Does the size of the connective tissue graft influence the outcomes of bilaminar techniques for coverage of gingival recessions? A randomized, double blind, clinical trial

Le dimensioni dell'innesto connettivale possono influenzare i risultati clinici della tecnica bilaminare per il trattamento delle recessioni gengivali?Uno studio clinico randomizzato

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Summary

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Aim: The aim of the present randomized controlled clinical study was to compare root coverage, aesthetic results and patient morbidity of bilaminar techniques using different CTG thickness and height (apical-coronal dimension). *Methods:* 60 isolated Miller class I and II gingival recessions (\geq 3mm in depth) were treated with the CAF+CTG. In 30 gingival recessions (control group), randomly selected, the thickness of the CTG was >1mm and the height was 1mm greater than the depth of bone dehiscence (BD) while the in other 30 (test group) defects the CTG thickness was <1mm and height was 4mm. The post-operative patient morbidity was assessed 1 week after the surgery. The clinical and esthetic evaluations, made by the patient and independent periodontist, were performed 1 year after the surgery. *Results:* No statistically significant differences were demonstrated between the two groups in terms of recession reduction, complete root coverage and patient esthetic VAS scores. Better post-operative course and periodontist esthetic (color parameter) evaluations were reported after the use of small CTG. Greater GT and KTH increase were observed in the control treated sites. *Conclusions:* Single type gingival recessions can be successfully covered with CAF associated with CTG of reduced thickness (<1mm) and height (4mm). Studies are advocated to confirm long term maintenance of 1 year successful results.

Riassunto

Scopo: lo scopo di questo studio randomizzato e controllato era quello di confrontare la tecnica bilaminare (CAF+CTG) per il trattamento di recessioni gengivali singole utilizzando innesti connettivali differenti in spessore ed altezza. Materiali e Metodi: sono stati trattati 60 pazienti con recessioni singole (profondità \geq 3mm) di I e II classe di Miller con CAF+CTG. In 30 recessioni gengivali (gruppo conrollo) lo spessore di CTG era >1mm e l'altezza era 1 mm maggiore rispetto alla profondità della deiscenza ossea (BD) mentre per le altre 30 recessioni (gruppo test), lo spessore del CTG era <1 mm e l'altezza standard di 4 mm. La morbidità postoperatoria è stata valutata ad una settimana dalla chirurgia. Le valutazioni di paramentri clinici ed estetici, eseguite dai pazienti e da unparodontologo esperto, sono state rilevate ad un anno dalla chirurgia. Risultati: Non sono state dimostrate differenze tra i due gruppi in termini di copertura radicolare, di riduzione della profondità delle recessioni e valutazione estetica dei pazienti. L'utilizzo di un CTG di dimensioni ridotte ha dimostrato un miglior decorso postoperatorio e miglior valutazione oggettiva dell'esperto. Maggior aumento di GT e KTH sono stati osservati nel gruppo controllo.

Conclusioni: le recessioni gengivali singole possono essere trattate con successo utilizzando il Caf con un innesto connettivale di spessore (<1mm) ed altezza (4mm) ridotti.

Introduction

Gingival recession can be defined as a shift of the gingival margin to a position apical to the cemento-enamel junction (CEJ) with oral exposure of the root surface²³. The ultimate goal of a root coverage procedure is the complete coverage (CRC) of the recession defect with good appearance related to adjacent soft tissues and minimal probing depth (PD)^{6,17,22}. The most recent systematic review^{3,5} showed that coronally advanced flap (CAF) is a safe and predictable approach for root coverage and connective tissue graft (CTG) in conjunction with CAF procedure enhances the probability to obtain CRC and to improve recession reduction in Miller Class I and Il single gingival recession. The use of a CTG under a pedicle flap improves the CRC predictability but the aesthetic result can be jeopardized due the chromatic difference between the uncovered epithelized portion of the graft and the adjacent soft tissues^{15,21}; or to the dischromy associated with the partial exposure of connective tissue graft due to a dehiscence of the covering flap^{2,18,24}. Recently it was suggested²⁶ that the reduced thickness and apico-coronal dimension of the CTG, together with its positioning apical to the CEJ, facilitated graft coverage by the CAF and improved the aesthetic outcome. Furthermore, the reduced CTG size and thickness minimized patient postoperative morbidity caused by the palatal wound healing²⁸. The aim of the present study was to compare patient morbidity and root coverage and aesthetic results of bilaminar techniques using different CTG thickness and height (apical-coronal dimension).

