# EVALUATING CLINICAL EFFICACY AND COMPLICATION MANAGEMENT IN ADDITIVELY MANUFACTURED SUBPERIOSTEAL IMPLANTS: LITERATURE REVIEW

AUDRA, J.[1*] – AVIAD, H.[2] – DAVID, Y.[3] – AINE, J.[2] – DAINIUS, R.[1] – ZYGIMANTAS, P.[1]

[1] *Department of Maxillofacial Surgery, Lithuanian University of Health Sciences, Kaunas, Lithuania.*

[2] *Faculty of Odontology, Lithuanian University of Health Sciences, Kaunas, Lithuania.*

[3] *Faculty of Medicine, Lithuanian University of Health Sciences, Kaunas, Lithuania.*

**Corresponding author*
*e-mail: a.janovskiene[at]gmail.com*

(Received 24th August 2024; revised 28th November 2024; accepted 07th December 2024)

**Abstract.** Subperiosteal implants are a practical option for patients with significant bone atrophy for whom traditional dental implants are not viable. Recent advances in additive manufacturing (AM) have made it possible to design exact, patient-specific implants that reduce complications and improve outcomes. This systematic review evaluates the clinical success and postoperative complications associated with AM subperiosteal implants. The PubMed and Cochrane Library databases were searched for studies published from January 2019 to January 2024. Keywords included "additively manufactured subperiosteal implants" and "3D printed implants". The review included randomized controlled trials, non-randomized trials, and observational studies. Quality assessment was performed using the Downs and Black checklist to ensure the reliability of the included studies. Out of 235 initial records, four studies were selected for the final analysis, involving 60 patients who received AM subperiosteal implants. Complication rates varied from 6.25% to 30%, with peri-implantitis being the most common issue. Nevertheless, the overall success rate of implants was high, with over 90% of cases achieving satisfactory outcomes. 3D imaging technology allowed for highly accurate implant fitting and reduced surgical time. AM subperiosteally implants significantly advance dental implantology, particularly for patients with complex bone conditions. While the results are promising, further long-term research must confirm their durability and success in a broader range of patients.
**Keywords**: *subperiosteal implants, additive manufacturing, dental implants, bone atrophy*

## Introduction

Subperiosteal implants represent one of the most important steps in the evolution of dental implantology. They offer a valid solution for patients with serious bone atrophies when classic implant techniques are not effective. These implants, custom-made to rest on the surface of the bone beneath the periosteum, were first introduced in the 1940s and have undergone significant advancements over the decades, particularly with the advent of additive manufacturing technologies (Schou et al., 2000). The development of subperiosteal implants dates back to 1943 when Dahl introduced the first implant. This implant further required restoring patients with inadequate bone volume for the conventional endosseous implants. Early designs were fabricated from a series of cobalt-chromium alloys and required a direct impression of the bone exposed at surgery. Although the technique represented an innovation in implant technology, it was highly invasive and fraught with several problems, both discomfort to the patient and complications due to the fit and stability of the implant (Schou et al., 2000).

The second major innovation was the implantation of titanium in the 1970s and 1980s. The pioneers, like Branemark, emphasized osseointegration- the assimilation of the implant with the bone- thereby making titanium the first choice due to its biocompatibility and the ability to attach directly to the bone tissue. Introducing titanium alloys, such as Ti-6Al-4V, enhanced mechanical properties to provide greater strength and durability, especially in load-bearing applications (Branemark, 1985). Beginning in the early 21st century, additive manufacturing contributed a step further in developing subperiosteal implants- from conventional to highly customized implants that perfectly matched the unique anatomy of the bone for each patient. The process generally includes high-resolution imaging, such as CT or CBCT, where very minute details of the patient's bone anatomy are captured. Further, these images are used to construct a 3D digital model through the use of CAD software, which acts as a blueprint for 3D printing (Onică et al., 2024; Nemtoi et al., 2022).

