

Silicone ring versus pneumatic cuff tourniquet: a comparative quantitative study in healthy individuals

Georgios I. Drosos · Nikolaos I. Stavropoulos ·
Konstantinos Kazakos · Grigorios Tripsianis ·
Athanasios Ververidis · Dionisios-Alexandros Verettas

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Abstract

Introduction The aim of the present study was to compare a new silicone ring tourniquet (SRT) with a classic pneumatic cuff tourniquet (PT) in terms of tolerance and recovery time following their use in healthy volunteers.

Methods Both tourniquets were applied in the arm and thigh of 15 healthy unmedicated volunteers. PT pressure was kept at 100 mmHg above the systolic blood pressure. The appropriate model of the SRT was used according to the systolic blood pressure. Pain was assessed by visual analogue scale and arterial blood pressure, pulse rate and oxygen saturation were monitored in all volunteers.

Results There was no statistically significant difference in tolerance time between SRT and PT in the arm (19.13 vs. 18.25 min) and thigh (21.52 vs. 21.39 min) nor in recovery time between the two devices.

Conclusion The SRT performed similarly to the classic PT in terms of tolerance and recovery time when applied in the arm and thigh of unmedicated healthy volunteers.

Keywords Tourniquet · Silicone ring tourniquet · Esmarch · Tourniquet pain

G. I. Drosos (✉) · K. Kazakos · A. Ververidis · D.-A. Verettas
Department of Orthopaedic Surgery,
Medical School, Democritus University of Thrace,
University General Hospital of Alexandroupolis,
68100 Alexandroupolis, Greece
e-mail: drosos@otenet.gr

N. I. Stavropoulos
General Hospital of Kalamata, Kalamata, Greece

G. Tripsianis
Department of Medical Statistics,
Medical School, Democritus University of Thrace,
68100 Alexandroupolis, Greece

Introduction

Tourniquet use is widespread in orthopaedic surgery to provide a bloodless operating field during surgical procedures involving the extremities and for intravenous regional anaesthesia. Pneumatic tourniquet (PT) is the most commonly used tourniquet since its introduction by Harvey Cushing in 1904 [1]. The Esmarch tourniquet is generally considered less safe than PTs, although some surgeons continue to use this device [2, 3].

Modern PTs are designed to minimize the incidence of complications [4], and recent prospective randomized clinical trials have shown no significant long-term deleterious effects of using PTs in extremity surgery [5–8].

Although serious complications of the use of a PT are rare, there is a definite morbidity [9–16] and even mortality [17].

Nowadays, it is generally accepted that wide-cuff PT systems inflated at low-pressure allow more predictable and precise pressure regulation at the site of application resulting in improved safety for extremity surgery [4]. Nevertheless, a recent survey shows that the incidence of tourniquet complications is still at least as high as that estimated in the 1970s [16].

In order to eliminate these complications, the PTs should be kept in good condition by routinely checking all valves and gauges, daily calibration checks, intraoperative frequent monitoring of tourniquet function and monthly performance-assurance tests. The tourniquet should be tested by inflation and then completely deflated before application and experienced personnel should apply the appropriated padding and the tourniquet cuff around the limb [1, 4].

While research continues regarding many aspects of PTs such as application, safety and sequela [18–23], a new device has been introduced in clinical practice recently [24–26].

The silicone ring tourniquet (SRT) is a novel device (S-MART™, OHK Medical Devices, Haifa, Israel) consisting of a silicone ring wrapped within an elastic sleeve (stockinet) and two straps attached to pull handles. The device is inserted over the patient's fingers or toes and is then rolled proximally up the limb, compressing the limb and expelling the blood into the central circulation. The ring is positioned at the proximal occlusion location while the stockinet unfolds onto the limb to provide a sterile draping, as the entire device is sterile (Figs. 2, 3). The use of SRT avoids all time- and personnel-consuming procedures related to the maintenance and application, and it can be applied and removed easily and quickly by the surgeon alone, thereby eliminating the need for assistance from the operating room staff. The sterility of the device allows application after skin preparation and draping, thus shortening tourniquet time. On the other hand, the SRT has a preset applied pressure that cannot be changed and the limb circumference at the occlusion site should be in the range of 20–60 cm for the leg and 20–40 cm for the arm.

