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## RESEARCH ARTICLE

# A COMPARATIVE STUDY ON THE EFFICACY OF A COMMERCIAL FIBRIN ADHESIVE (TISSEEL) AS ALTERNATIVE TO SILK SUTURES IN THE TREATMENT OF GINGIVAL RECESSION

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**ABSTRACT**

**Aim:** The purpose of the study was to clinically evaluate and compare the efficacy of human fibrin sealant (Tisseel®) with non-absorbable surgical suture in the treatment of localized gingival recession.
**Methods:** The study population consisted of 30 identical gingival recession defects. The selected gingival recession sites were randomly assigned either to 1) Control site A(lateral pedicle flap with suture) or 2) Test site B(lateral pedicle flap with Tisseel®). The clinical parameters plaque index, gingival index, recession width, width of keratinizedgingiva, and recession depth were recorded at baseline 7, 30 day postoperatively. Clinical attachment level were recorded only at baseline and 1 months post-operatively.
**Results:** At 1 month the recession width and depth were reduced in both the groups (Control site A & Test site B) with mean root coverage of 34% and 47%respectively.On intergroup comparison, the mean difference in different clinical parameters was statistically not significant.
**Conclusion:** Both groups showed the potential of achieving root coverage; however on comparison between the two groups, the results obtained of lateral pedicle with Tisseel group were slightly better although statistically not significant.



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## INTRODUCTION

"Gingival recession" is the exposure of root surface due to apical migration of gingival margins (Michael *et al.,* 2006). It may result in the root exposure on the labial or lingual surface of a single tooth or multi rooted tooth (Smuckler, 1976). When the recession extends to or through the muco gingival line, it causes a break in the continuity of the attached gingiva and a localized shall owing of the vestibular fornix. The predominant cause for localized gingival recessions in populations maintaining high standards of oral hygiene is tooth brushing trauma. In contrast, all tooth surfaces are usually affected with soft tissue recession in periodontally untreated populations due to loss of attachment. Other causes of gingival recession include, labially/buccaly positioned teeth, frenal and muscle attachments that encroach on marginal gingiva and orthodontic tooth movement through a thin buccal osseous plate. Many patients seek treatment because of concerns with esthetic appearance, root sensitivity or fear of early loss of the affected teeth. However, other complications that can arise are root caries and tooth discoloration. Marginal tissue recession is a common feature in populations with high standards of oral hygiene as well as in populations with poor oral hygiene. It is generally held that the surgical treatment of these defects and associated mucogingival problems may best be accomplished by the reestablishment of functional zone of attached gingival (Friedman, 1957). Grupe & Warren were the first to describe the sliding flap as a method to repair isolated gingival defects (1956). Sutures plays an important role in mucogingival surgeries, & previous reports shows that placement of sutures sometimes leads to inflammation around themselves &also accumulate food & plaque, suturing provides only marginal fixation & provides mechanical stress such as trauma to the flap & also requires special skills. One of the first reported uses of fibrin as a biomaterial was in 1909 when it was used as a degradable hemostatic agent (Young, 1940). Fibrinogen was first reported as an adhesive material in 1940, when it was used to anastamose experimentally severed sciatic nerves in rabbits (Cronkite *et al.,* 1944). The desire for an agent which will produce a bios table union between tissue planes has led to the development of tissue adhesive, fibrin sealant ie, TISSUCOL. This biological two-component system (FFSS), which acts by forming fibrin clot, is able to achieve hemostasis, seal leakages, glue tissues or support sutures (Trombelli *et al.,* 1995). In the past decade studies were done to compare the efficacy of human fibrin sealants with sutures in various surgical procedures such as using sub epithelial connective tissue graft & modified widman flap procedure & coronally

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positioned flap procedure. Sowe have done the study on to compare the efficacy of human fibrin sealant with suture bylateral pedicle flap procedure. The purpose of the study was "to compare the clinical efficacy of human fibrin sealants with non absorbable surgical sutures in the treatment of localized gingival recession-a clinical study".

