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Clinical Retrospective Study

SURGICAL APPROACH IN PATIENTS WHO ARE CANDIDATES FOR BPS THERAPY ON DENTAL ELEMENTS WITH UNCERTAIN PERIODONTAL PROGNOSIS: EVALUATION OF PI% AND BOP%

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ABSTRACT

Periodontal disease is a risk factor for the development of bisphosphonate osteonecrosis; in fact, it is present in 84% of patients with osteonecrotic lesions. The aim is to provide the clinician with a diagnostic guide, through the application of the Plaque Index and Bleeding Index, to determine which patients are likely to be candidates for dental extractions prior to antiresorptive drug therapy in cases of elements that are periodontally compromised. The study was carried out by selecting sample subjects from the total pool of patients treated from 2010 to 2016 at the Operative Unit of Odontostomatology, Department of Oncologic Dentistry, IRCCS San Gerardo in Monza, Italy. Selected patients are placed within a protocol of professional oral hygiene sessions, during which their periodontal records are compiled. The results obtained from the study show that a low periodontal health condition, assessed by PI% and BoP%, out of which, however, only BoP% finds statistical significance, appears to be related to the risk of osteonecrosis. In conclusion, in this study, a threshold value of BoP% of 15% has been found. Below this value, the clinician can take into consideration, for dental elements with uncertain periodontal prognosis (fair or poor), a conservative or extractive treatment.

KEYWORDS: *bisphosphonates, osteonecrosis, periodontal disease, plaque index, bleeding index, retrospective study*

INTRODUCTION

Osteonecrosis is defined as a drug-related adverse response characterized by the progressive destruction and necrosis of mandibular and/or maxillary bone hard tissues in individuals exposed to medication treatment (1). Medication-related osteonecrotic lesions of the jaw (also known as MRONJ, the abbreviation for “Medication-related osteonecrosis of the jaw”) is a difficult medical complication that hurts patients' quality of life. To date, more than 2,400 cases of osteonecrotic injury of the jaws have been reported worldwide (2).

The first cases of osteonecrotic injury of the jaws were reported by Marx Re et al. in 2003 (3): they noticed a connection between osteonecrotic injury, and the pharmacological therapy carried out by using bisphosphonates. As a

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result, the acronym BRONJ (bisphosphonate-related osteonecrosis of the jaws) was coined to identify only those osteonecrotic lesions associated with bisphosphonate therapy (4).

The almost exclusive localization of these lesions in the jaw bones is one of the main characteristics of these lesions. The causes of this phenomenon are merely yet theorized but not entirely known, among them are:

- bone turnover of the maxillary bones that is physiologically higher than the remaining human bones (3);
- poor mandibular vascularization (5);
- thin muco-periosteal lining protecting bone tissue (3);
- presence of high oral cavity bacterial microflora (6);
- the dento-alveolar interface that would predispose to exposure of the bone tissue in the presence of oral-dental disease or surgery (7).

Bisphosphonates

Bisphosphonates are antiresorptive molecules that are effective in the treatment of cancer-related conditions such as spinal cord compression and pathologic fractures resulting from bone metastases in patients with solid tumors, such as breast, prostate, lung, and multiple myeloma cancers (7-9). However, although their potential in improving cancer-specific survival is still a controversial topic, these drugs still have a positive impact on patients' quality of life by reducing or preventing skeletal tissue-related events (8, 9).

These molecules act by inhibiting bone turnover in order to block cell renewal; they accomplish their action by accumulating in areas that are useful for bone remodeling, acting in the same way as pyrophosphate (9). In addition, due to their high affinity, they can bond to bone calcium. Now the osteoclast is activated, the environment is acidified, leading to the release of bisphosphonate trapped in the bone matrix acting on the involved osteoclast. This mechanism explains the long-acting duration of the drug. However, several studies (10-13) have proven that bisphosphonates (BPs) are not the only agents responsible for the outbreak of this condition: other antiresorptive drugs (ARs), anti-angiogenic agents (AAs), and nuclear factor kappa-B ligand activating receptor (RANKL) inhibitors (such as denosumab) can also cause osteonecrosis of the jaws. Therefore, in 2014, the American Association of Oral and Maxillofacial Surgeons (AAOMS) proposed the term MRONJ to include all drugs involved (14).

Osteonecrosis and periodontal disease

There are many risk factors for the development of bisphosphonate osteonecrosis. The presence of periodontal disease is one of the most significant (14, 15), which is characterized by the occurrence of bacterial colonies. In the 84% sample of patients with osteonecrotic lesion, periodontal disease was diagnosed (16). This finding illustrates how periodontal infection plays an important role in the development of BRONJ and how it represents a negative prognostic factor of the clinical picture in diagnosed osteonecrosis (17). Consequently, in the presence of signs of periodontal tissue involvement, in patient under treatment with bisphosphonates, the dentist should be alert as there is the possible presence of early BRONJ (18).

In specimens taken from patients with osteonecrosis of the jaws, there is the presence of necrotic bone and a complex polymicrobial biofilm, composed particularly of bacteria belonging to the Actinomycetes species, which confirms this relationship (19). Specifically, the bacterial colonies are populated mainly by Gram-negative species and generate increased bone resorption through the production of lipopolysaccharide, promoting the production of local cytokines. GRAM+ and GRAM- type bacteria, represented by S. Aureus and P. Aeruginosa, together with microbial biofilms are capable of enhancing bone resorption (19). This activity is due to the adhesion of bacteria to hydroxyapatite and to the direct conditioning of RANKL (nuclear factor activating receptor kB ligand) production in gingival fibroblasts and periodontal ligament cells (20).

Recent literature reviews and articles (13, 21-24) suggest the need to perform periodontal screenings for at-risk patients to determine the right multidisciplinary approach. It may seem reasonable to suggest that proper management of infectious foci related to periodontal disease may hinder the onset of drug-related jaw osteonecrosis; however, further research is needed to clarify this possibility.

Periodontal indices: plaque index (PI) and bleeding on probing parameter (BoP)

The patient's poor oral hygiene leading to the presence of bacterial plaque is the etiologic agent of periodontal disease. Periodontitis is characterized by alteration in the color and shape of the gingiva presenting with redness and swelling and an increased tendency to bleed during probing performed in the periodontal pocket area. In the presence of periodontal disease, there may exist, also, less resistance to probing and/or gingival recession. Advanced disease states are associated with mobility, tooth migration and alveolar bone loss (25). The advanced state of periodontal disease is determined with the following parameters: probing depth; bleeding on probing (BoP); clinical attachment level; furcation involvement;

tooth mobility; and plaque index (PI). In this study, the Plaque Index and bleeding on probing were used to determine the prognosis of periodontal elements.

The plaque index is calculated through the formula No. areas with plaque/ No. areas examined x100. A detector solution is used to identify plaque, and this index expresses the patient's manual skill in their oral hygiene. A high plaque index accompanied by bleeding means that plaque has been present long enough to generate inflammation. On the contrary, a high plaque index without bleeding means that the plaque accumulation is very recent and that it is nevertheless removed frequently by the patient to prevent the appearance of inflammation.

The second index used in this study is the index of bleeding on probing, which accurately expresses the extent of gingivitis to provide detailed information on the patient's level of cooperation. This index is measured after sliding the probe over the gingival margin of the sulcus or pocket; it is calculated through the formula No. areas with bleeding / No. areas examined x 100. The presence of high gingival bleeding accompanied by the presence of plaque indicates that plaque has been present for a prolonged period, leading to inflammation. On the contrary, if high gingival bleeding is observed in the absence of plaque, it indicates that plaque was removed shortly before the examination, without giving adequate time to reduce inflammation.

The choice of using these two periodontal indices has several reasons: the plaque index is the most reliable method of understanding the patient's oral hygiene habits both in general as well as during the visit. However, it is not a strictly specific and precise index: in fact, the measurement, made by erythrosine tablets, is positive even a few hours after thorough home oral hygiene. The bleeding index was chosen because it is a predictor of periodontal stability since it does not receive changes within the entire daily span and is not reducible with careful same-day home oral hygiene. The use of these indices is effective because being able to diagnose periodontal prognosis is critical in patients who, being candidates for bisphosphonate therapy, are referred to the dentist for examination. The purpose is to assess on which elements to perform preventive extractions so as to minimize the risk of developing BRONJ.

These premises provide the best understanding of the goal of our study, which is to provide the clinician with diagnostic and therapeutic guidance, through the use of two simple and rapid periodontal indices, so that he or she can discern, accurately, which patients are candidates for preventive dental extractions for antiresorptive drug therapy in cases of elements that are not totally periodontally compromised.

MATERIALS AND METHODS

A retrospective clinical investigation was conducted, aimed to correlate the incidence of BRONJ to periodontal indices in a statistically significant manner. The purpose is to predict in patients on antiresorptive therapy the candidacy for surgical-extractive therapy of elements with doubtful prognosis as not totally periodontally compromised.

Protocol procedure

The survey was conducted by selecting study sample subjects from the pool of patients treated from 2010 to 2016 at the Operating Unit of Odontostomatology, Department of Oncologic Dentistry, IRCCS San Gerardo in Monza, Italy. The patients who are undergoing cancer therapy here, in the form of chemotherapy, monoclonal antibodies, anti-tumor drugs or radiotherapy, undergo preventive pre-therapy examinations and close intra-therapy checkups to avoid side effects, local or systemic, that can be associated with certain therapeutic molecules.

The study population was divided into two groups according to whether or not they developed the drug-related osteonecrotic lesion of the jaws. Therefore, the first group includes subjects whose medical records report the development of BRONJ, which can be attributed to different causes: spontaneous lesion, post-extraction, from periodontal infection, from prosthetic trauma. The second group consists of those subjects whose medical records report that, despite having taken antiresorptive drugs, they have not manifested clinical and/or radiographic osteonecrotic pathology.

Subjects' medical records were analyzed in order to identify, firstly, the study inclusion and exclusion criteria and, secondly, the periodontal indices to be considered based on their clinical significance. At last, a statistical analysis was conducted through:

- evaluation of data distribution and curve type (Gaussian or non-Gaussian);
- scatter-plot diagram to highlight the presence or absence of correlation between periodontal indices;
- determination of the p-value in relation to the type of curve associated with the data distribution;
- cutoff analysis and research of the most clinically useful value to meet the study purpose.

Inclusion criteria

- being treated or a prospective candidate for bisphosphonate therapy in 2010, i.e. the year of the beginning of the observation period of the present retrospective study;
- male and female;
- age > 18 years;
- in possession of periodontal records;
- undergoing treatment at the Department of Oncologic Dentistry at IRCCS San Gerardo dei Tintori.

Exclusion criteria

Subjects who had undergone or were a candidate in 2010 for anti-tumor therapy with non-BPs anti-resorptive drugs.

In identifying the inclusion and exclusion criteria, eliminating confounding factors that might be present within the survey was essential in order to obtain a study of scientific validity. Specifically, given that osteonecrotic lesions can also occur following therapy with non-BPs drugs, we wanted to select only those patients being treated or planned for treatment during the observation period of the study with BPs drugs alone.

Clinical measures

As extensively described in the introduction to this study, the PI% and BoP% indices were chosen to be analyzed because they are easy to apply and manage for both the practitioner and the patient. These parameters provide useful information to understand the patient's oral health status and to highlight the effectiveness of their daily home oral hygiene habits.

Subsequent to the first dental visit, patients being treated at the Department of Oncology Dentistry are included within the Oral Hygiene protocol defined for individuals being treated with cancer therapy and/or bisphosphonates. The scheme involves professional oral hygiene sessions every 4 to 6 months, depending on the subject's risk conditions (systemic and/or local). During these visits, instructions to proper home oral hygiene are renewed and periodontal records are compiled to detect PI% plaque and BoP% bleeding indices. For the following retrospective study, PI% and BoP% values derived from the average of individual detections that occurred during the observation period (2010-2016) were considered for each patient.

RESULTS

The results are reported as follows with reference to the descriptive analysis of clinical information and the resulting statistical analysis.

Descriptive analysis-clinical data of PI% and BoP%

The data belong to the patients selected for the study according to the inclusion and exclusion criteria, whose medical records were found in the archives of the O.U. of Odontostomatology of IRCCS San Gerardo dei Tintori (Monza, Italy), Department of Oncologic Dentistry.

Twenty-two patients were selected for the BRONJ group, displayed in Table I (subjects who manifested osteonecrotic pathology) and 34 patients for the NO-BRONJ group displayed in Table II (patients treated with clinically and radiologically healthy BPs), for a total number of 56 subjects belonging to the study sample. In both groups, the PI% and BoP% values of each patient are reported.

Table I. *PI% and BoP% Index values in BRONJ group (n= 22).*

Patient	PI%	BoP%
A	77	32
B	74	29
C	40	21
D	65	22
E	68	28
F	40	18
G	42	15
H	68	19
I	70	19
L	65	15
M	90	25
N	50	18
O	41	17
P	42	15
Q	98	15
R	65	19
S	53	5
T	57	17
U	91	21
V	92	38
Z	62	18
X	43	10

Table II. *PI% and BoP% Index values in NO-BRONJ group (n= 34).*

Patient	PI%	BoP%
A	45	5
B	53	12
C	21	0
D	67	9
E	100	13
F	44	0
G	73	0
H	12	5
I	89	21
L	70	11
M	100	43
N	50	30
O	41	0
P	42	7
Q	32	0
R	67	10
S	10	0
T	57	0
U	62	5
V	100	11
Z	91	0
X	45	10
Y	50	0
J	65	0
K	100	12
W	32	3
AA	26	0
BB	17	0
CC	26	6
DD	54	0
EE	61	12
FF	79	22
GG	100	33
HH	17	0

Statistical analysis

Statistical analysis is conducted by evaluating the graphical distribution of PI% and BoP% values, investigating a potential correlation between the two periodontal indices by Scatter-plot diagram, determining the p-value, and finding the cutoff value.

