ORIGINAL RESEARCH PAPER | Dental Science | Volume : 6 | Issue : 11 | November 2016 | ISSN - 2249-555X | IF : 3.919 | IC Value : 74.50

A Customized Mandibular Reconstruction Implant With Integrated Dental Implants to Treat Mandibular Continuity Defects

KEYWORDS: Mandibular continuity defect, tumor resection, mandibular reconstruction, customized mandibular implant, integrated dental implants

Philipp Sembdner	Jutta Markwardt	Matthias C. Schulz
Department of Mechanical Engineering,Institute of Machine Elements and Machine Design (Head: Prof. Dr. R. Stelzer), Technische Universität Dresden, Dresden,Germany	Department of Oral and Maxillofacial Surgery (Head: Prof. Dr. Dr. G. Lauer), Medical Faculty "Carl Gustav Carus", Technische Universität Dresden, Dresden, Germany	Department of Oral and Maxillofacial Surgery (Head: Prof. Dr. Dr. G. Lauer), Medical Faculty "Carl Gustav Carus", Technische Universität Dresden, Dresden, Germany

Raoul Lesche	Hans-Jürgen Ullrich	Gert Richter
H+E Product Development Company GmbH (Head: Dipl.-Ing. G. Engel, Boxdorf/Dresden, Germany	Institute for Lightweight Construction and Plastics Engineering, Technische Universität Dresden, Dresden, Germany	Department of Prosthetic Dentistry (Head: Prof. Dr. M. Walter), University Hospital "Carl Gustav Carus", Technische Universität Dresden, Dresden, Germany

Heike Meißner	* Bernd Reitemeier
Department of Prosthetic Dentistry (Head: Prof. Dr. M. Walter), University Hospital "Carl Gustav Carus", Technische Universität Dresden, Dresden, Germany	Department of Prosthetic Dentistry (Head: Prof. Dr. M. Walter), University Hospital "Carl Gustav Carus", Technische Universität Dresden, Dresden, Germany * Corresponding author

ABSTRACT *In cases of mandibular continuity defects following tumor resection or comminuted fractures the functionality of the orofacial system is severely impaired. Dislocation of the remaining stumps by muscular tension hampering a stable occlusion and food ingestion might be a consequence. By applying pre-fabricated bridging plates a satisfying compensation is mostly not achieved yet. A potential approach using a customized mandibular reconstruction implant and integrated dental implants is presented based on the treatment of an initial patient case. The customized mandibular reconstruction implant might serve as a pre-requisite to minimize the functional disruption of the orofacial system and as support for a sufficient oral rehabilitation. The medical and engineering cooperation required to perform such a new treatment is described in the presented case.*

Introduction

In recent years, digital methods have been increasingly applied for the design and fabrication of fixed and removable dentures [1-3]. Such technologies have also been used for maxillofacial prostheses, radiation applicators and customized tracheal cannulas [4-7].

Untreated mandibular continuity defects caused by comminuted injuries, partial resections following the treatment of malignant oro-pharyngeal tumors or after severe infections lead to extensive functional deficits in the oro-facial system. Muscular tension might cause a dislocation of the remaining mandibular stumps resulting in the loss of stable occlusal relationships [8]. For the patient, consequences including dysfunctions in mouth opening, chewing and swallowing as well as respiration and speech might occur. Moreover, there is a pronounced esthetic and physiognomic impairment [8-10]. In order to minimize these problems, reconstructive surgery should be performed immediately after the resection of the mandible. Autologous bone grafts are considered of superior suitability compared to alloplastic materials in primary and secondary mandibular reconstruction. However, in cancer patients undergoing radiotherapy and radiochemotherapy complications such as severe chronic soft tissue and bone inflammation, osteoradionecrosis of parts of the jaw or radiation fibroses of the soft tissue frequently occur. In those cases, mandibular reconstruction using bone is impossible. To stabilize the mandibular stumps straight pre-fabricated "bridging plates" are used. These metal reconstruction plates are fixed on the vestibular surfaces of the mandibular stumps. On the one hand, this results in a large difference in rigidity between the mandibular bone and the titanium bridging plate. However, this type of treatment does not permit reconstruction in the original shape of the jaw. The pre-fabricated plates must be bent and fitted to the patient's mandible before or during the mandibular resection. This not only requires a great deal of strength but also involves considerable inaccuracy in fitting as well as damage to the material (such as cold strain hardening and formation of cracks). Subsequently, due in large part to the dynamic load caused by chewing more than 40% of these patients experience problems such as plate fractures, loosening of screws and thus, intra- or extraoral exposure of the plates. These complications might result in extensive functional and esthetic disadvantages as well as additional stress for the patient [11-14]. The necessity of finding improved options to treat mandibular continuity defects led the authors