Another contribution to developing subperiosteal implants is Direct Metal Sintering technology (DMLS) in Additive Manufacturing (AM). This combination could allow the layer-by-layer fabrication of implants with powdered titanium sintered together by a high-powered laser. Therefore, this process provides great precision, emphasizing strength to produce a dense and durable implant well-fitted for complex and robust structures. The benefits of DMLS are that fine details can be produced with excellent mechanical properties; thus, for patient-specific implants requiring high strength and durability, DMLS is one of the finest methods. Compared to DMLS, other additive manufacturing methods used in the fabrication of subperiosteal implants include Selective Laser Melting (SLM). SLM works based on a principle similar to DMLS but is usually capable of processing with a broader range of materials, which allows its mechanical properties to be tuned. SLM has been used in developing complex geometrical implants that enhance osseointegration, hence improving the overall success rates in dental implant applications. Another modern fabrication method is Electron Beam Melting (EBM), which also works based on the principle of a powder bed fusion technique but uses an electron beam instead of the laser. EBM has several advantages since it can make implants of high density and low residual stresses and thus is used to fabricate big load-carrying implants that require very high strength and fatigue resistance (Van den Borre et al., 2021).

In recent times, lattice-like additive manufacturing has also proven to be a very prospective approach to fabricating subperiosteal implants. The technique fabricates implants with a lattice structure similar to natural bone architecture, combining strength with lightweight properties. The Lattice-like structures are designed to be optimal in the distribution of mechanical forces, improving biological integration between surrounding bone tissues and the implant. The connected porous network in designs allows good irrigation and bone in-growth to ensure proper long-term stability and success of the implant. Lattice-like structures are very effective in the presence of severely atrophic bone, as the design can compensate for the bone's lack of volume by providing additional support and promoting the growth of bone tissue (Bai et al., 2022). The aim of this systematic review is to evaluate the clinical efficacy, precision, and complication management associated with additively manufactured (AM) subperiosteal implants. Specifically, this review aims to analyze the success rates, complication profiles, and benefits of advanced imaging and AM technology in improving patient-specific implant outcomes in cases of severe bone atrophy.

## Materials and Methods

### *Search strategy*

The systematic review was prepared according to the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) statement (Page et al., 2021). The electronic search was conducted independently by two authors using PubMed and the Cochrane Library, with the search terms ('Additively AND Manufactured AND Subperiosteal AND Implants' OR '3D AND Printed AND Subperiosteal AND Implants'). The search was limited to English-language publications between January 2019 and January 2024, without restrictions on country or publication status. In cases of disagreement between the two authors, a third author was consulted to resolve the discrepancy.

### *Selection criteria*

The inclusion criteria include: (1) Studies that utilize AM subperiosteal implant; (2) Studies that described clearly the surgical procedures; (3) Studies contain related postoperative follow-up and effect changes; (4) Randomized Controlled Trials; (5) Non–Randomized Controlled Clinical Trials; (6) Observational cohort study; and (7) Cross-sectional study. Meanwhile, the exclusion criteria include: (1) Studies that utilize conventional subperiosteal implant methods; (2) CRRs with incomplete case information; (3) Literature reviews and meta-analyses; (4) Research that does not contain post-treatment clinical information; and (5) Literature not in the English Language.

### *Risk of bias*

The quality of the included studies was assessed using the Downs and Black checklist (Downs and Black, 1998), which consisted of 27 questions on the reporting, external validity, internal validity, and power of the studies. Each question can be scored as one of two possible values: 0, which indicates a 'no' answer or an inability to determine the answer, and one, which indicates a 'yes' answer, except for question 5, which also has a third possible answer score, 2. Studies were classified according to the number of points: poor quality: <14 points, fair quality: 15-19 points, good quality: 20-25 points, excellent quality: >25 points.

