Blood flow management in hand surgery using the S-MART™ device: a prospective randomized controlled study

E. Calif [a], S. Stahl [a]

Abstract

Aim: Tourniquets are commonly used in ambulatory upper-limb surgery, but are still associated with complications, malfunction, and pain. We evaluated the S-MART™ device for blood-flow management compared to a conventional pneumatic tourniquet.

Methods: Sixty patients were assigned to study and control groups, where arterial occlusion was achieved by S-MART™ device and pneumatic tourniquet, respectively.

Results: S-MART™ was safe, but more difficult to apply and caused more pain.

Conclusion: The S-MART™ proved to be a fast and safe tool, but induced a compression discomfort. The costs of using this disposable product should be contemplated when considering its addition to day-care operating room armamentarium.

Keywords: Tourniquet, Esmarch, Exsanguination, Arterial occlusion, Hand, Carpal tunnel release, Evaluation, Pain, Complication.

Authors' addresses: The Unit of Hand Surgery, Rambam Medical Center, P.O. Box 9602, Haifa 31096, Israel.

Corresponding author: J. E. Calif *Tel* +972-4-8542619 *Fax:* +972-4-8542750 *E-mail* Edikal@hotmail.com

Introduction

Achieving a bloodless surgical field enhances the surgeon's capability to identify fine structures, shortens the duration of anaesthesia and surgery, and minimizes intraoperative blood loss. In surgical procedures performed on the upper extremity, proper visualisation is crucial, and the pneumatic tourniquet is often an inherent element of the surgical landscape. Attaining a bloodless surgical field necessitates an exsanguination followed by arterial occlusion proximal to the surgical site. The former action is often achieved by using the Esmarch technique, while the latter is achieved by using a pneumatic tourniquet.

The use of the conventional pneumatic tourniquet is associated with morbidity [1] and rare mortality [2]. Despite the paucity of information regarding the incidence of individual complications, the rate of complications associated with using the pneumatic tourniquet is estimated as 0.013% to 1.15% [3]. Potential local complications include tourniquet failure causing inadequate hemostasis, skin trauma, muscular and neuro-vascular injuries, wound infection, wound hematoma, edema, and compartment syndrome. Local discomfort or pain may increase steadily until becoming unbearable. Systemic complications include volume overload, arterial hypertension, cerebral infarction, rhabdomyolysis, pulmonary embolism, and metabolic disturbances [1,3].

Conventional exsanguination using the Esmarch technique is performed by tightly wrapping a rubber band around the limb, and thereby propelling the blood proximally. The surgeon has no quantitative indication on the pressure applied to the patient's limb, and therefore, local complications are mostly related to the uncontrolled excessive pressures generated (pressures in excess of 1000mmHg have been reported). The twisting, compressive, and shearing forces generated jeopardize the skin and soft tissue integrity. Severe systemic complications including fatal pulmonary embolism have been reported [4]. Furthermore, pneumatic tourniquets are prone to various operational problems, and their technical reliability and consistency are limited. Regular maintenance is essential. Still, technical failure due to malfunctioning components causing air leakage, pressure drop, and inadvertent excessive pressure are unavoidable.

The various techniques for exsanguination have limited reliability and reproducibility. Studies on changes in local blood volumes in limbs based on either plethysmographic or scintigraphic methods [5] showed that the effectiveness of the ordinary exsanguination techniques is limited. Blond et al [6] used a Gamma camera to assess the reduction in regional blood volume in upper limbs of healthy male volunteers given an autologous injection of 99mTc-labeled erythrocytes. They evaluated the effectiveness of different exsanguination techniques. The median percentage reductions of blood volume ranged between 42% when hand-over technique was used and 69% when the Esmarch technique was used. Comparable reduction rates were measured in lower limb exsanguinations [7].

Many surgical procedures on the upper limb are performed under local anaesthesia. The patient, therefore, experiences some level of discomfort or pain induced by the compressive forces applied by the pneumatic cuff. This may subjectively range from an unpleasant experience to unbearable pain, which frequently causes patient restlessness and occasionally requires discontinuation of surgery. In an attempt to decrease this discomfort, investigators have suggested various technical and ergonomic modifications, including alterations in the inflation pressure, shape, dimensions, design and location of the tourniquet [8–10].