Materials and Methods

Subject and site selection

60 subjects with aesthetic and/or hypersensitivity complaints due to the presence of single type gingival recession were enrolled in the study. The patients were selected, on a consecutive basis, among individuals referred to the University of Bologna, Dental School in the period comprised between January 2008 and January 2010. The study protocol, questionnaires, and informed consent in full accordance with the ethical principles of the Declaration of Helsinki of 1975, as revisited in 2000, was approved by the Institutional Review Board and received the approval by the local ethic committee. All participants met the study inclusion criteria:

- Age >18 years;
- Periodontally and systemically healthy
- FMPS e FMBS < 15% (4 sites per tooth)
- isolated Miller Class I and II (Miller 1985) recession defects (≥3mm in depth) in the upper jaw;
- Presence of identifiable CEJ (a step ≤1mm at CEJ level and/or presence of a root abrasion, but with an identifiable CEJ, were accepted)

Study exclusion criteria:

-smoking more than 10 cigarettes a day.

-contraindications for periodontal surgery, taking medications known to interfere with periodontal tissue health or healing; previous periodontal surgery on the involved sites.

-recession defects associated with demineralization/caries, deep abrasion or restoration as well as teeth with evidence of pulpal pathology.

Molar teeth were also excluded.

Study Design

The study was a double-masked, randomized, controlled clinical trial, with a parallel design, comparing CTGs of different thickness and height, in association with the CAF, for the treatment of single type gingival recession. The CTGs resulted from the de-epithelialization with the knife blade of a free gingival graft. In the control group the height of the free graft was 1mm greater

than the depth of bone dehiscence (BD) and its thickness was approximately 2mm; in the test group the height of the free graft was 4mm and its thickness was approximately 1mm. The study protocol involved a screening appointment to verify eligibility, followed by initial therapy to establish a-traumatic "roll" tooth brushing technique, optimal plaque control and gingival health conditions; surgical therapy; strict maintenance phase; evaluation of postoperative morbidity 1 week after the surgery; clinical and esthetic, made by the patient and by an independent periodontist, evaluations 1 year after the surgery.

Randomization

Patients were assigned to one of the two treatment groups with the use of computer generated randomization table. Each patient participated in the study with a single recession defects. Thirty patients (with 30 gingival recessions) were assigned to the control group and the other 30 patients (with 30 recession defects) belonged to the test group. Allocation concealment was obtained using sealed coded opaque envelope containing the treatment to the specific subject. The sealed envelope containing treatment assignment was opened at time of the surgery immediately after treatment of the root surfaces.

Initial therapy and Clinical measurements

Following the screening examination, all subjects received a session of prophylaxis including instruction in proper oral hygiene measures, scaling and professional tooth cleaning with the use of a rubber cup and a low abrasive polishing paste. A coronally directed "roll technique" was prescribed for teeth with recession type defects in order to minimize the tooth brushing trauma to the gingival margin. Surgical treatment of the recession defects was not scheduled until the patient could demonstrate an adequate standard of supragingival plaque control.

All clinical measurements were carried out by a single masked examiner (MS) at baseline and 1 year after the surgery. The examiner did not perform the surgeries and was unaware of the treatment assignment. Prior to the study, the examiner was calibrated to reduce intraexaminer error and to establish reliability and consistency. Measurement of RD, as the distance between the CEJ and gingival margin, was repeated three times by the examiner for a total of 50 defects with a K coefficient of 0.86.

Full mouth (FMPS) and local plaque score were recorded as the percentage of total surfaces (4 aspects per tooth) which revealed the presence of plaque¹⁹. Bleeding on probing was assessed dichotomously at a force of 0.3 N with a manual pressure-sensitive probe¹. Full mouth (FMBS) and local bleeding score were recorded as the percentage of total surfaces (4 aspects per tooth) which revealed the presence of bleeding upon probing.

The following clinical measurements were taken 1 week before the surgery and at the 1 year follow up visit at the midbuccal aspect of the study teeth:

- gingival recession depth (RD) measured as the distance from the cemento-enamel junction (CEJ) to the most apical extension of the gingival margin;
- probing depth (PD), measured from the gingival margin to the bottom of gingival sulcus;
- clinical attachment level (CAL), measured from the CEJ to the bottom of the gingival sulcus;
- keratinized tissue height (KTH): the distance between the gingival margin and mucogingival junction (MGJ). The MGJ was identified by means of Lugol staining.

