



A NEW APPROACH TO REHABILITATE THE SEVERELY ATROPHIC MAXILLA USING EXTRAMAXILLARY ANCHORED IMPLANTS IN IMMEDIATE FUNCTION: A PILOT STUDY

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Statement of problem. There is a need to simplify implant treatment for complete arch rehabilitation of severely atrophic maxillae, as well as a desire to eliminate grafting and provide quality rehabilitation in terms of esthetics, function, and comfort for the patient.

Purpose. The purpose of this study was to report on the initial results of rehabilitation of the complete edentulous atrophied maxillae using a new surgical approach and a newly designed extra long implant, placed externally to the maxillary bone (implant only accommodated in the maxillary bone) and anchored in the zygomatic bone.

Material and methods. The pilot study included 29 patients (21 women and 8 men), with an age range of 32-75 years (mean=52.4 years), followed between 6 and 18 months, with a mean follow-up time of 1 year. The patients presenting severe atrophy in the maxillae (Cawood and Howell classification C-VI and D-V or D-VI) were rehabilitated either by using 1, 2, or 4 extra long implants (30 to 50 mm in length; Nobel Biocare AB) placed in the zygomatic bone in conjunction with standard implants (21 patients): or 4 extra long implants (9 patients), all placed in immediate function. The criteria used to evaluate implant outcome were: implants function as support for reconstruction; implants stable when individually and manually tested; no signs of infection observed; and good esthetic outcome of the rehabilitation. To evaluate the secondary objective of assessing the stability and health of the soft tissue covering the implants, the mucosal seal efficacy evaluation index (MSEE) was used. This index was modified from the probing depth for standard implants and performed with a 0.25-N calibrated plastic periodontal probe measuring the depth (mm) of the space between the implant and the mucosa. Data were analyzed with descriptive and inferential analyses.

Results. The cumulative implant survival rate and prosthetic survival rate at 1 year were 98.5% and 100%, respectively. The mean and median values of the MSEE at 2 months (2.9 mm, 3 mm), 4 months (2.5 mm, 2.8 mm), 6 months (2.9 mm, 2.8 mm), and 1 year (2.8 mm, 2.5 mm) are comparable to the values of probing depths assessed for standard implants.

Conclusions. The results indicate that, within the limitations of this preliminary study, the rehabilitation of maxillae with severe atrophy can be performed using extra long implants placed external to the maxilla and anchored only in the zygomatic bone, and placed in immediate function. (J Prosthet Dent 2008;100:•••-••)

CLINICAL IMPLICATIONS

This pilot study indicates that the concept of 4 extra long implants or 2 extra long and 2 standard implants for rehabilitating edentulous maxillae that have undergone severe bone atrophy, with immediate function, is a viable treatment option.

Insufficient height and/or width of the alveolar ridge when placing implants for oral rehabilitation in the atrophied maxilla is a challenge.¹ The solution can include complex surgical techniques, such as bone grafting procedures, but patient discomfort, sensitivity, and pain can result in the

donor site.²⁻⁴ Another problem with this approach is the generally lower success rate associated with implants placed in augmented bone.⁵ Further considerations are the issues of additional cost, high degree of difficulty requiring surgical expertise, and inability of some patients, such as el-

derly patients, patients with specific health problems, or fearful patients, to accept this type of rehabilitation. An alternative solution is the use of implants placed in the zygomatic bone, alone or in conjunction with standard endosseous implants, offering predictable rehabilitation.⁶⁻⁸

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However, the placement of zygoma-anchored implants using standard techniques often causes the implant heads to emerge too palatal for an optimal prosthetic solution, especially in situations of extreme atrophy, since the residual ridge becomes more palatally oriented when it atrophies.⁹ This results in a large prosthesis, of a size that may interfere with phonetics, dental hygiene, and mechanical resistance of the prosthesis. Moreover, clinical signs of maxillary sinus pathology must be considered when using this procedure.

The technique presented in this study attempts to address these concerns by using a new design: extra long implants external to the maxillary sinus, anchored in the zygomatic bone, only, and covered by soft tissue after emerging from the bone. This allows for the position of the implant head to be more prosthetically correct. In addition, some of the complexity and previously indicated problems may be minimized.

Rehabilitation with zygomatic implants is usually performed with a 2-stage surgical technique, but an immediate function approach is also possible, alone or in conjunction with regular implants,¹⁰⁻¹³ provided an insertion torque above 30 N is achieved.¹⁴ Immediate function is an important psychological factor for the patient and an advantage for the clinical team.¹⁵⁻¹⁷ The rehabilitation of the nonatrophied edentulous maxilla with immediate-function implants is documented with high survival rates in short- and medium-term follow-up situations.^{14,18-21}

To rehabilitate the edentulous maxilla, 2 techniques have proven to be valid treatment options. The first option involves the use of 4 implants anchored in the zygoma and maxillary bones.²²⁻²³ The second option involves 4 strategically placed standard implants, 2 anterior implants placed in the axial position and 2 posterior implants angled distally, placed in immediate function (All-on-4 concept; Nobel Biocare AB, Göteborg, Sweden).²⁴

For rehabilitating the atrophied maxilla, the use of 4 implants anchored in the zygoma and maxillary bone has also been shown to be successful.²³⁻²⁴ The technique described in this study complements the All-on-4 concept, as 1 to 4 standard implants with extra long implants are placed externally to the maxilla and anchored only in the zygomatic bone, making this technique an option for all types of maxillae with bone atrophy. With this novel approach, most of the implant length will be outside the maxillae but covered with soft tissue. It is suggested that the oxidized surface is an advantage regarding integration,²⁵⁻²⁷ and may play a role in the adhesion of the periimplant soft tissue,²⁸ providing stability and health for the soft tissue in bone-covered implants.²⁹⁻³⁰ However, there is a need for clinical long-term results with respect to the soft tissue outcomes when using this novel approach. The purpose of this pilot study was to report on the initial clinical survival rate and periimplant soft tissue response in the rehabilitation of completely edentulous atrophied maxillae using a new surgical approach with extra long implants placed external to the maxillae, in the zygomatic bone, only, and with immediate function.

