A Step-by-step technical report on the novel 'PREMADE protocol' for fabricating acrylic provisional prostheses for all-on-4® treatment concept

Alberto Pitino^{1*} Francesco Gianfreda^{2*} Alessandro Dolci³ Edoardo Fossati⁴ Gloria Voghera⁵ Patrizio Bollero⁶ Marco Gargari³ Karimi Dora¹ Mirko Martelli³

¹ DDS, Oral Rehabilitation Department, Pitino Clinic, Turin, Italy

- ² Department of Industrial Engineering, University of Rome "Tor Vergata", Rome, Italy
- ³ Department of Clinical Sciences and Translational Medicine, University of Rome
- "Tor Vergata", Rome, Italy
- ⁴DDS, Research Department, Pitino Clinic, Turin, Italy
- ⁵ Dental Hygienist, Oral Health Department, Pitino Clinic, Turin, Italy

⁶Department of System Medicine, University of Rome Tor Vergata, Rome, Italy

Corresponding author: Francesco Gianfreda e-mail: fgianfreda37@gmail.com

*Equally contributed first author

Abstract

Background: This technical report describes how to use a prosthetic protocol with a standardized immediate and fixed prosthesis that is the same for all patients. The prosthesis called "PREMADE" is adapted to various arch sizes (narrow, regular, and wide, with uniform teeth in all cases). This aim is to obviate the need for all laboratory procedures following the positioning of the implant.

Case Presentation: This report details the application of the PREMADE protocol in a clinical setting. It illustrates its use in a patient requiring immediate dental implant loading, highlighting the protocol's step-by-step technical nuances. The case underscores the protocol's efficiency in reducing laboratory phases and chair time, facilitated by its innovative approach of utilizing a standardized prefabricated arch adaptable to various jaw sizes. The procedure's success is evident in the minimized patient discomfort and improved osseointegration, attributed to the protocol's stability and micromotion control.

Conclusions: The PREMADE protocol signifies a transformative advancement in immediate dental implant loading, enhancing procedural efficiency and patient outcomes. Its application demonstrates the potential to reduce procedural complexity and time, thereby improving the patient experience. However, further research is required to establish its universal applicability and to compare it with other immediate loading protocols. The future integration of this protocol in all-on-4 rehabilitation could revolutionize the prosthetic phase, making advanced dental treatments more accessible

Keywords: All-on-four, Acrylic provisional Prostheses, Immediate implant loading

Background

Implant treatment can often be a source of significant apprehension and discomfort for patients. The immediate loading technique, which involves the application of an implant-supported prosthesis within the initial 48 hours post-implantation, stands in contrast to the conventional loading protocol (1). The latter necessitates a healing timeframe ranging from three to six months, followed by a similar duration for osseointegration, thereby extending the patient's discomfort (2). Adopting immediate placement and loading

Authors

Alberto Pitino - DDS, Oral Rehabilitation Department, Pitino Clinic, Turin, Italy

Francesco Gianfreda - Department of Industrial Engineering, University of Rome "Tor Vergata", Rome, Italy

Alessandro Dolci - Department of Clinical Sciences and Translational Medicine, University of Rome "Tor Vergata", Rome, Italy

Edoardo Fossati - DDS, Research Department, Pitino Clinic, Turin, Italy

Gloria Voghera - Dental Hygienist, Oral Health Department, Pitino Clinic, Turin, Italy

Patrizio Bollero - Department of System Medicine, University of Rome Tor Vergata, Rome, Italy

Marco Gargari - Department of Clinical Sciences and Translational Medicine, University of Rome "Tor Vergata", Rome, Italy

Karimi Dora - DDS, Oral Rehabilitation Department, Pitino Clinic, Turin, Italy

Mirko Martelli - Department of Clinical Sciences and Translational Medicine, University of Rome "Tor Vergata", Rome, Italy



License

This work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License.

Authors contributing to Oral and Implantology agree to publish their articles under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License, which allows third parties to copy and redistribute the material providing appropriate credit and a link to the

license but does not allow to use the material for commercial purposes and to use the material if it has been remixed, transformed or built upon.

How to Cite

A. Pitino, F. Gianfreda, A. Dolci, E. Fossati, G. Voghera, P. Bollero, M. Gargari, D. Karimi, M. Martelli. A Step-by-step technical report on the novel 'PREMADE protocol' for fabricating acrylic provisional prostheses for allon-4® treatment concept. Oral and Implantology Vol. 16 No. 3 (2024), 133-139. techniques aims to curtail these periods of recovery and associated discomfort, facilitated by the introduction of advanced methods for quantitative assessment of the implant's initial stability.

