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Stress–Relaxation and Tension Relief System for Immediate Primary Closure of Large and Huge Soft Tissue Defects: An Old–New Concept

New Concept for Direct Closure of Large Defects

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Abstract: Stress–relaxation is a well-established mechanism for laboratory skin stretching, with limited clinical application in conventional suturing techniques due to the inherent, concomitant induction of ischemia, necrosis and subsequent suture failure. Skin defects that cannot be primarily closed are a common difficulty during reconstructive surgery. The TopClosure® tension-relief system (TRS) is a novel device for wound closure closure, providing secured attachment to the skin through a wide area of attachment, in an adjustable manner, enabling primary closure of medium to large skin defects.

The aim of this study was to evaluate the efficiency of the TopClosure® TRS as a substitute for skin grafting and flaps for primary closure of large soft tissue defects by stress–relaxation.

We present three demonstrative cases requiring resection of large to huge tumors customarily requiring closure by skin graft or flaps. TRS was applied during surgery serving as a tension-relief platform for tension sutures, to enable primary skin-defect closure by cycling of stress–relaxation, and following surgery as skin-secure system until complete wound closure.

All skin defects ranging from 7 to 26 cm in width were manipulated by the TRS through stress–relaxation, without undermining of skin, enabling primary skin closure and eliminating the need for skin grafts and flaps. Immediate wound closure ranged 26 to 135 min. TRS was applied for 3 to 4 weeks. Complications were minimal and donor site morbidity was eliminated. Surgical time, hospital stay and costs were reduced and wound aesthetics were improved.

In this case series we present a novel technology that enables the utilization of the viscoelastic properties of the skin to an extreme level, extending the limits of primary wound closure by the stress–relaxation principle. This is achieved via a simple device application that may aid immediate primary wound closure and downgrade the complexity of surgical procedures for a wide range of applications on a global scale.

(*Medicine* 93(28):e234)

Abbreviations: APs = attachment plates, AS = approximation strap, TRS = tension-relief system.

INTRODUCTION

Closure of large soft tissue defects following ablative surgery or trauma, constitutes a substantial and common reconstructive challenge. Immediate primary suture closure of wounds is commonly the optimal solution because of its simplicity and acceptable outcome, yet it may be impeded by high-tension closure. The alternative application of skin grafts, flaps, or tissue expansion is often associated with relatively more complex surgical procedures, significant morbidity and extended hospitalization and recovery periods. Previous reports of external tissue expanders are inherently limited by the size of the defects that can be managed and the need for staged surgical procedures for the closure of large wounds.[1,2]

The TopClosure® Tension-Relief System (TRS) is an innovative method that enables the employment of both mechanisms of stress–relaxation and mechanical creep for skin stretching. Its use has been previously reported to enable the primary closure of medium to large soft tissue defects.[3,4] The system is comprised of 2 malleable polymer attachment plates (APs) that are fixed to the skin by adhesive or regular skin staples or sutures through a large area of adherence. The APs are placed a distance from the wound margins, and are pulled together manually by an interconnecting flexible approximation strap (AS) for incremental advancement of wound edges, through a lock/release ratchet mechanism. The APs may also serve as a tension-relief platform for tension sutures when high tension is indicated, to avoid damage to the underlying skin, such as in high-tension closure of large gaps and inelastic skin. This enables application of acute, intra-operative cycling of stress–relaxation by an ultra-high force (up to 50–60 N). Immediate primary wound closure is achieved, with infliction of $\sim 10^5$ less stress to the skin, compared with conventional suturing[3] (Table 1). Delayed primary closure can be achieved using TRS, through gradual pre- and post-operative approximation of the skin by mechanical creep, thus serving as an external tissue expander. Multiple sets of TRS can be applied perpendicular to the wound's longitudinal axis to accommodate selective local vectors of tension along the wound margins, thus fitting a wide range of wound sizes.

Editor: Robert Gaines.
Received: August 6, 2014; revised: October 4, 2014; accepted: October 9, 2014.
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The authors have no funding and conflicts of interest to disclose.

