Zygomatic Implants Placed Using the Zygomatic Anatomy-Guided Approach versus the Classical Technique: A Proposed System to Report Rhinosinusitis Diagnosis

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ABSTRACT

Purpose: The first aim of this study is to compare the outcomes in rehabilitating the atrophic maxilla using zygomatic implants (ZIs) and regular implants (RIs) using the classical zygomatic technique (CZT) versus the zygomatic anatomy-guided approach (ZAGA). The second goal of this paper is to propose a standardized system to report rhinosinusitis diagnosis.

Materials and Methods: Twenty-two consecutive zygomatic patients operated on from 1998 to 2002 and 80 consecutive zygomatic patients operated on from 2004 to October 2009 were selected. All included patients were in a maintenance program. Survival rates (SRs) of ZI and RI were recorded. Implants were individually tested using Periotest® (Periotest value [PTv], Siemens AG, Bensheim, UK). Sinus health was radiographically and clinically assessed according to Lund-Mackay system and Lanza and Kennedy survey recommended by Task Force on Rhinosinusitis for research outcomes. A satisfaction questionnaire (Oral Health Impact Profile for assessing health-related quality of life in Edentulous adults) and different anatomical measurements were also performed.

Results: No significant differences ($p = .602$) were observed with respect to SR between the two groups (95.12% vs 96.79%). Significant differences ($p = .000$) were found comparing measurements of ZI head distance to the alveolar crest (5.12 ± 2.38 mm vs 2.92 ± 2.30 mm). With the CZT, more palatal emergence of ZI was observed. PTv gave significantly greater stability for the CZT compared with the ZAGA group in both measurements (-4.38 ± 1.75 vs -2.49 ± 4.31, $p = .000$; -4.94 ± 1.46 vs -3.11 ± 5.06, $p = .000$). Lund-Mackay score was significantly lower for the ZAGA group (2.38 ± 3.86 vs 0.56 ± 1.26, $p = .042$). Statistically significant difference ($p = .047$) regarding the percentage of patients with no signs or symptoms of rhinosinusitis (Lanza and Kennedy test negative and Lund-Mackay score zero) was observed between groups (54.55% vs 76.25%, $p = .047$).

Conclusions: Both procedures had similar clinical outcomes with respect to implant survival. The ZAGA concept is able to immediately rehabilitate the severely atrophic maxillae, minimizing the risk of maxillary sinus-associated pathology. Moreover, less bulky, more comfortable, and easy to clean prostheses are achieved.

KEY WORDS: atrophic maxilla, immediate load, rhinosinusitis diagnosis report, zygomatic anatomy-guided approach, zygomatic implants

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INTRODUCTION

The prosthetic rehabilitation of patients with insufficient maxillary bone for placement and integration of dental implants constitutes a therapeutic challenge.[1] Many different approaches using bone grafts have been presented in the literature, and the choice of a method is dictated by the severity of the resorption and its effect on facial morphology.[2–4] Zygomatic implants (ZIs) were introduced for the prosthetic rehabilitation of patients with extensive defects of the maxilla caused by tumor resections, trauma, and congenital conditions. During the last two decades, ZIs have proven to be an effective option in the management of the atrophic edentulous maxilla, as well as for maxillectomy defects.[5] The technique has enabled sufficient rehabilitation of these patients, with restored function and improved aesthetics. Subsequently, the ZI indications have been widened to include routine cases as well.[6,7] Yet, despite the fact that ZIs have been used for more than two decades, there are no randomized controlled trials evaluating their clinical effectiveness in relation to alternative means for rehabilitating patients with atrophic edentulous maxillae.[8]

The original Brånemark protocol[9] made use of an intrasinus path for the implant body. This often resulted in a nonoptimal osteotomy from an implant stability point of view because all available bone in the area was not utilized for anchorage. Moreover, in patients with pronounced buccal concavities on the lateral aspect of the maxillary sinus, the use of an intrasinus path results in excessive angulation in the palatal emergence of the implant head. This often results in a bulky dental bridge at the palatal aspect followed by patient discomfort and complaints about difficulty with hygiene procedures. In addition, problems related to the penetration of the maxillary sinus through thin palate bone have also been reported.[10–16]

Several proposals for changes and simplifications of the original Brånemark technique have been made. The possibility of using an extrasinusal approach for the placement of ZIs has been proposed by different authors[11,15,17–22] in patients with extreme buccal concavities in the maxillary sinus areas. With this novel approach, no initial window or slot is opened at the lateral wall of the maxillary sinus. The extrasinusal technique allows placement of the implant head at or near the top of the residual crest, which results in a more normal extension of the bridge framework. The concept of zygomatic anatomy-guided approach (ZAGA) was described by Aparicio[23,24] as a refinement of the extrasinusal technique. The concept applies not only to patients with extreme buccal concavities but also to all the maxillary anatomies from the flat maxillary wall to the very concave or atrophied maxillae. The placement of the ZI is guided by an anatomically and prosthetically driven approach. This is achieved by understanding the possibility of finding not only interindividual anatomy differences but also intraindividual ones. By following specific prosthetic, biomechanical, and anatomical factors, the establishment of the intraoral entrance point depends on the vertical and horizontal resorption of the alveolar/basal process and on the anterior maxillary wall curvature. As a result, a classification for the zygomatic patient has been proposed by establishing the relationship of the zygomatic buttress/alveolar crest complex to the various anatomy-guided ZI pathways (ZAGA). The possibility[23] of placing ZIs with part or all of their body out of the maxillary sinus could result in fewer sinus complications because of the following: (i) a smaller part of the implant is inside the sinus; (ii) implants are placed more crestally, with less possibility of oroantral communication. Moreover, the understanding of the ZAGA concept would help the clinician to better use the available crestal bone allowing for the following: (i) bone integration also at the implant neck and body level in most of the ZAGA types and (ii) better soft tissue control to predictably cover the ZI in comparison with an exclusively extra-maxillary technique.

