



# Strength analysis of selectively laser sintered titanium alloy dental implant-scaffolds for immediate implantation applications

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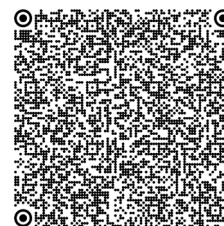
## ABSTRACT

**Purpose:** The article presents an analysis of the design assumptions of innovative implant-scaffolds developed by the Authors, which constitute an alternative to implantation directly after tooth extraction for typical screw implants designed according to the Brannemark concept.

**Design/methodology/approach:** The scope of work was divided into modelling using the digital twin method and manufacturing these implantable elements in real conditions. The computational analysis of bone base models obtained to create a digital twin for real conditions prevailing in the oral cavity was presented and the finite element method FEM analysis of the implant-scaffolds state after installation in the patient's bone under different occlusal conditions was performed to determine the maximum loads and compare them with the strength properties of these implantable elements manufactured by selective laser sintering from TiAl4V6 Extra Low Interstitials (ELI) grade 23 alloy.

**Findings:** The results of the simulation studies performed using the FEM method when loading the bone-implant-scaffold model with occlusal forces with an integrated prosthetic crown abutment-screw illustrate the stress distribution occurring in the entire system, in particular those acting on the implant-scaffold. Extreme cases of these forces occurring directly on the tooth cusp at angles of 0, 15, 30 degrees with different forces of 200, 500 or 1500 N were taken into account, simulating the average and maximum forces obtained using the masticatory muscles and in the case of external impact forces acting in the adopted system. The analysis performed confirms that the use of the new additive manufacturing technology and the introduction of unique geometric features guarantees the correct transfer of occlusal forces in the bone-implant system in various load cases simulating the situation of premature contact, which is usually a critical situation for the durability of the implant-prosthetic restoration.

**Research limitations/implications:** In subsequent studies, the Authors plan to compare the results obtained in this work with models of bone-screw implants, prosthetic abutments, and prosthetic crowns according to the Brannemark concept. This will allow the determination of the optimal parameters for using individual solutions depending on the clinical conditions of different types of teeth.



**Practical implications:** The developed innovative implant-scaffold, thanks to the use of an innovative design of the prosthetic connector and the placement of the prosthetic screw in the supragingival zone of the implant-scaffold, can easily transfer stress without damaging the element even with a force of 1500 N applied directly to the cusp of the prosthetic crown without destroying its structure. This force simulates an extreme situation that will cause the patient's bone to break. Despite this, the implant-scaffold will not be damaged. Therefore, the studies confirm that the use of additive manufacturing technology by the selective laser sintering (SLS) method and the innovative design of the implant-scaffold allow for the high strength properties of prosthetic elements and the surrounding bone tissues to be obtained.

**Originality/value:** An original patent by the Authors for implant-scaffolds construction was developed, which is particularly useful in the case of immediate implantation in the same procedure in which the damaged natural tooth was extracted. Optimization of manufacturing conditions and their correct selection, especially laser power, enables precise reproduction of specific geometric solutions from the project. In particular, the possibilities of additive technology, the selective laser sintering method, allows the use of a laser spot diameter of 30-40 micrometres and a single layer height of 25 micrometres, which allows for achieving print accuracy concerning the project with an error not exceeding 50 micrometres, making this technology optimal for the production of dental implants.

**Keywords:** Selective Laser Sintering, Titanium alloys, Implant-scaffold, Finite Elements Analysis, Dentistry 4.0, Implantology, Digital dentistry, Dental engineering

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## BIOMEDICAL AND DENTAL MATERIALS AND ENGINEERING

### 1. Introduction

In this article, the Authors focus on a specific area of medical applications of additive manufacturing in dental engineering. They highlight significant needs and opportunities to utilise this technology for the benefit of patients, with the potential to have a substantial impact on the overall health of society. The Authors suggest that the results of broad literature research on both the current development of the industry and the presentation of a holistic model in this area [1-4], the global health situation resulting from dental diseases [4-6] and a broad view of the issues of additive manufacturing and the possibilities of its practical application [7,8], have been published by them in numerous review articles and books by the Authors. The essence of additive manufacturing is the production of three-dimensional objects, usually layer by layer, under computer control. The global additive manufacturing market is expected to reach USD 70.08 billion by 2030, with a compound annual growth rate (CAGR) of 21.1%. Within this framework, the global additive manufacturing market for metal materials is expected to grow at a rate of 18.21% and reach USD 11.45 billion during the same period. Various application areas of these technologies can be identified, from the most unexpected ones, such as construction, through the automotive and aerospace

industries, where numerous car and aircraft components are manufactured, as well as, for example, the production of very avant-garde footwear, to numerous biomedical applications with bioprinting of various human organs and cells as a unique scope of additive manufacturing [9,10]. The global medical additive manufacturing market is expected to grow at a high CAGR of 22.6% to reach USD 9.9 billion by 2030. The laser sintering technology segment dominated the market as it enables the production of high-quality, complex geometries in a shorter time. The medical implant segment accounted for the largest revenue share, exceeding 30%, as of 2021. [2]. The essence of additive manufacturing is the production of three-dimensional objects, usually layer by layer, under computer control. [3] The authors indicate that the results of pervasive literature research on both the current development of the industry and the presentation of a holistic model in this matter [3-5, 11], the global health situation resulting from dental diseases [5,6, 11-14] and a broad view of the issues of additive manufacturing and the possibilities of its practical application [7-10, 12, 15-17], have been published by them in numerous review articles and books by the Authors, which is why this was not done in this article, referring to the source mentioned above works, referring to hundreds of cited articles.

Ensuring a healthy life and well-being is the general premise of global development currently set by the UN

Sustainable Development Goals, particularly in the third. Serious medical problems that affect up to 60% of the world's population include dental diseases, mainly caries and periodontal disease, which together are the leading causes of missing teeth and edentulism [4,13,18].

