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Management of postoperative bleeding in surgically debrided wounds: topical haemostat versus electrocautery

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Management of postoperative bleeding in surgically debrided wounds: topical haemostat versus electrocautery

Objective: To compare the effectiveness of a temporary topical external haemostat (OMNI-STAT Granules, Omni-stat Medical Inc., US) versus the use of electrocautery for bleeding control in patients who have undergone surgical wound debridement. Time saved in the operating room (OR) was evaluated.
Method: A prospective evaluation of use of a topical haemostat in an OR setting was compared with retrospective data collected using electrocautery to understand the time-saving benefits of using a topical haemostat versus electrocautery.
Results: A total of 52 patients were treated with the topical haemostat, and 89 patients with electrocautery. The topical haemostat was shown to be as effective in achieving haemostasis post-surgical debridement as electrocautery, with the added benefits of significant time savings in the OR (reducing the mean total OR time by 19.1%). Additionally, preprocedure and surgical procedure times in patients treated with the topical haemostat were significantly reduced. The results showed that wounds treated with the topical haemostat demonstrated a more advanced stage of healing, which may be a result of the lack of tissue damage demonstrated with the topical haemostat compared with electrocautery.
Conclusion: This study found that the temporary topical haemostat was equally as effective as cauterisation in achieving haemostasis. In addition, significant saving in OR time was demonstrated relative to electrocautery. The improved OR times may translate into increased cost-effectiveness, relative to electrocautery, by increasing the number of surgical cases per day and/or using resources more effectively to treat more patients. It may also enable bleeding control in the outpatient clinic or at the bedside, freeing up costly OR time and enabling more effective management of healthcare resources.
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chitosan-based haemostat • electrocautery • Omni-stat granules • operating room time • procedure time • topical haemostat

In the normal wound healing process, healing is aided by the removal of dead (necrotic) and damaged tissue through the process of autolytic debridement.[1] However, in hard-to-heal wounds, this necrotic tissue may build up on the wound bed, acting as a physical barrier to wound progression, and prevent granulation tissue formation if it is not removed.[2] Necrotic tissue also provides a nidus for bacterial growth, leading to biofilm formation and possible infection.[3] Whether by natural means (autolysis) or by clinical intervention (for example, surgical), removal of necrotic tissue is a prerequisite for healing,[3,4] thus removing a major physical obstacle to healing[5] and 'normalising' the wound environment by providing a healthier wound bed to support wound repair.[6,7]

Debridement is a recommended practice for a number of different wound types where the presence of devitalised tissue is a problem. These wounds include diabetic foot ulcers (DFUs),[8,9] venous leg ulcers (VLUs),[10,11] pressure ulcers (PUs)[12,13] and burns.[14,15] Although wound debridement can be achieved in a number of different ways (for example, enzymatic, mechanical, surgical), the preferred method depends upon several factors, including wound characteristics, patient comorbidities and clinical history, clinical resource availability and wound care provider expertise.[16] In addition, each mode of debridement has its own advantages and disadvantages.[17,18]

Surgical (also termed sharp) debridement uses scalpel (or scissors) to excise devitalised tissue from the wound bed.[19,20] Since the devitalised tissue is removed from the underlying healthy tissue,[21,22] some bleeding may occur using this method and is the most common complication of surgical debridement.[23] It is important to limit this bleeding and prevent excessive blood loss and is particularly important for patients with blood circulation or blood clotting problems, or for those receiving anticoagulant therapy.[24,25] Surgical debridement is generally performed in the operating room (OR) under general anaesthetic, although it can be done at the bedside.[26] If bleeding is not controlled effectively this may lead to patients returning to the OR.[27] Patients must be closely monitored for excessive blood loss and, if necessary, the bleeding managed using a number of methods of haemostasis, including

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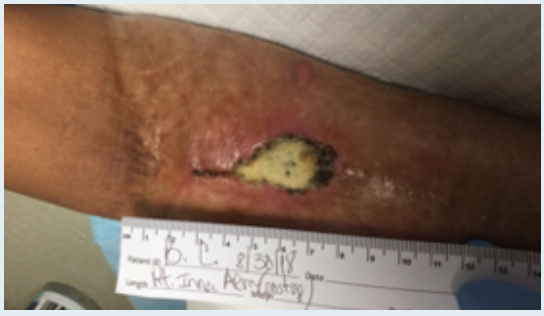
Fig 1. Electrocauterisation of a surgical wound. A mid-foot amputation, 12×8cm. An electrocautery pen was used to achieve haemostasis (image provided by Dr Matthew Regulski)

