

2 Layer Systems in Compression Therapy

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

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

Jobst Development Specification (2010)

based on compression consensus*

2-layer system
(with open toe outer stocking)

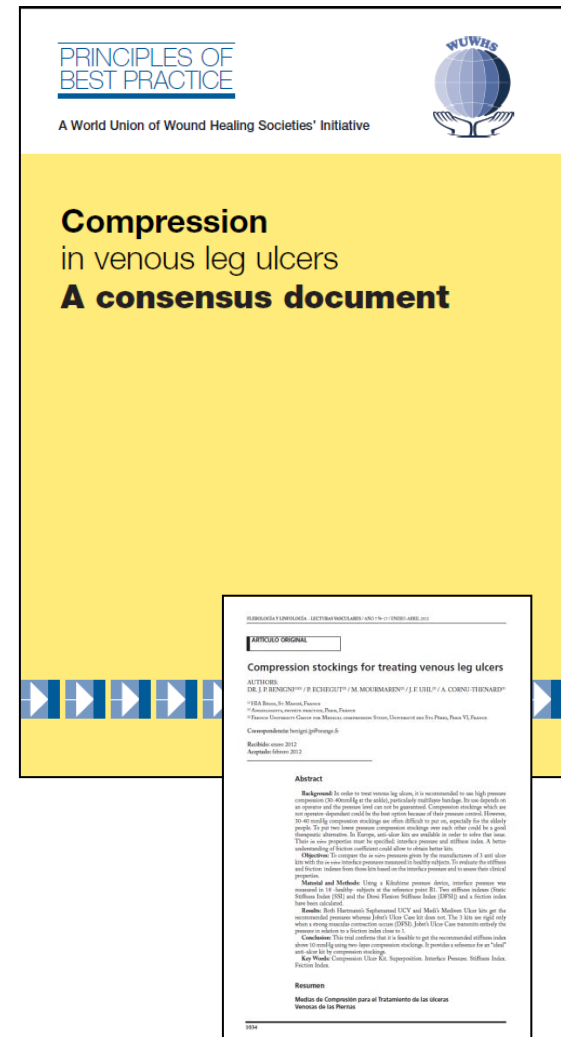
Total pressure of system
(~40mmHg @ B) [30-40 mmHg]**

Split total pressure approximately 1:1 between
liner and stocking (tendency liner lower)
[liner ≤ 15 mmHg]**

SSI superior to 10mmHg/cm

Easy to don

[Friction Index close to 1]**



* World Union of Wound Healing Societies (WUWHS). Principles of best practice: Compression in venous leg ulcers. A consensus document. London: MEP Ltd, 2008

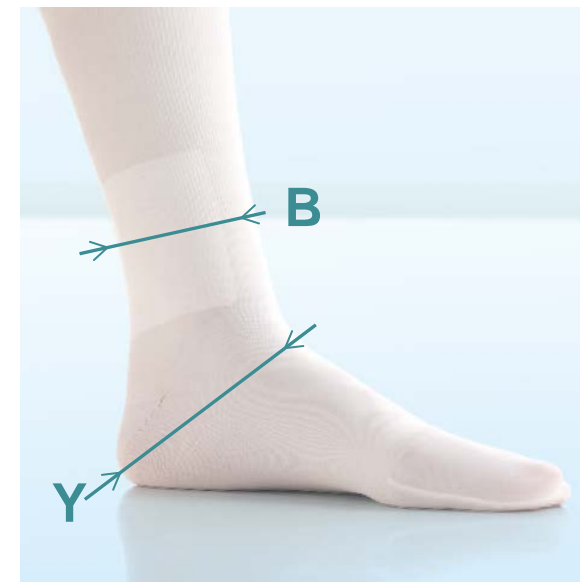
**See also: Compression stockings for treating venous leg ulcers, J. P. Benigni et al, Feb. 2012

