Modeling of a New Percutaneous Orthopedic Implant System to Control the Post-surgery Osseointegration Process

Mohamed Faoussi (PhD)[1]*, Salim Bounou (PhD)[1], Mohammed Wahbi (PhD)[2]

[1]Euromed Research Center, BiomedTech Engineering School, University EUROMED de Fès, Fez, Morocco
[2]Systems Engineering Laboratory, The Intelligent Systems and Sensor Networks team, EHTP, Casablanca Morocco

ABSTRACT

This study presents a mechanical model of a novel medical device designed to optimize the osseointegration process in upper and lower limb amputees, leading to the promotion of optimal rehabilitation. The medical device is developed to reduce the risk of implant failure, leading to re-amputation above the implant. The proposed model serves several purposes: 1) to guide the osseointegration process by providing electrical endo-stimulation directly to the bone-implant contact site, using an invasive electrical stimulation system, which is implanted in the bone permanently, 2) to locally transmit stem cells after implantation, without the need for opening the skin or perforating the bone, which is particularly useful for regenerative medicine after partial healing of the implant, 3) to transmit necessary nutrients from the bone, also without opening the skin or puncturing the bone, and 4) to combat infections by locally administering drugs after implantation.

Citation: Faoussi M, Bounou S, Wahbi M. Modeling of a New Percutaneous Or-thopedic Implant System to Control the Post-surgery Osseointegration Process. *J Biomed Phys Eng*. 2024;14(2):199-208. doi: 10.31661/jbpe.v0i0.2304-1612.

Keyword

Osteointegration; Amputees; Implant; Orthopedic Surgery; Electrical Endo-Stimulation

Introduction

Traumatic amputations or those resulting from oncological surgery frequently occur in proximity near to the adjacent joint, posing challenges related to infection and wound healing. Based on a conventional socket prosthesis, achieving optimal rehabilitation outcomes is often difficult for the patients (Figure 1A) [1]. The traditional socket prosthesis fails to fulfill the criteria of comfort, safety, freedom of movement, and cosmetic considerations, significantly impacting the amputee's quality of life.

However, osseointegration presents an optimal solution to improve the quality of life of amputees, this technique is widely used in dental surgery, facial reconstructions, hearing aids, and as an alternative to the conventional suspended prosthesis for patients suffering from upper/lower limb amputations.

According to the principle of osseointegration, the prosthesis anchored directly in the bone is attached to the residual limb without the use of any contact socket, eliminating all problems related to heat, perspiration, and discomfort (Figure 1 B).

Osseointegration is the direct contact between bone tissue and a biomaterial, without any fibrosis. The use of titanium as a biomaterial is

*Corresponding author:
Mohamed Faoussi
Euromed Research Center, BiomedTech Engineering School, University EUROMED de Fès, Fez 3000, Morocco
E-mail: m.faoussi@ueuromed.org

Received: 28 April 2023
Accepted: 20 May 2023

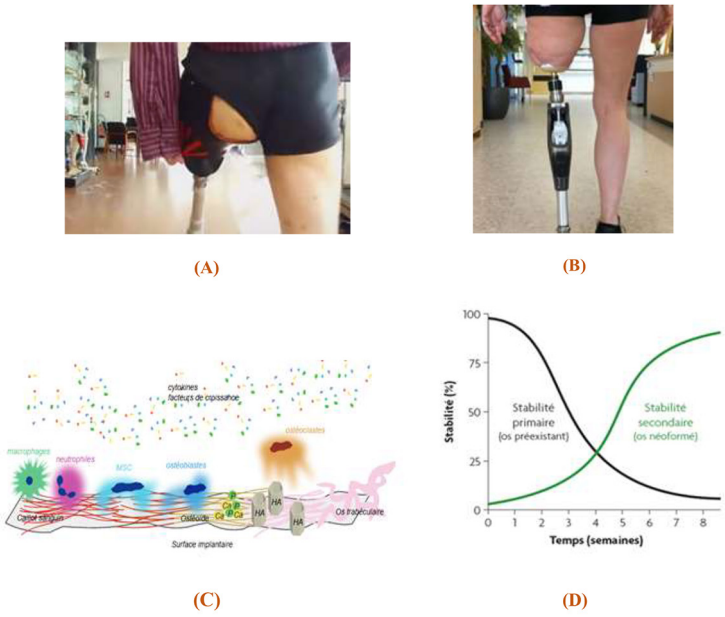

Figure 1: Picture of two patients with traditional and bone anchored prosthesis, plus two diagrams of the osseointegration process. (**A**) a patient with a traditional socket prosthesis, (**B**) a prosthesis anchored directly in the bone according to the principle of Osseointegration, (**C**) a biological program of the Osseointegration process, (**D**) a diagram of the two phases of osseointegration "Mechanical phase" and "Biological phase".

