RADIOGRAPHIC OUTCOMES OF TRANSCRESTAL AND LATERAL SINUS FLOOR ELEVATION: ONE-YEAR RESULTS OF A BI-CENTER, PARALLEL-ARM RANDOMIZED TRIAL

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Abstract

The aim is to comparatively evaluate the radiographic outcomes of transcrestal and lateral sinus floor elevation (tSFE and lSFE, respectively) when applied concomitantly with implant placement.

Patients with ≥1 site with residual bone height (RBH) of 3-6 mm were enrolled in a randomized trial. Both tSFE (n= 26) and lSFE (n= 28) were associated with a xenograft, and implants were inserted concomitantly. Marginal bone loss and the maturation of the grafted area were evaluated on periapical radiographs at 6 and 12 months. Twelve-month CT/CBCT was used to assess the effect of grafting procedures circumferentially around the implant.

At 12 months, the implant surface was, on average, entirely embedded in a radiopaque area in both tSFE and lSFE groups. Sub-optimal bone-to-implant contact was observed in 13% and 3.6% of tSFE and lSFE cases, respectively. In both groups, marginal bone loss was minimal (≤ 1 mm) and infrequent, and the radiographic aspect was suggestive of an advanced stage of maturation.

At sites with RBH of 3-6 mm, tSFE and lSFE can similarly result in a substantial increase in peri-implant bone support at 12 months.

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Introduction

At maxillary posterior sites where post-extraction pneumatization of the maxillary sinus has contributed the dimensional reduction of the residual bone crest following tooth loss (Eufinger et al. 1997, 1999, Farina et al. 2011, Pramstraller et al. 2011), maxillary sinus floor elevation with a lateral (lSFE) or transcrestal (tSFE) approach represent two options to enhance the available bone and restore the local conditions compatible with the placement and long-term survival of dental implants (Pjetursson et al. 2008, Tan et al. 2008, Listl & Faggion 2010, Tetsch et al. 2010, Esposito et al. 2014).

Indications to apply tSFE or lSFE should be determined primarily on the basis of their potential to enhance the peri-implant bony support. Due to the possibility to visualize directly the sinus cavity through the lateral antrostomy and extend the elevation of the sinus membrane according to individual needs and local anatomy, lSFE has several technical premises for achieving substantial augmentation. Confirmatory data come from studies

reporting a mean vertical extent of sinus lift (as evaluated radiographically) varying from about 8 mm to more than 14 mm when lSFE was obtained with a bovine-derived xenograft (Felice et al. 2009, Chackartchi et al. 2011, Merli et al. 2013). On the other hand, tSFE has limitations related to its closed approach to the sinus, including the difficulty in determining the extent of sinus lift achievable in relation to the presumed tensile resistance of the sinus membrane. Consistently, several clinical trials reported a vertical extent of sinus lift (as assessed radiographically) lower than that reported for lSFE, with mean values ranging between 1.7 mm (Pjetursson et al. 2009) and more than 8 mm (Kfir et al. 2007, Sisti et al. 2012).

To date, studies that comparatively evaluated tSFE and lSFE either lack of a randomized design or refer to different surgical conditions between treatments (Zitzmann & Schärer 1998, Rodoni et al. 2005, Krenmair et al. 2007, Jurisic et al. 2008, Cannizzaro et al. 2009, Tetsch et al. 2010, Kim et al. 2011, Al-Almaie et al. 2013, Yu et al. 2017, Temmerman et al. 2017). Most of them included a radiographic assessment based on bi-dimensional radiographic exams such as ortopanthomography and/or periapical radiographs (Rodoni et al. 2005, Krenmair et al. 2007, Jurisic et al. 2008, Cannizzaro et al. 2009, Tetsch et al. 2010, Kim et al. 2011, Al-Almaie et al. 2013, Yu et al. 2017), with the impossibility to evaluate the extent of peri-implant bone augmentation circumferentially around the implant. Tridimensional radiographic exams such as conventional or cone-beam computed tomography (CT or CBCT, respectively) were used in a limited number of studies, only in a subsample of consenting patients (Zitzmann & Schärer 1998) or at very short post-surgery intervals (Temmerman et al. 2017).