The aim of this study was to compare the classic PT with this new device designed for exsanguination and occlusion of the blood flow to the limb.

Materials and methods

Study design

Fifteen adult healthy unmedicated volunteers with no previous fracture or operation in the limbs or any type of anaemia participated in a four-test study. Data regarding volunteer's age, height, weight, sporting activity and smoking were recorded. A Hospital Ethics Committee approval for this study was obtained. The procedure was also described to each volunteer prior to obtaining written consent.

The two different tourniquets were applied on the dominant upper and lower limb of each volunteer, one each time, with a 2-day interval after each application. In half of the volunteers (every other volunteer) the PT was studied first and on the other half the SRT. Also in half of the volunteers the tourniquet was applied on the arm first and on the other half in the leg. The only variable in this study was the type of tourniquet used.

Tourniquet types

A standard PT with an 8-cm-wide cuff for the upper arm and a 14-cm-wide cuff for the thigh was used (Fig. 1). The SRT comes in two sizes; a small size for the arm (circumference of the limb at occlusion site up to 40 cm) and a large size for the leg (circumference of the limb at



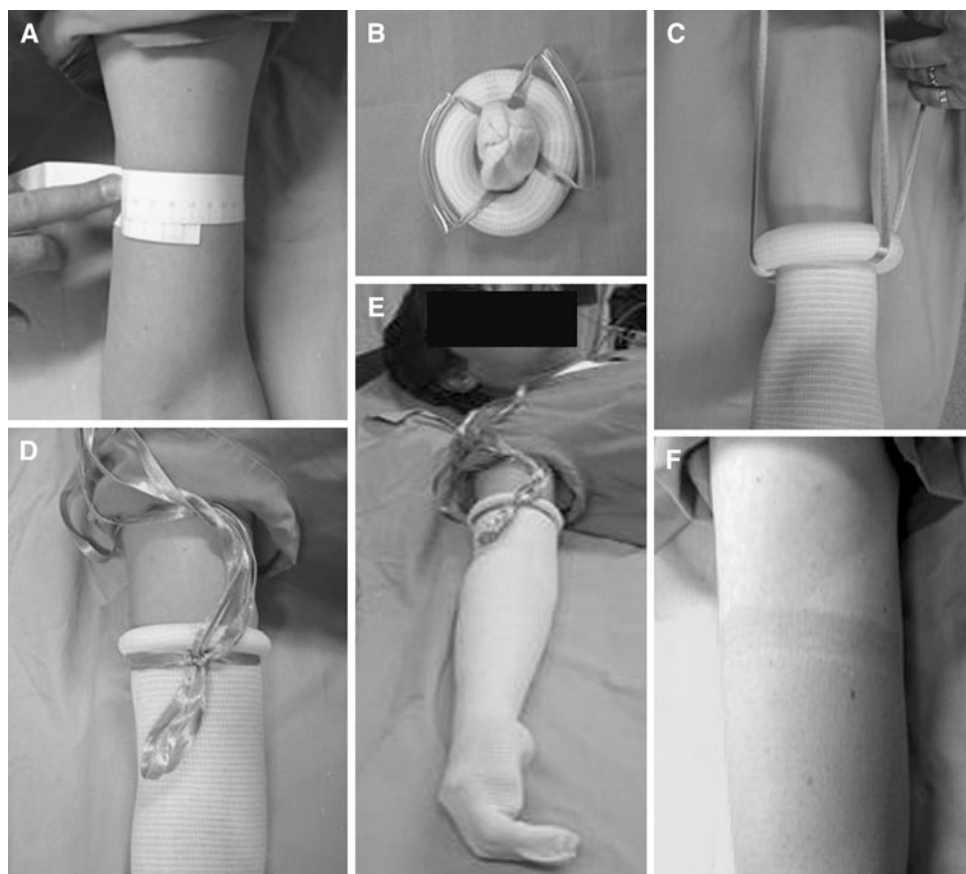
Fig. 1 Pneumatic tourniquet study with the cuff applied on the upper arm and thigh

occlusion site up to 60 cm). Each size has three tension models, and for each patient the appropriate model is used according to the systolic blood pressure measured in the operating room before the placement of the device. The device is inserted over the patient's fingers or toes and is then rolled proximally up the limb, compressing the limb and expelling the blood into the central circulation. The ring is positioned at the proximal occlusion location while the stockinet unfolds onto the limb to provide a sterile draping, as the entire device is sterile (Fig. 2, 3).

