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Horizon scanning technology prioritising summary

Dynamic wound closure

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PRIORITISING SUMMARY

REGISTER ID **S000099**

NAME OF TECHNOLOGY **DYNAMIC WOUND CLOSURE**

PURPOSE AND TARGET GROUP **TREATMENT OF PATIENTS WITH FASCIOTOMY WOUNDS AND INFECTED STERNAL WOUNDS**

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- ☑ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☐ Yes
- ☑ No
- ☐ Not applicable

ARTG number: N/A

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	**Limited Use**	**Widely Diffused**
Canada	✓		
United States	✓		

IMPACT SUMMARY

The ABRA® Dynamic Wound Closure System (Canica Design Inc., Almonte, ON, Canada) applies gentle but ongoing tension uniformly across a wound to gradually close it. ABRA can be used to treat limb and abdominal fasciotomy wounds and infected sternal wounds.

BACKGROUND

For most wounds, the normal wound healing process proceeds spontaneously without the need for anything more than conservative management. However, some wounds, particularly large or infected wounds, do not heal spontaneously and require treatment in order to achieve full closure. Dynamic wound closure is a technique that can be used to treat such wounds and to date has been used on infected sternal wounds and fasciotomy wounds.

Sternal wound infection after cardiac surgery frequently requires aggressive surgical debridement that makes subsequent wound closure difficult (Price et al. 2007). Conventional treatments for sternal wounds include tissue transfers, such as pectoral flaps, where a flap of pectoralis major muscle is used to fill in the mediastinum and to lend stability to the chest wall. Tissue transfers are effective but are associated with significant morbidity and poor cosmesis. Mobilisation of the pectoral muscles can cause significant pain, as well as changes in chest wall mechanics, and requires that already unwell patients undergo additional surgical procedures (Price et al. 2007). Dynamic wound closure could facilitate delayed primary closure of sternal wounds without the need for further surgical procedures.

Fasciotomy may be performed in order to ease the increased pressure associated with compartment syndrome, which often occurs as a result of fracture or crush injuries. In compartment syndrome, increased pressure within a fascial compartment in the body, usually due to inflammation, results in impaired blood supply. If left untreated, this can lead to nerve damage and muscle death. While fasciotomy is effective in relieving the underlying pressure, it can result in a large, open wound. Such wounds are most commonly treated using split-thickness skin grafting. While effective, skin grafting does require an additional surgical procedure and a suitable donor site, and can result in poor cosmesis and impaired sensation at the wound site (Taylor et al. 2003). These issues could potentially be avoided by using dynamic wound closure.

The ABRA Dynamic Wound Closure System is composed of adhesive anchors and elastic silicone cords called elastomers (Price et al. 2007). Anchors are placed on the skin on either side of the wound and, depending on the wound type, attached either with adhesive textile strips or small slits in the surrounding healthy skin. Elastomers are then connected between each pair of anchors and laced across the wound. The elastomers are then tightened every 3 to 4 days, which places constant tension on the tissues, until complete wound closure is achieved. A number of potential advantages of delayed wound closure over conventional methods of wound management have been identified, including versatile and straightforward bedside application, the ability to close large skin defects or defects that exhibit excessive tension, adequate and customised tensile strength, elasticity, and durability over a full range of motion (Taylor et al. 2003).

CLINICAL NEED AND BURDEN OF DISEASE

It is not possible to estimate the total number of people in Australia with wounds of various aetiologies who may benefit from treatment with dynamic wound closure. However, a recent study reported that the incidence of deep sternal wound infection following open heart surgery in an Australian hospital was 1% (Wong et al. 2006), which was comparable to the reported world-wide incidence of 0.4-5% (Sarr et al. 1984). In Australia, approximately 53 debridement procedures were performed on sternotomy wounds during 2008/2009 (Medicare Australia, 2009). While sternal wound infection is relatively uncommon, it can result in significant morbidity and hospital cost, and has been associated with a mortality rate of up to 70% (Cheung et al. 1985).

There is a lack of data on the incidence, prevalence and economic burden of fasciotomy wounds; however, in Australia, approximately 1743 limb fasciotomy procedures were performed during 2008/2009 (Medicare Australia, 2009).

