

Film Compression Bandage

A new modality to improve Sclerotherapy of Superficial Varicosities.

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Disclosures

- inventor of film compression bandage
 - patents WO2015124669A1, EP20140155794
 - investigational use
 - no financial support for study or presentation
-

Polymer Film Compression Bandage



- stretchable, elastic, very thin ($< 20 \mu$)
 - transparent ("invisible")
 - breathable/vapor permeable by micropores
 - self-adhesive (hypoallergenic glue)
-

The disease begins long before reflux or symptoms



symptoms: 0 – 10

10 – 20

> 20

> 30 yr.

diagnostics

severity

Future of Venous Insufficiency

Maybe, in 30 years venous insufficiency can be prevented?

- compression stockings
- vein stripping
- phlebectomy

- endovenous treatment
- varices: sclerofoam + film
- stockings: prevention



100 years



30 years

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Rethink Compression

Purpose of compression after endovenous treatments

- prevention of edema, thrombosis: few cases
 - limitation of bleedings: < 2 h (pad, bandage)
 - **regression of treated veins**
 - **focus on (large) superficial varices**
-

Standards in Phlebology

Collection: Phlebectomy and foam sclerotherapy from physician's website advertisements, meant to impress positively! (But: Residuals, stainings, scars)



Aims

for superficial varicosities

- one-step solution
- immediate effect
- fast, reasonable
- method to replace surgery



Aims

More than 15 Mio. cases per year to treat*!

- optimized sclerofoam
- film compression bandage
- stockings: optional
- **no anesthesia, no wounds, no nerve lesions, no scars**



* estimation world-wide for European standard populations

Aims

To improve compression after foam sclerotherapy:

1) effectivity (no more bulging)

2) continuity

3) comfort

→ clinical success



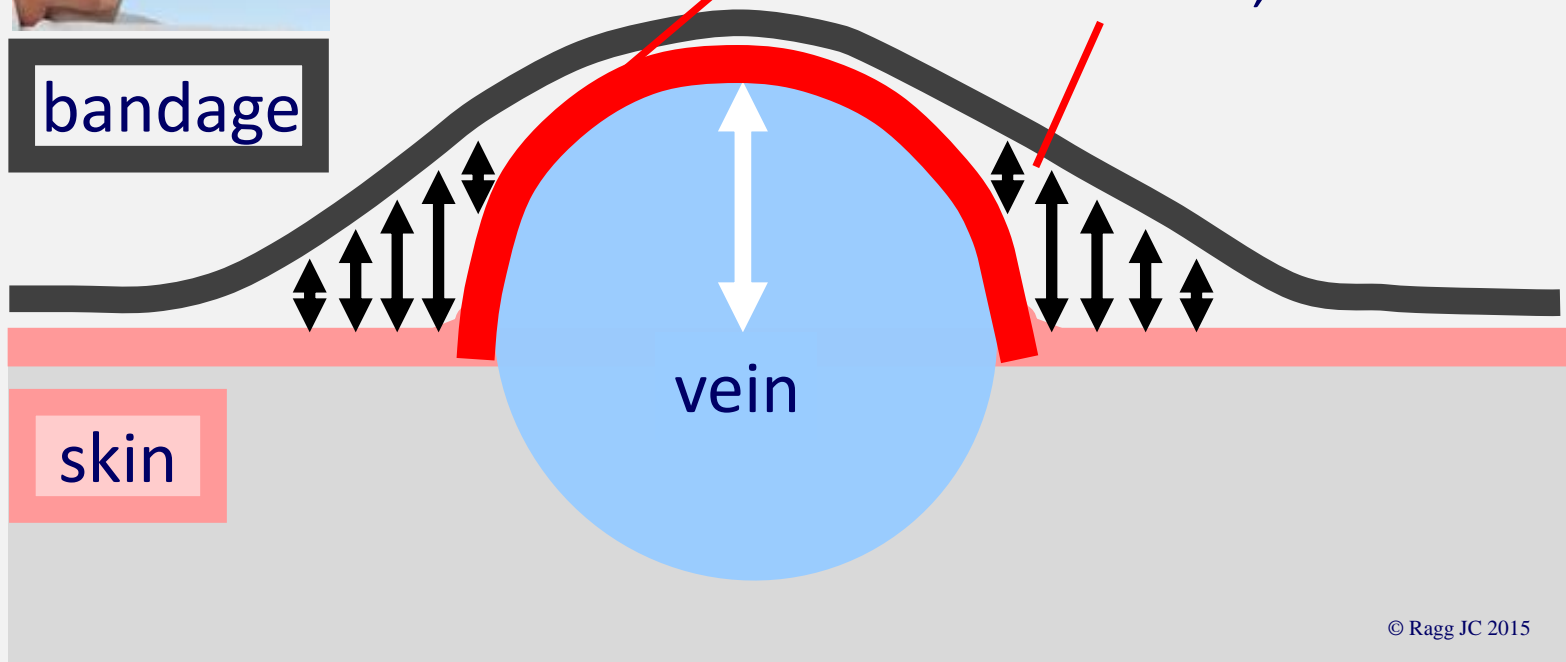
closure & absence of symptoms

How does it work?



bandage

protruding vein:
maximum contact of vein
and skin
textile media:
no adhesion, weak fixation

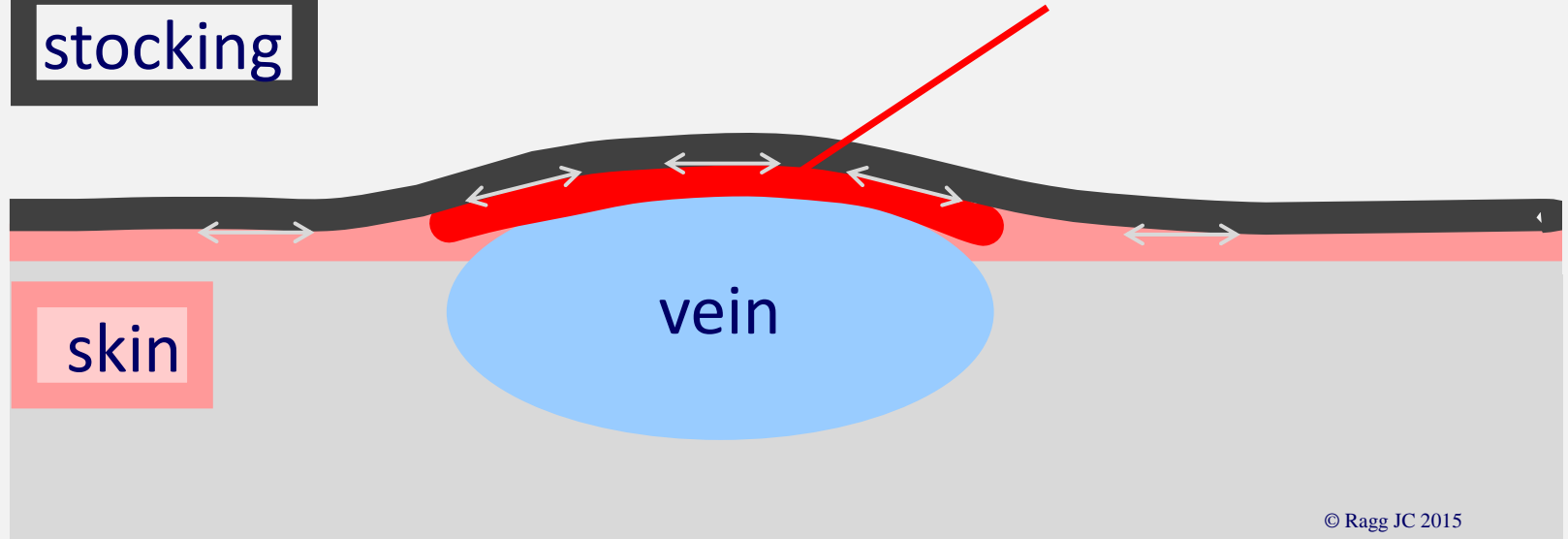


Textile Compression

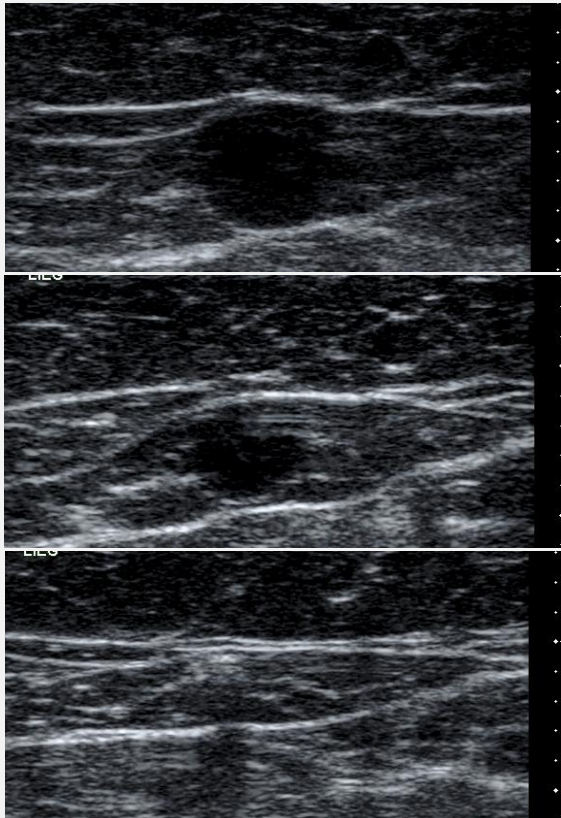


stocking

- no continuous use
- medium will slide on skin
- vein will partially protrude again
- still considerable contact zone