Procedure

The procedure was explained to all participants. They also instructed how to use the Visual Analogue Scale for discomfort/pain, 0 = no discomfort/pain to 10 = the worst pain [27]. The volunteer was placed in a comfortable, supine

Fig. 2 Silicone Ring Tourniquet study on the arm. **a** Measurement of the upper arm circumference, **b** selection of the appropriate tension model, **c** the device is inserted over the patient's arm and is rolled proximally up the limb, **d** and **e** the tourniquet has been applied on the upper arm, **f** the arm after the tourniquet removal



position out of site of clocks or monitoring equipment. For ethical reasons it was decided to discontinue the study when the volunteers felt that pain at either the tourniquet application site or in the extremity distal to the tourniquet reached the VAS level of 8.

The circulatory variables of systolic and diastolic blood pressure, pulse rate, as well as PO_2 , were monitored using a noninvasive monitor and cuff/cables were applied in the non-dominant upper limb. After a 15-min period to allow stabilization of all recorded variables, the values of these variables just before the tourniquet application were used as standards.

The PT cuff was applied over two thicknesses of smoothly applied cast padding. The limb elevated for 3 min before the tourniquet inflation. The PT inflation pressure was 100 mmHg above the standard systolic blood pressure. The appropriate model of SRT was selected according to the standard systolic blood pressure and applied as recommended by the manufacturer.

The circulatory variables, PO_2 , and VAS levels for pain at the tourniquet application site as well as in the limb distal to the tourniquet were recorded (a) just after tourniquet application, (b) every 5 min during maintenance of the tourniquet on the limb, (c) just before the tourniquet removal (tolerance time), (d) every 5 min after the tourniquet

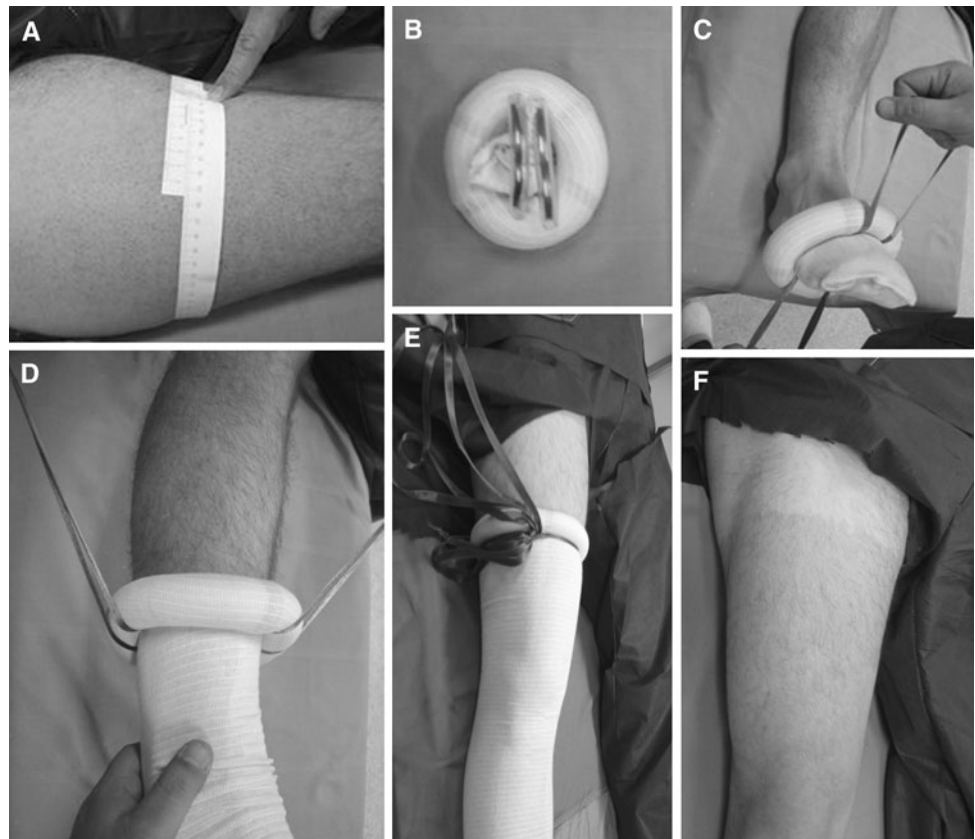
removal, and (e) at the time of complete recovery from any symptoms (recovery time).

