Novel Forms of Compression

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Clinical Innovation - Definitions

Clinical Innovation is stuff that we do that makes a difference and benefits patients and society

Harding 2014

It consists of

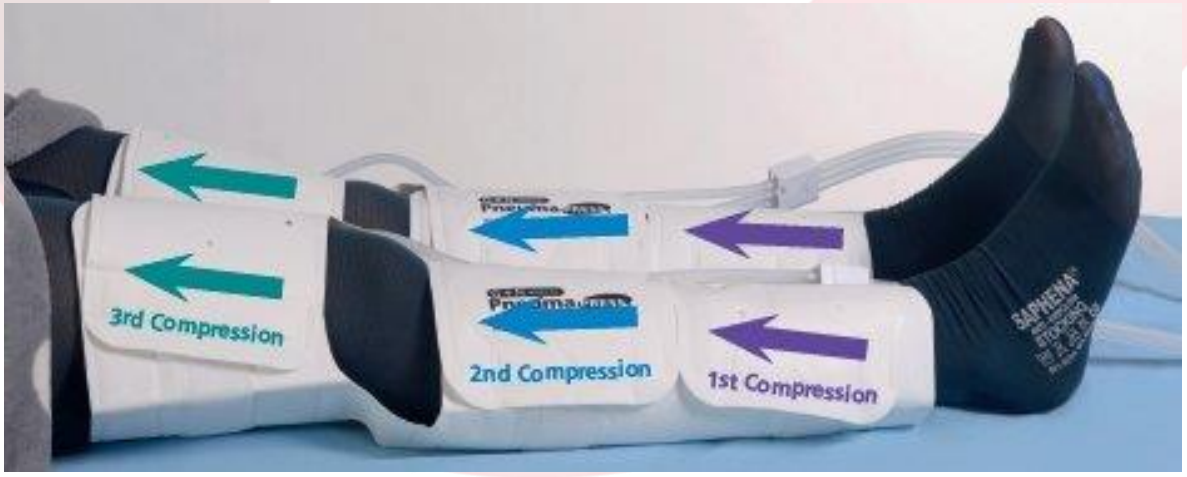
Technological Innovation

and

Service and process Innovation

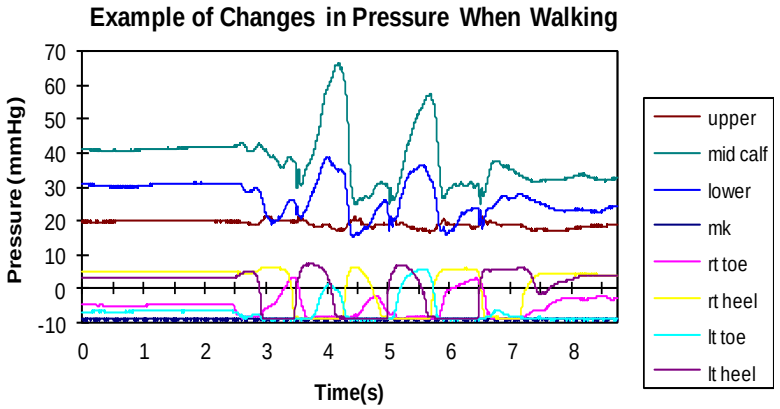
and

Social Innovation


3rd Compression
2nd Compression
1st Compression

Dilemmas that still exist

- How does compression work?
- Is it specific pressure ?
- Is it control of oedema?
- Is it limited by patient?
- No direct test of efficacy?
- What is graduated compression all about?
- What about availability?
- What about Patient involvement?
- What about patient choice?
- How do you get knowledge/skills and attitudes to change?
- How do measure success?



Indications for Compression ?

- **Venous insufficiency**
- **Lymphoedema**
- **Lipoedema**
- Cardiac Oedema
- Renal Oedema
- Nutritional Oedema
- Dependent Oedema
- Post Cellulitic oedema
- Post Traumatic oedema
- Wheelchair oedema
- Diabetic foot and leg complications
- Any swollen leg that does not have ischaemic/inflammatory disease

Main effects of compression

Main effects	Mode of action
Reduction of oedema	• Reduction of capillary filtration • Fluid shift into non-compressed regions • Improved lymphatic drainage
Venous narrowing	• Increase of venous blood flow velocity • Reduction of venous pooling • Improved venous pumping action
Microcirculation and cytokines	• Increase of shear stress • Release of anti-inflammatory mediators
Arterial inflow	• Increase of arterial flow due to sustained pressure (intermittent or moderate) • Reduction of arterial flow if compression exceeds perfusion pressure.