Main Design targets

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

Design targets conflict

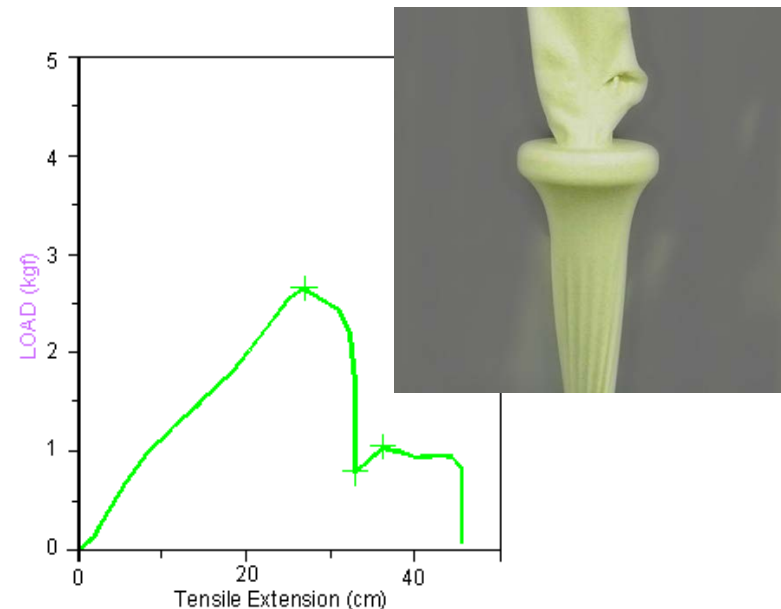
- High stiffness
 - ➔ results in a high increase in pressure for any increase in circumference
- Y/B circumference ratio is typically 1.3 – 1.5
- Example: for B = 25 @ 35mmHg
 - ➔ pressure increase at Y of ~22mmHg or more (@ ~+5% mmHg/cm)



2. Development

Methods used for the Analysis

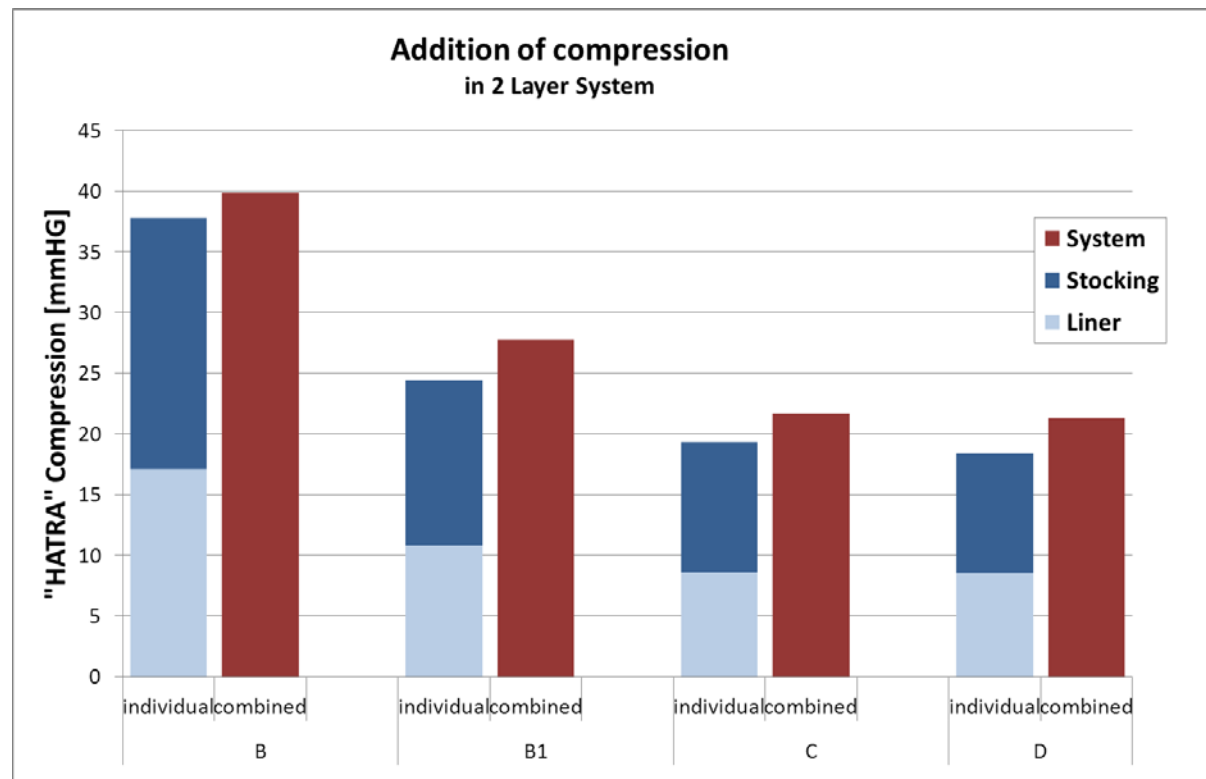
- HATRA
 - To determine compression [mmHg]
- Kikuhime (small probe)
 - To measure interfacial pressure in supine and standing position
 - And calculate Static Stiffness Index*
- Simple donning force evaluation
 - BSN lab method
 - Simulates the force required to don medical compression stockings
 - Takes size and friction parameters into account



