

Evaluation of satisfaction of individuals rehabilitated with zygomatic implants as regards anesthetic and sedative procedure: A prospective cohort study



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HIGHLIGHTS

- Wilcoxon test revealed that the emotional condition of the individuals differed at the beginning and end of treatment.
- General satisfaction with treatment was high.
- From the emotional point of view of the individuals there was emotional improvement thus improving the quality of life.

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ABSTRACT

Purpose: To evaluate the satisfaction of individuals with atrophic maxilla, rehabilitated with fixed dental prostheses, anchored on zygomatic implants, with variables being the anesthetic procedure: general anesthesia, or local with sedation.

Materials and Methods: By means of the clinical record charts from the Training Course in Advanced Hospital Surgeries for Implant Dentists conducted at the Campinas-SP unit of the São Leopoldo Mandic School of Dentistry, 30 individuals were randomly selected. They had zygomatic implant placement surgeries performed, and were rehabilitated with fixed implant supported complete dentures, between the years 2005 and 2011. One group of 15 individuals underwent surgery in hospital, under general anesthesia. The other 15 were treated in the post-graduation clinic at the School of Dentistry, under local anesthesia and sedation.

Results: From the emotional point of view, the Wilcoxon test revealed that irrespective of the anesthesia procedure used, at the beginning of treatment, the emotional condition of individuals differed from that verified after conclusion of the treatment ($p < 0.0001$).

Conclusion: There was no difference between the two groups as regards the anesthetic procedure. General satisfaction was high; there was emotional improvement after conclusion of the treatment, thus improving the quality of life.

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1. Introduction

Rehabilitating individuals with atrophic maxilla has always been and still is a challenging treatment. Dental surgeons are always concerned about the rehabilitation of these individuals, and over the course of several years, new surgical techniques and dental prostheses have been developed. At present there is a large variety

of options for rehabilitating maxillary edentulism. There are patients who wish to have fixed dental prostheses supported by osseointegrated implants. Thus, depending on the degree of superior maxillary atrophy, we may resort to different types of treatments, such as bone grafts, inclined and zygomatic implants.

Frequently, the alveolar ridge resorption is so extensive, that it is not possible to place conventional implants in the posterior region of the maxilla. In these cases, zygomatic implants may be used, either associated with conventional implants in the anterior area, or not [1]. Initially, zygomatic implants were introduced by professor Branemark [2]. The surgical procedure was performed in hospital, under general anesthesia, with nasal intubation. Local

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anesthesia was injected into the maxillary regions and palate. At present, surgery may also be performed in the outpatients' clinic, with local anesthesia [3] and intravenous [3] or oral sedation. When searching the literature, there are innumerable studies showing the success of therapy with zygomatic [4] implants, however, few studies refer to the satisfaction of individuals [5–7].

The purpose of this research was to evaluate the satisfaction of individuals with regard to the surgical procedure, and in this context, observe the benefits of surgery performed under general or local anesthesia with intravenous or oral sedation. Thus broader knowledge about these subjects would be acquired, to know which procedures were most recommended by both professionals and individuals, for use in future treatments.

2. Materials and Methods

After approval by the Research Ethics Committee (REC) of the São Leopoldo Mandic Dental School, protocol number 2011/0431, this prospective cohort study was conducted with a sample established by convenience. This was composed of 46 clinical record charts of the Department of Dental Surgery, São Leopoldo Mandic Institute and Dental Research Center, of individuals who underwent zygomatic implant placement surgeries. These patients were rehabilitated with fixed implant supported screw-retained dental prostheses (hybrid type), in the years between 2005 and 2011, in the Training Course in Advanced Hospital Surgeries for Implant Dentists conducted at the Campinas-SP unit of the São Leopoldo Mandic School of Dentistry, at the unit in Campinas-SP, Brazil. Of the 46 clinical record charts selected, only 32 individuals were localized after sending letters, e-mails and making telephone calls. Of these individuals, 17 were submitted to surgery in hospital, under general anesthesia, and are here denominated Group 1. The others (fifteen) had surgeries performed at the dental school, in the post-graduate clinic, with local anesthesia and intravenous or oral sedation (Group 2). During surgical planning, the individuals were presented with three options: general anesthesia (performed in hospital); local anesthesia with intravenous sedation (performed in the dental school outpatient clinic); and local anesthesia with oral sedation (also performed in the dental school outpatient clinic). The decision was subject to the complexity of the surgeries (time) and dental surgeon's experience. Seventeen (17) individuals preferred to have the procedure performed in hospital under general anesthesia, when informed that the estimated time of the surgery would be 4 h. Twelve (12) individuals preferred to have the surgery performed at the dental school with local anesthesia and intravenous sedation, under the supervision of an anesthetist doctor; and only 3 individuals underwent the procedure with local anesthesia and oral sedation, when they were informed that the surgical time would be under 1.5 h, and that the surgery would be performed by highly experienced surgeons.

