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The edentulous posterior ridge: novel diagnostic and therapeutic approaches for bone augmentation

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CONTENT

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals:

I. BRESSAN E, FERRARESE N, PRAMSTRALLER M, LOPS D, FARINA R & TOMASI C.

Ridge dimensions of the edentulous mandible in posterior sextants: an observational study on cone beam computed tomography radiographs.

Implant Dentistry 2017 Feb;26(1):66-72.

II. PRAMSTRALLER M, SCHINCAGLIA GP, VECCHIATINI R, FARINA R & TROMBELLI L.

Alveolar ridge dimensions in mandibular posterior regions: a retrospective comparative study of dentate and edentulous sites using computerized tomography data

submitted

III. FRANCESCHETTI G, RIZZI A, MINENNA L, PRAMSTRALLER M, TROMBELLI L & FARINA R.

Patient-reported outcomes of implant placement performed concomitantly with transcrestal sinus floor elevation or entirely in native bone.

Clinical Oral Implants Research 2017 Feb;28(2):156-162.

CHAPTER 1

INTRODUCTION

In the international literature a lot of studies analyzed bone volume in different way and in different region. Quirynen et al.(2003) and Tepper et al. (2001) measured the size of the mandible using CT, but these measurements were limited to the interforaminal region. The anterior region of the mandible, even if it was the first area that received osseointegrated dental implant, is not the only oral area which need dental implant to allow a functional and/or esthetic rehabilitation. For example, the posterior mandibular region is one of the most delicate area to insert an implant caused by the presence of important anatomic limitations (i.e. inferior alveolar canal, undercut in the lingual border). The international literature presented many articles describing the bone dimensions but most of analysis were only in a bi-dimensional point of view with panoramic radiographs. For these reasons determining the 3D bone size and morphology in the posterior edentulous mandible is important as well as the bone dimension modification following tooth extraction.

Another region of the oral cavity where may be difficult to place an implant is the posterior maxillary region. In this area the majority of case needed a bone augmentation procedure, such as sinus lift, because bone height is not sufficient to receive an implant (Pramstraller et al. 2011, Farina et al. 2011). In the international literature different procedures to obtain the sinus floor elevation are described. It is well known, thanks to systematic review, the transcrestal sinus floor elevation is better tolerated by patients than the lateral approach. The trend of the medical surgery and in particular the oral surgery is to become minimally invasive. Data about the different perception of patient-reported outcome between implant placement entirely in native bone or concomitantly with trascrestal sinus floor elevation (according to different transcrestal sinus floor elevation techniques) are not still present in the international literature. For this reason is important to validate the minimally invasive procedure of the novel therapeutic approach for sinus floor elevation (i.e. Smart Lift technique).

AIMS

The aims of the Ph.D. project were:

1. to evaluate the residual dimensions of the edentulous mandible at posterior sites;

2. to estimate the extent of the dimensional alteration following tooth extraction in the posterior mandible by comparing dentate and contralateral edentulous sites within the same patient;

3. to evaluate a novel bone augmentation procedure of the posterior edentulous ridge and its impact on patient-related outcomes

CHAPTER 2

THE EDENTULOUS POSTERIOR MANDIBLE:

Study #1: A novel methodology to assess the ridge dimensions on cone beam computed tomography

Study #2: A retrospective comparative study of dentate and edentulous sites using computerized tomography data

INTRODUCTION

Dimensional changes of the alveolar ridge following tooth extraction

The healing of an extraction socket following tooth removal was studied in different animal models (Schram 1929, Claflin 1936, Simpson 1960, Kuboki et al. 1988, Lin et al. 1994). The experiments demonstrated that during the healing process a series of events occurred, such as (i) formation and maturation of a blood clot, (ii) infiltration of fibroblast to replace the coagulum, and eventually (iii) establishment of a provisional matrix (PCT) that allowed for bone tissue formation. Unfortunately, the observation period of these studies was relatively short. For this reason, the information related to later phases of socket healing (including the process of remodeling of the newly formed bone tissue in various parts of the alveolus) was limited. The healing of extraction sockets in human volunteers was studied by Amler (1969) and Evian et al. (1982). Amler stated that following tooth extraction, the first 24 hours are characterized by the formation of a *blood clot* in the socket. Within 2–3 days the blood clot is gradually being replaced with *granulation tissue*. After 4–5 days, the *epithelium* from the margins of the soft tissue starts to proliferate to cover the granulation tissue in the socket. One week after extraction, the socket contains granulation tissue, *young connective tissue*, and *osteoid* formation is ongoing in the apical portion of the socket. After 3 weeks, the socket contains connective tissue and there are signs of mineralization of the osteoid. The epithelium covers the wound. After 6 weeks of healing, bone formation in the socket is pronounced and trabeculae of newly formed bone can be seen. Amler's study was of short duration, so it could only evaluate events that took place in the marginal portion of the healing socket. His experimental data did not include the important later phase of socket healing that involves the processes of modeling and remodeling of the newly formed tissue in various parts of the alveolus. Thus, the tissue composition of the fully healed extraction site was not documented in that study (Araujo & Lindhe 2008). Cardaropoli et al. (2003) published a long-term experiment in the dog. This study described more in detail the various phases of socket healing including processes of both modeling and remodeling. The team used nine mongrel dogs for the experiment. In this study the authors decided to extract the distal roots of mandibular premolars and the socket with surrounding soft and mineralized tissue was denoted ''experimental unit''. The dogs were killed 1, 3, 7, 14, 30, 60, 90, 120 and 180 days after the root extractions. Biopsies including the experimental units were demineralized in EDTA, dehydrated in ethanol and embedded in paraffin. Morphometric measurements were performed to determine the volume occupied by different types of tissues in the marginal, central and apical compartments of the extraction socket at different intervals. The results showed that the empty socket is first filled with blood and a coagulum

(clot) forms (Day 1-3). Inflammatory cells (polymorphonuclear leukocytes and monocytes/ macrophages) migrate into the coagulum and start to phagocytose elements of necrotic tissue. The process of wound cleansing is initiated. Sprouts of newly formed vessels and mesenchymal cells (from the severed periodontal ligament) enter the coagulum and granulation tissue is formed. The granulation tissue is gradually replaced with provisional connective tissue and subsequently immature bone (woven bone) is laid down (Day 7). The hard tissue walls of the socket – the alveolar bone proper or the bundle bone – are resorbed and the socket wound becomes filled with woven bone (Day 14-30). The initial phases of the healing process are now completed. In subsequent phases the woven bone in the socket is gradually remodeled into lamellar bone and marrow (Day 60-180) (Cardaropoli et al. 2003, Araujo & Lindhe 2008).

An other important leap forward in the knowledge of biological modification following tooth extraction was done by Araujo and Lindle (2005). The aim of the experiment conducted on dogs was to study some dimensional alterations of the alveolar ridge that occurred following tooth extraction as well as processes of bone modelling and remodelling associated with such change. Biopsy specimens, including an individual extraction socket and adjacent roots, were obtained after 1, 2, 4, and 8 weeks of healing. The blocks were sectioned in the buccal–lingual plane.

- 1 week after tooth extraction. At this interval the socket is occupied by a coagulum. Furthermore, a large number of osteoclasts can be seen on the outside as well as on the inside of the buccal and lingual bone walls. The presence of osteoclasts on the inner surface of the socket walls indicates that the bundle bone is being resorbed.

- 2 weeks after tooth extraction. Newly formed immature bone (woven bone) resides in the apical and lateral parts of the socket, while more central and marginal portions are occupied by a provisional connective tissue. In the marginal and outer portions of the socket walls numerous osteoclasts can be seen. In several parts of the socket walls the bundle bone has been replaced with woven bone.

- 4 weeks after tooth extraction. The entire socket is occupied with woven bone at this stage of healing. Large numbers of osteoclasts are present in the outer and marginal portions of the hard tissue walls. Osteoclasts also line the trabeculae of woven bone present in the central and lateral aspects of the socket. In other words the newly formed woven bone is being replaced with a more mature type of bone.

- 8 weeks after tooth extraction. A layer of cortical bone covers the entrance to the extraction site. Corticalization has occurred. The woven bone that was present in the socket at the 4-week

interval is replaced with bone marrow and some trabeculae of lamellar bone in the 8-week specimens. On the outside and on the top of the buccal and lingual bone wall there are signs of ongoing hard tissue resorption. The crest of the buccal bone wall is located apical of its lingual counterpart.

The present experiment demonstrated that marked dimensional alterations occurred during the early phase – 8 weeks – following the extraction of mandibular premolars. Thus, in this interval there was a marked osteoclastic activity resulting in resorption of the crestal region of both the buccal and the lingual bone wall. The reduction of the height of the walls was more pronounced at the buccal than at the lingual aspect of the extraction socket. At the 1-week interval, the buccal bone crest (B) was found to be located on the average 0.3±0.2 mm (SD) ‘‘coronal’’ to the lingual crest (L), while at the 2-, 4-, and 8-week intervals the buccal crest was consistently located ‘‘apical’’ of its lingual counterpart. Thus, after 2 weeks of healing the distance between B and L was 0.3±0.1mm. The corresponding distances after 4 and 8 weeks of healing were 0.9±0.3 and 1.9±0.2 mm. In conclusions the relative reduction of the height of the buccal bone wall between the 1- and 8-week intervals was 2.2±0.2 mm, while the level of the margin of the lingual wall remained reasonably unchanged. The authors motivated the more bone loss occurred in the buccal than in the lingual wall because the marginal 1–2 mm of the crest of the buccal bone wall was occupied exclusively by bundle bone. The bundle bone is a tooth-dependent tissue and will gradually disappear after tooth extraction. This tissue is the portion of the bone of the alveolar process that surrounds teeth and into which the collagen fibers of the periodontal ligament are embedded. Only a minor fraction of the crest of the lingual wall contained bundle bone (lingual bone was comprised of a combination of bundle bone and lamellar bone) (Figure 4).

Methods to assess the dimensions of the edentulous ridge

There are different modality to analyzed the dimensions of maxillary and mandibular bone. The main studies in the international literature were conducted on radiographs or on anatomic specimens.

Studies on 2D radiographs

A lot of authors (Xie et al. 1997; Saglam 2002; Juodzbalys & Raustia 2004; Güler et al. 2005, Canger &Celenk 2010) chose the 2D X-ray exams for the morphology evaluation of the edentulous maxillary and mandibular alveolar crest, probably because the conventional 2D radiographs, for example

panoramic radiographs, are widely used radiological modalities to assess the bone quantity (and quality) prior to implant placement (Kutuk et al 2014; Dagassan-Berndt et al. 2016). Xie et al. (1997) examined the variation of the vertical measurements in the mandible and maxilla between edentulous and dentate subjects. In these groups the horizontal locations of first premolar and molar were calculated to determine the measurement sites in the edentulous jaws. According to results from the dentate subjects, 34% of the length of the mandibular body from the midline was the position of first premolar and 53% represented the position of first molar in the mandible. The results of the study showed highly significant ($p<0.001$) differences in the heights of the mandibular body and maxilla between the elderly dentate and edentulous subjects of both sexes, with the edentulous having much smaller heights of the mandibular body and maxilla than the dentate. The decreases in heights were greater ($p<0.001$) in the edentulous mandible than in the edentulous maxilla. The results showed also the elderly edentulous women had a more pronounced reduction in the height of the mandible than did the men. The authors concluded that the reduction in the residual alveolar ridge of the edentulous mandible was greater than that of the maxilla. In addition, the differences between elderly edentulous men and women in percentages of reductions in heights of the maxilla were not significant and the percentage reduction in the mandible of women was greater than that in men. Saglam in 2002 reproduced a similar analysis with a grater number of subjects. A total of 192 alveolar ridges (96 dentate and 96 edentulous) were examined. In the dentate group there were no statistically difference in the maxilla's height between man and women, instead the height of the mandible was statistically higher in men than in women. The reductions in height of maxilla and mandible were significantly more pronounced in women than in men. In partially contrast opinion with the study of Xie et al., the author concluded that there were differences between the sexes in alveolar ridge resorption after tooth loss both in upper in lower jaw. Guler et al. in 2005 designed a study on panoramic radiographs to determine the variations of the vertical height measurements in the edentulous maxilla and mandible, and to assess positions of important anatomic structures (i.e. maxillary sinus, mandibular foramen, and mandibular canal). These anatomic limits influenced the choice of implant dimensions. The study was confined to the analysis of edentulous arches of 214 patients. The dentate arches of 63 patient were used for location of the first premolar and molar area. The results showed that the height of the maxilla and the mandible in the anterior, first premolar, and first molar regions were significantly greater in men than in women. A majority of the most inferior border of the maxillary sinuses was located anterior to the first molar area both in men and women. Although, the vertical distances from the upper border of the mandibular canal to the alveolar crest in the first molar area was statistically different between edentulous men and edentulous women for. The results were similar to the study of Saglam (2002)., and the authors found the most pronounced percentage reduction in total height of the mandibular body at the first

premolar and first molar sites. The last article of the 2-D analysis I want to describe in this thesis is the study of Canger & Celenk (2010). The aim of this study was to evaluate the reduction of residual alveolar ridge height on panoramic radiographs and the differences between denture wearers and non-denture wearers. The study analyzed 147 individuals (74 men and 73 women) [50 were denture wearers, 50 non-denture wearers (examination groups) and 47 of them were dentate (control group)]. The authors wanted to divide the population by the use of denture because previous author thought that a reduction in the residual alveolar ridge is closely associated with the use of dentures (Atwood 1971, Carlsson 2003). The reason is linked to the compressive forces directed onto the mucous membrane from prosthetic restorations. These forces affect the metabolism of the underlying tissues by obstructing blood flow and initiating residual alveolar ridge (Artwood 1962, Mercier & Bellavance 2002) and mucosal inflammation. These reaction can cause resorption via the generation of arachidonic acid metabolites or interleukins (Kingsmill 1999). The method used in this study to assess the bone dimensions was the same developed by Xie et al. (1997) and reused by Saglam (2002) and Guler et al. (2005). The results indicated a significant differences between the alveolar ridge heights of dentate and edentulous groups ($p < 0.001$). This difference ($p < 0.001$) was still present between the denture wearer group and the non-denture wearer groups only the lower jaw. No significant difference in the upper jaw was found. There were also differences between men and women ($p < 0.005$) at every measurement sites.

The panoramic radiographs are widely available in the routine dental practice and are frequently used for preoperative diagnosis in all dental fields, even in the preoperative diagnosis of implant treatment. This type of exam presented several disadvantages, the two most important are image distortion and magnifications, which lead to inaccurate information of dimensions (Hanazawa et al. 2004). For these reasons the studies conducted on panoramic radiographs, even if with a great sample size, presented an important limitation to determine the bone dimensions or to calculate the distances from anatomic landmarks.

Studies on cadavers

The studies conducted on anatomic specimens presented similar results. Razavi et al. (1995) analyzed seventeen edentulous cadavers, 8 males and 9 females of ages ranging from 59 to 90 years. The maxillary alveolar process of each cadaver were dissected and removed for anatomic evaluation. Each maxilla was sectioned into 4 regions. In the regions corresponding to second premolar and molars sites the bone height was insufficient to implant placement without any bone augmentation procedures. In region 3 (second premolar - first molar) the mean bone height was

6.1±2.8 and in region 4 (first molar - second molar) was 8.5±2.2. In this study the authors conclude with a recommendation: “It is imperative to recognize all possible variations that exist in the treatment of every patient. Use of linear and computer tomography can aid in the determination of the bone architecture” (Razavi et al. 1995). In the same year Ulm et al. conducted a study on 47 anatomic specimens (30 women, 17 men, age range 53-94years). The purpose of this study was to analyze quantitatively the vertical and horizontal dimensions of alveolar bone available for placement of endosseous implants under the maxillary sinus area (M1= area of first molar; M2= area of second molar). The study also dealt with possible differences in bone dimensions between partially dentate and completely edentulous maxillae relative to different ridge forms. The results showed no significant differences between female and male specimens. The mean alveolar ridge heights (distance between the crest of the alveolar ridge and the floor of the maxillary sinus) varied between 2.23 - 7.97 mm at site M1 and between 5.68 - 9.30 mm at site M2; the mean alveolar ridge width measured 1 mm below crest of ridge varied 3.31- 6.10 mm at site M1 and between 4.42 - 7.40 mm and at site M2. These authors concluded with this important sentence: “computerized tomography (CT) seem to be the methods of choice for assessment of the available bone volume for endosseous implant placement. With CT data and appropriate software programs, the prospective insertion site may be visualized in all planes and in three dimensions. Panoramic radiography alone does not permit precise assessment of the ridge configuration” (Ulm et al. 1995). The studies conducted on anatomic specimens, although providing the tri-dimensional and accurate evaluation of the ridge dimensions, are biased by a limited sample size. An other limitations of this modality of assessing the bone dimensions is the not reproducibility in clinical practice.

The limits of both modalities to assess bone dimensions (panoramic radiographs and anatomic specimens) led several authors to analyze the accuracy of CT scans and use this technology to assess bone dimensions. Naitoh et al. (2002) concluded conventional tomography is more accurate than panoramic radiography in measuring bone size. In 2009 Kamburoglu et al. decided to assess the accuracy and reproducibility of cone-beam CT measurements of specific distances around the mandibular canal by comparing them to direct digital caliper measurements. They concluded that the accuracy of cone-beam CT measurements of various distances surrounding the mandibular canal was comparable to that of digital caliper measurements. Moreover the 3D CT images seem to give significantly more surgically relevant information for diagnosis and implant surgery planning compared to 2-D images (de Brito et al 2016; Tadinada et al. 2016)

THE EDENTULOUS POSTERIOR MANDIBLE:

Study #1: A novel methodology to assess the ridge dimensions on cone beam computed tomography

ABSTRACT

Aims: to evaluate the ridge dimensions of posterior sextant in totally edentulous mandibles by using a novel methodology.

Material & methods: Cone beam computed tomography (CBCT) scans of 136 patients were retrospectively included for analysis. At sites corresponding to the second premolar (site a) and the mesial and distal root of first molar (sites b and c, respectively), bone height (BH) and bone width (BW) were measured.

Results: BH significantly decreased from site a (11.20 ± 4.03 mm) to site c (10.28 ± 3.33 mm). Males showed a significantly higher BH compared to females at all sites ($p<0.001$), No significant impact of age on BH was found. BW increased from coronal to apical at all sites. At all height levels, BW increased from mesial to distal (BWc>BWb>BWa).

Conclusions: BH decreased from mesial to distal, while BW showed an increase. Gender showed a significant impact on bone height, with males having on average a 2.8 mm greater height than females, but not on bone width. Age did not significantly influence the dimensions of the residual bone crest.

Key words: tooth loss; diagnostic imaging; jaw; body weights and measures.

AIM OF THE STUDY

The aim of the present observational study was to evaluate the alveolar ridge horizontal and vertical dimensions of the mandible in edentulous patient by using a novel methodology.

MATERIALS AND METHODS

Study population

De-identified data were obtained from a convenience sample of patients retrospectively selected among those referred for a cone beam computerized tomography (CBCT) to a radiologic center (TECNO-MED, Verona, Italy) between January 2012 and September 2012. All CBCT scans were acquired using a Planmeca ProMax 3Ds, 2011 (Planmeca Oy, Helsinki, Finland). The scan plane had been set parallel to the inferior border of mandibular jaw. Axial (parallel to the scan plane), panoramic (perpendicular to the scan plane, latero-lateral direction) and cross-section (perpendicular to the scan plane, antero-posterior direction), 0.4mm slices were obtained. CT scans were performed according to the following protocol: pitch 1 :1, matrix 512x 512 and field of view 20cm diameter and 10cm height, 120 kVp, and 100 mA. The effective radiation dose was 304.5 micro Sv. CT scans were post-processed with Planmeca Romexis software (Planmeca Oy, Helsinki, Finland). Each patient provided a written informed consent before undergoing the CBCT examination. When a patient had undergone more than one CBCT examination, the most recent CBCT scan was selected for the study. Therefore, each patient contributed one CBCT examination.

Radiographs were included in the analysis according to the following criteria regarding the subject: (i) age ≥21 years; (ii) totally edentulous mandible (iii) presence of a clearly identifiable ridge contour in the edentulous site/s of interest. Radiographs were excluded from the analysis if positive for at least one of the following criteria: (i) total osseous retention of one or more teeth in the mandible; (ii) radiographic evidence of bone augmentation procedures or signs of invasive surgery; (iii) presence of a radiolucent or a radiopaque area related to pathological conditions. (iv) partial or total osseous retention of one or more residual roots; (v) presence of a dental implant posterior to mental foramina; (vi) presence of osteosynthesis plaques; (vii) unreadable CBCT.

