Miniature Scalp–Implantable Antennas for Telemetry in the MICS and ISM Bands: Design, Safety Considerations and Link Budget Analysis

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Abstract—We study the design and radiation performance of novel miniature antennas for integration in head–implanted medical devices operating in the MICS (402.0–405.0 MHz) and ISM (433.1–434.8, 868.0–868.6 and 902.8–928.0 MHz) bands. A parametric model of a skin–implantable antenna is proposed, and a prototype is fabricated and tested. To speed–up antenna design, a two–step methodology is suggested. This involves approximate antenna design inside a simplified geometry and further Quasi–Newton optimization inside a canonical model of the intended implantation site. Antennas are further analyzed inside an anatomical human head model. Results indicate strong dependence of the exhibited radiation performance (radiation pattern, gain, specific absorption rate and quality of communication with exterior equipment) on design parameters and operation frequency. The study provides valuable insight into the design of implantable antennas, addressing the suitability of canonical against anatomical tissue models for design purposes, and assessing patient safety and link budget at various frequencies. Finite Element and Finite Difference Time Domain numerical solvers are used at different stages of the antenna design and analysis procedures to suit specific needs. The proposed design methodology can be applied to optimize antennas for several implantation scenarios and biotelemetry applications.

Index Terms—Implantable antenna, industrial, scientific and medical band, medical implant communications service band, optimization, telemetry, specific absorption rate (SAR).

I. INTRODUCTION

Implanted medical devices are recently used to perform an expanding variety of diagnostic and therapeutic functions [1]–[4]. To be truly beneficial while preserving patient comfort, these devices need to communicate wirelessly with exterior equipment. Antenna–enabled biotelemetry for implants is gaining considerable attention in an attempt to overcome the limitations of inductive biotelemetry related to low data rate, restricted communication range and sensitivity to inter–coil misalignment [5], [6]. Implantable antenna design attracts high scientific interest to deal with the challenges of miniaturization, biocompatibility, impedance–matching, reliable data exchange and patient safety.

Various frequency bands are approved for medical implants. The medical implant communications service (MICS) band (402.0–405.0 MHz) is most commonly used, universally, for medical implant communications [7]. Circular [8] and square [9] stacked planar inverted–F antennas (PIFAs) have recently been presented for skin–implantation and biotelemetry in the MICS band, emphasizing on miniaturization and enhanced bandwidth. Simplified MICS half–wavelength dipoles [1], as well as MICS magnetic–type loop antennas [10] have also been reported for implantation inside the human head. The 433.1–434.8, 868–868.6 and 902.8–928.0 MHz industrial, scientific and medical (ISM) bands are additionally suggested for biotelemetry in some countries [11]. Quality of communication between electrically–short linear wire antennas has been assessed for artificial joint monitoring at 433 MHz [12]. Design and performance of a rectangular meandered PIFA for radio frequency identification (RFID) applications at 868 MHz has been investigated [13]. Radiation performance of a vaginally–located compact loop antenna, emulated as a forced single–cell excitation, has also been analyzed at 916.5 MHz [14].

In this study, the first challenge lies in proposing a fast two–step design methodology for implantable PIFAs. Antennas are initially designed inside a small single–tissue simulating cube, where simulations run fast, and further optimized inside a canonical model of the intended implantation site, using Quasi–Newton optimization [15]. Canonical tissue models have long been used to study bioelectromagnetic interactions [12], [16], [17]. A parametric model of a skin–implantable PIFA is suggested and experimentally validated, and scalp–implantable antennas are designed for biotelemetry at 402, 433, 868, and 915 MHz following the proposed methodology (e.g. pressure monitoring, brain wave sensing for the paralyzed, brain edema evolution monitoring, position tracking, stroke rehabilitation, RFIDs etc). Optimized PIFAs are further implanted and analyzed inside an anatomical human head model. The proposed antennas occupy identical miniaturized physical (but not effective) dimensions. Antenna miniaturization shrinks the size of the implant accordingly.

