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# Human dermis graft versus autogenous connective tissue grafts for thickening soft tissue and covering multiple gingival recessions: 6-month results from a preference clinical trial

**Key words** aesthetic, connective tissue graft, gingival recession, preference controlled clinical trial, soft tissue augmentation

**Purpose:** To evaluate whether a human dermis graft (HDG) could be used instead of an autogenous connective tissue graft (ACT) to increase gingival thickness and to cover multiple gingival recessions. **Materials and methods:** Forty-two consecutive patients with multiple gingival recessions were offered the option to have their recessions covered either with ACTs harvested from their palate or with HDGs. Outcome measures were complications, gingival recession changes (REC), gingival biotype changes (BIO), probing attachment level changes (PAL), probing pocket depth changes (PPD) and keratinised mucosa height changes (KER) evaluated by an independent and masked assessor after 6 months.

**Results:** Twenty-one patients with 110 recessions opted for ACTs and 21 patients with 160 recessions opted for HDGs. No patients dropped out. Only one minor complication occurred at one HDG-treated site. Recessions significantly decreased in both groups (2.7 mm for ACT and 2.0 mm for HDG), however, ACTs resulted in a statistically significantly improved root coverage and CAL of 0.5 mm, as well as 18% more root coverage than HDGs.

**Conclusions:** HDGs can be an effective alternative to ACTs for covering exposed roots and increasing soft tissue thickness, especially when many recessions have to be treated in the same mouth, though they may provide slightly less root coverage than ACTs.

**Conflict-of-interest statement:** This study was partially supported by Tutogen Medical GmbH, Neunkirchen an Brand, Germany.

## ■ Introduction

Exposed root surfaces can be unaesthetic, more prone to hypersensitivity and root caries, and more difficult to be maintained clean of dental plaque. Gum recessions can be caused by high pressure while tooth brushing and iatrogenic dental treatments such

as orthodontic tooth movement. A thin gingival biotype and a buccal position of the tooth are the most relevant factors associated with increased gingival recessions, therefore a thick gingiva is less prone to recession. Various procedures are used for root coverage to thicken the buccal gingiva and improve aesthetics. These techniques include various lateral



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or coronal sliding flaps<sup>1</sup>, guided tissue regeneration<sup>2,3</sup>, and implantation of grafts<sup>3,4</sup>. A subepithelial connective tissue graft (ACT) harvested from the palate has been introduced to increase root coverage and gum thickness<sup>2,5</sup>. The ACT is placed underneath a split-thickness flap which can be coronally, laterally or not mobilised, thus the ACT is at least partially covered by the flap. Because of the good clinical success and colour match, ACTs have been regarded as the gold standard<sup>3,4</sup>. However, bleeding of the donor site, hyposensitivity of the palate, and postoperative pain and discomfort can occur. For patients with multiple recessions it may be difficult to harvest enough connective tissue from the palate and multiple surgeries may be necessary. Therefore, it might be advantageous to replace autogenous ACT with an alternative graft. Different types of human acellular freeze dried human dermis are currently used as homologue transplants to avoid a second site surgery<sup>6-8</sup>.

The aim of this preference controlled clinical trial was to evaluate whether a solvent dehydrated sterile human dermis graft (HDG) could be used instead of an ACT to increase gingival thickness and to cover multiple gingival recessions.

#### Materials and methods

Any patient, 18 years old or older, requesting gingival coverage at more than one tooth affected by Miller Class I and II recessions (no visible loss of interdental papilla and distance between cementoenamel junction [CEJ] to bone crest ≤ 2.5 mm measured on periapical radiographs, though, when present, Miller class III and IV recessions were also treated and considered in the analyses)<sup>9</sup>, and able to sign an informed consent form, was eligible for inclusion in this trial. Patients were not admitted to the study if any of the following exclusion criteria were present:

- any pathologic systemic condition
- smokers (ex-smokers could be included if not smoking for at least 6 months)
- affected by periodontitis
- poor oral hygiene and motivation (plaque and bleedings scores < 15% before surgery)</li>
- pregnant
- participant in other clinical studies within the last 6 months before surgery.

Patients were recruited and treated in one private practice by the same operator (MS), using similar procedures. The study was approved by the Ethics Commission International Freiburg, Germany (study code: TM-MS-2006-01: feci Code: 010/1462). The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. Patients were informed that they could choose between two different treatment options. Any potential advantages and disadvantages with each technique were explained by the operator, and the patients were left to choose what they preferred. All patients signed an informed consent form prior to being enrolled in the trial. Following initial examination, patients were instructed in oral hygiene and a professional tooth cleaning was delivered as required.