MATERIAL AND METHODS

This study was performed at a private dental office in Lisbon, Portugal, between January 2006 and July 2007. The study included 29 patients (21 women and 8 men), consecutively treated, with an age range of 32-75 years (mean=52.4 years). The patients were followed between 6 and 18 months, with a mean follow-up time of 1 year. The patients were referred to the clinic as candidates for bone grafting due to the edentulous atrophied maxillae, presenting with both extreme vertical and horizontal bone loss and pneumatization of the maxillary sinuses. Patients presenting with the following criteria were excluded: enough maxillary bone to be

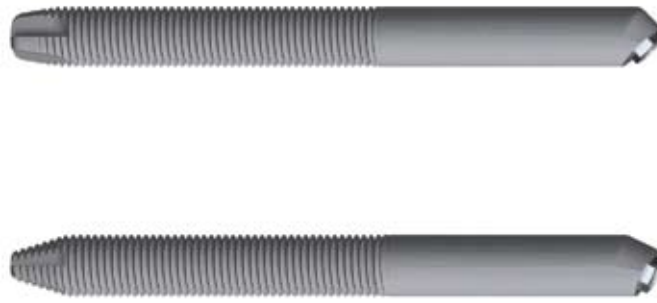
rehabilitated with conventional implants, a stressful social or professional situation, emotional instability (assessed at the screening appointment through interview), or unrealistic esthetic demands. Three of the included subjects were smokers. No systemic conditions judged to influence the treatment outcome, such as a history of chemotherapy or radiotherapy, were present in the study population. The patients provided written consent to participate in the study.

The patients were rehabilitated either by using 1 or 2 extra long implants in conjunction with standard implants (20 patients) or 4 extra long implants, only (9 patients). All implants were placed in immediate function. In 6 patients, additional standard implants (rescue implants) were placed. The reason for placing these implants was related to low primary stability in the anterior maxilla due to lack of bone volume and bone density in these patients.

The extra long implant used in this study was 5 mm in diameter, had an angulation of the implant head (45-degree angulation in the first prototype and 25-degree angulation in the second prototype), external connection, anodically oxidized surface (TiUnite; Nobel Biocare AB), no threads in the coronal third of the implant, and a narrow tip with engaging threads extending to the apex of the implant (second prototype, Nobel-Speedy tip; Nobel Biocare AB) (Fig. 1). The implants emerged between the lateral incisor and the first molar in the residual ridge crest in ideal prosthetic positions (implant heads emerging at the center of the ridge crest) (Table 1).

A clinical examination with a pre-operative panoramic radiograph and a computed tomography (CT) scan was used to plan the surgery.^{31,32} Four standard implants (All-on-4; Nobel Biocare AB) were placed when the maxillary bone crest was a minimum of 10 mm in height and 5 mm in width from the canine-to-canine region.²⁴ In this study, whenever the

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1 Implants used in study. First generation implant (top) and second generation implant (bottom). Both implants featuring angulation of implant head: 45-degree angulation in first prototype (top implant) and 25-degree angulation (bottom implant) in second prototype (NobelSpeedy tip; Nobel Biocare AB).

TABLE I. Study population characterization in relation to implant position of emergence, loading regimen, implant characteristics (type of implant, implant diameter, and implant length), opposing dentition, and patient presence at follow-up appointments

Pts.	Location of Implant Emergence										OD	Follow-up***				
	Right					Left						1	2	3	4	5
	First Molar	Second Premolar	First Premolar	Canine	Lateral Incisor	Lateral Incisor	Canine	First Premolar	Second Premolar	First Molar						
1	EM 5 × 50		EM 5 × 47.5						EM 5 × 47.5	EM 5 × 50	I	Y	Y	Y	N	Y
2			EM 5 × 50		EM 5 × 40	EM 5 × 45		EM 5 × 40			I	Y	N	Y	Y	Y
3		EM 5 × 47.5	EM 5 × 50					EM 5 × 47	EM 5 × 50		R	Y	N	Y	N	Y
4		EM 5 × 50			S 4 × 8.5	S 4 × 8.5			EM 5 × 50		I	Y	Y	Y	Y	Y
5	EM 5 × 50		S 4 × 10*		S 4 × 10	S 4 × 10			EM 5 × 50		I	Y	Y	Y	N	N
6	EM 5 × 45		S 4 × 13*		S 4 × 11.5	S 4 × 11.5		S 4 × 13*		EM 5 × 45	I	Y	Y	Y	N	Y
7		S 4 × 18		S 3.3 × 15	S 3.3 × 15*	S 4 × 15			EM 5 × 45		M	Y	Y	Y	Y	Y
8			EM 5 × 40		EM 5 × 45	EM 5 × 45		EM 5 × 40			R	Y	Y	N	Y	Y
9		EM 5 × 45			S 4 × 10	S 4 × 10**	EM 5 × 50		S 4 × 15		I	Y	Y	Y	Y	Y
10	EM 5 × 45				S 4 × 11.5	S 4 × 15				S 4 × 18	I	Y	Y	Y	Y	Y
11	EM 5 × 40		S 4 × 13*		S 4 × 8.5	S 4 × 8.5		S 4 × 8.5*		EM 5 × 40	M	Y	Y	Y	Y	Y
12			EM 5 × 37		S 4 × 8.5	S 4 × 8.5		EM 5 × 37			I	N	N	N	N	N
13		EM 5 × 50	S 4 × 15				EM 5 × 50		EM 5 × 50		I	Y	N	Y	Y	Y
14	EM 5 × 45				S 3.5 × 10	S 3.5 × 10				EM 5 × 50	I	Y	N	Y	N	N
15		EM 5 × 37			S 4 × 10	S 4 × 10			EM 5 × 40		I	Y	Y	N	Y	N
16	EM 5 × 40				S 4 × 10	S 4 × 10			EM 5 × 40		I	Y	Y	Y	Y	Y
17		EM 5 × 50		EM 5 × 50			EM 5 × 50		EM 5 × 45		I	Y	Y	Y	Y	Y
18	EM 5 × 30	EM 5 × 40			S 4 × 7*	S 4 × 7*			EM 5 × 40	EM 5 × 30	I	Y	Y	Y	N	Y
19				EM 5 × 45	S 4 × 7				EM 5 × 45		R	Y	Y	Y	Y	Y
20		EM 5 × 35		S 4 × 11.5			S 4 × 10		EM 5 × 37		I	Y	Y	Y	Y	N
21		EM 5 × 45		S 4 × 10		EM 5 × 50			EM 5 × 45		I	Y	Y	Y	Y	Y
22		S 4 × 18			S 4 × 15	S 4 × 15			EM 5 × 45		I	Y	Y	Y	Y	Y
23		EM 5 × 45			S 4 × 13	S 4 × 13			S 4 × 18		M	Y	N	Y	N	N
24			S 4 × 18		S 4 × 13	S 4 × 13		EM 5 × 50			I	Y	Y	Y	Y	N
25	EM 5 × 45				S 4 × 15	S 4 × 13				EM 5 × 50	I	Y	N	Y	Y	N
26	EM 5 × 40			S 4 × 8.5		S 4 × 8.5			EM 5 × 45		N	Y	Y	Y	Y	Y
27	EM 5 × 40				S 4 × 10	S 4 × 10			EM 5 × 40		I	Y	Y	Y	N	N
28			EM 5 × 40		S 4 × 13	S 4 × 15		EM 5 × 40			I	Y	N	N	Y	N
29	EM 5 × 37				S 3.5 × 10	S 4 × 10				EM 5 × 40	I	Y	Y	N	Y	N