ISSN: 0025-7974
DOI: 10.1097/MD.0000000000000234

TABLE 1. Shear Stress Inflicted at Suture Tearing Force and at Break Down Force of the TopClosure® TRS

Suture Type	Suture Diameter (mm)	Tearing Force (kg)	Maximal Stress/Shear Stress (kg/mm^2)	Tension Grade
6/0	0.07	0.873	227.0	Low
5/0	0.1	1.75	222.9	Low
4/0	0.15	2.6	147.2	Moderate
3/0	0.2	4.063	129.3	Moderate
2/0	0.3	>8.8	123.9	High
TopClosure® TRS	At break down force of 2.9 kg	0.0029	Extremely low (ultra-high by tension sutures)	

We present the implementation of stress–relaxation in extreme range of stress through the tension-relief system concept for immediate primary closure of large to huge skin defects, where suture closure would not be considered feasible.

REPRESENTATIVE CASE 1

A 60-year-old schizophrenic male patient was admitted to the hospital following a fall resulting in head injury. On physical examination, an incidental finding revealed a large ulcerated soft-tissue tumor on his right flank (Figure 1A). Following discharge, the patient was readmitted for elective resection of the tumor. With the patient under general anesthesia and lying in a lateral position the tumor was resected including the involved superficial muscular fascia, resulting in a 15×25 cm soft tissue defect (Figure 1B). A closure trial with the TopClosure® TRS (IVT Medical Ltd., Ra'anana, Israel), was initiated. Three pairs of APs (TopClosure®, 8 mm sets) were attached by adhesive to the skin, 1.5 cm away from the wound edges, and secured by skin staples (Weck Visistat® 35W, 6.5×4.7 mm, Teleflex Medical, NC, USA). A tension suture (Ethilon 1 KP-3 CONV, 90 mm 3/8C, Johnson & Johnson International) was inserted for each AP, first through one AP, then deep into the subcutaneous tissue across the tissue gap, and then out through the contralateral AP on the other side of the skin defect. The suture was then passed through the designated holes in the front part of the APs and over to the first plate. TRS served as a tension relief platform for the tension sutures. Multiple alternating pull (30 s) and release (1–2 min) cycles of stress–relaxation were performed over a period of about 20 min. Intermittent absorbable subcutaneous sutures (Vicril 0, Johnson & Johnson International) were applied concurrent with the pull on the tension sutures. The skin edges were gradually approximated without undermining until complete primary closure, within less than 30 min (Figure 1C). No drain was required as dead space was negligible. Histological findings revealed eroded basal cell carcinoma invading the subcutaneous fat and the underlying skeletal muscle. The tumor was completely excised.

The post-operative course was complicated by minor dehiscence of the wound edges due to both patient non-compliance and initial inadequate application of TRS sets and tension sutures, in order to properly accommodate the high-tension closure of the wound (Figure 1D). Bedside application of a new AS was performed to bring the wound edges together. Two extra sets of TRS and the application of 2 sets of tension sutures per TRS set would have been required in order to better secure high tension closure and to avoid dehiscence. It should be noted that there was no ischemia or necrosis of the wound edges in spite of the high-tension closure. The TopClosure® System, sutures and staples were removed in stages until 3 weeks following the surgery. Final complete closure of the wound with minimally depressed scar is demonstrated in Figure 1E.

REPRESENTATIVE CASE 2

A 35-year-old male patient was admitted for a wide excision of malignant melanoma of the right scapular region, following prior excisional biopsy confirmed histologically as an ulcerated nodular malignant melanoma incompactly excised at its margins. A wide excision was performed under general anesthesia, resulting in a 7×11.5 cm soft tissue defect that conventionally would have been closed by a split thickness skin graft (Figure 2A). An immediate primary closure of the defect was planned, applying 3 pairs of APs (TopClosure®, 8 mm sets) that were attached to the skin 2 cm away from the wound edges by adhesive, and secured by skin staples. A tension suture was inserted through both plates as described above, to advance the deep subcutaneous tissue on both sides of the wound. There was repeated cycling of stress–relaxation, (applying tension for 30 s and relaxation for 1–2 min), alternating between the TRS sets. The entire wound margins could be approximated within 35 min, bringing the skin and subcutaneous tissue, en bloc, into tight contact with practically no dead space, following placement of deep subcuticular vicryl 0 sutures and tightening of the tension sutures. Tension sutures were tightened and locked on top of the APs, and ASs were inserted for additional minimal approximation of skin and secured by the lock/release mechanism. Staples were applied for final alignment of skin edges. Closure of the wound was achieved within 60 min (Figure 2C). TRS were retained for up to 4 weeks to accommodate for the high tension closure, thus securing complete closure of the wound. The melanoma was fully resected with no immediate post-operative complications (Figure 2D), 18 months post operation a mild widening of the scar was observed (patient being an amateur bodybuilder), with no apparent local or distant recurrences (Figure 2E).

