

## Research Article

# Efficacy of Self-Filling Osmotic Tissue Expander in Augmenting Keratinized Tissue around Dentulous Region: Case Report

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## Abstract

**Background and objectives:** Tissue expansion has revolutionized plastic surgery in the last 30 years. Till date, to the best of our knowledge, no clinical trials have employed Self-Filling Osmotic Tissue Expanders (STE) to investigate the possibility of gaining soft tissue volume in the dentulous area. Hence, the present prospective, randomised controlled clinical trial was performed to explore the feasibility and efficacy of self-inflating hydrogel expander (Osmed®) to gain soft tissue volume around the dentulous area. Further, to evaluate its clinical possibility to increase vestibular depth and obtain root coverage.

**Materials and methods:** Ten healthy individuals satisfying the inclusion and exclusion criteria were recruited for the study. All the patients were implanted with STE in subperiosteal positions using the pouch technique in the mandibular anterior region. The clinical parameters (keratinized tissue width, vestibular depth, keratinized tissue thickness, gingival recession depth) were recorded at baseline; two weeks post expander retrieval, three months and six months post-operatively.

**Results:** Surgeries and post-operative sequelae were uneventful without any expander related complications. The clinical parameters did not demonstrate statistically significant differences from baseline to six months post-operatively. Optical scanning revealed significant gain in tissue thickness measured after expander retrieval which, however, gradually decreased at six months post-operatively.

**Conclusion:** Within the limits of this exploratory clinical study, it can be concluded that Osmed® STE proved to be ineffective in achieving significant gain in the keratinized tissue.

**Keywords:** Soft tissue augmentation; Soft tissue expander; Hydrogel; Keratinized tissue; Gingival augmentation

## Abbreviations

AAc: Acrylic acid; AAm: Acrylamide; AAP: American Academy of Periodontology; ADM: Acellular Dermal Matrix; AGG: Autogenous Gingival Graft; ASPRS: American Society of Plastic and Reconstructive Surgeons; BCM: Bilayer Collagen Matrix; BCT: Bilayered Cell Therapy; CBCT: Cone Beam Computed Tomography; CCD: Charged Coupled Device; CEJ: Cemento-enamel Junction; CMM: Coordinate Measuring Machine; DM: Diabetes Mellitus; ECM: Extracellular Matrix Membrane; FGG: Free Gingival Autograft; GBR: Guided Bone Regeneration; GI: Gingival Index; GR: Gingival Recession; HG: Hydrogel; KT: Keratinized Tissue; KTT: Keratinized Tissue Thickness; KTW: Keratinized Tissue Width

## Introduction

The attached keratinized gingiva is a dense, collagenous

connective tissue firmly linked to the underlying alveolar bone and root surface [1]. An adequate zone of attached gingiva shields the periodontium from injury caused by frictional forces encountered during mastication and dissipates the pull on the gingival margin created by the muscles of the adjacent alveolar mucosa [2]. Moreover, an “inadequate” zone of gingiva can promote subgingival plaque formation because of the improper pocket closure resulting from the movability of the marginal tissue and favour attachment loss and soft tissue recession because of less tissue resistance to apical spread of plaque-associated gingival lesions [3].

The importance of a functional and healthy mucogingival complex to underlying osseous stability around teeth is perceptible by the increasing attention given to soft tissue augmentation procedures in clinical practice, although minimum width requirements of this tissue type remain controversial [4].

Traditionally, soft tissue augmentation with autogenous grafts has been widely used in dentate as well as edentulous patients to augment areas with a lack of or a reduced width of Keratinized Tissue (KT), as well as to increase soft tissue volume [5]. Autogenous gingival grafts are still considered to be the gold standard procedure with unmatched success rates and clinical success [4]. However, the pitfalls of using autogenous tissue are mainly due to the harvesting procedure, which leads to a prolonged healing time at the donor site and therefore to an increased patient's morbidity [5]. Patients often complain about pain and numbness for several weeks after the surgery [5]. On the other hand, anatomical and individual limitations exist [5]. Depending on the shape of the palatal vault, the patient's sex and age, the quantity and quality of tissue that can be retrieved varies [5]. Thus, these stumbling blocks continue to spur interest for less-invasive alternatives.

