 1996 the Global Burden of Disease (Global Burden of Disease and Injury Series Vol 1) (Cambridge: Harvard School of Public Health)
[2] Cross M et al 2014 Ann. Rheum. Dis. 73 1323–30
[3] Lespasio M J, Sultan A A, Piazzi N S, Khlopas A, Husni M E, Muschler G F and Mont M A 2018 Perm. J. 22 17–84
[4] OECD 2017 Hip and Knee replacement Health at a Glance 2017: OECD Indicators, ed OECD (Paris: OECD Publishing)
[5] Kurtz S, Ong K, Lau E, Mowat F and Halpern M 2007 J. Bone Joint Surg. Am. 89 780–5
[6] Pabinger C, Lothaller H, Portner N and Geissler A 2018 Hip Int. 28 498–506
[7] Pabinger C and Geissler A 2014 Osteoarthr. Cartil. 22 734–41
[8] Kurtz S M, Ong K L, Lau E and Bozic K J 2014 J. Bone Joint Surg. Am. 96 624–30
[9] Patil S, Garbuz D S, Greidanus N V, Masri B A and Duncan C P 2008 J. Arthroplasty 23 550–3
[10] Ong K L, Lau E, Suggs J, Kurtz S M and Manley M T 2010 Clin. Orthop. Relat. Res. 468 3070–6
[11] Bitton R 2009 Am. J. Manag. Care 15 230–5
[12] Ong K L, Mowat F S, Chan N, Lau E, Halpern M T and Kurtz S M 2006 Clin. Orthop. Relat. Res. 446 22–28
[13] Rydell N W 1966 Acta Orthop. Scand. 37 1–132
[14] Bergmann G, Graichen F, Sirakaj J, Jendrzynski H and Rohlmann A 1988 J. Biomech. 21 169–76
[15] Graichen F, Bergmann G and Rohlmann A 1999 J. Biomech. 32 1113–7
[16] Westerhoff P, Graichen F, Bender A, Rohlmann A and Bergmann G 2009 Med. Eng. Phys. 31 207–13
[17] Marschner U, Gratz H, Jettkaan B, Ruwisch D, Wold G, Fischer W-J and Claussmuller B 2009 Sensors Actuators A 156 145–54
[18] Heinlein B, Graichen F, Bender A, Rohlmann A and Bergmann G 2007 J. Bone Joint Surg. Am. 89 40–10
[19] D’Lima D D, Townsend C P, Armas S W, Morris B A and Colwell C W 2005 J. Biomech. 38 299–304
[20] Brown R H, Burstein A H and Franklin V H 1982 J. Biomech. 15 815–23
[21] Davy D T, Kotzar G M, Brown R H, Heiple K G, Goldberg V M, Berilla J and Burstein A H 1988 J. Bone Joint Surg. Am. 70 45–50
[22] Hodge W A, Carlson K L, Fijan R S, Burgess R G, Riley P O, Harris W H and Mann R W 1989 J. Bone Joint Surg. 71 1378–86
[23] Waugh T R 1966 Acta Orthop. Scand. 93 1–87
[24] Rohlmann A, Graichen F, Bender A, Kayser R and Bergmann G 2008 Clinical Biomech. (Bristol, Avon) 23 147–58
[25] Schmidt C, Zimmermann U and van Rienen U 2015 IEEE J. Biomed. Health Inform. 19 1321–30
[26] Raben H, Kammerer P W, Bader R and van Rienen U 2019 Appl. Sci. 9 2160
[27] Soares Dos Santos M P, Marote A, Santos T, Torrão J, Ramos A, Simões J A O, da Cruz E Silva O A B, Furlani E P, Vieira S I and Ferreira J A F 2016 Sensors Actuators A 213 19–28
[28] Reis J, Frias C, Canto E Castro C, Botelho M L, Marques A T, Simões J A O, Capela E Silva F and Potes J 2012 J. Biomed. Biotechnol. 2012 613403
[29] Ledet E H, Liddell B, Kradinova K and Harper S 2018 Innov. Entrepreneurship Health 5 41–51
[30] Sodano H A, Inman D J and Park G 2004 Shock Vib. Dig. 36 197–205
[31] Roberts V L 1966 Exp. Mech. 6 19A–22A
[32] Mittelmeier W, Lehner S, Kraus W, Matter H P, Gerdesmeyer L and Steinhauser E 2004 Arch. Orthop. Trauma Surg. 124 86–91
[33] Bergmann G (ed) 1990 Implantable Telemetry in Orthopaedics: Proceedings and Additional Papers of a Workshop, April 26–28,1990, Berlin (Berlin: Freie Universität Berlin)
[34] Carlson C E, Mann R W and Harris W H 1974 IEEE Trans. Biomed. Eng. 21 257–64
[35] Platt S R, Farritor S, Garvin K and Haider H 2005 \textit{IEEE/ASME Trans. Mechatronics} \textbf{10} 455–61

[36] Almouahed S, Gourou M, Hamitouche C, Stindel E and Roux C 2010 \textit{Ann. Int. Conf. IEEE Eng. Med. Biol. Soc.} \textbf{2010} 5121–4

[37] Almouahed S, Hamitouche C, Poignet P and Stindel E 2017 \textit{2017 IEEE: Healthcare Innovations and Point-of-Care Technologies (HI-POCT)} (Bethesda, MD, USA, 06. 11.2017-08.11.2017)

