

Comparison of Clinical and Physiological Efficacies of Different Intermittent Sequential Pneumatic Compression Devices in Preventing Deep Vein Thrombosis: A Prospective Randomized Study

Ki Hyoung Koo, MD, Jae-Sung Choi, MD*, Ji Hyun Ahn, MD, Jae Hyun Kwon, MD[†], Keun-Tae Cho, MD[‡]

Department of Orthopedic Surgery, Dongguk University Ilsan Hospital, Dongguk University College of Medicine, Goyang,

**Department of Thoracic and Cardiovascular Surgery, SMG-SNU Boramae Medical Center, Seoul,*

Departments of [†]Radiology and [‡]Neurosurgery, Dongguk University Ilsan Hospital, Dongguk University College of Medicine, Goyang, Korea

Background: There are few comparative studies about the optimal method of pneumatic compression to prevent deep vein thrombosis (DVT). The aim of this prospective randomized study was to compare venous hemodynamic changes and their clinical influences between two graded sequential compression groups (an alternate sequential compression device [ASCD] vs. a simultaneous sequential compression device [SSCD]).

Methods: In total, 34 patients (68 limbs) undergoing knee and spine operations were prospectively randomized into two device groups (ASCD vs. SSCD groups). Duplex ultrasonography examinations were performed on the 4th and 7th postoperative days for the detection of DVT and the evaluation of venous hemodynamics. Continuous data for the two groups were analyzed using a two-tailed, unpaired *t*-test. Relative frequencies of unpaired samples were compared using Fisher exact test. Mixed effects models that might be viewed as ANCOVA models were also considered.

Results: DVT developed in 7 patients (20.6%), all of whom were asymptomatic for isolated calf DVTs. Two of these patients were from the ASCD group (11.8%) and the other five were from the SSCD group (29.4%), but there was no significant difference ($p = 0.331$). Baseline peak velocity, mean velocity, peak volume flow, and total volume flow were enhanced significantly in both device groups ($p < 0.001$). However, the degrees of flow and velocity enhancement did not differ significantly between the groups. The accumulated expelled volumes for an hour were in favor of the ASCD group.

Conclusions: Both graded sequential compression devices showed similar results both in clinical and physiological efficacies. Further studies are required to investigate the optimal intermittent pneumatic compression method for enhanced hemodynamic efficacy and better thromboprophylaxis.

Keywords: *Venous thrombosis, Venous thromboembolism, Intermittent pneumatic compression device, Hemodynamics*

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Correspondence to: Jae-Sung Choi, MD

Department of Thoracic and Cardiovascular Surgery, SMG-SNU Boramae Medical Center, 20 Boramae-ro 5-gil, Dongjak-gu, Seoul 156-707, Korea

Tel: +82-2-870-2293, Fax: +82-2-831-2826

E-mail: turedsreal@hanmail.net

Venous thromboembolism (VTE) is a common and potentially lethal disease that includes both deep vein thrombosis (DVT) and pulmonary embolism (PE). It can lead to severe morbidity with poor quality of life and even sudden death related to PE.¹⁾

Most of the literature and international guidelines on VTE emphasize that prevention is more important and

cost-effective than treatment, because once VTE develops, it can only be cured at considerable expense.^{2,3)} Although approximately two-thirds of all VTE events result from hospitalization, only one-third of all hospitalized patients at risk receive adequate prophylactic treatment.²⁾

Intermittent pneumatic compression (IPC) is a relatively well-studied mechanical thromboprophylaxis modality with much evidence for its efficacy, although it has been studied much less intensively than anticoagulation-based prevention methods.^{4,6)} IPC is now used increasingly because it is a good alternative to anticoagulation and is chosen primarily in patients at high risk of bleeding.