*According to consensus document, H.Partsch et al. 2006

Compression (HATRA)

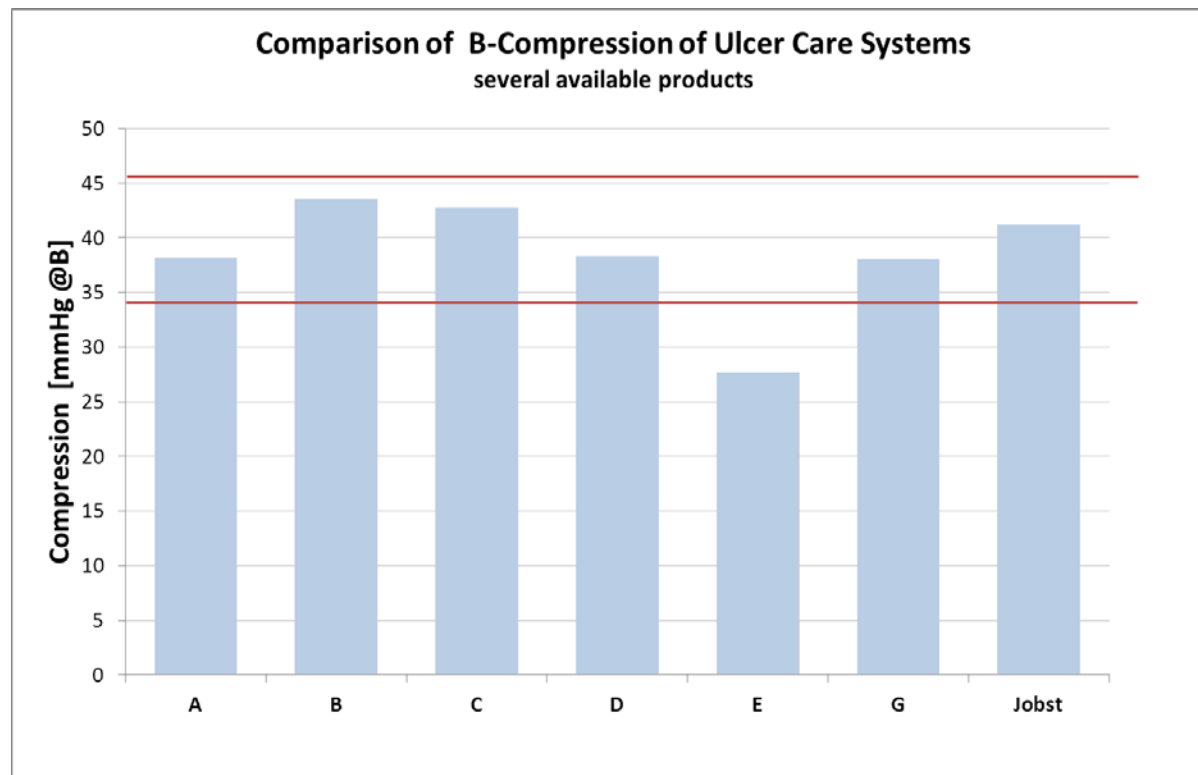
- Prove: $C_{\text{liner}} + C_{\text{stocking}} = C_{\text{system}}$
 - Liner + Stocking compressions are additive (slight difference from HATRA intrinsic principle - outer stocking is stretched to a larger diameter)