Processing of CBCT scans and radiographic measurements

Recently, the Reasearch Centre for the Study of Periodontal and Peri-implant Diseases of University of Ferrara decided to focused the attention on the study of CT scans since 2010 (Pramstraller et al. 2011, Farina et al. 2011, Bressan et al. 2017, Pramstraller et al. 2017). The first two studies (Pramstraller et al. 2011, Farina et al. 2011) analyzed the bone dimensions of the upper jaw and are not precisely analyzed in the present Thesis. On the other hand, the others two (Bressan et al. 2017, Pramstraller et al. 2017), are part of the present PhD Thesis and analyzed the mandibular jaw.

We first applied this methodology to analyzed the ridge dimensions of the edentulous posterior maxilla (Pramstraller et al. 2011). Computerized tomography (CT) scans of 65 males and 62 females (mean age: 55.2 10.1 years) with at least one missing tooth in the maxillary posterior sextants were analyzed. On CT cross sections of first premolar, second premolar, first molar and second molar edentulous sites the following novel measurement were recorded: (i) bone height (BH = measured as the distance from the most coronal point of the alveolar crest to the most oral point of the maxillary sinus); (ii) bone width (BW = measured as the width of the alveolar crest at 1, 3 and 7 mm from the most coronal point of the alveolar crest); (iii) the relative vertical ridge position (rVRP = measured as the distance from the most coronal point of the alveolar crest to the line passing through the CEJ of the canine and parallel to the CT scan plane). The results showed the sinus presence in 50.8% at first premolar edentulous site and more than 93.3% in the other sites. The median BH ranged between 13.1 mm (first premolar site) and 5.4 mm (first molar site). All comparisons for BH between first premolar, second premolar, and first molar sites were statistically significant ($P \leq 0.001$ for all comparisons). The median BW at 1 mm apical to the most coronal point of the alveolar crest ranged between 4.8 mm (second premolar site) to 6.6 mm (second molar edentulous sites). The median BW was higher at the second molar site when compared with first and second premolar sites ($P \leq 0.001$ for both comparisons). The median rVRP were 4.6 mm (2.92–6.12 mm) at first premolar, 5.1 mm (3.5–5.95 mm) at second premolar, 5.4mm (3.95–6.57mm) at first molar and 5.7 mm (4.05–7.15 mm) at second molar site. The presence/absence of adjacent teeth significantly influenced rVRP only at the first molar site. In this study the frequency of sites with BH≥8 mm and $BW_{1\ mm}$≥6 mm was counted for each edentulous site and was 28.3%, 18.4%, 8.0% and 18.2% at first premolar, second premolar, first molar and second molar sites, respectively. The results of the study indicate that at all sites, the dimensions of the alveolar crest may call for bone augmentation procedures for proper implant placement in a substantial amount of edentulous patients. In Farina et al. (2011) the same novel methodology was used to compare the alveolar ridge dimensions between edentulous sites and contralateral dentate sites of maxillary posterior sextants in the same individuals . The parameters analyzed were the same (BH, BW; relative ridge position

(rRP): measured as rVRP and relative position of the sinus floor (rSF): measured as the distance from the most apical point of the maxillary sinus floor to the line passing through the CEJ of the canine and parallel to the CT scan plane). The variation in BH between edentulous and dentate sites ranged between 13.9% (first premolar) to 40.7% (first molar). Both first and second premolar edentulous sites showed significantly lower BW_{1mm} than dentate sites ($P \leq 0.001$ for both comparisons), while the second molar showed a borderline significance ($P = 0.001$). In edentulous sextants, the prevalence of sites with $BH \geq 8$ mm and $BW_{1\ mm} \geq 6$ mm was 34.4% (11/32), 12.5% (4/32), 3.1% (1/32) and 12.5% (4/32) at first premolar, second premolar, first molar and second molar sites, respectively. The results of our study indicate that the reductions of horizontal and vertical dimensions of the posterior maxilla occurring after tooth loss seems to heavily affect the possibility to place implants of adequate length and width.

In the present study, both sides of each edentulous mandible, the CBCT cross-sections at 6 mm, 11 mm, and 16 mm (site a, b and c, respectively) posterior to the most distal section including the mental foramen were used for radiographic measurements (Figure 1). These positions correspond to the second premolar and the mesial and distal roots of the first molar (Yashar et al. 2012). On each cross-section, lines were traced parallel to the inferior border of the mandible and passing through (i) the most coronal point of the alveolar crest (p_{crest}), (ii) 1, 3, and 5 mm apical to pcrest ($h_{1\ mm}$, $h_{3\ mm}$ and $h_{5\ mm}$, respectively) and (iii) the most coronal point of the mandibular canal (p_{AC}). At sites a, b and c, bone height (BH) and bone width (BW) were assessed. BH was measured as the distance (in mm) between pcrest and p_{AC} (Fig. 2). BH was not measured when the mandibular canal was not evident on the selected cross-section. Bucco-lingual bone width (BW) was measured at 1, 3, and 5 mm apical to pcrest ($BW_{1\ mm}$, $BW_{3\ mm}$, and $BW_{5\ mm}$, respectively) (Figure 2). When BH was 5 mm or lower, BW_{5mm} was not recorded. When BH was 3 mm or lower, BW_{5mm} and BW_{3mm} were not recorded. BW assessments were not performed when BH was lower than 1 mm.

Radiographic measurements were performed by two trained examiners (N. F. and M. P.) using magnification loops (x12) and a digital ruler with a 0.01 mm scale. Prior to study initiation, both examiners were involved in a calibration session, consisting of two sessions (at a 1-week distance) of radiographic assessments on CBCT scans of 5 edentulous patients not included in the study. The reliability analysis revealed an excellent intra-rater (ICC= 0.994 and 0.996) and inter-rater agreement (ICC= 0.995).

Statistical analysis

Descriptive statistics was performed using a specifically designed software (IBM SPSS 21, USA). After having evaluated the normality of the data by the use of Kolmogorov-Smirnov test, parametric paired t-test was used to test for differences between the 2 sides of the mandibles. The mean difference between left and right measurements (systematic error) was 0.08 mm, and no significant within-subject differences in each radiographic measurement were observed between contralateral sites. Therefore, the subject was considered as the statistical unit. For each site (a, b or c), each subject was represented by a single value which was derived as the average of the left and right measurements.

A multilevel model was then built to estimate the standard errors of the measurements taking in to account the potential clustering of the data. The 2 level considered were the measurement and the subject. The model included bone height BH and bone width BW as outcome variables and was therefore a multivariate multilevel model. A parsimonious model including the predictors that had a statistically significant impact ($p<0.05$) on one or more of the outcomes was named as the “Final Model”. The coefficients were estimated using iterative generalized least squares (IGLS) and the significance of each covariate was tested using a Wald test. Nested models were tested for significant improvements in model fit by comparing the reduction in -2LL (-2 log likelihood) with a Chi-squared distribution.

RESULTS

Study population

One hundred forty-one CBCT scans were examined. Two radiographs were excluded from the study due to the presence of osteosynthesis plaques, two for signs of invasive surgery and one CBCT was not readable in the mandibular posterior sextants. Therefore, data were retrieved from CBCT scans of 136 subjects (mean age: 67.4 years; range: 27–92 years), including 69 males (mean age: 66.2 years; range: 27 – 92 years) and 67 females (mean age: 68.7 years; range: 31 – 91 years).

Radiographic measurements

Radiographic measurements are reported in Table 1. In the overall study population, BH significantly decreased from site a (11.20 ± 4.03 mm; range: 2.22 - 19.80 mm) to site c (10.28 ± 3.33 mm; 2.40 - 17.40 mm) ($p<0.001$). BW_{1mm} was 3.98 ± 1.42 mm (range: 1.80 – 9.00 mm) at site a, 4.54 ± 1.74 mm (range: 1.60 – 10.20 mm) at site b, and 5.39 ± 2.21 mm (range: 2.00 – 12.60 mm) at site c. Moving from mesial to distal, mean BW measurements showed a significant increase ($BW_c>BW_b>BW_a$) at all height levels (1, 3 and 5 mm from p_{crest}). BW significantly increased from coronal to apical at all sites, the mean value increasing from 3.98 mm to 9.21 mm at site a and from 5.39 mm to 11.39 mm at site c.

Radiographic measurements in female and male subjects are reported in Figures 3 and 4, respectively. Males showed a significantly higher BH compared to females at all sites ($p<0.001$), while BW measurements were not significantly different between male and female subjects.

The cumulative frequency distribution of BH in female and male subjects is illustrated in Figures 5 and 6, respectively. At site a, BH was 9 mm or higher in 55.2% of females and 82.8% of males. At site c, BH was 9 mm or higher in 49.9% of females and 77.9% of males. Using a BH threshold of 11 mm, the prevalence at site a was 36.6% for females and 68.1% for males, while the prevalence at site c was 20.0% for females and 57.3% for males.

The cumulative frequency distribution of BW_{1mm}, BW_{3mm}, and BW_{5mm} is illustrated in Figures 7, 8 and 9, respectively. BW_{1mm} was 5 mm or higher in 22.1% of subjects at site a, in 30.8% of subjects at site b, and 40.7% of subjects at site c. BW_{3mm} was 5 mm or higher in 83.4% of subjects at site a, 86.3% of subjects at site b and 92.5% of subjects at site c.

Multilevel analysis

To investigate the effect of different parameters on the dimensions of the edentulous bone crest and to evaluate the correlation between the measurements, a multilevel multivariate model was built with 2 levels (subject and site) and 2 outcome variables (BH and BW).

Males showed a significantly higher BH compared to females at all sites ($p<0.001$), the average difference as calculated from the multilevel model being 2.82 ± 1.16 mm. The analysis of the interaction factor between gender and site showed a significant, stronger effect of gender on BH at site c compared to site a. The model showed no significant impact of age on BH ($p=0.54$) and no

significant impact of age and gender on BW (p=0.83 and p= 0.53, respectively). A significant covariance between BH and BW (-0.7) was detected from the model.

DISCUSSION

Panoramic radiograph is often the first choice exam for the evaluation of jaw overall shape, such as mental foramen and mandibular canal position (Güler et al. 2005, Canger & Celenk 2012). The major advantages of such exam are the visualization of all oral areas, low radiation exposure and the effectiveness. Instead, major disadvantages are resolution, lack of tridimensional view, high distortion and presence of phantom images (Juodzbalys & Kubilius 2013). Further, the average of linear error during bone assessments is 24% for panoramic radiograph and 1.8% for computer tomography scans, respectively (Sonic et al. 1994). As reported by Peker et al. (2008) computer tomography (CT) three-dimensional images are more accurate than panoramic radiographic images. The efficiency of CT with the potential of low radiation exposure has been shown for CBCT (Angelopoulos 2008).

The lack of information on post-extraction healing time may represent a limitation of our study. The time elapsed from extraction was previously shown to be associated with the extent of ridge resorption. In particular, the change in ridge height and width averages 0.64–2.03 mm (depending on the socket aspect) and 3.87 mm, respectively, after a period of 3–12 months following tooth extraction (Van der Weijden et al. 2009). Residual ridge resorption may progress further, with a variable rate being maximum within 2 years after tooth extraction and progressively decreasing thereafter (Carlsson & Persson 1967, Likeman 1974). All CBCT scans of present cohort showed a clearly identifiable ridge contour with no evidence of the profile of the socket walls, thus suggesting an advanced healing status of the extraction sites. On the basis of these considerations, it may be speculated that the ridge dimensions reported here are derived from a cohort of edentulous patients where the major dimensional modifications of the ridge following tooth loss had already occurred.

Currently, there are few data in the literature on the vertical dimension of the mandibular bone crest in totally edentulous subjects. Most of the reports (Güler et al. 1995, Xie et al. 1997)compared dentate and edentulous subjects. Furthermore, in such studies monoedentulism was considered. The height of the mandible body as measured from the inferior border of the mandible to the alveolar crest was studied by several authors on panoramic radiographs (Güler 1995, Sağlam 2002, Xie et al. 1997, Panchbhai 2013). As described by Xie et al. (1997), the average height of mandible body in the first premolar region was greater than in first molar region; such finding was observed for both

male and female edentulous subjects. The authors demonstrated that alveolar ridge resorption is usually more rapid in the premolar and molar region compared to the anterior region. Moreover, Saglam (2002) confirmed that the premolar site has greater vertical dimension than the molar. In a study on panoramic radiographs, Guler et al. (1995) evaluated the distance between the alveolar crest and mandibular canal on panoramic radiographs. In the first molar area, the distance was 9.24 for females and 11.44 mm for males, the values being consistent with those reported in the present study.

The study of different sections (site a,b,c) by using CBCT images was already reported by Yashar et al. (2012) and Watanabe et al. (2010). BH at the site a, b and c was significantly greater in men than in women ($p<0.001$). As confirmed by the literature (Güler et al. 1995, Sağlam 2002, Xie et al. 1997, Canger & Celenk 2012, Panchbhai 2013), that bone resorption in female patients is greater than in male patients. Similarly, Soikkonen et al. (1996) reported that mandibular alveolar atrophy was more severe in woman than in men ($p<0.001$). Such finding was mainly related to hormonal influences such as post-menopausal depletion of estrogens or secondary or primary hyperparathyroidism and resulting in calcium metabolism. Conversely, Yuguzullu et al. (2009) concluded that bone heights in the first premolar and molar regions were similar in men and women.

In the present study, BH was not correlated with age. Consistently, Soikkonen et al. (1996) reported no significant differences in mandibular bone height between three different age cohort. Also, Yuguzullu et al. (2009) reported that bone height of the premolar and molar regions were similar between different age groups. Other studies, however, suggested that increasing age is associated with a decrease in bone height possibly due to increased bone resorption (Panchbhai 2013). BW increased from mesial to distal, with no statistical difference in BW between males and females. This finding is consistent with previous studies (Katranji 2007).

In conclusion, in the posterior sextants of totally edentulous mandibles, mean residual bone height and width showed a decrease and an increase, respectively, in the mesio-distal direction. Gender showed a significant impact on bone height, with males having on average a 2.8 mm greater height than females, but not on bone width. Age did not significantly influence the dimensions of the residual bone crest.

TABLE & FIGURES

Table 1. Bone height (BH) and bone width (BW) at site a, b and c as measured in the overall study population and in males and females subgroups. In the overall study population, BH significantly decreased from site a to site c ($p<0.001$). Moving from mesial to distal, mean BW measurements showed a significant increase (BWc>BWb>BWa) at all height levels (1, 3 and 5 mm from pcrest). BW significantly increased from coronal to apical at all sites.

		Site a				Site b				Site c			
		BH	$BW_{1\,mm}$	$BW_{3\,mm}$	$BW_{5\,mm}$	BH	$BW_{1\,mm}$	$BW_{3\,mm}$	$BW_{5\,mm}$	BH	$BW_{1\,mm}$	$BW_{3\,mm}$	$BW_{5\,mm}$
Female	N	67	67	64	55	67	67	64	55	67	67	65	57
	Mean	9.76	4.00	7.33	9.03	9.76	4.58	8.42	10.13	8.98	5.39	9.71	11.42
	Median	9.80	3.79	7.08	8.79	9.60	3.90	8.30	10.20	9.40	4.80	9.79	11.40
	SD	3.79	1.61	2.29	2.09	3.79	2.03	2.59	1.95	3.06	2.40	2.63	2.08
	Minimum	2.60	1.80	3.15	4.85	2.60	1.60	3.60	5.40	2.40	2.00	4.20	5.55
	Maximum	17.60	9.00	12.40	13.80	17.60	10.20	13.28	14.00	16.85	12.60	15.38	15.80
Male	N	69	68	66	65	68	67	65	64	67	67	67	64
	Mean	12.61	3.96	7.19	9.35	12.14	4.50	8.13	10.38	11.58	5.38	9.30	11.36
	Median	12.66	3.80	7.20	9.60	11.70	4.55	8.20	10.32	11.80	5.00	9.05	11.60
	SD	3.78	1.21	1.64	2.00	3.54	1.41	2.00	2.20	3.08	2.02	2.25	2.25
	Minimum	2.22	1.86	3.40	5.00	3.60	1.80	4.60	5.45	3.80	2.05	3.55	5.60
	Maximum	19.80	7.40	10.80	13.57	19.20	10.00	12.80	15.26	17.40	11.60	15.20	16.48
Total	N	136	135	130	120	135	134	129	119	134	134	132	121
	Mean	11.20	3.80	7.26	9.21	10.70	4.54	8.27	10.26	10.28	5.39	9.50	11.39
	Median	11.36	3.60	7.20	9.20	10.75	4.28	8.20	10.24	10.05	4.80	9.40	11.60
	SD	4.03	1.42	1.98	2.04	3.74	1.74	2.30	2.08	3.33	2.21	2.44	2.16
	Minimum	2.22	1.80	3.15	4.85	2.40	1.60	3.60	5.40	2.40	2.00	3.55	5.55
	Maximum	19.80	9.00	12.40	13.80	19.20	10.20	13.28	15.26	17.40	12.60	15.38	16.48

Table 2. Multivariate multilevel model. A 2-level (subject and site) multivariate model was built in order to investigate the effect of different parameters on bone height (BH) and bone width (BW), and to evaluate the correlation between measurements. Males showed a significantly higher BH compared to females at all sites. The analysis of the interaction factor between gender and site showed a significant, stronger effect of gender on BH at site c compared to site a. The model showed no significant impact of age on BH and no significant impact of age and gender on BW. A significant covariance between BH and BW (-0.7) was detected.

	"Empty Model"	Standard Error	"Final Model"	Standard Error	
Fixed Part - Bone height (BH)					
Intercept	10.68	0.31	10.90	1.91	
Site (ref. site a)					
Site b			-0.52	0.11	p<0.001
Site c			-0.76	0.11	p<0.001
Gender Male (ref. Female)			2.82	0.59	p<0.001
Age			-0.02	0.03	p=0.54
Gender X Distance					
Male site b			-0.11	0.15	p=0.47
Male site c			-0.47	0.15	p<0.001
Fixed Part – Bone width (BW)					
Intercept	7.68	0.14	3.87	0.94	
Vertical distance (ref. BW1mm)					
BW3mm			3.31	0.15	p<0.001
BW5mm			5.37	0.15	p<0.001
Gender Male (ref. Female)			-0.18	0.29	p=0.53
Age			0.00	0.01	p=0.83
Dist. f. (ref. Site a) X Vert. dist.					
BWb1mm			0.55	0.15	p<0.001
BWc1mm			1.38	0.15	p<0.001
BWb3mm			0.99	0.16	p<0.001
BWc3mm			2.17	0.15	p<0.001
BWb5mm			1.02	0.16	p<0.001
BWc5mm			2.06	0.16	p<0.001

Figure 1. Site used for the assessment of bone height (BH) and bone width (BW). In both sides of each edentulous mandible, the CBCT cross-sections at 6 mm, 11 mm, and 16 mm (site a, b and c, respectively) posterior to the most distal section including the mental foramen were used for radiographic measurements. According to previous studies, these positions correspond to the second premolar and the mesial and distal roots of the first molar (Yashar et al. 2012).

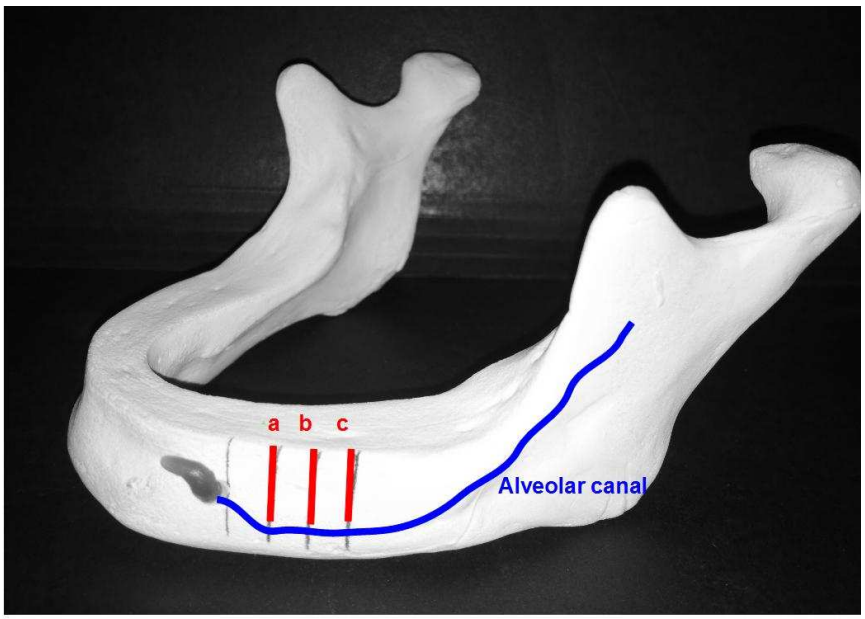


Figure 2. Reference points and bone height (BH) and bone width (BW) measurements on the CBCT cross-section. On each cross-section, lines were traced parallel to the inferior border of the mandible and passing through (i) the most coronal point of the alveolar crest (p_{crest}), (ii) 1, 3, and 5 mm apical to pcrest and (iii) the most coronal point of the mandibular canal (p_{AC}). BH was measured as the distance (in mm) between pcrest and p_{AC} Bucco-lingual bone width (BW) was measured at 1, 3, and 5 mm apical to pcrest ($BW_{1\ mm}$, $BW_{3\ mm}$, and $BW_{5\ mm}$, respectively).

