Randomized controlled multicenter study comparing short dental implants (6mm) versus longer dental implants (11-15mm) in combination with sinus floor elevation procedures. Part 2: clinical and radiographic outcomes at 1 year of loading

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Abstract: AIM To compare, clinically and radiographically, short dental implants (6mm) to long implants (11-15 mm) placed with sinus grafting. METHODS Participants with 5-7 mm of bone height in the posterior maxilla were randomly allocated to receive short implants (GS) or long implants with sinus grafting (GG). Implants were loaded with single crowns 6 months after placement (PR). Patients were re-evaluated 12 months after loading (FU-1). Outcome variables included: Implant survival rate (CSR), marginal bone level alteration (MBL), periodontal probing depth (PPD), bleeding on probing (BoP), plaque control record (PCR) and crown-to-implant ratios (C/I). Statistical analysis was performed using non-parametric tests. RESULTS In 97 subjects, 132 implants were re-evaluated at FU-1. The CSR was 100%. The MBL from implant placement (IP) to (PR) was -0.22±0.4mm for GG and -0.3±0.45mm for GS ($p<0.001$). MBL from IP to FU-1 was -0.37±0.59mm for GG and -0.22±0.3mm for GS ($p<0.001$). Intergroup comparisons showed non significant differences for MBL ($p>0.05$), PPD ($p=1$) and PCR ($p=0.09$). BoP was higher in the GS ($p=0.04$). The C/I was 0.99 ±0.17 for GG and 1.86 ± 0.23 for GS ($p<0.001$). No correlation was observed between C/I and MBL, (GG: $p=0.13$; GS: $p=0.38$). CONCLUSIONS Both treatment modalities provided similar outcomes.

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Randomized controlled multicenter study comparing short dental implants (6mm) versus longer dental implants (11-15mm) in combination with sinus floor elevation procedures. Part 2: clinical and radiographic outcomes at 1 year of loading

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Running title: short implants vs. sinus floor elevation procedures

Key words: dental implant, sinus floor elevation, sinus grafting, short dental implant, multicenter, randomized controlled clinical trial, bone augmentation.

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Abstract

Aim. To compare, clinically and radiographically, short dental implants (6mm) to long implants (11-15 mm) placed with sinus grafting.

Methods. Participants with 5-7 mm of bone height in the posterior maxilla were randomly allocated to receive short implants (GS) or long implants with sinus grafting (GG). Implants were loaded with single crowns 6 months after placement (PR). Patients were re-evaluated 12 months after loading (FU-1). Outcome variables included: Implant survival rate (CSR), marginal bone level alteration (MBL), periodontal probing depth (PPD), bleeding on probing (BoP), plaque control record (PCR) and crown-to-implant ratios (C/I). Statistical analysis was performed using non-parametric tests.

Results: In 97 subjects**,** 132 implants were re-evaluated at FU-1. The CSR was 100%. The MBL from implant placement (IP) to (PR) was -0.22±0.4mm for GG and -0.3±0.45mm for GS ($p<0.001$). MBL from IP to FU-1 was -0.37±0.59mm for GG and -0.22±0.3mm for GS ($p<0.001$). Intergroup comparisons showed non significant differences for MBL ($p>0.05$), PPD (

p=1) and PCR (p=0.09). BoP was higher in the GS (p=0.04). The C/I was 0.99 ±0.17 for GG and 1.86 ± 0.23 for GS (p<0.001). No correlation was observed between C/I and MBL, (GG: p=0.13; GS: p=0.38).

Conclusions: Both treatment modalities provided similar outcomes.

CLINICAL RELEVANCE

Scientific rationale for the study: an increased pneumatization of the maxillary sinus and loss of alveolar bone may result in an atrophic posterior maxilla. In these cases, implant therapy is conducted using a sinus floor elevation procedure in combination with the placement of longer dental implants. This procedure is associated with morbidity and a relatively high rate of complications. Therefore, the use of shorter dental implants without sinus grafting has been proposed.

Principal findings: Both treatment options demonstrated similar outcomes at 1 year of function with respect to implant survival rates and marginal bone level alterations. Crown to implant ratio was not found to affect the marginal bone level.

Practical implications: Within the limitations of this study both treatment options can be recommended to restore the posterior maxilla with dental implants.

Introduction

Following tooth loss, the residual ridge undergoes continuous modeling and remodeling processes (Araujo and Lindhe, 2005). In particular, the modeling process in the posterior maxilla is the result of alveolar ridge resorption and an increased maxillary sinus pneumatization (Farina et al., 2011). Sinus floor elevation using a trans-alveolar or a lateral window approach (Boyne and James, 1980, Summers, 1994), is considered the gold standard to augment the atrophic

posterior maxilla in a cranial direction. Sinus floor elevation procedures using the lateral window approach have proven to be predictable, providing high implant survival rates, either using simultaneous implant placement or a staged approach (Pjetursson et al., 2008).

An alternative treatment strategy, in case of reduced bone volume, is the use of short dental implants (Renouard and Nisand, 2005). This approach may offer several advantages when compared to sinus augmentation procedures, including fewer interventions, shorter treatment time, reduced costs and a lower patient morbidity Recent systematic reviews on survival rates of short dental implants showed outcomes similar to longer implants (Srinivasan et al., 2013, Annibali et al., 2012, Sun et al., 2011, Atieh et al., 2012, Telleman et al., 2011). However, the peak failure rate of short implants (<10mm) was found to be 2.5 years earlier when compared to longer implants (Monje et al., 2013). This might be attributed to the lower amount of supporting bone surrounding short implants. Hence, in addition to implant survival rates, the marginal bone level stability becomes a very important parameter to evaluate (Garaicoa-Pazmino et al., 2014, Monje et al., 2013). For that purpose, measurements of marginal bone level alterations (MBL), have been utilized to assess the long-term performance of dental implants. Originally, a mean crestal bone loss of ≥1,5mm after the first year of function and a ≥0,2 mm loss per year afterwards, were considered as threshold values to determine implant success (Albrektsson et al., 1986). Thereafter, this success criterion has been revised, since a smaller amount of MBL could be observed long-term, in well-maintained patients (Roos et al., 1997). Recent randomized controlled studies evaluating simultaneous placement of implants with sinus floor elevation, reported an average MBL ranging from -1,2 mm to -0.1 mm (Esposito et al., 2011, Cannizzaro et al., 2013, Gulje et al., 2014, Pistilli et al., 2013) after 1 year of function. In

comparison, randomized controlled studies on shorter dental implants (<8mm) in posterior maxilla rendered a MBL averaging from -1.02 mm to -0.1mm (Esposito et al., 2014, Cannizzaro et al., 2013, Gulje et al., 2013, Gulje et al., 2014, Pistilli et al., 2013, Esposito et al., 2011)