useful due to its biocompatibility and resistance to corrosion [2-3]. Also, the titanium bone during osseointegration is integrated by plastic deformation of the bone/implant interface, i.e., titanium is incorporated into the bone permanently [4-5].

After placing the implant, the osseointegration process is a well-defined biological program, as follows (Figure 1 C) [6-7]:

-The osseointegration process involves several steps, including 1) an alliance forms between proteins of the inflammatory response and blood platelets, resulting in the formation of a fibrin network. Fibrin network serves as a foundation for the cells required for bone remodeling to move into place. The second stage is the release of chemical mediators, triggering a cascade of cell activations, including macrophages and neutrophils. The macrophages and neutrophils cells are responsible for cleaning up the site, removing pathogens, and managing the inflammatory metabolism.

-The previously formed fibrin network also causes Mesenchymal Stem Cells (MSC) to migrate into the site. Mesenchymal Stem Cells (MSCs) differentiate into osteoblasts, gradually replacing the fibrin matrix with a collagen bone matrix. Calcium (Ca) and phosphate (P) ions are deposited on this collagen matrix to form crystals of Hydroxyapatite (HA).

-Finally, osteoclasts start to remodel neosynthesized bone tissue. The combination of osteoblasts and osteoclasts helps to remove small imperfections and make mature bone stronger [7-8].

According to the well-defined biological program of Osseointegration, the scaffold is essential for the migration of osteoblasts and mesenchymal cells to form a compact bone, resulting in immediate stability of the implant after surgical placement. To achieve this cell migration, the implant must be immediately stable after surgical insertion. In the literature, this immediate stability is referred to as "pri-

mary" or "mechanical" stability [9-10], showing the level of immobility of an implant after surgical placement. Primary stability is a mechanistic criterion that promotes bone healing [9].

After gradually decreasing the initial mechanical stability, it is replaced by "secondary stability", or "biological stability = biological process of osseointegration" [10] (Figure 1 D).

Accordingly, the bone formation and remodeling at the implant interface resulted in a larger bone-implant contact surface. However, primary instability leads to experiencing persistent micromovements of the bone-implant interface. The important micromovements lead to fibrointegration of the implant, synonymous with implant failure. Today, it is feasible to quantify the magnitude of acceptable micromovements, typically ranging between 1000 and 2000 Å (Angstroms) [11-12].

In addition, an extensive comparative study examining various bone-anchored implant concepts [1, 13] introduced a new implant (Patent No. MA41535) [14]. This innovative implant combines three techniques, namely threading, skeletal integration through a microporous structure, and Morse fixation on the lateral sides. The result is comprehensive mechanical stability, as demonstrated by the study.

Besides, many research teams have shown the benefit of electrical simulation to consolidate and repair fractures [15-17], including the activation of osteoblast differentiation in the early stages of bone healing. In the literature [18], three operating modes are taken into consideration for this purpose:

1. Invasive mode: both electrodes are directly implanted at the fracture site.

2. Semi-invasive mode: In this mode, only the cathode is implanted, while the anode is placed on the skin.

3. Capacitive mode: In this mode, both electrodes are positioned on the skin on either side of the fracture.

The invasive mode of electrical stimulation, including direct bone-electrode contact, is highly effective, despite the risk of infection as the doctor needs to either open the skin or pierce the bone. Alternatively, the semi-invasive mode utilizes only the implanted cathode, with the anode placed on the skin. In the capacitive mode, both electrodes are positioned on the skin on either side of the fracture. While the invasive mode demonstrates effectiveness due to direct bone-electrode contact, it is important to consider the associated risk of infection [19].

However, the new technique includes a medical device that enables the osseointegration process for monitoring from t. The new technique incorporates a medical device that facilitates the monitoring of the osseointegration process externally following the surgical placement of the orthopedic implant. The medical device consists of several components, including:

1. Invasive electrical stimulation system: establishing direct contact between the electrical stimulation and the bone-implant interface, promoting osseointegration.

