A novel elastic exsanguination tourniquet as an alternative to the pneumatic cuff in pediatric orthopedic limb surgery

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We describe our experience with a novel surgical exsanguination tourniquet (S-MART; OHK Medical Devices, Haifa, Israel) in clinical pediatric orthopedics. We evaluated the surgical exsanguination tourniquet's properties and clinical use in 51 patients and compared our observations with our long-standing experience with the Esmarch bandage, pneumatic tourniquet and sterile stockinet. Using the surgical exsanguination tourniquet, we found superior exsanguination quality, quick application and the ability to place the occlusion ring closer to the surgical field. No side effects or ischemic complications were observed. After removal, the skin under the ring was intact in all cases. We conclude that the surgical exsanguination tourniquet is safe and valuable in our practice. ***J Pediatr Orthop B*** **15:379–384 © 2006 Lippincott Williams & Wilkins.**

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Introduction

A bloodless technique is used in most limb surgical procedures, including pediatric orthopedics. The surgical care of the child's limb, however, often presents special circumstances that render the use of the traditional methods difficult or impossible. The two most unique problems are (i) the size of the limb, in which there is little or no space left for the tourniquet on the patient's thigh or upper arm, and (ii) the acute taper of the young child's thigh, which often results in inadvertent distal sliding of the tourniquet. The latter may result in loss of tourniquet compression and cause blood leakage into the surgical field. In addition, many tourniquets slide too close to the surgical incision, causing a breach of sterility and interference in the surgical field. Additional problems that are known to be associated with use of pneumatic tourniquets and are not necessarily unique to the pediatric population are tourniquet chemical burns and abrasions and mechanical failure of the tourniquet and its compressed air and pressure regulation support system [1,2]. In cases in which non-sterile pneumatic tourniquets are used, the risk of cross contamination is not negligible [3]. We hereby report our initial experience with an alternative novel elastic surgical exsanguination tourniquet (SET) (S-MART; OHK Medical Devices, Haifa, Israel).

Methods and patients

The SET was approved for clinical use by the Israel Ministry of Health, Department of Medical Devices. We performed 51 surgical procedures on 43 patients aged 4–17 years (mean ± SD, 9.9 ± 3.9 years; median, 10 years) during 2004. outlines the patients' demographics, diagnoses and procedures performed.

Patient selection

Only patients with limb dimensions within the range specified by the manufacturer (circumference > 24 cm) were included. Exclusion criteria included patients with grossly misaligned and unstable limb fracture or dislocation, deep vein thrombosis, severe skin disorders and procedures with tourniquet time expected to last longer than 2 h.

Evaluation criteria

The following criteria were considered to evaluate the benefits and usefulness of the new device.

1. Ease of application
2. Time of application
3. Tourniquet position on the limb
4. Quality of exsanguination – bleeding upon first incision
5. Prevention of subsequent bleeding – throughout the entire procedure
6. Interference with surgical site/procedure
7. Limb/joint mobility distal and proximal to the tourniquet ring
8. Quality of stockinet cover
9. Ease of removal
10. Postoperative complications

a. Surgical outcome
b. Infection

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Demographics, diagnoses and procedures of the patients