The second challenge lies in comparing the radiation performance of the scalp–implantable PIFAs. This involves evaluation of the exhibited radiation pattern and gain values, compliance with international guidelines for the specific
absorption rate (SAR) (IEEE C95.1–1999 [18] and IEEE C95.1–2005 [19]), and quality of communication with exterior equipment. Our goal is to evaluate dependency of the PIFAs’ radiation performance upon operation frequency and size.

Design and analysis is thus presented for scalp–implantable PIFAs at four frequency bands. In the literature, a 2.45 GHz PIFA [4] and a MICS loop antenna [10] have been presented for scalp–implantation, but no comparison with other frequency bands was reported. Comparative analyses of implantable antennas operating at various frequencies have been performed in [14] and [20]. In these studies, vagina and gastric/bladder/cardiac implants were presented, respectively, and evaluated at two frequency bands. In both papers, single cell excitation was considered to calculate radiation patterns and inherent net body losses. The studies did not address safety issues. A comparative study for scalp–implantable loop and short dipole antennas was reported in [21] considering four frequency bands. Comparison was limited to the exhibited radiation patterns and gains, while antenna (both physical and effective) dimensions were not scaled to each frequency band.

In this paper, an attempt is made to provide valuable insight into implantable PIFA design and selection of biotelemetry frequency. Simulations based on the Finite Element (FE) and Finite Difference Time Domain (FDTD) methods [22] are carried out within different stages of the antenna design and analysis procedures to suit specific needs. The paper is organized as follows. Section II describes the models and methods used in the study. Prototype fabrication and testing is performed in Section III. Numerical results are presented and discussed in Section IV. The paper concludes in Section V.

II. MODELS AND METHODS

A. Antenna Model

A parametric model of a miniature PIFA is proposed for skin–implantation, as shown in Fig. 1. The model consists of a 6 mm–radius ground plane and two 5 mm–radius vertically–stacked, meandered patches. Circular shape is chosen to avoid sharp edges. In actual applications, the antenna will be mounted on a medical implant device which will also serve as its ground plane. Throughout this study, the origin of the coordinate system is located at the center of the PIFA ground plane, according to Fig. 1. Rogers RO 3210 (permittivity, $\varepsilon_r$ = 10.2, loss tangent, tan$\delta$ = 0.003), which has long been used in implantable antenna design, is chosen as the dielectric material [23]–[25]. Patches are printed on 0.6 mm–thick substrate layers and fed by a 50–Ohm coaxial cable ($x = 0$ mm, $y = 4$ mm). A 0.6 mm–thick superstrate layer covers the structure to preserve its biocompatibility and robustness. Patch stacking and meandering lengthen the effective current path, thus helping achieve the desired resonance characteristics.

In the lower patch to further assist in miniaturization [26]. Tuning the $x_{ij}$, $x_s$, and $y_s$ variables alters the effective antenna size and helps achieve the desired resonance characteristics.

B. Design Methodology

To reduce simulation time, a two–step PIFA design methodology is proposed, as summarized in Fig. 2. The basic idea is that since antennas are intended for skin–implantation, they can be approximately designed while in a simple skin–tissue simulating model [27], [28]. In this way, design is accelerated by two means: (1) scaling required to fine–tune the antenna inside the skin in case it was initially designed in free–space is avoided, and (2) shape and size of the surrounding skin–tissue model are found to insignificantly influence antenna resonance, and can, thus, be selected adequately simple and small to speed–up simulations. The reflection coefficient and target resonance frequency of the PIFA are denoted by $S_{11}$ and $f_0$, respectively.

In the first step, an initial, approximate design is performed. The PIFA is positioned in the center of a 100 mm–edge skin–tissue simulating cube (Fig. 3(a)), where simulations run fast. All thirteen $x_{ij}$, $x_s$, and $y_s$ variables of the parametric PIFA model are manually updated in an iterative way. The iterative procedure stops when

$$S_{11} \leq f_0 \text{ (in skin cube)} < -20 \text{ dB}.$$  \hspace{1cm} (1)

Further implantation of the designed PIFA inside a specific part of the body is expected to result in a slight, yet significant, frequency detuning. This phenomenon has been studied by the authors [27], [28], and is attributed to the loading of the surrounding tissues and exterior air on the antenna in each of the implantation scenarios.