* Rescue implant; ** Rescue implant not loaded.

Type of implants: EM- Extramaxillary implant; S- Standard implant; OD- Opposing dentition: I- Implant supported prosthesis; N- Natural teeth; R- Removable prosthesis;

M- Mixed (natural teeth + removable prosthesis)

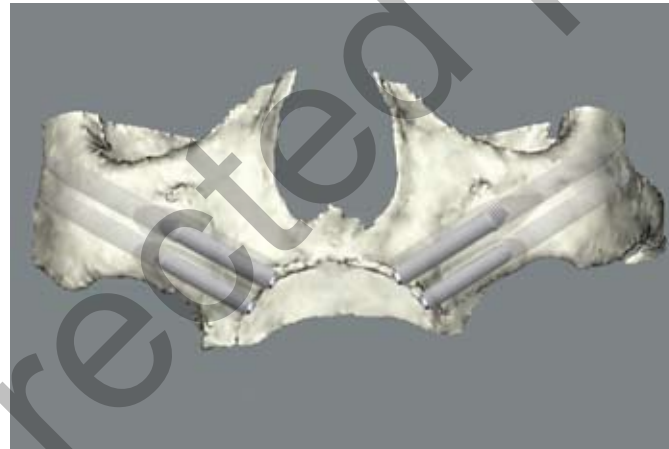
***Follow-up. Patient present at follow-up appointments (Y/N) at 1: 10 days; 2: 2 months; 3: 4 months; 4: 6 months; 5: 1 year

intercanine alveolar crest did not fulfill these bone quantity prerequisites, an extramaxillary implant was used alone or in combination with standard implants. Whenever the maxillary bone quantity in the posterior region did not meet the previously mentioned protocol (All-on-Four; Nobel Biocare AB), but the bone proximal to the middle line was maintained, 2 extramaxillary implants were placed in the posterior region and 2 standard implants were placed in the anterior region (All-on-4 Hybrid; Nobel Biocare AB). This meant that if the 14 transaxial maxillary sections of the CT scan (at 1-mm intervals) immediately proximal to the middle line (corresponding to the central and lateral incisors) demonstrated a minimum bone quantity of 7 mm in height and 4 mm in width (C-VI, Cawood and Howell classification),³³ an anterior standard maxillary anchored implant was placed on each side; and for the posterior implants, when the maxillary bone quantity was a D-V or D-VI Cawood and Howell classification,³³ 2 extramaxillary implants with zygoma anchorage were placed. In situations in which the residual bone crest did not fulfill the minimum prerequisite to allow a standard maxillary implant placement proximal to the midline (more than C-VI, Cawood and Howell Classification),³³ 4 extramaxillary implants were used, 2 on each side (All-on-4 Extra Maxilla; Nobel Biocare AB). The length and position of the extramaxillary implants were determined during surgery (Figs. 2 and 3). For both techniques (the standard implants with maxillary anchorage together with extra long implants with zygoma anchorage or 4 extra long implants with zygoma anchorage), the planned prosthetic screw openings were located on or slightly palatal to the occlusal surfaces of the prosthetic teeth.

Preoperative photographs and preliminary irreversible hydrocolloid impressions (Orthoprint, Orthodontic Alginate Extra Fast Setting; Zhermack SpA, Badia Polesine, Italy) were



2 Illustration representing implant positions in All-on-4 Hybrid situation. One standard maxillary anchored implant and 1 extramaxillary implant were placed bilaterally. Note extramaxillary implant placed posteriorly in inferior edge of zygoma, 3 mm from posterior vertical edge of zygomatic bone. Extramaxillary implant used exclusively zygomatic anchorage. Only maxillary crest accommodates implant, meaning that implant osseointegration only occurs in zygomatic bone. Note infraorbital foramen indicated by arrow.



3 Illustration representing implant positions in All-on-4 Extra Maxilla situation. Two extra long implants with zygomatic anchorage placed bilaterally. Minimum of 5-mm distance needed between implants. Note distance kept between infraorbital foramen and anterior extramaxillary implant.

made, and an esthetic analysis was performed according to an edentulous rehabilitation planning protocol developed by the authors (Table II). The patient preoperative occlusal vertical dimension was evaluated according to the Thompson functional and the Willis esthetic methods, in combination.³⁴ The Thompson physiological method was used to analyze the interocclusal distance between the incisal teeth edges after the patient was asked to swallow (corresponding to a space of 2 to 4 mm in the correct occlusal vertical dimension), with higher

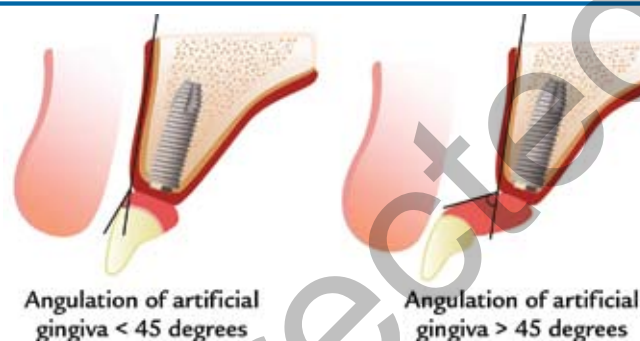
values corresponding to a decreased occlusal vertical dimension. The Willis method is based on a morphologic evaluation. The distance between the eye and the corner of the lip is equal to the distance from the ala of the nose to the inferior border of the mandible at the correct occlusal vertical dimension.