BSN internal data, not final released product testing

Compression (HATRA)

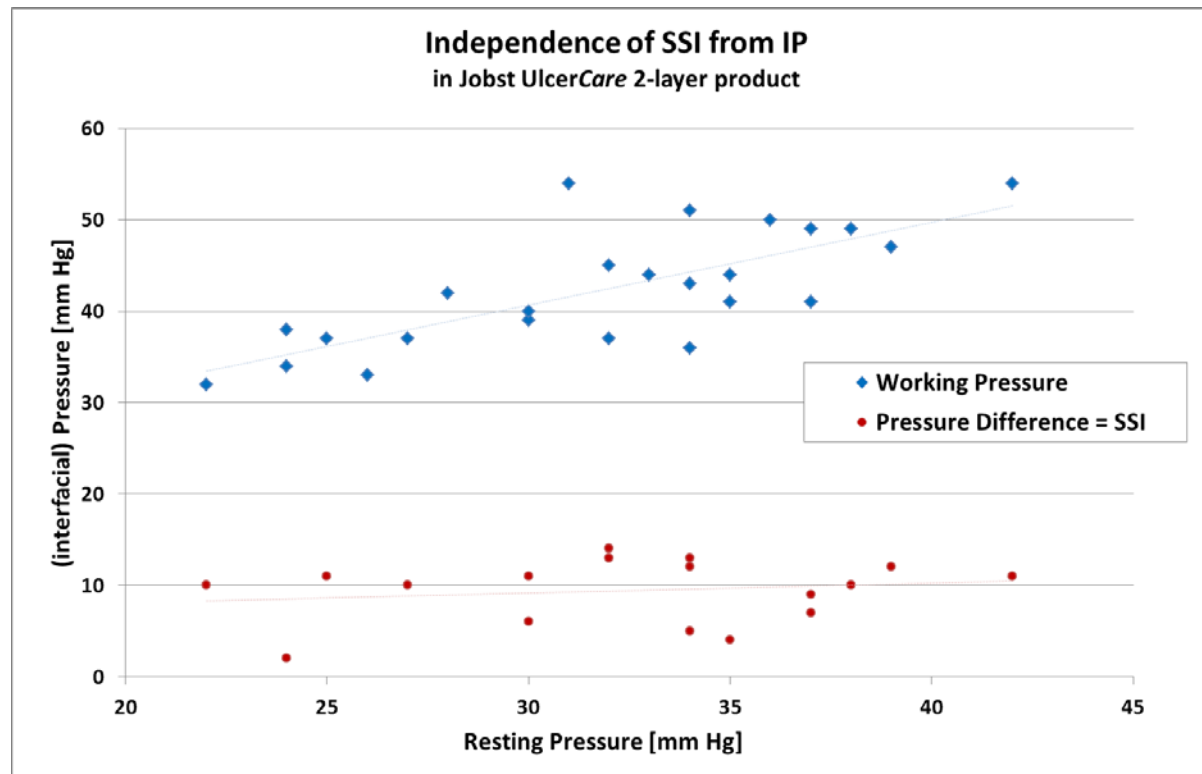
- Observation on available systems
 - Almost all systems comply with the RAL specification (34-46mmHg)