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In this regard, augmentation of soft tissue volume with expander has been proposed as a novel alternative treatment modality. There are several soft tissue expanders and one such expander is the Self-filling Osmotic Expander (SOE). It consists of a polymer of methyl methacrylate and vinylpyrrolidone ensheathed with silicone shell containing multiple perforations and expand due to absorption of body fluids; while the rate of influx overtime is controlled by the number of perforations [6,7]. They have been successfully used to treat difficult anterior palatal fistulas, cleft palate patients, congenital nasal hypoplasia patients, scalp reconstructions and congenital nevi reconstructions [8-10]. Its application has also been seen in edentulous ridges for the antecedent improvement of soft tissue quality and quantity for graft coverage prior to the placement of implants [11-14].

Hence, we consider SOE could also be used as an alternative promising technique to increase the keratinized gingiva around dentulous area. Till date, no studies have explored this role and are divulged in the literature. Thus, the purpose of this study is to investigate the efficiency of SOE in the augmentation of keratinised tissue around the dentulous region.

## Material and Methods

### Source of data

Ten healthy adult patients in the age range of 25-40 years were selected for the study from the outpatient section of the Department of Periodontology, Krishnadevaraya College of Dental Sciences, and Bengaluru. Patients were recruited from among those exhibiting inadequate keratinized tissue in the mandibular anterior region. The study was conducted from November 2016 to June 2018. Patients willing to participate in the study with above 18 years of age [11], patients exhibiting keratinized tissue width <2 mm [15], patients manifesting Miller's Class I or Class II recession, Systemically healthy patients [11], patients who demonstrate good plaque control (PI<10%) and showing good compliance and uncompromised adjacent teeth with healthy gingival conditions were included in the study whereas, patients with untreated periodontal disease, caries [12,16], insufficient oral hygiene, thin biotype (<0.8 mm), use of tobacco [16], previous radiation therapy [12], patients with known systemic diseases and conditions as uncontrolled diabetes mellitus or haemorrhagic disorders [12], pregnant and lactating women and non-compliant patients were excluded.

### Study design

The design of this study is a unicenter, prospective, randomised controlled clinical trial according to the Consolidated Standards of Reporting Trials (CONSORT) criteria, 2010. The study was conducted in accordance with the declared ethical principles of the World Medical Association Declaration of Helsinki, version VI, 2002) and was approved by the Ethical committee of Krishnadevaraya College of Dental Sciences, affiliated to the Rajiv Gandhi University of Health Sciences. All eligible subjects who volunteered were informed of the nature, potential risks and benefits of their participation in the study and a signed informed consent was obtained from them at the beginning of the study.

### Intra-examiner calibration for periodontal examination

Intra-examiner calibration exercise for clinical parameters was performed on five patients for before the commencement of the actual study. The recording for clinical parameters was conducted at 1 week interval. The order of patients was changed in between the examinations. The periodontal probing depth estimation as judged

to be reproducible if the intra examiner agreement within  $\pm 1$  mm between repeated measurements was at least 80%. The kappa value for intra-examiner agreement between the two measurements was recorded to be 0.9.

### Clinical measurements

One single-blinded and calibrated examiner recorded all the clinical outcome variables at baseline, two weeks post-retrieval, three months and six months visits. All the measurements were recorded using a customised acrylic stents, which were prepared on the study model of the patients.

The following clinical parameters were assessed in millimeters using the customised acrylic stent and University of North Carolina-15\* (UNC-15) periodontal probe.

**Apico-coronal width of keratinized tissue (KTW):** Measured from the most apical gingival margin to the mucogingival junction (MGJ) [17].

**Vestibular depth (VD):** Measured from Cemento-Enamel Junction (CEJ) to the deepest part of vestibular mucosa and the measurements were taken with the UNC-15 probe [18].

**Keratinized tissue thickness (KTT):** a) Clinical - measured at the mid-buccal aspect of the study tooth just below the marginal gingiva using an endodontic file [19].

b) Optical scanning for volumetric analysis of tissue thickness - alginate impressions were made at the baseline prior to expander placement, immediately after the removal of expander and 6 months post-augmentation. The prepared casts were assessed for soft tissue changes by optical scan using 3D camera (Intellidenta AG, Basel, Switzerland). The obtained digital images of the casts reflecting the different treatment time were then superimposed and matched in one common coordinate system. The buccal surfaces of the study teeth were used as a reference point for the superimposition of different images. Subsequently, defined areas of interest at each site were measured and the difference in the linear distance between the time points was calculated [20].

**Level of gingival margin:** Measured at the mid-buccal aspect of the study tooth from the CEJ to the most apical extension of gingival margin (using UNC-15 probe).

**Color and texture match to the surrounding tissue:** Binary ratings of "equal or not equal to surrounding native tissue" assigned upon clinical examination.