Due to various medical factors, it is justified both to carry out all preventive measures to limit the spread of these diseases and to use all available treatment procedures, such as endodontic treatment, which can enable the use of the infected tooth for many years to come, in fact creating a kind of natural implant from it. To ensure the most extended retention of such teeth in the oral cavity, according to the Authors' research, the gold standard is to use the method of filling root canals with liquid gutta-percha [19]. When changes in the tissues surrounding the tooth are irreversible, mainly when there has been fundamental atrophy of the bone base and periapical modifications that cannot be cured, it is necessary to extract such teeth. To maintain the functionality of the entire stomatognathic system while maintaining all functions, in particular, those related to the ability to tear off and grind food, and to keep the correct physiological relationship between individual bones, muscles and joints in the stomatognathic appliance, while maintaining the correct occlusal relationship of the upper and lower arches, it is necessary to reconstruct the lost teeth using reconstructive dentistry. In this case, dentures, crowns based on adjacent teeth, and optimal implants can be used to rebuild the roots of lost teeth and crowns. The most challenging issue is the functional and aesthetic reconstruction of edentulism, where all the lost 14 teeth of one arch are optimally reconstructed on 4 or 6 implants. Limiting the number of implants to 4 is often desirable due to the usually difficult skeletal conditions associated with dental atrophy, especially in the posterior segments, where implant insertion usually requires many time-consuming and frequently risky procedures of bone regeneration and reconstruction based on bone substitute materials and/or materials based on the patient's bone. In such cases, the strength properties of such a young bone are difficult to determine and often insufficient for a long time to transmit occlusal forces properly.

Implant prosthetic reconstructions have a significant advantage over other prosthetic solutions due to the most faithful reproduction of previously lost healthy teeth. Their mounting makes it possible to reduce the cross-sections necessary for proper maintenance and sufficient strength of all components. In addition, what is most important for the patient is that it is possible to restore the full functionality of the entire stomatognathic appliance, which allows the avoidance of numerous systemic complications, ranging from gastric diseases to dysfunctions of the cerebral hippocampus responsible for memory and spatial orientation, and what is often the most crucial reason for such treatment, radical improvement of the aesthetic of the

entire dentition, leading to the reconstruction of high the patient's self-esteem, rebuilding self-confidence and increasing social acceptance, often restoring the patient's mental balance. It must be clearly stated that this is a multifaceted and challenging therapeutic action, requiring comprehensive engineering support, and not merely cosmetic, as this activity is sometimes attempted to be disavowed.

Dental implant-prosthetic treatment is one of the complex activities in which dentists perform medical activities to ensure the shortest time of performing the entire treatment plan combined with the achievement of the highest strength parameters of the prosthetic restoration while guaranteeing the highest aesthetics of the restoration, both in the phase of diagnosing the severity of the disease with the use of CBCT cone beam tomography, as well as in the subsequent stages of design and manufacture of implants and prosthetic restorations, as well as during their installation in the patient's mouth. Modern engineering-supported treatment is always entirely individual, and therefore, after diagnostics with the use of CBCT, a detailed treatment plan is made to optimally place the implants in the patient's bone base, taking into account its deficits, to ensure optimal axial load of the implants, ensuring their parallelism to each other and surrounding the implant with a sufficient volume of bone tissue. This process should be supported by the Finite Element Method (FEM) analysis of the state of effort. Finite element analysis (FEM) is an efficient method for predicting the effect of stresses caused by, for example, chewing forces on various tissue structures and the material of implant-prosthetic restorations, which attracts the attention of researchers dealing with the issue of dental engineering [20-29]. Each case of im-plant insertion, especially in the case of a limited bone base, should, first of all, be implemented into the design software, where the risk of complications in the form of bone atrophy as a result of overload will be analysed, and the correctness of the implant de-sign will be analysed. Its strength will be ensured under the designed occlusal force loads. This analysis enables the placement of implants in a manner that allows for the accurate design of the prosthetic restorations' geometric features, ensuring their subsequent installation in the patient's mouth with the required precision and without the need for any corrections [30,31]. This analysis enables the placement of implants in a manner that allows for the accurate design of the prosthetic restorations' geometric features, ensuring their subsequent installation in the patient's mouth with the required precision and without the need for any corrections [30,31].

It should be noted that the analysis conducted deliberately omitted the study of the fatigue strength of implants because, in this study, analyses were conducted of the bone-implant system in which the bone is a significantly

weaker element. The bone strength is substantially lower than that of the implant, ranging from 100 to 150 MPa in the case of cortical bone. When the stress of the Ti6Al4V alloy stabilised on the Woehler curve, even after 10 trillion cycles, it is still not lower than ~400 MPa. [32] For this reason, there is no doubt that the bone is the weaker element of this system, and there is no practical possibility for the implant to be destroyed before the bone is destroyed or disappears. For this reason, considerations in this area should be omitted as irrelevant.

Since the invention of Ingvar Branemark in the mid-1960s [33-35], dental screw implants, screwed into pre-drilled holes in the patient's dental process, have become widespread. The material commonly used for such applications is the titanium alloy Ti6Al4V and, less often, pure titanium due to the required strength properties and good biocompatibility. Surface treatments are used to increase roughness, which is recognised as a factor in improving the quality of osseointegration, i.e., the fixation of implants in the patient's bone [36,37].

Despite the attempts made, the presented solution should not be used in the so-called immediate implantation procedure, which involves implantation in one step with tooth extraction, if there are no periapical lesions. Typically, such an implant must be placed deep in the socket, which can lead to complications in the design and execution of implant prosthetic reconstruction.

In this paper, based on several years of clinical Authors' experience, the focus is on the issues of the correct selection of the geometric form of implants in the case of the desire to replace a single lost tooth without periapical lesions with the use of one of the three innovative, patented by the Authors, implant-scarlets under the trade name Una Erinaceus implant [38,39]. The analysed solution contains surface porous zones or surface protrusion zones, guaranteeing effective osseointegration through the growth of osteoblast cells into these porous zones or projection zones. The patented solution also changes the method of implantation from screwing to insertion with the use of a unique device patented by the Authors.

The article does not compare the placement of the implant-scaffold directly in the tooth socket, filling its entire volume, with the placement of a screw implant in these conditions according to the Branemark concept, because these situations were not identical. Using a screw implant would require sinking it significantly below the neckline of the adjacent teeth, which usually also involves the need to use bone substitute materials to fill the empty spaces around the implant. In a few clinical cases, it is possible to widen the tooth socket to the width of the implant, which has a larger diameter than the widest point of the tooth socket cross-section. This study aimed to confirm the correctness of the adopted design assumptions of the implant-scaffold,

and not to conduct a comparative analysis of its usefulness about other solutions already available on the market, mainly since the indicated circumstances constitute fundamental contradictions in the assumptions of such comparisons.

This approach enables the accurate placement of the implant in terms of design. It allows for the final implant prosthetic reconstruction without replacing it after the healing period. The ideal representation of implant placement enables the use of a prosthetic abutment integrated with the implant, featuring appropriate geometric characteristics, on which an optimal prosthetic restoration can be placed with an innovative fixation, also patented by the Authors [40].