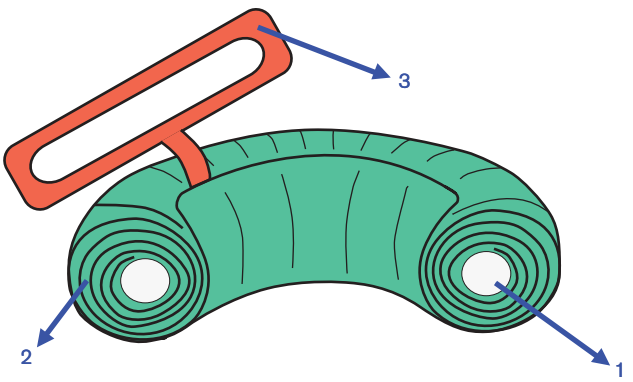
No.	Model	Tourniquet time (min)	Area of application	Procedure	Sex	Diagnosis	Side	Age (years)
1	Yellow	50	Mid thigh	Hamstrings release and vulpius procedure	M	Cerebral palsy	Left	4
2	Blue	30	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	14
3	Blue	30	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	14
4	Blue	35	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	13
5	Blue	70	Distal leg	Tendon lengthening + subtalar fusion	M	Cerebral palsy	Right	17
6	Yellow	65	Mid leg	Calcaneal lengthening	M	Cerebral palsy	Bilateral	11
7	Yellow	65	Mid leg	Calcaneal lengthening	M	Cerebral palsy	Bilateral	11
8	Yellow	35	Mid thigh	Hamstrings release and vulpius procedure	M	Cerebral palsy	Right	6
9	Yellow	35	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	7
10	Yellow	40	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	7
11	Yellow	30	Mid thigh	Hamstrings release and vulpius procedure	M	Cerebral palsy	Right	5
12	Blue	30	Mid thigh	Hamstrings release	F	Cerebral palsy	Right	10
13	Blue	40	Mid thigh	Hamstrings release and vulpius procedure	F	Cerebral palsy	Bilateral	13
14	Yellow	30	Mid thigh	Closed reduction + internal fixation by Nancy nails	F	Fracture of femur	Left	9
15	Blue	20	Mid Thigh	Insertion of Nancy nails	M	Fracture of femur	Right	9
16	Yellow	15	Mid Thigh	Insertion of nails	F	Fracture of femur	Left	6
17	Yellow	50	Mid arm	Open reduction + Kirschner wires	M	Fracture of lateral condyle	Left	8
18	Yellow	50	Mid arm	ORIF by three Kirschner wires	F	Lateral condyle fracture of the humerus	Right	6
19	Yellow	60	Mid thigh	Knee flexion, contracture release	F	Arthrogryposis	Left	7
20	Yellow	70	Mid thigh	Knee flexion, contracture release	F	Arthrogryposis	Left	7
21	Blue	40	Mid thigh	ORIF	M	Avulsion of tibial eminence	Right	14
22	Blue	20	Distal thigh	High tibial osteotomy, applied for osteotomy only	M	Blount disease	Right	14
23	Blue	70	Mid leg	Feet reconstruction (circumference was enhanced with elastic bandage)	F	Cleft feet	Bilateral	14
24	Blue	75	Mid leg	Feet reconstruction (circumference was enhanced with elastic bandage)	F	Cleft feet	Bilateral	14
25	Yellow	65	Mid leg	Tibialis anterior transfer	M	Clubfoot	Right	5
26	Yellow	70	Mid leg	Tibialis anterior transfer	M	Clubfoot	Left	7
28	Yellow	50	Above knee	Through knee amputation	F	Congenital short femur and tibial aplasia	Right	6
29	Yellow	35	Mid arm	Valgus osteotomy of the humerus	M	Cubitus varus	Left	9
30	Yellow	30	Mid leg	Bilateral tendon Achilles lengthening	M	Duchenne muscular atrophy	Bilateral	7
31	Yellow	30	Mid leg	Bilateral tendon Achilles lengthening	M	Duchenne muscular atrophy	Bilateral	7
32	Yellow	70	Mid leg	Tendon transfer	M	Equinovarus	Right	6
33	Blue	45	Mid thigh	Excision of exostosis	M	Exostosis of proximal tibia leg	Right	16
34	Yellow	65	Mid thigh	Tibial osteotomy	M	Fibrous dysplasia	Right	6
35	Yellow	70	Distal tibia	Calcaneal osteotomy	M	Flat feet	Bilateral	12
36	Yellow	65	Distal Tibia	Calcaneal osteotomy	M	Flat feet	Bilateral	12
37	Yellow	20	Proximal leg	Adductor halucis release	M	Metatarsus Varus	Right	3
38	Yellow	65	Mid leg	Excisional biopsy	F	Osteoid osteoma distal tibia	Left	11
39	Blue	40	Mid thigh	Excisional biopsy	M	Popliteal cyst	Right	11
40	Yellow	40	Mid leg	Excisional biopsy	F	Soft-tissue tumor of the leg	Left	4
41	Blue	25	Mid thigh	Removal of Nancy nails from the femur	M	Status after femoral fracture	Right	7
42	Blue	35	Mid thigh	Removal of nails and revision of the scar	M	Status after nailing of the femur	Left	11
43	Yellow	30	Distal leg	Excision of exostosis	F	Subinguinal exostosis	Right	11
44	Yellow	40	Mid arm	Open reduction and internal fixation by three Kirschner wires	M	Supracondylar fracture of the humerus	Left	9
45	Blue	30	Mid leg	Tendon Achilles lengthening	M	Thigh Achilles	Bilateral	12
46	Blue	30	Mid leg	Tendon Achilles lengthening	M	Thigh Achilles	Bilateral	12
47	Yellow	25	Mid thigh	High tibial osteotomy (osteotomy only)	M	Tibia valga	Right	16