The S-MART™ device (OHK Medical Devices – a division of Oneg HaKarmel Ltd., Haifa, Israel) was designed to achieve a combination of exsanguination, arterial flow occlusion and a sterile surgical field. The device is listed by the United States Food and Drug Administration and certified by the Israeli Ministry of Health. Boiko and Roffman [11] have published their clinical experience in using this device in upper limb surgery. They reported a quick device application and removal, and the achievement of an excellent bloodless field. Our prospective, randomized, and controlled study aimed at comparing the S-MART™ to the standard upper-arm pneumatic tourniquet,

regarding efficiency and potential adverse effects, including quantitative assessment of induced pain.

Patients and Methods

The S-MART™

The S-MART™ (OHK Medical Devices – Division of Oneg HaKarmel Ltd., Haifa, Israel) is composed of an elastic silicon ring with an inner diameter of 52mm and outer diameter of 76mm, wrapped in an elastic tubular stockinette sleeve and two straps, each ending in a pull handle (Fig. 1)

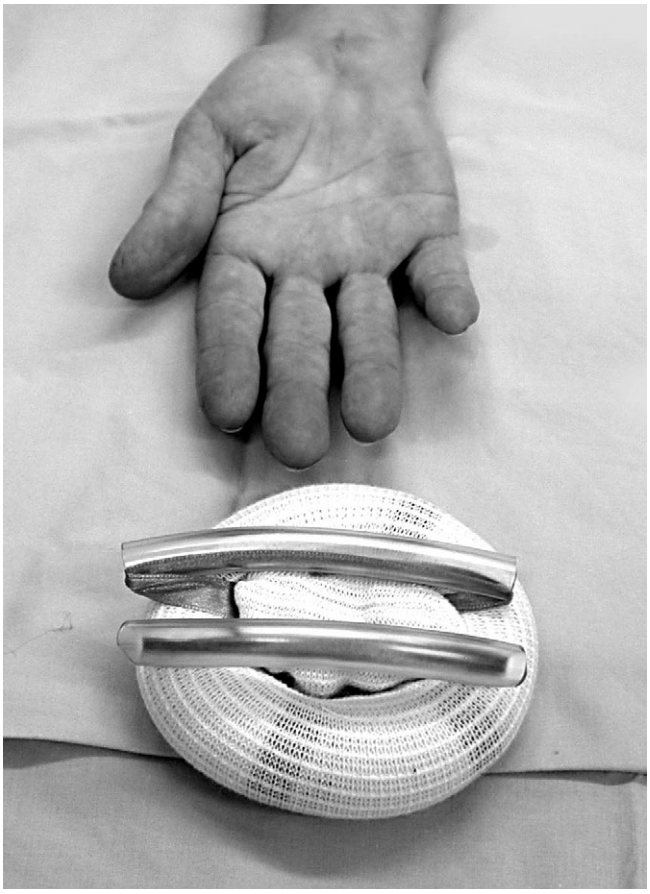

Figure 1 The S-MART™ device.

The device is provided sterile and double-packaged. It is applied to the limb after skin preparation and draping by placing the ring on the fingertips, and then pulling on both handles proximally (Fig. 2).

Figure 2 The surgeon places the ring on the fingertips and then pulls the two straps proximally.

As the ring rolls proximally it exerts a supra-systolic pressure wave upon the limb, which both exsanguinates the limb by propelling the blood proximally and occludes the arterial flow at the level of device positioning. While rolling the ring, the stockinette unfolds onto the limb, covering it up to the occlusion location, thus placing a sterile covering (Fig. 3).

Figure 3 The silicone ring rolls up the limb and the stockinette unfolds onto the forearm during the motion.