The 32 individual located were contacted by telephone and/or e-mail, to present to the São Leopoldo Mandic dental school, on an appointed day and time, to undergo clinical evaluation. All the individuals of Group 1 had surgeries performed in hospital under general anesthesia. In this group, local infiltrative anesthesia was also administered to contain bleeding in the trans-operative period. In Group 2, 12 individual were submitted to local anesthesia and intravenous sedation (Diazepam 10 mg/Midazolam 10 mg), monitored by an anesthetist doctor, and three received local anesthesia and orally administered sedation (1 tablet of Midazolam 15/mg, 30 min before surgery). In clinical practice, in a surgical time of under 1.5 h, sedation with Midazolam 15 mg has the same effect as that of intravenous sedation, and this was the reason why these patients were included in Group 2). During evaluation, the patients'

oral health was examined, and data were collected by means of a personalized questionnaire, associated with a 10 cm long visual analog scale (VAS) (Table 1). The VAS 0 indicated complete dissatisfaction, and 10, complete satisfaction. Similar scales have been used in other studies [6]. Explanations or help were offered, when necessary.

All the individuals signed the term of free and informed consent, and went through the following inclusion and exclusion criteria:

a) Inclusion Criteria:

- Individuals of the male and female gender.
- Minimum age: 35 years;
- Smokers or nonsmokers;
- Who had received at least one zygomatic implant;
- Late loading;
- Immediate loading (initial insertion torque of 35 Ncm); [1]
- Those who received fixed, implant supported, screw-retained dental prostheses (hybrid).

b) Exclusion Criteria:

- Blind, deaf and/or dumb individuals;
- Those who had some type of mental deficiency;
- Who received implant supported overdenture prostheses;
- Those who failed to respond any question in the questionnaire.

The patients were instructed about their oral health status, especially the peri-implant tissue, and about cleaning and prevention care and techniques. We randomly removed 2 samples from Group 1 to maintain the groups paired to enable us to use tests with a correlation structure, resulting in a sample of 30 individuals, with 15 in Group 1 and 15 in Group 2. By means of clinical record charts and panoramic radiographs, the authors counted that 30 individuals selected received a total of 131 implants, of the company Conexão Sistemas de Prótese, with 64 being of the zygomatic and 67 of the conventional type. Group 1 received 40 zygomatic and 28 conventional implants; and Group 2 received 24 zygomatic and 39 conventional implants.

The data collected were submitted to descriptive and inferential statistical approaches. The confidence interval for the mean was calculated. The non parametric Wilcoxon test was used to compare the participants' emotional condition in the intervals of the beginning and conclusion of the treatment, irrespective of the anesthetic procedure used. The non parametric G test was applied to verify whether there was difference in the individuals' emotional condition in at the beginning of treatment, considering the type of anesthetic procedure adopted. The same test was used to compare whether there was difference in the emotional condition on conclusion of the treatment, according to the anesthetic procedure. The non parametric Mann-Whitney test was used to compare the degree of satisfaction reported by individuals whose surgeries were performed under general and local anesthesia with sedation, considering the different indicators evaluated. The Exact Fisher test was used to analyze whether there was difference with regard to the individuals' expectations about treatment when the surgical procedures were performed under general, or local anesthesia with sedation. The level of significance adopted was ($P < 0,05$), and the statistical calculations were performed in the BioEstat program 5.0.

3. Results

The clinical record charts evaluated belonged to 30 individuals, with a follow-up period of 6 years, of whom 11 were men, representing 36.7% of the sample, and 19 women, totaling 63.3% of the sample. As regards age-range, the individuals were between 43 and 72 years of age, with a mean age of 56.5 and standard deviation of

Table 1
Questionnaire.

-
1. The zygomatic implant placement surgery was performed:
 - a. In hospital, under general anesthesia
 - b. At the SLMandic School of Dentistry, with local anesthetic and endovenous or oral sedation.