Volume : 6 | Issue : 11 | November 2016 | ISSN - 2249-555X | IF : 3.919 | IC Value : 74.50

to combine innovative technologies in order to develop a customized mandibular reconstruction implant made of pure titanium that enables the integration of pre-fabricated dental implants and thus, serves as basis to provide a sufficient oral rehabilitation. This was possible only with an intensive, well-coordinated interdisciplinary cooperation. The team required to develop this solution was composed of technical design and production specialists as well as oral and maxillofacial surgeons and dental specialists. Numerous preliminary experimental studies were conducted during this project [15-20].

Clinical and Technical Report

A 58-year old male patient presented at the Department of Oral and Maxillofacial Surgery at the Dresden University Hospital, Dresden, Germany. He was histologically diagnosed with a squamous cell carcinoma of the floor of the mouth infiltrating the right side of the mandible. The standard diagnostic procedures included a computed tomography (CT) scan of the patient's head and neck area. In the following section, the medical and technical steps required to provide the patient with a customized mandibular implant are presented. An overview of the steps and the involved co-operator is given in table 1:

1 - Clinical, histological and radiological **diagnostic procedures** including a CT scan of the patient's head and neck area to determine the extension of the tumor progression (Figure 1)

2 - Generation of iso-surfaces from the CT slices in order to design a virtual **three-dimensional polygon model** of the lower jaw

3 - **Planning of the customized mandibular implant**: determination of the later resection plane by the surgeon who will perform the operation (oral and maxillofacial surgeon) on the computer taking into account all diagnostic data (Figure 2 top), determination of the planned positions of the fixing screws considering the thicknesses of the bone layers of the lower jaw [16]; determination of the positions and axes of the pre-fabricated dental implants considering the overall planning for the provision of the prosthesis using the "Kontito" software tool based on the three-dimensional polygon model [21] (Figure 2 bottom)

4 - Reverse engineering of the three-dimensional polygon model to generate a **solid** for ongoing design purposes

5 - **virtual design of the cutting guides** that will enable one-to-one guidance of the saw during the resection at those points specified on the computer as described above (Figure 3)

6 - **virtual design of the customized mandibular implant**: structural design of the areas of the customized mandibular implant to be linked with the mandibular stumps; the later step milling of the mandibular stumps was virtually planned in advance; determination of the position of the screw bosses used to connect the two-part customized mandibular implant; structural integration of the pre-fabricated dental implants in coordination with the positions of the screw bosses (Figures 4 and 5); determination of the drilling holes in the areas to be connected to the mandibular stumps via which the screws used to fix the customized mandibular implant during the following surgery will be inserted

7 - **manufacturing of the patient-related parts**: two cutting guides and a two-part, customized mandibular implant – equipment: M2 cusing; CONCEPT laser; material for the cutting guides: stainless steel 1.4404; material for the customized mandibular implant: pure titanium, ASTM grade 2; technology: LaserCUSING® [22]. This is a laser melt process that generates layers and facilitates the production of graceful and complex shaped components

8 - **fixing of the prefabricated dental implants** (Straumann Standard implant, SP Ø 4.1 RN, length: 14 mm; Straumann, Freiburg, Germany) in the lingual part of the customized mandibular implant (Connexion; Degussa); testing the bond tightness was done via a micro-CT system (phoenix v / tome/x, General Electric); the testing of the torque load produced values up to 94 Ncm, which was higher than relevant data in the literature [23,24].

