2 Layer Systems in Compression Therapy

An Approach to Deliver Medical Efficacy in Combination with Patient compliance
Agenda

1. General Specification

2. Development
   - Observations / Benchmarking / Results
   - Compression / Stiffness / Donning

3. JOBST® UlcerCARE

4. Results in Practice
   - Case studies / clinical results

5. Outlook / Recommendations
   - From a developers perspective
# 1. General Specifications


<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-layer system</td>
<td>(with open toe outer stocking)</td>
</tr>
<tr>
<td>Total pressure of system</td>
<td>(~40mmHg @ B) [30-40 mmHg]**</td>
</tr>
<tr>
<td>Split total pressure approximately 1:1 between liner and stocking</td>
<td>(tendency liner lower) [liner &lt;= 15 mmHg]**</td>
</tr>
<tr>
<td>SSI superior to 10mmHg/cm</td>
<td></td>
</tr>
<tr>
<td>Easy to don</td>
<td></td>
</tr>
<tr>
<td>Friction Index close to 1</td>
<td></td>
</tr>
</tbody>
</table>

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**See also: Compression stockings for treating venous leg ulcers, J. P. Benigni et al, Feb. 2012
2. Development

Main Design targets

- Medical efficacy according to standards
  - Compression
  - Static stiffness
- Compliance parameters
  - Donning
  - Moisture transport
  - Compatible with normal shoes

Design targets conflict

- High stiffness
  - Results in a high increase in pressure for any increase in circumference
- Y/B circumference ratio is typically 1.3 – 1.5
- Example: for B = 25 @ 35mmHg
  - Pressure increase at Y of ~22mmHg or more (@ ~+5% mmHg/cm)
2. Development

Methods used for the Analysis

- **HATRA**
  - To determine compression [mmHg]

- **Kikuhime (small probe)**
  - To measure interfacial pressure in supine and standing position
  - And calculate Static Stiffness Index*

- **Simple donning force evaluation**
  - BSN lab method
  - Simulates the force required to don medical compression stockings
  - Takes size and friction parameters into account

*According to consensus document, H.Partsch et al. 2006
2. Development - Observations

Compression (HATRA)

- Prove: $C_{\text{liner}} + C_{\text{stocking}} = C_{\text{system}}$
  - Liner + Stocking compressions are additive (slight difference from HATRA intrinsic principle - outer stocking is stretched to a larger diameter)

![Graph showing addition of compression in 2 Layer System](attachment:image.png)

BSN internal data, not final released product testing
2. Development - Benchmarking

Compression (HATRA)

- Observation on available systems
  - Almost all systems comply with the RAL specification (34-46mmHg)

![Comparison of Compression of Ulcer Care Systems](image)

BSN internal data, 2011
2. Development - Observations

Independence of Static Stiffness Index

- Static Stiffness Index vs. resting/working pressure (applied compression)
  - In the developed system, SSI is independent of working pressure ensuring high stiffness throughout the complete size (run). Average is 10.6mmHg/cm

![Graph showing independence of SSI from IP in Jobst UlcerCare 2-layer product](image)
In Vitro predictability of SSI
- Static Stiffness Index - in vivo vs. in vitro
  - No correlation between in vitro (HATRA) and in vivo (Kikuhieme) measurements could be established (available systems)

BSN internal data, 2011
In vivo determination of SSI

- Multiple measurements of available systems (n=13 to n=35)
  - Most systems fail to meet target of SSI = 10 mmHg/cm
  - High variation (30%-60%) on individual systems due to subjects anatomy
2. Development - Results

Relative force to don

- Specific knit and stocking construction & material selection
  - Comparison of available systems proves advantage of donning (lab donning assessment, force normalized to compression)

![Comparison of Donning Force of Ulcer Care Systems](image)

BSN internal data, 2011
2. Development - Results

**Static Stiffness Index vs. relative force to don**
- No correlation is visible (based on BSN lab method)
  - Optimization of both parameters is possible (to a certain extent)

![Graph showing SSI vs. Donning Force of Ulcer Care Systems](image-url)
## 2. Development - Summary

### Jobst Development Specification (2010) based on compression consensus

<table>
<thead>
<tr>
<th>Requirement</th>
<th>JOBST® Ulcer CARE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-layer system (with open toe outer stocking)</td>
<td>✓</td>
</tr>
<tr>
<td>Total pressure of system (∼40mmHg @ B at rest) [30-40 mmHg]*</td>
<td>✓ (and complies with RAL GZ)</td>
</tr>
<tr>
<td>Split total pressure approximately 1:1 between liner and stocking [liner ≤ 15 mmHg]*</td>
<td>✓ (liner ~ 17mmHg)</td>
</tr>
<tr>
<td>SSI superior to 10mmHg/cm</td>
<td>✓</td>
</tr>
<tr>
<td>Easy to don</td>
<td>✓ (lowest force in the market)</td>
</tr>
<tr>
<td>[Friction Index close to 1]*</td>
<td>N.A.</td>
</tr>
</tbody>
</table>

*See also: Compression stockings for treating venous leg ulcers, J. P. Benigni et al, Feb. 2012*
3. JOBST® UlcerCARE

Introduction of product concept

- 2-layer system
- Inner liner + outer stocking (w & w/o zipper)
- Part of a therapy approach
- Venous leg ulcer
- No (or mild) edema
- It is important that the stocking fits well ➔ in case of edema, decongestion with bandaging first
4. Results in Practice

Individual results from product monitoring

- Product performance is monitored since launch in 2011 (1.5 years)
  - In several case studies, customer questionnaires

- Medical Response
  - Very good healing speed and closure rates
    In combination with adequate bandaging and wound care
  
  - Has also produced good results in the management of difficult wounds
    (long history, multiple or large ulcers)

  - Individual cases (with no/mild edema) also show that this product's
    stiffness (and compression) is beneficial for ulcer closing
4. Results in Practice

Individual results from product monitoring

- Medical Response

**Multiple venous leg ulcers**

68 years, male, smoker, ABPI 1, around the leg, since 3 months, slough

BSN internal data, 2011
4. Results in Practice

Individual results from product monitoring

- **Patient Feedback**
  - Extremely well received by patients due to ease of use

- "I had already many other compression stockings but I perceived the UlcerCARE as very pleasant and effective." (Austria)
- "Mi piace, regressione completa del dolore." (Italy)
- "Molto soddisfatto - risultato eccellente" (Italy)
- "Soddisfatto, comfort d`indosso eccellente" (Italy)
- "Ich habe Kompressionstrümpfe schon vor dem UlcerCARE system getragen und empfand den UlcerCARE als große Erleichterung und ich fühle mich besser" (Germany)

BSN internal data, 2011
4. Summary

Consequently focusing on the main design parameters
  - Compression
  - Static stiffness
  - Donning

And de-couple the conflicting design targets as much as possible

Enables a product

- With a good Medical efficacy
- And high patient compliance
5. Outlook / Recommendations

What would have made the development even better?

- A generally accepted set of best practice methods to assess stiffness
  - In vivo
    ideally with a low dependency on individual handling
    (and optimally anatomy and tissue composition)
  - In vitro
    with the necessary statistical correlation to the in vivo measurement
    ideally with a good integration with today’s lab methods
  ➢ (Develop and) standardize practical methods and procedures
    (suitable for industry use) and facilitate an agreed consensus

- Clear medical evidence for stiffness „categories“
  - Better target definition and trade of balance with compliance
  ➢ Intensify research on efficacy of stiffness „categories“ and differentiation
    (and subsequent treatment recommendations)
Thank you for your attention