The Silicone Ring Tourniquet in Orthopaedic Operations of the Extremities

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ABSTRACT

Tourniquets provide a bloodless field in limb operations and their introduction in orthopaedic operative technique has been considered as a landmark. A new tourniquet device, a silicone ring tourniquet (SRT) (HemaClear or S-MART, OHK Medical Devices, Haifa, Israel), was introduced into clinical practice a few years ago. A few clinical studies as well as comparative studies in volunteers have reported its use in a relatively small number of cases.

The aim of this prospective study is to report the clinical use of this device in a large number of patients, including all possible applications of a tourniquet. The SRT was used in 536 cases including 337 male and 119 female patients with a mean age of 43.7 years (range 6 to 87 years). The average tourniquet time was 58.5

minutes (range 6 to 180 minutes). It was applied in 362 (67.5%) elective and in 174 (32.5%) trauma cases including fractures (n:109, 62.6%) and soft-tissue injuries (n:65, 37.4%). The most frequent application site was the femur (n:255, 47.6%), followed by the forearm (n:154, 28.7%), humerus (n:65, 12.1%), and calf (n:62, 11.6%).

Because the device is sterile it was possible to use it in operations in which the pneumatic tourniquet cannot be used, such as open reduction and internal fixation of humeral shaft and femoral supracondylar fractures. In 14 patients (2.6%), the tourniquet failed intraoperatively, and the cause was an unexpected raised blood pressure. The SRT - with a pre-set pressure according to the size and the tension model - is easy to apply. It is sterile, and occupies a narrow area of the limb. Its application combines three functions at the same time: exsanguination, tourniquet, and stockinet application. Although it cannot entirely replace the classic pneumatic tourniquet, it is a safe and useful device in orthopaedic operations because of its advantages.

INTRODUCTION

A tourniquet is a constricting or compressing device used to control venous and arterial circulation to an extremity for a period of time. This device provides a bloodless field in limb operations and its introduction in orthopaedic operative technique has been considered a landmark.[1] The bloodless field provided by a tourniquet: (a) enables easier surgical interventions on the extremities, (b) in delicate operations of the hand is essential for accurate dissection and to avoid damaging small vital structures, and (c) theoretically, provides a better cement-bone interface in a cemented arthroplasty.[2–4]

Pneumatic tourniquet (PT) is the most commonly used tourniquet since its introduction by Harvey Cushing in 1904[1]; its use has become almost routine as it is considered the safest device.[5] The Esmarch tourniquet is considered less safe than a pneumatic tourniquet, but is still in use by some surgeons mainly in podiatric surgery.[6,7]

Nevertheless, pneumatic tourniquet use is associated with potential risks of complications as well as clinically relevant sequels,[5] and although serious

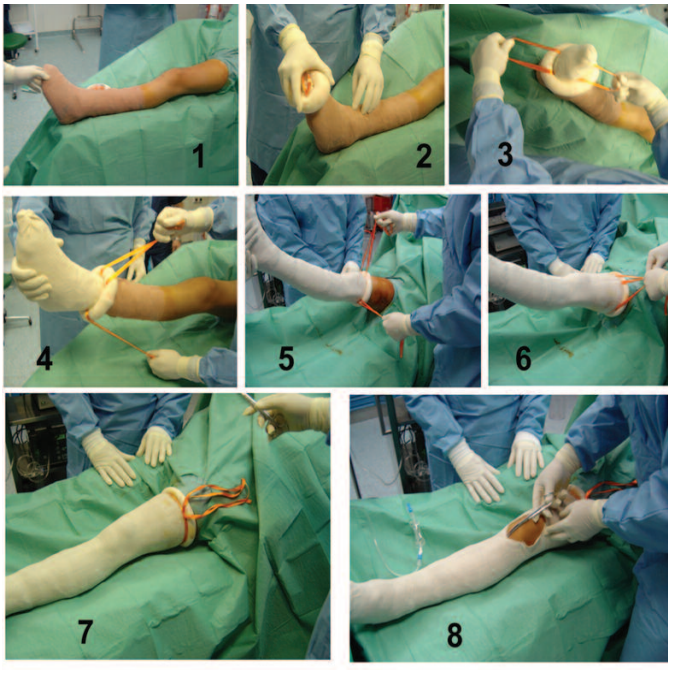


Figure 1. Above knee application of a silicone ring tourniquet.