(*Continued*)

No.	Model	Tourniquet time (min)	Area of application	Procedure	Sex	Diagnosis	Side	Age (years)
48	Blue	35	Mid thigh	Bilateral stapling of the tibia	M	Tibia vara bilateral	Left	17
49	Blue	40	Mid thigh	Bilateral stapling of the tibia	M	Tibia vara bilateral	Left	17
50	Blue	40	Mid thigh	High tibia osteotomy	M	Tibial torsion	Right	16
51	Yellow	60	Distal leg	Naviculectomy	M	Vertical talus	Left	4
52	Yellow	30	Mid forearm	Excisional biopsy	F	Wrist ganglion	Left	12

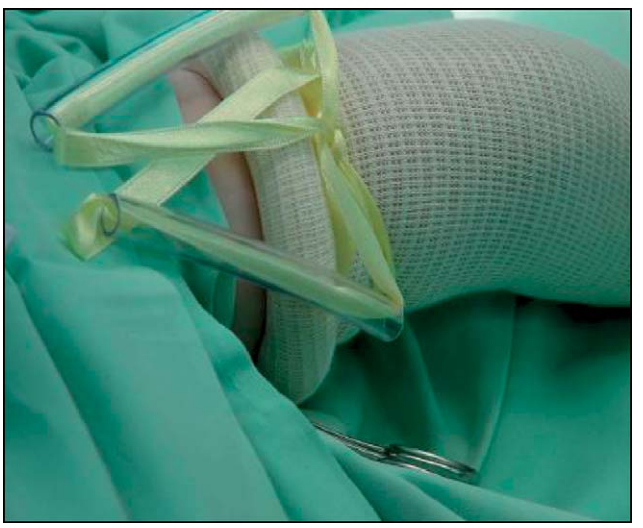
DVT, deep vein thrombosis.

Fig. 1



Schematics of the surgical exsanguination tourniquet showing the inner elastic ring (1), the stockinet wrapped around it (2), and the straps with pull handles (3).

Fig. 2



Application of surgical exsanguination tourniquet to the tapered thigh of the young child. Note the straps wrapped around the limb, preventing the ring from rolling back.

c. Postoperative deep vein thrombosis
d. Postoperative motor/sensory deficit
e. Compartment syndrome
f. Postoperative pain at tourniquet ring site
g. Abrasion, petechia, or chemical burn at tourniquet ring site.