DIFFUSION

The ABRA® Dynamic Wound Closure System (Canica Design Inc., Almonte, ON, Canada) is listed on the FDA; however, it is not known if dynamic wound closure is currently being utilised widely in any part of the world. In Australia, the device is not currently listed on the ARTG, and there is no evidence that this procedure has been widely adopted as standard procedure within the healthcare system.

COMPARATORS

Currently, there are no other dynamic wound closure systems that are comparable to the ABRA® Dynamic Wound Closure System. The comparator procedures for dynamic wound closure include:

- Split-thickness skin grafting (Fasciotomy wounds)
- Vacuum-assisted closure (Fasciotomy wounds and infected sternal wounds)
- Pectoral flaps (Infected sternal wounds)

SAFETY AND EFFECTIVENESS ISSUES

Study description

Four case series studies have used the ABRA® Dynamic Wound Closure System (Canica Design Inc, Almonte, ON, Canada) for patients with sternal wounds and fasciotomy wounds.

Price et al (2007) reported on patients who underwent dynamic wound closure after debridement for sternal wound infection. In this retrospective study, the dynamic wound closure device was applied in three adult patients (1 male and 2 female) an average of 99.3 days (range 19 to 189 days) after coronary artery bypass graft surgery and 6.3 days (range 2 to 13 days) after sternal wound debridement. The average age of patients was 58.6 years (range 49 to 73 years). All patients were then discharged home with a course of antibiotics following application of the device. Follow-up ranged from 33 to 231 days following device application.

A retrospective case series study by Taylor et al (2003) examined the feasibility of dynamic wound closure for fasciotomy incisions. Dynamic wound closure was used on six fasciotomy incisions that were performed for compartment syndrome (3 in the upper extremity and 3 in the lower extremity) in five adult patients (3 male and 2 female) between December 1999 and September 2001. In two of these patients, an earlier attempt at delayed primary wound closure had failed. The average age of the patients was 48 years (range 28 to 83 years). The fasciotomy incisions averaged 28.0 cm in length (range 17 to 34 cm) and 8.5 cm in width (range 6 to 12 cm). The average time from fasciotomy to application of the dynamic wound closure device was 9.8 days (range 6 to 21 days). The length of follow-up was not reported in this study.

A more recent prospective case series by Singh et al (2008) described the use of dynamic wound closure for the treatment of decompressive leg fasciotomy wounds. Eligible patients were those who presented to the 28th Combat Support Hospital in Baghdad, Iraq between December 2006 and February 2007 and who had impending compartment syndrome of the leg, compartment syndrome of the leg or a recent fasciotomy for compartment syndrome of the leg. Eleven consecutive patients who underwent placement of the delayed wound closure device on the lateral incision after medial wound closure were included in the study. Five of the 11 patients underwent a vascular repair (three superficial femoral artery injuries and two below-knee popliteal artery injuries), while the six remaining patients had orthopaedic injuries (three comminuted tibial fractures, two fibula fractures, and one closed pilon fracture). The length of follow-up was not reported in this study.

Reimer et al (2008) aimed to evaluate the use of dynamic wound closure for the management of open abdominal wounds. Specifically, this retrospective study was focused on determining the time to fascial closure, the complications associated with the procedure, and the risk factors for unsuccessful closure. A total of 23 patients (15 male and 8 female) treated between September 2000 and September 2005 for open abdomens that could not be primarily closed more than 7 days after the cause for primary surgical intervention had resolved were included. The average age of the patients was 55 years (range 20 to 86 years). Patients were not consecutive and were selected for inclusion in the study based on the availability of the device and the opinion of the consulting surgeon that conventional wound management approaches would not allow fascial reapproximation. The primary pathology of the included patients was trauma (n=3), cardiovascular (n=5), gastrointestinal (n=10) and abdominal compartment syndrome (ACS) (n=4). The average time between creation of the open abdomen and application of the device was 18 days. The length of follow-up was not reported in this study.

Safety

Price et al (2007) did not report any safety data.

The study by Taylor et al (2003) reported no cases of wound infection or skin edge necrosis.

In the case series by Singh et al (2008) one patient developed heparin-induced thrombocytopenia and subsequently required bilateral above the knee amputation.

Reimer et al (2008) reported that the rate of hernia formation was 26% (6/23), while the rate of enterocutaneous fistulisation was 9% (2/23).

