On the Optimization of the Hip Stem for an Electrostimulative Hip Revision System

***Ulf Zimmermann*[*1], *and Ursula van Rienen*[2]**

[1]Institute of General Electrical Engineering, University of Rostock, Albert-Einstein-Str. 2, 18059 Rostock, Germany.
Tel.: +49 381 4987078, Fax: +49 381 4987081, Email: ulf.zimmermann@uni-rostock.de

[2]Institute of General Electrical Engineering, University of Rostock, Email: ursula.van-rienen@uni-rostock.de

Abstract

Since the 1980s electrostimulative systems are used to improve bone regeneration. This concept is now being implemented in a total hip revision system to accelerate bone regeneration after surgery. In prior works, an electrostimulative acetabular cup has been introduced and optimized. Nevertheless, the stimulation- and thus the optimization concept for the acetabular cup cannot be applied to the femoral part in the thigh bone. Therefore, this paper presents a computational model of the electrostimulative hip stem as well as an approach to optimize the field distribution in close proximity to the femoral bone.

3.Introduction

In the United States the number of total hip arthroplasty (THA) revisions doubled between 1990 and 2002 [1]. Between 2005 and 2030 the caseload of THA revisions is expected to grow by 137 % [2]. Most of these surgeries are necessary because of the loss of bone material which is no longer able to provide a mechanically stable support for the primary implant [3]. For this reason, revision implants are often larger and more complicated than a primary implant. Nevertheless, 27.4 % of these implants have to be revised again within 15 years which leads to an even more defective bone than there has been before the first revision.

In 1974 Bassett characterized the accelerating effect of electromagnetic fields on the development of osseous cells and bone tissue [4]. Since then several stimulation methods have been developed, which use high- and low-frequency electromagnetic fields to enhance the regeneration of damaged and fractured bones [5, 6]. In cellular experiments, low-frequency approaches have been proven to provide an increased collagen synthesis [7]. For this reason a low-frequency electrostimulative hip revision system has been developed in a joint project with the orthopaedic clinic at the University Medicine of Rostock. The main goal is to provide an enhanced bone growth at the interface to the implant leading to improved mechanical stability and durability.

In previous publications the acetabular part of the hip revision system has been introduced for the pelvic bone [8, 9]. Here a limited number of stimulation electrodes is attached to the acetabular cup to generate an electric field at the interface between bone and implant. These electrodes include a small coil, so that the energy can be transferred inductively at a frequency of 20 Hz. The main goal for the optimization of the acetabular part is to generate an electrode arrangement that provides sufficient stimulation for a specific damage category with six or less electrodes being hooked up just before surgery.

In contrast, since the hip stem is inserted into the thigh bone in a press-fit fixation, a different type of electrode had to be designed which is included into the implant during its manufacturing. Therefore, the conventional hip stem, which is also called femoral implant, is modified by milling a notch into both planar sides (see Fig. 1a). Using biocompatible materials this notch is filled with an insulator and a wire, which serves as stimulation electrode. According to the method of Kraus an electric field between 5 and 70 V/m has to be achieved [10]. Since the implant is made of a conducting material, the electric field rapidly decreases with increasing distance to the stimulation electrode. For this reason the dimensions of insulator and electrode as well as the corresponding stimulation potential have to be optimized to achieve sufficient field strengths at the interface between bone and implant.

2. Methods

In previous experiments our simulations have been validated using the prototype of the electrostimulative femoral stem in a porcine femur (see Fig. 1b). For the simulation of the electric fields in the Finite Integration Technique program CST EM Studio®, a CAD model is used, which bases upon the reconstruction from CT scans of the porcine femur plus the CAD model of the hip stem (see Fig. 1c). This model is utilized to proof the concept of the optimization presented in this paper.

