

# VenoTrain® angioflow COMBINATION OF CVI AND PAD: THE BENEFITS OF A SPECIALLY DESIGNED COMPRESSION STOCKING

STÜCKER, M., HOFFMANN, M. & REICH-SCHUPKE, S.

Background: Up until now, only special bandage systems have been available for compression therapy in patients with a combination of chronic venous insufficiency (CVI) and peripheral artery disease (PAD). The effects of a newly designed suitable compression stocking have now been investigated for the first time.

#### STUDY DESIGN

- Prospective case series
- 50 patients with combined CVI (CEAP: C3 C5) and PAD (ABI
   < 0.9 and > 0.5; absolute ankle-arterial pressure of > 60 mmHg)
- 14 days wearing period, VenoTrain angioflow, at least 6 h a day
- Method: Blood pressure by means of acral photoplethysmography (APPG) and the CVI-specific symptom score using the VVSymQ questionnaire, subjectively assessed pain-free walking distance achieved, wearing comfort

#### RESULTS AND CONCLUSION

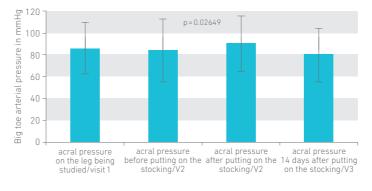
The systolic arterial pressure (big toe) showed no reduction and even significantly increased shortly after putting on the medical compression stockings (MCS). The VVSymQ score significantly improved over the course of the wearing period, while the subjectively assessed pain-free walking distance\* had also been significantly increased at the end of the study.

The VenoTrain angioflow compression stocking was well tolerated by patients with combined CVI/PAD.

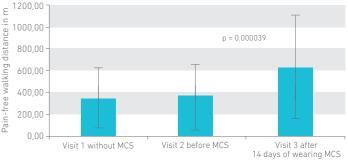
The VenoTrain angioflow compression stocking showed no negative effects on systolic arterial pressure.

The VenoTrain angioflow compression stocking significantly improved CVI symptoms and significantly extended the subjectively assessed pain-free walking distance\*.

#### Systolic arterial pressure in the big toe



#### Pain-free walking distance



Stücker, M., Danneil, O., Dörler, M., Hoffmann, M., Kröger, E., & Reich-Schupke, S. (2020). Sicherheit eines Kompressionsstrumpfes für Patienten mit chronischer venöser Insuffizienz (CVI) und peripherer arterieller Verschlusskrankheit (pAVK). JDDG: Journal der Deutschen Dermatologischen Gesellschaft, 18(3), 207-214.

\* unpublished data of the study

# VenoTrain® cocoon INFLUENCE OF MEDICAL COMPRESSION STOCKINGS ON SKIN MOISTURE IN PATIENTS WITH CHRONIC VENOUS INSUFFICIENCY

WESTPHAL, T., KONSCHAKE, W., HAASE, H., VOLLMER, M., JÜNGER, M., & RIEBE, H.

Background: Skin dryness and itchiness can be side effects of CVI therapy with MCS. MCS with integrated skin care can therefore have a positive effect on skin moisture.

#### STUDY DESIGN

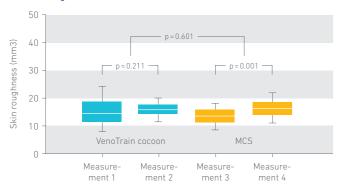
- Randomized, prospective, controlled study
- Comparison of the VenoTrain cocoon with a conventional MCS (VenoTrain micro) in Ccl 2
- 50 patients with CVI
- Observation period of 28 days, wearing period of 8 hours daily
- Primary parameter: skin moisture on the lower leg, measured on day 1 (before wearing the stocking, V1) and 28 (V2)
- Other parameters: roughness of the skin, wearing comfort, and quality of life

#### RESULTS AND CONCLUSION

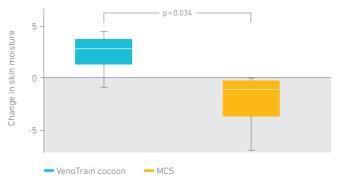
- Significant superiority in terms of maintaining skin moisture when wearing the VenoTrain cocoon
- No increase in skin roughness when wearing the VenoTrain cocoon
- These protective effects were found particularly in patients with initially low skin moisture levels and in male patients
- The VenoTrain cocoon was rated as significantly more comfortable
- No differences between the compression stockings with regard to leg symptoms, functionality, and decrease in leg volume

The VenoTrain cocoon shows a positive effect on maintaining the skin barrier due to its integrated skin care.

