Extramaxillary Surgical Technique: Clinical Outcome of 352 Patients Rehabilitated with 747 Zygomatic Implants with a Follow-Up between 6 Months and 7 Years

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ABSTRACT

Background: The use of zygomatic implants inserted in immediate function through the extramaxillary technique needs validation.

Purpose: To report the outcome of rehabilitating 352 patients with complete edentulous atrophied maxillae using 747 zygomatic implants in immediate function inserted through the extramaxillary technique.

Materials and Methods: Three hundred-fifty-two consecutive edentulous patients with atrophic maxillae were rehabilitated between 2006 and 2012 with 747 zygomatic implants and 795 conventional implants. Implant and prosthetic cumulative survival and success rates were estimated through Kaplan–Meier product limit estimator. Biological and prosthetic complications were recorded after 10 days; 2, 4, and 6 months; and thereafter every 6 months.

Results: Forty-three patients (12.2%) dropped-out, one patient lost the prosthesis (cumulative survival rate = 99.7%), and four patients lost 7 zygomatic implants, rendering an estimated cumulative survival rate of 98.2% (Kaplan–Meier). Ten patients lost 17 conventional implants (patient-specific and implant-specific cumulative survival rates of 96.7% and 97.9%, respectively). Biological complications were observed in 80 patients (22.7%) and resolved in the majority of situations, rendering an estimated cumulative success rate of 94.4% at 7 years for zygomatic implants (Kaplan–Meier). Mechanical complications occurred in 156 patients (44%), with one-third of these complications occurring in patients diagnosed with bruxism before the rehabilitation.

Conclusions: The rehabilitation of atrophic maxillae with zygomatic implants inserted through the extramaxillary technique in immediate function, alone or in combination with standard implants, is a viable procedure. Until the biomechanical aspects are more predictable and also because of the complexity of the surgical technique, this rehabilitation approach is not ready for every implant clinician to begin using in practice, and prior special training is recommended.

KEY WORDS: All-on-4, completely edentulous, dental implants, immediate function, zygomatic implants

INTRODUCTION

The use of zygomatic implants has become a good treatment alternative for the rehabilitation of the severely atrophic maxilla,[1–3] providing reduced morbidity for the patient and shorter treatment periods compared with bone grafting and implant placement.[2,3]

The use of immediate function with zygomatic implants is a developing clinical trend around the world, with several authors reporting survival rates between 96% and 100%,[4–13] but still documentation is lacking.

There is generally a low frequency of complications reported in the literature with the use of zygomatic implants: The most prevalent complication seems to be sinus infections,[1,2,7,14–17] followed by mechanical complications[8,17] and, to a smaller degree, functional

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complications.[18,19] This group of complications may have a connection to standard surgical techniques for inserting zygomatic implants.[20]

The surgical technique for inserting zygomatic implants has been the subject of modification and development, with today essentially two major variations existing: the internal technique, in which the implant is inserted internal to the maxillary sinus as initially reported by Brånemark and colleagues,[21] and the external technique, in which the implant is inserted primarily external to the maxillary sinus before anchoring in the zygomatic bone, covered only by soft tissue along its lateral maxillary surface.[7,22] The extramaxillary technique was described in a previous study,[7,22] with the objective of complementing the spectrum of the All-on-4® treatment concept[23] for rehabilitation of completely edentulous maxillae, in situations where a rehabilitation with conventional implants is not possible without the use of bone grafting procedures.

The purpose of this study was to report the outcome of rehabilitating 352 patients with atrophic, completely edentulous maxillae using 747 zygomatic implants inserted through the extramaxillary technique and placed in immediate function.