 2. You received your denture:
 - a. Up to one week after surgery - immediate load
 - b. After a period of waiting for healing (5 months)


 3. During the period of waiting for placement of the denture, did you use a provisional denture:
 - a. Yes
 - b. No

 4. Before the placement of zygomatic implants, did you:
 - a. have all the teeth in the maxillary arch (not considering the wisdom tooth) needing to be extracted because of periodontal disease (gingiva)
 - b. have some teeth missing in the maxillary arch, and did or didn't you use a fixed and/or removable denture
 - c. I used a denture
 - d. I didn't use anything

 5. From the emotional point of view, of the characteristics listed below, into which of them do you fit before treatment began:
 - a. Nervous (a)
 - b. Calm (a)
 - c. Anxious (a)
 - d. Reconciled (a)


 6. General satisfaction with treatment:







 7. Satisfaction related to:


Post-Operative Pain






Post-Operative Edema





Esthetics




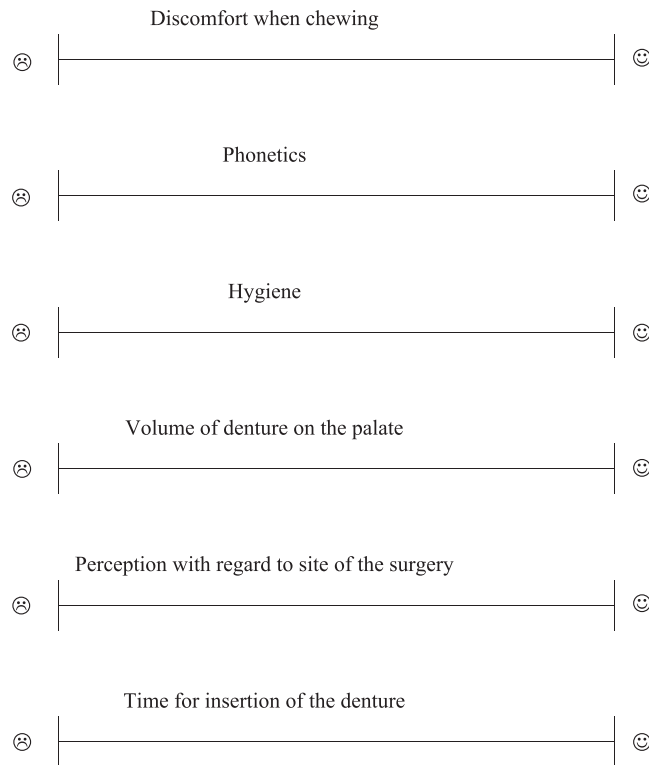
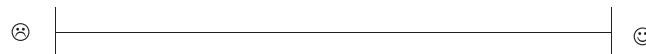


Table 1 (continued)



In your assessment with regard to doubts, complaints and dissatisfaction arising from treatment, what interest did the School of Dentistry demonstrate in addressing these



In your assessment with regard to doubts, complaints and dissatisfaction arising from treatment, what interest did the team of professors and students demonstrate in addressing these



8. Did you have a different expectation of the treatment:

- a. Yes
- b. No

9. From the emotional point of view, of the characteristics listed below, into which of them would you after conclusion of the treatment:

- a. Calm (a)
- b. Nervous (a)
- c. Reconciled (a)
- d. Anxious (a)

6.5 years. Of the 30 individuals whose record charts were evaluated, 23 (76.7%) were nonsmokers, and 7 (23.3%), were smokers.

With reference to the number of zygomatic implants, four of the individuals (13.3%) had only 1. Of these four individuals, two also

had 3 conventional implants, one had 5, and the other had 6 conventional implants; 22 individuals (73.3%) had 2 zygomatic implants. Among the 22, 19 also had 2 conventional implants, with the remainder (3) had 4 conventional implants. In the total of 30

individuals, 4 (13.3%) received 4 zygomatic implants, and these were not associated with conventional implants.

For 22 individuals (73.3%) participating in this research, the implants received immediate loading, while for 8 (26.7%), loading was not immediate. As regards the use of provisional dental prostheses, 22 individuals (73.3%) did not use any, while 8 (26.7%) made use of them. In the pre-operative condition, 22 individuals (73.3%) were complete denture wearers. The remainder; that is 8 (26.7%) were partially edentulous.

