

# CIRC Meeting 2017

October 21, 2017

Patient-oriented compression therapy –  
Stockings must be easy to don and doff

C Buset

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## *Conflict of interest*

- The medical stocking companies Bauerfeind, Medileg, Salzmänn medico, and SIGVARIS (in alphabetic order) supported the studies with according stockings
- The STOCKNLEGGINGS (SLLL) four-layer stocking system was designed by J.Hafner and manufactured by SIGVARIS
- The JH Rahn Foundation (Zurich) supported the studies financially (application at the Ethical Committee, purchases of special study material if applicable)

# Background

- Robust evidence of MCS in prevention and treatment of venous leg ulcers
- Consensus document on indications for medical compression stockings (MCS) in venous and lymphatic disorder, under the auspices of the International Compression Club (ICC); Phlebology 2017
- **30-40%** of patients with advanced chronic venous insufficiency **do not comply with compression therapy**

Nelson EA et al.: J Vasc Surg 2006;44:803-808.; Reich-Schupke S et al.: Int Angiol 2009;28:385-393.; Rabe E et al.: JDDG 2013 Mar;11(3):257-61.

# Background

## Most common reasons to fail treatment adherence:

- **Difficulties in donning**
  - **Age**
  - **Inability to reach the feet with the hands**
  - **Obesity**
  - **Weakness of hands**
  - **Lack of instruction**
- Dryness of skin
- Itchiness
- Feeling of constriction
- Non-conviction of benefit

# Four methods of overcoming donning difficulties

- **The use of donning devices**

- Sippel K et al. Donning devices (foot slips and frames) enable elderly people with severe chronic venous insufficiency to put on compression stockings. Eur J Vasc Endovasc Surg. 2015

- **The use of moldable superimposed Velcro wraps**

- Mosti G et al. Adjustable Velcro Compression Devices are more effective than inelastic bandages. Eur J Vasc Endovasc Surg 2015.

- Partsch H et al. The use of pressure change on standing as a surrogate measure of the stiffness of a compression bandage. Eur J Vasc Endovasc Surg 2005;30:415e21.

- **The use of a divided compression stocking composed of a sock and a separate legging**

- Hirai M et al. Development of separated elastic stockings. Phlebology 2013.

- **The use of superimposed light stockings**

- Cornu-Thenard A et al. Superimposed elastic stockings: pressure measurements. Dermatol Surg 2007

Eur J Vasc Endovasc Surg (2015) 49, 221–229

# Donning Devices (Foot Slips and Frames) Enable Elderly People with Severe Chronic Venous Insufficiency to put on Compression Stockings

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## Objective

- To investigate the benefit of donning devices in ‘real’ elderly patients with CVI



## Parameters examined

- Donning success (X successful / n participants)
- Subjective scoring of donning attempt by the patients
- Correlation of patient-related parameter with donning success rate of the donning procedures

## Participants

- 40 patients, > 65y old, with advanced CVI (C4-C6)

# Compression stockings

- “**strong**” compression - one stocking:
    - SIGVARIS Cotton 223 A-D; CEN class III (34-46 mmHg); open and closed toe
- = *CS40-open-toe; CS40-closed-toe*



- “**light**” compression – two superimposed stockings:
    - SALZMANN MEDICO Venosan 5001 A-D; CEN class I (18-21 mmHg); open and closed toe
- = *CS20+20-open-toe; CS20+20-closed-toe*



