Evaluation of Clinical Soft Tissue Parameters for Extramaxillary Zygomatic Implants and Conventional Implants in All-on-4 Hybrid Rehabilitations: Short-Term Outcome and Proposal of Clinical Recommendations for Intervention in Recall Appointments

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Purpose: *This prospective cohort study aimed to investigate the short-term soft tissue clinical outcomes and recommendation for evaluation and follow-up after a new hybrid All-on-4 rehabilitation.*

Methods: *Forty consecutively included patients rehabilitated in the complete edentulous atrophic maxillae through a hybrid All-on-4 treatment concept (4 immediate function implants in a combination between zygomatic and conventional implants). Periimplant conditions at zygomatic and conventional implants were compared. Four clinical levels (CLs) were used to classify the presence and severity of periimplant conditions.*

Results: *Four patients withdrew from the study. No significant differences were found for periimplant conditions at zygomatic and conventional implants. The distribution was 28, 2, 1, and 9 patients with CL1, CL2, CL3, and CL4, respectively.*

Conclusions: *Soft tissue clinical outcomes of extramaxillary zygomatic implants and conventional implants seem to follow a similar distribution. The proposed classification system stratifies patients, supports decision making, and with further validation may elucidate recommendations for frequency of recall appointments and intervention to enhance long-term success. (Implant Dent 2015;24:1–8)*

Key Words: dental implants, zygoma, implant maintenance

The rehabilitation of the severely atrophic maxillae is a challenge. Often, limited bone quantity and poor bone quality limit the use of conventional implants, particularly in the posterior segments with pneumatization of the maxillary sinus.[1,2] The first alternative to overcome such challenge was using bone grafting procedures to reconstruct the maxilla and provide enough support for the use of conventional implants.[3] However, disadvantages associated with this surgical technique, such as the postsurgical morbidity (in the situation of using autogenous bone graft from different donor sites) or the necessary extended healing period for the graft,[3] limited the use of immediate function in the rehabilitation process of these patients, eliminating the option of implant insertion, abutment, and prosthesis connection on the same day of surgery.

The insertion of a longer zygomatic implant, anchored in the zygomatic bone, emerged as a treatment alternative to bone grafting procedures,[1–17] enabling the reconstruction and rehabilitation of the complete edentulous atrophic maxilla in one step, and offering the possibility of choosing immediate function[2,5,12–16] over delayed function,[3,8,17] and reducing the treatment period. Furthermore, patients may benefit from an immediate function protocol, with significant improvements in esthetics, prosthetic retention, speech, and mastication, immediately.[2,12,13] An additional advantage consists of

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providing a more comfortable rehabilitation procedure by reducing the prolonged healing phase that is associated with bone grafting and maxillary sinus lift procedures.[2–4,7–9] The survival rate of zygomatic implants used for rehabilitation of severely atrophic maxillae ranges between 89% and 100% and is therefore considered to be a predictable procedure.[1,2,4–6,8–17] Today, zygomatic implants are increasingly used alone or in combination with conventional implants placed in limited residual bone[2,4,5,12–17] for rehabilitating patients with a severely atrophic maxilla (Cawood and Howell Classification C-VI and D-V or D-VI) but are not limited to these situations: Several studies report rehabilitations performed in patients who had overcome severe health conditions (such as cancer),[1,3,9] and even absence of a maxillary support.[18]

The most common biological complications reported for zygomatic implants are sinusitis, soft tissue infections, paresthesia, and oroantral fistula, making it mandatory to perform extra interventions during the recall phase to resolve these situations.[4,6,10,12,13,15,16] Furthermore, mechanical complications can occur not only in patients with bruxism[2,12,13] and functional complications,[12] but also due to the biomechanical challenge imposed by the possible cantilever effects on zygomatic implant rehabilitations.[19]

Brånemark et al[20] introduced the technique for insertion of zygomatic implants (the classical technique) with zygomatic implants anchored in the zygomatic bone and placed through the sinus. This classical technique was later simplified for maxillae with a pronounced concavity by Stella and Warner,[21] by creating a fenestration on the implant medial portion. In 2008, the extramaxillary surgical technique was first introduced,[2] which allowed zygomatic implants to be placed in immediate function, external to the sinus, anchored in the zygomatic bone, and covered only by soft tissue.[2,12,13] This extramaxillary surgical technique minimized the rate of ruptures of the sinus membrane during implant insertion compared with the classical technique. The technique itself differs in that the positioning of the implant head is more vestibular so that the prosthetic screw access hole is closer or, in some situations, even at the center of the prosthetic crown. This surgical technique further evolved into 2 additional treatment variations one with the insertion of 4 extramaxillary zygomatic implants (All-on-4 Double Zygoma) and the second using a combination of 1 to 3 extramaxillary zygomatic implants together with 1 to 3 conventional implants a hybrid of the All-on-4 treatment concept (Nobel Biocare AB).[2,12,13]