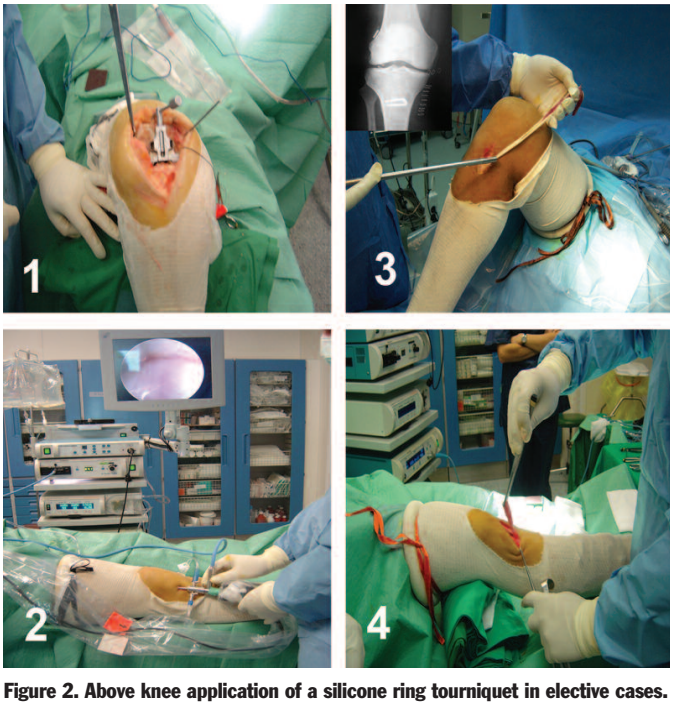


Figure 2. Above knee application of a silicone ring tourniquet in elective cases. (1) Total knee replacement, (2) knee arthroscopy, (3) ACL reconstruction with hamstrings graft, (4) ACL reconstruction with patellar tendon graft.

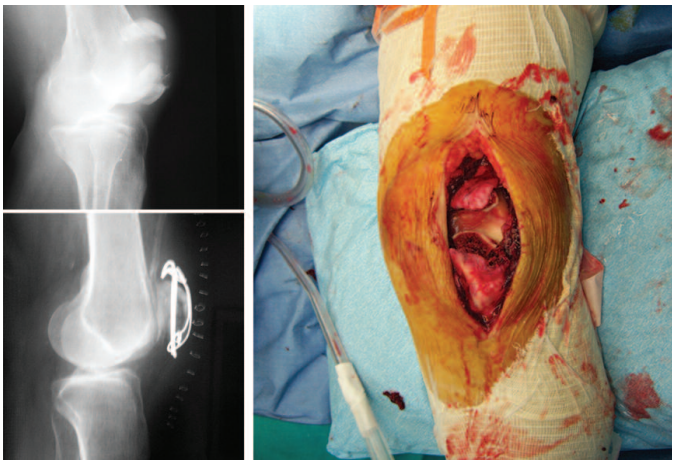


Figure 3. Open reduction and internal fixation of a patellar fracture using a femoral silicone ring tourniquet.

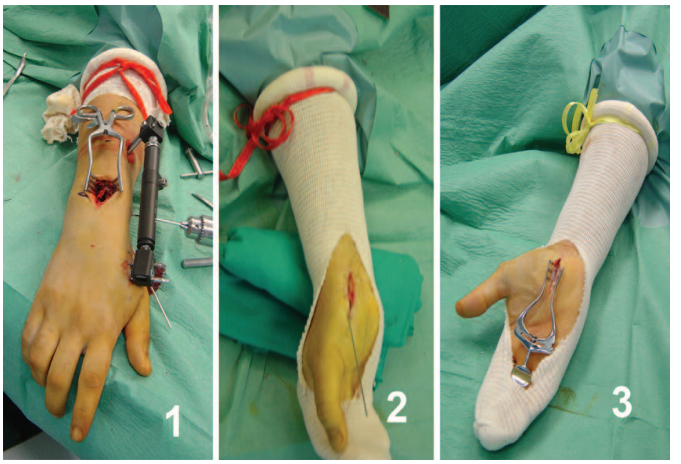


Figure 4. Forearm application of a silicone ring tourniquet. (1) Fixation of a distal radial fracture, (2) scaphoid fracture fixation, (3) carpal tunnel release.

complications of the use of a tourniquet are rare, there is a definite morbidity.[8] Because of the known risks, much effort has been directed at assessing the safe time and pressure for their use.[9]

Apart from the well-known contraindications and measures to avoid, regular checks and tests are required even for modern pneumatic tourniquet device complications.[5] One important issue is whether the selected tourniquet pressure actually is applied by the device at the tourniquet application site during the whole procedure.

A new tourniquet device (HemaClear or S-MART, OHK Medical Devices, Haifa, Israel) was introduced into clinical practice a few years ago.[10–14] This device consists of a silicone ring wrapped within an elastic sleeve (stockinet) and two straps attached to pull handles, and is designed for exsanguination and occlusion of the blood flow to the limb. The entire device is sterile and comes in different sizes and different tension models, and the pressure that is applied to the limb is preset. There are four different sizes: (a) a small size for pediatric use; (b) a medium size for the upper limb (circumference of the limb at the occlusion site 24–40 cm); (c) a large size for the leg (circumference of the limb at the occlusion site 30–55 cm); and (d) an extra-large size for the leg (circumference of the limb at the occlusion site 50–90 cm and systolic blood pressure ≤160 mmHg). There are also three tension models (systolic blood pressure ≤130 mmHg, <160 mmHg, <190 mmHg) for the medium and large sizes, and the appropriate model is selected for each patient according to the systolic blood pressure measured in the operating room before the placement of the device.[14] The device is removed by cutting the ring, which cannot be re-attached.