**Plaque index [21] (PI) (Silness and Loe, 1964)**

**Gingival index [22] (GI) (Loe and Silness 1963)**

### Pre-surgical procedures

Initial therapy included scaling and root planning which was completed one month prior to the surgical procedure. The patients were re-examined 2-4 weeks after phase I therapy and subjected to surgical procedure accordingly. The patients who demonstrated  $\leq 20\%$  O'Leary plaque index were subjected to the study protocol. One week before the surgery, baseline clinical measurements were recorded using a standardised acrylic stent fabricated on study cast and UNC-15 probe.

### Implantation of tissue expander

The appropriate expander type and size (round-ended cylinders

with 0.24 ml final volume, Osmed®†) (Figures 1 and 2) were selected for the sites using a specific surgical template corresponding to the initial and final volumes of the expander. The patients were prescribed Amoxicillin (500 mg) 3 times a day for 5 days starting 1 hr before surgery on the day of expander placement (Figure 3).



Figure 1: Surgical template.



Figure 2: Osmed® self-inflating hydrogel expander (0.24 ml).



Figure 3: Gingival recession depth.

a) Gingival recession depth at baseline (2 mm) b) Gingival recession depth at 2 weeks (2 mm) c) Gingival recession depth at 3 months (3mm) d) Gingival recession depth at 6months (3 mm).

1. The patients were instructed to rinse with 0.2% chlorhexidine mouthwash for 30 seconds prior to surgical procedure.

2. Local anaesthesia was obtained using 2.0% lignocaine HCl containing 1:80000 adrenaline‡ using bilateral mental nerve blocks.

3. A small vertical incision, adapted to the diameter of the hydrogel expander, was made with #15 scalpel blade at the mesial line angle of the adjacent tooth which started below the gingival margin extending from the keratinized tissue above the MGJ to the non-keratinized tissue beyond the MGJ (Figure 4A).

†Hu-Friedy, Chicago, IL, USA.

4. A minimally invasive preparation of a subperiosteal pouch was performed with KPA tunnelling knife§ (Figure 4B). The size of the pouch was controlled with the specific surgical template\*\* to ensure the device easily fits into the prepared pouch without tension (Figure 1). Further, it was ensured that the pouch dimensions corresponded to the final expander volume of 0.25 ml (length-12 mm mesio-distally and diameter of 6 mm) (Figure 4C).

5. The expander was handled carefully by holding its flat end with a tweezer. To prevent any dislocation or potential migration, expanders were secured in the correct position with a bone fixation screw, at the flat end, which does not possess an expansion capability (Figures 4D and F).

6. The wound was closed with 3-0 silk suture using simple interrupted sutures.

### Post-operative instructions

Post-operative analgesics (Diclofenac sodium 50 mg thrice a day) and antibiotics (Amoxicillin 500 mg three times a day) were prescribed for a period of 5 days and 0.2% chlorhexidine mouth wash was prescribed for 2 weeks until retrieval of the expander. Patients were asked to abstain from smoking during the healing period and sutures were removed 10 days after expander insertion.

### Post-surgical evaluation

Recall visits were scheduled once every 3-4 days to assess the amount of expansion and reinforce oral hygiene instructions. Any complications, such as expander expulsion, and soft tissue changes in terms of colour, inflammation and bleeding were documented throughout the expansion period.

### Expander retrieval

Appointment was scheduled for expander retrieval after fifteen days when the expansion phase was deemed to be successfully completed. Under local anaesthesia, a vertical incision was placed approximately over the same region where the incision was placed for expander placement. The screw was unscrewed followed by retrieval of both the expander and the screw (Figure 4H). The expander was then examined for its consistency and the color of osmotically accumulated tissue fluid inside it (Figure 5). The overlying tissues were also inspected for signs of inflammation and color and texture match to the surrounding tissues. The bone surface was carefully examined for any signs of potential resorption due to pressure from the expander. Incision line was closed with 3-0 silk suture.

## Results

The present prospective, randomised controlled clinical trial was conducted to explore the feasibility and efficacy of self-inflating hydrogel expander (Osmed®) to gain soft tissue volume around the



Figure 4: Surgical procedure for expander implantation. a) Placement of incision b) Pouch preparation c) Pouch dimensions corresponding to final expander volume d) Bone fixation screw secured in the flat end of expander e) Implantation of the expander into the prepared pouch f) Expander secured in the pouch g) Post-operative view of the treated site on 15th day before retrieval h) Retrieval of expander.

dentulous area and also to evaluate its clinical applicability to increase vestibular depth and obtain root coverage.