978-1-4673-5225-3/14/$31.00 ©2014 IEEE

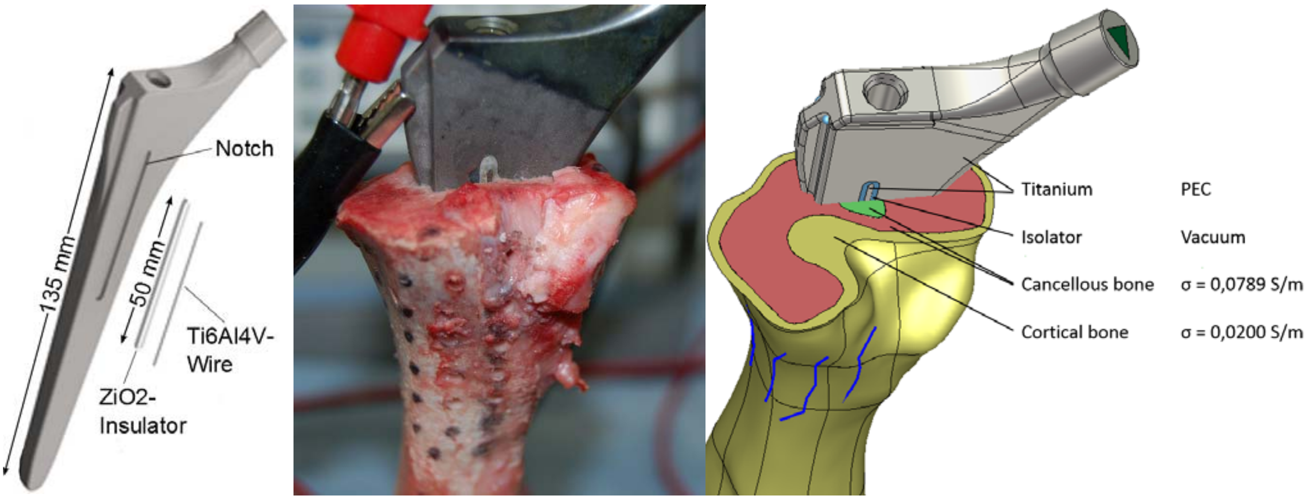

Figure 1: a) Conceptual design of the electrostimulative size 2 hip stem (left), b) validation experiment of the prototype in a porcine femur (middle), and c) simulation model (right).

The different biological tissues are defined using the conductivities as investigated by Gabriel for 20 Hz [11]. As it can be seen in Fig. 1c, a third biological tissue (green) has also been modelled and considered for the validation mentioned above. This is the bone marrow, which occurs in a young pig but not in that region of an adult human bone. For this reason it is substituted by cancellous bone during the optimization. Since the conductivity of the titanium is substantially higher than the conductivity of the tissue, it is approximated by a perfect electric conductor (PEC) to minimize the computational effort. The insulator has a relatively low conductivity compared to that of the biological tissue and thus is defined as perfect electric insulator (Vacuum) for the same reason.

It is taken advantage of CST EM Studio®'s Enhanced Fast Perfect Boundary Approximation (EFPBA) which minimizes the geometrical error and achieves 2nd order convergence even for a hexahedral mesh as it was chosen here. In addition, the adaptive mesh refinement has been used during the first simulations to improve the hexahedral mesh automatically. The final mesh consists of approximately 9.55 million hexahedral mesh cells. Because of the stimulation frequency of 20 Hz, the capacitive properties of the tissues can be neglected. For this reason the stationary current solver of CST EM Studio® can be used to solve Laplace's equation. Prior tests showed that the error, made by this simplification, is below 0.5 % compared to quasistatic solutions while the computational effort is reduced drastically. Thus the computation time for one simulation run and a solver accuracy of $1 \cdot 10^{-9}$ is below ten minutes using a work station computer (4 x 2.53 GHz, 12 GB RAM).

According to Kraus, a successful stimulation is achieved using an electric field between 5 and 70 V/m at the interface between bone and implant as well in close proximity to the hip stem. Because the implant itself is an electrode assigned with a voltage of 0 V, the electric field is strongly dependent on the width of the insulator and the stimulation electrode. These widths, as well as the potential of the stimulation electrode are the parameters for the optimization. For both width, certain boundaries were given, so that the stimulation electrode is not thinner than 0.5 mm or bigger than the insulator, which should also not be bigger than 5 mm on each side.