This covering is incised to gain access to the surgical field. For carpal tunnel release we placed the device at the junction of the upper and middle thirds of forearm, where an adequate mass of soft tissue interposes between the elastic ring and bony structures. We used the S-MART™ designed for the upper limb, which is provided in three color-coded models, each designated to apply the appropriate occlusion pressure for different ranges of systolic blood pressure, covering the range of systolic blood pressure up to 180mmHg. The pressure created is supra-systolic and ranges between 250mmHg-350mmHg in limbs with a circumference between 24cm and 40cm.

Patients

Sixty patients scheduled for elective open carpal tunnel release in an outpatient setting for idiopathic primary carpal tunnel syndrome were enrolled in the study. We included patients who were 18–85 years of age and whose circumference at the occlusion site was between 24cm and 40cm. We excluded patients with a systolic blood pressure in excess of 180mmHg, and patients with congestive heart failure or chronic vascular disorders. Other exclusion criteria were clinical evidence or history of deep vein thrombosis, clinical evidence for instability of bones or joints, and infection in the limb. The S-MART device is approved and certified by the Medical Devices Department of the Israeli Ministry of Health for clinical use. All patients were provided thorough information regarding the device prior to enrolling them in the study group. The open carpal tunnel release was performed under local anaesthesia (local infiltration/ injection of 5-10ml of lidocaine 2%), by three hand surgeons.

Study Protocol

The patients were randomly assigned to one of two groups: The study group (n=30) and the control group (n=30). Blood pressure (systolic and diastolic) was measured and mean blood pressure was calculated immediately before the application of the tourniquet. Patients in the study group had the exsanguination and the arterial occlusion achieved by the S-MART™ using the appropriate model as dictated by the systolic blood pressure. The device was placed at the junction of upper and middle thirds of the forearm after skin preparation and draping. An inflatable cuff was placed at the mid-arm to be inflated in cases that the S-MART™ failed or had to be abandoned. When surgery was concluded, the device was released by cutting the silicone ring and the stockinette sleeve after protecting the skin beneath with a blunt blade, and haemostasis was then undertaken and skin sutured.

In the control group a pneumatic tourniquet was used (Tourniquet 2500, VBM medizintecknik, GmbH, Sulzan, Germany). The apparatus consisted of an inflatable cuff (fabric single cuff, width – 7cm) inflated with compressed air, a pressure regulator, display and connecting tubing. The cuff was adequately padded and positioned at mid-arm. After skin preparation, draping and infiltrating the local anaesthetic agent, exsanguination was achieved by exerting external compression using an elastic bandage wrapped around the limb from fingertips up to the draped elbow, then the cuff was inflated up to a pressure of 250mmHg, the bandage unwrapped, and the surgery commenced. At the end of the surgery, the cuff was deflated, haemostasis was performed and the skin sutured. Failure of the S-MART™ or the pneumatic tourniquet was defined as poor visual quality due to an unacceptable bleeding at the surgical field, mechanical failure of the device, or patient's intolerance to pain caused by the device.

Evaluation

All patients were inquired regarding coexistent diseases and disorders including bleeding diatheses and coagulopathies, medications including analgesics (consumed within 4 hours before surgery). All relevant details were recorded in a report form for every case in both groups. The form was completed by the surgeon and included the time needed for placing the device (both exsanguination and arterial occlusion), technical difficulty in applying the device and cutting a window for the surgical site (ranked as simple, moderate, or difficult), the absence of radial and ulnar pulse and capillary filling, and the efficiency in providing a bloodless field rated from 1 (poor) to 5 (excellent). In cases where the efficiency was insufficient the blood pressure was measured and recorded. The surgeon quantified the bleeding at the surgical field either by milliliters of blood or the number of blood soaked gauzes. The surgeon also ranked the restlessness of the patient, measured the time to remove the device and ranked the difficulty in removing it, verified the resumption of arterial flow, and ranked his own overall satisfaction of the device. The duration of surgery from skin incision to wound closure was recorded as well (time needed for the application of the occlusion devices was excluded).