A total of ten healthy patients (five males and five females) with a mean age of 35.2 years and standard deviation of 3.73 (Table 1) who satisfied the inclusion and exclusion criteria were enrolled for the study. Surgeries and post-operative sequelae were uneventful and no patient developed any significant complication. Data of all the patients were analysed and subjected to statistical analyses. All the measurements were recorded at baseline except treatment dependent measures of colour and texture. The clinical parameters were then assessed two weeks post expander retrieval, three months and six months post-surgically.

Optical scanning for volumetric analysis of study models was performed to objectively determine the changes in tissue thickness from baseline to post expander retrieval and six months post-operatively. Exocad® DentalCAD software package was employed to accurately reconstruct optically scanned 3D study models and evaluate the linear changes using the measurement tools rendered in the software (Figure 6).



Figure 5: Retrieved expander.

Table 1: Demographics of Study Patients.

Measures	Mean $\pm$ SD	Frequency	Percentage
Age	35.20 $\pm$ 3.736		
Sex			
Male		5/10	50
Female		5/10	50
Site			
31		8	30.8
32		4	15.4
41		9	34.6
42		5	19.2

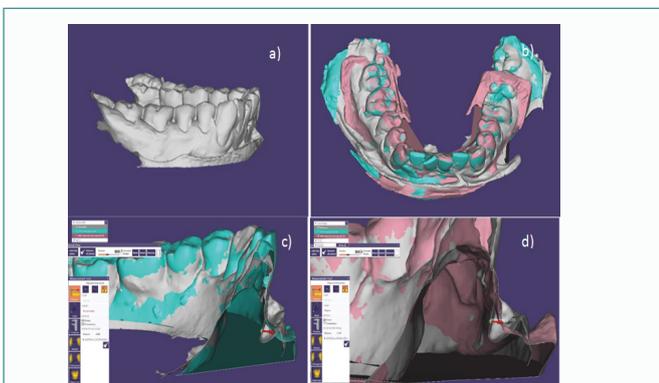


Figure 6: Optical scanning of study model of the patient. a) Pre-operative view of the model b) Overlapping of the registered meshes c) Measurement of soft tissue gain by optical scan from baseline to immediate post-retrieval - 2.06 mm d) Measurement of soft tissue gain from baseline to 6 months - 1.10 mm.

The data collected was entered in Microsoft Excel and Statistical analyses were performed using the Statistical Package for Social Science-SPSS for window version 18.5 (SPSS Inc. Chicago, IL, USA) software. The normality of the data was evaluated using Shapiro-Wilk test. The 'p' value of the Shapiro-Wilk test was greater than 0.05 which indicated that the data was normally distributed. Therefore, parametric tests were employed for all the clinical measures except for color and texture match that were evaluated using non-parametric test (Pearson's chi square test). The parametric test applied was One Way Analysis of Variance (ANOVA) test followed by Tukeys post hoc test to evaluate multiple individual pair-wise comparisons among the various time intervals. A student paired 't' test was performed to determine whether there were differences between the pre and post measurements on Optical scanning for volumetric analysis of tissue thickness.

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\*\*GmbH, Ilmenau, Germany.

The non-parametric test applied was Pearson's chi square test for assessing esthetic harmony with surrounding native tissue. The 'p' value <0.05 was considered statistically significant.

### Clinical Observation

When the patients presented for the two weeks post-insertion of STE, there were no signs of any inflammatory reaction, which confirms the findings of Weise, who described the biocompatibility of hydrogel expanders. The expanders were clearly palpable and the expanded tissue did not differ clinically from the unexpanded tissue. Post-retrieval of STE, all the surgical sites healed completely without any complications. At three months follow up, the STE treated sites showed excellent color and texture match to the surrounding tissues. At six months visit, the STE treated sites manifested good aesthetic harmony with the adjacent native tissues. However, it was noted that the soft tissues gradually returned to their pre-expansion status over a period of six months. Table 2 and 3 outlines the descriptive statistics for all clinical parameters. The following clinical parameters were assessed.

#### Keratinized tissue width

The mean keratinized tissue width at baseline was 1.81 mm  $\pm$  0.749 mm, whereas at two weeks post expander removal the value is 2.35 mm  $\pm$  0.629 mm, three months post-surgery is 2.38 mm  $\pm$  0.941 mm and at six months is 2.27 mm  $\pm$  1.041 mm. The mean difference from baseline to six months is 0.46 mm  $\pm$  0.292 mm which is statistically not significant (p = 0.061). There is no mean gain in keratinized tissue width from baseline to six months post treatment (Table 2 and 3, Graph 2).