Estimates of the actual and the ideal occlusal vertical dimensions were noted to guide the fabrication of the implant-supported prostheses. If inadequate upper lip support was present, the surgeon attempted to

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TABLE II. Edentulous rehabilitation planning protocol

Variable	Procedure
Occlusal vertical dimension (OVD)	Willis esthetic method and Thompson functional method ³⁴
Lip support (LS)	Upper lip retraction to base of nose in sagittal plane Severity of wrinkled appearance
Smile line (SL)	Digital photograph registration of visible natural gingival level without removable prosthesis in maximum smile
Arch relation	Patient arch relation was classified according Kennedy classification Vertical and horizontal overlap
Occlusion	Canine protected vs. group function Presence of occlusal prematurities and interferences
Harmony and esthetics of complete arch prosthesis	Shade and shape of prosthetic teeth, artificial gingiva, papilla occlusal plane/compensating curve, and esthetic harmony selected according to patients' demands and esthetics of face



4 Illustration of lip support provided by implant-supported fixed prosthesis. Angulation between implants and prosthesis should not exceed 45 degrees. Increased angulation may compromise lip movement when smiling and provide food trap in transition zone.

compensate through different buccal-palatal implant positioning and angulation. Angulated abutments were also used with the same purpose. These procedures were performed to avoid an improper prosthesis angulation that could be uncomfortable for the patient, as it would cause difficulty in performing oral hygiene and also affect the upper lip when the patient smiled (Fig. 4).

An evaluation of the visible natural gingival level without the existing removable prosthesis was performed to evaluate the smile line (SL). Whenever natural gingiva was visible, bone reduction was performed to avoid visibility of the transition zone between natural and artificial gingiva in maximum smile. The transition zone can

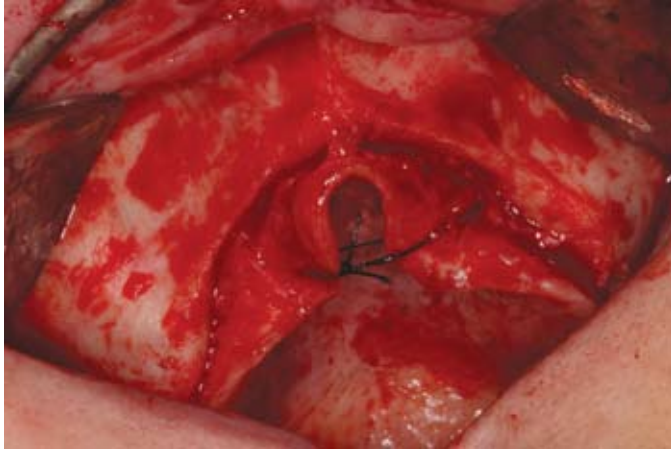
be unesthetic when artificial gingiva is used in prosthetic rehabilitations supported by implants. Usually in the severely atrophic maxillae, the natural gingiva is not visible in maximum smile. The arch relation was carefully studied before surgery in order to detect and correct previously existing slight occlusal discrepancies. The patient was restored at the predetermined occlusal vertical dimension.

The surgery was performed with general anesthesia or local anesthesia according to the patient's desires. A mucoperiosteal incision was performed along the crest of the ridge, slightly palatal, from molar to molar area with 2 vertical-releasing incisions over the zygomatic process. Flap reflection allowed for infraorbital

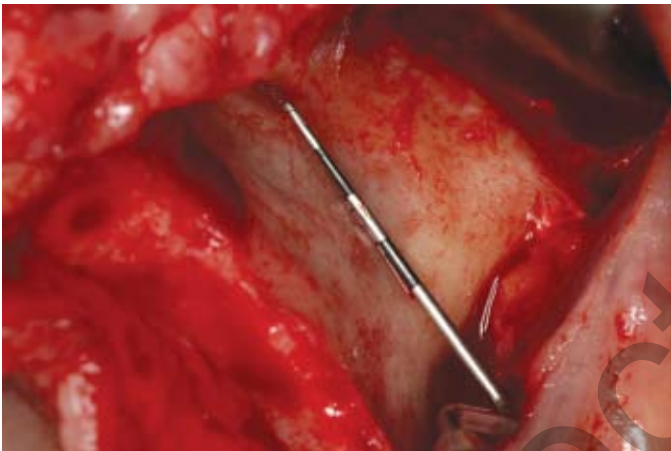
nerve identification and direct observation of the inferior edge of the zygomatic bone and the insertion of the masseter fascia in the zygomatic arch (distal limit) (Figs. 5 and 6). The palatal mucosa was also reflected. A zygoma retractor, a surgical instrument that combines the retractor and periosteal instrument functions (Modified Austin Tissue Retractor; Hu-Friedy, Leimen, Germany), was used to retract the soft tissues (Fig. 7). Depending on the degree of irregularity of the alveolar ridge, recontouring was performed with a bone bur alone, or in combination with either a rongeur (Rongeur Bayer; Hu-Friedy) or ultrasound device (EMS, Nyon, Switzerland). According to the smile line evaluation, an additional

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5 Intraoral photograph after incision and flap reflection. Note severe resorption with residual ridge crest reduced to thin layer.



6 Note length of zygoma's inferior edge and its relation with maxillary crest.



7 Soft tissue reflection during surgical procedure using zygoma retractor. Instrument allowed proper flap retraction and correct visualization of surgical region and surrounding anatomical structures. Note emergence of infraorbital nerve (marked by circle). In All-on-4 Extra Maxilla situations, minimum distance of 3 mm was maintained between anterior zygomatic implant and infraorbital nerve.

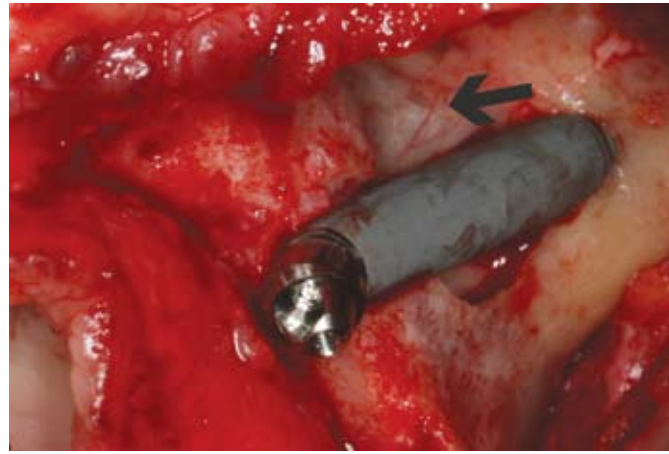
horizontal osteotomy was performed, if needed, to prevent future visibility of the transition zone between artificial and natural gingiva.