Recently, we performed a bi-center, parallel-arm, randomized trial comparatively evaluating tSFE and lSFE when applied concomitantly with implant placement at sites with limited (3-6 mm) residual bone. The results of the study have been partly published, and allowed for the identification of differences in the morbidity following the two interventions (Farina et al. 2018). Based on bi- and tri-dimensional radiographic assessments conducted by Farina et al. (2018), the purpose of the present study is to comparatively evaluate the extent of bone augmentation (with particular emphasis to the contribution of each intervention to the peri-implant bony support) obtained at 1 year following either tSFE or lSFE and concomitant implant placement.

Materials and Methods

Experimental design

The study is a bi-center, parallel-arm, single-blind, randomized controlled clinical trial, and is part of a larger project which comparatively evaluated tSFE and lSFE under several perspectives. Information on ethical approval and trial registration, the methodological aspects of the study and the surgical aspects of the procedures have been reported in a recent publication on the morbidity of tSFE and lSFE (Farina et al. 2018). The present study reports only methodological aspects and data functional to evaluate the radiographic outcomes of the two investigated interventions.

Study population

Patients were recruited at two University-Hospitals (Ferrara and Modena, Italy) according to selection criteria reported by Farina et al. (2018). Briefly, each patient contributed the study with one maxillary quadrant (identified as “experimental”) with ≥1 maxillary posterior site edentulous for at least 6 months and showing a residual bone height (RBH) of 3÷6 mm. RBH was measured on CT or CBCT performed while wearing a radiological stent with 4-mm thick radiopaque indicators.

Surgical and post-surgical procedures

The surgical aspects of tSFE and lSFE and the post-surgical procedures are described briefly in the following paragraphs. Additional details have been reported in a previous publication (Farina et al. 2018).

tSFE was performed according to the *Smart Lift* technique (Trombelli et al. 2008, 2010a,b). After placing a plug of collagen matrix (Mucograft Seal®; Geistlich Pharma, AG, Wolhusen, Switzerland), the trephined bone core was condensed and malleted with a calibrated osteotome (*Smart Lift Elevator*) to fracture the sinus floor. Membrane perforation was assessed by the Valsalva maneuver. If no perforation was detected, a pre-determined amount of deproteinized bovine bone mineral (DBBM; Bio-Oss® spongiosa granules, particle size 0.25-1.0 mm; Geistlich Pharma, AG, Wolhusen, Switzerland), which was related to the programmed extent of implant penetration into the sinus, was pushed through each implant site by gradual increments with the *Smart Lift Elevator.* When membrane perforation was detected, it was treated with repeated insertions of plugs trimmed from a collagen matrix (Mucograft Seal®; Geistlich Pharma AG, Wolhusen, Switzerland) in the apical portion of the crestal access. The Valsalva maneuver was then re-assessed: if negative, the grafting procedure was completed and the implant was inserted; if positive, the patient exited the study, and tSFE and concomitant implant placement were postponed at 4 months following first surgery.

In patients assigned to lSFE, lateral access to the maxillary sinus was obtained with rotating and/or manual instruments. The grafting procedure was performed with DBBM (Bio-Oss® spongiosa granules, particle size 0.25-1.0 mm or 1-2 mm; Geistlich Pharma, AG, Wolhusen, Switzerland) immediately after the elevation of the sinus membrane with manual instruments (Hu-Friedy, Chicago, US). The particle size and amount of graft material were left at operator discretion. Implant bed preparation was, then, performed according to the sequence of burs recommended by the implant manufacturer (Thommen Medical AG; Grenchen, Switzerland). The window in the lateral wall was covered with a resorbable collagen membrane (Bio-Gide; Geistlich Pharma, AG, Wolhusen, Switzerland). When membrane perforation (as visually detected) occurred, it was treated according to Fugazzotto & Vlassis (2003), and the grafting procedure was completed.

In both tSFE and lSFE groups, implants (SPI Inicell Element©; Thommen Medical AG, Grenchen, Switzerland) were inserted immediately after the completion of the grafting procedure with the 1.0 mm polished collar above the bone crest. The healing protocol (submerged or transmucosal) was left at the operator's discretion.

Implants placed with a submerged healing protocol at day 0 were surgically exposed at 20 weeks post-surgery, and a healing abutment was positioned. Implants were loaded with a provisional or definitive restoration (according to their treatment plan) between week +24 and week +32. The patient exited the study at week +48.

Radiographic exams and measurements

At the time of implant loading with a provisional or definitive restoration (performed between week +24 and week +32) and at week +48 ± 4 weeks (identified as 6- and 12-month follow-up visits, respectively), peri-apical radiographs were obtained with a paralleling technique using a Rinn film holder with a rigid film-object X-ray source, and were then scanned, digitized, and stored at a resolution of 600 dpi. Also, a CT or a CBCT of the implant areas was performed at 12-month visit, and data were saved in Digital Imaging and Communications in Medicine (DICOM) file format.