This article was written following the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (http://www.strobe-statement.org).[24]

MATERIAL AND METHODS

This study was approved by the Ethics Committee for Health (Lisbon, Portugal; authorization no. 002/2012). This retrospective study was performed at a private rehabilitation center between January 2006 and July 2012. The study included 352 consecutively treated patients (281 women and 71 men), with an age range of 17 to 85 years (mean = 55.2 years). The patients were identified from the medical records as having consented to completely edentulous maxillary rehabilitation with the use of implants inserted into the zygomatic bone. 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. Patients with active radiotherapy or chemotherapy or presenting emotional instability were excluded. Sixty-six patients were smokers, and 132 patients presented with the following conditions: hepatitis (7 patients), cardiovascular disease (71 patients), thyroid dysfunction (20 patients), diabetes (16 patients), autoimmune disease (26 patients), HIV (1 patient), oncologic condition (9 patients), neurologic condition (1 patient). There were 19 patients presenting more than one condition. Eighty-five patients were diagnosed as heavy bruxers prior to the prosthetic rehabilitation. The patients were followed for between 6 months and 7 years. The patients were rehabilitated either by using one to four zygomatic implants in conjunction with conventional implants (301 patients) or four zygomatic implants only (51 patients) (Table 1). All implants were placed in immediate function (minimum insertion torque of 30 Ncm was achieved for all implants). The zygomatic implants used in this study were Brånemark System Zygoma (TiUnite surface; Nobel Biocare AB, Gothenburg, Sweden) and typically emerged between the lateral incisor and the first molar on the residual crest of the ridge, near the ideal prosthetic position (implant head emerging at the center of the ridge crest).[25]

Surgical Protocol

Surgeries were performed by two surgeons (P.M. and A.L.) and were described in full detail in previous studies.[7,22] In brief, a clinical examination with a preoperative panoramic radiograph and a computed

TABLE 1 Distribution of Patients by Number of Zygomatic Implants

Number of Implants	Number of Patients	Percentage	Valid Percentage	Cumulative Percentage
1	73	20.7	20.7	20.7
2	214	60.8	60.8	81.5
3	14	4.0	4.0	85.5
4	51	14.5	14.5	100
Total	352	100	100	

TABLE 2 Estimated Patient-Specific Survival of Zygomatic Implants

Time (Months)	Status*	Cumulative Percentage Surviving at the Time		Number of Cumulative Events	Number of Patients at Risk
		Estimate	Standard Error		
0	0	NA	NA	0	352
3	1	99.7	0.003	1	351
6	0				346
9	0				325
9	1	99.4	0.004	2	324
12	0				312
17	1	99.0	0.006	3	280
24	0				237
36	0				168
47	1	98.2	0.01	4	112
48	0				104
60	0				60
72	0				17
84	0				1

Estimated using the Kaplan–Meier product limit estimator.
*0 = no failure; 1 = failure.
NA = not applicable.

tomography or cone beam computed tomography 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)[26] immediately proximal to the midline (corresponding to the area of the central and lateral incisors), an anterior conventional maxillary anchored implant (NobelSpeedy, Nobel Biocare AB, Göteborg, Sweden) 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[26]), two implants with zygomatic anchorage were placed (Figure 1; All-on-4 Hybrid; Nobel Biocare AB). In the patients where the anterior residual crestal bone did not fulfill the minimum prerequisite to allow a conventional maxillary implant placement proximal to the midline (more than C-VI, Cawood and Howell Classification),[26] four implants with zygomatic anchorage were used, two implants bilaterally (Figure 2; All-on-4 Double Zygoma; Nobel Biocare AB).

The surgery was performed under general anesthesia or local anesthesia alone, according to the patient's wishes. 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 in order 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 (Figure 3). The palatal mucosa was also reflected, and crestal bone recontouring was performed with a rongeur (Rongeur Bayer; Hu-Friedy, Chicago, IL, USA) or bur, depending on the degree of irregularity of the alveolar ridge. In some cases, an additional vertical ostectomy was performed (according to an evaluation of the patient's "smile-line") in order to prevent any future visibility of the transition zone between prosthetic and native gingiva.