Vein Lumen pre and post Sclerofoam



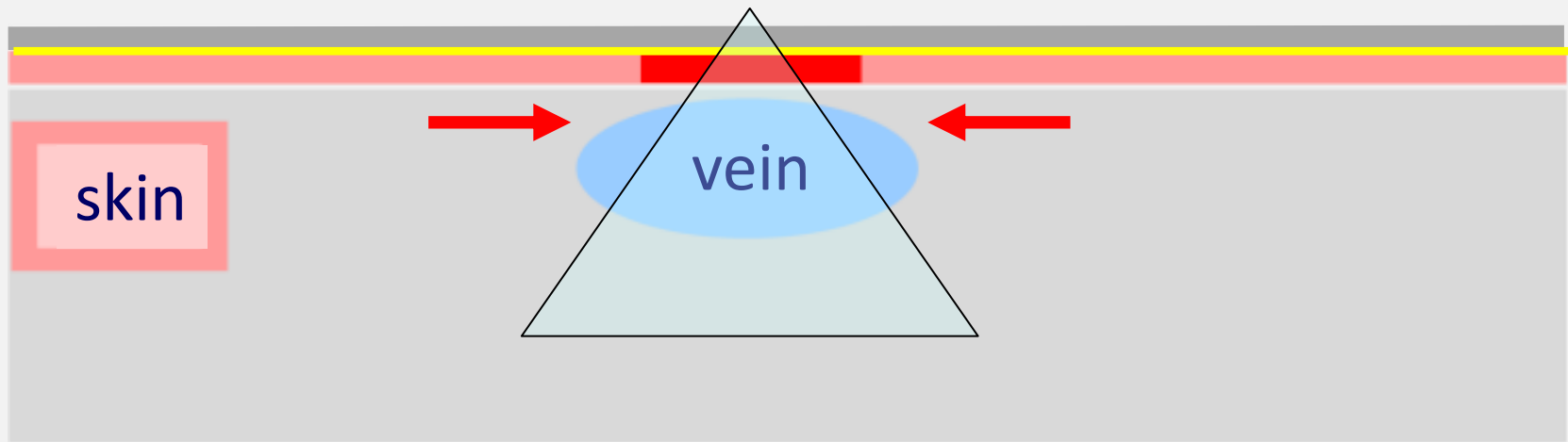
GSV, patient standing

GSV, horizontal position

GSV 2 min. post sclerofoam

1. Effectivity: Synergy of Film, Glue and Skin

Unit of film and skin: When the vein tries to regain its previous size, it is limited by the elasticity of the film AND the elasticity of the skin, local AND whole circumference (“triangle of constriction”)!



Compression Film Bandage

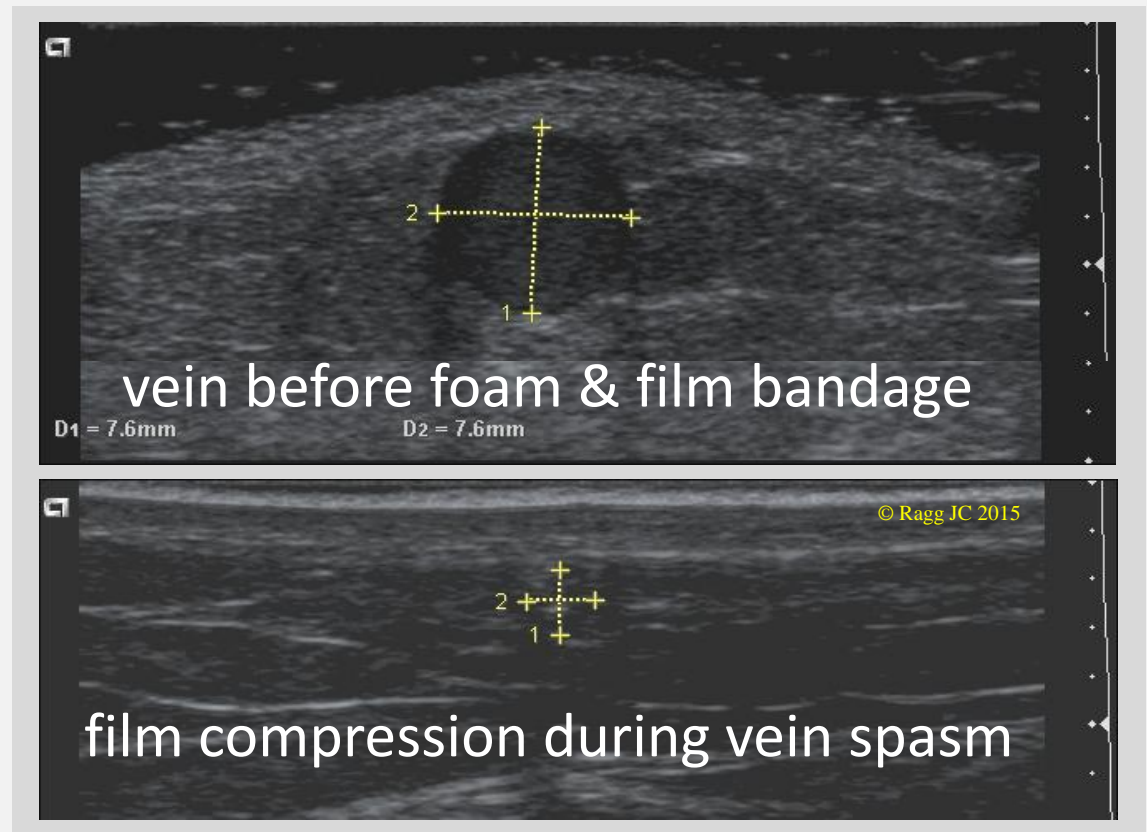
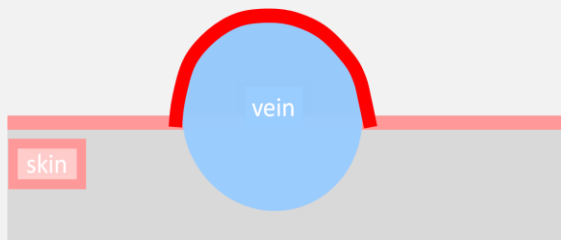


film

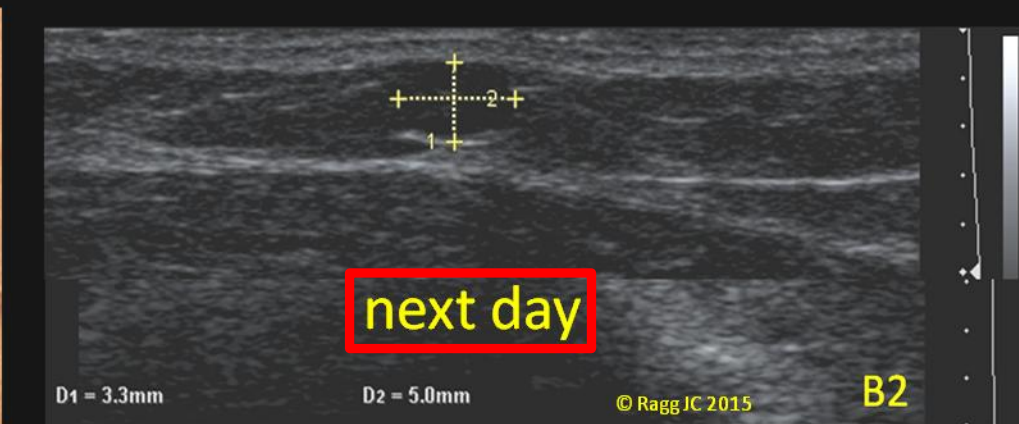
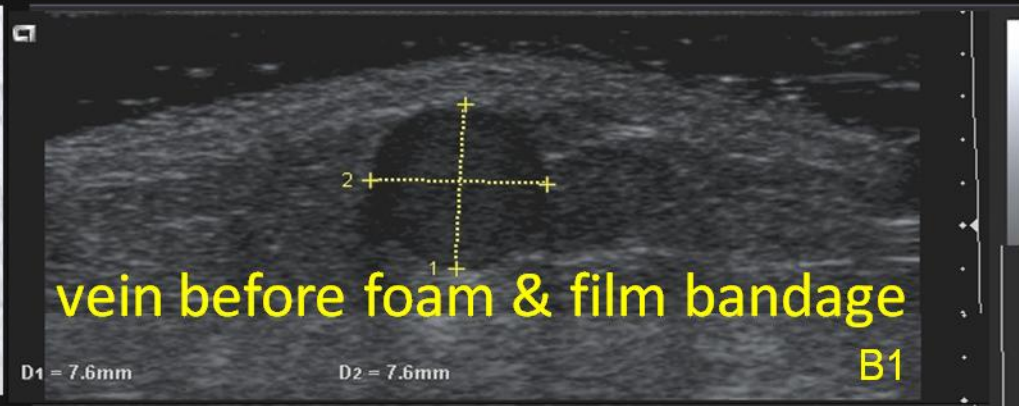
- functional unit of film and skin
- vein expansion space is reduced
- contact zone to skin is reduced
- less blood to resorb
- less inflammation
- less staining