## Results and Discussion

### *Study selection*

The search resulted in 235 records. Ten duplicates were removed, while 225 records were screened. Titles of these records were screened, which further led to the exclusion of 125 records. The abstracts of the remaining 110 records were reviewed, and 60 records were excluded. Fifty full-text articles were reviewed for eligibility assessment, and 46 were excluded based on the criteria that were defined in advance. In the end, four studies were included in the qualitative synthesis results (Onică et al., 2024; Bai et al., 2022; Nemtoi et al., 2022; Van den Borre et al., 2021) (*Figure 1*).

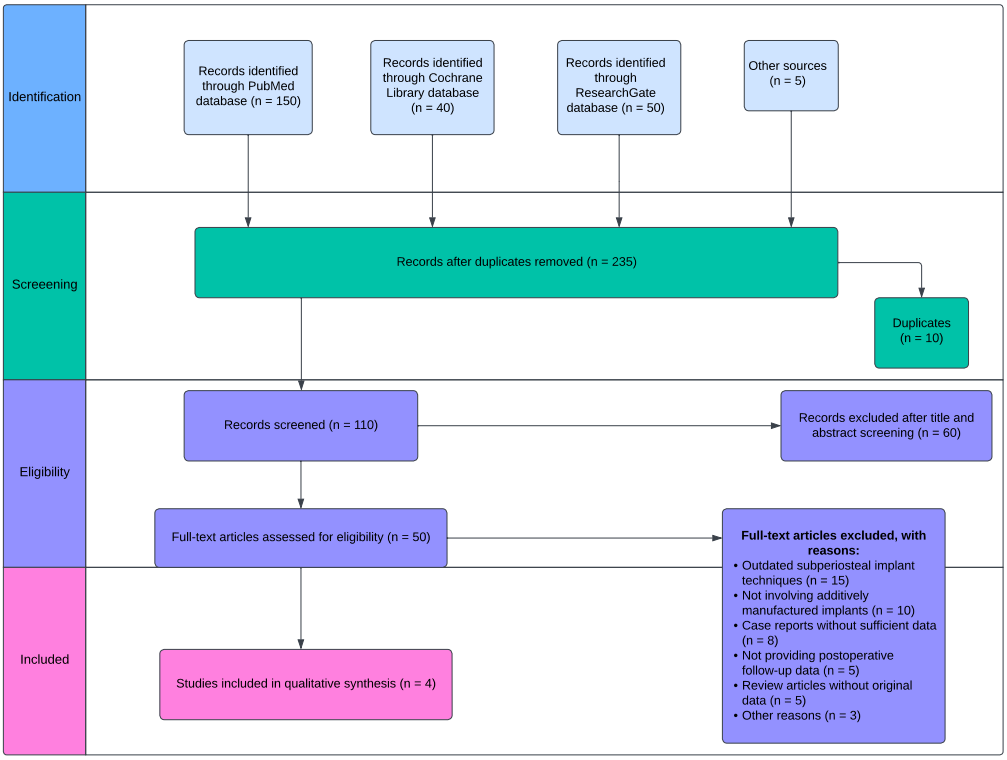


***Figure 1.*** *The flow chart.*

## *Quality assessment of included studies*

The quality of studies included was assessed through the Downs and Black checklist by two reviewers independently (Downs and Black, 1998). The tool evaluates both randomized and non-randomised studies and is based on reporting objectives of the study, the characteristics of patients and the intervention, and measures of outcome. The overall quality of the studies was then classified as poor, fair, good, or excellent, according to the total score. Disagreements were resolved through discussion with the third author consulted where necessary. The studies were ranked as follows: 2 studies were rated as good (Nemtoi et al., 2022; Van den Borre et al., 2021), and two were rated as fair (Onică et al., 2024; Bai et al., 2022), with checklist scores ranging from 14 to 21 points. Most studies documented the objectives and patient characteristics for both included and excluded patients, and the timespans for patient inclusion were clearly stated. Additionally, all the patients in the subgroup of studies were from the same population, with impressive data consistency and no randomization or blinding of patients about the interventions performed (Onică et al., 2024; Bai et al., 2022; Nemtoi et al., 2022; Van den Borre et al., 2021). Moreover, Bai et al. (2022) and Nemtoi et al. (2022) performed explicit follow up on effects of loss concerning patients. The scoring and signaling questions criteria are displayed (*Table 1*).

