

TopClosure Tension Relief System for wound closure

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the TopClosure Tension Relief System (TRS). It is used to stretch skin to improve wound closure after injury or surgical procedures.
- The **innovative aspects** are that it can be used for 2 skin stretching techniques; stress-relaxation and mechanical creep. This system also allows stitches to be placed over high-tension wounds without causing ischaemia, necrosis and wound failure which can sometimes arise.
- The intended **place in therapy** would be in the closure of wounds as an alternative to skin grafts, skin flaps or internal tissue expanders in people with large wounds, such as those from trauma, amputation or tumour excision.

- The **main points from the evidence** summarised in this briefing are from 5 studies. These comprised 1 study including a case series and case reports, 1 case series, 2 individual case reports and 1 technical study, with a total of 41 patients altogether. The findings suggest that the TopClosure TRS may help secure wound closure with minimal scarring.
- **Uncertainties** are that the evidence base is not comparative and is very limited in size.
- The **cost** of the TopClosure TRS is £56.40 to £72.50 (exclusive of VAT) for a single set (currency conversion on 22 November 2016). If TopClosure TRS were shown to help faster wound closure and healing compared with standard care, then it could have a resource impact for the NHS in reducing the cost of treating medium and large wounds.

The technology

The TopClosure Tension Relief System (TRS; IVT Medical) is a skin stretching system to help close medium to large soft tissue wounds. It is designed to allow skin to be stretched to reduce the tension across a wound that would otherwise be under high mechanical stress or tension during closure, for example, wounds over joints or where large areas of skin have been removed after tumour excision. Reducing tension across such wounds aims to improve primary wound closure, reduce the risk of wound failure by relieving tension on stitches, and avoid the need for skin grafts, flap closures or internal tissue expanders. The TopClosure TRS can also act as a topical tension-relief platform for tension sutures.

The manufacturer claims that using the TopClosure TRS can prevent ischaemia and tissue tears caused by tension sutures used to close high-stress wounds. The system is designed to distribute tension more evenly around the closed wound and away from the wound's edges, to avoid rupture of the wound. This may improve the quality and look of the resulting scar.

The technology is made up of 2 attachment plates, which are fixed to the skin on each side of the wound, using either adhesive (described as 'non-invasive use') or by skin staples or stitches (described as 'invasive use'). The plates cover a relatively large area, to spread the tension across the wound. 'Invasive use' of the TopClosure TRS is recommended by the manufacturer for wounds that are under very high stress, for which tension sutures would not be appropriate (for example, wounds created by removing a large area of skin or for wounds over poorly vascularised areas such as bones and

tendons).

After fixing the attachment plates to the skin, a flexible approximation strap is threaded through them to connect them together. The strap is gradually pulled through the attachment plates, using a lock-release ratchet mechanism similar to a cable-tie, so that the system tightens and moves the 2 sides of the wound closer together. This procedure is done by a healthcare professional who has been trained in using the technology, such as a surgeon or a wound healing specialist nurse. They also decide how often and over what period the strap is tightened, based on the size and nature of the wound being treated. This gradual movement is described as a 'mechanical creep mechanism' because it allows the wound edges to be pulled together gradually over a period of time. The TopClosure TRS can be used for delayed primary wound closure after surgery.

The TopClosure TRS can be used as a method of temporary skin stretching during surgery, known as 'stress-relaxation'. This method involves using the TopClosure TRS invasively, with staples to attach the plates to the skin and with tension sutures connecting the attachment plates instead of the approximation strap.

The TopClosure TRS can also be used before surgery to temporarily stretch the skin around the area where surgery is planned, using the mechanical creep mechanism. This could avoid the need for internal tissue expanders to stretch the skin and may help primary closure of the wound. Pre-surgical stretching can be done in an outpatient clinic or at home by a trained patient or family member. The length of time for this process will depend on skin elasticity and the anticipated size and nature of the wound, as well as tension on closure.

