Current study demonstrates the high variance of biomechanical properties of standard commercially available MTPS

Biomechanical characterisation of medical thrombosis prophylaxis stockings (MTPS)

By Wegener U, Kraft M, Kröger K, et al. Gefäßchirurgie 2013;18:278-286

Introduction

The current German AWMF guideline recommends the use of medicinal and/or physical measures for the prevention of venous thromboembolisms[1]. Among the physical measures, medical thrombosis prophylaxis stockings (MTPS), in particular, have been used in Germany for the prevention of thromboembolic complications for over 30 years. However, the guideline is cautious in its recommendations regarding MTPS, as a high level of evidence is lacking from current randomised, controlled clinical trials (RCTs) at present. A Cochrane Review published in 2010, which summarises the effectiveness of MTPS investigated on their own or supplementary to medicinal prophylaxis in 18 RCTs, demonstrates the efficacy of the sole application of MTPS compared with controls (without prophylaxis)[2]. However, it also shows the superiority of the combined application of MTPS with medicinal prophylaxis compared with MTPS alone. Here, it must be noted that the review comprises studies published between 1971 and 1996. Since then, medicinal prophylaxis as well as textile technology for the production of MTPS have developed further.

In international guidelines, the prospective, randomised CLOTS 1 trial is often cited, which failed to show a significant difference between patients with and without MTPS with regard to newly occurring thrombosis in patients after an acute stroke[3]. Although this trial is frequently cited, it is mostly overlooked that the MTPS T.E.D. (Covidien, USA) was used in this study for reasons of comparability with other study results. However, it is well known that the MTPS produced by different manufacturers differ markedly from each other with regard to their biomechanical properties (cf. ACCP)[4]. This heterogeneity makes it difficult to compare them with each other and hampers an assessment of their effect compared with other prophylactic measures. However, a uniform evaluation of MTPS with regard to their thrombosis prophylactic benefit will only produce meaningful results if MTPS achieve the same biomechanical effect and a predictable reduction in vessel cross-sections on the patient. Stockings with a different pressure profile and possibly better biomechanical properties have yet to be subject to a comparative clinical assessment. Therefore, the objective of the investigation described here was to biomechanically characterise MTPS produced by different manufacturers with regard to their specific pressure profiles.

Biomechanical principles of the effect of MTPS

The objective of compression therapy is to increase the velocity of blood flow in the veins and thus counteract the risk of thromboses developing. This is achieved physically by reducing the total cross-section of the venous system in the lower limbs. To this end, a contact pressure of 18 mmHg is applied in the area of the ankle and should decline continuously from distal to proximal. MTPS are supplied as round-knit stockings. In order to guarantee a continuously declining pressure gradient, an elastic compression thread with a defined pre-tension is inserted during production. The elasticity of the knitting thread and the type of mesh formation also play a considerable role in the range of sizes and longitudinal elasticity of the knitted fabric and can differ correspondingly from manufacturer to manufacturer.

Requirements

At present, there are no recognised standards for evaluating MTPS. A preliminary standard drawn up by the German Institute for Standardisation (Deutsches Institut für Normung, DIN ENV 12719:2001) has stipulated four requirements for optimum MTPS, which can be employed as criteria for evaluating MTPS (see box)[5]: In the present investigation, MTPS produced by different manufacturers were measured in relation to these criteria and compared with each other

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Requirements placed on MTPS (ENV 12719:2001)

a. The practical stretching (residual stretching at maximum leg profile) may not amount to less than 15% over the entire length of the stocking.

b. The compression of the stocking at the ankle must be between 13 mmHg and 18 mmHg. The compression at the ankle may not exceed a limit value of ±3 mmHg.

c. The residual pressure behaviour of the stockings must be within the following ranges:
   - Ankle (measuring point B1): 80% to 100%
   - Lower leg/Calf (measuring point C): 60% to 80%
   - Thigh (measuring point G): 30% to 70%

d. Constantly declining pressure profile: The residual pressure may not show a higher value at any measuring point along the leg (apart from in the area of the topband) than the residual pressure at the distal reference point.

Material and Method

Ten MTPS test samples of medium size from each of four different manufacturers were measured:

- Comprinet® pro (BSN medical)
- T.E.D.™ (Covidien)
- Cambren® (Hartmann)
- mediven® thrombexin® 18 (medi GmbH & Co KG)

The test method used was the Hohenstein System (HOSY) for determination of the pressure profiles based on the measuring methodology of the DIN 58133 and RAL GZ-387. The advantage of this procedure is that the results can be compared effectively with the results of previous comparative investigations conducted by other authors. The leg profiles of all MTPS investigated for which no details on leg profiles were available from the manufacturers were supplemented linearly according to RAL specifications. A good approximation between the manufacturers' details and determination of the leg profiles according to RAL was only achieved by the products Comprinet® pro (BSN medical) and mediven® thrombexin® 18 (medi GmbH).