This device has been compared with the pneumatic tourniquet in healthy volunteers,[15–17] and in two clinical studies of patients who underwent upper-extremity operations.[11,14]

A relatively small number of cases have been included in both the clinical as well as the volunteers' studies. Nevertheless, no complications have been reported in any of these studies, but a failure of the device was reported in some cases in one study.[11] Furthermore, apart from the study in children, the other clinical studies are referred to the upper limb applications.

The aim of this prospective study is to report the clinical use of this device in a large number of patients, including all possible applications of a tourniquet.

PATIENTS AND METHODS

The SRT was used routinely in all upper and lower limb operations including elective and trauma cases in the department of orthopaedic surgery in two hospitals: the Athens Naval Hospital and the University General Hospital of Alexandroupolis. Our contraindications were the same as for every tourniquet device and included patients with (a) peripheral vascular disease or having an underlying prosthetic vascular graft, (b) sickle cell disease, (c) open fractures, and (d) intramedullary nailing.

The appropriated SRT model was used, according to the systolic blood pressure measured in the operating room directly before the placement of the device. Any failure of the tourniquet intraoperatively was recorded.

Patients' demographics, diagnosis and type of operation, site of tourniquet

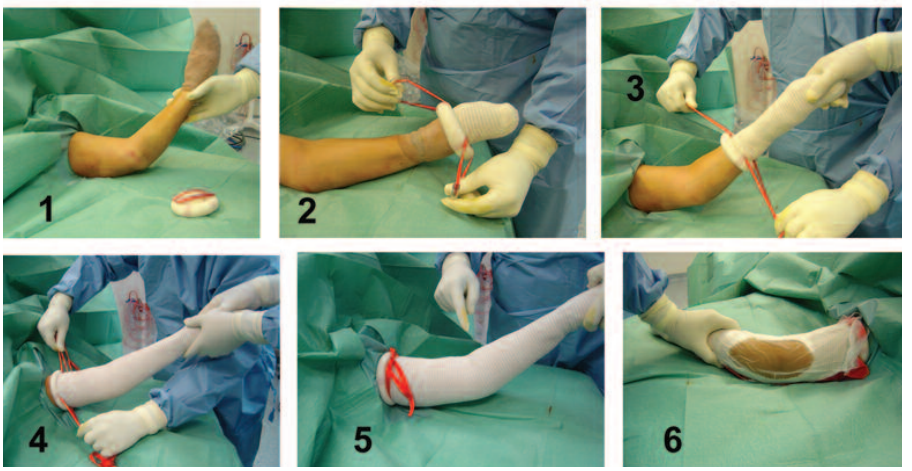


Figure 5. Humeral application of a silicone ring tourniquet.

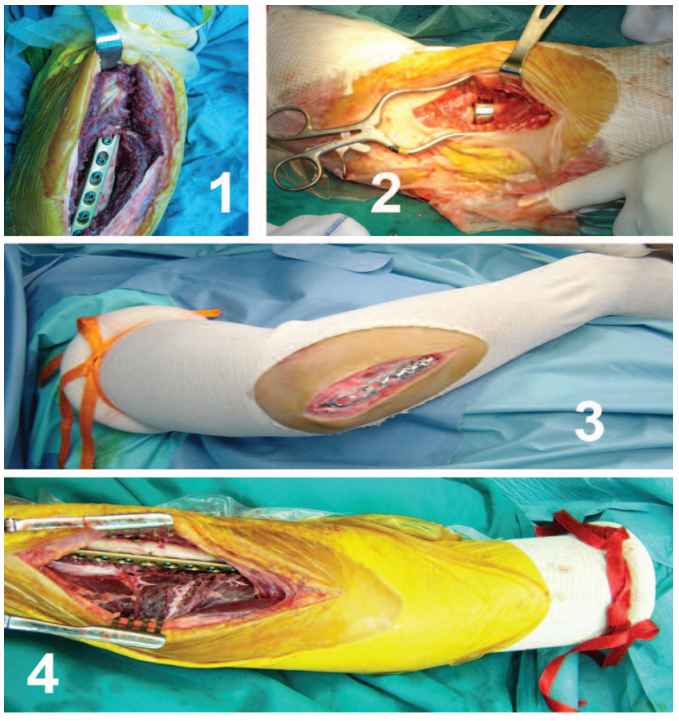


Figure 6. Humeral application of a silicone ring tourniquet. (1) Internal fixation of a humeral shaft fracture, (2) radial head replacement, (3) removal of ulnar plate, (4) internal fixation of a radial fracture.

