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Multidisciplinary Investigations on the Use of TiNb Alloy Orthopedic Device Equipped with Low Profile Antenna as Smart Sensor

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Abstract

In this paper, a new complex medical device is proposed using TiNb based metallic alloy, acting also as a ground plane for a low profile printed antenna sited on a Polydimethylsiloxane (PDMS) substrate. The first step of the research is oriented on the experimental study of the properties of TiNb based alloy and on the development of the orthopedic device. The second step is focalized on the electromagnetic characterization of the implanted printed antennas. The resulting smart orthopedic device incorporating the antenna and when embedded in a body environment is numerically analyzed from communication point of view. In particular, the radiation characteristics, necessary for the calculation of the link budget when the device is used for communication with the external to the body receiver is considered. Such scenario finds its applications in monitoring some vital human functions for example in post chirurgical rehabilitation or other long-term surveys.

Keywords: Ti alloy; bimedical; structural characterizatin; electro-magnetic characterization

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1. Introduction

Due to their excellent mechanical properties, appropriate corrosion resistance and good biocompatibility some metallic alloys are widely employed for biomedical purposes. The high strength and resistance to fracture they can exhibit when appropriately developed, offer reliable performance primarily in the fields of orthopedics and dentistry. Since the late 1960's, Ti and its alloys have more and more been used for the development of orthopedic implants, especially for fracture fixation and joint replacement. Furthermore, they exhibit a strong osseointegration tendency that is important for such applications. Mechanical behavior, biocompatibility in body environment and tissues and chemical stability are the most important requirements for the effective use of any bio-implant materials in the human body and in particular for internal support and biological tissue replacement [1-3]. Among the known metals and alloys, stainless steels, CoCr, CoCrMo alloys, Ti and its alloys are the mostly used materials in such applications [4-6]. In case of their use, one of the most important engineering approach is to guarantee minor biological stress to the human system and to maintain as much as possible the whole integrity and functionality of the human being. Thanks to the remarkable mechanical properties, in terms of strength, hardness and toughness, combined to a suitable corrosion resistance and good biocompatibility, metallic materials are continuously used in the fields of orthopedics and dentistry [7-9]. Apart from other characteristics, in biomedical fields, the level of the elastic modulus is very important. This value has to be as close as possible to the elastic modulus of cortical bones (about 30 GPa) [4-6, 10] in order to avoid, as much as possible the "stress shielding" which actually takes place, for many implant materials. For their lower elastic moduli compared to other metallic biomaterials (100–110 GPa compared to 200–220 GPa), and for their solid osseo-integration tendency, Ti and its alloys have been employed more and more since the late 1960's for the orthopaedic implants, mainly for fracture fixation and joint replacement. For β -Ti alloy, to reveal Gum unique properties, it has to contain elements belonging to the IVa and Va groups and they have to simultaneously satisfy the following characteristics: average compositional valence electron number e/a $\approx$ 4.24, bond order number/Bo $\approx$ 2.87, "d" electron orbital energy level/Md $\approx$ 2.45 eV. According to [11] the oxygen in Gum Metal is the most important alloying element for obtaining the outstanding mechanical properties and the unique deformation behaviour.

Oxygen plays a key role in stabilizing the bcc crystal structure by controlling the martensitic transformation temperature and forms nanosized clusters with zirconium [12], which can suppress the dislocation activity up to the ideal strength. One of the most attractive characteristic of this alloy is related to its elastic modulus, which decreases after cold working. According to the literature after 90% of cold working, the modulus can arrive under 40 GPa, and the strength can simultaneously increase up to 1200 MPa, important features in application such as artificial bone.

On the other hand, polydimethylsiloxane (PDMS) elastomer can be used in biomedical field for the production of a large number of active and passive implantation devices, that are in direct, and sometimes prolonged contact with the human tissues [13, 14]. The low cost elastomer PDMS has various benefits, i.e. biocompatibility, flexibility, stability over a wide range of temperatures and offers the possibility to develop patterned substrates [15].

