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ORIGINAL PAPER

The effect of TopClosure® TRS in the treatment of large abdominal wall defect

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Abstract

Background Large abdominal wall defects, which are not suitable for primary closure partly due to the expected high tension closure and the considerable rate of recurrence, represent a substantial reconstructive challenge. The study is aimed to evaluate the clinical value of TopClosure® Tension-Relief System (TRS) in the treatment of large abdominal wall defect.

Methods Thirteen patients with large abdominal wall defect were treated using TopClosure® TRS, and the average healing time, patients' satisfaction, and complication were recorded.

Results After being treated with TopClosure® TRS, 10 cases were primary healing, three-case second-intention healing due to the thickened abdominal wall with mild scar. The average healing time and hospitalization time are shortened, while the primary healing rate and VAS satisfactory value improved. Logistic regression analyses indicated that age, BMI, defect area, wound infection, and diabetes may influence the effect of TopClosure® TRS in the repair of large abdominal wall defect.

Conclusion Large abdominal wall defect can be treated using TopClosure® TRS, effectively and easily, which can be generalized to be used in clinics.

Level of evidence: Level IV, therapeutic study.

Keywords Large abdominal wall defect · TopClosure® · Tension-Relief System · Primary healing

Introduction

Abdominal wall defects (AWDs) result from trauma, tumor, infection of necrotizing, burns, surgery which lead the lack of partial or the full layer of the abdominal wall [1]. A partial-thickness defect describes a wound where either the skin or the subcutaneous tissue is resected, whereas full-thickness defects encompass a loss of both superficial soft tissue and the deeper musculofascial layers [2]. Partial-thickness defects are more amendable to primary closure, negative-pressure assisted closure, and skin grafting. Full-thickness defects often require musculofascial reinforcement and therefore need composite flap coverage with or without mesh to prevent herniation and bulge formation.

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Small-size AWDs can be closed easily using the residual abdominal wall soft tissues; however, the closure of large-size AWDs which usually cause infection usually cannot be closed using conventional surgical suture because of the tension that remain a huge challenge in current general surgical practice [3, 4]. 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 [5, 6]. In 1976, Barrer firstly used skin stretching device to repair small area skin defect. Then, it is widely used for the closure of large-area flap wounds followed by a variety of more developed kinds of skin stretching device, such as Sureclosure®, Dermaclose®. TopClosure® Tension-Relief System (TRS) 3S System has been designed and applied to harness the viscoelastic properties of the skin by both mechanical creep and stress-relaxation principles in both

noninvasive and invasive manners [7]. TopClosure® TRS can minimize damage to the skin and suppress the formation of scars. Previously, we have reported the TopClosure® TRS for the immediate closing of the large skin defects of the anterior chest wall following large keloid excision [8].

In this study, we shared our experience of using TopClosure® TRS to help the repair of large abdominal skin defects and assess its clinical effectiveness.

Material and methods

Device structure and characteristics

The TopClosure® 3S System is composed by two attachment plates (AP) and one approximation strap (AS). While APs are adhered to the skin by hypoallergenic, biocompatible adhesive on their undersurface, the long and flexible AS links the opposing APs, enabling approximation and advancing the APs by incremental pull on the AS. The AS is inserted on the proximal AP until being secured by the AS's wings through the lock/release ratchet mechanism (L/RM). Next, it is inserted into the L/RM on the opposing AP to allow gradual controlled stretching of the underlying skin. The AS is locked or released by lightly pressing or lifting the L/RM's lever.

Patients

Patients aged 18–75 years who had large-size abdominal wall defects were eligible for participation in the study. Exclusion criteria included (1) younger than 18 or older than 75, (2) severe wound infection, (3) pregnancy or lactation, (4) mental status, (5) known or suspected bowel obstruction or perforation, (6) severe chronic renal failure (creatinine clearance < 30 ml/min), (7) severe congestive heart failure (New York Heart Association class III or IV), and (8) uncontrolled hypertension (systolic blood pressure > 170 mmHg, diastolic blood pressure > 100 mmHg).

