NICE advice

HemaClear for bloodless surgical field during limb surgery

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is HemaClear. It is used for limb exsanguination during limb surgery to provide a bloodless surgical field.
- The **innovative aspects** are that it is a single-use sterile device, which the company claims is quicker and simpler to use and reduces the number of adverse events compared with existing devices. It may also be used outside of the operating theatre (for example, in a procedure room for minor cases).
- The intended **place in therapy** would be as an alternative to the pneumatic tourniquet system in people needing limb surgery where a bloodless field is needed.

- The **main points from the evidence** summarised in this briefing are from 6 studies: 3 prospective randomised comparative studies, 2 retrospective comparative studies and 1 mixed retrospective/prospective comparative study. Out of a total of 539 patients, 328 patients used the device (named as S-MART or HemaClear depending on the date of the study) in the operating theatre. They show that the device may be as effective as pneumatic tourniquets in providing a bloodless field in the adult population.
- **Key uncertainties** around the evidence or technology are that there is uncertainty surrounding some outcomes such as pain and complications and a lack of medium- to long-term follow up.
- The **cost** of HemaClear is between £15.95 and £41.80 (excluding VAT) per unit. The **resource impact** could be lower if its use shortened surgery time or reduced the number of adverse events.

The technology

HemaClear (Oneg HaKarmel Limited) is a sterile elastic tourniquet designed to stop severe loss of blood during limb surgery. It was previously marketed as S-MART (Oneg HaKarmel Limited), which was functionally identical to HemaClear. HemaClear consists of an elastic silicone ring, a stockinette and straps with handles. By pulling on the straps, it can be unrolled along the limb proximal to the surgical area. The device squeezes blood into the central circulation and prevents blood re-entering the limb. The stockinette can be cut where surgery needs to be done, providing a surrounding sterile field. The company state it can be used for all surgical procedures involving limbs where a bloodless field is needed, including trauma, orthopaedic, hand, foot and ankle, plastic and vascular cases.

The device comes in a variety of models for different limb circumferences (14 cm to 85 cm) and different systolic blood pressure limits (less than 130 mmHg, less than 160 mmHg and less than 190 mmHg).

Current care pathway

There is no widely agreed standard care and current practice varies. According to the company, most limb surgeries in the UK use pneumatic tourniquets. In most cases, a non-sterile tourniquet cuff is used, however some institutions have started to use sterile tourniquet cuffs. Some surgeons do not use pneumatic tourniquets because of concerns

about adverse events. Pneumatic tourniquets used in the UK come as sterile or non-sterile and are designed for multi-patient use. They include a limb exsanguinator device, such as a Rhys-Davies device or Esmarch bandage, a tourniquet cuff, a pneumatic pump and padding. The cuff is applied over the padding proximal to the surgical site, connected to the pump tubing and the limb exsanguination device is applied to drain blood from the extremity. The cuff is then inflated to the pressure needed.

The Association of periOperative Registered Nurses (AORN) have produced recommended practices for the use of the pneumatic tourniquet in the perioperative practice setting. AORN highlights that it is the responsibility of the perioperative registered nurse to assess the patient before surgery for risks and contraindications against using pneumatic tourniquets. Surgeons and anaesthetists should work together, monitoring inflation time and patient condition throughout. Patient safety should be the main consideration when choosing the pneumatic tourniquet. Safe use of tourniquets includes adequate padding beneath the tourniquet, staying within the safe limit of tourniquet pressure, not exceeding maximum duration of use and providing adequate analgesia. NICE's guideline on surgical site infections recommends earlier intravenous antibiotic prophylaxis (before starting anaesthesia) in cases when a tourniquet has been used, to reduce the risk of surgical site infection.

Innovations

HemaClear is a single-use sterile device, which the company claims provides better limb exsanguination and fewer side effects, such as tourniquet-induced skin damage, neuropraxia and pain, compared with pneumatic tourniquet devices. It could also reduce tourniquet time, thereby reducing surgery time.