Sinusitis in patients with ZIs should be diagnosed in the same way as sinusitis in conventional patients, with some particularities. However, in dental literature, there is no consensus on how to report rhinosinusitis diagnosis. According to the ear, nose, and throat (ENT) literature,[10] two or more symptoms must be present to make the diagnosis of chronic rhinosinusitis (CRS). A definitive diagnosis of CRS requires objective confirmation of disease either by nasal endoscopy or sinus computerized tomography (CT) scanning because objective documentation of mucosal inflammation is required. Typical findings on sinus CT scans include sinus ostial narrowing or obstruction, sinus mucosal thickening or opacification, and, less commonly, air-fluid levels in the sinuses. In most of the studies, using ZIs, the term used to describe the sinus pathology is sinusitis, without clarifying the type, the associated signs and symptoms, or whether a CT scan or endoscopy was performed to confirm the diagnosis. For these reasons, it is not possible to determine sufficient useful detail of the sinusitis described.

The first aim of this study is to compare long-term outcomes (survival rate [SR], implant stability, sinus conditions, prostheses design, soft tissue sealing, etc.) in a cohort group of patients treated with the classical zygomatic technique (CZT) versus another cohort group of patients treated with the ZAGA. The second goal of this paper is to propose a standardized system to report rhinosinusitis diagnosis.

MATERIALS AND METHODS

The study was conducted in accordance with the ethical principles originated in the Declaration of Helsinki. It has been reported according to the Strengthening the Reporting of Observational Studies in Epidemiology statement (http://www.strobe-statement.org/). This clinical study was approved by an independent ethical committee (School of Medicine, University of Barcelona). All patients received thorough explanations and signed a written informed consent prior to participating in the study. An independent investigator (K.F.) fully explained the nature of the study, along with the aims, methods, potential hazards, and discomfort that participation might entail. The patient was given the opportunity to read and ask questions about the patient information leaflet prior to signing the informed consent form to enroll in the survey. The clinical part of this comparison study was conducted in a single center (Clinica Aparicio, Barcelona, Spain). For the assessment of sinus health, an independent otolaryngologist (P.C.) was enrolled in the study. Albrektsson and Isidor's[25] implant success criteria were used to evaluate the implant condition.

Patient Selection

Twenty-two consecutive patients with severely atrophic edentulous maxillae restored with zygomatic and regular implants (RIs) following the CZT, who participated in a previous study,[26] with at least 10 years of follow-up, were included in the study as control group. A cohort group of 80 consecutive patients treated with implants according to the ZAGA surgical and prosthetic principles and undergoing a periodic maintenance program were included in the study as the test group. The surgery period was January 2004 to October 2009, with a mean follow-up of 4.62 years. All patients included in the test group had at least 3 years of prosthetic follow-up and we were able to compare a presurgical to a final CT.

All patients were contacted for a final radiological and clinical evaluation and were invited to answer two specific questionnaires to assess implant and sinus health status and their degree of satisfaction regarding the treatment received. The methodology used to evaluate the results was the same as the one used in a retrospective study to evaluate the 10-year follow-up of the original technique.[26]

The following *inclusion criteria* were applied:

- Age ≥ 18 years.
- Absence of relevant medical conditions contraindicating surgical interventions.
- A residual alveolar crest less than 4 mm in width and height, immediately distal to the canine eminence.
- Enough residual alveolar crest to place 7-mm-long implants on the anterior maxillae was required for CZT. The latter was not a ZAGA inclusion criterion because in cases where this amount of residual bone was not present, four ZIs were placed instead.
- In the case of partial edentulism, the possibility of establishing a tripodization by placing a minimum of three implants per quadrant (one zygomatic plus two regulars) was required.
- Willingness to enroll in a regular maintenance program.

Patients were *excluded* on the basis of the following:

- Erratic compliance with the maintenance program.

The classification of patients in the two groups was carried out on the basis of the ZI surgical technique: ZCT versus ZAGA principles.

Implant Placement

A total of eight hundred fifty-seven titanium implants were placed by a single surgeon (C.A.) in the maxillary bone. Six hundred sixty were RIs with lengths from 7 to 18 mm and diameters from 3.3 to 4 mm. A total of one hundred ninety-seven ZIs, machined surface (Nobel Biocare AB, Göteborg, Sweden), with lengths from 30 to 50 mm were positioned.

- Classical approach (November 1998–June 2002): one hundred thirty-one RIs (Nobel Biocare AB) were placed, 94 had machined titanium surface, and 37 belonged to mkIII TiUnite surface type. Fifty-five of the RIs were anchored in the residual bone at the canine areas, 42 were intentionally anchored in the subnasal crest penetrating the nasal cavity, after raising the nasal floor, and five were placed in the anterior nasal spine. Twenty-nine RIs were placed in the pterygoid process of the sphenoid bone and the pyramidal process of the palatine bone. All 41 ZIs were placed according to the original technique, described elsewhere,[9,27] in the zygomatic bone following an intrasinusal path that was controlled with the help of a maxillary *window*. All the ZIs, except for two, achieved good primary stability at insertion time. A two-stage procedure with 5 to 6 months of healing between placement and abutment connection was used. One week after surgery, sutures were removed and patients were controlled monthly in follow-up appointments both to assess the soft tissue health and to adjust the provisional prosthesis. Twenty to 27 weeks later, healing abutments were screwed in Nobel Biocare AB in a second-stage surgery and, after soft tissue healing, the healing abutments were substituted for standard abutments (Nobel Biocare AB).
- Transition period (August 2002–December 2003): this period was considered a transition between the two techniques. Patients that underwent surgery in this transitional period are not included in this study.
- ZAGA (January 2004–October 2009): a total of five hundred twenty-nine RIs were placed, five hundred five were TiUnite surface (Nobel Biocare AB), and 24 were Full Osseotite® surface (3·I Biomed, Barcelona, Spain). One hundred ninety-two RIs were anchored in the anterior alveolar crest and one hundred one in the pterygoid process of the sphenoid bone and the pyramidal process of the palatine bone. A total of one hundred fifty-seven ZIs were placed according to the modified surgical protocol described in 2008 in which ZIs were placed with an anatomy-guided approach.[17] According to the anatomy of buccal concavity of maxilla and the ZI pathway, patients were divided into five categories[23] (Figures 1–5): 17% of patients were recorded as ZAGA type 0 (Figure 1), 52% were ZAGA type 1 (Figure 2), 21% were ZAGA type 2 (Figure 3), 7% were ZAGA type 3 (Figure 4), and finally, 3% of patients were identified as ZAGA type 4 (Figure 5). A one-stage procedure with abutment connection and a provisional prosthesis installation at 24 hours after surgery was used. The immediate loading technique applied in this report was described by different authors.[17,28–33] One week after surgery, sutures were removed, and patients were controlled monthly in follow-up appointments to assess the soft tissue health and to check the provisional prosthesis.

