

**HUMAN RANDOMIZED CONTROLLED TRIAL**

Impact of connective tissue graft thickness on surgical outcomes: A pilot randomized clinical trial

David H. Moisa¹ | Julie A. Connolly¹ | Bin Cheng² | Evanthia Lalla¹

¹Division of Periodontics, College of Dental Medicine, Columbia University, New York, NY, USA

²Department of Biostatistics, Mailman School of Public Health, Columbia University, New York, NY, USA

Correspondence

Evanthia Lalla, Columbia University College of Dental Medicine, Division of Periodontics, 630 West 168th St., PH7E-112, New York, NY 10032.

Email: EL94@cumc.columbia.edu

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Abstract

Background: The aim of this study was to compare thick versus thin connective tissue grafts (CTG) for the treatment of gingival recession, over a 3-month period.

Methods: Forty-two CTG procedures were performed on single tooth Miller Class I or II recession defects at either premolar or anterior sites in 30 individuals. Procedures were randomized (1:1 ratio) to CTG thickness of 1 or 2 mm (parallel group design). Primary outcomes were the change in the width of the zone of keratinized tissue and the amount of root coverage achieved 3 months postoperatively at the recipient site. Secondary outcomes included change in the thickness of keratinized tissue at 3 months and patient-reported outcomes, such as pain, bleeding, and swelling at both the recipient and donor sites at 1 week, 2 weeks, 1 month, and 3 months.

Results: No significant differences were found between the two groups for any of the primary or secondary outcomes. Mean root coverage achieved was 2.1 ± 0.2 mm in the 1-mm thick group and 2.5 ± 0.2 mm in the 2-mm thick group ($P = 0.33$). Keratinized tissue width was increased by 2.2 ± 0.2 mm in the 1-mm thick group and by 2.7 ± 0.3 mm in the 2-mm thick group ($P = 0.18$). Keratinized tissue thickness was increased by 1.0 ± 0.1 mm and by 1.2 ± 0.1 mm in the 1- and 2-mm thick groups, respectively ($P = 0.09$).

Conclusion: Within the current study limitations, our results suggest that similar root coverage and increase in the width and thickness of keratinized tissue can be achieved at 3 months whether a 1- or 2-mm thick CTG is used.

KEYWORDS

gingival recession, patient reported outcomes, randomized clinical trial, tissue grafts

1 | INTRODUCTION

Surgical procedures have long been used for the treatment of gingival recession. These procedures aim to cover the exposed root surfaces of involved teeth and to increase the width and thickness of keratinized tissue.¹ The increased root coverage can provide decreased tooth sensitivity, reduction of the risk for root caries, and improved esthetics.² Different techniques have been used, including free gingival grafts, coronally advanced flaps, lateral sliding flaps, double pedicle

grafts, and subepithelial connective tissue grafts (CTGs).^{3–7} Many different combinations and surgical approaches to the procedures listed above have also been reported, including guided tissue regeneration, as well as the use of allograft and xenograft materials.^{8–10} Clinicians must decide the appropriate surgical procedure and technique to use in each individual case, and often use the technique that is most predictable in their hands. A literature review in 1996 reported that many of these surgical procedures attain rates of root coverage ranging from 50% to 98%.¹ A systematic review in 2008 labeled CTG



as the “gold-standard” surgical procedure in the treatment of recession defects.¹¹ In the 1996 review, as well as in the American Academy of Periodontology Regeneration Workshop in 2015, CTGs were shown to have the best long-term results.^{1,2} Many studies have evaluated individual aspects of the CTG procedure, such as root surface treatment, flap thickness, flap design, graft de-epithelialization, and others.^{12–15} A recent systematic review¹⁶ assessed the effects of a broad array of such factors, concluding that CTG is a predictable procedure to achieve root coverage in Miller Class I and II recession defects and that several factors have a critical role in the outcome of root coverage. However, no study to date has directly compared grafts of different thickness and the potential impact on surgical outcomes.