Measurements on digitized periapical radiographs were performed using an image-processing software (NIS Elements® v4.2; Nikon Instruments, Campi Bisenzio, Firenze, Italy), while a software for implant planning was used for measurements on CT and CBCT scans

(Nobel clinician© v2.6.3.2; Nobel Biocare Services AG, Kloten, Switzerland). All radiographic measurements were performed by a single trained examiner (G.F.) who had previously undergone a calibration session for linear radiographic measurements 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 on sinus lift procedures (Trombelli et al. 2008, 2010a,b, 2012, 2014, 2015, Franceschetti et al. 2014, 2015, 2017, Farina et al. 2018). The examiner was kept blinded as to treatment group and observation interval.

On digitized periapical radiographs taken at 6- and 12-month visit, the following measurements were performed using a digital caliper:

- radiographic implant length (rIL): distance (in mm) from the apical margin of the implant shoulder to the implant apex as assessed at the mesial or distal aspect of the implant;
- peri-implant bone level at the mesial (mPBL) and distal (dPBL) aspects of the implant: distance (in mm) from the apical margin of the implant shoulder to the first bone-to-implant contact at the mesial and distal aspect of the implant, respectively. To account for radiographic distorsion, mPBL and dPBL were adjusted for a coefficient derived from the ratio: true length of the implant / radiographic implant length (rIL);
- maturation of the grafted space: assessed using the sinus grafting remodeling index (SGRI) (Brägger et al. 2004).

On CT and CBCT scans performed at 12-month visit, the following parameters were assessed:

- percentage ratio between the linear length (in mm) of the implant surface in direct contact with the peri-implant radiopaque area (native bone + newly formed bone) and the linear length (in mm) of implant surface (CON%). CON% measurements were performed on each of 180 CT/CBCT sections (with a 1° difference in angle between adjacent sections) parallel to the long axis of the implant and passing through the mid portion of the implant. CON% measurements from the 180 CT/CBCT sections were averaged (totCON%). Also, CON% were reported separately for the mesial, distal and apical aspect of the implant as assessed on the CT/CBCT mesio-distal section (mCON%, dCON%, and $aCON\%_{m\text{-}d}$, respectively) and for the buccal, palatal and apical aspect of the implant as assessed on bucco-lingual CT/CBCT section (bCON%, pCON%, and $aCON\%_{b\text{-}p}$, respectively);
- height of the radiopaque area apical to the implant apex (aGH): distance (in mm) occupied by a radiopaque area between the implant apex and the most apical position of the radiopaque area as assessed at the mid portion of the implant on the CT/CBCT section passing through the mid portion of the implant apex.

Statistical Analysis

Sample size calculation

totCON% was the primary outcome variable of the study. Since no data on totCON% related to the investigated interventions could be derived from previous comparative studies, sample size calculation was based on aGH. Assuming a standard deviation in sinus lift of 2.0 mm for both tSFE, as derived from an internal analysis of data from the studies by Trombelli et al. (2012, 2014) and Franceschetti et al. (2014), and lSFE (Chackartchi et al. 2011, Merli et al. 2013), and an expected inter-group difference in sinus lift of 3.0 mm (Zitzmann & Schärer 1998), a *per protocol* study population of at least 48 patients (24 treated with tSFE, 24 treated with lSFE) was needed for a two-tailed test to detect an inter-group difference in aGH with a power higher than 95% and a p-level of 0.05.

Descriptive and inferential statistics

A *per-protocol* (PP) analysis was performed. The patient was regarded as the statistical unit. Therefore, for patients receiving two implants concomitantly with sinus floor elevation in the

experimental quadrant, only the implant showing the lowest totCON% was included for analysis. If multiple implants within the experimental quadrant had the same totCON%, only the implant with the lowest aGH was included for analysis. Since all numerical variables showed a non-normal and non-symmetric distribution, they were expressed as median and interquartile range (IR). Within-group comparisons for mPBL, dPBL and SGRI were performed between 6- and 12-month visits using Wilcoxon test. Treatment groups were compared using χ^2 test or Fisher's exact test for categorical variables and Mann-Whitney U-test for numerical and ordinal variables. The level of statistical significance was fixed at 0.05, and the analysis was done using Stata 13 for Windows (StataCorp, College Station, TX).