Study design

This is a retrospective study with consecutive outpatients undergoing wound closure of large abdominal wall defect at the Department of plastic surgery, Renmin Hospital of Wuhan University in China. The study protocol and informed consent form were approved by the institutional review board of Renmin Hospital of Wuhan University (2018-C007).

Treatment process

After the physical examination and evaluation (such as serology), with or without the debridement and/or vacuum sealing drainage (VSD), the defects of patients were closed using TopClosure® TRS with general anesthesia. Changes of dressing on wound were done every 2 days. The wound status, healing time, and complications were recorded. TopClosure® TRS were removed at day 5 and took out stitches at day 7. VAS value was used for evaluating patients' satisfaction.

Statistics

Data are expressed as the mean ± SD. The difference among groups was determined by ANOVA, and the difference between groups was analyzed by the Student's *t* test using SPSS 17.0 for Microsoft Windows (SPSS Inc., Chicago, IL, USA). A value of $P < 0.05$ was considered to indicate a statistically significant result.

STROCSS criteria

The work has been reported in line with the STROCSS criteria [9].

Results

Patient characteristics

From September 2014 to August 2018, 13 patients (8 male, 5 female) with large abdominal skin defect in our hospital were treated with TopClosure® TRS. The age of these patient ranges from 33 to 65, and the mean age is 49.3. All defects of 13 patients result from postoperative dehiscence of the wound edges that cannot be closed easily. The largest area of these defects is 68 cm^2 and the average is 31 cm^2. And the mean depth is 1.5 cm. The patients' information is shown in Tables 1 and 2.

Outcomes of TopClosure® TRS

After being treated with TopClosure® TRS, 10 cases were first-intention healing, three-case second-intention healing due to the thickened abdominal wall with mild scar. The average healing time is 10.4 ± 1.7 days and hospitalization time is 14.2 ± 2.4 days. In addition, the primary healing rate is 75%. No complication occurs in this duration. Every patient with his or her family members was satisfactory with the treating effect and the

Table 1 Baseline characteristics of the study patients

	Abdominal wall defect patients
Gender	
Male (*n*, %)	8 (61.5)
Female (*n*, %)	5 (38.5)
Age (years, mean ± SD)	49.3 ± 10.9
< 50 (*n*, %)	6 (38.5)
> 50 (*n*, %)	7(61.5)
BMI (kg/m^2, mean ± SD)	25.1 ± 2.6
< 24 (*n*, %)	4 (30.8)
> 24 (*n*, %)	9 (69.2)
Defect area (m^2, mean ± SD)	46.5 ± 11.6
< 37 (*n*, %)	3 (23.1)
> 37 (*n*, %)	10 (76.9)
Defect depth (cm, mean ± SD)	1.5 ± 0.55
< 1.5 (*n*, %)	7 (53.8)
> 1.5 (*n*, %)	6 (46.2)
Wound infection	3(23.1)
Diabetes (*n*, %)	2 (15.4)
Defect types	
Post-operative dehiscence	7 (53.8)
Post-operative ulcer	6 (46.2)

VAS satisfactory value is 84.5 ± 6.1. The patients' information is shown in Table 1.

Factors associated with effect of TopClosure® TRS in the repair of large abdominal wall defect

Using TopClosure® TRS to treat large abdominal wall defect, young patients' (≤ 50 years old) wound healing time and hospitalization time are shorter than that of old patients (> 50 years old), and VAS value is higher. Also, for patients who have low BMI, small defect area, without wound infection and diabetes, whose defect caused by post-operative dehiscence will benefit most from TopClosure® TRS.

Logistic regression analyses were performed to identify any significant factors for associated with effect of TopClosure® TRS in the repair of large abdominal wall defect (Table 3). The factors which influenced wound healing time were age, body mass index (BMI), defect area, wound infection, and defect type, which associated with hospitalization time were age, BMI, wound infection, and defect type; diabetes and defect type were the factors that play a role in primary healing rate, which associated with VAS satisfactory value were age, BMI, defect area, and defect type. The multivariate analysis indicated that age (OR 1.917, $p = 0.048$) was significantly associated with healing time; diabetes (OR − 2.276, $p = 0.023$) was significantly associated with hospitalization time. The factors associated with effect of TopClosure® TRS in the repair of large abdominal wall defect are shown in Tables 3 and 4.