Description of the S-MART surgical exsanguination tourniquet

The SET (S-MART; OHK Medical Devices; www.ohkmed.com) consists of a tension-calibrated elastic ring wrapped around by a cylindrical sleeve and pull-straps (Fig. 1). The toroid-shaped device is sterile and for single-patient use. It is placed on the fingers or toes of the patients and, when the straps are pulled, the SET rolls up the limb quickly and without effort. While rolling, the constricting elastic ring squeezes the blood from the vessels back into the central circulation, while blocking the re-entry of blood into the limb through the arteries. A third effect of rolling up the SET is the sterile sleeve that is left behind, coating the limb from distal to proximal, thereby providing a sterile field. The SET thus replaces the Esmarch bandage, the pneumatic tourniquet (plus controller) and the sterile stockinet. Two sizes of the S-MART were available to us during the study – a smaller device (S-MART/40) suitable for limbs with a circumference of 24–40 cm and a larger one (S-MART/60) used on limbs that are 30–60 cm in circumference. In two instances in which the limb circumference was smaller than 24 cm, we wrapped a sterile ace bandage around the limb at the site we wished the ring to be located, in order to build the circumference up to the minimum level recommended by the manufacturer [4].

Results

The SET was applied successfully on all the patients and generated a superior surgical field easily and effectively. Table 2 summarizes our observations for the entire group according to the evaluation criteria listed above. The average tourniquet time with the SET was 44 ± 17 min (mean ± SD; median = 40 min). The SET was placed at thigh level in 26 procedures, at the lower leg level in 18 procedures, at the upper arm level in four procedures and on the forearm in one procedure. No adverse effects were noted. The SET ring remained in place even on sharply

Table 2 Evaluation of the surgical exsanguination tourniquet (SET) per criteria

Criterion	Observation
Ease of application	Applying the SET was rated 'very easy' in all cases
Time of application	The SET was applied within 15 s
Tourniquet position on the limb	Upper arm Forearm Thigh Lower leg
Quality of exsanguination – bleeding upon first incision	The exsanguination quality was superior to conventional method. Essentially no bleeding was observed. Sponges or electro-coagulation were not used.
Prevention of subsequent bleeding – throughout the entire procedure	Bloodless field was sustained throughout the entire surgical procedure.
Interference with surgical site/procedure	The SET did not interfere with the surgical site.
Limb/joint mobility distal and proximal to the tourniquet ring	Limb mobility and joint flexibility distal and proximal to the tourniquet ring were rated 'very good'
Quality of stockinet cover	Stockinet is elastic and snug to the skin surface and therefore does not shift during the surgical procedure
Ease of removal	The SET is easily removed by cutting the elastic ring using a scalpel. A cutting card supplied with the device is inserted beneath the ring to prevent accidental nicking of the skin while cutting
Postoperative complications	
Surgical outcome	No adverse effects were observed in the study population
Infection	No surgical wound infections were found
Postoperative DVT	No postoperative DVT cases were seen
Postoperative motor/sensory deficit	No motor or sensory neurological deficits were observed in the operated limb
Compartment syndrome	No patients had compartment syndrome in the study population
Postoperative pain at tourniquet ring site	None of the patients complained postoperatively on pain at the site of the tourniquet ring
Abrasion, petechia, or chemical burn at tourniquet ring site	No signs of skin or tissue damage were observed in short and long-term follow-up