Fig 2. Application of topical haemostat in a surgical wound postoperatively. A traumatic wound, 3.5×2.5cm. Granules were applied at the time of debridement



externally applied topical pressure, direct ligation, electrocautery (Fig 1) or the application of an external topical haemostat.[27–29]

This paper focuses on the use of surgical debridement for the removal of devitalised tissue and the methods for achieving haemostasis associated with bleeding resulting from the surgical procedure. Specifically, the methods of achieving haemostasis were electrocautery using a MEGADYNE cautery pencil (Ethicon, US) and ValleyLab electrosurgical generator (Medtronic, UK) that uses heat to seal blood vessels and prevent/stop bleeding, which was compared with the use of a chitosan-based topical haemostat (OMNI-STAT Granules, Omni-stat Inc., US). The mechanism of action of this temporary topical external haemostat is independent of the normal coagulation pathway and involves the absorption of fluid in the blood. The granules then swell and gel together, trapping red blood cells to form a robust mechanical gel-like clot that plugs the bleeding source and seals the wound.[30]

Study objectives

The primary aim of the study was to compare the effectiveness of a standard method of haemostasis (electrocautery) versus the use of the chitosan-based topical haemostat in surgical debridement.

Additional study objectives included measuring the effect of the use of these haemostasis methods on total time in the OR and procedure time. The effect on wound healing was also taken into consideration.

Method

Study design

This study was undertaken in two phases:

- Phase 1: prospective evaluation of the effectiveness of the temporary topical external haemostat on patients undergoing surgical wound debridement and requiring haemostasis
- Phase 2: retrospective evaluation of the effectiveness of electrocautery on patients undergoing surgical wound debridement and requiring haemostasis.

Both phases were conducted over two separate nine-month periods at the Opelousas General Health System, Opelousas, Louisiana, US.

Phase 1: prospective cohort

Patients were enrolled in the study if they required surgical debridement of their wounds to enable wound progression.

All patients were treated equally with the clinical centre's standard wound care protocol. Procedures were limited to post-sharp wound debridement carried out in the OR under general anaesthetic. Any patients receiving antiplatelet and/or anticoagulant treatments remained on this medication. All nonviable tissue was debrided down to healthy tissue using a scalpel, rongeur and scissors.

Once debridement was complete, the temporary topical external haemostat was applied to the wound bed (Fig 2). The product was supplied in a sterile pouch filled with 3g of chitosan-based granules. The package was opened, and enough granules were poured onto the wound to fill the cavity and cover the entire bleeding area. As per the manufacturer's instructions, the wound was then covered with standard gauze, 1–3 minutes of firm pressure was applied, depending on the severity of bleeding. In this study, the surgeon felt that the application of a pressure dressing was sufficient to apply pressure.

After application of the topical haemostat, a Mesalt sodium chloride-impregnated gauze (Mölnlycke, Sweden) was used and pressure was applied via the use of a pressure dressing. The type of pressure dressing used varied and selection was based upon the specific wound type. Sacral wounds were covered with a multilayer border dressing, DFUs were covered with an antimicrobial cling and all-cotton elastic (ACE) wrap, and VLUs were covered with a Gelocast (compression boot, BSN Medical, Germany). Pressure dressings were then kept in place until the next dressing change (every second day).

Phase 2: retrospective cohort

Patients were enrolled into the study if they required surgical debridement of their wounds to enable wound progression. The surgical procedure was as per phase 1.