Many investigators in favor of IPC use have suggested an increased venous flow and enhanced fibrinolytic activity as possible mechanisms for VTE prevention and have demonstrated that the mechanism can be influenced by the different types of IPC devices.⁷⁻¹²⁾ Despite more than 30 years of experience using IPC to prevent DVT, there are still controversies about its physiological properties and the clinical impact of numerous issues, including the variety of cuff length, inflation rate, compression sequence, compression-relaxation cycle rate, and pressure generation characteristics.⁷⁻¹⁰⁾

There are two general types of sequential compression devices. They are alternate sequential compression device (ASCD) that can compress limbs alternately and simultaneous sequential compression device (SSCD) that can compress both limbs simultaneously and sequentially. A recent study using a new sequential compression device (SCD Express, Tyco Healthcare, Kendall, MA, USA) showed promising venous hemodynamic performance. The SCD Express provided alternate sequential compression with customized compression-relaxation cycles in accordance with an individual's separate venous refill times in their lower limbs, but does not provide simultaneous bilateral compression in the limbs.¹³⁾ Moreover, it has been asked whether this refill time-adjusted compression works optimally throughout the duration of IPC, considering that venous hemodynamics can change with irregular intervals and vary depending on position, postoperative day, and the activity of the subjects.¹⁴⁻¹⁶⁾ However, there is a theoretical presumption that simultaneous sequential compression of both legs (SSCD) may be superior to alternate compression in the effort to augment venous return and to improve hemodynamics, which seemed to be true from the results of our pilot study comparing hemodynamic data from four normal adult volunteers.¹⁷⁾

Thus, our hypothesis is that a SSCD will be superior to an ASCD and the aim of this prospective randomized study was to compare the venous hemodynamic changes

and their clinical influences between the two graded sequential compression groups (ASCD vs. SSCD).

METHODS

Study Population

After Institutional Review Board approval, 34 patients who underwent knee and spine operations and had a moderate or higher risk of VTE were enrolled in this study. They were prospectively randomized into two different device groups (ASCD vs. SSCD), with 68 limbs used in the physiological study. Patients were randomized with a computerized tool. Clinical data are summarized in Table 1. The mean age was 66 years in ASCD and was 71 years in SSCD. There were no differences in body mass indices or body surface areas (BSAs) between the groups. In 25 knee and femur operations (ASCD, 14; SSCD, 11), 24 patients underwent total knee replacement arthroplasties (TKRAs) and one patient underwent a closed reduction and internal fixation for a left femur shaft fracture. Among the nine patients who underwent spine operations (ASCD, 3; SSCD, 6), eight patients underwent interbody fusions of the lumbar or lumbosacral spine and one patient underwent an open reduction for a lumbosacral spine fracture.

All subjects in this study were at the level of more than moderate risk of VTE and isolated IPC without anticoagulation could be justified according to the 8th American College of Chest Physicians evidence-based clinical practice guidelines (ACCP guidelines).²⁾ Preoperatively, the potential subjects for this study were interviewed thoroughly, examined clinically, and tested by duplex ultrasonography to see whether they had any of the exclusion criteria. The exclusion criteria were (1) chronic superficial or deep venous insufficiency, (2) venous anomalies, such as duplication of the superficial femoral vein, (3) previous VTE history, (4) being under anticoagulation therapy presently, (5) severe arteriosclerosis obliterans with no palpable dorsalis pedis pulse, (6) open fracture, hemorrhagic condition, or extensive dermatitis of the lower legs, and (7) congestive heart failure. Additional exclusion criteria included a documented malignant tumor, because pharmacoprophylaxis with anticoagulants would be more reasonable in such a case. D-dimer levels were checked on day 1 preoperatively and on day 3 postoperatively, to serve as a guide to the extent of VTE.

The primary outcome measure was the incidence of DVT, detected by bilateral duplex ultrasonography. Detection of a DVT warranted the addition of low-molecular-weight heparin therapy. The secondary outcome measure was venous hemodynamic data.