#### Microtopographic analysis of skin roughness before and after wearing MCS



#### Patients with initial low skin moisture showed a significant improvement after 28 days of wearing MCS



#### VenoTrain® cocoon EVIDENCE OF IMPROVED BENEFITS OF MEDICAL COMPRESSION STOCKINGS DUE TO INTEGRATED SKIN CARE

**BAUERFEIND ACADEMY** 

#### **FUNCTIONAL MATERIAL TESTING**

### OBSERVATIONAL STUDY DURING THE DEVELOPMENT PHASE

5

#### STUDY DESIGN

- Wash test with 180 washes to simulate 6 months of MCS use
- Concentration of skincare substance in the knitted fabric determined by the Thuringian Institute of Textile and Plastics Research (TITK)

#### STUDY DESIGN

- VenoTrain cocoon compared to competitor MCS (with skincare substance)
- 40 patients with CVI
- Primary parameter: skin moisture

#### RESULTS AND CONCLUSION

- After 180 washes the average for six months' use 70% of the skincare complex is still retained in the thread structure
- The VenoTrain cocoon retains 70% of the skincare substance despite multiple washes.

#### **RESULTS AND CONCLUSION**

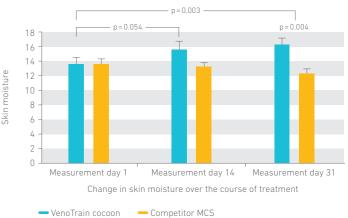
- VenoTrain cocoon improves the skin moisture significantly over 4 weeks
- Significantly improved skin moisture compared to competitor MCS also found after 4 weeks

Compared with another MCS with skin care, the VenoTrain cocoon can significantly improve skin moisture.

#### ${\bf Skincare\ substance\ content\ in\ VenoTrain\ cocoon\ during\ functional\ material\ testing}$



#### Wearing test with CVI patients



Westphal, T., Konschake, W., Haase, H., Vollmer, M., Jünger, M., & Riebe, H. (2019). Medical compression stockings on the skin moisture in patients with chronic venous disease. Vasa.

### EVIDENCE OF THE EFFICACY OF MEDICAL COMPRESSION STOCKINGS OF RAL CLASS 1

FOR MILD LEG SYMPTOMS AND MILD CHRONIC VENOUS INSUFFICIENCY BLÄTTLER, W., THOMÄ, H. J., WINKLER, C., & AMSLER, F.

Background: One reason for the low prescription rates of MCS in RAL class 1 (Ccl 1, 18–21 mmHg) is physicians' low level of confidence in the clinical efficacy of these MCS for venous leg symptoms and the mild form of CVI. However, the difficulty associated with putting on a higher compression class MCS often leads to reduced compliance amongst patients with mild leg symptoms.

#### STUDY DESIGN

- 46 healthy test subjects
- Leg volume measurement (BODYTRONIC 600) during 10 minutes of standing directly after 3 minutes of lying down
- Day 1 measurement without MCS, recording of leg symptoms, numerical rating scale (NRS 1–10)
- Day 2 measurement (D1) with VenoTrain micro balance Ccl 1 (discontinued) on test subjects who reported leg symptoms (n = 24)
- Day 3 measurement (D2) with VenoTrain micro Ccl 2 on the same test subjects

#### RESULTS AND CONCLUSION

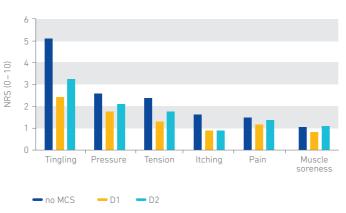
- During 10 minutes of standing, a continuous increase in volume of the lower leg was measured (44 ml without MCS)
- By contrast, the increase in leg volume was just 28 ml (64%) with MCS Ccl 1 and 22 ml (50%) with MCS Ccl 2
- The symptoms which occurred were alleviated to the same extent by both classes of stocking

MCS Ccl 1 were able to reduce the volume increase of the lower leg by a similar degree as an MCS Ccl 2, and the same applies to the recorded leg symptoms.

