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# Connective tissue grafts for thickening peri-implant tissues at implant placement. One-year results from an explanatory split-mouth randomised controlled clinical trial

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**Key words** *aesthetic, connective tissue graft, dental implant, soft tissue augmentation, randomised controlled clinical trial*

**Conflict of interest:** Nothing to declare.

**Objectives:** To evaluate whether connective tissue grafts performed at implant placement could be effective in augmenting peri-implant soft tissues.
**Materials and methods:** Ten partially edentulous patients requiring at least one single implant in the premolar or molar areas of both sides of the mandible were randomised to have one side augmented at implant placement with a connective soft tissue graft harvested from the palate or no augmentation. After 3 months of submerged healing, abutments were placed and within 1 month definitive crowns were permanently cemented. Outcome measures were implant success, any complications, peri-implant marginal bone level changes, patient satisfaction and preference, thickness of the soft tissues and aesthetics (pink aesthetic score) evaluated by an independent and blinded assessor 1 year after loading.
**Results:** One year after loading, no patients dropped out, no implants failed and no complications occurred. Both groups lost statistically significant amounts of peri-implant bone 1 year after loading (0.8 mm in the grafted group and 0.6 mm in the non-grafted group), but there was no statistically significant difference between groups. Soft tissues at augmented sites were 1.3 mm thicker ($P < 0.001$) and had a significantly better pink aesthetic score ($P < 0.001$). Patients were highly satisfied (no statistically significant differences between treatments) though they preferred the aesthetics of the augmented sites ($P = 0.031$). However, five patients would not undergo the grafting procedure again and two were uncertain.
**Conclusions:** Connective tissue grafts are effective in increasing soft tissue thickness, thus improving aesthetics. Longer follow-ups are needed to evaluate the stability of peri-implant tissues over time.

## ■ Introduction

After tooth loss, alveolar bone resorbs to various degrees[1-4]. Lost teeth can be successfully replaced by dental implants even if some portions of the alveolar bone are resorbed, but this can cause aesthetic problems, especially for patients who show their upper front gums while smiling or talking. Various techniques are commonly used to thicken the tissues around dental implants for improving

aesthetics[5-8]. In principle, both soft and hard tissues can be augmented to improve aesthetics. The effectiveness of bone augmentation techniques has been summarised in a Cochrane systematic review[6], but only three randomised controlled clinical trials could be included[9-11]. It is difficult to evaluate the efficacy of the procedures used for improving aesthetics since no aesthetic outcomes were assessed, however different procedures were tested: the use of non-resorbable barriers alone[12], autogenous bone mixed with anorganic bovine bone with resorbable and non-resorbable barriers[10] and bovine anorganic bone with and without bone morphogenetic proteins[11]. Another approach is to augment only the soft tissues. Soft tissues can be manipulated at the time of implant insertion or at abutment connection. Tissues can be rolled into the defect, or an autogenous connective tissue graft taken from the palate or the maxillary tuberosity can be used. Different grafting techniques have been described[5,7,8].

Despite the fact that many soft tissue augmentation procedures are widely performed all over the world, a recent Cochrane systematic review[13] evaluating the efficacy of various techniques to manipulate soft tissue identified only one randomised controlled clinical trial[14] evaluating the efficacy of these techniques. This trial, published in Chinese, compared the use of an acellular dermal matrix to improve aesthetics of single dental implants in the anterior maxilla (25 patients) with dental implants without augmentation (25 patients). Twelve weeks after surgery, the mean horizontal width of the alveolar crest in the augmented group increased 3.1 mm.

The aim of this randomised controlled clinical trial was to evaluate whether connective soft tissue grafts at implant placement could be effective in augmenting the peri-implant soft tissues. The present article is reported according the CONSORT statement for improving the quality of reports of parallel-group randomised trials (http://www.consort-statement.org/).

## ■ Materials and methods

Any patient requiring at least one implant bilaterally in the posterior mandible (premolar and molar areas), aged 25 to 70 and able to sign an informed consent form, was eligible for inclusion in this trial. Patients were not admitted in the study if any of the following exclusion criteria were present: 1) general contraindications to implant surgery, 2) smoker, 3) subjected to irradiation in the head and neck area, 4) treated or under treatment with intravenous amino-bisphosphonates, 5) affected by active periodontitis, or has poor oral hygiene and motivation, 6) uncontrolled diabetes, 7) pregnant or lactating, 8) substance abuse, 9) psychiatric problems or unrealistic expectations, 10) acute infection in the area intended for implant placement, 11) extraction sites with less than 3 months of healing, and 12) requiring any sort of bone augmentation procedure.