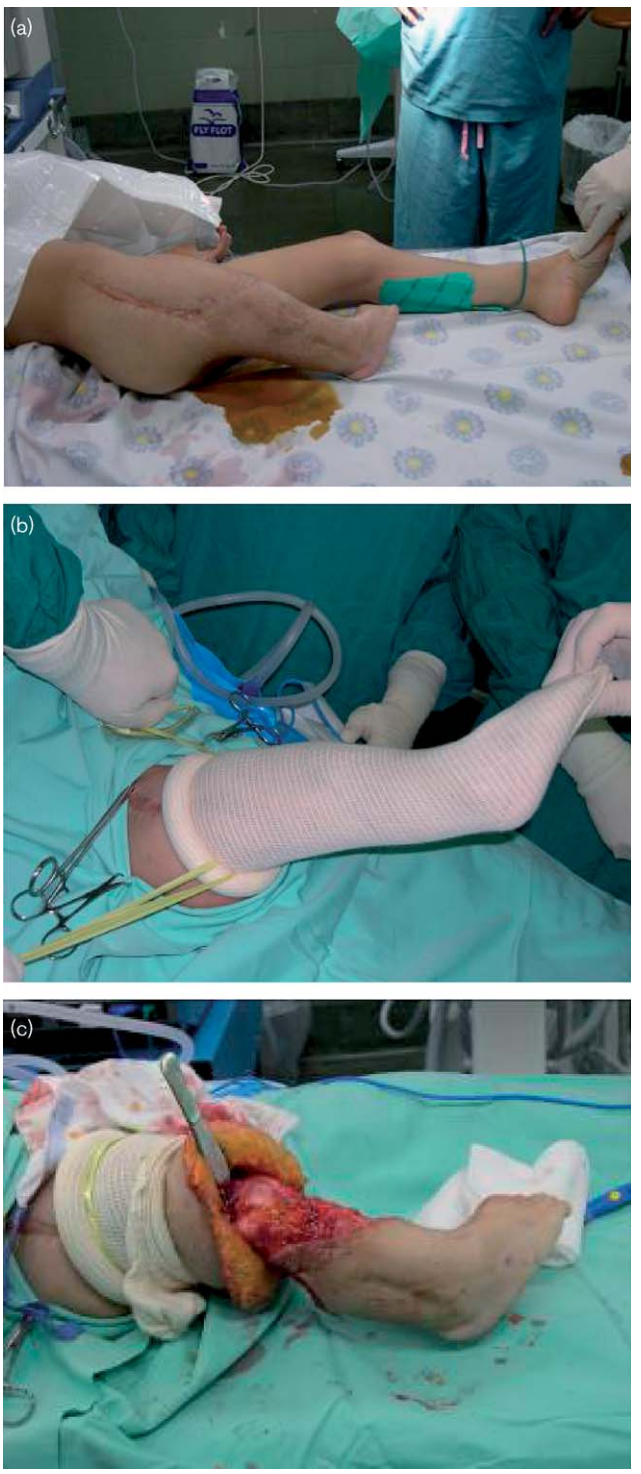
DVT, deep vein thrombosis.

tapered limbs (Fig. 2) and there was no loss of occlusion in any of the patients.

In several cases, the SET was found to be essential in facilitating a bloodless field in procedures that would otherwise have to be done in a non-bloodless fashion. These include, in particular, cases in which surgery was performed on a relatively proximal segment of the limb. An example is a case of congenital femoral deficiency and tibial hemimelia (Figs 3a–c).

Postoperatively, we examined all patients for dermal, vascular or neurological deficit. The clinical evaluation included observation of the skin, estimation of soft-tissue tenderness at the site of the SET ring, pulses and capillary filling, venous congestion or distal swelling, sensation and motor use of the limb. In none of the patients did we find signs or symptoms of soft-tissue damage, vascular occlusion, deep vein thrombosis, compartment syndrome or neurological deficit.

Fig. 3



(a) Short limb through-knee amputation whereby the remaining length of the stump is too short for a conventional pneumatic tourniquet. (b) The surgical exsanguination tourniquet placed on the limb, preventing bleeding and facilitating a 'dry' surgical field (c).

Table 3 Comparison between the surgical exsanguination tourniquet and traditional Esmarch/pneumatic tourniquet method

Property	New exsanguination tourniquet	Pneumatic tourniquet
Quality of exsanguination	Excellent	Pressure dependent
Sterility	Sterile, single patient use	Non-sterile, multi-use
Speed of application	Quick, 10–15 s	5–10 min
Application by:	Surgical team	Applied before the procedure
Site of application	Distal or proximal	Only proximal
Volume of ischemic tissue	Reduced for distal site	Entire limb
Compressed tissue volume	Reduced, only under ring	Larger, under entire cuff
Pressure selection	Three levels only, per systolic blood pressure	Continuous selection
Stability of occlusion	Stable	Occasional occlusion loss
Release	Ring cutting	Pressure release
Re-exsanguination	Not possible	Tourniquet re-pressurized
Skin at site of compression	No lesions	No lesions
Sizes	Adult sizes only (24–60 cm)	Pediatric size available

