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ORIGINAL ARTICLE

A clinical study on the 6-year outcomes of immediately loaded three implants for completely edentulous mandibles: "the all-on-3 concept"

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Abstract
The objective of the current study was to demonstrate the 6-year clinical and radiological treatment outcomes of the technique performed by immediately loading of three implants (single straight in the mid-line and two tilted distal implants) for the management of total edentulous mandibles and introduce a simple decision matrix for selection of the most appropriate protocol in cases with insufficient length of the interforaminal area. Re-assessments were performed over a total observation period of 6 years after surgery via measurement of bone resorption around implants, bleeding on probing, plaque accumulation, periodontal probing depth, bite force measurements and oral health impact profile. A total of 29 patients (45% women and 55% men) with a mean age of 65 ± 6 years enrolled in the study. 14 patients received an acryl-based bridge as definitive prosthetic restoration and 15 patients received a ceramic-based restoration. Both during the immediate loading phase and during the 6-year follow-up, there was no implantation loss. Regardless of the implant position, all implants showed continuous bone loss over the observation time. The bone loss around dental implants during observation period was only maximum 1.0 ± 1 mm and it remained well within the limits for 'success' according to the 2007 Pisa consensus (< 2 mm). The plaque index showed no significant fluctuations between the implant positions and the individual examination times. The approach described herein might help the surgeon by avoiding unnecessary loss of bone strength, selecting implant sites, and establishing the biomechanical advantage of increased A–P spread for immediate function.

Keywords Mandible · Immediate loading · Implant · Tilted

Introduction

Among multitude of surgical and prosthodontic concepts employing different implant numbers, inclinations and suprastructures, no ideal treatment option exists in the management of completely edentulous jaws. Therefore, patient-oriented therapy, which depends on the patient's needs and preferences, plays a key role in meeting patients' expectations. Due to the increased patients' demands, made on re-establishment of accurate function and esthetics within the shortest possible time, immediate loading of the implant-supported prosthesis for the rehabilitation of the edentulous jaws outshine as a fast and reliable therapy option in the daily dental practice.

A relatively recent technique developed for the rehabilitation of edentulous jaws with immediate loading is the so called 'All-on-4™' concept, which was originally introduced by Maló and coworkers in 2003 [1]. The technique is based on immediate loading of bilaterally placed two tilted distal implants in the premolar and two straight implants in the lateral incisor area. The main advantage of the technique is avoiding the transitional period of implant systems with delayed loading. Moreover, in the cases where a lack of sufficient bone volume at the posterior region exists, the need for inlay and/or onlay bones grafting of the posterior implant

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recipient sites could be avoided [2, 3]. The long-term outcomes of the technique have been the main concern of several studies, thus the fate of the immediately loaded four implants for rehabilitation of total edentulism was unpredictable. However, recent studies have demonstrated the long-term success of the concept in terms of peri-implant status, bite force re-establishment and oral health impact profile [4].

In All-on-4 protocol, rounded semi-circle shape of the mandible is suitable for obtaining a significant distance between the anterior and posterior implants, thus constituting a large support polygon. The meeting of two straight anterior implants which were typically inserted in lateral or central incisor position with an imaginary line shall determine the anterior limit of the support polygon. With this implant arrangement, a large inter-implant distance would allow a favorable stress distribution. Therefore, the anatomical structure of the interforaminal region plays a crucial role in this concept, thus the greatest available bone height in completely edentulous mandible is located in this area. Moreover, this region exhibits optimal density of one for implant support and ease of implant placement. Krekmanov et al. [5] have described the most anterior wall of the foramen, where the nerve will loop forward of the exit from the mandible 2–4 mm as the N-point (nerve point) as a guide for implant placement in this technique. The tilted implant should pass anterior to the N-point, but is still inserted posterior to the foramen when placed at a 30° angle, which facilitates an increased A–P spread of several millimeters, corresponding one bicuspid [6].

It is well known that the cervical distance between two implants should be greater than 3 mm to minimize the probability of resorption of interproximal alveolar crestal bone loss. According to Resnick [7], five implants of 4–5 mm diameter can usually be placed with general insertion guidelines of 3 mm between implants and 2–3 mm from the mental foramen and the mean interforaminal distance among Caucasians has been shown to be approximately 53 mm [8]. Despite recent advances in 3D implant planning, image-guided template production techniques, and computer-aided surgery, in cases where the interforaminal distance is limited and the course of the anterior loop of the inferior alveolar nerve overhangs the implant recipient site, accurate placement of the four implants in the interforaminal region could be challenging. In addition, the preferred length of implants for All-on-4 technique in the mandible is between 13 and 18 mm [9, 10]. Therefore, additional care should be taken in the selection of the anterior implant positions not to come in conflict with the apex of the tilted posterior implants [11]. Considering the necessary implant length, inter-implant distances and the possible risk of a confliction between apex of tilted and straight implants, the available distance between two N points is of great importance in facilitating accurate implant positions, which would affect the stress distribution, interproximal alveolar bone loss and thereby the long-term success of the therapy.

