“All-on-4” IMMEDIATE-FUNCTION CONCEPT FOR COMPLETELY EDENTULOUS MAXILLAE: A CLINICAL REPORT ON THE MEDIUM (3 YEARS) AND LONG-TERM (5 YEARS) OUTCOMES

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ABSTRACT

Background: Immediate implant function has become an accepted treatment modality for fixed restorations in totally edentulous mandibles, whereas experience from immediate function in the edentulous maxilla is limited.

Purpose: The purpose of this study was to report on the medium and long term outcomes of a protocol for immediate function of four implants (All-on-4, Nobel Biocare AB, Göteborg, Sweden) supporting a fixed prosthesis in the completely edentulous maxilla.

Materials and Methods: This retrospective clinical study included 242 patients with 968 immediately loaded implants (Brånemark System® TiUnite™, Nobelspeedy™, Nobel Biocare AB) supporting fixed complete-arch maxillary all-acrylic prostheses. A specially designed surgical guide was used to facilitate implant positioning and tilting of the posterior implants to achieve good bone anchorage and large inter-implant distance for good prosthetic support. Follow-up examinations were performed at 6 months, 1 year and thereafter every 6 months. Radiographic assessment of the marginal bone level was performed after 3 and 5 years in function. Survival was estimated at patient level and implant level using the Kaplan-Meier product limit estimation with 95% confidence intervals.

Results: Nineteen immediately loaded implants were lost in seventeen patients, giving a 5-years survival rate estimation of 93% and 98% at patient and implant level, respectively. The survival rate of the prosthesis was 100%. The marginal bone level was, on average, 1.52 mm (SD 0.3 mm) and 1.95 mm (SD 0.4 mm) from the implant/abutment junction after 3 years and 5 years, respectively.

Conclusion: The high survival rates at patient and implant level indicates that the immediate function concept for completely edentulous maxillae using the present protocol is viable in the medium and long term outcomes.
INTRODUCTION

In a previous study, an immediate function concept for the edentulous mandible was presented with its clinical follow-up (All-on-4, Nobel Biocare AB, Göteborg, Sweden). The protocol used a surgical guide for the positioning of four implants between the mental foramina to reach a favourable biomechanical prosthetic support. Advantageous load conditions made it possible to use provisional all-acrylic prosthesis, delivered within the same day of surgery. This constituted the starting point for the rehabilitation of the complete edentulous maxilla using the same treatment concept. Evidence on immediate/early function in the edentulous maxilla is scarce. Owing to lower bone density in the maxilla, immediate loading in this jaw region is perceived as a greater challenge than in the mandible. Furthermore, implant anchorage in the totally edentulous maxilla is often restricted owing to bone resorption, which is especially frequent in the posterior region of the maxillary arch, where bone grafting is often indicated. The use of implant tilting in the maxilla has been demonstrated to be an alternative to bone grafting. By tilting the distal implant, a more posterior implant position can be reached reducing the cantilever, and improved implant anchorage can be achieved by benefiting from the cortical bone of the wall of the sinus and the nasal fossae. The use of four implants in the maxilla is encouraged by results from in vivo implant load analyses demonstrating that favourable load distribution for complete-arch prostheses can be achieved with four implants provided that they are placed as “cornerstones”: two posterior and two anterior and well spread. Biomechanical analyses indicate that the most anterior and posterior implants supporting a reconstruction take the major load share at cantilever loading, irrespective of the number of intermediate implants. For a given distance between the anterior and the posterior implant, the load supported by the most heavily loaded implant (the distal implant) is virtually independent of the total number of implants that support the restoration. These theoretic findings are supported by the in vivo measurements. In addition, by using a finite element analysis model to compare the coronal stress when applying occlusal load, it is possible to conclude that there is a biomechanical advantage to use implants tilted distally, opposing to the use of axial implants supporting a larger number of cantilever teeth. Good clinical outcomes from studies using protocols in which four implants were placed to support a full-arch prosthesis indicate that the placement of larger numbers of implants may not be necessary for successful implant treatment of edentulous jaws.

The purpose of this study was to demonstrate the development of an immediate function protocol for fixed complete-arch prostheses in the completely edentulous maxilla supported by four implants (All-on-4), of which the two distal implants were tilted along the anterior sinus wall, and to present its clinical documentation for the medium and long-term outcomes with a follow-up of 5 years.
The research hypothesis was: the rehabilitation of complete edentulous maxillae through fixed prosthesis supported by immediate function implants using a standardized concept “All-on-Four” is possible with the same survival distribution in the long term as the rehabilitation of complete edentulous maxillae through fixed prosthesis supported by implants inserted through immediate/early loading surgical protocols.