Table 1. Clinical Data and Incidences of Deep Vein Thrombosis

Variable	ASCD group (SCD Express) (n = 17)	SSCD group (DVT-3000) (n = 17)	p-value
Age (yr)	66.1 ± 7.6	70.5 ± 8.2	0.119
Gender (male : female)	1 : 16	2 : 15	0.545
Body mass index (kg/m ²)	27.2 ± 4.0	25.4 ± 4.0	0.199
Body surface area (m ²)	1.64 ± 0.18	1.59 ± 0.12	0.385
Operation*			
Knee	13	11	0.838
Spine	3	6	
Femur	1	0	
D-dimer (ng/mL)			
Baseline	282.1 ± 392.0	281.8 ± 241.3	0.436
Postoperative	496.9 ± 301.4	565.8 ± 339.3	0.541
Low extremity DVT			
DVT (+)*,†	2	5	0.331
DVT (-)	15	12	

ASCD: alternate sequential compression device, SSCD: simultaneous sequential compression device, DVT: deep vein thrombosis.

*Distributions of different operations and incidences of DVT were compared with Fisher exact test. †All DVTs were confined to the calf and were asymptomatic.

Description of IPC Devices (SCD Express and DVT-3000) and Their Use

In the ASCD group, SCD Express devices (Tyco Healthcare) were used, which provide alternate sequential compression with customized compression-relaxation cycles in accordance with an individual's separate venous refill times in the lower limbs. In the SSCD group, DVT-3000 devices (DS MAREF, Gunpo, Korea) were used, which can provide simultaneous sequential compression of both legs (Fig. 1). The two devices used were designed to improve overall compliance of both patients and the medical team, and therefore optimize thromboprophylaxis. Both manufacturers had reduced the size and weight (< 2 kg) to improve portability and for better handling. The SCD Express has optional battery power, which can support full function for 6–8 hours and the DVT-3000 for 8–10 hours. Noise had been reduced to 60 dB in the DVT-3000 and 80 dB in the SCD Express. Similarly, the sleeves consisted of three air chambers running the length from the foot to the lower thigh and inflated sequentially. However, the compression profiles differed. DVT-3000 provided 12 seconds of sequential inflation, with a maximum lower calf pressure of 40–45 mmHg, which was similar to that

of the SCD Express. Device refill time, or relaxation time, was constant, but could be set to three different values (24, 48, 60 seconds). We selected 48 seconds as the fixed relaxation time on the basis of pilot study results. Thus, the cycling rate of the DVT-3000 was fixed as 60 cycles/hr and the compression was simultaneous. In contrast, the SCD Express provided 11 seconds of inflation and a customized device refill time, which varied with the individual's venous refill time. Using the technique of segmental air plethysmography,^{11,16)} the SCD Express measures the post-compression time of the two legs separately and then uses the longest refill time for both legs. Thus, the cycling rate of the SCD Express was not fixed and the compression was not simultaneous.

It was recommended that all patients used IPC devices during their hospital stay. All patients began using graduated compression stockings during their operations and were supported by IPC after operation completion. IPC was applied at 6 cycles per day. One cycle consisted of a continuous 2-hour compression and subsequent 2-hour interruption. On the general ward, the sleeves were removed and the patients ambulated during these 2-hour interruptions.



Fig. 1. Two types of sequential compression devices. (A, B) SCD Express devices (Tyco Healthcare, Kendall, MA, USA) for alternate sequential compression device group. SCD Express devices can provide alternate sequential compression with customized compression-relaxation cycles in accordance with an individual's separate venous refill times in lower limbs. (C, D) DVT-3000 devices (DS MAREF, Gunpo, Korea) for simultaneous sequential compression device group. DVT-3000 devices can provide simultaneous sequential compression of both legs.