#### Surgical procedure

Besides complete root coverage, the aim of the surgery was to increase the thickness of the gingival tissue. All surgeries were performed by the same operator (MS). No antibiotics were provided. After local anaesthesia, the exposed roots were scaled and planed to the bottom of the pocket with rotating burs, ultrasonic instruments and curettes. Deeper instrumentation was avoided to prevent damage to the periodontal ligament. In addition, prominent roots were flattened. No chemical root conditioning was performed. After sulcular incision, a coronally displaced split-thickness flap was performed without releasing incision according to the incision outline described by Zucchelli<sup>10</sup>, though a complete split-thickness flap was elevated. The flap was considered to be mobilised enough when it stayed passively at a level slightly coronal to the CEJ. According to patient preference, subepithelial connective tissue grafts (Fig 1) were harvested from one or two palatal sides, depending on the amount of tissue needed, or human dermis acellular allografts (Fig 2) were used.

Tutoplast® Dermis Allograft Tissue Matrix (Tutogen Medical, Neunkirchen am Brand, Germany [now available as Puros® Dermis, Zimmer Dental, Carlsbad, CA, USA]) was used as a human dermis graft. The allograft retains the natural collagen matrix and mechanical properties of native dermis<sup>11</sup>. The



**Fig 1** Clinical pictures of one patient included in the connective tissue graft group: a) preoperative situation, b) just after suturing, c) after 6 months.

**Fig 2** Clinical pictures of one patient included in the human dermis group: a) preoperative situation, b) after positioning of the human dermis graft, c) after 6 months.

tissue processing also inactivates bacterial, viral and prion contamination and eliminates antigenicity. The solvent-dried material is packaged with the absence of residual antibiotics and terminally sterilised by low-dose gamma irradiation. The graft was rehydrated for 30 minutes in sterile saline, adapted in size, placed underneath the flap and fixed around the recipient teeth with sling sutures (Prolene, 6-0, Braun, Melsungen, Germany). The most coronal position was about 1 mm below the CEJ. The flap was coronally advanced to completely cover the graft and was also fixed with sling sutures to accomplish a precise adap-

tation around teeth. Suture knots were placed on the lingual aspect to decrease patient discomfort during removal.

When subepithelial connective tissue grafts were used, a single incision parallel to the gingival margin using a scalpel with a 15c blade was made in the palate<sup>12</sup>. After the separation of the tissue graft with two horizontal and two vertical incisions, the connective tissue was removed, leaving the periosteum attached to the bone. The donor region was sutured and epithelium was carefully removed from the graft. The ACTs were handled exactly in the same manner as the HDGs.

Patients were instructed to avoid any mechanical trauma to the wound and to rinse with chlorhexidine mouthwash (0.12%) twice a day for 1 minute, for 4 weeks. Ibuprofen (400 mg) was prescribed as an analgesic and anti-inflammatory medication. Sutures were removed after 2 weeks and patients were recalled 1, 2 and 6 months after surgery for professional supragingival tooth cleaning and reinforcement of motivation for good oral hygiene. Patients were also instructed to use a gentle roll technique with soft brushes for brushing their teeth.

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:

- Complication: any complication that occurred during or after the grafting procedure for the entire follow-up period.
- Gingival recession changes (REC): measured from the CEJ to the most apical position of the gingiva on the buccal aspect of the root. It was expressed in percentages according to the following formula: 100 × ([REC baseline – REC 6 months]/ REC baseline). When not visible, the CEJ position was estimated by the outcome assessor.
- Gingival biotype changes (BIO): gingiva was considered to be thick when the probe was not visible through the tissue; if visible, it was classified as thin biotype.
- Probing pocket depth changes (PPD): measured from the most apical position of the gingiva on the buccal aspect of the root to the bottom of the gingival sulcus.
- Probing attachment level changes (PAL): calculated by following the formula: PAL = REC + PPD.
- Keratinised mucosa width changes (KER): measured from the gingival margin to the mucogingival junction (MGJ).

All clinical periodontal measurements were made prior to surgery (baseline) and 6 months after with a pressure sensitive periodontal probe (PCP-UNC 15 probe, Hu-Friedy, USA) using a calibrated force of 0.3 Ncm to the nearest 0.5 mm by one independent, experienced and blinded dental hygienist (Tatjana Huck).

No sample size calculation was performed. A biostatistician 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 complications were compared between the groups using the Fisher exact probability test. Differences of means at patient level for continuous outcomes between groups were compared by t tests. Comparisons between the baseline measurements and 6 months after augmentation were made by paired t tests. All statistical comparisons were conducted at the 0.05 level of significance.

#### Results

Forty-two patients who were interested in having their recession treated for aesthetic reasons were considered eligible and were consecutively enrolled in the trial. Twenty-one patients opted to donate their own tissues and 21 preferred to be treated with a human dermis. All patients were treated according to their own preference. Patients were treated between September 2005 and January 2010. 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 no apparent significant baseline imbalances between the two groups with the exception of more recessions per patient in the group treated with human dermis (7.6 versus 5.2 mm).