MATERIAL AND METHODS

This article was written following the Strobe (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.26 This clinical study was performed in a private clinic, Malo Clinic, in Lisbon, Portugal, and was approved by an independent Ethical Committee. Two-hundred-forty-two patients (101 males and 141 females; mean age=55.4 years; range: 25-87 years) were consecutively included from November 2002 to November 2006 provided that they met the inclusion criteria and gave their written consent to participate in the study.

Inclusion and Exclusion Criteria

The inclusion criteria were the need for complete rehabilitation of the edentulous maxilla and the possibility of placing a minimum of four implants (at least 10 mm long) into the completely edentulous maxilla, using tilting implants in distal sites. The opposing dentitions were implant-supported prostheses (107 patients), natural teeth (68 patients), a combination of both (60 patients), and removable prosthesis (7 patients). As exclusion criteria, the patients with implants placed in periodontally compromised areas (implant inserted on an extraction socket of a periodontally compromised tooth), extraction sockets (with more than 2/3 of the implant inserted on the extraction socket) or presenting with bone dehiscences or fenestrations at surgery were excluded from the study.

Implant Components

A total of 968 implants (Brånemark System TiUnite Mk III and Mk IV; Nobelspeedy™, Nobel Biocare AB) were placed and immediately loaded (within the same day of surgery). The length of the implants ranged from 10 mm to 18 mm. Straight and angulated (17 and 30 degrees) Multiunit abutments (Brånemark System) were used.

Surgical Protocol

The surgical procedures were performed under local anesthesia, articaine clorhidrate (72mg/1.8ml) with epinephrine (0.018mg/1.8ml) 1:100,000 (Artinibsa 2%, Inibsa Laboratory, Barcelona, Spain). All patients were sedated with diazepam (Valium® 10 mg, Roche, Amadora, Portugal) prior to surgery. Antibiotics (amoxicillin 875 mg + clavulanic acid 125 mg, Labesfal, Campo de Besteiro, Portugal) were given 1 hour prior to surgery and daily for 6 days thereafter. Cortisone medication (prednisone 5
mg [Meticorten® Schering-Plough Farma, Lda, Agualva-Cacém, Portugal]) was given daily in a regression mode (15 mg to 5 mg) from the day of surgery until 4 days postoperatively. Antiinflammatory medication (ibuprofen, 600 mg, Ratipharma, Lda, Carnaxide, Portugal) was administered for 4 days postoperatively starting on day 4. Analgesics (clonixine [300 mg, Clonix®, Janssen-Cilag Farmaceutica, Lda, Barcarena, Portugal]) were given on the day of surgery and postoperatively for the first 3 days if needed. Antacid medication (omeprazole, 20 mg, Lisboa, Portugal) was given on the day of surgery and daily for 6 days postoperatively.

The surgical protocol followed was described in length in a previous publication. Teeth were extracted, when needed, at the time of surgery before implant placement. A mucoperiosteal flap was raised at the ridge crest with relieving incisions on the buccal aspect in the molar area. A small window was opened to the sinus using a round bur for identification of the exact position of the anterior sinus wall. The implants and abutments were placed in one position at a time, starting with the posterior ones. A special guide (edentulous guide, Nobel Biocare AB, Goteborg, Sweden) was used to assist implant and abutment placement. This guide was placed into a 2 mm osteotomy made at the midline of the jaw and the titanium band is bent so that the occlusal centerline of the opposing jaw was followed. By doing this, it was possible to guide the implants to be placed in the center of the opposing prosthesis and at the same time find the optimal position and inclination for best implant anchorage and prosthetic support.

The insertion of the implants followed standard procedures, except that underpreparation was used to achieve an insertion torque of at least 35 Ncm before final seating of the implant. The preparation was typically done by full drill depth with a 2mm twist drill followed by 2.4/2.8mm step drill and 3.2/3.6mm (depending on bone density). In cases of high density bone, the 3.8/4.2mm step drills were used only in the cortical bone. The implant neck was aimed to be positioned at bone level, and bicortical anchorage was established whenever possible.

