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Simulation and Experimental Investigation of a Hollow, Bipolar Needle Electrode

Abstract: Localized impedance measurements at the needle tip identifying the present tissue type could aid clinicians in needle procedures. To assess the sensitivity field of a hollow, bipolar needle electrode, a 3D finite element approach using COMSOL Multiphysics was chosen. The simulated bipolar needle electrode consists of two hypodermic needles (17 G and 23 G) with an insulating layer of polytetrafluoroethylene (PTFE) in between. Impedance values were recorded while steadily increasing the insertion depth of the needle electrode in a layered tissue structure of skin (dermis), fat, and blood. Simulation results reveal a highly local sensitivity volume around the needle tip that can be approximated by half a tri-axial ellipsoid with elliptic radii of 0.735 mm, 2.886 mm, and 1.774 mm. A comparison with simulated and measured impedance values shows great correspondence.

Keywords: Simulation, COMSOL, Impedance Measurement

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1 Introduction

Blood draw is the most common invasive needle insertion routine worldwide with over 2.7 million daily procedures performed in the USA alone [1, 2]. Even though this procedure is very commonplace, complications still arise due to incorrect needle positioning [1]. The most common scenarios are partial puncture of the vein and needle overshoot, both resulting in leakage of blood into the tissue, forming a hematoma [1]. In studies, minor bruising and hematoma were seen to occur in 12,3 % of the cases [3]. In addition, the World Health Organization (WHO) estimates an incidence rate of 2-3 % for hematomas, which are associated with blood donation [2]. The difficulties are even exacerbated by the physiology of, e. g., pediatric, geriatric, obese, or dark-skinned individuals [4].

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Figure 1: Finite element model of a hollow, bipolar needle electrode that is inserted into a layered tissue structure with a layer thickness of 8 mm.

One approach to improve needle procedures is the utilization of bioelectrical impedance measurements. Research on monopolar impedance measurement setups has been conducted, showing successful identification of fat and muscle tissue [5]. To avoid the necessity of patch electrodes on the skin, bipolar setups have also been investigated [6–9]. Some of the bipolar designs consist of a hollow needle with a coated copper wire that was inserted into the needle and exposed at the needle tip. Others consist of two concentric needles that are separated by an insulating layer. In the field of impedance measurement, spatial sensitivity and polarization effects are highly relevant aspects. Different approaches to handle electrode polarization effects exist. Efforts can be taken to reduce polarization effects as much as possible, e. g., tetrapolar needle electrodes have been fabricated and tested for this purpose [10]. An alternative is to measure the resulting overall electrode impedance including all polarization effects [8].

In this paper, a finite element (FE) model of a bipolar needle electrode is presented that is penetrating through a layered structure of skin (dermis), fat, and blood. The finite element model is implemented in COMSOL Multiphysics 5.6 (COMSOL Inc., Burlington, MA, USA) in combination with Creo Parametric 5.0.0.0 (PTC Inc., Boston, MA, USA). The spatial sensitivity of the needle electrode is assessed by means of electric potential distribution and total current density. The resulting impedances are validated with experiments with a self-fabricated bipolar needle electrode.

2 Materials and Methods

2.1 Geometrical Model

The electrode design (Figure 2) is comprised of an outer 17 G needle, represented by a hollow cylinder with an outer diameter (OD) of 1.47 mm and an inner diameter (ID) of 1.22 mm (SFM Hospital Products GmbH, Berlin, DEU), and a second 23 G needle, also represented by a hollow cylinder with an OD of 0.6 mm and an ID of 0.39 mm (B. Braun Melsungen AG, Melsungen, DEU), which is positioned concentrically. The insulating layer between the needles thus has an OD of 1.22 mm and an ID of 0.6 mm. According to the manufacturing process of hypodermic needles, the first bevel angle is set to 12° [11]. The rotation angle is set to 60° and the second bevel angle to 18° [12]. The whole model is jointly cut using the rotation and bevel angles as described, and not separately. This approximation is to reduce the complexity of the FE model.

The layered tissue structure is implemented by means of the in-built COMSOL features to create geometries and consists of three cuboids, representing the three different tissue types that are stacked. Each cuboid is 10 mm long, 10 mm wide, and 8 mm high. The needle is inserted rectangular to the surface as can be seen in Figure 1.

2.2 Finite Element Model

Geometry: A STEP-file of the needle CAD-model was imported, rotated, and displaced to its starting position 2 mm above the layered tissue structure, which together formed a union. COMSOL's feature to remove details is used to avoid an unnecessary increase in model complexity.

Materials: Stainless Steel (SS) 410 annealed from COMSOL's material library is used for the hypodermic needles. The insulating layer consists of polytetrafluoroethylene (PTFE). The electrical properties can be found in Table 1.

Physics: The Electrical Currents interface was used to describe the physics and the boundary conditions. An electric potential of 2 V was applied to the inner needle which is the electrode exciting. Correspondingly, 0 V was applied to the outer needle. All exterior boundaries were chosen to be electrically insulating, ensuring that there were no electric fields outside the boundary. The continuity equation for the electric potential was applied to all interior boundaries by adding the Current Conservation node to the model.

