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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.

Lancet 14 Mar 8;383(9920):880-8.



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.
J Wound Care. 2004;13:291-294.

Checking compliance of MCS

- **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

Ann. Vasc. Surg. 2007 Nov; 21(6): 790-5

Checking compliance of MCS

Could not state a specific reason 30%		Cosmetic, poor appearance	2%
Not recommended by doctor	25%	Aggravating, itching, dermatitis	2%
Ineffective, did not help	15 %	Made symptoms worse	1%
Binding, cuts off circulation, poor fit	13%	Lack of self-discipline	0.5%
Too hot	7%	Cost considerations	0.4%
Soreness	2%	Work-related	0.2%
Needs application assistance	2%		

Checking compliance of MCS

- 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

Checking compliance of MCS

- 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

Checking compliance of MCS

- **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)

Checking compliance of CS

Highlights of « inventory »

- Compliance according to CEAP class
- Age and BMI
- Type of MCS
- Difficulties of application
- Poor recommendations

Checking compliance of compression stockings

How to monitor compliance ?



Checking compliance of MCS

- Wearing time of MCS by a patient cannot be controlled
 - It is only according to the patient's statements ...

Checking compliance of MCS

- But if we don't know whether MCS is really worn by the patient
- All results on clinical efficiency of MCS are questionable !



Checking compliance of MCS

- The use a thermo button could help control the wearing of MCS



Checking compliance of MCS

- 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




Checking compliance of MCS

The Thermotrack® can be sewn into the hem of the stocking



Checking compliance of MCS

- 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

Checking compliance of MCS

□ 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.

Method : the thermotrack « SPY »

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

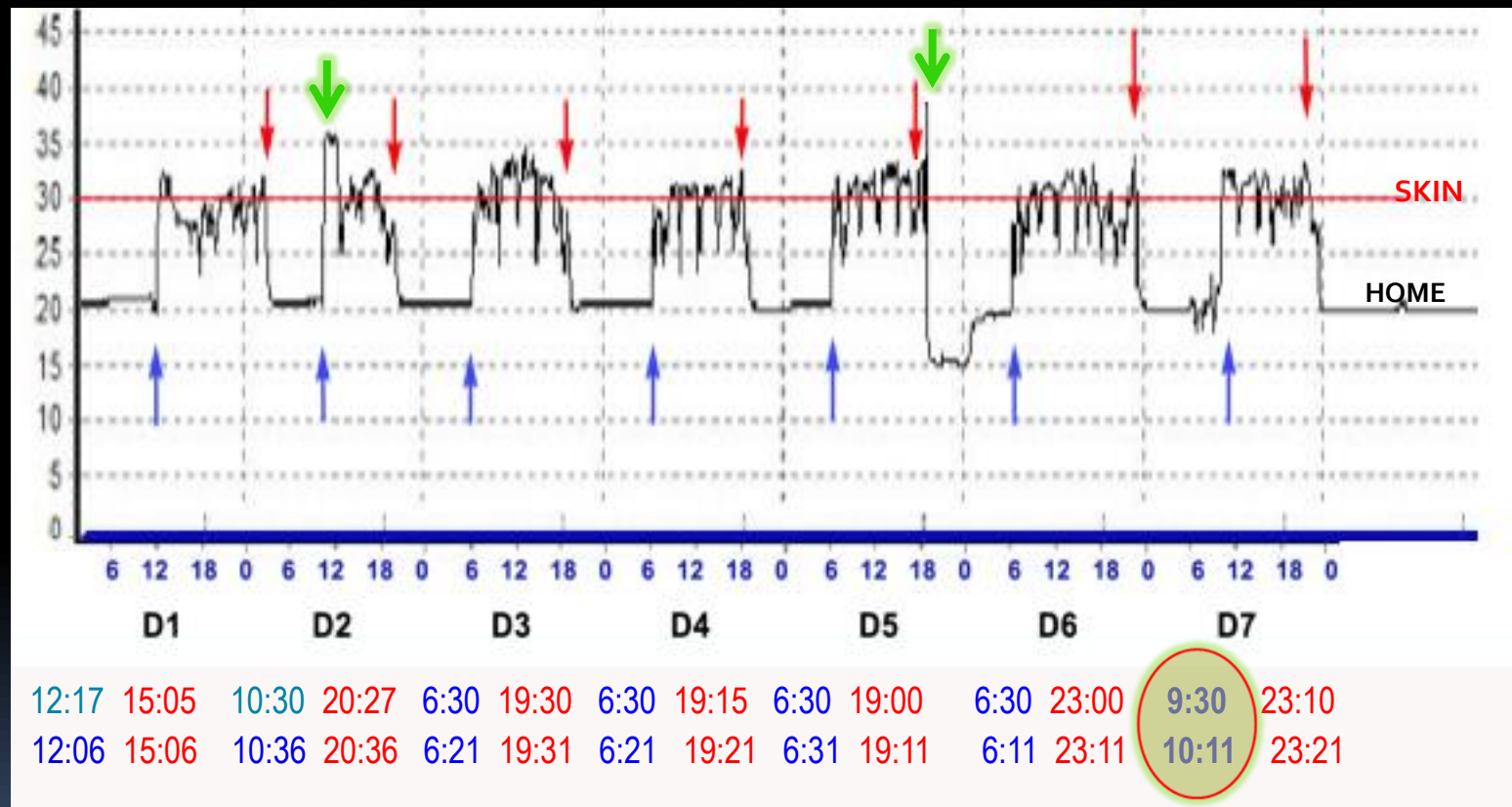
The recorded data were then
analysed by a dedicated software to
provide a **thermal curve**.