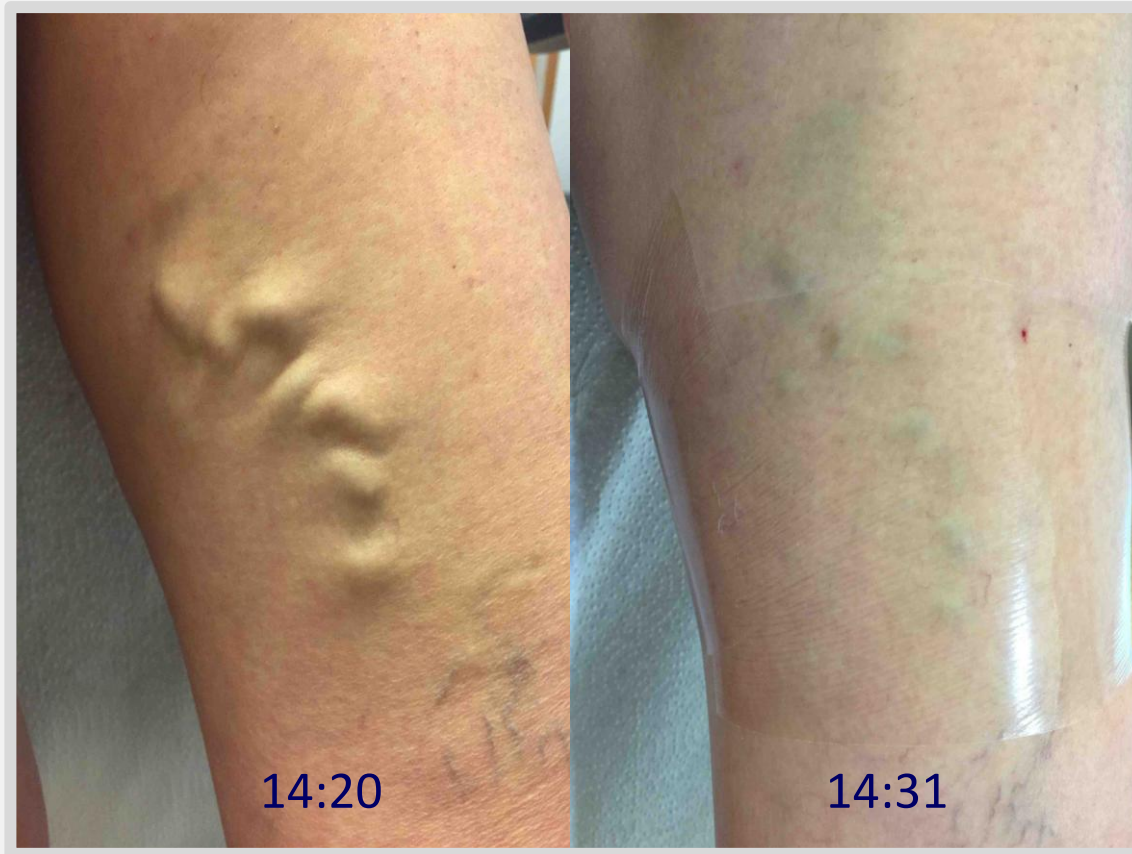
Minimize Vein Diameter, get it Fixed!



... achieved by adhesive film!



1. Effectivity (no more bulging veins)



Best effect:

- bulging varice (space limitation)
- small radius (pressure)

Effectivity (no more bulging veins)



53 yr. old female, varice known for 30 years. Pre and two days after foam sclerotherapy and film compression bandage (+ MCS)

Effectivity (no more bulging veins)



25 y/o female football amateur, CFB, no MCS

Effectivity in spite of Low Concentric Pressure



12 – 15 (- 23) mmHg
10 – 15 – 30% elongation

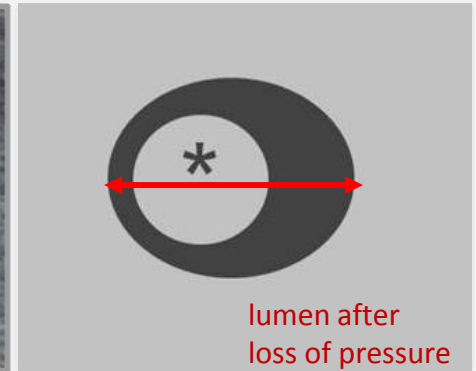
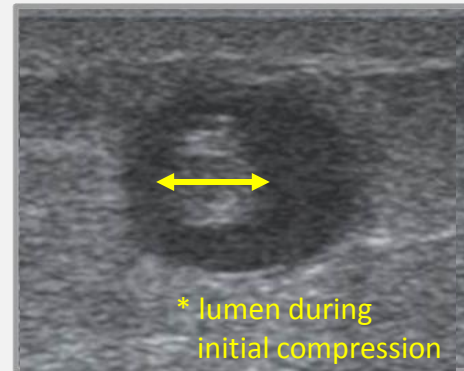


2. Benefit of Continuous Compression

common media:

- pressure discontinued
- veins refill
- more thrombus to resorb
- more inflammation

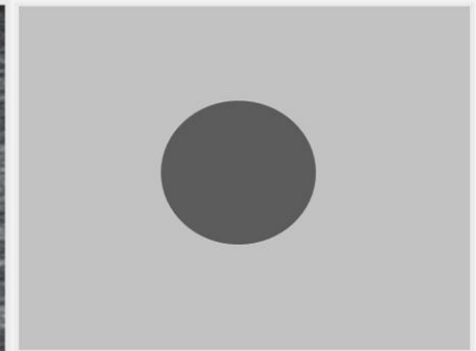
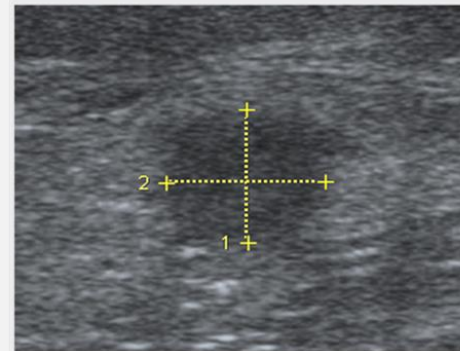
A



aim:

- continuous pressure
- vein size remains small
- less inflammation
- less stainings

B



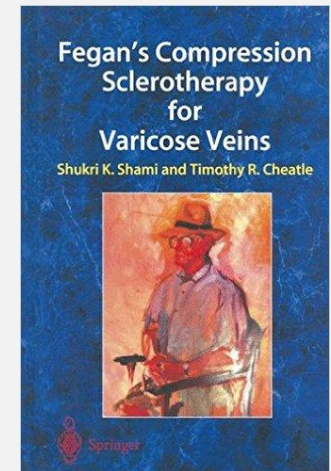
Continuous and effective compression...

... has been a demand since the very early days of sclerotherapy, but difficult to practice.

(FEGAN, Lancet **1963**;2:109)

Current compression techniques
(e.g. medical CS for 2 – 6 weeks day over)

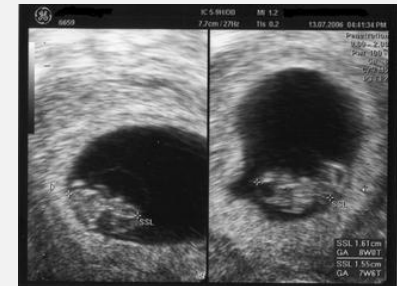
- symptomatic inflammations
- local discomfort
- nasty stainings in 20 – 60% of the cases
in particular in superficial varices
incidence increases with vein size.



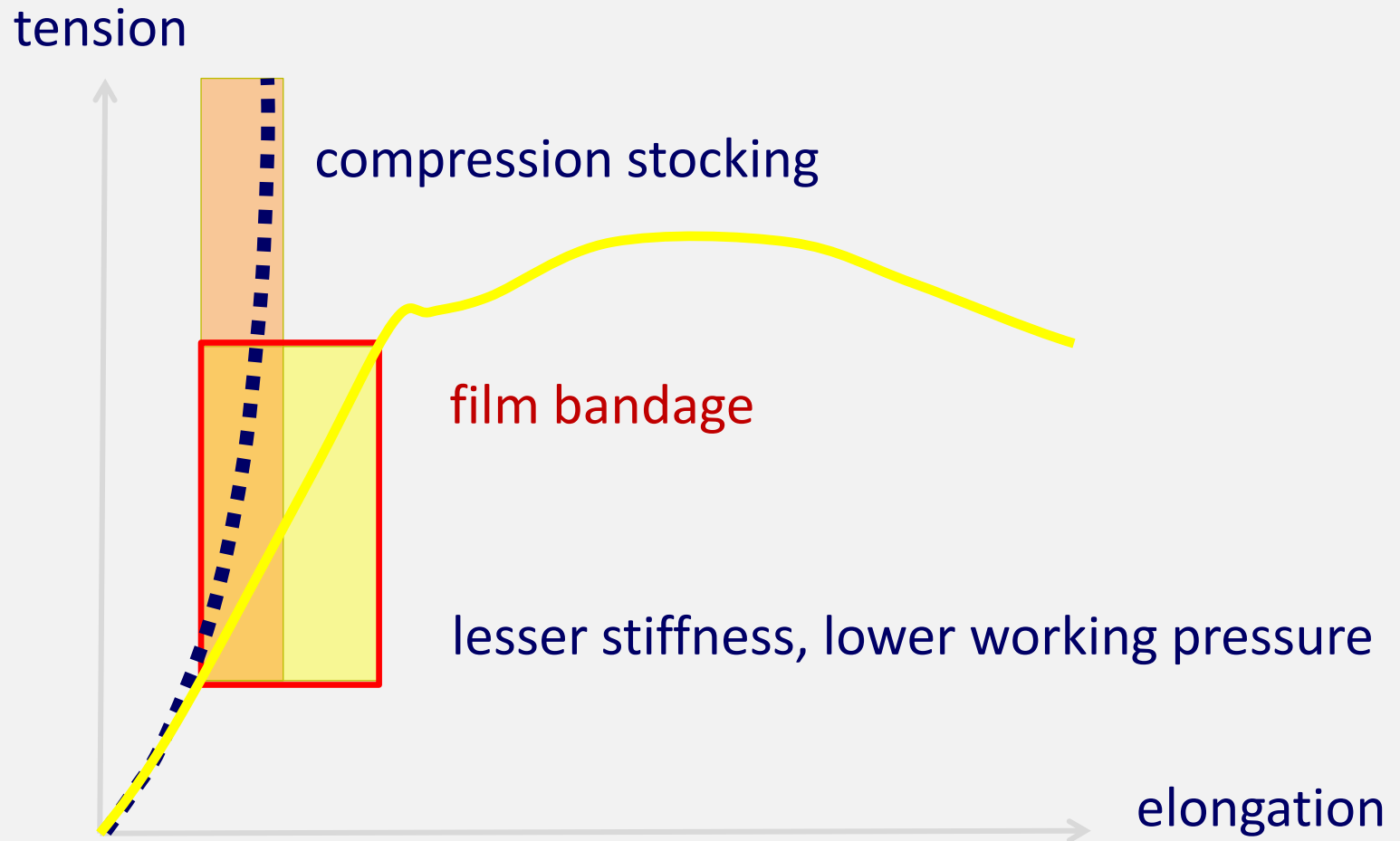
3. Comfort of Compression

Best: Compression by water!