REPRESENTATIVE CASE 3

A 41-year-old woman presented with recurrent low to moderate-grade spindle cell sarcoma of the supraclavicular area, extending to the lateral neck, measuring 25×18 cm (Figure 1A, B). The patient underwent a resection of the tumor, resulting in a defect reaching a width of 26 cm (Figure 1C). Primary closure of the defect was attempted, applying the TRS Systems. Six pairs of APs (TopClosure®, 8 mm sets) were attached by adhesive to the skin, 2 cm away from the wound margins, and reinforced by skin staples. A pair of tension sutures were inserted through each TRS set, connecting both plates, as described above, to advance the deep subcutaneous

FIGURE 1. Reconstruction of a huge soft tissue defect in right flank (REPRESENTATIVE CASE 1) by the tension-relief system. A. Large ulcerated squamous cell carcinoma in the right flank. B. Ablative tumor resection resulted in a defect of 15 × 25 cm. C. Immediate primary closure of wound within less than 30 min. D. Post-operative day 1, a small, limited dehiscence. Wound edges are secured by tension sutures, avoiding complete dehiscence of surgical wound. E. Six months following surgery, uneventful recovery, with minor widening and depression of the scar and additional skin tumor to be excised.

tissue on both sides of the wound. Repeated cycling of stress–relaxation were applied, initiating at the highest tension region, at the center of the wound (inducing tension for 30 s. and relaxation for 1–2 min), and alternating between the TRS sets during the closure process. The entire wound margins could be approximated, bringing the skin and subcutaneous tissue, en bloc, into tight contact with practically no dead space, following placement of deep subcuticular and tension sutures. Tension sutures were tightened and locked on top of the APs, and ASs were inserted for additional minimal tightening of the skin and were then secured by the lock/release mechanism. Staples were used for final alignment of the skin edges. The huge defect was primarily closed in just over 2 hours, under ultra-high tension (Figure 3D). The skin was not undermined, thus maintaining good blood supply to the wound margins and, as dead space was minimal, a drain was not applied to the wound. A demonstrative video of the surgical procedure is presented in the Web link below.[5] TopClosure®, tension sutures and staples were retained, in order to secure the wound closure for up to 23 days, achieving full closure of the wound. Complete tissue viability along the entire wound edges was observed during the post-operative period. Additionally, there was early patient ambulation, minimal local morbidity, elimination of donor site morbidity, acceptable cosmesis, with late limitation in range of Lt. shoulder motion in abduction that was improved by physical therapy, all preferable to the alternative conventional skin graft or free flap closure techniques (Figure 3D, E).

The TopClosure® was approved for clinical use in compliance with the clinical trial that was approved by the institutional review board, research No.: 0049–09-HYMC. Patient's informed consent was given prior to all surgical procedures performed is this study. A summary of the patient's details and comparison between surgical procedures and follow-ups is presented in Table 2.

DISCUSSION

There are 2 main mechanisms for skin stretching that may assist in primary wound closure: stress–relaxation and mechanical creep.[6,7] Mechanical creep is the phenomenon where skin will stretch and elongate incrementally with time as long as force is applied. This can be comprehended and visualized by the physiological process of skin stretching during pregnancy or under the impact of the forces created by extreme body weight gain or inflation of tissue expanders leading to steady skin expansion. If the skin is acutely stretched to a constant distance, tension will rise sharply and will decrease with time in a state of gradual relaxation. If stress–relaxation is repeatedly applied over time, a deformation of the skin will result in permanent elongation. These biomechanical mechanisms allow skin to stretch beyond the conventional suturing limits of its inherent extensibility and is made possible by alteration of its basic structural components. Under external tension, the interrelated networks of collagen, elastin, and ground substance in the extracellular matrix of the tissue deform, inflicting tissue elongation, allowing skin stretching to a limited extent.