Measurements of Venous Hemodynamics (Flow and Velocity)

Duplex ultrasonography exams were performed on the 4th and 7th postoperative days in the knee and spine surgery patients, respectively. All exams were performed by single radiologist using a 12.5 MHz linear-array transducer (iU22, Philips Ultrasound, Bothell, WA, USA). To obtain flow and velocity measurements, we followed the detailed methodology described by Kakkos et al.¹¹⁾ Briefly, longitudinal scans of bilateral superficial femoral veins, just distal to the confluence of the profunda femoral veins, were performed. Baseline velocity, flow pattern, and augmented flow for 11 seconds (ASCD group) or 12 seconds (SSCD group) were recorded. Under a fixed state of other ultrasound scan parameters, peak velocity (PV) was measured by determining the maximum point of the augmented waveform. Total volume flow (TVF) was calculated automatically by the software. Peak volume flow (PVF) was also calculated with a 1-second interval around the PV. Expelled volume was calculated theoretically to determine how much blood was squeezed by the compression for 1 hour: expelled total volume (ETV) = single cycle augmented TVF × cycling rate (cycles/hr), expelled peak volume (EPV) = single cycle augmented PVF × cycling rate (cycles/hr). All the measurements were performed in the supine position. More than four consecutive measurements were recorded and the mean value calculated.

Statistical Analyses

We performed a small-scale preliminary physiological study that included four subjects for the program to ascertain the basic values for the venous hemodynamic parameters and they were used in the determination of an appropriate sample size. Statistical power was set at 80% and *p* levels were set at 0.05. The continuous data of the two groups are expressed as means ± standard deviation and analyzed using a two-tailed, unpaired *t*-test. Relative frequencies of unpaired samples were compared using Fisher exact test. We considered mixed effects models that might be viewed as ANCOVA models, but allowed violating independence. A *p* < 0.05 was considered to indicate statistical significance. The SPSS ver. 14.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses.

RESULTS

Primary Outcome: The Rate of DVT

The rates of DVT developed after the operation are shown in Table 1. In total, 34 patients were provided with IPC support postoperatively. DVT developed in 7 patients (20.6%). Two of them were in the ASCD group (SCD Express, 11.8%) and the other five were in the SSCD group (DVT-3000, 29.4%). The difference was not significant (*p* = 0.331). No patient was symptomatic. Although the evaluation of potential PEs using chest computed tomography

should be made if a proximal DVT is found, there was no proximal DVT. All DVTs were confined to the calves. All of them involved axial veins of the calves. In the SSCD group (DVT-3000), four patients with DVT underwent

unilateral TKRA. All DVTs developed on the ipsilateral side in TKRA patients. In the ASCD group (SCD Express), one patient with DVT underwent bilateral TKRA and the other patient, an open reduction of lumbosacral spine. Both of these patients showed bilateral DVT. The device model, age, and the method of operation were not significant risk factors as a result of risk factor analysis for development of DVT using a multivariate logistic regression model (Table 2).

Table 2. Risk Factor Analysis for Development of Deep Vein Thrombosis

Risk factor	Odds ratio	<i>p</i> -value
Device (DVT-3000)	2.296	0.396
Age	1.083	0.300
Operation	1.111	0.915

A multivariate logistic regression model was used to determine statistical significance.

Secondary Outcome: Venous Velocity and Flow

Venous hemodynamic data are shown in Table 3. For the comparison of hemodynamic values in the same group (baseline vs. augmented values), baseline PV, mean velocity, PVF, and TVF were enhanced significantly as much as, or more than 2-fold, in both device groups

Table 3. Comparison of Hemodynamic Parameters Evaluated by Duplex Ultrasonography