Partsch et al BJD 2015

Methods of compression

Description	Level of compression
Inelastic	Very high
Short-stretch: single component	High
Short-stretch: two component	High
Short-stretch + long-stretch: multi-component	High
Long-stretch elastic	Low
Compression stockings	Medium
Short-stretch: Velcro devices	Medium- high
Extremity pump	Variable
Hybrid pumps: Adaptive compression therapy	Variable

Partsch et al BJD 2015

Delivery of compression

- Substantial variation in sub-bandage pressure
  - Proportion achieving desired pressure (30-50 mm Hg)
    - 39 of 62 nurses (63%) 2 component bandage
    - 28 of 68 nurses (41%) elastic bandage
    - 27 of 68 nurses (40%) inelastic bandage
- Conclusion: a substantial proportion of patients with VLU do not receive adequate compression

Zarchi & Jemec JAMA Dermatology 2014

Factors influencing use of Compression

- **Health care system**
- Reimbursement
- Confusion of which to use
- Inconsistent and incorrect use
- Cost Effectiveness
- Lack of financial incentives
- Lack of specialist services

WINT consensus 2016

Factors influencing use of Compression

Clinician factors

- Lack of Knowledge in diagnosis
  of importance of compression
  different systems
- Seen as Specialist role
- Lack of Skill in application
- Lack of time at appointment
- Lack of referral pathways

WINT consensus 2016

Factors influencing use of Compression

- **Patient Factors**
- Lack of understanding
- Unable to pay for compression
- Previous negative experiences
- Lack of access to competent clinician
- Unwillingness to wear for social/practical reasons
- Inability to attend for appointments

WINT consensus 2016

Evidence for compression therapy

- Pathophysiological effects [1]
- Promotes healing in venous leg ulceration [2]
- Enhances physical range of movement [3]
- Patients report a reduction in pain [4]

Clinical evidence for compression therapy in leg ulcers

O'Meara et al (2012) Compression for venous leg ulcers*
Compression increases ulcer healing rates compared with no compression
Multi-component systems are more effective than single component systems
Multi-component systems containing elastic bandage appear more effective than those composed of inelastic constituents
Two-component bandage systems appear to perform as well as the four layer bandages (4LB)
Patients receiving the 4LB heal faster than those allocated to the short-stretch bandages (SSB)
More patients heal on high-compression stocking systems than with SSB
Further data are required before the difference between high-compression stockings and the 4LB can be established

*O'Meara S, Cullum N, Nelson EA, Dumville JC (2012) Compression for venous leg ulcers. Cochrane Database Systematic reviews.
11: CD000265

Partsch et al BJD 2015

Current challenges

- 50% patients treated with multi-layer bandaging systems are non-concordant [5]
- Difficulties in applying compression therapy [6]
- Potential deterioration in surrounding skin [7]
- Self-application of wrap systems are associated with greater independence, self-efficacy and sense of control for patients with lymphoedema [8]

Practical recommendations for the application of compression bandages

- Establish suitability for compression therapy with ABPI assessment
- Maximum dorsiflexion of the foot during application "toes to nose"
- Ensure the tibialis anterior tendon protruding during dorsiflexion is padded
- Follow manufacturer instructions
- Adjust the stretch to the curvature of the leg
- Allow patients to walk after application to ensure the bandaging is not painful
- Change bandage as it becomes loose or when there is exudate strike through
- Dressing changes on average 1-2 a week

Partsch et al BJD 2015

Rationale for Compression

- Safe
- Effective
- Cost effective
- Acceptable to the patient

Evidence to support novel compression therapies

- Damstra and Partsch (2013) Prospective, randomised controlled trial comparing the effectiveness of adjustable compression VELCRO® wraps versus inelastic multi-component compression bandages in the initial treatment of leg lymphedema [9]

- Mosti et al (2015) Adjustable Velcro compression devices are more effective than inelastic bandages in reducing venous edema in the initial treatment phase: a randomised controlled trial [10]

- NICE. The Juxta-CURES adjustable compression system for treating venous leg ulcers [11]

- Nelson et al (2014) Intermittent Pneumatic Compression for treating venous leg ulcers. Cochrane Database of Systematic Reviews [12]

Patient managed compression: CircAid®

- In compliant patients, venous leg ulcers randomized to nonelastic compression (CircAid®) had a significantly faster healing rate per week than ulcers treated by the conventional four-layer compression system.