These mechanisms assist primary suture closure of wounds of minor to moderate skin defects only. In vitro

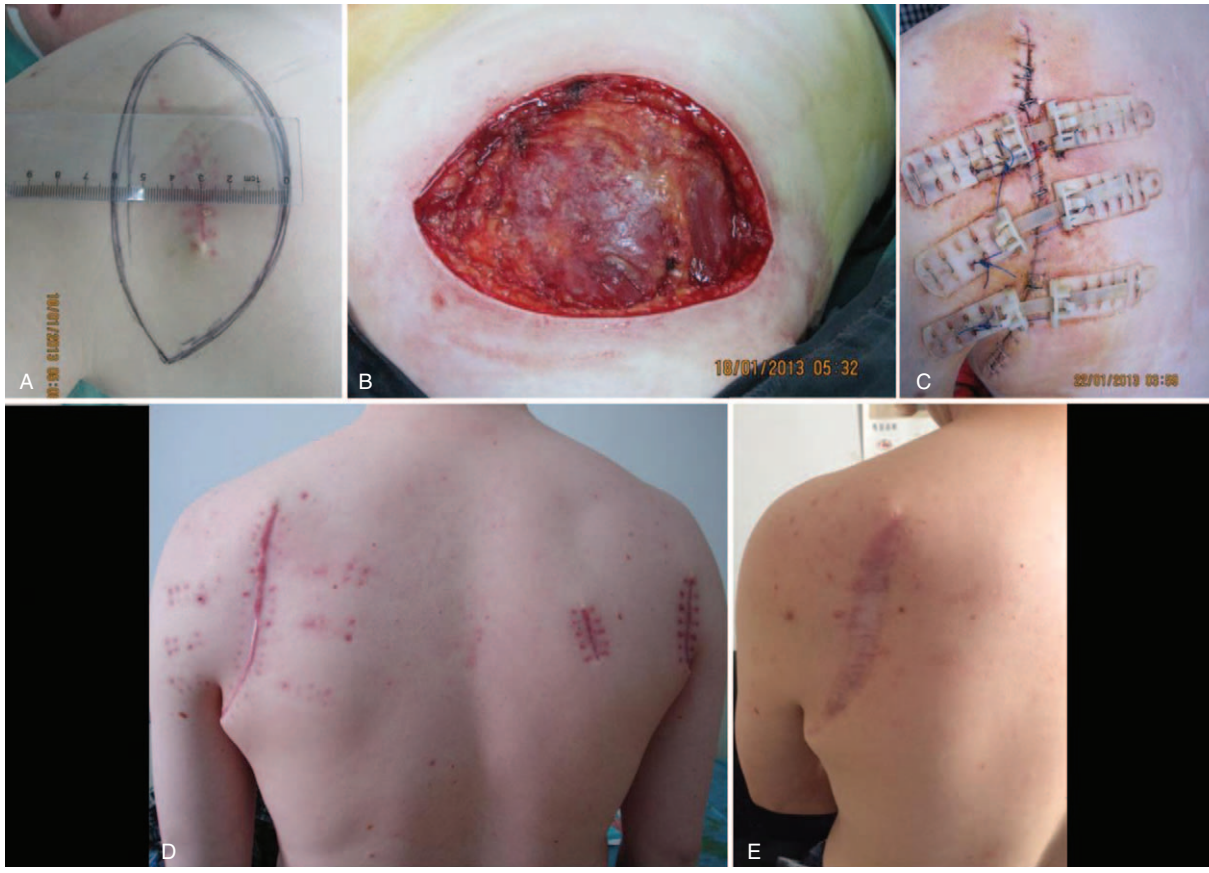

FIGURE 2. Reconstruction of a large soft tissue defect in the Lt. scapular region after wide ablation of malignant melanoma (REPRESENTATIVE CASE 2). A. Post-incomplete excisional biopsy of malignant melanoma lesion in scapular area. B. Tumor ablation resulted in a defect of 7 × 11.5 cm. C. Immediate primary closure was achieved; utilizing 3 TopClosure® 8 mm sets. D. Six weeks following surgery, acceptable aesthetic result, mild, partial hypertrophic scar. E. Eighteen months following surgery, mild widening of scar is observed.

laboratory work has demonstrated the ability to stretch skin in a stress–strain curve through both the elastic and plastic properties of the skin.[8]

Stress–relaxation–strain hysteresis pattern curve is limited in its clinical application by the concurrent ischemia and necrosis that results from the application of excessive tension on sutures approximating wound edges, leading to wound closure failure and dehiscence of suture line. The resulting strain that could be achieved so far by stress–relaxation through conventional suturing techniques is thus limited in its clinical application to few percent only.