#### Volume increase in the lower leg during the standing test



Nature and perception of the symptoms occurring during the standing test



### HEMODYNAMIC EFFECT OF COMPRESSION STOCKINGS

LATTIMER, C., KALODIKI, E., AZZAM, M., & GEROULAKOS, G.



Background: The effect and performance of medical compression stockings depends on a patient's hemodynamic disease profile. The study compares the hemodynamic effects of VenoTrain compression stockings in Ccl 1 and Ccl 2 on patients and healthy test subjects.

#### STUDY DESIGN

- 12 healthy test subjects (control), 12 patients per group:
- 1) with varicose veins (VV);
- 2) with post-thrombotic syndrome (PTS), and
- 3) lymphedema (lymph)
- Recorded parameters: Air-plethysmography before and after wearing the MCS (including working venous volume, venous filling index, venous drainage index, ejection fraction) and the maximum increase in calf volume und outflow fraction

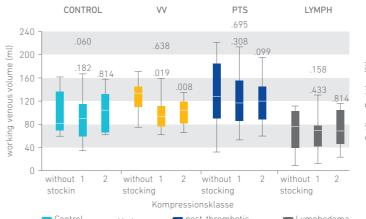
#### RESULTS AND CONCLUSION

- Patients with varicose veins showed a significant reduction in the working venous volume and venous filling index using MCS Ccl1
- The increase in the maximum ankle volume was improved in all groups, except for patients with post-thrombotic syndrome
- The outflow fraction only showed a significant improvement in healthy test subjects and patients with varicose veins

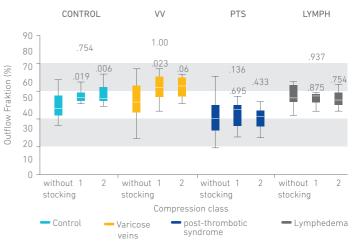
2 Patients with varicose veins benefitted the most from MCS.

The performance of the MCS depends more on the disease pathophysiology than on the compression strength.

#### Working venous volume



#### Outflow fraction



Lattimer C., Kalodiki E., Azzam M., Geroulakos G. Haemodynamic performance of low strength below knee graduated elastic compression stockings in health, venous disease, and lymphoedema. European Journal of Vascular and Endovascular Surgery, 2016;52(1):105–12.

### VenoTrain® ulcertec TREATMENT OF VENOUS LEG ULCERS

EFFICACY OF THE VENOTRAIN ULCERTEC COMPARED WITH A CONVENTIONAL COMPRESSION BANDAGE JÜNGER, M., WOLLINA, U., KOHNEN, R., & RABE, E.

"For patients with venous leg ulcers, higher healing rates are achieved with compression therapy using VenoTrain ulcertec than when using conventional compression bandages."

#### Prof. Dr. Michael Jünger

Director of the Department of Dermatology, University Hospital Greifswald

#### STUDY DESIGN

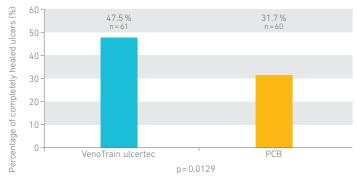
- 121 patients with venous leg ulcers (ITT population)
- Study of the efficacy of the VenoTrain ulcertec compared with a phlebological compression bandage (PCB)
- Compression therapy for a minimum of 8 hours per day
- Observation over 12 weeks or until the ulcer is healed

#### RESULTS AND CONCLUSION

- Significant superiority of the stocking system with a healing rate of 47.5% compared with 31.7% for the compression bandage
- 30% more mobility with use of VenoTrain ulcertec
- Very good usability ratings by the patients themselves and by medical professionals

The VenoTrain ulcertec stocking system led to higher healing rates in comparison with the phlebological compression bandage – along with improved wearing comfort and greater acceptance among nursing staff.