The success of applying this solution is enhanced by additive manufacturing, which is the focus of this paper. An interesting aspect related to the production of porous materials used for the production of implant-scaffolds is the possibility of producing unique composite materials in which the porous skeleton produced additively by the SLS method is flooded with melted metal with a melting point lower than that appropriate for the skeleton. After solidification, these materials can be utilised for various purposes, including biomedical applications [38,41]. However, this aspect is not addressed in this paper.

This study presents an analysis of the justification for the use of implant scaffolds, based on the patented idea of the Authors, in specific clinical applications using engineering data. The authors aimed to demonstrate that the use of implant scaffolds brings measurable benefits related to their use in the case of immediate implantation performed directly after the extraction of single-root teeth. The analysis aims to confirm that the use of a new production technology and the introduction of unique geometric features thanks to its use guarantees the correct transfer of occlusal forces in the bone-implant apparatus in various load cases simulating a situation of premature contact, which is usually a critical situation for the durability of an implant-prosthetic restoration.

## 2. Additive manufacturing as the basis for modern design solutions in dental implant-prosthetic treatment

Selective Laser Sintering is the basis for producing both implant scaffolds discussed in this paper and prosthetic restorations, such as bridges and crowns, which are not analysed here. As mentioned earlier, the elements used by dentists in implant-prosthetic treatment are manufactured by the Authors from metal powders of titanium and its alloys, as well as from Co alloys type Vitalium. It should be emphasised that the complex geometric features of implant-scaffolds and the high precision required exaggerate the



need to use additive manufacturing technology for this purpose. The Authors' many years of practical experience indicate the advantage of the Selective Laser Sintering SLS method in this area. The Authors use additive manufacturing by Stereolithography STL using polymer materials, which is also not analysed in this paper, to produce surgical guides.

The new approach is possible thanks to implementing additive manufacturing using metal powders into everyday engineering and medical practice. The preferred material for this application is Ti6Al4V alloy powder grade 23 or pure titanium powder grade 4. The technological revolution in this area took about 10 years when the production process was stabilised in reactive materials such as titanium in devices with compact dimensions.

The Authors team implemented SLS as the basic additive manufacturing technology in 2021 and is constantly developing it for implementation in dental engineering. This technology is much more attractive than CNC milling, mainly because it must comply with the six basic principles of material selection, presented as octahedron  $6 \times R$ , which include actions of rethinking, rejecting, repairing, reducing, reusing and recycling, saving labor, energy and materials, and faithfully ensuring the shapes designed. In this specific application related to the production of an implant scaffold with a geometry containing spaces whose cross-section does not exceed 650 micrometers, the use of CNC milling technology cannot be practical, as such production would take several hundred times longer than in the case of SLS/SLM technology.

The use of other 3D printing technologies was also considered, but only those that produce directly in the target material without the use of a polymer binder, guaranteeing the achievement of the expected print resolution, as well as cost. For this reason, technologies such as EBM were rejected.

The use of SLS/SLM technology requires the use of the idea of a digital twin to develop both a clinical procedure ensuring the proper placement of implants/implant-scaffolds, as well as an analysis of the state of strain of these elements in the prosthetic restoration - implant/implant-scaffolds - patient's bone system using the finite element method. Simulations made in this way enable the proper production of implants/implant-scaffolds and prosthetic restorations and the precise performance of all clinical procedures, ensuring maximum durability of such an implant-prosthetic restoration, as well as its reliability and providing the possibility of trouble-free service over a long period of use, reducing costs both for the patient and for the consumption of materials and energy necessary to re-manufacture these elements (Fig. 1).

### 3. Description of the implant-scaffold structure

The implant-scaffolds are highly developed, one-piece dental implants characterised by a monolayer, multilayer or gradient surface microstructure. The structure of the implant-scaffold consists of an endosseous part, which is ultimately permanently connected to the surrounding bone tissue. In its structure, we distinguish the root zone in the form of a core in the shape of a cuboid with a cross-section of various geometric figures, which is permanently connected to the protrusions located on its circumference in the form of rods covered or not covered with a thin layer of bioactive material, and the apical zone corresponding to the shape of the anatomical features of the tooth or replaced with an arrowhead. The second is the intra-gingival part, which is in contact with the soft tissues of the gum and contains a bacteriostatic disc located under the gum line.

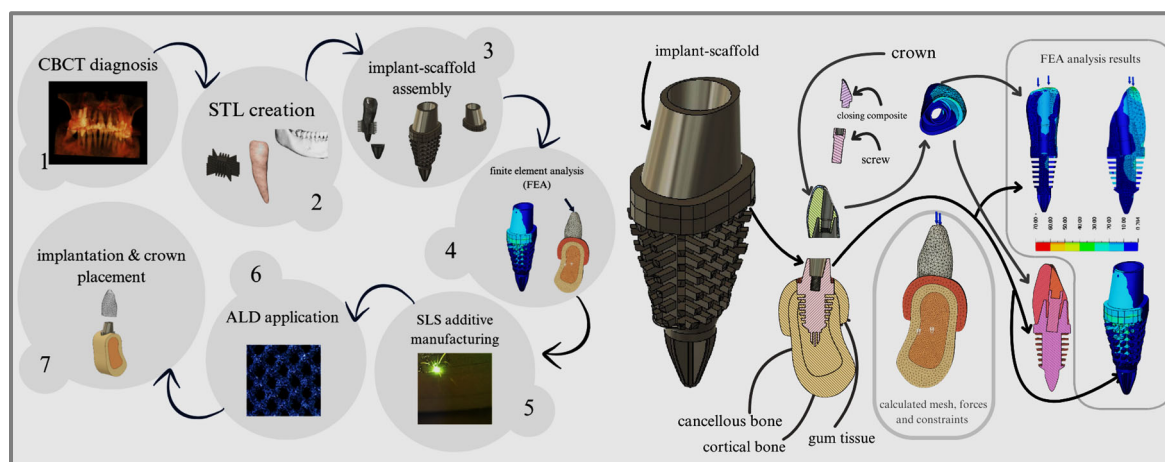


Fig. 1. Diagram of the sequence of activities related to the design, fabrication and installation of implant-scaffolds in the patient's mouth (left) and the principle of a twin of digital strain analysis implant-scaffolds using the FEM finite element method (right)