Actually, in the literature, the main attention is oriented to the necessary impedance matching realization in the body environment and considers only some features related to the communication channel between the inside-outside body environments [16, 17]. At the best of the author knowledge, the biocompatibility of the material used for the development of the antenna or of the shielding screen to fulfill electromagnetic interference reduction is only marginally considered with no clear definition of the material used and of their properties.

In this framework, in the present paper a new complex medical device will be proposed using TiNb based metallic alloy and Polydimethylsiloxane (PDMS). The first step of the research is oriented on the study of the properties of TiNb based alloy and on the development of the orthopedic device, while the further step consists of the design of inter-body printed implanted antennas on the orthopedic device. The incorporated antennas on the orthopedic device is placed inside the body-simulated environment and numerically characterized for communication with the external surroundings. The results confirm that it can be efficiently used for data transmission to an external base station or between different nodes of a network to monitor some human vital functions.

2. Experimental

In the present study, TiNb ("Gum Metal") metallic alloy with the chemical composition reported in Table 1 has been prepared by cold crucible levitation melting (CCLM) casting technology. Some samples have been submitted to hot forging followed by a final heat treatment at 850°C for 15 minutes and cooling in air.

Table 1. Chemical composition (at %) of the TiNb alloy.

	Ti	Nb	Ta	Zr	O	Average atomic numbers		
						e/a	Md	Bo
TiNb alloy	71,4	24	1	3	0,6	4,24	2,46	2,83
Average atomic numbers for "Gum Metal"						4,24	2,45	2,87

The morphological analysis has been performed on samples, in the as-cast condition and after hot forging, by a standard metallographic technique by mounting and polishing procedures, using Light Microscope and Scanning Electron Microscopy (LM, MeF4 Reichart-Jung, SEM, Leo 1450VP, Nikon-Omnimet-Buehler, SEM, Leo 1450VP, Zeiss, Ramsey, NJ, United States) equipped with Energy X-rays Dispersive Spectroscopy unit (EDS, Oxford microprobe, Leo 1450VP, Zeiss, Ramsey, NJ, United States). Etching has been carried out using a water solution with 10 % vol of HF and 10% vol of HNO3 for 10 minutes. X-Ray analysis has been performed using X'Pert PRO X-Ray Diffractometer.

The mechanical performances have been investigated by tensile test, carried out according to the UNI-EN 10002/1 Standard, using a dynamometer (Zwick Z100 tool) with a cell load of 100 kN and setting a deformation speed of 10 mm/min. On the polished samples hardness measurements have been performed using a Emco test machine. A force of 200 N has been applied for 15 s for each measurement. The alloy biocompatibility has been evaluated by corrosion resistance measurement after static immersion test according to the route specified in the Standard ISO 10271/2011 at 37°C (± 1°C). The samples were maintained in acid solution (7.5 ml lactic acid, 5.85 g NaCl, 300 ml H2O di grade 2 purity, and 700 ml H2O) at pH~7.4, simulating a real body environment. The samples were monitored after the permanence in such solution for 28 days. Ti6Al4V has been us as reference material, and as blank a solution maintained in the same condition with no any metallic alloy inside was used.

Sylgard 184 Silicone Elastomer Kit has been used for the preparation of the PDMS used as substrate to be situated between the metallic ground plane and antenna. The same is used to cover the overall structure (superstrate) basically to reinforce the stability of the radiator with respect to its ground plane. Such a solution could also be employed when the metallic parts are not biocompatible, since as mentioned above PDMS is so, but this is not the case in the present investigation. The procedure involves the mixture of the elastomer and the curing agent at a 10: 1-part ratio. The mixture has been degassed in a vacuum chamber. During pouring PDMS, it is essential to reduce as much as possible the formation of air bubbles when transferring the PDMS in the die. For the casting procedure, an extendable metallic die has been used containing the artificial medical devices, which has to be coated with the PDMS. The casting has been carried in two steps: firstly, pouring of PDMS around the metallic device; after its hardening the antenna has been introduced and a second layer of PDM has been applied (the prepared medical device is presented afterward in this paper).