Venous hemodynamics	ASCD group (34 limbs)	SSCD group (34 limbs)	<i>p</i> -value*
Baseline PV (cm/sec)	25.2 ± 7.6	23.6 ± 6.3	0.619
Baseline MV (cm/sec)	9.9 ± 3.5	9.1 ± 4.4	0.765
Baseline PVF (mL/min)	178 ± 83.2	150.5 ± 95.9	0.599
Baseline TVF (mL/min)	152.1 ± 77.8	132.7 ± 91.3	0.858
Cycling rate (cycles/hr) [†]	81.8 ± 18.1	60	<0.001
Compression time (sec)	11	12	-
Augmented PV (cm/sec) [‡]	48.9 ± 11.8	46.7 ± 17.5	0.615
Augmented MV (cm/sec) [‡]	18.2 ± 4.7	17.4 ± 10.9	0.922
Augmented PVF (mL/min) [‡]	430.8 ± 229.5	359.0 ± 193.1	0.635
Augmented TVF (mL/min) [‡]	284.5 ± 138.7	237.4 ± 142.0	0.629
ETV (mL/hr)	4,315.8 ± 2,231.9	2,890.6 ± 1,660.7	-
ETV index (ETV/BSA, mL/hr/m ²)	2,632.8 ± 1,245.1	1,833.9 ± 1,089.7	0.072
EPV (mL/hr)	584.2 ± 337.0	359.0 ± 193.1	-
EPV index (EPV/BSA, mL/hr/m ²)	357.1 ± 184.4	229.1 ± 129.1	0.039
PV ratio	2.1 ± 0.8	2.2 ± 1.2	0.696
MV ratio	2.1 ± 0.9	2.4 ± 2.1	0.500
PVF ratio	2.7 ± 1.4	3.5 ± 2.9	0.454
TVF ratio	2.2 ± 1.3	2.6 ± 2.2	0.519

Values are presented as means ± standard deviation. Statistical analyses were performed by paired *t*-test within the same group and by mixed effects model with adjustments for age, leg laterality, and operation between the two groups. Ratio = augmented value / baseline value.

ASCD: alternate sequential compression device, SSCD: simultaneous sequential compression device, PV: peak velocity, MV: mean velocity, PVF: peak volume flow, TVF: total volume flow, ETV: expelled total volume, BSA: body surface area, EPV: expelled peak volume.

*All *p*-values were for the hemodynamic values divided by BSA. [†]Cycling rate of DVT-3000 was fixed at 60. [‡]All augmented values increased significantly compared with the corresponding baseline values in both device groups (all, *p* < 0.001).