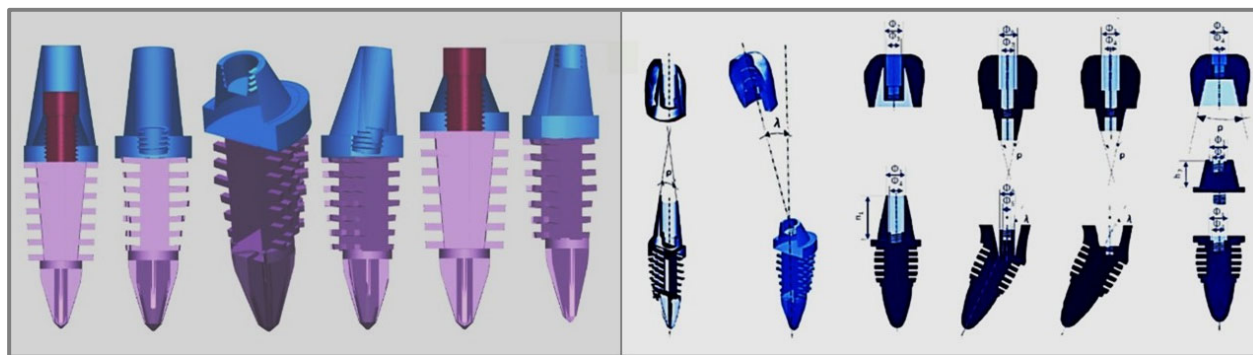


Fig. 2. Examples of design solutions for the method of fixing crowns are based on implants or implant scaffolds with a conical connection between the implant and the crown

Additionally, it features a prosthetic step that adheres to the intraosseous part, thereby preventing bacterial penetration. The last part is the supragingival part – the integrated abutment, which does not come into contact with bone tissues or gum tissues. There is a hole in the abutment that allows the crown to be screwed to the threading inside the implant. In the case of molars and premolars, the hole may be centrally located at the top, as the hole formed in the crown attached to the abutment will not be visible. For teeth in the anterior section (incisors and canines), it is necessary to design angle connectors that allow the holes for the screw to be hidden on the inside so that they do not affect the aesthetic effect of the entire reconstruction (Fig. 2).

The scaffold implant also has an innovative structure that allows to reduce the occlusal forces directly affecting the prosthetic screw by using the appropriate shape of the entire abutment and changing the typical shape of the prosthetic abutment crown. It allows occlusal forces to be transmitted directly to the intra-gingival part, where the implant-scaffold cross-section is the largest and can transmit the most significant forces without the risk of its rupture. In addition, integrating midosseous elements with intra-gingival and supragingival elements reduces the number of zones potentially conducive to periimplantitis infection. All components are made of the same biocompatible material, which also positively minimises the risk of a galvanic cell negatively affecting the maintenance of bone tissues around the implant.

A prosthetic crown placed on a scaffold implant has an innovative structure. It has a cut-out in the shape of the outer outline of the connector for its installation and a step on which the head of the connecting screw rests. There is also a variant in which an additional part is embedded inside the crown within the opening of the implant abutment. Crowns that only have a cut-out of the outline of the fastener do not have threading in the area through which the connecting screw passes. Instead, there are two types of zones to be used inside the crown that goes into the abutment hole through

which the connecting screw passes: the zone with an internal thread (the same as inside the implant-scaffold) and a zone without thread.

The implant-scaffolds can be placed in the alveolar bone using a mounting accessory (Fig. 3), enabling precise insertion of the implant along the axis of the root of the extracted tooth [6]. The accessory consists of a muco-dental plate, the size of which is selected depending on the patient's anatomical conditions, equipped with a socket determining the location of the implant together with a bed for fixing the outer sleeve, fixing eyes for inserting mounting wedges and a piston socket for placing the implant, injection apparatus or inserting apparatus.

#### 4. Purpose, scope and methods of the work performed

This paper aims to present one of the three types of individual dental implant-scaffolds according to the Authors' concept and its design and additive manufacturing method, using the selective laser sintering method as a practical possibility for immediate implants. In the design procedure, FEM finite element analysis is routinely used as one of the stages of verification of design assumptions and one of the stages of optimisation of the geometric features of both the designed implant and the prosthetic restoration placed on it, to verify the strength of the entire bone-implant-prosthetic restoration system finally. The analysis is based on actual data obtained, specifically from CBCT cone-beam computed tomography for a particular patient.

The analysed family of implant scaffolds, the Una Erinaceus implant, is dedicated to solutions related to the replacement of single teeth. Root extraction can be performed without disturbing the surrounding bone tissues, allowing the insertion of an implant scaffold with the same geometric features as the removed tooth root during the procedure of immediate implantation.



Fig. 3. Diagram of an accessory for mounting implant-scaffolds in the patient's mouth by pressing or inserting (top left) implant-scaffolds in combination with a plunger (top right) and a sequence of successive stages of implantation with mucosal-dental plaque (bottom)

The scope of work was divided into modelling using the digital twin method and producing these implantable elements in actual conditions. The paper presents examples of the results of the work to present methodological aspects. As part of the virtual computational analysis, a computational analysis of the method for designing implant scaffold arrangements using specialised *in vivo* software was presented. Based on the digital models of the bone base that were obtained to constitute a digital twin for actual conditions prevailing in the oral cavity in the same software, FEA finite element analyses were then carried out in the Fusion 360 software. In this manner, an analysis of the state of implant scaffolds after installation in the patient's bone under various occlusal conditions was conducted to determine the maximum loads and compare them with the strength properties of these implantable elements produced by selective laser sintering.

The implant scaffold was designed using PowerShape software from Autodesk. The prosthetic restoration was designed using specialised CAD Exocad software. The production of the finished element was carried out on the production line of the Asklepios Dental Engineering Center, utilising Orlas software to differentiate the manufacturing conditions. These conditions included laser power, laser spot diameter, laser scanning speed, the density of laser paths, and the degree of overlap of adjacent laser paths. Tests of strength on microsamples were conducted using the Zwick/Roell Z020 static testing machine. Tensile strength tests and three-point bending tests were performed. Metallographic treatments were performed using a Struers technological line, which enabled polishing with diamond pastes. The samples prepared in this manner were microscopically examined at 100x and 200x magnification using the Leica DMI08 metallographic microscope with the Leica Application Suite (LAS) stereo software. Studies were

also conducted using the Discovery V12 Zeiss stereo microscope, the SEM SUPRA 35 scanning electron microscope from ZEISS, and thin film studies in the high-resolution transmission electron microscope (HRTEM) S/TEM TITAN 80-300 from FEI. The results of previous research by the Authors were used [5,6,13].