2. Regenerative medicine capability: transitioning stem cells from the outside, offering the potential for regenerative medicine applications after implant placement.

3. Local transmission of drugs: enabling the targeted delivery of drugs directly to the affected area, leading to the injection of necessary nutrients if required.

Technical Presentation

This study introduces an intelligent medical device model designed to regulate the osseointegration process after the surgical placement of an orthopedic implant and subsequent closure of the skin. This device leads to medical specialists to intervene directly at the bone/implant interface externally to prevent implant failure in amputee patients. Developed using Catia V5 computer-aided design software on the 3DEXPERIENCE platform, the novel medical device offers doctors enhanced flex-

ibility in implementing medical protocols for bone healing. This includes the capability to inject drugs, and nutrients, and apply electrical stimulation as necessary (Figure 2 A).

An invasive system of electrodes for electrical endo-stimulation, directly on the internal part of Bone-Implant contact without opening the skin or piercing the bone (Figure 2 B, C, and D). A mechanical system with multiple functions, according to the decision of the surgeon causes the following issues (Figures 2 B, 3 A, B).

•Local administration of stem cells, in case of regenerative medicine.

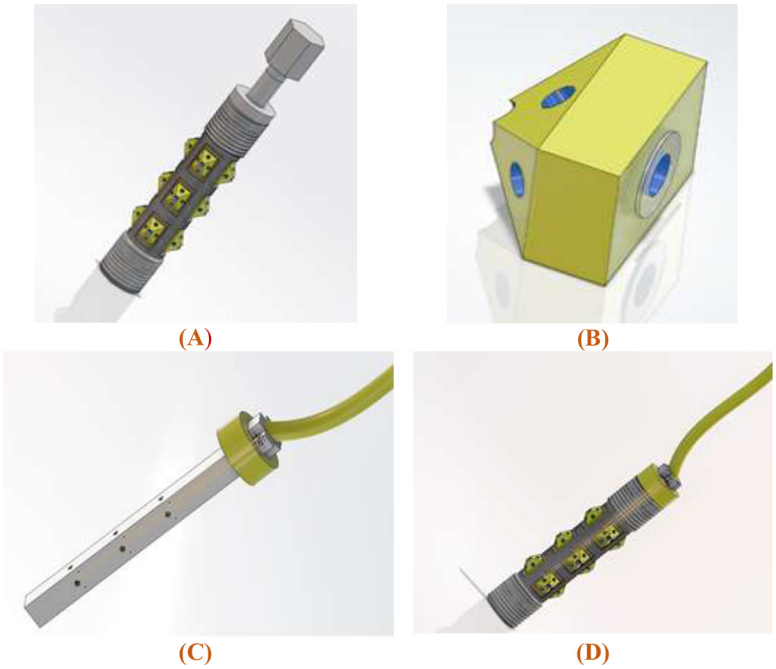

Figure 2: Compositions of our electrical stimulation system; (**A**) Intelligent Osseointegrated Orthopedic Implant System, (**B**) A multifunctional mechanical part, which is at the same time: mechanical fixation pin; electrical stimulation electrode or tubing for the transmission of stem cells, drugs and nutrients, (**C**) An external electrical stimulation system, attached to the secondary cylinder and placed in contact with the initial mechanical fixation pins in order to transform them into electrical cathodes to ensure direct electrical stimulation (DES), without the need for intervention surgery to remove these cathodes, (**D**) Combination of our medical device with the external electrostimulation system

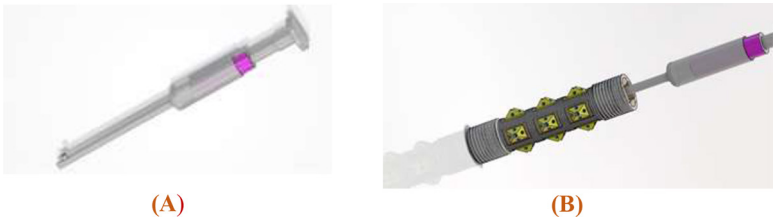

Figure 3: Picture of injecting: stem cells, transmitting drugs or nutrients according to the decision of the surgical specialist; (**A**): An external system for injecting stem cells, transmitting drugs or nutrients according to the decision of the surgical specialist, (**B**): An external ancillary injection of the desired substance (stem cells, medicine or nutrients)

•Local transmission of drugs in case of infections or bone nutrients when needed.

