

# Classification for elastic tubes, medical socks and soft bandaging?

Dr. Martin Abel

Head of Medical & Regulatory Affairs, Lohmann & Rauscher GmbH & Co KG

Copenhagen, 17.05.2013



#### Standard "Bandages" in UK and Consensus Paper

Group RAL-GZ	type BS 7505	level of compression	British standard (mmHg) (bandages)	German standard (mmHg) (stockings)	Consensus (Partsch et al 2008) (bandages)
KK 1	3A	light	up to 20	18,4 - 21,2	< 20 (light) 20-40 (moderate) 40-60 (strong) > 60 (extra-strong)
KK 2	3B	moderate	21-30	25,1 - 32.1	
KK 3	3C	high	31-40	36,4 - 46,5	
KK 4	3D	extra high	41-60	>59	

- British Standards Institute, Specification for the elastic properties of flat, non-adhesive, extensible fabric bandages. BS 7505;1995. London; British Standards Institute, 1995.
- Deutsches Institut für Gütesicherung und Kennzeichnung Medizinische Kompressionsstrümpfe (compression stockings) RAL-GZ 387, Berlin: Beuth-Verlag, 1987. (KK= class of compression)
- Partsch H et al. Classification of compression bandages: practical aspects. Derm Surg (2008)
   34: 600-609

# CEN (European Prestandard 2001)

Class	Pressure in mmHg	Level of Compression
Ccl A	10-14	Light
I	15-21	Mild
II	23-32	Moderate
III	34-46	Strong
IV	<u>≥</u> 49	Very strong



#### Clinical indications and compression

Clinical indication	Intended effect	Pressure required	
Oedema	Prevention (long sitting)	10-20 mmHg	
	Therapy	20-60 mmHg *	
Thromboprophylaxis	Acceleration of venous flow (lying position)	10-15 mm Hg	
Venous occlusion after	Occlusion of dissected branches,	Lower leg >70 mm Hg,	
surgery, endovenous	"empty vein"	Thigh 30-60 mmHg	
therapy	Standing:		
Chronic venous	Intermittent narrowing of veins	50-80 mmHg **	
insufficiency (refluxes)	during walking		

Partsch H. Physics of compression



#### Stage-orientated Compression Therapy – eg in Leg Ulcer

#### 18 (20) – 60 mmHg (or higher)



Bandages (Multilayer systems)
up to healing of ulcer
oedema reduction
"Therapy phase –
acute therapy"



**Stockings** 

after healing,
prevention of recurrence/relapse
"Maintanence Phase"



### Early prevention with TPS, Medical Socks and Elastic Tubes

14 – 18 mmHg

8 – 14 mmHg







**TPS Stockings** 

Elastic tubes

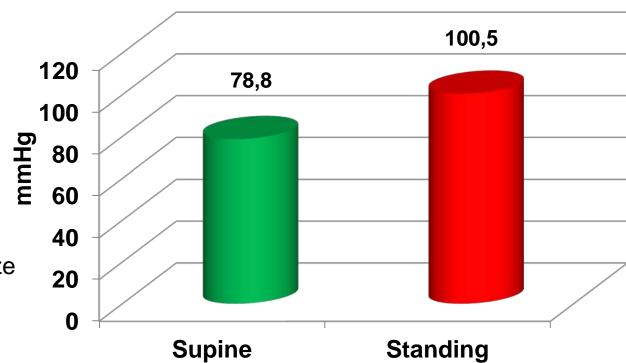
Support wear





#### Rosidal K (with tension)





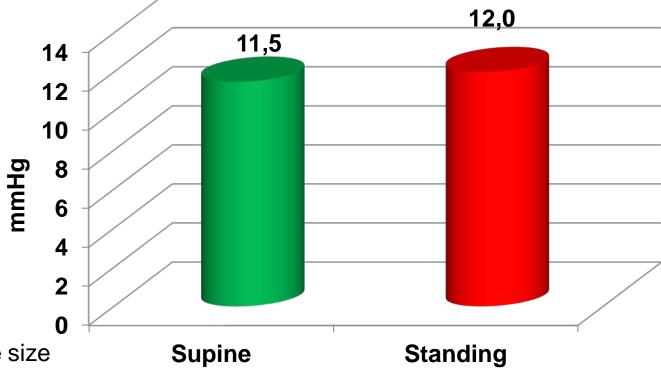
- n=4 (measurement)
- male volunteers
- 8 and 10cm bandage size
- without any padding
- bandaged direct on the healthy skin
- PicoPress, small probe
- B1 position
- circumference (calf): 40.6 cm
- circumference(ankle): 22,4 cm