## MATERIALS AND METHODS

A total of 15 patients in the age group of 20-40 years subjects in this study were selected from the outpatient department of periodontics, college of dental science advancer. The study design was a split mouth and total of 30 teeth from 15 patients with localized gingival recession were enrolled for the present study. Patients were made aware of the procedure and the purpose of the study and prior informed consent was obtained. Inclusion criteria in this study were i. Patients with age group between 20-40 years. ii. Presence of periodontal diseases like localized periodontitis in the anterior maxilla and mandible. iii. Subjects having bilateral identical gingival recession defects, labially / buccally as evaluated according to the Miller's index 1985.Exclusion criteria in this study were subjects with systemic diseases, Patient with known allergic response, Smokers, Pregnant or lactating women, Patients who had periodontal therapy for the past 6months, those undergoing radiation therapy, Presence of cervical abrasion, erosion or root caries that would require Restoration.

All the patients were subjected to phase 1 therapy and detailed instructions regarding self performed plaque control measures and instructions to eliminate habits related to the etiology of gingival recession defects and to improve gingival health were given. Trauma from occlusion if detected was eliminated. At the end only those patients demonstrating the acceptable oral hygiene standards and gingival health were considered for the present study. Before recording the baseline data alginate impressions were made and study casts were prepared for each patient. A customized acrylic stent was fabricated for each patients tofit it over the selected sites. A groove was made on the stent corresponding to the test site to guide the position and angulation of periodontal probe during the clinical measurements at baseline and the subsequent follow up visits
Clinical parameters: The clinical parameters assessed were Recession depth, Recession width (Guinard *et al.,* 1958) and Percentage of Root coverage [Recession depth(preoperative - postoperative) X 100/Recession depth preoperative.]

The parameters like recession depth were measured on Mid-facial surface with the help of occlusal stent (with guiding grooves) and the William's periodontal probe. Grooves (guide plane), were made on the stent in relation to each involved surface toguide the periodontal probe while taking measurements. This technique provided a fixed reference point and fixed angulation for measurements at each site at different time intervals. All the customized acrylic stents were stored on the prepared study casts throughout the study period to minimize their distortion. All the above clinical parameters except the clinical attachment level were recorded at the baseline, 7 days and 1 month postoperatively.

The technique used was a split mouth design. The selected recession defects we reassigned randomly either to Control site A or Test site B as follows:

- CONTROL site. A: 15 sites were treated with lateral pedicle flap procedure (Fig 1and 2).
- TEST site. B: 15 sites were treated with fibrin-fibronectin sealing system (Tisseel)with lateral pedicle flap procedure (Fig 3,4,5,6,7and 8).

Treatment of Control Site A: LATERALLY POSITIONED FLAP (Originally described by Grupe & Warren in 1956.[4] as a laterally sliding flap) with sutures.

Treatment of Test Site B: Laterally positioned flap (Originally described by Grupe & Warren in 1956.6 as a laterally sliding flap) with Tisseel (adhesive agent) as applied by manufacturer guidelines. Composition of Fibrin–fibronectin sealing system (Tissucol®/Tisseel) system (Bartolucci *et al.,* 1982): The Fibrin adhesive system (FAS) used in this study was BAXTER TISSEEL KIT. 1.0ml, two component fibrin sealant manufactured by BAXTER AG, Vienna, Austria &Imported & marketed in India by BAXTER (India) Pvt. Ltd, Gurgaon (Fig 9). This tissue adhesive is a two component fibrin adhesive.[9] The first component is prepared by mixing Tisseel and aprotinin and the second component by mixing thrombin and calcium chloride. Either thrombin 4 or thrombin 500 can be used. Thrombin 4 causes slow solidification of the FAS (within a minute) whereas thrombin500 causes quick solidification (within seconds).The first and second components are in turn mixed with each other and applied to thetissues.

Storage: Before use, the Tisseel® kit was stored between +2° c to +8° c. Kit for reconstitution and application of the two components contains the DUPLOJECT ® application System. It contains disposable syringes (blue and black scaled), hypodermic disposable needles, duploject, joining piece and application needles.

On 7th day following surgery, the periodontal dressing was removed and the area was thoroughly irrigated with saline. Any signs of swelling, infection, flap displacement, haematoma and necrosis were noted and the re-dressing was done for another week (if necessary). Symptoms regarding discomfort, pain and sensitivity were asked to the patient. Recall appointments were made after a month post-surgery and at each visit, oral hygiene instructions were reinforced and scaling was done whenever necessary. Patients were advised for chlorhexidine mouth rinse twice daily for another 3 weeks.

## RESULTS

All the clinical parameters recorded were subjected to the following statistical analysis: 1) For intragroup variations, Paired t-test was performed. 2) For comparison between the two groups / inter-group variations Unpaired t-test was performed.