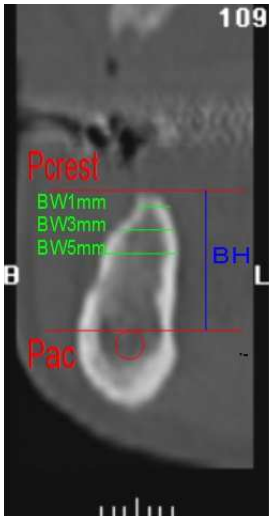


Figure 3. Bone height (BH) and bone width (BW) measurements at sites a, b, and c in female subjects. At all sites, BH values were significantly lower compared to those recorded in males ($p<0.001$), while BW measurements were not significantly different between male and female subjects.

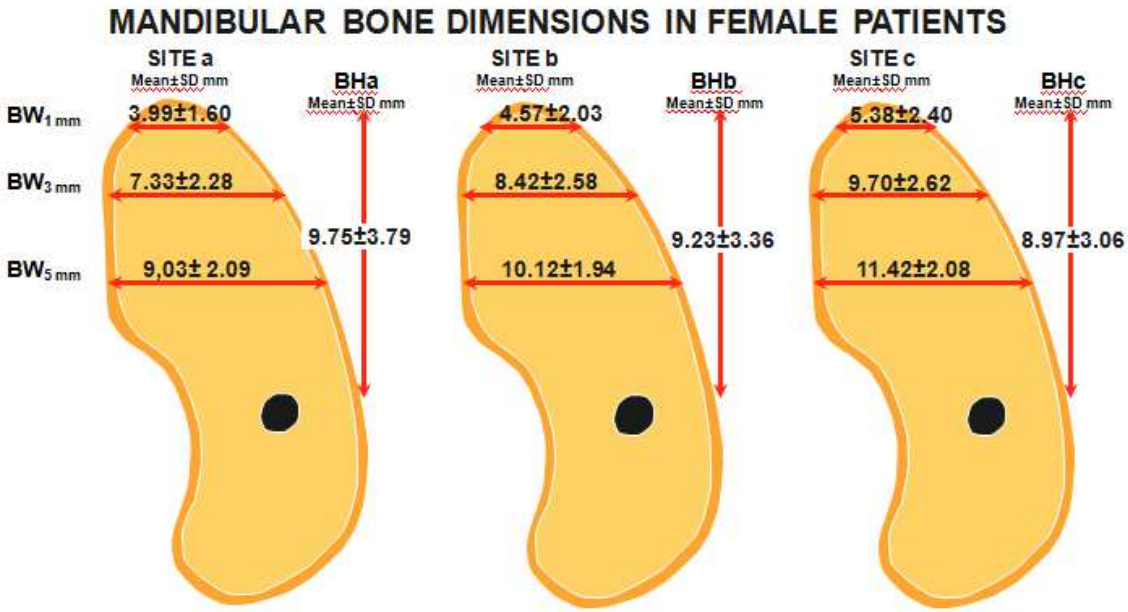


Figure 4. Bone height (BH) and bone width (BW) measurements at sites a, b, and c in male subjects. At all sites, BH values were significantly higher compared to those recorded in females ($p<0.001$), while BW measurements were not significantly different between male and female subjects.

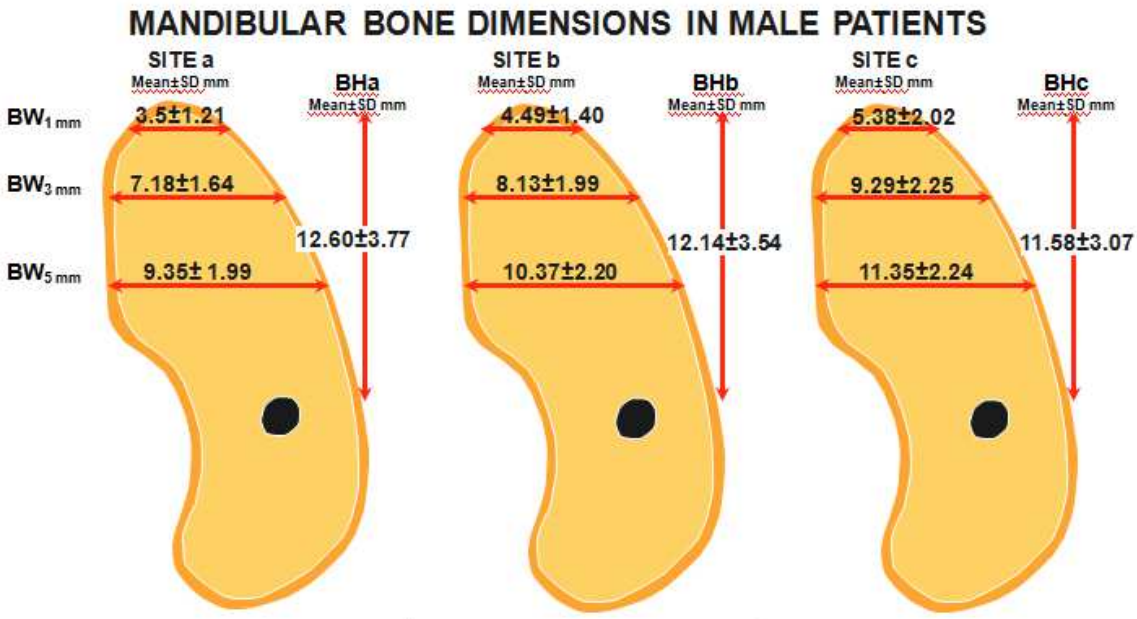


Figure 5. Cumulative frequency distribution of females according to bone height (BH). In females, a BH of 9 mm or higher was present in 55.2% and 49.9% of subjects at site a and c, respectively. Using a BH threshold of 11 mm, the prevalence at site a and c was 36.6% and 20.0%, respectively.

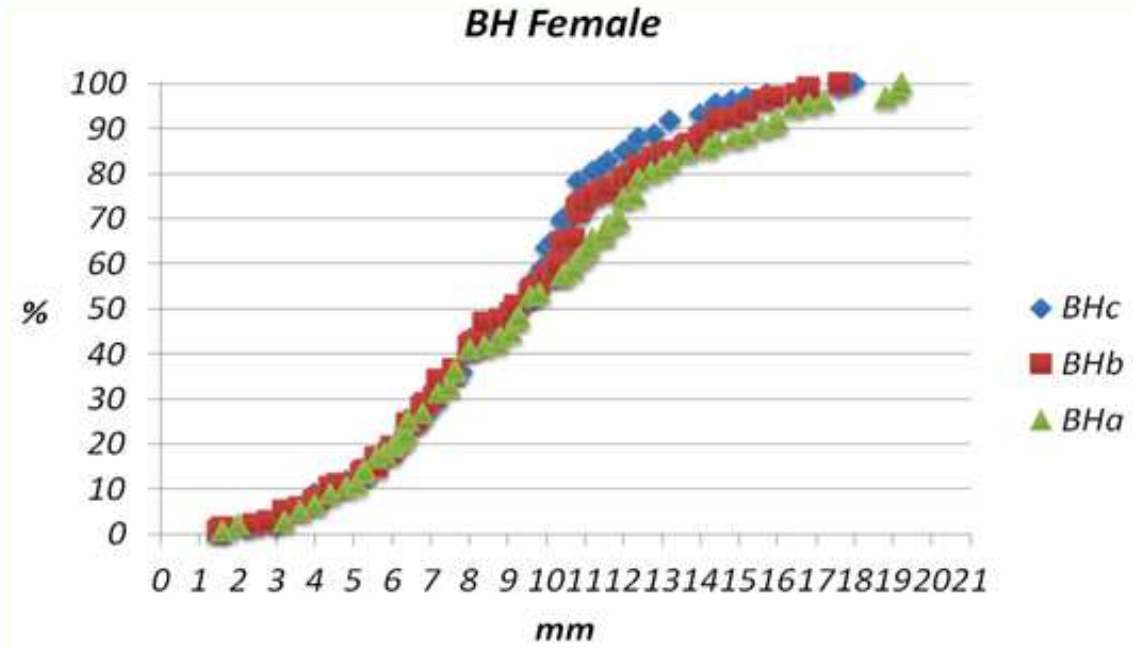


Figure 6. Cumulative frequency distribution of males according to bone height (BH). In males, a BH of 9 mm or higher was present in 82.8% and 77.9% of subjects at site a and c, respectively. Using a BH threshold of 11 mm, the prevalence at site a and c was 68.1% and 57.3%, respectively.

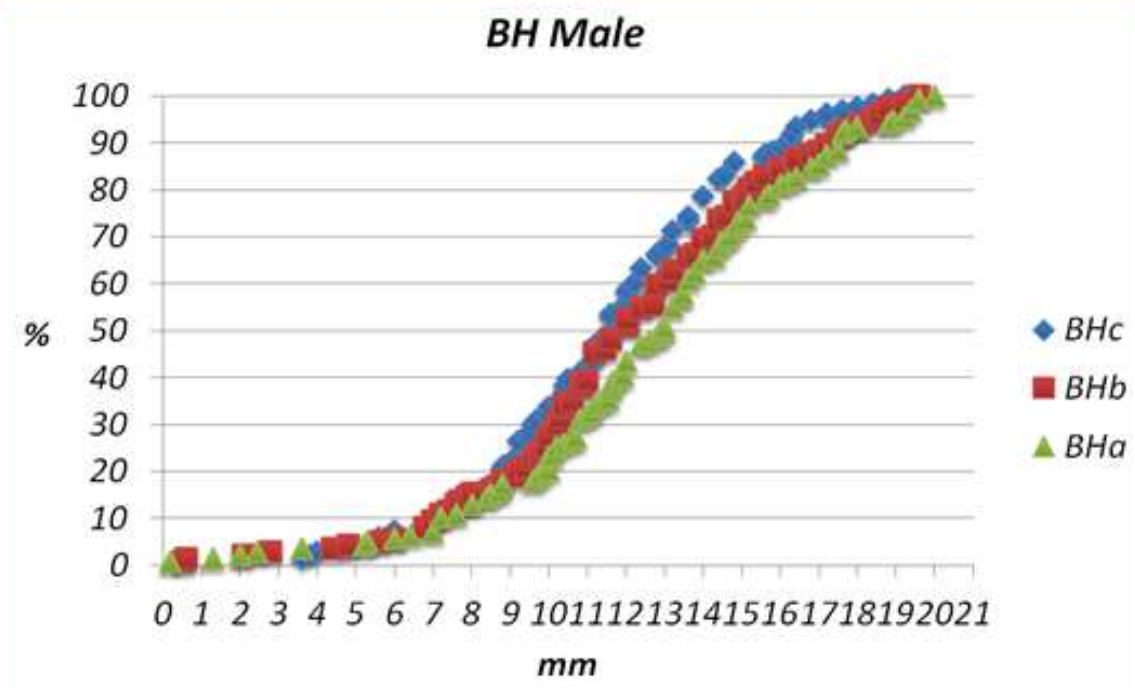


Figure 7. Cumulative frequency distribution of subjects according to bone width at 1 mm apical to pcrest (BW_{1mm}). BW1mm was 5 mm or higher in 22.1% of subjects at site a, in 30.8% of subjects at site b, and 40.7% of subjects at site c.

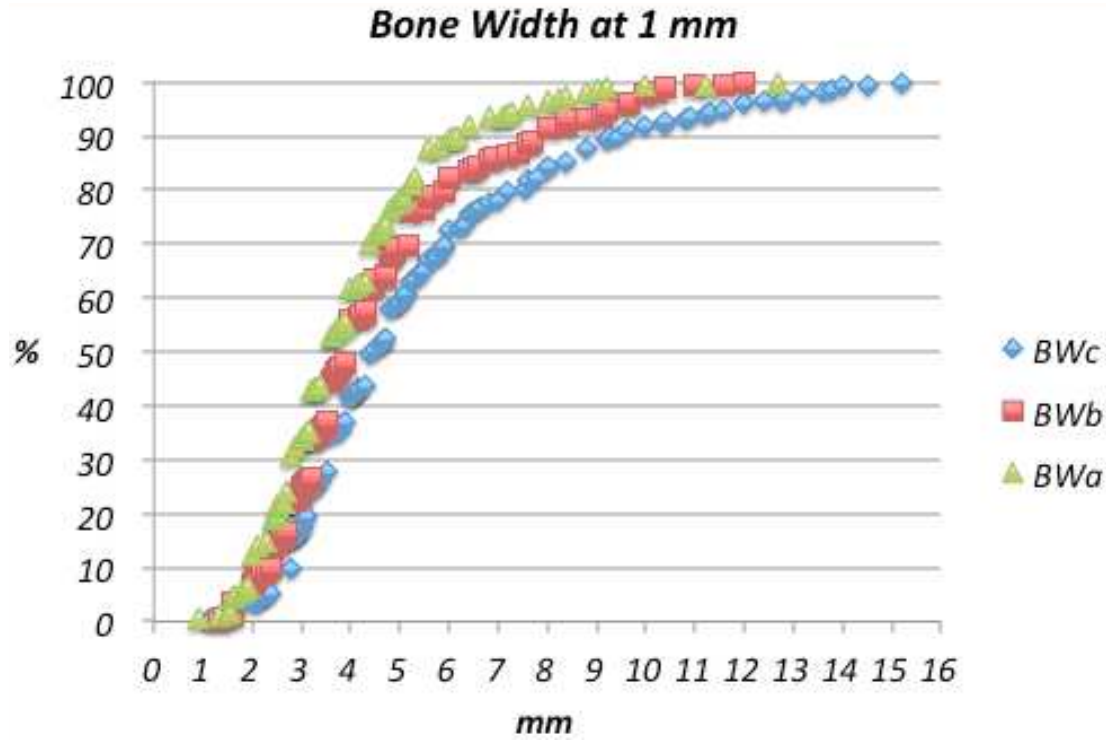


Figure 8. Cumulative frequency distribution of subjects according to bone width at 3 mm apical to pcrest (BW_{3mm}). BW3mm was 5 mm or higher in 83.4% of subjects at site a, 86.3% of subjects at site b and 92.5% of subjects at site c.

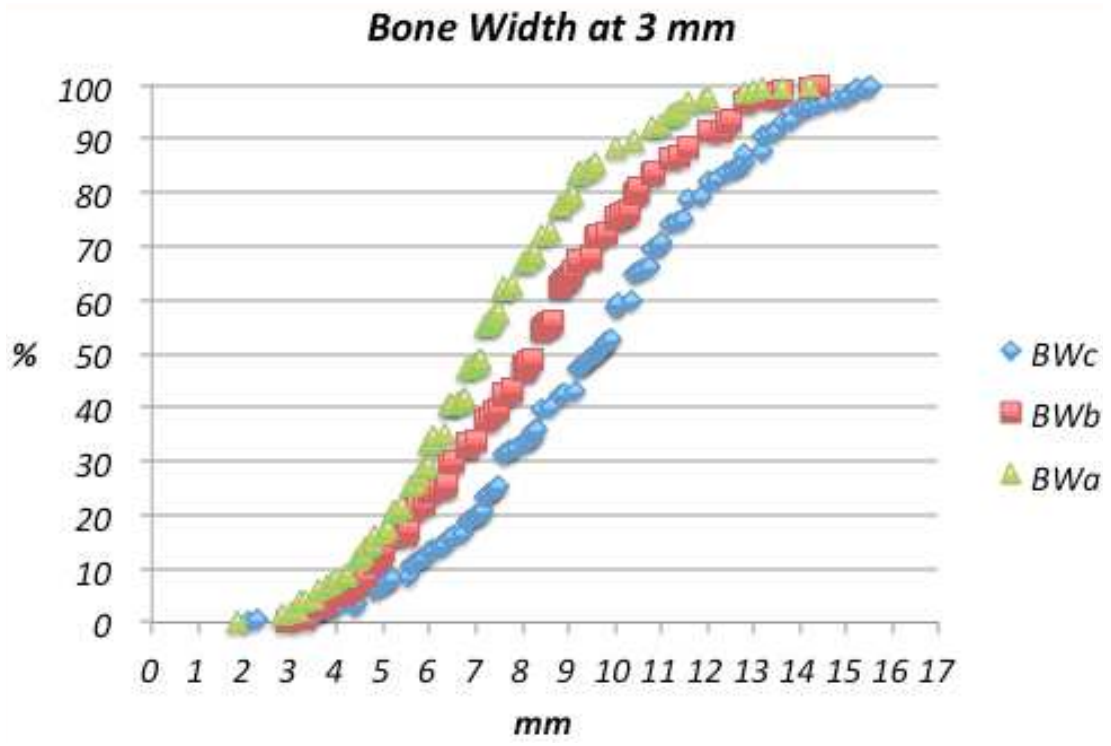
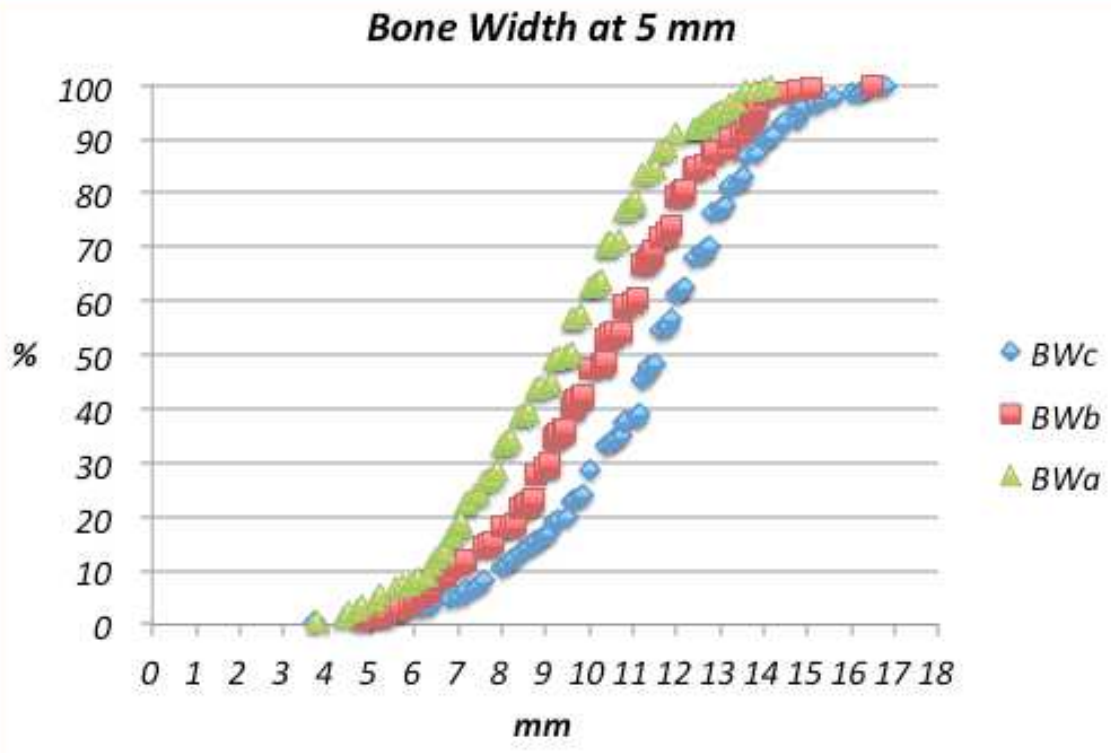


Figure 9. Cumulative frequency distribution of subjects according to bone width at 5 mm apical to pcrest (BW_{5mm}). At all sites (a, b and c), BW5mm was 5 mm or higher in the great majority (≥ 95%) of subjects.



THE EDENTULOUS POSTERIOR MANDIBLE:

Study #2: A retrospective comparative study of dentate and edentulous sites using computerized tomography data

ABSTRACT

Aim: The present study was performed to evaluate ridge dimensions at edentulous, mandibular posterior sites and contralateral dentate sites by using a novel methodology as previously described in Study #1.