From a historical point of view, the rehabilitation of edentulous mandibular arches utilizing the All-on-4[™] treatment concept (Nobel Biocare AB, Göteborg, Sweden), introduced in 2003, involves the placement of four implants, with the distal ones being angled and immediately loaded with a fixed screw-retained prosthesis (3). These distal implants are positioned anterior to the mental foramen and angled posteriorly by approximately 30°, facilitating robust anchorage and minimizing the prosthetic cantilever extension (4). This protocol has revolutionized the surgical approach to atrophic mandibles, circumventing complex procedures such as inferior alveolar nerve transposition or bone grafting, often necessitated by significant bone resorption in the regions posterior to tooth loss (5).

The literature reports high medium to long-term survival rates for fixed prostheses supported by immediately loaded implants in the mandible (6-7). This success has prompted the application of similarly angled implants in the rehabilitation of edentulous maxillary arches, where posterior bone resorption might otherwise necessitate bone grafting (4, 8, 9). The distal angulation of the implants allows for an extended posterior placement, thereby reducing the cantilever and positioning the implant between the anterior wall of the maxillary sinus and the nasal fossa. This strategy has enabled the application of the All-on-4[™] treatment concept to the fully edentulous maxilla, showing promising results for medium and long-term outcomes (10).

In a recent literature review by Del Fabbro et al., 2,735 total prostheses supported by 11,205 implants with the All-on.4 protocol were considered. In a range between 3 and 18 years of follow-up, the cumulative survival rate for implants and prostheses was 93.91% and 99.31%, respectively (11).

Some clinical studies have also considered the Columbus Bridge protocol, which, similarly to the one proposed by Malò, provided for inclined and axial implants with immediate loading based on a metal framework (12). In this case, the cumulative survival rate of the implants at 10 years amounted to 93.55%, demonstrating the great reliability of the inclined implants with the immediate loading protocol (13).

After the implant placement and the insertion of the multiunit abutments, various prosthetic protocols have been proposed for delivering the screw-retained provisional prosthesis within a maximum of 48 hours.

In the case of the All-on-4[®] protocol, chair-side direct protocols have been proposed, as have indirect protocols that require sending impressions to the dental technician (14-15).

Over the years, various techniques have been proposed for immediate loading. The provisionalization methods have been defined as direct and indirect. Even if the immediate loading provisional generally has an occlusion defined as "canine-to-canine," many pitfalls can arise in the prosthetic phases in the chair and the laboratory (3) (Table 1).

This technical report aims to describe how utilizing a standardized 'premade' prosthesis, which is adaptable to various arch dimensions (narrow, regular, and wide, with uniform teeth across all cases), can prevent the need for all laboratory procedures following implant placement.

Case presentation

We propose an innovative method for immediate loading using a prosthesis, which we term "PREMADE." This method is delineated in a step-by-step approach below. Its core involves prefabricated prostheses designed with standard dimensions to fit a broad patient base.

A vital feature of these prostheses is their adaptability: they can be adjusted regarding vertical dimension and positioning. This adjustment can be accomplished using

Table 1. Pro and Contro of direct and indirect techniques for All-On-4 immediate loading prosthesis.

Technique	Pro	Contro
Direct	 Complete denture conversion. It is not necessary to send the prosthesis to the technician. 	 The dental elements are mounted according to the principles of removable prosthesis. In cases of severe atrophy there is a risk of
	Passivity of the prosthesis relined intraorally.	cross-bite assembly.
		• Problems regarding the vertical dimension may be present if a previous prosthesis is used
		If a major osteotomy is necessary it can be difficult follow this technique.
		Inability to insert a reinforcing bar
		Difficulty in finishing the prosthesis
Indirect	Adequate mounting of the models in the articulator.	Need to send the prosthesis to an external laboratory.
	 Possibility to appropriately program the size of the orthopedic portion of the prosthesis. 	The patient will not have the prosthesis immediately after the prosthetic surgery
	Possibility of inserting a reinforcement bar.	Potential loss of structures passivity.

Alberto Pitino et al.

an articulator or by the patient, ensuring a personalized fit. The primary objective of this protocol is to evaluate a novel temporary prosthetic approach. This approach is designed to immediately load four implants in the jaw, utilizing a total screw-retained prosthesis. The innovation lies in its simplicity and efficiency, streamlining existing techniques and significantly reducing surgical duration. Furthermore, this method is particularly beneficial for dental practitioners who need more immediate access to a dental technician. It enables the delivery of a temporary restoration within a few hours post-surgery, enhancing patient care and convenience.