All measurements were performed by means of the manual probe and were rounded up to the nearest millimeter

- gingival thickness (GT): determined 1,5mm apical to the gingival margin with a short needle for anaesthesia and a 3mm-diameter silicon disk stop.

1 PCP-UNC 15 probe tip, Hu Friedy, Chicago, IL, equipped with a Brodontic spring device (Dentramar, Waalwijk, Holland.

Gingival thickness was performed 1,5 mm apical from the gingival margin. The penetration depth was measured with a digital caliper accurate to the nearest 0,1mm^{9,14,20}.

Intrasurgical measurement

The depth of bone dehiscence (BD) was measured as the distance from the cemento-enamel junction (CEJ) to the most apical extension of buccal bone crest.

The thickness of the graft (CTGTa) was measured in both test and control groups just before being sutured after de-epithelialization and removal of fatty tissue when present. All measurements were made 1,5 apical to the coronal border with the digital caliper. The width (CTGW) (mesial-distal dimension) and the height (CTGH) (apical-coronal dimension) of the CTG were measured just before being sutured with the manual probe and rounded up to the nearest millimeter. Graft measurements were performed by a different examiner (CM) independent from the clinical

Patient morbidity

examiner.

Post-operative pain was indirectly evaluated on the basis of the mean assumption (in mg) of analgesics (ibuprofen)²⁵.

Patient's post-operative discomfort, bleeding, and inability to chew was evaluated with a questionnaire given to patients 1 week following surgery. Questionnaire included the evaluation of the intensity of the given event on a visual analogic scale (VAS) of 100mm^{7,8,27,28}. Discomfort was defined as the level of soreness/pain experienced by the patients during the first postoperative week due to the palatal wound. Bleeding was considered to be the prolonged hemorrhaging during the post-surgical week reported by the patients. Inability to chew was described as the level of variation of the patient's eating habits due to the presence of the palatal wound.

Patient Evaluation of Esthetics

Patient aesthetic satisfaction was evaluated at the 1 year follow-up visits based on a VAS. Patients were asked to select among 100 scores (0 indicating very bad, 50 average and 100 indicating excellent)^{7,8,27,28}.

Objective Evaluation of Esthetics

The objective evaluation of color match (blending), contour (correct outline of the gingival margin in adjacent teeth), contiguity (evaluated based on the visible confluence between the treated area and the adjacent soft tissues), and the degree of keloid formation was scored 1 year after surgery by an expert periodontist. He was independent of the clinical examiner and did not perform the surgeries. He was asked to rate the color match and contour among 100 VAS values (0 indicating very bad, 50 indicating average, and 100 indicating excellent); contiguity was rated as yes (visible confluence between the treated area and the adjacent soft tissues) or no (invisible confluence between the treated area and the adjacent soft tissues). Keloids were scored as absent or present¹.

Treatment of the root surfaces

Treatment of root surface was performed, prior to starting the surgery. The mechanical treatment terminated when a "smooth and hard" root surface was obtained. Chemical treatment of the instrumented root was performed by means of 24% EDTA gel maintained on the root surface for 2 minutes¹¹.

Fig. 1. Preoperative gingival recession in test (a,b) and control (c,d) group



Surgical Techniques

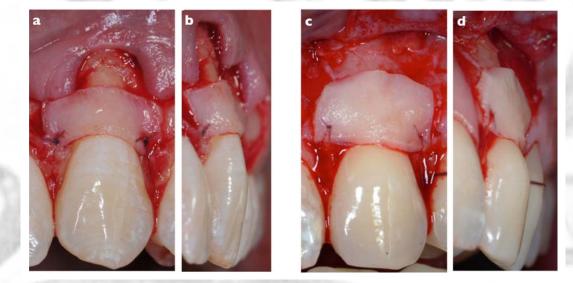
All surgeries were performed by the same expert periodontists (GZ). The surgeon was informed on which type of root coverage approach to perform (CAF or CAF+CTG), just after completing the treatment of the exposed root surfaces, by opening the envelope labelled with the patient's number which contained the treatment assigned. All gingival recessions were treated with the CAF¹⁰ with the adjunct of a CTG resulting from the de-epithelialization with the knife blade of a free gingival graft^{26,28}. The only difference between control and test groups resided in the height and thickness of the free gingival graft at time of harvesting.