Schrovenwever K, Griesshammer K, Abel M (2013)

#### Rosidal K (without tension)







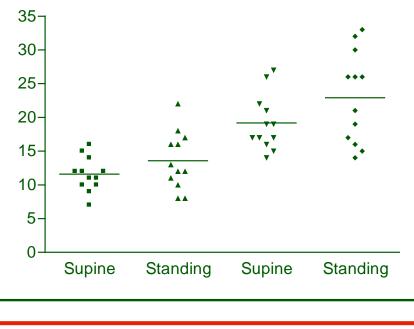
- n=4 (measurement)
- male volunteers
- 8 and 10cm bandage size
- without any padding
- bandaged direct on the healthy skin
- PicoPress, small probe
- B1 position
- circumference (calf): 40.6 cm
- circumference(ankle): 22,4 cm



#### Padding bandage – soft bandaging

### Rosidal soft (padding)





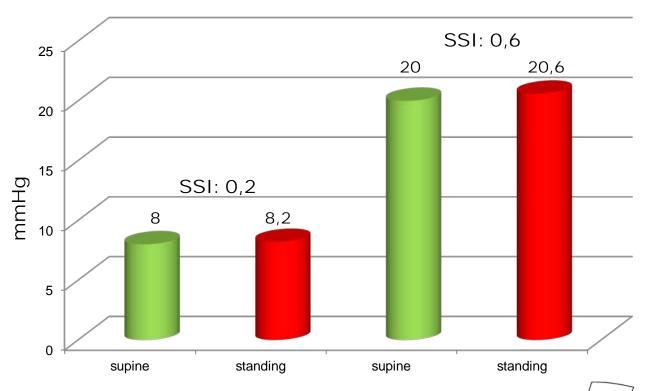
b1-Position, Kikuhime, small probe

(Partsch H. 2005)



#### Elastic Tube - tg grip





**Position B** 

n= 5 (measurements)

- PicoPress, small probe
- tg grip F (10 cm) for leg
- circumference position B (ankle): 22,9 cm
- circumference position C (calf): 40,4 cm
- application directly on the healthy skin

**Position C** 





#### Light compression increase the venous blood flow

In the supine position, light stockings with a pressure range on the distal leg of 10–20mmHg are able to narrow the veins and to increase venous blood flow velocity. This has been seen to be effective in preventing deep vein thrombosis in non-ambulatory patients.

Partsch H, Kahn P.

Venöse Strömungsbeschleunigung in Bein und Becken durch Anti-Thrombosestrümpfe.

Klinikarzt 1982;11:609–12

In:

Partsch H.

Do we still need compression bandages? Haemodynamic effects of compression stockings and bandages.

Phlebology 2006; 21: 132-138



#### Liberal selection of mild compression material

Partsch H, Winiger J, Lun B.

Compression stockings reduce occupational leg swelling.

Dermatol Surg. 2004 May;30(5):737-43; discussion 743.

In 12 volunteers, the volume of both lower legs was measured in the morning and 7 h later, the difference being defined as evening edema (mL).

RESULTS: The average evening edema of the noncompressed legs was 62.4 mL on the left side and 94.4 mL on the right side (n.s.). Evening edema was significantly reduced to 40.3 mL by light support stockings, to -34.1 mL by compression class A, to -39.6 by compression class I, and to -59.1 mL by compression class II. Mainly stockings exerting a pressure above 10 mmHg improved subjective symptoms.

#### **CONCLUSION:**

Calf-length compression stockings with a pressure range between 11 and 21 mmHg are able to reduce or totally prevent evening edema and may therefore be recommended for people with a profession connected with long periods of sitting or standing.