The main results 6 months after the augmentation procedure are summarised in Table 2. Only one minor postoperative complication was observed during the entire follow-up period: at suture removal, 7 days after grafting, a HDG was exposed. This thin biotype site with no keratinised gingiva showed dermis exposition due to recession of the coronally repositioned flap. The exposed HDG resorbed over time and the recession improved from 4 to 2.5 mm. After 6 months, the site was still characterised as a thin biotype but about 1 mm of keratinised gingiva was present.

Six months after grafting, recessions in both groups were statistically significantly reduced (2.7 mm for ACTs and 2.0 mm for HDGs; Table 3). On average, there was 0.5 mm less recession at ACT-treated sites, and this was statistically significant (Table 2). More specifically, ACTs determined 17.8% more root coverage than HDGs, which was statistically significant (Table 2).

 Table 1
 Baseline patient and site characteristics.

	ACT (n = 21)	HDG (n = 21)
Number of females	17	16
Age (range)	45.6 (24-65)	47.3 (25-70)
Mean number of recessions per patient	5.2	7.6
number of recessions	110	160
Number of maxillary incisors	6	26
Number of maxillary canines	18	28
Number of maxillary premolars	23	40
Number of maxillary molars	12	24
Number of mandibular incisors	18	11
Number of mandibular canines	12	6
Number of mandibular premolars	14	18
Number of mandibular molars	7	7
Number of Miller class I recessions	67	108
Number of Miller class II recessions	30	33
Number of Miller class III recessions	12	18
Number of Miller class IV recessions	1	1
Number of thin biotype sites	62	97
Number of thick biotype sites	48	63
Mean biotype proportion thin/thick (SD)	0.30 (0.30)	0.34 (0.29)
Mean recessions mm (SD)	2.90 (0.84)	2.76 (0.76)
Mean keratinised mucosa heights mm (SD)	1.70 (1.09)	2.12 (0.94)
Mean probing pocket depths mm (SD)	1.61 (0.57)	1.79 (0.48)
Mean probing attachment levels mm (SD)	4.51 (1.11)	4.55 (1.06)

 Table 2
 Summary of the main results 6 months after grafting and difference between groups.

	ACT (n = 21)	HDG (n = 21)	Difference (standard error)	95% CI	<i>P</i> value
Proportion of patient with complications	0	0.048 (0.05)	0.048 (0.05)	* * *	1.00
Number of thin biotype sites*	10	20			
Number of thick biotype sites*	100	140			
Mean biotype proportion thin/thick (SD)	0.89 (0.30)	0.88 (0.16)	0.02 (0.07)	-0.13, 0.17	0.819
Mean recessions mm (SD)	0.21 (0.38)	0.73 (0.46)	-0.52 (0.13)	-0.78, -0.26	<0.001**
Root coverage in percentage (SD)	93.6% (11.2)	75.8% (15.6)	17.8% (4.2)	9.31, 26.2	<0.001**
Mean keratinised mucosa heights mm (SD)	3.43 (1.37)	3.07 (0.88)	0.37 (0.36)	-035, 1.08	0.307
Mean probing attachment levels mm (SD)	1.75 (0.62)	2.27 (0.63)	-0.52 (0.19)	-0.91, -0.13	0.001**
Mean probing pocket depths mm (SD)	1.54 (0.48)	1.55 (0.38)	-0.01 (0.14)	-0.27, 0.27	0.998

<sup>\*</sup>Based on site data (clustered within patients); no analysis undertaken

<sup>\*\*</sup>Statistically significant values P < 0.001

<sup>\*\*\*</sup>Exact calculation not possible with zero count cells

**ACT REC** HDG REC ACT BIO HDG BIO ACT KER HDG KER ACT PAL HDG PAL **ACT PPD** HTG PPD Baseline 2.90 (0.84) 2.76 (0.76) 0.30 (0.30) 0.34 (0.29) 1.70 (1.09) 2.12 (0.94) 4.51 (1.11) 4.55 (1.06) 1.61 (0.57) 1.79 (0.48) 0.21 (0.38) 0.89 (0.30) 3.07 (0.88) 1.75 (0.62) 2.27 (0.63) 1.54 (0.48) 6 months 0.73 (0.46) 0.88 (0.16) 3.43 (1.37) 1.55 (0.38) Difference 2.68 (0.71) 2.03 (0.64) 0.60 (36) 0.54 (0.25) 1.73 (1.60) 0.95 (1.01) 2.75 (0.95) 2.28 (0.98) -0.07 (0.47) -0.24 (0.63) 95% CI 2.36, 3.01 1.74, 2.33 0.43, 0.76 0.42, 0.65 1.00, 2.46 0.49, 1.41 2.32, 3.19 1.83, 2.72 -0.28, 0.14 -0.53, 0.05 <0.001\* P value < 0.001\* < 0.001\* < 0.001\* < 0.001\* < 0.001 \* < 0.001\* < 0.001\* 0.51 0.10

Table 3 Comparison of clinical outcomes in mm (SD) at baseline and after 6 months for the two study groups (n = 21 in each group).