Materials & Methods: Relative ridge position (rRP), bone height (BH), alveolar canal height (ACH), basal bone height (BBH) and bone width (BW), were measured at second premolar, first molar and second molar dentate sites and contralateral edentulous sites.

Results: When compared to dentate sites, edentulous sites showed lower BH, a more apical position of the ridge, lower BW1mm, lower ACH, and similar BBH. The difference in each radiographic measurement between edentulous and contralateral dentate sites was not significantly different between females and males. The prevalence of edentulous sites with BH≥ 9 mm and BW1mm≥ 6 mm and/or BH≥ 11 mm and BW3mm≥ 6 mm was higher in females compared to males at second premolar, while was higher in males compared to females at molar sites

Conclusions: edentulous sites show a reduced height and bucco-lingual ridge width compared to contralateral dentate sites. Gender seems to have a limited impact on the extent of ridge resorption

Key words: jaw, edentulous, partially; mandible; alveolar process; bone resorption; spiral cone-beam computed tomography; tooth extraction.

AIM

The present study was performed to evaluate ridge dimensions at edentulous, mandibular posterior sites and contralateral dentate sites by using a novel methodology as previously described in Study #1.

MATERIALS AND METHODS

Study design and ethical aspects

The study is a retrospective analysis of a convenience patient sample. The study protocol was approved by the Ethical Committee of Ferrara, Italy (protocol number: 161185). Each patient had provided a written informed consent before CT examination.

Study population

De-identified data were obtained from the record charts and radiographic examinations of patients referred to a specialist radiologic center ("Centro Medico Rovigo", Rovigo, Italy) for a spiral computerized tomography (CT) of the mandible from January, 2011 to December, 2016. Each patient contributed the study with one CT examination.

Patients were included if positive for each of the following criteria: (i) ≥21 years old; (ii) absence of all teeth distal to mental foramen (i.e. second premolar, first molar and second molar) in one mandibular quadrant, and presence of all teeth distal to mental foramen in the contralateral mandibular quadrant (iii) presence of the canine or first premolar in both mandibular quadrants; (iv) presence of a clearly identifiable ridge contour in the edentulous site/s of interest; (v) horizontal Spee curve. Patients were excluded if positive for one or more of the following criteria (all related to the areas distal to the mental foramen in both mandibular quadrants): (i) total or partial osseous retention of one or more teeth (apart from the third molars); (ii) radiographic evidence of bone augmentation procedures or signs of invasive surgery; (iii) presence of a radiolucent or a radiopaque area related to pathological conditions; (iv) presence of a dental implant; (v) presence of osteosynthesis plaques; (vi) unreadable CT; (vii) internal borders of one or more extraction sockets clearly identifiable in the CT scan (thus suggesting recent tooth extraction and incomplete wound healing process).

CT examination

All CT scans had been acquired with "Presto" Whole-Body X-ray Scanner (Hitachi Medical Corporation, Tokyo, Japan). The scan plane had been set parallel to the occlusal plane of mandibular teeth or, when the occlusal plane was not identifiable, to the mandibular alveolar crest. Axial (parallel to the scan plane), panoramic (perpendicular to the scan plane, latero-lateral direction) and cross-section (perpendicular to the scan plane, antero-posterior direction) 1 mm – slices were obtained. The following protocol had been used: pitch 1:1, matrix 512 512, field of view 13.8, 120 Kvp and 100 mA. The effective radiation dose was 304.5 micro Sv.

Identification of premolar and molar dentate and edentulous sites as a fixed reference point for linear measurements

CT scans were post-processed with an AquariusNET software v.4.3.2.5 (TeraRecon Inc., San Mateo, CA, USA). In the dentate part, the middle CT cross-sections including each tooth (second premolar, first molar and second molar) were considered as the CT cross-sections to be used for the radiographic measurements. This CT cross-section was, therefore, regarded as the "section of interest" (SOI). For each patient, the distance between the center of the mental spines, as assessed at the middle CT cross-section including the mental spines, and the SOI of each single tooth of the dentate part was recorded. These distances were then referred to the contralateral edentulous lacuna in order to identify the SOI at sites corresponding to the location of missing teeth. Therefore, the distance from SOI to the mental spines was symmetric for each dentate/edentulous site in each patient.

Processing of CT scans

On the panoramic slice of each CT scan, a digital line parallel to the CT scan plane was traced passing through the CEJ of the homolateral canine or first premolar (Figure 1). This digital line was visualized on the SOI of dentate and edentulous sites as a reference point (P) to perform vertical linear measurements. On the SOI of dentate and edentulous sites, lines were traced parallel to the CT scan plane and passing through: (i) P (h_{CEJ}); (ii) the most coronal point of the alveolar crest (in dentate sites) or the ridge (in edentulous sites) (h_{crest}); (iii) 1, 3, and 5mm apically to the most coronal point of the alveolar crest/ridge (h_{1mm}, h_{3mm} and h_{5mm}, respectively); (iv) the most coronal point of the

alveolar canal (h_{cAC}); (v) the most apical point of the alveolar canal (h_{aAC}); (vi) the most apical point of the mandibular inferior border (h_{MIB}) (Figures 2, 3).

On the SOI, the following recordings were performed:

- *relative ridge position* (rRP): measured as the distance (in mm) from hCEJ to h_{crest} in the SOI of dentate/edentulous sites;

- *bone height* (BH): measured as the distance (in mm) from h_{crest} to h_{cAC} in the SOI of dentate and edentulous sites;

- *bone width* (BW): measured as the width (in mm) of the alveolar crest recorded on h_{1mm} (BW_{1mm}), h_{3mm} (BW_{3mm}) and h_{5mm} (BW_{5mm}) in the SOI of dentate and edentulous sites. BW was not measured when the reference line (i.e. h_{1mm}, h_{3mm}, or h_{5mm}) crossed or was apical to the alveolar canal. In dentate sextants, BW was not measured when the buccal and/ or lingual cortical bone were not present;

- *alveolar canal height* (ACH): measured as the distance (in mm) from h_{cAC} to the most h_{aAC} in the SOI of dentate and edentulous sites;

- *basal bone height* (BBH): measured as the distance (in mm) from h_{aAC} to h_{MIB} in the SOI of dentate and edentulous sites

All measurements were performed with a digital ruler at 0.1 mm increments by a single calibrated examiner (M.P.)

Statistical analysis

Data were entered in a SPSS Statistics 22.0 (SPSS Inc, Chicago, IL). The patient was regarded as the statistical unit. Therefore, for each patient, measurements were compared between dentate and the respective edentulous sites. Kolmogorov-Smirnov goodness-of-fit tests were computed for each variable and intra-subject variation in each variable to assess whether they were normally distributed. Data were expressed as mean and standard deviation (SD). For each parameter, difference between edentulous and dentate sites was calculated. A negative value indicates a lower recording at edentulous site compared with contralateral dentate site, while a positive value indicates a higher recording at edentulous site compared with contralateral dentate site. Dentate and edentulous sites were compared using paired Student's t test. Because of the limited sample size, which in turn may affect the statistical power of the study, the level of significance was set at p<

0.001. We also calculated the prevalence (%) of dentate/edentulous sites that satisfied at least one of the following conditions: BH≥ 9 mm and BW1mm≥ 6 mm; BH≥ 11 mm and BW3mm≥ 6 mm. Since previous studies reported a significantly higher BH in males compared to females (Bressan et al 2016), a sub-analysis was conducted to evaluate the influence of gender on the differences in ridge dimensions between edentulous and dentate sites. In particular, the difference in each radiographic measurements between edentulous and contralateral dentate sites was calculated for males and females separately, and compared between genders using the Student's t test for independent observations.

RESULTS

Study population

Twenty-four subjects (12 males and 12 females; mean age: 57.42 ± 8.92 years, range: 39–72 years) were included for analysis. Male subjects had a mean age of 57.30 ± 8.55 years (range: 39 – 68 years), while females had a mean age of 57.91 ± 9.62 years (range: 44 - 72 years).

Comparison between edentulous and dentate sites

Radiographic measurements

Data related to rRP, BH, BW, ACH and BBH in dentate and edentulous sites as observed in the overall study population are reported in Table 1. At all positions, edentulous sites showed a significantly higher rRP and lower BH compared to dentate sites. The difference in rRP between edentulous and dentate sites was 3.30 mm (2.22 to 4.30 mm) at second premolar, 3.35 mm (2.62 to 5.00 mm) at first molar, and 3.60 mm (2.17 to 4.60 mm) at second molar site. The difference in BH between edentulous and dentate sites was -2.00 mm (-3.27 to -0.70 mm) at second premolar, -2.50 mm (-3.70 to -0.80 mm) at first molar, and -2.30 mm (-3.40 to -1.47 mm) at second molar site. At all positions, edentulous sites showed a significantly lower BW1mm compared to dentate sites. The difference in BW1mm between edentulous and dentate site was -3.30 (-4.42 to -2.50 mm) at second premolar, -4.70 mm (-5.97 to -2.97 mm) at first molar, and -3.50 mm (-4.90 to -1.37 mm) at second molar site. Minor, although still significant differences in BW3mm were observed between edentulous and dentate second premolar and first molar sites. At all positions, ACH was significantly lower at edentulous compared to contralateral dentate sites, while no significant difference in BBH was observed edentulous and contralateral dentate sites.

Prevalence of sites above specific bone height and width thresholds

The prevalence of edentulous site with BH≥ 9mm and BW1mm≥ 6mm and/or BH≥ 11 mm and BW3mm≥ 6mm as derived from the overall study population is shown in Figure 4. Depending on the position, the mean prevalence ranged between 70.8% and 79.2%.

Ridge dimensions in males and females

Radiographic measurements in males and females are reported in Tables 2 and 3. Both genders had significantly higher rRP in edentulous sites compared to dentate sites. BH was significantly lower in first molar and second molar edentulous sites compared to contralateral dentate sites, while females did not show significant differences in BH edentulous and dentate sites. All edentulous sites in males showed a significantly lower BW1mm compared to their dentate counterparts, while in females this finding reached statistical significance only at second premolar and first molar sites. ACH was significantly lower at edentulous compared to contralateral dentate sites at all positions in females, and at first molar and second molar sites in males. BBH was similar at edentulous and contralateral dentate sites irrespective of gender. The difference in each radiographic measurement (i.e., rRP, BH, ACH, BBH, BW1mm, BW3mm, BW5mm) between edentulous and contralateral dentate sites did not show significant differences between females and males.

The prevalence of edentulous site with BH≥ 9mm and BW1mm≥ 6mm and/or BH≥ 11 mm and BW3mm≥ 6mm as observed in males and females is shown in Figure 4. At second premolar, the prevalence was higher in females (83.3%) compared to males (58.3%), while was higher in males compared to females at first molar (83.3% vs 66.6%) and second molar (83.3% vs 75.0%).

DISCUSSION

The present study was performed to comparatively evaluate the ridge dimensions at edentulous and contralateral dentate sites in the posterior mandible. CT scans of 24 mandibles of partially edentulous subjects with one fully edentulous and one fully dentate area posterior to the mental foramen were retrospectively obtained and used for radiographic assessments.

At all positions, a significant difference in BH, rRP, ACH, BW1mm, but not in BBH, was observed between dentate and edentulous sites. Overall, these findings seem to indicate that the dimensional alterations of the alveolar ridge occurring following tooth extraction in the posterior mandible involve

the tissue compartment coronal to the inferior alveolar canal, and not basal bone. Consistently, clinical and/or radiographic observations reported in previous studies demonstrated that marked alterations in height and width of the alveolar compartment occur following the loss of one or more teeth (Pietrokovski & Massler 1967, Xie et al. 1996, 1997, Lekovic et al. 1997, 1998, Schropp et al. 2003, Araujo & Lindhe 2005, Canger & Celenk 2012).

According to the present data, the lower values of BH at edentulous sites compared to dentate sites were associated with higher rRP and lower ACH. These findings suggest that the modifications in bone height occurring following tooth extraction are mainly due to an apical displacement of the position of the alveolar crest as well demonstrated in previous studies (Araujo & Lindhe 2005, Farina et al. 2011) and a reduction in the lumen of the inferior alveolar canal. Since no difference in BBH was observed between dentate and edentulous sites, the post-extraction reduction in the lumen of the canal seems to be due to the apical displacement of its superior border rather than a coronal displacement of its inferior border. It can be speculated that this alteration may occur due to the loss of nerves and vessels within and above the canal. To the best of our knowledge, this is the first study suggesting a contribution of the inferior alveolar canal in determining the residual ridge dimensions after tooth loss.

In a dedicated sub-analysis, the prevalence of edentulous sites at or above specific BH and BW thresholds was evaluated. In particular, we calculated the prevalence of sites with BH≥ 9mm and BW1mm≥ 6mm and/or BH≥ 11 mm and BW3mm≥ 6mm. On the bucco-lingual axis, BW thresholds ensured the placement of a 4-mm wide implant with a 1-mm safety margin from the outer surfaces of the buccal and oral cortical plates. On the vertical axis, BH thresholds allowed for the placement of a 6-mm long implant at 1 or 3 mm apical to the crest (if BW1mm≥ 6mm or BW3mm≥ 6mm, respectively) and with a 2-mm safety margin from the inferior alveolar canal. The use of short implants has been extensively investigated in the literature. Studies comparing the performance of short implants and long (> 8mm) implants placed concomitantly or after bone augmentation reported lower operative time, morbidity and costs for short implants compared to long implants (Thoma et al. 2015, Schincaglia et al. 2015, Bechara et al 2016, Felice et al. 2016). Morever, a recent meta-analysis reported that short implants placed in the posterior mandible should be preferred to vertical augmentation procedures and placement of longer implants, which are associated with similar implant and prosthetic failure rates but greater morbidity (Octavi et al. 2016). According to our analysis, residual ridge dimensions would have allowed for the placement of short implants without bone reconstructive procedures in 70.8% 75.0% and 79.2% of cases at second premolar, first molar and second molar sites, respectively. Conversely, these data indicate that a proportion of edentulous,

mandibular posterior sites ranging from about 20 to 30% may require bone augmentation to allow for implant placement.

In our material, the magnitude of the difference observed in each radiographic measurement between edentulous and contralateral dentate sites did not differ between males and females. This finding suggests that gender may have a limited impact on the dynamics of ridge resorption following tooth loss. On the other hand, differences between genders were observed in the prevalence of edentulous sites with anatomical characteristics suitable for implant placement. In particular, the prevalence was higher in females (83.3%) compared to males (58.3%) at second premolar, while was higher in males compared to females at first molar (83.3% vs 66.6%) and second molar (83.3% vs 75.0%). It is reasonable to hypothesize that these differences may be partly explained by different pre-extraction dimensions of the alveolar ridge in males and females.

To analyze the difference between the dentate and the edentulous sites, the position of SOI was defined with respect to the center of the mental spine as fixed reference point. Therefore, a necessary assumption to interpret our results is that the posterior mandibular dentition develops with a substantial degree of left–right symmetry. Previous studies have reported limited variations in the dimensions between mandibular left and right sides (Adeyemi & Isiekwe 2004). Early investigations on the symmetry of the mandibular arches indicated that in both gender the left and the right heme-mandibular segments were similar without significant differences in size or shape (Ferrario et al. 1993, de Araujo et al. 1994). Due to the retrospective nature of the study design, it is impossible to exclude that differences in teeth position and alignment between left and right side of the posterior mandible could have partly influenced the measurements in the ridge dimension assessed at dentate vs. edentulous sites. Other limitations of the study have to be considered due to the use of de-identified data. Hence no information was available in relation to patient medical and dental history, and status, use of prosthetic devices and para-functional habits. Also, it was not possible to know the interval from the time of patient imaging and the time of tooth extraction. However, in the present cohort, all the edentulous sites showed a radiographic appearance of advanced healing since the internal borders of the socket walls were not identifiable on the CT cross sections (Pramstraller 2011, Farina 2011, Bressan et al. 2016).

In conclusion, the results of the present study indicate that (i) edentulous sites in the posterior mandible show a reduced height and bucco-lingual width of the ridge when compared with contralateral dentate sites; (ii) gender seems to have a limited impact on the dynamics of ridge resorption following tooth loss.

TABLE & FIGURES

Table 1. Relative ridge position (rRP),bone height (BH), alveolar canal height (ACH),basal bone height (BBH) and bone width as assessed at 1, 3 and 5 mm from the alveolar crest (BW1 mm, BW3 mm and BW5 mm, respectively) at second premolar, first molar and second molar sites in dentate and edentulous mandibular posterior part

	N°	Dentate sites		Edentulous sites		Inter-group difference				P-value for inter-group comparison
		Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Median (mm)	IR (mm)	
rRP										
	Second premolar	24	4.11	1.03	7.25	1.45	3.14	1.38	3.30	(2.22 to 4.30)	0.000
	First molar	24	4.37	1.40	8.10	1.93	3.72	1.60	3.35	(2.62 to 5.00)	0.000
	Second molar	24	3.77	1.10	7.27	1.92	3.50	1.58	3.60	(2.17 to 4.60)	0.000
BH										
	Second premolar	24	16.56	2.65	14.37	2.84	-2.19	1.87	-2.00	(-3.27 to -0.70)	0.000
	First molar	24	16.08	2.96	13.41	2.82	-2.67	2.18	-2.50	(-3.70 to -0.80)	0.000
	Second molar	24	14.99	2.67	12.43	3.02	-2.56	1.75	-2.30	(-3.40 to -1.47)	0.000
ACH										
	Second premolar	24	3.35	0.53	2.89	0.48	-0.45	0.45	-0.60	(-0.70 to -0.12)	0.000
	First molar	24	3.53	0.54	2.70	0.29	-0.82	0.56	-0.80	(-1.00 to -0.42)	0.000
	Second molar	24	3.75	0.55	2.81	0.52	-0.94	0.55	-0.90	(-1.27 to -0.72)	0.000
BBH										
	Second premolar	24	7.85	1.29	8.07	1.30	0.22	0.59	0.20	(-0.1 to 0.47)	0.081
	First molar	24	6.42	1.46	6.69	1.39	0.26	0.71	0.30	(-0.07 to 0.60)	0.085
	Second molar	24	6.54	0.92	6.72	0.93	0.18	0.56	0.05	(-0.10 to 0.37)	0.124
BW_{1mm}										
	Second premolar	24	8.35	0.97	4.99	1.22	-3.36	1.31	-3.30	(-4.42 to -2.50)	0.000
	First molar	24	10.23	0.70	5.99	2.13	-4.24	2.14	-4.70	(-5.97 to -2.97)	0.000
	Second molar	24	10.52	1.23	7.67	2.48	-2.84	2.81	-3.50	(-4.90 to -1.37)	0.000
BW_{3mm}										
	Second premolar	24	9.20	1.33	7.04	1.37	-2.16	1.04	-2.00	(-2.82 to -1.30)	0.000
	First molar	24	11.13	1.03	8.87	2.23	-2.25	2.13	-2.90	(-3.87 to -0.75)	0.000
	Second molar	24	11.75	0.83	11.15	2.52	-0.59	2.37	-0.95	(-2.35 to 1.00)	0.232
BW_{5mm}										
	Second premolar	24	9.79	1.65	8.80	1.70	-0.98	1.29	-0.80	(-1.87 to 0.50)	0.001
	First molar	24	11.92	1.31	10.98	2.15	0.93	1.93	-0.90	(-2.27 to -0.32)	0.027
	Second molar	24	13.25	1.63	12.87	2.36	0.38	2.33	-0.70	(-1.65 to 1.17)	0.430

Table 2. Relative ridge position (rRP),bone height (BH), alveolar canal height (ACH),basal bone height (BBH) and bone width as assessed at 1, 3 and 5 mm from the alveolar crest (BW1 mm, BW3 mm and BW5 mm, respectively) at second premolar, first molar and second molar sites in dentate and edentulous mandibular posterior part in female population