The primary outcome of concern was the tolerance time and recovery time for each tourniquet type. Secondary outcome was the changes of the systolic and diastolic blood pressure, pulse rate and PO_2 for each tourniquet type.

Statistical analysis

Statistical analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS), version 11.0 (SPSS, Inc., Chicago, IL, USA). Continuous variables were expressed as mean \pm standard deviation and categorical variables were expressed as frequencies and percentages. The normality of continuous variables was tested with Kolmogorov–Smirnov test. Student's *t* test was used to compare the pre-application values of the circulatory variables and PO_2 between PT and SRT devices, while paired samples *t* test was used to assess any device-related differences in the tolerance and recovery time. Repeated measures analysis of variance (ANOVA) was used to examine the changes of the circulatory variables and PO_2 throughout the application of the devices; post hoc analysis was performed using Bonferroni's correction. The interaction between the different devices and the change of all these

Fig. 3 Silicone Ring Tourniquet study on the arm. **a** Measurement of the thigh circumference, **b** selection of the appropriate tension model, **c** the device is inserted over the patient's foot, **d** the tourniquet is rolled proximally up the limb, **e** the tourniquet has been applied on the thigh, **f** the thigh after the tourniquet removal



variables over time was established by two-way ANOVA. One-way analysis of covariance (ANCOVA) was performed to investigate the effect of the devices on circulatory variables and PO_2 on each measurement, adjusting for pre-application values. All tests were two tailed and statistical significance was considered for p values less than 0.05.

Results

Patient data

The study population was comprised of 15 male volunteers, with a mean age of 32.80 ± 4.60 years (range 24–41 years), mean height of 178.07 ± 7.39 cm (range 165–192 cm) and mean weight of 84.47 ± 7.37 kg (range 72–97 kg). The majority of them were smokers (73.3%; 11 men), while 7 men (53.3%) indulged in sporting activities.

Pain and other symptoms

SRT application produced an immediate pain at the site of the tourniquet application, while in the PT study tourniquet inflation was followed by only some if any discomfort (a pressure sensation). In the SRT study, the pain partially subsided to a tolerable level within a few minutes,

followed by numbness in the hand or foot and again gradually worsened as the time was passing. In the PT study, the pain levels at the site of the tourniquet application were low for the most part of the study, but were becoming worse gradually and further quickly just before the tolerance time.

After the application of the tourniquet the volunteers started feeling numbness in the hand or the foot at a variable interval time. The numbness was initially felt in the little finger (ulnar nerve distribution) or in the dorsal first web space (radial nerve distribution) of the hand, and in the medial side (saphenous nerve distribution), or in the dorsum of the foot (peroneal nerve distribution). This numbness gradually occupied the rest of the hand or foot, and while it was extending proximally, the hand or foot was becoming 'paralyzed'. Eventually, the volunteers were describing an 'aching abnormal feeling' of the limb distal to the tourniquet application site.

The tourniquets were removed when the pain reached the VAS level of 8 and this time was recorded as tolerance time. In both SRT and PT studies the volunteers requested to have tourniquet removed because of pain distal to the tourniquet despite the pain level at the tourniquet site being less than 8 of VAS.

After the tourniquet removal, an initial relief was followed by an unpleasant tingling which lasted for several

minutes. Subsequently the ‘paralysis’ disappeared followed by a gradual relief from numbness.

No difference in the sequence of these subjective feelings was noted between the two different tourniquets.

Tolerance and recovery time

The tolerance and recovery time for each device at the arm and thigh is shown in Table 1.

In the arm, the tolerance time of PT ranged from 9.58 to 29.15 min with a mean value of 18.25 ± 4.60 min, while the tolerance time of SRT ranged from 12.55 to 34.29 min with a mean value of 19.13 ± 5.73 min. Moreover, the recovery time of PT ranged from 3.40 to 15.03 min with a mean value of 7.74 ± 3.48 min, while the recovery time of SRT ranged from 4.00 to 15.00 min with a mean value of 8.52 ± 3.23 min. SRT device presented a 4.8% and a 10.1% elevation in the tolerance and recovery time, respectively, compared with PT device, but none of these differences reached statistical significance ($p = 0.220$ and $p = 0.339$, respectively).