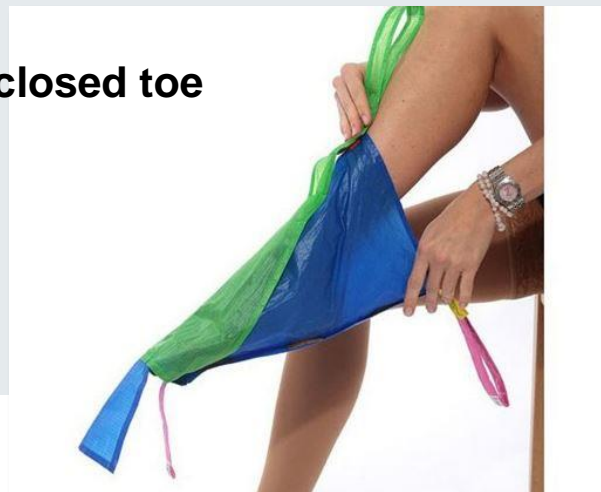


# Donning devices

Foot slips for stocking with open toe



Foot slips for stocking with closed toe



# Donning devices

Frames for stocking with open/ closed toe



## Donning success - overview

- Number of patients ( $n=40$ ) that (at least once) successfully donned either CS40 or CS20+20 stockings either without, or with at least one of the eight donning devices

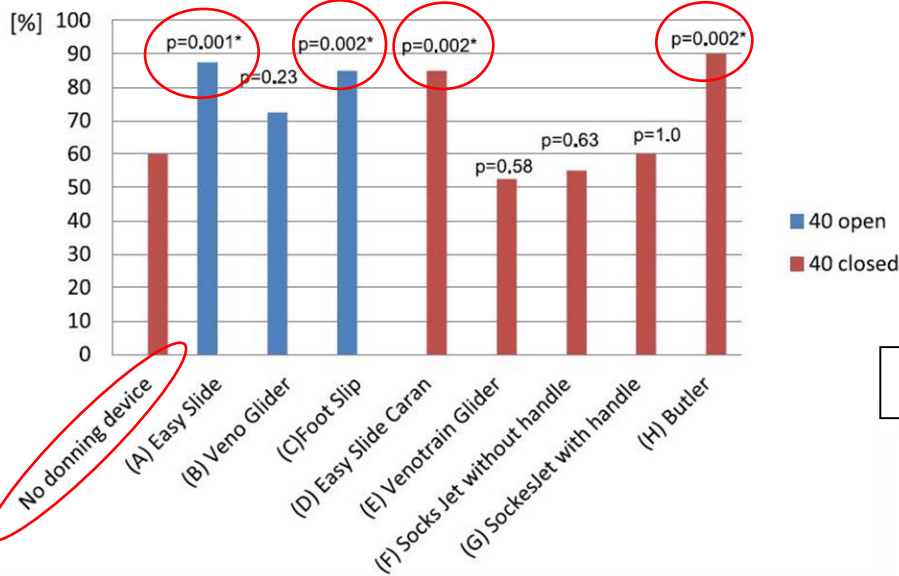
Only without device	0 [ 0 %]	Total without device	Total with device
Without device and with device	29 [73 %]		
Only with device	8 [20 %]		37 [93 %]
Neither with nor without device	3 [ 8 %]		

**$P = .008$**   
***McNemar test***

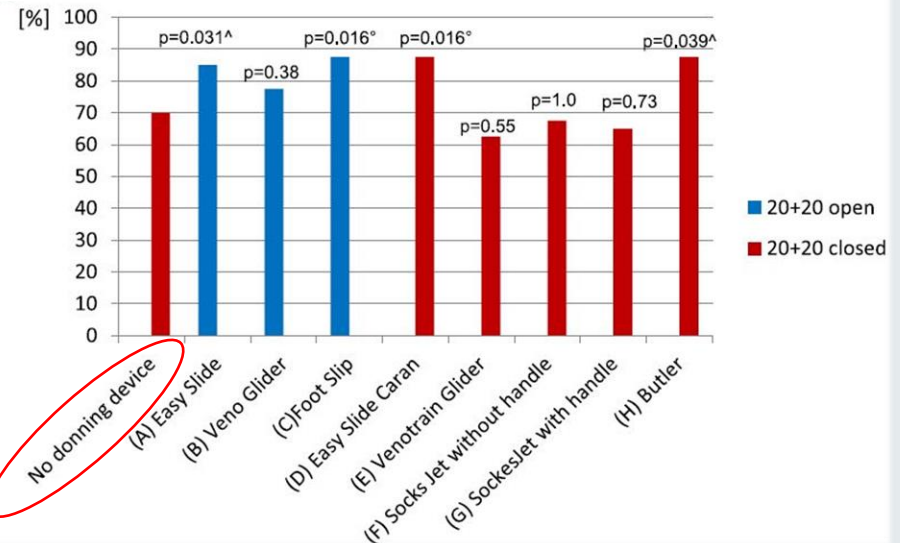
Sippel K. Eur J Vasc Endovasc Surg. 2015 Feb;49(2):221-9