	N°	Dentate sites		Edentulous sites		Inter-group difference				P-value for inter-group comparison
		Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Median (mm)	IR (mm)	
rRP										
Second premolar	12	4.05	1.08	7.19	1.47	3.13	1.41	3.30	(2.52 to 4.12)	0.000
First molar	12	4.40	0.95	7.62	1.74	3.22	1.70	2.95	(1.87 to 3.77)	0.000
Second molar	12	3.95	1.24	7.46	2.02	3.50	1.70	3.85	(1.97 to 4.82)	0.000
BH										
Second premolar	12	15.95	2.72	13.90	2.44	-2.04	1.70	-1.55	(-3.00 to -0.85)	0.002
First molar	12	15.84	2.76	13.50	2.71	-3.34	2.42	-1.20	(-3.75 to -0.52)	0.007
Second molar	12	14.62	3.04	12.76	3.47	-1.85	1.69	-1.60	(-3.05 to -0.47)	0.003
ACH										
Second premolar	12	3.25	0.51	2.75	0.42	-0.50	0.34	-0.60	(-0.70 to -0.12)	0.000
First molar	12	3.32	0.44	2.62	0.12	-0.70	0.42	-0.60	(-1.00 to -0.32)	0.000
Second molar	12	3.56	0.47	2.53	0.29	-1.03	0.57	-1.00	(-1.35 to -0.72)	0.000
BBH										
Second premolar	12	7.50	0.84	7.70	0.84	0.20	0.48	0.30	(-0.1 to 0.47)	0.185
First molar	12	6.22	1.33	6.35	1.27	0.13	0.67	0.30	(-0.42 to 0.57)	0.509
Second molar	12	6.45	0.88	6.50	0.86	0.05	0.42	0.05	(-0.17 to 0.30)	0.647
BW_{1mm}										
Second premolar	12	8.27	0.93	4.79	0.98	-3.48	1.39	-3.10	(-4.41 to -2.50)	0.000
First molar	12	9.96	0.65	5.67	2.16	-4.29	2.27	-4.80	(-6.27 to -3.10)	0.000
Second molar	12	9.87	1.00	7.59	2.82	-2.28	3.17	-3.05	(-4.90 to -0.27)	0.030
BW_{3mm}										
Second premolar	12	9.07	1.39	7.06	1.09	-2.00	1.18	-1.80	(-2.37 to -1.35)	0.000
First molar	12	10.80	0.78	8.39	2.22	-2.41	2.44	-3.30	(-4.17 to -01.05)	0.006
Second molar	12	11.52	0.66	10.90	2.70	-0.61	2.82	-0.65	(-3.55 to 1.30)	0.466
BW_{5mm}										
Second premolar	12	9.61	1.82	8.82	1.54	-0.79	1.51	-0.50	(-1.05 to 0.20)	0.097
First molar	12	11.62	1.26	10.85	2.41	-0.77	2.35	-0.90	(-2.37 to -0.10)	0.279
Second molar	12	13.15	1.91	12.70	2.79	-0.45	2.77	-0.55	(-2.17 to 1.42)	0.579

Table 3. Relative ridge position (rRP),bone height (BH), alveolar canal height (ACH),basal bone height (BBH) and bone width as assessed at 1, 3 and 5 mm from the alveolar crest (BW1 mm, BW3 mm and BW5 mm, respectively) at second premolar, first molar and second molar sites in dentate and edentulous mandibular posterior part in male population

	N°	Dentate sites		Edentulous sites		Inter-group difference				P-value for inter-group comparison
		Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Median (mm)	IR (mm)	
rRP										
Second premolar	12	4.16	1.02	7.32	1.49	3.15	1.41	3.30	(2.12 to 4.37)	0.000
First molar	12	4.35	1.78	8.57	2.06	4.22	1.40	4.40	(3.07 to 5.45)	0.000
Second molar	12	3.58	0.94	7.07	1.88	4.49	1.52	3.60	(2.17 to 4.45)	0.000
BH										
Second premolar	12	17.17	2.55	14.83	3.23	-2.34	2.10	-2.75	(-3.90 to -0.55)	0.003
First molar	12	16.33	3.26	13.33	3.04	-3.00	1.97	-2.80	(-3.70 to -1.42)	0.000
Second molar	12	15.36	2.32	12.10	2.60	-3.26	1.58	-2.70	(-3.95 to -2.20)	0.000
ACH										
Second premolar	12	3.43	0.57	3.03	0.51	-0.40	0.54	-0.50	(-0.85 to -0.07)	0.028
First molar	12	3.75	0.56	2.79	0.38	-0.95	0.67	-0.90	(-1.07 to -0.55)	0.000
Second molar	12	3.94	0.58	3.09	0.57	-0.85	0.53	-0.85	(-1.25 to 0.42)	0.000
BBH										
Second premolar	12	8.19	1.59	8.43	1.60	0.24	0.70	0.15	(-0.17 to 0.57)	0.258
First molar	12	6.63	1.60	7.02	1.47	0.39	0.75	0.25	(-0.07 to 0.92)	0.101
Second molar	12	6.64	0.99	6.95	0.98	0.30	0.66	0.05	(-0.10 to 0.90)	0.137
BW_{1mm}										
Second premolar	12	8.44	1.04	5.20	1.43	-3.24	1.27	-3.30	(-4.50 to -2.00)	0.000
First molar	12	10.50	0.66	6.30	2.14	-4.20	2.09	-0.42	(-5.97 to -2.97)	0.000
Second molar	12	11.16	1.12	7.75	2.20	-3.40	2.40	-3.50	(-5.10 to -2.57)	0.000
BW_{3mm}										
Second premolar	12	9.33	1.32	7.01	1.65	-2.31	0.91	-2.60	(-3.00 to -1.22)	0.000
First molar	12	11.45	1.18	9.36	2.23	-2.09	1.86	-1.95	(-3.77 to -0.37)	0.003
Second molar	12	11.97	0.94	11.40	2.42	-0.57	1.95	-1.20	(-2.05 to 0.90)	0.330
BW_{5mm}										
Second premolar	12	9.96	1.51	8.78	1.92	-1.18	1.05	-1.40	(-2.17 to -0.15)	0.003
First molar	12	12.21	1.36	11.12	1.95	-1.09	1.50	-0.90	(-1.97 to -0.35)	0.028
Second molar	12	13.35	1.39	13.04	1.94	-0.30	1.92	-0.70	(-1.15 to 0.77)	0.591

Figure 1. On the panoramic slice of each CT scan, a digital line parallel to the CT scan plane was traced passing through the CEJ of the homolateral canine or first premolar.

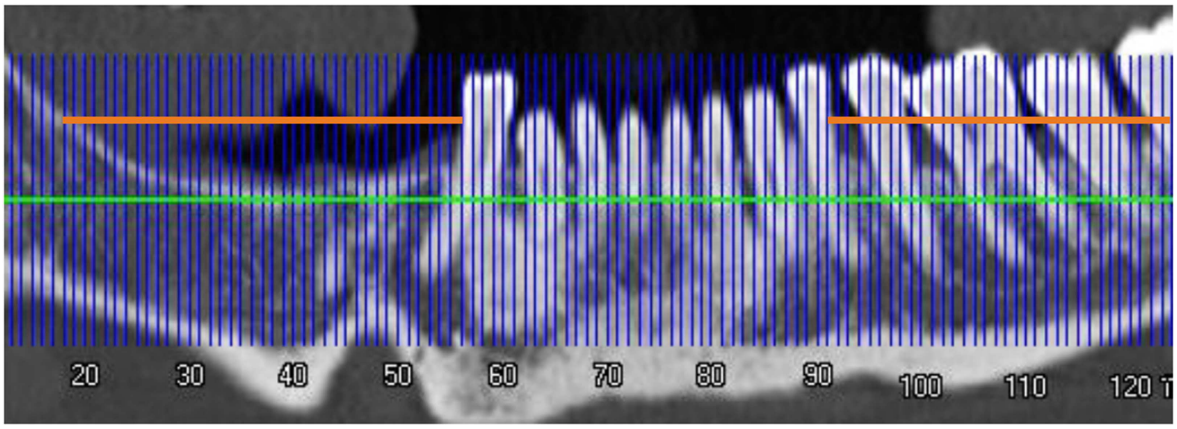


Figure 2. Reference lines and radiographic measurements at dentate sites.

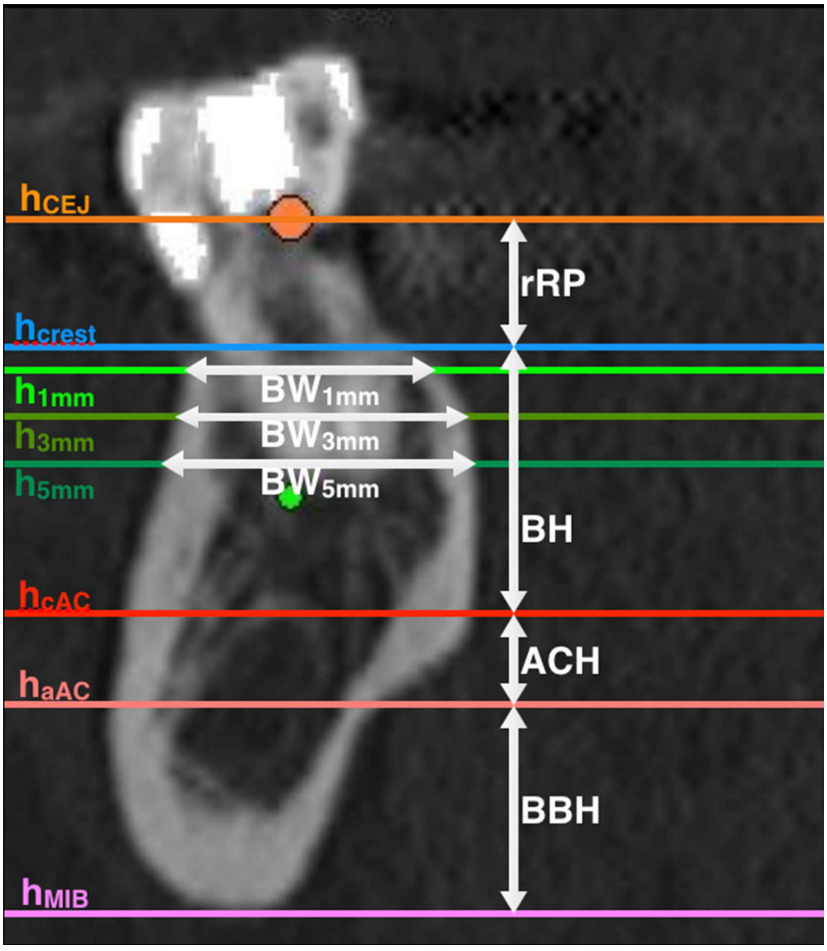


Figure 3. Reference lines and radiographic measurements at edentulous sites.

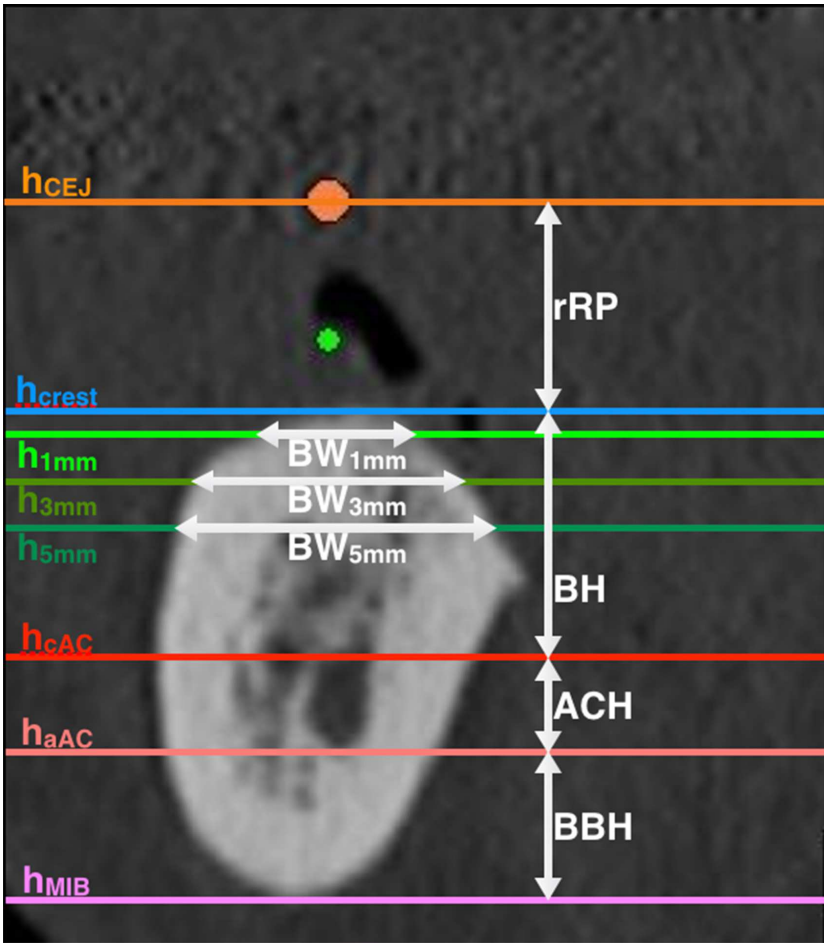
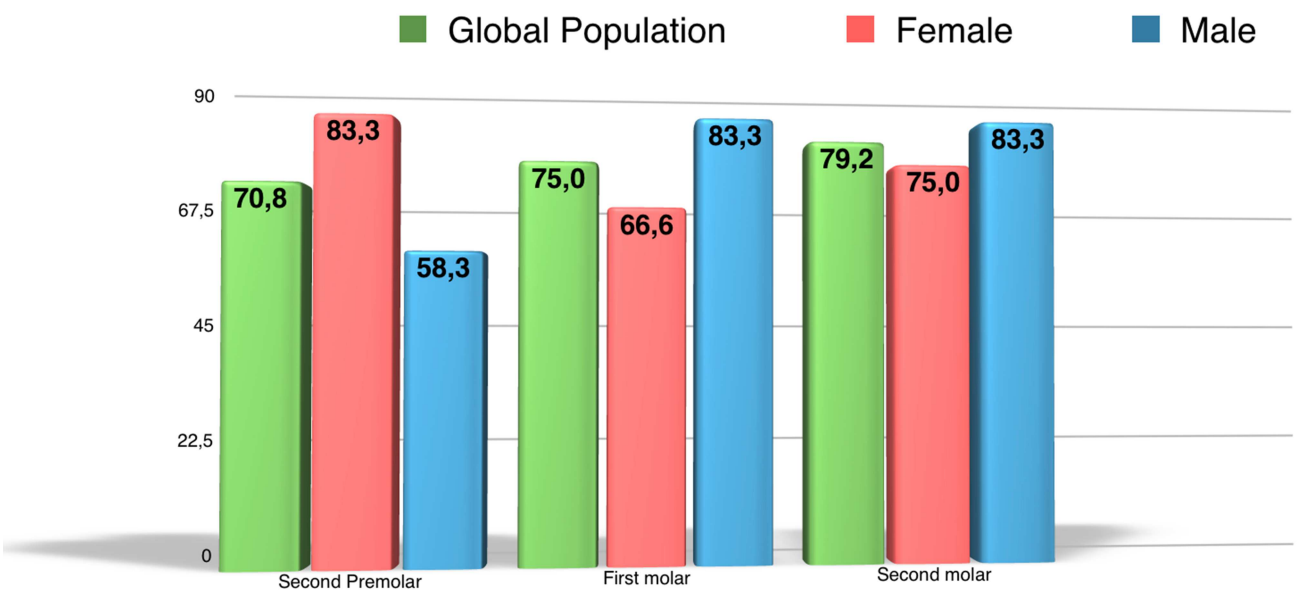


Figure 4. Proportion of edentulous sites with BH≥ 9mm and BW1mm≥ 6mm and/or BH≥ 11 mm and BW3mm≥ 6mm as derived from (i) the overall study population, (ii) males and (iii) females.



CHAPTER 3

THE EDENTULOUS POSTERIOR MAXILLAE:

Patient-reported outcomes of implant placement performed concomitantly with transcrestal sinus floor elevation or entirely in native bone

ABSTRACT

Aim: Based on the hypothesis that maxillary sinus floor elevation with a transcrestal approach (tSFE) does not increase the morbidity of implant surgery, the study evaluated the patient-reported outcomes as well as the type and incidence of complications when implants are placed either concomitantly with a novel tSFE procedure (Trombelli et al. 2008, 2010a,b) or entirely in native bone.

Methods: Data from the record charts of patients undergone implant placement for single-tooth rehabilitation in the posterior maxilla were retrospectively obtained from four clinical centers. Cases for tSFE group were included if they showed an extent of sinus lift ≥4 mm concomitantly to implant placement. Cases for N group were included when implant placement was performed entirely in native bone. Patient-reported outcomes had been assessed using 100-mm visual analog scales (postoperative pain, VAS_{pain}) and visual rating scales (level of discomfort, $VRS_{discomfort}$; willingness to undergo the same surgery, VRSwillingness). The dose of analgesics had been self- recorded.

Results: A convenience sample of 14 patients and 17 patients (contributing with one implant site each) treated with tSFE and N, respectively, was obtained for this study. Membrane perforation occurred in 1 tSFE case, without compromising the completion of the procedure. VAS_{pain} remained low (<12) in both groups. A tendency of VAS_{pain} to decrease with time was observed in both groups. The area under the curve for VAS_{pain} (AUC_{pain}), indicating the level of pain experience through the first week following surgery, was 18.0 (IR: 8.5–85.0) and 11.5 (IR: 4.5–18.5) in tSFE and N groups, respectively, with no significant inter-group differences (P = 0.084). The dose of analgesics was similarly low between groups. No significant inter-group difference in $VRS_{discomfort}$ and $VRS_{willingness}$ was observed.

Conclusions: Implant placement performed either concomitantly with tSFE (according to Trombelli et al. 2008, 2010a,b) or entirely in native bone is associated with limited incidence of complications, low postoperative pain and medication and are both well tolerated.

Key words: dental implants, dental implants, single tooth, maxillary sinus, morbidity, operative time, sinus floor augmentation

INTRODUCTION

Anatomical considerations

The Maxillary Sinus or Antrum of Highmore (sinus maxillaris) is a large pyramidal cavity, within the body of the maxilla: its apex, directed lateralward, is formed by the zygomatic process; its base, directed medialward, by the lateral wall of the nose. Its walls are everywhere exceedingly thin, and correspond to the nasal orbital, anterior, and infratemporal surfaces of the body of the bone. Its nasal wall, or base, presents, in the disarticulated bone, a large, irregular aperture, communicating with the nasal cavity. In the articulated skull this aperture is much reduced in size by the following bones: the uncinate process of the ethmoid above, the ethmoidal process of the inferior nasal concha below, the vertical part of the palatine behind, and a small part of the lacrimal above and in front; the sinus communicates with the middle meatus of the nose, generally by two small apertures left between the above-mentioned bones. In the fresh state, usually only one small opening exists, near the upper part of the cavity; the other is closed by mucous membrane. On the posterior wall are the alveolar canals, transmitting the posterior superior alveolar vessels and nerves to the molar teeth. The floor is formed by the alveolar process of the maxilla, and, if the sinus be of an average size, is on a level with the floor of the nose; if the sinus be large it reaches below this level.

The maxillary sinus is frequently reinforced with internal vertical septa termed “Underwood’s septa”, creating further intrasinus cavities. The overall prevalence of one or more sinus septa is between 26.5% and 31% (Ulm et al. 1995; Kim et al. 2006) and is most common in the area between the second premolar and first molar. Edentulous segments have a higher prevalence of sinus septa than dentate maxillary segments. The size of the sinus varies from individual to individual. In the adult the mean width is 35 mm at the base and the mean height is 25 mm (Small et al. 1993). The maxillary sinus maintains its overall size while the posterior teeth remain in function. It is, however, well known, that the sinus expands with age, and especially when posterior teeth are lost. The average volume of a fully developed sinus is about 15 ml but may range between 4.5 and 35.2 ml. The sinus cavity expands both inferiorly and laterally, potentially invading the canine region. This phenomenon is possibly the result of atrophy caused by reduced strain from occlusal function.

The sinus is lined with respiratory epithelium (pseudo-stratified ciliated columnar epithelium) that covers a loose, highly vascular connective tissue. Underneath the connective tissue, immediately next to the bony walls of the sinus, is the periosteum. These structures (epithelium, connective tissue, and periosteum) are collectively referred to as the Schneiderian membrane.

The blood supply to the maxillary sinus is derived primarily from the maxillary artery and, to a lesser degree, from the anterior ethmoidal and superior labial arteries. The sinus floor receives blood supply from the greater/lesser palatine and sphenopalatine arteries. These vessels penetrate the bony palate and ramify within the medial, lateral, and inferior walls of the sinus. The posterior superior alveolar artery has tributaries that perfuse the posterior and lateral walls. Venous drainage is into the sphenopalatine vein and pterygomaxillary plexus. Neural supply comes from branches of the maxillary nerve (Araujo & Lindhe 2008).