Today, there is a tendency to shift the focus of these zygomatic implant supported rehabilitation procedures, from the fixture and prosthetic survival to the quality of their survival, with more attention being given to the outcome of complications (biological and mechanical). Comparing with conventional implants, the insertion of zygomatic implants introduced modifications in the periimplant complex as a consequence of the implant design and the surgical technique. Few previous studies report a higher incidence of biological complications of gingival hyperplasia and bleeding on probing during recall of patients with zygomatic implants compared with conventional implants.[1,22] Furthermore, the regular presence of isolated single localized bleeding observed in the mucosal margin, together with probing pocket depths (PPD) over 4 mm in extramaxillary zygomatic implants on short- and medium-term outcomes is also reported to be higher.[2,12,13] Thus, it is mandatory to focus on the soft tissue outcomes when establishing the maintenance protocol for zygomatic implants, especially when considering the extramaxillary technique, where no maxillary bone anchorage is provided.

The aims of this investigation were to evaluate the short-term soft tissue outcome of extramaxillary placed zygomatic implants used in combination with conventional implants and to propose a clinical recommendation for intervention based on the clinical monitoring.

MATERIALS AND METHODS

This study was approved by an Ethical Committee (Ethics Committee for Health, Lisbon, Portugal, authorization no. 16/2010) and performed according to the Declaration of Helsinki. This prospective cohort study was performed at a private practice between October 2011 and July 2013, including 40 consecutively treated patients (31 women and 9 men), with an average age of 56.6 years (range, 31–82 years). Inclusion criteria were candidacy for immediate fixed implant supported rehabilitation of the atrophic, completely edentulous maxilla, with extreme horizontal and vertical bone loss, and pneumatization of the maxillary sinuses. The patients underwent complete edentulous maxillary rehabilitation with the use of implants inserted into the zygomatic bone in conjunction with conventional implants. Patients with active radiotherapy, chemotherapy, or presenting emotional instability were excluded. Seven patients were smokers, and 18 presented with the following conditions: cardiovascular diseases (n = 12 patients), controlled diabetes (n = 4 patients), hepatitis (n = 2 patients), thyroid dysfunction (n = 2 patients), osteoporosis (n = 2 patients), neurological condition (n = 1 patient), and previous oncologic condition (n = 1 patient). Five patients were presented with more than 1 comorbidity. Three patients were diagnosed as heavy bruxers; one of the patients was also diagnosed with sinusitis before the prosthetic rehabilitation.

The zygomatic fixture (Brånemark System Extramaxillary Zygoma TiUnite fixture) featured no angulation on the implant head, 5 mm of width with a 4-mm implant platform, external hexagon connection, no threads in the coronal third of the implant, and a narrow tip with engaging threads extending to the apex of the implant (NobelSpeedy tip) (Fig. 1). A total of 72 zygomatic implants with various lengths were inserted through the extramaxillary surgical technique, together with a total of 88 conventional implants, both inserted in immediate function. The distribution of zygomatic implants by width and length was as follows: 5 × 35 mm (n = 7 implants), 5 × 40 mm (n = 27 implants), 5 × 42.5 mm (n = 3 implants), 5 × 45 mm (n = 30 implants), 5 × 47.5 mm (n = 1 implant), and 5 × 50 mm (n = 4 implants), whereas the distribution of conventional implants by width and length was as follows: 4 × 7 mm

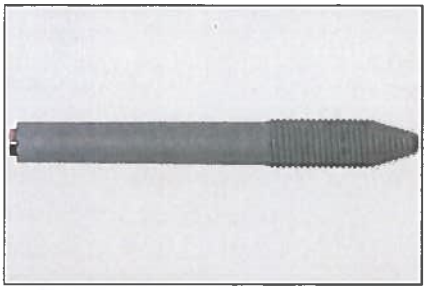

Fig. 1. Brånemark system Extramaxillary Zygoma implant.

Fig. 2. All-on-4 hybrid rehabilitation (Nobel Biocare AB). A combination of 1 to 3 zygomatic implants with 1 to 3 conventional implants (total of 4 implants) inserted in immediate function. The zygomatic implants are inserted through the extramaxillary surgical technique, only anchored in the zygomatic bone without maxillary anchorage, and only covered by soft tissue after emerging from the bone.