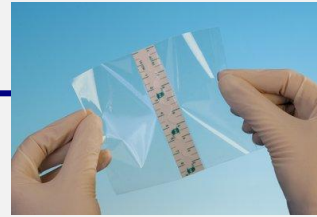
- very smooth pressure gradient
- no “stiffness”
- may be partially imitated by compression film



Physical Issues



Film Patch



aids for cover removal

Tegaderm® Roll
OpSite®

There may be suitable films, known from transparent patches, but they are not applicable as a bandage



non-elastic support film
film layer
glue layer
glue cover

Film Compression Bandage



aids for cover removal

perforations

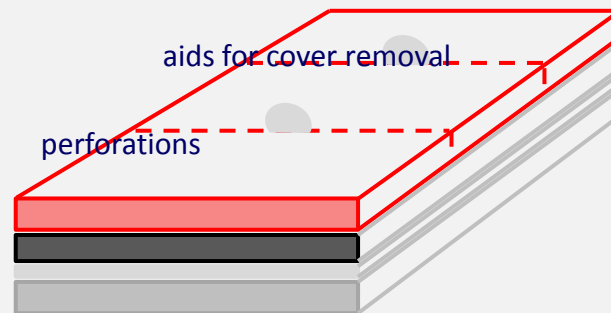
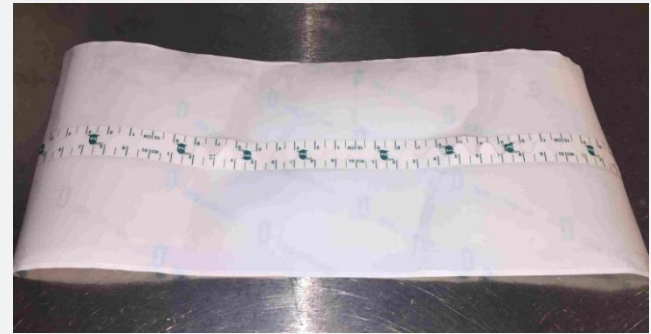
support film:
elastic and segmented
to allow pretension
film layer (polyurethane)
acrylic glue layer
glue cover



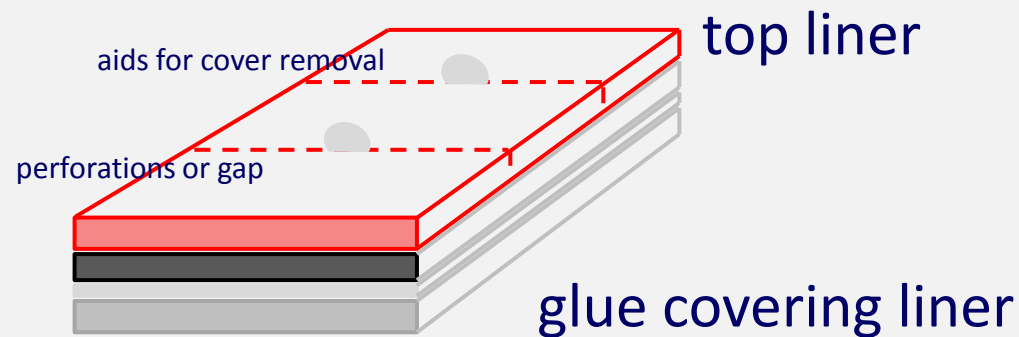
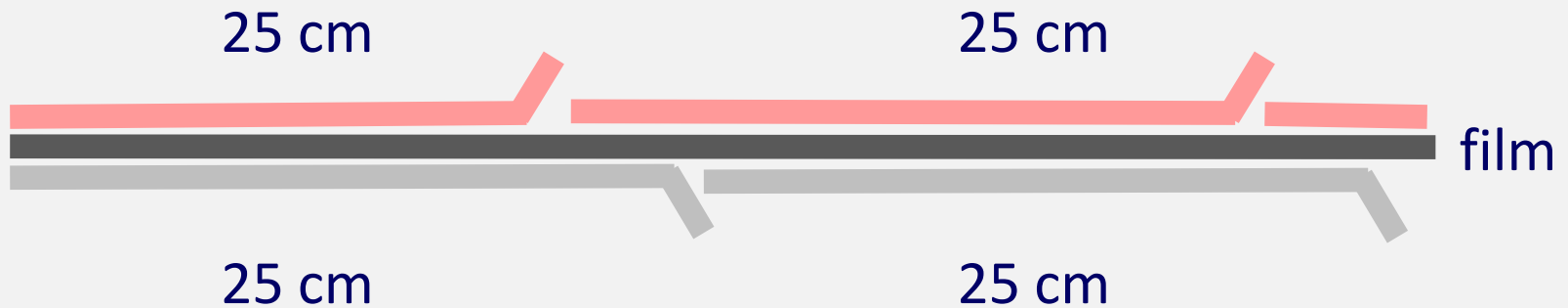
Film Compression Bandage

prototype manufacturing (120 x 2000 mm)

- removal of standard lower liner
- segmentation of lower liner
- overlapping repositioning of lower liner
- removal of upper liner
- segmentation of upper liner
- overlapping reposition of upper liner
- option: exchanging upper liner to a flexible film (coloured cling film)



Purpose: Longitudinal Removal of Liners



First Prospective Randomized Study (2014)*

Prototypes using approved film and glue (3M Inc.)
with modified supportive layers (Venartis Inc.)

- 82 patients (49 f, 33 m, 26 – 68 y.)
- 120 legs (shaved)
- superficial varicosities, 5 - 12 mm Ø (mean: 7.8)
- sports and showers ≥ 4 x per week
- foam sclerotherapy (Aethoxysklerol 1%, 1+4)

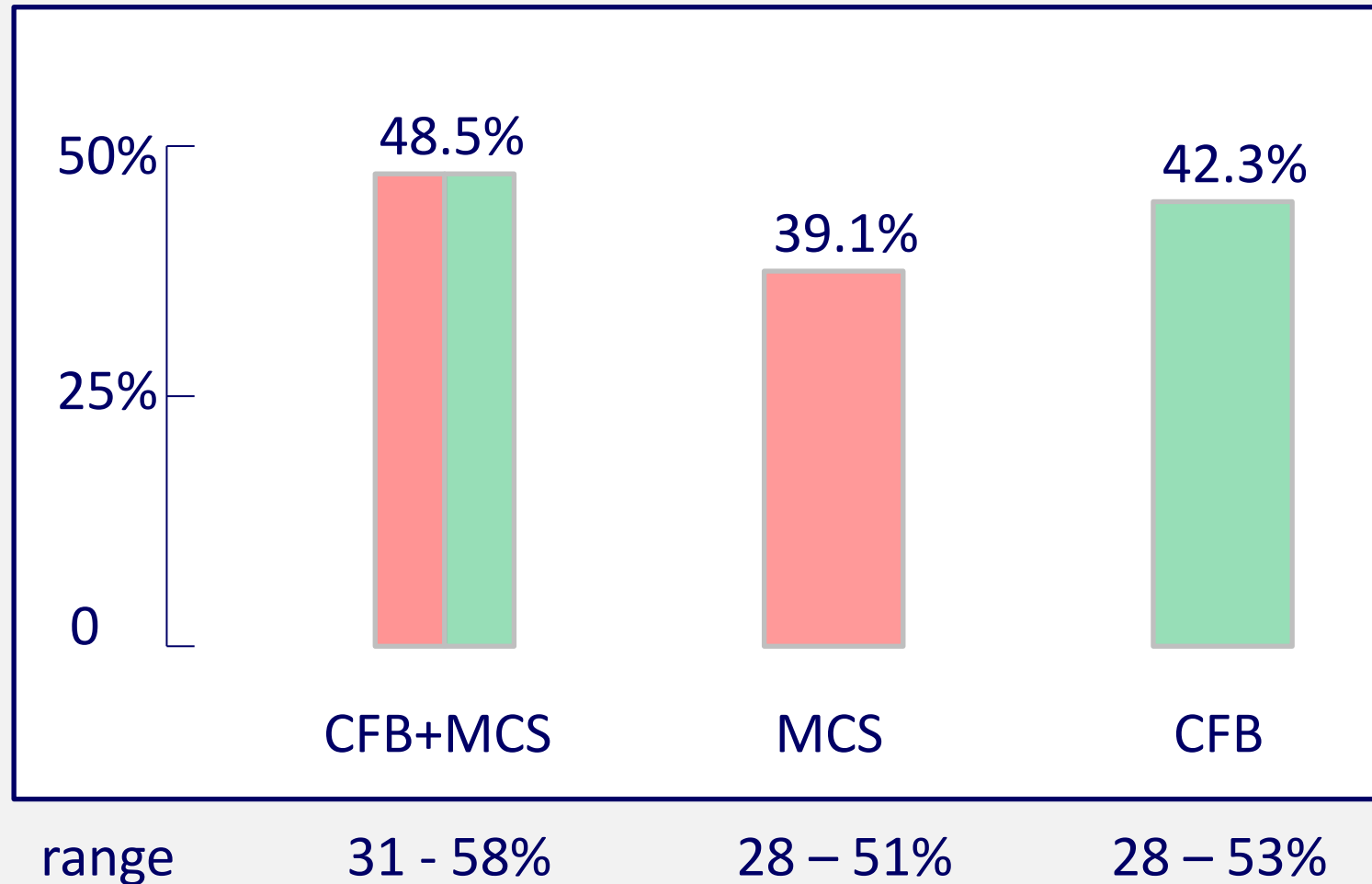
* Ragg, JC: Compression film bandage. A new modality providing continuous and sports-suitable vein compression after foam sclerotherapy. *Phlebologie* 2015; 44 (5), 225–292