9 - **ultrasound cleaning** of the implant and the cutting guides

10 - **fastening of the patient-specific markings** for one-to-one use in the patient

11 - **sterilization** of the cutting guides and the customized mandibular reconstruction implant

12 – **surgical interventions** (positive vote - file number: 231211): usual soft tissue preparation; use of the cutting guides to find the sawing planes specified above; resection of the part of the lower jaw affected by the tumor with security margins; step milling in the marginal area of the customized mandibular implant at the mandibular stumps (Figure 6); fitting of the customized mandibular implant and fixing thereof using commercially available self-cutting titanium mini-screws (diameter: 2 mm; length: 5 and 7 mm; KLS Martin, Tuttlingen, Germany) to the mandibular stumps (Figure 7); before fastening, the remaining cavities in the mandibular implant were filled with a mixture of the patient's own blood and bone substitute material (NanoBone Granulate; ARTOSS, Rostock, Germany) to promote osteoinduction [25]; clinical testing of the stability of the bonds; covering with micro-anastomosed radial forearm flap, suturing of soft tissue (Figure 8)

13 -After complete wound healing, the implants will be uncovered and the patient provided with an **implant-based prosthesis**.

Discussion

Whenever possible, an immediate reconstruction of mandibular continuity defects using autologous bone and soft tissue grafts is recommended [26]. However, due to the general condition of the patient this is not always possible. In those cases, the reconstruction of the mandibular defect using a customized mandibular reconstruction implant might be an approach. Based on the CT of the patient's head and neck area which was carried out as part of the diagnostic procedures a virtual three-dimensional model of the patient's mandible was created. As far as a CT scan is routinely performed to evaluate the potential bone infiltration of the tumor so no delay in the diagnostic work up is caused. The scan served as the base for the interdisciplinary work leading to the virtual planning of the customized mandibular reconstruction implant and its manufacturing using LaserCUSING®. The surgical method performed in the presented case was tested in cadaver and in an *in vivo* study [18-20]. No surgical or technical problems were obvious during the surgical intervention. It is particularly noteworthy that pre-fabricated dental implants were integrated in the mandibular implant which might enable the provision of an implant-based prosthesis.

Volume : 6 | Issue : 11 | November 2016 | ISSN - 2249-555X | IF : 3.919 | IC Value : 74.50

One drawback of all pre-fabricated means of reconstructions the fact that no intra-operative changes are possible. Thus, the resection planes have to be determined extensively to prevent a recurrence of the tumor [27]. In order to minimize the risk of alterations to the planned procedure necessary to intra-operatively findings the application of functional imaging such as positron emitting tomography/ computed tomography might be benefical [28]. However, in the presented case no such changes of the planned procedure were necessary.

The functional deficits in the orofacial system described above could be minimized. Thanks to excellent coordination and intensive co-operation of the project partners the manufacturing time of the customized treatment components was reduced to 7 working days so that there was no delay in the care and treatment process for the patient. This initial treatment must be followed by additional cases in order to perform detailed function and quality tests [29]. In addition, other defect sites must be taken into account in the future as well.

Acknowledgements
The authors wish to thank the European Union Grant 13423 and the Free State of Saxony Grant 2273 for the financial support. Furthermore, the authors are grateful to Mrs. Gabriele Bellmann for the technical support in the study.

Conflict of Interest
Philipp Sembdner, Jutta Markwardt, Matthias C. Schulz, Hans-Jürgen Ullrich, Gert Richter, Heike Meissner and Bernd Reitemeier are employees of the Technical University Dresden (Technische Universität Dresden). Raoul Lesche is employee of Hofmann und Engel, Produktentwicklung Boxdorf/Dresden, Germany. The authors declare that there is no conflict of interest.