The patient was interrogated after the operation whether he experienced pain or inconvenience at the site of the device placement, and he had to rank this experience according to the "Visual Analogue Scale" for pain intensity – V.A.S. from 1 - "haven't experienced any pain" to 10 - "experienced intolerable pain". Failure of the device in each of the groups was declared when its use had to be discontinued, either because of ineffectiveness in securing an adequately bloodless field, inducing unbearable pain, or causing unacceptable adverse effect.

The limb was evaluated immediately after surgery and at a follow-up visit a week later, seeking local signs, and performing a complete neuro-vascular examination.

Statistical Analysis

Results were tabulated and expressed as means ±SD and ranges. Results were evaluated with unpaired two-tailed Student's t-tests, two-tailed chi-square tests, and F-test in order to check statistical differences between the two groups. P value of less than 0.05 was considered statistically significant.

We used an intention-to-treat analysis. We considered patients to be in the group to which they were assigned (even if S-MART™ failed and was substituted by the pneumatic tourniquet), and the denominator for each group was all patients assigned to that group.

Results

We enrolled 60 patients at the Rambam Medical Center (Haifa, Israel), and Ha'emek Hospital (Afula, Israel). Thirty patients were assigned to each group. The characteristics of the patients in the two groups are detailed in Table 1.

Table 1 Characteristics of the patients in the two groups[a].

Characteristic	Study group (n=30)	Control group (n=30)	P Value
Sex – M/F	7/23	8/22	0.77
Age – Yr	56±11 Range [38–79]	53±14 Range [26–84]	0.3
Systolic blood pressure	139±22	141±24	0.68
Mean arterial pressure	98±14	97±16	0.86
Analgesics – Yes/No	5/25	1/29	0.085

a Plus-Minus values are mean ± SD. All values are two-tailed.

The clinical characteristics including diagnosis, surgical procedure, anaesthesia, sex ratio (male:female), age, systolic blood pressure, and mean arterial pressure were similar in the two groups. The proportion of patients who used oral analgesic drugs within 4 hours before surgery was significantly higher in the study group. The mean duration of surgery was significantly higher in the control group ($P<0.001$) (Table 2Nevertheless, the application of the pneumatic tourniquet was reported as simple and straightforward in all control cases, while the technical difficulty in 13 applying the S-MART™ was graded as moderate in half of study cases. The SMART ™ application time averaged 10.8sec, and showed a trend of getting shorter as the study progressed, while average removal time was 9.4sec (Table 2).

Table 2 Intra-operative measurements in the two groups[a].

Characteristic	Study group (n=30)	Control group (n=30)	P Value
Duration of surgery - min	15±5 Range [8-30]	19±3 Range [14-26]	<0.001
Time of application - sec	10.8±2.6		
Difficulty in application (Simple/Moderate/Difficult)	15/15/0	30/0/0	
Time to remove device	9.4±2.3		
Analgesics – Yes/No	5/25	1/29	0.085

a Plus-Minus values are mean ± SD. All values are two-tailed.

We planned to quantify any bleeding occurring in either group by measuring the volume of blood loss (ml) and counting the gauzes saturated with blood. However, both devices were overall excellent in providing a bloodless field. In one case in the study group – a

female with a blood pressure of 163/85 mmHg – a yellow model of the S-MART™ was used; after skin incision a continuous bleeding obscured the surgical field. Blood pressure was measured and found to be within the indicated limits for the yellow model. Measures for local haemostasis were unsuccessful, and consequently the S-MART™ was released four minutes after starting surgery owing to unacceptable visual quality. Exsanguination was redone using an elastic bandage, and the pre-installed pneumatic cuff was inflated to a pressure of 250mmHg. The operation was completed in a completely bloodless field. All but one patient in the control group had a bloodless field and an excellent visual quality. In a case of a male with a blood pressure of 102/68 mmHg, minor bleeding was observed and the surgical field was ranked at 4 (in a scale of five degrees). This apparently was due to venous congestion caused by inappropriate exsanguination. The visual quality, however, was acceptable and the operation proceeded uneventfully.