In the thigh, the tolerance time of PT ranged from 13.00 to 34.54 min with a mean value of 21.39 ± 5.44 min, while the tolerance time of SRT ranged from 14.00 to 30.04 min with a mean value of 21.52 ± 5.28 min; the recovery time of PCT ranged from 5.00 to 12.00 min with a mean value of 7.64 ± 1.84 min, while the recovery time of SRT ranged from 4.50 to 12.00 min with a mean value of 7.62 ± 2.21 min. There were no statistically significant differences in the tolerance ($p = 0.928$) and recovery ($p = 0.959$) time between PT and SRT devices.

There was a marginal positive correlation between the tolerance time of the arm and the thigh ($r = 0.329$, $p = 0.076$), when the data from the two devices were combined; this association was more pronounced in PT ($r = 0.534$, $p = 0.040$) than in SRT ($r = 0.164$, $p = 0.559$) device.

On the contrary, a statistically significant positive correlation was found between the recovery time of the arm and the thigh in the combined group ($r = 0.511$, $p = 0.004$),

in PT ($r = 0.513$, $p = 0.050$) and in SRT ($r = 0.526$, $p = 0.044$) device.

Among the combined group, there was a statistically significant positive correlation between the tolerance and recovery time in the arm ($r = 0.438$, $p = 0.015$), but not in the thigh ($r = 0.126$, $p = 0.509$).

Systolic blood pressure

The pre- and post-application mean systolic blood pressure for each device at the arm and thigh is shown in Tables 2 and 3. One-way repeated measures ANOVA showed statistically significant changes of mean systolic blood pressure over time (arm: $p < 0.001$ for PT and $p < 0.001$ for SRT; thigh: $p = 0.020$ for PT and $p < 0.001$ for SRT). The interaction between the two devices and the change of systolic blood pressure over time was not statistically significant ($p = 0.290$). Overall, SRT tourniquet demonstrated significantly higher values of systolic blood pressure on tolerance time ($p = 0.050$), as well as higher mean maximum ($p = 0.037$) values compared with patients’ PT tourniquet.

Diastolic blood pressure

The pre- and post-application mean diastolic blood pressure for each device at the arm and thigh is shown in Tables 2 and 3. The interaction between the two devices and the change of diastolic blood pressure values over time was not statistically significant either ($p = 0.056$). At both sides, there was not any statistically significant tourniquet-related difference in the values of diastolic blood pressure on any of the five time frames or in the mean total and maximum diastolic blood pressure (Tables 2, 3).

Pulse rate

The pre- and post-application values of pulse rate for each device at the arm and thigh are shown in Tables 2 and 3. Overall, pulse rate fluctuated statistically significantly

Table 1 Tolerance and recovery time for arm and leg application of both tourniquets

	Device		<i>p</i> value	95% CI of difference
	PT Time in minutes (mean \pm SD)	SRT Time in minutes (mean \pm SD)		
Arm				
Tolerance time	18.25 ± 4.60	19.13 ± 5.73	0.220	−2.35 to 0.59
Recovery time	7.74 ± 3.48	8.52 ± 3.23	0.339	−2.44 to 0.90
Leg				
Tolerance time	21.39 ± 5.44	21.52 ± 5.28	0.928	−3.08 to 2.83
Recovery time	7.64 ± 1.84	7.62 ± 2.21	0.959	−0.85 to 0.89

Table 2 The pre- and post-application values of systolic BP, diastolic BP, pulse rate, and PO_2 for the arm