[38] Holmberg J, Alexander L, Rajaraman R and Bechtold J E 2013 \textit{J. Med. Device} \textbf{7} 11006

[39] Wilson B E, Anton S R and Meneghini R M 2014 \textit{ASME 2014 Conference on Smart Materials, Adaptive Structures and Intelligent Systems} (New York, NY, ASME) pp V002T02A018

[40] Wilson B E 2015 \textit{Master’s Thesis} Faculty of the College of Graduate Studies, Tennessee Technological University

[41] Safaei M, Meneghini R M and Anton S R 2017 \textit{Smart Mater. Struct.} \textbf{26} 94002

[42] Safaei M, Meneghini R M and Anton S R 2018 \textit{Smart Mater. Struct.} \textbf{27} 114007

[43] Luciano V, Sardini F, Serpelloni M and Baronio G 2014 \textit{Meas. Sci. Technol.} \textbf{25} 25702

[44] Morais R, Silva N, Santos P, Frias C, Ferreira J, Ramos A, Simões J, Baptista J and Reis M 2010 \textit{Procedia Eng.} \textbf{5} 766–9

[45] Santos M et al 2012 \textit{International Conference on Biomedical Electronics and Devices} (S.L.: SciTePress) pp 71–81

[46] Silva N, Santos P, Ferreira J, Santos M, Reis M and Morais R 2012 \textit{Procedia Eng.} \textbf{47} 722–5

[47] Soodmand E, Kluess D, Varady P A, Alt V, Haarman H J T M, Seidel H and Kempf I 2006 \textit{Practice of Intramedullary Locked Nails} (Berlin: Springer)

[48] Saha S and Pal S 1984 \textit{J. Biomed. Mater. Res.} \textbf{18} 435–62

[49] Kurtz S M 2009 \textit{UHMWPE Biomaterials Handbook} 2nd edn (New York: Academic)

[50] P I Ceramic GmbH 2017 \textit{Material Coefficients PIC255: v4.3}

[51] Berlincourt D A O N, Curran D R and Jaffe H 1964 \textit{Piezoelectric and piezomagnetic materials and their function in transducers Physical Acoustics: Principles and Methods}, ed W Mason (New York: Academic) pp 169–270

[52] Safaei M 2019 \textit{Dissertation} Faculty of the College of Graduate Studies, Tennessee Technological University

[53] Safaei M and Anton S R 2017 \textit{ASME 2017 Conf. on Smart Materials, Adaptive Structures and Intelligent Systems} (ASME) V001T07A011

[54] Kurtz S M and Devine J N 2007 Biomaterials \textbf{28} 4845–69

[55] Rupitsch S J 2019 \textit{Piezoelectric Sensors and Actuators: Fundamentals and Applications} (Topics in Mining, Metallurgy and Materials Engineering) (Berlin: Springer)

[56] Polgár K, Gill H S, Viceconti M, Murray D W and O’Connor J J 2003 \textit{Proc. Inst. Mech. Eng. H} \textbf{217} 173–89

[57] Taylor M E, Tanner K E, Freeman M A R and Yettram A L 2007 \textit{Piezoelectric and piezomagnetic materials and their function in transducers Physical Acoustics: Principles and Methods}, ed W Mason (New York: Academic) pp 169–270

[58] Taylor M E, Kusuma K, Liu K H, Sader M, Mittelmeier W and Bader R 2018 \textit{Mater. Test.} \textbf{60} 489–94

[59] PI Ceramic GmbH 2019 \textit{Data sheet Round PICMA® Chip Actuators: miniature Multilayer Piezo Actuators with and without Inner Hole}

[60] Wang H, Cooper T A, Lin H-T and Wereszczańczak A A 2010 \textit{J. Phys. D: Appl. Phys.} \textbf{108} 84107

[61] Linear Technology LTC3588-1: nanopower Energy Harvesting Power Supply Data Sheet (Linear Technology)

[62] Safaei M, Meneghini R M and Anton S R 2018 \textit{IEEE/ASME Trans. Mechatronics} \textbf{23} 864–74

[63] Massin P 2017 \textit{Orthop. Traumatol. Surg. Res.} \textbf{103} 21–27

[64] Platt S R, Farritor S and Haider H 2005 \textit{IEEE/ASME Trans. Mechatronics} \textbf{10} 240–52

[65] Almouahed S, Hamitouche C and Stindel E 2017 \textit{IRBM} \textbf{38} 250–5

[66] Morais R, Silva N M, Santos P M, Frias C M, Ferreira J A F, Ramos A M, Simões J A O, Baptista J M R and Reis M C 2011 \textit{Sensors Actuators A} \textbf{172} 259–68

[67] Chen H, Liu M, Hao W, Chen Y, Jia C, Zhang C and Wang Z 2009 \textit{IEEE Trans. Biomed. Circuits Syst.} \textbf{3} 437–43

[68] Dauben T J, Ziebart J, Brender T, Zaatreh S, Kreikemeyer B and Bader R 2016 \textit{Biomed. Res. Int.} \textbf{2016} 5178640

[69] Schileo E, Taddei F, Malandrino A, Cristofolini L and Viceconti M 2007 \textit{J. Biomech.} \textbf{40} 2982–9

[70] Bergmann G, Bender A, Dymke J, Duda G and Damm P 2016 \textit{PloS One} \textbf{11} e0155612