Blecken et al J Vasc Surgery 2005

Adaptive compression therapy

- Comparison of ACT with 4LB
  - Ulcer healing rate similar
  - Improved exudate management and skin protection
  - Improved QoL
- But only a small study……

Harding et al, Int Wound Journal, 2014

ACTitouch™

Hybrid Compression

Hybrid Compression

Development

ACTitouch™

– Below Knee Device –

Sustained Compression:

- Sock worn against skin
- Four chambers: 1 Foot, 3 Calf
- Controller unit (battery operated)
  - Monitors and adjusts chamber pressures every 30 mins

Intermittent Compression:

- Gradient compression: foot to calf
- Must be connected to AC outlet

Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

– *Two **Dose-Response** Clinical Studies* –

(Subjects with Chronic Venous Edema)

Phase I – *Sustained Pneumatic Compression (SPC)*

Phase II – *Intermittent Pneumatic Compression (IPC)*

Vanscheidt W et al
J Vasc Surg 2009; 49:395-402

Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

– *Two Dose-Response Clinical Studies* –

Phase I – *Sustained Pneumatic Compression (SPC)*

- *12 subjects in seated position*
- *Six sustained pressure profiles vs. no compression*
- *Applied for 6 hours each (worst leg)*
- *≥48 hours between profiles*
- *Endpoint: Edema reduction (H_2O displacement)*

Vanscheidt W et al
J Vasc Surg 2009; 49:395-402

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Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

Phase I Study

– *Sustained Pneumatic Compression (SPC)* –

Foot	Gaiter *(mmHg)*		Calf *(mmHg)*
10	20		10, 0
20	30	Graduated	20, 10
30	40		30, 20
10	20		20, 20
20	30	Non Graduated	30, 30
30	40		40, 40

Vanscheidt W et al
J Vasc Surg 2009; 49:395-402

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Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

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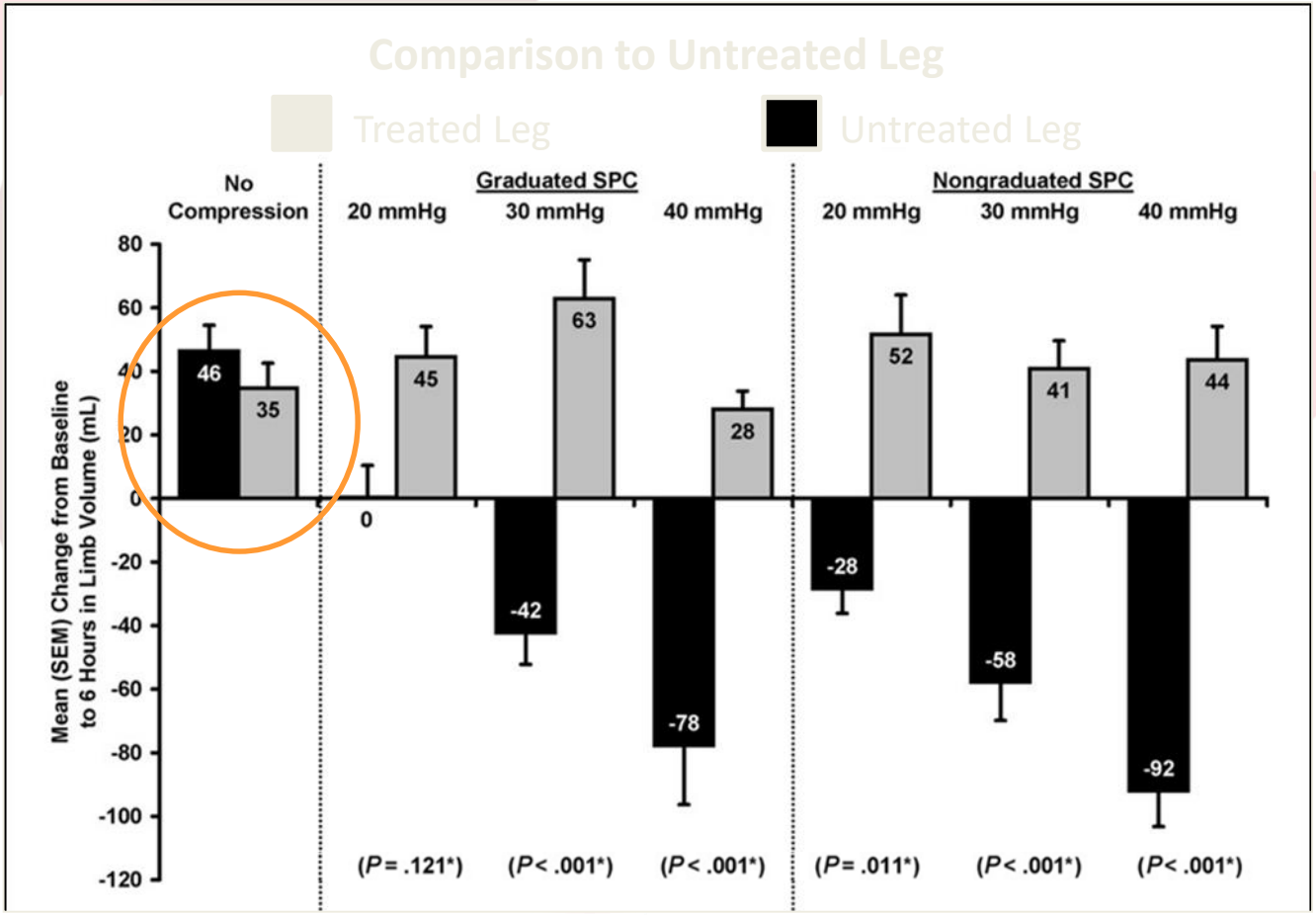
Results