Results

Study population

Twenty-nine patients and 28 patients were randomly allocated to tSFE and lSFE group, respectively (Figure 1). In tSFE group, 1 implant was immediately removed after placement due to the lack of primary stability, while 1 implant in another patient failed to osseointegrate and was removed at 2 months after insertion. Both patients were excluded from the present analysis, and received an implant of same dimensions 6 months later without additional bone augmentation. Another patient in tSFE group suffered acute myocardial infarction after the 6-month visit, postponed all the 12-month radiographic exams and was therefore excluded from the study. The PP study population consisted of 26 patients in the tSFE group and 28 patients in the lSFE group (Figure 1). Patient and implant characteristics in tSFE and lSFE groups are reported in Table 1.

Radiographic outcomes

In tSFE group, DICOM files of three 12-month CT/CBCT exams could not be analyzed due to technical issues. Therefore, totCON% and aGH measurements in tSFE group were performed on 23 patients. Radiographic outcomes are reported in Table 2 and Figures 2-5. Each patient is consistently identified with the same numeric code through Figures 2-5.

No center effect on totCON% and aGH was found. Data on CON% are reported in Table 2 and Figure 2. totCON% was 100% in both groups, with no significant inter-group difference (p= 0.580) (Table 2). Three patients (13.0%) in the tSFE group showed totCON% lower than 100%, with totCON% values ranging between 71.1% and 86.3%. In tSFE group, toCON% lower than 100% was mainly due to the absence of a peri-implant radiopaque area in the apical part of the implant (i.e., $aCON\%_{b\text{-}p}$ and $aCON\%_{m\text{-}d}$ = 0) (Figure 2). One patient (3.6%) in lSFE group showed totCON% lower than 100% (totCON%= 77.6%) due to the partial absence of a peri-implant radiopaque area at the palatal aspect (i.e., pCON%= 60%) (Figure 2).

aGH was significantly higher in lSFE group (6.2 mm; IR: 3.3 – 8.3) compared to tSFE group (0.6 mm; IR: 0.5 – 1.6) (p< 0.0001). aGH was positive in 20 patients (87.0%) and 27 patients (96.4%) in tSFE and lSFE groups, respectively, and was 0 in the other patients (Figure 3).

At 6 months, mPBL and dPBL were 0 mm (IR: 0 - 0) in both groups (p= 0.637 and p= 0.790, respectively). Two patients (7.7%) in the tSFE group and 1 patient (3.6%) in the lSFE group showed mPBL and/or dPBL > 0 mm. At 12 months, mPBL and dPBL were 0 mm (IR: 0 – 0) in both groups (p= 0.600 and p= 0.553, respectively). Four (15.4%) patients in the tSFE group and 5 (17.9%) patients in the lSFE group showed mPBL and/or dPBL> 0 mm (Figure 4). No significant changes in mPBL and dPBL were observed between the 6-month and 12-month visit.

SGRI values as observed at 6 and 12 months in each patient are reported in Figure 5. At 6 months, SGRI was significantly higher in lSFE group (3.0; IR: 2.0 - 3.0) compared to tSFE group (2.0; IR: 2.0 – 3.0) (p= 0.006). The score was 3 at 20 sites, and 2 at 8 sites in lSFE group, whereas 3 at 9 sites, 2 at 11 sites, 1 at 4 sites, and 0 at 2 sites in the tSFE group. At 12 months, SGRI was significantly higher in lSFE group (3.0; IR: 3.0 - 3.0) compared to tSFE group (3.0; IR: 2.0 – 3.0) (p= 0.026). The score was 3 at 24 sites, and 2 at 4 sites in lSFE group, whereas 3 at 14 sites, 2 at 6 sites, 1 at 4 sites, and 0 at 2 sites in the tSFE group. The variation in SGRI as observed between 6 and 12-month visit was significant only in tSFE group (p= 0.043).

Conclusions

In conclusion, the results of the present study demonstrated that tSFE (when performed according to the *Smart Lift* technique) and lSFE similarly contribute to increase substantially the peri-implant bone support at sites with residual bone height of 3-6 mm at 12 months post-surgery.

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Conflict of interest

The Authors declare they have no conflict of interest related to the present study.