To define the optimization goals, points of interest were selected in close proximity to the electrode and to the implant but also within the bone. These points cover nearly the whole area between the stimulated plane of the implant and the cortical bone. Two optimization goals were defined for these points: 1.) to keep the electric field at all points close to the implant below 70 V/m, and 2.) to keep as many points in the area of interest between 5 and 70 V/m. Goal one is a specialization of goal two, but it is necessary to avoid excessive stimulation (electric field above 70 V/m). On the other hand, distant points do not reach the minimal stimulation field, but the stimulation in these regions is not as necessary as the avoidance of overstimulation at the hip stem since this could damage cells instead of providing cell growth. For this reason, both goals are assigned with the same weight. Because the bone tissue does not connect well to the insulator and because the size of the insulator also influences the mechanical stability of the hip stem, its size is optimized to be as minimal as possible. This third goal is set to the same weight as the optimal field distribution within the bone. For the calculation, the internal optimizer of CST EM Studio® uses the Trust Region Framework.

3. Results

Figure 2a shows the electric field distribution on a cut plane within the bone and the implant. The dimensions of the insulator (1 mm at both sides) and of the stimulation electrode (1 mm) are the same as in the validation experiment mentioned above. The stimulation voltage is 0.2 V and as expected, there is overstimulation in close proximity to the electrode. On the other hand, the bone is within stimulation range at a distance of about 5 mm from the stimulation electrode as it can also be seen in Fig. 3a and 3b. One characteristic quality to evaluate the different electric fields, is the

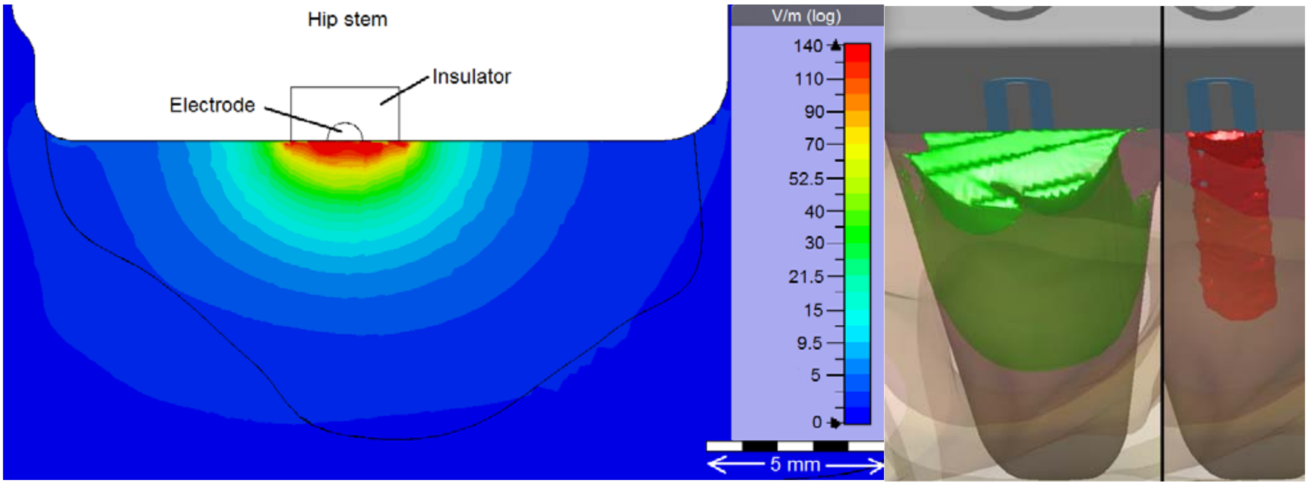

Figure 2: a) Electric field distribution in a cut plane perpendicular to the implant using the initial configuration as in the validation experiment (left), b) isosurfaces of the electric field at 5 V/m (green) and 70 V/m (red) within the optimized configuration (right)

distance between the overstimulated area, which ends 0.85 mm above the stimulation electrode, and the stimulated area, which ends at 4.7 mm in that case. Thus, the stimulation distance is 3.85 mm. Since this distance nearly represents the radius of a cylindrical volume of stimulated tissue (see Fig. 2b), it can be used to compare different configurations.