Population, setting and intended user

HemaClear can be used in the operating theatre for trauma, orthopaedic, plastic and vascular cases. The company also claims that HemaClear could be used in a procedure room or accident and emergency departments rather than operating theatre for minor operative cases. The company identified the following groups of patients who may benefit most from HemaClear:

- patients who are obese (BMI over 35 kg/m^2) and having knee surgery
- children

- patients having surgery on the elbow and above
- patients who are immune-compromised (for example, those with HIV or diabetes mellitus, or those having chemotherapy)
- patients having endoscopic procedures (for example, endoscopic carpal tunnel release).

Surgeons should use HemaClear with the help of nurses or other operating theatre staff. Because of its effect on the cardiovascular system, anaesthetists should also be involved. The company states that the device should not be used in patients with an existing deep vein thrombosis, poor peripheral blood flow, oedema, an infected limb or limb with malignancy. It should also not be used directly on fragile skin or skin with significant lesions. HemaClear should not be applied directly over the ulnar nerve (at the elbow) or peroneal nerve (at the upper part of the tibia). The device should not be left on a patient's limb for more than 120 minutes.

Staff training, which lasts about 20 to 25 minutes, is recommended by the company every 2 to 3 years and is included in the cost of the device.

Costs

Technology costs

HemaClear costs between £15.95 and £41.80 (excluding VAT) depending on the model (see table 1). Each model is sold in boxes of 10 to 12.

Table 1 Costs of HemaClear models

Description	Cost (excluding VAT)	Limb circumference (cm)	Systolic blood pressure limit (mmHg)	Additional information
HemaClear-Small (pink)	£30.25	14 to 28	Less than 130	For use in paediatric orthopaedic surgeries.

HemaClear-Medium (green, red, yellow)	£32.45	24 to 40	Green: less than 130 Red: less than 160 Yellow: less than 190	–
HemaClear-Large (brown, orange, blue)	£39.60	30 to 55	Blue: less than 130 Orange: less than 160 Brown: less than 190	–
HemaClear-Extra Large (black and white)	£41.80	50 to 85	Less than 160	–
HemaClear-Model-A (silver)	£23.08	22 to 32	Less than 160	For the ankle.
HemaClear-Model-F (white)	£15.95	14 to 34	Less than 160	For the forearm.

Costs of standard care

Company estimates of costs associated with the pneumatic tourniquet system are in table 2.

Table 2 Costs of pneumatic tourniquet system

Description	Cost	Additional information
Pneumatic tourniquet device	£3,000.00 to £5,000.00	Capital cost for device. Company estimate 600 uses per year for 5 years (3000 uses).

Annual service cost of pneumatic tourniquet device	£300.00 to £500.00	–
Periodic pump calibration	£200.00 to £300.00	Figure represents calibration done by external company.
Tourniquet cuff	£20.00 to £25.00	–
Esmarch bandage	£3.00 to £5.00	Cost dependent on width. 2 may be needed per case.
Padding/stockinette	£5.00 to £8.00	–

Resource consequences

The company states that there are around 50 UK organisations who are currently using HemaClear. The company claims that HemaClear is likely to result in cost savings because of reduced adverse events, such as surgical site infection, post-operative tourniquet pain and neuropraxia. Although Jenny et al. (2016) showed fewer complications in patients using HemaClear, Pereira et al. (2015) estimate the cost per patient of using HemaClear as 30€ more than the pneumatic tourniquet. The company also claims a reduction in theatre time and overall hospital stay. Pereira et al. 2015 and Jenny et al. 2016 note substantial reductions in operative time with HemaClear compared with pneumatic tourniquet.

Regulatory information

HemaClear is a CE-marked class I medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The company indicates that HemaClear might have the greatest benefits in patients who

are obese and are having knee surgery, children, and patients who are immune compromised (for example, those with HIV or diabetes mellitus, or those having chemotherapy). HemaClear can be used in all patients with a limb circumference less than 85 cm.