The objective of the current study was to demonstrate the 6-year clinical and radiological treatment outcomes of the technique performed by immediately loading of three implants (single straight in the mid-line and two tilted distal implants) (Fig. 1) for the management of total edentulous mandibles and introduce a simple decision matrix for selection of the most appropriate protocol in cases with insufficient length of the interforaminal area.

Materials and methods

Study group

During the period between July 2011 and May 2012, patients with edentulous mandibles, in whom the immediately loaded three implants supported overdenture (Fig. 1) was planned, were screened for participation in the trial and underwent thorough anamnesis and clinical examination. The study was approved by the Ethics Review Committee (NEAH/12.15.2015#498).

The inclusion criteria were as follows:

- Atrophy of the edentulous mandible with the rehabilitation option of 'All-on-4™' concept.
- An interforaminal distance (measured by axial scans CT between N points) of 40 mm (Fig. 1).

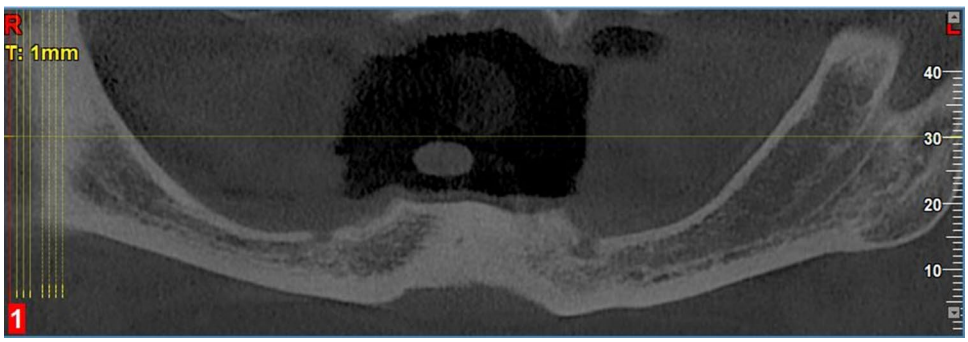

Fig. 1 Measurement of the interforaminal distance between two "N" points

- Opposing natural dentition or implant-based prosthesis
- An interforaminal bone width ≥ 5 mm, and bone height ≥ 8 mm.
- Completely healed, at least 6 month postextraction socket(s).

The exclusion criteria were as follows:

- General systemic contraindications against implant surgery (psychiatric disorders, pregnancy, metabolic bone diseases, diabetes, osteoporosis, etc.)
- The use of drugs which may negatively affect the osseointegration process (bisphosphonates, corticosteroids, etc.)
- Active inflammation or neighboring pathologies in the areas intended for implant placement.
- Radiation therapy to the head and/or neck region in the preceding 12 months.
- Smoking habit.
- Requirement of bone augmentation during implant placement.
- Clinically significant parafunctions and poor oral hygiene and/or compliance.
- A branch of the sublingual artery in the mid-line of the mandible which might cause a possible hemorrhagic complication (Fig. 2).

Eligible patients were informed orally and in writing about the goals and the duration of the study (observation period of 6 years) and the pertinent risks and benefits of the procedure and of the respective suprastructures. After receiving this information, 19 patients, receiving a total of 57 implants, declared written informed consent to participate. The patients were assigned to the different suprastructure groups (ceramics/acrylic) according to their own choice after comprehensive informed consent; the main decision criterion was the substantial difference in the price.

Surgical protocol

All patients received three external hex thread implants with Integrated Surface™–Large Grid Sand Blasted, Acid Etched (internal hex, Hi-Tec® implants LOGIC PLUS™) according to the All-on-4™ protocol; however, despite two straight anterior implants, a single implant was placed in the mid-line (Figs. 3, 4). Implant sizes were 4.3 × 13 mm anterior and 4.3 × 16 mm distal, the longer distal implants providing bicortical anchoring. All implants were immediately loaded within 24 h. The implants were placed with the 'Elcomed SA-310' surgical unit (W&H Deutschland, Laufen, Germany).