The new medical device encompasses several elements, and their principles and methods of operation are elaborated as follows:

1. Osteo-integrated, intelligent, and Percutaneous Orthopedic Implant System (Figure 2 A), ensuring complete primary stability by combining three techniques: threading, a microporous structure, and fixation pins. It provides direct access to the bone-implant interface through conduits within the fixing pins, leading to various interventions, such as regenerative medicine (injection of stem cells), administration of drugs for infections, and the delivery of necessary nutrients. Importantly, these interventions can be performed without reopening the skin or piercing the bone.

Additionally, the medical device enables bone consolidation through direct electrical stimulation (DES) after implant placement, eliminating the requirement for additional surgical procedures to implant cathodes for electrical stimulation. Instead, the mechanical attachment pins serve as direct electrical stimulation cathodes when combined with the external electrical system.

Moreover, the surgeon retains the capability to access the medullary canal of the femur directly (inside the hollow main cylinder housed in the bone, as depicted in Figure 4 A) after implant placement, without resorting to surgery. This eliminates the possibility of micro-movements, leading to infections or implant loosening, ultimately preventing implant failure.

Figure 4: Composition of the osseointegrated orthopedic implant system; (**A**): Hollow Main Cylinder of our Medical Device, (**B**): Specific ancillary tool for positioning the hollow main cylinder in the medulla canal, (**C**): A secondary cylinder of our Medical Device (in the left) with Specific ancillary for it's positioning in the hollow main cylinder, (**D**): A permanent spacing maintenance system for the secondary cylinders, with a transcutaneous side, (**E**): An abutment on the transcutaneous side of the spacer maintenance system, which is an attachment system for the removable orthopedic prosthesis

This medical device is distinguished by the following characteristics:

1. Hybrid mechanical system for complete initial fixation: The device incorporates a combination of three techniques - threading, microporous surface, and fixation pin - to ensure comprehensive initial fixation of the implant. This hybrid mechanical system enhances stability and promotes successful osseointegration.

2. Multifunction mechanical system: The medical device features a versatile mechanical system, adapted based on the surgeon's decision (Figure 2 B), leading to the local administration of stem cells for regenerative medicine without the need to open the skin or perforate the bone. Additionally, it enables local transmission of drugs in cases of infections or delivery of nutritive substances to the bone, which this investigation can be performed without invasive procedures.

3. DC: In situations, in which bone consolidation is necessary after implant placement, the device incorporates a direct electrical stimulation system. This obviates the need for surgery to implant separate electrodes. Instead, the mechanical fixing pins are transformed into electrical cathodes, working in synergy with an external electrical system. The electrical stimulation pathway passes through the medullary canal and inside the existing hollow main cylinder lodged within the bone.

These characteristics collectively contribute to the efficacy and versatility of the medical device, offering enhanced treatment options and avoiding the need for additional surgical interventions. This intelligent implant system includes:

-A hollow main cylinder (Figure 4 A), housed in the bone thanks to its ancillary (Figure 4 B).

-A secondary cylinder (Figure 4 C) in four fragments, placed inside the main cylinder (Figure 4 A) using a specific ancillary (Figure 4 C).

-A multifunctional mechanical part (Figure 2 B), which is at the same time: mechanical fixation pin; electrical stimulation electrode or tubing for the transmission of stem cells, drugs, and nutrients.

-An external electrical stimulation system (Figure 2 C), attached to the secondary cylinder (Figure 4 C) and placed in contact with the initial mechanical fixation pins to transform them into electrical cathodes to ensure direct DC electrostimulation, without the need for intervention surgery to remove these cathodes (Figure 2 B). This system is connected by an electrical cable to a device external to the implant, which controls the electrical stimulation (Figure 2 D).

-An external system for: injecting stem cells, and transmitting drugs or nutrients according to the decision of the surgical specialist (Figure 3 A, B).

-A permanent spacing maintenance system (Figure 4 D) for the secondary cylinders, with a transcutaneous side.

-An abutment (Figure 4 E) on the transcutaneous side of the spacer maintenance system, which is an attachment system for the removable orthopedic prosthesis.