Innovations

The TopClosure TRS is a single system that can be used for both mechanical creep and stress-relaxation and can be applied in various clinical situations.

The manufacturer claims that using the TopClosure TRS prevents undermining of the skin edges and nearby tissue, potentially decreasing the risk of dead space, seroma and haematoma formation and with the aim of reducing the need for drainage and the risk of infection.

The TopClosure TRS may simplify surgical technique and could potentially reduce hospital stay because most wound closure procedures using the device can be done under local

anaesthetic.

Current NHS pathway or current care pathway

The closure of large soft tissue wounds from surgery or trauma is challenging for surgeons and there is no national guidance on this area. Immediate primary suture closure is thought to be the best approach, but may not be possible for wounds that are under high tension because of location and limited skin elasticity, such as wounds over joints and the scalp, or because of the risk of the skin tearing around the edges of the primary sutures, such as for large excision wounds ([Topaz et al. 2012](#); [Topaz et al. 2014a](#); [Topaz et al. 2014b](#)).

For these wounds different techniques are used, such as skin grafts, flaps or internal tissue expanders. Skin grafts involve taking healthy skin from an unaffected area of the body to cover lost or damaged skin. Grafting may be used for open fractures, large wounds, surgical removal of an area of skin (for example tumour excision) and burns. The skin graft will usually be held in place using stitches, staples, clips or special glue. The area will be covered with a sterile dressing until it has connected with the surrounding blood supply.

Skin flap surgery involves the transfer of a living piece of tissue (including the blood vessels) from one part of the body to another. Flap surgery may be used for breast reconstruction, open fractures and large wounds. In most cases, the skin remains partially attached to the body, creating a "flap" which is then repositioned and stitched over the damaged area. As flap surgery allows the blood supply to the repaired area to be maintained, there is a lower risk of the repair failing compared to a skin graft.

Tissue expansion involves inserting a balloon-like device called an expander under the skin near the area to be repaired. This is gradually filled with saline over time, causing the skin to gradually stretch and grow. Time involved in tissue expansion can vary depending on the size of the area to be repaired. If a large area of skin is involved, it can take up to 3 or 4 months for the skin to grow enough. Once the skin has expanded sufficiently, a second operation is needed to remove the expander and reposition the new tissue ([NHS Choices](#)).

These methods are complex and are associated with additional surgery involving general or local anaesthetic. Risks associated with these techniques include graft or flap failure if the blood supply to the area is restricted, donor site complications, poor tissue matches, complications such as infection or blood loss requiring transfusion, pain and discomfort

and scarring ([NHS Choices](#)).

Population, setting and intended user

The TopClosure TRS could be used in adults and children for treating traumatic wounds or for planned procedures, such as skin or soft tissue tumour excision.

The TopClosure TRS is currently designed to be used by appropriately trained surgeons in a secondary care, for post-operative wound healing.

Pre-operative skin stretching could be done in the home by the patient or a family member after appropriate training. It could also be done in an outpatient setting by a healthcare professional who has training in using the system.

TopClosure TRS should not be used in people with a known allergy to adhesives, over infected tissue, or where the skin is damaged or weakened. The [manufacturer's website](#) has a full list of contraindications and instructions for use.

Costs

Technology costs

The manufacturer currently does not have a UK distributor but has provided the expected retail prices shown in table 1. Costs for shipping or local taxes may vary. The average cost per treatment will vary depending on the size and type of wound.

Table 1 TopClosure TRS costs

Description	Cost	Additional information
TopClosure TRS 1S (1 set in a pack)	US\$70 to US\$90	£56.40 to £72.50 (currency conversion on 22 November 2016)
TopClosure TRS 3S (3 sets in a pack)	US\$170 to US\$190	£136.70 to £152.80 (currency conversion on 22 November 2016)

Costs of standard care

Wound closure in the NHS is currently done by direct stitching or stapling, skin grafts or flaps, or internal tissue expanders if the wounds are large. The cost of these procedures varies according to patient need, with the choice of procedure and equipment (for example, the suturing kit) depending on factors such as type and anatomic location of the wound, thickness of the skin, degree of tension and the desired cosmetic result.