Patients were recruited and treated in three different private practices by the same operator (GW), using similar procedures. The study was approved by the ethics committee of the University of Innsbruck, Austria. The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. All patients received thorough explanations and signed a written informed consent form prior to being enrolled in the trial.

Patients were instructed in oral hygiene. All patients received 1 g of amoxicillin + clavulanic acid (Augmentin®, GlaxoSmithKline, Wien, Austria) 1 hour before implant placement as antibiotic prophylaxis. The envelopes containing the randomisation code were opened just prior to surgery and implant sites were allocated to soft tissue grafting or not. Patients were treated under local anaesthesia with articaine + adrenaline 1:100,000. No intravenous sedation was used. A crestal incision was made and a split thickness flap was elevated so that the bone was not denuded (Fig 1). Titanium sand-blasted screw-shaped conical implants (Neoss®, Harrogate, UK) with a diameter of 4 mm and lengths between 9 and 13 mm were placed according to the instructions of the manufacturer. Each patient received one dental implant on the left and one on the right mandibular quadrant. Both implants were placed in the same session. Once both implants were placed, the side allocated to the graft was augmented with a subepithelial connective tissue graft harvested from the palate by making a single incision parallel to the gingival margin and using a scalpel with a size 15 blade[15] (Fig 2).

After the separation of the tissue graft with 2 horizontal and 2 vertical incisions, the connective tissue

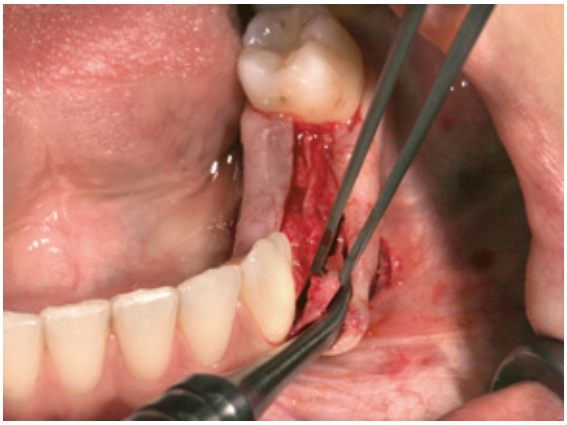

**Fig 1** A partial thickness flap was elevated to avoid bone denudation.

**Fig 2** A single incision parallel to the gingival margin was performed to harvest a subepithelial connective tissue graft, leaving the periosteum attached to the bone.

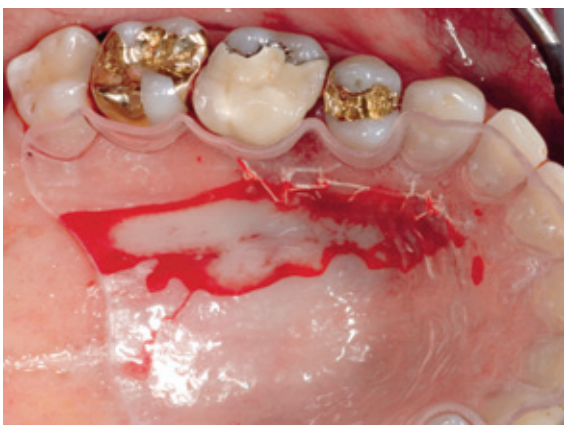

**Fig 3** The donor region was sutured and covered with a deep-drawing template.

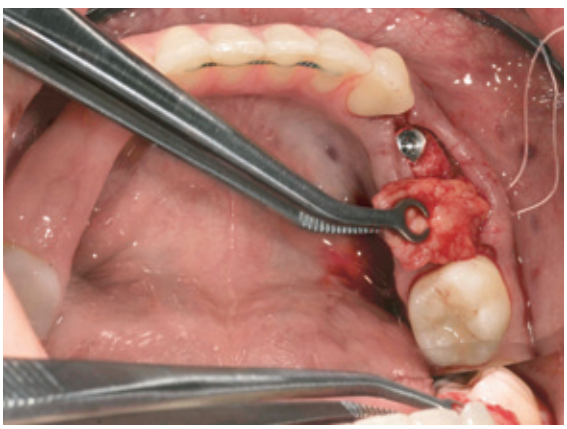

**Fig 4** The connective tissue graft is positioned on top of the implant, attempting to cover both the buccal and lingual side, and then sutured on the periosteum.

