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Abstract

Background Mechanical skin stretching (SS) is now becoming one of the commonly sought after procedures for wound healing. This study was aimed to assess the efficacy of preoperative SS for the closure of large wounds and to evaluate various postoperative outcome parameters.

Methodology An observational study was conducted from December 2017 to May 2019 where a sample size of 30 patients was included with inclusion criteria being wounds of \geq 5 cm width that require surgical management, presence of sufficient healthy skin edge of the wound/scar (at least one) for the stretching procedure, and age between 18 and 70 years. SS devices used were the top closure tension relief system. Postoperatively, various parameters were recorded to evaluate outcomes and complications.

Results Majority of wounds that is 16 (53.3%) were <50 cm², 9 (30%) were between 50 and 75 cm², and 5 (16.7%) were >75 cm². The mean duration of stretch was 2.3 ± 0.82 weeks. For 30 wounds treated with staged cycles of wound closure, there was a significant difference between every two visit points, i.e., 10%. The mean patientreported patient and observer scar assessment scale score was 3.5 ± 0.93 . Twenty-five cases (83.3%) had uneventful postoperative recovery. Twenty-seven patients (90%) reported an improved aesthetic outcome. Fourteen patients (46.7%) reported some improvement in function.

Conclusion The study concluded that the SS devices are the simple and effective method for the primary closure of large and challenging wounds and skin defects.

Keywords

- ► Skin
- ► Tension
- Stretching
- Device
- ► Wound

Introduction

Large wounds which are difficult to close primarily in a tensionless manner are considered as a challenge for the plastic surgeon. Since the postinjury scarring results in poor aesthetic and functional outcomes, primary wound closure may result in a better outcome. But due to increased skin tension, closure of larger defects is difficult and challenging.

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Conventional options for closure of such large wounds include—skin grafting, flap cover, closure using tissue expansion, and healing by secondary intention. However, the disadvantages of these options are complexity of procedure, increased morbidity, prolonged healing time, cosmetically inferior outcome, and increased cost of treatment. Mechanical skin stretching (SS) is now becoming one of the commonly sought after procedure for wound healing. SS is proposed to allow tensionless primary closure of defects as a single-step procedure by making the use of the viscoelastic property of tissues in response to mechanical loading. Biomechanical and viscoelastic properties of the skin¹ which allow it to stretch to close the wound within a relatively short period of time are mechanical creep and stress relaxation.² Our study was aimed to access the efficacy of preoperative SS technique as an alternative to conventional techniques for wound closure and to assess various outcome parameters related to the same. No similar study using the tension relief system (TRS) has been reported before in the past literature from India.

Materials and Methods

An observational study was conducted from December 2017 to May 2019 following the approval by the Institutional Ethics committee with no. F.No. TP (DM/Mch) (15/2017)/IEC/PGIMER /RMLH 2090 in plastic surgery department where a sample size of 30 patients was included in the study with inclusion criteria being wounds ≥ 5 cm, presence of sufficient healthy skin edge of the wound/scar (at least one) for the stretching procedure, and age between 18 and 70 years. Patients having wound width ≥ 25 cm; recently diagnosed or uncontrolled systemic disorders such as diabetes mellitus, immunodeficiency, or arterial insufficiency not on any treatment; use of corticosteroids; psychiatric illness (e.g., auto-mutilation); skin diseases and connective tissue disorders such as Ehlers Danlos; and radiated skin were excluded from the study.

SS devices used were the top closure TRS (IVT Medical Ltd., Ra'anana, Israel). Written and informed consent was obtained from all the patients.

Preoperatively, patient wounds were marked, dimensions were noted, and when needed serial dressings were done to make the wound fit for closure. The application of the TRS device was first described by Topaz et al.^{3,4} The TRS set consisted of two attachment plates (APs) and approximation strap (AS).⁵ An SS device was applied onto shaven dried normal skin around 2 cm from the wound margin under local anesthesia. The APs were attached and connected to the AS (**Fig. 1A–C**). The device was kept in place for a period until sufficient skin laxity was obtained for primary closure as judged by the surgeon.