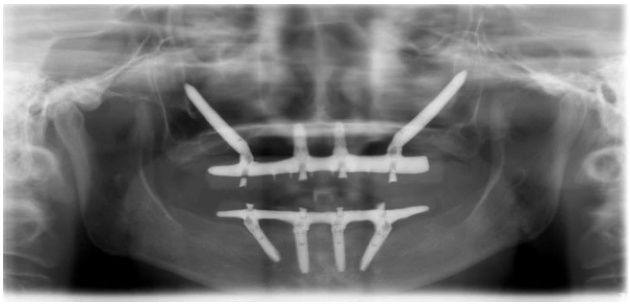

Figure 1 Orthopantomography showing implant positions in an All-on-4 Hybrid case (two standard implants in the anterior maxilla and two extramaxillary zygomatic implants).

TABLE 3 Estimated Patient-Specific Success of Zygomatic Implants

Time (Months)	Status*	Cumulative Percentage Surviving at the Time		Number of Cumulative Events	Number of Patients at Risk
		Estimate	Standard Error		
0	0	NA	NA	0	352
2	1	99.7	0.003	1	351
3	1	99.1	0.005	3	349
4	1	98.9	0.006	4	348
5	1	98.3	0.007	6	346
6	0				341
7	1	98.0	0.008	7	340
8	0				327
8	1	97.7	0.008	8	326
9	0				320
9	1	97.0	0.009	10	319
12	0				305
12	1	96.7	0.01	11	304
14	0				292
14	1	96.4	0.01	12	291
17	0				268
17	1	96.0	0.11	13	267
24	0				224
36	0				163
41	0				132
41	1	95.3	0.13	14	131
47	0				109
47	1	94.4	0.16	15	108
48	0				99
60	0				55
72	0				17
84	0				1

Estimated using the Kaplan–Meier product limit estimator.
*0 = no failure; 1 = failure.
NA = not applicable.

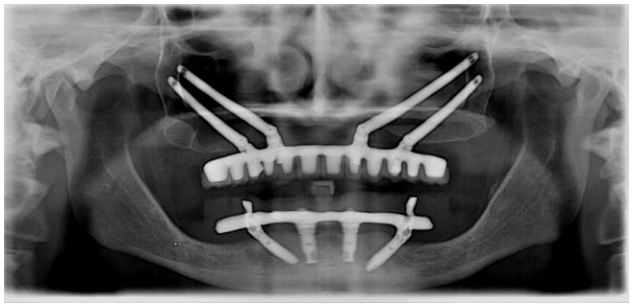

Figure 2 Orthopantomography representing implant positions in an All-on-4 Double Zygoma case (maxilla). Two zygomatic extramaxillary implants were placed bilaterally.

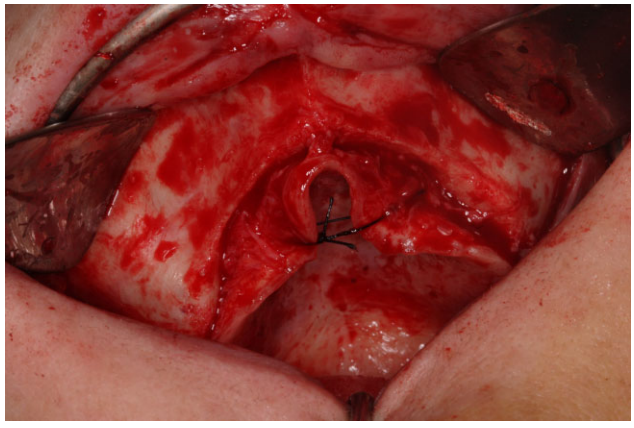

Figure 3 Intraoral photograph after flap reflection.

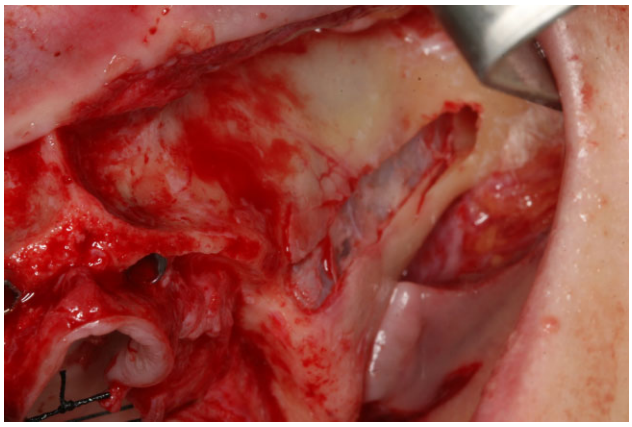

Figure 4 Intraoral photograph showing the "channel" created to accommodate the zygomatic implant placed via the extramaxillary technique, with preservation of the sinus membrane.