Graphical distribution of PI% and BoP%

For both indices, graphs are constructed with the number of subjects, expressed as a percentage value of the total sample, in the ordinate and the value of the analyzed index in the abscissa.

Fig. 1 shows the distribution of PI% values in the two groups, and NO-BRONJ. In neither group do the PI% data follow a Gaussian distribution.

Fig. 2 shows the distribution of BoP% values in the two groups, BRONJ and NO-BRONJ. In neither group do the BoP% data follow a Gaussian distribution.

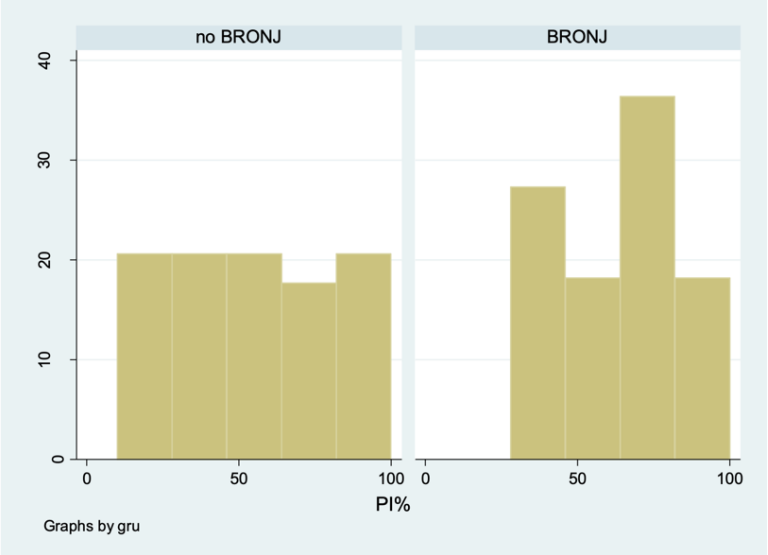

Fig. 1. *Graphical distribution of PI% in groups BRONJ e NO-BRONJ.*

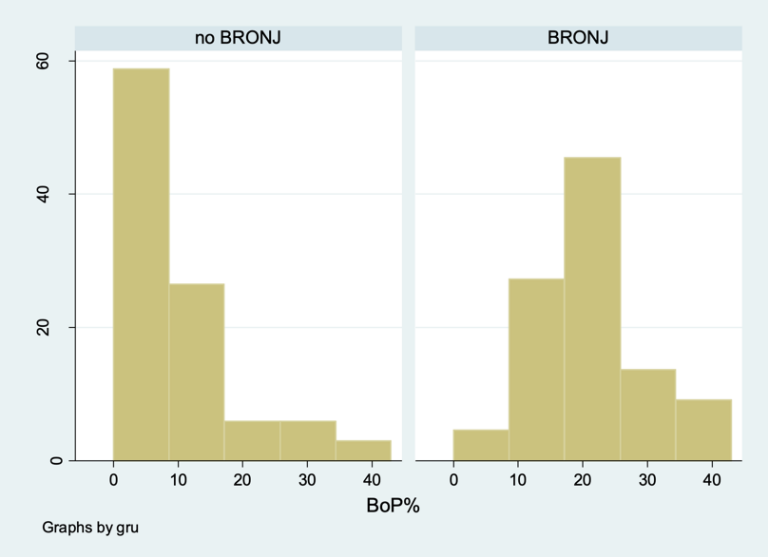

Fig. 2. *Graphical distribution of BoP% in groups BRONJ e NO-BRONJ.*

Scatter-plot diagram of PI% and BoP%

Fig. 3 and Fig. 4 represent the scatter-plot plots: parameter pairs for each patient are identified in the total sample of patients enrolled in the study and divided into the two study groups according to the presence or absence of osteonecrotic lesion (NO-BRONJ group and BRONJ group). Scatter-plot graphs allow intercepting the presence of a correlation (e.g., linear type) between the two indices taken into analysis on a per-patient basis.

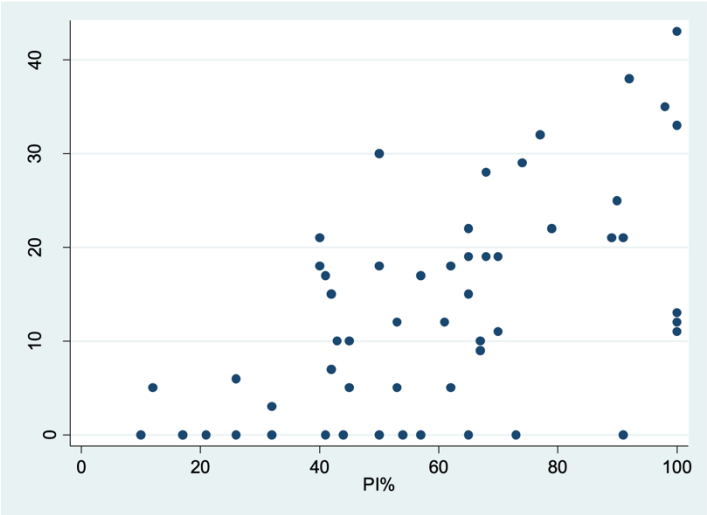

Fig. 3. *Scatter-plot (BoP% on Y-axis, PI% on X-axis) of BRONJ and NO-BRONJ subjects in the total study sample (N= 56).*

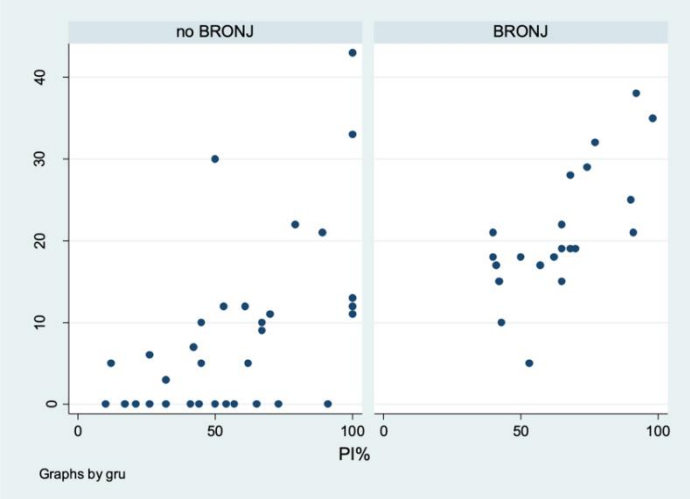

Fig. 4. *Scatter-plot (BoP% on Y-axis, PI% on X-axis) of BRONJ and NO-BRONJ subjects divided into their respective study groups.*

Linear regression analysis between the values of PI% and BoP%

In the NO-BRONJ group, the linear regression (Table III) shows a low R-square value of 0.3365, confirming the low correlation between the PI% and BoP% parameters evidenced qualitatively in the graph (Fig. 4), despite the fact that the regression line has a significantly different angle coefficient from zero (0.000).

Table III. *Linear regression analysis for the NO-BRONJ group of patients.*

GRUPPO = noBRONJ			
Source	SS	df	MS
Model	85.982.263,0000	1	85.982.263,0000
Residual	169.567.149,0000	32	52.989.734,00000
Total	255.549.412,0000	33	774.392.157,000000

Number of obs = 34
F (1.32) = 16.23
Prob > F = 0.0003
R-squared = 0.3365
C = 0.3157
Root MSE = 23.019

pi	Coef.	Std. Err.	t	P>|t|	[95% Conf. Interval]
bop	1.514.196,000000	0.375901	4.03	0,00	0.7485105 - 2.279881
cons	4.335.368,00000	5.016.801	8.64	0,00	33.13479 - 53.57257

In the BRONJ group, the linear regression (Table IV) shows a higher R-square value of 0.5195 than in the previous group. As in the NO-BRONJ group, the regression line has a significantly different angular coefficient from zero (0.000).

Table IV. *Linear regression analysis for the BRONJ group of patients.*

GRUPPO = BRONJ			
Source	SS	df	MS
Model	370.637.488,0000	1	370.637.488,0000
Residual	342.839.784,0000	20	171.419.892,00000
Total	713.477.273,0000	21	339.751.082,000000

Number of obs = 22
F (1. 32) = 21.62
Prob > F = 0.0002
R-squared = 0.5195
C = 0.4955
Root MSE = 13.093

pi	Coef.	Std. Err.	t	P>|t|	[95% Conf. Interval]
bop	1.694.801,000000	0.3644807	4.65	0,000	0.9345072 - 2.455094
cons	2.818.959,00000	8.053.892	3.5	0,000	11.38946 - 44.98971

Searching for the cutoff

ROC curves were used to find the cutoff of PI% and BoP% to predict the occurrence of BRONJ in patients. The curves were constructed by placing the sensitivity on the ordinate (y-axis) and the complement to 1 of the specificity on the abscissa (x-axis).

Next, each individual value of the parameter under study was assumed to be a possible cutoff, then calculated its corresponding sensitivity and specificity values and entered the results into the graph (Fig. 5, 6).

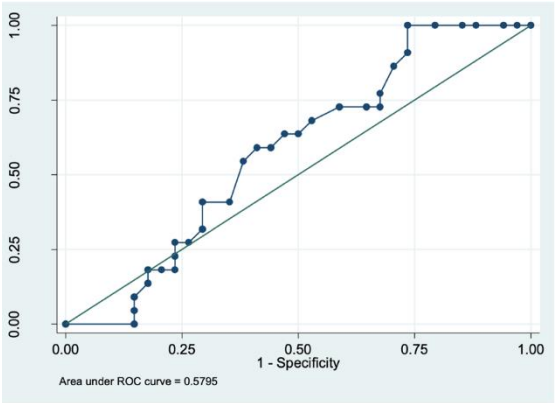

Fig. 5. *ROC curve for the PI% parameter.*

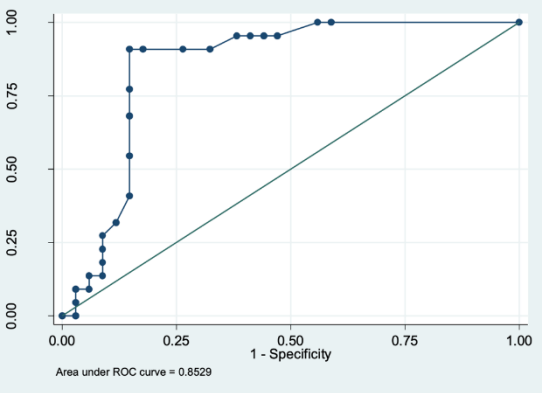

Fig. 6. *ROC curve for the parameter BoP%.*

Quantitative analysis has been conducted by calculating the area under the curve (AUC) and comparing it with the area under the bisector, which is associated with the total randomness of assignment of subjects to the stratification groups. If the AUC is higher than 0.5 and its 95% confidence interval does not include the value 0.5, then it can be said that the parameter under analysis is effective in predicting the assignment of the subject to the corresponding group. Qualitative analysis concerns the observation of the graph, assessing whether there is a detachment of the collected data from the bisector (Table V, VI).

Table V. *Quantitative analysis for the PI% parameter.*

ROC		Asymptotic Normal	
Obs	Area	Std. Err.	[95% Conf. Interval]
56	0.5795	0.0766	0.42949 0.72960

Table VI. *Quantitative analysis for the parameter BoP%.*

ROC		Asymptotic Normal	
Obs	Area	Std. Err.	[95% Conf. Interval]
56	0.8529	0.0547	0.746 - 0.960

Qualitative intuition is confirmed with the determination of the confidence interval and the involvement or noninvolvement of the value 0.5.

ROC curves and qualitative and quantitative analyses prove that the PI% parameter is not useful in predicting the risk of occurrence of BRONJ osteonecrotic lesion (AUC: 0.580; IC95%: 0.429-0.730). In contrast, the BoP% value shows a statistically significant ROC curve (AUC: 0.853; IC95%: 0.746-0.960), and the CutOFF value for BoP% was therefore sought (Table VII).

Table VII. *Finding the cutoff for the BoP% parameter.*

Correctly					
Cutpoint	Sensitivity	Specificity	Classified	LR+	LR-
(>= 0)	100,00%	0,00%	39.29%	1+E3E3:E8	
(>= 3)	100,00%	41.18%	64.29%	1.7	0
(>= 5)	100,00%	44.12%	66.07%	17.895,0000	0
(>= 6)	95.45%	52.94%	69.64%	20.284,0000	0.0859
(>= 7)	95.45%	55.88%	71.43%	21.636,0000	0.0813
(>= 9)	95.45%	58.82%	73.21%	23.182,0000	0.0773
(>= 10)	95.45%	61.76%	75.00%	24.965,0000	0.0736
(>= 11)	90.91%	67.65%	76.79%	28.099,0000	0.1344
(>= 12)	90.91%	73.53%	80.36%	34.343,0000	0.1236
(>= 13)	90.91%	82.35%	85.71%	51.515,0000	0.1104
(>= 15)	90.91%	85.29%	87.50%	61.818,0000	0.1066
(>= 17)	77.27%	85.29%	82.14%	52.545,0000	0.2665
(>= 18)	68.18%	85.29%	78.57%	46.364,0000	0.373
(>= 19)	54.55%	85.29%	73.21%	37.091,0000	0.5329
(>= 21)	40.91%	85.29%	67.86%	27.818,0000	0.6928
(>= 22)	31.82%	88.24%	66.07%	27.045,0000	0.7727
(>= 25)	27.27%	91.18%	66.07%	30.909,0000	0.7977
(>= 28)	22.73%	91.18%	64.29%	25.758,0000	0.8475
(>= 29)	18.18%	91.18%	62.50%	20.606,0000	0.8974
(>= 30)	13.64%	91.18%	60.71%	15.455,0000	0.9472

The sensitivity and specificity values corresponding to the different values of cutoff that can be used, up to BoP% = 30%, were given in Table VII. The cutoff was identified in the value 15%, especially for the good level of accuracy (Table VIII).