Maxillary sinus modifications

Pneumatization is a physiologic process that occurs in all paranasal sinuses during the growth period, causing them to increase in volume (Shea 1936, Thomas & Raman 1989). Histologic examination has shown that the pneumatization process occurs by osteoclastic resorption of the cortical walls of the sinus and the layering of osteoid inferior to it (Wehrbein H & Diedrich P. 1992). The reasons for sinus pneumatization are poorly understood. Among the factors that influence this process are heredity (Shea 1936, Nowak R & Mehlis G. 1975), the pneumatization drive of the mucous membrane of the nose (Thomas & Raman 1989), craniofacial configuration (Shapiro R & Schorr S. 1980), density of the bone (Shapiro R & Schorr S. 1980), growth hormones (Shapiro R & Schorr S. 1980), sinus air pressure (Thomas & Raman 1989, Drettner 1965, Ikeda et al. 1998), increase in positive intra-antral pressure (Smiller et al. 1992) and sinus surgery (Kosko et al. 1996). Independently from the reason, the contribution of sinus pneumatization to the reduction in alveolar crest height following tooth loss ranged between 20% to 46% (Farina et al. 2011). Farina et al. (2011) evaluated the intra-subject variations in Bone Height (BH) between dentate and edentulous sites due to either vertical ridge resorption or sinus pneumatization (Figure 1). The variation in BH between edentulous and dentate sites was 13.9% (28.4 to 0.5%) at first premolar, 36.4% (43.9 to 24.7%) at second premolar, 40.7% (57.6 to 27.8%) at first molar, and 29.9% (61.4 to 17.3%) at second molar site. The contribution of either vertical ridge resorption or sinus pneumatization to the intra-subject variation in BH between dentate and edentulous sites was 76% and 24%, respectively, at first premolar site, 54% and 46%, respectively, at second premolar site, 80% and 20%, respectively, at first molar site, and 75% and 25%, respectively, at second molar site. The results of this study indicate the reductions of vertical dimensions of the posterior maxilla occurring after tooth loss seems to heavily affect the possibility to place implants of adequate length, confirming that the edentulous posterior maxilla is a critical area for implant placement without bone augmentation procedures (Eufinger et al. 1997). The reduced vertical dimensions observed in edentulous sextants

are primarily associated with a more apical position of the ridge, however, sinus pneumatization may account for up to 46% of the variation in BH.

Surgical procedures for sinus floor elevation

Successful implant therapy is dependent upon an adequate volume of bone at the site of implant placement, since the long-term prognosis of dental implants is adversely affected by inadequate bone volume (Lekholm et al. 1986). Lack of bone volume may be due to congenital, post-traumatic, or post- surgical defects or result from disease processes induced oral surgeons to create ridge augmentation procedure. Different methods to increase the rate of bone formation and to augment bone volume were described in literature: osteoinduction by the use of appropriate growth factors (Reddi 1981; Urist 1965); osteoconduction, where a grafting material serves as a scaffold for new bone growth (Buch et al. 1986; Reddi et al. 1987); distraction osteogenesis, by which a fracture is surgically induced and the two fragments are then slowly pulled apart (Ilizarov 1989a,b); and, guided tissue regeneration (GTR) and guided bone regeneration (GBR), which allows spaces maintained by barrier membranes to be filled with new bone (Dahlin et al. 1988, 1991; Kostopoulos & Karring 1994; Nyman & Lang 1994, Karring *et al*. 1980; Nyman *et al*. 1980, 1989, 1990). A similar but different situation could be observed in the posterior maxillary region. Reduced bone volume due to alveolar bone resorption and pneumatization of the sinus cavity makes it more difficult to place standard implants to support a dental prosthesis (Sharan & Madjar 2008, Pramstraller et al 2011, Farina et. al. 2011). The elevation of the maxillary sinus floor is an option in solving the problem of implant insertion. Various surgical techniques have been presented to enter the sinus cavity elevating the sinus membrane and placing bone grafts (Boyne & James 1980, Tatum 1986, Summers 1994, Torella et al. 1998, Fugazzotto 2001, Trombelli et al. 2008, Tilotta et al 2008, Troedhan 2010, Crespi et al. 2012). Today, two main procedures of sinus floor elevation for dental implant placement are in use: the lateral window approach, and the transcrestal approach. The decision to use the one- or the two-stage technique for the timining of implant placement is based on the amount of residual bone available and the possibility of achieving primary stability for the inserted implants.

Lateral Approach

Elevation of the maxillary sinus floor was first reported by Boyne in the 1960s. Fifteen years later, Boyne & James (1980) reported on elevation of the maxillary sinus floor in patients with large, pneumatized sinus cavities in preparation for the placement of blade implants. The authors

described a two-stage procedure, where the maxillary sinus was grafted using autogenous particulate iliac bone at the first stage of surgery. After approximately 3 months, a second stage surgery was performed in which blade implants were placed and later used to support fixed or removable reconstructions (Boyne & James 1980). The original Caldwell-Luc technique, commonly referred to as the lateral window or lateral approach, describes an osteotomy prepared in a superior position just anterior to the zygomatic buttress. Two other positions have also been described: a mid-maxillary position between the alveolar crest and zygomatic buttress area, and a low anterior position near the level of the existing alveolar ridge (Lazzara 1996; Zitzmann & Scharer 1998). The technique currently used is a mix of these techniques. Independently from the technique, the initial incision is midcrestal extending well beyond the planned extension of the osteotomy. The incision is carried on forward beyond the anterior border of the maxillary sinus. Releasing incisions are made anteriorly extending into the buccal vestibulum to facilitate reflection of a full-thickness mucoperiosteal flap. A mucoperiosteal flap is raised slightly superior to the anticipated height of the lateral window. After the lateral sinus wall has been exposed, a round carbide bur in a straight hand piece is used to mark the outline of the osteotomy. When the bone has been trimmed down to a thin bony plate, the preparation is continued with a round diamond bur in a straight hand piece until a bluish hue of the sinus membrane is observed (Pjetursson & Lang 2008). To avoid the complications of perforation, Torella et al (1998) and Vercellotti et al. (2001) have proposed using an ultrasonic ostectomy to obtain access to the sinus. Three methods for handling the buccal cortical bone plate have been proposed. The most common one is the thinning of the buccal bone to a paper-thin bone lamella using a round bur or ultrasonic instruments, and removing it prior to the elevation of the sinus membrane. The second method is to fracture the cortical bony plate like a trap-door and use it as the superior border to the sinus compartment, leaving it attached to the underlying mucosa. Since the cortical bony plate is resistant to bone resorption this may protect the graft. The third method proposed is to remove the cortical bony plate during sinus floor elevation and replace it on the lateral aspect of the graft at the end of the grafting procedure. The next step will be chosen according to the technique used. If the buccal wall is eliminated, the sinus membrane is elevated directly with blunt instruments. On the other hand, gentle tapping is continued until movement of the bony plate is observed if the “trap-door” technique is used. Then, in combination with the elevation of the sinus membrane in the inferior part of the sinus, the bony plate is rotated inwards and upwards to provide adequate space for grafting material. Care should be taken not to perforate the sinus membrane. Grafting material is placed in the compartment made by the elevation of the sinus membrane. The grafting material should not be densely packed, because this reduces the space needed for ingrowth of newly forming bone. In addition, pressurizing the thin sinus membrane may result in a late perforation. Depending on the clinical condition and the surgeon’s preference, a delayed (two-stage)

or a one-stage sinus floor elevation simultaneously with the implant installation is chosen. After the compartment has been filled with grafting material, the lateral window is closed by covering it with a resorbable or a non-resorbable barrier membrane. The reasons to use a membrane is linked to histomorphometric evidence of enhanced bone formation following membrane placement over the lateral window is available. In a randomized controlled clinical trial (Tarnow et al. 2000), a split mouth design with bilateral sinus grafts was performed for 12 patients with or without covering the lateral window using a membrane. After 12 months, histologic samples were taken through the lateral window. The mean percentage of vital bone formation was 25.5% with and 11.9% without a covering barrier. Subsequently, the flap is closed free of tension. In most conditions, there is a need for deep periosteal incisions to achieve tension-free closure (Pjetursson & Lang 2008).

The sinus lift with lateral approach "should be considered a highly predictable and effective therapeutic modality" (Jensen et al. 1996). In 2003, Wallace and Froum published a systematic review on the effect of maxillary sinus floor elevations and the survival of dental implants. The main results indicated (i) A survival rate of implants placed in conjunction with sinus floor elevation with the lateral approach varied between 61.7% and 100%, with an average of 91.8%; (ii) Implant survival rates compared favorably with reported survival rates for implants placed in the non-grafted maxillae (Wallace and Froum 2005). In 2008, Pjetursson et al, published a systematic review on sinus lift with lateral approach. In this review the authors analyzed also the complications of this procedure. The most common intra-operative complication was the perforation of the sinus membrane. This was reported in 20 studies and ranged from 0–58.3%. The mean prevalence of membrane perforation was 19.5%. An other complication analyzed in this article was the infection of the grafted sinuses. This was reported in 24 studies and the mean incidence was 2.9%, ranging from 0–7.4% (Table 2). The risk for infection seemed to increase with membrane perforation. Other complications like excessive bleeding from the bony window or the sinus membrane, haematoma, wound dehiscences, injury of the infraorbital neurovascular bundle, implant migration into the sinus cavity were also reported occasionally (Pjetursson et al. 2008). Sinusitis is another complication that may occur after sinus grafting (Timmenga et al. 1997). The post-operatory pain is one of the main disadvantage of this technique. Temmerman et al. (2017) studied the post-operative pain provoked by various surgical technique for sinus augmentation. The results indicated the lateral approach was the worst tolerated by patients ($p < 0.05$), and from day 3 onwards, the lateral approach scored significantly more in subjective swelling when compared to transcrestal approach.

Transcrestal Approach

A transalveolar technique for sinus floor elevation with subsequent placement of implants was first suggested by Tatum (1986). Utilizing this approach, a ‘‘socket former’’ for the selected implant size was used to prepare the implant site. A ‘‘green-stick fracture’’ of the sinus floor was accomplished by hand tapping the ‘‘socket former’’ in the vertical direction. After preparation of the implant site, a root-formed implant was placed and allowed to heal in a submerged manner. Summers (1994) described another transalveolar technique: the osteotome technique for sinus floor elevation, using a set of osteotomes of varying diameters to prepare the implant site. The concept intended to increase the density of the soft, type III and IV (Lekholm and Zarb 1985) maxillary bone, resulting in better primary stability of inserted dental implants. Bone was conserved by the osteotome technique because drilling was not performed. The bone-added osteotome sinus floor elevation, may be considered to be more conservative and less invasive than the lateral approach. A small osteotomy is performed through the alveolar crest of the edentulous ridge at the inferior border of the maxillary sinus. The Schneiderian membrane is elevated using these osteotomes from a crestal approach without the preparation of a lateral window. This intrusion osteotomy procedure elevates the sinus membrane, thus creating a ‘‘tent’’. This provides space for bone graft placement or blood clot formation (Tan et al. 2008). The Summers osteotome technique has been modified by several authors (Cosci & Luccioli 2000, Fugazzotto 2001, Trombelli et al. 2008, Tilotta et al 2008, Troedhan 2010). The aim of these modifications was to continue reduce discomfort and pain for patients. Cosci and Liccioli proposed to perforate (not fracture) the cortical bone of sinus floor by the use of particular lifting drills with a small cutting angle of 30 degrees and a built-in water flow system. The authors asserted the shape of the drill tip prevented perforation of the membrane and for this reason the technique is atraumatic. Fugazzotto proposed the use of specific rotate instrument to reduce the morbidity of the procedure. The author described the surgical technique with the following words: “A calibrated trephine bur with the largest external diameter of 3.0 mm was placed on the crest of the alveolar ridge at the anticipated site of implant placement. Utilizing preoperative radiographs and residual ridge morphology as a guide, the trephine was used to prepare the site to within approximately 1 to 2 mm of the sinus membrane at a maximum cutting speed of 500 rpm. Following removal of the trephine bur a calibrated, offset osteotome was selected to correspond to the diameter of the trephine preparation. The osteotome was utilized under gentle malleting forces, to implode the trephine bone core to a depth approximately 1 mm less than that of the prepared site” (Fugazzotto 2001). The main advantage of this technique was the reduction of discomfort for patients. When a thick layer of alveolar bone remains coronal to the sinus floor, the osteotome technique may require extensive malleting trauma during the sinus floor elevation, which may eventually cause post-surgery

sequelae such as benign paroxysmal positional vertigo (BPPV) (Galli et. al. 2004, Rodrıguez Gutierrez & Rodrıguez Gomez 2007, Penarrocha-Diago et al. 2008). The utilization of a trephine and an osteotome is less traumatic and disconcerting to the patient than repeated malleting (Fugazzotto 2001). The main disadvantage was the possible instrument accidental penetration into the sinus cavity. In 2008 Tilotta et al. presented a new modification. They introduced the Osteosinus kit. This kit was composed of 6 trephines with internal diameters of 3 mm, 6 trephines with internal diameters of 4 mm, 6 curved osteotomes with 3-mm diameters and 6 curved osteotomes with 4-mm diameters. These trephines and osteotomes have an insertion guard ranging from 3 to 8 mm. The guard prevents the trephines or osteotome from accidentally invading the sinus cavity. The main advantage was the reduction of instrument accidental penetration into the sinus cavity. The main disadvantage of this technique was the elevated number of instrument to use in the different clinical situation. In 2010 Troedhan et al. developed the minimal invasive transcrestal hydrodynamic ultrasonic cavitational Sinus lift (tHUCSL-Intralift). The protocol started with a set of diamond-coated ultrasonic tip to prepare the access to the sinus membrane. Then, the sinus membrane was atraumatically separated from the antral bone with the hydrodynamic (the basic process can be circumscribed as detaching and elevating the membrane with water-pressure) ultrasonic cavitational applicator at a flow rate of saline solution of 30mL/min for 5 seconds thus creating a subantral volume of 2,5 ccm under the elevated sinus membrane. Once the elevated sinus-membrane was verified to float free and unperforated/unruptured, a form stable collagenous sponge of approximately 2 ccm was inserted subantrally to stabilize the elevated sinus membrane as well as the blood clot forming underneath and maintain the elevation volume achieved with the tHUCSL-Intralift procedure. This technique was proposed as a two-stages. The main advantages were linked to the hydrodynamic pressure applied by ultrasounds over the membrane that is homogeneously distributed because of its centrifugal orientation. The cavitation effect of ultrasounds leads to a progressive detachment of the Schneiderian membrane. Moreover, a uniform pressure is applied to the sinus membrane, especially at the delicate margins where the sinus membrane is still attached to the bony floor. Like previous techniques, the main disadvantage was the possible instrument accidental penetration into the sinus cavity.

The Smart Lift procedure for the transcrestal sinus floor elevation

Due to the minimally invasive surgical trend, the Reasearch Centre for the Study of Periodontal and Peri-implant Deseases of University of Ferrara created a novel transcrestal sinus floor elevation technique (Smart Lift) in 2008. The surgical treatment palanning is decided according to the

prosthetic treatment planning, and the residual bone height at such locations was first measured on periapical radiographs as the distance from the bone crest to the sinus floor and confirmed by a computerized tomography scan as needed. This measure represented the radiographic working length (rWL). Surgical stents based on a diagnostic wax-up were only used when indicated by the prosthetic treatment plan. The preparation of the implant site is performed according to a standardized sequence of manual and rotating instruments. All instruments in the surgical set are characterized by laser marks at 4-5-6-7-8-9-10-11 mm with corresponding adjustable stop devices to allow for a precise control of the working length (Figure 2). The major novelty of the Smart Lift resides in the fact that all manual and rotating instruments are used with adjustable stop devices that restrict the working action of burs and osteotomes to the vertical amount of residual bone, thereby preventing the accidental penetration of instruments into the sinus cavity. The use of adjustable stop devices would dictate the extent of the working action of manual and rotating instruments, thus minimizing the risk for membrane perforation and post-surgical infections. After the full-thikness flap elevation, the first drill (Locator Drill) is used to perforate the cortical bone to a depth ≤ 3.5 mm at the site where the implant is to be placed. A second drill (Probe Drill), with a diameter of 1.2 mm and cutting only at the top edge, is used to define the position and orientation of the implant. In order to minimize the risk of sinus floor perforation, this bur is used with an adjustable stop device which is set at least 1 mm shorter than the rWL. Then, the “Probe Osteotome” (Ø 1.2 mm) is carefully inserted into the site prepared by the Probe Drill, and gently forced in an apical direction through the cancellous bone until the cortical bone resistance of the sinus floor is met. Therefore, the Probe Osteotome will provide the “surgical working length” (sWL), which is the true anatomical distance from the bone crest to the sinus floor in the exact location where the implant should be placed. Thus, the working action of all manual and rotating instruments that will be used in subsequent surgical steps will be now set at the sWL by using the proper adjustable stop device. A Radiographic Pin (Ø 1.2 mm) can also be used to check the angulation and depth of the prepared site by means of a periapical x-ray. The Radiographic Pin handle has a diameter of 4.0 mm, thus permitting to evaluate the spatial relationship between the prepared site and the bucco-lingual as well as mesio-distal dimensions of the alveolar ridge. This will help the clinician to determine the diameter of the implant to be placed. Then, a “Guide Drill” diameter 3.2 mm (for implants with a diameter of 3.75 - 4.5 mm) or 4.0 mm (for implants with a diameter of 4.8 - 5.0 mm) is used. This drill follows the preparation of the Guide Drill and creates a crestal countersink, 2 mm deep, where the trephine bur (Smart Lift Drill) will be inserted. Such countersink enables to centre the working action of the trephine bur. The “Smart Lift Drill” (Ø 3.2 or 4.0), set at the sWL, produces a bone core up to the sinus floor. After the removal of the trephine bur, the bone core is then condensed and malleted to fracture the sinus floor by means of a calibrated osteotome (Smart Lift Elevator, diameter of 3.2 or 4.0) that corresponds to

the diameter of the trephine preparation (Fig. 5). The osteotome is used under gently malleting forces to implode the trephined bone core over the sinus floor. In relation to the extent of vertical bone augmentation to be achieved, a cortical bone particulate or a bone substitute can be further grafted and condensed into the sinus by the osteotome. Again, the Smart Lift Elevator is used with the adjustable stop device at the sWL, thus preventing any unwanted penetration of the instruments into the sinus cavity. Provided that the residual bone may ensure an adequate primary stability, an implant can be inserted during the same surgical session. Otherwise, a staged approach is recommended. During the last 9 years, several studies on the Smart Lift technique have been conducted by the Research Centre for Periodontal and Peri-implant Diseases (Trombelli et al. 2008a, Trombelli et al. 2008b, Trombelli et al. 2010a, Trombelli et al. 2010b, Trombelli et al. 2010c, Trombelli et al. 2012, Franceschetti et al. 2012, Pramstraller et al. 2013, Trombelli et al. 2014, Franceschetti et al. 2014, Trombelli et al. 2015, Franceschetti et al. 2015, Franceschetti et al. 2017). In these articles were analyzed treatment outcomes, postoperative morbidity and patient-related outcomes of this technique. First of al, this is an high efficacy procedure. In all treated cases reported in pertinent studies, the Smart Lift technique allowed for the placement of an implant concomitant to tSFE (Trombelli et al. 2010a, Trombelli et al. 2010c, Trombelli et al. 2012, Trombelli et al. 2014, Franceschetti et al. 2014, Franceschetti et al. 2015). The mean implant length ranged between 9.5 and 10 mm among studies (Trombelli et al. 2010a, Trombelli et al. 2012, Franceschetti et al. 2014, Trombelli et al. 2014). Only one implant failed to osseointegrate before the 6-month follow-up (Franceschetti et al. 2014). The mean extent of sinus lift ranged between 6.5 to 7.7 mm (Trombelli et al. 2012, Franceschetti et al. 2014, Franceschetti et al. 2015). The mean height of the radiopaque area over the implant apex (as evaluated as distance occupied by a radiopaque area between the implant apex and the sinus floor as assessed at the mid portion of the implant) as reported in different cohort and randomized controlled trials ranged between 2.0 and 3.0 mm (Trombelli et al. 2012, Franceschetti et al. 2014, Franceschetti et al. 2015). The performance of the Smart Lift technique in conjunction with DBBM (deproteinized bovine bone mineral) or a S-HA (collagen-enriched synthetic hydroxyapatite) was evaluated in a randomized controlled trial. Both DBBM and S-HA treated sites showed substantial extent of sinus lift and amount of radiopaque material apical to the implant apex immediately after surgery, which were maintained at 6 months (Trombelli et al. 2012). The results of another RCT showed that both DBBM and ß–tricalcium phosphate (ß-TCP) may safely support tSFE when performed with the Smart Lift technique. At 6 months, a significant reduction in the radiopaque area apical to the implant apex as well as in the extent of sinus lift was observed with respect to post-surgery values in the ß-TCP group (Trombelli et al. 2014). To analyzed the influence of smocking status a special study was designed (Franceschetti et al. 2014). The results showed that tSFE performed with the Smart Lift technique may similarly result in a substantial