Table 1. Baseline patient demographics

Parameter	Electrocautery (n=89)	Topical haemostat (n=52)
Gender, n (%)		
Male	37 (41.6)	28 (53.8)
Female	52 (58.4)	24 (46.2)
Age range, years	16–93	25–86
Male	16–90	25–73
Female	22–93	28–86
Wound type, n (%)		
Skin/pressure ulcer	17 (19.1)	9 (17.3)
Diabetic foot ulcer	45 (50.5)	30 (57.7)
Traumatic wound	7 (7.9)	5 (9.6)
Infection	20 (22.5)	8 (15.4)
Antiplatelet/anticoagulant use, n (%)	54 (60.7)	22 (42.3)
Successful haemostasis, n (%)	89 (100)	52 (100)
Wound area, cm^2, median (range)	24 (0.25–1276)	30 (4–1250)

Once debridement was complete, haemostasis was achieved through cauterisation, using the pencil and generator previously noted. Standard settings were 30W for incisions, increasing to 50–80W depending upon individual wound types. Following cautery, the wounds were dressed with the same Mesalt sodium chloride-impregnated gauze as the prospective cohort and a pressure dressing was selected and applied, based on the type of wound. Pressure dressings were then kept in place until the next dressing change (every second day).

Inclusion and exclusion criteria

The criteria for inclusion were as follows:

- Patients aged ≥18 years old
- Patients with any wounds that required surgical debridement
- Signed consent form.

Exclusion criteria were:

- Patients <18 years of age
- Patients who would have difficulty following the study protocol
- Patients with severe underlying disease(s) judged, by the investigator, to interfere with the study treatment.

Measurement parameters

The following measurement parameters were recorded for phase 1 and 2 patients:

- The effectiveness of the haemostat: whether bleeding was halted
- Total OR time: defined as from the start to end of anaesthesia
- Total procedure time: defined as being from the start of the surgical debridement, when the surgeon applied the scalpel to the patient and the application of a haemostat, up to the point where haemostasis was achieved and the primary dressing was applied
- Preprocedure time: defined as from the time the patient entered the room to the time the procedure began
- Post-procedure: defined as from the time the procedure ended to the time anaesthesia stopped
- Postoperative: 48 hours following the procedure when dressing was removed.

Regulatory requirements

Approval to use the product was obtained from the Value Analysis Committee of the hospital and the product already had section 510(k) clearance from the US Food and Drug Administration. Written informed consent was obtained from all patients in both phases of the study, including for the use of photographs.

Adverse events

Any adverse events arising from the procedures relating to, for example, excessive bleeding, exsanguination, or any other deleterious effects that might be harmful to the patient, were noted in the clinical study notes.

Statistical analysis

Descriptive statistics including means, standard deviations (SD), medians, minimums and maximums were presented for baseline characteristics. Unpaired two-sample t-tests were used to test for significant difference between the prospective and retrospective groups of patients. The p-value was set at 0.05.

Results

A total of 52 patients took part in phase 1 of the study, and 89 patients in phase 2. Baseline demographics are presented in Table 1. All patients achieved haemostasis post-debridement with the temporary topical external haemostat (n=52) and electrocautery (n=89). Age ranges for the topical haemostat group and electrocautery group were similar at 25–86 years and 16–93 years, respectively. In both treatment groups, DFUs were the major wound type. In both the electrocautery and topical haemostat groups, a proportion of patients received antiplatelet/anticoagulant drugs (60.7% and 42.3%, respectively). Median wound areas were comparable (Table 1), in that they showed no significant differences between the two groups (p=0.57).

All patients achieved haemostasis post-debridement, leading to cessation of bleeding in all surgically debrided wounds (Table 1). There was a significant difference in total OR time between the topical haemostat and electrocautery groups (Fig 3). Overall OR time was reduced and there was a shift to shorter preprocedure and procedure times. The mean total OR time for surgical debridement and associated haemostasis in the topical haemostat group was significantly less compared with the electrocautery group (38 minutes (mins) 58 seconds (s) versus 48mins 11s, p<0.001, respectively, Table 2), corresponding to a 19.1% reduction in OR time. In cases where the topical haemostat was used as

Table 2. Total operating room time comparison

Time, minutes	Electrocautery mean±SD	Topical haemostat mean±SD	Difference minutes (% change)	Two-sample t-test p-value
Preprocedure	24mins 53s ±10mins 9s	20mins 37s ±6mins 45s	−4mins 16s (−17.1%)	p=0.003
Procedure	14mins 37s ±9mins 12s	10mins 10s ±6mins 19s	−4mins 27s (−30.4%)	p<0.001
Postprocedure	8mins 40s ±3mins 42s	8mins 10s ±3mins 59s	−0mins 30s (−5.8%)	p=0462
Total	**48mins 11s ±15mins 14s**	**38mins 58s ±9mins 37s**	**−9mins 13s (−19.1%)**	**p<0.001**