Resource consequences

An undated report on the [NHS England Innovation Portal](#) estimates using the TopClosure TRS after tumour excisions would save between £1,000 and £3,700 per patient, depending on wound size, compared with the cost of standard care. No information was given on how these cost savings were calculated and so the relevance of this information is not clear.

The TopClosure TRS is not currently used in the NHS.

The system impact of implementing TopClosure would be minimal, with only a short training period needed for use. Uptake may be slow because there is no UK supplier, but the technology can be bought directly from the manufacturer. Training is included as part of the cost and would generally be done through a workshop and practical training.

The cost of the technology may be offset by the overall savings from reducing the need for skin grafts, skin flaps, or internal tissue expanders. Overall, using the TopClosure TRS could reduce morbidity associated with current wound closure techniques. The might result in reduced surgery times, inpatient bed days and better outcomes for patients.

Regulatory information

The TopClosure Tension Relief System was CE marked as a class I sterile device in April 2014. The recertification of the device was issued in February 2017. It is distributed by IVT Medical, Israel.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

No equality issues were identified relating to the TopClosure Tension Relief System, but it should not be used in people with fragile, sensitive or thin skin, which might include older people, children, and people with conditions that cause thin skin such as those needing long-term steroid treatment.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Five studies, published as full journal articles, are summarised in this briefing including 1 case series study ([Topaz et al. 2012](#)), 3 case reports ([Topaz et al. 2014a](#); [Topaz et al. 2014b](#); [Zhu et al. 2015](#)) and a single technical report ([Katzengold et al. 2016](#)). A total of 41 patients were included in these 5 studies, with clinical outcomes reported for 38 patients and the wounds from 3 patients were used to develop a model to assess stresses applied to wounds.

[Table 2](#) summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

Overall, the current evidence for the TopClosure Tension Relief System (TRS) is of very low quality, comprised mainly of individual case reports and all but 1 study (Zhu et al.) funded and done by the manufacturer. There is no evidence available to compare the TopClosure TRS with other methods of wound closure, such as direct stitching, skin graft, flap or internal tissue expansion.

The existing evidence indicates that it is a safe and possibly effective system for wound closure and may result in a better cosmetic outcome for patients. For example, if a skin flap is avoided then the patient would not have scarring at the donor site.

The manufacturer has reported that a study comparing the TopClosure TRS with stitches in people having mastectomy has been submitted for publication, which could add comparative evidence.

Table 2 Summary of selected studies

Katzengold et al. (2016)	
Study size, design and location	Technical study modelling the biomechanical efficacy of TopClosure TRS. Data from 3 patients used for computational FE modelling. Israel.
Intervention and comparators	TopClosure TRS. Surgical suturing. The study used information from wounds in 3 patients to create simulations. All the wounds were treated using the TopClosure TRS. The model was based on the actual number of attachment plates used to close leg and scalp wounds (1 set or 2 plates), and a back wound (3 sets or 6 plates).