The posterior implant tilting allowed a position shift on the implant head from a vertically placed implant in the canine / first premolar region to a tilted implant in the second pre-molar / first molar region, following the anterior sinus wall up to 45 degrees of inclination. Thirty degrees angulated abutments were connected to the implant correcting the inclination to a maximum of 15 degrees. The posterior implants were mostly of 4 mm in diameter.

The anterior implants were oriented vertically by a guide pin replacing the edentulous guide (Nobel Biocare AB). Care was taken in the selection of the anterior implant positions not to come in conflict with the apex of the tilted posterior implants, which normally reached the canine area.

The anterior implants were 3.3 mm, 3.75 mm, or 4 mm of diameter and typically inserted in lateral or central incisor positions. With this implant arrangement, the authors aimed at allowing good implant anchorage, a large inter-implant distance, and short cantilever length with the posterior implants typically emerging at the second premolar / first molar position.
After closing and suturing the flap with 3-0 nonresorbable suture, the abutments were accessed by means of a punch if needed, and impression copings were placed.

**Immediate Prosthetic Protocol**

Complete arch acrylic resin (Heraeus Kulzer GmbH, Hanau, Germany) prostheses were inserted on the day of surgery (n=242). The fabrication of the implantsupported prosthesis followed standard procedures. After suturing, an impression with putty material (Elite HD+ Putty 50ft Fast; Zhermack 5pA) was made in a custom open tray. After tray removal, healing caps (Nobel Biocare AB) were placed to support the periimplant mucosa during the fabrication of the prosthesis. A high-density acrylic resin (PalaXpress Ultra; Heraeus Kulzer GmbH) prosthesis with titanium cylinders (Nobel Biocare AB) was manufactured at the dental laboratory, and inserted on the same day usually 2 to 3 hours post-surgically. Anterior occlusal contacts and canine guidance during lateral movements were preferred in the provisional prosthesis.

**Final Prosthetic Protocol**

Considering patient desires, a metal ceramic implant supported fixed prosthesis with a titanium framework and all-ceramic crowns (Procera titanium framework, Procera crowns, Nobel Rondo ceramics; Nobel Biocare AB), or a metal-acrylic resin implant-supported fixed prosthesis with a titanium framework (Procera titanium framework; Nobel Biocare AB) and acrylic resin prosthetic teeth (Heraeus Kulzer GmbH), was used to replace the provisional prosthesis. If an adjustment of the angulated abutment was needed for better positioning of the screw access hole, the impression for the final prosthesis was taken at implant level. The abutment position was then decided at the laboratory and was adjusted in the patient’s mouth. In this final prosthesis, the occlusion mimicked natural dentition. The final prosthesis was delivered typically 6 months post-surgically. Representative photographs of a patient with a bi-maxilar rehabilitation through the All-on-4 concept with a fixed prosthetic rehabilitation with 5 years of follow-up were included (Figures 1 to 3).

**Drop-out Rate and Implant Survival Criteria**

Eighteen patients withdrew from the study. Seven patients in the first 6 months, 4 patients between 6 months and 1 year, 3 patients between 1 and 2 years, 3 patients between 2 and 3 years, and 1 patient between 3 and 4 years. An implant was classified as a survival according to the Malo Clinic survival criteria: (1) it fulfilled its purported function as support for reconstruction; (2) it was stable when individually and manually tested; (3) no signs of infection observed; (4) no radiolucent areas around the implants; (5) demonstrated a good aesthetic outcome of the rehabilitation; and (6) allowed a construction of the implant supported fixed prosthesis which provided patient comfort and good hygiene maintenance.

The implants removed were classified as failures. Survival estimates were computed on patient level and implant level using the Kaplan-Meier product limit estimation with 95% confidence intervals (CI).
Follow-Up and Marginal Bone Level

Follow-up examinations were performed at 6 months, 1 year after implant placement and thereafter every 6 months. Intraoral or panoramic radiograph examinations were performed at the 1-year follow-up (no baseline at surgery was established), 3 years and at 5 years of follow-up. For the intraoral technique, a conventional radiograph holder was used, the position of which was adjusted manually to ensure orthogonal film positioning. The implant-abutment interface was taken as a reference point for the bone level measurements. A blinded operator examined all radiographs of the implants for marginal bone resorption. Each periapical radiograph was scanned at 300 dpi with a scanner (HP Scanjet 4890, HP Portugal, Paço de Arcos, Portugal), and the marginal bone level was assessed with image analysis software (Image J version 1.40g for Windows, National Institutes of Health, USA). The reference point for the reading was the implant platform (the horizontal interface between the implant and the abutment), and marginal bone remodelling was defined as the difference in marginal bone level relative to the bone level at time of surgery. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads; a clear thread guarantees both sharpness and an orthogonal direction of the radiographic beam towards the implant axis.