All patients in both groups reported local discomfort caused by the device. However, experiencing true pain was significantly higher in the study group (P=0.0062) (Table 3). The average V.A.S. grading was higher in the study group (P=0.05), while variability of the grading was similar in both groups. Two patients in the study group ranked their pain severity as 10 on the V.A.S.. One patient reported a severity of 10 at the end of operation, which lasted 15 min. The other patient reported a severity of 10 two minutes after applying the S-MART™. The device was consequently released and substituted by a pneumatic cuff, which the patient tolerated well throughout the rest of the operation. In both cases, the surgeon reported patient's restlessness, which was graded as "unacceptable" in the latter.

The overall surgeon's satisfaction was similar in both groups. Apart from local skin redness at the site of device placement, which was uniformly observed in all patients in both groups and completely disappeared a few minutes thereafter, no skin complications, neurovascular compromise, or any other adverse effects were encountered postoperatively.

Discussion

Surgical operations on the upper limb usually involve delicate structures. Optimizing the surgical arena and ensuring adequate sighting is therefore crucial. A bloodless surgical field is an essential prerequisite for high visual quality. Hand surgeries are sometimes undertaken under local anaesthesia, and the patient may, therefore, experience some discomfort or even a distressing pain caused by the compressive force applied by the tourniquet device.

Using pneumatic tourniquets as an effective means of achieving a bloodless field has become a common practice in hand surgery. However, the effectiveness of the pneumatic device is not absolute, it is associated with potential complications, occasional technical malfunctioning and local sensation of discomfort. The SMART ™ device is designed for performing three sequential functions of limb exsanguination, arterial blood flow occlusion and placement of sterile field covering. The centripetally oriented force generated by the silicon ring provide a circumferentially even and consistent supra-systolic pressure, that is independent of gas tubing, pressure regulation, and electric connections. The S-MART™ is therefore suitable for interventions undertaken at outpatient and clinic settings.

The S-MART™ can be applied to the upper arm, as well as to the forearm. By applying the device on the forearm in operations performed at distal parts of the limb, ischemia of a significant portion of the limb is spared, and the anticipated re-perfusion effect is diminished. The S-MART™ is sterile and its placement in proximity to the surgical field is possible, which further decreases the ischemic mass of tissue.

Since the S-MART™ is a sterile single-use product, the surgeon applies and removes it without the need for assistance of any non-sterile personnel. However, alternate inactivation and activation of the flow occlusion, for haemostatic purposes for example, is unfeasible. The problem of device contamination with the patient's blood and the potential for consequent cross-contamination is avoided as well. However, a comparative evaluation of the costs of using and maintaining the reusable standard tourniquets and the disposable S-MART™ is required.

Table 3 Outcome in the two groups[a].

Criterion	Study group (n=30)	Control group (n=30)	P Value
Failure of device - No. of cases	2 [b]	0	0.15
Quality of bloodless field: 1 (poor) to 5 (excellent)	4.86±0.73	4.96±0.18	0.47
Patient reported inconvenience- Yes/No	30/0	30/0	
Patient reported pain – Yes/No	15/15	25/5	0.0062
V.A.S. [c] - 1 to10	5.7±2.5	4.53±1.99	0.05 (F-test P=0.22)
Surgeon reported patient's restlessness – 1 (unacceptable) to 5 (excellent)	4.77±0.77	5±0	0.10
Local signs	30 (redness)	30 (redness)	Local signs
Overall surgeon's satisfaction – 1 to 5	4.87±0.73	4.97±0.18	0.47

[a] Plus-Minus values are means ± SD. All values are two-tailed.

[b] Failure was declared due to bleeding and unacceptable visual quality in one patient and due to intolerable pain with patient's restlessness in another.

[c] V.A.S. denotes Visual Analogue Scale. A pain severity scale: from 1 – No pain, to 10 – intolerable pain.

The average application time for the S-MART™ was found to be as short as 10.8 sec, though the application was graded as moderately difficult in half of the cases. This was explained by the difficulty in rolling the ring across the wider zone of the metacarpophalangeal joints. Application of the pneumatic tourniquet is multistage and involves padding, wrapping and fastening the cuff, connecting the tubes, exsanguination, adjusting and inflation. These actions are not done in continuity and, therefore, attempts at measuring the time needed for performing them were unsuccessful.