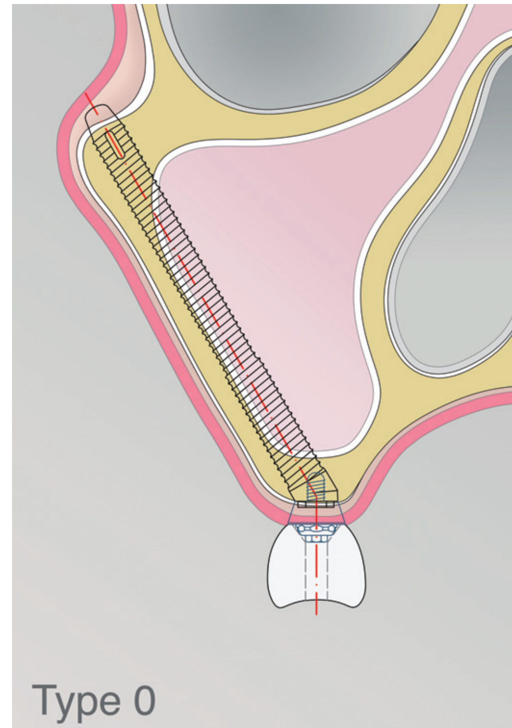

Figure 1 Zygomatic anatomy-guided approach type 0. The anterior maxillary wall is very flat. The implant head is located on the alveolar crest. The implant body has an intrasinus path. The implant comes in contact with bone at the alveolar crest and zygomatic bone and sometimes at the internal side of the sinus wall.

Prosthesis Rehabilitation

The one hundred two implant-fixed bridges of both groups, anchored on one hundred ninety-seven zygomatic and six hundred sixty standard implants, were completed approximately 12 to 16 weeks after surgery. Ninety-five bridges were screw-retained (Figure 6, A and B) and seven were cemented. One of the patients received a partial prosthesis. Regarding denture

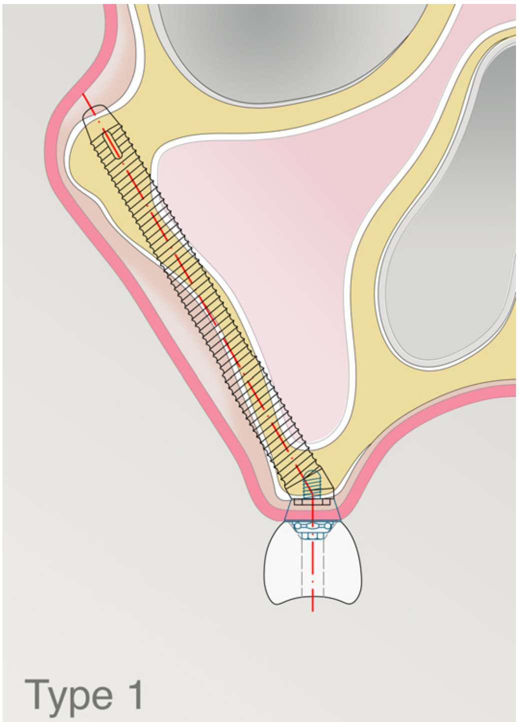

Figure 2 Zygomatic anatomy-guided approach type 1. The anterior maxillary wall is slightly concave. The implant head is located on the alveolar crest. The drill has performed the osteotomy slightly through the wall. Most of the implant body has an intrasinus path. The implant comes in contact with bone at the alveolar crest, lateral sinus wall, and zygomatic bone.

TABLE 1 Task Force on Rhinosinusitis Criteria for the Diagnosis of Rhinosinusitis. From Lanza and Kennedy[35]

Major Criteria	Minor Criteria
Facial pain or pressure	Headache
Facial congestion or fullness	Fever (all nonacute)
Nasal obstruction	Halitosis
Purulent discharge	Fatigue
Hyposmia or anosmia	Dental pain
Purulence on examination	Cough
Fever (acute only)	Otalgia or aural fullness
Diagnosis on rhinosinusitis requires: – two or more major criteria – one major and two or more minor criteria – purulence on nasal examination	

material, 76 dental prostheses were metal-resin full-arch design and 26 were metal-porcelain bridges.

Clinical Examination

For the subjects who experienced implant loss, data related to the causes and the timing of explantation were collected.

Periotest (PT) Measurements. Implant stability was measured individually using the Periotest® device (Siemens AG, Bensheim, UK) according to Olive and Aparicio.[34] Measurements were made on the day of bridge delivery and annually thereafter. Patients who were not wearing a screw-retained prosthesis were excluded. The aim of the measurements was to compare the PT values obtained before prosthesis placement and the stability of the same implants after definitive prosthesis delivery throughout the follow-up period.

Sinus Symptomatology (Questionnaire for Research Outcomes). A patient questionnaire (Table 1) to identify the presence of sinusitis symptoms, as specified by the Task

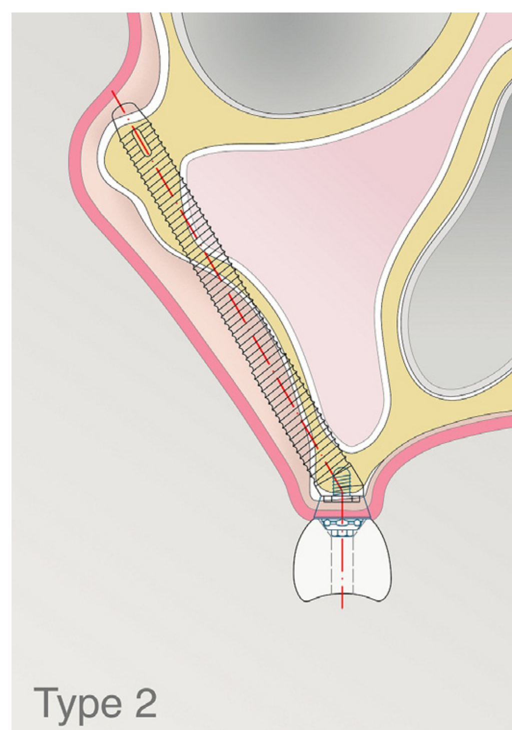

Figure 3 Zygomatic anatomy-guided approach type 2. The anterior maxillary wall is concave. The implant head is located on the alveolar crest. The drill has performed the osteotomy through the wall. The implant can be seen through the wall and most of the body has an extrasinus path. The implant comes in contact with bone at the alveolar crest, lateral sinus wall, and zygomatic bone.