6-month vertical augmentation along with a limited incidence of complications in smoker and non-smoker patients (Franceschetti et al. 2014). An other study tested the influence of the operator experience (Franceschetti et al. 2015). In this study sixty patients were treated with the Smart Lift technique by three operators with different levels of experience in implant surgery (expert, moderately experienced and low experienced, as assessed in terms of years of clinical activity, number of implants placed prior to their participation in the trial, and previous experience in tSFE procedures) and inexperienced with respect to the Smart Lift technique. All treatment groups showed substantial extent of sinus lift in a limited operation time, along with minimal incidence of membrane perforation and postoperative assumption of anti-inflammatory drugs, thus suggesting that the Smart Lift technique may be considered as a user-friendly option for tSFE. The outcomes of the procedure, however, were found to be influenced by the operator level of experience in implant surgery (Franceschetti et al. 2015). In the majority of articles were analyzed the post-surgery morbidity. One of the parameters was the duration of surgical procedure. The mean duration of the sinus floor elevation procedure (as the time elapsed from cortical perforation with the Locator Drill to the completion of the grafting procedure, immediately before implant placement) as reported in different cohort and randomized controlled trials ranged between 19 and 25 minutes (Trombelli et al. 2010a, Trombelli et al. 2010c, Trombelli et al. 2012, Trombelli et al. 2014, Franceschetti et al. 2015). The second important parameter was the intra- and post-surgical complications. Five studies reported data on the intra- and post-surgical complications associated with the use of the Smart Lift technique (Trombelli et al. 2010a, Trombelli et al. 2012, Trombelli et al. 2014, Franceschetti et al. 2014, Franceschetti et al. 2015). Membrane perforation was the most frequent complication, and ranged from 0% (Trombelli et al. 2010a) to 13% of cases (Trombelli et al. 2014). In all cases, the perforation was managed with the insertion of a surgical haemostatic dressing (Gingistat®; GABA Vebas, S. Giuliano Milanese, Milan, Italy) through the crestal access. Then, the grafting procedure was completed and the implant was inserted. At 6 months following implant placement, 4 studies reported an implant survival rate of 100% and the finalization of the prosthetic rehabilitation in all treated cases (Trombelli et al. 2010a, Trombelli et al. 2012, Trombelli et al. 2014, Franceschetti et al. 2015), while one study reported one case of failed osseointegration over a total of 45 implants (Franceschetti et al. 2014). Rarely, other types of complications, i.e. paresthesia in the suborbital area (1 case) (Franceschetti et al. 2014), tinnitus (1 case) (Franceschetti et al. 2014), and BPPV (1 case) (Trombelli et al. 2014) occurred. All these complications spontaneously subsided within the first week following surgery. Others two parameters were analyzed: pain and discomfort. These variables were recorded immediately after surgery and the mean scores for discomfort and pain (as assessed on a 0-100 Visual Analogue Scale, VAS) (McCormack et al. 1988) ranged between 0 and 17 (Trombelli et al. 2010a, Trombelli et al. 2012) and between 2 and 9 (Trombelli et al. 2010a,

Trombelli et al. 2012) respectively. The 7-day mean VAS score for pain ranged between 1 and 2.1, depending on the study (Trombelli et al. 2010a, Trombelli et al. 2010c, Trombelli et al. 2012, Franceschetti et al. 2015). The low scores for pain and discomfort were further corroborated by the results of a recent study, where 33 over 38 patients manifested no problem to repeat the same type of surgery if needed (Trombelli et al. 2014). In conclusion, among the techniques for tSFE which have been proposed in the literature, the Smart Lift technique represents a simplified, user-friendly option, since it allows for a substantial extent of sinus lift at limited operation times along with limited morbidity (Pramstraller et al. 2013)

AIM

This study was based on the hypothesis that tSFE does not increase the intra- and postoperative morbidity of implant surgery. To test this hypothesis, a multicenter retrospective case series was implemented to evaluate the patient-reported outcomes as well as the type and incidence of complications when implants are placed either concomitantly with a novel tSFE procedure (i.e. Smart Lift) or in native bone.

MATERIAL & METHODS

Study design

The study was designed as a multicenter retrospective case series. The study protocol was approved by the Local Ethical Committee of Ferrara, Italy. The investigated treatments were implant placement entirely in native bone (N) or concomitantly with the novel tSFE (tSFE).

Surgical procedures were performed at the Research Centre for the Study of Periodontal and Peri-implant Diseases, University of Ferrara, Italy, and three private dental offices by three clinicians (L. T., L. M., G. F.) expert in implant surgery and involved in previous clinical trials on the investigated tSFE procedure (Trombelli et al. 2010b, 2012, 2014, 2015; Franceschetti et al. 2014, 2015). De-identified data were derived by an examiner not involved in clinical procedures (R. F.) from the record charts of adult (≥18 years) patients without systemic or local contraindications to implant surgery undergone implant placement for single-tooth rehabilitation in the posterior maxilla. A convenience sample of tSFE and N cases positive for the following criteria was selected: (i) availability of pertinent data on the investigated outcome variables; (ii) placement of single implant in the posterior maxilla. Cases for tSFE group were included if they showed an extent of sinus lift (SL) (see “Radiographic

measurements" for details) of at least 4 mm concomitantly to implant placement. Cases for N group were included when implant placement was performed entirely in native bone (i.e. with the implant apex coronal to the sinus floor).

Interventions

Treatments were performed as part of the oral rehabilitation plan which had been previously agreed between patients and operators. Before the surgical procedure, all oral diseases, including periodontal disease, were thoroughly treated. Two grams of amoxicillin (Zimox 1 g; Pfizer Italia S.r.l., Borgo San Michele, Italy) were administered to each patient 1 hour prior to the initiation of the surgical procedure.

Mepivacaine 2% with 1 : 100,000 epinephrine was administered through supraperiosteal injection technique (Malamed 2004). A full-thickness flap with vertical releasing incisions was elevated, with the mesio-distal extension kept limited to the future implant site.

In N group, the preparation of the implant site required the consecutive use of drills of increasing diameter. The type and sequence of drills was dependent on the implant system adopted (Thommen MedicalTM, Grenchen, Switzerland; Nobel BiocareTM, Zurich, Switzerland; StraumannTM, Basel, Switzerland; SwedenTM, Due Carrare, Italy). Drilling was performed by exerting slight pressure intermittently under abundant irrigation with saline solution. In tSFE group, the preparation of the implant site was performed according to the novel technique for sinus lift with standardized sequence of instruments (Fig. 3a–i; Trombelli et al. 2008, 2010a,b, 2012, 2014, 2015; Franceschetti et al. 2014, 2015). A first drill was used to perforate the cortical bone at the site where the implant had to be placed (Fig. 3a). A second drill was used to define the orientation of the implant, with an adjustable stop device set at least 1 mm shorter than the rWL (Fig. 3b). A calibrated osteotome was gently forced in an apical direction until the cortical bone resistance of the sinus floor is met, thus providing the "surgical working length" (sWL; i.e. the anatomical distance between the bone crest and the sinus floor in the exact location where the implant had to be placed; Fig. 3c). At the operator's discretion, a radiographic pin was used to confirm the rWL (Fig. 3d). The working action of all manual and rotating instruments included in the succeeding surgical steps was set at the sWL using the proper adjustable stop device. A drill was then used to create a crestal countersink (Fig. 3e), where the trephine bur was subsequently inserted producing a bone core up to the sinus floor (Fig. 3f). The bone core was condensed and malleted to fracture the sinus floor by means of the calibrated osteotome (Fig. 3g, h). In all cases, an additional graft was pushed into the sinus by gradual

increments using the calibrated osteotome. The type of graft material chosen among different hydroxyapatite-based (Bio-Oss" spongiosa granules 0.25–1.0 mm; Geistlich Pharma, AG, Wolhusen, Switzerland; Biostite"; GABA Vebas, S. Giuliano Milanese, Milan, Italy; Gen-Os"; Osteobiol Tecnoss Dental, Pianez- za, Torino, Italy) or β-tricalcium phosphate-based (Ceros", granules 0.5–0.7 mm; Thommen Medical, Waldenburg, Switzerland) biomaterials. The amount of graft material was determined on the basis of previously reported criteria (Trombelli et al. 2014). The clinical application of the investigated technique is illustrated in Fig. 2.

In both N and tSFE groups, the implant was inserted immediately after site preparation, and a transmucosal healing protocol was adopted.

All patients were prescribed a single dose of anti-inflammatory drug (i.e., ibuprofen 600 mg tablets) on the first postoperative day (evening) and were instructed to take it *pro re nata* (prn) for the following 6 postoperative days. A 0.12% chlorhexidine mouthrinse, to be used 10 ml t.i.d. for 3 weeks, was also prescribed. Sutures were removed 7 days after surgery.

Study parameters

Patient-reported outcomes

At the completion of the surgical procedure, each patient was provided with a self-administered questionnaire. The questionnaire had been prepared by an examiner not involved in the clinical procedures (R. F.) and had been used in previous clinical trials on the same investigated tSFE procedure (Trombelli et al. 2012, 2014). Each operator provided patients with verbal instructions on questionnaire filling.

The following patient-reported outcomes were recorded with the questionnaire:

- level of discomfort perceived by the patient ($VRS_{discomfort}$): recorded immediately after surgery on a 5-point visual rating scale (VRS) ranging from “0 – no discomfort” to “4 – very severe discom- fort”;

- willingness to undergo the same type of surgery ($VRS_{willingness}$): recorded immediately after surgery on a 4-point visual rating scale (VRS) ranging from “0 – I will never undergo this type of surgery again” to “3 – no problem to repeat surgery if needed”;

- level of pain perceived by the patient (VAS_{pain}): recorded daily (evening) for 7 days following surgery on a 100-mm visual analog scale (VAS) (ranging from “0 – no pain” to “100 – intolerable pain”);

- dosage of rescue anti-inflammatory drug (i.e. number of ibuprofen 600 mg tablets) assumed by the patient from second to the seventh postoperative day, as self-recorded by the patient on a specifically dedicated form.

Surgical and post-surgical complications

The incidence of membrane perforation was evaluated by the Valsalva maneuver after the preparation of the implant site (in N group) and after either the fracture of the sinus floor or the completion of the grafting procedure (in tSFE group). Other surgical or post-surgical complications, generally related to implant surgery in the posterior maxillary area (including postoperative infection, post- operative hemorrhage, nasal bleeding, blocked nose, hematomas) or specifically associated with tSFE procedures (including benign paroxysmal positional vertigo) were also recorded.

Duration of the procedure

The duration of the procedure was recorded as the time (in minutes) elapsed from (i) cortical perforation with the first drill to (ii) either the completion of site preparation with the last drill of the sequence (for N group) or the completion of the grafting procedure (for tSFE group) immediately before implant insertion.

Radiographic measurements

At all centers, periapical radiographs were obtained immediately after surgery and at 6 months with a paralleling technique using a Rinn film holder with a rigid film-object X-ray source, then scanned and digitized. Using an image-processing software, digitized images were stored at a resolution of 600 dpi. In the tSFE group, the following radiographic measurements were performed on radiographs taken immediately after surgery using a software for image analysis (NIS Elements" v4.2; Nikon Instruments, Campi Bisenzio, Firenze, Italy):

- radiographic implant length (rIL): distance (in mm) between the implant shoulder and the implant apex as assessed at the mid portion of the implant;

- residual bone height at the mesial (mRBH) and distal (dRBH) aspects of the implant: distance (in mm) between the mesial and distal aspect of the implant shoulder, respectively, and the sinus floor;

- height of the graft apically (aGH): distance (in mm) occupied by a radiopaque area between the implant apex and the sinus floor as assessed at the mid portion of the implant.

To account for radiographic distortion, radiographic measurements (i.e., mRBH, dRBH and aGH) on each radiograph were adjusted for a coefficient derived from the ratio: true length of the implant/rIL. For each patient, the following derived radiographic parameters were obtained:

- RBH: calculated as the mean value of mRBH and dRBH;

- implant penetration (IP): calculated as the difference between rIL and RBH;

- extent of the SL: calculated as the sum of IP and aGH.

All measurements were performed by a single trained examiner (G. F.) who had previously undergone a calibration session for aGH assessment on a sample of 15 patients not included in the study (Cohen's k-coefficient for intra-examiner agreement: 0.981) and had participated as clinical examiner in previous clinical trials using the same radiographic measurements (Trombelli et al. 2012; Franceschetti et al. 2014, 2015).

Statistical analysis

Data were entered in a unique database file (STATISTICA software version 7.1; StatSoft, Italia s.r.l., Vigonza, Italy) and expressed as median and interquartile range (IR). The patient was regarded as the statistical unit. Therefore, only one eligible implant site was considered for each patient. VAS_{pain} was regarded as the primary outcome variable. To express the level of pain experience through the first week following surgery, for each patient the area under the curve (AUC) was calculated for VASpain (AUC_{pain}). The other patient-centered outcomes (i.e. $VRS_{discomfort}$, $VRS_{willingness}$, dosage of rescue anti-inflammatory drug) and the incidence of complications were regarded as the secondary outcome variables. Inter-group comparisons were performed with Fisher's exact test and Mann–Whitney U-test. The level of statistical significance was fixed at 0.05. A web-based software (http://www.dss- research.com/KnowledgeCenter/toolkitcalculators/statisticalpowercalculators.aspx) was used for the calculation of the sample size of the study. Assuming a standard deviation in 100-mm

VAS_{pain} of 5 and an expected inter-group difference in 100-mm VAS_{pain} of 5 on the basis of previous studies using VAS to evaluate postoperative pain at 1 week following implant surgery either in combination with tSFE (Trombelli et al. 2014) or not (Al- Khabbaz et al. 2007), a per protocol study population of 24 patients (i.e. 12 patients per treatment group) was needed to detect a significant inter-group difference (at P = 0.05) with a one-sided test with a statistical power of 80%. A post hoc power calculation revealed that the study had a power of 87%.

RESULTS

Study population

A convenience sample of 14 patients (51 years, IR: 48.3–55.8; 2 current smokers) and 17 patients (52 years, IR: 39.0–57.0; years, four current smokers) treated from January 2010 to January 2014 with tSFE and N, respectively, was obtained for the present study. No significant differences in age and patient distribution according to either gender or smoking status were observed between groups. In the tSFE group and N group, 2 vials (IR: 2.0–2.8) and 3 vials (IR: 2.0–3.0) of anesthetics, respectively, were used during surgery (P > 0.05).

Treatment outcomes

The frequency distribution of patients accord- ing to the location of the implant site (i.e. first premolar, second premolar, first molar, second molar) was 0, 2, 11, 1, respectively, in the tSFE group, and 8, 5, 4, 0, respectively, in N group. Radiographic measurements in tSFE group are shown in Table1. RBH was 6.0 mm (IR: 5.6–6.8), and the tSFE procedure allowed for the placement of implants with a length of 9.8 mm (IR: 9.5–11.0). Immediately after the tSFE procedure, IP was 4.0 mm (IR: 3.6–4.8) and SL was 6.8 mm (IR: 5.7–7.6). In N group, implants with a length of 9.5 mm (IR: 9.5–11.0) were placed. No significant difference in implant length was observed between groups. At 6 months after surgery, no implant failure was recorded, and the prosthetic rehabilitation was finalized at all implant sites.

Patient-reported outcomes

No significant difference in $VRS_{discomfort}$ or $VRS_{willingness}$ was observed between groups (Table 2). VAS_{pain} in tSFE and N groups is reported in Table 3 and illustrated in Fig. 4. On day +1, VAS_{pain} was

low in both treatment groups. During the following postoperative days, a tendency of VAS_{pain} to decrease was observed in both groups. AUC_{pain} was 18.0 (IR: 8.5– 85.0) and 11.5 (IR: 4.5–18.5) in tSFE and N groups, respectively, with no significant inter-group differences (P = 0.084).

The total number of rescue anti-inflammatory drug used from the second to the seventh postoperative day was 0 (IR: 0–1.8; min– max: 0–9) in tSFE group and 1 (IR: 0–1.0; min–max: 0–6) in N group (P = 0.860). No significant difference in either the prevalence of subjects using analgesics or the dose of rescue anti-inflammatory drug was observed between groups at each postoperative day (Table 2).

Surgical and post-surgical complications

Membrane perforation was detected at Valsalva maneuver only in 1 case in tSFE group after graft placement. No statistically significant difference in the incidence of membrane perforation was observed between treatment groups. Membrane perforation was treated with the insertion of a collagen matrix (Mucograft; Geistlich Pharma AG) through the crestal access, and systemic antibiotics (amoxicillin + clavulanic acid, 1 g t.i.d. for 6 days) were administered postoperatively. The grafting procedure was completed, and the implant was inserted and the case included for analysis.

No other intra- and postoperative complications were either observed by the operators or self-reported by the patients in both treatment groups.

Duration of the procedure

The duration of the procedure was significantly longer in tSFE group (25 min, IR: 20.8–34.8) compared to N group (10 min, IR: 9.0–11.0) (P < 0.001).

DISCUSSION

In the present study, a retrospective multicenter design has been implemented to test our hypothesis. It may be argued whether or not the retrospective nature of the study may represent a methodological limitation. It must be considered, however, that the two investigated treatments (N and tSFE) have different local indications according to the height of the residual bone crest, thus limiting the possibility to apply a prospective, randomized controlled design. In this context, the

scientific value of data from retrospective cohorts seems to be sufficiently adequate to test our hypothesis. In addition, the participation of three different clinical operators to the trial may raise an issue related to the potential influence of the level of experience in implant surgery, in general, and the investigated tSFE procedure, in particular, on the study outcomes. In a recent study (Franceschetti et al. 2015), the effectiveness of the procedure (in terms of extent of SL) appeared to be affected by the level of experience in implant dentistry. However, we also demonstrated that the learning curve of the investigated tSFE procedure is steep, thus allowing for inexpert operators to reach a high performance within a limited number of cases. Also, the incidence of intra- and postoperative complications and the self-administered dosage of analgesics were similarly low irrespective of the level of operator experience (Franceschetti et al. 2015). Although considering that the three clinical operators were all expert in implant surgery and had been previously involved in clinical trials on the investigated tSFE procedure (Trombelli et al. 2010b, 2012, 2014, 2015; Franceschetti et al. 2014, 2015), it cannot be excluded that the presence of different operators within the trial may have had an influence on the study outcomes.

In our material, implant placement concomitantly with tSFE required longer operative time compared to implant placement in native bone. The operative time of tSFE is consistent with previous studies on the investigated technique (Trombelli et al. 2010a,b, 2012, 2014; Franceschetti et al. 2014). The longer time in tSFE group compared to N group is justified by the number of instruments included in the tSFE sequence (six instruments) which was greater than the number of drills included in the conventional drilling sequence for implant site preparation. In all cases, a graft material was used in the tSFE procedure to expand the sinus membrane following the fracture of the sinus floor. To prevent membrane perforation, sinus grafting is based on repeated increments of small amount of the biomaterial, thus resulting in a time-consuming procedure.

Due to the retrospective nature of the study, the assessment of patient-reported outcomes was focused on aspects related to pain and use of analgesics, discomfort and patient acceptance. Among these parameters, the level of postoperative pain, as assessed through the use of a 100-mm VAS, was regarded as the primary outcome variable of the study. The use of VAS as tools for the assessment of patient perception has become increasingly frequent in dental research during the last decades due to their ease of administration and reproducibility. In this respect, VAS were used to measure the anxiety of patients before and after dental treatment as well as their level of pain following different non-surgical and surgical procedures (Seymour et al. 1983; Luyk et al. 1988; Matthews & McCulloch 1993; Canakci & Canakci 2007; Fardal & McCulloch 2012; Tan et al. 2014). More recently, the use of VAS has been extended to implant research. In particular, VAS were used to measure pain levels following implant surgery (Al-Khabbaz et al. 2007; Fardal & McCulloch 2012;

Tan et al. 2014) and, less frequently, other aspects of post-surgery sequelae such as swelling, bleeding and bruising (Tan et al. 2014). In the present study, VAS levels reported for tSFE treatment were similarly low when compared with those reported in previous trials on the same procedure (Trombelli et al. 2012, 2014). In group N, pain levels were consistent with previous studies (Tan et al. 2014), but differed with those reported by other authors for conventional implant surgery (Al-Khabbaz et al. 2007). It must be considered, however, that the comparison of data on pain levels among studies is complicated by differences in pain assessment methods, technical aspects (e.g. flap design and extension) and pharmacological protocol for pain control.