Zygomatic implant positions were determined during surgery according to the anatomy of the zygoma and surrounding structures. When extramaxillary implants were used, the osteotomy was begun at a point as posterior as possible, keeping a safe 3-mm distance from the posterior vertical edge of the zygomatic bone. This position was used first to eliminate or reduce the cantilever of the fixed implant-supported prosthesis, and secondly, to allow placement of an additional zygomatic implant, if needed. When the anterior maxilla was severely resorbed (less than 7 mm in height and 4 mm in width), the surgical procedure was performed with 2 extra long implants placed bilaterally (All-on-4 Extra Maxilla; Nobel Biocare AB). In this situation, a minimum of 5 mm was maintained between the 2 implants, with the reference being the posterior implant placed as described for the All-on-4 Hybrid (Nobel Biocare AB) procedure. The orbit, the infraorbital nerve, and the anatomy of the bone determined the drilling direction (Figs. 2 and 3). The maxillary bone was only prepared to allow direct access of the burs to the zygoma inferior edge, and was not used for anchoring the extramaxillary implant. The extramaxillary implant used exclusively zygomatic anchorage. After the round bur, a 2.9-mm twist drill (Nobel Biocare AB) was used. During this procedure, the surgeon's thumb was positioned at the external surface of the upper edge of the zygoma to feel the preparation of the external cortical bone (superior edge). Subsequently, a depth indicator was used to assess the correct length of the implant. The extramaxillary implant length was measured from the posterior-superior cortical of the zygoma to 2 mm apical to the maxillary crest. According to the bone density, the sequence of drills continued as followed: 3.5-mm pilot drills, 3.5-

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563	618	673
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566	621	676
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4.0-, and 4.4-mm twist drills (Nobel Biocare AB). Particular attention was given to the infraorbital nerve and the base of the orbit to avoid damaging these anatomical structures during implant site preparation (Fig. 7). The soft tissue was protected during drilling by using retraction and drill guards. Proper soft tissue retraction prevented infraorbital nerve damage, as it allowed direct observation of this anatomical structure. The extra long implants were placed with an insertion torque of at least 30 Ncm for sufficient primary stability. During site preparation it was possible to avoid the maxillary sinus wall and membrane destruction in most situations (Fig. 8). However, when the patients presented with an overcontoured external maxillary sinus wall, the maxillary sinus membrane was inevitably perforated, as it was in the pathway of drill direction. Three-dimensional CT scans that include the maxillary bone, the zygoma bone, and the floor and external wall of the orbit, seen in the correct rotation, can assist in predicting the overcontoured external maxillary sinus wall. The rotation needed is that which allows positioning of the facial bones in the same relation they have when the surgeon is placing zygoma implants, that is, from the palate to the superior edge of the zygoma with a superiorly and externally oriented vector direction.

As the distance between the superior zygoma edge and the maxillary crest is shorter in the posterior region, the distal extramaxillary implant is usually shorter than the anterior one. The head of the distal implant emerged in the first molar to second premolar region, and the head of the anterior implant emerged in the canine to lateral incisor region. To obtain a hygienic, esthetic, comfortable, and mechanically resistant prosthesis, the 4 abutments were selected so that they could be leveled at the same height and with the correct emergence of the prosthetic screws in the fixed prosthesis. The implant inclination was compensated for with an an-



8 Intraoral view after zygoma implant placement with complete maxillary sinus membrane preservation. Intact maxillary sinus membrane marked by arrow.

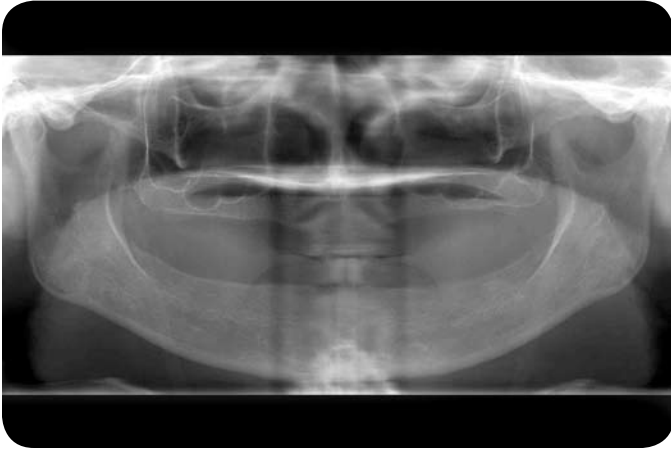
gulated abutment (30-degree Multi-unit Abutment; Nobel Biocare AB). The edges of the flaps were trimmed to remove excess tissue and approximated with interrupted sutures. Buccal keratinized gingiva was preserved whenever possible, especially around the implants, without buccal muscle tension.

Complete arch acrylic resin (Heraeus Kulzer GmbH, Hanau, Germany) prostheses were inserted on the day of surgery.²¹ After suturing, open tray impression copings (Nobel Biocare AB) were placed and connected with a metal bar (Remanium Edgewise Wire, 0.55 x 0.70 mm; Dentaurem, Ispringen, Germany) and acrylic resin (Pattern Resin LS; GC America, Inc, Alsip, Ill). The fabrication of the implant-supported prosthesis followed standard procedures.²⁴ An impression with putty material (Elite HD+ Putty Soft Fast; Zhermack SpA) 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. 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 ceram-

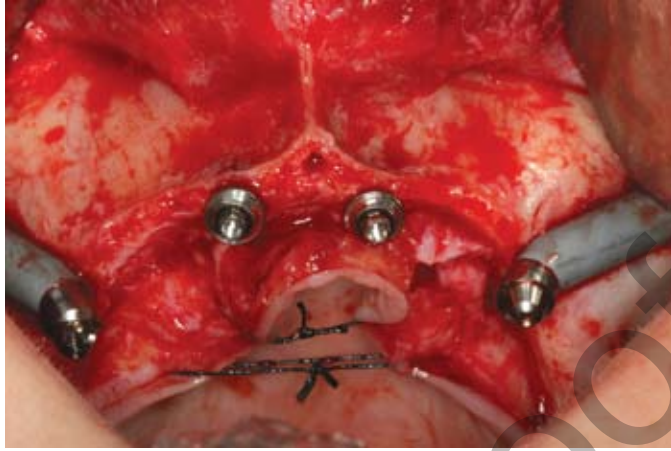
ics; Nobel Biocare AB), or a metal-acrylic resin implant-supported fixed prosthesis with a titanium framework (Procera titanium framework; Nobel Biocare AB) and acrylic resin prosthetic teeth (Heraeus Kulzer GmbH), was used to replace the provisional prosthesis. A clinical situation is presented in Figures 9-15, representing a patient eligible for a completely edentulous maxillary rehabilitation through the All-on-4 Hybrid (Nobel Biocare AB) solution.