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

There are over 20 peer-reviewed studies evaluating HemaClear or S-MART, including more than 2,000 patients. Of these, there are 4 UK studies with over 300 patients and 50 volunteers. This medtech innovation briefing contains a selection of studies based on quality and relevance of outcomes. Six studies, including 1 UK study, are summarised in this briefing: 3 prospective randomised comparative studies, 2 retrospective comparative studies and 1 mixed retrospective/prospective comparative study. Out of a total of 539 patients, 328 patients had the device (named as S-MART or HemaClear depending on the date of the study).

Clinically relevant outcomes that were reported include: efficacy of limb exsanguination, patient-reported level of pain, need for a blood transfusion, complications and infection rates.

Table 3 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

All of the included studies evaluating HemaClear were comparative studies comparing HemaClear or S-MART with pneumatic tourniquets. Blinding was not possible because the visual differences between the 2 devices. Overall, HemaClear appears to be as good as a pneumatic tourniquet at achieving a bloodless field (Calif and Stahl 2008, Pereira et al. 2015). Brin et al. (2015) also showed that HemaClear may reduce the amount of post-

operative blood collected and reduce the haemoglobin drop compared with pneumatic tourniquets. However, both Brin et al. 2015 and Jenny et al. (2016) noted that HemaClear did not reduce the number of blood transfusions needed. HemaClear appears to be as painful or more painful than pneumatic tourniquets, with only 1 included study suggesting it may be less painful (Drosos et al. 2013).

Despite being contraindicated in patients with a known deep vein thrombosis, there are still concerns about use in patients who may be at risk of developing a venous thromboembolism. A case report by Feldman et al. (2015) showed 2 patients with traumatic injuries who developed pulmonary emboli after using HemaClear, 1 of which was fatal. They suggest caution in using the device and highlight a safety concern that HemaClear could dislodge a pre-existing deep vein thrombosis. Brin et al. 2015 also saw 2 cases of deep vein thrombosis with HemaClear.

There is limited further evidence in different specialities. Ladenheim et al. (2013) and Bourquelot and Levy (2016) reviewed HemaClear in haemodialysis access surgery and Tang et al. (2013) assessed its use in haemorrhagic shock and trauma. Further evidence in specialities such as plastic surgery in addition to its use outside of the operating theatre are needed to back up the company's claims about its potential use in these areas.

Table 3 Summary of selected studies

Thompson et al. (2011)	
Study size, design and location	A multicentre prospective randomised trial involving 70 patients having elective knee procedures. Location: UK.
Intervention and comparator(s)	Intervention: S-MART (n=36). Comparator: pneumatic tourniquet (n=34).
Key outcomes	23 out of 34 non-sterile pneumatic tourniquets were contaminated (68%). 0 out of 36 sterile tourniquets were contaminated. This difference was statistically significant ($p<0.01$). Coagulase-negative *Staphylococcus spp* grew in 11 out of 23 positive samples (48%), *Bacillus spp* in 8 samples (35%), *Coliform spp* in 3 samples (13%) and *Sphingomonas paucimobilis* in 1 sample (4%). Colony counts were described as low, ranging from 1 to over 61.