One of the concerns raised by clinician using shorter dental implants, is the possible detrimental effect on MBL and implant survival in case of an increased crown to implant ratio (C/I) (Blanes, 2009, Garaicoa-Pazmino et al., 2014). It has been suggested that loading forces of high magnitude may affect marginal bone stability (Isidor, 2006). A C/I between 0.5 to 1 was proposed to limit the amount of non-axial forces and to reduce the risk of excessive crestal bone loss (Glantz and Nilner, 1998). Despite these clinical recommendations, the current evidence seems to indicate that MBL is not influenced by the C/I (Garaicoa-Pazmino et al., 2014). However, in the majority of the available studies, short implants were splinted to longer ones and to date, limited information is available on short implants supporting unsplinted crowns in the posterior maxilla.

Even though, both treatment approaches for the atrophic maxilla, short dental implants and sinus elevation plus longer implants demonstrated to be clinically successful in terms of survival rates of dental implants, only a limited number of studies compared both procedures in a randomized controlled clinical trial (Thoma et al., 2015b). In order to provide more scientific data, a multicenter randomized controlled clinical trial was performed. In part 1 report of the study, patient centred outcomes, cost and treatment time were compared between short implants and implants 11-15 mm long placed in combination with sinus elevation with lateral window. The results suggested a significantly lower morbidity, cost and treatment time when using short

implants(Thoma et al., 2015a). Clinical and radiographic data were not provided so far. The aim of the present study was therefore to test whether or not the use of short dental implants (6mm) results in similar clinical and radiographic outcomes compared to long implants (11-15mm) in combination with sinus grafting

Materials and methods

The present trial was designed as a prospective, randomized controlled, multicenter study. Five clinical centers participated. An investigator meeting for calibration was done prior to study initiation. After approval by the respective local ethics committees, 101 patients were recruited and signed the informed consent before entering of the study.

The design of the experimental study was previously described in detail(Thoma et al., 2015a). Briefly, subjects with partial edentulism in the posterior maxilla, with a residual bone height of 5-7 mm and ridge width of ≥ 6 mm, were considered for the study. In sites with 5 mm of bone height, implants were inserted without additional treatments. The implants were placed penetrating 1 mm inside the sinus and no precautions were taken to prevent the perforation of the Schneiderian membrane.

Inclusion and exclusion criteria are presented in Fig. 1. Qualifying participants were randomly allocated to receive either one of the following treatments: group short (GS), placement of 1-4 implants 6 mm in length and 4 mm in diameter (ASTRA TECH Implant System OsseoSpeed^{TM} 4.0S; DENTSPLY Implants, Mölndal, Sweden) or group graft (GG) placement 1-4 implants 11,13 or 15 mm in length and 4 mm in diameter (ASTRA TECH Implant System OsseoSpeed^{TM}

4.0S; DENTSPLY Implants, Mölndal, Sweden) in combination with sinus grafting using a lateral window technique (Boyne and James, 1980). Visit schema and study timelines are reported in Appendix 1.

Surgical Treatment (IP)

Implant placement was performed according to the manufacturer's recommendations (ASTRA TECH Implant System; DENTSPLY Implants, Mölndal, Sweden). Preoperatively, patients were pre-medicated with antibiotics and analgesics (according to the center's normal routine) and subsequently rinsed with 0.2% chlorhexidine solution for one minute. The surgical procedure was performed under local anesthesia. Parenteral oral or intravenous sedation was utilized upon the surgeon's preference. The sinus was grafted using a xenograft (Bioss Granules, Geistlich-Switzerland) and the window closed using a resorbable membrane (Biogide, Geistlich-Switzerland). No further bone substitute materials were applied. The implants were left for a trans-mucosal healing. In case of poor primary stability, as judged by the investigator, a conventional two-stage approach was used. Patients were instructed to rinse with 0.12% chlorhexidine solution (twice a day until suture removal) and were given antibiotics and analgesics, if deemed necessary by the investigator and following the center's normal routine. Sutures were removed 7-14 days later.

Prosthetic procedures: impression (IM) and insertion of the final prosthetic reconstruction (PR)

Five months after implant placement (IP), an impression of the implant(s) was made and a final restoration fabricated. In case of a submerged healing, a minimal flap elevation was performed to connect the abutment. Six to seven months after implant placement, the final prosthetic

restoration was inserted (PR). No restrictions were made regarding the material and the type of retention (screw-retained or cemented) and all implants were restored with single non-splinted crowns.

Follow-up visit (FU-1)

Twelve months after delivery of the final restoration (PR), a clinical examination was conducted. Plaque control record (PCR) (O'Leary et al., 1972), bleeding on probing (BoP) and probing pocket depth (PPD) were measured at four sites of the implant(s) (mesial, distal, buccal, lingual).

Radiographic examination.

Standardized periapical radiographs using the paralleling technique with a Rinn® (Dentsply Rinn, Elgin, Illinois, USA) film holder were taken at IP, at PR, and at FU-1.

Primary and secondary outcome variables

The main response variable was the cumulative implant survival rate (CSR). Secondary outcomes variable included: PPD, BoP, PCR, MBL and the C/I.

