

# Electro-Stimulating Implants for Bone Regeneration: Parameter Analysis on Design and Implant Position

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**Abstract:** The aim of a clinical treatment which applies an alternating electromagnetic field using a screw implant to the weak bone in the femoral head is to speed up bone regeneration in case of avascular necrosis of the femoral head. A BISS (bipolar induction screw system), as the depicted ASNIS S-Series screw with integrated coil and electrodes, is the subject matter of this project. Numerical simulation of the electric field caused by the ASNIS-s screw in the femoral head was carried out using the finite element method. Effects of different designs of the ASNIS-s screw on electric field distribution were studied. Three kinds of design variations were completed, such as shape of the screw tip, position of the screw in the femoral head and size of the isolation area in the screw.

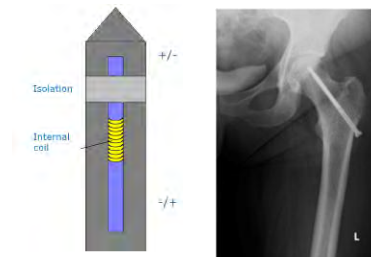
**Keywords:** avascular necrosis, electro-stimulation, implant, treatment

## 1. Introduction

A common clinical treatment is applying alternating electromagnetic fields to the weak bone within the femoral head in case of avascular necrosis. Some researchers have reported the underlying biological mechanisms. For instance, Fukada and Yasuda [1] presented the piezo-electric properties of bone tissue in 1957. Friedenbergl and Brighton [2] reported that a bio-electric potential can be generated by the healthy bone. Bassett et al [3] found that the behavior of bone cells could be influenced by externally applied electric energy. This shows that the biological systems have the capability to transduce mechanical to electric energy. Recently Soda et al [4] showed that applying low frequency electromagnetic fields on the bone can increase collagen synthesis in osteoblasts. Almost all the authors presented that applying electromagnetic fields to the osseous tissue can speed up bone regeneration. In our present work the bipolar induction screw system [5] as the depicted ASNIS S-Series screw (Stryker Trauma, Kiel, Germany) (Fig. 1 (left)) with integrated coil and electrodes were investigated.

An extracorporeal primary coil is used to generate an oscillation magnetic field at 20 Hz

and this field can induce a sinusoidal alternating voltage of 700 mV into the screw.



**Figure 1.** Sketch of ASNIS-s screw (left), X-ray of the femoral head with ASNIS-s screw (right)

Figure 1 (right) shows an X-ray image from a patient who has an implanted ASNIS-s screw into the center of the femoral head. From 2003 to 2010, Mittelmeier, Ellenrieder et al. performed a retrospective clinical study for 58 patients with ASNIS-s screw. In this study, all of these patients did not undergo an intertrochanteric osteotomy in the past and none of their avascular necrosis was higher than grade III according to the Steinberg classification [6]. In the end, the results showed that only 3 patients had deformations or osteoarthritis 9 months after removing the ASNIS-s screw.

Although the ASNIS-s screw has outstanding improvements on the medical condition, it still has some limitations. For instance, the ASNIS-s screw is only suitable for the case where the femoral head shows sclerosis and no collapse on cancellous bone respectively. This means, as long as the cartilage of the femoral head is not damaged, the electro-stimulation therapy with the ASNIS-s screw can be applied. When the cartilage is ruptured and the femoral head shows flattening, other therapies such as a total hip replacement have to be considered. Besides this, there is another disadvantage of the ASNIS-s screw. MRI is not recommended until the ASNIS-s screw has been removed from the patient after 3 months treatment.

As the ASNIS-s screw is been used for internal electro-stimulation of the bone healing

process, it is worthy to investigate optimized positioning and design of the screw to achieve the best therapeutic effect for avascular necrosis of the femoral head.

The aim of this study is to analyze how different screw designs impact the electric field distribution in the human femoral head. Three kinds of design parameters of ASNIS-s screw in femoral head were carried out, such as different tip geometries, different location and different isolation length.