	PT	SMART	<i>p</i> value
Systolic BP (mmHg)			
Pre-operative	110.93 ± 7.64	114.27 ± 9.54	0.300
After application	113.00 ± 5.52	117.73 ± 12.60	0.387
Tolerance time	117.53 ± 6.96	126.00 ± 14.70	0.106
Removal	113.20 ± 8.37	119.40 ± 10.91	0.110
Final	111.07 ± 6.70	117.47 ± 10.88	0.032
Total	565.73 ± 32.98	594.87 ± 52.97	0.028
Maximum value	118.40 ± 7.77	128.13 ± 13.99	0.036
Diastolic BP (mmHg)			
Pre-operative	70.47 ± 6.08	73.67 ± 9.63	0.288
After application	72.60 ± 7.17	75.13 ± 9.66	0.837
Tolerance time	75.07 ± 7.01	82.27 ± 10.75	0.080
Removal	73.93 ± 7.07	80.53 ± 10.18	0.051
Final	72.27 ± 6.11	81.20 ± 10.21	0.007
Total	364.33 ± 30.87	392.80 ± 42.74	0.018
Maximum value	77.07 ± 7.97	87.53 ± 11.90	0.008
Pulse rate			
Pre-operative	70.87 ± 8.29	71.60 ± 7.65	0.803
After application	72.53 ± 8.63	73.20 ± 10.97	0.992
Tolerance time	72.00 ± 8.77	73.93 ± 7.90	0.376
Removal	69.93 ± 7.79	68.27 ± 8.03	0.138
Final	69.87 ± 8.76	69.67 ± 7.42	0.495
Total	355.20 ± 40.04	356.67 ± 38.48	0.685
Maximum value	74.80 ± 8.06	76.60 ± 9.76	0.541
PO_2			
Pre-operative	95.93 ± 2.40	95.73 ± 2.63	0.830
After application	96.07 ± 2.22	95.80 ± 2.60	0.797
Tolerance time	96.33 ± 2.23	96.47 ± 2.23	0.576
Removal	96.73 ± 2.19	96.00 ± 2.67	0.376
Final	96.13 ± 2.20	96.27 ± 2.40	0.498
Total	481.20 ± 10.22	480.27 ± 11.22	0.921
Maximum value	97.20 ± 2.18	97.07 ± 2.40	0.886

throughout the application of the two devices at both sides (arm: $p = 0.063$ for PT and $p = 0.001$ for SRT; thigh: $p = 0.026$ for PT and $p = 0.004$ for SRT). Furthermore, at both sides, there was no statistically significant difference in pulse rate between the two devices on any of the five time frames; no significant differences were also found in the mean total or maximum pulse rate (Tables 2, 3).

PO_2

The pre- and post-application values of PO_2 for each device at the arm and thigh are also shown in Tables 2 and 3. The effect of the application of both tourniquets on the pulmonary function at any site (arm and thigh) was not significant

Table 3 The pre- and post-application values of systolic BP, diastolic BP, pulse rate, and PO_2 for the leg

	PT	SMART	<i>p</i> value
Systolic BP (mmHg)			
Pre-operative	117.67 ± 12.62	120.80 ± 11.09	0.476
After application	123.00 ± 10.95	128.67 ± 10.42	0.165
Tolerance time	122.47 ± 13.07	131.00 ± 11.92	0.050
Removal	123.60 ± 7.05	123.07 ± 13.42	0.276
Final	120.47 ± 9.16	121.47 ± 11.90	0.507
Total	607.20 ± 48.67	625.00 ± 52.14	0.395
Maximum value	127.93 ± 9.28	134.93 ± 10.01	0.037
Diastolic BP (mmHg)			
Pre-operative	74.00 ± 12.22	81.20 ± 14.08	0.146
After application	80.73 ± 8.45	83.80 ± 10.27	0.770
Tolerance time	78.93 ± 8.61	82.20 ± 10.16	0.709
Removal	81.13 ± 7.61	78.80 ± 6.16	0.084
Final	80.13 ± 6.44	79.60 ± 8.58	0.258
Total	394.93 ± 38.06	405.60 ± 37.19	0.624
Maximum value	83.00 ± 8.25	90.07 ± 12.67	0.309
Pulse rate			
Pre-operative	73.60 ± 10.07	76.87 ± 11.34	0.411
After application	74.93 ± 9.87	77.00 ± 10.76	0.867
Tolerance time	75.40 ± 9.63	79.13 ± 10.07	0.554
Removal	70.53 ± 9.75	72.07 ± 10.78	0.860
Final	71.07 ± 10.99	73.60 ± 11.44	0.974
Total	365.53 ± 45.24	378.67 ± 49.10	0.968
Maximum value	79.53 ± 9.69	82.33 ± 10.71	0.983
PO_2			
Pre-operative	95.80 ± 1.90	96.27 ± 1.49	0.460
After application	95.80 ± 2.57	96.80 ± 1.61	0.281
Tolerance time	96.07 ± 2.25	96.53 ± 1.96	0.988
Removal	96.33 ± 1.88	96.53 ± 1.81	0.636
Final	96.20 ± 2.04	96.20 ± 1.47	0.162
Total	480.20 ± 9.97	482.33 ± 7.53	0.938
Maximum value	96.93 ± 1.98	97.20 ± 1.70	0.547