Fig. 1 and Fig. 2 demonstrate the emotional categories of individuals before and after conclusion of the treatment. In fact, the Wilcoxon test revealed that at the beginning of treatment, the emotional condition of the individuals differed from that verified after the conclusion of treatment ($p < 0.0001$). Therefore, irrespective of the anesthesia procedure used, before the surgical intervention, 73.3% of the individuals were characterized as anxious and nervous, emotional conditions that were not maintained after conclusion of the treatment, a time when 90% of the participants reported that they fitted into the categories of mediators or calm.

When the reported characteristics were compared, considering the anesthetic procedure, from the results of the G test the authors observed that there were no significant differences between the patients belonging to the group submitted to general anesthesia and those submitted to local anesthesia with sedation, both in the following time intervals: (pre-operative) before the treatment began ($p = 0.1871$), and (post-operative) after conclusion of the treatment ($p = 0.1641$). Fig. 3 demonstrates the number of individuals in each emotional category, according to the anesthetic procedure adopted.

Table 2 and Fig. 4 demonstrate the descriptive analysis of the indicators evaluated to compare the satisfaction of individuals rehabilitated with zygomatic implants, considering the surgical procedure performed under general anesthesia, and local anesthesia with sedation. For all aspects analyzed, the Mann-Whitney tests revealed there was no significant difference in the satisfaction of individuals submitted to general anesthesia, or local with sedation, as may be verified by the p-values shown in Table 2.

When asked whether they had different expectations as regards treatment, 21 individuals (70.0%) responded negatively, while 9 (30.0%), responded positively. The exact Fisher test revealed that there was no difference in the frequency of positive and negative responses about treatment expectations, when general and local

anesthesia with sedation were compared ($p = 0.5000$), as shown in Table 3. The confidence interval for the mean is presented in Table 4.

4. Discussion

When reviewing the literature, the authors perceived that various studies related to zygomatic implants were about surgical techniques, success rates of implants and dental prostheses in the long term, in addition to problems resulting from this type of therapy [8,9]. Success was based on scientific evidence found by researchers and not from the point of view of individuals. One study evaluated the satisfaction of individuals rehabilitated with fixed dentures in the maxillary arch, with zygomatic implants versus the conventional type, and discovered that the satisfaction of individuals rehabilitated with implant supported fixed dentures in the zygomatic group was similar to that of the group that received conventional implants [5]. By means of the OHIP-14 questionnaires and VAS, the quality of life of edentulous individuals rehabilitated with zygomatic implants was studied. Rehabilitation with implants was found to have a positive impact in the majority of the categories tested, and there was a statistically significant increase in satisfaction after the placement of implant supported dental prostheses [6]. A research about the satisfaction of individuals who had zygomatic implants placed concluded that they were satisfied with the implants and the dental prostheses, and that that treatments with zygomatic implants was predictable and reliable [7]. In view of the foregoing, the authors perceived that the satisfaction criteria were frequently based on the type of implant placed and dental prostheses used.

The few existent studies about the evaluation of satisfaction did not use comparative data such as gender; age; educational level; social profile; associated risk factors (systemic diseases, smoking, bruxism); and type of anesthesia [5,7]. In our research, we chose this latter variable for crossing and analyses of information, with a view to discovering up to what point the anesthetic procedure used could influence the satisfaction of individuals.

In this research we evaluated satisfaction by means of a personalized questionnaire, associated with a visual analog scale (VAS) of 10 cm. Values close to 10 meant greater satisfaction, and are used to evaluate subjective questions put to individuals. Some authors [5,6,10] have also used VAS to evaluate satisfaction.