Table 2 Factors influence the effect of TopClosure®

	Healing time (days, mean ± SD)	*P* value	Hospitalization time (days, mean ± SD)	*P* value	Primary healing rate *n* (%)	*P* value	VAS value (mean ± SD)	*P* value
	10.4 ± 1.7		14.2 ± 2.4				84.5 ± 6.1	
Gender								
Male	10.1 ± 1.6	0.650	14.4 ± 2.4	0.790	1(12.5)	0.252	84.8 ± 6.6	0.910
Female	10.6 ± 2.0		14.0 ± 2.5		2(40)		84.0 ± 5.9	
Age (years, mean ± SD)								
≤ 50	9.0 ± 0.6	0.001	12.7 ± 2.0	0.020	0(0)	0.137	89.0 ± 1.4	0.007
> 50	11.6 ± 1.3		15.6 ± 1.9		3(42.9)		80.6 ± 5.9	
BMI (kg/m^2, mean ± SD)								
≤ 24	8.8 ± 0.5	0.001	12.5 ± 0.6	< 0.001	0(0)	0.188	89.5 ± 1.3	0.007
> 24	11.1 ± 1.5		15.4 ± 1.7		3(37.5)		82.2 ± 6.1	
Defect area (m^2, mean ± SD)								
≤ 40	9.2 ± 0.8	0.018	12.8 ± 2.2	0.093	0(0)	0.118	81.6 ± 6.2	0.01
> 40	11.1 ± 1.6		15.1 ± 2.2		3(60)		89.0 ± 1.2	
Defect depth (cm, mean ± SD)								
≤ 1.5	10.7 ± 2.0	0.449	14.9 ± 2.8	0.313	2(28.6)	0.612	82.1 ± 7.2	0.132
> 1.5	10.0 ± 1.3		13.5 ± 1.8		1(16.7)		87.2 ± 3.3	
Wound infection								
Yes	11.8 ± 1.3	0.043	16.8 ± 1.0	< 0.001	2(50)	0.125	80.0 ± 7.1	0.171
No	9.8 ± 1.5		13.1 ± 1.9		1(12.5)		86.4 ± 4.7	
Diabetes								
Yes	11.7 ± 1.5	0.190	16.3 ± 0.6	0.006	2(66.7)	0.04	82.0 ± 7.0	0.525
No	10.0 ± 1.6		13.6 ± 2.4		1(10.0)		85.2 ± 6.0	
Defect types								
Post-operative dehiscence	9.3 ± 1.03	0.027	12.7 ± 2.0	0.017	2(33.3)	0.05	79.7 ± 5.8	0.011
Post-operative ulcer	11.5 ± 1.64		15.8 ± 0.9		1(85.7)		88.7 ± 2.1	

Table 3 Univariate analysis of factor influences the effect of TopClosure®

	Healing time		Hospitalization time		Primary healing rate		VAS value	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age	2.571 (1.308 to 3.835)	< 0.001	2.905 (0.239 to 5.270)	0.021	0.429 (− 0.055 to 0.912)	0.077	− 8.429 (− 13.851 to − 3.006)	0.006
BMI	2.361 (0.686 to 4.036)	0.010	3.944 (1.942 to 5.947)	0.001	0.333 (− 0.231 to 0.897)	0.220	− 7.278 (− 14.168 to − 0.387)	0.040
Defect area	1.925 (0.164 to 3.686)	0.035	2.325 (− 0.395 to 5.045)	0.087	0.375 (− 0.143 to 0.893)	0.139	− 7.375 (− 13.681 to − 1.067)	0.026
Wound infection	− 1.972 (− 3.856 to − 0.089)	0.042	− 3.639 (− 5.882 to − 1.396)	0.004	11.518 (− 1.283 to 24.317)	0.071	− 0.389 (0.159 to − 0.937)	0.147
Diabetes	− 1.667 (− 3.923 to 0.589)	0.132	− 2.733 (− 5.855 to 0.388)	0.080	− 0.567 (− 1.113 to − 0.020)	0.043	3.200 (− 5.770 to 12.170)	0.449
Defect types	− 2.071 (− 3.690 to − 0.453)	0.017	− 2.978 (− 5.302 to − 0.650)	0.017	− 0.500 (− 0.952 to − 0.048)	0.033	8.905 (3.828 to 13.981)	0.003