Recession Depth: (Table 1)

In control Site the mean recession depth at at baseline was 7.4 ±1.40 mm which was reduced to 5.2 ± 2.24 mm at 1 week and at 1 month, the recession depth was reduced to 5 ± .392 mm, which was statistically highly significant ($P<0.001$). In test Site B mean recession depth at baseline was 7.2 ±2.6 mm which was reduced to 3.4 ± 2.8 mm at 1 week At 1 month, the recession depth was reduced to 3.2 ± 2.7 mm, which was statistically highly significant ($P<0.001$). On comparison of the

mean reduction of recession depth between the two groups at baseline, 1 week and 1 month revealed a difference of 0.13 mm, 1.7 mm and 1.6 mm respectively, which were statistically not significant.

Recession Width: (Table 2)

**Table 1. Mean reduction in Recession Depth (in mm):**

| Time of assesment | Control Site A ( with sutures ) | | | | Test Site B ( with sealant ) | | | | Site a vs site b | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean ± sd | Diff from base line | % difference | T* P | Mean ± sd | Diff from base line | % difference | T* p | Mean difference | T** | P |
| Baseline | 7.4 ± 1.40 | - | - | - | 7.2 ± 2.6 | - | - | - | .13 | .175 | .86 NS |
| 1 week | 5.2 ± 2.24 | 2.2 ± 2.07 | 29.72 | .001 HS | 3.4 ± 2.8 | 3.8 ± 3.4 | 52.77 | .001 HS | 1.7 | 1.84 | .07 NS |
| 1 month | 5 ± .392 | 2.4± 2.09 | 32.43 | .001 HS | 3.2± 2.7 | 3.9 ± 3.4 | 55.55 | .001 HS | 1.6 | 1.81 | .08 NS |

*Paired t-test (Intragroup comparisons); **Unpaired t-test (Intergroup comparisons); P<0.001 Highly significant (Hs); P <0.05, P <0.01, Significant (S); P >0.05, Not singnificant (NS)

**Table 2. Mean reduction in Recession Width (in mm)**

| Time of assesment | Control Site A ( with sutures ) | | | | Test Site B ( with sealant ) | | | | Site a vs site b | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean ± sd | Diff from base line | % difference | T* P | Mean ± sd | Diff from base line | % difference | T* P | Mean difference | T** | P |
| Baseline | 3.60 ± .828 | - | - | - | 3.27 ± .70 | - | - | - | .333 | 1.18 | 0.245 NS |
| 1 week | 2.53 ± 1.30 | 1.06 ± .961 | 30.55 | 0.001 HS | 1.93 ± 1.33 | 1.33± 1.11 | 39.68 | 0.000 HS | .600 | 1.24 | 0.223 NS |
| 1 month | 2.33 ± 1.54 | 1.26 ±1.23 | 36.11 | 0.001 HS | 1.80 ± 1.42 | 1.46± 1.18 | 43.75 | 0.000 HS | .533 | .984 | 0.334 NS |

*Paired t-test (Intragroup comparisons); **Unpaired t-test (Intergroup comparisons); P<0.001 Highly significant (Hs); P <0.05, P <0.01, Significant (S); P >0.05, Not singnificant (NS)

In control Site the mean recession width at baseline was 3.60 ± 0.82 mm, which reduced to 2.53 ± 1.80 mm at 1 week. At 1month, the recession width was reduced to 1.06 ± .961 mm, which was also statistically highly significant (P<0.001). In test Site B the mean recession width at baseline was 3.27 ± 0.70 mm, which reduced to 1.93 ± 1.33 mm at 1 week. At 1 month, the recession width was reduced to 1.80 ± 1.42 mm, which was also statistically highly significant (P<0.001).On comparison of mean reduction in recession width between the two groups at baseline, 1 week and 1 month showed the mean difference of reduction in recession width of 0.33 mm, 0.60 mm and 0.53 mm respectively, which were statistically not significant.