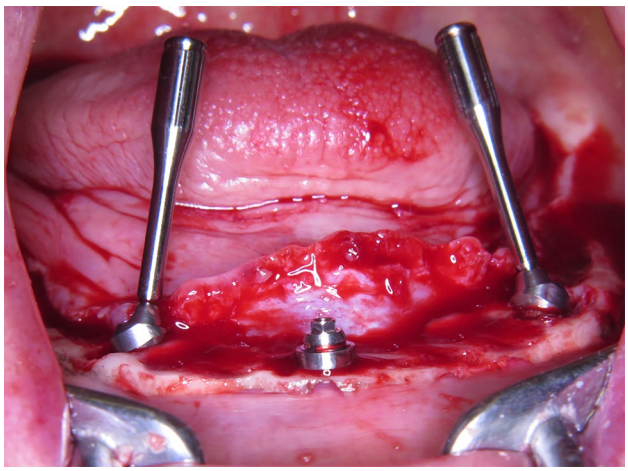

Fig. 3 Surgical insertion of the implants

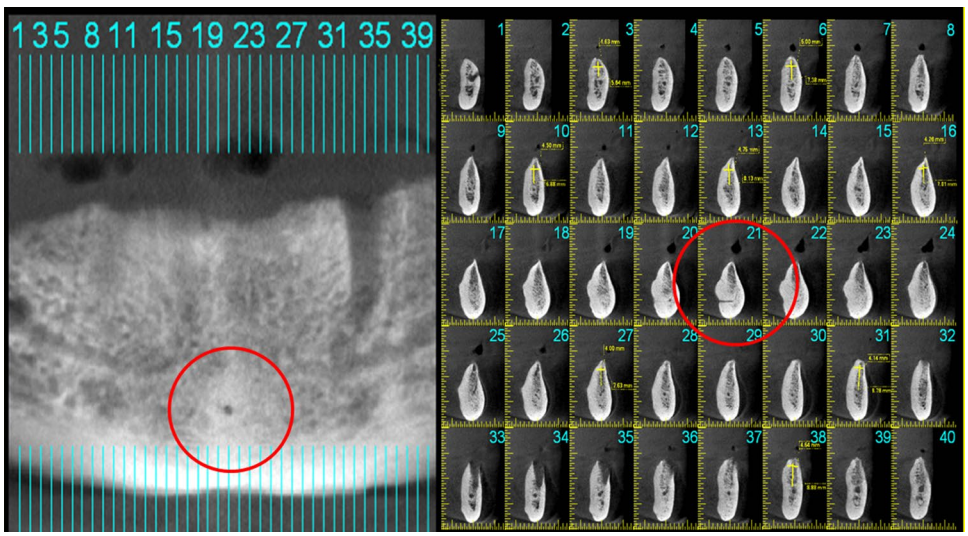

Fig. 2 Genial spinal canal in the mid-line of the mandible which might cause a possible hemorrhagic complication

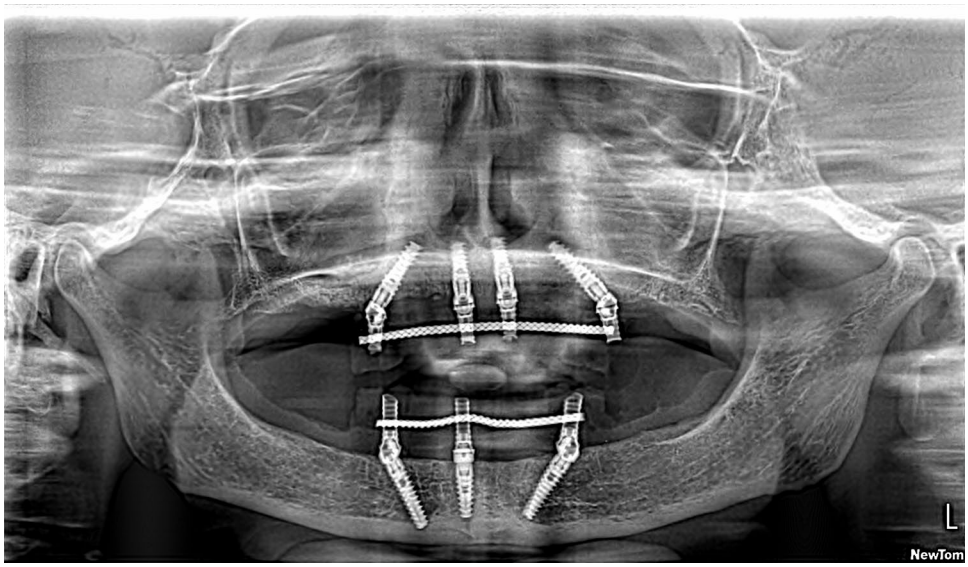

Fig. 4 Ortopantomograph taken after implant placement with provisional acrylic suprastructures in situ

The straight implants (n:19) were inserted with significantly less torque than the angulated implants in region 35(n:19) and 45(n:19) ($p < 0.0001$). The manufacturer-recommended threshold of 35 N was met or exceeded in all implants. The straight implants become a 0° multiunit abutment and the angulated implants 30° multiunit abutments. All procedures were performed by the same dental surgeons (M.A. and A.G.) under local anesthesia.