Strengths and limitations	This was a relatively good sample size. The study was done in the UK study so the results are generalisable to the NHS. Laboratory scientists were blinded to the source of tourniquet samples. The study only assessed sterility, other outcomes such as ability to exsanguinate the limb and ease of use were not evaluated. There was no patient follow up so the clinical importance of colonisation cannot be determined, for example, development of surgical site infections.
Drosos et al. (2013)	
Study size, design and location	A prospective, randomised, comparative study involving 50 patients having carpal tunnel release surgery. Location: Greece.
Intervention and comparator(s)	Intervention: silicone ring tourniquet (S-MART or HemaClear; n=25). Comparator: pneumatic tourniquet (n=25).
Key outcomes	VAS pain scores were measured at 3 intervals: at application (T_0), 5 minutes (T_5) and at removal (T_{final}). Mean VAS pain scores were similar between SRT and PT groups at T_0 (3.92±2.12 versus. 3.12±2.05, p=0.181) and T_5 (4.44±1.80 versus. 3.88±1.92, p=0.294). The increase in pain from T_0 to T_{final} was significantly greater in the PT group compared with SRT (88.5% versus 26.5%, p=0.002) and mean T_{final} was significantly higher in the PT than SRT group (5.88±1.48 versus 4.96±1.65, p=0.043). There were no complications related to the tourniquet in either group.
Strengths and limitations	Patients had similar baseline characteristics and were randomised using a stratified and block method, minimising the effect of potential confounders. A 30-day follow-up period enabled observation for further complications. Validated VAS scale used for measuring pain. Only observed in 1 surgical procedure and 1 site (forearm). Strict inclusion criteria may limit generalisability to target population. No information on how 50 patients were identified and selected.
Calif and Stahl (2008)	
Study size, design and location	A multicentre prospective randomised controlled study involving 60 patients having elective carpal tunnel surgery. Location: Israel.

Intervention and comparator(s)	Intervention: S-MART (n=30). Comparator: pneumatic tourniquet (n=30).
Key outcomes	A bloodless field was obtained in 29 out of 30 cases in both S-MART and PT group. The S-MART device failed in 2 out of 30 patients compared with 0 patients in PT group. Failure constituted bleeding with inadequate visual quality in 1 case and intolerable pain in another. Higher VAS pain scores were reported in S-MART group compared with PT group, which neared significance (5.7±2.5 versus 4.53±1.99, p=0.05). S-MART was rated more difficult to apply compared with PT group (15 cases 'simple' compared with 15 cases 'moderate' difficulty in S-MART group, compared with all 30 cases rated 'simple' to apply in PT group). Local skin redness was seen after surgery in 100% of patients. No post-operative neurovascular complications were noted.
Strengths and limitations	Intention to treat analysis used. Similar baseline characteristics between the 2 groups. Mean duration of surgery significantly higher in control group (p<0.001), which may have affected results. One week follow up for observation of complications. Higher proportion of patients having analgesics before surgery in S-MART group neared significance (p=0.085) and will likely have reduced pain scores. Strict inclusion criteria, for example, excluding patients with congestive heart failure or chronic vascular disorders may limit generalisability to the target population. Surgeon completed intra-operative measurements, such as ease of device application, creating ascertainment bias. No random allocation to the 2 groups may also have introduced bias. Oneg HaKarmel Ltd supplied the S-MART devices free of charge to be used in the study.
Jenny et al. (2016)	
Study size, design and location	A single-centre mixed retrospective and prospective comparative study of 72 patients having total knee arthroplasty between May 2014 and June 2015. Location: France.
Intervention and comparator(s)	Intervention: HemaClear (n=33). Comparator: pneumatic tourniquet (n=39).

Key outcomes	Comparing the HemaClear group with the PT group, there was no significant difference in mean blood loss (901±488 ml compared with 989±505 ml), mean haemoglobin drop (1.8±0.8 g/dl compared with 2.2±1.0 g/dl), blood transfusion requirements (4 compared with 10 units) or mean VAS day 3 pain scores (3.2±1.3 compared with 2.9±1.7). The reduction in discharge delay in the HemaClear group compared with PT neared significance (mean 3.8 compared with 5.4 days, p=0.05). There were significantly fewer complications (1 compared with 9 cases, p=0.02) in the HemaClear group compared with PT group. The complication in the HemaClear group was wound dehiscence.
Strengths and limitations	3-month follow-up period. A power calculation was used for sample size to detect a difference of 200 ml of blood loss. Consecutive patient inclusion with no loss to follow up. Potential biases from lack of randomisation and the use of only 1 surgeon for all procedures. There was a significant difference in tourniquet time comparing HemaClear with PT group (86±18 minutes compared with 95±18 minutes, p=0.04), which limits comparability of certain outcomes such as pain score. The study was not controlled, because the control group used retrospective data, whereas intervention group used prospective data with at most an 11-month gap between procedures. Although the authors state no change in operating technique or post-operative care, the lack of controlled conditions does limit comparability.
Brin et al. (2014)	
Study size, design and location	A single-centre retrospective comparative study involving 211 patients having elective unilateral total knee arthroplasty between 2006 and 2011. Location: Israel.
Intervention and comparator(s)	Intervention: HemaClear (n=166). Comparator: pneumatic tourniquet (n=145).