Implant Survival

Any implant that was removed after implant placement was considered as a failure, In addition, all implants not present at follow-up, for the "worst case scenario", were considered as failed. CSR was calculated by dividing the number of non-failed by the number of installed implants.

Clinical measurements

PPD and BoP were assessed at four aspects per implant (mesial, distal, buccal and palatal) by using a periodontal probe. PPD was measured as the distance from the mucosal margin to the bottom of the probable pocket in mm. BoP was recorded as presence or absence of bleeding when probing to the

bottom of the pocket. The level of oral hygiene was evaluated using the Plaque Control Record (PCR) (O'Leary et al., 1972). Presence of plaque on the four surfaces of each investigated implant was recorded as being present or not.

Marginal bone level alteration

MBL was determined based on radiographs and expressed as the distance from the implant shoulder to the most coronal bone-to-implant contact on the mesial and distal side of the implant. An independent examiner performed all the radiographic measurements. The mean values were calculated for each implant. The change in MBL from IP and/or PR to FU-1 was calculated.

Crown-to-implant ratio

The height of the crowns was measured on the radiographs from the implant-abutment interface to the most coronal point on the crown. A radiologist, independent from the investigational group, evaluated all radiographs. The C/I was calculated based on x-rays taken at FU-1.

Statistical analysis

The statistical software used was IBM SPSS (IBM Corp., Armonk, NY), StatXact (Cytel, Cambridge, MA, USA) and Excel (Microsoft, Redmond, WA, USA). The subject was the statistical unit. In addition, statistical analysis was also performed at the implant level. Independent variables recorded were patient age, gender, oral conditions, implant position, reason for tooth loss at the implant site. A post-hoc power analysis was calculated for the secondary outcome variable MBL. A statistical power of 95% resulted to detect difference between the groups of 0.5 mm assuming a standard deviation of the change of 0.3mm. A parametric statistical approach was applied. For continuous data the Student –t test was used to compare the means between treatment groups (GG vs GS), Paired t-test was used to compare

changes within each treatment group. Fisher's exact test was used for nominal data and survival rates. Also, nominal data were presented using descriptive statistics. C/I ratio in relation to MBL was calculated at implant level and the correlation was analyzed using the Spearman Rank Correlation test. A P-value below 0.05 was considered as statistically significant. No adjustment for multiplicity was applied.

Results

The patient recruitment phase ranged from October 2009 to February 2011. Details on demographics, patient-reported outcome measures, surgical time and costs were reported earlier(Thoma et al., 2015a). A total of 101 subjects with 137 implants entered the clinical trial. Baseline demographics, reason for tooth loss at the implant site and oral conditions are summarized in Appendix 2. Implant sites distribution is presented in Appendix 3. Ninety-seven patients and 132 implants were available for re-evaluation at FU-1. Seven implants had no primary stability and the 2-stage surgery approach was applied. Five implants were in group graft and 2 in group short. Patient flow and allocation is presented in Appendix 4.

Implant survival

All 132 implants in 97 patients examined at FU-1 were clinically stable, thereby providing a 100% CSR. For the "worst case" scenario (all implants of patients not followed-up and therefore considered as failed), the CSR for GG was 98.6% (1 implant considered as lost) and for GS 97.0% (2 implants considered as lost) ($p>0.05$).

Marginal bone level alterations (MBL)

Between and within group analysis of MBLs at subject level are presented in Tab. 1. Radiographs of 52, 51 and 52 implants were available in the GG for the measurements of Δ (IP-PR), Δ (IP- FU-1) and Δ (PR- FU-1) respectively; whereas for the GS , radiographs of 52, 43 and 41 implants were available for the measurements Δ (IP-PR) and Δ (IP- FU-1) and Δ (PR- FU-1) respectively. A statistically significant loss of marginal bone was observed in both GG and GS from IP to PR, and from IP to FU-1. However, no significant changes were observed in MBL from PR to FU-1. The differences between GG and tGS were not statistically significant for MBL at any time point (Tab.1). Table 2 displays the distribution of MBL at implant level between the groups from IP to FU-1 and from PR to FU-1.

Cumulative representation of implants MBL distribution from PR to FU-1 is showed in Fig.2.

Clinical measurements

PPD measured at FU-1 was 2.3±1.4mm and 2.8±0.9mm for GG and GS respectively and no statistically significant difference was observed (p=0.1). Also, no statistically significant differences were observed for PCR recorded at FU-1 between GG and GS (p=0.2). However, BoP recorded at FU-1 showed a statistically significant difference between the groups (p=0.038) with a higher number of subjects with BoP in GS The proportion of implants with BoP was 38% and 53% for GG and GS respectively (Tab 3).

Since none of the implant with BoP presented a MBL >1 mm, according to the European Federation of Periodontology case definition (Sanz et al., 2012) these values represented the incidence of peri-implant mucositis observed after 12 months of loading. Bleeding surfaces distribution is presented in appendix 5.

Crown to implant ratio.

The mean crown length was 11.85±1.7mm and 11.22±1.4 for the group graft and group short respectively, and the difference between the groups was statistically significant (p=0.049). The mean C/I was 0.99 ±0.17 and 1.86 ± 0.23 for GG and GS respectively and the difference in C/I between the groups was statistically significant (p<0.001; CI=95%: -0.96,-0.83).

The distribution of MBL in relation to C/I for GG and GS group from IP to FU-1 and from PR to FU-I is presented in Fig. 3 and 4. The Spearman Rank Correlation coefficient between MBL and C/I was 0.21 (p=0.13) and -0.13 (p=0.38) for group GG and GS respectively and was not statistically significant.

Discussion

In the present multicenter randomized controlled study, the use of short implants in the treatment of atrophic posterior maxilla provided similar clinical and radiographic outcomes compared to long implants placed in combination with sinus grafting at one year of loading.