Operatively, once the surrounding skin was sufficiently stretched, an assessment was made and primary closure was done. The wound was closed in two layers. The wound was covered with suture strips, non-adherent dressings, and gauzes. No antibiotics were used in the postoperative period routinely. If the closure was still under tension, the SS device was applied over the dressed closed wound to support the closure.

Patient variables such as age, gender, comorbidities, history of smoking, and previous surgery, and various postoperative outcome parameters were recorded. Patients were reviewed at 1 week, 6 weeks, and 3 months.

Statistical Methods

Standard application percentage, means, and standard deviation were used. *p*-Value <0.05 was considered to be statistically significant. The patient and observer scar assessment scale (POSAS) is a reliable and valid scar assessment scale which was used in this study.⁶ It has two components—patient component included pliability, thickness, relief, color, pruritis, and pain and observer component which was scored by a clinician not involved in the study, and included pliability, thickness, relief, vascularization, pigmentation, and surface area. Each parameter was







Fig. 1 (A) Left side ischial pressure sore. (B) Application of tension relief system with the wound gap of approximately 2 cm. (C) Nearly approximated wound.

Table 1 Characteristics of the wound (total n = 30)

Etiology	Number
Postsurgical	16
Trauma	10
Infection	2
Burns	2
Previous surgery	Number
Yes	4
No	26
Site	Number
Upper limb	8
Lower limb	15
Torso	6
Head and neck	1
Smoking	Number
Yes	4
No	26
Size	Number
<50 cm ²	16
50 to 75 cm ²	9
>75 cm ²	5

scored on a 10-point rating scale system where 10 was the worst outcome. A mean total score was calculated by taking an average of the six items for the patient and observer.

For statistical analysis, the residual wound (RW) width during TRS therapy was calculated as RW%:

 $RW\%\!=\!RW$ width (cm)/original wound width (cm) \times 100%. One-way analysis of variance tests were used to calculate the statistical significance of mean RW% decrease between every two visits.

Observations and Results

The following observations were noted (**Tables 1** and **2**).

The mean (standard deviation [SD]) age of the participants was 39.2 ± 12.5 years with the minimum of 18 years and the maximum of 68 years. Majority of patients, i.e., 26 were males (86.7%), while the remaining four patients (13.3%) were females. More than half the wounds, i.e., 16 (53.3%) were postsurgical, 10 (33.3%) were posttraumatic, 2 (6.7%) were postinfective, and 2 (6.7%) were postburns. Five patients had pre-existing comorbidity complicating wound management, four patients (13.3%) had hypertension, and one patient (3.3%) had diabetes mellitus. Four patients (13.3%) had undergone a previous surgical attempt at wound closure by one of the conventional methods and presented to us after having a failure of the same. Four of the 30 patients (13.3%) were active smokers, while the

remaining were either non-smokers or had quit for a period over 2 years.

Half of the wounds, i.e., 15 (50%) were on the lower limb (►Fig. 2A–C), 5 wounds (17%) were on the torso, 8 wounds (26.7%) were on the upper limb (►Fig. 3A–C), and 2 over the scalp (6.7%).

Majority of wounds, i.e., 16 (53.3%) were $<50 \, \text{cm}^2$, 9 (30%) were between 50 and $75 \, \text{cm}^2$, and 5 (16.7%) were $>75 \, \text{cm}^2$ with the minimum wound dimension across closure being 5 cm.

A total of 32 SS cycles were used. Thirty cycles were applied before suturing for 30 wounds in 30 patients. Subsequently, two wounds over the scalp region underwent further cycle to secure the closure of high-tension sutured wounds. A total of 90 sets of the SS device were applied (mean \pm [SD], 2.75 ± 0.10 sets per wound). The number of sets of the device was strongly correlated with wound length (p < 0.05), on average, one set per 5.40 ± 1.32 cm. The mean duration of stretch was 2.3 ± 0.82 weeks with minimum duration being 0.4 weeks and maximum being 6 weeks. There was a significant difference between every two visit points of staged cycle, i.e., 10%. The trend of RW% decrease is also shown in **Fig. 4**.