1. Intelligent Osseointegrated orthopaedic implant system (Figure 2 A) according to part 1, characterized in that main hollow cylinder (Figure 4 A), comprises the external cylindrical face: two parts screwed at the bottom and top of the implant (lower base and upper base); A part impacted in the bone, thanks to a microporous surface structure; A third part comprising windows for the exit of mechanical parts of multiple functions (mechanical fixation, electrical stimulation, transmission of stem cells, drugs, and nutritive substances) This cylinder (Figure 4 A) also has, on its internal longitudinal cylindrical surface, ribs for guiding the ancillary device during its insertion (Figure 4 B). These ribs also serve as beams to reinforce the main cylinder (Figure 4 A).

2. Intelligent Osteointegrated orthopedic implant system (Figure 2 A) according to parts 1 and 2, characterized in that said secondary cylinder (Figure 4 C), made of electrically in-

sulating biocompatible composite materials, to electrically isolate the mechanical fixing pins (which become direct electrical stimulation (DES) cathodes in combination with the external electrical system) of the entire orthopedic implant system, this technique allows the surgeon to apply DES very precisely and in the desired area (the desired fixing pins) without passing the electric current through the entire external implant surface. This secondary cylinder is divided into four fragments, each fragment has windows for the installation of multifunction mechanical parts (Figure 2 B) according to a surgical protocol validated by the doctor. This secondary cylinder (Figure 4 C) also has a doublé groove at the top and bottom on the internal longitudinal face of each fragment, serving as an ancillary double guide for its placement (Figure 4 C).

3. Intelligent osseointegrated orthopaedic implant system (Figure 2 A) according to parts 1, 2, and 3, characterized in that said a matrix for depositing the multifunctional parts. This matrix (Figure 5) is a 2D orthogonal projection of our 3D implant system with a distribution marking of the multifunctional mechanical parts (Figure 2 B) to facilitate implantation. The objective is to leave degrees of freedom to the surgeon in the choice of the composition of the secondary cylinder elements (pins, electrical electrodes or transmission tubing).

4. Intelligent Osteointegrated orthopedic implant system (Figure 2 A) according to parts 1 to 4, characterized in that said multifunctional mechanical part which serves as:

-**Mechanical fixing pins** thanks to its mechanical shape (pyramid or cone) (Figure 2 B).

-**Direct electrical stimulation (DES) cathode** even after implant placement surgery and without the need for any other surgery, this is feasible by combining with our external electrical stimulation system which passes inside the hollow main cylinder and which is already impacted in the bone (Figure 2 C, D).

-**Tubing for the transmission** of stem cells (regenerative medicine), nutrients, or drugs through channels inside this mechanical part (in the case of infections). This transmission of stem cells, medicine, or nutrients, will be possible by an external ancillary injection of the desired substance (Figure 3 A, B).

5. Intelligent Osseointegrated orthopedic implant system (Figure 2 A) according to parts 1, 2, 3, and 5, characterized in that said

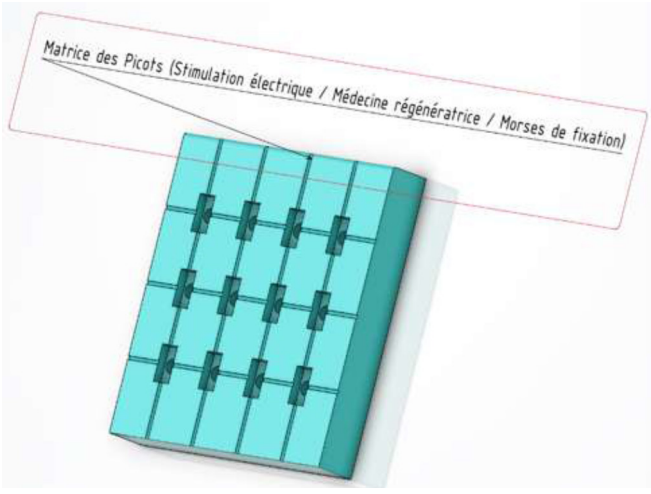

Figure 5: Matrix, which is a 2D orthogonal projection of our 3D implant system with a distribution marking of the multifunctional mechanical parts to facilitate implantation. The objective is to leave degrees of freedom to the surgeon in the choice of the composition of the secondary cylinder elements (pins, electrical electrodes, or transmission tubing)

electrical stimulation system (Figure 2 C). This system is connected by cable to an external electrical device (Figure 2 D), which controls the process of Osseointegration after the surgical placement of the implant and according to a therapy protocol validated by a medical surgeon specialist. The system (Figure 2 C) is made of an electrically insulating biomaterial and has on the external face contact points with our mechanical fixation pins in order to transform them into DES cathodes, even if after the implant surgical installation and without any need for a second surgery. So the objective is to generate DES, targeting the desired area and without the need for surgical deposition of electrical cathodes.