Mins—minutes; s—seconds

the method of haemostasis, both mean preprocedure and procedure times were significantly less (17.1% and 30.4% reductions (20mins 37s versus 24mins 53s and 10mins 10s versus 14mins 37s, p=0.003 and p<0.001, respectively, Table 2), compared with the electrocautery group. No significant difference was seen in mean postprocedure times in surgical debridement protocols (8mins 10s versus 8mins 40s, respectively, p=0.462; Table 2).

The use of the topical haemostat resulted in a shift to shorter procedure times compared with the use of electrocautery (Fig 4). For example, 65% of procedures took ≤10 minutes to complete in the topical haemostat group compared with 43% in the electrocautery group. In the topical haemostat group, only 14% of procedures took >16 minutes compared with 36% of procedures in the electrocautery group (Fig 4).

The number of patients receiving antiplatelet/anticoagulant drugs in the electrocautery group was 54 (60.7%) and 22 (42.3%) in the topical haemostat group.

It was observed by the wound care team that, postoperatively, patients in the topical haemostat group showed a better quality of re-epithelialisation when compared with the wounds treated with cauterisation (Fig 5).

Fig 3. Operating room time comparison between electrocautery and temporary topical external haemostat group. Mins—minutes; s—seconds

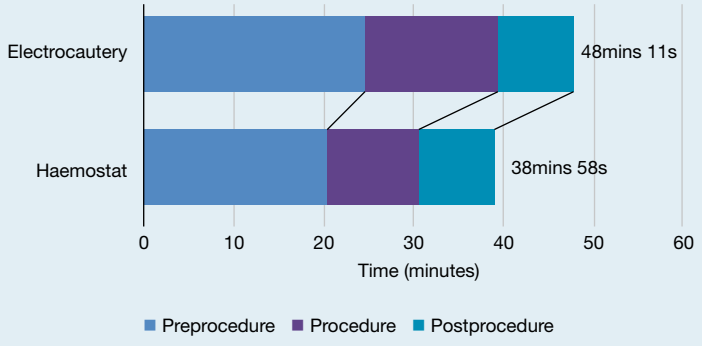
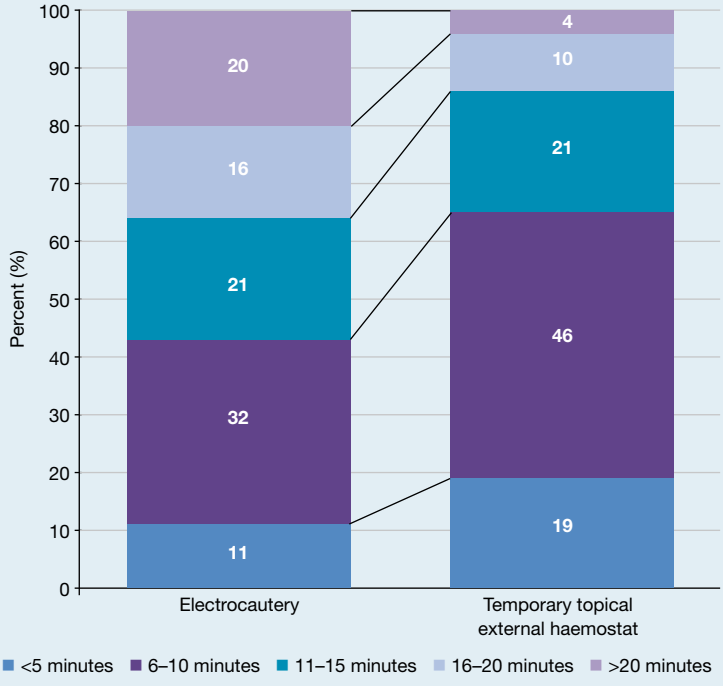