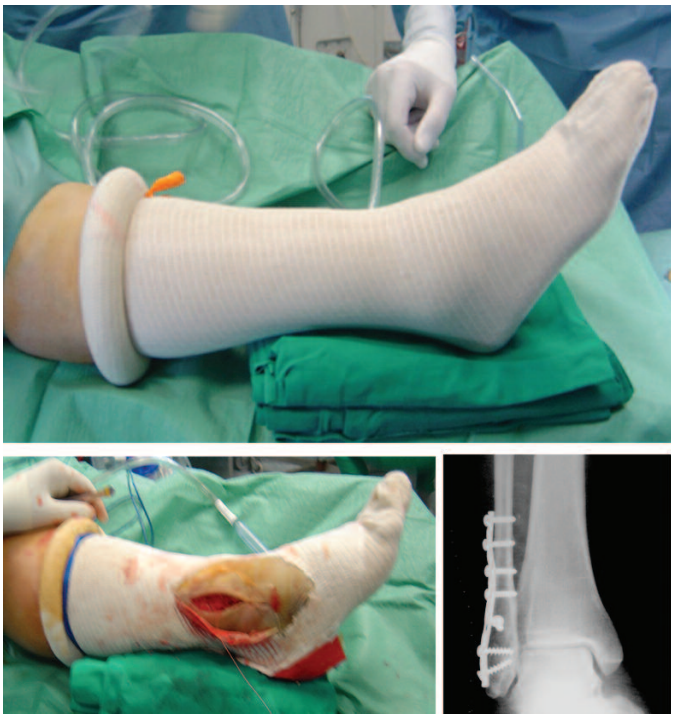
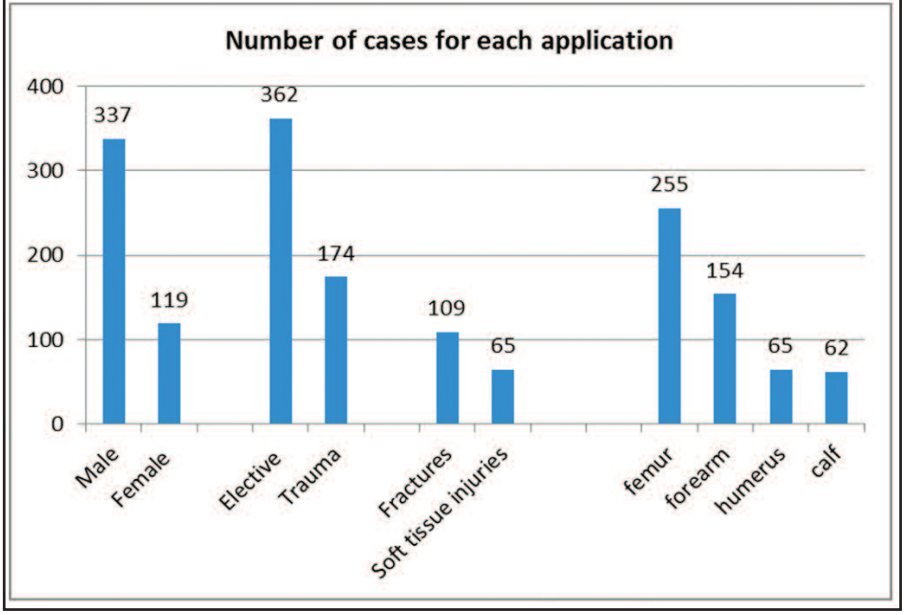


Figure 7. Open reduction and internal fixation of a lateral malleolar fracture using a calf silicone ring tourniquet.

application, and tourniquet time were recorded. All patients were routinely monitored postoperatively and were reviewed the first postoperative day and every day while staying in the hospital and subsequently at two weeks postoperatively. Complications that may be related to the tourniquet were recorded, and these included: (a) skin injuries underneath the tourniquet, (b) post-tourniquet syndrome, (c) nerve paralysis that was followed by either complete recovery (neurapraxia) or permanent nerve damage (paralysis), and (d) any other immediate intraoperative or postoperative complication that may be related to the tourniquet use.

Surgeons were asked to make comments regarding the ease of the application of the device and the quality of the exsanguination, particularly in hand operations.

Table I
Results of the Data Collection



RESULTS

The SRT was used in 536 cases including 337 male and 119 female patients with a mean age of 43.7 years (range 6 to 87 years). The average tourniquet time was 58.5 minutes (range 6 to 180 minutes) (Table I).