Legends of Illustrations
Fig. 1 Orthopantomogram of the patient's mandible before treatment.

Fig. 2 After preparation of the model of the head and neck CT data, the later resection planes (top) were processed at the virtual 3D-model using "Kontito" software. The pre-fabricated dental implant and the position, direction and length of the fixing screws were virtually integrated into the virtual 3D - model using "Kontito" software (bottom).

Fig. 3 By means of the 3D - model the two-piece cutting guides were designed to enable one-to-one guidance of the saw at the points specified in Figure 2 left.

Fig. 4 On the basis of the planning the individual two-piece mandibular implant was designed under consideration of the pre-fabricated dental implants. The lingual part with the virtually integrated dental implants is shown here (top). The two pieces of the customized mandibular implant are shown here; blue - lingual part; grey - vestibular part (bottom).

Fig. 5 The designed complete mandibular implant integrated in the 3D - model of the mandible.

Fig. 6 Within the frame of the project specific step milling cutters were developed (Reitemeier/Markwardt) which helped with the integration of the bonding area to the mandibular stumps (21XL06 or 21XL10 WST-UK- implant milling cutters with guiding spike and stop; Busch).

Fig. 7 Surgical situation after fixed of the customized mandibular implant at the patient.

Fig. 8 The orthopantomogram shows the situation of the patient eight days after the surgery.

Table 1 – Overview over treatment steps and involved co-operators

Step	Involved co-operator
diagnostic procedures	oral and maxillofacial surgeon
three-dimensional polygon model	engineer/CAD specialist
planning of the customized mandibular implant	oral and maxillofacial surgeon/ engineer/CAD specialist/ prosthodontist
reverse engineering of the solid	engineer/CAD specialist
virtual design of the cutting guides	engineer/CAD specialist
virtual design of the customized mandibular implant	oral and maxillofacial surgeon/ engineer/CAD specialist
manufacturing of the patient-related parts	engineer/CAD specialist
fixing of the prefabricated dental implants	dental technician
ultrasound cleaning	dental technician
fastening of the patient-specific markings	oral and maxillofacial surgeon
sterilization	oral and maxillofacial surgical team
surgical interventions	oral and maxillofacial surgeon
implant-based prosthesis	prosthodontist

Fig. 1

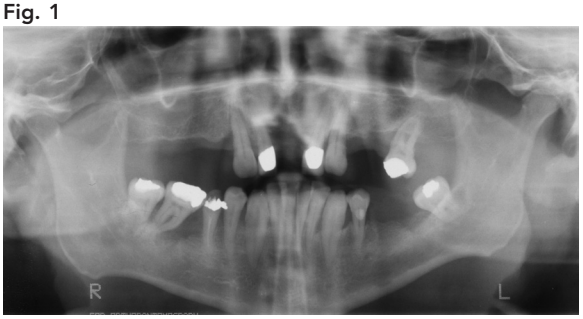
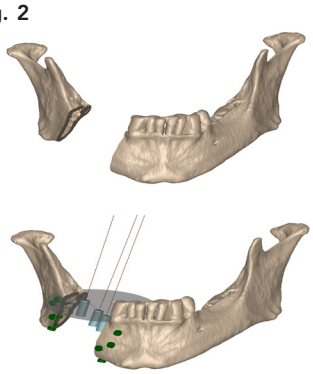


Fig. 2



Volume : 6 | Issue : 11 | November 2016 | ISSN - 2249-555X | IF : 3.919 | IC Value : 74.50