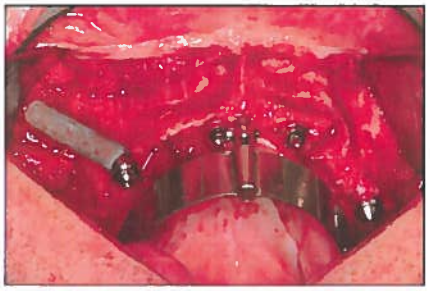

Fig. 3. Intraoral view after the insertion of the zygomatic implant through extramaxillary surgical technique. Note there is no maxillary anchorage for the zygomatic implant.

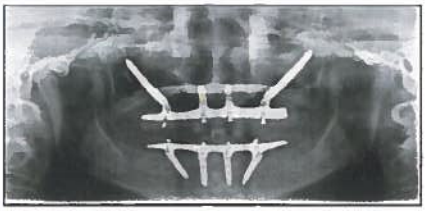

Fig. 4. Orthopantomography after 1 year of an All-on-4 hybrid (Nobel Biocare AB) rehabilitation in the maxilla with 2 conventional implants inserted in the anterior area and 2 posterior zygomatic implants inserted through the extramaxillary surgical technique.

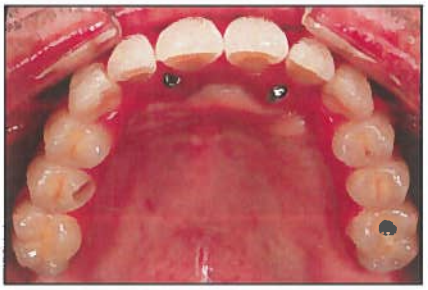

Fig. 5. Intraoral occlusal view of an All-on-4 hybrid (Nobel Biocare AB) rehabilitation in the maxilla. Note the prosthetic access screws of the zygomatic implants emerging on the occlusal aspect of the crowns.

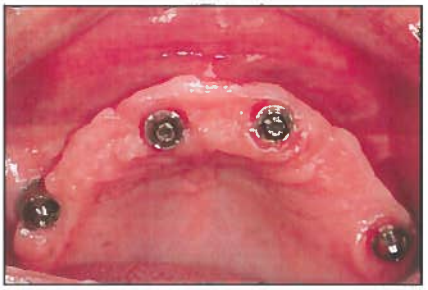

Fig. 6. Intraoral occlusal view after removal of the prosthesis at 1 year of follow-up. Note the soft tissue around the zygomatic implants (with keratinized tissue) is maintained.

(n = 8 implants), 4 × 8.5 mm (n = 24 implants), 3.3 × 10 mm (n = 6 implants), 4 × 10 mm (n = 20 implants), 3.3 × 11.5 mm (n = 2 implants), 4 × 11.5 mm (n = 7 implants), 3.3 × 15 mm (n = 1 implant), 4 × 15 mm (n = 6 implants), 4 × 18 mm (n = 4 implants), and 4 × 22 mm (n = 1 implant).

Surgical Protocol

Surgeries were performed by 2 surgeons (P.M. and A.L.) and were described in full detail in previous studies.[2,12,13] In brief, a clinical examination with a preoperative panoramic radiograph and a computed tomography (CT) or cone beam CT scan was used to plan the surgery. In this study, whenever the intercanine alveolar crest demonstrated a minimum bone quantity of 7 mm in height and 4 mm in width (C-VI, Cawood and Howell classification)[23] immediately proximal to the midline (corresponding to the area of the central and lateral incisors), an anterior conventional maxillary anchored implant (NobelSpeedy Groovy or Shorty, Nobel Biocare) was placed; and for the posterior implants, when the maxillary bone quantity was a D-V or D-VI (Cawood and Howell classification[23]), 1 to 2 implants with zygomatic anchorage were placed (Figs. 2 and 3 All-on-4 hybrid). In this study, the All-on-4 hybrid comprised of 4 implants for the rehabilitation of the complete edentulous atrophic maxillae in combination with 1 to 3 extramaxillary zygomatic implants with 1 to 3 conventional implants all inserted in immediate function.