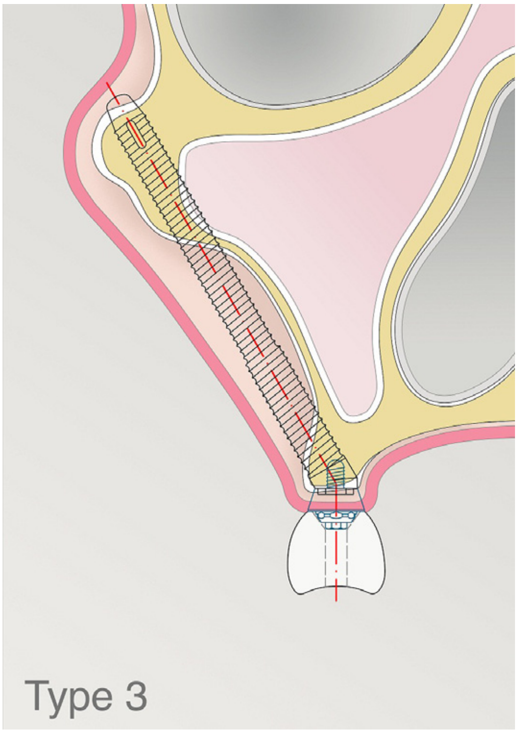

Figure 4 Zygomatic anatomy-guided approach type 3. The anterior maxillary wall is very concave. The implant head is located on the alveolar crest. Most of the implant body has an anterior extrasinus path. The middle part of the implant body is not touching the most concave part of the wall. The implant contacts bone in the coronal alveolar and apical zygomatic bone.

Force on Rhinosinusitis (TFR) diagnostic criteria,[35,36] was given to each patient at the final examination. Each symptom question is answered by "yes" or "no." Diagnosis of sinusitis requires a "yes" answer in two or more major criteria, one major and two or more minor criteria, or purulence on nasal examination.

Radiographic Examination

Lund-Mackay (L-M) Score. Each Cone Beam Computerized Tomography (CBCT) scan was scored by an independent otolaryngological researcher (P.C.) using the L-M staging system, a validated scoring system recommended by the TFR for research outcomes[37–39] (Table 2 and Figure 7). The test includes six regions: anterior ethmoid, posterior ethmoid, maxillary, frontal, sphenoid, and ostiomeatal complex. Each region is given a score of 0, 1, or 2, 0 representing normality no opacification, 1 partial opacification, and 2 total opacification. Osteomeatal complex can only be scored 0 or 2. Total scores range from 0 to 24. For purposes of this study, a normal or "negative" scan was defined as any scan with a L-M score of 0. Any scan with a score >0 was considered an abnormal or "positive" scan.

Anatomical Measurements. CBCT scans (Kodak 9500 Cone Beam 3D System, Rochester, NY, USA) were performed on the one hundred two patients and analyzed by two independent researchers: an otorhinolaryngologist (P.C.) and a fellow clinical researcher (K.F.). Images in the coronal and horizontal axial planes were obtained for each of the ZIs studied. Special emphasis was devoted to assessing and storing the status of both right and left osteomeatal complex permeability and on the axial plane to be able to relate the ZI head position to the bone crest on each side (Figure 8, A and B). Four anatomical measurements (numbered 1–4 in Table 3) were performed to assess the following: (i) the height of the alveolar ridge at the location of the head of the ZI (measurement 2 minus 1) and (ii) the position of the head of the ZI with regard to the center of the crest of the alveolar ridge in the horizontal axial dimension (measurement 4 minus 3). A positive value on this implant head position to the alveolar ridge relationship indicates a palatal position of the implant, whereas a negative value indicates a buccal emergency.

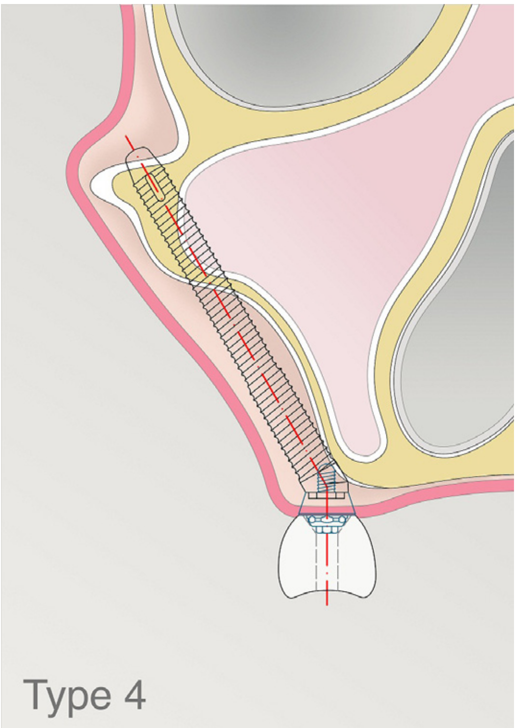

Figure 5 Zygomatic anatomy-guided approach type 4. The maxilla and the alveolar bone show extreme vertical and horizontal atrophy. The implant head is located buccally of the alveolar crest. There is no or minimal osteotomy at this level. The drill has arrived at the apical zygomatic entrance following a path outside the sinus wall. The implant contacts bone in the zygomatic bone and part of the lateral sinus wall.