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Table 1. Patient and implant characteristics in tSFE and lSFE groups.

	n° patients/implants	age (years)	gender	smoking status	RBH (mm)	implant diameter (mm)	implant length (mm)
	n	median (IR)	n° males / n° females	n° current smokers / former smokers/never smoked	median (IR)	median (IR)	median (IR)
tSFE group	26	51.6 (47.0 – 58.5)	15 / 11	4 / 2/ 20	5.0 (4.1 - 5.4)	4.0 (4.0 - 4.0)	9.5 (9.5 – 11.0)
lSFE group	28	53.0 (48.5 - 59.0)	11 / 17	3 / 2 / 23	4.1 (4.0 – 5.1)	4.0 (4.0 - 4.0)	9.5 (9.5 – 11.0)
p value		0.461	0.176	0.882	0.123	0.146	0.485

Table legend
IR: inter-quartile range; RBH: residual bone height; tSFE: transcrestal sinus floor elevation (*Smart Lift* technique); lSFE: lateral sinus floor elevation.

Table 2. Proportion of the implant surface in direct contact with the radiopaque area (CON%) as assessed at 12 months post-surgery on the CT/CBCT. CON% measurements were performed on the CT/CBCT mesio-distal section assessing CON% on mesial, distal and apical aspect of the implant (mCON%, dCON%, and $aCON\%_{m-d}$, respectively) and on bucco-lingual CT/CBCT section assessing CON% on buccal, palatal and apical aspect of the implant (bCON%, pCON%, and $aCON\%_{b-p}$, respectively). totCON% expresses the proportion of the implant surface in direct contact with the radiopaque area obtained by averaging CON% measurements of all 180 CT/CBCT sections parallel to the long axis of the implant and passing through the mid portion of the implant.

	totCON%	bCON%	$aCON\%_{b-p}$	pCON%	mCON%	$aCON\%_{m-d}$	dCON%
tSFE group *	100 (IR: 100 - 100; min: 71.1 - max: 100)	100 (IR: 100 - 100; min: 72.6 - max: 100)	100 (IR: 100 - 100; min: 0 - max: 100)	100 (IR: 100 - 100; min: 60.0 - 100)	100 (IR: 100 - 100; min: 73.6 - max: 100)	100 (IR: 100 - 100; min: 0 - max: 100)	100 (IR: 100 - 100; min: 100 - max: 100)
lSFE group	100 (IR: 100 - 100; min: 77.6- max: 100)	100 (IR: 100 - 100; min: 100 - max: 100)	100 (IR: 100 - 100; min: 60.0 - max: 100)	100 (IR: 100 - 100; min: 60.0 - max: 100)	100 (IR: 100 - 100; min: 100 - max: 100)	100 (IR: 100 - 100; min: 100 - max: 100)	100 (IR: 100 - 100; min: 100 - max: 100)
p value	0.580	0.606	0.554	0.963	0.800	0.435	0.992

Table legend
IR: inter-quartile range; lSFE: lateral sinus floor elevation; min: minimum value; max: maximum value; tSFE: transcrestal sinus floor elevation.
* In tSFE group, DICOM files of three 12-month CT/CBCT exams could not be analyzed due to technical issues. Therefore, CON% measurements in tSFE group were performed on 23, and not 26, patients.

Figure 1. Flow chart of patient inclusion and follow-up.