Discussion

In the present study, we report our experience using a new exsanguination tourniquet in pediatric orthopedics. Our overall rating of the new device is high and we feel that it is a very useful contribution to clinical practice. Table 3 summarizes the comparison between the SET and the traditional Esmarch/pneumatic tourniquet method. In particular, we found the new device to be indispensable in procedures that involve surgical incisions that are only a few centimeters from the axilla or the groin area, where the space is insufficient for using a pneumatic tourniquet. Another advantage that is unique to pediatric orthopedics practice is the new device's stability even on most tapered anatomy as often encountered in well-fed babies. This taper is often associated with distal 'migration' of the pneumatic tourniquet with reduction in cuff pressure which turns the arterial tourniquet into a venous occlusion device with flooding of the surgical field. Another occasional difficulty associated with this migration is the appearance of the non-sterile tourniquet in the surgical field. None of these problems were encountered with the SET.

Exsanguination and surgical field quality

The SET exsanguinates the blood from the limb very effectively, creating a superior quality surgical field that requires virtually no hemostasis during the surgical procedure [5]. In our hands, a drier surgical field facilitates more accurate dissection, better alignment of structures and more straightforward progress of the procedure.

Time saving

We estimate that the procedures done with the SET took less operating room time, required a shorter anesthesia time and had a shorter tourniquet time than with the standard Esmarch/pneumatic tourniquet method.

Safety and pressure

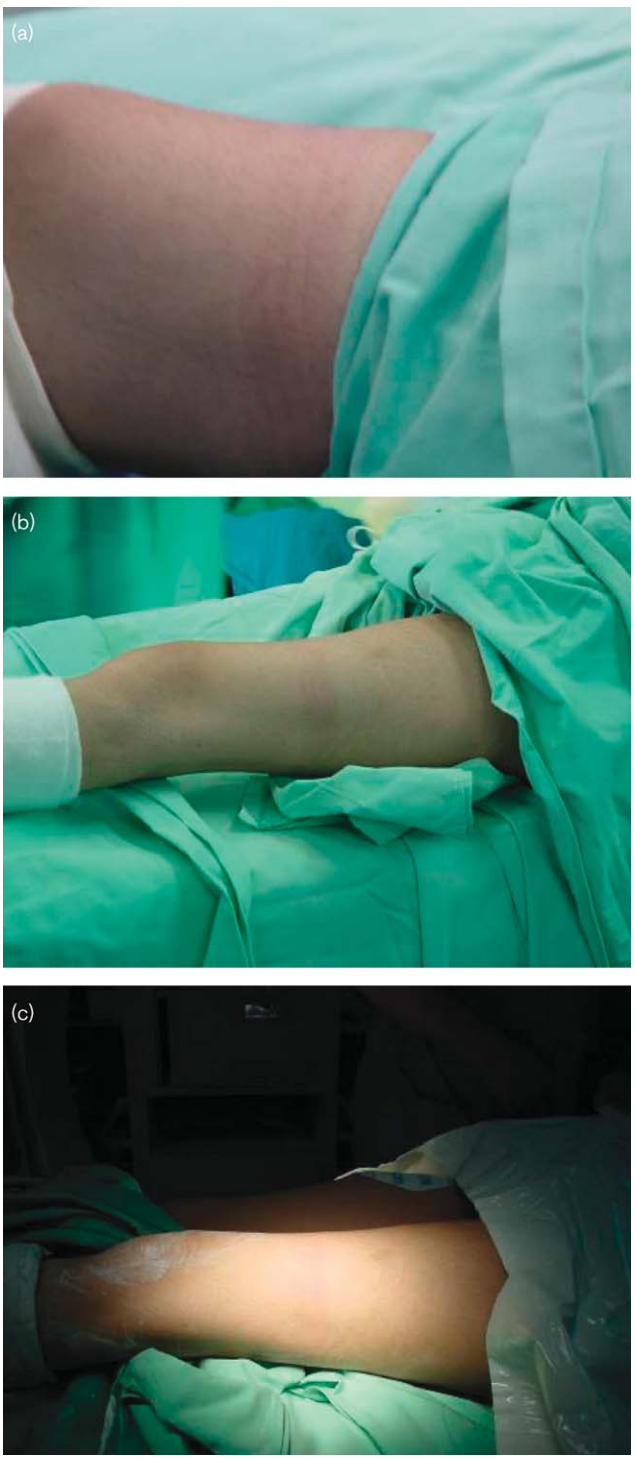
The SET differs from the pneumatic tourniquet in its mechanics. The constricting elastic ring is factory calibrated to provide a localized pressure that is sufficient to block the arterial flow into the limb without causing excessive tissue compression. In all patients, the SET provided continuous arterial occlusion for the entire duration of the procedure. The pressure range as reported by the manufacturer is 227 ± 37 mmHg (mean ± range) for the smaller SET (S-MART/40, yellow) and 246 ± 86 mmHg for the larger SET (S-MART/60, blue). These pressures are similar to the levels we usually use in pediatric orthopedics. We found no local adverse effects at the ring site postoperatively. We observed the skin condition immediately after removal of the SET and found very fine skin marks, similar to those seen on the ankle after wearing a sock. These marks disappeared within less than an hour after removal of the SET (Fig. 4a–c). Furthermore, there were no cutaneous adverse effects of the SET on subsequent postoperative follow-up. No signs of chemical burn, mechanical abrasions or micro/gross hematomas were observed at the site of the ring, as occasionally seen with the use of the pneumatic tourniquet [6].