Mesh: Meshes were generated using the following element size parameters: max. element size 0.5 mm, min.

Figure 2: Detailed view of the needle electrode tip. The radii of the components (in mm) and the first bevel angle are depicted.

element size 0.03 mm, max. element growth rate 1.5, curvature factor 0.3, resolution of narrow regions 0.5.

Study: A parametric sweep was conducted with the parameter being the displacement of the needle, ranging from 0 mm to 24 mm. As the needle is starting 2 mm above the top surface, the range corresponds to an insertion depth of -2 mm to 22 mm. A single sinusoidal excitation frequency of 100 kHz, matching the benchwork experiments, was used.

Results: An electric potential plot, representing the sensitivity field, together with an arrow plot, representing the magnitude of the current density, was chosen for visualization.

2.3 Experimental Setup

To mimic the electrical properties of realistic tissue, water-based phantoms with agar and gelatin as gelling agents were produced. Each layer had a thickness of 8 mm. The targeted conductivities were 0.7 S/m for blood, 0.25 S/m for skin (dermis), and 0.04 S/m for fat [13].

The bipolar needle electrode was fabricated using the components as described in 2.1, and connected to an AD5933 impedance analyzer chip (Analog Devices Inc., Norwood, Massachusetts, USA). To perform the insertion into the tissue phantom with a constant velocity of 1 mm/s, a universal testing machine (QUASAR 25, Cesare Galdabini SPA, Cardano al Campo, ITA) was used.

Table 1: Electrical properties of the materials used in COMSOL.

	Conductivity σ (S/m) at 100 kHz	Rel. permittivity ϵ_r at 100 kHz
SSt 410 anneal.	$1.74 \cdot 10^6$	1.00
PTFE	$1.00 \cdot 10^{-18}$ [14]	2.10 [15]
Skin (dermis)	0.25 [13]	$1.24 \cdot 10^4$ [16]
Fat	0.04 [13]	$1.01 \cdot 10^2$ [17]
Blood	0.70 [13]	$5.12 \cdot 10^3$ [17]

3 Results

3.1 Spatial Sensitivity

Figure 3: The electric potential distribution (V) is given by the color bar. The current density is represented by the size of the arrows. The intersection planes pass through the common needle axis. (A) shows a XZ view. (B) shows a YZ view.

Simulation results show a highly local measurement sensitivity. The largest potential gradient and the highest current density are found in close proximity of the exciting electrode. According to Figure 3, the potential gradient in x-direction is spatially very limited, not exceeding the diameter of the needle electrode, resulting in a really local sensitivity and measurement range in respect to x. Also, the potential distribution in respect to y is very restricted, exceeding the needle diameter only by approximately 1 mm. Assuming the described distribution in x- and y-direction, the sensitivity volume can be approximated by half a tri-axial ellipsoid, located on the intersection of first cutting plane and needle axis, with the following elliptic radii, determined using

trigonometric functions: a (x-direction) = 0.735 mm (half of the largest OD), b (along the cutting plane) = 2.886 mm, and c (perpendicular to the cutting plane) = 1.774 mm.

3.2 Comparison of Impedance Values

In Figure 4, the recorded impedances for simulation and experiments (mean out of 10 measurements) are plotted against the displacement. The experimental data start from approximately 15 k Ω which is when the needle is still in air. Once both electrodes are inside the material, the impedance drops to roughly 1 k Ω . However, this drop does not happen immediately. The needle has to advance roughly 4 mm more before a constant value is reached. As the layer thickness is 8 mm, the second layer is interfaced after a displacement of 11 mm. The same behavior can be observed here: a rise in impedance due to transitioning into the less conductive fat layer, but not an immediate rise. Transitioning into the highly conductive blood leads to a drop in impedance again to roughly 300 Ω . The simulation starts from approximately 370 k Ω and shows a very similar behavior. The impedance decreases to roughly 900 Ω which is in great accordance to the 1 k Ω obtained experimentally. Also, a gradual decrease is observed. The simulated impedance for fat is around 1.9 k Ω which is lower than the experimental result. However, blood with a simulated impedance of 300 Ω corresponds very well again (1.42 % deviation).

Figure 4: Comparison of impedance values on a logarithmic scale. The experimental data are mean values; the error bars depict the standard deviation ($n = 10$).

4 Discussion

The comparison of simulated and experimentally determined impedances show great correspondence. Variations (skin 20.12 %, fat 43.82 %, blood 1.42 %) still exist, which can be caused by geometric simplifications that were accepted in favor of a less complex FE model. In addition, the needle electrode used in the benchwork experiments was self-fabricated and did not follow a standardized manufacturing process. Also, the mesh resolution and the mesh quality could be improved further. The average element quality of the mesh is 0.6679, where 1 would be a perfectly regular element, and 0 a degenerated element. The large standard deviations when transitioning between two layers might be caused by an imperfect tissue phantom. The thickness within one layer is not completely constant, resulting in changes in impedance that occur with varying displacement.