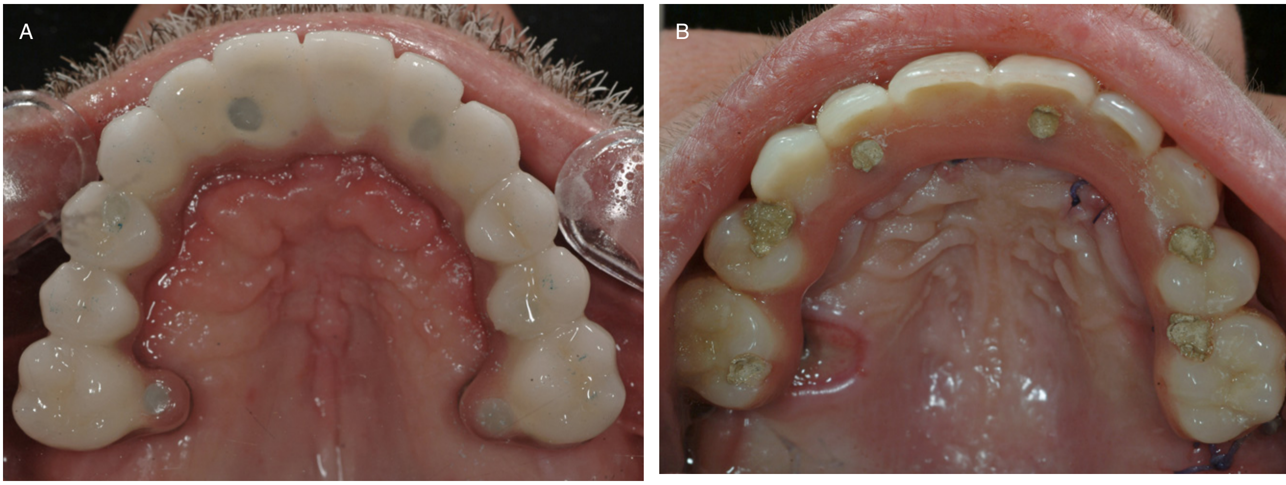

Figure 6 *A*, Occlusal view of a screw-retained bridge on four regular and two zygomatic implants according to the original intrasinusal protocol. Note the palatal emergence of the zygomatic implants. *B*, Occlusal view of a screw-retained provisional bridge on four regular and two zygomatic implants according to the zygomatic anatomy-guided approach protocol, 1 week after implant placement. Notice the emergence of the zygomatic implants closer to the crest.

Satisfaction Questionnaire

The satisfaction level and the masticatory capacity were evaluated by means of the Oral Health Impact Profile for assessing health-related quality of life in Edentulous adults (OHIP-EDENT).[40] Patients answered questions regarding their ability or lack of ability to comminute hard and soft foods relating it to the discomfort and instability of the dentures, their perception of satisfaction in relation to the aesthetics, pleasure when eating, level of comfort, and self-assurance. Patients answered nine questions about their dentures, the answer scale ranging from 0 to 4[40,41] (Table 4). The highest scores represent the worst satisfaction levels and the lowest scores represent the best satisfaction levels. The maximum score is 36. Results were translated into percentage values of satisfaction, 0% representing worst possible satisfaction level and 100% representing best possible satisfaction level.

TABLE 2 Lund-Mackay[37] Staging Worksheet. Each Region Is Scored 0, 1, or 2, 0 Representing No Abnormality, 1 Partial Opacification, and 2 Total Opacification. OM Complex Can Only Be Scored 0 or 2. The Minimum Possible Score Is 0 (Negative CT), and the Maximum Score Is 24

		No Abnormality	Partial Opacification	Total Opacification
Anterior ethmoid	R	0	1	2
	L	0	1	2
Posterior ethmoid	R	0	1	2
	L	0	1	2
Maxillary	R	0	1	2
	L	0	1	2
Frontal	R	0	1	2
	L	0	1	2
Sphenoid	R	0	1	2
	L	0	1	2
		Not obstructed	Obstructed	
Ostiomeatal complex	R	0	2	
	L	0	2	
Total score			___	

CT = computerized tomography; L = left; OM = ostiomeatal; R = right.

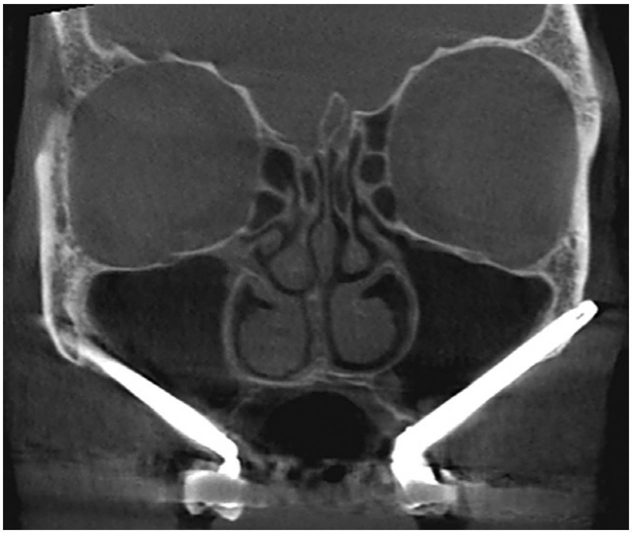

Figure 7 Example of a positive Lund-Mackay score. Coronal cuts like this were employed to assess the different anatomical measurements and the Lund-Mackay score. Observe the differences on the permeability of the left and right osteomeatal complex.

Data Analysis

The heterogeneity between the two groups with respect to gender, smoking, and rhinosinusitis criteria was assessed using the Mann-Whitney test. A p-value <.05 was considered to indicate a statistically significant difference.

The SR was calculated and compared between the different groups using the Kaplan-Meier analysis.

The intergroup comparison of age, horizontal and vertical CBCT measurements, L-M score, and PT values was performed using the unpaired t-test. A p-value <.05 was considered to indicate a statistically significant difference.

The data analysis was performed using a commercially available statistical software package. All statistical analyses were performed using SPSS 13.0 software (SPSS Inc., Chicago, IL, USA).

RESULTS

At the time of implant placement, no statistical differences ($p > .05$) were identified between groups with respect to gender and smoking. However, statistically significant differences ($p = .001$) were found with respect to age (53.81 ± 10.97 years vs 63.10 ± 9.00 years) (Table 5).