Table 4 Multivariate analysis of factors influence the effect of TopClosure®

	Healing time		Hospitalization time		Primary healing rate		VAS value	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age	1.917 (0.019 to 3.815)	0.048	0.586 (− 1.652 to 2.824)	0.563	–	–	− 6.028 (− 13.733 to 1.678)	0.108
BMI	− 0.142 (− 2.353 to 2.068)	0.883	2.017 (− 0.653 to 4.687)	0.120	–	–	1.841 (− 6.790 to 10.473)	0.636
Defect area	0.483 (− 1.497 to 2.464)	0.582	–	–	–	–	0.124 (− 7.805 to 8.053)	0.972
Wound infection	− 1.222 (− 2.788 to 0.344)	0.108	–	–	–	–	–	–
Diabetes	–	–	− 2.276 (− 4.138 to − 0.414)	0.023	− 2.212 (− 0.754 to 0.329)	0.404-	–	–
Defect types	− 0.321 (− 2.422 to 1.780)	0.728	− 0.690 (− 2.685 to 1.306)	0.448	− 0.424 (− 0.926 to 0.077)	0.089	6.744 (− 1.543 to 15.033)	0.097

Representative case 1

A 67-year-old male patient was admitted for post-operative dehiscence of the wound edges. One month ago, the patient was admitted for colon cancer and underwent a resection by laparotomy. When took out stitches, the operative wound edge dehiscenced and could not be closed by the dressing changes. There was a post-operative dehiscence of the wound reaching a length of 16.2 cm with neat edge (Fig. 1a). The patient had moderate malnutrition.

After the physical examination and evaluation, nutrition administration was carried out to improve the patient's nutritional status. The defect was closed using TopClosure® TRS (two TopClosure® TRS 3S Systems were positioned at the edge of wound) with general anesthesia (Fig. 1b). Then, changes of dressing on wound were done every 2 days. The drainage tube was removed at day 3 and TopClosure® TRS was removed at day 5. After the stitches were taken out, the wound did not dehiscence. When the wound was re-examined 1 month later, the wound was healed and patient was satisfactory with the treatment effect.

Representative case 2

A 63-year-old female patient was presented with post-operative ulcer of abdominal skin. The patient underwent a resection for abdominal lymphatic cyst and large post-operative ulcer appeared on the abdominal skin wound because of wound infection. Unfortunately, dressing changes could not improve it. There was a large post-operative ulcer reaching 13.2 cm × 4.1 cm appeared on the abdominal skin with light-yellow purulent secretion and necrotic tissue (Fig. 2a).

After the physical examination and evaluation, purulent secretion and necrotic tissue were removed with debridement and vacuum sealing drainage (VSD). When the status of the wound improved (new granulation appears and the local microcirculation improved), three TopClosure® TRS 3S Systems were positioned to close the wound (Fig. 2b). The drainage tube was removed at day 3 and TopClosure® TRS was removed at day 5. The wound healed well (Fig. 2c).

Discussion

Abdominal wall is characteristic with its large-area soft skin, and because of that, it is common to find large abdominal wall defect. Closure of large, wide, open wounds such as the large abdominal wall defect could often not be achieved by conventional suturing techniques due to critical tissue deformations and ischemia that is inflicted on the skin by the focal tension points around the sutures [10]. The primary goals of treating wounds in general and skin incisions in particular are rapid closure with the creation of a functional and esthetic scar [11]. Stress–relaxation and mechanical creep are the two main mechanisms for skin stretching that may assist in primary wound closure [12, 13]. Mechanical forces play a significant role in the formation and structuring of tissues, mainly the skin, during repair processes, determining their three-dimensional shape, as well as structural and remodeling properties affecting tissue on cellular and subcellular levels [14, 15]. If the skin is stretched to a constant distance in a state of stress relaxation, it will expand, leading to a