Antibiotics (amoxicillin, 875 mg and clavulanic acid, 125 mg; Labesfal, Campo de Besteiros, Portugal) were given every 8 hours daily for 4 days, and every 12 hours thereafter until day 8. For control of the inflammatory response, Corticosteroid medication (Meticorten; Schering-Plough Farma Lda, Agualva-Cacém, Portugal) was given daily in a regressive mode (15 mg at surgery, 10 mg on the first 2 days postoperatively, and 5 mg on days 3 and 4 postoperatively). Anti-inflammatory medication (ibuprofen, 600 mg; Ratiopharm Lda, Carnaxide, Portugal) was administered every 12 hours on days 4 through 8 postoperatively. Analgesics (Clonix 300 mg; Janssen-Cilag, High Wycombe, UK) were administered postoperatively for the first 3 days if needed. All study implants were loaded on the day of surgery, achieving immediate function. Oral hygiene instructions were given to the patients to follow for a 6-month period, according to a pre-

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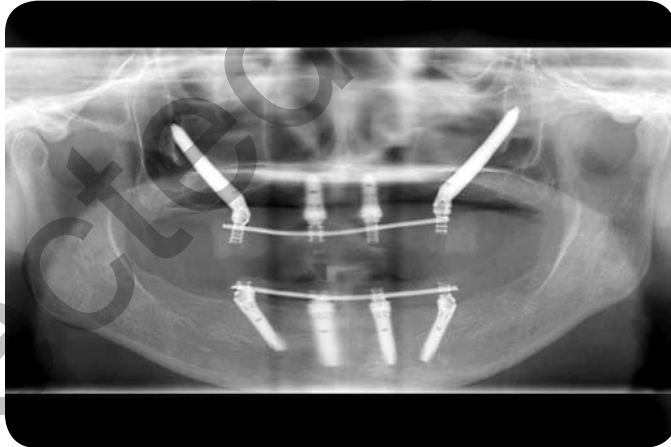
9 Preoperative panoramic radiograph. Note maxillary sinus pneumatization and amount of bone available in premaxilla. Although All-on-4 Hybrid (Nobel Biocare AB) rehabilitation seems likely in this situation, treatment plan is always confirmed with transaxial sections from maxillary CT scan.



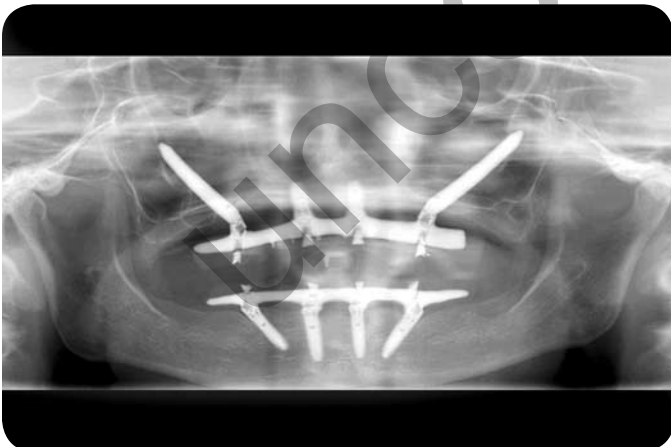
10 Maxillary intraoral view after implant placement representing All-on-4 Hybrid situation. Two standard implants placed in premaxilla, and 2 zygomatic implants placed posteriorly in zygomatic bone.



11 Provisional prosthesis in place.



12 Postoperative panoramic radiographs with provisional prosthesis.



13 Panoramic radiograph with definitive prosthesis.



14 Occlusal view of definitive prosthesis. Note position of screw access openings placed on or slightly palatal to incisal/occlusal surface.

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15 Patient with definitive prosthesis in place.

viously described protocol.³⁵ The patients were instructed to eat a soft food diet for 2 months, and to use a hyaluronic acid gel (Gengigel; Ric-erfarma srl, Milan, Italy) in their daily dental hygiene routine for the first 2 months and a chlorhexidine gel (Elugel; Pierre-Fabre Dermo-Cosmetique, Lisbon, Portugal) between the 2- and 6-month follow-up appointments.

All patients were included in a prospective follow-up protocol and were evaluated clinically (at 10 days, 2, 4, and 6 months, and every 6 months thereafter) and radiologically (at the 10-day, 6-month, and 1-year follow-up visits). The prostheses were removed at each follow-up appointment to perform the clinical assessments. The following clinical data were recorded: modified bleeding index (mBI), clinical mobility (Mob), suppuration (Sup), and the mucosal seal efficacy evaluation (MSEE). The mBI was assessed by inserting a periodontal probe 1 mm into the sulcus, circumferentially around the implant/abutment, and recorded in an ordinal scale with values between 0 and 3 (0: no bleeding visible; 1: isolated bleeding spot visible; 2: the blood formed a confluent red line on the margin; and 3: heavy or profuse bleeding).³⁶ Mob was evaluated using manual movement to assess individual implant mobility and registered as present or absent.¹⁴ Sup was evaluated by applying finger pressure to the periimplant complex and registered as present or absent,¹⁴ and MSEE, modified from

the regular probing depth for standard implants (usually up to 4 mm in depth) and performed with a 0.25-N calibrated plastic periodontal probe (HaweNeos, Bioggio, Switzerland),³⁵ recorded in millimeters the space between the implant and the mucosa. This modification was made as the implant was placed in the palatal, mesial, and distal aspects of the maxillary bone, with no buccal support, and, therefore, the traditional criteria did not apply. The radiological evaluation was made with panoramic radiographs, but no bone height could be recorded as the implant platform slightly superimposed the marginal bone.