Table VIII. *Sensibility, accurancy, positive predicting value (VPP) and Negative Predicting Value (VPN) at cutoff 15%.*

	Sensibility	*Specificity*	*Accuracy*	*Positive Predictive Value*	*Negative Predictive Value*
BoP% ≥ 15%	90.9%	85.3%	87.5%	80.0%	93.5%

DISCUSSION

After adjusting for inclusion and exclusion criteria, the total number of patients included in the study, whose indices were statistically analyzed, was 56 individuals. The study subjects were distributed into two groups: those with BRONJ and those without BRONJ. The index analysis was carried out by analyzing each index separately, this allowed us to observe that both indices do not respect a Gaussian distribution. Next, inferential analysis of the statistical indicators, mean standard deviation, median, range, and nonparametric rank test was performed. The p-value was calculated, considering a p-value<0.05 as significant.

The analysis of each index was carried out independently of the other since at the time of trying to evaluate the correlation between the two indices in the BRONJ and NO-BRONJ samples, through scatter plot analysis, a negative result was obtained. Once the p-value of each individual index was obtained, p-value of BoP% (p=0.0001) and PI% (p= 0.318) were analyzed.

The analysis shows that only the p-value of BoP has statistical significance. At the clinical level, this finding can be explained by the variation of PI throughout the day. PI% is low as soon as home oral hygiene ends but can increase rapidly in the following hours, thus showing little stability. In contrast, BoP% evidences a situation of chronic inflammation that is more stable over time.

Having established the significance of the indices, ROC curves were used to determine which CutOFF was better in terms of Sensitivity and Specificity. For PI%, the confidence interval includes the value 0.50 (CI= 0-42949 -0.72960), which coincides with the bisector of the graph, so it cannot be considered a reliable index to establish a clinically useful CutOFF. On the other hand, for BoP% analysis, the confidence interval is 0.74579 - 0.96009, which is well above the bisector, thus indicating a reliable index. The choice of CutOFF point was based on the value that showed the highest accuracy.

Thus, the data obtained from the study show that poor periodontal health status, as measured by PI% and BoP%, of which, however, only BoP% finds statistical significance, appears to be related to the risk of osteonecrosis. This result is also confirmed by four other studies conducted previously:

- Carmagnola et al, 2008: indicate worse than average periodontal health in the 39 BRONJ patients observed over the course of one year, but without a statistically significant p-value (p = 0.156) (26);
- Kos, 2014: shows instead with greater statistical significance periodontal lesions (p = 0.001), caries (p = 0.05) and poor hygiene (p = 0.065) in patients who developed BRONJ (24);
- Nicolatou-Galitis et al. 2015: state that at the time of clinical analysis, the involvement of periodontal tissue should alert the dentist to the possible presence of early ONJ, and if so, extraction of the tooth should be considered under appropriate conditions of care (27);
- Lorenzo-Pouso et al. in 2019: through a systematic review and meta-analysis conclude that periodontal disease appears to be frequent among patients with drug-related osteonecrosis of the jaw compared with unaffected but at-risk patients (28).

Drug-related osteonecrosis represents an uncomfortable and disabling, although manageable, complication of dental concern given by taking BPs or other antiresorptive drugs. Its treatment can be surgical or medical, but its prevention and, consequently, the need to minimize or eliminate risk factors wherever possible, plays a key role. Preventive extractions of compromised elements can minimize the risk of developing BRONJ. However, the crucial point is that if on a patient who is not a candidate for BPs therapy it is possible to retain elements whose prognosis is not only good or fair, the ethical and professional doubt arises about patients taking antiresorptive drugs, on whom oral surgical procedures should be limited as much as possible from the start of drug therapy.

In literature articles (13, 14, 16, 23), the need for extraction therapy of dental elements with poor and irrecoverable prognosis is reiterated at least 2 months prior to the initiation of BPs treatment. Doubt remains regarding the preservation or extraction of potentially recoverable elements, since, to date, there are still no guidelines indicating precisely in which cases of periodontal lesion it is possible to preserve the element.

It should be emphasized that in the presence of endodontic or carious lesions, the therapeutic approach with excessively prolonged sessions, excessively declivous positions, and the use of the dam are often unfavorable and, consequently, contraindicated in cases of metastases to the spine or patients with nausea. Nevertheless, the use of the dam is essential in the endodontic root canal or reconstructive therapies to minimize the risk of periapical infection or secondary caries with evolution into pulpal disease. Both conditions represent risk factors for the occurrence of BRONJ.

In the context thus described, the statistical analysis of the data collected in the following retrospective study allowed for an evaluation that would allow the determination of a cutoff useful for the choice of treatment, prior to the intake of BPs, of conservative or surgical type for elements with doubtful prognosis. Thanks to the analyses conducted, a BoP% cut-off value of 15% was identified below which patients with dental elements with uncertain periodontal prognosis (fair or poor) can face conservative treatments aimed at maintaining the same elements, since the risk of developing osteonecrosis, according to the investigation carried out, is minimal.

Should the items need to be extracted later, it will be necessary to proceed with dental avulsions after observing the guidelines on antibiotic coverage and disinfection of the oral cavity (disinfection of pathogenic foci, therapies conducted in sterility, and dual GRAM+ and GRAM antibiotic therapy) (13, 23).

The study conducted deliberately does not analyze the correlation between the incidence of BRONJ nor:

- age of the subject;

- type of drug molecule used in BPs treatment;
- route of administration of BPs;
- copresence of systemic diseases not associated with cancer metastasis (ex. diabetes, cardiovascular events, etc.).

The reason for the choice lies in the objective of the study, which is based on determining a cutoff value useful for clinician decision making that is as standardized as possible.

The clinical application of the investigation carried out lies in the indication of BoP% as a predictor of BRONJ in patients taking BPs and, consequently, is useful in the decision-making process of choosing between exodontic or conservative treatment of dental elements, aimed at improving the patient's comfort and quality of life.

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ORAL HEALTH IN "SPECIAL-NEEDS" PATIENTS: THE UNIVERSITY OF MILANO BICOCCA DENTAL CLINIC EXPERIENCE

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ABSTRACT

To understand dentistry for special-need patients, it is crucial to define the population and its complex characteristics. Historically, "disability" had a negative connotation, indicating physical or mental impairments, and led to social marginalization. The WHO's 2001 International Classification on Functioning, Disability and Health (ICF) introduced a more inclusive definition, considering environmental and socio-cultural factors. This shift emphasizes that disability results from both individual conditions and societal influences. The concept of inclusion has evolved, advocating for societal changes to accommodate individuals with special needs. Special-need, disabled, and fragile individuals share greater socio-health vulnerabilities, requiring tailored healthcare services and protocols. The Authors present a clinical protocol and an epidemiological analysis of the patients who presented at the Clinical Center for the Care of Special-need Patients of IRCCS San Gerardo Hospital in Monza, Italy.

KEYWORDS: *special-need dentistry disability and health, inclusion and societal changes, socio-health vulnerabilities, clinical protocol, epidemiological analysis*

INTRODUCTION

To speak comprehensively about dentistry for special-need patients, it is necessary to define the population that needs to be addressed in terms of its complex characteristics. With regard to the "special-need" definition, profound confusion has been present over the years.

In the past, disability was a condition of non-health with a negative meaning, indicating the persistence, temporary or chronic, of a physical and/or mental impairment. In the social context, the term "umbrella" was used to indicate, above all, disability as an extremely varied condition. In this way, it contributed to highlighting the persistence of a minus in these subjects, or rather a lack of those active requirements that society inevitably requires of its citizens. The consequence has been the marginalization of disabled people at the edges of society, reserving them a mainly passive role. To date, thanks to the reception of progressive reflections of a medical, pedagogical, and social nature by the new

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classification of the International Classification on Functioning, Disability and Health (ICF), developed by the WHO in May 2001, a new perspective emerged, now more inclusive and complete (1-3).

With this novel definition, the disabled person is defined not only on the basis of his non-health conditions but also, above all, in relation to the environment and the socio-cultural conditions in which it is inserted. Moreover, the ICF classification allows us to define "disabled" as someone who is in an unfavorable environment despite having a health condition (1, 3).

The result is the delineation of a more equitable, humanistic, and comprehensive vision, affirming the need for greater awareness of the role of disability. Disability is no longer understood as an exclusive attribute of the person but rather as the overall sum of conditions often produced or influenced by the environmental and social fabric. The change that affected society was essential: when we talked about inclusion, we thought that the objective was to provide special-need subjects with the skills that would allow them to fit into the society to which they belonged. Nowadays, however, this ideology has undergone a revolution. Today, inclusion means that society is changing, shaping itself to place the person with special needs at its center, providing the necessary help and, above all, to those who deal with them. It is the concept of 360° personalization of routes for everyone (1-4).

In the medical field, over the years, attempts have been made to find a definitive answer to attribute patterns of precise characteristics to subjects with special needs, disabled, and fragile subjects. The objective was to diversify the three conditions.

After 1988, the child with special needs is recognized as having a greater risk of a chronic physical, developmental, behavioral, or emotional condition, existing or potential, which requires healthcare and/or related services of a higher amount than the pediatric population in general. Differently, the disabled person is the one who presents difficulty or a full-blown dependence in carrying out essential activities for an independent and quality life. In contrast, the fragile person is the one who reveals a physiological state of greater vulnerability to stress factors. However, a profound characteristic common to the three profiles emerged from identifying their peculiarities: the persistence of greater socio-health vulnerabilities (5, 6).

This socio-health vulnerability starts from different causes, which are no longer of medical relevance alone but also in the need for additional attention and services on the part of healthcare and society. It is, therefore, possible to adopt the term “patient with special needs” overall for all three forms, contrasting it with the general healthcare population. This way, starting from the definition, the condition is underlined positively. Therefore, a health vulnerability is recognized, and operators must pay greater attention. This implies the implementation of services and the creation of treatment protocols. The latter can indeed be standardized, but they must be able to be customized in response to the extreme variety and complexity of the conditions involved, which frequently appear to have blurred contours and are difficult to identify (1, 7-10). He we report the experience of the Dental Clinic of Milano Bicocca University.

MATERIALS AND METHODS

The patient with special needs, as defined by the Italian Ministry of Health (2019), requires different times and methods from the routine in preventive, diagnostic, and therapeutic operations. When in a state of "non-cooperation," they also need an appropriately equipped operational environment and adequately trained medical and support staff.

These were the premises behind creating the Clinical Center for the Care of Special-need Patients at the Dental Clinic of IRCCS San Gerardo Hospital in Monza in response to the huge requests for dental care in vulnerable patients.

This study was designed as a retrospective study, and it involved the analysis of medical records belonging to patients who presented at the Clinical Center for the Care of Special-need Patients. In conducting this study, all policies and recommendations stated in the 2008 Declaration of Helsinki were respected. All patients signed informed consent forms, agreeing to future anonymous use of the information in their medical records. The following inclusion criteria were taken into consideration:

- hospitalized patients with vulnerabilities at IRCCS San Gerardo Hospital with dental pathology;
- non-hospitalized patients with vulnerabilities who presented to the Clinical Center for the Care of Special-need Patients at the IRCCS San Gerardo Hospital Dental Clinic.

The following exclusion criteria were followed: patients without vulnerabilities and patients for whom important information was missing from the medical history and record (e.g., gender, diagnosis, age).

Several variables were investigated and used to obtain important results. These variables were age (pediatric patients 1-14 years), adults (15-63 years), geriatric patients (over 64 years), gender, type of clinical vulnerability, and dental pathologies. The medical history, the clinical procedures, and the evolution of the case through to the dental follow-up of the patient were also identified and noted (11, 12).

A clinical protocol was set and followed by the team at the Clinical Center for the Care of Special-need Patients at the Dental Clinic of IRCCS San Gerardo Hospital.

RESULTS

During the analyzed period (September 2022 – September 2023), 370 patients presented at the Clinical Center to care for Special-need Patients.

Of the total number of patients, 181 (48.9%) were male, and 189 (51.1%) were female. The gender differences were not statistically significant. The patients at the time of the first access were the following: age 1-14: 258 patients; age 15-63: 29 patients; age over 64: 83 patients. The mean age was 25.5 years ± 29.0. The primary diagnosis for special-need patients with dental pathologies is shown in Table I. The most common pathology was represented by dental caries (67%), followed by periodontal disease (63%). Three hundred forty patients (91.89%) received dental treatment in an outpatient regime, while 30 (8.11%) were treated under general anesthesia.

Table I. *Diagnosis for special-needs patients with dental pathologies.*

1) First visit:

a) anamnesis of recent and past pathological history. Ample space is given to communication with caregivers and the collection of information on current or previously undertaken healthcare pathways at other facilities for the creation of an easily consultable and usable summary document;
b) clinical examination: physical examination supplemented by any necessary radiographic investigations;
c) initial assessment of the patient's level of cooperation;
d) discussion of the treatment plan with the patient and possibly with the caregivers.

2) Second visit:

a) final assessment of the level of cooperation and autonomy only after an initial intervention attempt with an appropriate psychological approach. A trust-based relationship between the operator and the patient is possible thanks to a specially trained team;
b) an initial intervention attempt can be a professional oral hygiene session or a conservative treatment;
c) if the patient is cooperative, they will be placed in an outpatient regime to undergo less invasive conservative therapies or exodontic therapies. If uncooperative, they will be treated under narcosis or general anesthesia;
d) a clinical pathway is defined based on the urgency level. Priorities for intervention, associated risks, organizational methods, and appropriate treatment timing should be indicated;
e) from an administrative point of view a specific “management” pathway is organized to fulfill all administrative practices.

3) Follow-up appointments

a. personalization of the care pathway: attention to waiting times, arrival times and methods, pre-sedation and sedation times when necessary, patient and caregiver reception areas;
b. multidisciplinary clinical evaluations for treating possible comorbidities and a holistic multidisciplinary approach:

- major precautions to be taken into account because of clinical fragilities;
- combined treatments for multiple issues in a single session under general anesthesia.