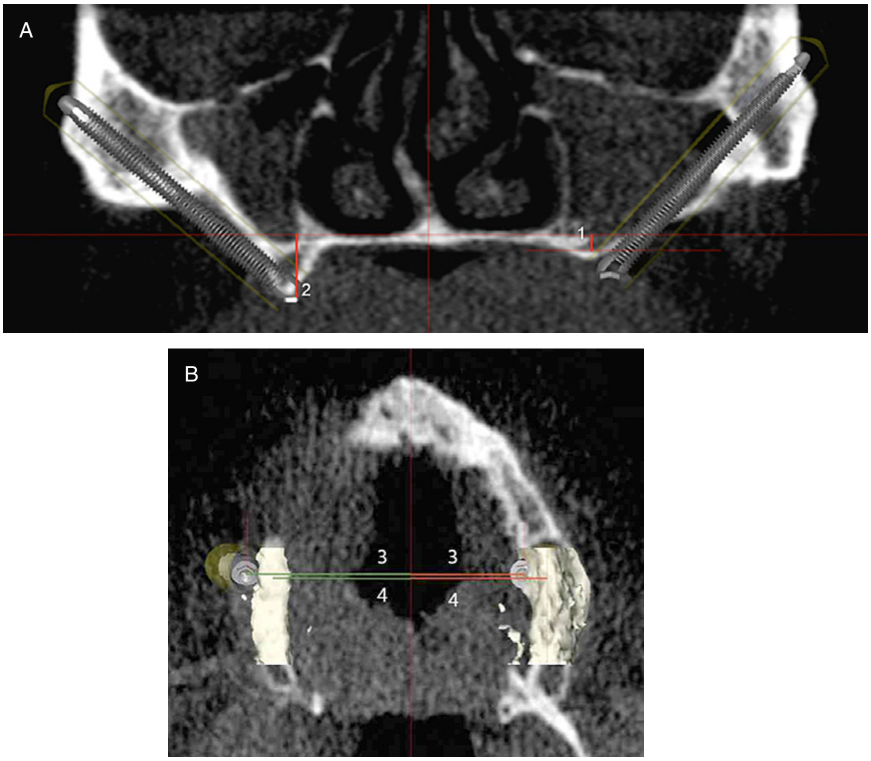

Figure 8 *A*, In this figure, the anatomical measurements performed on each patient computerized tomography scan are graphically represented. The number 1 value represents the distance between the tangent to the floor of the nose and sinus floor at the entrance of the zygoma implant. Number 2 represents the distance between the tangent to the floor of the nose and the crest of the alveolar ridge at the entrance of the zygoma implant. *B*, Number 3 represents the distance between the midline of the palate and the center of the zygoma implant head. Number 4 represents the distance between the midline of the palate and the center of the alveolar ridge.

TABLE 3 CBCT Anatomical Measurements Worksheet for Right and Left Zygomatic Implants

Measurements	Right Z (mm)	Left Z (mm)
1. Perpendicular distance between the tangent to the floor of the nose and sinus floor at the entrance of the zygoma implant level.		
2. Perpendicular distance between the tangent to the floor of the nose and the crest of the alveolar ridge at the entrance of the zygoma implant level.		
3. Distance between the midline of the palate and the center of the zygoma implant head.		
4. Distance between the midline of the palate and the center of the alveolar ridge.		

CBCT = Cone Beam Computerized Tomography.

With the classical technique, three implants, mechanized surface, failed. Two failed between implant installation and prosthesis placement; one after 3 years of function. No failures of RIs were observed on the ZAGA group. Although none of the ZIs were removed because of disosseointegration, during the follow-up period, seven ZIs were considered failures, yielding a total SR of 96.95%. No early failures were observed. In the classical technique group, two ZIs were cut 10 years after placement through the surgical maxillary window and partially removed (both in the same patient, a heavy smoker) due to extreme peri-implant infection with complete dissolution of the palatal bone. In the ZAGA group, one ZI fractured, and four zygoma implants (in the same patient) had clear clinical mobility at the crestal portion of the implant. The final SR for ZIs on control and test groups was 95.12% and 97.44%, respectively. However, no statistically significant differences ($p = .602$) were observed between the SRs of the two groups (Tables 6 and 7).

TABLE 4 Satisfaction Level Questionaire.[40,41] Nine Questions in a Scale Ranging from 0 to 4, 0 Representing Total Satisfaction and 4 Total Dissatisfaction. The Maximum Score Is 36 and the Minimum Is 0, This Representing the Best Satisfaction Level and Masticatory Ability

1	How do you feel about the pleasure you get from food, compared with the time when you had natural teeth?	0	1	2	3	4
2	With respect to chewing, how satisfied are you with your dentures?					
3	With respect to appearance, how satisfied are you with your dentures?					
4	With respect to how comfortable your dentures are, how satisfied are you?					
5	With respect to being self-assured and self-conscious, how satisfied are you with your denture?					
6	With respect to your social and affective relationship, how satisfied are you with your oral conditions?					
7	With respect to your professional performance, how satisfied are you with your oral conditions?					
8	With respect to eating, how satisfied are you with your dentures?					
9	Are you satisfied with your smile (aesthetics)?					

TABLE 5 Patient Population

	Classic Procedure	ZAGA	Significance
Number of patients	22	80	
Number of total ZI	41	156	
Follow-up (years)	11.27 ± 1.07	4.62 ± 1.63	
Mean age ± SD (years)	53.81 ± 10.97	63.10 ± 9.00	$\boldsymbol{p = .001}$*
Gender	8(M); 14(F)	25(M); 55 (F)	$p = .651^{\dagger}$
Smokers	22.73%	30.00%	$p = .505^{\dagger}$

Mean ± SD.
*Unpaired *t*-test, $p < .05$.
†Mann-Whitney *U*-test.
F = female; M = male; SD = standard deviation; ZAGA = zygomatic anatomy-guided approach; ZI = zygomatic implant.

TABLE 6 Life Table for Zygomatic Implants on the Control Group ($n = 41$)

Follow-Up (Years)	Number of Implants	Failures	Survival Rate	Cumulative Survival Rate
0-Prosthesis placement	41	0	100	100
Prosthesis placement-1	41	0	100	100
1–2	41	0	100	100
2–3	41	0	100	100
3–4	41	0	100	100
4–5	41	0	100	100
5–6	41	0	100	100
6–7	41	0	100	100
7–8	41	0	100	100
8–9	41	0	100	100
9–10	41	2	95.12%	95.12%

Anatomical measurements, performed on the CBCT scans, showed a mean alveolar ridge at the entrance of the ZI of 2.44 ± 1.00 mm for the classic group and 2.31 ± 1.24 mm for the ZAGA group. No statistically significant differences were found. However, statistically significant differences ($p = .000$) were found between groups on comparing measurements of ZI head rising horizontally to the center of the alveolar crest (5.12 ± 2.38 mm vs 2.92 ± 2.30 mm). With the classic technique, a more palatal emergence of ZI to the centre of the ridge was observed (Table 8).

Tables 9 and 10 summarize the outcomes related to sinus health. The L-M score was statistically significantly lower for the ZAGA group (2.36 ± 3.86 vs 0.56 ± 1.26, $p = .042$). Similarly, a statistically significant difference ($p = .047$) regarding the percentage of patients with no radiological signs or clinical symptoms of rhinosinusitis (L-M score zero and Lanza and Kennedy test negative) was observed between groups (54.55% vs 76.25%, $p = .047$). No statistically significant differences were observed for the other three categories of sinusitis reaction between groups.