Fig. 3

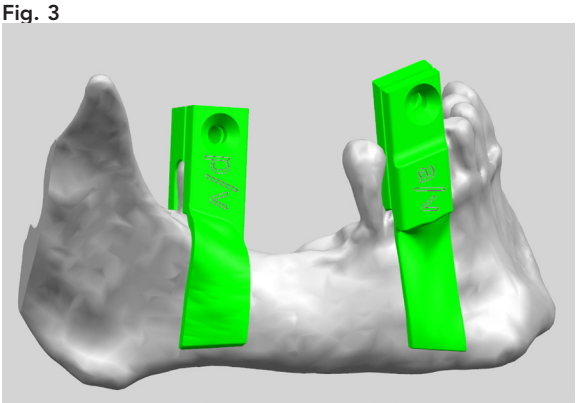


Fig. 4

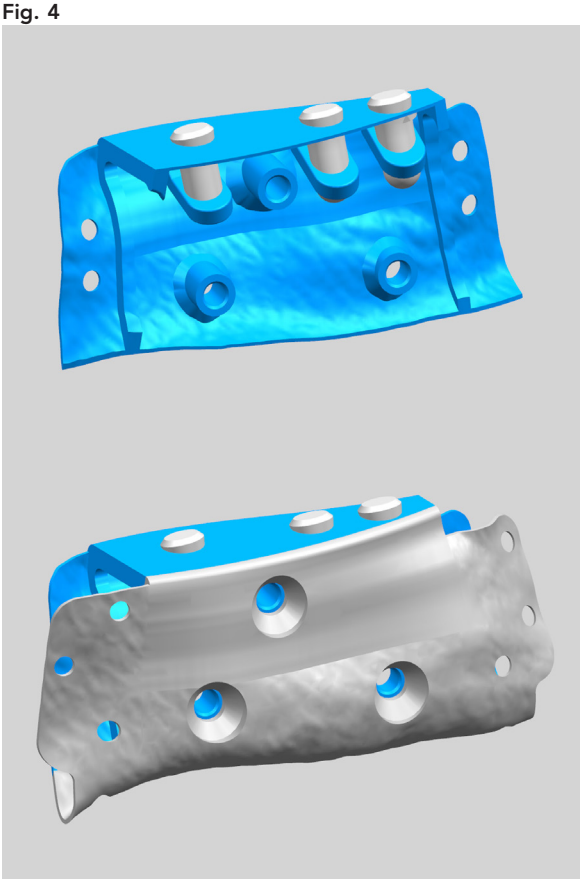


Fig. 5

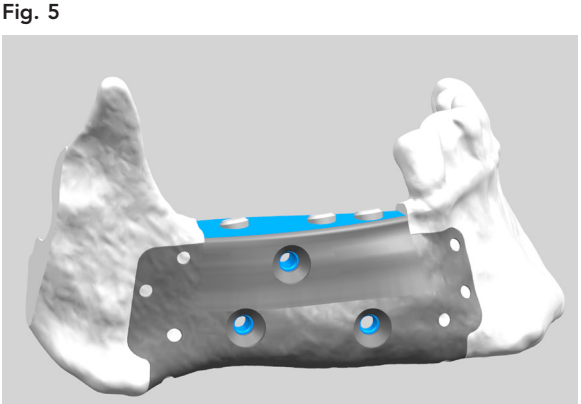


Fig. 6

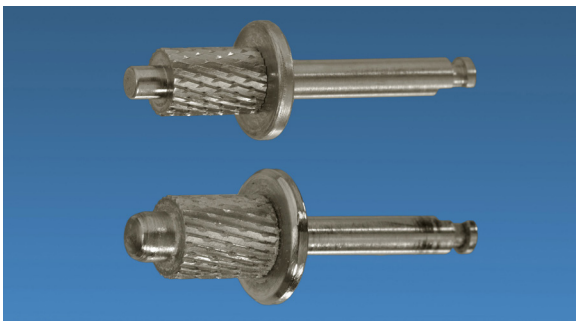


Fig. 7

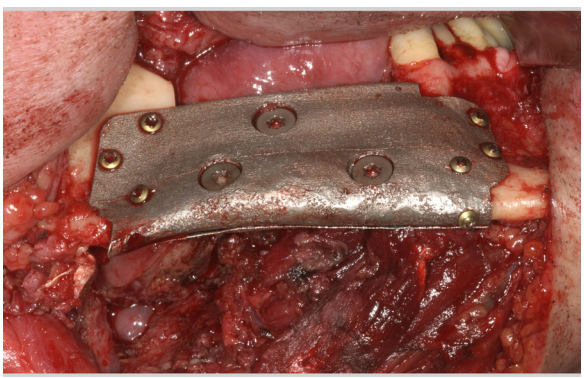
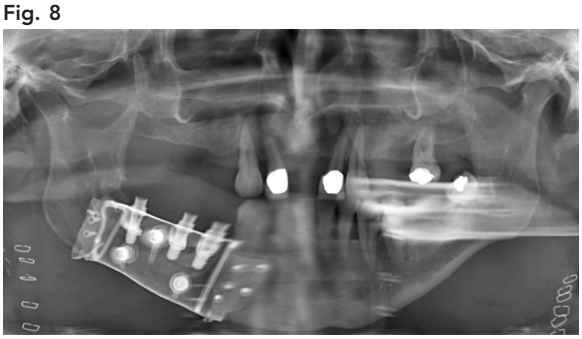


Fig. 8



References

1 - Reich S, Fischer S, Sobotta B, Klapper H, Gozdowski S. A preliminary study on the short-term efficacy of chairside computer-aided design/ computer-assisted manufacturing- generated posterior lithium disilicate crowns. Int J Prosthodont. 2010;23:214-216.

2 - Lima JMC, Anami LC, Araujo RM, Pavanelli CA. Removable partial dentures: use of rapid prototyping. J Prosthodont. 2014;23:588-591.

3 - Lin W, Harris BT, Zandinejad A, Morton D. Use of digital data acquisition and CAD/CAM technology for the fabrication of a fixed complete dental prosthesis on dental implants. J Prosthet Dent. 2014;111:1-5.

4 - Ciocca L, Scotti R. CAD-CAM generated ear cast by means of a laser scanner and rapid prototyping machine. J Prosthet Dent. 2004;92:591-595.

5 - Schreiber S, Reitemeier B, Herrmann T, Fichtner D, Walter M. A process for making cutaneous radiation applicators based on digital data. Strahlenther Onkol. 2006;182:349-352.

6 - Reitemeier B, Götzel B, Schöne C, Stockmann F, Müller R, Lexmann J, et al. Creation and utilization of a digital database for nasal prosthesis models. Onkologie. 2013;36:7-11.