Percentage of Root Coverage: (Table: 3)

**Table 3 Percentage Root Coverage (in mm)**

| | Control Site A( with sutures ) | Test Site B( with sealant ) | Difference between site a & b | t-value | p- value |
|---|---|---|---|---|---|
| Mean sd | 34.45 ± 31.8 | 46.39 ± 35.6 | 11.94 % | 0.967 | 0.342 NS |
| Range | 30 -100% | 40 – 100% | | | |

*Paired t-test (Intragroup comparisons); **Unpaired t-test (Intergroup comparisons); P<0.001 Highly significant (Hs); P <0.05, P <0.01, Significant (S); P >0.05, Not singnificant (NS)

In Control Site A the range of root coverage was 30 -100% and mean root coverage achieved was 34.45 ± 31.8 at 1 month. In test Site B the range of root coverage was 40 -100% and mean root coverage achieved was 46.39 ± 35 at 1 month. On comparison between the two groups at 1 month revealed a statistically non significant result (P>0.34).

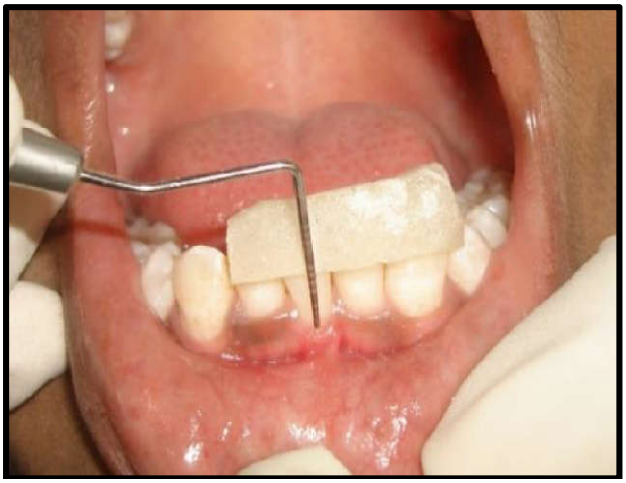

**Fig. 1. Pre OP(control site A)**

**Fig. 2. Post Op (control site A)**

**Fig. 3. Pre Op recession height**

**Fig. 4. Pedicle Transferred**

**Fig. 5. Tisseel Placed Beneath Flap**

**Fig. 6. Stabilised Pedicle After Tisseel Application**

**Fig. 7. 1 Week Post Op**

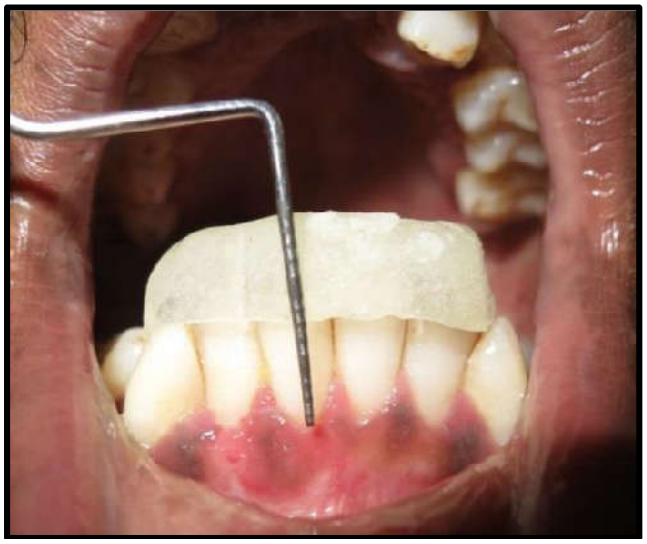

**Fig. 8. 1 Month Post Op**


**Fig. 9. Tisseel Kit**

## DISCUSSION

Periodontists have used soft tissue grafts to correct the mucogingival defects, for decades. Since many century, different techniques have been developed to cover the denuded roots. One of the acceptable technique used for root coverage is the lateral pedicle tissue graft (lpf). The development lateral pedicle tissue graft has enhanced our ability to restore the gingival form and function. The success of the lateral pedicle tissue graft is attributed to the blood supply at the recipient site and in the present study, root preparation included scaling &root planning was done (Guinard and Caffesse, 1978). There are isolated case reports and clinical studies wherein suturing was used along with lateral pedicle graft for the treatment of gingival recession defects (Guinard and Caffesse, 1978). In another study, the fibrin sealant product along with sutures is used in the treatment of shallow recession defects (Nalini Jain *et al.,* 2014). The results in both the studies were encouraging. However, no long term clinical trials have been reported in the literature using fibrin sealant alone in the treatment of gingival recession. Hence, the present study was undertaken using fibrin sealant, for the treatment of localized gingival recession and achieving the root coverage. Commercially available tissue adhesives like TISSEEL contains concentrated fibrinogen, fibronectin and factor XIII and have been used to enhance the wound healing and to promote an early and stable bond between the mucogingival flap and the exposed root surface. Fibrin and factor XIII are known to promote fibroblast adhesion and multiplication. Tissue adhesives have been shown to provide early wound strength due to increased fibroblast growth and enhanced collagen production. Fibrin sealant was first used to fix periodontal flaps and grafts in 1982 (Nalini Jain, 2014). Later, the fibrin –fibronectin sealing system was used with guided tissue regeneration (Matras, 1985) in the treatment of gingival recession. It was used with lateral pedicle flap to treat gingival recession defects.44&, recently it was used along with guided tissue regeneration to treat periodontal defects & gingival recession, in experimental animals (Dogan *et al.,* 1992).