Control group. The width of the free gingival graft was 6 mm greater than the width of the recession measured at the level of the CEJ. The height of the free graft was 1mm more than the BD. The thickness of the free gingival graft was >1mm.

Test group. The free gingival graft width was 6 mm greater than the width of the recession measured at the level of the CEJ. The height of the free graft was 4mm. The thickness of the graft, was ≤ 1 mm.

After de-epithelialization (under 4x magnification vision) with the 15c knife blade the CTG was positioned at the level of the CEJ and anchored at the base of the anatomic de-epithelialized papillae with two interrupted sutures (Fig 2). Care was taken to completely cover the graft with the CAF at time of suturing.

Fig. 2. Small and thin (a,b) and big and thick (c,d) graft positioned at the level of the CEJ and nchored at the base of the anatomic de-epithelialized papillae with two interrupted sutures.

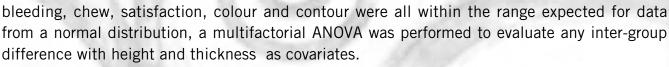


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Postsurgical instructions and infection control

Post-operative pain and edema were controlled with ibuprofen. Patients received 600-mg tablet at the beginning of the surgical procedure and were instructed to take another tablet 6 hours later. Subsequent doses were taken only if necessary to control pain. Plaque control in the surgically treated area was maintained by chlorhexidine rinsing. All patients were recalled for prophylaxis and reinforcement of motivation and instruction for a-traumatic tooth brushing technique 2 and 4 weeks after suture removal, once a month for the following 3 months and subsequently every 3 months until the final examination (1 year).

Fig.3 One year follow-up in test (a,b) and control (c,d) group. Complete root coverage was achieved.



The χ^2 test was used to compare the two groups with regard to contiguity and keloids as evaluated by the independent periodontist.

After controlling the standardized skewness and standardized kurtosis values for pain, discomfort,

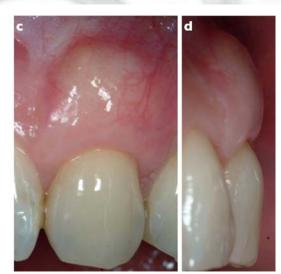
General linear models were fitted and multiple regression ANOVA for repeated measures with split plot design was used to evaluate the existence of any significant difference regarding RD, CAL, KT and GT between techniques (thin graft vs thick graft), time, and the interaction between techniques and time. In case of significance, Bonferroni t test was applied as a multiple comparison test.

Results

Data Analysis

Following the initial oral hygiene phase as well as at the post-treatment examinations, all subjects showed low frequencies of plaque harboring tooth surfaces (FMPS <15%) and bleeding gingival units (FMBS <15%), indicating good standard of supragingival plaque control during the study period. Healing was uneventful for all treated cases. Early (2 weeks) shrinkage of the covering flap with graft exposure occurred in 12 control and 4 test patients.

A comparison between baseline and 1 year clinical outcome of patients treated by means of the control and test bilaminar techniques are shown in Fig 1 and 3 respectively. The descriptive statistics for the clinical parameters measured at baseline and 1 year after surgery for both groups, as well as the mean differences within and between groups are shown in Table 1. At baseline, there were no statistically significant differences between the two groups for any of the



considered clinical parameters (F=.67 for RD; F=1.08 for PD and F=1.2 for KTH), indicating that the randomization process had been effective. In the control group the mean recession depth was $3,93 \pm 0.90$ (range 3-7mm). The mean PD was $1,16 \pm 0.37$ and the mean KTH was $1,13 \pm 0.73$. In the test group mean RD was $3,8 \pm 0.96$ (range 3-7mm). PD and KTH were $1,16 \pm 0.37$ and $1,33 \pm 0.71$ respectively.