Zygomatic implant lengths and positions were determined perioperatively and were dependent on the anatomy of the region. The "channel" osteotomy began as posteriorly as possible at the maxillary crest level with a channel drill directed along a planned implant direction that 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 zygomatic bone for the implant drills without any tissue interference, and typically helped to "buttress" the implant against the lateral maxillary wall (Figure 4).

Next, a round bur and then the 2.9-mm zygoma twist drill (Nobel Biocare AB) 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) as it neared completion in order 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 mm, 4.0 mm, and 4.4 mm twist (Nobel Biocare AB) – was used. Particular attention was given to the infraorbital nerve and the base of the orbit to avoid damaging these anatomical structures during implant site preparation, especially in "double zygoma" cases. The zygomatic implants inserted through extramaxillary technique were placed with an insertion torque of at least 30 Ncm for sufficient primary stability.

For the surgical procedures performed with two zygomatic implants in the same zygoma, either unilateral or bilateral, a minimum distance of approximately 5 mm was maintained between the two implants, with the anterior implant serving as reference. The orbit, the infraorbital nerve, and the bony anatomy were factors in determining implant directions. The head of the distal implant emerged usually around the first molar/second premolar region, and the head of the anterior implant emerged usually in the canine-to-lateral-incisor region. This protocol allowed the implant's head to be positioned near the buccal aspect of the residual crest and be less palatal, compared with the surgical protocol described by Brånemark and colleagues.[21]

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

Immediate and Final Prosthetic Protocol[22]

A high-density acrylic resin (PalaXpress Ultra, Heraeus Kulzer GmbH, Hanau, Germany) prosthesis with titanium cylinders (Nobel Biocare AB) was manufactured at the dental laboratory and inserted the same day.

Typically 6 months after surgery, according to patient preference and clinical considerations, either a "metal–ceramic" implant-supported fixed prosthesis consisting of a titanium framework (NobelProcera, Nobel Biocare AB) and all-ceramic crowns (NobelProcera crowns and Rondo Ceramics; Nobel Biocare AB) or a "metal–acrylic resin" implant-supported fixed prosthesis consisting of a titanium framework (NobelProcera, Nobel Biocare AB) and acrylic resin prosthetic teeth (Heraeus Kulzer GmbH) were used to replace the provisional prosthesis. This protocol typically allowed the prosthetic screw head to exit near the occlusal surface of the crown or slightly palatal to that surface, which may or may not coincide with the center of the residual ridge crest.

Follow-Up

Follow-up clinical examinations were performed at 10 days; 2, 4, and 6 months; and every 6 months thereafter. The prostheses were removed at each follow-up appointment to perform the clinical assessments.

Primary Outcome Measures

The primary outcome measures were prosthetic success, implant success, and complications.

- The prosthetic success was judged in terms of function. The prosthesis was considered a failure if it needed to be replaced by a new prosthesis.
- An implant was classified as successful according to the criteria developed by the authors if:[7] (1) it fulfilled its purported function as support for reconstruction; (2) it was stable when individually and manually tested;[27] (3) no signs of persistent prevalent infection were observed; (4) it demonstrated a good aesthetic and functional outcome of the rehabilitation; and (5) it allowed fabrication of the implant-supported fixed prosthesis that provided patient comfort and hygiene. In the situations where the implants did not fulfill the criteria for success but remained in site, these were considered survivals. In situations of implant removal, these were considered as failures.
- The following complication parameters were assessed: fracture or loosening of mechanical and prosthetic components (mechanical complications); soft tissue inflammation, fistula formation, pain, maxillary sinus infections, and peri-implant pathology (probing pocket depths > 4 mm together with bleeding of the peri-implant soft tissue and/or presence of dental plaque) (biologic complications); aesthetic complaints of the patient or dentist (aesthetic complications); phonetic complaints, masticatory complaints, comfort complaints, or hygienic complaints (functional complications).