The implant survival rate was not significantly different between the two groups. The CSR reported in the present study is consistent with previous reports on implants placed in combination with sinus grafting (Del Fabbro et al., 2013, Nkenke and Stelzle, 2009, Pjetursson et al., 2008) and on shorter implants in posterior maxilla (Pistilli et al., 2013, Gulje et al., 2014). In addition, short implants (<8mm) seem to provide similar short-term survival rate when compared to longer ones placed in combination with augmentation procedures based on systematic reviews and randomized controlled clinical trials(Esposito et al., 2014, Gulje et al., 2014, Lee et al., 2014, Thoma et al., 2015b).

In order to guarantee long-term clinical service, the maintenance of a stable marginal bone level becomes more critical when short implants are used (Monje et al., 2013). MBL is a generally

accepted parameter to assess the bone response around dental implants (Salvi and Lang, 2004). The mean MBL reported in this study was -0.22±0.4mm and -0.37±0.59 mm for GS and GG respectively. In addition, 93% and 84% of the implants in the GS and GG group respectively, showed bone loss <0.5 mm from prosthesis insertion to the one-year follow-up. This level of MBL is smaller than what was reported by other studies using other types of short implants in the posterior regions (Renouard and Nisand, 2005) (Rossi et al., 2010, Pistilli et al., 2013); e.g. in a recently published study using a similar design, a mean MBL of -1.02±0.06 mm was shown for short implants placed in the posterior maxilla after 1 year of function (Pistilli et al., 2013). The small MBL observed in the present investigation is consistent with the data obtained with the same type of implant (Gulje et al., 2013, Gulje et al., 2014) and may be partly explained by the implant design and surface configuration. The implants used in this study features a platform switching connection. Several animal and human studies provide evidence that implants with a platform switching connection show significantly less MBL compared to implants with a butt joint connection (Chrcanovic et al., 2015). Also, the micro-threaded design in the most coronal aspect of the implant may explain the improved marginal bone response (Orsini et al., 2012). Clinical trials indicated greater resistance to marginal bone loss and maintenance of bone levels when the micro-threaded design extended to the neck of the implant (Shin et al., 2006, Bratu et al., 2009). The fluoride-modified micro-rough implant surfaces of the implant used in this trial showed to improved bone to implant contact both *in vitro* and in animal studies (Berglundh et al., 2007). The fluoridated surface may play a role in providing a stable marginal bone level even in challenging clinical situations with a high C/I and poor bone quality (Berglundh et al., 2007, Ellingsen et al., 2004).

The study design allowed implants being left to heal with a trans-mucosal abutment (1-stage). or submerged under the oral mucosa (2-stage). The effect of 1-stage versus 2-stage approach on soft tissue and hard tissue remodeling was investigated previously on animal and clinical studies (Abrahamsson et al., 1999, Collaert and De Bruyn, 1998) and no difference was reported when comparing the two approaches.

Soft tissue peri-implant conditions were assessed using PPD and BoP. Whereas PPD was similar between the groups, a significantly higher BoP was recorded for GS. This result was observed despite there was no difference in PCR. The importance of BoP as a diagnostic index has been evaluated around teeth and implants (Luterbacher et al., 2000, Lang et al., 1986). Data indicate the absence of BoP had a very high negative predictive value for disease progression. Conversely, the significance of a single recording of positive BoP in determining disease progression is controversial (Lang et al., 1986). Since no difference in MBL and PPD was observed between the groups, the higher value of BoP observed in the GS sample may have just trivial significance at this time point. Further evaluation is needed at a longer follow up.
The presence of BoP with marginal bone loss of 1 /1.5 mm, after the remodeling phase post implant placement, has been advocated as case definition for peri-implantitis in prospective studies (Sanz and Chapple 2012) . In the present trial only 4 implants in the group graft presented MBL≤-1mm from PR to FU-1 (Tab.2). However none of these implants reported sites with BoP .

The C/I has been always considered a critical factor for long term success of implant supported restorations, and a C/I ranging between 0.5 to 1 was recommended as ideal (Glantz and Nilner, 1998). However, recent systematic reviews and meta-analysis were unable to confirm this

clinical recommendation. On the contrary, implants with unfavorable C/I presented with a smaller MBL. (Garaicoa-Pazmino et al., 2014, Blanes, 2009). The present investigation partly confirm these results.The C/I in the GS was significantly higher than in the GG Despite this, no difference in MBL was observed between the groups. In addition, the correlation between C/I and MBL was not statistically significant. This outcome is even more relevant considering that all implants were restored with unsplinted single crowns. However, the lack of significant correlation between C/I on MBL has to be taken with caution. In the present study the C/I was never higher that 2.5 (Fig.3) and in a recent report a significant marginal bone loss was observed only when the anatomical and clinical crown to implant ratio was higher than 3.4 and 3.1 respectively (Malchiodi et al., 2014). Another factor that seems to be negatively influenced by an unfavorable C/I, is the prevalence of prosthetic failures. In fact a C/I > 1.5 and crown high space >15mm may increase the risk of mechanical failure of the prosthetic components (Nissan et al., 2011, Quaranta et al., 2014) .

In the present study the length of the anatomical crowns was 11.85±1.7mm and 11.22±1.4 for group graft and group short respectively , with significantly longer crowns in the group graft. However these values were lower than 15mm, considered a threshold value above which an increased risk of prosthetic failure has been reported (Nissan et al., 2011, Quaranta et al., 2014). This may in part explain why only 6 events of complications relative to abutment and screw failures were observed over the first year of function, with no difference between the groups(Thoma et al., 2015a). This is consistent with the results of Mezzomo et al. (Mezzomo et al., 2014) that in a systematic review and meta-analysis calculated a 2,8% incidence of prosthetic complications (CI 1.4-5,7%), when utilizing unsplinted restorations supported by shorter dental implants in the posterior region.

Within the limitations of this trial and the relatively short observation period of one year of loading, the clinical and radiographic outcomes indicate that both treatment options for the posterior atrophied maxilla were successful. Hence, this may contribute to a paradigm shift from sinus grafting with long implants to short implants for the treatment of this clinical condition.