The SRT was applied in 362 (67.5%) elective operations and in 174 (32.5%) trauma cases including fractures (n:109, 62.6%) and soft-tissue injuries (n:65, 37.4%). The most frequent application site was the femur (n:255, 47.6%) (Figs. 1–3), followed by the forearm (n:154, 28.7%) (Fig. 4), humerus (n:65, 12.1%) (Figs. 5 & 6), and calf (n:62, 11.6%) (Fig. 7).

In the forearm applications in particular, a general anaesthesia was applied in 50 patients (32.5%), a local anaesthesia in 43 patients (27.9%), and a Bier's block in 61 patients (39.6%).

In cases with Bier's block (either humeral or forearm) (Figs. 8 & 9), if the

patient experiences discomfort at the occlusion site, the silicone ring can be rolled distally a few centimeters (over the anaesthetized area) and the procedure can be extended.

Because the device is sterile it was possible to use it in operations where the pneumatic tourniquet cannot be used such as open reduction and internal fixation of humeral shaft and femoral supracondylar fractures (Fig. 6).

In 14 patients (2.6%) the tourniquet failed intraoperatively, and the cause was an unexpected raised blood pressure.

Surgeons described the following advantages of the devices: (a) the device is applied easily by the surgeon and one assistant; (b) three steps are done together, exsanguination, tourniquet, and stockinet application; (c) the exsanguination was excellent in all cases (Fig. 10); (d) the device is sterile and can be applied after skin preparation and draping and also can be used in certain applications where the pneumatic tourniquet cannot be used; and (e) there is no need for regular check and maintenance.

On the other hand, they noticed two disadvantages: (a) there is a limitation concerning the limb circumference of the limb at occlusion site, and (b) the applied pressure is pre-set and cannot change unless the tourniquet is cut and another model re-applied.

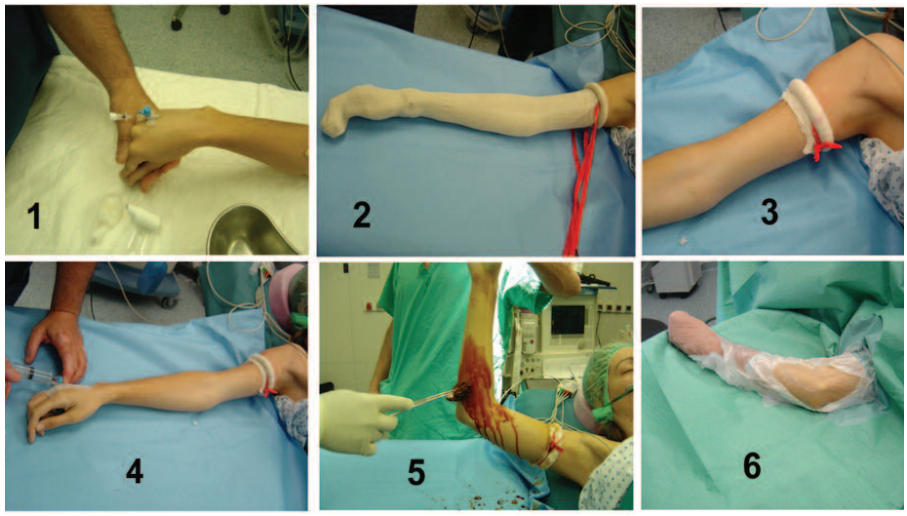


Figure 8. Bier's block using a humeral silicone ring tourniquet.

DISCUSSION

The traditional teaching and belief among orthopaedic surgeons is that a wide pneumatic cuff is safer compared with a narrow cuff (and much safer compared with a narrow elastic ring) as far as the soft tissue damage and nerve injury in particular are concerned. Our initial concern was what would happen if we kept a narrow elastic ring around the limb for 1 or 2 hours. Eventually, the results of this study showed that the SRT is safe and practical and is in agreement with previous clinical studies concerning this device.[10–14]

It seems to be the first report of its clinical use in all possible applications in a significantly large number of cases compared with the previous reports.[10–14]

We found no complications related to its use, while surgeons noticed several advantages. Actually, SRT can replace