* *Progres plus, France* www.thermotrack.com



Results of subject # 2

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



REAL
Temp

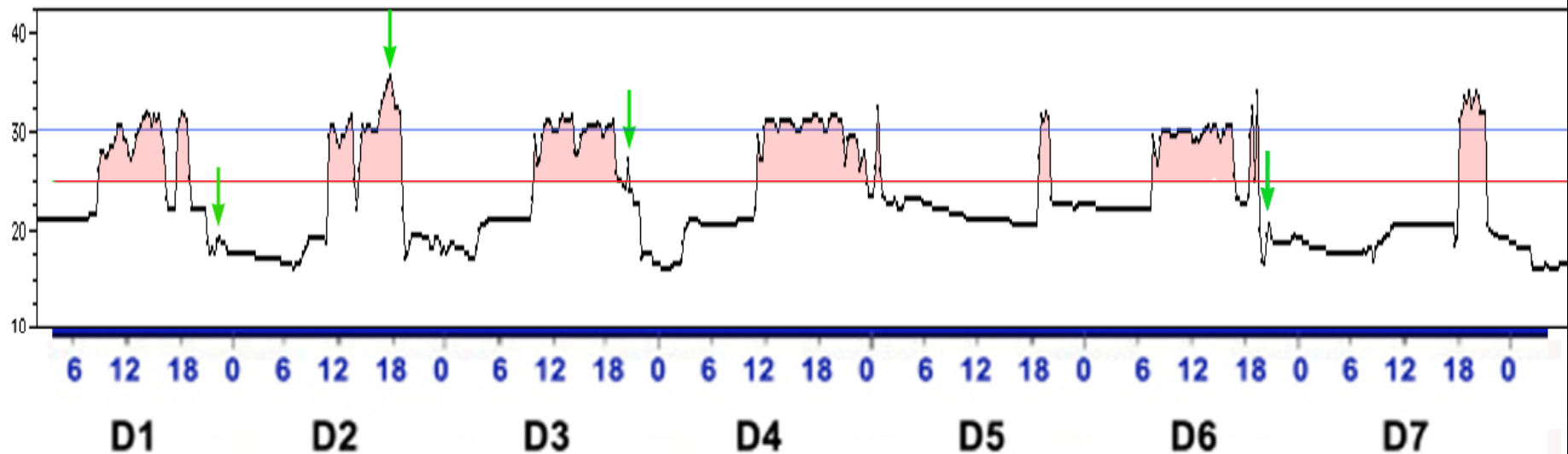
Temp at home 20 °C average skin temp 30 °C