Conclusions

Within the limitation of the present study, the obtained results indicate that short implants (6mm) provided a similar clinical and radiographic performance compared to longer implants (11-15 mm) placed in combination with a sinus augmentation procedure (lateral window). In addition, the increased C/I reported for the GS seemed to have no detrimental effect on MBL and the prevalence of restorative complications during the 12 months of observation. Longer follow up data are necessary to confirm these results.

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Bibliography

Abrahamsson, I., Berglundh, T., Moon, I. S. & Lindhe, J. (1999) Peri-implant tissues at submerged and non-submerged titanium implants. *J Clin Periodontol* 26, 600-607.

Albrektsson, T., Zarb, G., Worthington, P. & Eriksson, A. R. (1986) The long-term efficacy of currently used dental implants: a review and proposed criteria of success. *Int J Oral*

Maxillofac Implants **1**, 11-25.

Annibali, S., Cristalli, M. P., Dell'Aquila, D., Bignozzi, I., La Monaca, G. & Pilloni, A. (2012) Short dental implants: a systematic review. *J Dent Res* **91**, 25-32. doi:10.1177/0022034511425675.

Araujo, M. G. & Lindhe, J. (2005) Dimensional ridge alterations following tooth extraction. An experimental study in the dog. *J Clin Periodontol* **32**, 212-218. doi:10.1111/j.1600-051X.2005.00642.x.

Atieh, M. A., Zadeh, H., Stanford, C. M. & Cooper, L. F. (2012) Survival of short dental implants for treatment of posterior partial edentulism: a systematic review. *Int J Oral Maxillofac Implants* **27**, 1323-1331.

Berglundh, T., Abrahamsson, I., Albouy, J. P. & Lindhe, J. (2007) Bone healing at implants with a fluoride-modified surface: an experimental study in dogs. *Clin Oral Implants Res* **18**, 147-152. doi:10.1111/j.1600-0501.2006.01309.x.

Blanes, R. J. (2009) To what extent does the crown-implant ratio affect the survival and complications of implant-supported reconstructions? A systematic review. *Clin Oral Implants Res* **20 Suppl 4**, 67-72. doi:10.1111/j.1600-0501.2009.01762.x.

Boyne, P. J. & James, R. A. (1980) Grafting of the maxillary sinus floor with autogenous marrow and bone. *J Oral Surg* **38**, 613-616.

Bratu, E. A., Tandlich, M. & Shapira, L. (2009) A rough surface implant neck with microthreads reduces the amount of marginal bone loss: a prospective clinical study. *Clin Oral Implants Res* **20**, 827-832. doi:10.1111/j.1600-0501.2009.01730.x.

Cannizzaro, G., Felice, P., Minciarelli, A. F., Leone, M., Viola, P. & Esposito, M. (2013) Early implant loading in the atrophic posterior maxilla: 1-stage lateral versus crestal sinus lift and 8 mm hydroxyapatite-coated implants. A 5-year randomised controlled trial. *Eur J Oral Implantol* **6**, 13-25.

Chrcanovic, B. R., Albrektsson, T. & Wennerberg, A. (2015) Platform switch and dental implants: A meta-analysis. *J Dent*. doi:10.1016/j.jdent.2014.12.013.

Collaert, B. & De Bruyn, H. (1998) Comparison of Branemark fixture integration and short-term survival using one-stage or two-stage surgery in completely and partially edentulous mandibles. *Clin Oral Implants Res* **9**, 131-135.

Del Fabbro, M., Wallace, S. S. & Testori, T. (2013) Long-term implant survival in the grafted maxillary sinus: a systematic review. *Int J Periodontics Restorative Dent* **33**, 773-783. doi:10.11607/prd.1288.

Ellingsen, J. E., Johansson, C. B., Wennerberg, A. & Holmen, A. (2004) Improved retention and bone-toImplant contact with fluoride-modified titanium implants. *Int J Oral Maxillofac Implants* **19**, 659-666.

Esposito, M., Pellegrino, G., Pistilli, R. & Felice, P. (2011) Rehabilitation of postrior atrophic edentulous jaws: prostheses supported by 5 mm short implants or by longer implants in augmented bone? One-year results from a pilot randomised clinical trial. *Eur J Oral Implantol* **4**, 21-30.

Esposito, M., Pistilli, R., Barausse, C. & Felice, P. (2014) Three-year results from a randomised controlled trial comparing prostheses supported by 5-mm long implants or by longer implants in augmented bone in posterior atrophic edentulous jaws. *Eur J Oral Implantol* **7**, 383-395.

Farina, R., Pramstraller, M., Franceschetti, G., Pramstraller, C. & Trombelli, L. (2011) Alveolar ridge

dimensions in maxillary posterior sextants: a retrospective comparative study of dentate and edentulous sites using computerized tomography data. *Clin Oral Implants Res* **22**, 1138-1144. doi:10.1111/j.1600-0501.2010.02087.x.

Garaicoa-Pazmino, C., Suarez-Lopez del Amo, F., Monje, A., Catena, A., Ortega-Oller, I., Galindo-Moreno, P. & Wang, H. L. (2014) Influence of crown/implant ratio on marginal bone loss: a systematic review. *J Periodontol* **85**, 1214-1221. doi:10.1902/jop.2014.130615.

Glantz, P. O. & Nilner, K. (1998) Biomechanical aspects of prosthetic implant-borne reconstructions. *Periodontol 2000* **17**, 119-124.

Gulje, F., Abrahamsson, I., Chen, S., Stanford, C., Zadeh, H. & Palmer, R. (2013) Implants of 6 mm vs. 11 mm lengths in the posterior maxilla and mandible: a 1-year multicenter randomized controlled trial. *Clin Oral Implants Res* **24**, 1325-1331. doi:10.1111/clr.12001.

Gulje, F. L., Raghoebar, G. M., Vissink, A. & Meijer, H. J. (2014) Single crowns in the resorbed posterior maxilla supported by either 6-mm implants or by 11-mm implants combined with sinus floor elevation surgery: a 1-year randomised controlled trial. *Eur J Oral Implantol* **7**, 247-255.