Surgery was performed under general anesthesia or local anesthesia according to the patient desire. A mucoperiosteal incision was made along the crest of the ridge, staying slightly palatal, from molar area to molar area, with buccal vertical releasing incisions made posteriorly to expose the zygomaticomaxillary buttress and the prominence of the zygoma. Flap reflection allowed for infraorbital nerve identification and protection as well as direct observation of the lateral aspect of the zygomatic bone. The palatal mucosa was also reflected, and crestal bone recontouring was performed with a rongeur (Rongeur Bayer; HuFriedy) or bur, depending on the degree of irregularity of the alveolar ridge. In some cases, an additional vertical osteotomy was performed (according to an evaluation of the patient's "smile-line") to prevent any future visibility of the transition zone between prosthetic and native gingiva.

Zygomatic implant lengths and positions were determined perioperatively and were dependent on the anatomy of the region. The "channel" osteotomy began as posterior as possible at the maxillary crest level with a channel drill directed along a planned implant direction, which maintained a minimum safe distance of approximately 3 mm from the posterior-inferior edge of the zygomatic bone, making an effort to not damage the membrane of the sinus. The sinus membrane was then carefully elevated from the internal wall of the sinus. This "channel" facilitated access, and an optimal path to the

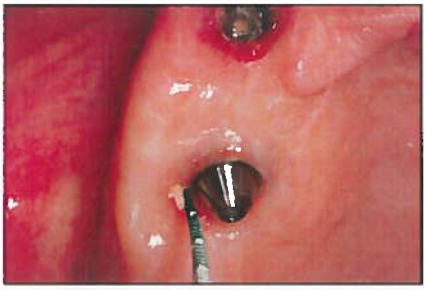

Fig. 7. Intraoral view demonstrating the evaluation of the mPLI and the mBI. Note the presence of bacterial plaque and isolated bleeding spots visible around the abutment.

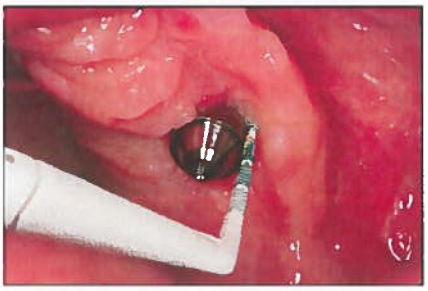

Fig. 8. Intraoral view representative of CL1. This CL represents the main goal to achieve for long-term maintenance of extramaxillary zygomatic implants. Note the probing pocket depth of 2 mm with concurrent absence of bacterial plaque and bleeding.

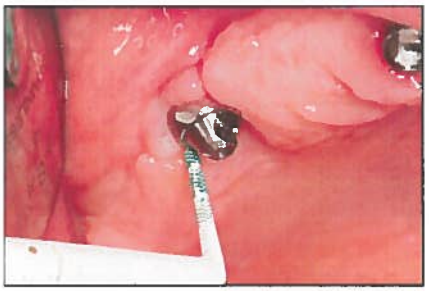

Fig. 9. Intraoral view representative of CL2. Despite the probing pocket depth of more than 4 mm, there is an absence of bacterial plaque and bleeding.

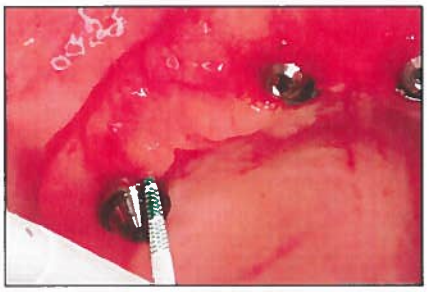

Fig. 10. Intraoral view representative of CL3. Note the probing pocket depth of more than 4 mm with concurrent presence of bleeding and absence of bacterial plaque.

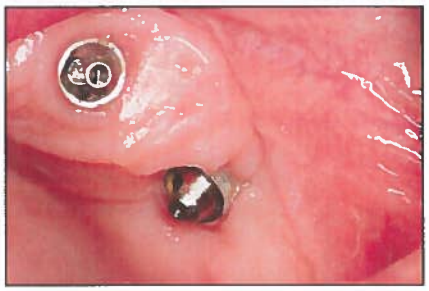

Fig. 11. Intraoral view representative of CL4. Note the presence of bacterial plaque before the probing pocket depth evaluation.

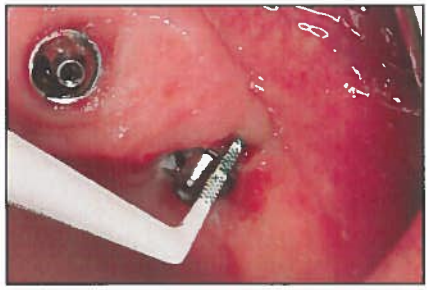

Fig. 12. Intraoral view representative of CL4. Note the probing pocket depth of more than 4 mm with concurrent presence of bleeding and bacterial plaque (demonstrated in Fig. 11).

zygomatic bone for the implant drills without any tissue interference and typically helped to counterfort the implant against the lateral maxillary wall.

