An innovative therapy for peri-implantitis based on radio frequency electric current: numerical simulation results and clinical evidence

G. Cosoli, L. Scalise, G. Tricarico, E.P. Tomasini, G. Cerri

Abstract— **Peri-implantitis is a severe inflammatory pathology that affects soft and hard tissues surrounding dental implants. Nowadays, only prevention is effective to contrast peri-implantitis, but, in recent years, there is the clinical evidence of the efficiency of a therapy based on the application of radio frequency electric current, reporting that 81% of the cases (66 implants, 46 patients) were successfully treated. The aim of this paper is to present the therapy mechanism, exploring the distribution of the electric currents in normal and pathologic tissues. A 3D numerical FEM model of tooth root with a dental implant screwed in the alveolar bone has been realized and the therapy has been simulated in COMSOL Multiphysics® environment. Results show that the electric current is focused in the inflamed zone around the implant, due to the fact that its conductivity is higher than the healthy tissue one. Moreover, by means of a movable return electrode, the electric current and field lines can be guided in the most inflamed area, limiting the interference on healthy tissues and improving the therapy in the area of interest. In conclusion, it can be stated that this innovative therapy would make a personalized therapy for peri-implantitis possible, also through impedance measurements, allowing the clinician to evaluate the tissue inflammation state.**

I. Introduction

Peri-implantitis is a very serious disease, affecting tissues that surround a dental implant [1]. In fact, it causes bone loss, inflammation of soft tissue (i.e. gingiva and connective tissue in general) and bacterial infection (which determines bacteria adhesion to the implant surface) [2]. This pathology can be caused by different factors, such as bad positioning of the implant, poor oral hygiene, poor quality of alveolar bone and untreated periodontitis or dental caries near the implant itself [1]. The prevalence of this pathology was recently estimated at 9.6% of annually placed dental implants [3], that is a significant number if it is considered that in Italy alone over a million implants are placed every year [4]. Peri-implantitis is still the main cause of implant failure [5], since no completely effective therapies are acknowledged so far. In fact, in clinical practice, different therapies have been experimented, like mechanical non-surgical treatments, administration of antibiotics and antiseptics or laser therapy [6]. However, the success rate is not satisfying, so that at present prevention is the only mean to contrast peri-implantitis.

But in recent years (2002-2015) an innovative therapy has been given by Dr. Tricarico in his dental laboratory [7]. This treatment consists in the application of radio frequency alternating electric current, which produces beneficial effects on the peri-implant tissues affected by peri-implantitis. It can be hypothesized that these results are linked to the properties of electromagnetic irradiation, which permits the inhibition of bacterial growth, supports the antibiotic effect, accelerates bone healing and peri-implant bone formation, reduces bone resorption and decreases the inflammatory response [5]. It can be immediately observed that there are effects just on the main characteristics of peri-implant pathology. So, such a therapy can provide a chance to recover a dental implant, which otherwise would be fated to removal.

In this work, at first the authors will present the clinical evidence of this therapy by means of the follow-up data revised up to the last year (i.e. 2015). Moreover, in order to better understand the therapy acting mechanism, a 3D numerical FEM model will be shown and so the therapy simulation. In this way, it will be possible to observe the electric current and field distribution in peri-implant tissues and also to think at methods to improve the therapy and to personalize it according to the pathology severity.

II. Materials and Methods

A. Clinical follow-up

55 patients (27 males, 28 females, aged 55±8), for a total of 81 implants, were treated with the innovative therapy (following the principles outlined in the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects). It consisted in the application of a radio frequency (hundreds of kHz) alternating current, with a duration of few hundreds of milliseconds, between two electrodes: an active electrode, screwed to the implant (in order to make a good electrical connection), and an electrode of return, put in contact with the gingiva. In case of particularly severe pathology, the treatment was repeated, up to a maximum of three times. Follow-up data are relative to 2002-2015 years.

The implants included in the therapeutic treatment were placed in different positions, as reported in "Fig. 1 A)"; the number of treated implants per year is reported in "Fig. 1 B)".

The success of the therapy was evaluated by observing the colour of the gingiva, bleeding, the probing depth of peri-implant pockets, suppuration and also by means of x-rays (to measure the bone height around the implant), that is the typical peri-implantitis diagnosis [8].