Isidor, F. (2006) Influence of forces on peri-implant bone. *Clin Oral Implants Res* **17 Suppl 2**, 8-18. doi:10.1111/j.1600-0501.2006.01360.x.

Lang, N. P., Joss, A., Orsanic, T., Gusberti, F. A. & Siegrist, B. E. (1986) Bleeding on probing. A predictor for the progression of periodontal disease? *J Clin Periodontol* **13**, 590-596.

Lee, S. A., Lee, C. T., Fu, M. M., Elmisalati, W. & Chuang, S. K. (2014) Systematic review and meta-analysis of randomized controlled trials for the management of limited vertical height in the posterior region: short implants (5 to 8 mm) vs longer implants (> 8 mm) in vertically augmented sites. *Int J Oral Maxillofac Implants* **29**, 1085-1097. doi:10.11607/jomi.3504.

Luterbacher, S., Mayfield, L., Bragger, U. & Lang, N. P. (2000) Diagnostic characteristics of clinical and microbiological tests for monitoring periodontal and peri-implant mucosal tissue conditions during supportive periodontal therapy (SPT). *Clin Oral Implants Res* **11**, 521-529.

Malchiodi, L., Cucchi, A., Ghensi, P., Consonni, D. & Nocini, P. F. (2014) Influence of crown-implant ratio on implant success rates and crestal bone levels: a 36-month follow-up prospective study. *Clin Oral Implants Res* **25**, 240-251. doi:10.1111/clr.12105.

Mezzomo, L. A., Miller, R., Triches, D., Alonso, F. & Shinkai, R. S. (2014) Meta-analysis of single crowns supported by short (<10 mm) implants in the posterior region. *J Clin Periodontol* **41**, 191-213. doi:10.1111/jcpe.12180.

Monje, A., Chan, H. L., Fu, J. H., Suarez, F., Galindo-Moreno, P. & Wang, H. L. (2013) Are short dental implants (<10 mm) effective? a meta-analysis on prospective clinical trials. *J Periodontol* **84**, 895-904. doi:10.1902/jop.2012.120328.

Nissan, J., Ghelfan, O., Gross, O., Priel, I., Gross, M. & Chaushu, G. (2011) The effect of crown/implant ratio and crown height space on stress distribution in unsplinted implant supporting restorations. *J Oral Maxillofac Surg* **69**, 1934-1939. doi:10.1016/j.joms.2011.01.036.

Nkenke, E. & Stelzle, F. (2009) Clinical outcomes of sinus floor augmentation for implant placement using autogenous bone or bone substitutes: a systematic review. *Clin Oral Implants Res* **20 Suppl 4**, 124-133. doi:10.1111/j.1600-0501.2009.01776.x.

O'Leary, T. J., Drake, R. B. & Naylor, J. E. (1972) The plaque control record. *J Periodontol* **43**, 38. doi:10.1902/jop.1972.43.1.38.

Orsini, E., Giavaresi, G., Trire, A., Ottani, V. & Salgarello, S. (2012) Dental implant thread pitch and its influence on the osseointegration process: an in vivo comparison study. *Int J Oral Maxillofac Implants* 27, 383-392.

Pistilli, R., Felice, P., Cannizzaro, G., Piatelli, M., Corvino, V., Barausse, C., Buti, J., Soardi, E. & Esposito, M. (2013) Posterior atrophic jaws rehabilitated with prostheses supported by 6 mm long 4 mm wide implants or by longer implants in augmented bone. One-year post-loading results from a pilot randomised controlled trial. *Eur J Oral Implantol* 6, 359-372.

Pjetursson, B. E., Tan, W. C., Zwahlen, M. & Lang, N. P. (2008) A systematic review of the success of sinus floor elevation and survival of implants inserted in combination with sinus floor elevation. *J Clin Periodontol* 35, 216-240. doi:10.1111/j.1600-051X.2008.01272.x.

Quaranta, A., Piemontese, M., Rappelli, G., Sammartino, G. & Procaccini, M. (2014) Technical and biological complications related to crown to implant ratio: a systematic review. *Implant Dent* 23, 180-187. doi:10.1097/ID.0000000000000026.

Renouard, F. & Nisand, D. (2005) Short implants in the severely resorbed maxilla: a 2-year retrospective clinical study. *Clin Implant Dent Relat Res* 7 Suppl 1, S104-110.

Roos, J., Sennerby, L., Lekholm, U., Jemt, T., Grondahl, K. & Albrektsson, T. (1997) A qualitative and quantitative method for evaluating implant success: a 5-year retrospective analysis of the Branemark implant. *Int J Oral Maxillofac Implants* 12, 504-514.

Rossi, F., Ricci, E., Marchetti, C., Lang, N. P. & Botticelli, D. (2010) Early loading of single crowns supported by 6-mm-long implants with a moderately rough surface: a prospective 2-year follow-up cohort study. *Clin Oral Implants Res* 21, 937-943. doi:10.1111/j.1600-0501.2010.01942.x.

Salvi, G. E. & Lang, N. P. (2004) Diagnostic parameters for monitoring peri-implant conditions. *Int J Oral Maxillofac Implants* 19 Suppl, 116-127.

Sanz, M., Chapple, I. L. & Working Group 4 of the, V. E. W. o. P. (2012) Clinical research on peri-implant diseases: consensus report of Working Group 4. *J Clin Periodontol* 39 Suppl 12, 202-206. doi:10.1111/j.1600-051X.2011.01837.x.

Shin, Y. K., Han, C. H., Heo, S. J., Kim, S. & Chun, H. J. (2006) Radiographic evaluation of marginal bone level around implants with different neck designs after 1 year. *Int J Oral Maxillofac Implants* 21, 789-794.