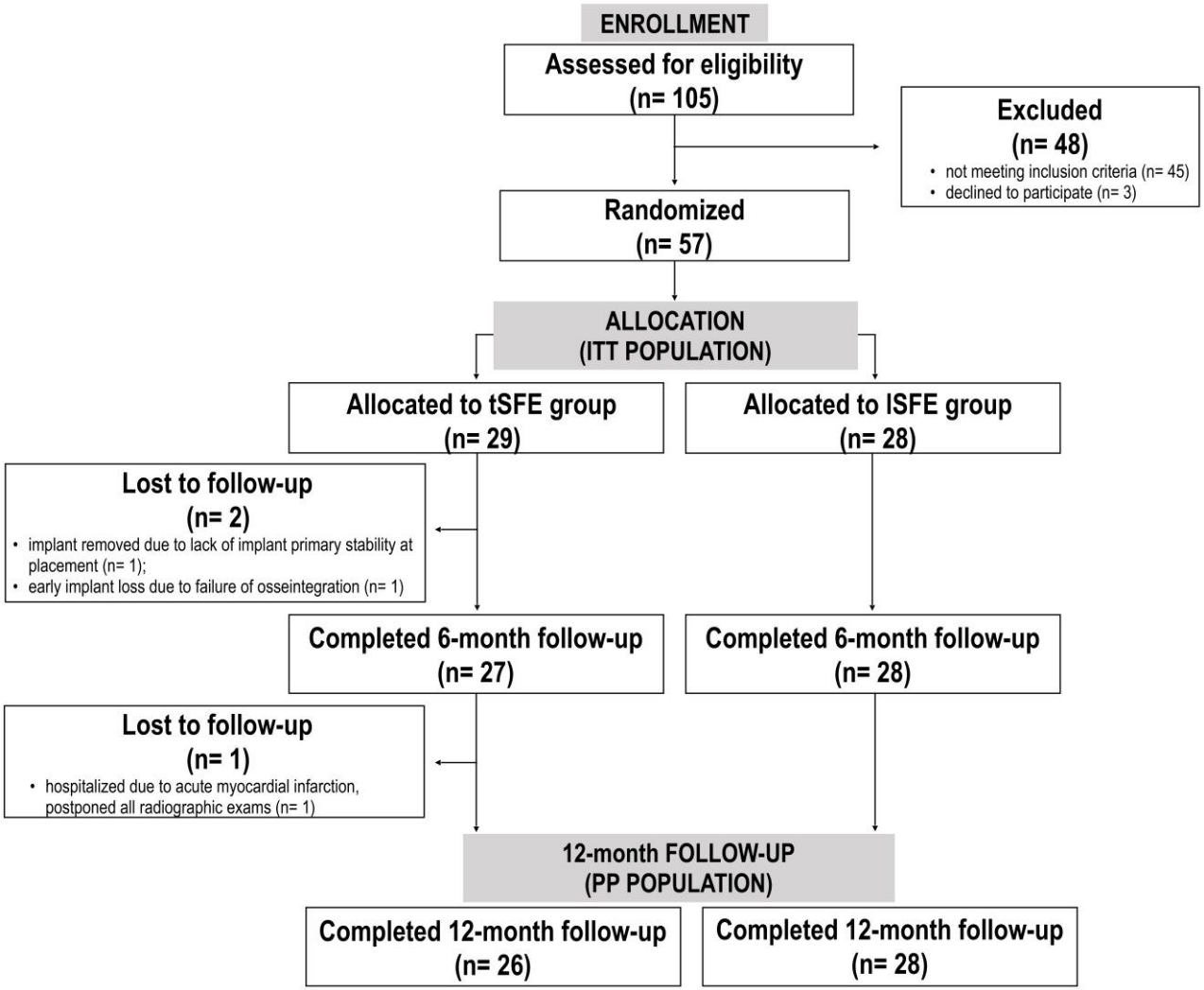

Figure 2. CON% (percentage proportion of the implant surface in direct contact with the radiopaque area) values as assessed on the 12-month CT/CBCT of each patient in tSFE and lSFE groups.

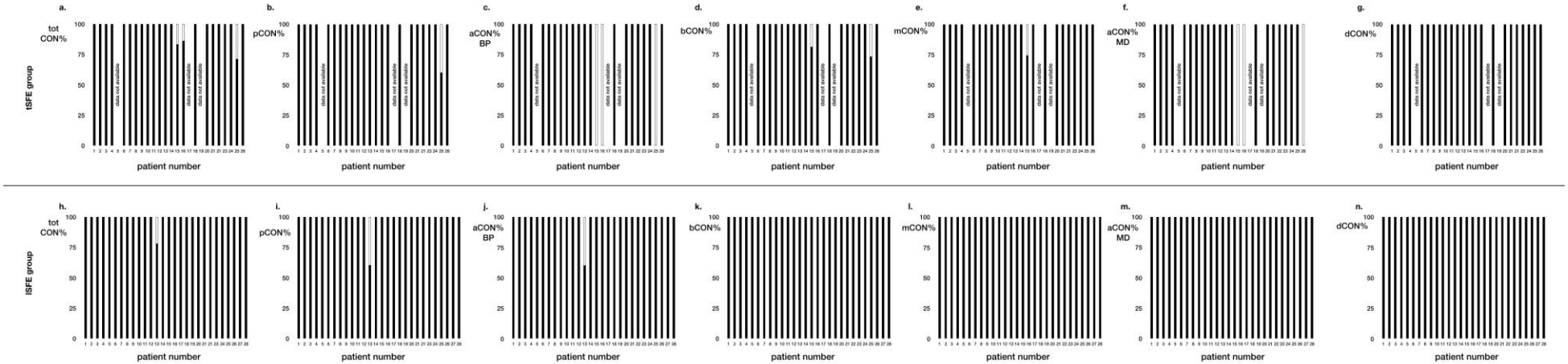

Figure 3. Height of the radiopaque area apical to the implant apex (aGH) as assessed in mm on the 12-month CT/CBCT of each patient in the tSFE group (a) and lSFE group (b).