In the second step, PIFA design is optimized for the implantation scenario under consideration. Quasi–Newton optimization is selected for its speed and accuracy in cases of insignificant numerical noise [15]. Optimization is performed inside a canonical model of the intended implantation site. To speed–up design, the position of the shorting pin ($x_s$, $y_s$) is kept fixed to that of the initial PIFA, and the eleven $x_{ij}$ variables are only considered as dimensions in the solution space. These are initialized to the values obtained in the first step and vary within the range [–4.6 mm, 4.6 mm]. The minimum and maximum step values are set to 0.1 and 0.4 mm, respectively.
Numerical Methods and Tissue Models

Canonical tissue models are used in carrying out FE simulations in Ansoft HFSS. The tetrahedron–shaped basic mesh element accelerates solving of curved geometries, while a Quasi–Newton optimizer is integrated into the platform. PIFA designs are validated for anatomically–based geometries in Remcom XFDTD, which enables efficient modeling of detailed anatomical human body parts. The antenna model is transferred to XFDTD in terms of exporting .sol files from HFSS, importing these into XFDTD, and re–meshing.

Optimization of scalp–implantable PIFAs is performed inside the scalp of a 100 mm–radius, 3–layer spherical human head model consisting of skin (scalp), cortical bone (skull) and grey matter (brain) tissues (Fig. 3(b)). Thickness of the scalp and skull layers is set to 0.5 cm, each [16]. Investigations within the scalp of a 13–tissue (Table I) anatomical human head model (Fig. 3(c) [28]) are also performed. In this way, PIFA design is validated for anatomically–based geometries and more realistic simulation results are obtained. Tissue dielectric properties (permittivity, $\varepsilon_r$, and conductivity, $\sigma$) used in this study are indicated in Table I [29]–[31], and approximated as constant inside a 200 MHz frequency range around $f_0$. Using this approximation, the maximum errors of $\varepsilon_r$ and $\sigma$ at 402 MHz are given by 6.59% and 8.89%, respectively [28]. Accuracy is further improved at higher frequencies.

Simulation parameters are given as follows. Absorbing boundaries are set $\lambda_0/4$ ($\lambda_0$ is the free–space wavelength) away from all simulation set–ups in order to take free–space radiation into account and extend radiation infinitely far. The FE solver automatically meshes the geometry in an iterative way. Meshing is perturbed by 30% between each pass, and the refinement procedure stops when the maximum change in $|S_{11}|$ between two consecutive passes is less than 0.02 or when the number of passes exceeds 10. The solver works in the frequency–domain, performing a 2000 point–frequency sweep by ±100 MHz around $f_0$. In the FDTD simulations, biological tissue is meshed in 2.5 (skin–cube, canonical head) and 1.25 mm 3 (anatomical head) cells. Non–cubical mesh of 0.1 mm × 0.2 mm is used for the PIFA in order to preserve accuracy in patch–surface modeling (the minimum step value of the optimizer equals 0.1 mm) without aimlessly delaying simulations (the 0.6 mm–thick dielectric layers can adequately be modeled in 0.2 mm steps). Cells of 3.5 mm in edge ($\Delta x$) model free–space so as to meet the FDTD spatial step constraint ($\Delta x < \lambda_{min}/10$, where $\lambda_{min}$ indicates the wavelength of the highest frequency of interest) for all simulation set–ups. This sets the maximum simulation frequency ($f_{max}$) to 8.6 GHz ($f_{max} = c / (10\Delta x)$, where $c$ is the speed of light) and time step ($\Delta t$) to 6.736 ps ($\Delta t = \Delta x/c\sqrt{\varepsilon_r}$), as referenced to free–space. In each set–up, the actual $f_{max}$ will be determined by the highest–permittivity tissue material. Sinusoidal and Gaussian (pulse width of 32 time steps) sources are used for the single frequency and broadband simulations, respectively. Calculations continue until a 30 dB convergence is achieved.