Randomization and Wearing Time

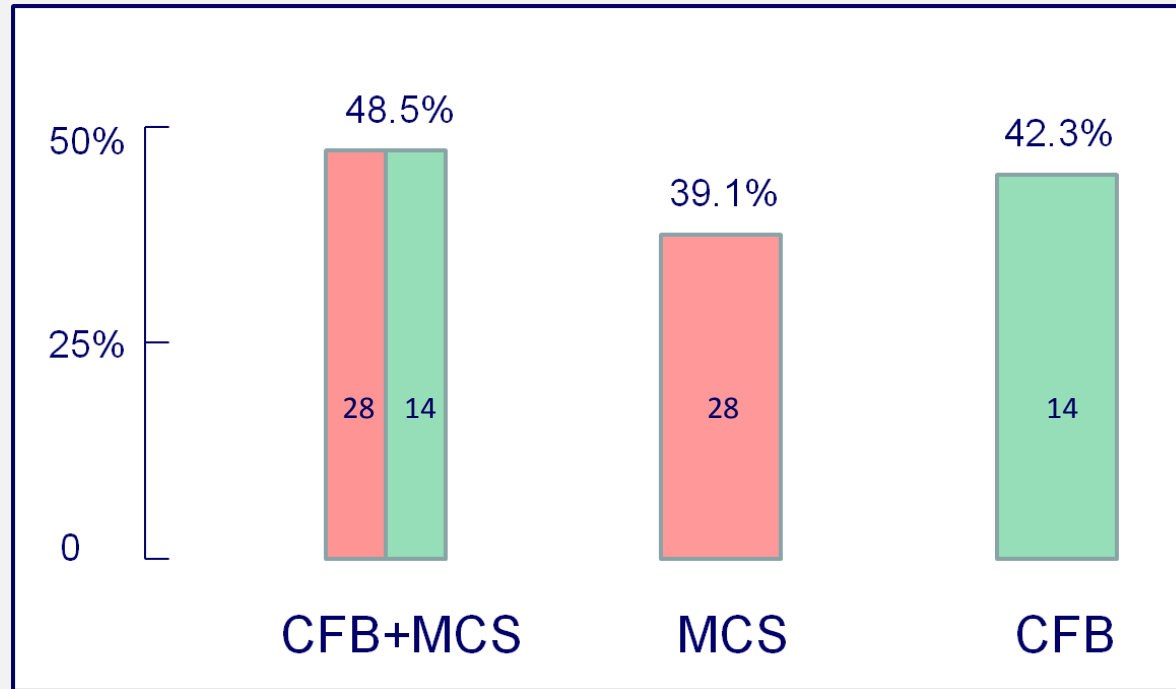
modality	wearing time (days)*	n
A) CFB + MCS	14 d CFB + 14 d MCS	40
B) MCS	28 d	40
C) CFB	14 d	40

* CFB limited to 14 due to prior microbiological testing. Bacterial growth reduced with film bandages compared to compression stockings; Ragg JC, Phlebologie 2014; 43; A

Mean Vein Diameter Reduction (week 4)

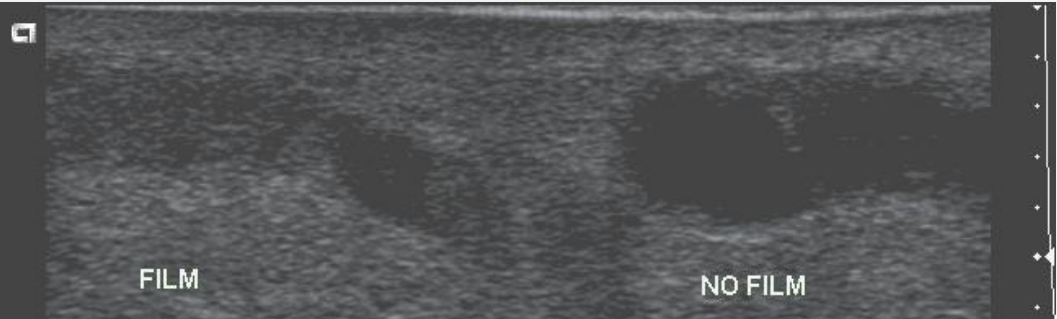


Mean Vein Diameter Reduction (week 4)

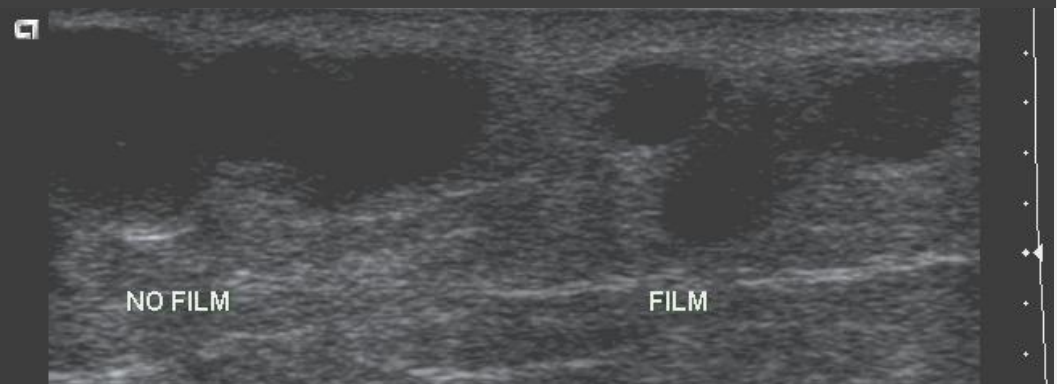


- Effect of CFB14 + MCS28: just slightly better than CFB14 alone.
 - Additional 14 d of MCS does not provide relevant improvement compared to CFB alone (but + 14 d CFB does!).
-

Diameter Reduction (week 2, MCS)



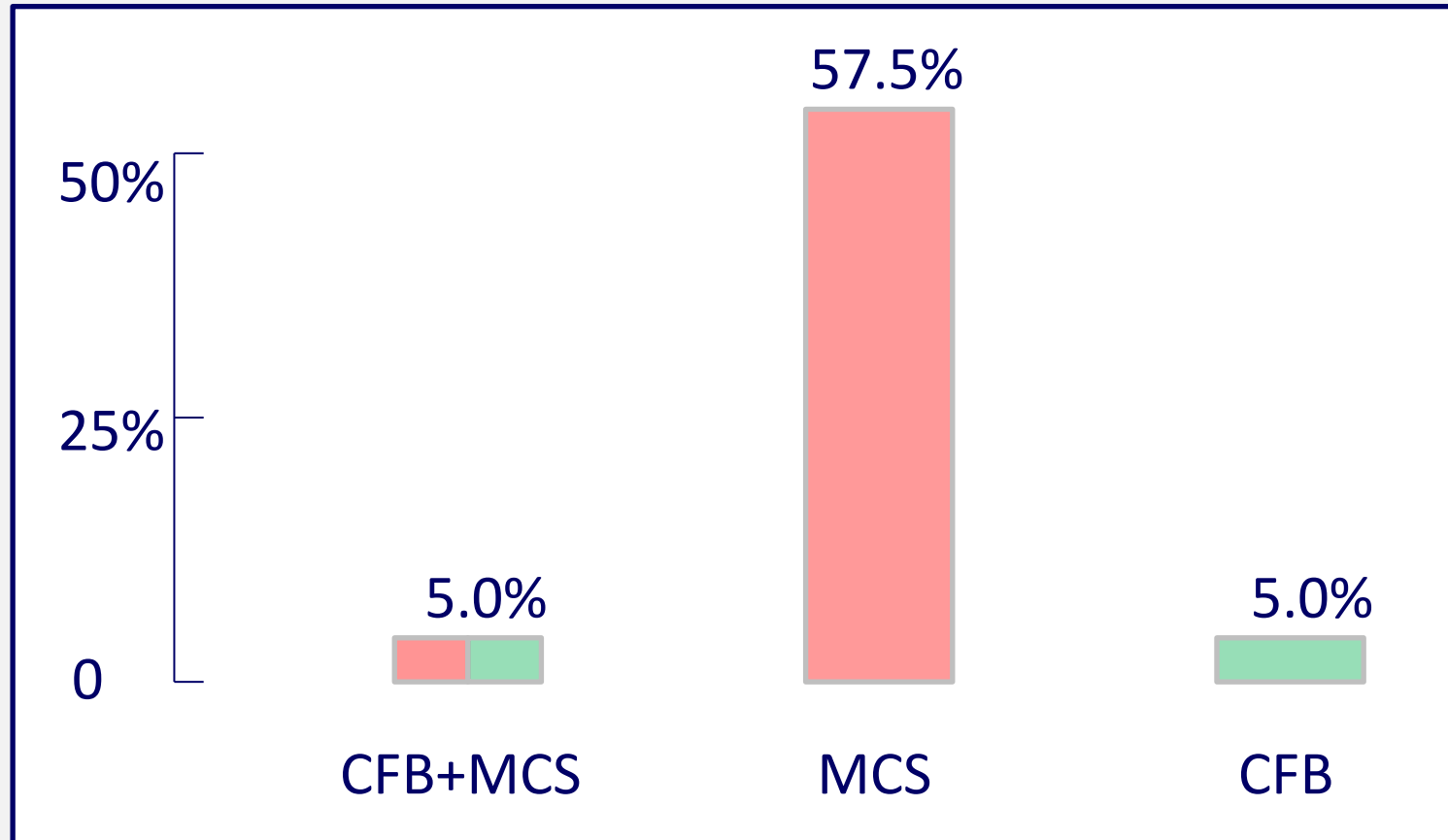
Although the mean diameter reduction was rather similar ($\pm 10\%$) with different compression media, it was significantly different in certain areas with and without film.