The thin metallic sheet used as antenna and feeding microstrip line has been cut out from the castings using diamond and corundum wires and glass sphere as cutting materials and the most appropriate one (diamond wire) has been selected following morphological observation and the final sheet has been removed and used for the numerical investigation.

Numerical simulations have been carried out using Microwave Office form CST, a commercial available software package [18] to numerically investigate, from electromagnetic point of view, the complete structure, i.e. the printed implanted antenna on the orthopedic device in its actual working environment.

3. Results and discussions

The driving idea behind the current paper is:

- to present the possibility of using a large available ground plane for implanted planar antennas, reducing in this way the required space (since the ground plane is already available, and planar configurations are not space demanding), and
- at the same time to improve the antenna performances, by reducing the effect of the finite ground plane, as for example the diffraction from its edges. Because of the available space, the antenna element can also be larger, as it was chosen in the reported example, giving rise to a wide beam antenna with quasi-omnidirectional coverage.

Measurements for such deeply positioned radiators within the body environment are challenging, because of the strong influences of the different highly dispersive and lossy materials. The presented numerical results, considering a simplified, but still accurate model of the different basic tissue types are encouraging for us, and in the future is our intent to experimentally verify the proposed antenna type.

3.1. Structural, microstructural and mechanical investigation

The typical microstructures of the TiNb alloy are reported in Fig.1, in as- cast state (a), after hot deformation (b). The alloy reveals a pure equiaxed β grain microstructure and the average β grain size is about 161 μm for the as-cast samples and after hot forging the grain size is about 138 μm. Generally, the mechanisms of deformation of β Ti alloys differ depending on the stability of the alloys. The main mechanisms of deformation of this phase are dislocation slip. According to the literature [13], in such alloys with no Oxygen within their microstructure some large bands can be observed, which usually do not appear in the alloy with Oxygen, nether in as-cast state nor after deformation. The microstructure consists in β grain with no any presence of twinning. The porosity level, about 0.55% in as cast condition, evaluated by Leica microscope image analysis software further decreases after the deformation process.

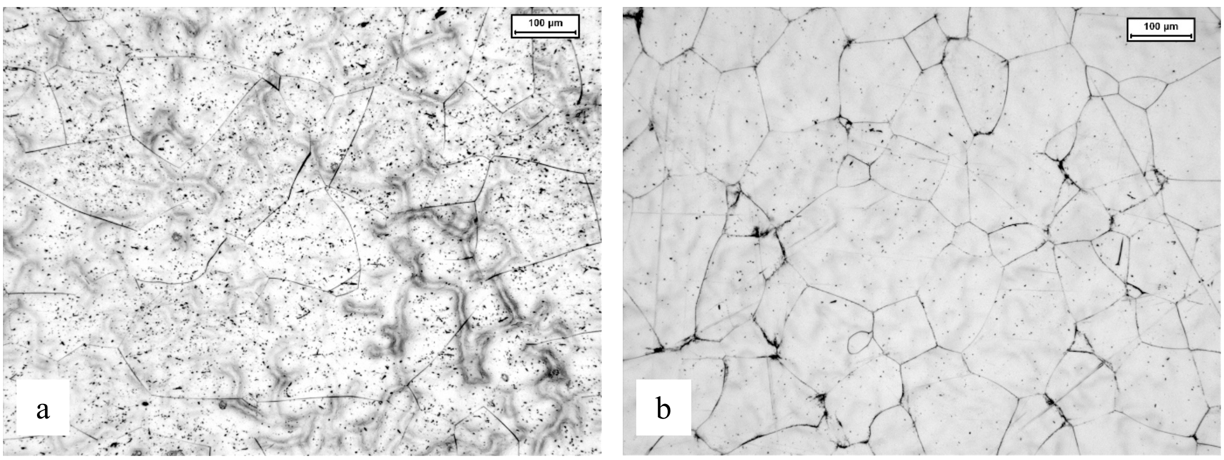

Fig.1. OM microstructures: as-cast TiNb alloy (a) and after hot deformation (b).