## 5. Results of experimental studies

The design process begins with obtaining data from CBCT (cone beam computed tomography) and implementing it into the design software, where creating a digital twin of the clinical situation is possible. This digital model then serves as the foundation for the entire design process. After selecting the appropriate isometric values and the working area that covers the implanted zone, the tooth to be extracted is segmented, and STL models of the tooth and the bone bed are created. Based on the 3D models obtained in this manner, the dental engineer designs an individual implant scaffold. The implant-scaffold is designed using the geometry of the extracted tooth, featuring an appropriate solid core and a surrounding zone formed by evenly spaced protrusions. The next stage is to design an abutment that is integrated with the implant, with the angle of inclination determined by the anatomical conditions in the patient's oral cavity. By separating the crown in advance, it is possible to decide on the angle of inclination of each individual connector. The abutment is designed in such a way that the hole for the prosthetic screw is not on the labial surface or the chewing surface of the incisor tooth crown. It is also possible to replace the apical zone with a tip to enhance the aggressiveness of the inserted implant, facilitating its placement in the bone base. The finished implant-scaffold



model should be placed in the digital twin of the bone to confirm the implant's fit.

The material used to produce implant-scaffolds is Ti6Al4V alloy as a metal powder with ELI grade 23. The powder consists of particles with diameters ranging from 15 to 63  $\mu\text{m}$  and a chemical composition as listed in Table 1. Ti6Al4V6 Extra Low Interstitials (ELI) grade 23 is a higher-purity alloy. This grade has lower oxygen, carbon, and iron contents than conventional grades. Among other applications, it is utilized in biomedical fields, including surgical implants and instruments. According to its legal status, this alloy does not require additional clinical tests. Figure 4 shows a microscopic image of this alloy powder.

Systematic research on the conditions of selective SLS laser sintering optimised them, indicating that the essential factor determining the strength properties of this alloy is the minimisation of porosity. It is worth noting that many publications suggest that additive manufacturing is not beneficial, as it produces porosity comparable to that of cast materials. The use of factory conditions suggested by manufacturers of additive manufacturing equipment ensures

that the porosity of the manufactured metal alloys is greater than 5%.

The optimisation of the selective laser sintering process for Ti6Al4V powders, carried out as part of the authors' research, enabled the production of a material with low porosity (Fig. 4), resulting in high tensile and bending strengths (Tab. 2).

## 6. Results of computational analyses

In this study, the analysis used a system consisting of an implant-scaffold, a titanium crown veneered with a composite material, a screw connecting the set, closing the crown hole located in bone tissues consisting of a cortical and spongy part characterised by different densities and strength, and surrounding gingival tissues. The bone-gingival-implant-scaffold-prosthetic crown model was virtually loaded with occlusal forces of 200 N and 500 N, respectively, and, for highly exaggerated conditions, also with a force of 1500 N, at angles of 0, 15, and 30 degrees to the implant axis, as shown in Figure 5.

Table 1.

Chemical composition of titanium alloy powder Ti6Al4V ELI grade 23

| Element       | Elements concentration, weight% |         |         |             |              |              |               |                         |
|---------------|---------------------------------|---------|---------|-------------|--------------|--------------|---------------|-------------------------|
|               | Ti                              | Al      | V       | Fe          | C            | N            | H             | Other: each, total      |
| Concentration | Rest                            | 5.5-6.5 | 3.5-4.5 | $\leq 0.25$ | $\leq 0.080$ | $\leq 0.030$ | $\leq 0.0125$ | $\leq 0.10$ $\leq 0.40$ |

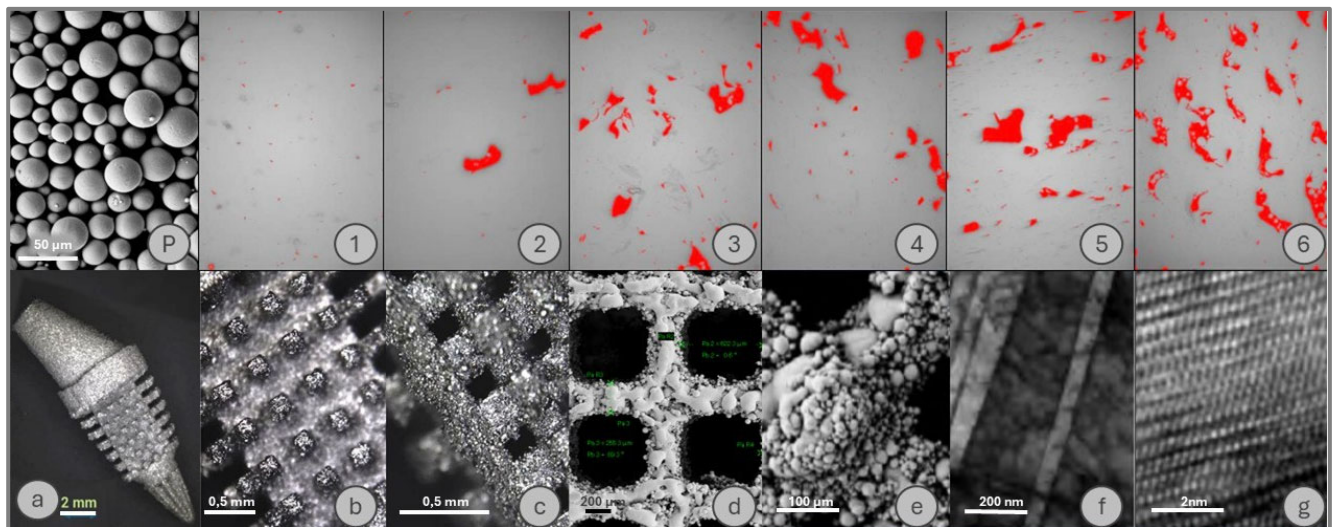


Fig. 4. Materialographic test results: (P) Ti6Al4V ELI grade 23 alloy powder; (1-6) porosity of Ti6Al4V ELI grade 23 alloy samples produced under the conditions given in Table 2; (a) an implant-scaffold view produced by the SLS method with surface projections; (b) the view of the tabs; (c) view of the porous zone; (d) porous zone (SEM); (d) Porous zone node (SEM); (e)  $\alpha$ -Ti martensitic structure (HRTEM); (f) imaging of the arrangement of atoms in the structure of Ti6Al4V alloy (HRTEM)



Table 2.