Both procedures thickened biotype in the same way (Tables 1–3) with no differences between the two procedures (Table 2).

Both procedures were able to increase the height of keratinised mucosa (on average 1.73 mm for ACTs and 0.95 mm for HDGs; Table 3), the difference between groups being not statistically significant (Table 2). Probing attachment levels significantly improved for both groups (on average 2.75 mm for ACTs and 2.28 mm for HDGs; Table 3), though ACTs provided, on average, an additional significant improvement of 0.52 mm (Table 2).

There were no significant changes for probing pocket depths over time (Table 3) and between groups (Table 2).

#### Discussion

This patient preference trial was designed to assess whether HDGs could replace autogenous ACTs for treating multiple root recessions. Both procedures were effective in covering the exposed roots and in increasing soft tissue thickness, though slightly better clinical results were obtained using ACTs. When attempting to compare the present results with those of similar trials, the present authors could identify only four randomised controlled trials (RCTs)<sup>13-16</sup> comparing ACTs with another acellular dermal matrix graft (Alloderm, Life Cell Corporation, The Woodlands, TX, USA), which were evaluated in a systematic review<sup>7</sup>. The meta-analyses of these four trials (60 patients per group) for root coverage and KER did not show any statistically significant differences 6 months after grafting between the two different procedures. When comparing directly the same HDGs used in the present investigation (Tutoplast Dermis) with the previously mentioned acellular dermal matrix graft (Alloderm) in one split-mouth RCT including 14 patients with 56 recessions<sup>8</sup>, no statistically significant difference could be observed after 6 months for root coverage, KER, PAL and PPD.

The main limitations of the present study are the lack of randomisation, the strict inclusion criteria, the lack of assessment of postoperative pain, the lack of colour match evaluation of the grafted areas, and the small sample size. The clinical investigator decided to let patients choose the intervention they preferred because this was considered to be the simpler way to run this trial in a private practice setting. However, patients can be influenced by the clinician's views, therefore group allocation is at a high risk of bias. Curiously, the patient choice generated two groups with an equal number of patients. Though group allocation was not performed at random, all assessments were performed by a masked outcome assessor.

The results of this study may not be generalised with confidence to other populations due to the strict inclusion criteria and lack of randomisation. It is not possible to definitively recommend any of the tested procedures since personal values are involved. Patients should be correctly informed that there could be more postoperative pain/discomfort and a slightly better (18% more gingival coverage) aesthetic outcome when using their own tissues, and should decide by themselves what they prefer.

#### Conclusions

Human dermis grafts could be an alternative treatment option to autogenous connective tissue grafts for covering exposed roots and increasing soft tissue thickness. While HDGs provided slightly inferior root coverage, they may cause less postoperative pain/discomfort.

<sup>\*</sup>Statistically significant values

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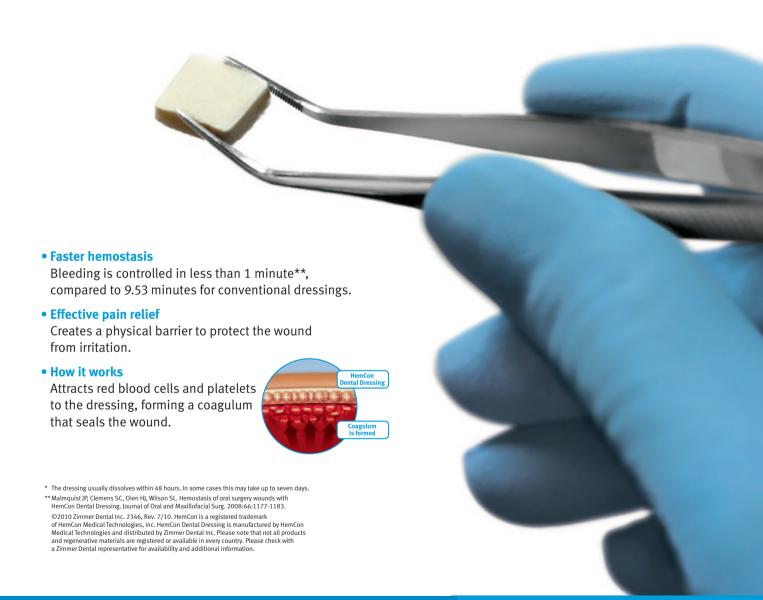
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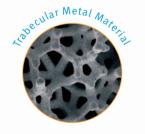


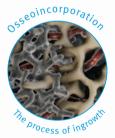




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