#### Vestibular depth

The mean vestibular depth at baseline was 7.77 mm  $\pm$  1.681 mm, whereas at two weeks post expander removal the value is 7.62 mm  $\pm$  1.299 mm, three months post-operatively 7.69 mm  $\pm$  1.050 mm and at six months is 7.65 mm  $\pm$  1.056 mm. The mean dimensional change from baseline to six months is 0.12 mm  $\pm$  0.625 mm which is statistically not significant (p = 0.977). Thus, there is no mean increase in vestibular depth from baseline to six months post-operatively (Table 2 and 3, Graph 2).

### Keratinized tissue thickness

The mean keratinized tissue thickness at baseline was 1.865 mm  $\pm$  0.459 mm, whereas at two weeks post expander removal the value is 1.904 mm  $\pm$  0.529 mm, three months post-operatively is 1.731 mm  $\pm$  0.529 mm and at six months is 1.750 mm  $\pm$  0.587 mm. The mean dimensional change from baseline to six months is 0.115 mm  $\pm$  0.128 mm which is statistically not significant ( $p = 0.592$ ). Thus, there is no mean increase in keratinized tissue thickness from baseline to six months post-operatively (Table 2 and 3, Graph 2).

### Optical scanning for volumetric analysis of tissue thickness

The mean dimensional change observed on optical scanning of study models upon expander retrieval was 3.452  $\pm$  0.844 mm whereas at six months, the mean change observed was 1.892  $\pm$  0.595 mm. Overall, the mean change in linear tissue thickness from expander retrieval to six months post-operatively is 1.56  $\pm$  0.249 mm which is statistically significant ( $p < 0.001$ ). Thus, there is a mean reduction in tissue thickness from expander retrieval visit to six months post operatively (Graph 1).

### Gingival recession depth

The mean gingival recession depth at baseline was 3.58 mm  $\pm$  1.332 mm, whereas at two weeks post expander removal the value is 3.19 mm  $\pm$  1.327 mm, three months post-surgically is 3.23 mm  $\pm$  1.394 mm and at six months is 3.19 mm  $\pm$  1.415 mm. The mean dimensional change from baseline to six months is 0.39 mm  $\pm$  0.083 mm which is statistically not significant ( $p=0.693$ ). Thus, there is no mean reduction in gingival recession depth from baseline to six months post-operatively (Tables 2 and 3, Graph 2).

### Colour and texture match to the surrounding tissue

All the sites treated with SOE achieved good color and texture matches with the adjacent native tissues post-expander retrieval to six month post-operative visit with a  $p$  value  $< 0.001$  which is statistically significant (Table 4).

### Plaque Index

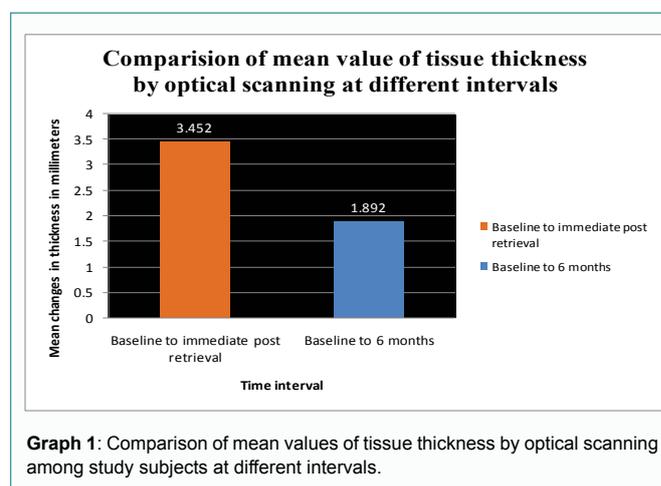
The mean value of plaque index at baseline is 0.62  $\pm$  0.266 and reduced to 0.59  $\pm$  0.179 at two weeks post expander retrieval, 0.58  $\pm$  0.092 at three months and 0.53  $\pm$  0.082 at six months with a  $p$  value of 0.732 which is statistically not significant (Tables 2 and 3, Graph 2).

### Gingival index

The mean value of gingival index at baseline is 0.82 mm  $\pm$  0.322 mm and decreased to 0.82 mm  $\pm$  0.225 mm at two weeks post expander retrieval, 0.64 mm  $\pm$  0.267 mm at three months and 0.62 mm  $\pm$  0.169 mm at six months with a  $p$  value of 0.147 which is statistically not significant (Tables 2 and 3, Graph 2).