One of the common challenges to attaining a CTG from the palate, the usual CTG donor site, is a lack of thickness of the subepithelial palatal tissue. Studer et al.¹⁷ showed that palatal tissue could be as thin as 1.8 mm in the area of the first maxillary molar. In those situations, underlying anatomical structures and inability to access are the main challenges to attaining a CTG. Ultimately, this often deters operators from attempting to attain a palatal CTG altogether. Determining that a uniformly thinner CTG can provide similar surgical outcomes, and possibly less patient morbidity, will allow for including a palatal CTG as a treatment option for patients with thinner palatal tissue.

Therefore, the goal of the current study was to determine the effect of the thickness of CTG, used for the treatment of gingival recession, on several postoperative outcomes.

2 | MATERIALS AND METHODS

2.1 | Study design

This study was a 3-month pilot RCT conducted with the approval of the Institutional Review Board of Columbia University, New York, NY, and in accordance with the Declaration of Helsinki, as revised in 2013. Patients provided written informed consent and completed standard Columbia University College of Dental Medicine medical and dental history forms (which were reviewed orally as well). Before inclusion into the study, patients underwent non-surgical mechanical periodontal therapy, as indicated. Parallel group design was implemented. CTG surgical procedures were randomized in a 1:1 ratio to either a thin or a thick graft, as described in detail below. Block randomization (block size = 2) was computer-generated by the study statistician (BC) and the treatment assignment was sequentially delivered to the clinical examiner/operator for implementation. In the thin CTG group, the palatal graft was harvested using a parallel blade technique, as described by Harris,¹⁸ with the blades set at 1 mm apart. In the thick group, the parallel blades were

set at 2 mm apart. Patients returned for follow-up visits at 1 week, 2 weeks, 1 month, and 3 months postoperatively.

2.2 | Patient recruitment

Study participants were recruited from the clinics of the Columbia University College of Dental Medicine, as well as via flyers posted at the Columbia University Medical Center. Interested individuals were referred to one of the investigators for initial screening. The study opened for enrollment in March 2015 and the final 3-month visits were completed by July 2016.

2.3 | Inclusion and exclusion criteria

The following inclusion criteria were used: individuals aged ≥ 18 years, presence of Miller Class I or II gingival recession¹⁹ on a premolar or an anterior tooth, and probing depths ≤ 4 mm on the tooth to be treated at the time of the surgical procedure. Exclusion criteria included systemic factors such as smoking, uncontrolled systemic diseases with compromised healing potential (such as diabetes mellitus with a recent HbA1c $> 7\%$), medications known to cause gingival enlargement, anticoagulants with International Normalized Ratio (INR) > 2.5 , or pregnancy. Local factors for exclusion were: adjacent edentulous area, history of surgical periodontal treatment of the involved site, full coverage restoration or restoration on the buccal surface of the candidate tooth causing an undetectable cemento-enamel junction, pulpal pathology, severe malposition or open contacts, and current or planned orthodontic treatment during the 3-month course of the study. Patients with a frenum and/or muscle attachment encroaching on marginal gingiva could be included, 6 weeks after a frenectomy procedure was performed.

2.4 | Null hypothesis, primary and secondary outcomes, clinical measurements

The null hypothesis was that there would be no significant differences between the two treatment groups with regard to the primary outcomes of change in keratinized tissue width and root coverage, or with regard to secondary outcomes of change in keratinized tissue thickness and patient-reported outcomes (PRO).

Clinical measurements taken at baseline and at 3 months included gingival recession, keratinized tissue width, and keratinized tissue thickness. A single examiner (DHM), who was not masked to group assignment, performed all measurements. PRO on root sensitivity, effect on eating, as well as pain, swelling, and bleeding (at donor and recipient sites) were collected preoperatively and at 1 week, 2 weeks, 1 month, and 3 months postoperatively, using questionnaires completed by study participants.

2.5 | Surgical procedure

A single operator (DHM) performed all procedures. A modified Raetzke envelope flap²⁰ was performed at the recipient site. The modification involved using only sulcular incisions to prepare the flap, whereas the original technique used a sub-marginal incision to remove the sulcular epithelium. Raetzke's surgical technique also did not include any sutures for the graft, while in the current study, two tacking sutures, and sometimes a sling suture, were placed.