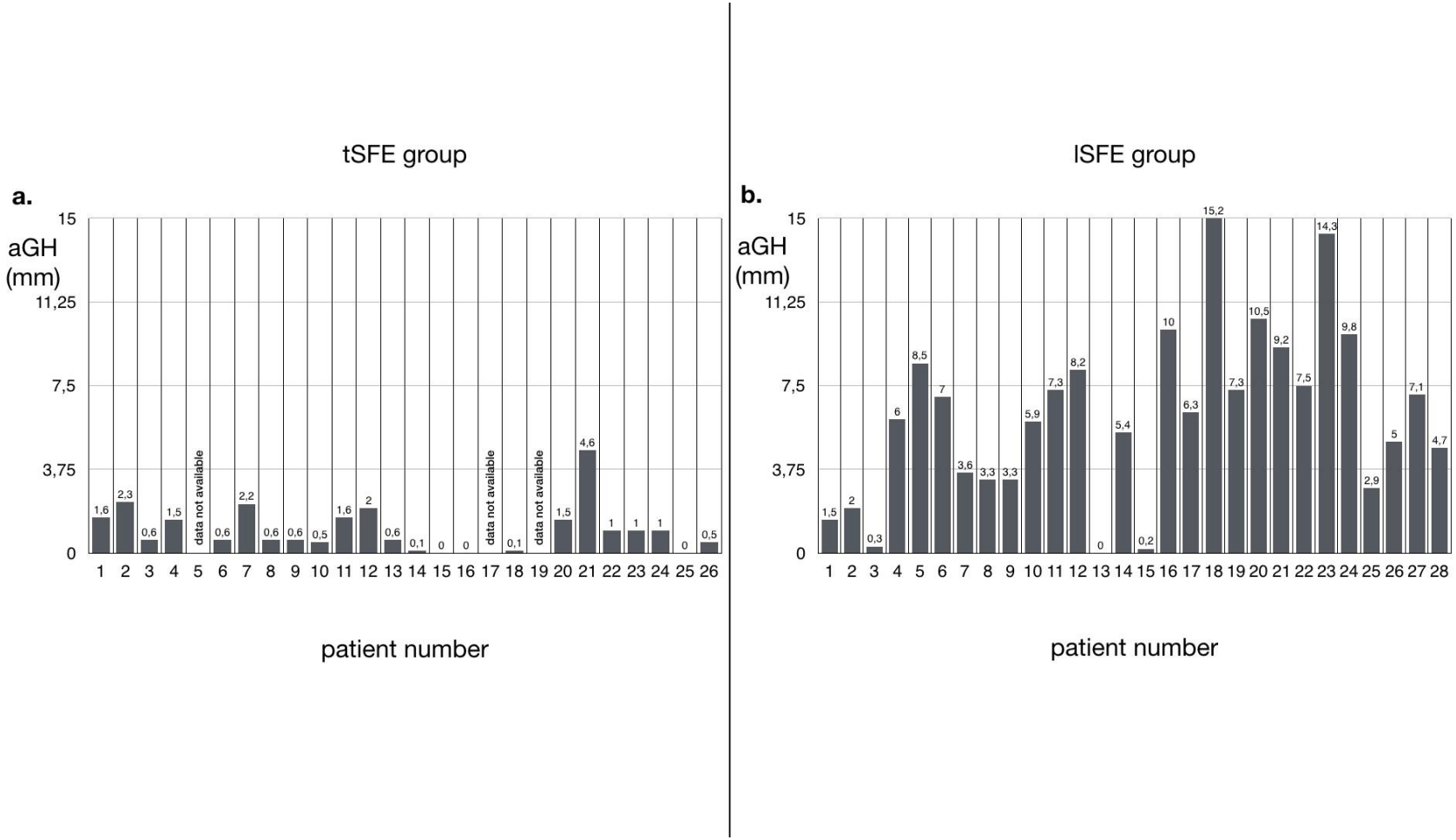

Figure 4. Peri-implant bone level (as assessed in mm on the 12-month periapical radiograph) at the mesial and distal aspects of the implant (mPBL and dPBL, respectively): **a)** mPBL in each patient of the tSFE group; **b)** dPBL in each patient of the tSFE group; **c)** mPBL in each patient of the lSFE group; **d)** dPBL in each patient of the lSFE group.

