Immediate Implant Placement in Conjunction with Acellular Dermal Matrix or Connective Tissue Graft: A Randomized Controlled Clinical Volumetric Study

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Connective tissue grafts have become a standard for compensating horizontal volume loss in immediate implant placement. The use of new biomaterials like acellular matrices may avoid the need to harvest autogenous grafts, yielding less postoperative morbidity. This randomized comparative study evaluated the clinical outcomes following extraction and immediate implant placement in conjunction with anorganic bovine bone mineral (ABBM) and the use of a porcine acellular dermal matrix (ADM) vs an autogenous connective tissue graft (CTG) in the anterior maxilla. Twenty patients (11 men, 9 women) with a mean age of 48.9 years (range: 21 to 72 years) were included in the study and randomly assigned to either the test (ADM) or control (CTG) group. They underwent tooth extraction and immediate implant placement together with ABBM for socket grafting and either ADM or CTG for soft tissue augmentation. Twelve months after implant placement, the cases were evaluated clinically and volumetrically. All implants achieved osseointegration and were restored. The average horizontal change of the ridge dimension at 1 year postsurgery was –0.55 ± 0.32 mm for the ADM group and –0.60 ± 0.49 mm for the CTG group. Patients of the ADM group reported significantly less postoperative pain. Using xenografts for hard and soft tissue augmentation in conjunction with immediate implant placement showed no difference in the volume change in comparison to an autogenous soft tissue graft, and showed significantly less postoperative morbidity. Int J Periodontics Restorative Dent 2022;42:381–390. doi: 10.11607/prd.5632

Immediate implant placement is a well-documented treatment that allows, in select cases, extraction of failing teeth and implant placement in the same session. The scientific data suggest that implants placed in sockets immediately after extraction lead to a better esthetic outcome than an early or delayed approach. However, there is a risk of soft tissue deterioration and horizontal ridge deficiency with loss of the midfacial contour. These phenomena seem to be caused by resorption of the buccal wall of the extraction socket. Specific risk factors for the loss of the midfacial contour have been identified, including the individual periodontal biotype, a buccal position of the implant, and a thin or damaged buccal plate.

After various studies showed that augmenting the gap between the implant and the buccal plate with bone substitutes like anorganic bovine bone mineral (ABBM) decreases horizontal resorption and improves the clinical outcome, the augmentation of the buccal soft tissue with autogenous connective tissue grafts (CTGs) in conjunction with immediate implant placement became subject to clinical research and showed reliable results in terms of compensating for the volume changes of the facial tissues after immediate implant placement. The use of soft tissue grafts buccal to immediate implants...
leads to a thicker peri-implant mucosa that is located more coronally\textsuperscript{14} and to a better esthetic outcome\textsuperscript{15} when compared to surgery without soft tissue grafting.

Subepithelial CTGs have been used for many years in plastic periodontal surgery in the esthetic zone, but apparently the additional surgical site at the palate (donor site) leads to higher postoperative morbidity for the patient.\textsuperscript{16,17} That is the reason that collagen biomaterials like the xenogeneic acellular dermal matrix (ADM) have been introduced in order to replace autogenous soft tissue grafts. These dermal matrices show good biocompatibility and have demonstrated their potential to thicken mucosa at teeth\textsuperscript{18} and implant sites.\textsuperscript{19–22} However, only scarce evidence is available today regarding the use of these materials in conjunction with immediate implant placement in the esthetic zone.

The objective of this randomized clinical study was to compare the clinical outcomes of immediate implant placement in the anterior maxilla in conjunction with soft tissue augmentation using a porcine ADM vs subepithelial CTG with a focus on the volume of the facial tissues.

Materials and Methods

This study was conducted according to the revised Consolidated Standards of Reporting Trials (CONSORT) statement\textsuperscript{23} updated in 2010\textsuperscript{24} and was performed in accordance with Declaration of World’s Medical Associations of Helsinki, the German Medical Devices law, ISO 14155 clinical investigation of medical devices, and good clinical practice. The study protocol was approved by the local ethical committee (2012-513-b-5). This survey was designed and registered as a randomized prospective comparative study of 20 patients receiving immediate implant placement in the anterior maxilla with either soft tissue augmentation using a porcine ADM or subepithelial CTG.