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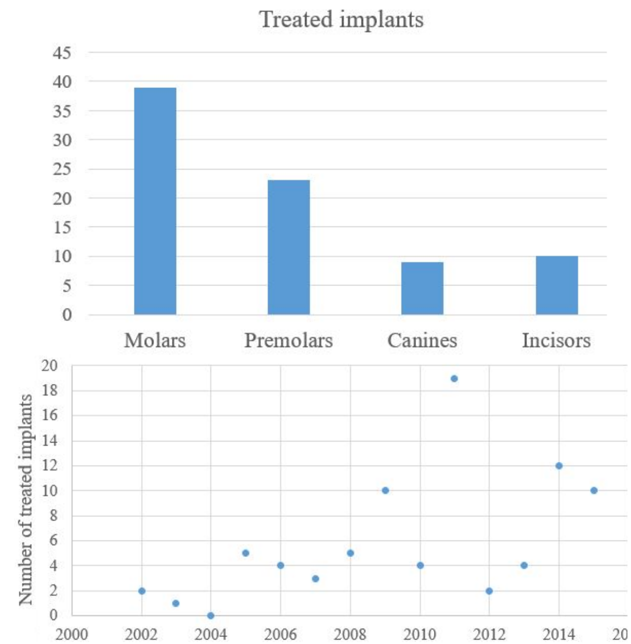

Figure 1: A) Position of the treated implants and B) Number of implants treated per year

B. 3D numerical FEM model

A 3D numerical FEM model was built in COMSOL Multiphysics® environment [9] in order to reproduce the peri-implant tissues treated by means of radio frequency electric current. A simplified geometry was considered: alveolar bone, gingiva (considered more generally as connective tissue) and inflamed gingiva. The dental implant dimensions were similar to those of a premolar tooth root [10]: 14 mm in length, 4 mm in diameter. For the sake of simplicity, changes in geometric dimensions of the inflamed tissue were not considered, even if the inflammatory process is actually characterized by oedema (i.e. swollen tissue).

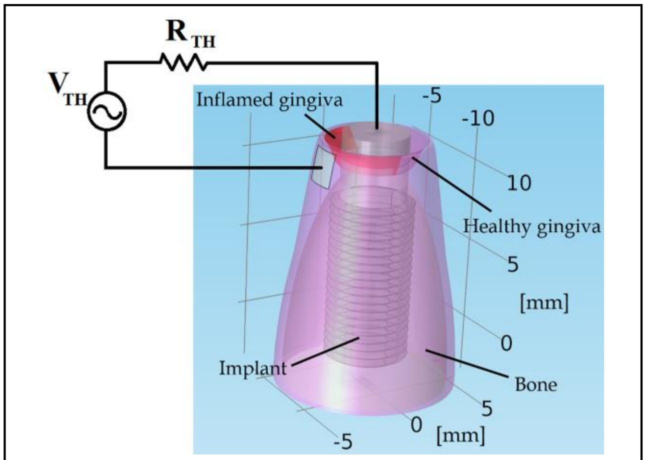

Figure 2: 3D numerical FEM model, formed by dental implant screwed in the alveolar bone and surrounded by gingiva (part of which is inflamed, red in Figure); the active electrode is the implant itself, while the return electrode is adhering the gingiva

In order to simulate the therapy, the implant (realized in titanium) was connected in series with a generator, modelled according to the Thevenin equivalent circuit of the medical device used in clinical practice. The return electrode was represented as a metallic square surface of about 4 mm^2 adhering to the gingiva and fixed at 0 V potential. The model is reported in "Fig. 2".

The tissues electrical parameters, particularly electrical conductivity, relative permittivity and relative permeability, were taken from the literature [11]–[13]. As regards the inflamed tissue, complying with the literature results [14], its conductivity (σ, [S/m]), was considered 2 folds higher than that of the corresponding healthy tissue, as described in (1):

$$\sigma_{inflamed\ gingiva} = 2 * \sigma_{healthy\ gingiva} \quad (1)$$

The relative permittivity of the inflamed gingiva was instead considered equal to the healthy gingiva one, since, to the authors' knowledge, there is no information on this issue in literature. Tissues electrical properties are reported in "Tab. 1".

TABLE I. TISSUES ELECTRICAL PROPERTIES

Tissue	Electrical properties	
	σ [S/m]	*ε_r []*
Gingiva	0.39	245
Inflamed gingiva	0.78	245
Bone (cortical)	0.021	190

The numerical study is carried out by solving the Laplace equation for complex potential (2):

$$J = J_c + J_d = \sigma E + j\omega\varepsilon_0\varepsilon_r E = (\sigma + j\omega\varepsilon_0\varepsilon_r)E \quad (2)$$

Electric field can be expressed as a gradient of scalar electric potential ($E = -\nabla V$), so, through the equation of charge conservation ($\nabla \cdot J = 0$), it is possible to write (3):

$$\nabla \cdot [(\sigma + j\omega\varepsilon_0\varepsilon_r) \nabla V] = 0 \quad (3)$$

The boundary conditions are V = V0 (where V0 is the amplitude of the generator voltage) on the active electrode, V = 0 V on the return one.