<p>Key outcomes</p>	<p>Closure using TopClosure TRS and tension sutures introduced local stresses in the skin and deeper tissues. The stresses reached maximal values around TopClosure's attachment plates and the suture insertion sites.</p> <p>Peak effective stresses on the skin increased with the level of closure and were 1 to 2 times lower with TopClosure TRS than with tension sutures because the attachment plates distributed the deformations more uniformly.</p>
<p>Strengths and limitations</p>	<p>TopClosure was compared with surgical suturing using data from 3 real wounds in a simulation.</p> <p>Modelling work is based on assumptions which may not be accurate and may not reflect the real-life clinical scenario.</p> <p>The simulations were not fully time-dependent because they did not account for skin elasticity.</p>
<p><u>Topaz et al. (2014a)</u></p>	
<p>Study size, design and location</p>	<p>Retrospective case series.</p> <p>Eight patients needing resection of 9 scalp tumours.</p> <p>Israel.</p>
<p>Intervention and comparator</p>	<p>TopClosure TRS.</p> <p>No comparator.</p>
<p>Key outcomes</p>	<p>All wounds were closed by immediate or delayed direct primary closure; 2 wounds had immediate primary closure and 7 wounds were closed using mechanical creep. No anaesthesia was needed during the gradual process of pulling the wound edges together.</p> <p>Six patients needed hospitalisation, for an average 2.5 days.</p> <p>No undermining was needed and no drainage was applied. Skin grafts or flaps were not needed.</p> <p>There were no significant complications, adverse events or device failures.</p>
<p>Strengths and limitations</p>	<p>Retrospective study with small sample size and no comparator.</p> <p>The study was authored by the developer and chairperson of the company that makes the device.</p>

<u>Topaz et al. (2014b)</u>	
Study size, design and location	<p>Case reports.</p> <p>Three patients with large wounds which were not suitable for closure using sutures: 1 head injury, 1 wide excision of melanoma, 1 with wound 26 cm wide after a tumour resection).</p> <p>Israel.</p>
Intervention and comparator	<p>TopClosure TRS for wound closure.</p> <p>No comparator.</p>
Key outcomes	<p>The wounds of all 3 patients closed with minimal and acceptable scarring.</p> <p>The post-operative course was complicated in one patient by minor rupture of the wound edges because the TopClosure TRS plates and tension sutures were not well applied and the patient did not follow advice.</p>
Strengths and limitations	<p>TopClosure was applied in 3 different clinical scenarios with similar success.</p> <p>There were only 3 patients in the study and no comparator or control group. The study was authored by the developer and chairperson of the company that makes the device.</p>
<u>Topaz et al. (2012)</u>	
Study size, design and location	<p>Case series of 21 wounds in 20 patients plus case reports for 6 additional patients giving a total of 26 patients.</p> <p>Israel.</p>
Intervention and comparator	<p>TopClosure TRS.</p> <p>No comparator.</p>
Key outcomes	<p>Summary data for 21 wounds in 20 patients showed a positive outcome with successful wound closure and minimal scarring in all patients.</p> <p>The case reports for 6 patients recorded complete wound closure, and 5 of them were satisfied with the appearance of the resulting scars.</p>

Strengths and limitations	<p>The TopClosure TRS was used in various conditions including wound closure after tumour excision, soft tissue damage from electric burns, infected surgical wounds and scar revision after reconstructive surgery.</p> <p>The number of patients was low, with no comparator or control treatments.</p> <p>The study was authored by the developer and chairperson of the company that makes the device.</p>
<u>Zhu et al. (2015)</u>	
Study size, design and location	<p>Case report.</p> <p>One patient; an otherwise healthy 10-day-old baby with a homogenous haemangioma that was completely removed, resulting in a 6.5 cm × 5.2 cm soft tissue scalp defect.</p> <p>China.</p>
Intervention and comparator	<p>TopClosure TRS.</p> <p>No comparator.</p>
Key outcomes	<p>TopClosure TRS was applied for 14 days to ensure wound closure. There was no ischaemia or necrosis of wound edges and the procedure was well tolerated, but there was no detail on how that tolerance had been assessed.</p> <p>Complete wound closure with a minimally depressed scar was reported at 6-month follow-up.</p>
Strengths and limitations	<p>Single case report, no comparator or control treatments.</p>

Recent and ongoing studies

- Efficacy of TopClosure System in Healing Complicated Pacemaker Wounds. ClinicalTrials.gov identifier: NCT01665963. Status: unknown. Indication: wounds and injuries. Devices: TopClosure TRS; pressure bandage.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 specialist commentators were familiar with the TopClosure Tension Relief System (TRS) although none had used it.