#### Comparison of response rates for completely healed ulcers (ITT population)



#### Jünger, M., Wollina, U., Kohnen, R., & Rabe, E. (2004). Efficacy and tolerability of an ulcer compression stocking for therapy of chronic venous ulcer compared with a below-knee compression bandage: results from a prospective, randomized, multicentre trial. Current medical research and opinion, 20(10), 1613–1623.

#### VenoTrain® ulcertec COMPRESSION IN THE TREATMENT OF CHRONIC VENOUS INSUFFICIENCY: EFFICACY DEPENDING ON THE LENGTH OF THE STOCKING

KONSCHAKE, W., RIEBE, H., PEDIADITI, P., HAASE, H., JÜNGER, M., & LUTZE, S.

Background: Compression therapy is the only effective conservative method in the treatment of chronic venous insufficiency (CVI). However, the extent to which the efficacy depends on the length of the compression stocking is unclear.

#### STUDY DESIGN

- Patients with CVI (n = 16, CEAP: C3-C6)
- Stocking varieties: one knee-length two-component compression stocking (VenoTrain ulcertec, 37 mmHg (AD) in total) and two two-component thigh-length compression stockings, (AD + AG; AG 37 mmHg and AG 45 mmHg in total), 1 week each
- Measurement technique: BODYTRONIC 600 (Bauerfeind AG) to measure the change in leg volume, plethysmography to measure the venous outflow fraction and the venous filling index, questionnaire to determine quality of life and wearing comfort

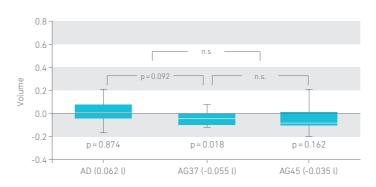
#### RESULTS AND CONCLUSION

The volume of the lower leg and thigh was reduced by the thigh-high compression stocking system, while the knee-high compression stocking system only reduced the volume of the lower leg. The venous ejection fraction and venous filling index were improved by all the compression stockings, but the effect of the thigh-high compression system was stronger. The quality of life and wearing comfort was rated the same for all compression stockings used.

Compression stockings are an effective method for treating CVI.

Thigh-high (AG) compression stocking systems have an improved effect and yet do not affect the wearing comfort.

#### Change in volume of the thigh



#### VenoTrain® ulcertec COMPRESSION STOCKINGS REDUCE HYPERTENSION OF CAPILLARIES AT THE TOE OF PATIENTS WITH CVI

OELERT, A., KITTEL, M., HAHN, M., HAASE, H., & JÜNGER, M.

Background: Chronic venous insufficiency (CVI) is characterized by altered hemodynamics in the veins of the legs that manifests in a number of ways, including hypertension of the capillaries in the foot. According to the hypothesis, it ought to be possible to reduce or normalize this by wearing compression stockings.

#### STUDY DESIGN

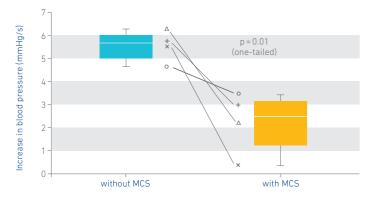
- Patients with CVI (n = 4, CEAP: C4 and C6)
- Method: Capillary pressure under "resting" and "dynamic" conditions when lying down, repeated measurements with and without MCS (VenoTrain ulcertec), targeted activation of the venous pump using a blood pressure cuff (60 mmHG for 60 seconds, servo-nulling technique)

#### RESULTS AND CONCLUSION

The capillary blood pressure was sharply increased through the targeted simulation of the calf muscle pump activity when not wearing MCS. It was possible to reduce this increase significantly by wearing compression stockings (VenoTrain ulcertec) at the same time

Compression stockings can significantly reduce capillary hypertension.

#### Change in blood pressure of capillaries at the toe



Oelert, A., Kittel, M., Hahn, M., Haase, H., & Juenger, M. (2018). Medical compression stockings reduce hypertension of nailfold capillaries at the toe of patients with chronic venous insufficiency. Clinical hemorheology and microcirculation, 69(1–2), 115–121.

