Compression film bandage

A new compression modality to improve foam sclerotherapy of superficial varicosities

Johann Chris Ragg, MD

founder & head of angioclinic® Vein Centers
Berlin – Munich – Zurich
Disclosures

- inventor of compression film bandage
- patents US 20160213607 A1, EP 2606828 A1
- investigative use, non-commercial
- no financial support by any companies

Background:

- Physics; Angiology, interventional radiology (Charité Berlin)
- Founder of Venartis Inc. (USA): Innovations for phlebology
- Founder of venartis.org non-commercial forum
Golden rules of endovenous therapy

Varices: 90 - 95 Vol-% = blood

1. Obtain empty vein (positioning, aspiration, perivenous fluid)
2. Destroy endothelium (thermal, laser light, chemical)
3. Option: destroy parts of media
4. Establish laminar flow around closure sites
5. **Stop/limit re-entry of blood for 4 – 8 weeks**

(foam & film)
Three conditions for optimal compression

1) **effective** to reduce the vein lumen (superficial varices: 60 – 75%)
2) **continuous** for some weeks to prevent vein refill
3) **comfortable** to support patient compliance

---

**effectivity and continuity**  
**comfort**
Partsch H, Mosti G, Uhl JF:
Unexpected Venous Diameter Reduction by Compression Stocking of Deep, but not of Superficial Veins.
Veins and Lymphatics, 2012 1(1)

“Standing magnetic resonance imaging ... showed... stockings with a pressure of 22 mmHg were able to reduce the calibre of deep calf veins, but not of superficial varices. These were compressed only by bandages exerting pressures between 51 and 83 mmHg. To empty a varicose vein after venous ablation much higher pressures are required.”

No myth, no paradox:
Just bandage-enhanced intrafascial compression by muscle activation ;)

Confusion of pressure and compression.
Need: Telemetric real-life 24h vein pressure measurement!
Concentric textile compression

protruding veins: large contact zone of vein and skin
Bandages: High pressure, but
  • concentric compression only
  • weak vein fixation
Concentric textile compression

- Textile media will slide on skin
- Elastic forces decrease with time
- Vein will partially protrude again
- Still considerable contact zone

© Ragg JC 2015
Eccentric compression

Large varicosities within or below skin level

Perivenous compression

No long-term compression with tumescent fluid, but with hyaluronan!


Dos Santos JB: Ultrasound Guided Foam Sclerotherapy Transcatheter in Great Saphenous Vein, Preceded of Tumescence. University of Sao Paulo
Perivenous compression by hyaluronan

Comparison to tumescent fluid, 14 days

- Asymptomatic post-interventional period
- Prevention of discolorations/residuals
- No external compression required
- Persistence: depending on substance, 4 – 26 weeks

Drawbacks of textile compression media

Major disadvantages:
• Not effective
• No continuous wearing
• Not comfortable
Compression film bandage for bulging varicosities

• polymer: elastic, flexible, very thin (18 μ)
• hypoallergenic glue, self-adhesive
• transparent
• vapor permeable by micropores
• water resistant

• put on immediately after sclerofoam therapy
• pre-elongation of 10 – 20 - 30%
• ankle pressure 8 – 12 – 18 mmHg
• left for 14 - 28 days
Compression Film Bandage

- Film forms functional unit with skin
- Film elasticity adds to skin elasticity
- Vein expansion space is reduced
- Vein shifted towards fatty tissue
- Contact zone to skin is reduced

© Ragg JC 2015
When placed with tension: **Tangential compression!**

Concentric, eccentric, perivenous, tangential...

---

First experience 2014: Segmental leg coverage

sound shadow of film margin

pre

post
Effectivity

- Film put on during vein spasm
- Vein before foam & film bandage
Compression film bandage: Effective lumen reduction

77% lumen reduction
Continuity

Discontinued or reduced compression (stocking)
Veins refill, more thrombus, more inflammation

Continuous pressure (film compression bandage)

(basics described by FEGAN, Lancet 1963;2:109)
Prototypes using approved film and glue (3M Inc.) with modified supportive layers (Venartis Inc.)

- 354 patients (23 – 74 y)
- 450 legs (shaved)
- superficial varicosities, 5 - 13 mm Ø
- sports and showers ≥ 4 x per week
- foam sclerotherapy (Aethoxysklerol 1%, 1+4)
## Randomization and wearing times

<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| 28 d (n=50)</td>
</tr>
<tr>
<td>B) CFB + MCS</td>
<td>14 d (n=100) + 28 d (n=50)</td>
<td>150</td>
</tr>
<tr>
<td>C) MCS alone</td>
<td>14 d (n=100)</td>
<td>150| 28 d (n=50)</td>
</tr>
</tbody>
</table>

CFB: Compression film bandage, MCS: Medical compression stockings.
## Results: Effectivity & continuity

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

CFB: Compression film bandage, MCS: Medical compression stockings.
Large varicosity at lower leg

Ultrasound imaging while bandage in place

pre

post day 14
Diameter reduction (week 4): CFB highly effective

28 days of compression are more effective than 14 days
CFB is more effective than compression stocking (p < 0.1)
CFB + stocking s just slightly more effective than CFB alone
Symptomatic inflammation until week 8 almost eliminated

Benefit of CFB: highly significant (p < 0.001)
Film bandage: 85% reduction of thrombus removal

(expression, aspiration)
Wearing comfort

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

Scale: Wearing comfort of compression media

0: Wearing not tolerated, finished < 1d
1: Wearing not tolerated, finished 1-4d
2: Frequent & significant discomfort (> 75% of wearing time or finished 15-28]
3: Occasional but significant discomfort (< 75% of wearing time, 28d completed)
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. travelling, 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 any activities
Very large varicosity at lower leg

male 68 y/o, physician

C4

“foam & film“ immediate result 14 min., including 2 large perforators
48 y/o male, mountain biker, large varicosities (6-18 mm) due to SSV insufficiency. CFB + MCS.
Knee region: Learning curve

male 56 y/o, table tennis amateur

Just CFB, no MCS

No signs of inflammation in spite of large varicosities.
Large thigh varicosity

Thigh: More difficult: Larger radius, more distance to bones
Bulging superficial varicosities, no size limit, 14 – 28 d

64 y/o female, both images in standing position.
Time to final result: 12 min.
early dissolution: 18/300 (6.0%)
skin reddening: 13/300 (4.3%)
skin lesion: 1/300 (0.3%)

- no allergy so far (acrylic glue)

- limitations in obese patients
- limitations in hot & humid climates
- application aids have to be developed
Summary: Different new strategies for different targets!


Conclusions

Compression film bandage for bulging superficial varicosities:

• safe, effective, highly comfortable
• allows any work, sports, showering
• more effective than compression stocking
• advantage of 28 vs. 14 days of wearing
• best current modality for bulging varices

Ragg JC. Film compression bandage: a new modality to improve sclerotherapy of superficial varicosities. Veins and Lymphatics 2017(6), 28-32
Thank you for your attention!

XIX CONGRESSO NAZIONALE
Collegio Italiano di Flebologia

THE VENOUS ENDOVASCULAR EVOLUTION AND MORE...

Modena

Scientific Work Group Dr. Ragg: www.venartis.org
The Private Market Place for Innovations in Phlebology!