Analyzing the X-ray diffraction pattern, reported in Fig. 2, there is the confirmation that the alloy develops a single-phase β microstructure, since only the peaks related to the body centered cubic structure of β phase is present. The formation of quenched martensite α’’ phases is suppressed by the addition of oxygen in the alloy composition.

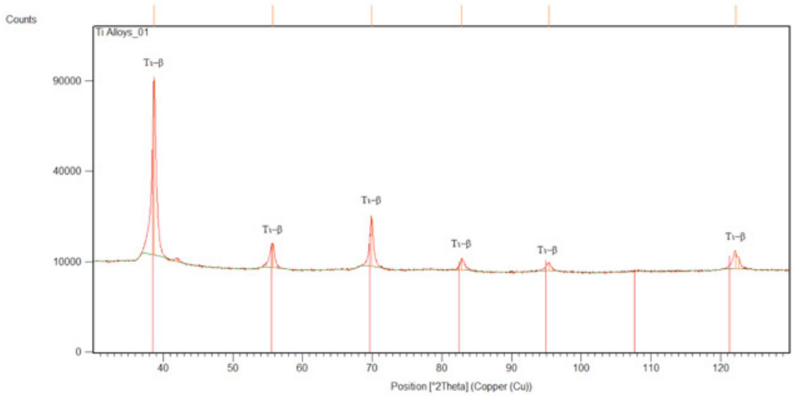

Fig. 2 X-ray diffraction pattern of the as-cast TiNb alloy

The isotropy of the alloys has been confirmed by hardness test and the corresponding results are reported in Fig. 3. The evolution of the hardness is in a good agreement with the morphology development. A relatively low value of standard deviation registered is a sign of the phase uniformity within the metal matrix. Comparable tensile strength and elongations at rupture have been obtained (Table 2), with a higher yield strength after hot forging, due to effect of the recrystallization. Additionally, an increased value of Young modulus has been obtained, which is considered as a drawback for such application. Hot forging, as mechanical processing after casting, is not capable to regulate the Young modulus and to obtain a value as closest as possible to the Young modulus of the bone.

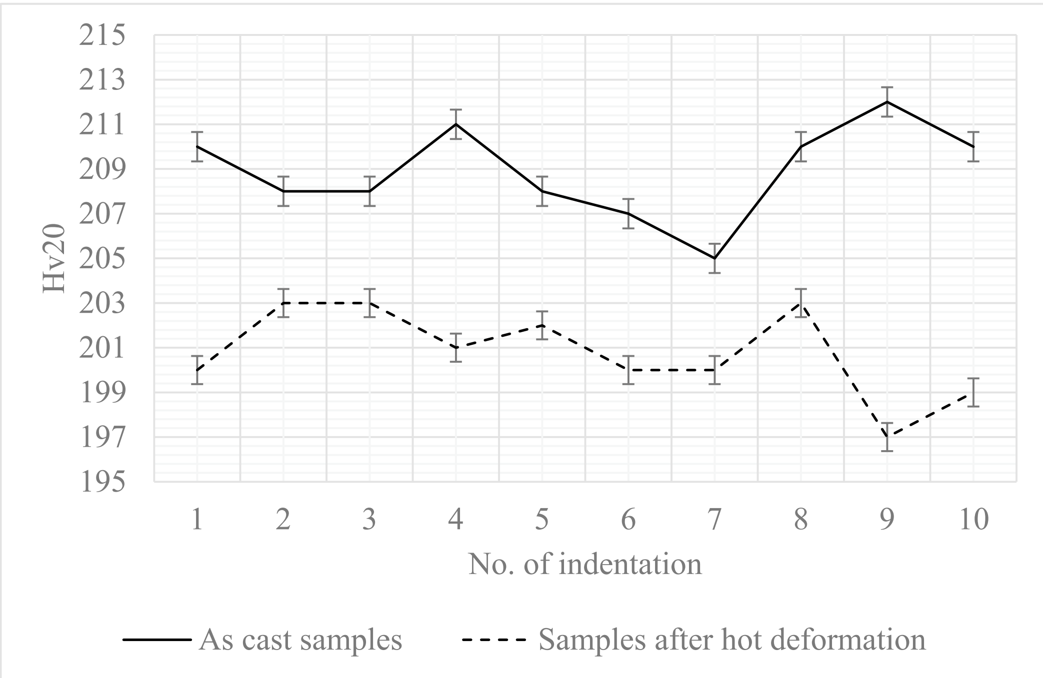

Fig. 3. Vickers hardness test results for the considered alloys.