After meshing, equation (3) is solved numerically and the current density distribution from (2) is calculated.

Moreover, the return electrode was placed in a different position, to prove the capability of driving the therapy just in the impaired area.

Finally, the electrical impedance of the tissues, that is their opposition to the passage of the therapeutic alternating current, was quantified.

III. RESULTS

A. Clinical follow-up

81% of the implants (i.e. 66), corresponding to 84% of the patients, were successfully treated by Dr. Tricarico in his dental laboratory. In fact, x-ray images show that the peri-implant bone healed after the therapy and the bone resorption was arrested (not more than 0.2 mm per year [15], which can be considered not pathologic). Finally, also the inflammation symptoms were absent after the treatment (i.e. not oedema, bleeding, suppuration nor redness of the gingiva). An example of x-ray images before and after the therapy is reported in "Fig. 3": it is possible to see that the bone completely regenerated after the therapy, allowing the dental implant to recover its stability. The unsuccessful cases were linked to very particular conditions, such as chemotherapy, serious aenemia or significant horizontal/vertical bone reduction; all these critical aspects will be considered as exclusion criteria for the therapy in the future.

B. 3D numerical FEM model: electric current and field distributions and electrical impedance values

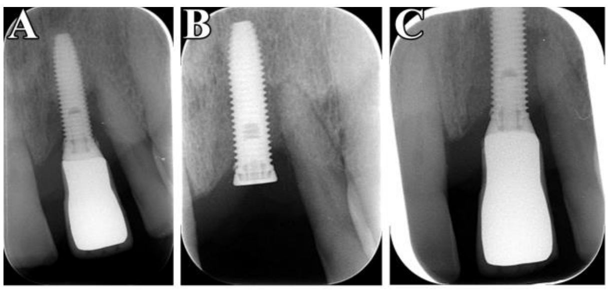

Figure 3: Example of x-ray image of an implant in three different moments: A) before the therapy B) 1 month after the treatment and C) 8 months after the treatment

Results provide the electric current ("Fig. 4") and field ("Fig. 5") distributions in the peri-implant tissues.

The distributions of electric current and field obviously depend on the electrical properties of biological tissues involved (soft tissues, like gingiva or connective tissue of parodont, but also hard tissue, such as periodontal bone).

Despite numerical errors linked to the edge effects, it can be observed that the maximum current density is in correspondence of the inflamed gingiva area, because its higher conductivity and so the greater easiness to be passed by electric current. On the contrary, the electric field crosses also hard tissues, possibly acting on the bone regeneration.

Moving the return electrode, it is possible to focus the therapy in a different area, driving the electric current and field lines; in "Fig. 6", there is an example of the electric

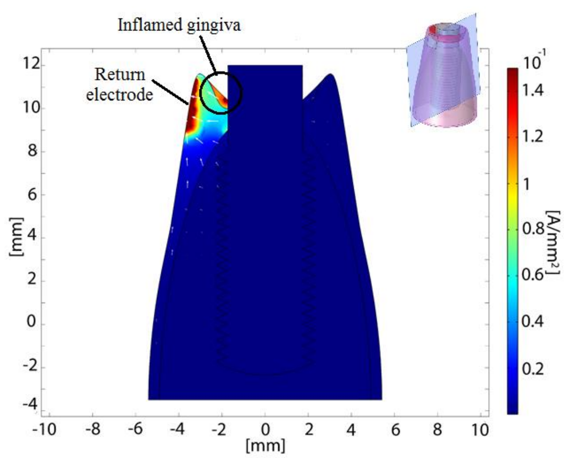

Figure 4: Distribution of electric current (frontal section of the model); apart from edge effects on the electrode, it can be observed that the maximum current density is in correspondence of the inflamed gingiva

current lines driven by the return electrode, placed lower on the gingiva.

As regards the electrical impedance values, the results are reported in "Tab. 2", both for the inflamed and the healthy side of the gingiva.