Local anesthesia was used at the donor and recipient sites. The root surface was debrided with a curet. Irregularities of the root surface were removed with a thin carbide bur. The recipient site was prepared by a split thickness flap, using a microsurgical spoon blade, as described above. The CTG was then harvested from the palate using a double blade handle* with parallel 15c blades, set at either 1 or 2 mm apart. Pressure was placed at the palatal donor site with moist gauze and the palate was sutured with 5-0 absorbable synthetic (polyglactin 910[†]) sutures. Periodontal dressing was not applied to the donor site. The graft was tacked into the recipient site using 6-0 polyglactin 910 sutures. A sling suture (5-0 polyglactin 910) was used when indicated for graft securement to the root surface.

Postoperatively, all patients were given the same prescriptions: amoxicillin 875 mg twice a day for 7 days, ibuprofen 600 mg, 12 tablets, four times a day for pain, as needed, and 0.12% chlorhexidine (to rinse with 15 mL twice a day for 30 seconds and to gently apply with a cotton tip applicator to the surgical site daily) for 2 weeks. Prescription bottles were not examined to monitor medication use. Instructions included not brushing the surgical area for 2 weeks, avoiding eating on the side of the surgery as much as possible, and avoiding any pulling of the lip or cheek around the surgical area.

Patients returned at 1 week for evaluation and completed a PRO form. At 2 weeks, patients returned for suture removal. Patients filled out another PRO form and were instructed to begin brushing the surgical area using the roll technique, and were provided with an extra soft toothbrush. Patients returned at 1 month for observation and 3 months for final clinical measurements. PRO forms were filled out at both of those visits as well.

2.6 | Statistical analysis

Power calculations indicated that 20 procedures would be needed in each group to detect a 1-mm difference in change of keratinized tissue width between the two groups with 80% power and a type 1 error rate of 5%. The baseline variables

of the two treatment groups were compared using either the *t*-test if continuous, or the Chi-square test if categorical. The absolute change in mm for recession, keratinized tissue width, and keratinized tissue thickness from baseline to 3 months was compared between the two treatment groups using the two-sample *t*-test. The analysis was performed using statistical software.[‡] Data are reported as mean \pm SE, or n (%). A *p* value < 0.05 was considered statistically significant.

3 | RESULTS

A total of 160 potential study participants were screened and 30 individuals entered the study (Fig. 1). All patients completed the 3-month follow-up for a total of 42 surgical procedures (20 patients underwent one procedure, eight patients underwent two procedures, and two patients underwent three procedures). The age of the study participants was 35.8 ± 2.1 years; 16 (53%) were females; 14 (47%) were Hispanic, 11 (37%) were Non-Hispanic white and four (13%) were Asian. There were no significant differences between the two treatment groups for any of the patient demographics recorded: age ($P = 0.34$), sex ($P = 0.43$), or race/ethnicity ($P = 0.20$). Twenty-five (60%) of the recession defects were located in the maxillary arch and 17 (40%) were in the mandibular arch. Specifically, in the 1-mm group there were 15 (71%) recessions in the maxilla and six (29%) in the mandible; in the 2-mm group there were 10 (48%) recessions in the maxilla, 11 (52%) in the mandible. Twenty-one (50%) were on anterior teeth, and the other 50% were on premolars. All participants denied tobacco use, and only one reported a diagnosis of diabetes (well controlled with medications). All patients reported having seen a dentist for an oral examination within 6 months before the study. Preoperative probing depths did not exceed 3 mm. Baseline recession, keratinized tissue width, and keratinized tissue thickness were similar in the two groups (Table 1). Seventy percent of patients reported some degree of root sensitivity and 23% reported negative effect on eating preoperatively (while only one patient reported root sensitivity postoperatively at 3 months and none reported any effect on eating at 3 months).

An example of a surgical procedure for the 1-mm thick CTG treatment group is shown in Figure 2, and an example of a procedure for the 2-mm thick CTG group is shown in Figure 3. Results for changes in gingival recession (i.e., root coverage achieved), keratinized tissue width, and thickness are shown in Figure 4. Both groups exhibited significant improvement. In the 1-mm group, the baseline recession of 2.8 ± 0.2 mm was decreased at 3 months by 2.1 ± 0.2 mm, to 0.6 ± 0.1 mm. In the 2-mm group, recession was reduced by

* Harris double blade handle, H&H, Ontario, Canada.