### **BODYTRONIC 600® – DIGITAL MEASUREMENT TECHNOLOGY FOR PREMIUM QUALITY CARE**

PRECISE, NON-INVASIVE DIGITAL 3D MEASUREMENT FOR PREMIUM QUALITY CARE

Measurement of leg circumference and leg volume: introduction of a new optical 3D measurement technique

Tischer, T., Oye, S., Wolf, A., Feldhege, F., Jacksteit, R., Mittelmeier, W., Bader, R., & Mau-Moeller, A.

#### STUDY DESIGN

- Review of measurement accuracy: comparative measurement of a human/test body and creation of 3D images using
   a) Radiation-free light projection (BODYTRONIC 600)
   b) Computed tomography (CT)
- Review of reproducibility: serial measurements of test bodies (n = 10) and humans (n = 20; 3 measurements each) with BODYTRONIC 600 to determine the circumference and volume of the lower extremities

Pilot study on the influence of MCS on post-operative leg swelling after arthroscopy

Tischer, T. S., Oye, S., Lenz, R., Kreuz, P., Mittelmeier, W., Bader, R., & Tischer, T.

#### STUDY DESIGN

- Randomized, controlled pilot study
- Use of Ccl 2 MCS (VenoTrain soft) for post-operative treatment after arthroscopy (after 24 hours of bandaging and prophylactic heparin treatment)
- n = 11 with MCS; n = 8 without MCS
- Primary parameters: measurement of leg circumference and leg volume taken after 1, 4 and 10 day(s) using BODYTRONIC 600 (without MCS)
- Secondary parameters: pain assessment using the visual analog scale (VAS) and range of motion (ROM)

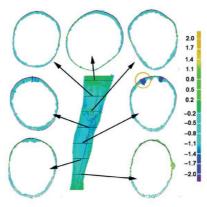
#### RESULTS AND CONCLUSION

- 3D surface analysis with BODYTRONIC 600 vs. CT predominantly showed max. ± 1 mm deviation
- Serial measurements (humans and test bodies) yielded very precise and reproducible values

Measurement using digital measurement technology is 11.5 times faster than manual measurement and delivers very accurate and reproducible values (error rate <1%, i.e. 0.5–5.0 ml).

BODYTRONIC 600 measurement technology has proven its competitiveness with the currently most accurate method (CT). Unlike CT, it does not expose the subject to radiation and can therefore be repeated as often as desired.

Deviation of surface measurement with 3D model – BT600 vs. CT scan  $\,$ 



Tischer, T., Oye, S., Wolf, A., Feldhege, F., Jacksteit, R., Mittelmeier, W., Bader, R., & Mau-Moeller, A. (2019). Measuring lower limb circumference and volume-introduction of a novel optical 3D volumetric measurement system. Biomedical Engineering/Bio-

#### **RESULTS AND CONCLUSION**

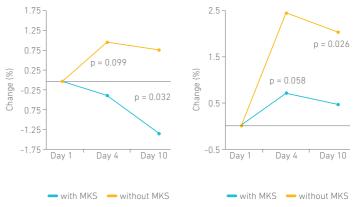
- Significant differences in circumference for cF (mid-thigh) and cD (knee) on Day 10
- Volume reduction of 1.35 percent with MCS vs. increase of 0.79 percent without MCS; significant differences in thigh volume between the groups on Day 1 and 4
- No differences in level of pain experienced between the groups  $% \left( 1\right) =\left( 1\right) \left( 1\right) \left($

Ccl 2 MCS significantly reduced post-operative swelling of the leg.

Measurement using BODYTRONIC 600 enables precision in a low percentage range.

Change in thigh circumference (cF))

Change in knee circumference (cD)



Tischer, T. S., Oye, S., Lenz, R., Kreuz, P., Mittelmeier, W., Bader, R., & Tischer, T. (2019). Impact of compression stockings on leg swelling after arthroscopy-a prospective randomised pilot study. BMC musculoskeletal disorders, 20(1), 161.

## ACUTE AND LONG-TERM EFFECT OF MEDICAL COMPRESSION STOCKINGS ON ENDURANCE ATHLETES WITH VENOUS INSUFFICIENCY

MOEHRLE, M., KEMMLER, J., RAUSCHENBACH, M., VENTER, C., NIESS, A., HÄFNER, H. M., & STROELIN, A.