Zygomatic implant placement surgery may be performed in

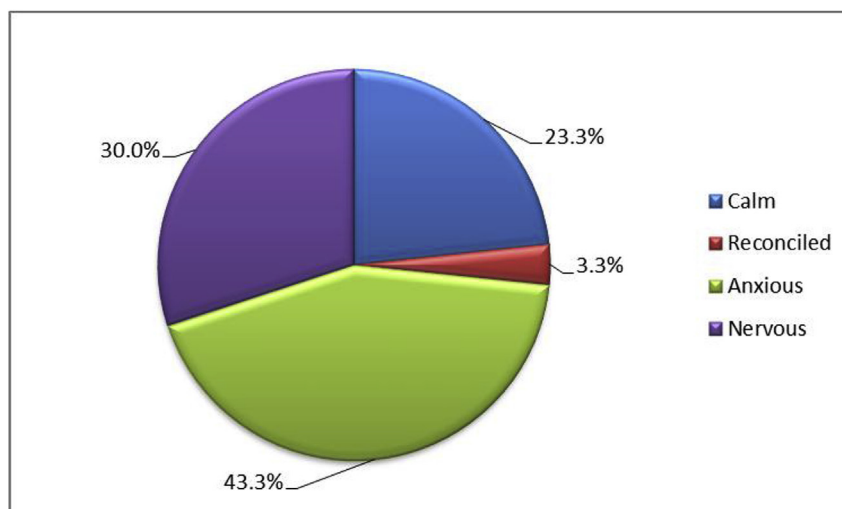


Fig. 1. Diagram of emotional category sectors into which the individuals classified themselves before the treatment began.

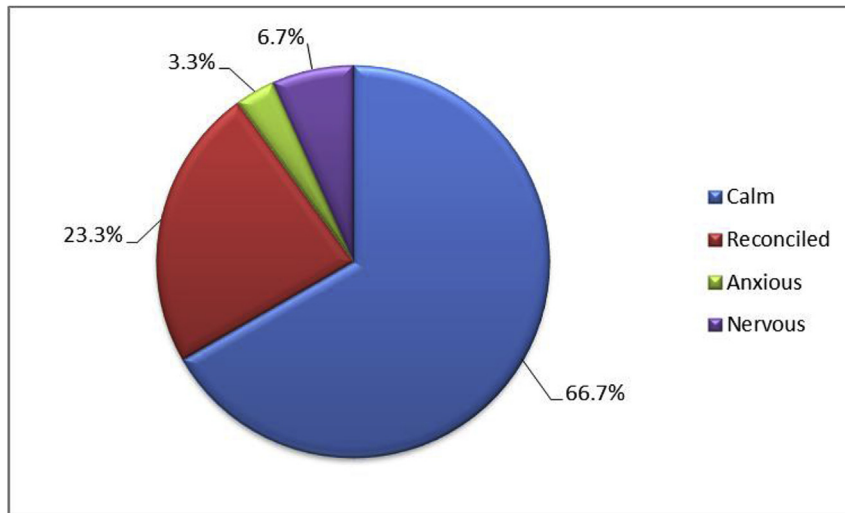


Fig. 2. Diagram of emotional category sectors into which the individuals classified themselves after conclusion of the treatment.

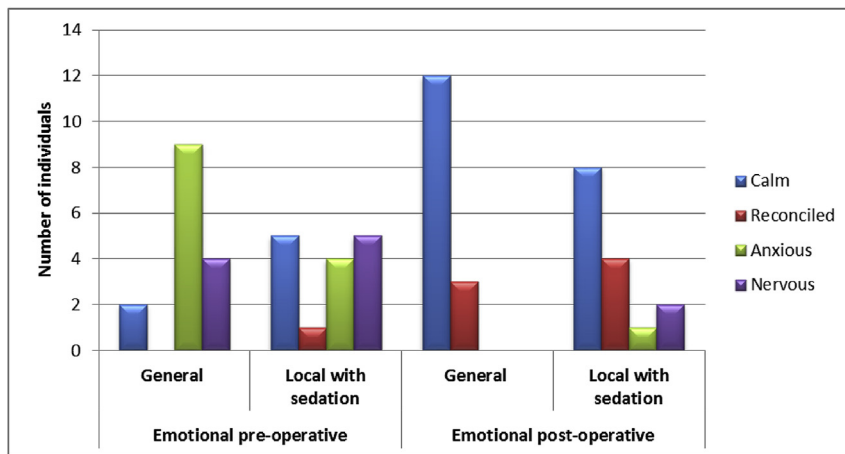


Fig. 3. Column diagram of emotional categories reported by individuals, according to the type of anesthetic procedure.

hospital, under general anesthesia [1,7,10–13] or in the outpatient clinic, with local anesthesia and with either intravenous [3,14–16] or oral [16] sedation. In one study [17] the authors reviewed the literature of the last six years and reported that general anesthesia

was used in the majority of the studies. Recently, the anesthetic protocol was simplified with the use of local anesthesia and oral or intravenous sedation. This procedure is recommended for experienced surgeons, and a surgical time programmed to last less than

Table 2

Descriptive analysis and results of the Mann-Whitney tests applied to the satisfaction indices reported by individuals submitted to general and local anesthesia association with sedation. *Level of significance of 5%.