– Reduction in Leg Volume with SPC –



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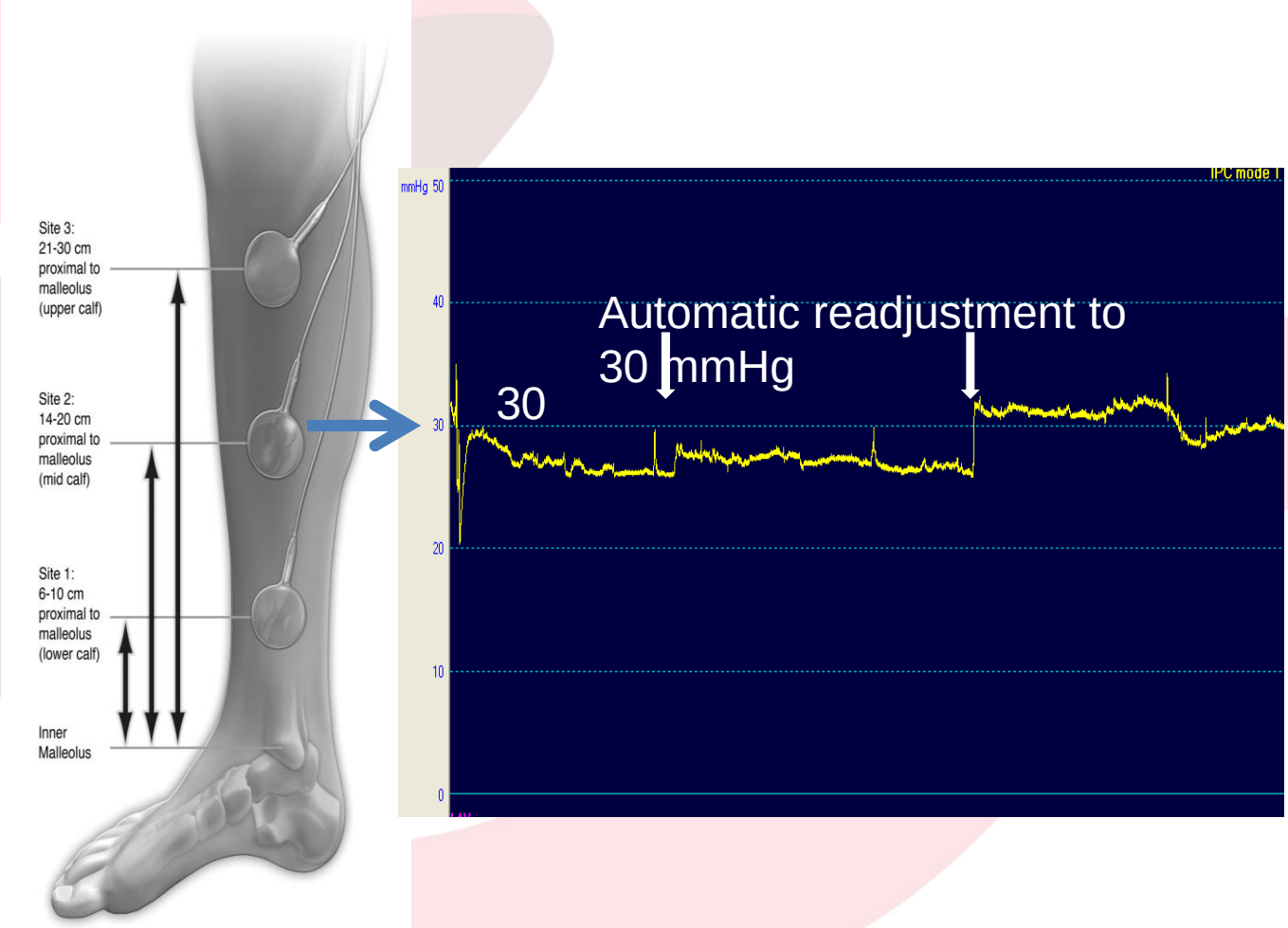
Sustained mode: Pressure readjustment (1h sitting)



Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

– Two **Dose-Response** Clinical Studies –

Phase II – *Intermittent Pneumatic Compression (IPC)*

- *16 subjects in seated position*
- *Three IPC profiles vs. no compression*
- *Applied for 2 hours each (worst leg)*
- *≥48 hours between profiles*
- *Endpoint: Leg volume (H_2O displacement)*
  Toe systolic pressure
  $TcPO_2$

Vanscheidt W et al
J Vasc Surg 2009; 49:395-402

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Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

Phase II Study

– *Intermittent Pneumatic Compression (IPC)* –

Foot	Gaiter *(mmHg)*	Calf *(mmHg)*
40	40	35, 30
50	50	45, 40
60	60	55, 50

Vanscheidt W et al
J Vasc Surg 2009; 49:395-402

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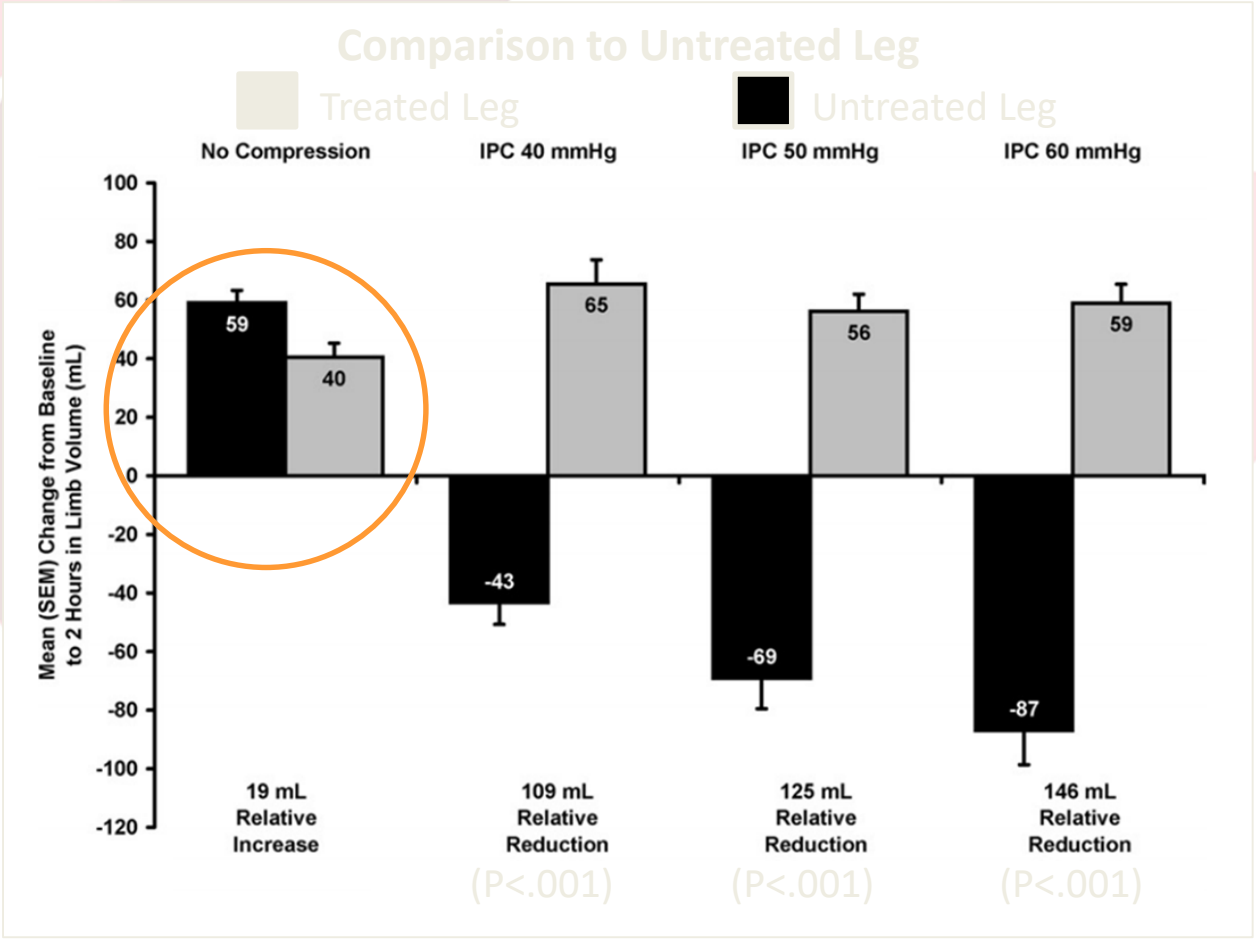
Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

Vanscheidt W et al
J Vasc Surg 2009; 49:395-402

Results

– Reduction in Leg Volume with IPC –



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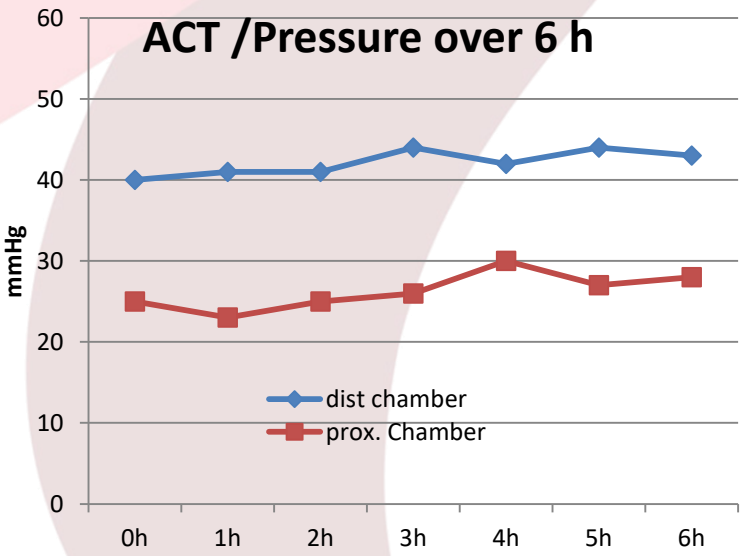
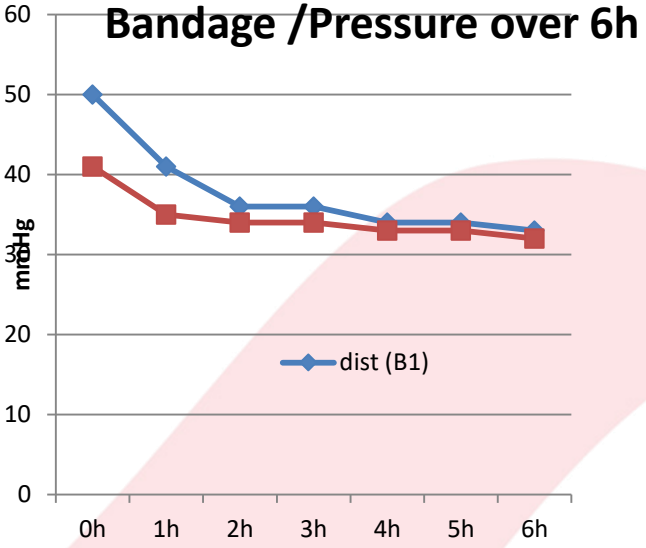
Pressure kept constant over time