Prosthetic rehabilitation

The patients were assigned to different superstructure groups (metal-supported ceramics or acrylic resin) of their own choosing; the primary decision criterion was the substantial difference in price between the techniques.

Immediate prosthetic procedure

After completing the surgical procedure, impression was taken with the open-tray techniques using polyether material. For both groups, a high-density screw-retained implant-supported acrylic resin prosthesis was then manufactured at the dental laboratory and mounted within 24 h post-surgery. All centric and lateral contacts were evaluated with articulating paper 40 microns and adjusted to obtain a correct occlusal contact. A full-arch interim acrylic prosthesis is placed and secured with prosthesis screws torqued to 15 N cm.

Final prosthetic procedure

Three months later, for the patients who were slated to receive an acrylic suprastructure, a metal-acrylic screw-retained implant-supported prosthesis was fabricated using CAD/CAM technology, and an acrylic prosthesis with acrylic resin prosthetic teeth was prepared.

For the patients who were slated to receive ceramic suprastructures, 3 months later, a metal-ceramic screw-retained implant-supported fixed prosthesis with a chrome-molybdenum framework was fabricated using CAD/CAM technology and connected to the implants with abutment screws to 15 N cm.

Outcome parameter

Re-assessments were performed over a total observation period of 6 years after implant placement. Following parameters were assessed.

Measurement of bone resorption

Radiographic examinations were performed immediately after implant insertion as well as after 1 and 6 years. Bone crest levels around the implants were measured with a standard right-angle parallel technique, based on single digital X-rays [12, 13]. The radiographs were scanned at 600 dpi (Trophy RVG UI USB Sensor, Kodak 5.0 Software, Carestream, Stuttgart, Germany), and image analysis software was used to assess bone level (UTHSCSA Image Tool version 3.00 for Windows, University of Texas Health Science Center, San Antonio, TX, USA) (Fig. 5). The software was calibrated for every image using the length and diameter of the implant as the known distance; the linear distance between implant neck and the most coronal bone-to-implant contact at the mesial and distal aspect was measured for each implant, and bone loss was calculated using the bone level immediately after implantation as the reference.