## 2. Model Generation

The numerical femoral bone in present study was based on data from high-resolution computed tomography (CT) scans of a composite femoral bone (Sawbones 4<sup>th</sup> generation, left, large). To be more realistic, future numerical simulation models for the femoral bone will be reconstructed from CT scans of native human femoral head specimens. At least two steps have to be completed in the model reconstructing procedure. First the software AMIRA 4.1 (Mercury Computer Systems Ins., MA, USA) [7] is used to generate a STL file with segmentation of the CT scans. Then the STL file is converted to a step file or iges file which can be easily imported to COMSOL with the software Geomagic (Geomagic, Inc., NC, USA) [8]. The CAD model of ASNIS-s screw was based on real screw size.

## 3. Use of COMSOL Multiphysics

COMSOL Multiphysics 4.1 was used to simulate the electric field distribution in the human femoral head caused by the ASNIS-s screw. Using the AC/DC modules/electric currents/frequency domain, the linear system was solved by the Conjugate Gradients Interactive solver.

In figure 2, two subdomains in the femoral bone are used, cortical bone and cancellous bone. The bone-surrounding soft tissue was replaced by blood in a cylinder. For the ASNIS-s screw, three subdomains are used, two electrodes and one isolation. The first electrode includes screw head, shaft and thread face and the second electrode is the tip of the screw which has no thread. In between of two electrodes it is the isolation. According to the practical application, the boundary condition of the screw's first electrode has an electric

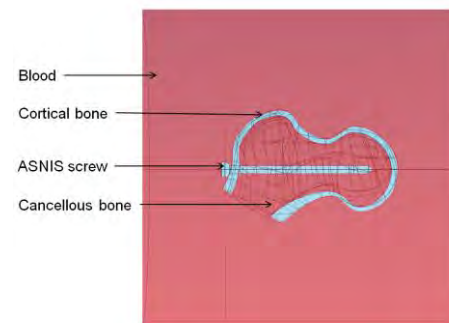
potential of -350mV and the second electrode has 350mv.

The ASNIS-s screw is made on titanium alloy (Ti6Al4V). The isolation layer is based on epoxy resin. To simplify the simulation model in figure 2, the femoral bone and surrounding replacement blood are considered as homogeneous and isotropic materials. The material properties in Table 1, which are used in the numerical simulation, are used according to research by Gabriel et al. [9,10,11].

**Table 1** Material properties used for numerical simulation according to [9,10,11]

Material	Conductivity	Relative permittivity
	$\sigma(S/m)$	$\epsilon$
Human Blood	0.7	5 260
Cortical Bone	0.020045	25 119
Cancellous Bone	0.078902	4 020 200

The femoral bone and the surrounding blood cylinder (Figure 2) were discretized by approximate 1,280,000 tetrahedral elements, resulting in 1,700,000 degrees of freedom. The electric field distribution for this numerical model was calculated under different parameters of the ASNIS-s screw in the femoral head, such as different tip geometries, different locations and different isolation lengths.



**Figure 2.** Model geometry in COMSOL

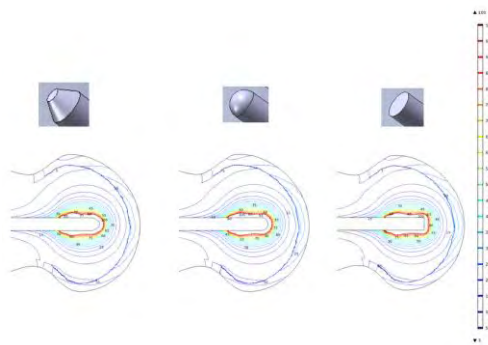
## 4. Results

Showing the effect of different ASNIS-s screw designs on the electric field distribution of the human femoral head numerical model, the results will be presented in 2D cut planes of femoral head with electric field contour lines and histograms of the node in the femoral

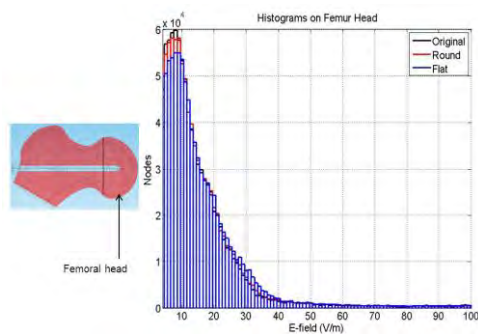
head explicitly. Results of different design such as different screw tip design, different lengths of isolation in screw and different positions of the screw within the femoral head are shown.

