CHECKING COMPLIANCE OF COMPRESSION STOCKINGS

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Checking compliance of CS

OUTLINE

- “Inventory”
- Thermotrack study
- Study of patient information quality
Checking compliance of compression stockings

- «Inventory»
  - In controlled studies
    - Compliance 90% after one month
    - 25% with a follow up over 5 years
Checking compliance of compression stockings

- Susan Kahn
- Compression stockings to prevent post-thrombotic syndrome: a randomized placebo-controlled trial
- MCS did not prevent PTS after a proximal DVT
- Compliance after 2 years: 45% of patients did not regularly wear MCS

Kahn SR et al
Compression stockings to prevent post-thrombotic syndrome: a randomised placebo-controlled trial.
Checking compliance of MCS

Causes of non-compliance

Key publications
Checking compliance of MCS

- Moffatt CJ.
  - Reviewed data (10 studies) on the reasons why compression therapy (MCS and bandages) for the treatment of venous ulcers was unacceptable by patients
  - Inapplicability, wear-comfort factors, feeling of constriction
  - Inefficacy

Moffatt C., Kommala D, Dourdin N, Choe Y
Factors that affect concordance with compression therapy.
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- Raju CJ et al
  - 3144 patients for 8 years
  - CEAP C0-2 67% C3 22% C4 4% C5 4% C6 3%
  - Only 21% used the stockings on a daily basis
  - 16% less often
  - 63% did not use the stockings

Raju S. et al.
Use of compression stockings in CVD: patient compliance and efficacy
Checking compliance of MCS

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could not state a specific reason</td>
<td>30%</td>
</tr>
<tr>
<td>Cosmetic, poor appearance</td>
<td>2%</td>
</tr>
<tr>
<td>Not recommended by doctor</td>
<td>25%</td>
</tr>
<tr>
<td>Aggravating, itching, dermatitis</td>
<td>2%</td>
</tr>
<tr>
<td>Ineffective, did not help</td>
<td>15%</td>
</tr>
<tr>
<td>Made symptoms worse</td>
<td>1%</td>
</tr>
<tr>
<td>Binding, cuts off circulation, poor fit</td>
<td>13%</td>
</tr>
<tr>
<td>Lack of self-discipline</td>
<td>0.5%</td>
</tr>
<tr>
<td>Too hot</td>
<td>7%</td>
</tr>
<tr>
<td>Cost considerations</td>
<td>0.4%</td>
</tr>
<tr>
<td>Soreness</td>
<td>2%</td>
</tr>
<tr>
<td>Work-related</td>
<td>0.2%</td>
</tr>
<tr>
<td>Needs application assistance</td>
<td>2%</td>
</tr>
</tbody>
</table>
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- Ziaja D et al.
  - 16770 patients with CVD used only by 25.6%
  - Use increased with higher clinical stages of CVD
  - 5.3% of patients discontinued the use of MCS

Zaija D., Kocelak P, Chidek J, Ziaja K.
Compliance with CS in patients with CVD
Phlebology 2011 Dec; 26(8): 353-60
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- High cost
- Sweating, itching, exudation lesions
- Cosmetic reason,
- Edema exacerbation
- Application difficulty
Checking compliance of MCS

- Reich-Schupke et al
  - 200 patients with CVD with a compression therapy time > 2 weeks
  - 110 returned questionnaires
  - > 60 years and BMI > 25 the help of another person to apply compression
  - BMI > 25 feeling of constriction

Reich-Scruple S. et al
Compression therapy in elderly and overweight patients
Vasa 2012 Mar; 41(2): 125-31
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- Allaert et al
  - Compliance of MCS in 2265 patients
  - 36.6% wore MCS every day
  - Poor compliance
    - Insufficient number of pairs of MCS in their disposition 24.5%
    - Difficulties of donning them 23.8%
    - Difficulties of taking them off 14.5%
    - Insufficient feelings of improvement 9.1%
Checking compliance of MCS

- Benigni et al
  - Comparison between graduated and progressive MCS
    - Progressive MCS were easier to putting on / taking off than graduated MCS

Benigni JP. et al
Difficulty associated with donning medical compression stockings: results from a survey comparing two different compression stockings.
*Women's Health (Lond Engl).* 2013 May; 9(3):291-300
Checking compliance of compression stockings

- **Below knee or thigh stocking?**

  - 267 patients with PTS, follow up 36 months
  - Below knee vs thigh stocking, 30-40mmHg
  - Efficiency in PTS: 35.6% vs 32.6% (NS)

  - Side effects of compression: 27.3% vs 40.7% (p=0.02)

- **Satisfactory compliance**: 82.6% vs 66.7% (p=0.003)
- **Better compliance with below knee stockings.**

- (CANANO Study in P. Prandoni Blood 2012)
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Highlights of « inventory »