"Typical CVI symptoms in athletes with venous insufficiency can be effectively alleviated using compression therapy."

#### Prof. Dr. Anke Strölin

Chief Physician, University Department of Dermatology, Tübingen

#### STUDY DESIGN

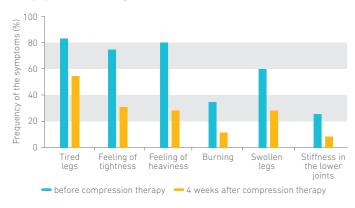
- 44 athletes (long-distance runners, cyclists) with venous insufficiency
- Standardized treadmill and bicycle ergometry multiple-level tests; testing with/without compression stocking and after 4-week compression therapy with the VenoTrain champion (now called VenoTrain business)
- Prospective and retrospective survey of subjective CVI symptoms

#### RESULTS AND CONCLUSION

- No significant effect on physiological parameters (lactate, heart rate) during the performance test after acute or four-week treatment with compression stockings
- Significant decrease in typical CVI symptoms in everyday life and after training
- No negative impact on performance by the compression therapy
- Positive subjective evaluation of the wearing comfort with a high level of compliance

Compression stockings led to a significant decrease of the symptoms and thus can be recommended to athletes with CVI

#### CVI symptoms after training



Moehrle, M., Kemmler, J., Rauschenbach, M., Venter, C., Niess, A., Häfner, H. M., & Stroelin, A. (2007). Akut-und Langzeiteffekt von Kompressionsstrümpfen bei Sportlern mit venöser Insuffizienz. Phlebologie, 36(06), 313 – 319.

### EFFECT OF ELASTIC COMPRESSION ON MARATHON RUNNERS

ALLAERT, F. A., GARDON-MOLLARD, C., & BENIGNI, J. P.

"By wearing compression stockings, marathon runners can optimize their performance during the race and positively influence the recovery of the muscles afterwards."

#### Prof. Dr. François André Allaert

Chaire d'Evaluation Médicale des Allégations de Santé, ESC, Dijon, France

#### STUDY DESIGN

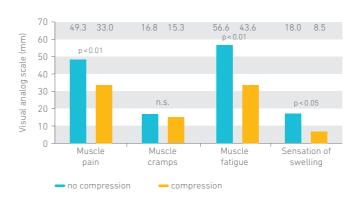
- Non-interventional, randomized case-control study on the adjustment of muscles to stress and recovery in marathon runners
- 43 test subjects ran a marathon with compression stockings (18 – 21 mmHg; G1) and 43 without (G2)
- After the race, and on the four days that followed, the test subjects were asked about various symptoms

#### RESULTS AND CONCLUSION

- Runners in G1 had a smaller gastrocnemius vein diameter and a less pronounced sensation of swelling (visual analog scale from 0 to 100) directly after the race
- After the race, they reported lower levels of muscle pain and muscle fatigue
- In the case of three of the four symptoms investigated, there was a significant improvement directly after the race and in the three days that followed

Medical compression stockings protect veins. They help muscles better adjust to the stress of endurance sport and promote regeneration.

#### Symptoms immediately after loading



Allaert, F. A., Gardon-Mollard, C., & Benigni, J. P. (2011). Effet d'une compression élastique de classe II française (18–21 mmHg) sur l'adaptation musculaire à l'effort et la récupération des marathoniens. Phlébologie, 64(4), 57–62.

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#### **BAUERFEIND SUPPORTS RESEARCH**

#### **DOCTORAL PROGRAM**



Bauerfeind AG and the German Society of Phlebology offer a support program for young scientists at national level. This is aimed at academics who wish to obtain a doctorate in the fields of phlebology or lymphology. Every year, the program awards EUR 5,000 each to a maximum of two applicants.

#### **BAUERFEIND PHLEBOLOGY AWARD**



Every two years, Bauerfeind AG awards the Bauerfeind Phlebology Award on an international level with EUR 20,000 in prize money, in association with the International Union of Phlebology (UIP). This prize commends scientists chosen by an international jury who have designed outstanding studies in the field of phlebology.