# Donning success - by compression stocking groups

## CS40 group



## CS20+20 group



K. Sippel et al. Eur J Endovasc Surg(2015)49,221-229

# Donning success – subjective patient evaluation

- **Both groups, CS40 and CS20+20, showed significantly better average gradings for donning with devices**
- Both groups rated the same devices as favorable
- **Overall tendency to favorite devices**
- **Individual patient evaluation varied greatly**





# Donning success – Influence of patient-related parameters on donning success rate

	Parameters (occurrence within patient group [n = 40]), n (%)	Association with donning success CS40 or CS20+20	
		Without donning device <i>p</i>	With donning device <i>p</i>
Sex, female			
Female	23 (57)	.590 <sup>a</sup>	.840 <sup>a</sup>
Male	17 (42)		
First time user			
Yes	13 (32)	.042 <sup>a,b</sup>	.550 <sup>a</sup>
No	27 (67)		
Able to access fore foot with the hand?			
Yes	35 (87)	.001 <sup>a,e</sup>	.001 <sup>a,e</sup>
No	5 (12)		
Age (y)			
Range	66–92	.180 <sup>c</sup>	.280 <sup>c</sup>
Mean ± SD	79 ± 6.39		
Median	78		
BMI (%)			
Mean ± SD	26.8 ± 4.3	.930 <sup>c,d</sup>	.740 <sup>c,d</sup>
≥25	63		
25–29	43		
≥30	20		
Abdominal circumference (cm)			
Range	88.0–133.0	.140 <sup>c</sup>	.120 <sup>c</sup>
Mean ± SD	104.7 ± 11.6		
Grip strength, measured by vigorimetry (bar)			
Female + male mean ± SD	0.54 ± 0.17	.003 <sup>c,e</sup>	.063 <sup>c</sup>
Female mean ± SD	0.44 ± 0.12	.036 <sup>c</sup>	.120 <sup>c</sup>
Male mean ± SD	0.66 ± 0.15	.022 <sup>c</sup>	.026 <sup>c</sup>

Note. Donning success rate is defined here as the total number of successfully donned C40 or CS20+20 stockings per patient after completion of all scheduled donning processes according to the protocol.

Sippel K. Eur J Vasc Endovasc Surg. 2015 Feb;49(2):221-9

Eur J Vasc Endovasc Surg (2016) 51, 434–440

## A Compression Kit of a Stocking and Three Superimposed Leggings Is Easy to Don and Dose Adjustable

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### Objective:

- To develop a compression stocking kit (composed of an understocking and superimposable leggings) that is easy to don and dose-adjustable