4) Clinical activity:

1. prevention: prevention is carried out by hygienists of the Dental Clinic in close collaboration with dentists. Implementing a preventive and therapeutic protocol includes frequent dental check-ups and oral hygiene sessions to maintain oral hygiene for as long as possible. Dental care is also provided in the inpatient departments of IRCCS San Gerardo Hospital.
   - teaching oral hygiene techniques at home, both for the patient and for the special-need family or caregivers;
   - information on the most appropriate diet and the prevention of bad habits;
   - periodic recalls. The challenges in this case involve maintaining proper oral hygiene at home and the lack of patient cooperation during the session with the dental hygienist.
2. treatment:
   - conservative;
   - exodontic;
   - rehabilitation is intended, on the one hand, as restoring masticatory function through implants or removable in idoneous patients with missing teeth.

Depending on the clinical examination and the main diagnosis, special-need patients received specific procedures, the most common of which were oral hygiene, caries filling, and dental avulsion.

DISCUSSION

The approach of our clinic is based on the adoption of a holistic behavioral philosophy, which is at the center of the individual with special needs and their vulnerabilities. By evaluating the multiple dental pathologies that affect the special-need population, the therapeutic protocol finds its basis in prevention, therapy, and rehabilitation.

Considering the fragile medical status of special-need patients and their vulnerability, dental pathologies could be frequent and must be addressed promptly. The predisposition to caries is due to the poor oral hygiene of patients, reduced motor function, and reduced degree of collaboration in carrying out oral hygiene maneuvers at home, often carried out by family members or carers (1, 13).

With regards to periodontal disease, its risk factors are recognized in altered salivary production, which is often altered. Moreover, the presence of macroglossia and alterations in the immune system have to be taken into account. Furthermore, the inability to correctly carry out oral hygiene maneuvers and the reduced chewing capacity due to altered neuromuscular function can predispose to the development of plaque (1, 14-16).

Oral lesions such as cheilitis, ulcers, gingival hyperplasia, aphthae, candidiasis, and erythema multiforme can occur following the intake of drugs, which often have xerostomia as an adverse effect, but also following stress conditions, immunosuppression or vitamin deficiency. Biting lesions on the genial and labial mucous membranes are also frequent, often due to self-harming behavior by patients with mental retardation (1, 16-19).

Dry mouth is often induced by drugs, and obstruction of the airways, secondary to the use of drugs such as antidepressants, antihistamines, and tranquilizers, is a frequent clinical finding. Dry mouth could also be subsequent to intubation (17- 19). Bruxism (grinding or clenching of the teeth) occurs more frequently in cerebral palsy and syndromic patients. Moreover, neuropathological mastication can be present; it is caused by the uncoordinated myotonic activity of the masticatory muscles and tongue following neuronal damage in the cerebral cortex, hypothalamus, or reticular/pyramidal systems due to brain injury, septic shock, hypoxia. Masticatory patterns during episodes of hyperactivity may include clenching, masticating, gnawing, and grinding; this abnormal chewing pattern lacks coordination with tongue movements. Tongue, lips, or oral mucosa may be positioned between the teeth with subsequent oral trauma (1, 17, 20).

The clinical protocol of the Clinical Center for the Care of Special-need Patients of the Dental Clinic of IRCCS San Gerardo Hospital sets operative guidelines for a holistic and behavioral approach to patients with dental pathologies and associated vulnerabilities.

During the first dental visit, enough time is reserved for communication with the family or the caregivers and the careful collection of medical history information and health care pathways in place or previously undertaken at other facilities. This supports communication between different professional figures within an extensive healthcare network. Subsequently, a clinical examination is performed, complementary to the radiographic and other instrumental investigation analysis, when possible. At the end of the visit, the patient's degree of collaboration is assessed, and the treatment plan is discussed. The latter can take two directions, depending on the autonomy and cooperation of the individual with special needs. If the patient is cooperative, he will be placed on an outpatient basis to be able to face less invasive conservative therapies or exodontic therapies. It is important to note that collaboration of the patient is not a given, especially in the case of pediatric patients (1, 2, 15, 21-26).

Where, however, the patient is not cooperative, he will be treated in a state of narcosis with an exodontic and surgical approach to the compromised dental elements. Sometimes, the ability of the dental clinician, with the support of the special-need patient family, to establish a relationship of trust with the patient, to place him in a favorable, harmonious, and familiar environment with the professional figures and the dental unit, can avoid clinical activity under narcosis or general anesthesia.

CONCLUSIONS

Patients with fragilities can be difficult for dentists and dental hygienists to manage and treat. Due to the high number of patients who need special assistance, dental practitioners must know about the most frequent oral alterations and diseases to offer adequate dental care to these individuals and be aware of their limitations.

Caretakers must learn about basic oral hygiene maneuvers since preserving teeth is the first step to maintaining a healthy oral condition for a special-needs patient. It would be important to develop health promotion measures, such as lectures to instruct parents and caretakers, emphasizing the importance of good oral hygiene and the problems that can

arise from its absence. Also, diet, psychological support, and a holistic approach between different medical specialists are of primary importance (15, 27).

This study has some limitations. First, the research was conducted in a single center in Northern Italy, and the information could vary in different medical centers in other regions. It is possible that the population in other regions of Italy presents other characteristics, and the results presented in this study could differ from those conducted in other regions. For this reason, a multicentric approach with national results is advisable to investigate special-need patients at a national level to gain an overview of this group and to be able to lay the foundations for national preventive programs. A holistic approach and easy access to dental clinics would be an important step in preventing the worsening of dental pathologies.

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Pre-Clinical Study

SINUS LIFT WITH LATERAL WALL BONY WINDOW: COMPARISON OF THREE METHODS FOR THE PERFORMANCE OF ACCESS ANTROSTOMY. A BLINDED RANDOMIZED PRE-CLINICAL TRIAL

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ABSTRACT

Maxillary sinus lift procedure with lateral wall bony window is now considered, among the pre-prosthetic surgical techniques, the one with the highest level of predictability. This blinded randomized trial, at a pre-clinical level, compared performances of rotating, piezoelectric, and DASK instruments for the antrostomy access to the lateral wall of the maxillary sinus to evaluate traumaticity and operative timing. Access antrostomy to sinus lift was performed on chicken eggs by 60 dental students divided randomly into three groups. Each group was asked to perform an antrostomy using conventional rotary instruments, piezoelectric surgery, and DASK instruments. The $\chi 2$ test was used to compare perforations, while the analysis of variance (ANOVA), with subsequent comparison of the variances obtained by Fisher's LSD test, allowed for evaluation of the timings recorded. The total drilling rate was 18.5%, while the percentage recorded for each technique used was 16.6%, 33%, and 5% for rotary, piezoelectric, and DASK instruments, respectively. Lower timings have been observed with rotary instruments rather than piezoelectric inserts and DASK instruments. DASK instruments proved to be an interesting alternative in terms of minimally invasive surgery, while, as far as the time factor is concerned, the best performance was achieved with rotary instruments. Despite the lengthening of the execution, timing, and the high number of perforations, the characteristics of reduced injury and increased handling have made piezosurgery the best method to convey greater safety to the operators.

KEYWORDS: *maxillary sinus lift, lateral access, DASK instruments*

INTRODUCTION

A sinus lift is a surgical procedure to increase the bone volume available on the posterolateral maxillary side, ensuring the possibility of rehabilitation with osseointegrated implants (1,2). The biological rationale of this method is based on the ability of a graft material to promote bone formation in a surgically set up compartment between Schneider's membrane and the sinus walls (3).

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This procedure can potentially rehabilitate atrophic maxillary bone associated with edentulism (1). As a result of the loss of dental elements and the decrease of masticatory forces in the maxillary jaw, the sinus walls undergo a gradual thinning secondary to the sinus pneumatization process. The prolongation of the edentulous state is also decisive for the extent of alveolar ridge resorption and antral pneumatization of the alveolar process (4). The maxillary sinus lift procedure with lateral wall bony window is now considered the one with the highest level of predictability among the pre-prosthetic surgical techniques (5).

When success is linked to implant outcome, a >90% implant survival rate has been recorded through a correct approach regarding the chosen implant surfaces (wrinkled), graft materials (xenografts), and the use of a membrane that acts as a barrier at the level of the antrostomy.

When success is measured according to the patient's outcome, a good result is attributable to a low incidence of complications that can be easily prevented with the help of careful pre-operative selection, correct surgical technique, and timely treatment of intra- and post-operative complications (6). The incidence of these latters, as reported by a systematic review of the literature, is low and stands at 3% (7). Although small, this type of surgery is associated with complications, which are often predictable and sometimes unavoidable (1).

Among the most common adverse events, hemorrhage is reported, which is essentially related to the lesion of the intramural artery, an anastomosis between the infraorbital artery (IOA) and the posterosuperior alveolar artery (PSAA), frequently located in the area used for antrostomy. This anastomosis supplies blood to the sinus membrane, the periosteum, and, above all, the sinus bone wall. The scientific literature reports an average distance of this vessel of 16.9 mm from the maxillary alveolar ridge. However, this may vary depending on the height of the residual bone crest, the class of maxillary atrophy, and the presence of dental elements. The diameter of such a pot is variable and is between 1-2.5 mm.

If the lesion of a vessel with a diameter of <2 mm can be considered of little relevance from a clinical point of view, the section of a vessel of greater width is likely to lead to copious bleeding and reduced visibility that can lead to perforation of the membrane, prolonging the operative timing and interfering with the grafting procedure.

In addition, bleeding from this vessel can displace the grafted material due to a "washing effect" due to blood pressure that reduces or impairs spatial filling below the Schneider's membrane. The appearance of a consistent hematoma at the level of the cheek and the creation of a fertile ground for bacterial reproduction with consequent infection is also documented (8).

However, perforation of the Schneider's membrane represents the most unfavorable and frequent complication related to sinus lift. The integrity of the membrane is considered essential to ensure the health and proper functioning of the maxillary sinus (4-9). The sinus membrane comprises pseudostratified, ciliated, and cuboid cells and is between 0.3 and 0.8 mm thick (10). The mucociliary system protects the sinus from infection by removing microorganisms trapped by the mucus using the natural ostium. The membrane also acts physically as a biological barrier, and any perforation would lead to an increased risk of infection since a large number of bacteria would have access to the grafted material. Membrane tearing negatively affects surgical outcomes, increasing the risk of iatrogenic sinusitis, impairing homeostatic function, and leading to dispersion of grafted material in the antral cavity and bacterial colonization (1).

Both anatomical predispositions and technical factors are involved in the risk of perforation. The following predisposing factors reported in the literature are antecedent inflammatory processes, irregularity of the sinus floor (often caused by root protrusion), membrane thickness of <1.5 mm, limited expansion of the anterior recess, and an angle between the medial and lateral wall <30°. Two anatomical factors are involved in determining membranous laceration: the presence of intrasinus septa and the residual height of the alveolar ridge. The maxillary sinus is divided into two or more recesses by bony septa (Underwood's septa), whose prevalence is between 13 and 35% (11) and, since the membrane is thinner in correspondence with these septa, the risk of perforation, especially during detachment of the membrane is greater (10). On the other hand, it is reported in the literature that with a residual crestal bone height of 6 mm, a risk of perforation is less than 25%, while this risk increases to 85% if the crestal height is <3 mm. 4.9% (12). While these anatomical factors often make perforation unavoidable, this can sometimes be prevented with the aid of a correct surgical technique.

From a technical point of view, sinus membrane perforation can arise both from the antrostomy technique and the detachment and lifting of the membrane. As far as antrostomy is concerned, the evolution of surgical techniques is directed toward reducing complications that negatively affect procedural success, decreasing the percentage of perforations and, consequently, the number of interruptions of the surgical procedure (5). It is shown that 10% of perforations cannot be repaired, inevitably resulting in a failure of the sinus lift procedure (13).

The amplitude of the antrostomy is a compromise between preserving the bone wall as a source of blood supply to the future grafted material and achieving sufficient access and visibility to practice membrane lifting and bone grafting (5).

Although the use of conventional rotary instruments has proven to be a predictable technique over the past 30 years, it is particularly prone to the previously listed complications of perforation and, above all, profuse intraosseous bleeding. Piezoelectric bone surgery is a valid alternative to rotating instruments, which use low-frequency ultrasonic vibrations to realize the antrostomy and lift the membrane.

This technique will likely be less traumatic to blood vessels and Schneider's membrane (14). Wallace et al. (15) showed that in a series of 100 cases in which piezoelectric surgery was used, the risk of perforation dropped from 30% to 7%.

However, there is no consensus on the superiority of this latter technique compared to the drill since several studies have found a comparable risk of perforation between the two techniques used (16). The less traumatic nature of the technique would seem to be defined by the surgeon's personal experience with one or the other method. However, an objective limitation of piezosurgery would seem to be the increased surgical timing required to complete the antrostomy compared to the conventional method (16, 17).

The DASK technique was developed to offer a non-piezoelectric alternative with the equivalent ability to reduce soft tissue complications. The lateral approach, described by Lozada et al. (17), consists of the progressive erosion of a bony window on the lateral wall of the maxillary sinus made with the aid of a single dome-shaped bur (6 or 8 mm in diameter and 4 mm in height) with non-aggressive diamond grain and internal and external irrigation. The bur is used with light pressure to erode the bone wall until the bluish appearance of the membrane is visible (5). According to the author's experience, this technique can potentially reduce surgical timing by using a single drill without piezoelectric inserts and other conventional additional instruments. At the same time, it can decrease the incidence of perforations.

This work aims, at a pre-clinical level, to compare conventional rotary instruments, piezoelectric inserts, and DASK instruments in the performance of the access antrostomy to the lateral wall of the maxillary sinus to evaluate traumaticity and operative timing.

MATERIALS AND METHODS

A blinded randomized pre-clinical trial was carried out at the Dental Clinic of the IRCSS Foundation San Gerardo in Monza, Italy. Sixty dental students were recruited for the study, using chicken eggs to simulate access antrostomy for a sinus lift. It is known that the sinus cavity is covered by Schneider's membrane and circumscribed by a bony compartment, which can be compared, for educational purposes, to the inside of a hen's egg enclosed in a shell and separated from it by the testaceous membrane (6, 18, 19).