***Table 1***. *Signaling questions criteria and scoring.*

| Category | A | B | C | D |
|---|---|---|---|---|
| Reporting | | | | |
| Is the objective of the study clear? | 1 | 1 | 1 | 1 |
| Are the main outcomes clearly described in the Introduction or Methods? | 1 | 1 | 1 | 1 |
| Are characteristics of the patients included in the study clearly described? | 1 | 1 | 1 | 1 |

| | | | | |
|---|---|---|---|---|
| Are the interventions clearly described? | 1 | 1 | 1 | 1 |
| Are the distributions of principal confounders in each group of subjects clearly described? | 0 | 1 | 1 | 1 |
| Are the main findings of the study clearly described? | 1 | 1 | 1 | 1 |
| Does the study estimate random variability in data for main outcomes? | 1 | 1 | 1 | 1 |
| Have all the important adverse events consequential to the intervention been reported? | 1 | 1 | 1 | 1 |
| Have characteristics of patients lost to follow-up been described? | 0 | 0 | 0 | 0 |
| Have actual probability values been reported for the main outcomes except probability < 0.001? | 1 | 1 | 1 | 1 |
| External validity | | | | |
| Were subjects who were asked to participate in the study representative of the entire population recruited? | 1 | 1 | 1 | 1 |
| Were those subjects who were prepared to participate representative of the recruited population? | 1 | 1 | 1 | 1 |
| Were staff, places, and facilities where patients were treated representative of treatment most received? | 1 | 1 | 1 | 1 |
| Internal validity | | | | |
| Was an attempt made to blind study subjects to the intervention? | 0 | 0 | 0 | 0 |
| Was an attempt made to blind those measuring the main outcomes? | 0 | 0 | 0 | 0 |
| If any of the results of the study were based on data dredging was this made clear? | 0 | 0 | 0 | 0 |
| Was the time period between intervention and outcome the same for intervention and control groups or adjusted for? | 1 | 1 | 1 | 1 |
| Were the statistical tests used to assess main outcomes appropriate? | 1 | 1 | 1 | 1 |
| Was compliance with the interventions reliable? | 1 | 1 | 1 | 1 |
| Were main outcome measures used accurate? (valid and reliable) | 1 | 1 | 1 | 1 |
| Internal validity-confounding (selection bias) | | | | |
| Were patients in different intervention groups recruited from the same population? | 1 | 1 | 1 | 1 |
| Were study subjects in different intervention groups recruited over the same period of time? | 1 | 1 | 1 | 1 |
| Were study subjects randomized to intervention groups? | 0 | 0 | 0 | 0 |
| Was the randomized intervention assignment concealed from patients and staff until recruitment was complete? | 0 | 0 | 0 | 0 |
| Was there adequate adjustment for confounding in the analyses from which main findings were drawn? | 0 | 1 | 1 | 1 |
| Were losses of patients to follow-up taken into account? | 0 | 0 | 1 | 0 |
| Power | | | | |
| Was the study sufficiently powered to detect clinically important effects where probability value for a difference due to chance is < 5%? | 0 | 1 | 2 | 2 |

*Note: A=Onică et al. (2024); B=Van den Borre et al. (2021); C=Bai L et al. (2022); D=Nemtoi et al. (2022); 1=Yes; 0=No; 2=Partially.*