Next, a round bur and then the 2.9-mm Brånemark System Zygoma twist drill (Nobel Biocare) were used to start and then define the extramaxillary zygomatic osteotomy. During this procedure, the surgeon's finger was positioned at the external surface of the upper edge of the zygoma to feel the preparation of the external cortical bone (superior edge) to not damage the overlying soft tissues. 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 aspect of the zygoma to the vestibular aspect of the residual crestal ridge. Then, according to the thickness and density of the zygoma, some variation of the successive drills, 3.5, 4.0, and 4.4 mm twist drill (Nobel Biocare), was used.

This surgical protocol is aimed to position the implant's head near the buccal aspect of the residual crest (Fig. 4) but less palatally compared with the classical surgical protocol.[20] The extramaxillary zygomatic implants typically emerged between the lateral incisor and the first molar on the residual ridge crest, aiming for an ideal prosthetic position (implant head emerging at the center of the ridge crest).[23]

For the conventional implants, the insertion followed standard procedures using under preparation: The preparation was typically done by full drill depth with a 2-mm twist drill followed by 2.4/2.8 and 3.2/3.6 mm twist step drill (depending on bone density). In cases of high-density bone, the 3.8/4.2 mm twist 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. Both zygomatic implants inserted through extramaxillary technique and conventional implants were placed with an insertion torque of at least 30 N·cm for sufficient primary stability.

The 4 Multi-unit abutments (Nobel Biocare) 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 with an angulated Multi-unit abutment (Nobel Biocare).

The edges of the flaps were reapproximated tension free with interrupted sutures. Buccal keratinized gingiva was preserved whenever possible, especially around the implants.

The combinations of extramaxillary zygoma and conventional implants per All-on-4 hybrid (Nobel Biocare AB) rehabilitation were as follows: 1 Extramaxillary Zygoma implant and 3 NobelSpeedy Groovy implants (n = 9 patients), 2 Extramaxillary Zygoma implants and 2 NobelSpeedy Groovy implants (n = 24 patients), 2 Extramaxillary Zygoma implants and 2 NobelSpeedy

Shorty implants (n = 2 patients), 2 Extramaxillary Zygoma implants, 1 NobelSpeedy Shorty implant, 1 NobelSpeedy Groovy implant (n = 4 patients), and 3 Extramaxillary Zygoma implants and 1 NobelSpeedy Shorty implant (n = 1 patient).

Immediate and Definitive Prosthetic Protocol

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Typically 6 months after surgery, according to patient preference, a "metal-ceramic" implant-supported fixed prosthesis with titanium framework (NobelProcera, Nobel Biocare AB) and all-ceramic crowns (NobelProcera crowns, Nobel Biocare AB; Heraceram Zirconia, Heraeus Kulzer GmbH, Hanau, Germany) or a "metal-acrylic resin" implant-supported fixed prosthesis with a titanium framework (NobelProcera, Nobel Biocare AB) and acrylic resin crowns (Premium teeth, Heraeus Kulzer GmbH) were used to replace the immediate provisional prosthesis. This protocol typically allowed the prosthetic screw head to exit near the occlusal surface of the crown or slightly palatal to that F5 surface (Fig. 5).

Clinical Examination and Maintenance Protocol

Follow-up clinical examinations were performed routinely at 10 days; 2, 4, and 6 months; and 1 year. The prostheses were removed at each follow-up appointment to perform the clinical assessments, dental hygiene instructions, and prophylaxis: removal of bacterial plaque with a plastic tip ultrasonic scaler (Instrument PI, EMS, Nyon, Switzerland) and polish the abutments at the abutment-mucosa interface with chlorhexidine gel. A clinical example of the soft tissue aspect after 1 year is presented in Figure 6. The clinical mobility index was assessed by introducing a dressing plier into the abutment and performing lateral movements, and registered as present or absent.[2] Suppuration was assessed by applying finger pressure to the periimplant complex, on each vestibular and palatine marginal mucosa and registered as present or absent. Modified plaque index (mPII)[25] and the modified bleeding index (mBI)[25] were performed by introducing a 0.25 N calibrated plastic probe (Hawe click probe; Kerr Hawe, Bioggio, Switzerland) 1 mm into the periimplant sulcus, performing a circle around the abutment and registered as present or absent (Fig. 7). The PPD[2] at the zygomatic and conventional implants were measured at the mesial, distal, vestibular, and palatal aspect using a 0.25 N calibrated plastic probe (Hawe click probe; Kerr Hawe) at 2, 4, 6 months and 1 year, and the presence or absence of pockets >4 mm was registered as present or absent.