Table 2 Mechanical characteristics measured for the studied alloys

	Young Modulus (GPa)	YS (MPa)	UTS (MPa)	ε_{Fmax} (%)
As cast alloy	59±3	234±30	672±10	35±5
Hot forged alloy	73±3	487±30	628±10	35±5

3.2. Corrosion resistance evaluation

The corrosion resistance has been assessed to estimate the biocompatibility of the alloy, in terms of ions release in the physiological solution. It was observed that the alloy reveals an excellent corrosion resistance in a simulated human environment, since no important release of any metallic ions has been detected for the period of 28 days (Fig. 4). Based on the experimentally obtained results, the alloy shows adequate properties for biomedical purpose. This is in accordance to some literature data obtained by electrochemical measurements [11]. For the reason that the as-cast alloy shows lower value of Young modulus and actually is the best candidate for the complete medical device construction, the numerically investigation of the "smart" orthopaedic device placed inside the body and used for communication with an external base stations to monitor some human vital functions have been oriented only on this alloy.

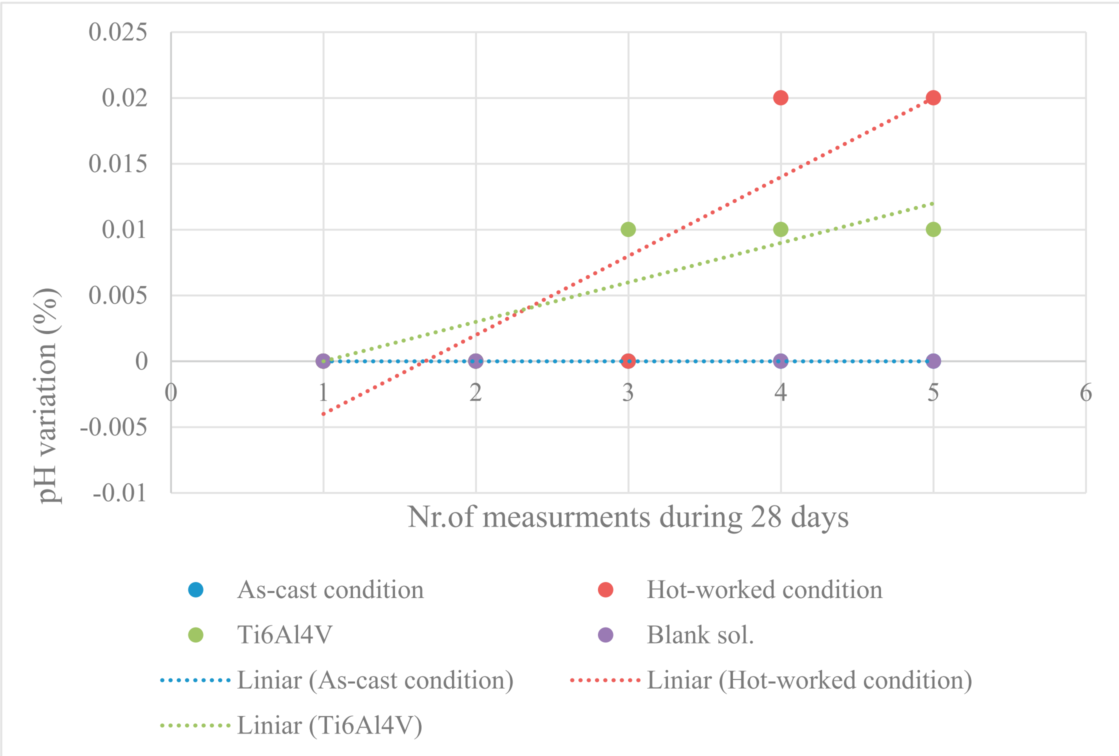

Fig. 4. Variation of the pH value during 28 days of investigation.