## *Surgical techniques*

The surgical techniques reviewed in the selected studies, including those by Onică et al. (2024), Nemtoi et al. (2022), Bai et al. (2022) and Van den Borre et al. (2021) were all based on advanced imaging procedures, with either CT or CBCT scans. For instance, Bai et al. (2022) found that CBCT scans helped to detail the bone structure, thus enabling the customization of the implants, using CAD software, to be so exact that the discrepancies in the fit were less than 0.3 mm. Van den Borre et al. (2021), for their part, used CBCT imaging to segment and superimpose pre-and-postoperative scans and determined there was an average bone loss of just 0.26 mm at the alveolar crest and just 0.088 mm at the basal frame after 12 months. Nemtoi et al. (2022) showed that these CAD-designed subperiosteal implants saved 20-30% of surgery time with increased accuracy of implant placement, which could reduce complications. This implant-adaptive precision of the aforementioned advanced methods is way superior compared to the traditional ones because most of those conventional techniques are needed to take the physical impression inside the patient's mouth. This implant-adaptive precision has been combined with additive manufacturing methods in order to obtain better integration and reduce surgery-associated risks. According to the studies, patient-specific implants were associated with not only reduced bone loss but also a higher implant success rate of more than 90%, even in cases of severe atrophic maxillae. These improvements have significantly enhanced patient outcomes by reducing complications and improving bone remodeling (Onică et al., 2024; Bai et al., 2022; Nemtoi et al., 2022; Van den Borre et al., 2021).

### *Postoperative considerations*

To develop additively manufactured subperiosteal implants, postoperative care is a critical concern among the reviewed studies. Nemtoi et al. (2022) mentioned that the only care follow-up needed with the DMLS titanium subperiosteal implants were antibiotics-clindamycin 300 mg-besides the pain relief medicines. In this, according to CT, the complication rate was 1 out of 16 patients, 6.25%. Follow-up was fixed at two weeks, six weeks, and three months after surgery, followed by a bi-annual check-up. Antiseptic mouthwash and mild brushing were advised as oral hygiene. Van den Borre et al. (2021) observed that the complication rate in the present study was 1/15 patients (6.6%). They emphasized the fact that postoperative imaging was required to verify the positioning of the implant and the remodeling of the bone. The postoperative visits comprised a visit after one week, 1, 3, and 6 months of the surgery, along with suggestions to take liquid and soft food and rinse the mouth with saline in the initial days of recovery. Onică et al. (2024) reported a complication rate in 3 out of 10 (30%) patients in their work 'Custom-Made 3D Printed Subperiosteal Titanium Implants'. Follow-up visits were routinely planned after two weeks, one month, three months, and every six months so that the patients could follow the course of healing and assimilation. The patients were advised to practice oral hygiene by doing a non-alcoholic antiseptic mouthwash and brushing their teeth using soft-bristled toothbrushes. Bai et al. (2022) noted that the complication rate was observed in 1 out of 6 patients (16.6%) in the case series of lattice-like additively manufactured subperiosteal implants. The follow-ups were planned in one week, one month, three months, and six months post-insertions. The patients were counseled to use chlorhexidine mouthwash and to avoid the pressure over the site of the implant during the initial phase of healing to ensure osseointegration as well as stability of the implant.

### *Considerations on complications*

Complication management is an essential element in postoperative care for subperiosteal implants, as the studies reviewed above have shown. Nemtoi et al. (2022) reported peri-implantitis in 1 out of 16 patients, accounting for a complication rate of 6.25%. Additionally, soft tissue reactions were observed in an even smaller proportion of patients. Regular follow-up visits, debridement, or systemic antibiotics nipped these issues in the bud right on time. Van den Borre et al. (2021) reported that in their study regarding AMSJI implants in the maxilla, the infection was 6.6%, which indicates 1 out of 15 patients. Implant mobility was detected in this study, and frequent imaging as well as follow-up are essential strategies to manage these complications. Surgical correction or the prescription of antibiotics was recommended as a prompt intervention to mitigate long-term problems. Onică et al. (2024) found complications in 3 out of 10 patients (30 %) ranging from infections to implant mobility. They further state that with proper patient follow-up and close monitoring, one can act fast enough by using antibiotics or surgical intervention to prevent these problems. Bai et al. (2022) recorded similar postoperative complications, which included a rate of infection in 1 out of 6 patients, that is, 16.6%, and failure in the case of one patient, or 16.6%. The situations were such that regular follow-ups facilitated the early detection of complications and necessary immediate interventions that guaranteed the extended survival of the implants.