7 - Müller R, Meissner H, Böttcher G, Jatzwauk L, Kant L, Schulz MC, et al. Development and first data of a customized short tracheal cannula based on digital data. Support Care Cancer. 2015;23:3089- 3093.

8 - Taylor TD. Diagnostic considerations for prosthodontic rehabilitation of

Volume : 6 | Issue : 11 | November 2016 | ISSN - 2249-555X | IF : 3.919 | IC Value : 74.50

the mandibulectomy patient. In: Taylor TD, editor, Clinical maxillofacial prosthetics. Carol Stream, Illinois: Quintessence; 2000. pp. 155-157.

9 - Reitemeier B, Unger M, Richter G, Ender B, Range U, Markwardt J. Clinical test of masticatory efficacy in patients with maxillary/mandibular defects due to tumors. Onkologie. 2012;35:170- 174.

10 - Müller R, Höhlein A, Wolf A, Markwardt J, Schulz MC, Range U, et al. Evaluation of selected speech parameters after prosthesis supply in patients with maxillary or mandibular defects. Onkologie. 2013;36:547-552.

11 - Müller F, Schädler M, Wahlmann U, Newton JP. The use of implant-supported prostheses in the functional and psychosocial rehabilitation of tumor patients. Int J Prosthodont. 2004;17:512-517.

12 - Knoll W, Gaida A, Maurer P. Analysis of mechanical stress in reconstruction plates for bridging mandibular angle defects. J Craniomaxillofac Surg. 2006;34:201-209.