Especially at the edges between electrode and insulator, overstimulation cannot be avoided without drastically reducing the stimulation potential and thus the stimulated area. For this reason the electric field on the surface of the implant is overstimulated in close proximity to the stimulation electrode, but decreases logarithmically with the distance to these edges (see Fig. 3a). Consequently, nearly the whole surface of the stimulated side of the hip stem is above the minimal stimulation field (5 V/m), as it can be seen in Figure 2a and 2b.

After the optimization process the area of overstimulation has been reduced substantially while the properly stimulated area increased, as it can be deduced from Figure 3a and 3b. Figure 3a shows the electric field along a line on the surface of the implant across the stimulation electrode and the insulator. The singularities at the edges as well as the general overstimulation is diminished due to the optimization, while the stimulation distance increases to 4.83 mm, i.e. 25 % larger, as it can be seen in Fig. 3b. To achieve this, the size of the insulator at both sides and of the stimulation electrode was increased from 1.00 mm to 1.40 mm and from 1.00 to 1.45 mm, respectively, while the stimulation potential has been reduced to 0.17 V.

4. Discussion

This paper investigated the possibility to optimize the hip stem for an electrostimulative hip revision system. The goals to increase the stimulated and to reduce the overstimulated volume without expanding the size of the insulator too much have been accomplished. However, overstimulation is still noticeable at the edges. In addition, the enlargement of the insulator and stimulation electrode resulted in an increased overstimulation across their surface, as it can be seen in Fig. 3a. Contrary, the maximal electric field amplitude, occurring within the overstimulated area, was reduced by about 35 %. Like in the case of the initial configuration, the electric field strength of nearly the whole vicinity of the simulated stem surface is above the stimulation threshold.

The initial configuration of the electrostimulative femoral implant has a notch with a width of 3 mm on both sides of the stem. It has been approved by the orthopaedic clinic at the University Medicine of Rostock because it passed a numerical static strength analysis for fatigue failure. This procedure has to be repeated for the optimized hip stem, which has a notch with a width of approximately 4.25 mm. If the improved implant fails the fatigue analysis, the optimization has to be repeated with an increased weight at the third optimization goal to reduce the size of the insulator.

Nevertheless, this proof of concept showed that it is possible to improve the very basic electrode configuration of the electrostimulative hip stem. The initial values were chosen in a raw guess and improved using equally weighted optimization goals. Changes in these weights resulted in drastically changed configurations. So the size of the insulator is highly dependent on these values and tends to increase drastically if the optimization goals for the electric field are preferred against the other two goals.

In future works, a multidimensional approach to this problem is pursued, to find a Pareto-amount of configurations like in the case of the electrostimulative acetabular cup (see [9]). This approach would allow for a reduction of the influence of the optimization weights and for an automatic selection of the electrode configuration. Thus,