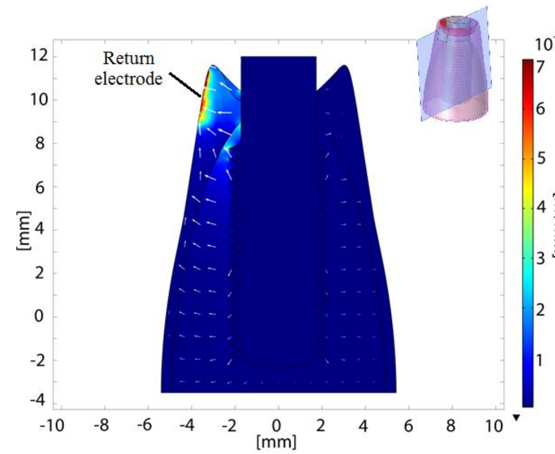

Figure 5: Distribution of electric field lines (frontal section of the model); it can be observed that they significantly involve also hard tissues, on the contrary of the electric current

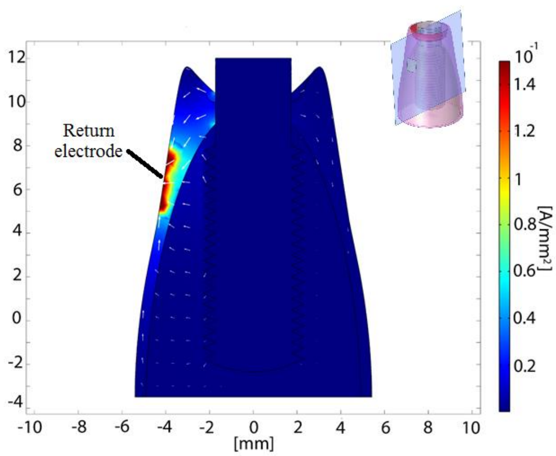

Figure 6: Distribution of electric current (frontal section of the model) in case of return electrode placed lower; it can be noted that current lines are driven by this electrode position

TABLE II. TISSUES ELECTRICAL IMPEDANCE VALUES

Inflamed side, Z [Ω][a]			Healthy side, Z [Ω][a]		
|Z|	*Z_Re*	*Z_Im*	*|Z|*	*Z_Re*	*Z_Im*
498.36	498.33	-5.56	557.56	557.52	-6.91

a. |Z| is the modulus of the electrical impedance modulus, Z_Re is its real part and Z_Im is its imaginary part

It can be noted that the impedance concerning the inflamed side is lower than that of the healthy one; in particular, if the impedance modulus is considered, a percentage difference higher of ≈10% can be computed.

IV. CONCLUSION

With the present work, the authors, supported by the clinical evidence of an innovative therapy for peri-implantitis (success rate equal to 81%), have built a 3D numerical FEM model of a dental implant with the typical peri-implant tissues (i.e. alveolar bone and gingiva) and have simulated the treatment, modeling the biomedical device by means of its Thevenin equivalent circuit.

This model allowed them to better understand both the working principle of such a therapy and the agents arousing beneficial effects on the pathology. In particular, it can be thought that the anti-inflammatory effect is linked to the electric current passing the soft tissues, while the bone healing is accelerated by the electric field (stimulation of bone formation by means of pulsed electromagnetic field is well documented in literature [16], [17]). Moreover, the presence of liquids in the inflamed tissues increases their electric conductivity and this makes the electric current focus on them, so localizing the therapy and minimizing the effects on non-interested areas. In addition, moving the return electrode in a proper position permits to drive the therapy in the impaired area.

Besides the therapy, such a medical device can include a part designated to the diagnosis of the inflamed tissues and of the severity of the pathology, which is somehow linked to the electrical impedance values measured. At present, a comparison between healthy and inflamed tissues is possible [18], but an individual classification is not, since it would be necessary to perform a wide measurement campaign to establish what the physiological range of the tissues impedance values is and what their variability is.

Such a use of bioimpedance measurements with a diagnostic aim would be a novel application of bioimpedancemetry, which nowadays is widely used in different area of medicine, such as the analysis of the body composition [19], the diagnosis and the monitoring of tumours [20] and inflammatory diseases [14], [21], [22].

This innovative therapy is now designed for peri-implantitis, but its application can be widened in the future to other kinds of implants and pathologies presenting similar characteristics (i.e. inflammation, bacterial growth and bone resorption). A fundamental aspect would be the design of the electrodes, which should be adapted to the treated tissues in order to guarantee an optimum electrical connection.

The success of radio frequency electric current would allow the clinician to recover implants otherwise destined to removal and could also bring economic advantages both to dentists and to patients, given that the global dental implantology market has a volume of some million dollars [23], [24].

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