The pain experience during the entire first postoperative week (as evaluated through AUC_{pain}) was not significantly different between groups, thus indicating that tSFE and N are both well tolerated. This consideration is corroborated further by the fact that tSFE did not determine an increased consumption of analgesics compared to implant insertion entirely in native bone. While from day +3, the median value of VAS_{pain} in N group was 0, the persistence of low pain levels (<5 on a 100-mm scale) was observed in tSFE group up to day +7. This finding could be explained, at least in part, by the longer operative time required for the tSFE group compared to the N group. In this respect, it was previously demonstrated that longer implant surgery sessions are associated with higher VAS pain scores during the first postoperative week when compared to shorter sessions (Tan et al. 2014). Also, it may be hypothesized that the detachment of the Schneiderian membrane may determine a transient increase in pain levels due to the stimulation of membrane innervation (Heasman 1984; van den Bergh et al. 2000). The absence of significant inter-group differences in AUC_{pain}, however, seems to suggest that persisting pain observed in tSFE patients at single time intervals was sporadic within each patient and of limited intensity compared to N treatment.

Osteotome-based procedures for tSFE, which have been developed since the original introduction of the osteotome technique (Summers 1994), require an extensive use of malleting to prepare the implant site and fracture the maxillary sinus floor. This may cause substantial clinical discomfort during the procedure as well as relevant post-surgical complications such as the benign paroxysmal positional vertigo (Penarrocha et al. 2001; Di Girolamo et al. 2005; Penarrocha & Garcia 2006). In the investigated technique, the surgical sequence was designed to approach the sinus floor without the need for osteotomes, and malleting is restricted to the fracture of the cortical sinus floor (Trombelli et al. 2008, 2010a,b). This peculiarity of the technique may lead to limited to null incidence of BPPV, as observed in the present study and reported in previous trials (Trombelli et al. 2008, 2010a,b, 2012, 2014, 2015; Franceschetti et al. 2014, 2015). Also, the low patient discomfort and the high propensity to undergo the same surgery again, which were similarly observed in tSFE and N

groups, seem to suggest that implant surgery concomitantly with tSFE is highly tolerated by the patient.

Complications were limited to 1 case of membrane perforation in tSFE group. Membrane perforation is the most frequent intra-operative complication during tSFE procedures (Tan et al. 2008). The low incidence of membrane perforation observed in the tSFE group, which is mainly due to the control of the working action of manual and mechanical instruments through the application of adjustable stop devices, is consistent with previous studies on the investigated technique (Trombelli et al. 2010a,b, 2012, 2014, 2015; Franceschetti et al. 2014). In addition, membrane perforation did not compromise the completion of the grafting procedure and the success of the implant-supported rehabilitation.

In conclusions, the results of the present study showed that implant placement performed either concomitantly with tSFE (according to the Trombelli et al. 2008, 2010a,b) or entirely in native bone are associated with limited incidence of complications, low postoperative pain and medication and are both well tolerated. When considering that (i) tSFE allowed for the concomitant placement of implants of proper dimensions in cases where the RBH would have otherwise impaired the implant-supported rehabilitation, (ii) tSFE did not determine an increased consumption of analgesics compared to implant placement in native bone and (iii) previous findings demonstrated that the proposed tSFE technique is a user-friendly, safe, predictable and minimally invasive procedure (Trombelli et al. 2010a,b, 2012, 2014, 2015; Franceschetti et al. 2014, 2015), tSFE seems to represent a well-accepted option with a favor- able risk-benefit ratio when used concomitantly with implant placement in the atrophic posterior maxilla.

TABLE & FIGURES

Table 1. Residual bone height (RBH), implant length and post-surgery extent of sinus lift (SL) as observed in each case treated in tSFE group.

	tSFE group (n= 14)		
Case number	RBH (mm)	implant length (mm)	post-surgery SL (mm)
#1	5.8	9.5	7.7
#2	2.7	9.5	8.2
#3	5.7	11.5	7.4
#4	6.1	11.0	6.4
#5	6.8	10.0	5.7
#6	5.8	9.5	7.5
#7	6.7	10.0	4.6
#8	7.2	9.5	4.6
#9	3.8	9.5	8.2
#10	7.0	11.5	5.7
#11	5.6	9.5	5.1
#12	6.8	11.0	7.6
#13	5.5	9.5	7.2
#14	7.5	11.0	6.1

Table 2. $VRS_{discomfort}$, $VRS_{willingness}$ and use of rescue anti-inflammatory drug in N group and tSFE group

	tSFE group (n= 14)	N group (n= 17)	p
Post-surgery discomfort ($VRS_{discomfort}$)	median, IR (min-max)	median, IR (min-max)	(Mann-Whitney)
0 - no discomfort 1 - slight discomfort 2 - mild discomfort 3 - severe discomfort 4 - very severe discomfort	0, IR: 0 - 2 (0-3)	0, IR: 0 - 0 (0-1)	0.200
Willingness to undergo the same surgery ($VRS_{willingness}$)	n° patients	n° patients	(Fisher's exact test)
3 - "*No problem to repeat surgery if needed*"	13	17	0.452
2 - "*I will repeat the surgery, but I would prefer to procrastinate it*"	1	0	
1 - "*I will repeat the surgery, but I expect to suffer severe pain*"	0	0	
0 - "*I will never undergo this type of surgery again*"	0	0	
Use of rescue anti-inflammatory drug (ibuprofen 100 mg tablets)	n° of patients assuming at least 1 tablet	n° of patients assuming at least 1 tablet	(Fisher's exact test)
	n° tablets median, IR (min-max)	n° tablets median, IR (min-max)	(Mann-Whitney)
2nd postoperative day	5	9	0.473
	0, IR: 0 - 1 (0-2)	1, IR: 0 - 1 (0-2)	0.710
3rd postoperative day	3	1	0.304
	0, IR: 0 - 0 (0-2)	0, IR: 0 - 0 (0-2)	0.493
4th postoperative day	3	1	0.304
	0, IR: 0 - 0 (0-3)	0, IR: 0 - 0 (0-2)	0.468
5th postoperative day	2	0	0.196
	0, IR: 0 - 0 (0-2)	0, IR: 0 - 0 (0-0)	0.518
6th postoperative day	1	0	0.452
	0, IR: 0 - 0 (0-1)	0, IR: 0 - 0 (0-0)	0.739
7th postoperative day	1	0	0.452
	0, IR: 0 - 0 (0-1)	0, IR: 0 - 0 (0-0)	0.739

Table 3. VAS_{pain} in tSFE and N group

		postoperative day						
		+1	+2	+3	+4	+5	+6	+7
tSFE group (n= 14)	median	7.0	4.0	4.5	1.0	2.0	2.0	1.5
	IR	4.3 – 13.8	1.3 – 22.3	1.3 – 14.8	0 – 17.8	0 – 6.0	0 – 2.8	0 – 2.8
	min - max	0 – 51.0	0 – 62.0	0 – 59.0	0 – 64.0	0 – 63.0	0 – 58.0	0 – 60.0
N group (n= 17)	median	11.0	5.0	0	0	0	0	0
	IR	7.0 – 15.0	0 – 10.0	0 - 0	0 - 0	0 - 0	0 - 0	0 - 0
	min - max	0 – 80.0	0 – 60.0	0 – 40.0	0 – 20.0	0 – 0	0 – 0	0 – 0

Figure 1. tSFE procedure (Trombelli et al. 2008, 2010a,b): sequence of rotating and manual instruments. (a) The *Locator Drill* is used to perforate the cortical bone at the site where the implant has to be placed. (b) The *Probe Drill* is used to define the orientation of the implant, with an adjustable stop device set at least 1 mm shorter than the radiographic working length. (c) The *Probe Osteotome* is gently forced in an apical direction until the cortical bone resistance of the sinus floor is met, thus providing the "surgical working length" (sWL). The working action of all instruments included in the succeeding surgical steps is set at the sWL using the proper adjustable stop device. (d) A radiographic pin may be used to check the orientation of the prepared site by means of a periapical radiograph. (e) The "Guide Drill" is used to create a crestal countersink. (f) The *Smart Lift Drill* produces a bone core up to the sinus floor. (g, h) The bone core is condensed and malleted to fracture the sinus floor by means of the *Smart Lift Elevator*. A graft biomaterial may be placed into the sinus cavity by gradual increments with the *Smart Lift Elevator* [reprinted from: Trombelli et al. (2012)].

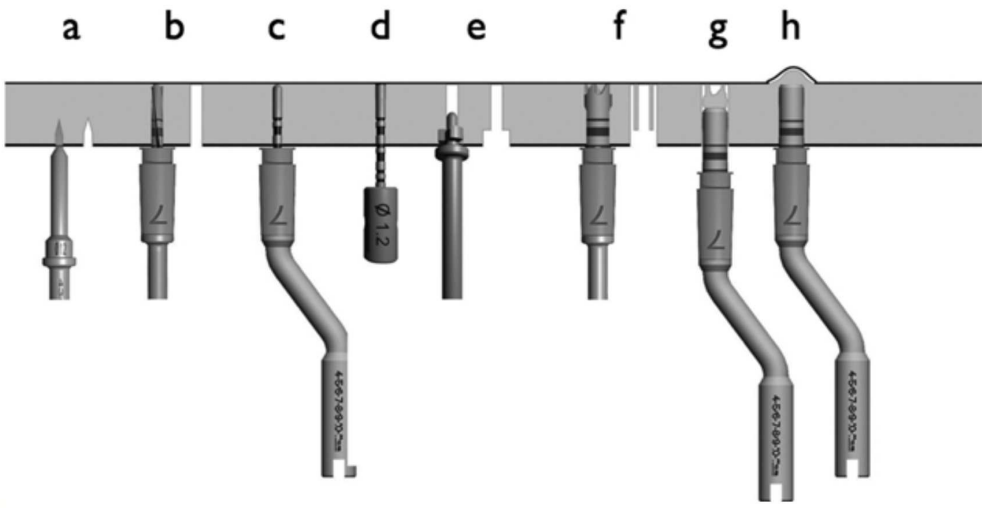


Figure 2. Profile of the alveolar ridge and sinus floor in dentate and edentulous maxillary posterior sextants. The profile has been based on data (expressed as mean SD) from patients where all vertical measurements (i.e., rSF, rRP, BH) were available at a specific site for both the edentulous and dentate sextant.

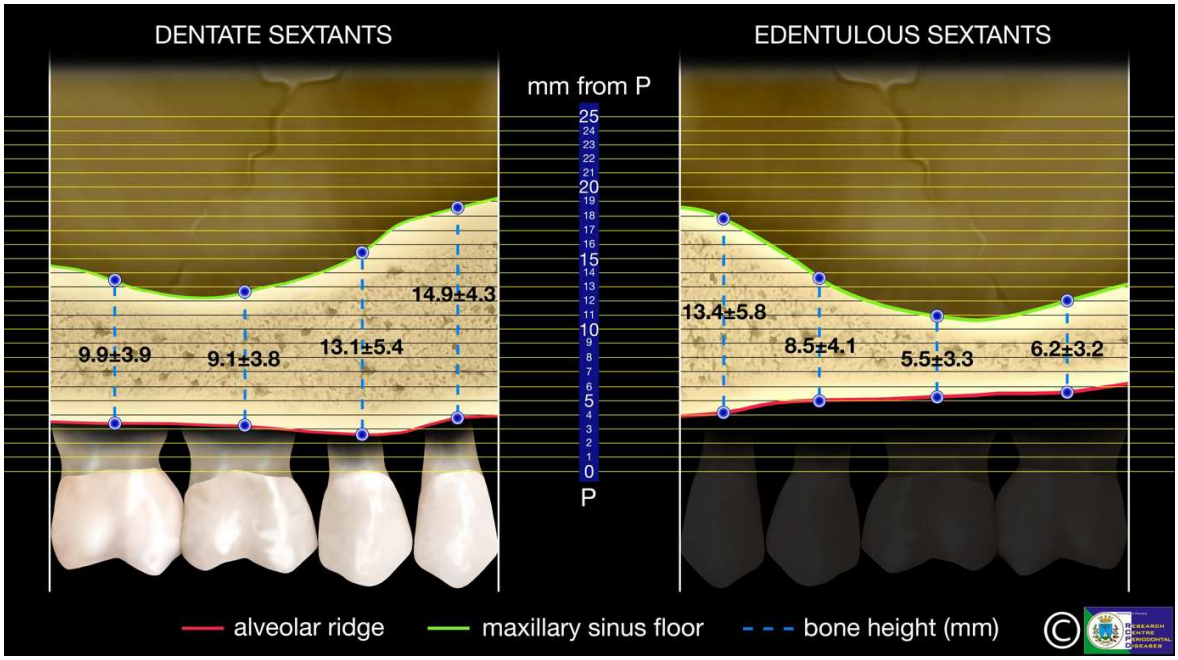


Figure 3. Clinical application of the investigated tSFE technique. (a) The pre-surgery tomographic exam showed a radiographic working length (rWL) of 6 mm. (b) The Locator Drill was used to perforate the cortical bone at the future implant site. (c) After the orientation of the implant had been defined by means of the Probe Drill used to with an adjustable stop device set at 5 mm, the Probe Osteotome was gently forced in an apical direction until the cortical bone resistance of the sinus floor was met, providing a surgical working length (sWL) of 5 mm. The work- ing action of all instruments included in the succeeding surgical steps was set at the sWL using the adjustable stop device of 5 mm. (d, e) The “Guide Drill” was used to create a crestal countersink. (f) The Smart Lift Drill produced a bone core up to the sinus floor. (g) The bone core was condensed and malleted to fracture the sinus floor by means of the Smart Lift Elevator. (h, i) A bovine-derived xenograft was placed into the sinus cavity by gradual increments with the Smart Lift Elevator. (j) The implant was placed and a transmucosal healing protocol was adopted. (k, l) Clinical and radiographic aspect at 6 months following surgery.

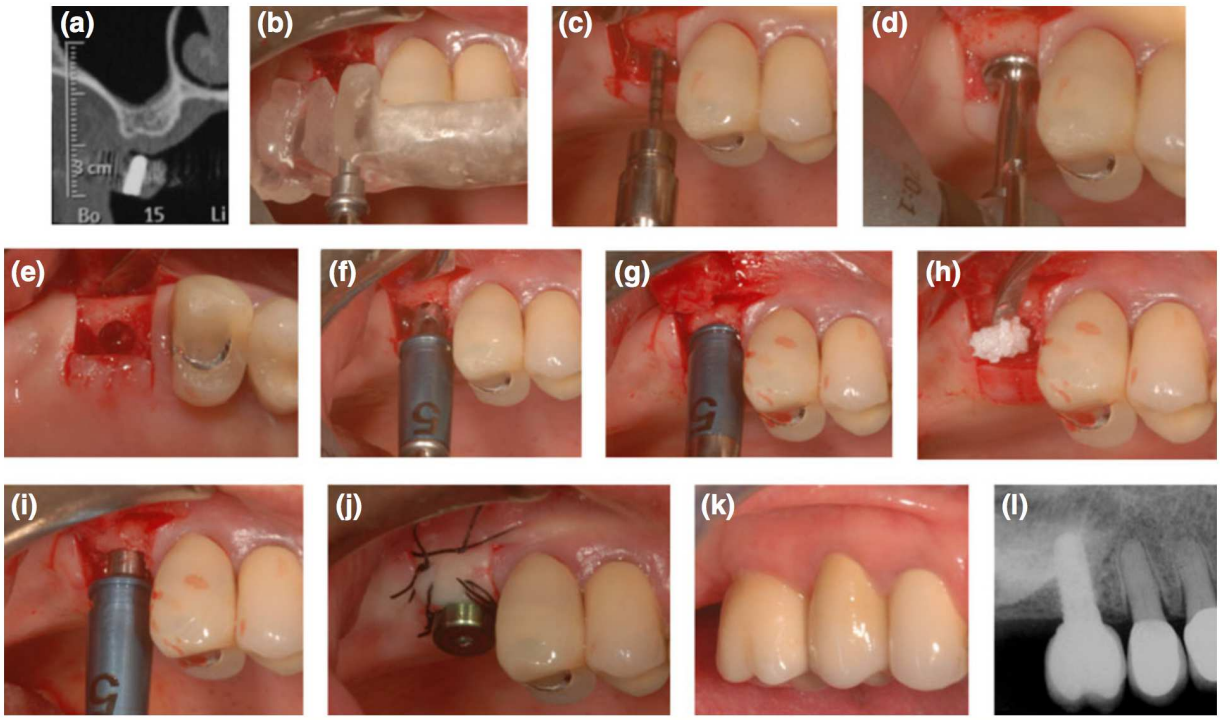
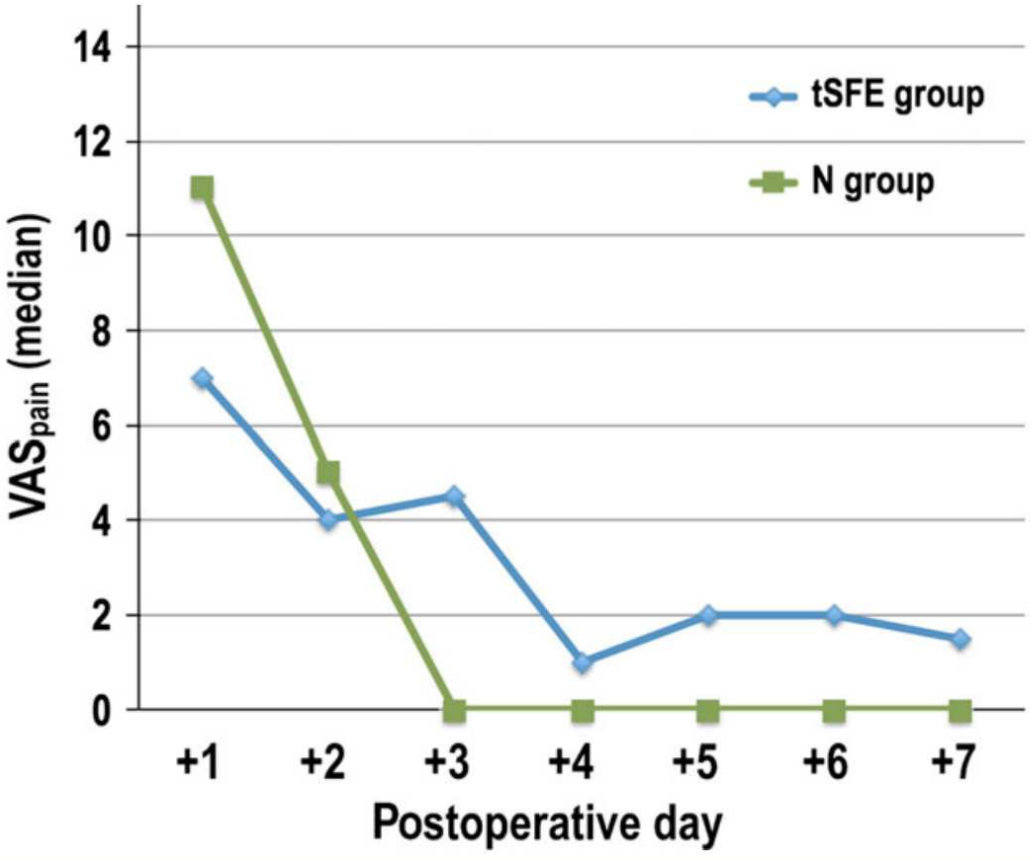


Figure 4. Median values of VAS_{pain} in N group and tSFE group.



CHAPTER 4

CONCLUSIVE REMARKS

In the current series of studies, the bone dimensions in the posterior mandible assessed with a novel methodology and the patients related outcomes following implant placement entirely in native bone or concomitantly with a novel bone regeneration procedure were evaluated. Findings from these studies were critically discussed in previous chapters. On the basis of the produced evidence, the following conclusions can be drawn:

I. In the posterior edentulous sites of mandibles, mean residual bone height and width showed a decrease and an increase, respectively, in the mesio-distal direction. The dimensional change of the bone height coronal to the IAC seems to be the result of apical displacement of the bony crest and the reduction of the lumen of the IAC (chapter 2).

II. Gender showed a significant impact on bone height, with males having on average a 2.8 mm greater height than females, but not on bone width. Gender seems to have a limited impact on the dynamics of ridge resorption following tooth loss (chapters 2).

III. Age did not significantly influence the dimensions of the residual bone crest. (chapters 2)

IV. The edentulous sites in the posterior mandible showed a reduced height and bucco-lingual width of the ridge when compared with contralateral dentate sites (chapter 2).

V. The novel tSFE (according to the Trombelli et al. 2008, 2010a,b) seems to represent a well-accepted option with a favorable risk-benefit ratio when used concomitantly with implant placement in the atrophic posterior maxilla (chapter 3).

VI. The implant placement performed either concomitantly with novel tSFE or entirely in native bone are associated with limited incidence of complications, low postoperative pain and medication (this novel tSFE did not determine an increased consumption of analgesics compared to implant placement in native bone) and are both well tolerated (chapter 3).

CHAPTER 5

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