# Prestudy: Compression Systems Examined

## ➤ **UlcerTec®**

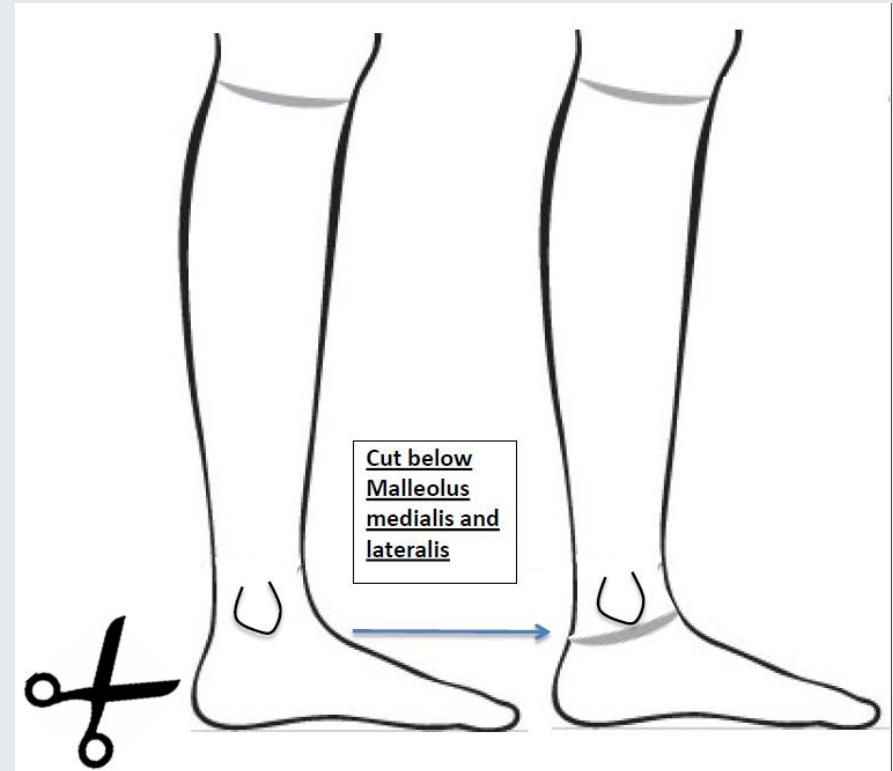
understocking 10 mmHg +  
upperstocking 30 mmHg

## ➤ **Ulcer X®**

understocking 13 - 21 mmHg +  
upperstocking 23-32 mmHg

## ➤ **Venosan 8000 Ulcerfit®**

understocking 10 mmHg +  
upperstocking 30 mmHg



Luder C. EJVS 2016 Mar;51(3):434-40.



# STOCKNLEGGINGS - Study

Understocking (17 mmHg at cB)

1<sup>st</sup> Legging (15 mmHg at cB)

2<sup>nd</sup> + 3<sup>rd</sup> Legging (10 mmHg at cB)



Luder C. EJVS 2016 Mar;51(3):434-40.

## Parameters examined

- Donning success (X successful / n participants)
- Subjective evaluation of donning success by the participants
- Static substocking pressure at level cB1 with the Picopress® device
- Dynamic Stiffness Index (DSI) at level cB1

## Participants

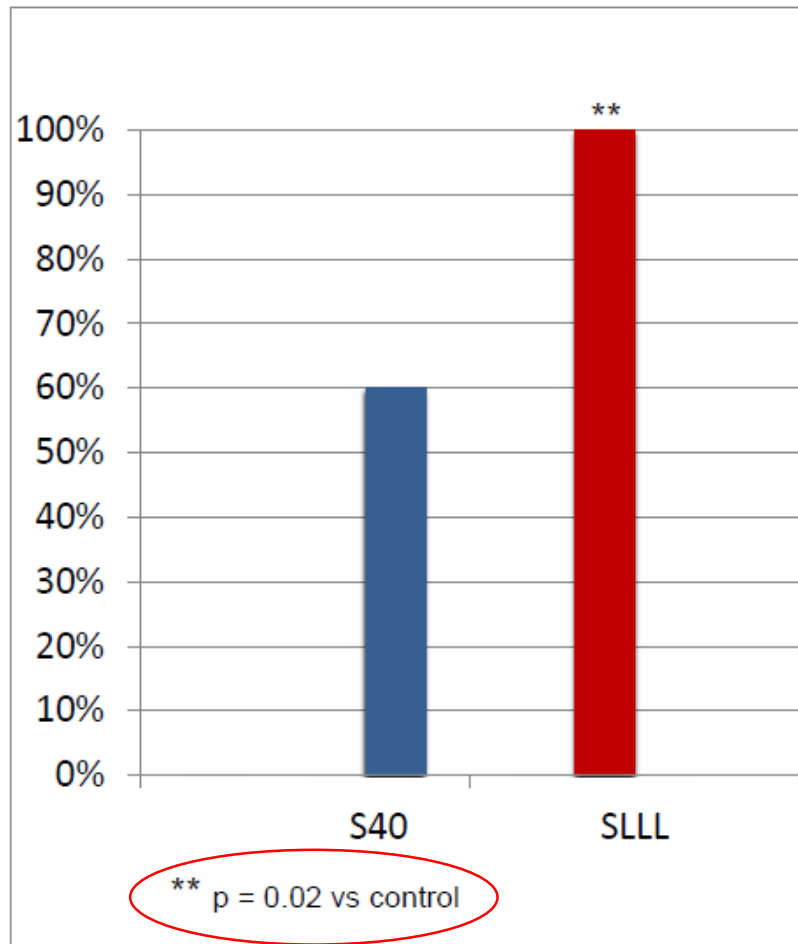
- 20 healthy volunteers
- 20 patients, > 65y old, with advanced CVI (C4-C5)