[†] Coated Vicryl, Ethicon US, Bridgewater, NJ.

[‡] SAS 9.4, SAS Institute, Cary, NC.

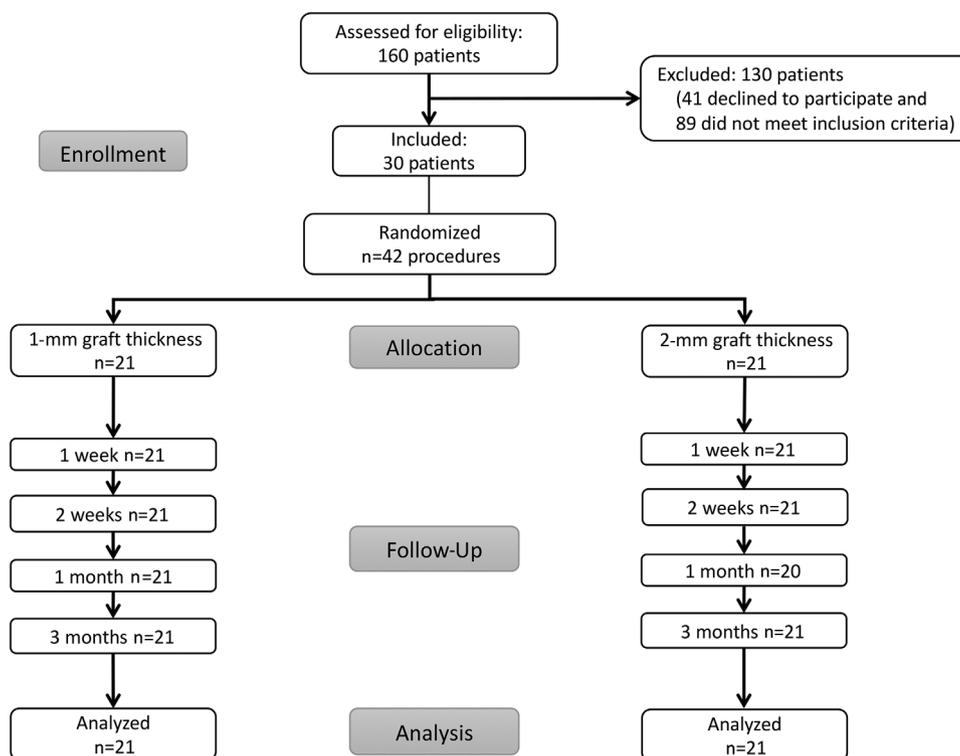


FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT)²⁷ flow diagram

TABLE 1 Baseline measurements of gingival recession, and the width and thickness of keratinized tissue in two treatment groups (1-mm thick CTG versus 2-mm thick CTG)

Variables (at baseline)	1-mm CTG	2-mm CTG	P value
Recession (mm)	2.8 ± 0.2	2.5 ± 0.2	0.34
Width of KT (mm)	2.2 ± 0.2	2.1 ± 0.2	0.77
Thickness of KT (mm)	1.0 ± 0.1	1.0 ± 0.1	0.84

Data shown as mean ± SE.

KT = keratinized tissue

2.5 ± 0.2 mm, from 2.5 ± 0.2 to 0.1 ± 0.1 mm (Fig. 4A). The difference in root coverage achieved between the two groups was not statistically significant ($P = 0.33$). The baseline keratinized tissue width of 2.2 ± 0.2 mm in the 1-mm group was increased by 2.2 ± 0.2 to 4.5 ± 0.3 mm. In the 2-mm group, keratinized tissue width was increased by 2.7 ± 0.3 mm, from 2.1 ± 0.2 to 4.9 ± 0.3 mm (Fig. 4B). The keratinized tissue width increase was not significantly different between the 1- and 2-mm groups ($P = 0.18$). The baseline keratinized tissue thickness of 1.0 ± 0.1 mm in the 1-mm group was increased by 1.0 ± 0.1 to 1.9 ± 0.1 mm. In the 2-mm group, keratinized tissue thickness was increased by 1.2 ± 0.1 mm, from 1.0 ± 0.1 to 2.2 ± 0.1 mm (Fig. 4C). The keratinized tissue width increase was not significantly different between the two groups ($P = 0.09$).