Sotirakis and Gonshor (18) also experimented on chicken eggs with a technique of maxillary sinus lift by hydraulic pressure, fracturing the shell and creating access to the testaceous membrane of 3.5-4 mm at one of the two poles of the egg.

Animal models are generally not good candidates for conducting such experiments because the sinus membrane that characterizes them is thicker and more resistant to perforations than humans. As seen from a study by Watzek comparing sinus membranes (Fig. 1), the testaceous membrane has a thickness most similar to that of the human membrane (20).

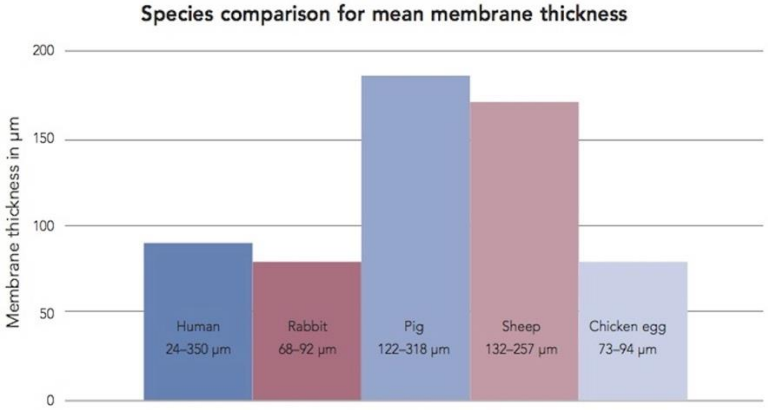

Fig. 1. *Species comparison for mean membrane thickness.*

Operators were selected following well-defined criteria regarding theoretical knowledge of the sinus lift technique, operational inexperience regarding this technique, and a good level of compliance and logistical problems. Operators were divided into three groups using a blind randomization process. Each group was asked to perform the rotary antrostomy with each type of technique analyzed: rotary instruments, piezoelectric surgery, and DASK instruments.

The experimentation was preceded by the screening of an illustrative video to provide the recruited subjects with a basic approach regarding the use of the three devices. The antrostomy with conventional rotary instruments involved the use of a round diamond cutter mounted on a straight handpiece for the design of the window on the eggshell. At the same time, the piezoelectric shell was carried out utilizing inserts dedicated to the ostectomy, working at low frequency and micro-vibrations between 20 and 60μm.

A dome-shaped cutter (6x4mm) was used to erode the eggshell using the DASK technique, applying light pressure, small circumferential movements, and keeping the device tilted at 45° concerning the work surface.

The antrostomy was carried out for each technique on eggs pre-marked by ellipsoidal stamping measuring 1.5x1cm. An examiner was also recruited to check each of the three instruments examined. The controllers carried out the task of timing each antrostomy performed in the order of tenths of a second and recording the perforations that occurred.

In this work, a reduction of bias and confounding factors was obtained, in addition to the application of strict inclusion criteria and the blind randomization process, concerning the following parameters: the use of identical samples, same location for each selected operator, and the aim of the study not available to the recruited operators, to have a blinded study.

To compare the perforation percentages for the three devices analyzed, the $\chi 2$ test was used. The evaluation of the timing of the antrostomies was conducted primarily by Analysis of Variance (ANOVA) and subsequent comparison of variances using the Fisher test with post hoc analysis by Fisher's LSD test.

RESULTS

The perforations that occurred in the trial were 10, 20, and 3, respectively, for the rotary, piezoelectric, and DASK instruments. Total perforations were 18.5% while the percentage recorded for each technique used was 16.6%, 33%, and 5% respectively for the rotary, piezoelectric, and DASK instruments (Fig. 2).

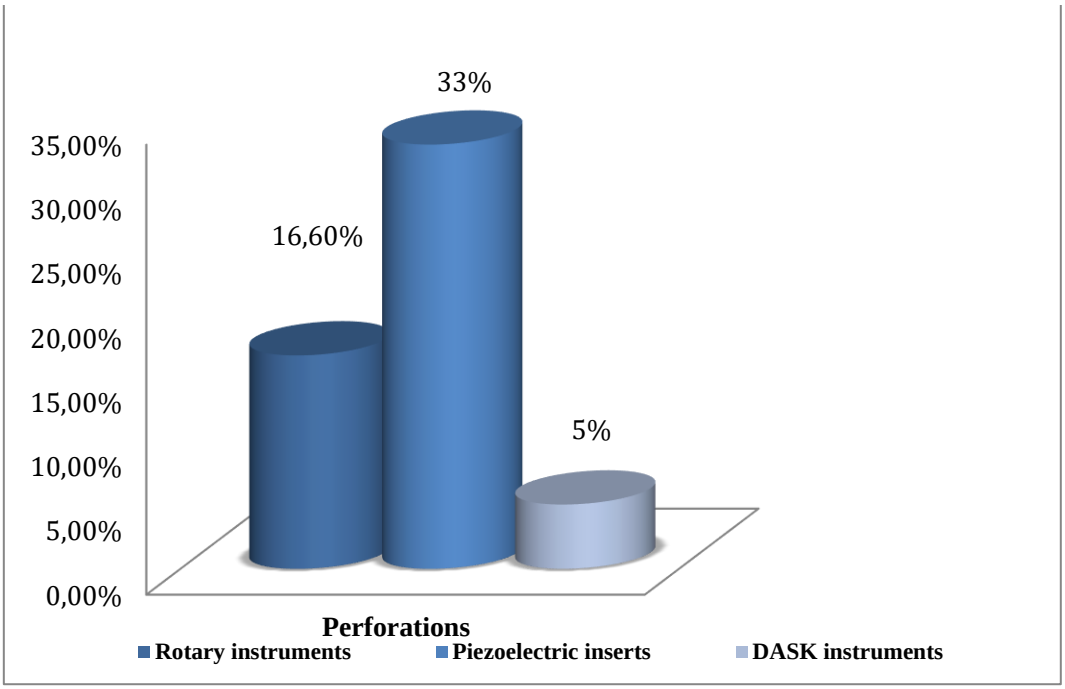

Fig. 2. *Perforation rates for the 3 methods.*

For the comparison between the percentages of perforations obtained, the $\chi 2$ test was used. It is a test that aims to evaluate whether the null hypothesis is probabilistically compatible with the data. In this study, the null hypothesis states that the observed difference between the percentages obtained is exclusively random and not attributable to the surgical technique used. The purpose of the χ^2 test is to know whether the observed frequencies (Table I) differ

significantly from the theoretical frequencies (Table II). Therefore, we started with constructing the contingency tables containing the obtained perforation values and those expected in which the latter were obtained considering a total perforation percentage of 18.5% regardless of the type of technique used.

Table I. *Frequencies of the study for the 3 methods.*

Method	Eggs with perforation	Eggs with no perforation	Total
Rotary instruments	10	50	60
Piezoelectric inserts	20	40	60
DASK instruments	3	57	60

Table II. *Frequencies expected regardless of the surgical technique.*

Method	Eggs with perforation	Eggs with no perforation	Total
Rotary instruments	11,1	48,9	60
Piezoelectric inserts	11,1	48,9	60
DASK instruments	11,1	48,9	60
Total	33,3	146,7	180

The chi-square formula is the sum of the ratios between observed and expected values and the expected ($\sum \frac{(O-E)^2}{E}$) between the squares of the differences frequencies, and the value obtained was χ^2=13.1.

The obtained value of $\chi 2 = 13.1$, in relation to distribution for k -1 = 3- 1 = 2 gdl (k indicates the number of groups), compared with the critical value χcrit2, that is the value of χ corresponding to the probability of type I error, ($P < 0.05$) is higher (χcrit2 = 5.99). This allowed us to conclude that there was a significant difference between the groups considered.

However, this value is not exhaustive because three proportions are compared, and it does not indicate which are significantly different. The comparison was therefore extended to a "post hoc" analysis to establish how many and which proportions are different.

There were essentially two comparisons between rotary instrumentation - DASK instruments and piezosurgery – DASK instrumentation. The resulting $\chi 2$ values of 4.23 and 15.4, respectively, were higher than χcrit2 by 1 gdl (3.84) at a probability level of 5%. It is, therefore, possible to admit the rejection of the null hypothesis according to which the observed differences are random, and to accept the alternative hypothesis that admits a real difference between the proportions obtained.

In addition to the percentage of perforation, this study aimed to evaluate the timing of antrostomy with the three surgical techniques listed above. Mean values and the respective standard deviations obtained with the rotary, piezoelectric, and DASK instruments are (Fig. 3): (2.77 min ± 1.56), (3.83 min± 1.87), (4.36 min±1.96).

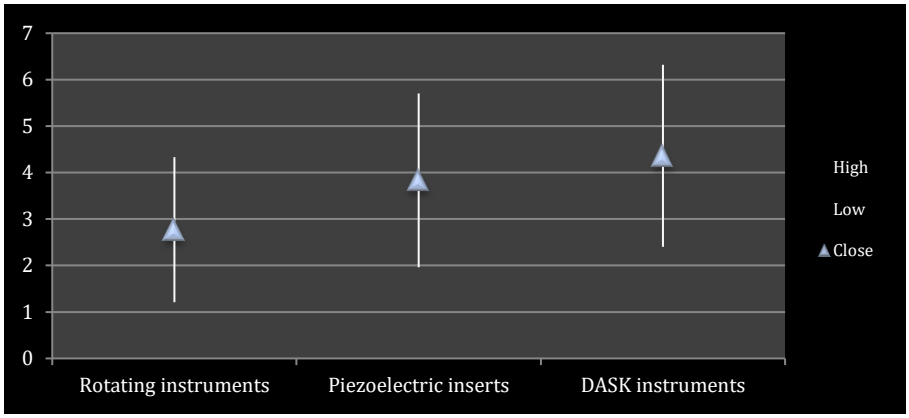

Fig. 3. *Timings measured for the 3 methods.*

The visible difference between the means may be attributable to the type of technique used (variance between groups), rather than to individual differences between recruited subjects and a random error (variance within groups). To test the hypothesis of difference between the three means, the ANOVA test (analysis of variance) was applied, which allows the comparison of more than two sets of data without increasing the probability of error.
Statistically, it is given by the sum of the squares of the data deviations from the general mean of all data (total variance) which can be divided into the sum of the squares of the deviations of the group means from the general mean (variance between groups) and the sum of the squares of the deviations of the data from the mean of each group (within-groups or error variance).

If the variability between groups and within-groups were equal, we could accept the null hypothesis that denies the presence of significant differences between the means and a possible effect of the type of surgical technique used.

On the other hand, if the variability between the groups is greater than the variability within the groups, we could reject the null hypothesis previously illustrated and accept the alternative one that admits the variability due to the method used.

The analysis of variance primarily involved the calculation of total deviance, deviance between the groups and within the groups (Table III).

Table III. *Calculation of deviances.*

	Deviance	**Degrees of freedom**
Total	$\sum(x_{ij} - \bar{x})^2 = 540.85$	$(N - 1) = 146$
Between groups	$\sum(x_j - \bar{x})^2 = 67.99$	$(k - 1) = 2$
Within groups	$\sum(x_{ij} - \bar{x})^2 = 472.86$	$(N - k) = 144$

x_{ij} *- i operator's response in the j group;* $\bar{x}$ *- overall average of all data;* x_j *- j group average; N - number of operators; k - number of conditions.*

The next step is to transform the deviances between and within groups into their respective variances, dividing by their number of degrees of freedom.

$$\sigma^2_{between} = \frac{67,99}{2} = 33.99,$$

$$\sigma^2_{within} = \frac{472,86}{144} = 3.28.$$

The analysis of the variance continued, then, with the comparison of using Fisher's statistical test, whose sample distribution is known.

$$F(K - 1, N - 1) = \frac{\sigma^2_{between}}{\sigma^2_{within}}$$

$$F(2,144) = \frac{33,99}{3,28} = 10.36.$$

From the comparison of the value of F obtained with the critical value, provided by the distribution tables, with 2.144 gdl and $\alpha = 0.05$, it was possible to reject the null hypothesis, according to which the difference between the observed means is due to chance. The F value of 10.36 was higher than the critical value of 3.0.

As previously considered, this result is insufficient as it states that the two averages are significantly different but do not indicate which ones. It is, therefore, necessary to carry out post-hoc comparisons to establish how many and which averages are different. In this study, Fisher's LSD (Least Significant Difference) test was used (Table IV).

$$LSD = \frac{\bar{x}_i - \bar{x}_j}{\sqrt{\sigma^2_{within}\left(1/n_i + 1/n_j\right)}},$$

which are the means and numbers of any two groups.

Table IV. *Calculation of Fisher's LSD.*

	LSD
Rotating instruments/piezoelectric inserts	$\frac{(2{,}77 - 3{,}83)}{\sqrt{3{,}28\left(1/50 + 1/40\right)}} = 2{,}78$
Rotating instruments/DASK instruments	$\frac{(2{,}77 - 4{,}36)}{\sqrt{3{,}28\left(1/50 + 1/57\right)}} = 5{,}1$
DASK instruments/piezoelectric inserts	$\frac{(4{,}36 - 3{,}83)}{\sqrt{3{,}28\left(1/57 + 1/40\right)}} = 1{,}60$

The obtained value of LSD was compared with the critical value provided by the distribution (Table IV), relating to the degrees of freedom of the error variance, 144°.

Suppose the values of LSD obtained from the comparison between rotary/piezoelectric instruments and between rotary/DASK instruments, respectively 2.78 and 5.1, exceed the critic value (1.64). In that case, the same does not occur for the LSD calculated from the comparison between DASK/piezoelectric instruments (1.60). The difference in the averages obtained for the execution of the antrostomy with the latter two techniques was, therefore, not statistically significant.

DISCUSSION

This pre-clinical randomized experimental trial aimed to evaluate the invasiveness, in the form of risk of perforation, and the rapidity of three different surgical techniques to realize the access antrostomy for sinus lift.