### III. PROTOTYPE AND ANTENNA MODEL VALIDATION

In order to validate the proposed PIFA model and verify simulation results, prototype testing is performed at 402 MHz. Following the first step of the design methodology described...
in Section II.B, variable values indicated in Table II, 402 MHz/init. are found to tune the antenna at 402 MHz inside the skin–tissue simulating cube. To accommodate fabrication–specific details, including the actual thickness of copper sheets (17 µm), gluing ($\varepsilon_r = 2$), coaxial cable type (semi–rigid EZ–47) and length (6 cm), slight design readjustments need to be performed. Based on parametric studies presented in [32], radius of the patches is increased to 5.9 mm, and variable values are modified to those of Table II, 402 MHz/prot. The simulated reflection coefficient frequency response of the prototype antenna is shown in Fig. 4(a) (solid).

A prototype is then built on Rogers RO 3210 substrate (Fig. 4(b)), and connected to a network analyzer (Fig. 4(c)). Reflection coefficient measurements are performed inside a 100 mm–edge cubic phantom filled with skin–tissue emulating liquid made from deionized water, sugar and salt ($\varepsilon_r = 46.7$, $\sigma = 0.69$ S/m at 402 MHz [2]) (Fig. 4(d)). Good agreement exists between simulations and measurements, as shown in Fig. 4(a). Slight discrepancies are observed which are within the uncertainty range imposed by the dependence of Rogers RO 3210 permittivity on frequency and fabrication inaccuracies (especially gluing and soldering).

IV. RESULTS AND DISCUSSION

A. Antenna Design

The proposed two–step design methodology is applied to obtain scalp–implantable PIFAs at 402, 433, 868 and 915 MHz. Initial (first–step) and optimized (second–step) variable values of the parametric PIFA model are shown in Table II. Fabrication–specific details have not been encountered in an attempt to provide generic PIFAs which can subsequently be adjusted to individual fabrication requirements. Optimized variables differ by up to 80% from the corresponding initial variables in absolute value. Longer meanders assist in lengthening the effective current path, thus achieving lower resonance frequencies. To visualize the proposed designs, optimized patch geometries are shown in Fig. 5. The shorting pin trace on the lower patch is also depicted.

Reflection coefficient frequency responses exhibited by the initial PIFAs inside the skin cube are displayed in Fig. 6 (solid). Antennas resonate at the desired frequency bands, satisfying the stopping criterion of Eq. (1). Implantation of these initial PIFAs inside the anatomical head model impacts antenna resonance, as discussed in Section II.B [27], [28] (dashed). Resonance detunings of around 17, 18, 38 and 41 MHz are observed, respectively.

Meanders of the optimized PIFAs are adjusted in length in order to overcome this effect while preserving good impedance–matching characteristics (minimization of Eq. (2)). The reflection coefficient frequency response of the optimized PIFAs inside the canonical and anatomical head models are shown in Fig. 7. Since PIFAs exhibit similar dielectric loading, insignificant discrepancies are observed. Antennas exhibit broad bandwidths (defined at $S_{11} \leq –10$ dB) of approximately 27, 28, 38 and 40 MHz inside the anatomical head model, respectively. Enhanced bandwidth is necessary to deal with variations in tissue dielectric properties [33], [34]. Bandwidth improvement with increasing frequency is attributed to the larger current surface area (see Fig. 5) [35].

B. Comparative Analysis of the Radiation Performance

To provide accurate and realistic results, radiation performance of the optimized PIFAs is evaluated considering the anatomical head scenario (Fig. 3(c)). Numerical analyses are performed using the FDTD method.

1) Radiation Pattern

The 3–D far–field gain radiation patterns exhibited by the optimized PIFAs inside the anatomical head model are shown in Fig. 8 (a)–(d). A near–zone (defined as the FDTD–meshed geometry) to far–field transformation is used to speed–up
calculations. Since the anatomical head model is an asymmetrical, inhomogeneous dielectric structure, radiation patterns, which depend on the structure and shape of the implantation site, are not symmetric either. Increased tissue absorption at high frequencies causes attenuation which deteriorates symmetry, and is consistent with the findings in [36], [37]. For comparison, the far-field radiation patterns of the initial PIFAs inside the skin cube are highly symmetric (Fig. 8 (e)–(h)). Shadowing is reduced due to the size of the implanting environment. Since PIFAs are electrically very small and symmetrically surrounded by a homogeneous medium, they radiate nearly omni-directional, monopole-like patterns. Because of the small PIFA size and high tissue loss, low values of gain are recorded, as indicated in Table III. High gain values at increased frequencies are attributed to the larger current surface area of the PIFAs (see Fig. 5) [35].