No statistically significant differences were noted between the two groups for any of the PRO measured at any of the time points. Shown as an example in Figure 5, are pain, swelling,

and bleeding outcomes, reported at the 1-week postoperative visit for both the recipient and donor sites. We did not monitor medication use, but none of the study participants in either group requested a stronger pain medication or a prescription refill.

4 | DISCUSSION

Gingival recession is a fairly common finding, reported in about one quarter of the population in the United States.²² CTG surgery is a predictable treatment modality to attain root coverage,^{1,7} but no previous studies have directly examined the role that the graft thickness may play on surgical outcomes.

The mean root coverage attained in the current study (both groups combined) was 86%. This is comparable with several previous studies^{12,14,23,24} using a similar surgical design (CTG with the envelope technique).

In the current study, the root surfaces were planed without any root surface conditioning, and no more than 3 mm of the graft was left exposed. Bouchard et al.¹² demonstrated that there was no difference in mean root coverage attained, whether or not citric acid root conditioning was performed before CTG surgery. Cordioli et al.¹⁴ demonstrated that 2.8 ± 1.1 mm of the CTG could be left exposed with no difference on resulting root coverage attained. Tozum et al.²⁵ showed that there was a significantly higher increase in the width of keratinized tissue attained when a CTG was left

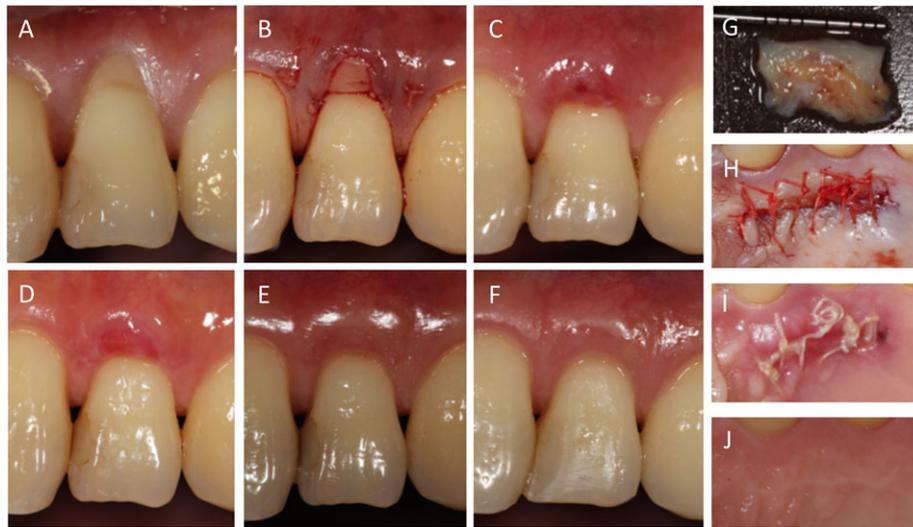


FIGURE 2 Representative surgical procedure, 1-mm CTG thickness group, tooth #10. Preoperative (A); immediate postoperative (B); 1-week postoperative (C); 2-week postoperative (D); 1-month postoperative (E); 3-month postoperative (F); 1-mm thick graft (G); immediate postoperative donor site (H), 1-week postoperative donor site (I); 3-month postoperative donor site (J)