No statistically significant differences were found between ZI PT values in the same group at the time of definitive prosthetic delivery and at last control (−4.38 ± 1.75 vs −4.94 ± 1.46, $p = .133$ and −2.49 ± 4.31 vs −3.11 ± 5.06, $p = .270$, respectively). Moreover, PT value yielded a statically significantly greater stability for the classic procedure group compared with the ZAGA group in both measurements (−4.38 ± 1.75 vs −2.49 ± 4.31, $p = .000$ and −4.94 ± 1.46 vs −3.11 ± 5.06, $p = .000$) (Table 11).

TABLE 7 Life Table for Zygomatic Implants of the ZAGA Group ($n = 157$)

Follow-Up (Years)	Number of Implants	Failures	Survival Rate	Cumulative Survival Rate
0-Prosthesis placement	157	0	100	100
Prosthesis placement-1	157	0	100	100
1–2	157	0	100	100
2–3	147	0	100	100
3–4	129	0	100	100
4–5	96	4	95.83	97.45
5–6	62	1	98.39	96.82
6–7	38	0	100	96.82
7–8	10	0	100	96.82

ZAGA = zygomatic anatomy-guided approach.

TABLE 8 Measurements

	Classic Procedure	ZAGA	Significance*
Vertical (4–3)	2.44 ± 1.00	2.31 ± 1.24	p = .519
Horizontal (10–9)	5.12 ± 2.38	2.92 ± 2.30	**p = .000**

Mean ± standard deviation.
*Unpaired t-test, $p < .05$.
ZAGA = zygomatic anatomy-guided approach.

TABLE 9 Lund-Mackay (L-M) Score

	Classic Procedure	ZAGA	Significance*
L-M	2.36 ± 3.86	0.56 ± 1.26	**p = .042**

Mean ± standard deviation.
*Unpaired t-test, $p < .05$.
ZAGA = zygomatic anatomy-guided approach.

Few mechanical and biological problems were observed during the follow-up period. Some of these problems were the following: loosening and fracture of prosthetic ZI screws, loosening of the abutments, fracture of ceramic prosthetic teeth, and fracture of resin prostheses. Records of these prosthetic complications and other biological complications are collected on Tables 12 and 13.

Finally, regarding satisfaction level, no statistically significant differences were identified between the two cohorts of study (Table 14).

DISCUSSION

The rationale of the ZAGA concept is to adapt the surgical technique to the patient, not the opposite. The concept may be applied in all maxillary wall shapes ranging from those with a flat sinus wall to the concave, very concave, or atrophied maxillae. The placement of the long implant following the ZAGA principles optimizes the bone support even at the level of the maxillary wall, which is critical in a patient suffering from extreme bone atrophy. The implant itself is sealing the wall osteotomy, which minimizes the risk of sinus contamination. Moreover, the clinician will be better able to use the available crestal bone, allowing also for bone

TABLE 10 Rhinosinusitis Diagnosis

	Classic Procedure	ZAGA	Significance*
Lanza and Kennedy test (+) Lund-Mackay score > 0	9.09%	3.75%	p = .307
Lanza and Kennedy test (+) Lund-Mackay score = 0	0%	1.25%	p = .600
Lanza and Kennedy test (–) Lund-Mackay score > 0	36.36%	18.75%	p = .081
Lanza and Kennedy test (–) Lund-Mackay score = 0	54.55%	76.25%	**p = .047**

Percentage of patients per group.
*Mann-Whitney U-test.
ZAGA = zygomatic anatomy-guided approach.

TABLE 11 PT Values

	Classic Procedure	ZAGA	Significance*
Pre	−4.38 ± 1.75	−2.49 ± 4.31	**p = .000**
Post	−4.94 ± 1.46	−3.11 ± 5.06	**p = .000**
Significance*	p = .133	p = .270	

.Mean and standard deviation.
*Unpaired t-test, $p < .05$.
Post = at last maintenance visit; Pre = before definitive prosthesis delivery; PT = Periotest; ZAGA = zygomatic anatomy-guided approach.

TABLE 12 Number of Complications during the 10-Year Follow-Up Period of the Classical Procedure. Failures of Implants Are Not Included. Ninety Percent of Biological Late Complications Belong to Two Patients and 74% of Prosthetic Complications Occurred in Five Patients

	Follow-Up (Years)	0-Prosthesis Placement	Prosthesis Placement-1	1–2	2–3	3–4	4–5	5–6	6–7	7–8	8–9	9–10	10–11	Total
Biological	Facial hematoma/edema	6												**6**
	Lip laceration	5												**5**
	Cheek and/or paranasal paresthesia (temporary)	6												**6**
	Suppuration of regular implant												1	**1**
	Acute/chronic sinusitis		1	1	1					1	1		1	**6**
	Orosinusal communication (per implant)								1				2	**3**
Mechanical	Fracture coating material: acrylic							1			1	1	1	**4**
	Fracture coating material: porcelain			2	1	2	1	3	6	4	1	2	3	**25**
	Fracture of metal framework					1			1					**2**
	Fracture screws					1		1			1	1	2	**6**
	Loosening of screws or abutment		1	1	2		1	2		2				**9**

TABLE 13 Number of Complications during the Follow-Up Period of the ZAGA Group. Failures of Implants Are Not Included

	Follow-Up (Years)	0-Prosthesis Placement	Prosthesis Placement-1	1–2	2–3	3–4	4–5	5–6	6–7	7–8	8–9	9–10	10–11	Total
Biological	Facial hematoma/edema	1	0	0	0	0	0	0	0	0	0	0	0	**1**
	Lip laceration	0	0	0	0	0	0	0	0	0	0	0	0	**0**
	Cheek and/or paranasal paresthesia (temporary)	1	0	0	0	0	0	0	0	0	0	0	0	**0**
	Suppuration of regular implant	2	0	2	1	0	0	0	0	0	0	0	0	**5**
	Acute/chronic sinusitis	0	0	1	0	2	0	0	0	0	0	0	**0**	3
	Orosinusal communication (per implant)	2	0	0	0	0	0	0	0	0	0	0	0	**2**
Mechanical	Fracture coating material: acrylic	1	5	7	21	11	11	12	1	2	0	0	0	**65**
	Fracture coating material: porcelain	0	0	0	1	1	0	0	0	0	0	0	0	**2**
	Fracture of metal framework	0	0	0	0	0	0	0	0	0	0	0	0	**0**
	Fracture screws	0	0	1	2	2	1	1	0	0	0	0	0	**7**
	Loosening of screws or abutment	0	5	5	5	1	1	0	1	0	0	0	0	**16**

ZAGA = zygomatic anatomy-guided approach.