was removed, leaving the periosteum attached to the bone. The donor region was sutured and covered with a deep-drawing template (Fig 3). The graft was placed on top of the implant, while trying to augment both the buccal and the lingual side, and sutured to the periosteum with an absorbable suture (Vicryl 6-0®, Ethicon, Norderstedt, Germany) (Fig 4). After grafting, flaps were closed and sutured with a non-absorbable polyamide suture (Supramid® 6-0, Braun, Melsungen, Germany) at both sites, submerging the implants.

Intraoral radiographs (baseline) were made with the paralleling technique (Fig 5 a and b). In cases where the bone levels around the study implants were hidden or difficult to be estimated, a second radiograph was made. Patients were instructed to use chlorhexidine mouthwash twice a day for 1 minute for 2 weeks. Six hours after implant placement, another 1 g of amoxicillin was administered. Sutures were removed after 7 to 10 days. No provisional prostheses were used during the entire healing period. After 3 months, small incisions were made on top of the implants, the cover screws were replaced by healing abutments and the implants were manually tested for stability. Impressions were taken after 10 days, and within 2 weeks definitive zirconia- or porcelain-fused-to-metal crowns were cemented with polycarboxylate cement (Durelon™, 3M ESPE, Seefeld, Germany) on conventional titanium abutments. Patients were recalled every 3 months for maintenance.

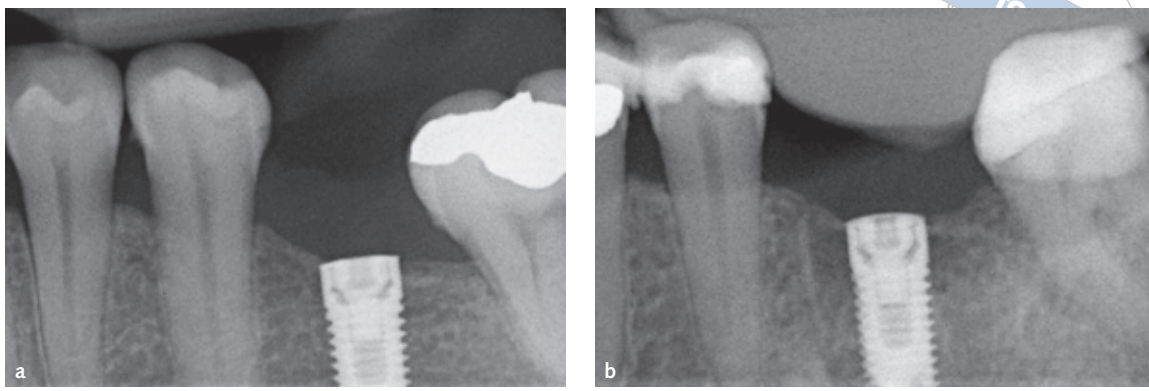


**Fig 5** Grafted compared to control implant: baseline periapical radiograph taken just after implant insertion of the grafted implant (a) and control implant (b).

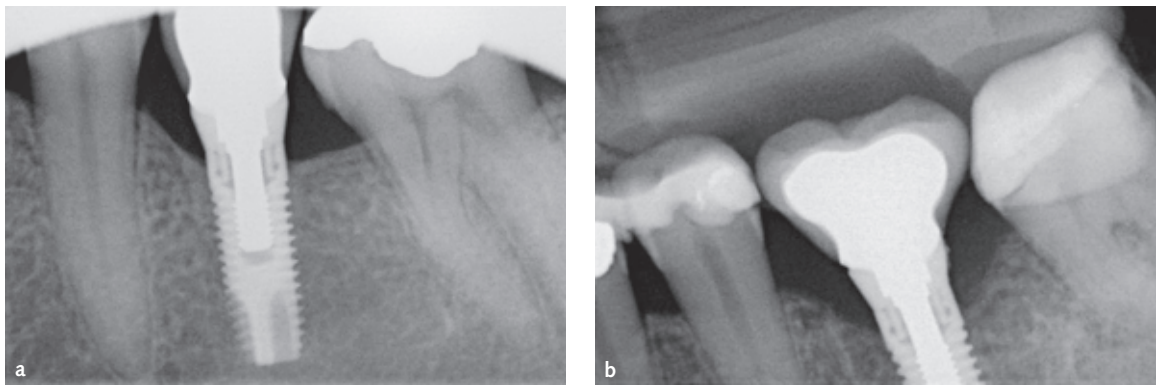


**Fig 6** Grafted compared to control implant: periapical radiograph taken 1 year after loading of the grafted implant (a) and control implant (b).