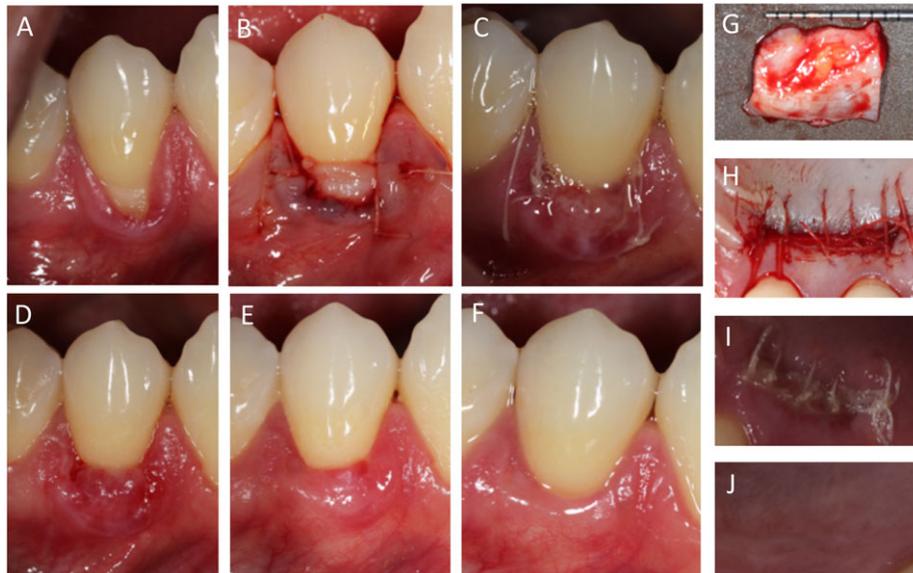


FIGURE 3 Representative surgical procedure, 2-mm CTG thickness group, tooth #28. Preoperative (A); immediate postoperative (B); 1-week postoperative (C); 2-week postoperative (D); 1-month postoperative (E); 3-month postoperative (F); 2-mm thick graft (G); immediate postoperative donor site (H), 1-week postoperative donor site (I); 3-month postoperative donor site (J)

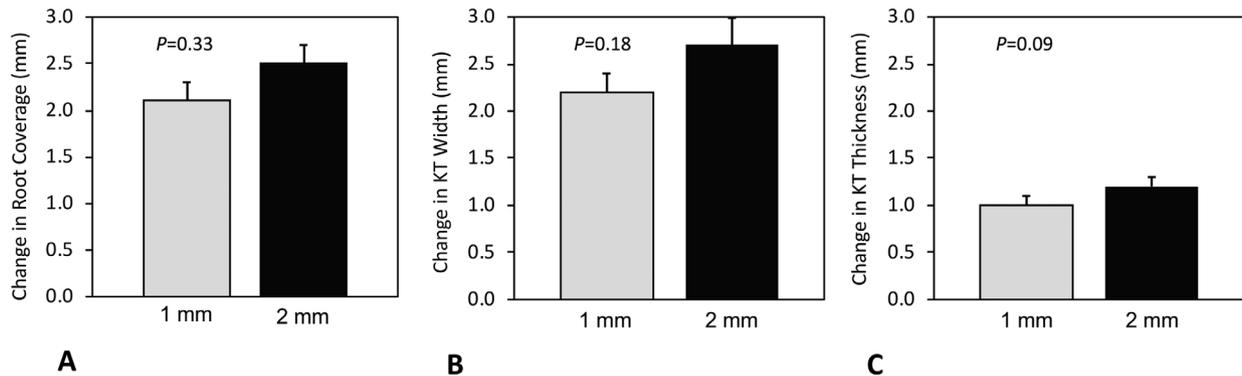


FIGURE 4 Change in root coverage (A), width of keratinized tissue (B), and thickness of keratinized tissue (C) for the two treatment groups from baseline to 3 months postoperatively