Complications

The following mechanical complication factors were assessed: fracture or loosening of mechanical and prosthetic components. The following biological complication parameters were assessed: fistula formation, pain or infection, soft-tissue inflammation (registered as present or absent), and implant stability (assessed by removing the bridge and manually applying lateral forces to the implant). The following functional complication factors were assessed: patient phonetics (assessing the complaints of the patient), cheek and lip biting, vertical dimension, chewing ability (assessing the complaints of the patient), and prosthesis retention (assessing the complaints of the patient). The following aesthetic complication factors were assessed: teeth aesthetics (assessing the complaints of the patient and dentist), lip support (assessed by performing the upper lip retraction to the base of the nose in the sagital plane and observing the severity of wrinkled appearance), and soft-tissue aesthetics (assessing the visibility of the transition zone between natural and artificial gingiva in maximum smile).

RESULTS

Implant Survival

One patient died due to causes unrelated to the implant treatment. A total of 968 immediate function implants were placed and 19 implants were lost (in 17 patients), with a higher incidence of failures in the first year of function (n=14). The survival rates at patient and implant level were 93% and 98.1%, respectively after 5 years of follow-up (Kaplan-Meier) (see Tables I and II). On patient level, the mean survival estimate was 75.7 months (95% CI: 73.3-78.2 months [the maximum registered follow-up for a patient was 81 months]). On implant level, the mean survival
The estimate was 79.5 months (95% CI: 78.9-80.2 months [the maximum registered follow-up for an implant was 81 months]). The survival rate of the prosthesis was 100%.

**Failures and Remedies**

A total of 19 implant failures were registered in 17 patients. The distribution of implant losses is illustrated in Table III.

Twelve of the 19 implants failures were posterior implants. In 14 patients, the prosthesis survived on the 3 remaining implants until the reinsertion of the lost implants (between 4 and 7 months in 10 patients, between 9 and 12 months in 3 patients and after 1 year in one patient); in 1 patient, the prosthesis survived on the 3 remaining 3 implants and the implant was not reinserted; in 1 patient with 2 implant failures, the implants were not reinserted due to the death of the patient.

**Marginal Bone Level**

At 3-years of follow-up, 621 implants in 196 patients had readable radiographs (81%). The bone level was in average 1.52 mm (SD 0.3mm) at 3 years (SD 0.4 mm) below the abutment-implant interface (Table IV).

At 5-years of follow-up, 106 implants in 33 patients had readable radiographs (82%). The bone level was in average 1.95mm (SD 0.4 mm) below the abutment-implant interface (Table IV).

**Complications**

The mechanical complications recorded were fractures of the provisional acrylic prosthesis (in 5 patients), abutment screw loosening (in 2 patients), prosthetic screw loosening (1 patient), and wear prosthetic and abutment screws (in 1 patient), all on the provisional prosthesis. One of the registered fractures of the prosthesis and one of the registered abutment screw loosening occurred in the same patient. The situations of fractured prostheses occurred in four bruxing patients. The situations were resolved by repairing the prosthesis, adjusting the occlusion and manufacturing an occlusal night-guard. The abutment and prosthetic screw loosening situations (3 patients) were resolved by retightening the prosthetic and abutment screws, controlling the occlusion and advising the patient not to overload the prosthesis. The wear prosthetic and abutment screws (in 1 patient) were resolved by replacing the prosthetic components, controlling the occlusion and advising the patient not to overload the prosthesis.

All prostheses were easily mended and served well after revision. No further mechanical complications were registered during the follow-up of this study.

The biological complications registered were an infection in 1 implant (occurred in the same patient with an abutment screw loosening and a fracture of the prosthesis). The situation was resolved by solving the prosthetic problems and through non-surgical treatment (removal of debris and irrigation with chlorhexidine). No further biological complications were observed.