Diameter Reduction (week 2, MCS)

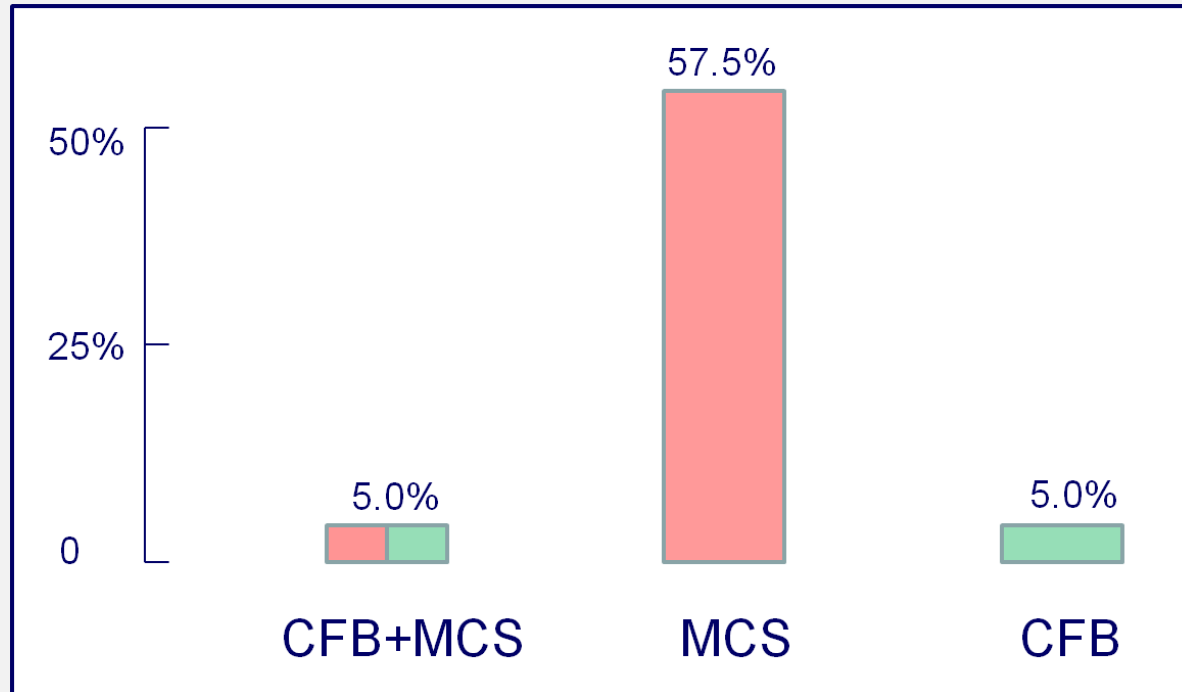


Symptomatic Inflammation (week 2)



pain, sensitive indurations or reddening along vein

Symptomatic Inflammation (week 2)



- CFB versus MCS: stat. highly significant
 - **no symptoms while CFB is on skin**
-

Example



43 y/o female
cleaning worker
sports: bicycling 1h/d

Early Experience – is phlebectomy redundant?



color markings left
for study purpose

Early Experience



No symptoms!

“no symptoms while CFB is on skin”



Case: male 56 y/o, table tennis amateur; CFB, no MCS;
No signs of inflammation in spite of large varicosities.

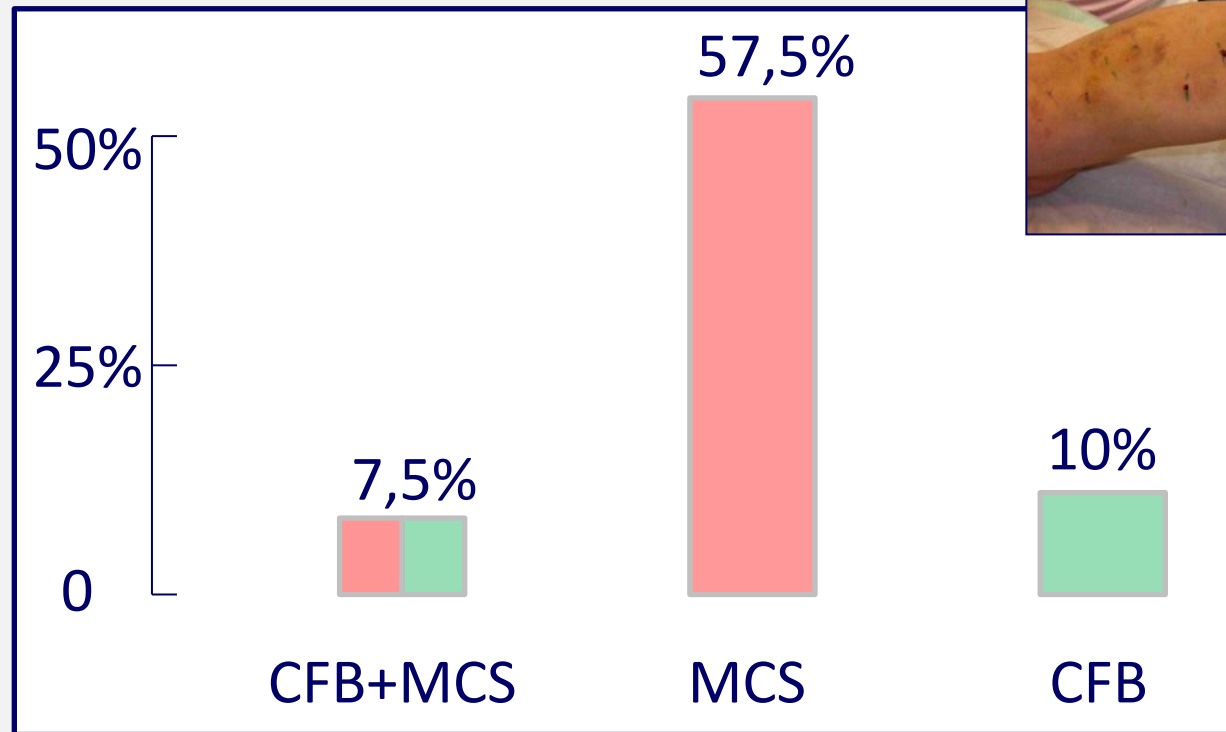
“no symptoms while CFB is on skin”



48 y/o male, mountain biker, large varicosities (6-18 mm)
due to LSV insufficiency. CFB + MCS.

Removal of Thrombus (until week 8)

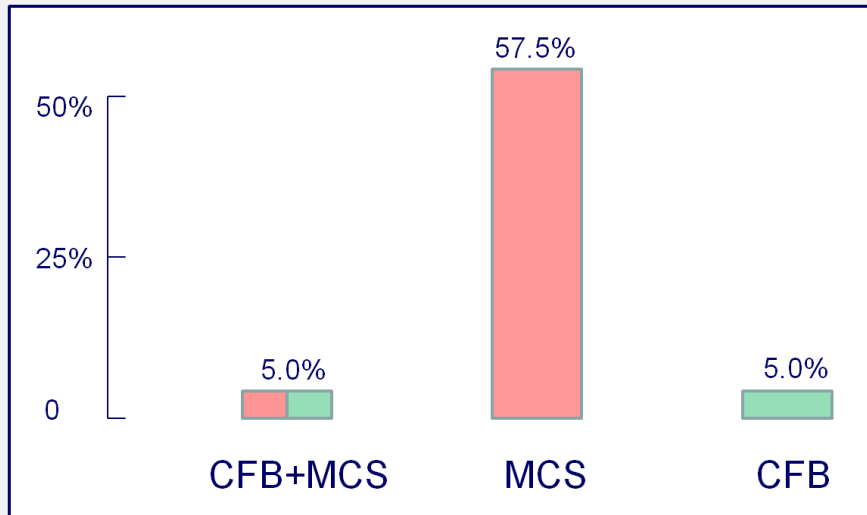
(expression, aspiration)



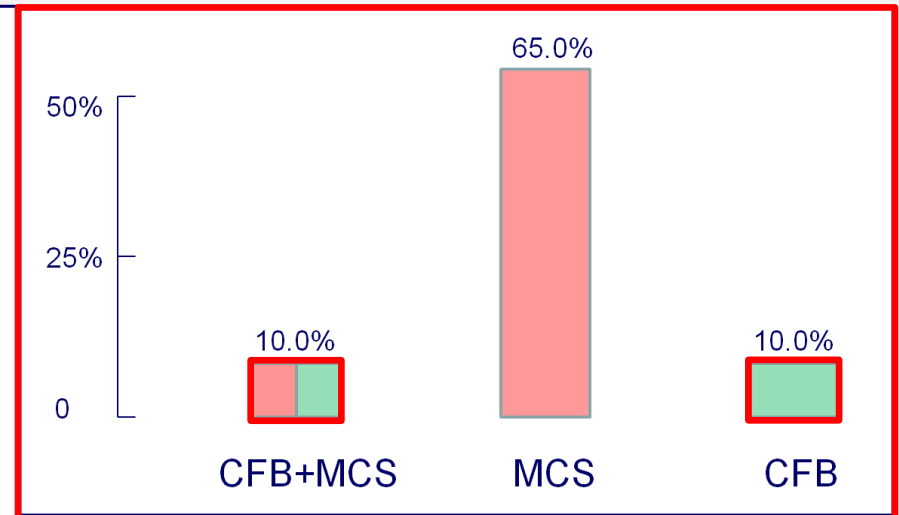
CFB vs. MCS: Reduction: > 85%

Symptomatic Inflammation

week 2



week 8



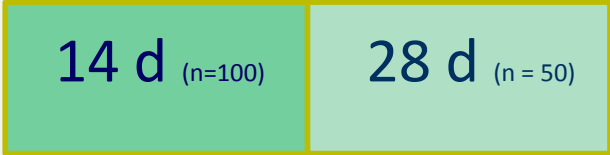


- some cases (10.0%) developed inflammatory symptoms after removal of film bandage.
 - may need film renewal + continuation (1 – 2 weeks)
-