# Study stockings - Comperator

- “**strong**” compression - one stocking:
    - MEDILEG SA Varisan Top Micro A-D; CEN class III (34-46 mmHg); closed toe
- = S40



# Donning success in patients with CVI



**Stocking and Leggings:**

**Easier to don than a strong compression stocking**



Zürich

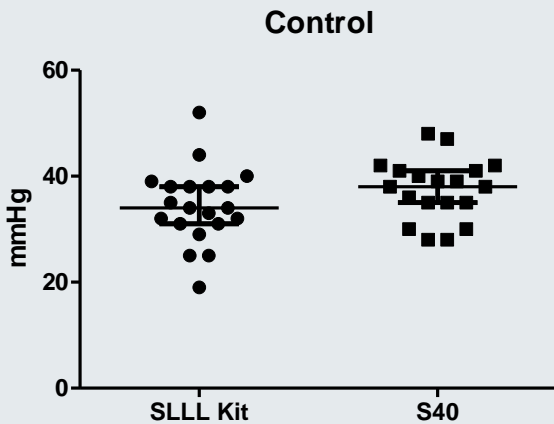
Luder C. EJVS 2016 Mar;51(3):434-40.



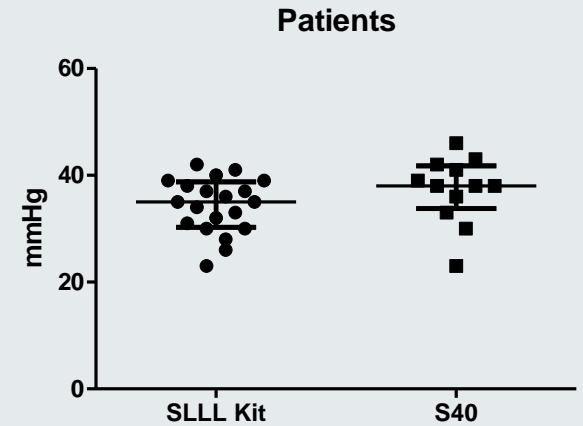
Universität  
Zürich<sup>UZH</sup>

# Static pressure values –

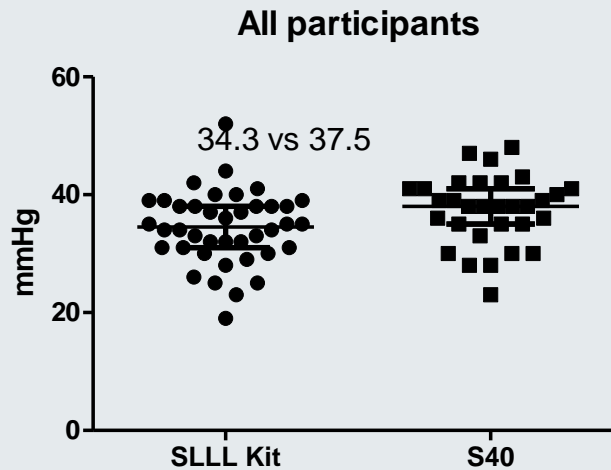
## Substocking Interface pressure (P) Level B1 at rest