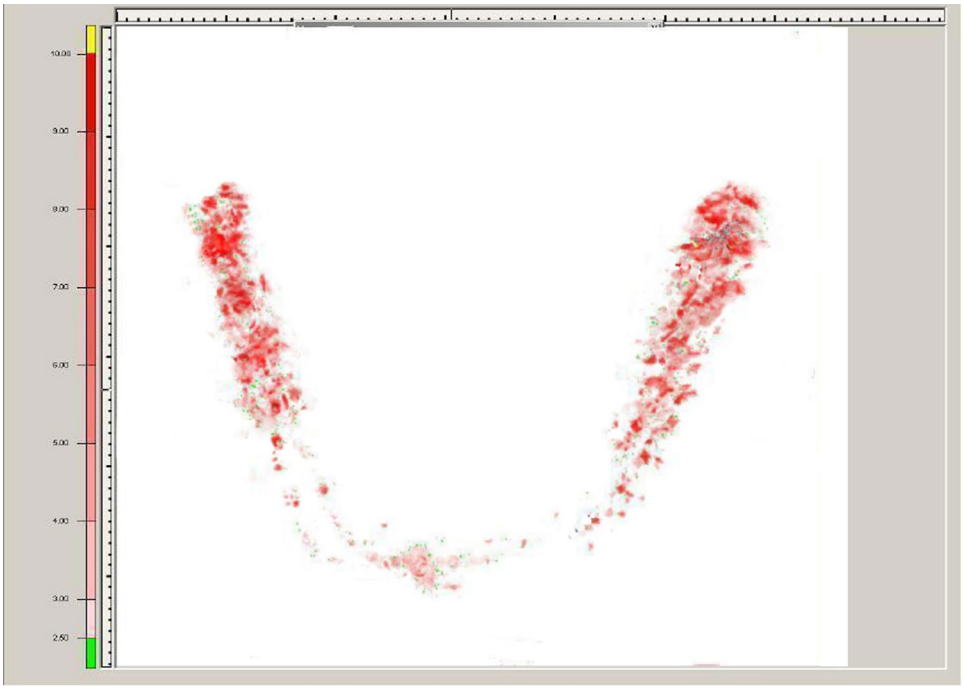

Fig. 5 Measurement of the occlusal forces with pressure-sensitive films

Peri-implant health status

A full-mouth examination (UNC-15 periodontal probe, Hu-Friedy, Rotterdam, Netherlands) was conducted, and plaque accumulation according to Mombelli et al. [14], periodontal probing depth (PPD) and bleeding on probing (BOP) were assessed according to established standard procedures. The observation of the clinical peri-implant health status was performed by a single researcher (M.A.). PPD was measured in millimeter at six peri-implant sites (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and distolingual), and bleeding was recorded at four sites (buccal, mesial, lingual, and distal). The deepest pocket was employed for analysis, and any bleeding on probing was recorded as 'yes'.

Measurement of the occlusal forces

Occlusal forces were measured and evaluated using a pressure-sensitive film and the appendant software (Dental Prescale 50H type R and Software FDP-8018E, Fuji Photo Film Co., Tokyo, Japan) (Fig. 4). The occlusal force measurements were performed before implantation with the conventional dentures, 1 week after integration of the immediate prosthesis, 1 week after integration of the definite prosthesis and upon final follow-up after 6 years.

Assessment of oral health-related quality of life

The impact of the reconstruction on quality of life was assessed with the oral health impact profile (OHIP), a very common instrument for the assessment of subjective treatment outcome in dentistry, particularly for implant-based fixed dentures [13]. In the present study, the German version of the OHIP 1430 was employed before surgery, immediately after implantation, 6 months after denture integration and 6 years after denture integration. The OHIP addresses 14 items in seven domains (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap) with a five-point verbal rating scale ranging from "never" (coded 0) to "very often" (coded 4). Therefore, low point scores represent a high quality of life.

Statistical analysis

The evaluation of the anonymized patient data was done with Microsoft EXCEL 2010 and IBM SPSS Statistics 23. Due to the multiple tests, a significance at a p value of <0.001 was defined. The sample size determination has been calculated using Survey Software® (Creative Research System, 2012) with a confidence level of 95%.

Results

A total of 29 patients (45% women and 55% men) with a mean age of 65 ± 6 years were included in the study. The age of the women (63 ± 6 years) was not significantly ($p = 0.629$) different from the men (66 ± 6 years) in the study group. The maximum insertion torque was significantly ($p < 0.001$)

Fig. 6 Definitive acrylic suprastructure

higher for the two lateral angulated implants (68 ± 5 and 65 ± 6 N cm) than for the medially inserted implant (52 ± 6 N cm).

14 patients received an acrylic resin-based prosthetic restoration with titanium framework (Fig. 6) and 15 patients received a metal-supported ceramic restoration with a chrome–molybdenum framework which was fabricated using CAD/CAM technology (Fig. 7). Both during the immediate loading phase and during the 6-year follow-up, there was no implantation loss. Among patients with acrylic suprastructures, all acrylic restorations showed some extent of abrasion. In addition, fracture of the suprastructure occurred in six patients. Four of those fractures (all on canine teeth) were superficial and could be repaired in situ, two reached the metal framework, and the denture had to be removed and repaired in the laboratory. In patients with