External tissue expansion was developed over 20 years ago with the intention to better harness the viscoelastic properties of the skin by fixing the device to the skin externally and applying mechanical creep mode of stretching in order to gain extended length, thus overcoming some of the major shortcomings of the internal tissue expansion techniques.[9] The Sure Closure®, the Wiseband®, and the Dermaclose® – skin stretching systems presented additional ability for both immediate and delayed primary wound closure. All these devices have an inherent limitations: they adhere to the skin edges at a relatively small area of contact thus the size of the gap that can be managed is relatively small, their adherence to the skin is close to the vulnerable wound edges, all of them can be applied invasively only and their ability to stretch the skin is mainly by mechanical creep.[10–12]

While serving as a tension relief platform, the TopClosure® TRS was shown in these cases to allow the clinical application of ultra-high stress by tension sutures to the skin without inflicting ischemia, necrosis and wound failure. TRS has provided the phenomenal ability of stretching the skin for immediate or delayed primary closure of large skin defects as was previously reported,[4] and of an even huge skin gaps being immediately, primarily closed, as now further demonstrated in the current case series.

There are notable advantages for applying the TopClosure® TRS: The ability to apply pre- and post-operative mechanical creep as through external skin stretching and acute intraoperative stress–relaxation as by TRS, for both low and high tension wound closure, respectively. TRS downgrades the surgical complexity, operating time is reduced and hospital stay can be substantially shortened. The resulted skin coverage quality in primary wound closure is by far superior to skin grafting. Undermining of the skin edges and adjacent tissues can be avoided maintaining blood supply to the wound margins and securing skin edges viability even under extreme tension. Avoidance of undermining eliminates dead space, seroma and hematoma accumulation and the need for drainage and reduces the risk of infection. Skin can be further approximated following stress relaxation by advancing the AS as a bedside procedure by mechanical creep, some cases under local anesthesia. When serving as a topical tension-relief platform for tension