Hybrid Compression

Summary

- Device development guided by "physician users"
- Easy to use
- Portable
- Delivers reliable pressures
- Self-adjusting
- Therapy tracker
- Delivers sustained and intermittent pneumatic compression

Dose-response of compression therapy for chronic venous edema—higher pressures are associated with greater volume reduction: Two randomized clinical studies

Conclusions

- Pneumatic compression was safe and well tolerated
- Dose response relationship observed
  Re: SPC/IPC pressures and edema reduction
- Higher pressures: *greater volume reduction in patients with chronic venous disease*

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Vanscheidt W et al
J Vasc Surg 2009; 49:395-402

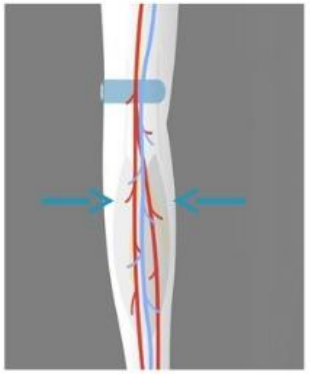
Where next in Compression?

- Improve the diagnosis
- Treat the venous disease whenever possible
  - When and how?
- Understand how and how much compression should be used
  - Graduated, progressive, tailored to the individual
- Develop more effective compression systems that are:
  - Responsive
  - Self managed
  - Comfortable
  - Allow patient managed care

Future? Venous return without compression

The Geko - How it works and mechanism of action

- The geko™ device stimulates the common peroneal nerve to activate the calf muscle pumps
- Increases blood flow volume and velocity
- Achieves a blood flow rate of 50-70% of walking - measured by duplex ultrasound in the femoral vein



A. T. Tucker, A. Maass, D. S. Bain et al. Augmentation of venous, arterial, and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve. Int. J. Angiol. 2010; 19 (1): e31-e37

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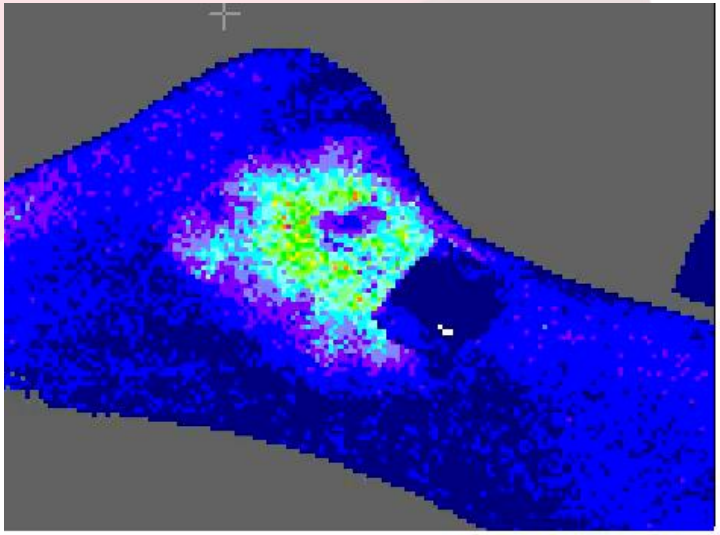
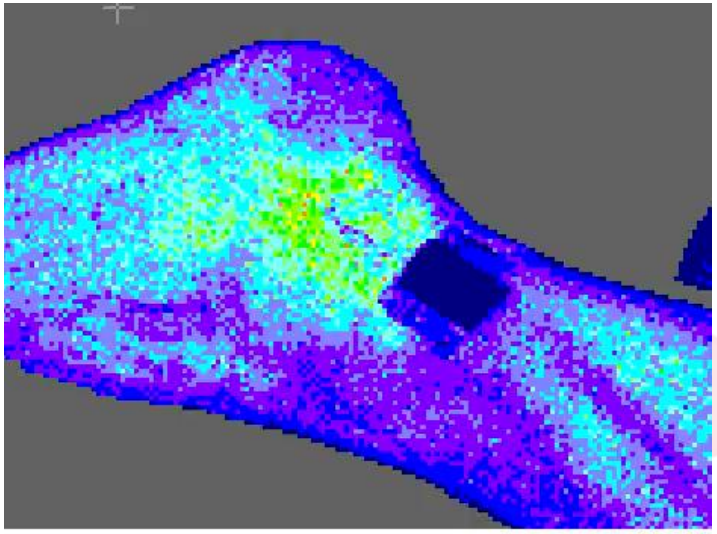
Venous Leg ulcer