#### 4.1 Tip design

Figure 3 depicts the flat tip design results in the strongest electric field in the cortical bone near to the articular gap. The round tip and original tip results show similar electric field distribution in both cortical and cancellous bone area of the femoral head.



**Figure 3.** Results of original tip (left), round tip (middle) and flat tip (right).

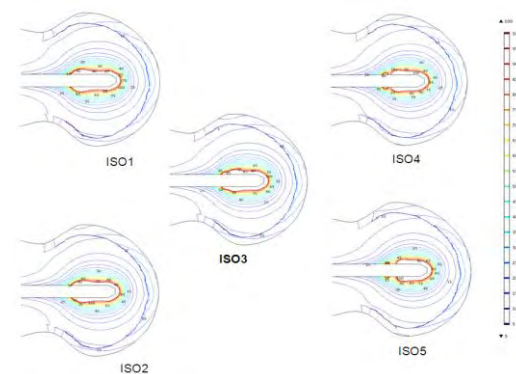


**Figure 4.** Results of original tip (left), round tip (middle) and flat tip (right).

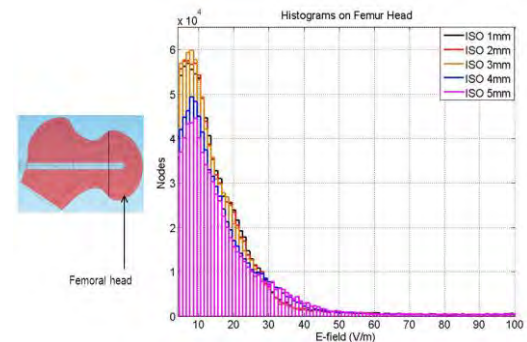
The histograms in figure 4 describe the original tip as well as the round tip and reveal similar electric field distribution at 5-100 V/m. The flat tip has the lowest intensity at 5-10 V/m. At an electric field intensity of 20-40 V/m the flat tip design results in a significant higher intensity than the other two designs. After changing the design to the flat tip, approximately 2.5% of the nodes in the femoral head are extended into the desired interval of electric field of about 5 to 100V/m. But when choosing the round tip design, this percentage is decreased to 0.5%.

#### 4.2 Isolation length of 1mm, 2mm, 3mm, 4mm and 5mm

Figure 5 shows that the electric field distribution in the isolation length 1mm and 2mm has no significant difference to 3mm design, but using the isolation designs 4mm and 5mm results in a higher intensity in the cancellous bone. The histogram in figure 6 represents that the isolation designs 1mm 2mm and 3mm have similar electric field distribution in the femoral head. After extending the isolation of the implant to 4mm and 5mm the electric field in the femoral head shifts from the lower intensity at 5-25 V/m to a higher intensity at 28-42 V/m.