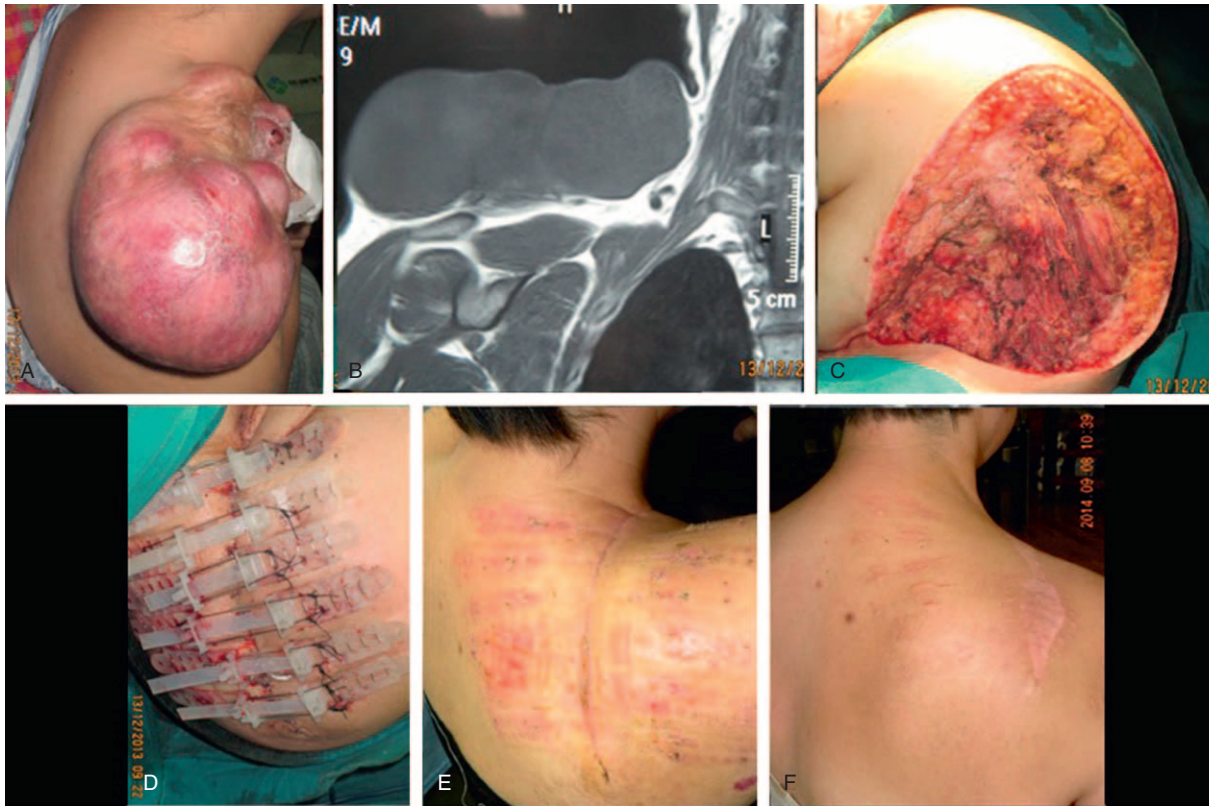

FIGURE 3. Reconstruction of a huge soft tissue defect in the right supraclavicular region, extending to the base of the neck by the TopClosure® tension-relief system (REPRESENTATIVE CASE 3). A. Large recurrent tumor of the right cervical/supraclavicular region, 18 × 25 cm. B. Coronal MRI section demonstrating the extent of tumor. C. Twenty-six centimeter wide defect following tumor ablation. D. Immediate, direct primary closure was achieved in just over 2 hours. E. Post-operative day 23, uneventful recovery. F. Ten months following surgery, slight widening of scar is observed.

TABLE 2. Clinical and Pathological Characteristics of Cases Presented, Intra and Post-Operative Wound Management and Results

	Case No. 1	Case No. 2	Case No. 3
Age	60	35	41
gender	M	M	F
Ethnicity	Caucasian	Oriental	Oriental
Histological findings	Basal cell carcinoma	Nodular malignant melanoma	Recurrent low to moderate-grade spindle cell sarcoma
Anatomical region	Flank	Scapular	Supraclavicular/lateral neck
Gap dimensions width × length (cm)	15 × 25	7 × 11.5	26 × 25
Number of TopClosure® TRS applied	3	3	6
Application of tension sutures	Yes	Yes	Yes
Mechanism of closure	Stress relaxation (Stretching 30 s, relaxation 1–2 min)	Stress relaxation (Stretching 30 s, relaxation 1–2 min)	Stress relaxation (Stretching 30 s, relaxation 1–2 min)
Time for gap closure (min)	≤26	≤60	<135
Wound edge undermining	No	No	No
Wound drainage	No	No	No
Early complications	Minimal wound dehiscence	Staple marks	Minimal blistering
Late complications	Minimally depressed scar	Scar widening	Scar widening, limitation in range of motion in abduction

sutures, it alleviates the typical tearing and scarring, traditionally inflicted by tension sutures. Skin graft donor site morbidity can be eliminated. For its simplicity, the TopClosure® TRS can be applied for a wide scope of indications in a wide range of global standards of surgical settings.

The sample of cases presented above demonstrates the extreme stretching capacity inherent in the viscoelastic properties of the skin that can be utilized by stress–relaxation coupled by the TRS. It is important to note that the technique presented in this case series especially in cases 1 and 3 are by far an extreme manifestation of the application of stress relaxation in clinical use. The authors indicate that the inexperienced surgeon could stop wound closure at any time, dress the wound, and further apply the TopClosure® TRS by mechanical creep for delayed primary closure at a later stage.

This novel technology changes the concept of wound closure with its ability to reduce the applied stress to the skin during the process of wound closure by up to 5 orders of magnitudes, thus safely enabling the clinical application of both stress–relaxation and mechanical creep. It simplifies the surgical technique by reducing ischemia during the process of wound closure to facilitate immediate primary wound closure in a relatively short time. This could not be achieved so far through the conventional suturing methods that have been applied in the same conceptual way for ages. To our knowledge, this is the first time that such large defects have been successfully closed by immediate primary closure, within a very short time, with very minor complications.

CONCLUSIONS

This case series report, together with our previous reported findings, demonstrate the vast potential harnessed by the viscoelastic properties of the skin for stretching to the extreme limits of its extensibility by stress–relaxation. This is made clinically possible through coupling with the unique TRS, to form a new wound closure concept that has not been previously conceivable using conventional suturing methods due to the inherent ischemia and necrosis inflicted by suture closure attempt of high-tension wounds. Further laboratory and clinical investigation is warranted in order to better comprehend the viscoelastic properties of the skin: stress–strain properties, mechanism of stress–relaxation and skin preconditioning under these extreme conditions and when coupling tension sutures with the TopClosure® TRS, for further optimization of wound closure. The prospective is quite positive for global implementation of this new/old concept in a wide range of surgical applications.

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