Study Population

Patients selected to participate in this prospective clinical study were counselled and signed a written consent. The inclusion criteria were as follows: Patients with a failing tooth in the anterior maxilla, needing immediate implant placement, and having an intact buccal wall after extraction. The exclusion criteria were as follows: Patients under 21 years with (1) general relevant medical conditions or basic diseases (any American Society of Anesthesiologists status other than ASA 1); (2) active periodontitis; (3) soft tissue recession or attachment loss on the tooth to be replaced; (4) a smoking habit > 10 cigarettes/day; (5) insufficient endodontic treatment of the adjacent teeth; and (6) fractured or absent buccal lamella after tooth extraction (socket anatomy other than Type I, according to Elian et al\textsuperscript{25}).

All patients underwent oral hygiene instructions (Fig 1). Twenty consecutive patients requiring tooth extraction and immediate single implant placement in the anterior maxilla (canine to canine) were enrolled in the study. Ten patients (5 men, 5 women) between the ages of 33 and 71 years (mean: 48.5 years) were randomly assigned to the test group (ADM), and 10 patients (6 men, 4 women) between the ages of 21 and 72 years (mean: 49.4 years) were assigned to the control group (CTG). All surgeries were performed by one oral surgeon with over 20 years of implant experience (A.H.).

Clinical Procedures

All patients underwent standardized diagnosis and treatment planning procedures, and all consented to the treatment. They were informed about the timeline of the study and the importance of the scheduled follow-ups (Fig 2).

Before surgery, impressions of the site were taken using high-precision silicone (Aquasil Ultra, Dentsply Sirona). The soft tissue biotype was determined clinically using a periodontal probe (Fig 3)
and the “shine-through of the periodontal probe” criterion (thick or thin biotype) according to Kan et al. Before extraction, pictures of the clinical site and radiographs of the surgical site were taken. After careful tooth removal, the condition of the buccal plate was assessed and the implant (Screw-Line Promote Plus, Camlog Biotechnologies) was inserted in the palatal compartment of the socket, leaving a minimum 2-mm gap to the buccal plate (Fig 4). The gap was filled with a combination of ABBM and collagen (Bio-Oss Collagen, Geistlich) (Fig 5). In order to augment the buccal mucosa, the recipient site was

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**Fig 1** Flowchart of participants according to the study design and the CONSORT statement.

**Fig 2** Treatment sequence and time points of the evaluation (t1 to t9).
prepared by making one intrasulcular incision and a split-thickness flap, without any releasing incisions, to create a buccal pouch. The graft type was randomly assigned by letters based on randomization lists.

In the test group, a 2-mm–thick porcine ADM (Mucoderm, Botiss Dental) was rehydrated and placed into the recipient site (Fig 6). After rehydration, the matrix thickness increased to 3 mm.

In the control group, a CTG was harvested as a free graft from the palate. Adipose tissue was removed from the graft, and a 15c blade was used to trim the graft to be 3 mm thick. The graft was then inserted in the buccal pouch with a standard operational protocol.

After soft tissue augmentation, a healing cap replaced the implant cover screw, and the mucosa was readapted, using surgical sutures to cover the graft to a considerable extent (6-0 Seralene, Serag-Wiessner) (Fig 7).

Patients were instructed not to brush in the surgical area for 14 days and to rinse with 0.2% chlorhexidine digluconate three times per day. Furthermore, each patient was prescribed 600 mg ibuprofen, taken as required. Antibiotic prophylaxis using 500 mg amoxicillin tid or 300 mg clindamycin tid was performed for each patient for 1 week postoperatively. Postoperative healing was monitored at 1, 2, and 4 weeks postsurgery.

Twelve weeks after implant placement, successful healing was evaluated clinically (Fig 8) and with periapical radiographs. At this time, implants were restored with zirconia abutments luted to a titanium base and all-ceramic single crowns (Figs 9 and 10).

Except for the mode of soft tissue grafting, the treatment, evaluation, and measurements were the same for both groups (an example of the CTG group is shown in Figs 11 to 13).
Data Acquisition

The treatment sequence and time points for evaluation are shown in Fig 2. In summary, the following evaluations were performed: (1) tissue volume immediately before and 12 months after immediate implant placement (t1 and t9, respectively); and (2) clinical evaluation of the healing process (clinical aspect and VAS-assessed pain) at 1, 2, and 4 weeks postoperative (t3, t4, and t5, respectively).