The present study tested the null hypothesis that there were no differences between the two procedures against the alternative hypothesis of a difference. Outcome measures were:

- Crown/implant failure: implant mobility and removal of stable implants dictated by progressive marginal bone loss or infection. Stability of individual implants was measured at abutment connection, delivery of the definitive crowns (4 months after implant placement), and 1 year after loading either by tightening abutment screws or with the metallic handles of 2 instruments.
- Any biological or prosthetic complications.
- Peri-implant marginal bone levels evaluated on standardised intraoral digital radiographs taken with the paralleling technique using customised x-ray holders (KKD®, Ellwangen/Jagst, Germany). Radiographs were taken at implant placement (Fig 5 a and b) and 1 year after loading (Fig 6 a and b). Peri-implant marginal bone levels were measured using the Sidexis XG software (Sirona, Bensheim, Germany). The software was calibrated for every image using the known implant diameter. Measurements of the mesial and distal bone crest level adjacent to each implant were made (Fig 7) to the nearest 0.01 mm and averaged at patient level and at the group level. Reference points for the linear measurements were the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact. Radiographic measurements were performed by Monica Scheibenbauer who was not aware which implants were augmented.
- Soft tissue thickness evaluated prior to implant placement and 1 year after loading at both buccal and lingual sites, after local anaesthesia with a Xylocain spray. An endodontic micro-opener (Dentsply Maillefer, Ballaigues, Switzerland) with a silicon stop was inserted about 1 cm below the centre of the crest into the mucosa until it felt in contact with the cortical bone (Fig 8). The length of the part of the instrument that penetrated into the soft tissue was measured with an endodontic longimetre (Fig 9), and rounded off to the nearest half mm. The buccal and lingual measurements were averaged for each implant. Soft

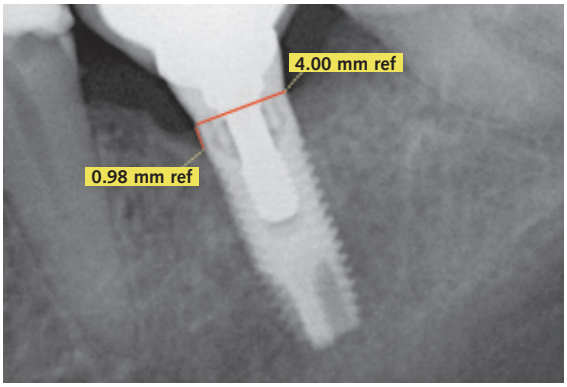


**Fig 7** Peri-implant marginal bone level measurements were made directly on the standardised digital periapical radiographs using Sidexis XG software. Measurements were calibrated with the known implant diameter (4 mm) to the nearest 0.01 mm.

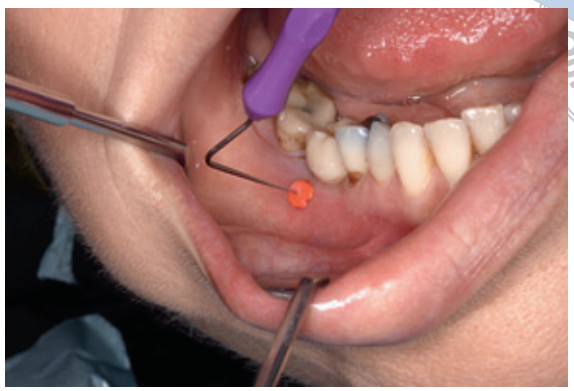

**Fig 8** Soft tissue thickness was measured with an endodontic micro-opener with a silicon stop inserted approximately 1 cm below the centre of the crest.