**Figure 5.** Electric field of isolation length of 1mm, 2mm, 3mm, 4mm and 5mm

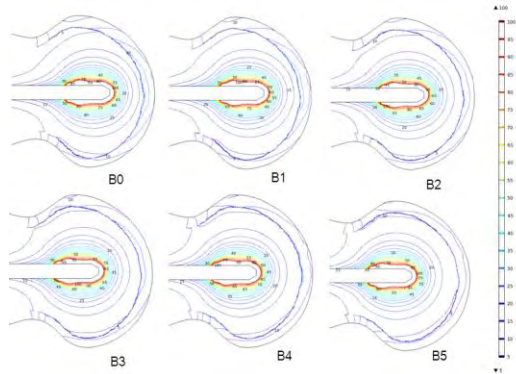


**Figure 6.** Histograms of nodes on femoral head with respect to isolation length

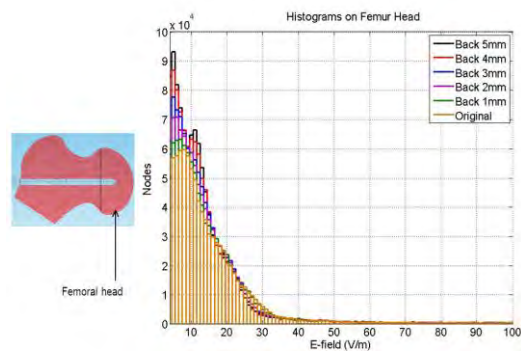
#### 4.3 Screw positioning in backward position of 0mm, 1mm, 2mm, 3mm, 4mm and 5mm

Figure 7 represents that backward movement of the implant in the femoral head has a clear impact on electric field distribution. The further the implant is moved out of the femoral head, the larger the electric field area in cancellous bone and the lower the intensity of electric field in cortical bone. The histogram in figure 8 shows that the 5 mm backward position has the highest electric intensity not

only at 5 V/m but also at 15 V/m. It shows that the geometry of the femoral head also impacts the on electric field distribution. After positioning the implant 5mm out to the femoral head, approximately 13.6% of the nodes are extended to the desired interval of the electric field intensity of about 5 to 100V/m.

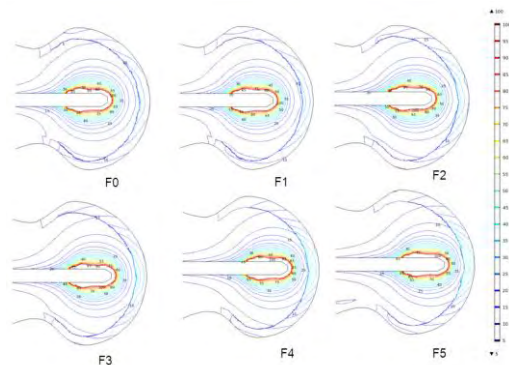


**Figure 7.** Electric field on original position (up left), back 1mm, 2mm, 3mm, 4mm and 5mm

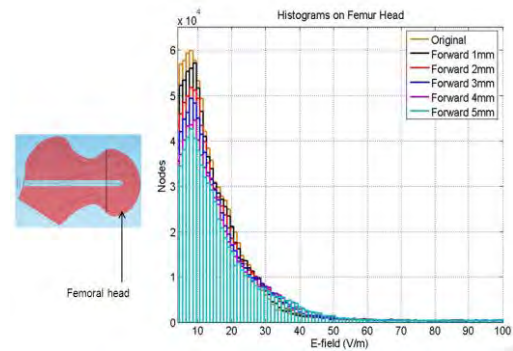


**Figure 8.** Histograms of nodes on femoral head with respect to screw position

#### 4.4 Screw positioning in forward position of 0mm, 1mm, 2mm, 3mm, 4mm and 5mm



**Figure 9.** Electric field on original position (up left), forward 1mm, 2mm, 3mm, 4mm and 5mm



**Figure 10.** Histograms of nodes on femoral head with respect to screw position

Figure 9 and figure 10 present the electric field changing from standard to the 5mm forward positioning of the ASNIS-s screw. As shown in Figure 9, the 5mm centralized position results in the strongest electric field in the cortical bone, but the least intense electric field in the area of the cancellous bone. The histogram in figure 10 quantifies this change in a shift from low intensity electric fields at 5-20 V/m into the range of high intensity at 30-58 V/m. After each 1mm movement of the implant into the femoral head, approximately 4% of the nodes are outside of the desired interval of 5-100V/m. After 5mm forward movement, this percentage is around 20%.

## 5. Conclusion

Use of numerical electric simulation is a new tool to modify electro-stimulation treatment of bone structures in clinical application. As represented in this paper, different implant designs can be simulated and a surgeon using these results could make adapted solutions for patient treatment. For instance, an electric field adaptation by the surgeon can be achieved by small movements of the ASNIS-s screw.

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