Summary of the results of the tensile and bending strength test of the Ti6Al4V alloy manufactured by the selective laser sintering (SLS) method depending on the manufacturing conditions and the obtained surface porosity

| Variant No. | Laser power, W | Laser beam width, $\mu\text{m}$ | Pore share, % | Average* Rm, MPa | Position for tensile | Average* Rg, MPa | Position for bending |
|-------------|----------------|---------------------------------|---------------|------------------|----------------------|------------------|----------------------|
| 1           | 110            | 120                             | 0.20          | 1151.76          | 1                    | 2464.03          | 1                    |
| 2           | 110            | 60                              | 1.62          | 1049.92          | 2                    | 2049.74          | 2                    |
| 3           | 80             | 60                              | 4.71          | 867.13           | 3                    | 1625.21          | 3                    |
| 4           | 80             | 120                             | 5.24          | 847.16           | 4                    | 1595.70          | 4                    |
| 5           | 60             | 60                              | 6.25          | 833.90           | 5                    | 1546.45          | 5                    |
| 6           | 60             | 120                             | 10.53         | 554.89           | 6                    | 1099.88          | 6                    |

\*Average values of tensile and bending strength are given; the statistical standard deviation is within the range of  $< \pm 0.5\%$

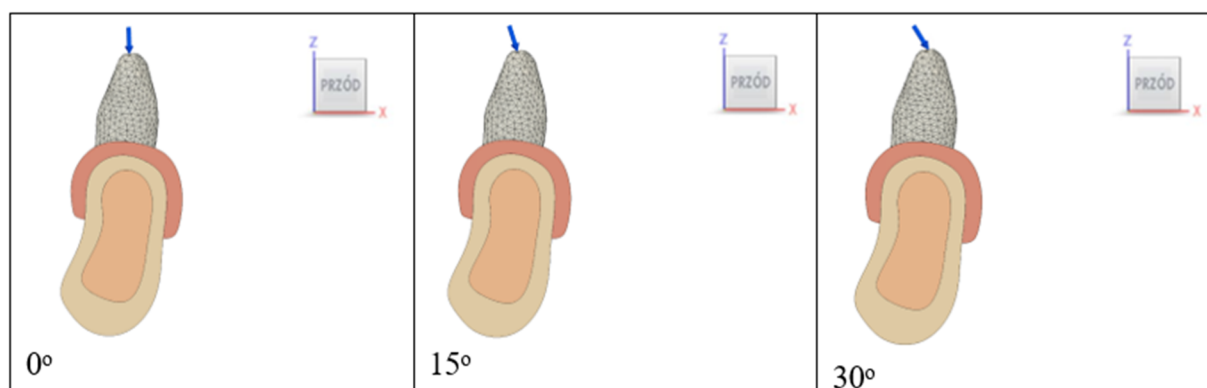


Fig. 5. Diagram of the load of the adopted model using implant-scaffold at different angles of application of the force loading the system

The FEM method works very well in the cases described in the article. It is not possible to subject a living patient to strength tests as there is no practical way to assess the impact of occlusal forces on the bone-implant system. This would be both inhumane and contrary to ethical principles and simply unfeasible. The study described was conducted using materials approved for medical applications, for which the implications for patient tissues have been frequently reported in specialist literature. Studies conducted in this way allow for finding answers to questions related to the correctness of design assumptions without the need to conduct studies on animals (which in such cases do not provide clear answers) and even more so on humans (which are impossible to perform).

For all elements made of Ti6Al4V alloy produced by the SLS method, the properties of the alloy presented in previously published work were adopted [6]. The results of the FEM simulations allow for a comparison of the occurring stresses both in the implant-scaffold and in the surrounding bone for each analysed case. For the analysis, a force of 200 N simulates typical occlusal forces occurring in the oral cavity in regular use, a force of 500 N simulates the maximum values of occlusal force obtained with the use of

masseter muscles, and a force of 1500 N simulates the patient's participation in an accident with a strong direct impact to the face causing the teeth to hit each other (an extreme case exceeding the patient's bone strength) were used. The summary of results obtained for the occlusal force of 200 N is presented in Table 3.

Table 4 presents the results of the FEM strain analysis for implant-scaffolds loaded with the occlusal force of 500 N.

In the first two cases, when the occlusal forces are 200 and 500 N, respectively (Tables 3 and 4), the FEM analysis simulates the patient biting off small elements. It is the most common cause of damage to prosthetic restoration under functional conditions. The results in Tables 3 and 4 confirm that the innovative implant-scaffold design can transfer occlusal forces from the prosthetic crown to the bone without reaching the material strength limits—the stresses occurring inside the scaffold implant range from 0 to 100 MPa. Compared to the results presented in Table 1, it can be seen that applying forces of both 200 N and 500 N does not achieve values close to the material's strength.

This means that even with an incorrectly executed production process for a laser power of 60W and the largest laser spot diameter, i.e., under manufacturing conditions

significantly different from optimal, the component still demonstrates sufficient strength to transmit occlusal forces. It means that even for implant-scaffolds with a porosity of

10%, it is possible to ensure the correct strength of the entire system with maximum occlusal forces. Therefore, under regular use, the incorrectly manufactured scaffold implant

Table 3.

Comparison of the results of stress simulation in the analysed system with a bite force of 200 N specific to the anterior teeth and incisors