Novel Prosthesis Design

For the fabrication of the prefabricated prostheses, the distances from the disto-buccal cusp of tooth 1.6 to the disto-buccal cusp of tooth 2.6 were measured in 250 adult patients. The dental arches were found to have an

average size of 56 mm. The smaller arches measured 53 mm, while the larger ones had an inter-molar distance of 59 mm. From a literature search, it was observed that these measures are like those reported by Burris and Harris on white and black American patients (16)

Therefore, three types of prostheses were designed: narrow arch (NA) 53 mm, regular arch (RA) 56 mm, and wide arch (WA) 59 mm, each with two distinct dental morphologies. The prefabricated bridge has the following characteristics: 12 elements in acrylic resin, the absence of a palate, a 10-degree anterior inclination of the occlusal plane relative to the Frankfurt plane, and an anterior height of 18 mm from the incisal edge of 2.1 to the upper margin of the pink flange (Figure 1).

Below are all the steps reported regarding a case carried out on a 64-year-old ASA-1 female patient. In the OPT X-ray, are periodontal lesions involving all the remaining teeth and some decay possible (Figure 2)?

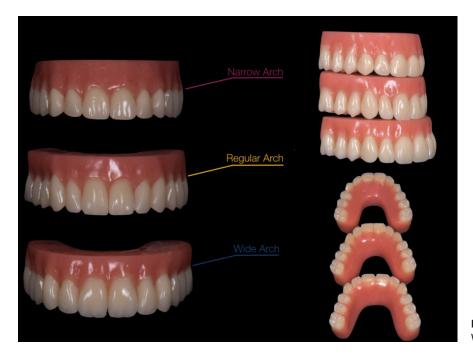


Figure 1. Small, Regular, and Wide PREMADE Prosthesis.

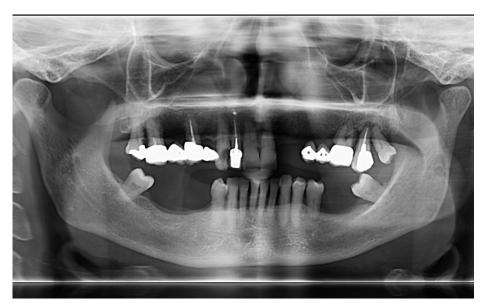


Figure 2. Orthopantomography of the patient at the baseline before implant treatment.

All the teeth were considered hopeless. The patient was informed about potential treatment plans and decided to perform extraction surgery and immediate loading implantology. The patient signed the informed consent form. Furthermore, the patient consented to the publication of her clinical case.

First appointment:

When the pre-surgical visit for the insertion of the 4 implants is carried out, the following prosthetic steps are additionally performed:

- 1. Taking impressions of the maxillaries in Alginate (Hydrogum 5, Zhermack SpA) using commercially available perforated aluminum impression trays (Zhermack SpA, Badia Polesine, Italy).
- Recording the facial references is necessary to establish a vertically correct aesthetic dimension, noting the extent of the increase in the Vertical Dimension of Occlusion (VDO).
- Construction of plaster models (Zeta®, Industria Zingardi Srl, Novi Ligure, Italy) and mounting in an articulator (Reference SL, Gamma Dental) using a facebow transfer (Gamma Dental) and mounting the mandibular model according to the patient's centric relation.

- 4. Transferring the increase in VDO (if performed) to the anterior rod of the articulator.
- 5. Measuring the width of the patient's maxillary arch with a compass from the disto-buccal cusp of 16 and 26 or, if absent, testing the prefabricated prosthesis on the plaster model of the edentulous patient.
- 6. Selection of the prefabricated prosthesis, available in 3 different sizes (NA, RA, WA).

First laboratory phase (can also be performed in the clinic with the support of a technician)

- 1. Positioning of the prefabricated prosthesis in the articulator, resting on the mandibular elements in a position of maximum intercuspation;
- 2. Filing of the maxillary plaster model, using a modeltrimming machine or a straight handpiece bur, at the level of the teeth (or edentulous ridge) until a toothless plaster model is obtained, sufficiently filed to accommodate the prefabricated bridge, according to the predetermined Vertical Dimension of Occlusion (VDO). The prosthesis is fixed to the plaster model with boxing wax (Zeta®, Industria Zingardi Srl) and adhesive wax (Renfert GmbH; Hilzingen, Germany);
- 3. Occlusal check in maximum intercuspation to adapt the bridge to the mandibular arch (Figs. 3, 4)

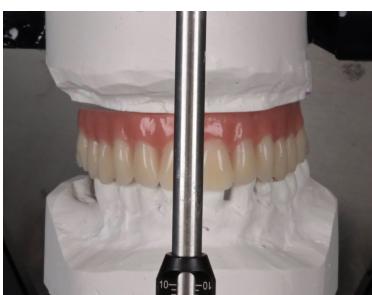


Figure 3. Assembly of the PREMADE prosthesis in the articulator.