An implant was classified as surviving, according to the survival criteria developed by the authors, when: (1) it fulfilled its purported function as support for the prosthesis; (2) it was stable when individually and manually tested; (3) no signs of infection were observed; (4) a good esthetic outcome of the rehabilitation was demonstrated; and (5) it allowed fabrication of the implant-supported fixed prosthesis, which provided patient comfort and allowed for hygiene. The following complication parameters were assessed: fracture or loosening of mechanical and prosthetic components (mechanical complications); soft tissue inflammation, fistula formation, pain, or maxillary sinus infections (biological complications); esthetic complaints of the patient or dentist (esthetic complications);

phonetic complaints, masticatory complaints, comfort complaints, or hygienic complaints (functional complications). The cumulative implant survival rate was evaluated using life table analysis. Descriptive statistics were used to perform univariate analysis of the clinical indexes (mBI, MSEE). Inferential statistical analysis (Kruskal-Wallis test) was used to determine the equality of mean ranks in the MSEE at each site ($\alpha=.05$)

RESULTS

A total of 67 specially designed extra long implants (Nobel Biocare AB) and 57 regular implants (NobelSpeedy; Nobel Biocare AB) were placed for 29 complete-arch maxillary reconstructions in 29 patients. The follow-up of the patients ranged between 6 months and 18 months (mean=13 months). The various lengths of the implants placed were: 30 mm (n=2), 35 mm (n=1), 37 mm (n=5), 40 mm (n=17), 45 mm (n=17), 47.5 mm (n=4), and 50 mm (n=21).

One extramaxillary implant in one patient presented clinical mobility at the 1-year follow-up, providing a survival rate of 98.5% at 1 year (Table III). Mobility of this implant was addressed by disconnecting the implant from the prosthesis, which allowed the implant to osseointegrate, making it possible to place the implant in function again 2 months later. The implant remained stable during the remainder of the study, 18 months. All prostheses were in function for all patients during the study period, providing a 100% prosthetic survival rate. No regular implant failed during the follow-up period, providing a 100% survival rate.

The mBI results are presented in Table IV and Figure 16. The mean results for mBI varied during the evaluations but eventually stabilized around the score of 1, meaning the mucosa around the implants presented with a single isolated bleeding spot visible when evaluated clinically. The MSEE results are presented in Table

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[T5] V and Figure 17. The MSEE observed
[F17] throughout the follow-up was generally characterized by a higher value in the distal/mesial aspects, in relation to the buccal/palatal aspects of the implants. MSEE values greater than 4 mm were observed in 12 of 67 implants (17.2%) in 9 patients. The occurrences were recorded in 4 implants in the first 6 months and 8 implants between 6 months and 1 year of follow-up.

The biological complications included 4 maxillary sinus infections in 4 patients: 1 at the 2-month, 2 at the 6-month, and 1 at the 1-year follow-

up appointment. This occurred in patients with diagnosed sinusitis prior to surgery and was related to the maxillary sinus membrane rupture during the surgical phase. The 2-month follow-up incident was treated successfully through administration of antibiotics. The remaining incidents were successfully addressed by surgical interventions to clean the maxillary sinus and reposition the soft tissue, allowing for more keratinized tissue to be present. For this purpose, a palatal incision was planned in order to obtain palatal flap rotation to the buccal side. In one patient, the time gap

between diagnosis and the successful resolution of the clinical situation was 1 year.

The outcome of the rehabilitations with rescue implants and without rescue implants rendered implant survival rates of 100% (no implant failures) and 98.4% (1 extramaxillary implant failure), respectively, and a prosthetic survival rate of 100% in both groups. Only 1 of 9 rescue implants was not loaded (Table I). Maxillary sinus infections were observed in 1 of 6 patients rehabilitated with rescue implants versus 3 of 23 patients rehabilitated without rescue implants.

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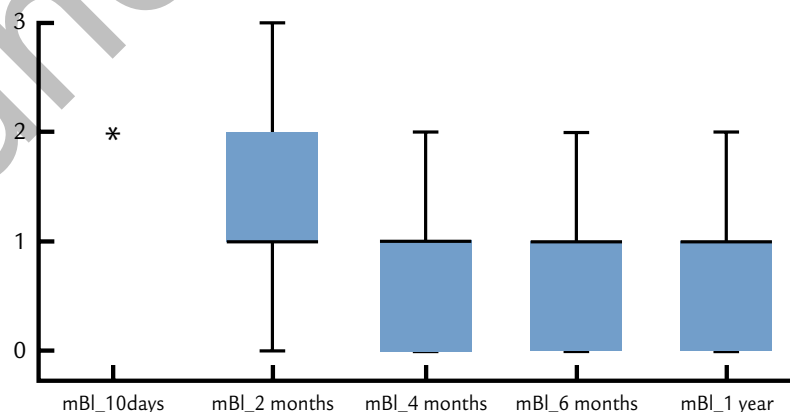
TABLE III. Cumulative survival rate of study implants

Time Period	Number in Function	Number Failed	Number Lost to Follow-up	Survival Rate	CSR (%)	Implants Removed
Loading – 6 months	67	0	2	100%	100%	0
6 months – 1 year	65	1	0	98.5%	98.5%	0
1 year – 2 years	36	0	0	100%	98.5%	0

CSR= cumulative survival rate

TABLE IV. Modified bleeding index (mBI) collected from Zygoma implants at 10 days, 2, 4, and 6 months, and 1 year

mBI (0-3)	n	Mean	Standard Deviation	Median
10 days	6	0.3	0.8	0
2 months	21	1.3	0.8	1
4 months	30	1.0	0.7	1
6 months	43	0.9	0.7	1
12 months	32	0.8	0.7	1