## Discussion

Minimal keratinized tissue width is required to maintain optimal gingival health. Gingival augmentation procedures around natural teeth are performed to facilitate plaque control, enhance patient comfort during tooth brushing, prevent future recession and to increase the zone of attached gingiva in conjunction with restorative, orthodontic, or prosthetic dentistry [23].



**Table 2:** One way ANOVA test for analysis of the parameters from baseline to two weeks, three months and six months post operatively.

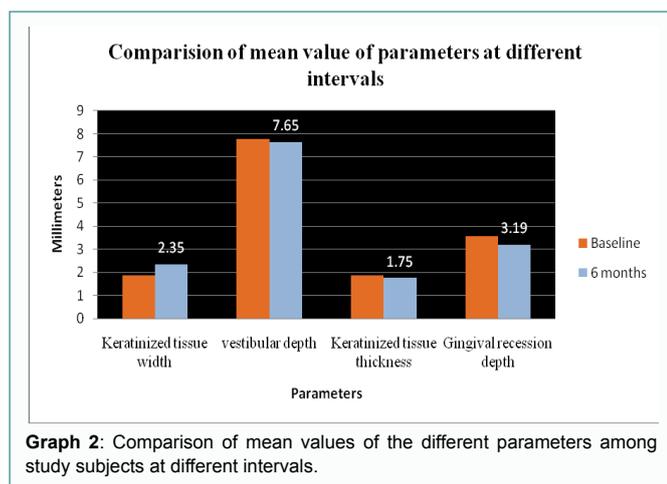
Parameters	n		Baseline	2 weeks	3 months	6 months	P value
Keratinized tissue width	26	Mean $\pm$ SD	1.81 $\pm$ 0.749	2.35 $\pm$ 0.629	2.38 $\pm$ 0.941	2.27 $\pm$ 1.041	0.061
Vestibular depth	26	Mean $\pm$ SD	7.77 $\pm$ 1.681	7.62 $\pm$ 1.299	7.69 $\pm$ 1.050	7.65 $\pm$ 1.056	0.977
Keratinized tissue thickness	26	Mean $\pm$ SD	1.865 $\pm$ 0.4595	1.904 $\pm$ 0.5295	1.731 $\pm$ 0.5870	1.750 $\pm$ 0.5874	0.592
Gingival recession depth	26	Mean $\pm$ SD	3.58 $\pm$ 1.332	3.19 $\pm$ 1.327	3.23 $\pm$ 1.394	3.19 $\pm$ 1.415	0.693
Plaque index	26	Mean $\pm$ SD	0.62 $\pm$ 0.266	0.59 $\pm$ 0.179	0.58 $\pm$ 0.092	0.53 $\pm$ 0.082	0.732
Gingival index	26	Mean $\pm$ SD	0.82 $\pm$ 0.322	0.82 $\pm$ 0.225	0.64 $\pm$ 0.267	0.6 $\pm$ 0.169	0.147

**Table 3:** Between the visit comparison of the parameters using Tukey's Post Hoc Test.

Parameters		Baseline v/s 2 weeks	Baseline v/s 3 months	Baseline v/s 6 months	2 weeks v/s 3 months	2 weeks v/s 6 months	3 months v/s 6 months
Keratinized tissue width	Mean difference	-0.538	-0.577	-0.462	-0.038	0.077	0.115
	'p' value	0.112	0.078	0.216	0.998	0.998	0.962
Vestibular depth	Mean difference	0.514	0.077	0.115	-0.077	-0.038	0.038
	'p' value	0.974	0.997	0.989	0.997	1	1
Keratinized tissue thickness	Mean difference	-0.038	0.315	0.115	0.173	0.154	-0.019
	'p' value	0.994	0.808	0.87	0.661	0.738	0.999
Gingival recession depth	Mean difference	0.385	0.346	0.385	-0.038	0	0.038
	'p' value	0.742	0.798	0.772	1	1	1
Plaque index	Mean difference	0.03	0.04	0.086	0.01	0.056	0.046
	'p' value	0.979	0.953	0.68	0.999	0.885	0.932
Gingival index	Mean difference	0	0.18	0.2	0.18	0.2	0.02
	'p' value	1	0.394	0.303	0.394	0.303	0.998