- Compliance according to CEAP class
- Age and BMI
- Type of MCS
- Difficulties of application
- Poor recommendations
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How to monitor compliance?
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- Wearing time of MCS by a patient cannot be controlled
  - It is only according to the patient’s statements ...
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- But if we don’t know whether MCS is really worn by the patient ..... 
- All results on clinical efficiency of MCS are questionable!
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- The use a thermo button could help control the wearing of MCS
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- A tool that measures the skin temperature
  - Programming over a month with a measurement every 21 min
  - Thermotrack® is waterproof
  - Record of temperature
    - From -40°C to 80°C Celsius
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The Thermotrack® can be sewn into the hem of the stocking
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- We did a pilot study before a broad use of Thermotrack®
  
  - Main objective
    - To validate the reliability of Thermotrack®
  
  - Secondary objective
    - To compare the concordance of Thermotrack® and a daily questionnaire with the exact schedule of the use of MCS.
Conflict of interest: this study was sponsored by MEDI Bayreuth
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- **Material and methods**
  - 10 healthy subjects (5 females and 5 males) wearing MCS (15-20 mmHg) with Thermotrack® for 7 days
  - All the stockings are provided with Thermotrack® device continuously recording the temperature during the whole week of use.
All the stockings were fitted with a Thermotrack® device sewn into the hem of the MCS.

It is a small disk recording the temperature (accuracy 1 °C) 4096 measurements.

The recorded data were then analysed by a dedicated software to provide a thermal curve.

* Progres plus, France  www.thermotrack.com
Results of subject #2

Interpretation of the thermal curve and comparison with the questionnaire for donning and removal

Temp at home 20 °C    average skin temp 30 °C    washing
Results of subject # 9

Interpretation of the thermal curve: how to automatize the wearing time computation?

Temp of the skin: 30.5 °C  Temp at home: 21 °C  washing

Red line cut-off average 25 °C
RESULTS

- Number of subjects: 10 (5 M, 5 F)
- Duration of the study: 7 days
- Average wearing hours per day: 10 H 07

<table>
<thead>
<tr>
<th>EVENTS</th>
<th>DONNING TAKE OFF</th>
<th>WASHING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number checked</td>
<td>106</td>
<td>18</td>
</tr>
<tr>
<td>Clear identification by thermal curve</td>
<td>90%</td>
<td>44%</td>
</tr>
</tbody>
</table>

Average Temp: 20°C, 30°C, 24°C
OVERALL RESULTS

The average difference is 3.6% (light overestimation by Thermotrack)

Average diary time = 10h 07    Thermal curve = 10h30

The average difference is 3.6% (light overestimation by Thermotrack)
DISCUSSION

No problem of comfort

Manual computation but it could be automatized.

(average cut-off $25^\circ$ C)

Main limitation: an external temperature $> 28^\circ$ C makes it difficult to use +++
Conclusion of Thermotrack Study

- Excellent concordance Thermotrack® / QS

Identification of 90% of donning & removing events

Wearing time was accurately measured (± 4%) 

The device is **reliable** in tracking patients’ compliance.
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Which parameters to assess?

- Compliance according to CEAP class
- Age and BMI
- Type of MCS
- Difficulties of application
- Recommendations
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- **Our choice**
  - To better evaluate the impact of medical recommendations given to the patients.
  - Thermotrack® device: a tool to assess patient’s compliance
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- **Title of the pilot study**
  Role of recommendations of good practice on wearing of an elastic compression stocking.

Control of compliance with a thermal sensor
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- **OBJECTIVES**
  - **Primary:**
    - Assess the role of recommendations as a factor for compliance or not.
    - Measure precisely the compliance of wearing compression stockings with a thermal sensor
  - **Secondary** (related to compliance)
    - Improvement of symptoms
    - Improvement of QOL
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- **MATERIALS AND METHODS**
  - 20-30 mmHg below knee stockings with Thermotrack
  - Randomized prospective **pilot study** with two arms of 20 patients
  - Group 1 Minimal Recommendations
  - Group 2 idem + SMS reminders twice a week

**DURATION:** 1 month excluding the period June / September
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INCLUSION CRITERIA

- Working women 20 to 60 years
- CEAP C2s
- Speaking French and able to understand the recommendations
- Having a mobile phone, email and Internet use
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NON INCLUSION CRITERIA

- BMI > 30
- Pregnant
- Other current treatment (sclerotherapy, veinoactive drugs, calcium channel blockers, statins)
- Patient under neuroleptic treatment
- Hand and/or shoulder rheumatologic disorders
- Foot static disorders
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At the beginning and end of study

- Self assessment questionnaire so-called venous symptoms by VAS
- Imputability Carpentier score equal to or > 3
- CEAP basic (CVR software)
- Duplex
- SF12 QoL Questionnaire
- Podoscopic examination
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**ASSESSMENT CRITERIA**

- Recording of the skin temperature with the sensor at short intervals (21 min)
- The daily wearing duration
- The number of days of wearing / no wearing during the month
- The number of days of wearing among the days of professional activity
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Temporary conclusion

- Pilot study: Number of patients for a conclusive study on the compliance

- No such study published today

- Compliance of MCS: Cornerstone of efficiency of compression therapy
- Thermal sensor: promising educational tool