Key outcomes	Comparing HemaClear with PT group, there was significantly less reduction in haemoglobin post-operatively on days 1 (2.53±0.95 compared with 2.78±0.98 g/dl, p<0.028) and 3 (3.00±1.14 compared with 3.28±1.18 g/dl p<0.045) and significantly less mean blood collected in drains at 24 hours (252.8 cc compared with 346.1 cc, p<0.001). There was no significant difference in the number of blood transfusions (no reported data) or incidence of wound complications (4.2% compared with 7.7%, p=0.189) between HemaClear and PT groups. There were 2 cases of deep vein thrombosis in HemaClear group compared with 1 case in PT group.
Strengths and limitations	Power calculation used to determine sample size. Similar baseline characteristics between the 2 groups. Use of historical control group operated on between 2006 and 2007 compared with HemaClear group operated on between 2010 and 2011. Long time between 2 groups does not assure groups were treated in the same way. No blinding when collecting study data from patient files. Same operating team and same procedure for all subjects may limit generalisability.
Pereira et al. (2015)	
Study size, design and location	A single-centre retrospective study involving 76 patients having carpal tunnel surgery during October 2013. Location: France.
Intervention and comparator(s)	Intervention: HemaClear Model-F (n=38). Comparator: pneumatic tourniquet (n=38).

Key outcomes	Limb exsanguination quality was measured by the operating surgeon as 0 (no bleeding) to 10 (uncontrollable bleeding). Tourniquet-related pain was measured from 0 (no pain) to 10 (worst pain). There was a significant difference (4.5 minutes compared with 5 minutes, p=0.03) in mean operative time comparing HemaClear with PT. Comparing HemaClear with PT group at the time of tourniquet release, the quality of limb exsanguination was not significantly different (0.5 compared with 0.3, p=0.7) and there was no significant difference in pain (0.3 compared with 0.9, p=0.1). No complications were noted in either group. Although the surgery was significantly faster in the HemaClear group compared with PT group, HemaClear was more expensive by 30€.
Strengths and limitations	Only 1 surgeon, 1 operative procedure and 1 model of HemaClear assessed, limiting generalisability of results. Surgeon-rated quality of limb exsanguination may introduce ascertainment bias. Difference in operative time between 2 groups limits comparability of outcomes such as pain. Provin Medical supplied HemaClear for the purpose of the study.
Abbreviations: SRT, silicone ring tourniquet; VAS, visual analogue scale; PT, pneumatic tourniquet.	

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

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

Three out of 4 commentators were familiar with or had used this technology before.

Level of innovation

All commentators considered HemaClear to have some novel concepts, including more rapid application reducing operative time, reduction in risk of tissue damage, better limb exsanguination and lack of a need for a pneumatic machine, air cylinder or electrical supply. One commentator identified that it is a single-use, sterile, disposable device, which can be placed higher up the limb, providing a larger sterile field for surgery. The same commentator also highlighted that it must be reapplied during lengthy surgery. Other commentators stated that HemaClear represents a refinement of current limb exsanguination technologies and has likely not been taken up because of added costs and unquantified, unclear benefits. One commentator identified 2 similar technologies currently available.