Statistical Evaluation

The cumulative survival and success rates were estimated using the Kaplan–Meier product limit estimator taking the patient as unit of analysis (first implant failure in any given patient), with indication of the mean survival estimate and 95% confidence intervals (95% CIs).[28] Descriptive statistics were applied to the variables of interest.

RESULTS

Dropout Rate

Forty-one patients (11.6%) with 86 zygomatic implants (11.5%) withdrew from the study: 1 patient with 1 implant during the first year (the patient became unreachable), 13 patients and 29 implants between 1 and 2 years (4 patients with 10 implants moved out of the country and 9 patients with 19 implants became unreachable), 8 patients with 19 implants between 2 and 3 years (1 patient with 1 implant moved out of the country and 7 patients with 18 implants became unreachable), 14 patients with 33 implants between 3 and 4 years (2 patients with 6 implants moved out of the country and 12 patients with 27 implants became unreachable), and 3 patients with 4 implants between 4 and 5 years (1 patient with 2 implants moved out of the country and 2 patients with 2 implants became unreachable).

Two patients (with 3 zygomatic implants) died after 8 and 30 months of follow-up, owing to causes unrelated to the implant rehabilitation.

Prosthesis Success

A total of 352 completely edentulous maxillary rehabilitations were performed in 352 patients. One patient lost the prosthesis owing to the failure of the four zygomatic implants, giving a prosthetic survival rate of 99.7%.

Implant Survival

A total of 1542 implants were inserted: 747 extramaxillary zygomatic implants and 795 conventional implants. Four patients lost 7 zygomatic implants: One patient lost 4 extramaxillary zygomatic implants along with the prosthesis after 3 months of follow-up; 3 patients lost 1 extramaxillary zygomatic implant each, after 9, 14, and 46 months respectively, with the prostheses surviving on the remaining implants. This rendered an estimated cumulative survival of 98.2% at 7 years of follow-up (Kaplan–Meier, Table 2, Figure 5). The estimated mean survival was 83.2 months (95% CI [82.1, 84.2] [Kaplan–Meier]) (maximum survival registered was 84.2 months). Ten patients lost 17 conventional implants, rendering patient-specific and implant-specific survival rates of 96.7% and 97.9%, respectively. The lost extramaxillary zygomatic implants and conventional implants presented clinical mobility at the time of failure and were removed, with the prostheses surviving on the remaining conventional and zygomatic implants. The lost implants were replaced on 5 patients and were not accounted for in the study.

Complications

Biologic complications were observed in 80 patients (22.7%). There were 26 maxillary sinus infections in 26

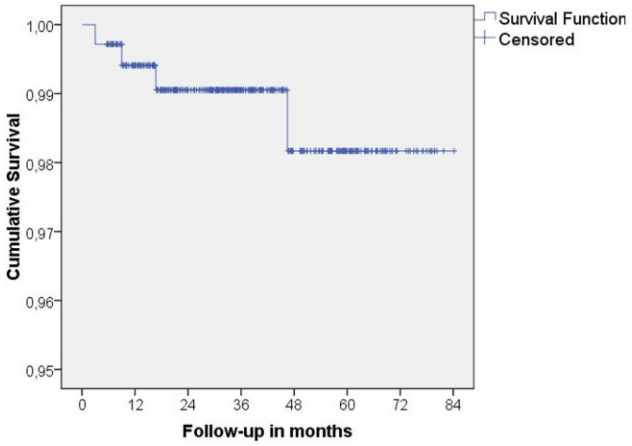

Figure 5 Estimated survival, estimated using the Kaplan–Meier product limit estimator.