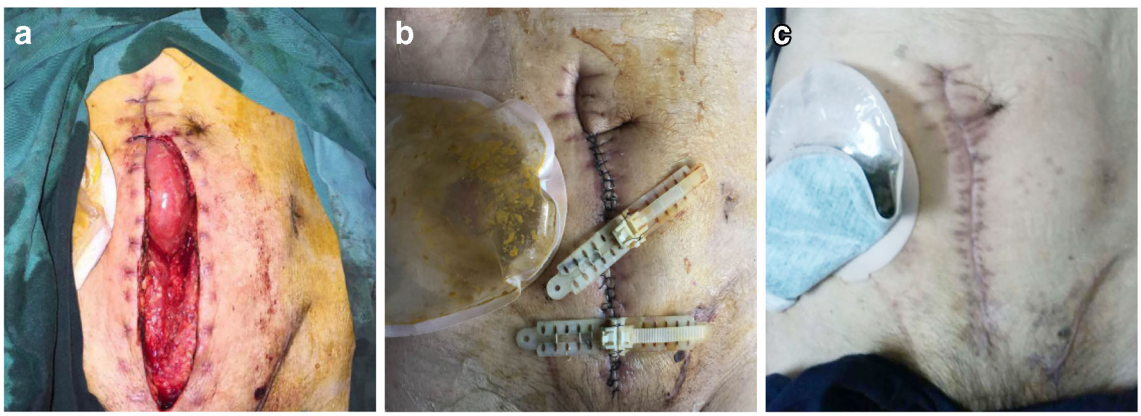

Fig. 1 The use of TopClosure® TRS on post-operative dehiscence of abdominal skin wound (**a** pre-operation; **b** intraoperative; **c** post-operation)

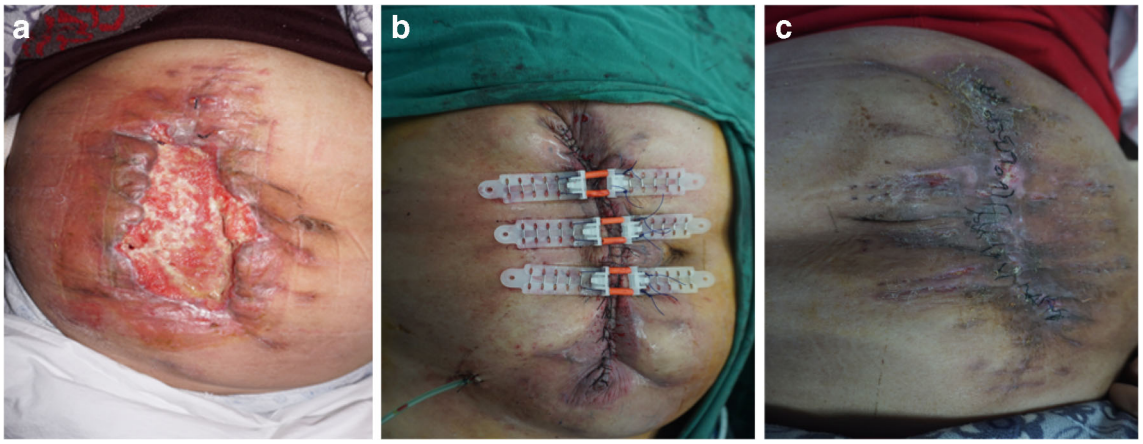

Fig. 2 The use of TopClosure® TRS on large post-operative ulcer of abdominal skin wound (**a** pre-operation; **b** intraoperative; **c** post-operation)

gradually reduced tension on the skin. As a result of skin stretching and elongation, wound closing tension decreases, allowing primary closure of relatively large defects [6].