3.3. Electromagnetic performances

Real-time monitoring or transmitting data from inside the body toward an external receiver requires the presence of an appropriate implanted system. Any such system includes an antenna, which shapes and dimensions are strongly influenced by different parameters, as for example the position inside the body. Managing space constraint is a challenging issue in the design of implanted antennas. The shape of the antenna in turn determines its electric performances, such as operational bandwidth, radiation efficiency, etc. Link-budget also requires special attention, since the power density decays vary rapidly in the dispersive, lossy medium as the body is. On the other hand, because of the different tissues present in the body, an accurate model of them is mandatory to avoid loss of communication and to longer the power supply operational time. Directivity, which is proportional to the antenna dimensions, is also important. For a larger value, corresponding to a higher capability of concentrated radiated energy in a given direction, larger dimensions are necessary, which are not always possible due to space constrain.

In this challenging operational scenario, the proposed conductive geometry of cylindrical shape can be used as ground plane for an implanted, conformal, printed antenna, representing an intrinsically reduced space solution, since no additional ground plane must be considered. In the following, such a configuration is presented: a sketch of the proposed multilayer body model configuration is reported in Fig. 5.

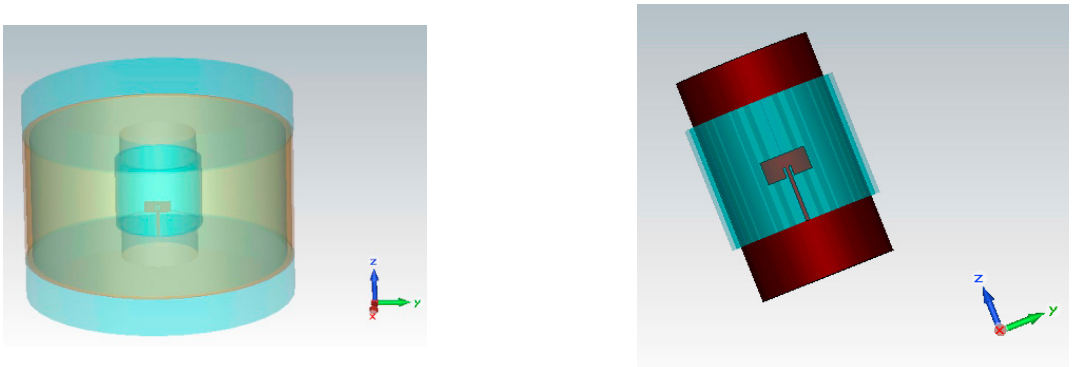

Fig. 5. CAD model of the proposed antenna configuration: (left) antenna embedded in a PDMS layer around the metallic cylinder; (right) antenna with the surrounding tissues. The top and bottom layers are electromagnetic absorbers, used in the numerical simulations.

In the CAD model, the different tissues have been modeled according to dielectric data available in the literature [19]. For convenience, the considered values are reported in Table 3. For the sake of completeness, it should be noted that the values chosen are averages that can vary by up to 50%, and that the electric parameters of bone and tissue are strongly frequency dependent (see, e.g. [20]) and this dispersion has been taken into consideration during the numerical analysis.

Table 3: Electric parameters of the different tissues and materials at the central frequency of the considered 2.4-2.5 GHz IMS band

Tissue	Relative dielectric constant	Electric conductivity [S/m]	Thickness [mm]	Note
Bone	13.1	0.09	30	-
Ti-Nb	-	1e7	30 (as Bone)	-

Muscle	57.1	0.79	70	-
Fat	5.6	0.04	4	-
Skin	46.7	0.69	2	-
PDMS	2.667	0.037	2+2=4	The antenna is located at the interface between the two layers.