The S-MART™ effectively provided a bloodless field in al but one case. The bleeding in this case has probably occurred due to either inadequate exsanguination causing venous congestion, or stress-related blood pressure fluctuation before skin incision beyond the indicated range of the yellow model causing arterial leakage.

Although the proportion of patients who consumed analgesics before surgery was higher, and the mean surgical time was significantly shorter in the study group, still, significantly more patients experienced pain caused by the S-MART™ than the pneumatic cuff. The mean V.A.S. score was higher in the study group (P=0.05), while the two groups showed similar score variability. The S-MART™ failed in one case due to intolerable pain and the surgeon reported unacceptable patient restlessness.

One additional clinical issue was observed. Following the cutting of the stockinette, small cloth residues were scattered over the skin, and entered the surgical field thereafter. This may be avoided by soaking the stockinette with a sterile fluid. Alternatively, close-ended stockinette should be replaced by an open-ended hemmed stockinette that covers the limb distally up to the surgical site.

In summery, the S-MART™ device performed well in providing a bloodless surgical field in all but one operation of carpal tunnel release. In two cases it caused unbearable pain and had to be released in one. This well-designed ergonomic device proved to be a fast and safe tool for blood flow management. However, it induced a compression discomfort that ranged between local inconvenience and intolerable pain. The costs of using this disposable product versus the reusable pneumatic system should be contemplated when considering the addition of the S-MART™ to the operating room armamentarium.

Acknowledgement

OHK Medical Devices, Haifa, Israel supplied all S-MART™ devices used in the study group free of charge. The authors have received no financial benefits, and have no financial interest in the device.

References

1. Wakai A, Winter DC, Street JT, Redmond PH. Pneumatic tourniquets in extremity surgery. ***J Am Acad Orthop Surg*** 2001;**9(5)**:345–51.
2. Gielen M. Cardiac arrest after tourniquet release [letter]. ***Can J Anaesth*** 1991;**38**:541.
3. Machold W, Mullner T, Vorderwinkler KP, Vecsei V. Technical defects of tourniquet manometers. ***Unfallchirurg*** 2002;**105(12)**:1097–9.
4. Darmanis S, Papanikolaou A, Pavlakis D. Fatal intra-operative pulmonary embolism following application of a Esmarch bandage. ***Injury*** 2002;**33(9)**:761–4.
5. Blond L, Madsen JL. Scintigraphic method for evaluating reduction in local blood volumes in human extremity. ***Scand J Clin Lab Invest*** 2000;**60(5)**:333–9.
6. Blond L, Madsen JL. Exsanguination of the upper limb in healthy young volunteers. ***J Bone Joint Surg [Br]*** 2002;**84(4)**:489–91.
7. Blond L, Kirketerp-Moller K, Sonne-Holm S, Madsen JL. Exsanguination of lower limbs in healthy male subjects. ***Acta Orthop Scand*** 2002;**73(1)**:89–92.
8. Crews JC, Hilgenhurst G, Leavitt B, Denson DD, Bridenbaugh PO, Stuebing RC. Tourniquet pain: the response to the maintenance of tourniquet inflation on the upper extremity of volunteers. ***Reg Anesth*** 1991;**16(6)**:314–7.
9. Tsai YC, Lai YY, Chang CL. Comparison of the effect of EMLA cream, subcutaneous ring anaesthesia and a double cuff technique in the prevention of tourniquet pain. ***Br J Anaesth*** 1993;**70(4)**:394–6.
10. Finsen V, Kasseth AM. Tourniquets in forefoot surgery: less pain when placed at the ankle. ***J Bone Joint Surg Br*** 1997;**79(1)**:99101.
11. Boiko M, Roffman M. Evaluation of a novel tourniquet device for bloodless surgery of the hand. ***J Hand Surg Br*** 2004;**29B(2)**:185–7.