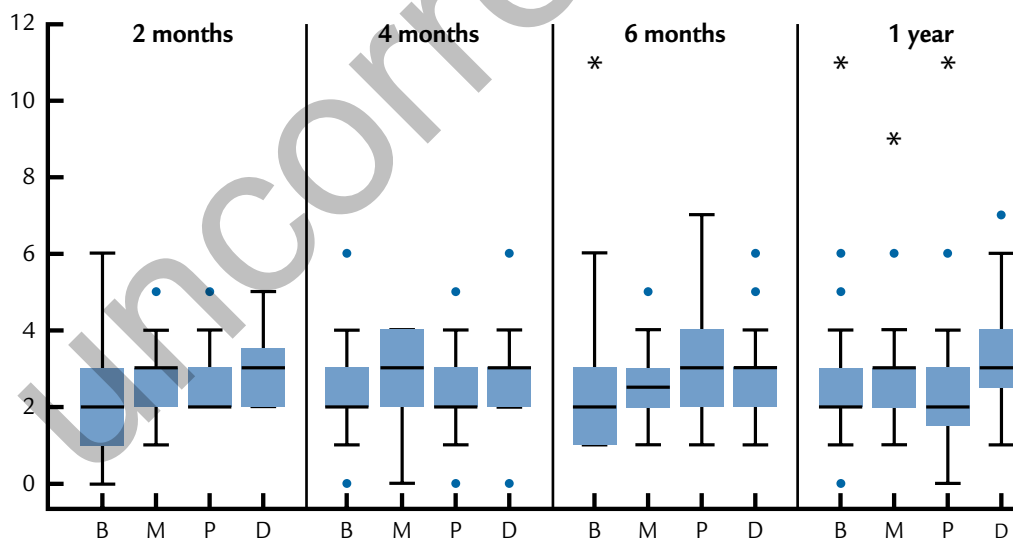


16 Boxplot representing descriptive analysis of mBI assessed at 10 days, 2, 4, and 6 months, and 1 year postsurgically. Box edges represent first and third quartiles of data (25% and 75% of all data collected in that period); black line represents median (50% of data); whiskers represent all data not suspected of being outlier; asterisk (*) represents outlier value.

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TABLE V. Mucosal seal efficacy evaluation (MSEE) and analysis (Kruskal-Wallis) for zygoma implants at 10 days, 2, 4, and 6 months, and 1 year

MSEE (in mm)		n	Mean	Standard Deviation	Median	P
2 months	buccal aspect	18	2.4	1.6	2	.229
	mesial aspect	17	2.8	1.0	3	
	palatal aspect	17	2.7	0.9	2	
	distal aspect	20	3.1	1.1	3	
4 months	buccal aspect	28	2.1	1.4	2	.184
	mesial aspect	28	2.6	1.4	3	
	palatal aspect	27	2.5	1.3	3	
	distal aspect	27	2.7	1.3	3	
6 months	buccal aspect	36	2.5	1.9	2	.109
	mesial aspect	35	2.5	1.0	3	
	palatal aspect	36	2.8	1.4	3	
	distal aspect	38	3.0	1.3	3	
12 months	buccal aspect	33	2.8	2.0	2	.017
	mesial aspect	34	3.0	1.5	3	
	palatal aspect	34	2.7	2.0	2	
	distal aspect	34	3.4	1.4	3	



17 Boxplot representing descriptive analysis of MSEE index assessed on buccal (B), mesial (M), palatal (P), and distal (D) sites at 2, 4, and 6 months, and 1 year postsurgically. Box edges represent first and third quartiles of data (25% and 75% of all data collected in that period); black line represents median (50% of data); whiskers represent all data not suspected of being outliers; the symbols • and * represent outlier values.

DISCUSSION

The 1-year implant (98.5%) and prosthesis (100%) survival rates compare favorably to data for the rehabilitation of the complete edentulous maxilla using standard implants.²⁰ Based on these merits, the concept should be further documented and developed. Due to the density of the zygomatic bone, and a drilling sequence adjusted to bone density, it was always possible to achieve primary implant stability with an insertion torque equal to or higher than 30 Ncm, and immediate function could be used in all situations. A single incidence of clinical mobility was noted in one patient and was solved by disconnecting the implant from the prosthesis for a short period of time. The implant was later connected without further complications.

It is possible that numerous incidences of maxillary sinus pathology may be avoided due to this surgical technique. One advantage of the technique is that the perforation of the maxillary sinus membrane is performed at a higher and more posterior point in the maxillary sinus, when compared to the classical technique.⁷⁻⁸ This allows for less maxillary sinus membrane disruption, and less space is occupied by the implant inside the maxillary sinus. Six patients were rehabilitated with the use of additional implants, because of low primary stability (<30 Ncm) of the anterior implants, which was related to lack of bone volume and bone density in the anterior maxilla. However, the outcomes of the rehabilitations with and without additional implants rendered similar results in implant and prosthesis survival, as well as the incidence of complications, demonstrating the flexibility of this concept.

The difference in MSEE values between the 4 sites was not significant at the 2-, 4-, and 6-month evaluations. The evaluation of the MSEE at the 1-year evaluation through the analysis of the box plot (Fig. 2) only makes it possible to descriptively identify the

differences between the MSEE groups, which may be attributed to the differences between the mesial and distal sites, which presented higher median values (3 mm), compared with the buccal and palatal sites, which presented lower median values (2 mm).

The incidence of MSEE values higher than 4 mm can be related to the extramaxillary approach. However, the mean and median values of the MSEE are comparable to the probing depth values generally assessed at regular implants.^{29,30} The higher values observed throughout the study in the distal aspects, when compared to the remaining aspects, are probably due to the position of the implant, as it is less embedded in the distal aspect due to the extramaxillary technique.

When rehabilitating patients with diagnosed maxillary sinusitis and/or a disrupted maxillary sinus membrane (during surgery), there seems to be a higher risk of maxillary sinus infections. However, these situations were resolved (with the exception of one patient having a 1-year time gap between diagnosis and resolution), with successful interventions in all patients. The limitations of the study include the following: a short follow-up time, only a single clinic was involved, only a single operator was involved, and the sample size was small. This technique offers advantages to patients and should be further investigated in longer-term clinical studies with increased sample sizes. Attention should be given to long-term soft tissue stability in future studies.

CONCLUSIONS

This pilot study indicates that the rehabilitation of patients with severely resorbed maxillae can be performed with extra long implants placed external to the maxilla, anchored in the zygomatic bone, only, and placed in immediate function.

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Queries:

Q1- Please approve edits, sentence beginning, “The implants emerged between...” (lines 222-227)

Q2- Please approve edits made to sentence beginning “Antiinflammatory medication...” (lines 869-874)

Q3- Reference 10: Although the individuals you listed (Rangert B, Malvez C, Bedrossian E, Renouard F, Malo P, Calandriello R) may be contributing authors, our search found this book only under the name of the editor, Ole T. Jensen. The citation has been changed accordingly. Please approve these edits. (line 1399)

Uncorrected proof