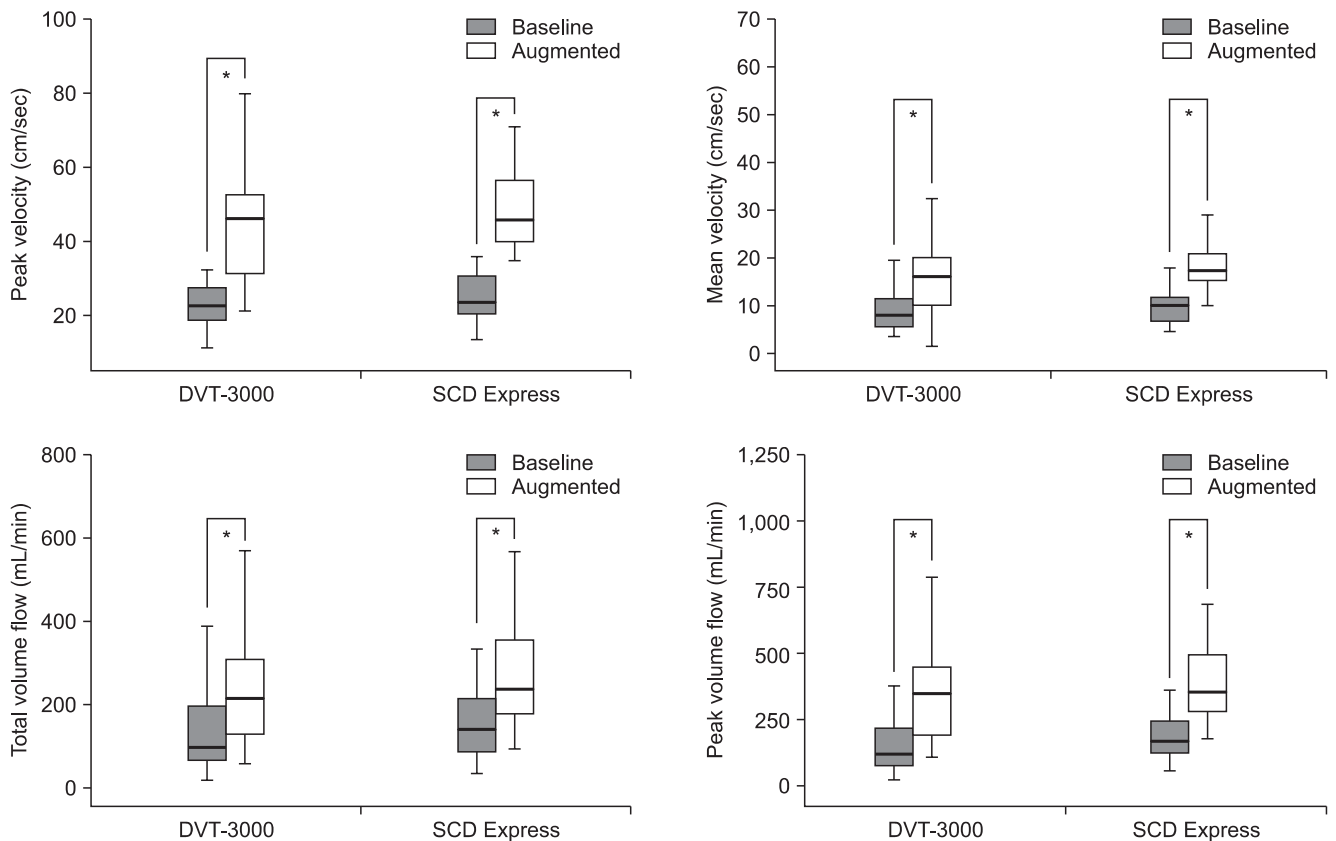


Fig. 2. Comparison of hemodynamic data. Baseline peak velocity, mean velocity, total volume flow, and peak volume flow were enhanced significantly, which more than doubled in both device groups. Asterisk (*) indicates significant difference between the baseline and the augmented values in the same group (all, $p < 0.001$).

(all $p < 0.001$) (Fig. 2). In particular, PVF enhancement in the SSCD group was impressive, reaching as much as a 3.5-fold increase. Comparing the two groups, the hemodynamic values divided by BSA, the value indices were used for the analysis. The baseline and augmented value indices were not significantly different between the groups. Furthermore, the amounts of venous flow and volume enhancements were not different between the devices. The mean value of ETV index (ETV/BSA) was 28.8% higher with the SCD Express (ASCD group; 2,632 mL/hr vs. 1,834 mL/hr; $p = 0.072$) and EPV index (EPV/BSA) 55.9% higher with the SCD Express (ASCD group; 357 mL/hr vs. 229 mL/hr; $p = 0.039$), compared with the DVT-3000 (SSCD group).

DISCUSSION

This was a prospectively randomized study to compare the clinical and physiological efficacies of two different IPC devices with respect to the prevention of VTE. The results demonstrated that (1) the clinical efficacies in preventing

DVT did not differ between the devices, (2) the DVT incidence in the patients undergoing surgery with a moderate-to-high risk of VTE was 20.6% and there was no proximal/symptomatic DVT, with postoperative application of IPC, and (3) venous flow and velocity were significantly improved by both the DVT-3000 and SCD Express, but there was no significant differences between the groups.