Shortly after surgery (t3 and t4), clinical parameters related to postoperative morbidity were assessed: pain on a VAS (ranging from 0 to 10, with 0 representing no pain and 10 representing the worst pain), swelling, paresthesia, and hematoma, etc, were documented on every patient. The clinical appearance of the site was evaluated at every appointment (color, paresthesia, necrosis, etc). Furthermore, dental impressions were taken. Radiographs were taken using the Rinn technique during the normal routine and 1 year after implant placement.

Evaluation of the Ridge Dimension Change

One year after implant placement, an impression was taken in order to assess the volume change over that period. To measure the change in ridge dimension, the present authors followed an approach that was previously well-described in the literature. Dental stone casts were fabricated (Fujirock, GC) and optically scanned with a CAD/CAM scanner (Imetric 3D, Imetric 4D Imaging). The data (STL [standard tessellation language] files) were then imported into a digital imaging program (SMOP, Swissmeda) to analyze the volumetric changes of the implant side (Fig 14). Both scans (preoperative and 1 year postoperative) were superimposed and matched in a common coordinate system using the best-fit algorithm at the tooth surface. Afterwards, the volumetric changes at the buccal implant site were measured in a defined trapezoid-shaped area of interest, localized 1 mm apical to the gingival margin. In consequence of different anatomical structures, the area of interest varies between patients but was kept constant at one patient for both measurements.

The volume change was analyzed descriptively due to different sizes of the area of interest in each patient. In this way, the volume could be compared apart from the selected size of the measured area. After collecting the data in a spreadsheet (Excel 2016, Microsoft), the data were evaluated with a statistical software (SPSS, IBM). The explorative statistical analysis with mean and SD values was tested for significance by Student t test with a P value of .05. For the visualization, Tukey box plots were used.
Results

All 20 implant sites healed uneventfully, and no infection occurred. All implants achieved osseointegration and could be restored after the 12-week healing phase. As expected, all patients with a smoking habit (two in the CTG group, one in the ADM group) showed mild complications up to 2 weeks post-operative, including superficial necrosis, and all grafts were still fibrin-covered.

In the ADM group, one soft tissue healing was delayed after a superficial necrosis of the mucosa, buccal to the graft. The site healed without scarring after 2 weeks.

All sites showed a volume loss at 12 months postsurgery (t9).

The mean change of the total volume was \(-27.7 \pm 19.24 \text{ mm}^3\) for the ADM group and \(-18.3 \pm 13.82 \text{ mm}^3\) for the CTG group, with no significant difference (\(P = .226\)) (Fig 15). In addition, the ratio of volume change to the measured area was calculated, as the measured area depends on the particular individual’s anatomy. No significant difference (\(P = .883\)) was found between the average scores for the ADM group (\(-0.23 \pm 0.128 \text{ mm}^3/\text{mm}^2\)) and the CTG group (\(-0.22 \pm 0.116 \text{ mm}^3/\text{mm}^2\)) (Fig 16).

To determine the linear change of the ridge, the mean distance between the two surface scans was evaluated, finding no significant difference (\(P = .157\)) for the ADM group (\(-0.55 \pm 0.330 \text{ mm}\)) and the CTG group (\(-0.60 \pm 0.491 \text{ mm}\)) (Fig 17).

When comparing the two groups, the main differences were found for pain reported on the VAS (Fig 18). After 1 week, pain was rated with a median of 1 and a variance of 2 in the ADM group, and a median of 4 and a variance of 8.4 for the CTG group. Comparison of the mean values showed a significant
difference ($P = .017$). After 2 weeks, all patients in the ADM group declared no pain, while 30% of CTG patients still suffered mild pain, with a median of 0.0 and a variance of 0.77 for the whole group (Tables 1 and 2).

**Discussion**

The cumulative implant success rate following single immediate tooth replacement and soft tissue augmentation with a xenograft or autogenous graft was 100%.