13 - Markwardt J, Pfeifer G, Eckelt U, Reitemeier B. Analysis of complications after reconstruction of bone defects involving complete mandibular resection using finite element modelling. Onkologie. 2007;30:121-126.

14 - Wilde F, Plail M, Riese C, Schramm A, Winter K. Mandible reconstruction with patient-specific pre-bent reconstruction plates: comparison of a transfer key method to the standard method--results of an in vitro study. Int J Comput Assist Radiol Surg. 2012;7:57-63.

15 - Schöne P, Stelzer R, Sembdner R, Betrol L, Markwardt J, Reitemeier B, et al. Individual contour adapted functional implant structures in titanium. In: Bartolo A, editor. Innovative developments in virtual and physical prototyping. London: Taylor & Francis Group; 2008. pp. 29-34.

16 - Markwardt J, Meissner H, Weber A, Laniado M, Reitemeier B. Computed tomography evaluation of human mandibles with regard to layer thickness and bone density of the cortical bone. Röfo. 2013;185:40-47.

17 - Markwardt J, Friedrichs J, Werner C, Davids A, Weise H, Lesche R, et al. Experimental study on the behavior of primary human osteoblasts on laser-cused pure titanium surfaces. J Biomed Mater Res B Appl Biomater. 2014;102:1422-1430.

18 - Markwardt J, Sembdner P, Lesche R, Jung R, Spekl K, Mai R, et al. Experimental findings on customized mandibular implants in Gottingen minipigs - a pilot study. Int J Surg. 2014;12:60- 66.

19 - Markwardt J, Weber T, Modler N, Sembdner P, Lesche R, Schulz MC, et al. One vs. two piece customized implants to reconstruct mandibular continuity defects: a preliminary study in pig cadavers. J Craniomaxillofac Surg. 2014;42:790-795.

20 - Reitemeier B, Schöne C, Lesche R, Lauer G, Schulz MC, Markwardt J. Contour identical implants to bridge mandibular continuity defects--individually generated by LaserCUSING(R)--A feasibility study in animal cadavers. Head Face Med. 2016;April 12:17. DOI: 10.1186/s13 005-016-0114-0.

21 - Sembdner P, Schöne R, Stelzer R. Forming the interface between doctor and designing engineer – an efficient software tool to define auxiliary geometries for the design of individualized lower jaw implants. Int J Comput Assist Radiol Surg. 2012;7, Suppl 1, 418-420.

22 - Gebhardt A. Rapid Prototyping. München: Hanser; 2003.pp. 136-8.

23 - Weiss EI, Kozak D, Gross MD. Effect of repeated closures on opening torque values in seven abutment-implant systems. J Prosthet Dent. 2000;84:194-199.

24 - Yilmaz B, L'Homme-Langlois E, Beck FM, McGlumphy E. Accuracy of mechanical torque-limiting devices for dental implants after clinical service. J Prosthet Dent. 2015; 114:378-382.

25 - Götz W, Lenz S, Reichert C, Henkel K, Bienengraber V, Pernicka L, et al. A preliminary study in osteoinduction by a nano-crystalline hydroxyapatite in the mini pig. Folia Histochem Cytobiol. 2010;48:589-596.

26 – Bak M, Jacobson AS, Buchbinder D, Urken ML. Contemporary reconstruction of the mandible. Oral oncol. 2010;46:71-76.

27 – Eckardt A, Barth EL, Kokemüller H, Wegener G. Recurrent carcinoma of the head and neck: treatment strategies and survival analysis in a 20-year period. Oral oncol. 2004;40: 427-432.

28 - Abd El-Hafez YG, Chen C, Ng S, Lin C, Wang H, Chan S, et al. Comparison of PET/CT and MRI for the detection of bone marrow invasion in patients with squamous cell carcinoma of the oral cavity. Oral Oncol. 2011;47:288-295.

29 - Light J. Functional assessment testing for maxillofacial prosthetics. J Prosthet Dent. 1997;77:388-393.