Level of innovation

All 3 specialist commentators stated that similar technologies are available and have been used in the NHS. Two commentators noted that the TopClosure TRS's method of attachment, using a combination of adhesives, staples and stitches to attach a tension band, was novel.

The commentators agreed that training would be needed to use the TopClosure TRS, and 2 of them thought that this would be minimal.

Potential patient impact

Two of the specialist commentators agreed that the technology could benefit patients because it offers a less invasive skin closure method. The third specialist noted that there is not enough available evidence to show any patient benefits, but it could benefit certain groups.

The specialists all identified people needing skin flaps for wound closure as a group which could benefit. One specialist also noted potential benefits for people having surgery for burns, skin and soft tissue tumours, or injuries, and people with peripheral arterial disease or diabetes who have ischaemia or infection. Other smaller groups who could benefit are those having pilonidal sinus excisions and people with wounds at high risk of breakdown, such as groin wounds in people who are obese. Using the TopClosure TRS has the potential to reduce skin donor site morbidity, the number of procedures needed, the number of hospital visits and morbidity and recovery time for patients.

The manufacturer claims that the TopClosure TRS could be used to treat hypertrophic or keloid scars but 1 specialist commentator felt that this use would not be appropriate.

One commentator identified a lack of evidence on pain or whether the technology caused dermal tears or stretch marks, both of which might be important considerations for the patient. Another commentator felt that attachment by staples would create further damage and possible scarring and so should be recognised as an aesthetic drawback.

Potential system impact

The specialist commentators agreed that the technology has the potential to reduce inpatient stay because it might allow some procedures to be done as day cases. One commentator noted that the TopClosure TRS needs to be removed at a further visit. Removal of the TopClosure TRS could be done in an outpatient setting, but more complicated procedures may need to be done in hospital, depending on the nature of the wound.

The commentators disagreed about the potential system impact of the TopClosure TRS. One noted that using the TopClosure TRS might make more invasive, inconvenient and expensive treatments for hard to heal wounds unnecessary, such as negative pressure wound therapy. Another felt that using this technology has the potential to increase the length of surgery and operating theatre use. The third commented that it may increase or decrease the length of surgery, depending on the alternative options for closure available for the person, but may reduce the duration of outpatient follow-up.

There were no anticipated changes to hospital infrastructure, but 1 commentator highlighted the need for hospital to keep stocks of the technology because it could be difficult to predict when it would be needed. This might increase costs if not used because the technology has a shelf-life.

All 3 commentators felt that the device had the potential to generate cost savings for the NHS, with 1 noting that the overall cost would depend on how often it was used.

General comments

One commentator noted uncertainty around management, specifically treating the wound and whether the TopClosure TRS should be removed or adjusted, if it became infected.

All the commentators raised concerns about the lack of comparative evidence available for this technology and that all available evidence was at risk of bias because the developer

was involved in the included studies.

Specific concerns were highlighted about claims that the TopClosure TRS is suitable for wound closure over open fractures because there is a lack of evidence on the rate of wound breakdown and osteomyelitis, which would be serious because wound breakdown is associated with limb amputation at a later stage. One commentator also noted the lack of updated information in trial registers about ongoing studies involving the TopClosure TRS and questioned whether this might show a failure to recruit patients to trials or a failure to report negative results.

Specialist commentators

The following clinicians contributed to this briefing:

- Professor Barry Powell, Professor in Plastic and Reconstructive Surgery, Consultant Plastic Surgeon, St George's Hospital, London. No conflicts of interest declared.
- Mr David A Russell, Consultant Vascular Surgeon and Honorary Clinical Associate Professor, Leeds Vascular Institute, Leeds General Infirmary. No conflicts of interest declared.
- Mr Ciaran O'Boyle, Consultant Plastic Surgeon, Nottingham University Hospitals NHS Trust. No conflicts of interest declared.

Development of this briefing

This briefing was developed for NICE by Cedar. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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