Hence, the purpose of this study was to compare the clinical efficacy of human fibrin sealants with non absorbable surgical sutures in the treatment of localized gingival recession-a clinical study. In the present study, only those patients were considered for periodontal surgery who showed good oral hygiene maintenance after the Phase-I therapy. The recession depth (RD) and recession width (RW) are the two important clinical parameters in the study of gingival recession treatment. Reduction in the mean RW and RD will result into root coverage and restoration of esthetics. In the present study, the mean recession depth (RD) and recession width (RW) on all the mid-facial surface was significantly ($P<0.001$) reduced in both the experimental groups when the baseline RD &RW were compared with the 1 month post-operative values. However when the mean RD of Control Site A and Test Site B were compared, the mean difference was statistically not significant. Similar trend was observed in other studies where in suturing & fibrinfibronectin system was used for the root coverage procedure. In the present randomized clinical study, the mean root coverage (RC) observed for the Control Site A was 34.45% showing a range of 30% - 100%. However, the root coverage was further improved to 46.39% (in the range of 40-100%) for Test Site B. The previous clinical studies reported the root coverage between 34% and 82% which falls well within the range shown in our study (Nourudeen Anie, 2013). The predictability of the lateral pedicle graft procedure is excellent. The main advantages are single surgical site, Good vascularity of the pedicle flap, Post operative color is in harmony with the surrounding tissue. Disadvantages are limited by the amount of adjacent keratinized attached gingiva, Possibility of recession at the donor site, Limited to one or two teeth with recession. The promising results obtained with the application of FFSS on LPG can be explained by the fact that the fibrin contains factors such as thrombin, fibrin, fibronectin and platelet derived growth factor, which are known to retain their biologic activities on cell proliferation and differentiation during wound healing. These factors potentially enhance the wound healing and regeneration of new tissues.

Barbosa M, Gregh S, *et al* in 2010 compared wound healing after the use of fibrin sealant and sutures for gum surgeries concluded that the usage of Fibrin sealant resulted in less inflammation as compared to the use of sutures (Barbosa *et al.,* 2010). A clinical study was carried out in localized periodontitis patients by Manimegalai *et al* in 2010, results showed that fibrin adhesive sealant (TISSEEL) was superior in all the parameters measured, i.e, haemostasis, fixation of tissues, reduction in plaque and gingival index and probing depth postoperatively and concluded that periodontal surgery using FAS enhances various periodontal regenerative surgical procedures (Manimegalai, 2010). Nalini Jain, *et al* done case report on a patient with class 1 recession defect in mandibular incisor region. Using Lateral pedicel graft along with FFSS (Fibrin Fibronectin Sealing System) was used to and One month postoperative results showed complete root coverage thus showing that addition of FFSS improved the amount of root coverage, especially in relatively Shallow defects (Nalini Jain *et al.,* 2014). In this study no post-operative complications other than those considered normal, following any surgical procedure either at the recipient or donor site were noticed. Also, no antigenic reactions were observed in any of the patients thereby, indicating the safety of Tisseel® and the human thrombin used for activation. Hence, the advent and use of this material represents a novel approach in the mucogingival therapy.

### Conclusion

Both groups showed the potential of achieving root coverage, however on comparison between the two groups, the results obtained of lateral pedicle with Tisseel group were slightly better although was statistically not significant. Tisseel has ideal bio-adhesive qualities for fixing of flaps& easier & quicker to use. Tisseel lessens the surgical time considerably and provides early hemostasis.

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