Surgical techniques studied in this review article, among which were Onică et al. (2024), Nemtoi et al. (2022), Bai et al. (2022) and Van den Borre et al. (2021) used

preoperative advanced imaging like CT or CBCT, for implant designing on CAD software, and then finally proceeded with 3D printing of the actual product. The above methods provided optimized possibilities for customizing the implant according to the patient's anatomy and saved precious operating time, thus leading to better overall patient outcomes (Onică et al., 2024; Bai et al., 2022; Nemtoi et al., 2022; Van den Borre et al., 2021). This is opposed to traditional techniques, as described by Arshad et al. (2023), Lauwers et al. (2019) and McCaffery et al. (2017), which involved taking physical impressions of the bone intraoperatively to create casts to fabricate the implant. Although these techniques gave good results, they had some drawbacks regarding an accurate fit since the processes followed were manual and might lead to longer surgical times and less-than-optimal results (Arshad et al., 2023; Lauwers et al., 2019; McCaffery et al., 2017). The progress that has been made with additive manufacturing allows not only for anatomically correct but also patient-specific implants; this has overcome the limitations of conventional techniques and thus provided better implant integration, which could be linked with fewer complications in the case of specific pathologies (Onică et al., 2024; Bai et al., 2022; Nemtoi et al., 2022; Van den Borre et al., 2021). Upon reviewing the postoperative care in the studies, this regimen focuses on structuring follow-up schedules in terms of regular visits at one week, one month, three months, and bi-annually thereafter. This routine is emphasized by studies done by Nemtoi et al. (2022) and Van den Borre et al. (2021).

Additionally it was observed that monitoring of the healing process, complication early detection, and in-time interventions (Nemtoi et al., 2022; Van den Borre et al., 2021). In contrast, previous studies by Arshad et al. (2023), Lauwers et al. (2019) and McCaffery et al. (2017) chose for postoperative patients a less traditional monitoring procedure with fewer seances or superficial overall periods of monitoring. For example, in these previous studies, the research was based principally upon postoperative recalls immediately after surgery but less prolonged. This may have resulted in complications not being picked up and managed promptly, which affects long-term results (Arshad et al., 2023; Lauwers et al., 2019; McCaffery et al., 2017). The more in-depth and long-term follow-up in more recent studies most likely can explain the more acceptable long-term results and the lower rate of complications in these more innovative procedures. The selection of the implant material and design plays a vital role in treating complications. The 3D printing technology used in the reviewed studies allowed the manufacture of optimized surface complex geometries to enhance osseointegration and typically minimize mechanical stress (Onică et al., 2024; Bai et al., 2022; Nemtoi et al., 2022; Van den Borre et al., 2021). Among the materials used was titanium, which has been identified with both biocompatibility and strength, reducing complications that included infections, implant mobility, and peri-implantitis (Bai et al., 2022; Van den Borre et al., 2021). Whereas the former studies applied traditional geometries of implant designs without complexity or offering surface treatment (Nemtoi et al., 2022; Mangano et al., 2020; Schou et al., 2000; Branemark, 1985), the materials were titanium or cobalt-chrome, but again, the absence of advanced manufacturing methods can affect the surface property and fit of such implants and consequently may lead to a higher rate of complications (Onică et al., 2024; Bai et al., 2022; Nemtoi et al., 2022; Van den Borre et al., 2021). Moreover, these two factors-advances in implant design and choice of material-have dramatically reduced the incidence of complications in the more recent studies, hence pointing out the success of the subperiosteal implants in these two factors.