The patch antenna and feeding line are made of the same TiNb material of thickness th_{met} = 0.5 mm. The overall structure is bended around the metallic cylinder and supported by a biocompatible PDMS layer of thickness th_{PDMS} = 2 mm. A second layer of PDMS of the same thickness has been used to cover the antenna. With such a solution, the antenna is fully embedded in the polymer. The PDSM layer(s) are totally covering the cylinder's perimeter for ease the manufacturing of the proposed configuration. Additionally, as it will be discussed later, this solution allows propagation of surface waves around the cylindrical ground (creeping wave). Due to the curvature of the conformal geometry, these waves propagating along the metal-dielectric interface will radiate in different directions (as leaky waves), that will generate a wide beam.

The width of the feeding line of w_{feed} = 1.5 mm has been obtained by numerical optimization enforcing the standard 50 Ω line characteristic impedance in the operating conditions, i.e. considering the curvature and multilayer substrate-superstrate scenario. The radiating element is a rectangular patch of dimensions l_{ant} = 9.86 mm, w_{ant} = 20 mm, that guarantees a matching of S_{11} = -35 dB at the central frequency f_c = 2.45 GHz of the Industrial Scientific and Medical (IMS) frequency band. In the present study the worldwide available 2.4-2.5 GHz band has been targeted [21]. The two identical slots (each of dimension 4.35 x 1 mm^2) on the two sides of the feeding line have the role of increasing the impedance match. The length of the antenna l_{ant} is well below the length of the hip of an adult. The length of the feeding line is longer than in the case of the actual system when the antenna is directly connected to the sensor node. Because of the high loss, the boundaries of the cylindrical geometries do not influence the considered performance – matching and radiation pattern, since the reflected field from the open end is very low. However, in the simulations an Ecosorb type material has been used at the two ends of the truncated structure to reduce the reflection.

The frequency response of the antenna is reported in Fig. 6.

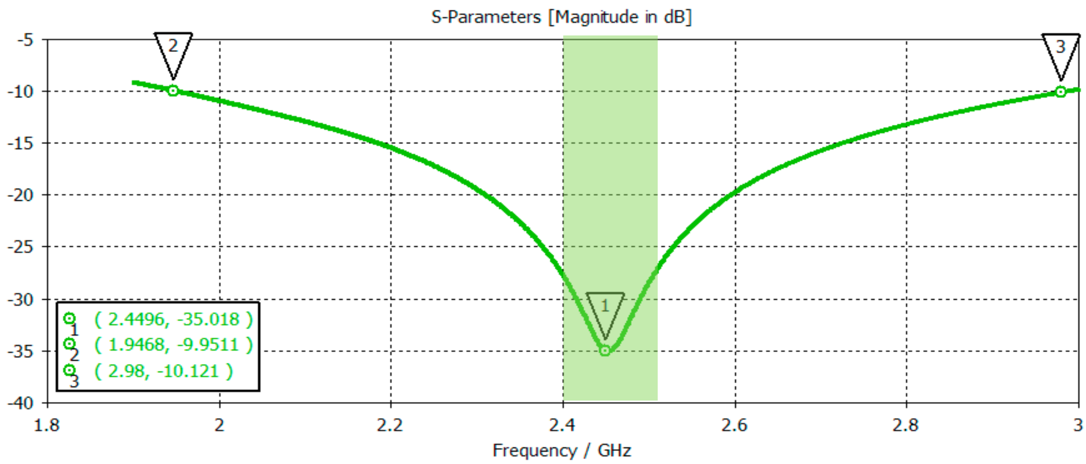

Fig. 6. The scattering parameter S_{11} of the proposed antenna inside the multilayer body model. The ISM band is explicitly indicated by the patterned rectangle. The -10 dB bandwidth limits are also clearly pointed out.

The 3D radiation pattern at the central frequency of the considered configuration is reported in Figure 7, while in Figure 8 2D cuts in the orthogonal to the cylinder axes plane are reported for the lowest, central and the highest frequency values. A wide-angle ±120 deg. coverage is observed with a ripple of less than 3 dB.