Satisfaction Indicator	General Anesthesia		Local Anesthesia/ Sedation		p-Value*
	Mean (sd)	Median	Mean (sd)	Median	
General satisfaction with treatment	9.0 (1.9)	10.0	7.4 (2.8)	8.5	0.285
Post-Operative Pain	7.7 (3.0)	8.9	7.8 (3.2)	9.5	0.775
Post-Operative Edema	7.3 (3.1)	9.1	7.8 (3.0)	9.4	0.539
Esthetics	9.4 (1.0)	10.0	8.3 (2.5)	9.5	0.267
Discomfort when chewing	9.1 (2.1)	10.0	9.4 (0.7)	9.9	0.412
Phonetics	8.5 (2.5)	9.6	8.0 (2.5)	8.9	0.486
Hygiene	7.4 (3.3)	9.3	6.8 (3.2)	7.0	0.486
Volume of denture on the palate	7.5 (3.7)	10.0	8.5 (2.0)	9.2	0.870
Perception with regard to site of the surgery	8.8 (2.7)	10.0	8.5 (3.0)	10.0	1.000
Time for insertion of the denture	9.1 (2.1)	10.0	8.6 (2.0)	10.0	0.461
Interest shown by school of dentistry in addressing doubts, complaints and dissatisfactions	8.9 (2.5)	10.0	8.3 (2.0)	9.0	0.357
Interest shown by professors and students in addressing doubts, complaints and dissatisfactions	8.5 (3.1)	10.0	8.7 (1.9)	10.0	0.683

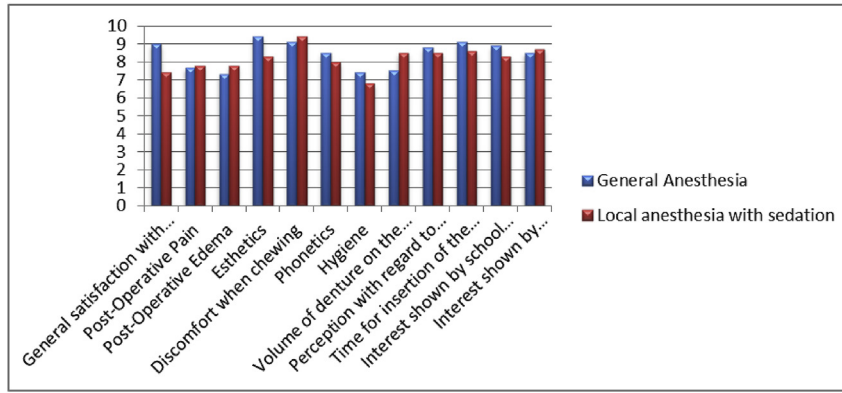


Fig. 4. Column diagram, revealing satisfaction indicators according to anesthetic procedure.

Table 3
Frequency of responses as regards the different expectations of treatment, according to type of anesthetic procedure.

Different expectation	Anesthetic Procedure		Total
	General	Local with sedation	
No	11	10	21
Yes	4	5	9
Total	15	15	30

1.5 h is well tolerated by the individual. The surgery is facilitated because it works with a conscious individual [16]. In this research, 3 individuals of Group 2 had the surgeries performed with local anesthesia and oral sedation, since they were performed by an experienced professional in a reduced surgical time.

The results of this research revealed there was no significant difference in the satisfaction of individuals submitted to general anesthesia, or local with sedation, from all the aspects analyzed.

These data allowed the authors to affirm that for the two groups of individuals studied, the anesthetic protocols did not have an influence on satisfaction, showing that it was possible to perform the surgical procedure in hospital under general anesthesia, or in the outpatient clinic with local anesthesia and sedation [16]. This is an important datum for surgeries, considering that with the appearance of new zygomatic implant placement techniques - the exteriorized and extramaxillary types [16,18,19], in which the zygomatic implants pass outside the maxillary sinus, the surgical time is reduced, allowing the surgical procedure to be performed in an outpatient clinic with local anesthesia and sedation, for both immediate and late loading [20,21]. For the individuals, having the procedure performed in an outpatient clinic reduces financial expenditure on hospital intervention, in addition to being able to go home soon after surgery is concluded, provided they are operated on by experienced professionals [16].