Update: Film Compression Bandage

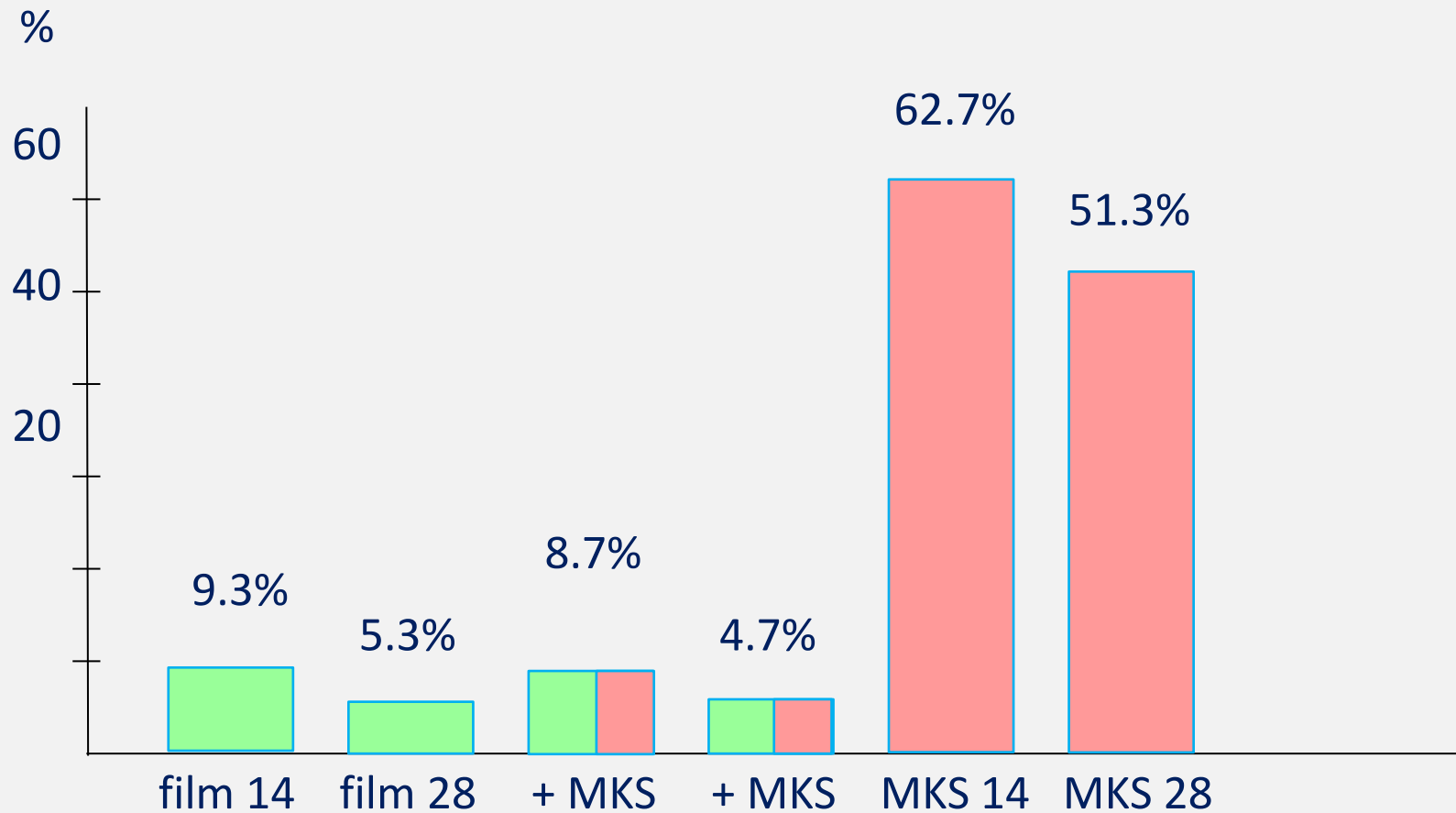
Studies continued:

- now including 450 cases
 - wearing time comparison 14 vs. 28 d
 - extension of indications
-

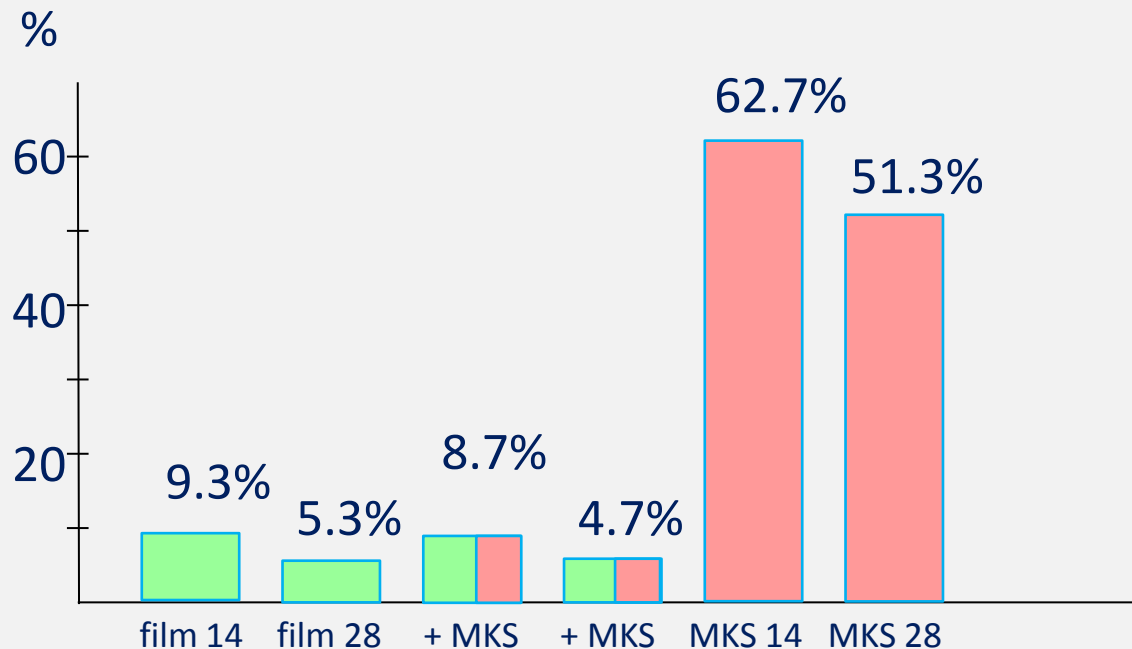
Update: Film Compression Bandage (8/2016)

Modality	wearing time (days)	n
A) CFB alone		150
B) CFB + MCS		150
C) MCS alone		150

Symptomatic Inflammation (until week 8)



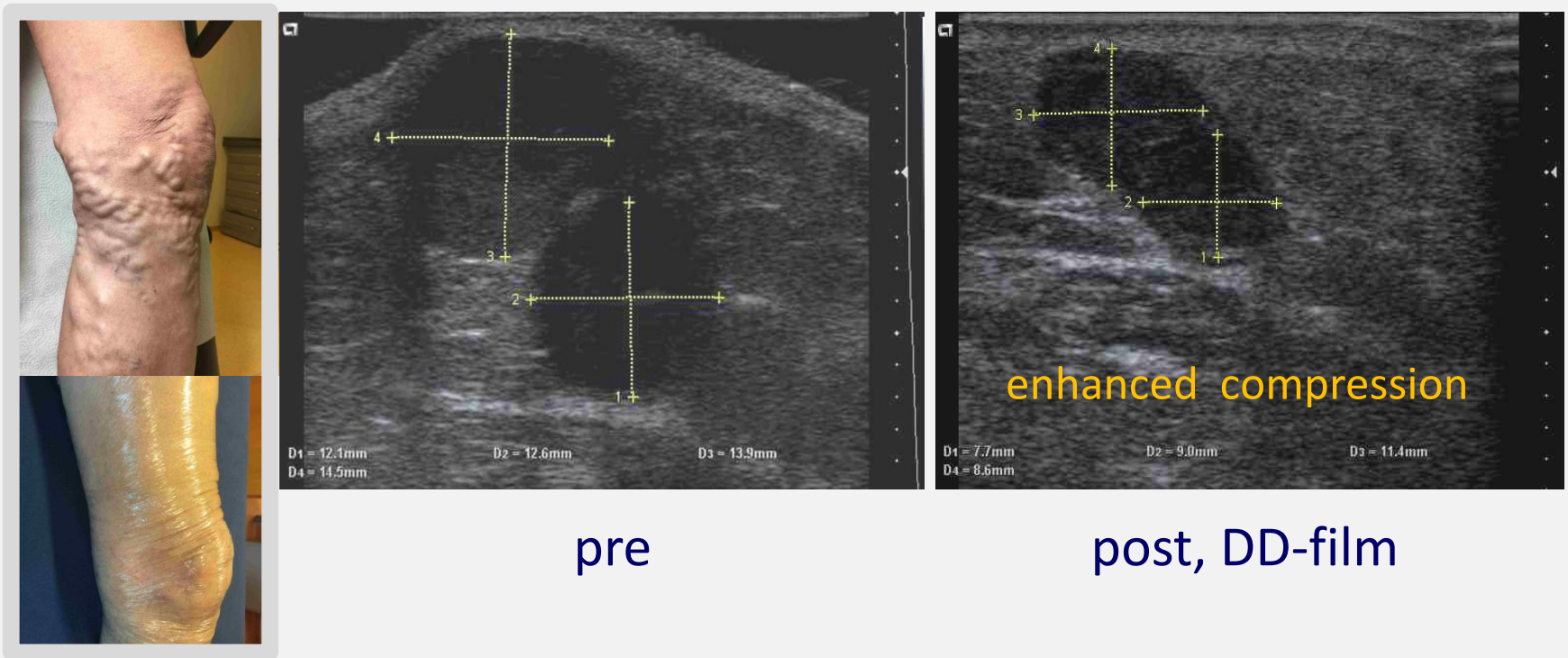
Symptomatic Inflammation (until week 8)



- 28 days of compression – always better than 14 d, but more effort & cost
 - future criteria for 2 x 14 d film : diameter > 8 mm, or uneven foam distribution
-

Alternative: “DD Film” (under evaluation)

Very large varicosities (> 8 mm): Higher pressure by increased elasticity (double diameter film, 30 μ)



Film-Related Problems

skin irritations

skin reddening 13/300 (4.3%)

sweating, heat, intense sports

allergies to acrylic glue: may occur



case shown: male 26 y/o, 23 km run, day 10.

Action: 15 min. blow-dryer, bandage renewed

Film-Related Problems

skin lesions: 13/300 (4.3 %)

causes:

- too much tension at margin
- unclear in some cases



Film-Related Problems



- Extra time may be required as no bloody spot should be covered with film.
- Solution:
Bandage room

Film Renewal (9.2%)



Insufficient overlapping. Bandage renewed day 7.

Film Renewal



Dissolution of film at the (upper) margin

- minor degree: $> 20\%$ of cases
- requiring film renewal: $< 5\%$ of cases

Case: Sports & shower every day.

Note: Discoloration almost zero below film!

Foot- or Ankle Edema



- In general, it is not intended to cover the foot with film (stress by walking, sweating at sole of foot)
- To avoid or to treat distal congestion:
Combine film with MCS.

3. Wearing Comfort

The majority of patients dislikes to wear compression stockings or bandages after endovenous treatments.