Figure 4. Occlusal control of the prosthesis in the articulator. Contacts in the canine-to-canine area are mandatory.

Alberto Pitino et al.

Surgical procedure for inserting 4 implants following the All-on-4[™] technique with immediate prosthesis delivery. At the end of the suturing, the following operational steps are carried out:

- Placement of the bridge in the oral cavity, resting on the crest where the implants have been inserted, and checking the Vertical Dimension of Occlusion (VDO). If the VDO appears aesthetically too high, the prefabricated prosthesis must be filed down at the level of the pink flange. The correct VDO is noted on the upper central incisors, and the measurement is transferred to the pink flange (Figure 5).
- 2) Possible filing of the prefabricated prosthesis on the pink flange with a model trimming machine. The prosthesis is then repositioned in the patient's oral cavity in maximum intercuspation position, and the VDO is rechecked aesthetically (Figure 6).



Figure 5. Use of the caliper to report the decrease in the vertical dimension of occlusion from the dental elements to the flange.



Figure 6. Lowering the vertical dimension using the model square to maintain the angulation of the occlusal plane.

 Detection of the implant positions with precision detection material (Fit Checker® Advanced, GC Italia Srl, San Giuliano Milanese, Italy) placed on the prefabricated bridge (Figure 7).



Figure 7. Imprint of the position of the MUA.

- 4) Drilling of the bridge at the implant positions.
- Placement of the temporary copings (Nobel Biocare AB) screwed onto the MUA with a torque of 15 Ncm.
- Positioning of the drilled bridge on the temporary copings.
- 7) Checking the VDO.
- Injection of pink resin (Paladur®, Kulzer GmbH) with a dedicated syringe into the holes of the prosthesis in which the temporary copings are housed.
- 9) Once the resin polymerization in the oral cavity is complete, the temporary copings are fixed, and the prosthesis is unscrewed. The pink resin is used to fill the gaps left during the intraoral phase; the resin is polymerized under a pressure of 2 atmospheres for 10 minutes, and then it is finished and polished (Figs. 8, 9).



Figure 8. Relining, polishing, and intraoral view of the screw-retained immediate load prosthesis.

10) Placement of the screwed prosthesis in the oral cavity, preferring contacts from canine to canine in maximum intercuspation and canine guidance in laterality, as suggested by Malò et al. in 2003 (3).

The control x-ray at the end of the PREMADE prosthesis insertion demonstrates the prosthetic product's passivity (Figure10). The patient's recovery was uneventful.

A Step-by-step technical report on the novel 'PREMADE protocol' for fabricating acrylic provisional prostheses for all-on-4® treatment concept



Figure 9. Extra-oral view at the end of immediate-loading protocols on the day of the surgery.

The patient reported great satisfaction from an aesthetic and functional point of view, and no fractures or mechanical complications occurred. The control x-ray at the end of the screwing of the definitive structure demonstrated the maintenance of the peri-implant bone with no early resorption of the bone (Figure 10). covery was uneventful, and great satisfaction was found from an aesthetic and functional point of view. No biomechanical complications occurred, and the marginal bone level remained unchanged from a radiographic point of view. This has demonstrated significant effectiveness in managing the emergency profile of the prosthesis and the absence of "food-trap" areas that could have led to immediate bone loss. The possibility of rebasing the temporary abutments intraorally also allowed for effective passivation of the structure.

The PREMADE protocol's chairside approach, predicated on the predetermined spatial positioning of a standard arch, minimizes the necessity for extensive laboratory phases and reduces chair time. Some research (18) (19) emphasizes the criticality of transverse arch stability, micromotion control, and minimizing prosthetic complications in immediate implant loading. These principles resonate deeply with the PREMADE protocol, where the innovative design of temporary acrylic prostheses potentially stabilizes the implant-abutment interface, thus mitigating micromotion and enhancing osseointegration (20) (21).