**Table 4:** Analysis of Color match and Texture Match to the Surrounding Tissue.

Time interval	Color match		p' value	Texture match		p' value
	Equal to surrounding native tissue	Not equal to surrounding native tissue		Equal to surrounding native tissue	Not equal to surrounding native tissue	
Immediately after expander retrieval	8 30.80%	18 69.20%	<0.001	17 65.40%	9 34.60%	<0.001
2 Weeks post-retrieval	15 57.70%	11 42.30%		26 1	0 0	
3 months	26 100%	0 0		26 1	0 0	
6 Months	26 100%	0 0		26 1	0 1	



**Graph 2:** Comparison of mean values of the different parameters among study subjects at different intervals.

In an attempt to gain keratinized tissue width, a number of autogenous, allogenic and xenogenic substitutes have been introduced and investigated. However, these procedures are more invasive and time consuming in nature. Thus, there is a strong desire to identify an alternative material that would reduce morbidity, patient pain and the number of surgical sites required as well as increases the number of teeth that could be treated in one surgical visit.

In recent times, there has been an increased demand to identify least invasive methods to gain keratinized tissue volume. One such material that has gained importance off late is tissue expanders. Published data from experimental studies have reported that a surplus of periosteum and soft tissue can be generated intraorally with an osmotic Soft Tissue Expander (STE) [6,24]. The redundant soft tissue thus created has been used to prevent wound dehiscence and achieve primary closure to cover bone grafts. Currently, STE are made up of hydrogel (Osmed®, Ilmenau, Germany), which is the same material that is used to fabricate contact lenses [7]. In the field of dentistry, STE has been effectively applied as a minimally invasive technique to gain soft tissue volume in edentulous areas and also to preserve sufficient microcirculation in the recipient site for its survival to avert complications like post-surgical wound dehiscence (associated with bone-grafting procedures) despite satisfactory initial primary closure [12,25,26].

Considering that STE is successful in gaining soft tissue volume over edentulous areas, in similar lines we believe that STE can also be employed to gain soft tissue volume in the dentulous area. Till date, to the best of our knowledge, there are no clinical trials that have been conducted evaluating this novel approach. Hence, the present study, which is first of its kind, is designed to explore the feasibility and efficacy of employing STE to gain soft tissue volume in terms of keratinised tissue width and thickness around the dentulous area.

In our study, to control variables like age and sex influencing the outcome, we selected subjects with equal number of males and females, who fell under the age range of 25-40 years with the same ethnicity. Additionally, our technique for expander implantation included a minimally invasive preparation of a subperiosteal pouch [14]. All the surgical procedures for all the patients were conducted only in the mandibular anterior region and performed by the same trained and experienced operator in periodontal plastic surgeries. Moreover, the inter-examiner variability was eliminated by having the same masked calibrated examiner performing all the clinical measurements. Furthermore, optical scanning was performed to accurately determine the soft tissue volume gain [14,27].

Our results showed that post-surgery healing was uneventful and there were no signs of any STE-related adverse events such as overlying soft tissue thinning or dehiscence, infection, hematoma, necrosis, pain or STE extrusion. In addition, it was also noticed that silicone coating covering the hydrogels also remained intact on expander retrieval. The results of our study were against our initial speculation as STE did not achieve the desired soft tissue gain in the dentulous region.

In terms of gain in keratinized tissue width, the mean difference observed is 0.46 mm ± 0.292 mm; p=0.061 and there is no statistically significant difference between baseline (1.81 mm ± 0.749 mm) and six months (2.27 mm ± 1.041 mm). In terms of vestibular depth, the mean difference observed is 0.12 mm ± 0.625 mm; p = 0.977 mm and there is no statistically significant gain from baseline (7.77 mm ± 1.681 mm) to six months (7.65 ± 1.056 mm). In regards to keratinized tissue thickness, the mean dimensional difference observed is 0.115 mm ± 0.128 mm; p = 0.592 mm and the treated sites did not show a statistically significant difference from baseline (1.865 mm ± 0.459 mm) to six months (1.750 mm ± 0.587 mm). In relation to gingival recession depth, the mean difference observed is 0.39 mm ± 0.083 mm; p=0.693 mm and no significant differences were noted from baseline (3.58 mm ± 1.332 mm) to six months (3.19 mm ± 1.415 mm).

In contradiction to our results, there are studies reported in the literature wherein substantial soft tissue volume in terms of keratinized tissue was achieved in the edentulous area. Abrahamsson et al. [11] demonstrated a mean soft tissue profile gain of 2.9 mm ± 1.1 mm at the attached gingival level when STE was implanted in horizontally deficient edentulous areas. In a pilot investigation of four cases, Asa'ad et al. [14] documented a mean soft tissue volume gain of 483.8 mm ± 251.7 mm after subperiosteal STE implantation in edentulous areas requiring vertical and/or lateral bone augmentation. The expanded sites, thus, permitted tension-free primary closure for successful dental implant placement four months following bone augmentation. The positive results observed in their studies was due to-First, implantation of STE entirely in the attached gingiva

consequently allowing the amplification of keratinized tissues to their full limit thereby manifesting impressive soft tissue volume gains. Second, guided bone regeneration was performed in all the studies following STE retrieval which could have prevented the retraction of the expanded tissue.