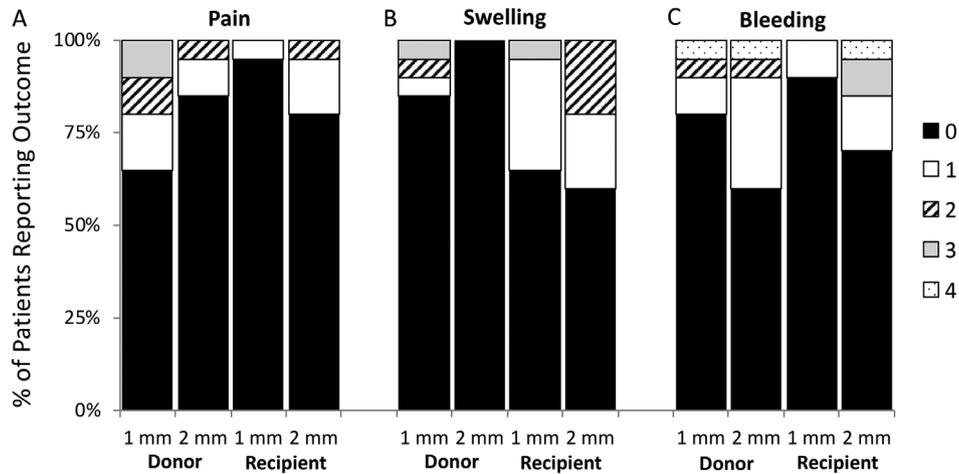


FIGURE 5 Patient-reported outcomes (PRO) at the 1-week postoperative visit for: pain (A), swelling (B), and bleeding (C), at both the donor and recipient sites. *Pain*: 0 = No discomfort; 1 = Little discomfort; 2 = Pain that bothered my normal activity; 3 = Pain that bothered me a lot; 4 = Pain that I could not tolerate. *Swelling and bleeding*: 0 = None; 1 = Very little; 2 = Somewhat noticeable; 3 = Very noticeable; 4 = Severe. No statistically significant differences were found for any of these outcomes

slightly exposed. In a recent systematic review, Dodge et al.²⁶ concluded that in cases of partial CTG exposure there is increased gain in the width of keratinized gingiva, while a fully covered CTG may allow for more root coverage.

The main goal of the current study was to evaluate the effect of the thickness of a CTG on the width and thickness of keratinized tissue and root coverage attained, for single-tooth recession defects classified as Miller Class I or II of anterior or premolar teeth. Thin palatal tissue can be a deterrent for clinicians to attempt a palatal CTG procedure. If a thinner CTG can attain similar surgical outcomes to a thicker CTG, clinicians can reconsider performing a CTG as opposed to other procedures, which may not have comparable long-term outcomes. The results of this study suggest that a thinner CTG can attain similar 3-month postoperative surgical outcomes as a thicker CTG.

In addition, postoperative palatal flap thickness has been shown to impact early wound healing and pain perception,²⁷ thus using a thicker CTG may lead to increased patient reported morbidity postoperatively from the donor site. This was not the case in the present study, as there were no significant differences in PRO between the two treatment groups. However, the current study first evaluated PRO at 1 week, and differences in the first few days postoperatively may have been missed.

During the course of the study, one patient missed the 1-month follow-up visit, but returned for the final visit, and was included in final data analysis. One other patient, from the 1-mm thick group, presented with graft sloughing at the 2-week follow-up visit. No root coverage was attained from the initial CTG procedure; however, the patient's keratinized tissue thickness was increased and root coverage was later attained by performing a secondary surgical procedure, outside the study protocol.

There are certain limitations to the present study. Our sample size was relatively small. Power calculations were performed, but only for one of the primary outcomes (keratinized tissue width). Also, the examiner was not masked to group assignment and the possibility of ascertainment bias cannot be ruled out. Lastly, follow-up did not continue beyond 3 months, therefore long-term stability/treatment outcomes are unavailable to us.

The present study did not reveal significant differences between the two treatment groups, but a tendency for improved outcomes for 2-mm thick grafts is noted. A larger comparative study may lead to statistically significant differences, but the magnitude of the differences will likely remain clinically insignificant. A properly powered equivalence study may be best in shedding more light into the questions posed here. Indeed, the current results can be used to inform the design of future clinical trials. Future studies could use a split-mouth approach to eliminate host response effects. It would also be beneficial to compare longer-term outcomes, at 6- or 12-months postoperatively. Regarding PRO, earlier patient responses, for example, at 1 to 3 days postoperatively, and close monitoring of pain medication use may be of value in assessing postoperative patient morbidity. A study directly comparing the use of a thin CTG to acellular dermal matrix would also be of interest.

5 | CONCLUSIONS

The current study is the first to directly compare thick versus thin CTG for the treatment of gingival recession. The use of thin (1 mm) grafts showed comparable results to the use of thick (2 mm) grafts for all clinical parameters measured 3 months following a CTG procedure at anterior or premolar teeth presenting with Miller Class I or II gingival recession.

PRO, including pain, bleeding, and swelling at both the recipient and donor sites, were similar in the two groups at 1 week, 2 weeks, 1 month, and 3 months. The limitations of this pilot study do not allow for broad generalizations, and although our current findings provide novel insights which can inform future larger, long-term trials, the latter will be necessary for any definitive conclusions or treatment guidelines.

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