(arm: $p = 0.272$ for PT and $p = 0.467$ for SRT; thigh: $p = 0.360$ for PT and $p = 0.297$ for SRT). The interaction between the two devices and the change of PO_2 values over time was not statistically significant either ($p = 0.586$ and $p = 0.220$ for arm and thigh, respectively). At both sides, there was not any statistically significant tourniquet-related difference in PO_2 values on any of the five time frames or in the mean total and maximum PO_2 value (Tables 2, 3).

Discussion

The main finding of this study was that there was no statistically significant difference in tolerance time and recovery

time between the two tourniquets. Although the difference was not statistically significant, volunteers could tolerate the SRT slightly longer than the PT. The recovery time was also longer for the SRT compared with PT. We believe that this is related to the longer tolerance time for SRT compared with PT, which implies that recovery of any symptoms will take more time.

There was a difference between PT and SRT in the initial sensation at the tourniquet application site. While SRT application produced an immediate pain at the site of the tourniquet application, tourniquet inflation in the PT study was followed by only some if any discomfort. The subjective descriptions by the volunteers ('feelings') produced by maintenance of tourniquet inflation on the extremity as well as after the tourniquet deflation and removal were consistent with previous published studies [28, 29] and similar in both SRT and PT studies. Therefore, apart from the initial difference after the SRT and PT application, no other difference in the sequence of the subjective feelings was noted between the two different tourniquets.

The aetiology and neural pathways involved in tourniquet pain remain controversial, but are probably multifactorial [30]. It is also not clear whether the mechanical pressure of the nerve or the nerve ischemia is the main factor responsible for the tourniquet induced nerve damage. The results of animal studies [31–33] and human volunteer studies [34–37] are controversial.

As far as the width of the tourniquet is concerned, it is known that wider cuffs require lower arterial flow occlusion pressure [38, 39] and thus it is accepted that the risk of tourniquet-induced injury to the underlying soft tissues is reduced. On the other hand, human volunteer studies have shown that wider tourniquets resulted in more pain and were tolerated for less time than narrow cuffs [28]. A more recent study found that this is true in higher pressures, but in lower pressures a wide tourniquet cuff is less painful than a narrow cuff [30]. Nerve conduction studies in volunteers have shown recently that wider cuffs resulted in more severe changes in the nerve than narrow cuffs inflated at the same pressure and time [40].

The observed changes in blood pressure are well known [41–44]. The so-called tourniquet hypertension was more pronounced in the SRT study and we think that this merits a further clinical investigation. If the SRT application itself results in higher values of blood pressure this should be considered from the anaesthetic point of view. An unexpected elevation of the systolic blood pressure above a certain value will result in SRT failure to occlude the blood circulation into the extremity.

A large inter-individual difference was noted in tourniquet tolerance time in our study similar to previous studies [29]. It has also been considered as an idiosyncratic response to tourniquet application [45]. Statistical analysis

of the results of our study showed a marginal positive correlation between the tolerance time of the arm and the thigh and a statistically significant positive correlation between the recovery time of the arm and the thigh. Therefore, it seems that a volunteer who tolerates an arm tourniquet longer than another volunteer is likely to tolerate a thigh tourniquet for longer time as well.

The limitations of this study are (a) the volunteer group is not comparable to the standard orthopaedic patient undergoing surgery, where the orthopaedic problem (i.e. osteoarthritis) or other comorbidities and medications may alter the perception of pain and (b) this study describes the immediate effects of a new device and compares these effects to the standard PT. The clinical relevance of the results of this study is not clear. Comparative clinical studies are required and in fact two of these studies are under way in our department.

Nevertheless, several tourniquet studies in the past have used this study protocol (i.e. healthy volunteers) in order to compare tourniquets with different cuff width [28–30], different pressure [29] and application of the same tourniquet in different sites [29, 46–48].

In conclusion, this novel device, the SRT—with the advantages and disadvantages previously described—performed in a similar way to PT as far as the immediate effects are concerned in unmedicated healthy volunteers.

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