All but one wound had no active discharge at the time of presentation. Three patients (10%) had wounds with surrounding inflammatory skin changes.

The mean visual analog scale was 1.9 ± 0.83 with the minimum score being 0 and maximum being 4. Majority of patients, that is, 25 (83.3%) were managed by oral non-steroidal anti-inflammatory drugs, two cases (6.7%) required tramadol, one case (3.3%) required intravenous sedation, while two cases did not require any analgesic use.

The mean patient-reported POSAS score was 3.5 ± 0.93 with the best POSAS score being 2 out of 10 and worst being 5 out of 10. We found that the median POSAS score was 5 among smokers as compared with 4 among non-smokers.

Twenty-five cases (83.3%) had uneventful postoperative recovery. The remaining five patients (16.7%) developed a total of seven complications. Three cases (3.3%) developed skin maceration, one case (3.3%) had skin infection, one case (3.3%) had seroma formation, and two cases (6.7%) had device extrusion requiring reapplication.

Two patients (6.7%) reported no improvement in aesthetic outcome over preoperative status, one patient reported a worse outcome, while 27 patients (90%) reported improved outcomes.

Sixteen patients (53.35%) reported no improvement in function per say, 14 patients (46.7%) reported some improvement in function, while no patient had reported a worsening of functionality.

The mean patient satisfaction score was 6.8 ± 0.46 , with minimum score being 5 and maximum being 7. Complications like skin maceration and seroma had resolved by 1 week, and only one patient (3.3%) had persistent signs of skin infection at follow-up.

Two of the 30 patients (6.7%) reported scar hypertrophy at 3 months follow-up.

Table 2 Outcomes of mechanical skin stretching using the TRS device

A	Details of tension relief system applied sets, $n = 90$			
	TRS treatment cycle (n = 32)	Before suturing	After suturing high tension wounds	
	Number of wounds	30	2	
В	Wound discharge	Number	Percentage	
	Yes	1	3.3	
	No	29	96.7	
С	Pain score	Mean	SD	
	VAS score	1.9	0.83	
D	Duration of each cycle of stretch	Mean	SD	
	Time taken (wk)	2.30	0.82	
E	Antibiotic used	Number	Percentage	
	Yes	2	6.7	
	No	28	93.3	
F	Subjective scar assessment	Mean	SD	
	POSAS score	3.5	0.93	
G	Smoking	Median POSAS score (IQR)	<i>p</i> -Value	
	Yes	5 (4.5–5)	0.005	
	No	3 (3-4)		
Н	Complications	Number	Percentage	
	None	25	83.3	
	Seroma	1	3.3	
	Skin maceration	3	10.0	
	Skin infection	1	3.3	
	Device extrusion	2	6.7	
I	Cosmetic result	Number	Percentage	
	0 (No change)	2	6.7	
	1 (worse)	1	3.3	
	2 (better)	27	90.0	
J	Functional result	Number	Percentage	
	0 (No change)	16	53.3	
	2 (better)	14	46.7	

Abbreviations: IQR, interquartile range; POSAS, patient and observer scar assessment scale; SD, standard deviation; TRS, tension relief system; VAS, visual analog scale.

Discussion

One of the earlier SS devices was first introduced by Hirshowitz et al in 1993.⁷ Since then, depending upon the viscoelastic properties of the skin, various designs of SS devices had been described.^{8–12} Various modifications have also been made to these devices like using rubber bands,¹³ Kirchner wires,¹⁴ serial tightening of loop sutures¹⁵, and spinal needles¹⁶ to enable the primary closure of the wound. The top closure system invented by Topaz et al³ provides the advantage that it can be adjusted to achieve the correct tension for the wound in an easy way, facilitating tension-free wound closure. More recently, an inexpensive dermatotraction technique to

close the medium to large size skin defects was also described using of Ty-Raps. ¹⁷