BSN internal data, 2011

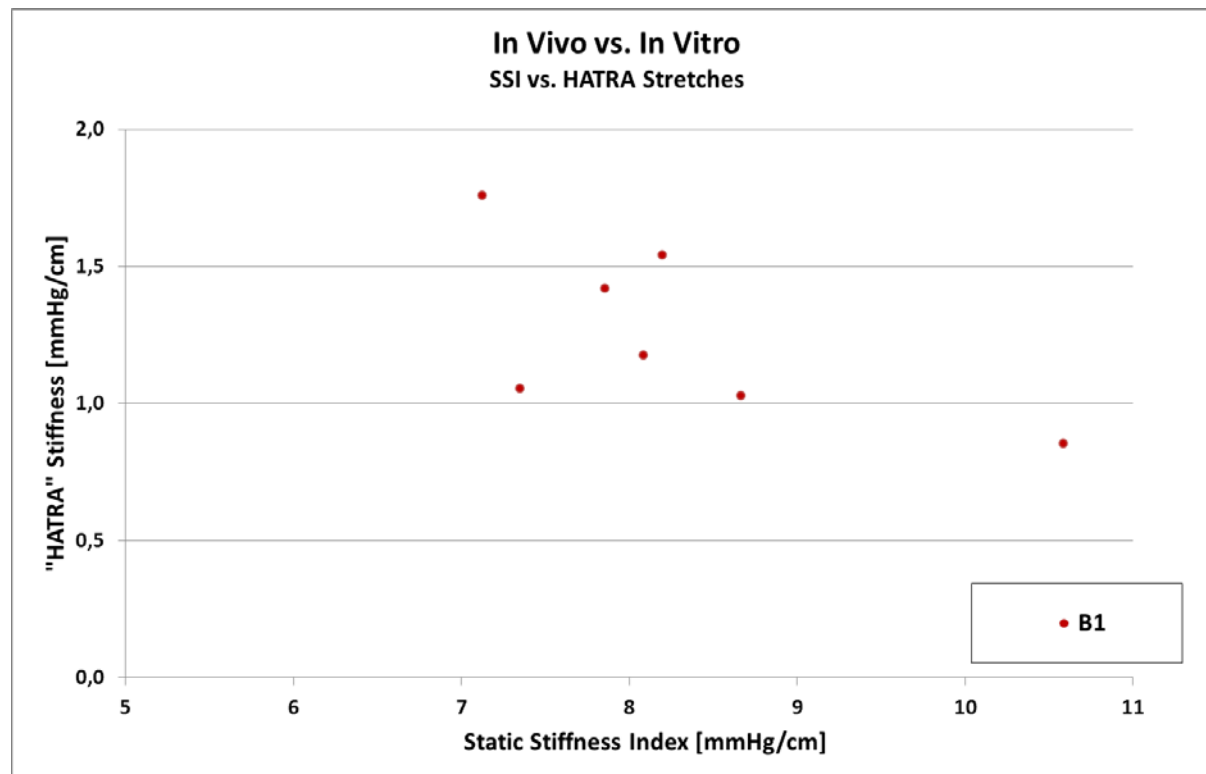
Independence of Static Stiffness Index

- 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



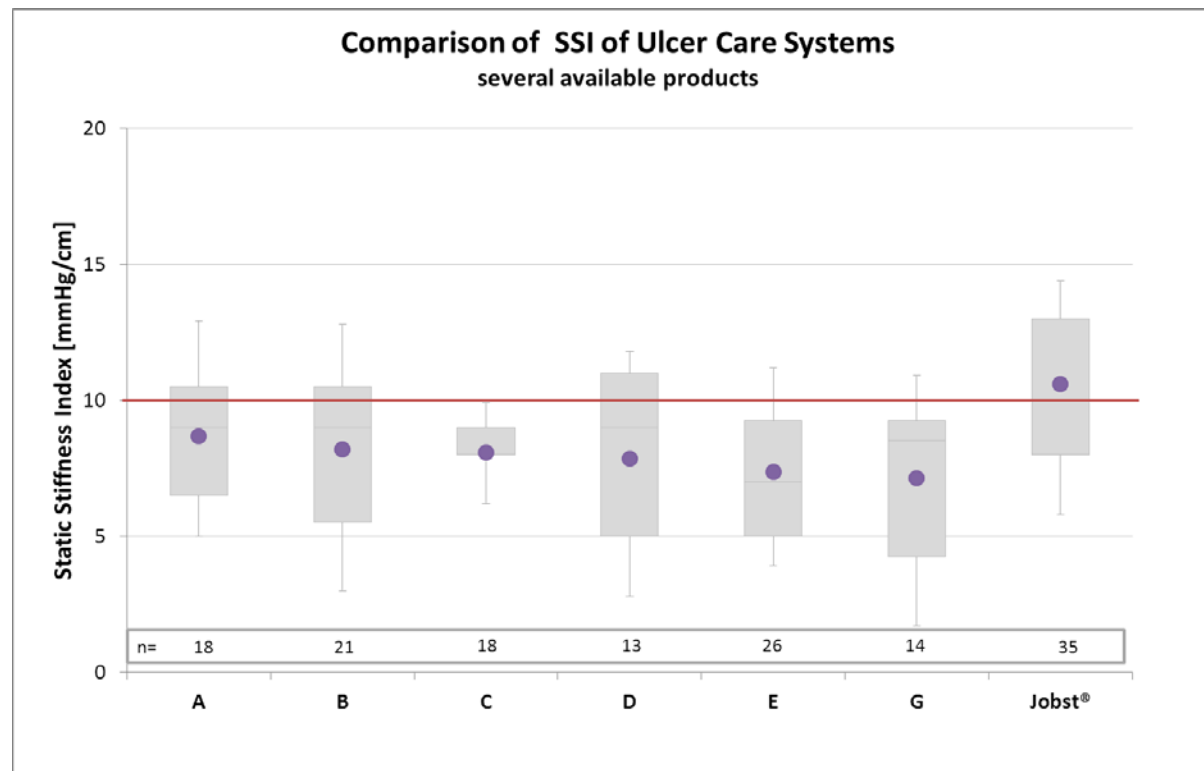
In Vitro predictability of SSI

- Static Stiffness Index - in vivo vs. in vitro
 - No correlation between in vitro (HATRA) and in vivo (Kikuhime) measurements could be established (available systems)