Efficacy

Price et al (2007) reported excellent healing of sternal wounds in all three patients, without the need for secondary surgery. The total duration of treatment with the device averaged 29 days (range 26-33 days).

In the case series by Taylor et al (2003), successful closure was achieved with each of the six fasciotomy incisions. None of the incisions required a split-thickness skin graft. The average number of days from application of the device to wound approximation was 11.5 (range 6 to 14 days), with a rate of closure of 1 cm per day. An average of 4.67 elastomer adjustments were required per patient. In each of the five patients, full range of motion was retained for the involved limbs throughout the treatment period. All patients were satisfied with the cosmetic result of their fasciotomy wound closure.

The study by Singh et al (2008) reported that successful delayed primary closure of the lateral wound was achieved in 10 of the 11 patients (91%), and none of the patients required a split-thickness skin graft. Wound closure was achieved in an average of 2.6 days (range 2 to 6 days), with the initial wound size averaging 8.1 cm (range 6.8 to 11.5 cm) and the posttreatment wound size averaging 2.7 cm (range 2.2 to 6 cm).

Reimer et al (2008) reported that successful delayed primary closure of wounds was achieved in 14 of the 23 patients (61%). Complete wound closure was achieved in all trauma and ACS patients, 2 of the 5 cardiovascular patients and 4 of the 10 gastrointestinal patients. In those patients who achieved successful wound closure, the device was applied for an average of 40 days. In the 9 patients in whom complete wound closure was not achieved, the wound area decreased by an average of 87% during the treatment period. A number of factors were strongly associated with a lower likelihood of wound closure, including advanced age, a higher probability of dying as determined by the Simplified Acute Physiology Score II (SAPS II), prolonged treatment with ABRA and gastrointestinal disease.

COST IMPACT

There are no cost-effectiveness studies on the use of dynamic wound closure for the treatment of wounds, and none of the four studies included in this summary discussed cost issues. The manufacturer of the ABRA® Dynamic Wound Closure System, Canica Design Inc, has suggested that many of the purported benefits of the device, including faster wound healing and reduced complication rates, mean that patients are able to leave hospital sooner and require less home care, which in turn results in considerable costs savings (Medical news today, 2008). Attempts to retrieve the cost of the device were unsuccessful.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

Other Issues

It should be noted that in the studies by Price et al (2007) and Reimer et al (2008), one of the authors, Dr Bell, is the co-inventor of the ABRA Dynamic Wound Closure System and a shareholder of Canica Design Inc. However, Price et al (2007) stated that all devices used in the study were hospital stock and were not paid for by the authors or Canica Design Inc. Reimer et al (2008) stated that Canica Design Inc. provided the devices used in the initial phases of the study free of charge, while the remaining devices were purchased at market rates.

Summary of Findings

There is a lack of high quality evidence on dynamic wound closure, with the majority of the available studies limited to small case series. All four included studies focused primarily on the feasibility of the procedure. The rate of successful wound closure ranged from 61% to 100% across the four studies. Successful wound closure was achieved within an average of 40 days for open abdominal wounds (1 study), 29 days for sternal wounds (1 study), 11.5 days for arm and leg fasciotomy wounds combined (1 study) and 2.6 days for leg fasciotomy wounds (1 study). In addition, factors such as older age and a high SAPS II score were predictive of a failure to achieve successful wound closure.

In summary, based on the findings of four small case series studies, it appears that dynamic wound closure is a feasible, potentially effective and cosmetically acceptable treatment for patients with fasciotomy wounds and infected sternal wounds, but the long-term safety and efficacy of this procedure are yet to be established. In order to establish the comparative efficacy of this procedure, future controlled studies examining long-term outcomes, including patient survival, are required. Future studies will also be required to determine the most appropriate timing for the application of the dynamic wound closure system, as well as the types of wounds for which this procedure is most appropriate.

HealthPACT Action

The initial results of the Dynamic Wound Closure System are promising. Considering its ease of use and potential diffusion, this technology will be monitored for 12 months.

Number of Studies included

Total number of studies	4
Level IV intervention evidence	4

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SEARCH CRITERIA TO BE USED

Dynamic wound closure
DWC
Canica
ABRA