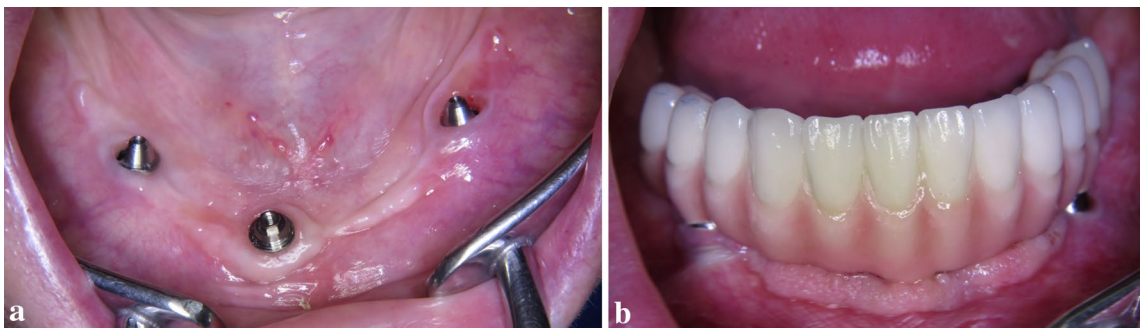

Fig. 7 **a** Implants in situ. **b** Definitive ceramic suprastructure

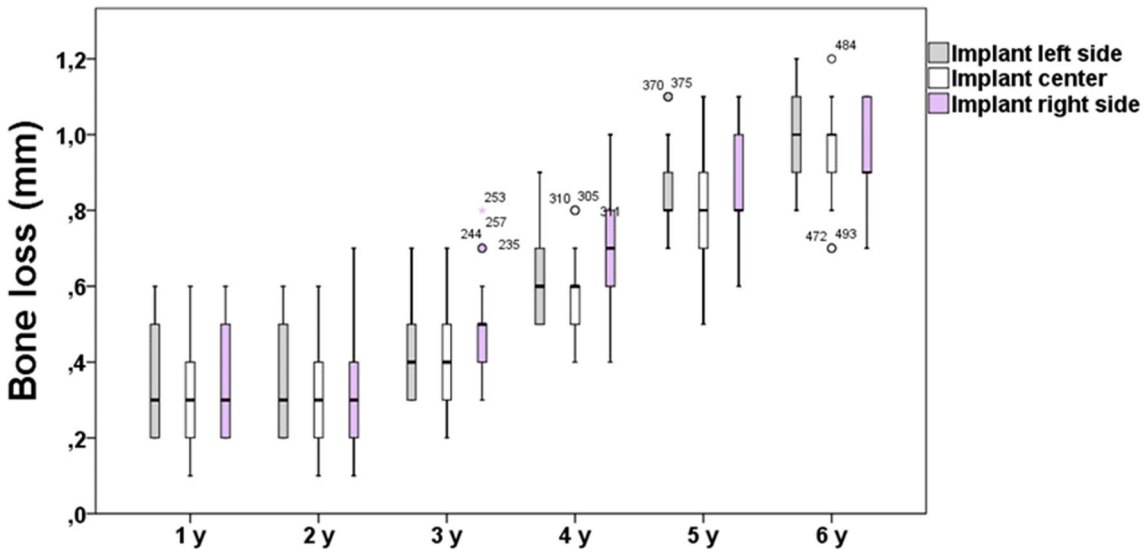

Fig. 8 Assessment of the marginal bone loss showed that regardless of the implant position, all implants show continuous bone loss over the observation time

ceramic suprastructures, superficial veneer fractures occured in two patients and could be repaired in situ.

Regardless of the implant position, all implants show continuous bone loss over the observation time (Fig. 8). At the latest from the fourth year after insertion, there is a significant ($p < 0.001$) bone loss for all implant positions in comparison to the initial findings in the first year. However, there is no difference between the implant positions within the individual follow-up points. After 6 years, on average, the bone loss around the angled implants is 0.9 ± 1 mm (left side) or 1.0 ± 1 mm (right side), and the straight inserted implant in the central position is 0.9 ± 1 mm. The plaque index shows no significant fluctuations between the implant positions and the individual examination times (Table 1). Corresponding to bone loss, a slow but continuous increase in pocket depth on the implants is detectable regardless of position by the fourth year at the latest, there is a significant ($p < 0.001$) increase in the pocket depth compared to the initial findings in the first year after implantation for all positions. At the respective times, there is no relevant difference between the pocket depths of the individual implant positions. After 6 years, on average, the pocket depth around the angled implants is 2.5 ± 0.5 mm (left side) or 2.6 ± 0.5 mm (right side) and the straight inserted implant in the central position is 2.5 ± 0.5 mm (Fig. 9). Both the OHIP and the bite force showed a significant ($p < 0.001$) improvement immediately after implantation with the provisional immediate restoration in comparison to the initial findings. The OHIP remains constant over the rest of the observation period. On the other hand, when measuring the chewing force, a slow, continuous increase is observed, whereby from the fifth year on an additional significant ($p < 0.001$) increase compared to the definitive restoration can be measured (Fig. 10).

Table 1 The plaque index shows no significant fluctuations between the implant positions and the individual examination times

	Plaque index implant position left side	Plaque index implant position central	Plaque index implant position right side
1 year	1.1 ± 0.8	1.2 ± 0.6	1.3 ± 0.7
2 years	1.2 ± 0.9	1.5 ± 0.6	1.5 ± 0.6
3 years	1.4 ± 0.7	1.5 ± 0.6	1.2 ± 0.7
4 years	1.4 ± 0.6	1.4 ± 0.7	1.4 ± 0.8
5 years	1.5 ± 0.8	1.4 ± 0.7	1.4 ± 0.7
6 years	1.2 ± 0.6	1.3 ± 0.7	1.4 ± 0.8