PARAMETER mean ± sd	TEST GROUP CONTROL GROUP 3.8± 0.96 3.93± 0.9 0.13±0.34 0.13±0.34 3,6 ± 0,93 3,7 ± 1,05	
RD baseline 12 months difference		
PD baseline 12 months difference	1,16±0,37 1,33±0,47 0,16 ± 0,53	1,16±0,37 1,33±0,47 0,16 ± 0,53
CAL baseline 12 months difference	4,73±0,73 1,46±0,57 3,26 ±0,78	5,1±0,95 1,46±0,57 3,56 ±1,10
KT baseline 12 months difference	$ \begin{array}{cccc} 1,33\pm 0,71 & & 1,13\pm 0,73 \\ 3,5\pm 0,62 & & 3,63\pm 0,66 \\ 2,16\pm 0,59 & & 2,5\pm 0,71 \end{array} $	
GT baseline 12 months difference	0,75± 0,15 0,71± 0,13 1,47± 0,16 2,11± 0,17 0,71±0,11 1,39±0,13	

Table 1. Clinical Parameters	(mm; mean \pm SD) at Baseline and	12 Months Post-Surgery
	(initi, incan ± cb) at Baseline and	

Intra-surgical measurements (Table 2-3)

In the *control* group the mean thickness of the free gingival graft immediately after being harvested (CTGT) was 2.11 ± 0.18 mm (range 1.8-2.5mm). After de-epithelialization and removing the fatty and glandular tissues, the thickness of the CTG, at the time of suturing, (CTGTa) was 1.61 ± 0.16 mm (range 1.4-2mm). The mean height of the CTG (CTGH) was 6.43 ± 1.16 mm (range 5-9mm), while the mean width (CTGW) was 10.9 ± 0.71 mm (range 10-12mm).

In the *test* group the mean thickness of the free gingival graft was 1.10 ± 0.10 mm (range 1-1.3mm)(CTGT). The mean thickness of the CTG after de-epithelialization and removal of fatty tissue (CTGTa) was $0,73\pm 0.10$ mm (range 0.6-1mm). The mean CTGH was $3,8\pm 0.40$ mm (range 3-4mm), while the mean CTGW11,13 ± 0.81 mm (range 10-13mm).

A statistically significant difference between test and control groups in CTGT (F=1.5) and CTGH (F=1.3) while no difference in CTGW (F=0.2) were demonstrated.

PARAMETER	TEST	CONTROL
CTGT	1,10± 0,1	$2,11 \pm 0,18$
CTGTa	0,73±0,1 1,61±0,16	
СТСН	3,8±0,4 6,43±1.16	
CTGW	11.13± 0,81	10,9± 0,71

Table 2. Intra-surgical measurements (mm; mean ± SD)

Table 3. Patient and independent periodontist evaluation

	TEST	CONTROL	F	р
OBJECTIVE EVALUATION (1 year)				
COLOR (VAS mm)	79 ±10,2 (60-100)	72,6±11,7 (60-100)	4,9	<0,05
CONTOUR (VAS mm)	83,6± 11,2 (60-100)	79,6±10,9 (60-100)	1,94	NS
CONTIGUITY (YES/NO)	0,36±0,49	0.5±0.5	1	NS
KELOID (YES/NO)	0,26± 0,44	0,43±0,5	1	NS
PATIENT EVALUATION				
SATISFACTION (VAS mm)(1 yr)	84,3±9,71 (70-100)	79,3±17,2 (60-100)	0,52	NS
DISCOMFORT (VAS mm) (1 week)	37,6±10,4 (0-50)	44,6±23.8 (0-80)	12,7	<0,01
PAIN (N TBT ASSUMPTION) (1 week)	1,83 (0-5)	4,2 (0-8)	16,3	<0,01
BLEEDING (VAS mm) (1 week)	20,6±18,1 (0-60)	34,0±21,9 (0-80)	6,6	<0,05
CHEWING (VAS mm) (1 week)	28,3±21,0 (0-60)	48,6±23,1 (0-80)	12,7	<0,05

Significance was obtained from multifactorial Anova statistical analysis.

The results from multifactorial ANOVA showed significant between-group differences as regards (Table 3):

-pain (F=16.3; p<.01) with a significant contribution of height (F= 4.1, p<.05) and thickness (F=11.0; p<.01)

-discomfort (F=12.7; p<.01) with a significant contribution of thickness (F=4.6; p<.05) -bleeding (F=6.6; p<.02)

-chew (F=12.7; p<.01) with a significant contribution of thickness (F=4.4; p<.05) -colour (F=4.9; p<.05)

No significant between-group differences were found as regards satisfaction (F=.52; NS) or contour (F=1.94; NS)

The results from χ^2 test did not show any significant between-group difference as regards contiguity ($\chi^2 1.1$) and keloid ($\chi^2 1.8$).