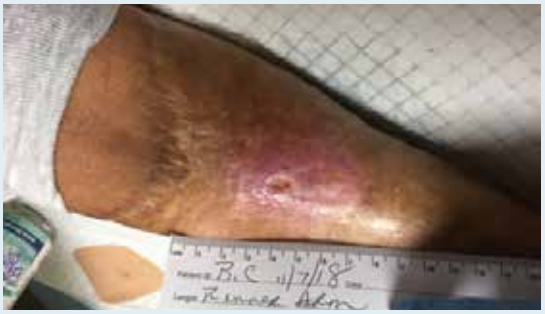
Fig 4. Comparison of debridement procedure time



Discussion

Electrocautery (also known as thermal cautery) is a routine method of haemostasis during cutaneous surgery.[31] It is one of the tools used by surgeons to promote haemostasis during surgical debridement,[32] and has been suggested to be particularly effective for clotting in small blood vessels (<2–3mm in diameter).[33] During electrocautery, an electric current is passed through a resistant metal wire electrode, generating heat within the electrode. The heated electrode is then applied to living tissue to achieve haemostasis.[31] Haemostasis is achieved by direct contact of the heated electrode to the bleeding vessel which induces necrosis and occlusion of the damaged vessel (Fig 1). This method is used in several surgical procedures[34,35] and electrocautery may be applied with either a line-powered or disposable battery-powered unit.

Fig 5. Wound progression in the topical haemostat-treated traumatic wound shown in Fig 2



Temporary topical external haemostatic agents are an alternative to the traditional methods of haemostasis.[36] They are designed to be applied directly on to the wound and to be removed once haemostasis has been achieved. The topical haemostat used in this study is a chitosan-based haemostatic device and is an example of these novel haemostatic agents. It is fast, safe and effective for controlling minor, moderate and severe bleeding in a range of conditions, including hard-to-heal wounds where sharp debridement is required.[37]

In this study, the results, in relation to the primary objective, have shown that the haemostatic effectiveness of both methods were equal in halting bleeding arising from the procedure. This study does highlight, however, that there were advantages to using the topical haemostat in terms of OR and procedure times associated with its use, the practicalities involved with haemostat application and the potential wound healing effects.

Specifically, improved OR times were associated with use of the topical haemostat. The electrocautery group had a much higher proportion of patients with longer procedure times compared with the topical haemostat group. This is believed to be due to a bleeding site after debridement potentially having multiple bleeding points. In the case of electrocautery, each point must be cauterised individually, whereas with the topical haemostatic granules, all bleeding points are covered with the single application of the haemostat.

There are advantages and disadvantages associated with the use of both electrocautery and the application of a temporary topical external haemostat during surgical debridement (Table 3). A disadvantage of electrocautery is the need to have several pieces of equipment, such as an electrocautery unit, smoke evacuator (if required), and ancillary items (for example, disposable pens, electrode tips) for the procedure (Table 4). All of these require time (during the preprocedure period) to be checked and prepared for use, including time to prepare the area on the patient where the grounding pad will be placed to ensure it is properly in situ. In contrast, only sachets of the topical haemostat are needed and no preparation time is required to prepare the patient or product. These preprocedure efficiencies also allow for reduced OR time.

Procedures are usually scheduled to be done in multiples and the use of the topical haemostat allows the surgeon to move from one procedure to another in a relatively short space of time. Time efficiencies can also be gained with use of the topical haemostat during operating time as only a single application to the site where bleeding occurs is required. With electrocautery, locating the bleeding site(s) may be problematic and time consuming, and the need to individually cauterise each bleed point may add significant time to the haemostasis process. These time savings offer the potential for providing significant cost savings given the relatively short duration of the procedure. Significant cost savings could also potentially be achieved via time savings through a reduction in nonoperative times allowing for an increase in the number of surgical cases per day.[38]

The results presented here show no difference in procedure times between the groups of patients using antiplatelet/anticoagulation drugs and those who did not receive any anticlotting therapy. The number of anti-coagulant-treated patients is increasing.[39] A major concern during surgery on patients receiving antiplatelet/anticoagulation therapy is the risk of haemorrhage or the increased risk of thromboembolism after perioperative discontinuation of anti-coagulation therapy. Electrocautery achieves haemostasis through a

Table 3. Comparison of electrocautery versus topical temporary external haemostat