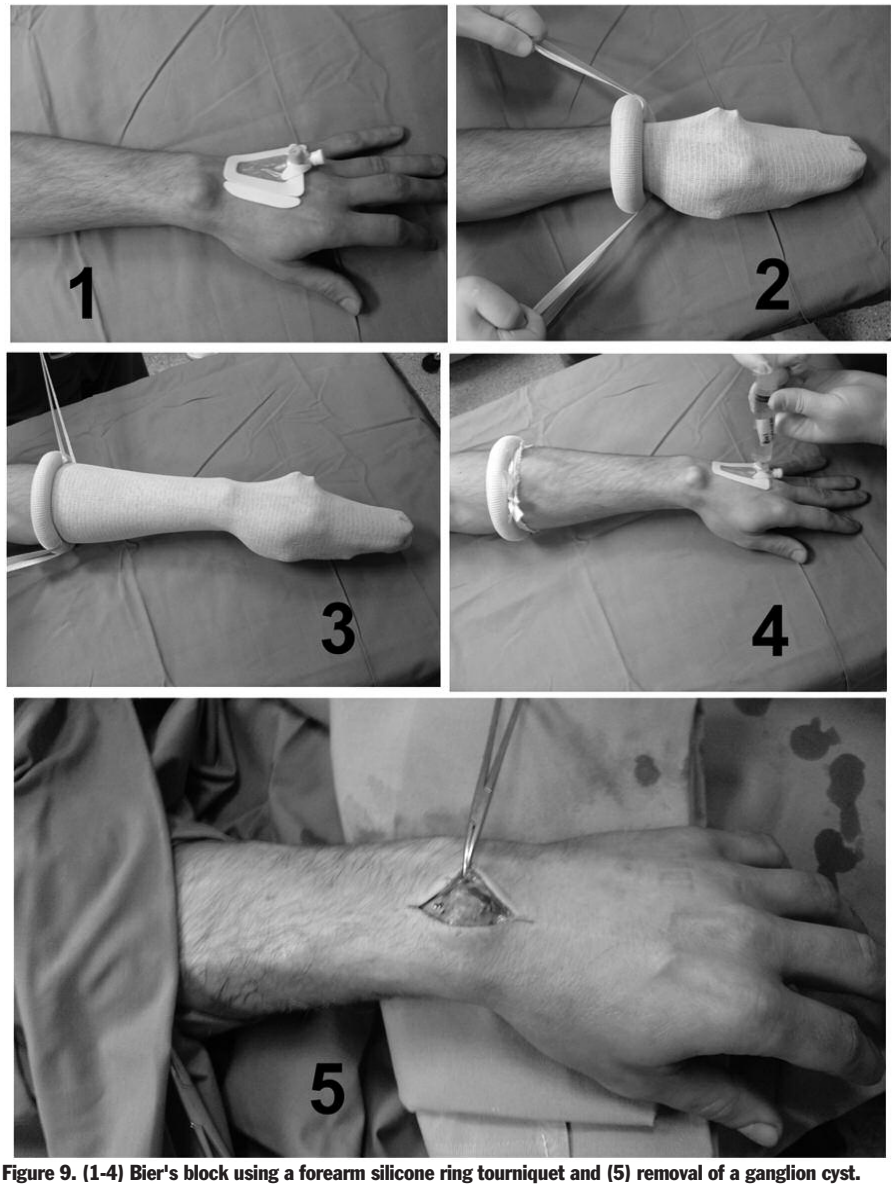


Figure 9. (1-4) Bier's block using a forearm silicone ring tourniquet and (5) removal of a ganglion cyst.

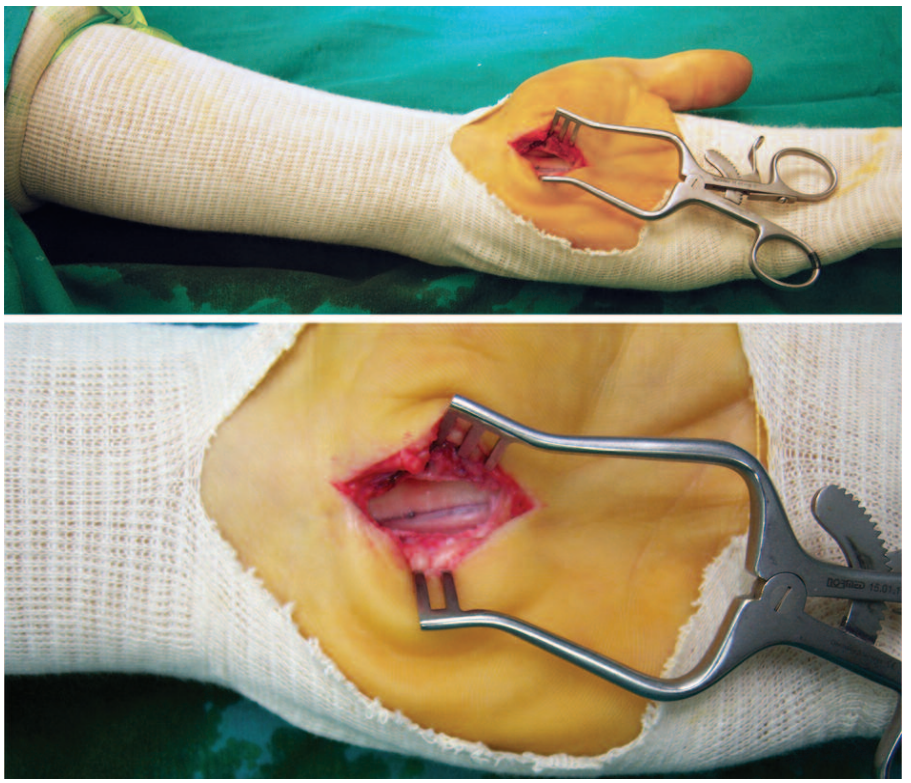


Figure 10. Carpal tunnel release. Excellent exsanguination of the hand using a forearm silicone ring tourniquet.

the pneumatic tourniquet in most — but not all — orthopaedic operations where a bloodless field is required. A pneumatic tourniquet is still required in our theaters because there is a limitation concerning the upper limb circumference at the occlusion site when the HemaClear tourniquet is used.