6. Orthopedic implant system (Figure 2 A) according to parts 1, 2, 3, and 5, is characterized in that said system definitively maintains the separation (Figure 4 D) of the secondary cylinder and for the final closure of our orthopedic implant system intelligent (Figure 2 A), it also includes on the transcutaneous part of the implant, an abutment (Figure 4 E) which is a mechanical system in the form of an attachment to fix a removable external prosthesis after a rehabilitation program is a spear.

Discussion

To better understand the principle of osseointegration, we have analyzed it in this work in order to control the fundamental factors of the success or failure of this process. We have therefore demonstrated that the process of osseointegration follows a well-defined biological program, therefore the scaffold formed by a network of fibrins is an essential element for the migration of osteoblasts and mesenchymal cells to form a compact bone, this results in immediate stability of the implant after its surgical placement, which was, initially, the subject of a national patent of invention No. MA 41535, validated by the Moroccan Office of Industrial and Commercial Property (OMPIC) on May 16, 2018, and issued directly without any questioning of a claim or a reply on the technical content of this innovation.

After primary healing, we have also demonstrated that secondary stability is determined by the biological response to surgical trauma, the patient's state of health, healing conditions, the material of which the implant is made, and its biocompatibility (properties physical, chemical, and mechanical).

To date, the available literature refers to osseointegration as the responsible mechanism that allows direct skeletal fixation of limb prostheses; however, insufficient evidence has been provided for most implant systems on the degree of osseointegration achieved with the different designs (OPRA systems, Press-fitt systems…). It is difficult to compare the available systems, as they have undergone several changes over time, and clinical trials continue to be limited. Consequently, surgeons find themselves in a situation of invisibility on the performance of the implants chosen compared to the others that exist.

In this article, we have modeled via the computer-aided mechanical design software (CATIA V5), a new medical device allowing us to satisfy the mechanistic factors of the primary phase of the process of osseointegration, to obtain a complete mechanical immobilization of our orthopedic implant (subject of patent N° MA 41535). In addition, the second very important thing about this new medical device is the possibility for doctors to intervene directly at the Bone/Implant interface, during the biological phase of the osseointegration process following partial bone healing. This is without resorting to surgery in case of need for injection of drugs (stem cells, nutrients) or electrical stimulation to consolidate the bone and avoid the worst scenario which is implant failure.

Conclusion

During this preliminary study, both the mechanical and biological phases of the osseointegration process were thoroughly examined. Our main objective was to gain a comprehen-

sive understanding of the various factors that contribute to the success or failure of implants. This knowledge will enable us to develop an optimal solution that has the potential to revolutionize the field of orthopedic implantology.

Acknowledgment

I would like to thank my parents and family for their support, especially my children Amir-Yazane and Iyad-Barae.

Authors' Contribution

All authors have provided vital contributions to each stage of preparation for this manuscript and meet the criteria for authorship as outlined in the author Guidelines. All authors have read and approved the final submitted manuscript.

Ethical Approval

This work is a mechanical modeling of an innovative medical device. The second step we will have to go through an ethics committee to start preclinical tests on animals.