Laser speckle contrast imaging



Baseline



geko™

Wound bed – 225% increase in flux ($p<0.001$)
Peri-wound – 67% increase in flux ($p<0.001$) – patient had active infection, this area therefore had more flux than usual so this figure is lower than expected

- 1. Partsch, H., Moffatt, C. An overview of the science behind compression bandaging for lymphoedema and chronic oedema. In: Compression Therapy: A Position Document on Compression Bandaging. International Lymphoedema Framework in Association with the World Alliance for Wound and Lymphoedema Care, pp.12–22, 2012.
- 2. Kelechi, T.J., Johnson, J.J., Yates, S. Chronic venous disease and venous leg ulcers: an evidence-base update. Journal of Vascular Nursing. 2015; 33: 2, 36-46.
- 3. Deng, J., Radina, E., Fu, M.R., et al. Self-care status, symptom burden, and reported infections in individuals with lower extremity primary lymphedema. Journal of Nursing Scholarship, 2014; 47:2, 126-134.
- 4. Fetzer, A., Wise, C. Living with lipoedema. Reviewing different self-management techniques. British Journal of Community Nursing, Chronic Oedema Supplement, 2015; 20:10, S14-19.
- 5. Miller, C., Kapp, S., Newall, N., et al. Predicting concordance with multi-layer compression bandaging. Journal of Wound Care. 2011; 20: 3, 101-112.
- 6. Partsch, H. Compression for the management of venous leg ulcers: which material do we have? Phlebology. 2014; 29: 1S, 140-145.

- 7. Lymphoedema Framework. Best Practice for the Management of Lymphoedema, International consensus. London: MEP Ltd, 2006.
- 8. Tidhar, D., Hodgson, P., Shay, C., Towers, A. A lymphedema self-management programme: Report on 30 Cases, Physiotherapy Canada. 2014; 66: 4, 404-412.
- 9. Damstra, R.J., Partsch, H. Prospective, randomised controlled trial comparing the effectiveness of adjustable compression VELCRO® wraps versus inelastic multi-component compression bandages in the initial treatment of leg lymphedema. Journal of Vascular Surgery: Venous and Lymphatic Disorders. 2013; 1: 1, 13-19.
- 10. Mosti, G., Cavezzi, A., Partsch, H., et al. Adjustable Velcro compression devices are more effective than inelastic bandages in reducing venous edema in the initial treatment phase: a randomised controlled trial. European Journal of Vascular and Endovascular Surgery. 2015; 50: 3, 368-374.
- 11. NICE. The Juxta-CURES adjustable compression system for treating venous leg ulcers. Available at: https://www.nice.org.uk/advice/mib25/chapter/Evidence-review, NICE Advice MIB25, March 2015.
- 12. Nelson et al (2014) Intermittent Pneumatic Compression for treating venous leg ulcers. Cochrane Database of Systematic Reviews. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001899.pub4/full

The Challenge of Clinical Practice : How to compress these patients?

The future

In conclusion, these four review papers describe advances in wound-healing research of relevance to the care of patients with wounds throughout the world. These expert authors confirm that a better understanding of the biology of wound healing is essential for therapeutic advances that will impact on patient care. As with other areas of dermatology, the prospect of precision medicine with targeted therapies for specific patients is also a realistic prospect for wound healing. However, the most important issue is to develop healthcare systems to widen access for patients with wounds to multidisciplinary teams of wound-healing clinicians. The evidence suggests that significant benefits to patients will accrue when wounds and wound healing receive the attention they need.

Harding BJD Aug 2015