No functional or aesthetical complications were observed.
DISCUSSION

The 93% and 98% survival rate at 5 years on patient and implant level, respectively, compares favourably with other reported immediate/early loading protocols for the same indication.\textsuperscript{2–18} Effectively, the cumulative success rate of implants placed for the complete rehabilitation of the maxilla ranged between 93.4% and 100%\textsuperscript{4,6,7,12,14} for early loading with a follow-up between 1 and 5 years; and between 91% and 100% for immediate function with a follow-up between 1 and 5 years.\textsuperscript{2,3,5,11,13,15-18}

The mean bone level (1.52 mm and 1.95 mm obtained after 3 years and 5 years of functional loading respectively) was in accordance with previous experience on early function with the same type of implants,\textsuperscript{13,27} on which the bone levels reported ranged between 0.8 mm and 1.2 mm after 1 year and 1.5 years of follow-up respectively.

These results allow us to support the hypothesis that the prosthetic rehabilitation of the edentulous maxillae through the All-on-4 concept is possible, with a survival distribution similar to other rehabilitation protocols for the same purpose. High survival rates have been frequently reported in the literature for immediate function of fixed mandibular complete-arch prostheses supported by three or four implants.\textsuperscript{1,28-31} However, when immediate loading is applied in the maxilla, a larger number of implants is generally used,\textsuperscript{2,5-7,10} although documented experience on delayed loading has shown equivalent outcomes when comparing the use of four or six maxillary implants as support for fixed full-arch prostheses.\textsuperscript{4,25}

The present treatment concept uses the load-bearing capacity of the maxillary bone in a favourable way. Owing to the freedom of tilting, the implants can be anchored in dense bone structures (anterior bone with higher density) and well spread anteriorly-posteriorly, giving an effective prosthetic base. By reducing the number of implants to four, each implant can be placed without coming into conflict with adjacent implants. This treatment approach, using tilting and few implants rather than inserting several implants competing for space, has demonstrated good results in a previous study with delayed loading,\textsuperscript{4} and in immediate function, as demonstrated in the previous publication with 1 year of follow-up.\textsuperscript{9}

To accomplish immediate function, all-acrylic prosthesis were placed within a few hours after surgery. All-acrylic prostheses are frequently used as provisional restorations for immediate loading. Although this type of prosthesis has sometimes been associated with fracture problems, it seems to function well if carefully designed and manufactured and if good implant support is provided.\textsuperscript{32-34}

In the present treatment concept, a distal position of the posterior implant is reached by tilting, reducing the maximum cantilever length to one tooth, resulting in reduced mechanical stress to the prosthesis. In vivo load measurements show that the acrylic material per se does not influence the load distribution in a reconstruction with short cantilever arms.\textsuperscript{35,36} In addition to this result, Zampelis et al. (2007)\textsuperscript{23} concluded (using a finite element analysis model to compare the coronal stress when
applying occlusal load), that there is a biomechanical advantage in using implants tilted distally, when compared to the use of axial implants supporting a higher number of cantilever teeth. Despite a higher number of failures being registered for tilted implants (12 tilted implants vs. 7 axial implants), the outcome was not compromised, as all prosthesis survived on the remaining implants until the reinsertion of the failed implants.

The 81% and 82% of readable radiographs for the 3 years and 5 years follow-ups are due to the challenge that the Maxilla anatomy represented (due to a high degree of resorption) to obtain an orthogonal placement of the holder in the patients, making it very difficult to have a reading of the marginal bone resorption when the implant threads were not clearly visible. Due to this fact, the x-rays that did not present clear visible implant threads were discarded for marginal bone resorption analysis, and only accounted for the survival analysis. However this issue represents a threat to the internal validity of this study, as it may have a possible influence on the marginal bone resorption measurements.

The dropout rate was small (19 patients=8% of the sample size) and accounts for a lack of follow-up bias.

Future research should focus on the documentation of this protocol at 10 years of follow-up.

CONCLUSIONS

The results obtained in this study allow us to conclude that the All-on-4 concept for the rehabilitation of the complete edentulous maxilla using 4 implants in immediate function is viable in the medium and long term, as demonstrated by the high survival rate (93% at patient level and 98% at implant level) after 5 years of follow-up.

Tilting of posterior implants was compatible with a high survival rate

REFERENCES


### TABLES

Table I: Estimated fractions for survival using the Kaplan-Meier product limit estimator for the All-on-4 concept at patient level

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Table III – Information on the Implant Loss- All-on-Four Maxilla

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<th>Patient</th>
<th>Gender</th>
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<th>Implant Position</th>
<th>Time of Loss in Months</th>
<th>Observations</th>
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<td>Smoker</td>
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<td>F</td>
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Table IV. Bone Loss Marginal Resorption 3 years and 5 years on Edentulous Rehabilitations

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</table>
ACKNOWLEDGEMENTS

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