Potential patient impact

Potential patient benefits were identified by all commentators. One commentator said HemaClear may reduce limb trauma and reduce ischaemic and operative times for patients having long lower-limb bypass surgeries. As a result, this would potentially reduce the effect of serious complications such as wound dehiscence, infections and pressure ulceration. Another commentator highlighted that compared with pneumatic tourniquets, the limb exsanguination and tourniquet effect is more effective and reliable, and the narrower width allows for its use in the treatment of more proximal arm fractures, ultimately resulting in less blood loss for these patients. Furthermore, the same commentator reported a case where HemaClear was able to be applied during a surgery to control unexpected bleeding, because of its rapid application and sterile properties. A different commentator identified benefits of quicker patient set up, better limb exsanguination compared with other exsanguinator devices, ability to apply HemaClear during the operation after surgically prepping the area, and no loss in pressure that can happen with current limb exsanguinators. It was also highlighted that it is less bulky and therefore may be useful in paediatric cases as a high arm tourniquet for operating on the mid to distal humerus.

Groups of patients identified by commentators who would particularly benefit from HemaClear included patients needing upper limb arterial surgery, vascular trauma surgery, below knee arterial bypass surgery, lower-limb procedures of knee, tibia, foot or ankle and upper limb surgery.

Potential system impact

Potential system benefits identified by commentators included better theatre and resource use. One commentator thought that HemaClear provides a better sterile field for surgery and potentially a reduced deep vein thrombosis rate. Furthermore, a commentator identified that there may be less surgical time lost because of avoidance of bleeding from a venous tourniquet.

Opinions on the cost of HemaClear varied among commentators. One commentator concluded that a modest reduction in operative time or rate of complications would be needed to be cost effective compared with current reusable devices in vascular surgery. Another commentator thought that HemaClear is less costly than single-use pneumatic tourniquets. It was considered similar in cost by another commentator, provided the clinical standards for reusable tourniquets are implemented.

Two commentators thought that HemaClear would replace standard care, 1 stating that this would be needed to justify the cost benefit. A different commentator emphasised replacement of current techniques would only be the case in eligible patients if the performance is satisfactory. A further commentator highlighted that HemaClear would replace pneumatic tourniquets in most cases, although there are still some cases where pneumatic tourniquets are preferable.

General comments

One commentator identified training needs for HemaClear as modest, suggesting that the device could be substituted for current techniques without changes to facilities or infrastructure. One commentator stated no additional specific safety concerns to HemaClear that are not already considered for other methods of limb exsanguination. A further commentator stated that apart from training needed and familiarity with sizing, HemaClear appears safe and easy to use. A different commentator suggested more safety evidence is needed and they would be concerned about using the device in someone with peripheral vascular disease and those at risk of deep venous thromboses and pulmonary embolisms.

The eligible population per annum was estimated to be between 5 and 10,000 by 1 commentator, and 2,000 by another commentator considering both elective and trauma cases at their hospital trust. A further commentator highlighted that the device would be suitable for between 10 and 20 patients in their practice each year, but emphasised that

operative practice and tourniquet use varies among surgeons. A different commentator thought it could be used in most surgical cases under tourniquet.

Adoption issues were identified by 2 commentators, including issues of cost and the need for HemaClear to show usability, effectiveness and satisfactory cost–benefit performance. The same commentators also identified that research is needed in the form of a randomised controlled trials to evaluate the device's effectiveness in vascular reconstruction across a range of outcomes and also to look at medium to long-term follow up, in addition to risks of venous thromboembolism.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Kevin Mercer, consultant vascular surgeon, Bradford Teaching Hospitals NHS Foundation Trust. Did not declare any interests.
- Mr Rhidian Morgan-Jones, orthopaedic consultant, Cardiff and Vale Trust. Did not declare any interests.
- Mr Nicholas Ferran, consultant shoulder and elbow surgeon, trauma and orthopaedics, London North West University Healthcare NHS Trust. Did not declare any interests.
- Mr Mohammed Abdus-Samee, consultant orthopaedic surgeon and clinical director, Lewisham and Greenwich NHS Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. 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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