patients (one patient with an oral–antral communication diagnosed at the 1-year follow-up appointment); 21 of the patients with maxillary sinus infections had a previous diagnosis of sinusitis prior to implant surgery. With 8 patients, the situation was resolved through nonsurgical treatment (removal of deposits from the implant surface and irrigation with chlorhexidine 0.2%); with 7 patients, the situation was resolved by administering nonsurgical treatment and antibiotics; with 5 patients, the situation was resolved after a surgical intervention (functional endoscopic sinus surgery); and in 6 patients the situation was not resolved (3 of these patients were lost to follow-up, 3 patients still pending intervention outcome; 1 of those patients, whose situation was resolved a first time via antibiotics, remained asymptomatic for 2 years and relapsed). Peri-implant pathology was observed in 54 patients and 54 implants. The situations were resolved in 43 patients: in 34 patients through nonsurgical treatment with scaling and irrigation with chlorhexidine; in 4 patients through the administration of nonsurgical treatment together with antibiotics; and in 5 patients through surgical intervention (removal of granulation tissue and decontamination of the implant surface with chlorhexidine 0.2%). In 11 patients the situation was not resolved (1 patient who was lost to follow-up, 1 patient in active chemotherapy, and 9 patients who presented an inability to maintain a minimum-standard level of oral hygiene, though the implants clinically remained stable during the follow-up period of the study).

Mechanical complications were observed in 156 patients (44%): 101 fractures of the prostheses, loosening of prosthetic components (53 patients), and crown avulsions (2 patients). One-third of these complications occurred in patients with a diagnosis of bruxism prior to the rehabilitation (52 patients), and 141 in patients whose prosthesis occluded with an implant-supported fixed prosthesis in the opposing dentition (46 patients with both conditions). The situations were resolved in 149 patients by repairing the prosthesis (fractures), tightening the prosthetic components (screw loosening), adjusting the occlusion, and manufacturing night guards. There were 7 patients with a prevalence of mechanical complications (4 patients who were heavy bruxers, 2 patients with implant-supported prosthesis as opposing dentition, and 1 patient who kept the provisional prosthesis as definitive).

Implant Success

The estimated cumulative success rate of the zygomatic implants at 7 years was 94.4% (Kaplan–Meier, Table 3, Figure 6) using the patient as unit of analysis, taking into consideration the implant failures in 4 patients and the unresolved biological complications in another 11 patients. The estimated mean success was 80.6 months (95% CI [78.7, 82.4]) (Kaplan–Meier). (Maximum follow-up registered was 84.2 months.)

DISCUSSION

Only 1 prosthesis and 7 zygomatic implants failed in 352 patients with a total 747 zygomatic implants during the follow-up period of the study, comparing favorably to previous reports using zygomatic and conventional implants placed in immediate function for the

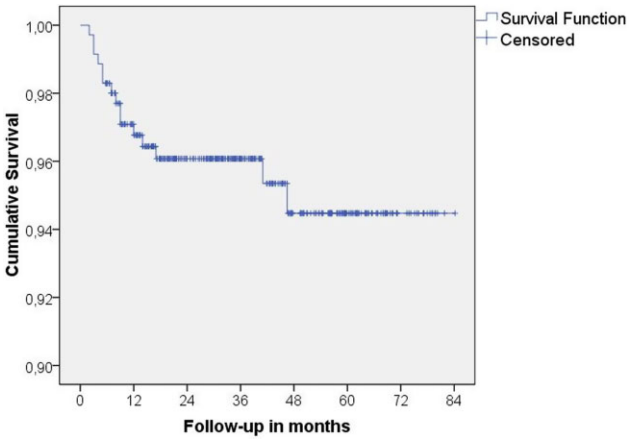

Figure 6 Estimated success, estimated using the Kaplan–Meier product limit estimator.

rehabilitation of the completely edentulous and severely atrophic maxilla,[4–13] with a follow-up between 1 and 7 years.[4–6,8,9,11,12] In our study, there was a large number of patients exceeding 5 years of follow-up ($n = 60$). The results achieved support optimism regarding viability in the long term. To establish a comparison, it is important to highlight the differences between this technique and the classical technique developed by Brånemark:[21] The technique described in this study is extramaxillary and extrasinusal, meaning the zygomatic implant is anchored in the zygomatic bone and lies primarily outside the maxilla and maxillary sinus (only buttressing against the maxillary bone).