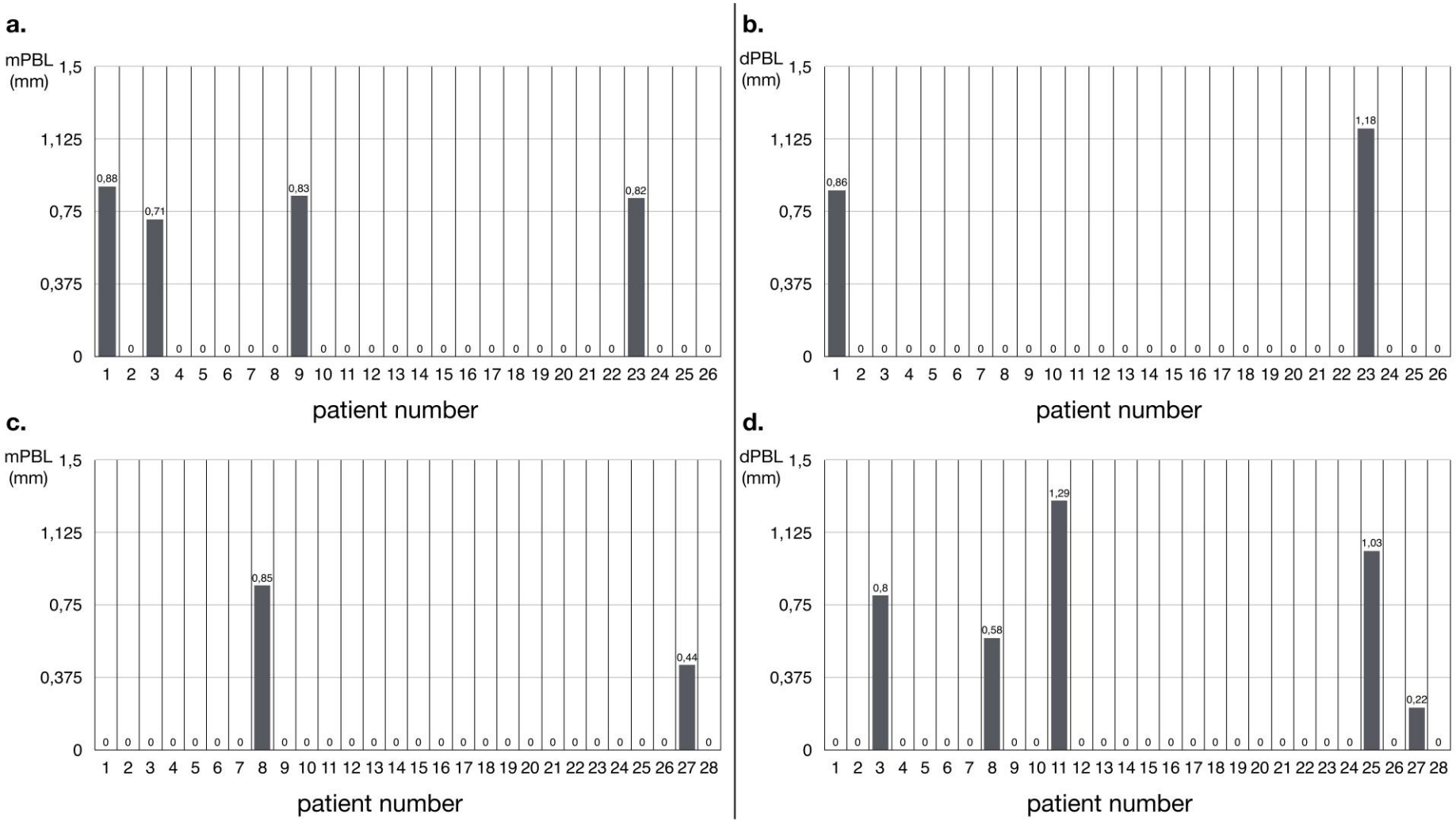

Figure 5. Sinus graft remodeling index (SGRI, Bragger et al. 2004) values as assessed on periapical radiograph in each patient of the tSFE group at **a)** 6 months and **b)** 12 months, and in each patient of the lSFE group at **c)** 6 months and **d)** 12 months.