In our study, it was found that the mean age of the participants was 39.2 ± 12.5 years with the youngest case being 18 years of age and the eldest being 68 years. In contrast to this, 40.9% of patients in the study by Cheng et al¹⁸ belonged to 51 to 70 years age group and 36.4% patients belonged to 71 to 90 year age group. Although age in itself is not a contraindication to complex reconstructive procedures or multiple procedures, these are often associated with increased risks for complications as well as the need for prolonged periods of optimization of accompanying comorbidities. SS techniques performed under local anesthesia with some postoperative precautions to be followed

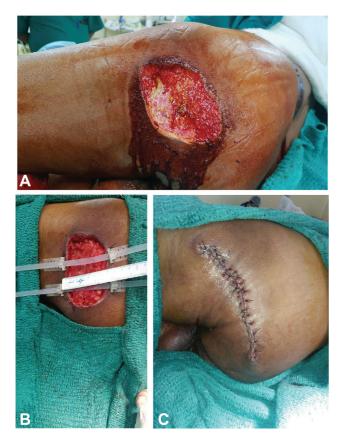


Fig. 2 (A) Left side gluteal pressure sore. (B) Application of tension relief system. (C) Complete closure of the wound.

serve as a bridge to avoid surgeries and associated risks in patients of advanced age while allowing for wound closure in chronic non-healing wounds.

In our study, more than half of the cases presented to us (53.3%) had a postsurgical wound with the most common cause being an amputation stump raw area. The remaining

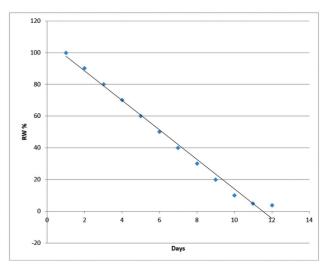


Fig. 4 Curve showing a decrease in residual wound width percentage (RW%) mean values after each cycle of stretching and wound closure.

causes included posttraumatic raw area (33.3%), postinfective raw area (6.7%), and postburn raw area (6.7%). When compared, Cheng et al¹⁸ had found pressure sores as the commonest cause in 45.4% of patients.

Ninety percent of the posttraumatic wounds were in males as they were found to be more commonly involved in road traffic accidents and assault cases. Raw areas over amputation stumps are a common problem presented to the plastic surgeon which does not always have a simple solution. In such a setting, preoperative SS with mechanical loads and simple wound closure helps in providing stable soft tissue coverage while avoiding the need for multiple complex and morbid procedures (►Fig. 5A-C).

Among our patients, 4 of the 30 (13.3%) were chronic smokers. Tobacco/nicotine decreases the oxygen and blood flow by causing cutaneous vasoconstriction, increases



Fig. 3 (A) Wound over postamputated stump right arm with the tension relief system. (B) Reduction in the wound width with skin stretching. (C) Complete closure of the wound.







Fig. 5 (A) Posttraumatic large wound over right thigh region. (B) Application of tension relief system. (C) Complete closure of the wound.

infection rates, slows down healing time, and decreases final scar strength. Hence, in chronic smokers, chances of wound breakdown are increased as also chances for flap survival and graft necrosis are higher compared with non-smokers. Therefore, it helps to avoid the usage of flaps or skin grafts or multiple complex surgeries in chronic smokers and attempts at the given site. Three out of the four smokers (75%) in our study also had co-existing hypertension adding further to the risk of surgery. Hence, in chronic smokers with associated comorbidities, it is possible to avoid complex procedures and associated risks by the use of simple SS devices.