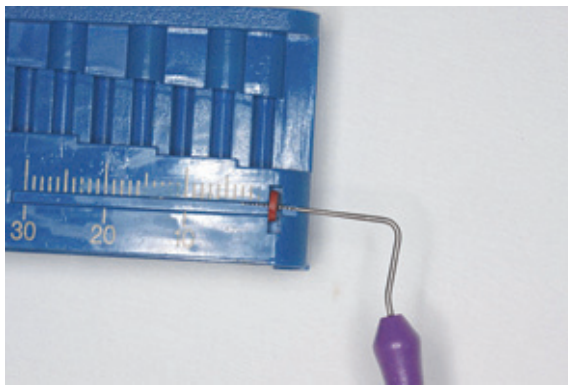


**Fig 9** An endodontic longimetre was used to measure the length of the portion of the instrument that penetrated into the soft tissues.

tissue thickness measurements were made by the surgeon, who was not blinded.

- Aesthetics evaluated using the pink aesthetic score (PES)[16]. At the recall visit, two clinical pictures (one vestibular and one occlusal digital photograph) were taken including both adjacent teeth of both the test and control sites under the same light conditions and using similar framing. Once all pictures were collected, an independent and blinded trained orthodontist (Monika Scheibenbauer) scored the pictures visualised on a computer screen for aesthetics. In brief, seven variables were evaluated: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies, soft tissue colour and texture. A 0-1-2 scoring system was used, 0 being the lowest and 2 being the highest value, with a maximum achievable score of 14[16].
- Patient satisfaction: at the recall appointment, an independent outcome assessor (Monika Scheibenbauer) provided a mirror to the patients showing both test and control implants on which patients had to express their opinions and asked 'are you satisfied with the aesthetic outcome of the gums surrounding this implant?' Then, indicating only the augmented site, the outcome assessor asked 'Would you undergo the same procedure again?' Possible answers to both questions were: 1) definitively yes, 2) yes, 3) uncertain, 4) no or 5) absolutely not. The questions were always posed with exactly the same wording.
- Patient preference: patients were asked which of the two sites they preferred, focussing their attention to their gums. Possible answers were: 1) the augmented site, 2) the non-augmented site, 3) both are equally nice or 4) both are equally bad.

Sample size was calculated to detect a preference of one group over another against the alternative hypothesis that the treatments are equally preferred. This reduces to a simple one sample proportion scenario. A one group chi-square test with a 0.050 two-sided significance level will have 80% power to detect the difference between the null hypothesis

**Table 1** Patient and baseline intervention characteristics.

| | Augmented (n = 10) | Control (n = 10) |
|---|---|---|
| Implant position: 1 premolar | 1 | 1 |
| Implant position: 2 premolar | 5 | 1 |
| Implant position: 1 molar | 4 | 8 |
| Soft tissue thickness, mm (SD) | 2.00 (0.47) | 2.05 (0.50) |
| Peri-implant bone levels, mm (SD) | 0.35 (0.24) | 0.44 (0.16) |

**Table 2** Summary of the main results at 1 year after loading.

| | Augmented (n = 10) | Control (n = 10) |
|---|---|---|
| Soft tissue thickness, mm (SD) | 3.20 (0.42) | 1.90 (0.32) |
| Peri-implant bone levels, mm (SD) | -1.14 (0.29) | -1.06 (0.41) |
| Pink aesthetic score (SD) | 11.32 (1.63) | 8.45 (1.46) |
| Patients definitively satisfied | 10 | 9 |
| Patients unsatisfied | 0 | 1 |

proportion of 0.500 and the alternative proportion of 0.900 when the sample size is 10. Ten subjects were therefore included in the present study.

Two identical, opaque, sealed envelopes were prepared for each patient. One envelope contained a paper indicating the right side and the other the left side. Just prior to the initiation of the implant placement procedure, the patient was asked to choose one of the two envelopes. The graft was performed on the side indicated by the envelope chosen by the patient.

A biostatistician (HW) with expertise in dentistry analysed the data, without knowing the group codes. The patient was the statistical unit of the analyses. Differences in the proportion of patients with crown/implant failures and complications (dichotomous outcomes) were to be compared between the groups using the McNemar chi-square test. Differences of means at patient level for continuous outcomes (radiographic peri-implant bone levels, thickness of the mucosa, and PES) between groups were compared by paired *t* tests. Comparisons between the baseline measurements and 1 year after loading were made by paired tests. Differences in patient satisfaction (ordinal data) were compared between groups using the Wilcoxon signed ranks test. Patient preference was calculated with odds ratios (OR) between patients preferring the augmented sites and those having no preference using the McNemar test from Stata using the epitab 'mcci' procedure. All statistical comparisons were conducted at the 0.05 level of significance.