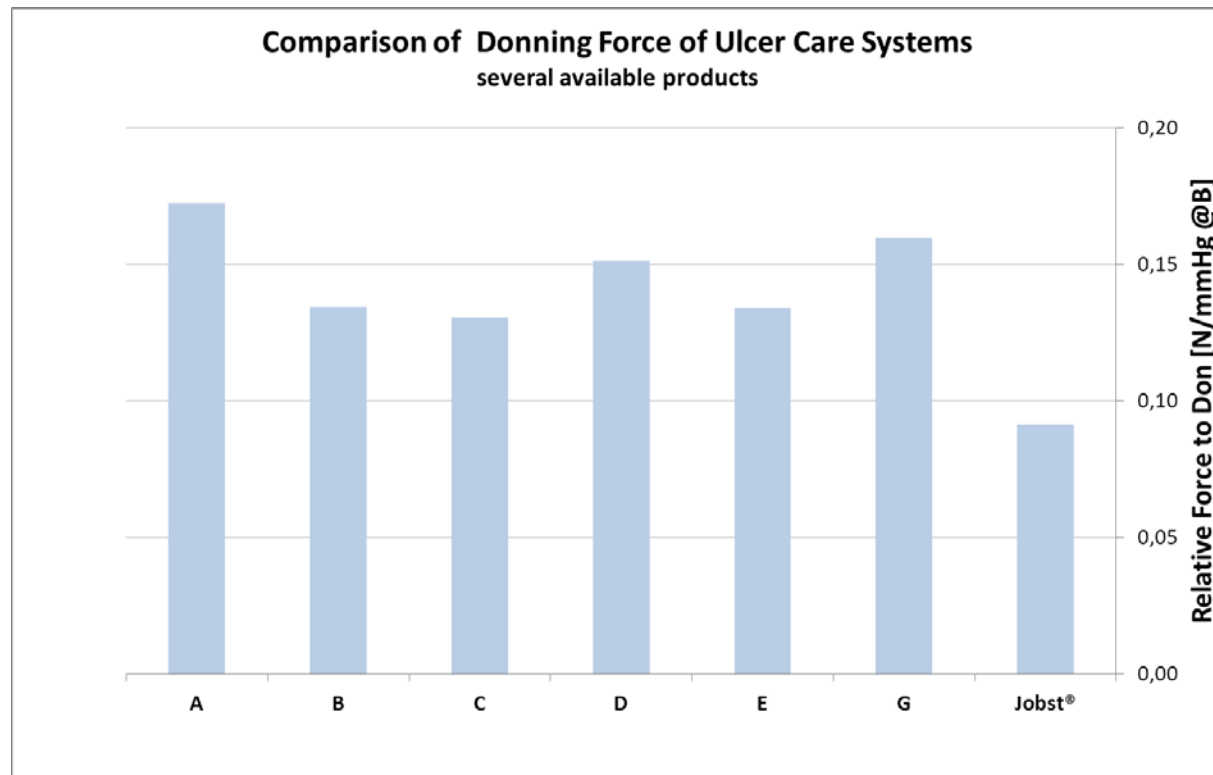
In vivo determination of SSI

- 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



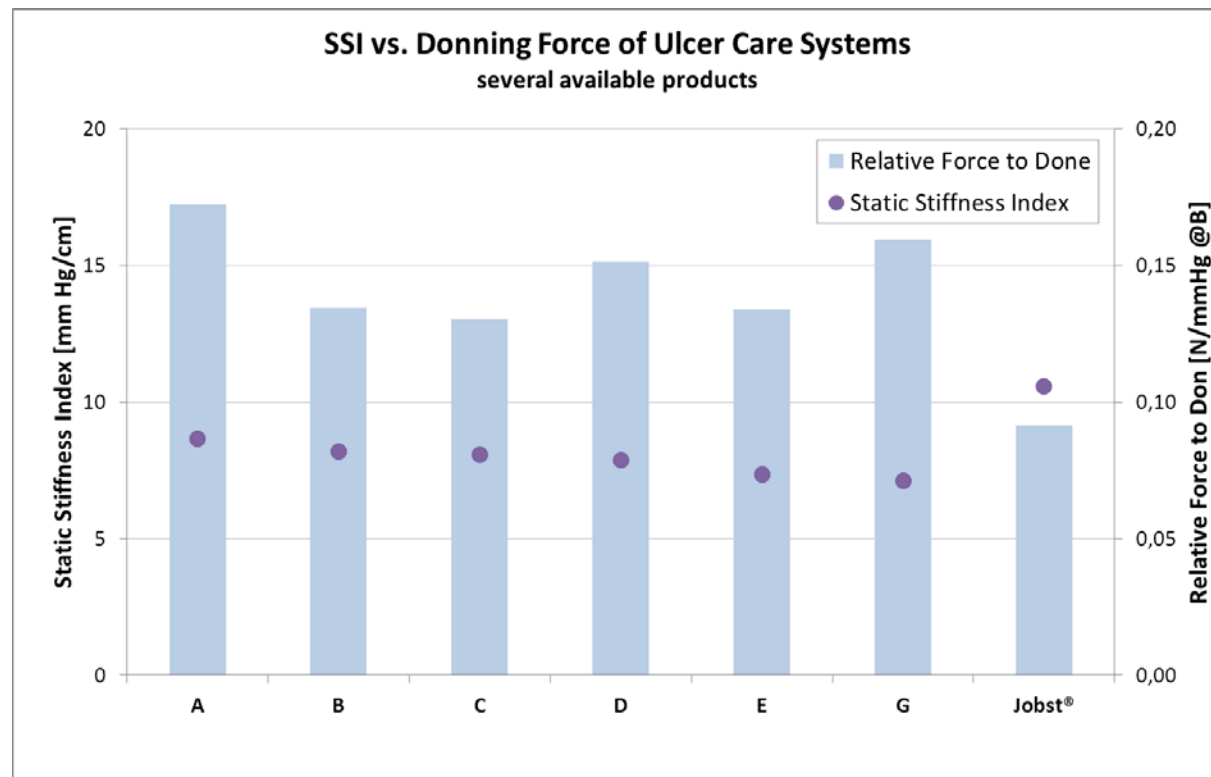
Relative force to don

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








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)



2. Development - Summary

Jobst Development Specification (2010) based on compression consensus	JOBST® Ulcer CARE
2-layer system (with open toe outer stocking)	
Total pressure of system (~40mmHg @ B at rest) [30-40 mmHg]*	 (and complies with RAL GZ)
Split total pressure approximately 1:1 between liner and stocking [liner <= 15 mmHg]*	 (liner ~ 17mmHg)
SSI superior to 10mmHg/cm	
Easy to don	 (lowest force in the market)
[Friction Index close to 1]*	N.A.

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