In the benchwork experiments, no measurement of the sensitivity field could be conducted. However, the slow inclines and declines in impedance, as seen in Figure 4, indicate a sensitivity field which is in accordance to the simulation. Only when the inner electrode is fully exposed to the same material (insertion depth of 4 mm), the impedance is constant and does not change with further insertion, supporting the idea of a highly local measurement. In this work, a straight forward approach to measure the overall electrode impedance including all polarization effects was chosen. This approach appears reasonable as simulation and experiments correspond well.

5 Conclusion

In this work, it is shown that a hollow, bipolar needle electrode has a highly local sensitivity field. Further work will focus on improving the manufacturing of actual needle electrodes.

Author Statement

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References

- [1] Buowari OY, "Complications of venepuncture," *Advances in Bioscience and Biotechnology*, vol. 04, no. 01, pp. 126–128, 2013.
- [2] Dhingra N, *WHO guidelines on drawing blood: Best practices in phlebotomy*. Geneva, Switzerland: Safe Injection Global Network, WHO, 2010.
- [3] Galena HJ, "Complications occurring from diagnostic venipuncture," *The Journal of Family Practice*, vol. 34, no. 5, pp. 582–584, 1992.
- [4] Walsh G, "Difficult Peripheral Venous Access: Recognizing and Managing the Patient at Risk," *Journal of the Association for Vascular Access*, vol. 13, no. 4, pp. 198–203, 2008.
- [5] Kalvøy H, "Needle Guidance in Clinical Applications based on Electrical Impedance," Dissertation, Department of Physics, University of Oslo, 2010.
- [6] Halonen S, Kari J, Ahonen P, Kronström K, and Hyttinen J, "Real-Time Bioimpedance-Based Biopsy Needle Can Identify Tissue Type with High Spatial Accuracy," *Annals of Biomedical Engineering*, vol. 47, no. 3, pp. 836–851, 2019.
- [7] Cheng Z, Davies BL, Caldwell DG, Barresi G, Xu Q, and Mattos LS, "A hand-held robotic device for peripheral intravenous catheterization," *Proc Inst Mech Eng H*, vol. 231, no. 12, pp. 1165–1177, 2017.
- [8] Trebbels D, Fellhauer F, Jugl M, Haimerl G, Min M, and Zengerle R, "Online tissue discrimination for transcutaneous needle guidance applications using broadband impedance spectroscopy," *IEEE Transactions on Biomedical Engineering*, vol. 59, no. 2, pp. 494–503, 2012.
- [9] Yun J, Kang G, Park Y, Kim HW, Cha J-J, and Lee J-H, "Electrochemical impedance spectroscopy with interdigitated electrodes at the end of hypodermic needle for depth profiling of biotissues," *Sensors and Actuators B: Chemical*, vol. 237, pp. 984–991, 2016.
- [10] Park J, Choi W-M, Kim K, Jeong W-I, Seo J-B, and Park I, "Biopsy Needle Integrated with Electrical Impedance Sensing Microelectrode Array towards Real-time Needle Guidance and Tissue Discrimination," *Sci Rep*, vol. 8, no. 1, pp. 1–12, 2018.
- [11] *Medizinische Kanülen: Teil 4: Anschliffarten, Anforderungen und Prüfung*, DIN 13097-4, Deutsches Institut für Normung e. V., Jun. 2019.
- [12] Wang Y, Chen RK, Tai BL, McLaughlin PW, and Shih AJ, "Optimal needle design for minimal insertion force and bevel length," *Medical Engineering & Physics*, vol. 36, no. 9, pp. 1093–1100, 2014.
- [13] Göhring C, Liu J, Schiele F, Möller K, and Pott PP, "Fabrication and Evaluation of Simple Tissue-Mimicking Phantoms for Electrical Impedance Sensing," in *IEEE EMBS Conference on Biomedical Engineering and Sciences*, March 1-3, Langkawi, Malaysia, 2021.
- [14] Champion AR, "Effect of Shock Compression on Electrical Resistivity of Three Polymers," *Journal of Applied Physics*, vol. 43, no. 5, pp. 2216–2220, 1972.
- [15] Koizumi N, Yano S, and Tsuji F, "Dielectric properties of polytetrafluoroethylene and tetrafluoroethylene-hexafluoropropylene copolymer," *J. Polym. Sci., C Polym. Symp.*, vol. 23, no. 2, pp. 499–508, 1968.
- [16] Tsai B, Xue H, Birgersson E, Ollmar S, and Birgersson U, "Dielectrical Properties of Living Epidermis and Dermis in the Frequency Range from 1 kHz to 1 MHz," *Journal of Electrical Bioimpedance*, vol. 10, no. 1, pp. 14–23, 2019.
- [17] Gabriel C, "Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies," Fort Belvoir, VA, 1996.