Srinivasan, M., Vazquez, L., Rieder, P., Moraguez, O., Bernard, J. P. & Belser, U. C. (2013) Survival rates of short (6 mm) micro-rough surface implants: a review of literature and meta-analysis. *Clin Oral Implants Res*. doi:10.1111/clr.12125.

Summers, R. B. (1994) A new concept in maxillary implant surgery: the osteotome technique. *Compendium* 15, 152, 154-156, 158 passim; quiz 162.

Sun, H. L., Huang, C., Wu, Y. R. & Shi, B. (2011) Failure rates of short (</= 10 mm) dental implants and factors influencing their failure: a systematic review. *Int J Oral Maxillofac Implants* 26, 816-825.

Telleman, G., Raghoebar, G. M., Vissink, A., den Hartog, L., Huddleston Slater, J. J. & Meijer, H. J. (2011) A systematic review of the prognosis of short (<10 mm) dental implants placed in the partially edentulous patient. *J Clin Periodontol* 38, 667-676. doi:10.1111/j.1600-051X.2011.01736.x.

Thoma, D. S., Haas, R., Tutak, M., Garcia, A., Schincaglia, G. P. & Hammerle, C. H. (2015a) Randomized controlled multicentre study comparing short dental implants (6 mm) versus longer

dental implants (11-15 mm) in combination with sinus floor elevation procedures. Part 1: demographics and patient-reported outcomes at 1 year of loading. *J Clin Periodontol* 42, 72-80. doi:10.1111/jcpe.12323.

Thoma, D. S., Zeltner, M., Husler, J., Hammerle, C. H. & Jung, R. E. (2015b) EAO Supplement Working Group 4 - EAO CC 2015 Short implants versus sinus lifting with longer implants to restore the posterior maxilla: a systematic review. *Clin Oral Implants Res*. doi:10.1111/clr.12615.

Legenda

Fig.1. Inclusion and exclusion criteria.

Fig.2. Cumulative rappresentation of marginal bone level alteration average (Gain/Loss) of group short and group graft from prosthesis insertion (PR) to the one-year follow up (FU-1).

Fig.3. Distribution of marginal bone level alteration average (Gain/Loss) of group short and group graft from implant placement (IP) to the one-year follow-up (FU-1) vs Crown to Implant Ratio. Implant level analysis.

Fig.4. Distribution of marginal bone level alteration average (Gain/Loss) of group short and group graft from prosthesis insertion (PR) to the one-year follow- to (FU-1) vs Crown to Implant Ratio. Implant level analysis.

Tables

Tab.1. Marginal bone level alteration: Intra group and between group analysis (Subjects level).

Tab.2. Distribution of marginal bone level alteration at implant level between groups from implant placement (IP) to the one-year follow-up (FU-1) and from prosthesis insertion (PR) to the one-year follow- to (FU-1).

Tab.3 Proportion of implants BoP- positive at FU-1: between group comparison.

Tab. 1

Marginal Bone Level Alteration (mm, Gain+/Loss -): Within Groups Comparison (Subject level analysis)			
MBL	**Δ (IP-PR)**	**Δ (IP-FU1)**	**Δ(PR-FU-1)**
GG **N of subj.** Mean(SD) *p- value* *CI=95%*	41 -0.22(0.4) *p<0.01* *(-0.36,-0.07)*	41 -0.39(0.62) *p<0.001* *(-0.59,-0.2)*	41 -0.16(0.62) *p=0.1* *(-.03,0.03)*
GS N of subj. Mean(SD) *p-value* *CI=95%*	40 -0.28(0.45) *p<0.001* *(-0.43,-0.14)*	35 -0.22(0.32) *p<0.001* *(-0.33,-0.11)*	33 0.02(0.3) *p=0.73* *(-0.10,0.14)*

Marginal Bone Level Alteration(mm, Gain+/Loss -): Between Groups Comparison (Subject level analysis)				
MBL **Δ**	**GG** **Mean(SD)** **n. of subjects**	**GS** **Mean(SD)** **n. of subjects**	**p-value**	**Confidence Interval CI=95%**
Δ (IP-PR)	-0.22(0.46) n=41	-0.28(0.45) n=40	P=0.55	(-0.14;0.26)
Δ (IP-FU-1)	-0.39(0.69) n=41	-0.22(0.32) n=35	P=0.14	(-0.4;0.06)
Δ (PR-FU-1)	-0.16(0.62) n=41	0.02(0.36) n=33	P=0.26	(-0.38;0.1)

Tab. 2.

Marginal Bone Level Alteration: Implant Distribution				
MBL interval (mm)	Δ IP –FU-1		Δ PR –FU-1	
Gain+/loss-	GG n. of implants	GS n. of implants	GG n. of implants	GS n. of implants
-2.5<MBL≤-2	2	0	1	0
-2<MBL≤-1.5	2	0	2	0
-1.5<MBL≤-1	2	1	1	0
-1<MBL≤-0.5	8	7	4	3
-0.5<MBL≤0	35	34	30	25
0<MBL≤0.5	1	1	11	8
0.5<MBL≤1	1	0	2	5
1<MBL≤1.5	0	0	1	0
1.5<MBL≤2	0	0	0	0
2<MBL≤2.5	0	0	0	0
Total	51	43	52	41

Tab.3

Proportion of Implants with BoP+ at FU-1			
	GG n.of implants (%)	GS n.of implants (%)	P value
BoP+	27(38%)	36(53%)	p=0.034 (Fisher-exact test)
BoP-	41(58%)	25(37%)	
Missing	2	6	
Total	70	67	

Appendix 1: Study procedures and time lines.