Although most of the subjects underwent TKRA, which has a high risk of postoperative VTE, and the other operations had a moderate risk of VTE,²⁾ the patients showed a relatively low incidence of DVT, with no symptomatic or proximal DVT. Without thromboprophylaxis, randomized clinical trials have demonstrated that venographic DVT was identified in 41%–85% and proximal DVT in 5%–22% of patients.^{2,18,19)} Although the prevalence of DVT after TKRA in Asian populations is known to be lower,^{20,21)} it is considered that both devices contributed to preventing DVT. IPC devices have important advantages and limitations. The most attractive advantage is the lack of bleeding potential, so that patients at high risk of bleeding can obtain thromboprophylaxis without depending

on an anticoagulation-based method. However, there are many specific IPC devices that have various non-standardized modes of operation that have never been assessed or compared in any clinical trial. In this study, we tried to determine differences in clinical efficacy and venous hemodynamic changes according to the different modes of sequential compression (simultaneous vs. alternate compression and fixed relaxation time vs. changing relaxation time in accordance with venous refill time).

The compression pressure, duration, cycling rate, compression area, and compression sequence have been major issues with respect to the optimal application of IPC, including the problem of poor compliance in patients and the medical team. Both the devices in this study adopted sequential IPC, covering the foot and calf, with cuff pressures of 130 mm Hg and 40 mm Hg, respectively, for 2 hours with 2-hour intervals. According to the results of some representative studies, the range of compression should include the foot and calf at applied pressures of 60–140 mm Hg to lower venous pressure effectively.²²⁾ Additionally, the use of sequential IPC has shown evidence of increased local and systemic fibrinolytic activity, adding some protection against acute DVT to the direct mechanical emptying of the lower leg veins.²³⁾ For the evidence-based reason why we adopted continuous application of IPC for 2 hours in this study, Giddings et al.²⁴⁾ indicated that IPC over 2 hours had a significant effect in enhancing fibrinolysis and suppressing procoagulant activation.

To our knowledge, there has been no reported study concerning the comparison of simultaneous versus alternate compression. It was observed that the SCD Express was providing near-alternate compression in both legs due to dealing with different compressions in accordance with the different refill times. From the results of this study, the augmented amounts of velocities and volume flows, expressed as ratios, were generally larger with the DVT-3000, but the differences were not significant between the devices. The accumulated volumes expelled per hour were in favor of the SCD Express, consistent with observations in similar studies.^{11,15)} It appeared that this significant difference was not directly associated with refill time-adjusted compression, but with increased cycling rates. That is, if we increased the cycling rate by reducing the relaxation time of DVT-3000, we are unsure whether the significant

difference would be maintained or reversed. Unfortunately, we did not distinguish more determining factors for optimal IPC between the simultaneous and refill time-adjusted alternate compression from the observations of our study. In a risk factor analysis for the development of DVT using a multivariate logistic regression model, IPC device was not a risk factor (Table 2). Thus, under the conditions tested, it was demonstrated that the contributions of the two devices in preventing DVT were equivalent.

During this study, as many as six patients were excluded, due to lack of adherence to the protocol. Unfortunately, the present study did not deal with the problem of compliance. In fact, relatively poor compliance with optimal fitting and following of instructions made the IPC less effective in clinical practice.^{21,25)} For this reason, the ACCP guidelines emphasize that careful attention should be directed towards ensuring the proper use of, and optimal adherence with, this mechanical thromboprophylaxis.²⁾ With respect to reduced size, improved portability, less noise, and simplified operation method, we felt that the two devices were equivalent, but an additional studies on true compliance and ease of use are warranted.

In conclusion, the two devices tested showed similar results not only in clinical efficacy of preventing DVT but also in the enhancing venous flow velocity and volume flow. The SSCD was not obviously superior to the ASCD. The accumulated volume flow (EPV and ETV indices) favored the IPC by the SCD Express, primarily due to the increased cycling rate. However, superiority between the devices defined by simultaneous and alternate refill time-adjusted compression was not determined. Further studies are required for the complete evaluation of combined simultaneous compression and a more frequent cycling rate.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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