Ideally, a wound closure method should be cost-effective, time-efficient, easy to perform, and produce the optimal cosmetic result. Many techniques have been applied for closure of large skin defects: skin grafts, local flaps, tissue stretching and expansion, free flaps, and closure by secondary intention. However, considerable morbidity, complexity, costly and esthetically inferior limit their use for the large abdominal wall defect [16]. Primary closure, if feasible, is regarded the optimal closure method; however, it can rarely exceed a gap width of 3 cm, even with extensive undermining [17, 18]. Moderate and large scalp skin defects, with skin gaps greater than 3 cm, almost always require application of skin grafts, healing by second intention, relaxing incisions, wide undermining, tissue expansion, and/or coverage by a flap, but frequently resulting in a poor-quality skin with a patch-like deformity requiring additional serial surgical procedures to improve the esthetics of the scar [19]. Negative pressure-assisted closure can provide for temporary coverage in anterior abdominal wall defects, but it may be not suitable for the large abdominal wall defect.

The TopClosure® TRS 3S System is an innovative method that enables the employment of both mechanisms of stress–relaxation and mechanical creep for skin. This new concept uses distribution of the force necessary to stretch the skin over a relatively wide area of adherence, away from the traumatized wound edges, using selective vector-oriented forces, continuously or cyclically, in both noninvasive and invasive manners.

Mechanical creep is the phenomenon where skin will stretch and elongate incrementally with time as long as force is applied. At the core of the new concept applied by the TopClosure® 3S System is the distribution of forces needed to stretch the skin on a relatively wide area of adherence, away from the traumatized wound edges, using selective vector-oriented forces. TopClosure's strong topical adherence to the underlying skin enables the application of significant pull to the skin with relatively minimal tangential shear stress, avoiding pain and excessive skin damage. The TopClosure® 3S Systems can, in many instances, replace tissue expanders by using gradual and slow skin stretching paced over a few days to several weeks. When indicated for scar or tumor removal, an integrated constant force over time is expected to affect the skin in a manner similar to tissue expanders. This is achieved by utilizing the mechanical creep properties of tissues but with much more flexible distance, close to and/or distant from the lesion's edges [20].

Stress relaxation is another biomechanical property of soft tissue behavior which describes the time-dependent decay of stress as the applied strain is held constant [21]. The quasi-linear viscoelastic constitutive model is one of the methods of characterizing stress relaxation behavior of skin. Stress relaxation allows skin to stretch intraoperatively beyond its inherent extensibility in a short period of time. As a result of skin stretching, wound closing tension decreases over time, allowing primary closure of relatively large defects. Load cycling of skin implies an incremental increase in the length of the skin. TopClosure® TRS can be applied to acutely, tangentially stretched skin over a period of 20–30 min, in intermittent, repetitive cycles of 3-min stretching,

applying a constant strain with an apparent period of tissue blanching (ischemia), followed by 1-min relaxation with capillary refilling (reperfusion) and led to an incremental skin elongation through the stress relaxation mechanism, facilitating primary skin closure.

There are notable advantages for applying the TopClosure® TRS 3S System for large abdominal wall defect: 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, shortens the operating time and hospital stay. The resulted skin coverage quality in primary wound closure is 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. Skin graft donor site morbidity can be eliminated. Although the scars associated with abdominal wall defect and sutures using TopClosure® TRS System are relatively small, they are still inevitable. So, TopClosure® TRS 3S System need to be improved later to reduce scar formation and ameliorate the appearance.

In conclusion, the TopClosure® TRS 3S System is an innovative technology that changes the concept of wound closure with its ability to reduce the applied stress to the skin during the process of wound closure by, thus safely enabling the clinical application of both stress–relaxation and mechanical creep. It can be utilized to modify and improve the current practice of large abdominal wall defect closure.

Compliance with ethical standards

Conflicts of interest Xiaoli Wang, Zhanyong Zhu, Yueqiang Zhao, Mosheng Yu, and Moris Topaz declare that they have no conflicts of interest to disclose. Moris Topaz is one of the inventors of TopClosure® TRS ad CEO of IVT Medical Ltd. manufacturer of the device.

Ethical approval An ethical committee approval for the above reported procedure was waived by the Medical Ethics Committee of the Renmin Hospital of Wuhan University Review Board (2018-C007).

Informed consent Following a detailed review of the intended surgical procedure, the patients consented for the publication of this study and the use medical information for the purposes of the study.

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