2) SAR and Maximum Allowable Input Power

International and national guidelines set the maximum allowable values for the SAR in an attempt to preserve patient safety. For example, the ICNIRP basic restrictions limit the SAR averaged over 10 g of contiguous tissue to less than 2 W/kg [38]. The IEEE C95.1–1999 standard restricts the SAR averaged over any 1 g of tissue in the shape of a cube (1 g–avg SAR) to less than 1.6 W/kg [18]. To harmonize with the ICNIRP guidelines, the IEEE C95.1–2005 standard restricts the SAR averaged over any 10 g of tissue in the shape of a cube (10–g avg SAR) to less than 2 W/kg [19].

In this study, conformance with the latest IEEE standards ([18], [19]) is assessed, and mass–averaging procedures recommended by IEEE are applied [39]. Net–input power to the PIFAs is initially set to 1 W. Maximum 1 g–avg and 10 g–avg SAR values computed in this case are shown in Table IV, along with the maximum allowable net–input power levels which satisfy the IEEE restrictions for the SAR. The IEEE C95.1–1999 standard is found to be much stricter, limiting the net–input power to more than 6 times lower than that imposed by the IEEE C95.1–2005 standard. Local SAR distributions generated in the surrounding tissues are shown in Fig. 9, for the FDTD slices where maximum local SAR values have been calculated (net–input power = 4.927 mW).
field distribution in the surrounding tissues are, thus, recorded. Similar results have been reported for ingestible antennas at various frequency bands in which physical dimensions were not scaled proportionally for each scenario under consideration [37]. However, in case of physically-scaled antennas, high operation frequencies and, thus, tissue conductivities, would be expected to result in increased SAR values and more concentrated SAR distributions [14].

1) Characterization of the Communication Link

Bi-directional, half-duplex communication is established between the optimized PIFAs and exterior antennas. In up-link transmission, the implanted and exterior antennas act as the transmitting (Tx) and receiving antennas (Rx), respectively. Tx and Rx roles interchange for down-link transmission.

Assuming far-field communication, the link power budget can be described in terms of

\[ P_{Rx} = P_{Tx} + G_{Tx} + G_{Rx} - \text{loss} \]

where \( P_{Rx} \) is the power received by the Rx, \( P_{Tx} \) is the power available at the Tx, \( G_{Tx} \), \( G_{Rx} \) are the gains of the Tx and Rx, respectively, and

\[ \text{loss} = PL + e_p + ML_{Tx} + ML_{Rx} \]

where \( PL \) is the path-loss, \( e_p \) is the polarization mismatch factor and \( ML_{Tx} \), \( ML_{Rx} \) are the Tx and Rx impedance mismatch losses, respectively [42]. PL can be calculated by the log-distance model as

\[ PL = 10n \log \left( \frac{d}{d_0} \right) + 10 \log \left( \frac{4\pi d_0}{\lambda_0} \right) + s \]

where \( n \) is the path loss exponent, \( d \) is the Tx–Rx distance, \( \lambda_0 \) is the free-space wavelength, \( d_0 \leq d \) is a reference distance and \( s \) is the random scatter around the mean [41]. In case of free-space propagation \( n = 2 \) (and Eq. (3) simplifies to the Friis equation), while for indoor-propagation \( n \) is environment-dependant.

In this study, we consider exterior half-wavelength dipole antennas (gain of 2.15 dB [40]) centered around the xy-plane, at a distance of \( d = 1–6 \) m. The azimuthal (xy-plane) radiation patterns of the optimized PIFAs inside the anatomic head model are shown in Fig. 10. Maximum (\( G_{max} \)), minimum (\( G_{min} \)) and average (\( G_{avg} \)) azimuthal gain values are recorded in Table III. Four communication scenarios are studied: (a) best-case free-space propagation (\( G_{max} \), \( n = 2 \)) (b) worst-case free-space propagation (\( G_{min} \), \( n = 2 \)), (c) line-of-sight (LOS) indoor propagation (\( G_{avg} \), \( n = 1.5 \), \( d_0 = 1 \) m, \( s_{db} = 0 \)) [25], and (d) non-line-of-sight (NLOS) indoor propagation (\( G_{avg} \), \( n = 3 \), \( d_0 = 1 \) m, \( s_{db} = 0 \)) [42]. Dipole antennas are assumed to be well-matched, so that their impedance mismatch losses can be approximated as 0 dB. Polarization mismatch losses (\( e_p \)) are also neglected.