In the study by Cheng et al, 18 only torso defects in 22 patients were included as in these anatomic areas extensive undermining of wound could be done easily than any other areas. In our study, wounds representing all body sites were covered, eight cases (26.7%) had wounds over upper limb, 15 cases (50%) had wounds over lower limb, five cases (17%) had wounds over torso, and only two (6.7%) had a wound over scalp. An inverse relation was found in past studies between the skin's thickness and Young's modulus (ratio of stress applied to the skin over skin deformation), and it was also shown that the skin thickness depends upon age, sex, and body site.¹⁹ Firooz et al found that skin elasticity is higher for females than in males.²⁰ The variability in skin elasticity by site meant that a $5 \times 6 \, \text{cm}$ wound over the anterior chest wall was much more significant and primary closure was difficult to achieve than a similar-sized wound over a site where skin was much more lax like the thigh. SS utilizing the viscoelastic properties worked well in enhancing the extensibility of the thin adherent skin at these sites. The quality of surrounding skin is important with regard to secure device fixation and good vascularity of undermined skin flaps.

The efficacy and duration of SS depend not only on the absolute dimensions of the wound but also on the skin elasticity which varied between individuals according to age, gender, and in the same individual according to the site and skin thickness. Perhaps more detailed studies shall be needed to individually form guidelines for cut-off wound size at different parts of the body that can be amenable to wound closure by SS. Until such objective studies are available, subjective tests and opinions like skin quality and skin pinch should guide the judgment for the judicious use of SS techniques.

As per the study by Cheng et al, ¹⁸ only minor complications were noted such as poor scarring in nine (40.9%) patients and pain in six (27.3%) patients. In our present study, only five patients had (16.7%) developed a total of seven complications. No major complications were reported. The most common reported complication was skin maceration in three out of thirty patients (10%). Two patients (6.7%) who had scalp defects with inflammatory changes in surrounding skin reported device extrusion at day 3 and day 4 of application. The device had to be reapplied with suture, and the patient was asked to restrict neck motion with a soft collar for 7 to 10 days along with local wound care to prevent excessive moisture.

In the study by Cheng et al, 18 the stony brooks scar evaluation score was used to assess scar. Twenty-one patients (95.5%) had reported a fair to good result, while one patient (4.5%) reported a poor result. In the study by Verhaegen et al²¹ where burn scar excision (SE) alone and with SS were done for wound closure, the mean total POSAS reported at 3 and 12 months by the patient was 3.9. In our study, patient-reported total mean POSAS was $3.5\pm0.93\,$ with the worst reported score being 5 and the best being 2 out of 10. Overall, 27 patients (90%) reported improved cosmesis, two patients (6.7%) reported no significant change, while one patient reported the worst outcome. This patient did not have a chronic wound and had undergone a simple sebaceous cyst excision elsewhere following which the defect could not be closed, the patient also had device extrusion once for which the device had to be reapplied, considering his preoperative status, and patient complained that there was no wound to start with, so any scar for him was a worse outcome.

Wound closure by itself does not have any effect on function but helps in faster rehabilitation and return to work. In the study by Verhaegen et al,²¹ 12 months postoperatively, 29% (4/14) of the patients in the SS group compared with 40% (6/15) in the SE group had hypertrophic scarring. In our study, two of the thirty patients (6.7%) were noted to have hypertrophic scars at 3 months and advised conservative measures for the same.

We noted that these patients had surrounding skin inflammation at the time of device application, one had developed infection postprocedure and one had to undergo repeat device application in view of device extrusion. These factors suggested chronic inflammation predisposing to hypertrophic scar formation. We found out that smoking might influence the risk of hypertrophy and might be responsible for the increased wound complication rate due to the mechanism of deterioration of proliferative and/or immunological response. In our study, we found that the median POSAS score in the smoking group was 5 when compared with non-smoking group of patients for whom it was 3, and the p-value was statistically significant (0.005). Smoking cessation strategies must be incorporated into patient care to improve healing outcomes in this population.

Conclusions

The study concluded that the SS devices are the simple and effective method for the primary closure of large and challenging wounds and skin defects.

Limitations

There are some limitations to our study. First, this was a single-center, non-randomized study. Second, the study involved only 30 wounds, and lastly, the short duration of follow-up was short. A large-scale randomized controlled study with a longer duration of follow-up is needed.

Ethics Approval

The study is in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2000.

Ethics Approval and Consent to Participate Duly informed consent was obtained in all the cases.

Conflict of Interests None declared.

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