TABLE 14 Satisfaction Level

	Classic Procedure	ZAGA	Significance*
Satisfaction 0–20% (min)	0%	2.50%	$p = .456$
Satisfaction 21–40%	4.55%	2.50%	$p = .617$
Satisfaction 41–60%	4.55%	6.25%	$p = .765$
Satisfaction 61–80%	13.63%	12.50%	$p = .888$
Satisfaction 81–100% (max)	77.27%	76.25%	$p = .921$

Percentage of patients per group.
*Mann-Whitney *U*-test.
ZAGA = zygomatic anatomy-guided approach.

integration at the implant body and neck level in most of the ZAGA types. As a result, implants are placed more crestally, with less possibility of oroantral communication. As well, the understanding of the ZAGA concept helps to better soft tissue control to predictably cover the ZI in comparison with an exclusively extra-maxillary technique.

In the last decade, a large number of publications have focused on ZI success and long-term survival to demonstrate that the procedure is a predictable solution for rehabilitation of atrophic maxilla. The outcomes of the present retrospective study showed that ZI's SR in both groups is in agreement with data from previous reports,[9,12,14–16,18–20,26,29–34,42–53] independent of the technique used. It seems that a low percentage of patients with ZIs will develop rhinosinusitis. Interestingly, the rate is not very different from the sinusitis rate in the general population or the sinusitis rate associated with sinus grafts.[10] Only few authors[12–14,54] have reported on biological and mechanical complications, the most common being the sinus infection. The relationship between the implant and the maxillary sinus structures remains controversial: zygoma implants could potentially cause inflammatory problems or infections at the level of the maxillary antrum. Oroantral communication is not necessarily related to an infectious process because often soft tissue is able to seal the interface around the implant head. Nevertheless, there is little evidence-based data concerning the relationship of the zygoma implants and the sinus cavity. Few studies have analyzed sinus reactions to zygoma implants.[10]

Currently, there is no consensus on how to report rhinosinus status. Usually, there is no systematic evaluation of the status of the sinus after placement of ZIs, either clinically or radiologically. There are few clinical studies evaluating the evolution of sinus reactions and sinus health from the clinical and/or radiological perspective after placement of ZIs. Plain radiographs are not useful for study of the sinus cavity or ostiomeatal complex, and CT scans are not routinely obtained. As yet there are only three published studies, performed by Nakai and colleagues,[55] Davó and colleagues,[56] and Aparicio and colleagues[26] using a CT scan after ZI placement.

The diagnosis and treatment (by ENT departments) must follow the current recommendations for the treatment of rhinosinusitis in conventional patients. Because there is no consensus in the reporting of the diagnosis of a sinusal pathology associated with the placement of ZIs, the authors of this study are proposing the use of the clinical and radiological scores recommended by the TFR as a standardized system to report on the diagnosis of rhinosinusitis associate with implant placement.

The results of this study, based on the TFR recommendations, indicate fewer sinusal adverse reactions to the treatment by following the ZAGA principles. Indeed, the L-M score was statistically significantly lower for the ZAGA group ($p = .042$) when compared with the group treated with the original technique. Similarly, a statistically significant difference ($p = .047$) regarding the percentage of patients with no signs or symptoms of rhinosinusitis (Lanza and Kennedy test negative and L-M score zero) was observed between groups representing a clear improvement in the overall result.

Because of time differences in which each technique was developed, the mean follow-up for the two groups was different: 11.27 ± 1.07 years for the classical ZI technique and 4.62 ± 1.63 years for the ZAGA. This could be a limitation of the present study. So may the lack of data regarding presurgical L-M score (CTBC) and sinus symptomatology of the classic approach group. Due to justified time-related reasons, it was not possible to compare intragroup (before and after ZI placement) and intergroup (presurgical data, classical vs modified technique) sinus health.

Some authors[9,15,16,18–20,30–34,44–46,48–53,57,58] have pointed out variations on the incidence of sinusitis being related to different factors such as implant design (the internal thread of the abutment chamber is communicated to the external surface, allowing an eventual pass of bacteria vs a closed design) and the type of implant surface used (rough vs machined). However, there are no data validating those findings individually as influencing in the development of sinusal complications. Another factor that has been claimed as important in decreasing the incidence of sinusal disease is the time of implant connection/loading (immediate vs delayed). From the available data,[10] sinusitis rates for the classic two-stage protocol are approximately 6.6%; for immediate function protocols, this is approximately 2.8%, and if both protocols are considered together, the rate is approximately 5.5%. However, the new surgical approaches, with less of the implant in the sinus and the placement of the implant head more crestally, also include the immediate loading of the implants as a part of the protocol. This may create confusion regarding the specific importance of a single factor, that is, surgical technique versus the load moment.

The main drawback of the original zygoma implant technique when using an intrasinus approach is the palatal emergence of the implant head, which is often the case because of the desire to maintain the implant body within the boundaries of the maxillary sinus. This commonly results in a bulky dental, fixed denture at the palatal aspect. When using the original surgical protocol, authors have reported on speech alterations and problems in maintaining correct hygiene of the dental prostheses, largely because of the palatine emergence of the head of the zygoma implant.[15,55,59,60] The use of the modified ZAGA allowed a substantial reduction in the mean distance from the zygoma implant to the central part of the residual crest: from 5.12 mm (SD 2.38) with the original technique to a mean value of 2.92 mm (SD 2.30) with ZAGA. The more favorable emergence position obtained by following the ZAGA principles can minimize these complications.

CONCLUSIONS

Within the limits of this study, the outcomes demonstrated that both procedures – the classical and the ZAGA – were found with similar positive clinical outcome with respect to implant survival. The ZAGA concept is able to immediately rehabilitate the severely atrophic maxillae, minimizing the risk of maxillary sinus-associated pathology in comparison with the classical ZI surgical technique. Moreover, less bulky, more comfortable, and easy to clean prostheses are achieved.

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