## ■ Results

Ten patients were considered eligible and were consecutively enrolled in the trial. All patients were treated according to the allocated interventions. No patient dropped out. Data from all patients were included in the statistical analyses and no deviation from the study protocol occurred.

The main baseline patient characteristics are presented in Table 1. There were 7 females and 3 males with a mean age of 39 years (range 25 to 60). There were no apparent significant baseline imbalances between the two groups. No implant failed and no complication occurred during the entire follow-up period. The main results 1 year after loading are summarised in Table 2.

One year after loading, both groups lost marginal peri-implant bone in a highly statistically significant way: augmented implants lost an average of 0.79 mm (SD = 0.30; 95% CI -1.00 to -0.58; $P < 0.001$) versus 0.62 mm (SD = 0.38; 95% CI -0.89 to -0.35; $P = 0.001$) for patients with non-augmented implants (Table 3). One year after loading, there was no statistically significant difference between the 2 groups for peri-implant bone levels (-0.08 mm, SD = 0.39; 95% CI -0.36 to 0.24; $P = 0.54$) or changes (-0.17 mm SD = 0.45; 95% CI -0.49 to 0.15).

At baseline, the soft peri-implant thickness was comparable between groups, approximately 2 mm in each group (Table 4). One year after loading, the average soft tissue thickness was significantly higher in the augmented group (3.20 mm) but remained

**Table 3** Comparison between mean marginal bone levels in mm (SD) at placement and 1 year after loading for the two study groups, and for changes from baseline within each group.

| | Augmented (n = 10) | Control (n= 10) | Difference between groups | 95% Confidence Interval | P value from paired t test |
|---|---|---|---|---|---|
| At implantation | 0.35 (0.24) | 0.44 (0.16) | | | |
| 1 year post loading | 1.14 (0.29) | 1.06 (0.41) | -0.08 (0.39) | -0.36 to 0.24 | 0.54 |
| Mean changes 1 year post loading | -0.79 (0.30) | -0.62 (0.38) | -0.17 (0.45) | -0.49 to 0.15 | 0.26 |
| *P* value from paired *t* test from baseline to 1 year post loading | *P* < 0.001* | *P* = 0.001* | | | |

*statistically significant values

**Table 4** Comparison between soft tissue thickness in mm (SD) at placement and 1 year after loading for the two study groups, and for changes from baseline within each group.

| | Augmented (n = 10) | Control (n= 10) | Difference between groups | 95% Confidence Interval | P value from paired t test |
|---|---|---|---|---|---|
| At implantation | 2.00 (0.47) | 2.05 (0.50) | | | |
| 1 year post loading | 3.20 (0.42) | 1.90 (0.32) | 1.30 (0.59) | 0.88 to 1.72 | *P* < 0.001* |
| Mean changes 1 year post loading | 1.20 (0.63) | -0.15 (0.34) | 1.35 (0.71) | 0.84 to 1.86 | *P* < 0.001* |
| *P* value from paired *t* test from baseline to 1 year post loading | *P* < 0.001* | *P* = 0.19 | | | |

*statistically significant values

stable in the control group (1.90 mm). The difference between groups was highly statistically significant (1.30 mm SD = 0.59; 95% CI 0.88 to 1.72; $P < 0.001$; Table 4).

One year after loading, the mean PES was 11.32 (SD 1.63) for the augmented group and 8.45 (SD 1.46) for the control group. This difference was highly statistically significant (2.87, SD = 1.30; 95% CI 1.94 to 3.80; paired samples *t* test $P < 0.001$), the peri-implant soft tissues in the augmented group had better aesthetics.

One year after loading, all patients were highly satisfied with the aesthetic outcome of all of their implants, with the exception of one patient who rated her control implant as not satisfactory (Table 2). There was no statistically significant difference between the procedures ($P = 0.32$, Wilcoxon signed rank test). The question of whether patients would undergo the same augmentation procedure again yielded the following answers: definitively yes (one patient), yes (two patients), uncertain (two patients), no (four patients) and absolutely not (one patient).

Six patients preferred the aesthetics of the augmented sites, whereas 4 patients had no preference and were satisfied with both procedures. Patients statistically significantly preferred the augmented sites (exact McNemar significance probability = 0.031; OR = 0; 95% CI 0 to 0.85).