Furthermore, the protocol's standard prefabricated arch ensures adequate resin thickness, removing the need for an internal metal bar and reducing prosthesis fracture

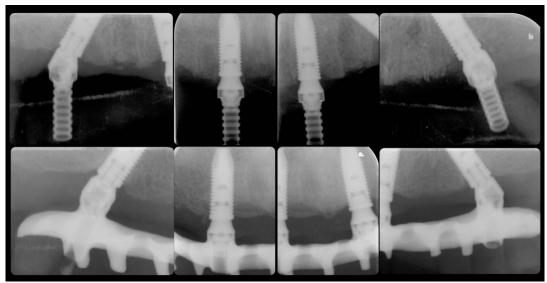


Figure 10. RX exams the day of the surgery and after 6 months after the definitive titanium-reinforced prosthesis delivery.

Discussion and conclusions

The PREMADE protocol, reflecting recent advancements in digital dentistry, revolutionizes the practice of immediate implant loading. Chen et al. (17) offer pivotal insights into the efficacy of digital prosthetics. This research demonstrates that digitally prefabricated prostheses substantially diminish procedural duration and postoperative discomfort compared to traditional methods. However, implementing a digital immediate loading protocol for interim prostheses necessitates advanced equipment such as digital scanners, photogrammetry, and skilled technicians.

In the case presented, it is possible to observe all the peculiar characteristics of the technique. The patient's rerisks. Combined with long implants and a rigid prosthetic structure, this approach promotes osseointegration even in upper jaws with D4 bone density near the maxillary sinus.

Despite these advancements, the PREMADE protocol's study results are primarily technical, and future research is needed to demonstrate its universal applicability. Comparative analyses with other immediate loading protocols are essential for a comprehensive evaluation (1) (22). Future integration of this protocol in all-on-4 rehabilitation could significantly reduce prosthetic phase creation time, enhance patient treatment perceptions, and, by lowering production costs, potentially democratize access to these dental treatments.

References

- Gianfreda F, Pesce P, Marcano E, Pistilli V, Bollero P, Canullo L. Clinical Outcome of Fully Dig-ital Workflow for Single-Implant-Supported Crowns: A Retrospective Clinical Study. Dent J (Ba-sel). 2022 Jul 27;10(8):139. doi: 10.3390/ dj10080139. PMID: 36005237; PMCID: PMC9406321.
- Bassir SH, El Kholy K, Chen CY, Lee KH, Intini G. Outcome of early dental implant placement versus other dental implant placement protocols: A systematic review and meta-analysis. J Perio-dontol. 2019 May;90(5):493-506. doi: 10.1002/JPER.18-0338. Epub 2018 Dec 5. PMID: 30395355; PMCID: PMC6500770.
- Malo P, Rangert B, Nobre M. "All-on-Four" immediate-function concept with Brånemark system implants for completely edentulous mandibles: a retrospective clinical study. Clin Implant Dent Relat Res 2003; 5:S2–S9.
- De Francesco M., Di Fiore A., Bruno G., Gargari M., Martelli M., Barnaba P., Marino M., Quer-cia A., Ceruso F.M. Fracture resistance of monolithic zirconia cantilevered frameworks in com-plete arch-prostheses supported by tilted or parallel implants. (2019) ORAL and Implantology, 12 (1), pp. 28-35.
- Colella G, Cannavale R, Vicidomini A, et al. Neurosensory disturbance of the inferior alveolar nerve after bilateral sagittal split osteotomy: a systematic review. J Oral Maxillofac Surg 2007; 65:1707–1715
- Esposito M, Grusovin MG, Achille H, et al. Interventions for replacing missing teeth: different times for loading dental implants. Cochrane Database Syst Rev 2009; (1): CD003878.
- Schnitman PA, Wöhrle PS, Rubenstein JE, et al. Ten-year results for Brånemark implants imme-diately loaded with fixed prostheses at implant placement. Int J Oral Maxillofac Implants 1997; 12:495–503.
- Barlattani A Jr., Franco R., Martelli M., Gianfreda F., Ferro R., Basili M., Bollero P. (2019) Guided bone regeneration in patients taking biphosphonates: two case series. ORAL and Implan-tology, 2019, 12(2), pp. 194-204
- A Minetti E, Gianfreda F, Palermo A, Bollero P. Autogenous Dentin Particulate Graft for Alveo-lar Ridge Augmentation with and without Use of Collagen Membrane: Preliminary Histological Analysis on Humans. Materials (Basel). 2022 Jun 18;15(12):4319. doi: 10.3390/ma15124319. PMID: 35744378; PMCID: PMC9230765.
- Maló P, de Araújo NM, Lopes A, et al. "All-on-4" immediate-function concept for completely edentulous maxillae: a clinical report on the medium (3 years) and longterm (5 years) outcomes. Clin Implant Dent Relat Res 2012;14:e139-e150.
- Del Fabbro M, Pozzi A, Romeo D, de Araújo Nobre M, Agliardi E. Outcomes of Fixed Full-Arch Rehabilitations Supported by Tilted and Axially Placed Implants: A Systematic Review and Meta-Analysis. Int J Oral Maxillofac Implants. 2022 Sep-Oct;37(5):1003-1025. doi: 10.11607/ jomi.9710. PMID: 36170316.