Pneumatic Tourniquets

Pneumatic tourniquets are essential devices in orthopaedic theaters. Although prospective randomized clinical trials have shown no significant long-term deleterious effects of using pneumatic tourniquets in extremity surgery,[18,19] their use is still associated with potentially serious morbidity[20–22] and even mortality.[23]

Modern pneumatic tourniquets are designed to minimize the incidence of complications,[5] but complications do still occur, and a recent study showed that the incidence of tourniquet complications is still at least as high as that estimated in the 1970s.[24]

Pneumatic tourniquets should be kept in good condition by routinely checking all valves and gauges by performing (a) daily calibration checks, (b) intraoperative monitoring of tourniquet function at frequently intervals, and (c) rigorous monthly performance-assurance tests.[25]

The tourniquet should be tested by inflation and then completely deflated before application, and before its application the limb should be padded with a soft dressing to prevent the wrinkles and blisters that may occur when the skin is pinched.[5]

Application should be performed only by experienced personnel who are knowledgeable about its use and potential complications.[5]

When exsanguination of the limb is needed, this is applied by (a) tightly wrapping an Esmarch bandage (soft rubber compression bandage or a cotton elastic bandage) around the limb starting from its distal end, after which a pneumatic cuff is inflated around the proximal limb,[3,5,26,27] or (b) elevating the limb for 3 to 5 minutes,[5] for 2 minutes,[3] or for 30 seconds.[9]

SRT

With SRT there is no need for maintenance; exsanguination and tourniquet application are done together.

The device is also sterile. It can be used in certain applications where the pneumatic tourniquet cannot be used — such as in certain humeral and femoral fractures — and in every case a device so close to the surgical site is not contaminated. A significant contamination with bacteria commonly implicated in surgical site infections has been found in most tourniquets and exsanguinators presently used in the orthopedic theaters.[28–30] The use of sterile single-use disposable tourniquets where possible has been recommended.[30] The same authors believe that the availability of an alternative should now set the new standard of care, and they also recommend adopting this as a current guideline for control of surgical site infection.[30]

In 43 cases, the SRT was used in hand operations under local anaesthesia and no additional medication was used. In all but one previously reported study, the SRT is at least as comfortable if not more comfortable than the pneumatic tourniquet in hand operations under local anaesthesia.[10,14–17]

The experience gained with previous studies[14,15] and this study as well, has shown that the application of SRT produces an immediate discomfort or pain at the site of the tourniquet application. This gradually subsides to a tolerable level within a few minutes. We believe that it is important to inform the patients about this initial feeling.

Finally, the SRT is disposable, so there is a direct cost. On the other hand, there is an indirect cost for pneumatic tourniquets as they require regular maintenance, repairs, and replacements, as well as routine checking and daily calibration.

CONCLUSION

This new tourniquet device — a silicone ring tourniquet with a pre-set pressure according to the size and the tension model — is easy to apply, is sterile, and occupies a narrow area of the limb. Its application combines three functions at the same time: exsanguination, tourniquet, and stockinet application. Although it cannot entirely replace the classic pneumatic tourniquet, it is a safe and useful device in orthopaedic operations because of its advantages. The device is available in the United States and in many European countries. STI

AUTHORS' DISCLOSURES

The authors have no financial interest in or benefit from this device.