## ■ Discussion

The present trial was designed to assess whether augmentation of the soft tissues with a connective tissue graft could improve aesthetics of peri-implant soft tissues. The augmentation procedure was effective in increasing the thickness of the peri-implant soft tissues which resulted in a statistically significantly better PES. While the assessment of the soft tissue thickness could have been potentially biased since the operator was the same person who performed the assessment, the PES was assessed by a blind and independent outcome assessor, therefore these findings should be considered reliable. When comparing the present results with other RCTs, only one trial, published in Chinese, could be identified[14]. In that trial, the efficacy of augmenting soft tissues with an acellular dermal matrix was evaluated. This approach has

the obvious advantage of reducing patient morbidity since no autogenous graft had to be harvested. After 12 weeks, an increase of 3.1 mm in the augmented group was reported. This increase was more than double that reported in the current trial (1.2 mm).

Several factors may have contributed to this difference, such as a different initial need for thickness augmentation, the availability of a larger quantity of acellular dermal matrix than autogenous connective tissue, the different assessment periods (3 versus 16 months) and the different methods used to assess thickness. On the other hand, in the Chinese trial the augmentation technique was not explained with sufficient detail to understand how it was conducted. There were no clinical pictures to help provide an idea of the exact augmentation procedure, and moreover, there was no aesthetic assessment. So, it is not known whether the aesthetics were actually improved after the augmentation procedure. It is necessary to conduct further trials to identify the most efficient technique for augmenting soft tissues for aesthetic reasons.

With respect to marginal bone levels, there were no statistically significant differences for bone loss 1 year after loading between the two groups. Augmented sites lost 0.8 mm of peri-implant bone versus 0.6 mm at the control sites from implant placement. Bilateral partial thickness flaps were performed at the graft recipient sites with the rationale that bone loss could be minimised if direct bone exposure was avoided. However, this was just an assumption which could be correct or not. Currently, it cannot be concluded that partial thickness flaps are necessary for obtaining good results.

There was no difference in satisfaction between the two procedures. All patients were very satisfied with the aesthetic outcome of both procedures with the exception of one patient who was dissatisfied with the outcome at the non-augmented implant. However, six patients preferred the augmented sites, and four patients had no preference since they were satisfied with the aesthetic outcome of both procedures. This difference was statistically significant and in perfect agreement with the outcome of the PES conducted by a blinded orthodontist. More intriguing, were the patients' answers to the question whether they would undergo again the soft tissue augmentation procedure. Five patients replied negatively and two were uncertain. One possible explanation for these apparently contradictory findings could be that the patients enrolled in the present trial did not have high aesthetic demands in non-visible areas, nor the need for augmentation. Patients were satisfied by the outcome which resulted in better aesthetics compared to no augmentation, however it is likely that they did not feel that the augmentation procedure was actually needed. This study was designed as a proof of principle to evaluate the efficacy of soft tissue augmentation. Ideally, patients with real aesthetic needs should have been included, however it may be difficult to recruit patients with these characteristics since most of them would like to receive some form of augmentation procedure and not to act as an untreated control.

The main limitations of the present study are the inclusion of implants placed in non-aesthetic areas, the strict inclusion criteria, the lack of assessment of post-operative pain, and the small sample size that, nevertheless, was sufficient to disclose a statistically significant difference in patient satisfaction. The present trial should be considered an explanatory pilot trial aimed to evaluate the efficacy of connective tissue grafts under well-controlled clinical conditions. It was decided, for ethical reasons, that it was preferable to include only implants placed in non-aesthetic areas and in the presence of minor tissue defects. Despite the lack of aesthetic demand and the small sample size, statistically significantly better aesthetic outcomes were recorded by an independent and blind assessor for sites augmented with soft tissues. Also, patients preferred the aesthetics of the augmented site in a statistically significant way. In addition, to the best knowledge of the authors, this is the first randomised controlled clinical trial evaluating this hypothesis published in English[13].

The results of this study can only be generalised to a limited population since strict inclusion criteria were used. Larger trials are needed to evaluate the effectiveness and the long-term results (5 years or more) of various soft tissue augmentation procedures for different clinical indications and, in particular, in aesthetic areas with substantial tissue defects. Another question that remains to be answered is whether this increased thickness of the tissues is retained over time. Only longer follow-ups will provide an evidence-based answer to this question.

## ■ Conclusions

Connective tissue grafts are effective in increasing soft tissue thickness, thus improving aesthetics. Longer follow-ups are needed to evaluate the stability of peri-implant tissues over time. The best technique for augmenting soft tissues for aesthetic reasons remains to be determined.

## ■ Acknowledgements

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