## Conclusion

The outcomes for the patients needing to receive subperiosteal implants, especially with severe bone atrophy, are constantly improved nowadays due to new rises in the design of the implant through additive manufacturing. Comparing these contemporary methods and their results to those of techniques used in the past shows that the more precise, individualized, and advanced materials used in these newer techniques have translated into better outcomes of surgeries, superior postoperative care, and fewer complications for patients. Future research should continue to evaluate the benefits of these developments over more extended periods and develop the techniques to enhance patient outcomes further.

## Acknowledgement

This research is self-funded.

## Conflict of interest

The authors confirm that there is no conflict of interest involve with any parties in this research study.

## REFERENCES

[1] Arshad, M., Khoramshahi, N., Shirani, G. (2023): Additively custom-made 3D-printed subperiosteal implants for the rehabilitation of the severely atrophic maxilla (a case report). – Clinical Case Reports 11(11): 16p.

[2] Bai, L., Zheng, L., Ji, P., Wan, H., Zhou, N., Liu, R., Wang, C. (2022): Additively manufactured lattice-like subperiosteal implants for rehabilitation of the severely atrophic ridge. – ACS Biomaterials Science & Engineering 8(2): 912-920.

[3] Branemark, P.I. (1985): Tissue-Integrated Prostheses. – Osseointegration in Clinical Dentistry 344p.

[4] Downs, S.H., Black, N. (1998): The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. – Journal of Epidemiology & Community Health 52(6): 377-384.

[5] Lauwers, F., Jalbert, F., Cavallier, Z., Prevost, A., Brandicourt, P., Roux, F., Delanoe, F. (2019): PEEK-custom made implants for facial reconstruction of complex congenital malformations. – International Journal of Oral and Maxillofacial Surgery 48: 1p.

[6] Mangano, C., Bianchi, A., Mangano, F.G., Dana, J., Colombo, M., Solop, I., Admakin, O. (2020): Custom-made 3D printed subperiosteal titanium implants for the prosthetic restoration of the atrophic posterior mandible of elderly patients: a case series. – 3D Printing in Medicine 6: 1-14.

[7] McCaffery, C., Dodd, M., Bekiroglu, F., Twohig, E. (2017): Synovial chondromatosis of the temporomandibular joint with extension into the middle cranial fossa and internal carotid canal. – International Journal of Oral and Maxillofacial Surgery 46(7): 867-870.

[8] Nemtoi, A., Covrig, V., Nemtoi, A., Stoica, G., Vatavu, R., Haba, D., Zetu, I. (2022): Custom-made direct metal laser sintering titanium subperiosteal implants in oral and maxillofacial surgery for severe bone-deficient patients-a pilot study. – Diagnostics 12(10): 12p.

[9] Onică, N., Budală, D.G., Baciu, E.R., Onică, C.A., Geleţu, G.L., Murariu, A., Balan, M., Pertea, M., Stelea, C. (2024): Long-Term Clinical Outcomes of 3D-Printed Subperiosteal Titanium Implants: A 6-Year Follow-Up. – Journal of Personalized Medicine 14(5): 13p.
[10] Page, M.J., McKenzie, J.E., Bossuyt, P.M., Boutron, I., Hoffmann, T.C., Mulrow, C.D., Shamseer, L., Tetzlaff, J.M., Akl, E.A., Brennan, S.E., Chou, R. (2021): The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. – BMJ 9p.
[11] Schou, S., Pallesen, L., Hjørting-Hansen, E., Pedersen, C.S., Fibæk, B. (2000): A 41-year history of a mandibular subperiosteal implant. – Clinical Oral Implants Research: Case report 11(2): 171-178.
[12] Van den Borre, C., Rinaldi, M., De Neef, B., Loomans, N.A., Nout, E., Van Doorne, L., Naert, I., Politis, C., Schouten, H., Klomp, G., Beckers, L. (2021): Radiographic evaluation of bone remodeling after additively manufactured subperiosteal jaw implantation (AMSJI) in the maxilla: a one-year follow-up study. – Journal of Clinical Medicine 10(16): 11p.