In up-link transmission, the maximum allowable \( P_{Rx} \) is limited by the safety guidelines for the SAR. To mitigate EM interference with other services, regulations restricting the effective isotropic radiated power (EIRP) of implantable antennas also confine their input power (EIRP \( \leq \) EIRP\text{max}, where EIRP\text{max} = –16 dBm, 7.85 dBm, 11.85 dBm and 36 dBm, for \( f_0 = 402\text{MHz}, 433\text{ MHz}, 868\text{ MHz and 915 MHz} \), respectively [11], [43]). However, gain values exhibited by the
proposed PIFAs are low enough, so that the maximum allowable power is determined by the regulated SAR limitations. The maximum allowable net–input power levels calculated in Table IV (IEEE C95.1–1999 standard) are, thus, considered. Values of $P_{Rx}$, (or, equivalently, the required $Rx$ sensitivity) versus distance are shown in Fig. 11, for all frequency and transmission scenarios under study.

PIFA operation frequency is found to not significantly alter the quality of the communication link. Even though enhanced gain values were observed at higher frequencies (Fig. 8, Table III), here we only consider the $G_{Tx}$ values achieved in the xy–plane. These are found to be comparable, regardless of the operation frequency (see Table III). Furthermore, results show that for the 402, 433 and 868 MHz PIFAs, indoor LOS links are more reliable, followed by the best–case free–space, worst–case free–space and indoor NLOS links. Discrepancies in the communication performance of the 915 MHz PIFA are attributed to the relatively high deviation between the exhibited $G_{max}$ and $G_{avg}$ values, as compared to the other frequency scenarios under consideration.

Quality of down–link transmission can be evaluated in the same way. In this case, however, $P_{Tx}$ is limited by the EIRP restrictions, so that

$$[P_{Tx}]_{dBm} \leq [EIRP]_{max} - [G_{Tx}]_{dB} = [EIRP]_{max} - 2.15 \quad (6)$$

Simulations indicate that SAR does not become an issue for the communication scenarios under study and the $P_{Tx}$ values given by Eq. (6). Reliability of the down–link is expected to improve with increasing frequency because of higher allowable EIRP values.

V. CONCLUSION

Based on a parametric model of a skin–implantable PIFA and a fast two–step design methodology, we proposed miniature scalp–implantable PIFAs at 402, 433, 868, and 915 MHz. Antennas exhibit identical volume of $\pi \times 6 \times 1.8 \text{ mm}^3$ and broad 10 dB–bandwidths of 27, 28, 38 and 40 MHz.

Insignificant discrepancies were observed in the antenna resonance performance within canonical and anatomical tissue models, and analysis inside a 13–tissue anatomical head model was performed. PIFAs at higher frequencies were found to achieve enhanced gains (10.7% increase at 915 MHz as compared to 402 MHz), reduced SAR values (9.2% and 1.3% decrease in the 1 g– and 10 g–avg SAR), increased maximum allowable net–input power levels (10.1% and 1.3% increase imposed by [18] and [19]), and more expanded SAR distributions. Results are attributed to our choice of keeping the PIFAs’ physical dimensions identical and modifying their effective size. Improved down–link communication was shown with increasing frequency because of more relaxed EIRP restrictions, while minor frequency dependence was found for the up–link scenarios under study.

Use of different numerical solvers within stages of the antenna design and analysis procedures with different requirements was highlighted. The proposed design methodology can be adjusted to suit several antenna models and implantation scenarios.

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REFERENCES

exposure to such Fields, 100 kHz to 300 GHz, IEEE Standard C95.3–2002, 2002.