- Pera P, Menini M, Bevilacqua M, Pesce P, Pera F, Signori A, Tealdo T. Factors affecting the out-come in the immediate loading rehabilitation of the maxilla: a 6-year prospective study. Int J Peri-odontics Restorative Dent. 2014 Sep-Oct;34(5):657-65. doi: 10.11607/prd.1970. PMID: 25171036.
- Pera P, Menini M, Pesce P, Bevilacqua M, Pera F, Tealdo T. Immediate Versus Delayed Loading of Dental Implants Supporting Fixed Full-Arch Maxillary Prostheses: A 10-year Follow-up Re-port. Int J Prosthodont. 2019 Jan/ Feb;32(1):27-31. doi: 10.11607/ijp.5804. PMID: 30677109.
- Enrico Agliardi, Davide Romeo. Tilted Implants: Implant-prosthetic Rehabilitation of the Atrophic Patient. Quintessence Publishing, Company Incorporated, 2020. ISBN 0867159936
- Agliardi EL, Pozzi A, Romeo D, Del Fabbro M. Clinical outcomes of full-arch immediate fixed prostheses supported by two axial and two tilted implants: A retrospective cohort study with 12-15 years of follow-up. Clin Oral Implants Res. 2023 Apr;34(4):351-366. doi: 10.1111/clr.14047. Epub 2023 Feb 22. PMID: 36760035.
- Burris BG, Harris EF. Maxillary arch size and shape in American blacks and whites. Angle Or-thod. 2000 Aug;70(4):297-302. doi: 10.1043/0003-3219(2000)070<0297:MA-SASI>2.0.CO;2. PMID: 10961779.
- Chen C, Lai H, Zhu H, Gu X. Digitally prefabricated versus conventionally fabricated implant-supported full-arch provisional prosthesis: a retrospective cohort study. BMC Oral Health. 2022 Aug 9;22(1):335. doi: 10.1186/s12903-022-02376-y. PMID: 35945572; PMCID: PMC9361685.
- Ghoul WE, Chidiac JJ. Prosthetic requirements for immediate implant loading: a review. J Pros-thodont. 2012 Feb;21(2):141-54. doi: 10.1111/j.1532-849X.2011.00819.x. PMID: 22380648.
- Drago C. Frequency and Type of Prosthetic Complications Associated with Interim, Immediately Loaded Full-Arch Prostheses: A 2-Year Retrospective Chart Review. J Prosthodont. 2016 Aug;25(6):433-9. doi: 10.1111/jopr.12343. Epub 2015 Sep 15. PMID: 26372550.
- Barlattani A Jr, Martelli M, Ceruso FM, Gargari M, Ottria L. Convergent implant transmucosal collar and healing abutment: aesthetics influence on soft tissues. A clinical study. J Biol Regul Homeost Agents. 2020 Jan-Feb;34(1 Suppl. 1):63-69. DENTAL SUPPLEMENT. PMID: 32064837.
- 21. Gianfreda F, Bollero P, Muzzi M, Di Giulio A, Nicolai E, Canullo L. The Effects of Ultrasonic Scaling and Air-Abrasive Powders on the Decontamination of 9 Implant-Abutment Surfaces: Scanning Electron Analysis and In Vitro Study. Dent J (Basel). 2022 Mar 1;10(3):36. doi: 10.3390/ dj10030036. PMID: 35323237; PMCID: PMC8947291.
- Ceruso FM, Ottria L, Martelli M, Gargari M, Barlattani A Jr. Transgingival implants with a con-vergent collar (PRAMA); surgical and screwed prosthetic approach. A case report. J Biol Regul Homeost Agents. 2020 Jan-Feb;34(1 Suppl. 1):71-77. DENTAL SUPPLEMENT. PMID: 32064838.