34.3 (range 19-52) vs 37.5 (28-48)



34.3 (range 28-42) vs 37.3 (23-43)



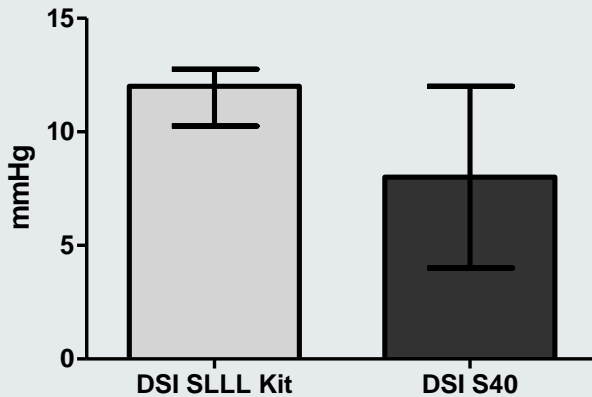
Static substocking pressures are comparable with strong stocking (40 mmHg level cB)

Minimum	19.00	23.00
25% Percentile	31.00	35.00
<b>Median</b>	<b>34.50</b>	<b>38.00</b>
75% Percentile	38.00	41.00
Maximum	52.00	48.00

Luder C. EJVS 2016 Mar;51(3):434-40.

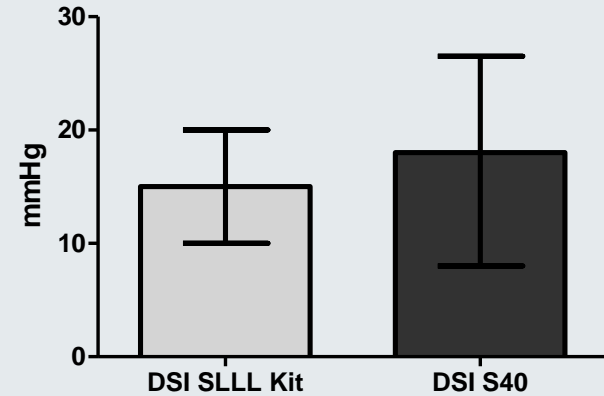
# Dynamic Stiffness Index

Control

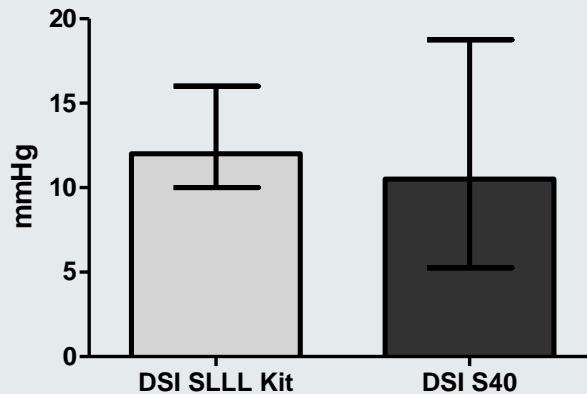


DSI 11.6 (range 8-17) vs. 9.5 (4-22)

Patients



DSI 16.1 (range 7-45) vs. 17.9 (range 3-34)



Minimum	7.000	0.0
25% Percentile	10.00	5.250
<b>Median</b>	<b>12.00</b>	<b>10.50</b>
75% Percentile	16.00	18.75
Maximum	45.00	34.00

# Conclusion

- **‘Donning devices’ – Sippel/ Hafner**
  - Means to facilitate donning will improve donnability in ‘real’ patients and consequently improve treatment adherence
  
- **‘STOCKNLEGGINGS’ – Luder/ Hafner**
  - Adapting traditional MCS design improves donnability whilst maintaining the physical properties (resting  $P$  and DSI)
  - The heel region is the main obstacle in donning strong compression stockings
  - Dose-adjustable MCS will improve comfort

# Ausblick ...





Herzlichen Dank für Ihre Aufmerksamkeit