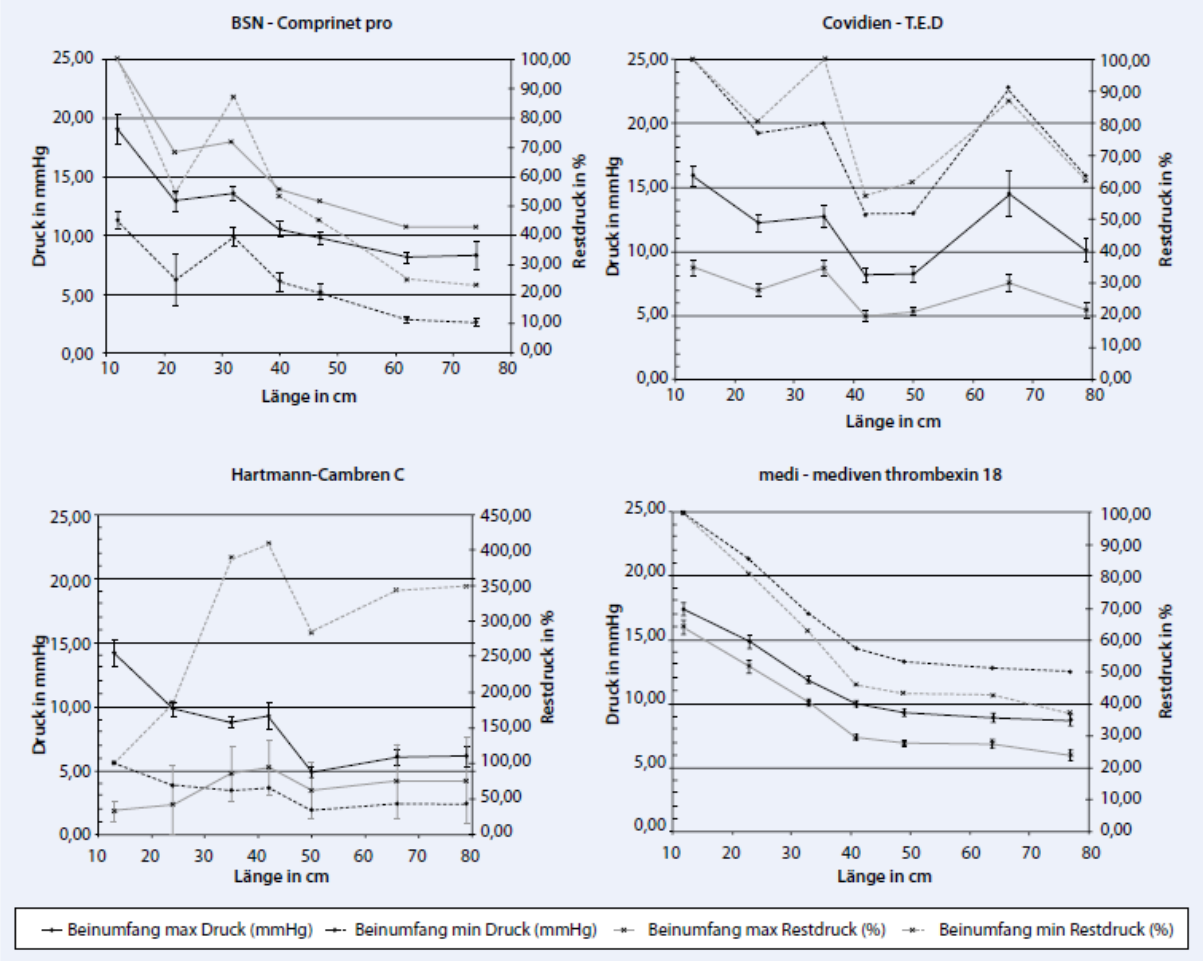
Results

The results show considerable variability in the pressure behaviour of the four MTPS investigated (see Figure). Here, the MTPS **mediven® thrombexin® 18 (**medi) showed a constantly declining pressure gradient. The compression declined continuously between 10 and 40 cm (calf) and also showed a constantly declining pressure in the area of the thigh (50 to 70 cm) (pressure in the area of the ankle 17.4 mmHg; pressure at the thigh 8.90 mmHg).