Study Procedures and Time Lines						
	Screening (SC)	Implant placement (IP)	Suture removal (SR)	Impression (IM)	Insertion of prosthetic reconstruction\ (PR)	1-year follow-up (FU-1)
Time Lines			IP+1-2w	IP+26w (±7days)	IP+26-30 w (±7days)	IP+12 m (±1 m)
Informed consent	x					
Subject demographics	x					
Medical/Surgical history	x					
Inclusion/Exclusion criteria	x					
Oral examination	x					
Randomization		x				
Radiographic examination	x	x			x	x
OHIP-49	x		x		x	x
Condition of periimplant mucosa (BOP, PPD)						x
Plaque control records (PCR)						x
Health economics	x	x				
AE/ADE		x	x	x	x	x
Implant stability		x		x	x	x
Clinical photography	x	x	x	x	x	x

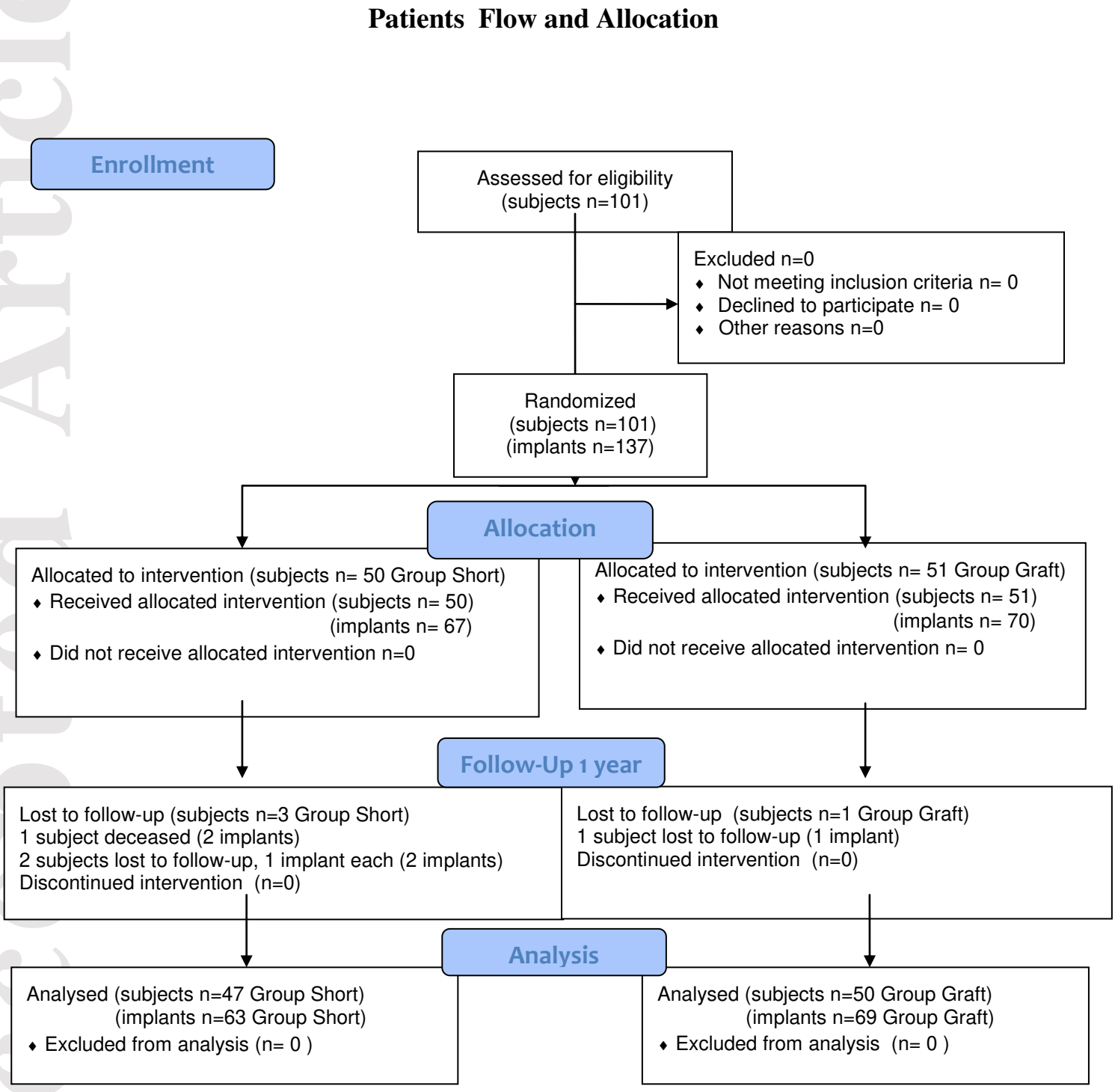
Appendix 2: Demographics

Demographics of the study population				
	Group Graft (GG)	**Group Short (GS)**	**Total**	*P-value*
N. of Implants	70	67	137	
N. of Subjects	51	50	101	
Age mean±SD (Range)	51±12.8 (20-77)	50±14.05 (23-76)	55.5 (20-77)	>0.7 Student -t
Gender	23 28 F M	29 21 F M	52 49 F M	0.27 Chi-Square
Smoking Status				
NS FS S	23(45%) 15(29%) 13(26%)	32(64%) 10(10%) 8(16%)	55 25 21	>0.16 Chi-Square
Reason for tooth loss				
Caries/endodontics Periodontics Trauma Others Not Known	58 5 1 2 5	62 2 0 3 4	120 7 1 5 9	
Oral Conditions				
Hyperkeratosis	0	0	0	
Hyperplasia	0	0	0	
Leukoplakia	1	0	1	
Periodontitis	12	9	21	
Bruxism	0	1	1	
Other	1	2	3	

Appendix 3: Implant sites distribution

IMPLANT SITES DISTRIBUTION								
TOOTH SITE	**14**	**15**	**16**	**17**	**24**	**25**	**26**	**27**
GG **Group Graft**	0	6	21	6	4	10	18	5
GS Group Short	3	11	23	4	0	6	13	7
TOTAL	3	17	44	10	4	16	31	12

Appendix 4: Patient flow and allocation.



Appendix 5: Distribution of sites with BoP

Distribution of surfaces with BoP.			
	Group Graft	**Group Short**	**Total**
Number of surfaces	272	244	515
Number of surfaces with BoP	42	54	96
Proportion of surfaces with BoP (%)	15.4	22.1	18.6