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

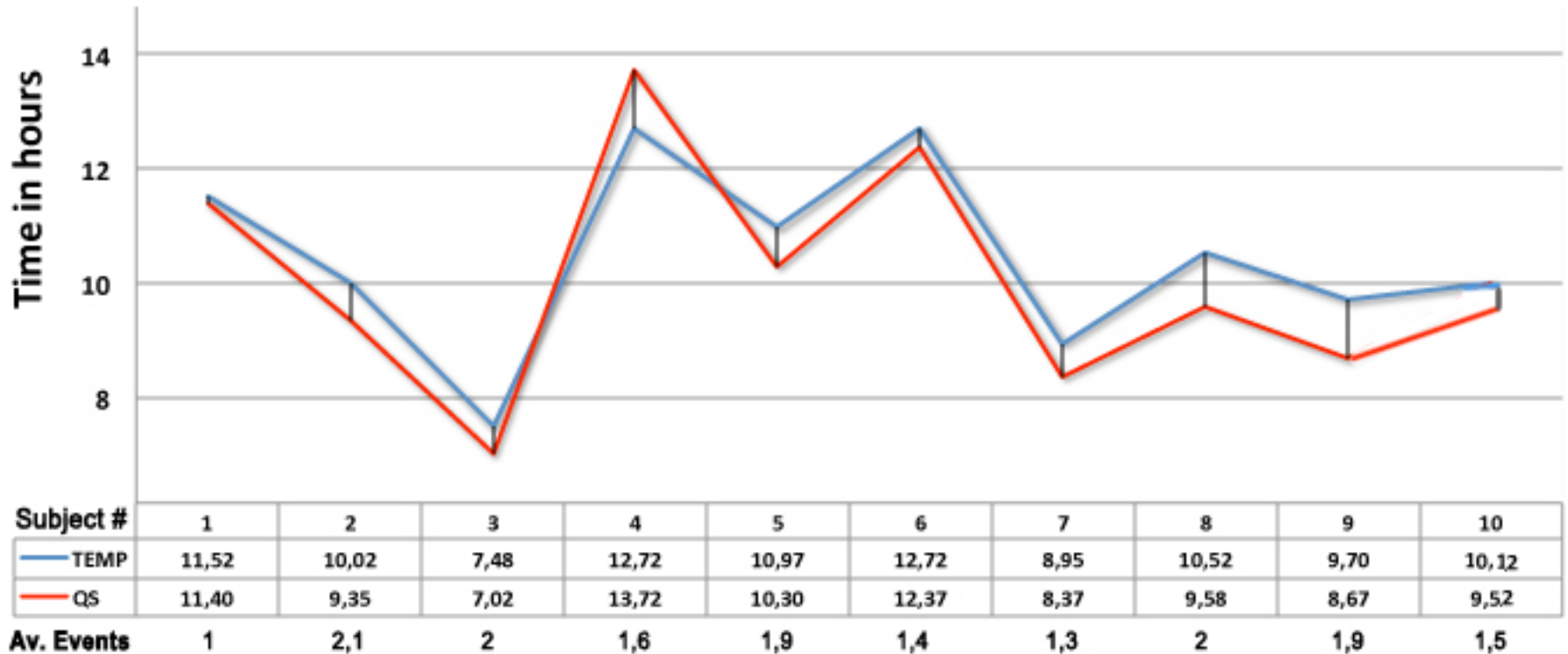
HOME SKIN cut-off for Thermotrack

Average Temp: 20°C 30°C 24°C

EVENTS	DONNING TAKE OFF	WASHING
Number checked	106	18
Clear identification by thermal curve	90%	44%

OVERALL RESULTS

Average wearing hours per day



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° 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.

Checking compliance of CS

Which parameters to assess ?

- Compliance according to CEAP class
- Age and BMI
- Type of MCS
- Difficulties of application
- **Recommendations**

Checking compliance of MCS

- Our choice
 - To better evaluate the impact of medical **recommendations** given to the patients.
 - Thermotrack® device : a tool to assess patient's compliance

Checking compliance of MCS

- 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



Checking compliance of MCS

- 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

Checking compliance of MCS

■ 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

Checking compliance of MCS

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

Checking compliance of MCS

NON INCLUSION CRITERIA

- BMI > 30
- Pregnant
- Other current treatment (sclerotherapy, vein active drugs, calcium channel blockers, statins)
- Patient under neuroleptic treatment
- Hand and/or shoulder rheumatologic disorders
- Foot static disorders

Checking compliance of MCS

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

Checking compliance of MCS

■ 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

Checking compliance of MCS

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