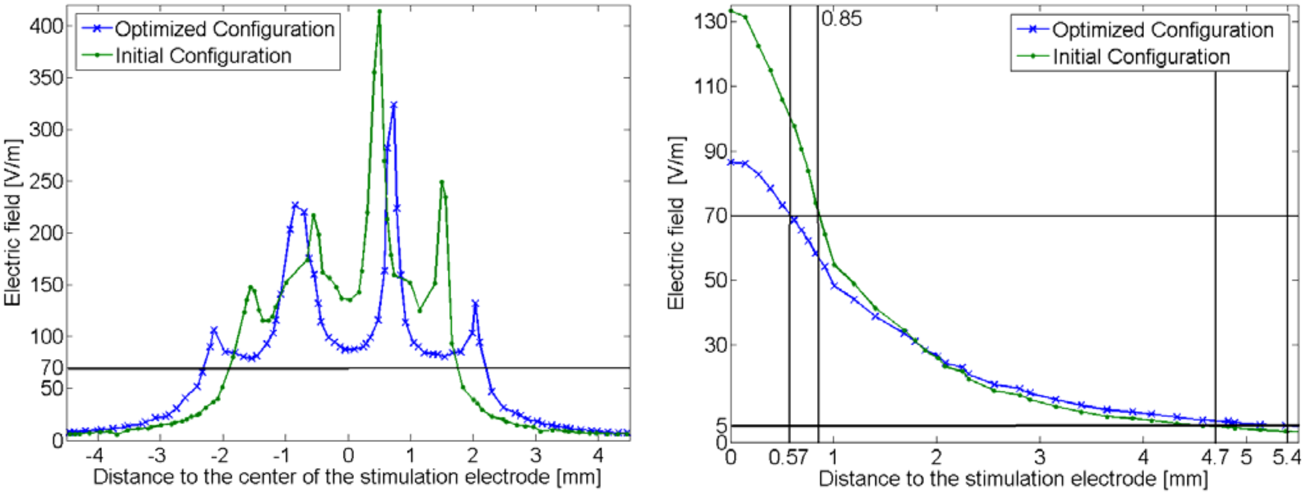

Figure 3: Electric field simulated along a line a) on the surface of the implant, b) perpendicular to the stimulation electrode (right).

it would be possible to directly determine the amount of the trade-off between optimal stimulation field and size of the insulator. In addition, further optimization goals as well as optimization parameters could then be defined and evaluated.

For example, one other optimization parameter could be the distance between two or more stimulation electrodes in a multi-electrode setting. In first tests, two thin stimulation electrodes achieved a more beneficial field distribution than one big stimulation electrode. Because of this, two or three stimulation electrodes per side would be a more appropriate option, particularly for bigger femoral implants. However, the option to use specially formed stimulation electrodes covering a bigger surface on the implant has already been suspended due to technical limitations.

5. References

1. S. M. Kurzt, K. L. Ong, J. Smier, K. Zhao, F. Mowat and E. Lau, "Primary and Revision Arthroplasty Surgery Caseloads in the United States from 1990 to 2004," *Journal of Arthroplasty*, **24**, February 2009, pp. 195-203.

2. S. Kurtz, K. Ong, E. Lau, F. Mowat, and M. Halpern, "Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030," *Journ. of Bone and Joint Surgery,* **89**, April 2007, pp. 780-785.

3. B. D. Springer, T. K. Fehring, W. L. Griffin, S. M. Odum and J. L. Masonis, "Why Revision Total Hip Arthroplasty Fails," *Clinical Orthopedics and Related Research,* **467**, January 2009, pp. 166 - 173.

4. C. A. L. Bassett, R. J. Pawluk, and A. A. Pilla, "Acceleration of fracture repair by electromagnetic fields. A surgically noninvasive method," *Ann. NY Acad. Sci.,* **238**, October 1974, pp. 242-262.

5. W. Latham and J. T. C. Lau, "Bone Stimulation. A Review of Its Use as an Adjunct," *Techniques in Orthopaedics*, **26**, March 2011, pp. 14 – 21.

6. R. K. Aaron, D. McK. Ciombor, and B. J. Simon, "Treatment of Nonunions With Electric and Electromagnetic Fields," *Clin. Orthop. Relat. Research*, **419**, February 2004, pp. 21-29.

7. A. Soda, T. Ikehara, Y. Kinouchi, and K. Yoshizaki, "Effect of exposure to an extremely low frequency-electromagnetic field on the cellular collagen with respect to signaling pathways in osteoblast-like cells," *Journal of Medical Investigation,* **55**, 2008, pp. 267-278.

8. C. Potratz, D. Kluess, H. Ewald, and U. van Rienen, "Multiobjective Optimization of an Electrostimulative Acetabular Revision System," *IEEE Trans. Bio. Eng.*, **57**, February 2010, pp. 460-468.

9. U. Zimmermann, and U. van Rienen, "An Automatic Pareto Classifier for the Multiobjective Optimization of an Electrostimulative Acetabular Revision System," IEEE *Trans. Magnetics,* in press.

10. W. Kraus, „Magnetfeldtherapie und magnetisch induzierte Elektrostimulation in der Orthopädie," *Orthopädie,* **13**, April 1984, pp. 78-92.

11. C. Gabriel, A. Peyman, and E. H. Grant, "Electrical conductivity of tissue at frequencies below 1 MHz," *Phys. Med. Biol.,* **54**, August 2009, pp. 4863-4878.