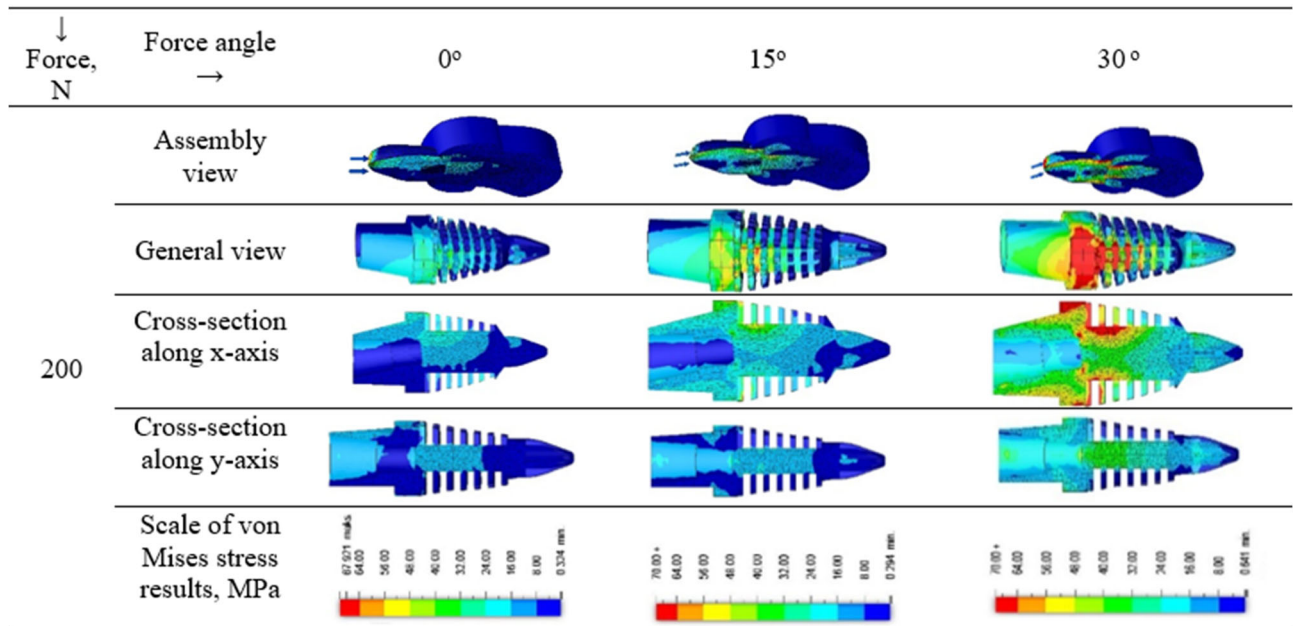
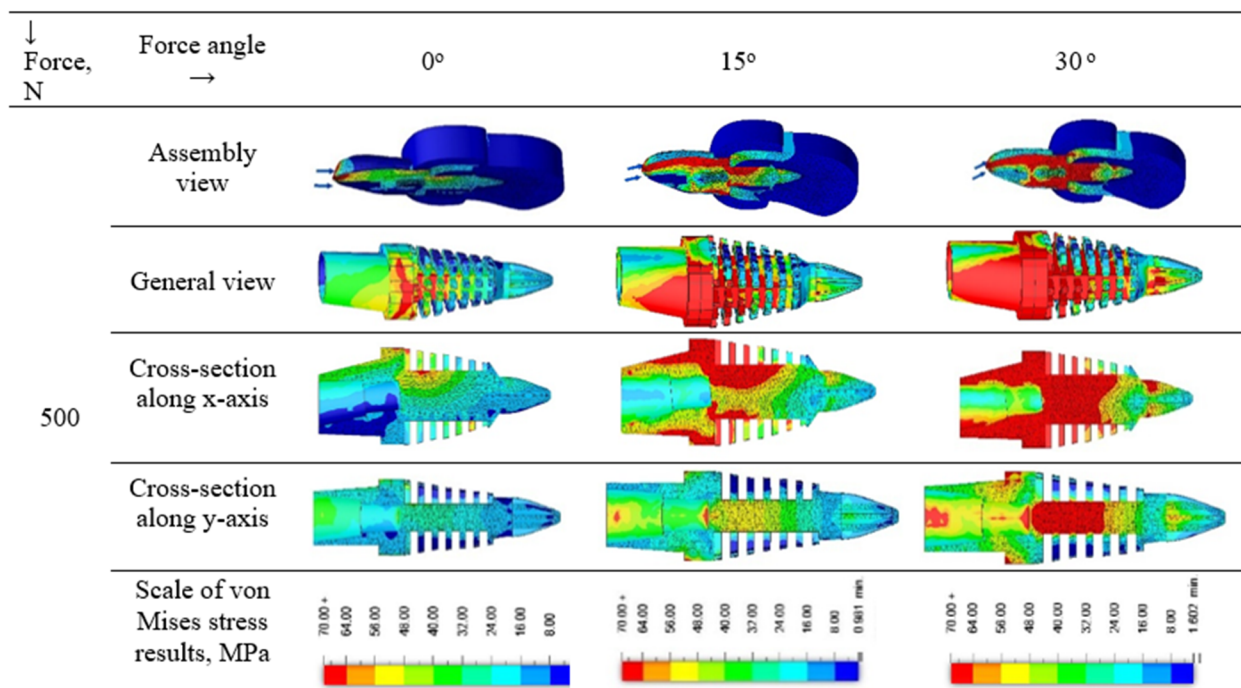


Table 4.

Comparison of the results of stress simulation in the analysed system at the occlusal force of 500 N specific to molars



can transmit typical occlusal forces applied at points, ensuring patient safety while protecting the manufacturer from technological errors. The analysis assumed three different angles of applying occlusal forces directly on the prosthetic crown nodule. Analyses confirm that in the case of a force deviated by 30 degrees relative to the axis of the implant-scaffold spinal cord, the highest stresses occur in the implant-scaffold core in the intraosseous zone. Still, their values do not reach 100 MPa, which ensures a very safe margin for using this solution, even when replacing incisors where the cross-sections are naturally the smallest.

Based on the obtained results, it can be seen that the stress values on the walls of the implant scaffolds, directed lingually and labially, increase with the increase in the force angle. The resulting stresses are concentrated in the intragingival parts and adjacent roots. However, both in the case of a force of 200 N and 500 N, the stress values in the implant-scaffold material are several times lower than those that could lead to the destruction of the implant material (destructive stresses range from 1100 to 2400 MPa depending on the obtained porosity of the material, ranging from 0.2 to 10% depending on the selected conditions of manufacturing the implant-scaffold using the SLS method). The results described in Tables 3 and 4 clearly confirm that reducing the core cross-section and introducing protrusions does not cause a loss of strength of the entire element, especially in the cervical zone, which in screw implants is a