Perforation of Schneider's membrane is the most common adverse event related to the sinus lift procedure, with a percentage between 7% and 56% (16, 21) and, as previously illustrated, it is due both to anatomical features (irregularity of the sinus floor, presence of bone septa, thickness of the membrane, etc.) and to an inadequate surgical technique. The chicken eggs used in this study, all identical, made it possible to neglect the anatomical factors by analyzing only the surgical technique used.

The perforation percentages obtained in this study showed a statistically significant difference. The post-hoc analysis carried out by applying the chi-square test on each pair of techniques examined showed, in contrast to some clinical results reported in the literature, a lower traumaticity of rotary instruments compared to piezoelectric ones with 16.6% of perforation of the former compared to 33% of the latter. The result obtained by us, however, does not differ from the experience of authors such as Rickert et al. (16) and Barone et al. (22), in which the comparison between the test group (piezosurgery) and the control group (rotary instruments) showed in the first case overlapping results and in the second case superior invasiveness of the tested technique, although statistical significance was not observed.

The differences observed between DASK instruments and the other two procedures examined were equally statistically significant. According to the results, the DASK cutter used was less traumatic than conventional instruments and piezoelectric inserts ($P<0.05$), where the P value indicates the probability of rejecting a true null hypothesis.

In agreement with the results obtained by Lozada et al. (17), the first to have experimented with this technique, who reported only one perforation out of 17 patients (5.8%), the outcomes of our study are placed with 3 perforations out of 60 treated samples (5%).

Although negligible from the point of view of procedural success, but not completely non-significant from an ergonomic point of view, especially in the case of a high thickness of the sinus bone wall, this study wanted to consider the time factor. A limitation of piezoelectric inserts that comes from the literature is related to the timing of the execution

of the antrostomy, which seems to be fivefold that used with rotary instruments. This appears to be caused by the reduced cutting capacity of piezoelectric inserts compared to conventional instruments. The creators of the DASK method, which is an antrostomy by erosion of the sinus bone wall, ensure the effectiveness of this technique and the reduction of perforations and operating times.

The mean timings and related standard deviations calculated in our study showed significant diversity. This significance was confirmed by the post-hoc analysis, using Fisher's LSD test, between rotary instruments and the other two methods analyzed. In clinical terms, this means using conventional instruments faster than piezoelectric inserts and DASK instruments. If the first result has been documented in the literature (16), the only available case studies for the second result are those provided by Lozada et al. (17).

In the comparison between DASK and piezosurgery, however, slightly higher than the first average compared to the second, the significance threshold was not reached. Therefore, the timing used for the latter two procedures appears to overlap.

Finally, the report of the evaluations obtained by the students showed how the piezoelectric method was capable of instilling greater safety in the operator than the other two techniques. This seems to arise from this instrumentation's easy handling and lightness compared to the heaviness and greater cutting capacity of rotary tools.

On the other hand, the DASK system proved unintuitive and less easy to use, probably due to the complex working setup required by the cutters.

CONCLUSIONS

Sinus lift aimed at implant rehabilitation of the posterior maxillary area is considered a predictable procedure that needs to follow some rules to obtain a good result. To this end, a correct surgical technique is essential, which must be oriented towards reducing the percentage of perforation of the Schneider's membrane, the most common reported adverse event which, while in most cases it can be resolved, in others it can cause the interruption of the elevation procedure.

The evolution of surgical techniques for access antrostomy first proposed piezosurgery and, in 2011, the DASK instrumentation (4,11). From the results obtained in this study, it can be concluded that if piezoelectric inserts did not provide any advantage over conventional instruments, the DASK method showed significantly less traumaticity.

Regarding the timing used, the best performance was the one conducted with the rotary instruments, while longer times were recorded for the other two techniques. The difference observed between the latter, however, was not significant. From a clinical point of view and for implant rehabilitation, reducing invasiveness is the most desirable feature of a surgical technique, with increased operating times.

However, the traumaticity tested in this study concerns only the first part of the sinus lift procedure, the antrostomy. It is well known that the risk of iatrogenic perforation can also arise from the detachment and lifting of Schneider's membrane. This evaluation goes beyond the scope of this work.

The DASK instrumentation has proved to be an interesting alternative from the point of view of minimally invasive surgery. We refer to future phase I clinical studies, a new comparison between the methods illustrated that also includes the membrane detachment phase and the introduction of instrumentation that preserves the reduced traumaticity of the DASK burs and, simultaneously, reduces the timing.

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Clinical Retrospective Study

A NEW PROTOCOL FOR SCANNING AND DESIGNING MONOLITHIC ZIRCONIA CROWNS ON IMPLANTS: A CLINICAL CASE

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ABSTRACT

The advancement of digital dentistry has been remarkable thanks to intraoral scanners (IOS), which have improved the accuracy and reliability of dental impressions compared to traditional methods. However, the accuracy of intraoral scans is influenced by numerous operator-related factors and patient-dependent variables, which can compromise the quality of scans and, consequently, the fabrication of prosthetics. This study presents a protocol to provide personalized calibration for intraoral scans used to fabricate definitive dental crowns. The protocol aims to minimize errors introduced by the operator and variables. Initially, a trial model is created, simulating the definitive crown. This model represents a transitional phase between the provisional and final crowns and will continue until accurate calibration of the detected impressions is achieved. The goal is to reduce the time required for delivering definitive crowns, allowing the operator to provide them without the need for further modifications during placement and screwing of the crown.

KEYWORDS: *digital impression, intraoral scanning, precision, digital workflow*

INTRODUCTION

The most significant development in dentistry in recent years is digital dentistry (1). Digital dentistry encompasses numerous innovations, one of the most significant being the intraoral scanner (IOS). The development of IOSs has been driven by the aspiration to improve traditional impression-taking processes, which are often prone to human error, with the ultimate goal of making impression no-operator dependant (2).

IOSs have marked a paradigm shift in the industry, offering substantial benefits ranging from increased patient comfort to producing higher-quality dental crowns through a new and more accurate impression (1-3). As a result, these digital technologies have gained profound recognition as reliable and precision-oriented tools for recording dental structures and are becoming increasingly popular in dental practices (4).

IOSs are equipped with cameras that record individual images or videos, which are subsequently processed by software (5). The multiple sets of points (or point clouds) generated through the optical sensors are recorded sub-

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sequentially (aligned with respect to each other). They are assembled into a surface pattern represented as a triangular mesh (5). The algorithms used by IOS software programs can generate files with different mesh densities. A mesh is a collection of vertices and triangles and includes information about how the vertices make up the triangles and how the triangles are connected. Higher-density meshes usually produce more accurate analysis results or a more detailed reproduction of the surface (6).

Based on the assumption that dental impressions, whether conventional or digital, have the main purpose of obtaining an impression of one or more prepared teeth, adjacent teeth, and antagonistic teeth, along with the inter-occlusal registration relationship (7). Therefore, reproducibility of the impression is a key criterion that reflects the outcome of the designed restoration. Beyond the operational and clinical differences (speed of use, need for powder and tip size) and costs (purchase and management) of the various scanners, the essential aspect to be considered must be the quality of the data derived from the scan, which is referred to as “accuracy” (8). Accuracy is the consolidation of two elements, both essential and complementary: “exactness” and “precision”. “The term 'accuracy” refers to the ability of a measurement to match the actual value of the measured quantity (8). Precision is defined as the ability of a measurement to be consistently repeated, or simply put, the scanner's ability to obtain repeatable results when applied to different measurements of the same object (8).

Multiple factors that may reduce the accuracy of IOS scanning have been identified in the dental literature. Understanding and recognizing these influencing factors will increase the predictability and reliability of dental treatments performed with digital workflows. These factors are operator- or patient-related.

Operator-dependent factors are the skills and professional decisions of the dentist that influence the accuracy of IOS scanning. These include IOS technology and system choice, scan head size, calibration, scanning distance, exposure of IOS to changes in ambient temperature, ambient humidity, ambient lighting conditions, operator experience, scanning pattern, scan extension and interruption, surveillance, and overlap procedures.

Technology and IOS system

The dentist's first decision is to choose an IOS system. Several scanning technologies and IOS systems are available on the market (5). Each IOS system has limitations determined by the hardware and software characteristics of the selected device. When choosing an IOS, the variations are initial cost, monthly subscription fees, scanning speed, size, ease of use, presence of a caries detection function, software features, wireless option, and manufacturer support. Discrepancies in scanning accuracy have been reported in the dental literature among the different scanning technologies and systems available based on various clinical applications (9).

Scan head sizes

Scan head sizes differ among the various IOS available on the market. Smaller head sizes are practical when acquiring digital intraoral scans with complex access constraints, such as for patients with limited mouth openings. However, very few IOS systems provide different scan tip sizes for the same IOS device.

Only a limited number of studies have evaluated the influence of scan head size on the accuracy of intraoral digital scans (10, 11). These have reported higher intraoral scan accuracy when using larger scan heads than smaller ones (10, 11). However, further studies are needed to evaluate the impact of scan head size on scan accuracy of different IOS further.

Ios calibration

All IOSs require the scanner to be calibrated by the operator or dental professional, except some commercial houses with an auto-calibration system. The calibration procedure should be included in daily protocols before the start of the data collection procedure so that a quality scan can be achieved (12).

Scanning distance

It is essential to distinguish the concept of scanning distance and scanning depth: scanning distance is the distance between the surface to be scanned and the tip of the IOS system. Scanning depth can be defined as the focal depth at which the scanner can acquire reliable data. However, the selected IOS hardware determines the optimal scanning distance and focal depth of the scanner. Each IOS manufacturer describes the optimal scanning distance for appropriate system management and to optimize IOS performance (13).

Variation in ambient temperature

The dental literature has recently identified exposure of the IOS to variations in environmental temperature, which can easily occur in a dental office, as a variable that can affect the accuracy of intraoral scanning (12). To minimize the influence of this variable on scan accuracy, IOSs should be calibrated before starting each working day.

Environmental humidity

Environmental humidity also appears to reduce the accuracy of intraoral scan identification (14); however, further studies are needed to determine the influence of this variable. The literature recommends that IOS be calibrated daily to minimize the effect of environmental humidity on IOS performance.

Ambient lighting

Ambient lighting conditions, i.e., the ambient light intensity of the room in which the intraoral digital scan is acquired, significantly impact the accuracy of IOS scanning in dental patients. Although no universal optimal illumination condition can maximize the accuracy of all IOSs, most IOSs perform best under ambient illumination conditions of 1000 lux, i.e., ambient illumination conditions (15). To achieve this ambient lighting condition, turning off the dental chair light while leaving the room ceiling light on is necessary. It is important to understand that each room or operating room may have different ambient lighting intensities; therefore, using a luxmeter placed on the patient's mouth is recommended to standardize the ambient lighting conditions (15).

The operator's experience

Operator experience is a factor that can affect scanning accuracy, where the more operator experience, the more accurate the intraoral digital scan. This report is based on the evidence that a patient with more experience with IOS reduces the scanning time to improve the efficiency of the digital procedure (16, 17).

Scanning scheme

The scanning pattern or digitizing sequence performed during the acquisition of an intraoral digital scan significantly affects the scanning accuracy of IOS (18). Therefore, if the scanning scheme is changed, the accuracy of the intraoral digital scan will vary (18). In general, following the scanning scheme recommended by the manufacturer of the chosen IOS guarantees better results.

The extension of the scan

The extent of the intraoral digital scan can affect the accuracy of IOS; the literature has reported higher accuracy on half-arch scans than on full-arch scans (19). Mid-arch scanning is indicated when making tooth- and implant-supported crowns and short-span fixed dentures (20).

Methods of cutting, rescanning, and overlapping intraoral scanning

In the dental literature, cutting and rescanning procedures have been identified as factors that can reduce the accuracy of intraoral scanning (21). Therefore, cutting and rescanning procedures should be completed to maximize the accuracy of scanning without allowing further modification of the preexisting digital intraoral scan (22).

In addition to operator-dependent factors, there are patient-dependent factors. These are represented by all of the patient's oral conditions that may affect the accuracy of the scan, such as tooth type, the presence of interdental spaces, variations in arch width, palatal characteristics, humidity, existing restorations, surface characteristics to be digitized, edentulous areas, interplanar distance, position, angulation, and depth of existing implants, and implant scan body selection.

The clinician cannot change the patient's intraoral conditions. However, systematic analysis of the patient's intraoral characteristics and identification of factors that may affect the digital intraoral scan's accuracy would improve the digital procedure's predictability and reliability.

Tooth type

Tooth type has recently been identified as a factor that can influence the accuracy of intraoral scanning. Results showed discrepancies in scanning accuracy between different tooth types: maxillary central and lateral incisor, canine, first and second premolar, and first and second molar, obtaining that the more posterior the tooth, the lower the calculated scanning accuracy. This could be explained by the more complex anatomy of the posterior teeth compared with the anterior dentition, which might represent a more difficult geometry to digitize with IOS (23).

Interdental spaces

The literature shows that the presence of diastemas and/or narrow spaces between dental preparations and adjacent teeth affect the accuracy of intraoral scanning. This is due to the limited accessibility of the IOS and the limited scan angle that makes data acquisition procedures difficult, resulting in reduced scan accuracy (24).

Arch width

This factor was considered as a value that could influence accuracy; however, no significant discrepancies were found with respect to scanning accuracy in arches with width differences (12). Further in vitro and in vivo investigations are needed to assess the influence of arch width on the scanning accuracy of IOS (25).

The presence of the palate

The influence of the palate as an influential factor on the accuracy of maxillary intraoral digital scans in entirely edentulous patients and implant-rehabilitated patients has not been carefully evaluated in the literature.

Only one study assessed the influence of palate digitization and palatal vault height (low, medium, or high) on the accuracy of maxillary intraoral digital scans (26). The results showed higher mean values of accuracy and precision when the palate was not included in the digital intraoral maxillary scan (26). It can be concluded that although the discrepancies were not statistically significant, the higher is the palatal vault, the more significant the discrepancies in scanning accuracy obtained, and the accuracy increases when the palate is not included in the scan (26).