All 20 implants achieved osseointegration, and the tested surgical approach yielded uneventful healing in all 20 sites, without major complications. All implants could be restored after the healing phase of 3 months. No adverse event was
observed, and only one mild complication occurred. The complication (superficial soft tissue necrosis) healed spontaneously within 2 weeks with very little pain (VAS score: 1), and the horizontal change was only −0.12 mm. This delayed healing did not compromise the final result. In contrast, rates of necrosis complications have been reported up to 20% in CTGs in combination with immediate implantation.

### Table 1 Clinical Parameters of the CTG Group

<table>
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<tr>
<th>Patient no.</th>
<th>VAS score 1 wk postoperative</th>
<th>Clinical appearance of the graft 1 wk postoperative</th>
<th>VAS score 2 wk postoperative</th>
<th>Clinical appearance of the graft 2 wk postoperative</th>
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<td>0</td>
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<td>Fibrin-covered</td>
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<tr>
<td>5</td>
<td>9</td>
<td>Fibrin-covered, necrosis</td>
<td>2</td>
<td>Fibrin-covered, necrosis</td>
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<td>4</td>
<td>Fibrin-covered</td>
<td>2</td>
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<td>Pink</td>
<td>0</td>
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<td>4</td>
<td>Fibrin-covered</td>
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<td>Fibrin-covered, swelling</td>
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Mean: 4.00, SD: 2.90

CTG = connective tissue graft; VAS = visual analog scale (0 = no pain; 10 = worst pain).

### Table 2 Clinical Parameters of the ADM Group

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<th>Patient no.</th>
<th>VAS score 1 wk postoperative</th>
<th>Clinical appearance of the graft 1 wk postoperative</th>
<th>VAS score 2 wk postoperative</th>
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</thead>
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<td>Pink/fibrin-covered</td>
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<tr>
<td>9</td>
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<td>Fibrin-covered, necrosis</td>
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<tr>
<td>10</td>
<td>0</td>
<td>Fibrin-covered</td>
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</table>

Mean: 1.30, SD: 1.41

ADM = acellular dermal matrix; VAS = visual analog scale (0 = no pain; 10 = worst pain).
placement. In the present CTG cohort, one soft tissue necrosis occurred and healed well after 2 weeks, but the graft appearance was fibrin-covered for more than 2 weeks postoperatively.

The ADM cohort showed a pink appearance for all grafts after 2 weeks. Within the limitations of the present study, the results show that using ADM as a substitute for CTG in conjunction with immediate implant placement showed good biocompatibility and clinical performance. The VAS pain evaluation showed postoperative scores ranging between 0 and 2, with the exception of one patient who reported a score of 5 in the first week. All patients reported absence of pain at 14 days postsurgery. From a clinical standpoint, that indicates that the approach was successful and showed good results, low postoperative morbidity, and no major complications.

A typical complication of immediate implant placement in fresh extraction sockets is the threedimensional volume change that occurs after healing, which may lead to recession and esthetic impairment. Grunder performed a comparative case series on immediate implant placement, treating two groups: one with and one without CTG. He reported on an average volume loss of 1.063 mm³ in the nongrafted group after a follow-up of 6 months. In the present study, the horizontal ridge change 12 months after implant placement was below 1 mm for all cases. No significant difference was found between the groups regarding volume change.

Limitations of this study include the limited number of patients and the relatively short 1-year follow-up period. Different authors report continued deterioration of the facial soft tissue over a period of 5 and 8 years after immediate implant placement. However, the present results show that it is possible to successfully replace failing anterior maxillary teeth with immediate implants in combination with hard and soft tissue augmentation using xenografts alone. Moreover, the results show that the use of the ADM yielded in significantly less postoperative morbidity for the patients, with comparable results regarding volume stability. The use of ADM in dental implantology might mitigate patients’ postoperative morbidity and facilitate the treatment.

Prospective randomized controlled trials and comparative studies with larger numbers of patients and longer follow-up periods are needed to confirm the present findings.

Conclusions

The approach using xenografts for hard and soft tissue augmentation in conjunction with immediate implant placement showed no difference in volume change in comparison to autogenous soft tissue grafts, but with significantly less postoperative morbidity.

Acknowledgments

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All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. The authors declare no conflicts of interest.

References