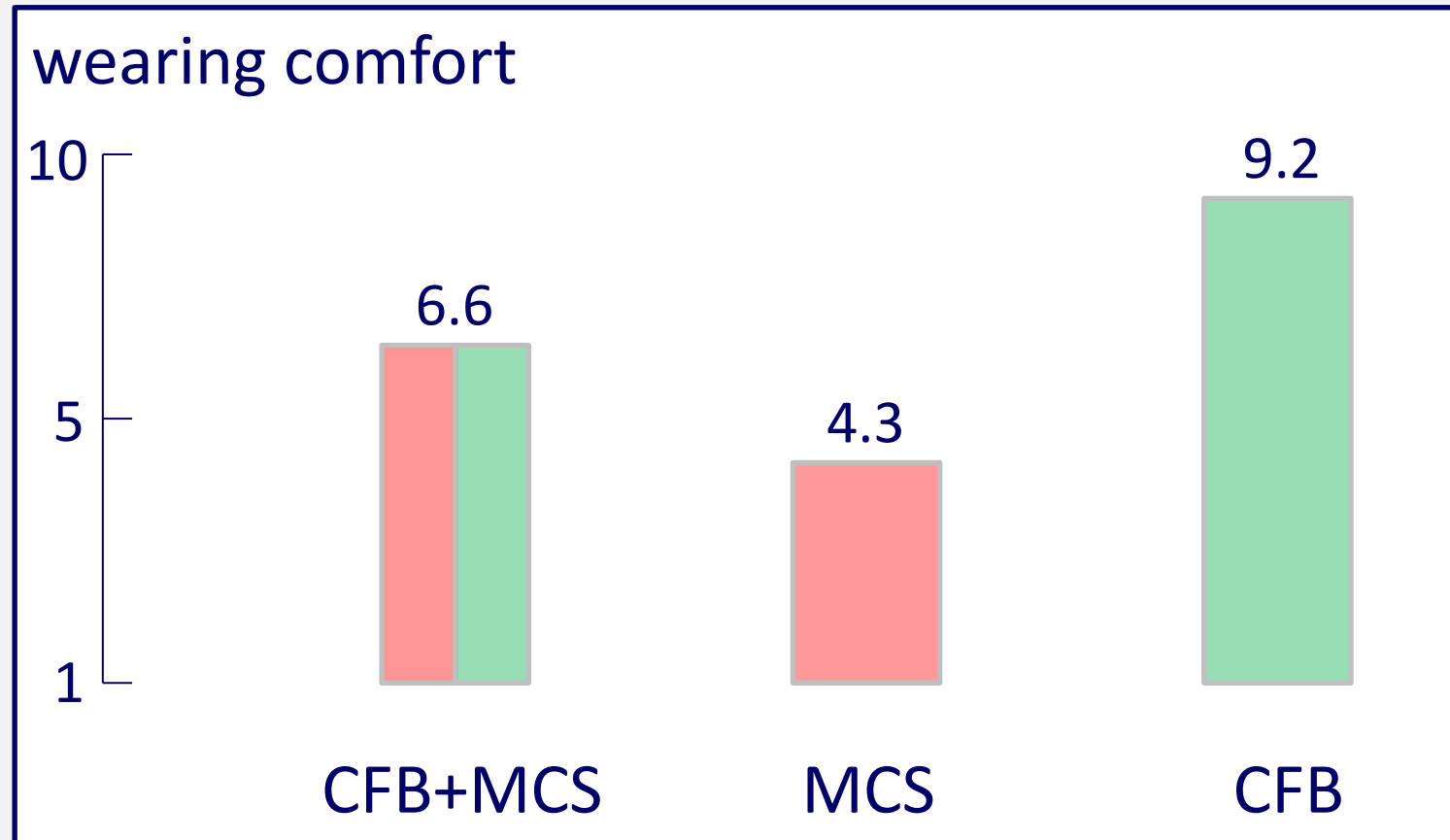
(but should get used to stockings to use them for prevention!)

Wearing Comfort Scale*

- 0 wearing not tolerated, finished < d 3
- 1 wearing not tolerated, finished d 4 - 12
- 2 frequent & significant discomfort (> 75% of wearing time)
- 3 occasional but significant discomfort (< 25% of wearing time)
- 4 moderate discomfort
- 5 minor discomfort (> 75% of wearing time)
- 6 occasional minor discomfort (< 25% of wearing time)
- 7 minor discomfort during particular stress (e.g. kneeling, sport movements)
- 8 occasional perception of the medium (< 25% of wearing time)
- 9 almost no perception of the medium during daily activities
- 10 no perception of the medium during daily activities and at night

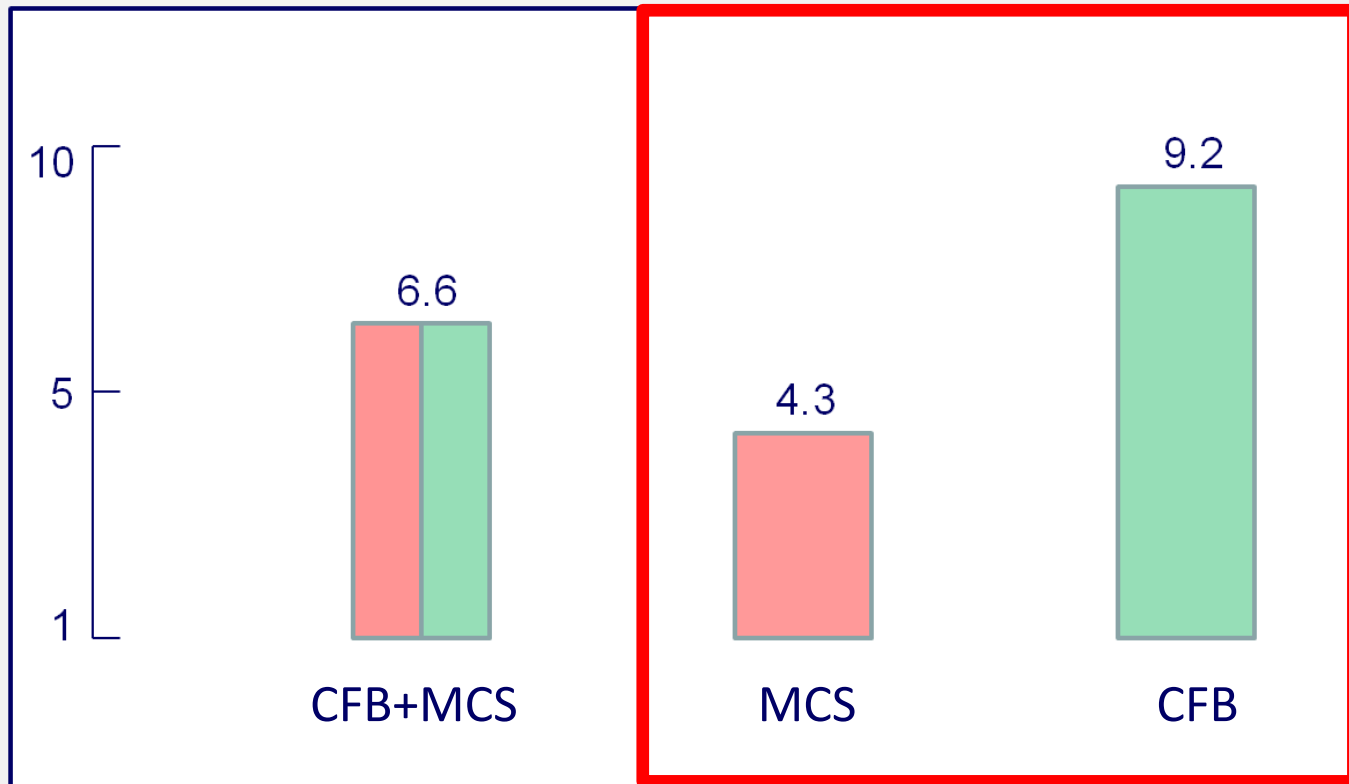
*Refers to wearing only! Does not include effort to put medium on or to take it off!

Mean Comfort Score



* rated by the patients, 10 degree scale (10 = perfect, no perception)

Wearing Comfort



➤ CFB is much more comfortable than MCS

Wearing Comfort



➤ CFB + MCS: more comfortable than MCS alone

Additional Comfort of CFB: Swimming next day



68 yr. old patient, daily swimming (arthritis)

Additional Comfort: Daily Showers



No problem!

Extended indications: Foot Varicosities



Patient can wear any shoes. Or none.

Note: Color marking left for study purpose. Film exchange 1-2 per week.

Extended indications: Foot Varicosities



64 y/o female, both images in standing position

Extended indications: Arm veins (esthetic)



(tested in few esthetic cases – which bandage is nicer?)

No improvisation as soon as professional solution is available!



Extended Indications: Complex Cases



Today it is possible to perform even complex cases with a single catheter access and rapidly achieve a stable, good-looking result. Patients love it!

Conclusions

Compression film bandage:

- significantly improves vein regression of foam-treated superficial varicosities ($p < 0.01$)
 - prevents symptomatic inflammation
 - provides most comfortable vein compression
 - allows any work, sports, showers, social life
-

Conclusions

Future recommendations:

- **Compression stockings** as far as general condition (e.g. PTS, edema, standing profession...) requires;
 - **Film bandage**: for 2-4 weeks after endovenous treatment in every case with superficial varicosities
 - **Film bandage plus compression stockings (low pressure)**: Very good option to get patients used to long-term wearing for venous prevention!
-

Conclusions

Prognosis:

- “Foam & film” is not comparable to microfoam alone. It takes the film to outperform phlebectomy.
 - “Foam & film” will replace phlebectomy just like thermo-occlusion replaced saphenous stripping
 - Reimbursement will rise, as quality and comfort rise.
 - > 15 Mio. cases worldwide per year waiting for compression film application
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Thank you for your attention!



Dr. Ragg Work Group: www.venartis.org

Ragg, JC: Compression film bandage. A new modality providing continuous and sports-suitable vein compression after foam sclerotherapy. Phlebologie 2015; 44 (5), 225–292