Due to the nature of the specific anatomical conditions, the extramaxillary zygomatic implants were distributed by 4 different clinical levels (CLs) according to the status of the clinical soft tissue parameters aiming to evaluate the presence and severity of periimplant conditions: CL1: No PPD >4 and no mPII or mBI (Fig. 8); CL2: F8 PPD >4 mm, without mPII and mBI (Fig. 9); CL3: PPD >4 mm with mBI F9 without mPII (Fig. 10); and CL4: PPD F10 >4 mm with mPII and with or without F6 presence of mBI (Figs. 11 and 12). F11 F12

Main Outcome Measures

The main outcome measures were the critical soft tissue parameters for monitoring the periimplant conditions, namely incidence of PPD >4 mm, mPII, mBI, clinical mobility, and suppuration.

Secondary Outcome Measures

The secondary outcome measures were implant survival and the incidence of mechanical complications (fracture or disconnection of any prosthetic component).

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Statistical Analysis

Descriptive statistics were applied to the variables of interest (clinical parameters). Inferential statistics

Table 1. Presence or Absence of Bacterial Plaque Using the mPII,[25] Bleeding Using the mBI,[25] and Probing Pocket Depths >4 mm (PPD >4 mm) Around Zygomatic and Conventional Implants During the Follow-up of the Study

	mPII, 10 d		mPII, 2 mo		mPII, 4 mo		mPII, 6 mo		mPII, 1 y	
	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent
Zygomatic implants, n (%)	10 (15)	57 (85)	12 (19)	52 (81)	13 (21)	49 (79)	17 (27)	46 (73)	23 (35)	43 (65)
Conventional implants, n (%)	13 (15)	72 (85)	16 (20)	64 (80)	17 (22)	59 (78)	17 (24)	54 (76)	19 (28)	49 (72)
	mBI, 10 d		mBI, 2 mo		mBI, 4 mo		mBI, 6 mo		mBI, 1 y	
	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent
Zygomatic implants, n (%)	7 (10)	60 (90)	12 (19)	52 (81)	8 (13)	54 (87)	8 (13)	55 (87)	13 (20)	53 (80)
Conventional implants, n (%)	8 (9)	77 (91)	13 (16)	67 (84)	10 (13)	66 (87)	9 (13)	62 (87)	18 (24)	57 (76)
	PPD >4 mm, 10 d		PPD >4 mm, 2 mo		PPD >4 mm, 4 mo		PPD >4 mm, 6 mo		PPD >4 mm, 1 y	
	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent
Zygomatic implants, n (%)	Not evaluated		6 (9)	58 (91)	4 (6)	58 (96)	6 (10)	57 (90)	6 (9)	60 (91)
Conventional implants, n (%)	Not evaluated		3 (4)	77 (96)	0 (0)	76 (100)	3 (4)	68 (96)	0 (0)	75 (100)

Table 2. Presence and Severity of PPD >4 mm Adjacent to Zygomatic Implants and Corresponding Clinical Status

		CL Status at Follow-up			
Patient No.	Implant Position	2 mo	4 mo	6 mo	1 y
1	25	3	3	3	4
1	15	1	1	1	4
2	15	4	4	Withdrawn. With implant mobility considered failure	
3	15	2	1	1	1
3	25	2	1	1	1
4	25	2	2	2	1
5	25	4	1	1	1
6	15	1	4	1	1
7	15	1	1	4	1
7	25	1	1	4	1
8	25	1	1	4	1
9	25	1	1	4	4
10	25	1	1	1	4
11	15	1	1	1	4
11	25	1	1	1	4

The crescent scale of the clinical status reflects the severity of the extramaxillary zygomatic implants' clinical condition. CL1, no PPD >4 mm; CL2, PPD >4 mm without mPII and mBI; CL3, PPD >4 mm and mBI without mPII; CL4, PPD >4 mm and mPII with or without mBI.

(McNemar test for dichotomous paired samples) were applied to evaluate the difference in the distribution of clinical parameters (PPD >4 mm, mPII, mBI, clinical mobility, and suppuration) between zygomatic extramaxillary implants and conventional implants at 5% confidence level.