The SET applies force on the skin surface that is distributed on a relatively small area, substantially smaller than the area beneath the pneumatic tourniquet, thereby minimizing the amount of tissue under compression. Despite other findings, the study by Ochoa *et al.* [7] clearly demonstrated the advantage of using a narrow cuff. Using electron microscopy, they showed that nerves compressed over a length elongate to cause intussusception (telescoping) of the nerve into itself at the nodes of Ranvier, leading to axonal disruption and damage. We did not observe any neural deficit or skin damage associated with the use of the SET.

Placement site and surgical exsanguination tourniquet dimensions

Another advantage of the SET's narrow profile and its non-migrating nature, together with its being sterile, is in situations in which surgery has to be performed in children in whom the limb length is shorter. The sterile

Fig. 4



The marks on the skin after removal of the surgical exsanguination tourniquet: (a) immediately after removal, (b) after 29 min, and (c) after 36 min. Note rapidly fading skin marks.

SET may be placed near the surgical incision with no concern of infection. Thus, when working on a distal structure (foot/ankle and wrist/hand), it was possible to place the SET ring just distal to the calf on the lower leg or on the mid-forearm.

Practicality of surgical exsanguination tourniquet use

SET directly replaces the Esmarch bandage, the sterile stockinet and the padding beneath the tourniquet. In addition, its use avoids the need for a sterile tourniquet, either *de novo* or by re-sterilization. As the SET is applied by the surgeon, its use obviates the need to wait for a technician to secure a tourniquet on a patient's limb and to calibrate and operate the controls of the regulator. The entire process of prepping the limb and applying the SET is substantially shorter than with the standard method. The time saved facilitates a shorter and thereby safer procedure and, in certain circumstances, may translate into cost saving.

Summary and conclusions

The SET is a new device for bloodless surgery that applies exsanguination, tourniquet and sterile stockinet in seconds. This report outlines the superior effectiveness of SET over the existing method, without adding any new safety concerns. A drier surgical field with no 'tourniquet failure', quicker application and the possibility of using it in situations in which pneumatic tourniquets are not feasible makes it particularly useful in pediatric orthopedics. We are satisfied that the new device is safe and free of soft-tissue, vascular or neurological side effects.

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