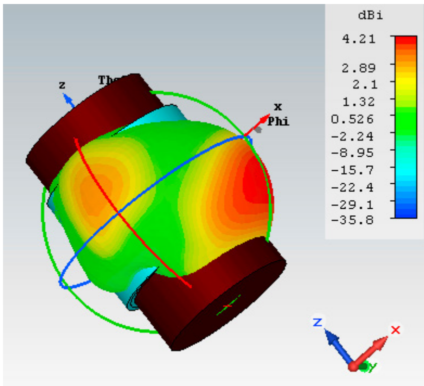

Fig. 7. Directivity at the central frequency of the IMS band, i.e., f_c=2.45 GHz.

As expected, the main radiation is in the direction orthogonal to the antenna (xz-plane). The small tilt is due to the radiation from the surface waves propagating parallel to the cylinder and from the feeding line. In the actual scenario the length of this line can be strongly reduced which in turn will also reduce the losses and the tilt angle. Furthermore, the radiation pattern presents two other lobes in the backward direction, symmetrically positioned with respect to the symmetry axis of the structure. They are due to the surface waves propagating along the metal-PDMS interface around the metallic cylinder. While usually the presence of different lobes is not desired because their presence reduces the gain of the antenna, in some applications their presence allows free movement of the incorporating body; the link between the body and the receiving external base station is guaranteed by the more omnidirectional-like pattern.

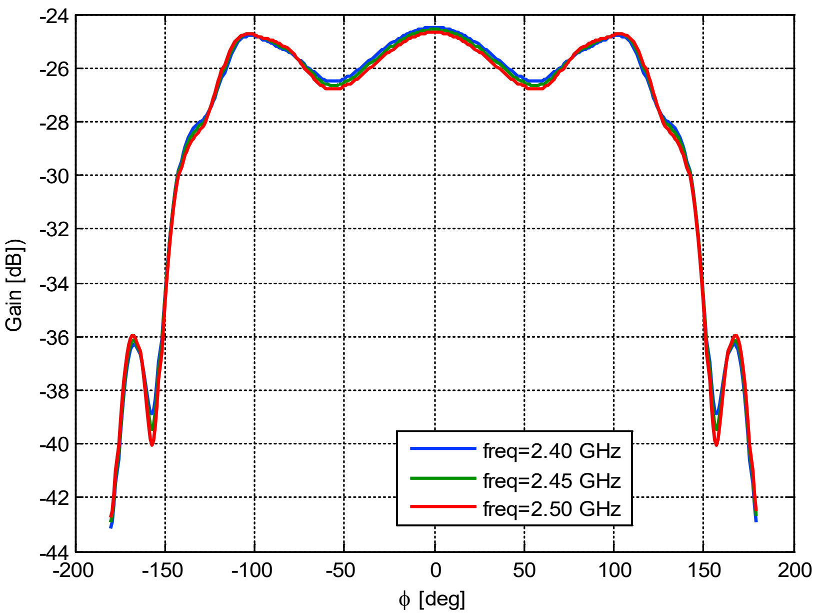

Fig. 8. Gain at the lowest, central and the highest frequency of the IMS band.

4. Conclusions

We investigated TiNb metallic alloy for biomedical applications and we use it, in as-cast condition, as ground plane for a conformal printed antenna. Cold Crucible Levitation Melting technique is able to produce a homogeneous structure with no any presence of inclusions or local defects as shown the microstructural and mechanical properties. From corrosion resistance point of view, the considered alloys fulfil the conditions required for the release of metal ions in the simulated biological solution.

The alloy exhibits good properties making it a good candidate for the considered application and for the realization of the "smart" orthopedic device. Application of PDMS layer on the metallic surface and introduction of the printed antenna embedded in a PDMS layer have successfully been realized. The numerically investigated structure exhibits good matching and radiation properties for body centered communication applications. The results obtained demonstrates that using such alloy without any further coatings is possible which is economically convenient and leads obtaining compact size of the devices.

Using this approach, it would be possible to monitor the human vital functions by placing such devices in the different helpful positions on and near the human body with the possibility to communicate with each other with no any negative health effects for the people.

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