#### New classification (proposal)

Class	Pressure	Level of	
 Range	(in mmHg)	Compression	
I	< 14	Extra mild	
(eg 5 or 8 - 14)			
П	14 - 20	Mild	
IV	21 - 30	Moderate	
V	31 - 40	Strong	
VI > 40		Very strong	



- Improve the compliance of the patient
  - Liberal selection of compression material
  - Depending of the indication (patient or healthy volunteer)
- Increase the early prevention with low pressure compression devices like TPS, Medical Socks, Elastic Tubes, Soft Bandaging
  - Increase of the compliance for compression (and their tolerance/adaption), especially if the disease deteriorate over time
- Integrate the low pressure devices in the compression classification system
  - prove their clinical effects in patients and on compliance / quality of life

- start early with an adequate compression level
- adapted on the daily life and individual situation of the human beings
- improve the tolerance/adaption of the patient for compression

## Extra mild compression

- better than no compression -



#### Thank you for your attention!







#### What are compression leveles?

Daylong Classification	Daylong mmHg Range	EU/ RAL Standard	EU/ RAL mmHg Range	UK Standard	UK mmHg Range	US Standard	US mmHg Range
EXTRA LIGHT UP TO 14 MMHG	< 14 mmHg	-	-	-	-	-	-
LIGHT 14-17 MMHG	14 - 17 mmHg	-	-	UK Class 1	14 - 17 mmHg	-	-
MODERATE 18 - 24 MMHG	18 - 24 mmHg	EU Class 1	18 - 21 mmHg	UK Class 2	18 - 24 mmHg	US Class 1	15 - 20 mmHg
FIRM 25-35 MMHG	25 - 35 mmHg	EU Class 2	23 - 32 mmHg	UK Class 3	25 - 35 mmHg	US Class 2	20 - 30 mmHg
EXTRA FIRM OVER 35 MMHG	Over 35 mmHg	EU Class 3	34 - 46 mmHg	-	-	US Class 3	30 - 40 mmHg

http://www.daylong.co.uk/compression/compression-definition.html



#### Liberal selection of mild compression material

J Vasc Surg. 2013 Feb 12.

Compression stockings significantly improve hemodynamic performance in <u>post-thrombotic syndrome</u> irrespective of class or length.

Lattimer CR, Azzam M, Kalodiki E, Makris GC, Geroulakos G.

#### **Tested**

class 1 (18-21 mm Hg) and class II (23-32 mm Hg), below-knee (BK) and above-knee thigh-length (AK).

#### **Conclusion:**

Compression significantly improved all hemodynamic parameters on air plethysmography. However, the hemodynamic benefit did not significantly change with the class or length of stocking.

These results support the <u>liberal</u> selection of a Graduated Elastic Compression (GEC) stocking based on patient preference.



#### Liberal selection of mild compression material – long term

Phlebology. 2013 Apr 5

Efficacy and comfort of medical compression stockings with low and moderate pressure six weeks after vein surgery.

Reich-Schupke S, Feldhaus F, Altmeyer P, Mumme A, Stücker M.

Female patients undergoing <u>vein surgery</u> were randomized for a compression therapy with low (18-21 mmHg, group A) or moderate (23-32 mmHg, group B) pressure MCSs. Follow-up was done by a phlebological experienced, blinded physician (pressure control, clinical aspect, duplex scan, and questionnaire) one and six weeks after surgery.

#### **CONCLUSION:**

Compression stockings with a pressure of 23-32 mmHg facilitate a <u>faster</u> resolution of clinical and ultrasound verified edema and the subjective feelings of pain, tightness, and discomfort of the leg in the early period after surgery <u>but have no difference in the longer post-surgical period compared to stockings with a pressure of 18-21 mmHg.</u>



Eur J Vasc Endovasc Surg. 2011 Aug;42(2):261-6.

Compression stockings with a negative pressure gradient have a more pronounced effect on venous pumping function than graduated elastic compression stockings.

Mosti G, Partsch H.

30 patients with **severe superficial chronic venous insufficiency** were enrolled. Two elastic stocking designs exerting a **pressure at ankle between 15 and 25 mmHg** were compared; a conventional GECS and a stocking exerting a higher pressure over the calf than over the ankle producing a "progressive" increase in compression (PECS).

In our present study, it was shown that **the significantly higher pressures over the calf achieved by the PECS (29 mmHg in supine, 33.5 mmHg during walking)** are significantly more effective than lower pressures in improving a disturbed venous pumping function. Despite this significant improvement, PECS are not able to restore a normal EF from the lower leg as it happens using inelastic bandages exerting comparable resting pressures.

The significantly improved efficacy of PECS stockings on the venous calf pump may not be extrapolated to other effects of such stockings like thromboprophylaxis, chronic oedema or lymphoedema reduction and deep venous damage following DVT.