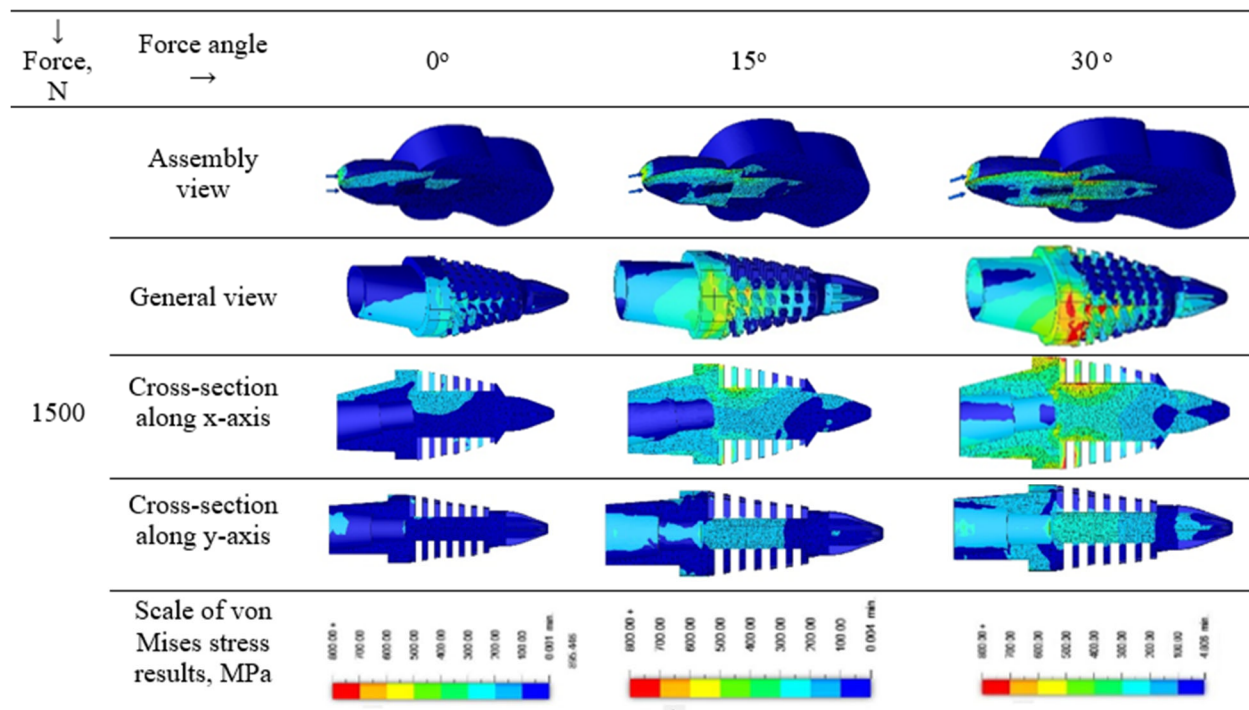
critical place of implant damage in the event of occlusal overloads. The presented results are far from the critical parameters that could cause potential damage to this element during normal, regular use in the oral cavity.

In the case of the results presented in Table 5 for an applied force of 1500 N, it can be seen that, similarly to the first two cases, the intragingival zone and the medulla extend into the intraosseous zone, which is most heavily loaded. In this case, the maximum stress values are approximately 800 MPa. This is still approximately 300 MPa less than the obtained material strength corresponding to the porosity indicated in Table 2.

The presented results clearly confirm that the use of the implant-scaffold following the authors' idea allows for ensuring sufficient cross-sections of the implant-prosthetic element to ensure the strength of this element in all conditions prevailing in the oral cavity, both in the case of typical values of occlusal forces and in the case of critical events related to external impact. This solution is dedicated to immediate filling of the tooth socket created after tooth extraction, determining the geometric features of the implant-scaffold, however, the presented FEM maps confirm that it is possible to significantly reduce these cross-sections while maintaining sufficient strength parameters of the entire element, which will be the subject of further research by the authors.

Table 5.

Comparison of the results of stress simulation in the analysed system at the bite force of 1500 N under extreme load conditions



Implant scaffolds designed by the authors offer a unique solution worldwide, featuring protrusions in their structure that allow for the introduction of controlled porosity of the element, enabling cells to colonise the endosteal zone. By providing space with a minimum size of holes of at least 630 micrometers in each plane, there is no doubt that osteoblasts will be adequately nourished and can create a tight connection with the implant scaffold. The implant scaffold design also includes a polished cervical zone, which prevents the easy penetration of bacteria along the prosthetic element. This is a solution to one of the most challenging problems of maintaining permanent osteointegration of typical screw implants. By creating a physical barrier between the subgingival zone and the bone zone, complications associated with loss of osteointegration due to hygiene issues during prosthetic restoration should be significantly reduced.

Additionally, the introduction of protrusions allows the use of implant scaffolds in much more difficult bone conditions than typical screw implants. This is because there are also large spaces of properly nourished osteoblast cells inside the implant, and as a result, the bone around the implant can be appropriately nourished even if its width around the implant is smaller than that required for screw implants of 1 mm.

At the same time, as shown by our FEM studies, even a 30-degree inclination of the implant about the occurring bite forces does not affect the durability of the entire solution in any way, because the forces acting on the bone are minimal. Providing radically larger cross-sections in the cervical part (approx. 1-1.5 mm instead of 0.2-0.4 mm as in the case of screw implants) allows for freedom in determining the final geometry of the implant connector.

Additionally, the authors corrected the method of mounting the prosthetic crown to the implant by introducing the prosthetic screw significantly above the line of the cervical zone. Changing the method of attachment from an internal hex to an external cone allows for reducing the forces acting on this screw, significantly contributing to an increase in the trouble-free time of use without the prosthetic work unscrewing and without the risk of this screw breaking in the long term, which is a common complication occurring in screw implants designed according to Branemark's assumptions.

All these unique, patented features of the implant-scaffold confirm that it is a very effective alternative to screw implants.

## 7. Conclusions

To sum up, the developed innovative scaffold implant, thanks to the use of an innovative construction of the

prosthetic abutment and the placement of the prosthetic screw in the supragingival zone of the scaffold implant, can easily transfer stress without damaging the element even for a force of 1500 N applied directly to the prosthetic crown nodule without destroying its structure. This force simulates an extreme situation that will cause the patient's bone to break. Still, implant-scaffold will not be corrupted. Therefore, the research confirms that the use of additive manufacturing technology, specifically the Selective Laser Sintering (SLS) method, and the innovative implant-scaffold design enable the achievement of high-strength properties in prosthetic elements and the surrounding bone tissues.

In subsequent studies, the Authors plan to compare the results obtained in this work with the models of bone-screw implants, prosthetic abutments, and prosthetic crowns according to the Brannemark concept. This will allow them to determine the optimal parameters for applying individual solutions depending on the clinical conditions of different types of teeth.

## Authors contribution

The authors declare a common and equal contribution to all phases of preparation of the publication, regarding conceptualisation, methodology, software, validation, formal analysis, investigation, resources, data curation, writing—original draft preparation, review and editing, visualisation, supervision, project administration, and funding acquisition. All authors have read and agreed to the published version of the manuscript.

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