Irrespective of the anesthetic protocol used, the emotional state of individuals at the beginning of treatment differed from that on conclusion of treatment, as a significant result was obtained. In

Table 4
Confidence interval for the mean.

Type of Anesthesia	Satisfaction	Mean	Median	S	N	Confidence Interval	
						Lower limit	Upper limit
General	Discomfort when chewing	9.09	10	2.12	15	7.77	10.42
General	Post-operative Pain	7.68	8.9	2.98	15	6.36	9.00
General	Edema	7.31	9.1	3.12	15	5.98	8.63
General	Esthetics	9.38	10	0.97	15	8.06	10.70
General	Phonetics	8.52	9.6	2.49	15	7.20	9.84
General	Hygiene	7.37	9.3	3.34	15	6.04	8.69
General	Surgical Site	8.84	10	2.67	15	7.52	10.16
General	Faculty Complaints	8.86	10	2.49	15	7.54	10.18
General	Professors' Complaints	8.53	10	3.14	15	7.20	9.85
General	General Satisfaction	8.99	10	1.86	15	7.67	10.32
General	Time	9.06	10	2.13	15	7.74	10.38
General	Volume	7.53	10	3.69	15	6.21	8.86
Sedation	Discomfort when chewing	9.40	9.9	0.73	15	8.08	10.72
Sedation	Post-operative Pain	7.79	9.5	3.22	15	6.46	9.11
Sedation	Edema	7.78	9.4	2.98	15	6.46	9.10
Sedation	Esthetics	8.25	9.5	2.51	15	6.93	9.58
Sedation	Phonetics	7.96	8.9	2.51	15	6.64	9.28
Sedation	Hygiene	6.77	7	3.22	15	5.44	8.09
Sedation	Surgical Site	8.54	10	3.00	15	7.22	9.86
Sedation	Faculty Complaints	8.32	9	1.96	11	6.77	9.86
Sedation	Professors' Complaints	8.70	10	1.89	11	7.15	10.25
Sedation	General Satisfaction	7.40	8.5	2.80	15	6.08	8.72
Sedation	Time	8.60	10	2.01	15	7.28	9.92
Sedation	Volume	8.45	9.2	1.98	15	7.13	9.78

S: Sample Standard Deviation.
N: Sample size.

truth, 22 individuals were completely edentulous (complete denture wearers) and 8 were partially edentulous. Only those who make use of removable partial dentures are able to explain what it is like to use them, thereby changing their emotional status, particularly in the work studied, in which the superior maxillae were atrophied, with little retention for complete and/or partial dental prostheses, with this situation being an indication for the placement of zygomatic implants. The fact of being rehabilitated with fixed zygomatic implant supported (hybrid) dental prostheses improved the emotional status of the individuals. This fact was perceived during the evaluation and measured by means of the high value placed on the requisite of general satisfaction with the treatment, promoting an improvement in the quality of life [6,7]. A limitation of this study was the low number of individuals that participated in this research, and the few scientific articles about satisfaction published up to now to enable data crossing [5–7]. Further multi centric researches are necessary with a view to increasing the number of individuals studied, with more studies evaluating satisfaction related to anesthetic protocols and other variables to enable the crossing of data and analyses of new items of information.

5. Conclusion

For the sample studied, there was no significant difference in any of the requisites evaluated with regard to the satisfaction of individuals rehabilitated with zygomatic implants, under general anesthesia, or local with intravenous or oral sedation. General satisfaction with treatment was high. From the emotional point of view of the individuals, irrespective of the anesthetic procedure used, there was emotional improvement after the conclusion of treatment ($p < 0.0001$), thus improving the quality of life. The authors suggest repetition of this study with a larger number of individuals, in addition to evaluating satisfaction based on other variables.

Ethical approval

Research Ethics Committee (REC) of the São Leopoldo Mandic Dental School, protocol number 2011/0431.

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None.

Author contribution

Study design: Paulo H. T. Almeida, Alexander D'Alvia Salvoni.
Data collection: Paulo H. T. Almeida, Alexander D'Alvia Salvoni.
Data analysis: Paulo H. T. Almeida.
Manuscript preparation: Paulo H. T. Almeida.

Critical revision: Paulo H. T. Almeida, Alexander D'Alvia Salvoni, Fabiana M. G. França.

Conflicts of interest

None declared.

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None declared.

Guarantor

Paulo Henrique Teles de Almeida.

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