RESULTS

Four patients with 6 extramaxillary zygomatic implants withdraw from the study, all in the first 6 months. Three patients with 5 extramaxillary zygomatic implants became unreachable and 1 patient with 1 extramaxillary zygomatic implant moved location and was no longer followed by our team.

Clinical mobility was present in 1 zygomatic implant in 1 patient at 2 months of follow-up with the patient withdrawing from the study (followed in another clinic) and therefore was considered as an implant failure, whereas 3 conventional implants in 2 patients presented clinical mobility and were lost (1 patient with 2 implants at 4 months and 1 patient with 1 implant at 1 year). Suppuration was registered in 3 patients: 1 patient with 1 zygomatic implant at 2 months (the same patient with clinical mobility on that zygomatic implant that has withdrawn from the study, with concurrent presence of PPD >4 mm, and presence of mBI and mPII); 1 patient with 2 zygomatic implants, 1 zygomatic implant at 6 months and both zygomatic implants at 1 year (with concurrent presence of PPD >4 mm, and presence of mPII); and 1 patient with 1 zygomatic implant at 1 year (with concurrent presence of PPD >4 mm, mBI, and mPII). The mPII and mBI evolution were characterized by an increasing tendency throughout the study's follow-up with no significant differences between zygomatic and conventional implants (Table 1). The PPD >4 mm was characterized by a higher percentage in zygomatic implants compared with conventional implants throughout the follow-up, nevertheless without significant differences at patient level (Table 1).

The CLs were collected using the patient as unit of analysis: there were 28 patients rated as CL1. In the 11 patients with 15 zygomatic implants presenting PPD >4 mm, severity was distributed per CL2 to 4 (Table 2) as follows: 2 patients with 3 zygomatic implants for CL2; 1 patient and 1 zygomatic implants for CL3; and 9 patients with 11 implants for CL4 (1 patient presented 1 implant with CL3 for the first 6 months and CL4 at 1 year and another implant with CL4 at 1 year). Four patients with 5 zygomatic implants were diagnosed with PPD >4 mm only at the 1-year appointment. During the follow-up, using the stratification system (CL1–CL4), the condition for patients with zygomatic implants improved in 3 patients with 4 zygomatic implants and deteriorated for 1 patient with 1 zygomatic implant (2 patients with 2 zygomatic implants withdrew from the study).

Implant survival was 98.6% for zygomatic implants and 97% for conventional implants at 1 year of follow-up.

Mechanical complications of the prosthetic restorations occurred in 19 patients: Fracture of the immediate provisional acrylic prosthesis occurred in 11 patients, abutment screw loosening occurred in 7 patients, and prosthetic screw loosening occurred in 1

Table 3. Rationale for Intervention in Extramaxillary Zygomatic Implants During Follow-up According With CLs

CL	mPII	mBI	PPD >4 mm	Clinical Intervention
1	–	–	–	Prophylaxis, oral hygiene education; maintain recall schedule
2	–	–	+	Prophylaxis, oral hygiene education; keep under observation* (possibly reducing recall schedule)
3	–	+	+	Treat bleeding† through prophylaxis and oral hygiene education; reevaluate
4	+	±	+	Treat periimplant pathology; ‡reevaluate

The rationale for intervention is based on a maximum of 6-month recall schedule for CL1. For CL3 and CL4, there are no recall regimens but reevaluations.
Recommendations for the clinical decision making and evidence from the scientific literature.
*Pseudopockets possess a higher probability of becoming pathological.[27]
†Strong correlation between absence of bleeding and absence of periodontal pathogens in microbiological samples.[28]
‡Bacterial plaque is a major etiological factor for periimplant pathology,[29,30] the concurrent presence of pockets account for an unsuccessful implant.[8]

patient. The situations were amended by repairing the prosthesis (fractures), tightening the prosthetic components (abutment and prosthetic screw loosening), adjusting the occlusion, and manufacturing night-guards (for all incidences). No further complications occurred.

DISCUSSION

This study focused on the soft tissue clinical parameters of zygomatic implants, considering the unique anatomical conditions induced by the extramaxillary surgical approach: In this situation, the zygomatic implants are anchored solely on the zygomatic bone without any maxillary anchorage and covered only by soft tissue on their vestibular aspect. This may reflect the higher frequency of zygomatic implants with PPD higher than 4 mm when compared with conventional implants, however with a nonsignificant difference registered in this study. Previous studies addressed the issue of higher PPD around zygomatic implants: Al-Nawas et al[9] reported PPD between 6.7 and 7.0 mm around machined surface zygomatic implants, and Maló et al[2] addressing the zygomatic implants inserted through the extramaxillary technique reported 21 patients with 30 implants revealing PPD >4 mm, with both studies attributing the probing pocket depth outcome to the anatomical conditions surrounding zygomatic implants induced by the surgical techniques of implantation.