REFERENCES

1. Klenerman L. The tourniquet in surgery. J Bone Joint Surg Br 1962;44-B;937-43.
2. Wakankar HM, Nicholl JE, Koka R, et al. The tourniquet in total knee arthroplasty. A prospective, randomised study. J Bone Joint Surg Br 1999;81(1):30-3.
3. Crenshaw AH Jr. General principles; surgical techniques and approaches. In: Canale ST (ed), Campbell's Operative Orthopaedics 10th ed. St. Louis: Mosby, pp 4-6, 2003.
4. Wright FE. The hand: basic surgical technique and after care. In: Canale ST (ed), Campbell's Operative Orthopaedics 10th ed. St. Louis: Mosby, pp 3381-2, 2003.
5. Wakai A, Winter DC, Street JT, et al. Pneumatic tourniquets in extremity surgery. J Am Acad Orthop Surg 2001;9(5):345-51.
6. Tarver HA, Oliver SK, Ramming GJ, et al. Techniques to maintain a bloodless Weld in lower extremity surgery. Orthop Nurs 2000;19(4):65-73.
7. Kalla TP, Younger A, McEwen JA, et al. Survey of tourniquet use in podiatric surgery. J Foot Ankle Surg 2003;42(2):68-76.
8. Klenerman L. Is a tourniquet really necessary for knee replacement? J Bone Joint Surg Br 1995;77(2):174-5.
9. Ogufere WE, Giddins GE, Thom JS. Upper arm tourniquet pain in local anaesthetic surgery. J Hand Surg Br 1995;20(3):413-4.
10. Boiko M, Roffman M. Evaluation of a novel tourniquet device for bloodless surgery of the hand. J Hand Surg Br 2004;29(2):185-7.
11. Orbay H, Unlü RE, Kerem M, et al. Clinical experiences with a new tourniquet device. Ann Plast Surg 2006;56(6):618-21.
12. Eidelman M, Katzman A, Bialik V. A novel elastic exsanguination tourniquet as an alternative to the pneumatic cuff in pediatric orthopedic limb surgery. J Pediatr Orthop B 2006; 15(5):379-84.
13. Norman D, Greenfield I, Ghrayeb N, et al. Use of a new exsanguination tourniquet in internal fixation of distal radius fractures. Tech Hand Up Extrem Surg 2009;13(4):173-5.
14. Drosos GI, Ververidis A, Stavropoulos NI, et al. Silicone ring tourniquet versus pneumatic cuff tourniquet in carpal tunnel release: a randomized comparative study. J Orthop Traumatol 2013 Jan 30. [Epub ahead of print].
15. Drosos GI, Stavropoulos NI, Kazakos K, et al. Silicone ring versus pneumatic cuff tourniquet: a comparative quantitative study in healthy individuals. Arch Orthop Trauma Surg 2011;131(4):447-54.
16. Mohan A, Baskaradas A, Solan M, et al. Pain and paraesthesia produced by silicone ring and pneumatic tourniquets. J Hand Surg Eur 2011;36(3):215-8.
17. Smith OJ, Heasley R, Eastwood G, et al. Comparison of pain perceived when using pneumatic or silicone ring tourniquets for local anaesthetic procedures in the upper limb. J Hand Surg Eur Vol 2012;37(9):842-7.
18. Kirkley A, Rampersaud R, Griffin S, et al. Tourniquet versus no tourniquet use in routine knee arthroscopy: a prospective, double-blind, randomized clinical trial. Arthroscopy 2000;16(2):121-6.
19. Johnson DS, Stewart H, Hirst P, et al. Is tourniquet use necessary for knee arthroscopy? Arthroscopy 2000;16(6):648-51.
20. Greene TL, Louis DS. Compartment syndrome of the arm: a complication of the pneumatic tourniquet. A case report. J Bone Joint Surg Am 1983;65(2):270-3.
21. Shenton DW, Spitzer SA, Mulrennan BM. Tourniquet-induced rhabdomyolysis: A case report. J Bone Joint Surg Am 1990;72(9) :1405-6.
22. Ogino Y, Tatsuoka Y, Matsuoka R, et al. Cerebral infarction after deflation of a pneumatic tourniquet during total knee replacement. Anesthesiology 1999;90(1):297-8.
23. Gielen M. Cardiac arrest after tourniquet release. Can J Anaesth 1991;38(4 Pt 1):541.
24. Odinsson A, Finsen V. Tourniquet use and its complications in Norway. J Bone Joint Surg Br 2006;88(8):1090-2.
25. McEwen JA. Complications of and improvements in pneumatic tourniquets used in surgery. Med Instrum 1981;15(4):253-7.
26. Reid HS, Camp RA, Jacob WH. Tourniquet hemostasis. A clinical study. Clin Orthop 1983;177:230-4.
27. Pedowitz RA, Gershuni DH, Botte MJ, et al. The use of lower tourniquet inflation pressures in extremity surgery facilitated by curved and wide tourniquets and an integrated cuff inflation system. Clin Orthop 1993;287:237-44.
28. Brennan SA, Walls RJ, Smyth E, et al. Tourniquets and exsanguinators: a potential source of infection in the orthopedic operating theater? Acta Orthop 2009;80(2):251-5.
29. Ahmed SM, Ahmad R, Case R, et al. A study of microbial colonisation of orthopaedic tourniquets. Ann R Coll Surg Engl 2009; 91(2):131-4.
30. Thompson SM, Middleton M, Farook M, et al. The effect of sterile versus non-sterile tourniquets on microbiological colonisation in lower limb surgery. Ann R Coll Surg Engl 2011;93(8):589-90.