	Electrocautery	Topical haemostat
Advantages	• Can be used in several different procedures • Safe and effective • Speed of localised haemostasis • Rapid targeting	• Can be used in several different procedures • Safe and effective • Speed of generalised area haemostasis • Independent of patient anticoagulation status • Does not result in tissue necrosis
Disadvantages	• Technical knowledge of instrument and technology • Risk of fire or explosion if flammable materials are near treatment site[47,48] • Transmission of infection—treatment electrode, surgical smoke, aerosolised blood microdroplets[49–51] • Need for ancillary procedures/equipment: smoke evacuation system, facial masks, protective eye wear • Accidental burns • Potential for vessel occlusion and necrosis of wound	• Residual product should be irrigated away with water or saline

mechanism independent of the clotting cascade by local physical tissue destruction leading to haemostasis.[31] Chitosan-derived materials have been shown to promote haemostasis independently of the clotting cascade,[40] and are able to act in the presence of antiplatelet/anticoagulant drugs[41,42] and in patients with coagulopathy.[43] A number of case reports and a clinical study have shown that a temporary topical external haemostat provides effective haemostasis in patients receiving anticoagulation therapy,[37,44] also suggesting that the mode of action is independent of the clotting cascade. The clinical data presented here provide additional evidence to support a mechanism of action for the topical haemostat that is independent of the body's clotting mechanism.

An improvement in wound healing was noted in the wounds treated with the topical haemostat, in particular a better quality of re-epithelialisation was observed compared with the results from cases the clinicians had previously treated with electrocautery (Fig 5). This observation was considered to be related to the beneficial effects of chitosan (a component of the topical haemostat) on healing.[45] A clinical study examining the quality of wound granulation tissue post-sharp surgical debridement showed a statistical improvement in tissue quality compared with standard care.[37] Tissue injury as a result of the electrocautery procedure itself is likely to contribute to an impaired wound healing response.[46] While not a main aim of this current study, the impact of temporary topical external haemostat use on wound healing outcomes warrants further investigation. A head-to-head prospective study directly comparing the two methods of achieving haemostasis should be undertaken which should include matched levels of wound blood loss after post-surgical debridement.

Limitations

The main limitations of this study were that retrospective and prospective data were used and the number of patients in the two populations differed. The rate of bleeding in each group was not recorded and the amount of blood loss from wounds was also not measured. Finally, wound healing assessment was based on subjective feedback from clinicians rather than from objective measurements.

Table 4. Comparison of procedures required for haemostat application

Surgical procedure	Electrocautery	Topical haemostat
Preprocedure	• Length of time required for method-specific preparation before surgery, for example electrocautery unit/ disposable pen, electrode tips, smoke evacuator, alcohol-free skin antiseptic	• Requires only availability of haemostat sachet
Procedure	• Training required for use of equipment • Locating bleed sites for cautery • Potential for multiple applications over numerous bleed sites	• Single application • Requires initial compression to facilitate haemostasis
Postprocedure	• Rebleeding • Disinfection of equipment, if required	• Rebleeding if haemostatic plug dislodges/removed

Conclusion

This study found that the topical temporary external haemostat was equally as effective as cauterisation in achieving haemostasis, but in addition, demonstrated significant time saving in OR time relative to electrocautery. Based on this study, preprocedure and surgical procedure times in patients treated with the topical haemostat were significantly reduced compared with the electrocautery group. The improved OR times associated with the topical haemostat may translate into superior cost effectiveness relative to electrocautery by increasing the number of surgical cases per day and/ or using resources more effectively. Another potential benefit of the haemostasis provided by the topical haemostat is the future opportunity to treat more patients in the outpatient clinic or at the bedside, thus reducing time in the operating room. This could free up costly OR time and provide further savings. The conclusions made in this study may not be generalisable and should be supported by a wholly prospective, randomised clinical study. **JWC**

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Reflective questions

- What are the main differences when using a topical haemostat versus electrocautery, in terms of physiological impact on the wound tissue?
- What can lead to increased operating room times when using electrocautery?
- What method shows benefit(s) in terms of patients who are undergoing anticoagulant therapy or have a bleeding disorder, and what is/are these benefit(s)?

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