Marginal bleeding was also present around 21% of the implants at the 1 year of follow-up, but this feature was not significantly different from conventional implants. The presence of marginal bleeding was also reported previously in zygomatic implants inserted through the extramaxillary technique, with Maló et al[2,12] showing a median of 1 for marginal bleeding (meaning a single localized bleeding observed) from 2 months to 3 years of follow-up.[2,12] Bleeding around zygomatic implants was significantly correlated with the presence of periodontal pathogens as reported by Al-Nawas et al.[1] In that study, the group of patients with bleeding on probing had a higher prevalence of periodontal pathogens compared with those patients with absence of bleeding on probing.

Taking into consideration the clinical features of zygomatic implants inserted through the extramaxillary technique, the patients were distributed by 4 different CL considering the pairing of the mPII, mBI, and PPD >4 mm clinical indexes. The reason for this CL classification was related to the necessity of monitoring the extramaxillary zygomatic implants and implementing a rationale for intervention based on the clinical parameters results to maximize the success outcome, as the absence of maxillary anchorage of these implants disables the marginal bone loss evaluation. However, the authors highlight that these CLs do not represent a treatment or any guaranty of success but rather a clinical guideline. The authors propose the following patient stratification to recommend a follow-up schedule and identify patients for clinical intervention (Table 3). The patients on CL1 represent the best clinical outcome of the zygomatic implant at any given clinical appointment, suggesting a simple maintenance appointment with clinical assessment, prophylaxis and oral hygiene education, without modification to the recall agenda (usually of 6 months as processed in this study after the completion of the functional osseointegration period). The large majority of patients in this study (72.5%) were rated as CL1 and that should represent the norm, whereas a smaller portion were distributed in CL2 to CL4. A CL2 patient meant the presence of periimplant pockets over 4 mm without the concurrent presence of bleeding (inflammatory sign) or bacterial plaque (etiological factor).[26] Previous reports on extramaxillary zygomatic implants suggested a nonsignificant impact of higher PPD on the success outcome,[12,13] nevertheless, periimplant pockets (pseudopockets) have a higher risk of becoming pathological,[27] thus the suggestion of keeping the implants under clinical observation (possibly reducing the recall period). A CL3 patient implies addressing clinically the inflammatory sign (bleeding) and reevaluating. Al-Nawas et al[9] reported 55% of zygomatic implants with soft tissue problems defined as PPD ≥5 mm and the presence of bleeding on probing, and furthermore strongly correlating the absence of bleeding with an absence of positive periodontal pathogens in microbiological samples. A CL4 patient meant the incidence of periimplant pathology. Bacterial plaque is a major risk factor for periodontal and periimplant pathologies,[26,28,29] as widely reported in several studies in conventional implants, and that makes it mandatory to intervene clinically to treat the pathology (surgically or nonsurgically and/or with antibiotics) and attempt to remove the etiological factor (bacterial plaque) through prophylaxis and patient education. Cross-sectional to these clinical features is the presence of suppuration that is mandatory to address, attempting to identify the origin (periimplant complex or sinus pathology) and defining a treatment strategy for its resolution (nonsurgical, surgical and/or with antibiotics).[13]

The extrapolation of the results from this study to the general population should be made with caution as this study presented a short-term follow-up was performed within a single center, and in a majority of Portuguese patients. The study design and the dropout rate within the accepted limits (<20%) of a prospective cohort study account for study strengths.[30] T3

Longer studies with prospective design on the long-term outcome of rehabilitations supported by zygomatic implants are needed, especially focusing on the soft tissue conditions.

CONCLUSIONS

The clinical parameters in this study seem to follow a similar pattern for zygomatic implants inserted through the extramaxillary technique and conventional implants with no significant differences registered during the follow-up. A CL classification based on the pairing of PPD >4 mm, mPII, and mBI may provide valid clinical guidelines for the long-term successful outcome at the regular recall appointments. The presented CL classification system based on presence of PPD >4 mm and severity using mPII and mBI stratifies patients with a good

distribution and may support clinical decision making for frequency of recall appointments and identification of patients for further intervention. Further validation is needed to identify whether it enhances treatment success in the long term.

DISCLOSURE

P. Maló is currently a consultant for Nobel Biocare. The remaining authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

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