Discussion

In the literature, there are numerous articles reporting treatment outcomes following the All-on-4 immediate loading concept, which was first described by Malo et al. [1] for the management of the edentulous mandibles. Despite the limited number of the studies focusing on the therapy outcomes of immediately loaded three implant-supported treatment protocols for edentulous jaws, immediate loading concept with three implants for the treatment of mandibular edentulism has been introduced by Branemark et al. [15] with satisfactory outcomes. The protocol described by Branemark et al. involved prefabricated components and surgical guides, elimination of the prosthetic impression procedure and attachment of the permanent fixed bridge on

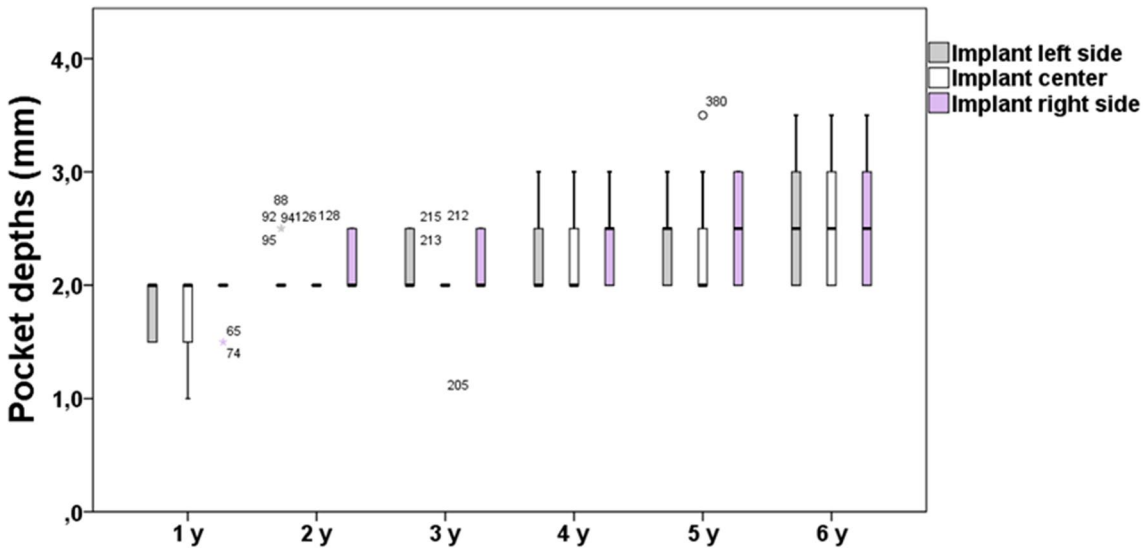

Fig. 9 Bite force measurement revealed a slow, continuous increase which is observed, whereby from the fifth year, an additional significant ($p < 0.001$) increase compared to the definitive restoration can be measured

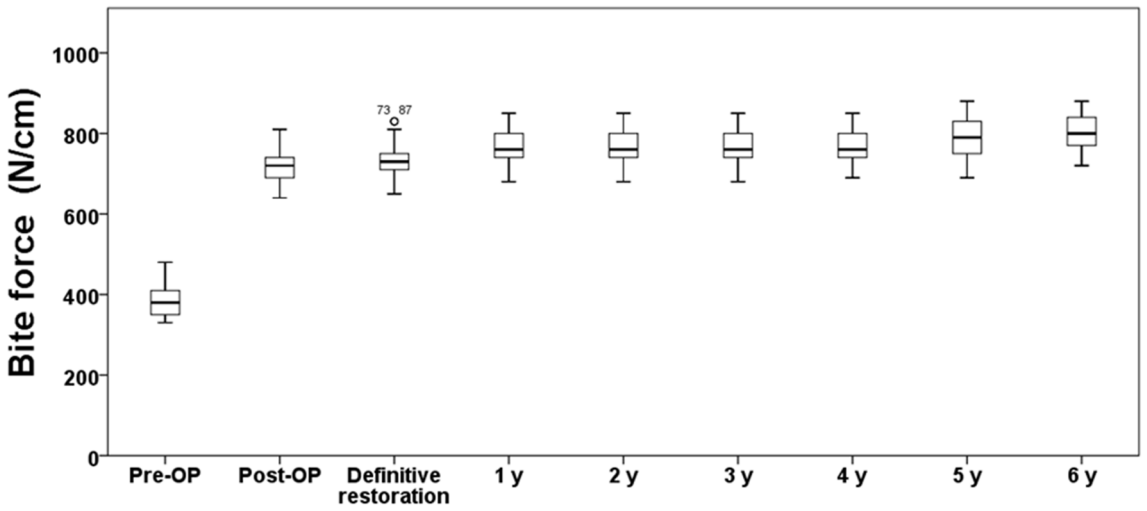

Fig. 10 The OHIP remains constant over the rest of the observation period

the day of implant placement on three straight implants. This concept has been the subject of two other studies [16, 17]; however, the literature on immediate loading concept for edentulous jaws has been dominated by All-on-4 researches. The technique described herein also involves an immediate loading concept; however, it differs from the so called—Novum concept—in tilting of the distal implants and the absence of a prefabricated component.