#### **Previous projects:**

#### Sophie Kindermann (2020)

"Side effects and wearing comfort of compression stockings in people with orthostatically caused discomfort and oedema based on sitting occupation"

Greifswald University Hospital, Department of Dermatology

#### André Janssen (2020)

"Venous hemodynamics of the femoral vessels in comparison of water pressure versus classical compression therapy" Schleswig-Holstein University Hospital, Clinic of dermatology, allergology and venereology



The 2020 sponsorship prize was awarded by Prof. Dr. Markus Stücker (President of the DGP [German Society of Phlebology], left) and Dr. Antje Mark (right) to Sophie Kindermann (2nd from left) and André Janssen (2nd from right)

#### Carolin Mitschang (2019)

"Quality of life in patients with diagnosed saphenous vein insufficiency before and after conducting radiofrequency ablation" Münster University Hospital, Clinic and Polyclinic for Skin Diseases

#### Irene Döll (2019)

"Evaluation of acceptance and user satisfaction after teledermatology treatment in the central emergency department of Greifswald University Hospital using the teledermatology system Mobil Skin®" Greifswald University Hospital, Department of Dermatology

#### **Previous winners:**

#### Prof. Mark Whiteley & Dr. Emma Budd (2019) - (UK)

The Whiteley Clinic

"Influence of compression treatment in patients with Pelvic Congestion Syndrome (PCS)"



The Bauerfeind Phlebology Award was awarded to Prof. Mark Whiteley (center) during the UIP Chapter Meeting 2019 in Krakow.

#### Alberto Caggiati (2018) – (I)

MD, PHD

"Skin sonography in swollen legs. Basic findings and effects of medical elastic compression stockings (MECS)"

#### Prof. Dr. Győző Szolnoky (2015) – (H)

Phlebo-Lymphology and Wound Care Unit, Departmentof Dermatology and Allergology, Univerity of Szeged, Szeged, Hungary "Elastic compressionelicited beneficial cardiovascular effects: acomplex clinical study in healthy, lymphedematousand lipedematous individuals"

#### Dr. Christopher Richard Lattimer (2013) – (UK)

Ealing and Northwick Park Hospitals

"Stocking Outflow Performance in Venous and Lymphatic Disease"





More information and all prize winners in recent years at:

www.bauerfeind-group.com/en/ knowledge/research-and-development/ bauerfeind-phlebology-award.html

#### THE RATSCHOW MEMORIAL MEDAL



With the support of the Curatorium Angiologiae Internationalis, Bauerfeind AG honors the lifetime achievements of scientists. Every year since its foundation in 1969, the Curatorium has been awarding the Ratschow Memorial Medal, named after Max Ratschow, the father of German angiology.

The distinguished French phlebologist and angiologist Dr. Michel Schadeck (middle) was awarded the Max-Ratschow-Memorial Medal to honor his life's work during the 62nd congress of the German Phlebologist Society in Leipzig. Dr. Schadeck was one of the pioneers of the ultrasound assisted liquid sclerotherapy of the saphenous veins. He presented the technique in 1985 during a conference in Paris, which started a paradigm shift of the sclerotherapy at that time.

This minimally invasive and outpatient surgery technique is used to close varices of the lower extremities and is with ca. 14,000 surgeries daily the most frequent and cost-efficient method worldwide.



Prof. Dr. Eberhard Rabe (president of the curatorium, left) and Dr. Antje Mark (Product Management Phlebology Bauerfeind AG, right) award the Ratschow Memorial Medal to Dr. Michel Schadeck (center).

#### **OUR SERVICE FOR YOU**

The daily routine of treating patients and managing a practice leaves little time for keeping up with the latest research findings and further training opportunities. Bauerfeind is committed to offering you support in this area. On our website you can find a variety of services designed to help you find

important information at a glance. You can access interesting case studies, a summary of (CME) training and event information, a handy overview of all VenoTrain products, and a list of medical aid numbers for a wide range of Bauerfeind products.



You can find this and much more at: www.bauerfeind-group.com/en/service/downloads.html



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