Comprinet® pro (BSN medical) showed a similar result, although the decrease in pressure in the area of the calf was not continuous (pressure in the area of the ankle 19.1 mmHg; pressure at the thigh 8.14 mmHg), increasing again between 20 and 30 cm.

T.E.D.™ (Covidien), like Comprinet® pro, did not show a continuously declining pressure gradient in the calf. In addition, it showed a pressure increase in the thigh between 60 and 70 cm. At this point, the pressure level in the area of the ankle (10 cm) was almost achieved (pressure in the area of the ankle 15.9 mmHg; pressure at the thigh 14.5 mmHg).

Cambren® C (Hartmann) showed very inhomogeneous results. Thus, none of the standard specifications were fulfilled in relation to the minimum figures. The required ankle pressure was not achieved by a considerable margin. In the case of the maximum figures, the leg profile also showed pressure increases in the area of the calf and thigh, even if they were not as marked in the thigh as those of the T.E.D.



Druck in mmHg = Pressure in mmHg
Restdruck in % = Residual pressure in %
Länge in cm = Length in cm

Beinumfang max Druck (mmHg) = Leg circumference max. pressure (mmHg)
Beinumfang min Druck (mmHg) = Leg circumference min. pressure (mmHg)
Beinumfang max Restdruck (mmHg) = Leg circumference max. residual pressure (%)
Beinumfang min Restdruck (mmHg) = Leg circumference min. residual pressure (%)

Figure: Shows the values for the pressure (DR ± standard deviation) and the residual pressure (RD) over the course of the different measurement points for the minimum and maximum circumference stated in each case. Note that the diagram for the Cambren® C (Hartmann) has a different scale for the residual pressure.

Evaluation from a technical point of view

If one considers the requirements mentioned above to be met by an optimum MTPS (see box), it can be ascertained that they are only fulfilled to a certain degree by the four MTPS:

Requirements	Comprinet® (BSN medical)	T.E.D.™ (Covidien)	Cambren® C (Hartmann)	mediven® thrombexin® 18 (medi)
a. Residual stretching not less than 15% at max. leg profile	**fulfilled**	**fulfilled**	**fulfilled**[a]	**fulfilled**
b. Required compression in the area of the ankle	**fulfilled**	not fulfilled	**fulfilled**[a]	**fulfilled**
c. Specified residual pressures in the zones	not fulfilled	not fulfilled	not fulfilled	**fulfilled**[b]
d. Constantly declining pressure profile	not fulfilled	not fulfilled	not fulfilled	**fulfilled**

[a] only with the manufacturer's maximum figures; in the case of the leg profile with the manufacturer's minimum figures, no requirements are fulfilled
[b] in the case of the leg profile with the manufacturer's minimum figures, only just fulfilled

Evaluation from a medical point of view

The results of the biomechanical characterisation show that the MTPS produced by different manufacturers differ considerably with regard to their compressive properties. This confirms the results of previous comparative investigations.[6,7] The results of clinical trials conducted to date have not sufficiently taken into account the variance in the biomechanical properties of the MTPS available on the market. Generalised conclusions regarding the thromboprophylactic benefit of MTPS as a class of products would thus appear to be ineligible. Thus, the CLOTS 1 trial is often cited as proof of the lack of efficacy of MTPS in stroke patients or also in the entire group of internal medical patients[3]. However, this trial used the T.E.D.™ stocking produced by Covidien, which achieved the worst results in the current investigation. Against this background, other stockings with a better pressure profile, like the mediven® thrombexin® 18 (fulfilled all criteria), might well have achieved better clinical results. Above all, the lack of a graduated pressure gradient and an increase in the residual pressure to over 100% at more proximal leg segments mechanically represents a strangulating constriction and can lead to an impairment of venous flow. MTPS with such properties present an intrinsic thromboembolic risk and are unsuitable for prophylaxis. In addition, the correct, regular measurement of the legs, if necessary renewed fitting and daily inspection of the leg are prerequisite for the proper use of MTPS.

Conclusion and implications for use in practice

The results of this biomechanical characterisation of MTPS show that the assumption that all MTPS are equally effective cannot be upheld. In particular, MTPS that have frequently been used in trials do not yield convincing results for their biomechanical properties. When using MTPS, it is important to choose one that preferably fulfils all of the criteria for an optimum pressure gradient. In addition, correct leg measurement, regular re-measurement, selection of the correct length of MTPS, and checking of the fit according to the manufacturer's specifications are absolutely necessary to achieve optimum benefit and exclude risks. In order to be able to draw more precise conclusions about the true haemodynamic effect of different MTPS, further in-vivo measurements should be performed on test subjects.

References

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