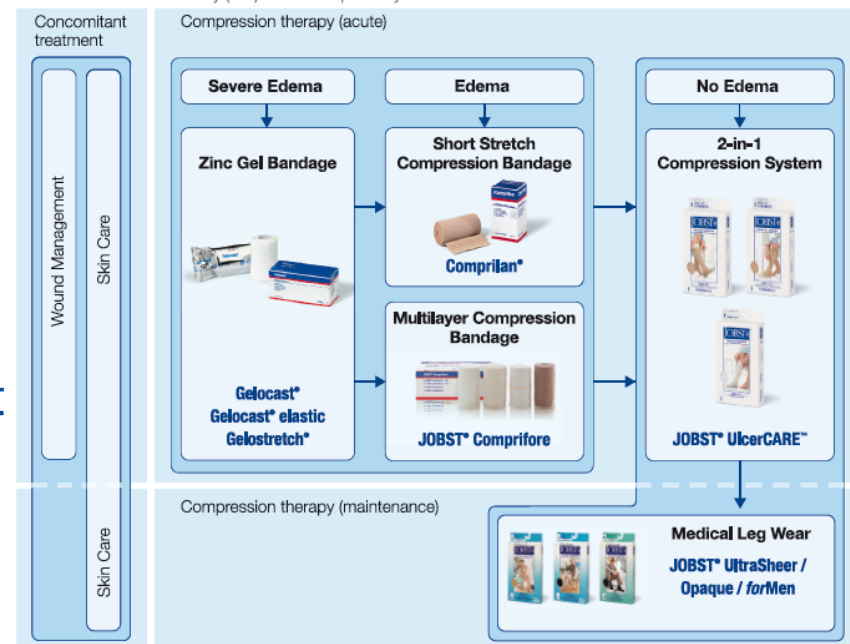
3. JOBST® UlcerCARE

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



Chronic venous insufficiency (CVI): treatment pathway



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

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

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)

"Soddisfatto, comfort d'indosso eccellente"
(Italy)

"Mi piace, regressione completa del dolore."
(Italy)

"Molto soddisfatto - risultato eccellente"
(Italy)

„Ich habe Kompressionsstrümpfe schon vor dem UlcerCARE system getragen und empfand den UlcerCARE als große Erleichterung und ich fühle mich besser"
(Germany)

BSN internal data, 2011

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**

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