Conflict of Interest

None

References

1. Faoussi M, Youbi Y, Moussetad M, Wahbi M. Study of Different Orthopedic Implant for the Femoral Amputees. 2019;163(1):148-58.
2. Sidhu SS, Singh H, Gepreel MA. A review on alloy design, biological response, and strengthening of β-titanium alloys as biomaterials. *Mater Sci Eng C Mater Biol Appl.* 2021;**121**:111661. doi: 10.1016/j.msec.2020.111661. PubMed PMID: 33579432.
3. Verma RP. Titanium based biomaterial for bone implants: A mini review. *Mater Today: Proc.* 2020;**26**:3148-51. doi: 10.1016/j.matpr.2020.02.649.
4. Branemark PI. Vital microscopy of bone marrow in rabbit. *Scand J Clin Lab Invest.* 1959;**11**(Supp 38):1-82. PubMed PMID: 13658913.
5. Sundgren JE, Bodö P, Lundström I. Auger electron spectroscopic studies of the interface between human tissue and implants of titanium and stainless steel. *J Colloid Interface Sci.* 1986;**110**(1):9-20. doi: 10.1016/0021-9797(86)90348-6.
6. Mavrogenis AF, Dimitriou R, Parvizi J, Babis GC. Biology of implant osseointegration. *J Musculoskelet Neuronal Interact.* 2009;**9**(2):61-71. PubMed PMID: 19516081.
7. Weivoda MM, Bradley EW. Macrophages and Bone Remodeling. *J Bone Miner Res.* 2023;**38**(3):359-69. doi: 10.1002/jbmr.4773. PubMed PMID: 36651575. PubMed PMCID: PMC10023335.
8. Boyan BD, Cheng A, Olivares-Navarrete R, Schwartz Z. Implant Surface Design Regulates Mesenchymal Stem Cell Differentiation and Maturation. *Adv Dent Res.* 2016;**28**(1):10-7. doi: 10.1177/0022034515624444. PubMed PMID: 26927483. PubMed PMCID: PMC4772337.
9. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. *Int J Oral Maxillofac Implants.* 1986;**1**(1):11-25. PubMed PMID: 3527955.
10. Bergamo ETP, Zahoui A, Barrera RB, Huwais S, Coelho PG, Karateew ED, Bonfante EA. Osseodensification effect on implants primary and secondary stability: Multicenter controlled clinical trial. *Clin Implant Dent Relat Res.* 2021;**23**(3):317-28. doi: 10.1111/cid.13007. PubMed PMID: 34047046. PubMed PMCID: PMC8362055.
11. Esposito M, Hirsch JM, Lekholm U, Thomsen P. Biological factors contributing to failures of osseointegrated oral implants. (I). Success criteria and epidemiology. *Eur J Oral Sci.* 1998;**106**(1):527-51. doi: 10.1046/j.0909-8836..t01-2-.x. PubMed PMID: 9527353.
12. Kotsakis GA, Romanos GE. Biological mechanisms underlying complications related to implant site preparation. *Periodontol 2000.* 2022;**88**(1):52-63. doi: 10.1111/prd.12410. PubMed PMID: 35103318.
13. Li Y, Felländer-Tsai L. The bone anchored prostheses for amputees - Historical development, current status, and future aspects. *Biomaterials.* 2021;**273**:120836. doi: 10.1016/j.biomaterials.2021.120836. PubMed PMID: 33894405.
14. Faoussim. Implant orthopedique osteo-integre destine aux amputes femoraux a moignons courts. Patent MA41535A1; Espacenet; 2019.
15. Goldstein C, Sprague S, Petrisor BA. Electrical stimulation for fracture healing: current evidence. *J Orthop Trauma.* 2010;**24**(Suppl 1):S62-5. doi: 10.1097/BOT.0b013e3181cdde1b. PubMed

PMID: 20182239.

16. Kuzyk PR, Schemitsch EH. The science of electrical stimulation therapy for fracture healing. *Indian J Orthop*. 2009;**43**(2):127-31. doi: 10.4103/0019-5413.50846. PubMed PMID: 19838360. PubMed PMCID: PMC2762253.
17. Hronik-Tupaj M, Kaplan DL. A review of the responses of two- and three-dimensional engineered tissues to electric fields. *Tissue Eng Part B Rev*. 2012;**18**(3):167-80. doi: 10.1089/ten.TEB.2011.0244. PubMed PMID: 22046979. PubMed PMCID: PMC3357076.
18. Leppik L, Oliveira KMC, Bhavsar MB, Barker JH. Electrical stimulation in bone tissue engineering treatments. *Eur J Trauma Emerg Surg.* 2020;**46**(2):231-44. doi: 10.1007/s00068-020-01324-1. PubMed PMID: 32078704. PubMed PMCID: PMC7113220.
19. Dergin G, Akta M, Gürsoy B, Devecioglu Y, Kürkçü M, Benlidayi E. Direct current electric stimulation in implant osseointegration: an experimental animal study with sheep. *J Oral Implantol.* 2013;**39**(6):671-9. doi: 10.1563/AAID-JOI-D-10-00172. PubMed PMID: 22103684.