The results of fitting a general linear statistical model relating GT to techniques, time, and the interaction between techniques and time, showed a significant relationship regarding time (F=399.3; p<.01), regarding the type of technique used (F=324.7; p<.01), and regarding the interaction between techniques and time (F=399.7; p<.01).

Concerning RD, CAL and KT, the results of fitting a general linear statistical model did not show any significant relationship regarding the type of technique but only regarding the time-related

changes (F=942.2; p<.01 regarding RD, F=814.5; p<.01 regarding CAL, and F=738.2; p<.01 regarding KT).

Both procedures resulted in the same percentage of root coverage and complete root coverage.

Discussion

Sub-epithelial connective tissue graft has been demonstrated the most predictable root coverage surgical technique. Very few studies have measured the size of the CTG to be used in combination with the CAF and tried to reduce it. Attempts have been made to improve the palatal healing and to decrease patient morbidity by introducing first¹² and then modifying^{13,16} primary intention healing connective tissue harvesting techniques. Nevertheless no affords have been made to reduce the size and thickness of the palatal withdrawal despite the clinical experience and, more recently, also a randomized clinical trial have indicated that post-operative patient pain and discomfort are primarily related to the apical-coronal dimension and depth of the palatal withdrawal²⁸.

The purpose of the present study was to compare 4mm- high and <1mm-thick CTG with CTG thicker than 1mm and extended until the buccal bone crest in association with the CAF in the treatment of gingival recession equal or deeper than 3mm. The present study demonstrated that equally effective root coverage results, both in terms of mean percentage and complete root coverage, while clinically and statistically significant less painful and more comfortable post operative course can be expected by using CTG of reduced thickness (<1mm) and height, compared to the bone dehiscence.

Furthermore better esthetic results as judged by an expert periodontist in terms of color and contiguity and keloid formation were reported for the smaller CTG. These differences could be ascribed to the greater tendency of bigger graft to expose during the healing process. The reduced thickness and height of the graft allowed to minimize the obstacle hindering the blood supply from the receiving connective tissue bed to the covering CAF. During the first healing phase, in fact, the CTG represents an obstacle to the nutritional exchanges between the periosteal beds lateral and apical to the bone dehiscence and the coronally advanced covering flap. The bigger and thicker the graft, the greater the obstacle and the greater the risk of covering flap dehiscence and consequently graft exposure. This is confirmed by the present data, which indicated a higher percentage (40%) of flap dehiscence in the control with respect to the test (13%) group. When the CTG is exposed, it rapidly becomes covered by a keratinized epithelium and its color and texture becomes similar to that of the patient's palate. The consequence of this is a poor camouflaging of the treated area with respect to the adjacent soft tissues. Surprisingly in the present study the difference in the healing patterns between groups influenced the esthetic evaluation made by an expert periodontist but not that one made by the patient. This is in contrast with what reported in a previous study²⁶ in which patient esthetic assessment varied between groups with different size of the CTG. The absence of difference in patient evaluations in the present study may be ascribed to the lower percentage of graft exposure even in the control group or to the different study design (split-mouth vs parallel) might have played a critical role in determining patient esthetic evaluation of the post-operative outcome. The great stability of sub-epithelial CTG was demonstrated by the present study data that have shown, that despite an overall greater increase in GT in the control group, no difference between the CTGT at time of suturing and GT increase at 1 year was reported in the test group, indicating that almost all the thickness of the grafted connective tissue was transformed in buccal GT. Conversely in the control group 0.21mm corresponding to 13% of the thickness of CTG at time of suturing did not became buccal GT at 1 year. It can be speculated that thicker CTG contain more loose connective tissue that is more prone to resorption during the healing period. Long term studies are advocated to demonstrated

that the increase in GT obtained with thin graft is adequate enough to prevent recurrence of gingival recession.

Conclusions

Within the limits of the present study the following conclusions can be drawn:

- Equally effective root coverage results, both in terms of mean percentage and complete root coverage, can be accomplished by using CTG of reduced thickness (<1mm) and height, compared to the bone dehiscence.
- Greater KTH and GT increase was achieved when thicker and bigger CTG were used. No difference between CTGT and 1year GT increase was obtained in the test treated sites indicating great stability of the thin (<1mm) de-epithelialized graft.
- Statistically significant less painful and more conformable post operative course can be expected with the use of CTG of reduced size and thickness
- Patient satisfaction with aesthetic was very high for both treatment groups with no difference between them.

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