Based on these results, it is possible to theorize that the rehabilitation of severely atrophic maxillae with zygomatic implants inserted through the extramaxillary surgical technique that are placed in immediate function might present a viable treatment alternative to bone grafting procedures.[29]

The incidence rate of maxillary sinus pathology in our study was very low, 7% ($n = 26$), and furthermore, it occurred in only 5 patients without a diagnosis of sinusitis before the rehabilitation, as patients with diagnosed sinus pathology previous to the implant rehabilitation were not excluded from the study. The incidence of sinus pathology is usually the most prevalent complication in these rehabilitations with zygomatic implants.[1,2,7,14–17] Compared with the extramaxillary technique, there are reports using the classical technique with an observed incidence rate after 5 years of at least twofold in sinus pathology.[1,21] Our results also stress the findings of previous reports that there seems to be a higher risk of maxillary sinus infections when rehabilitating patients with a previous diagnosis of maxillary sinusitis.[22]

The peri-implant pathology observed in this study (higher probing pocket depths together with bleeding of the peri-implant soft tissue and/or presence of dental plaque) accounted for the majority of biologic complications. The frequency of this type of biological complication (15%) is similar to that previously reported for standard implants in the rehabilitation of completely edentulous patients,[30] but this fact must be confirmed in future comparative studies. Most situations were resolved through nonsurgical therapy, with the implants becoming asymptomatic. The maintenance of a good standard of oral hygiene is recommended in patients rehabilitated with this technique, as the lateral aspect of the zygomatic implant body in the coronal and middle thirds is covered only with soft tissue. Poor hygiene might account for most of the unresolved situations, as the 9 patients with unresolved peri-implant pathologies displayed a low level of oral hygiene.

The frequency of mechanical complications was high, with most of the complications (nearly two-thirds) consisting of fractures of the prosthesis that did not threaten the rehabilitation, and the remaining one-third consisting of minor loosening of prosthetic or abutment screws. Two conditions were more prevalent in the patients presenting with mechanical complications: firstly, a third of these complications occurred in heavy bruxers, diagnosed prior to the rehabilitation, who were not excluded from participating in the study; secondly, 141 patients presented with an implant-supported fixed rehabilitation as the opposing dentition. Previous studies reported a higher risk for the occurrence of mechanical complications in the presence of these two conditions,[31–34] and that might account for most of the occurrences.

The limitations of the study include the retrospective design and the involvement of a single center. The dropout rate was low (11.5%, representing 41 patients). The patients failing to comply with the control appointments were contacted, and for those reached, the information about implant survival and complications was retrieved directly. However, the follow-up status (lost to follow-up) and follow-up time (follow-up time at last control appointment) remained unchanged for the estimation of success and survival.

Future studies should focus on the 10-year outcome of these rehabilitations.

CONCLUSIONS

The results of this study indicate that the rehabilitation of the severely atrophic maxilla through the All-on-4 concept utilizing one to four zygomatic implants placed with an extramaxillary surgical protocol into the zygomatic bone(s) and placed in immediate function is viable in long-term follow-up. However, until the biomechanical aspects are more predictable and also because of the complexity of the surgical technique, this rehabilitation approach is not ready for every implant clinician to begin using in practice, and prior special training is recommended.

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CONFLICTS OF INTEREST

Professor Paulo Maló is currently a consultant for Nobel Biocare AB. No further conflicts of interest are declared for the remaining authors.

AUTHOR CONTRIBUTIONS

Paulo Maló: concept/design, data analysis/interpretation, drafting article, critical revision of article, approval of article.

Miguel de Araújo Nobre: data analysis/interpretation, drafting article, critical revision of article, statistics, approval of article.

Armando Lopes: data analysis/interpretation, drafting article, critical revision of article, approval of article.

Ana Ferro: data analysis/interpretation, drafting article, critical revision of article, approval of article.

Steve Moss: data analysis/interpretation, drafting article, critical revision of article, approval of article.

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