Tooth surface moisture

The presence of moisture on the surface to be digitized can reduce the accuracy of intraoral scanning because light reflected from the surface of wet teeth is refracted by the effect of water on the surface, thus reducing the accuracy of IOS performance (27, 28). This factor can be minimized by drying the teeth with a syringe to not affect IOS accuracy values (27, 28).

The presence of restorations

The presence of restorations on the teeth to be digitized can reduce the accuracy of the intraoral scan; discrepancies in scan accuracy have been reported depending on the restorative materials to be digitized, including material type, transparency, and surface finish (29). The literature evidence that the lowest accuracy values were obtained when scanning highly noble metal specimens, while the highest accuracy values were measured when scanning polished PMMA specimens. This factor can be minimized by applying a uniform, thin state of intraoral scanning powder that can reduce the reflectivity of the restoration, facilitate digitizing methods, and reduce scanning time (30).

Surface characteristics

When analyzing the surface characteristics that significantly affect the accuracy of intraoral scanning, we mean the geometry of the tooth preparation, the position of the tooth, the depth of the pulpal floor, the depth of the gingival floor, and the position of the finish line of the tooth preparation (31).

Tooth preparation geometry is an important factor that can reduce the accuracy of intraoral scanning; therefore, clinicians should carefully review preparations before acquiring a digital intraoral scan to reduce sharp angles and irregular or rough surfaces (31). In addition, digitizing dental preparations for full-coverage restorations has demonstrated higher scan accuracy values than scanning intracoronal dental preparations such as inlay preparations (32).

An additional variable affecting the accuracy of intraoral scanning is the surface of the scanned tooth preparation: proximal surfaces are the most difficult to scan accurately with an IOS, and the visibility of subcutaneous areas below the contour height may be limited and appear as shadow regions that are difficult to scan accurately (33, 34).

In addition to the surface area of the dental preparation, the position of the finish line of a dental preparation also significantly affects the scan accuracy values: The apico-coronal position of the finish line of the dental preparation can affect the accuracy of the intraoral digital acquisition procedure-in fact, a more gingivally located finish line is more difficult to digitize and results in more scan failures.

Gingival retraction is recommended to expose the tooth preparation finish line and facilitate the digitization technique (34). Another influential variable on scan accuracy is the position of the tooth preparation, with posterior teeth achieving lower scan accuracy values than anterior dentition (35).

The last factor to consider is the depth of the pulpal planes; the greater the depth of the pulpal and gingival planes of tooth preparation, the more significant the discrepancy or lower scan accuracy values reported (35).

Edentulous spaces

Edentulous spaces have limited anatomical landmarks and represent difficult surfaces to digitize with an IOS (36). Several studies have revealed that IOSs can reproduce solid, attached mucosa as accurately as conventional impression methods; however, registration of mobile tissues is difficult, regardless of the technology and IOS system selected (37).

Interim plant distance, position, angulation, and depth of the implant

For intraoral scanning of implant elements, different variables have been identified that can influence and reduce the accuracy of intraoral scanning; among them, we can determine the distance between two adjacent implants, implant position in the dental arch, implant angulation, and depth of existing implants have been identified as variables that can reduce the accuracy of intraoral scanning (38, 39).

Although only a limited number of studies have analyzed the influence of inter-implant distance on intraoral scan accuracy, the literature shows that an intraoral scan error increases, for which accuracy decreases as the inter-implant distance increases (39).

Regarding implant position, the literature shows that the implant placed within a dental arch achieved significantly less distortion than the contralateral implant placed in an edentulous space (39). Contrary results have been reported regarding the influence of implant angle on the accuracy of intraoral scanning. Some studies reported that implant angle reduced the accuracy of IOS scanning. In contrast, other studies showed that implant angle did not affect the accuracy of intraoral scanning (39).

Similarly, contradictory results have been reported regarding the influence of implant depth on IOS accuracy. In general, accuracy decreases as implant depth increases. However, there are inconsistencies in the dental literature regarding the influence of these variables on the accuracy of intraoral scanning (38, 39). Further studies are needed to evaluate the impact of implant-related factors on IOS scan accuracy.

Scan bodies

Few data are available to determine the optimal geometry and material of the implant scan bodies to maximize the scanning accuracy of intraoral digital scans involving single or multiple implants (40). At placing a scan body, the variables to consider for scan accuracy, are the manufacturing tolerance of the scan bodies, distortion of the scan body position caused by the closure zone, and wear of the scan body due to multiple reuses (41).

It is difficult to establish protocols based on the number of times a scanned body can be sterilized and reused. The few data in the literature seem to highlight that scan bodies made of metal might be preferable to one-piece scan bodies made of PEEK (41).

There are numerous variables that can affect intraoral scans; some can be minimized, while others cannot. As a result, the design and fabrication of prosthetic restorations are subject to various sources of distortion. This results in the fact that the work designed and fabricated by the dental technician, based on a potentially distorted intraoral scan, may appear different once placed in the mouth than how it was designed in the laboratory. This results in more time needed in the chair to fit the work to the patient or, in some cases, the need to remake the prosthetic restoration.

This article aims to provide a simple and repeatable protocol that allows the dentist to obtain parameters by which final screw-retained crowns can be fabricated on implants that do not require retouching, thus minimizing the influence of variables that can distort the intraoral scan.

MATERIALS AND METHODS

This protocol involves the introduction of a 'specimen model' crown into the manufacturing process of a definitive single zirconia prosthetic crown on implants. Through this protocol, the dental laboratory obtains parameters that allow the design and fabrication of a definitive fixed crown that can be screwed in at the time of delivery without the need for occlusal and interproximal modifications, thus obtaining a benefit in terms of time and aesthetics. This result can be achieved by working in synergy with the dental laboratory and applying to single and multiple rehabilitations on implants and devitalized teeth. All scans taken by the author were made using the Cs3600 intraoral scanner.

The protocol involves making a 'test model'. The test model is a crown made on the basis of an intraoral scan and printed with a 30-day biocompatible resin using a 3D printer. The test model represents a simulation of the future definitive crown. The design and fabrication of the test model begin after the dentist has assessed that the temporary has remained in the patient's mouth long enough, and the "test model" can be fabricated. Then, the definitive crown can be made. This model makes it possible to assess the interdental spaces, gingival margin conditioning, and, above all, the

height of the occlusion of the fixed prosthesis and the contact with the antagonist. The latter is the parameter that is subject to the most retouching when a definitive zirconia crown is delivered.

The advantage of using 30-day biocompatible resin as the material of choice for making the test model lies in the greater elasticity of this material, which lends itself better to occlusal surface modifications than crowns made of monolithic zirconia. Similar to the final monolithic zirconia crown, the "test model" is also screwed onto the implant using the T-Base.

This protocol involves designing the test model using the Exocad software, using 3D images. The image of the arch is white and shows how the test model should fit in the patient's mouth according to the technician's design based on the scan sent by the dentist.

After design and printing, the "specimen model" crown is handed over to the dentist, who, once positioned and screwed in, takes an initial scan representing how the "specimen model" is located in the mouth, specifically in relation to the antagonist, gingival contour and interproximal spaces.

After screwing it in, the dentist checks and retouches the occlusal contacts, i.e., the height of the test model in relation to the antagonist. After the occlusal retouches necessary for the patient to perceive the correct height in occlusion, a subsequent scan is performed to represent how the patient perceives the "test model" at the correct height. In cases 1 and 2 shown, this moment is defined by the image in which the arch is orange.

CASE SERIES

Case 1

The first case presented concerns a "specimen model" of a crown on an implant in position 36 (Fig. 1). In Fig. 2, the "test model" crown is shown in white. As explained above, the blank indicates the crown design prepared and subsequently printed and delivered to the dentist by the dental laboratory on the basis of the scan sent by the dentist. As shown in Fig. 2, the crown was designed with an undercut to avoid pre-contact; the distance between a selected point and the equivalent point on the antagonist is 0.303 mm.

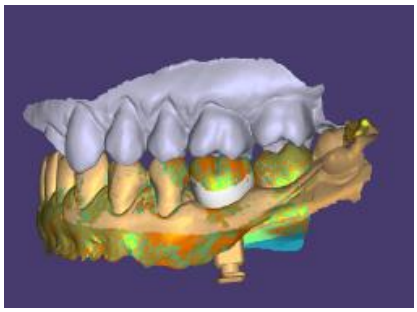

Fig. 1. *Crown on an implant in position 36.*

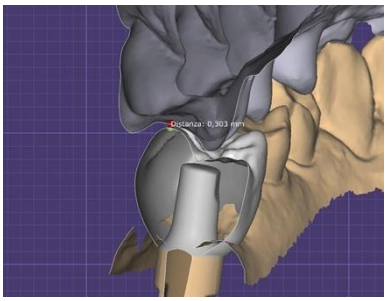

Fig. 2. *The "test model" crown is shown in white.*

In Fig. 3, the blue 'specimen model' represents the relationship between the crown, modeled in the laboratory and without modification, and the antagonist after screwing it into the mouth. As can be seen from Fig. 3, there is an area of contact between the crown and the antagonist, despite the fact that it was designed in under-occlusion. This figure demonstrates an alteration between the design and fabrication of the 'test model' and how the test model fits in occlusion compared to the patient's antagonist.

Fig. 4, where the distance between two equivalent points (0.429 mm) is shown, represents the occlusal anatomy of the test model at the moment when the patient perceives the height of the correct occlusion, following the modifications made in the mouth by the dentist. In case 1, the difference between the two equivalent points in Fig. 2, equal to 0.303 mm, and the two equivalent points in Fig. 4, equal to 0.429 mm, represents the value that, analyzed over a series of cases, takes on the role of the average value that allows the correct parameter to be obtained for the realization of a "definitive crown" with a distance from the antagonist that does not require any adjustment when the artifact is delivered to the patient.

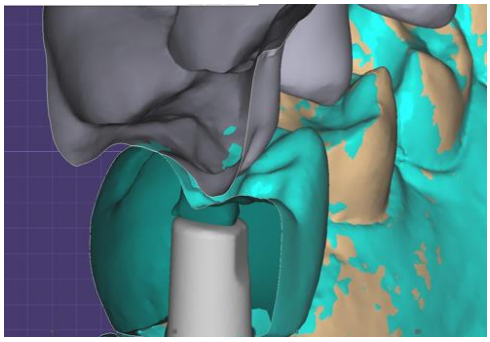

Fig. 3. *The blue 'specimen model' represents the relationship between the crown, modelled in the laboratory and without modification, and the antagonist after screwing it into the mouth.*

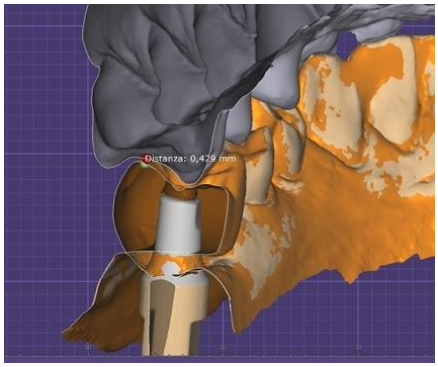

Fig. 4. *The distance between two equivalent points (0.429 mm) represents the occlusal anatomy of the test model when the patient perceives the height of the correct occlusion, following the modifications made in the mouth by the dentist.*

Case 2

Case 2 concerns a "test model" of a crown on an implant in position 25 (Fig. 5). Similar to the first case, in Fig. 5, the "test model" crown is white, representing the design of the crown prepared, printed and delivered by the dental technician based on the scan sent by the dentist. In Fig. 6, it can be seen that the crown is designed with an under occlusion on the buccal side and in contact on the palatal side.

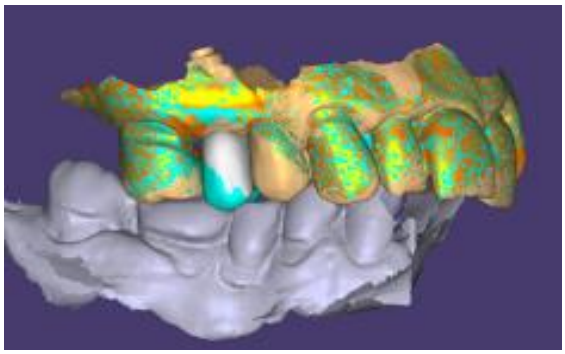

Fig. 5. *"Test model" of a crown on an implant in position 25.*

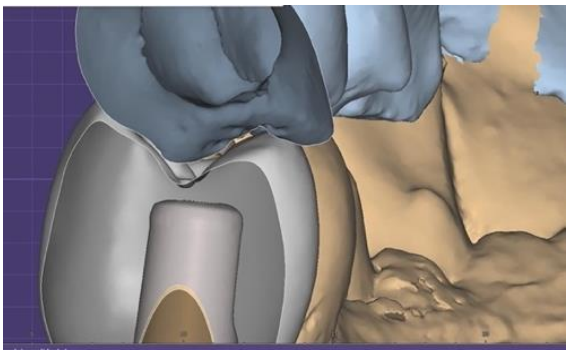

Fig. 6. *The crown is designed with an under-occlusion on the buccal side and in contact on the palatal side.*

In Fig. 7, the blue 'test model' represents the relationship between the lab-modeled crown and the antagonist immediately after screwing it into the mouth, i.e., without modification. As shown in Fig. 3, there is an area of vestibular contact between the crown and the antagonist despite the design made. As a result, the patient reports interference in occlusion.

