Film Compression Bandage

A new modality to improve Sclerotherapy of Superficial Varicosities.

Johann Chris Ragg, MD
founder & head of angioclinic® vein centers
founder & head of SWISS VX vein research labs
Berlin – Munich - Zurich
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 μ)
• 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
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?

protruding vein: maximum contact of vein and skin

textile media: no adhesion, weak fixation

© Ragg JC 2015
Textile Compression

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

© Ragg JC 2015
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

- 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!

vein before foam & film bandage

film compression during vein spasm

© Ragg JC 2015
... achieved by adhesive film!

vein before foam & film bandage

next day
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

aim:
- continuous pressure
- vein size remains small
- less inflammation
- less stainings
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.
Best: Compression by water!

- very smooth pressure gradient
- no "stiffness"
- may be partially imitated by compression film
Physical Issues

- Compression stocking
- Film bandage
- Lesser stiffness, lower working pressure
Film Patch

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

- Perforations
- Aids for cover removal

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
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)

<table>
<thead>
<tr>
<th>modality</th>
<th>wearing time (days)*</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) CFB + MCS</td>
<td>14 d CFB + 14 d MCS</td>
<td>40</td>
</tr>
<tr>
<td>B) MCS</td>
<td>28 d</td>
<td>40</td>
</tr>
<tr>
<td>C) CFB</td>
<td>14 d</td>
<td>40</td>
</tr>
</tbody>
</table>

*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)

- **CFB+MCS**: 48.5% (range 31-58%)
- **MCS**: 39.1% (range 28-51%)
- **CFB**: 42.3% (range 28-53%)
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 (+/- 10%) with different compression media, it was significantly different in certain areas with and without film.
Diameter Reduction (week 2, MCS)

Obvious when you compare to native varice!
Symptomatic Inflammation (week 2)

- CFB+MCS: 5.0%
- MCS: 57.5%
- CFB: 5.0%

pain, sensitive indurations or reddening along vein
Symptomatic Inflammation (week 2)

- CFB versus MCS: stat. highly significant
- no symptoms while CFB is on skin
43 y/o female
cleaning worker
sports: bicycling 1h/d
Early Experience – is phlebectomy redundant?

First application covering the knee

No MCS

color markings left for study purpose
Early Experience

2 weeks
No symptoms!

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

“no symptoms while CFB is on skin“
Removal of Thrombus (until week 8)

(expression, aspiration)

CFB vs. MCS: Reduction: > 85%

CFB vs. MCS: Reduction: > 85%
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)

<table>
<thead>
<tr>
<th>Modality</th>
<th>wearing time (days)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) CFB alone</td>
<td>14 d (n=100)</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>28 d (n = 50)</td>
<td></td>
</tr>
<tr>
<td>B) CFB + MCS</td>
<td>CFB (14/28)</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>+ MCS (14+28)</td>
<td></td>
</tr>
<tr>
<td>C) MCS alone</td>
<td>14 d (n = 100)</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>28 d (n = 50)</td>
<td></td>
</tr>
</tbody>
</table>

CFB: Compression film bandage, MCS: Medical compression
Symptomatic Inflammation (until week 8)

- Film 14: 9.3%
- Film 28: 5.3%
- + MKS: 8.7%
- + MKS: 4.7%
- MKS 14: 62.7%
- MKS 28: 51.3%
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
Very large varicosities (> 8 mm): Higher pressure by increased elasticity (double diameter film, 30μ)

Alternative: “DD Film” (under evaluation)
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.

(exhausting  cant´ do it  doesn´ t fit  no showers)

(looks ugly  worse than all treatment  feels terrible)

(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 of!
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!
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!
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 fo 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.
Thank you for your attention!

Dr. Ragg Work Group:  www.venartis.org