Further, results derived in this study are in accordance with the results obtained by Mertens et al. [26] who testified that despite achieving sufficient soft tissue gain using STE via subperiosteal tunnel technique in deficient edentulous areas, no gain in keratinized mucosa could be affirmed. They attributed this issue to the expansion technique wherein all the expanders were placed in the vestibular mucosa, and thus no increase in keratinized tissue could be expected, as the surrounding tissue is only alveolar mucosa. Therefore, the authors reported the necessity to perform an additional soft tissue surgery in terms of a free gingival graft in one of the patients to achieve a stable peri-implant mucosa.

The exact reason for the failure of STE in our study to gain the soft tissue volume in terms of keratinized tissue width and thickness is unknown and it could be contemplated to various reasons. First, the surgical design of the subperiosteal pouch was not encompassing the entire apico-coronal extension of the attached gingiva in order to maintain the integrity of the marginal tissue to prevent STE expulsion and could have hampered the expansion of keratinized tissue to the full extent [26]. Second, due to minimally invasive pouch technique, the time taken for securing the STE in the recipient site was prolonged which could have led to undesired expansion of STE (due to ingress of external fluid such as saliva) and might have compromised the gradual expansion of the soft tissue [28,29]. Third, for the volume maintenance during healing, it necessitates *in situ* suspension of STE. However, in our study, the retrieval of the expander was performed after two weeks and this may have given insufficient time for the soft tissue stabilisation and maturation causing retraction of the gained soft tissue. In addition, any reconstructive procedures were not planned after the expansion phase which might also have contributed to retraction of the gained tissue [11,25]. Fourth, we failed to objectively ascertain whether STE had reached its maximum expansion limit as the assessment of the magnitude of expansion was solely based on manufacturer guidelines and visual examination of the expanded tissue that would have resulted in premature retrieval of STE.

Since, the present study is a preliminary report; the results have to be interpreted with caution. Firstly, it is a short term clinical trial of six months with very limited sample size; hence, conclusive evidence could not be drawn regarding the stability of the expanded soft tissues in the long term. Secondly, the nature of the expanded tissue could not be comprehended in this study without human histology as obtaining this information would require amputation of the expanded soft tissue.

In our opinion, in future multicentre, randomised controlled trials incorporating larger sample size and longer follow up period with histological evaluation should be carried out to fully explore the potential of STE to achieve predictable outcomes of soft tissue gain. Future clinical investigations must execute comparative studies to evaluate the efficacy of STE at different intraoral locations and with different implantation approaches. Furthermore, the relationship between soft tissue expansion and tissue phenotype (thick vs. thin) must be addressed [7]. In addition, the relationship between the rate of expansion and tissue biotype and the determination of a suitable

expander insertion technique for each biotype should be evaluated as well [7]. Moreover, there is an unmet need to find a flexible envelope with no dead space so that expansion is even more gradual [30]. In future, the device design could be enhanced by the incorporation of drugs or growth factors in order to tailor the device to specific clinical indications. Thus, controlled soft tissue expansion may encourage the development of tissues which ideally match the color and texture thereby offering a new, safe and promising technique in reconstructive surgery.

Since, this clinical trial is an exploratory study, there are still many doubts and dilemmas and it would be too early for any concrete conclusions. Within the limits of our study, it can be concluded that even though Osmed® STE could generate surplus of soft tissue volume but it proved to be ineffective in achieving significant gain in the keratinized tissue. However, the gain thus obtained was not sustained. Thus, the technique investigated in the present pilot cases still requires improvement for being considered predictable and implemented routinely in everyday clinical practice.

## Conclusion

Since, this clinical trial is an exploratory study, there are still many doubts and dilemmas and it would be too early for any concrete conclusions. Within the limits of our study, it can be concluded that even though Osmed® STE could generate surplus of soft tissue volume but it proved to be ineffective in achieving significant gain in the keratinized tissue. However, the gain thus obtained was not sustained. Thus, the technique investigated in the present pilot cases still requires improvement for being considered predictable and implemented routinely in everyday clinical practice.

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