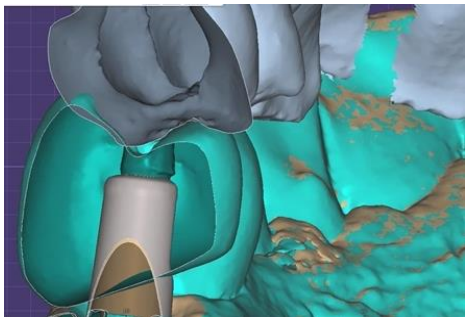

Fig. 7. *The blue 'test model' represents the relationship between the lab-modelled crown and the antagonist immediately after screwing it into the mouth, i.e. without modification.*

In Fig. 8, the distance between two points shows how, from the design phase to positioning in the mouth, the crown undergoes a rise of 0.506 mm. In Fig. 9, the crown is shown in orange, representing the crown after the modifications made by the dentist in the patient's mouth to eliminate the occlusal interference perceived by the patient and to obtain the correct occlusal height in relation to the antagonist.

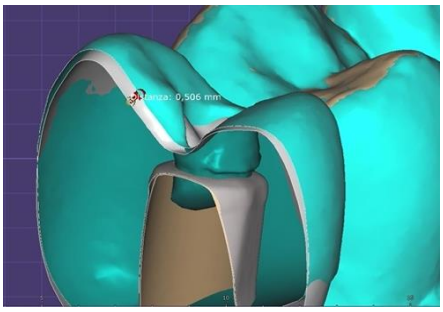

Fig. 8. *The distance between two points is shown. This distance is the difference between the design phase and the positioning in the mouth.*

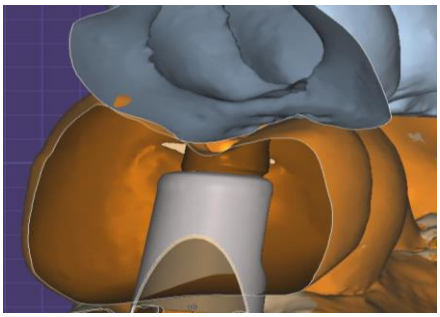

Fig. 9. *The crown is shown in orange, representing the crown after the modifications made by the dentist in the patient's mouth to eliminate the occlusal interference*

Fig. 10 shows the distance between two equivalent points: one selected on the white crown (the designed 'specimen model') and one on the orange crown (the 'specimen model' after occlusal modifications). The value is 0.396 mm. Fig. 11 represents, in section, the difference between the height of the "test model" in the mouth before occlusal changes by the dentist and after occlusal adjustments.

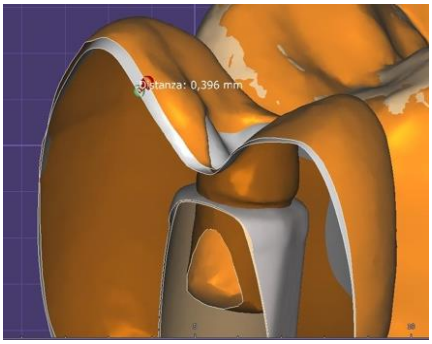

Fig. 10. *The distance between two equivalent points is shown: one selected on the white crown and one on the orange crown.*

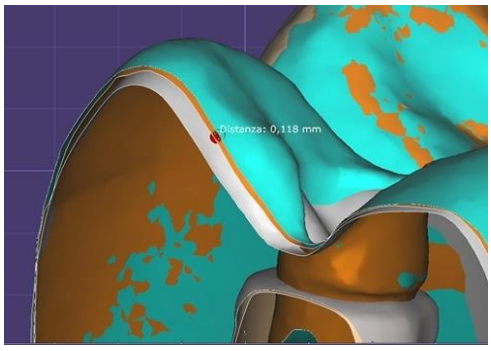

Fig. 11. *Represents, in section, the difference between the height of the "test model" in the mouth before occlusal changes by the dentist and after occlusal adjustments.*

The difference is 0.118 mm. This value, similar to Case 1, represents the value that, analyzed over a series of cases, makes it possible to obtain a correct parameter for the fabrication of a "definitive crown" with a distance from the antagonist that does not require chairside adjustments by the dentist at the time of delivery.

DISCUSSION

The cases realized according to this protocol show that the "specimen model" required modifications to the occlusal height in relation to the antagonist. After numerous cases were realized, it was possible, through the calculation of the difference between a precise point selected in the first scan and an equivalent point in the second scan (which is modified, compared to the position in the first scan, according to the patient's occlusion), to obtain an average value representing the ideal distance of the "test model" crown from the antagonist. The dental technician uses this average value as a reference parameter for the design and fabrication of all final crowns that do not require any occlusal changes with respect to the patient. Obtaining this average value makes it possible to avoid making the model and the test specimen, thus allowing the definitive crown to be designed and milled directly.

After 13 "calibrations" with a test specimen, the author obtained an average value of 0.3 mm. This value represents the reference parameter for the dental technician when designing the final monolithic zirconia crown in relation to the distance to the antagonist in occlusion.

The two cases shown are only for illustrative purposes to understand how the variables mentioned in the study can create distortions in the design phase, creating a final model that needs retouching. Some of the errors generated in impression-taking can be minimized (ambient lighting, humidity, use of opacifiers), while others are inherent in the characteristics of the operator. Therefore, there is a clear need to obtain parameters that facilitate both the design and the fabrication of the prosthetic artifact. In the specific case of this study, 13 'calibrations' with test specimens were necessary to achieve a correct occlusion during delivery.

The fact that a correct "calibration" of the operator was achieved does not exclude the possibility that a new "calibration" may be necessary in the future should new inconsistencies emerge during delivery. The occurrence of new "errors" may depend on many factors: some are operator-dependent and are probably linked to the growth of the operator's experience, while others are operator-independent, such as updating the scanning software, changing the scanning hardware, changing the equipment and materials used to make the prosthetic artifacts. Every time a change of materials and equipment is necessary, a new 'calibration' will have to be carried out, while the operator's technical skills will have to be addressed on a one-off basis when repeated errors occur during delivery.

CONCLUSIONS

For future perspectives, it would be interesting to consider the calibration of this scanner with different operators and to conduct a second study in which the same operator uses different scanners to scan full and partial jaws digitally. This approach would make it possible to assess the consistency of intraoperative acquisitions and compare the accuracy between different devices used by the same operator. This methodology could contribute to a better understanding of intraoperative and inter-device variations in digital scanning, providing useful data to optimize clinical practices and the reliability of digital acquisitions in dentistry.

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Letter to the Editor

A NEW SUTURE TECHNIQUE FOLLOWING THE AVULSION OF THE LOWER THIRD MOLAR: A TECHNICAL NOTE

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KEYWORDS: *third molar tooth, pericoronitis, dental suture technique, clinical attachment level.*

INTRODUCTION

The third molars are the most frequently impacted teeth in the human dentition. The worldwide prevalence of impacted third molars (M3) is approximately 25% (1). The etiology of the inclusion of third molars depends on a series of local and/or systemic factors: the reduced space in the arch, the primary malposition of the tooth germ, the obstruction of the eruption pathway, the alterations of the dental follicle but also genetic factors (pathologies involving bone catabolism such as osteopetrosis and cleidocranial dysplasia) and endocrine factors (hypopituitarism, hypothyroidism, hypoparathyroidism).

The presence of impacted third molars is associated with an increased risk of problems, including pericoronitis, periodontal disease localized to the adjacent dental element, dental caries affecting the impacted or partially impacted dental element, root resorption affecting the adjacent tooth (second molar), TMJ disorders, cysts and odontogenic neoplasms (2).

Because of these potential problems, impacted third molars are sometimes surgically removed for prophylactic purposes; however, surgical removal should only be performed in the presence of specific indications since the risk of developing serious problems such as cysts and odontogenic tumors is relatively low and since this operation is not free from possible complications or unwanted outcomes (3). Short-term complications associated with third molar removal include pain, swelling, TMJ injury, or permanent paresthesia. Medium-term complications consist of significantly higher rates of paresthesia and TMJ symptoms that extend beyond the immediate postoperative period (4).

Furthermore, usually on the distal side of the mandibular second molar (M2), the probing depth and the clinical attachment level (CAL) remain unchanged or worsen following the avulsion surgery of the impacted third molar. In subjects who preoperatively present optimal periodontal health at the M2 level, the indication for the removal of M3 must therefore be carefully evaluated as these subjects have an increased risk of worsening of PPD and CAL after the surgical removal of M3 (5). Another important complication to address is the risk of developing periodontal defects on the distal side of M2 after M3 extraction as reported by many studies (6-8).

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SURGICAL TECNIQUES

After literature has been investigated, searching on the databases PUBMED and Google Scholar, it's proposed a flap design and a new suture technique, which are described as follows. The flap is a triangular flap:

- Type A: if the wisdom tooth has not erupted, the flap starts distal to the third molar, continues in the sulcus of the tooth, and ends with an incision mesial to the third molar itself.
- Type B: if the wisdom tooth has partially erupted: the flap starts distal to the third molar visible part. It continues in the sulcus of the tooth and the second molar, and ends with an incision mesial to the second molar itself (Fig. 1).

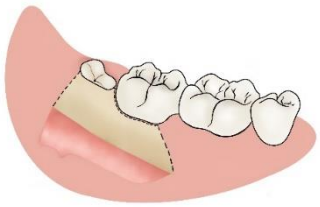

Fig. 1. *The flap starts distal to the third molar and continues in the sulcus of the tooth of the second molar, ending with an incision mesial to the second molar. The mesial displacement of the discharge cut will allow, during suturing, the flap to be rotated distally and lingually so as to completely cover the distal portion of the second molar and achieve healing by first intention..*

The suture proposed is (distal to the second molar):

- lingual flap: first suture lingual to vestibular (Fig. 2);
- vestibular flap: first suture vestibular to lingual (Fig. 3);
- vestibular flap: first lingual to vestibular over the second passage (Fig 4);
- surgical node vestibular.

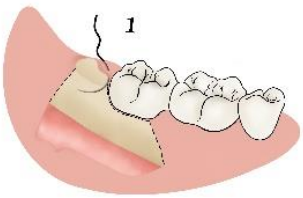

Fig. 2. *Lingual flap: the proposed suturing technique has the lingual slope of the third molar as its starting point; the ideal point for suture needle entry is 2-3mm from the free gingival margin and 1mm distal to the second molar. The needle penetrates the mucosal slope and exits the periosteal slope.*

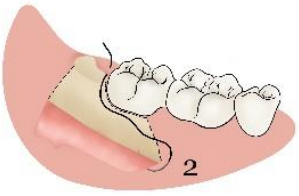

Fig. 3. *Vestibular flap: the second step of the proposed technique involves the needle penetrating the vestibular flap on the mucosal side and exiting on the periosteal side. The ideal suture needle entry point is 4-5mm from the free gingival margin and 2mm distal to the mesial discharge incision.*

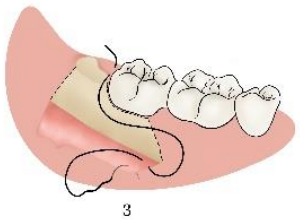

Fig. 4. *Vestibular flap: the third step of the proposed technique involves the needle penetrating the vestibular flap on the periosteal side and exiting on the mucosal side. The ideal suture needle entry point is 2-3mm from the free gingival margin and 2mm distal to the mesial discharge incision.*

RESULTS

Based on the literature findings it's clear that there isn't a clear unanimity regarding a specific surgical procedure, both in terms of flap type and suturing techniques. Horizontal mattress suturing technique is more effective than the simple interrupted suturing technique on wound healing and anchor suture and "8" suture are more beneficial to periodontal tissue healing than interrupted suture. With this suture technique the aim is to keep the CAL distal to the inferior second molar unchanged, trying to save its periodontium.

DISCUSSION

This suture technique should represent a safe protocol to reduce post-surgical complications, in particular a clinical attachment loss on the distal root of the inferior second molar. Further studies are necessary to validate this protocol.

Several studies have attempted to identify the best type of flap to use for the surgical removal of third molars to reduce postoperative discomfort and/or prevent periodontal problems on the distal side of M2 (9-12), however they have obtained conflicting results.

The modified Szmyd flap, which left intact gingiva around the second molar, results in better primary periodontal healing than the 3-cornered flap after surgical removal of the fully impacted vertically and mesioangularly inclined third molar (13).

The decision to use any of the various flap designs for access to mandibular third molars should be based on operator preference rather than on the assumption that periodontal health of the adjacent second molar will be improved (14-16). The selection of a flap design does not seem to have a lasting effect on the health of periodontal tissue (17-21).

Other studies have compared primary and secondary closure techniques after the removal of impacted third molars in terms of postoperative pain and swelling but probably due to the small differences between the two techniques, the literature available to date does not allow us to clearly establish which of they are superior and therefore preferable (22).

A meta-analysis showed that patients whose wounds had been closed primarily had significantly more pain than those whose wounds were closed secondarily. Patients whose wounds were closed secondarily had less swelling, and trismus is worse in the primary closure group than in the secondary group (23). Other studies undelight the irrespective of any closure technique, with no difference in terms of periodontal healing (24-26). Healing by second intention of the oblique relaxing incision by partial surgical wound closure, in our study, were superior to the primary closure in reduction of post-operative pain, swelling and trismus (27).

However, it is important to choose an adequate suturing technique which is essential for the correct success of the surgery and for obtaining a post-operative course free of complications. The placement of a suture, distal to the lower second molar, after raising a buccal envelope flap for lower third molar surgery, is superior to the suture-less technique, in decreasing post-operative pain and enhancing wound healing (28).

Horizontal mattress suturing technique (using 3/0 synthetic silk sutures) is more effective than the simple interrupted suturing technique on wound healing after impacted mandibular third molar surgery, although it does not decrease the levels of pain, trismus, and swelling (29). Interrupted sutures are usually the surgeon's first choice. The anchor suture is another suture technique, which fixes the distal buccal-lingual gingival flap to the adjacent tooth in an anchor-like manner to avoid the V-shaped gap formation in the distal adjacent tooth. Interrupted suture and "8" suture are

statistically significant in terms of PPD at 6 months after surgery. The “8” suture is more conducive to the healing of the distal periodontal tissue of the adjacent teeth. Anchor suture and “8” suture are more beneficial to periodontal tissue healing than interrupted suture (30).

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