The suprastructure-related outcome differences after All-on-4 protocol has been studied several times [18]. In addition, a recent article [19] has aimed to evaluate and compare the clinical and radiographic outcomes of mandibular rehabilitation with fixed prostheses on three implants with immediate versus delayed loading. According to their results, the three implant-supported fixed prosthesis protocol proved to be a viable therapeutic strategy for mandibular edentulous patient with maxillary complete dentures, regardless of whether loading was immediate or delayed, with no difference in peri-implant bone loss. However, an influence of implant number on stress distribution on peri-implant bone status has not been sufficiently assessed for the mandibular overdentures [20, 21].

In the current study, clinical and radiological parameters regarding the suprastructure-related differences were not analyzed; however, in the literature, it has been proclaimed that the prediction of the amount of stress in overdentures due to their dynamic nature cannot be done as simply as fixed prostheses [22]. This might increase elasticity and motion of the prosthesis, which could lead to unpredictability. In addition, the relatively higher rates of suprastructure fractures observed in the current study could be attributed also to the above-mentioned fact. From this point of view, it might be stated that, in the cases where three implants would be selected for immediate loading, ceramic suprastructures should be preferred over acrylic suprastructures.

The results described herein have also showed that, regardless of the implant position, all implants show continuous bone loss over the observation time. However, there is no difference between the implant positions within the individual follow-up points. In addition, after 6 years, on average, the bone loss around the angled implants is 0.9 ± 1 mm (left side) or 1.0 ± 1 mm (right side), and the straight inserted implant in the central position is 0.9 ± 1 mm. According to the existing literature, peri-implant bone loss has been an advanced criterion for long-term implant success and requires an extended observation period to be reliably implemented as a criterion for implant success [4, 12]. Basically, the success criterion according to Zarb and Alberktsson is less than 0.2 mm per year [23]. However, Zitzmann et al. have proclaimed that, for peri-implant bone loss, an observation period of ≥ 5 years is desirable for an outcome assessment that complies with the contemporary success criteria [24]. In the present study, it was observed that the bone loss around dental implants during the year observation period was only maximum 1.0 ± 1 mm and it remained well within the limits for 'success' according to the 2007 Pisa consensus (< 2 mm) [25].

It is obvious that shortening of the treatment duration and reducing the number of surgical interventions plays a great role in meeting the expectations of the dental implant candidates and could improve the oral health-related satisfaction levels [26]. In addition, the correlation between bite forces and satisfaction levels has been studied several times. According to Nogawa et al. [27], there appears to be a correlation between the OHIP and increased occlusal forces. Similarly, both the OHIP and bite measurements showed a significant ($p < 0.001$) improvement immediately after

implantation with the provisional immediate restoration in comparison to the initial findings. Further studies might be beneficial to determine the exact relation between patients' satisfaction an occlusal forces.

It could be suggested that, computer-guided surgery could be a viable and predictable treatment option in the immediate loading concept with tilted implants. However, to achieve the required peak insertion torque values for immediate loading with tilted implants, under-preparation of the implant cavity and bicortical anchorage were mostly preferred surgical techniques. It is obvious that, both techniques necessitate a higher knowledge about the bone type/density and the surgeon has to be experienced enough to conceive the condition of the tissue and implement spontaneous intraoperative solutions. Considering the fact that guided surgery could be sensitive to the experience of the surgeon and requirement of a learning curve [28], the preference of the surgeon about the conventional or guided surgery should depend on his own personal knowledge.

It should be kept in mind that the small number of patients in the study and the highly selected patient population with a low-risk profile and very good compliance do not make it possible to generalize this therapy concept for the edentulous patient in the lower jaw. Larger numbers of patients and the expansion of the patient collective are necessary to better determine the importance of this treatment concept in general dentistry. In addition, this therapy option is a technology-sensitive treatment concept, which requires not only a lot of experience in implantology but also in the adequate processing of prosthetic suprastructures. The results of this study are also certainly attributable to the very experienced practitioner with high case numbers and clinical expertise on this field.

Conclusion

The approach described herein might help the surgeon by avoiding unnecessary loss of bone strength, selecting implant sites, and establishing the biomechanical advantage of increased A–P spread for immediate function.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All the procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Review Committee (NEAH/12.15.2015#498).

Informed consent Informed consent was obtained from all individual participants included in the study.

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