

EVALUATION OF THE PERFORMANCE OF DEVICE THAT STIMULATES BLOOD CIRCULATION

Clinical evaluation

Sponsor

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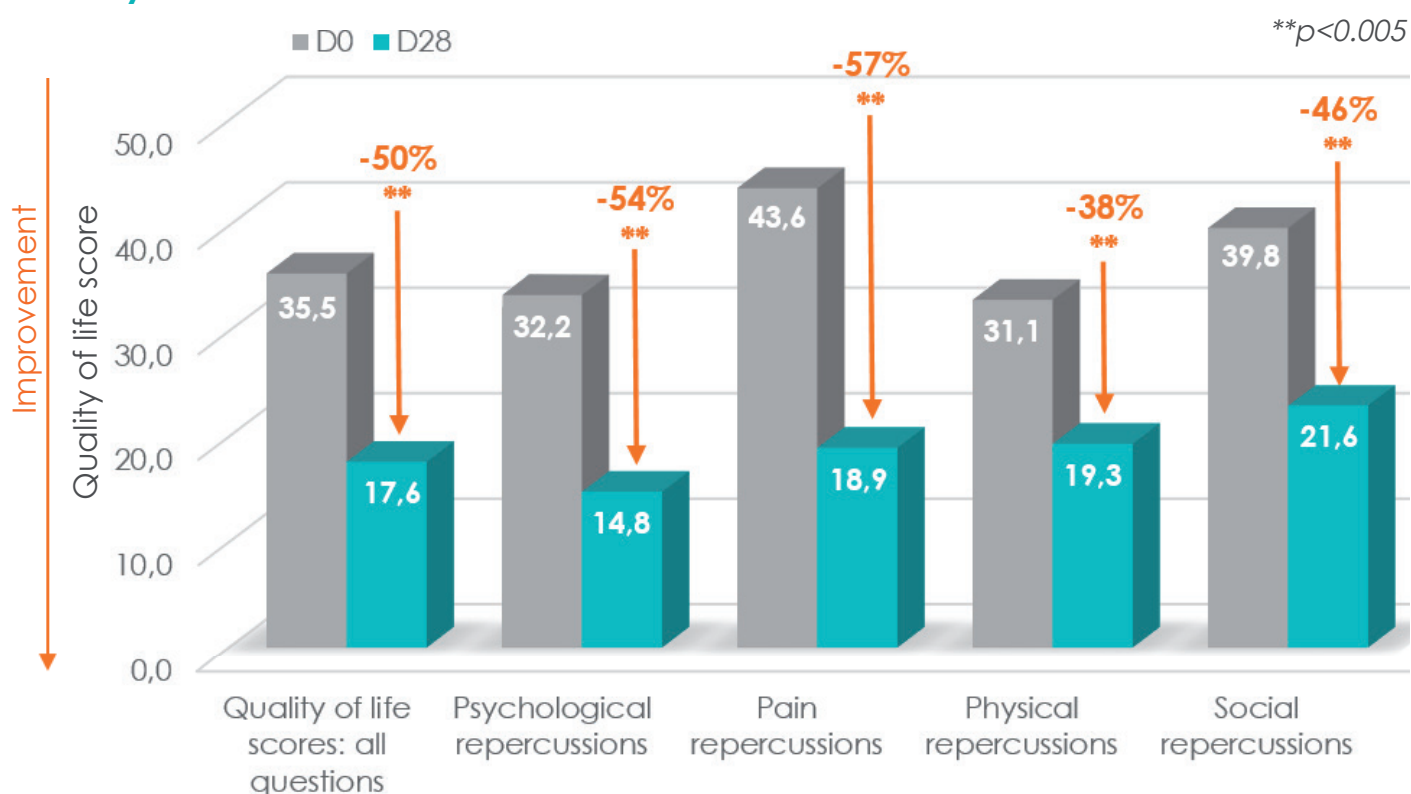


OBJECTIVES

- The main objective of the study was to evaluate the impact of **Drainastim® device** on quality of life after 28 days of use by subjects suffering from heavy legs and superficial venous insufficiency.
- The secondary objectives of the study were:
 - to evaluate the effect of **Drainastim® device** on the decrease of water retention;
 - to subjectively evaluate the effect of **Drainastim® device** on heavy legs and blood circulation.

RESULTS

Quality of life



Subjects with an improvement

91%

82%

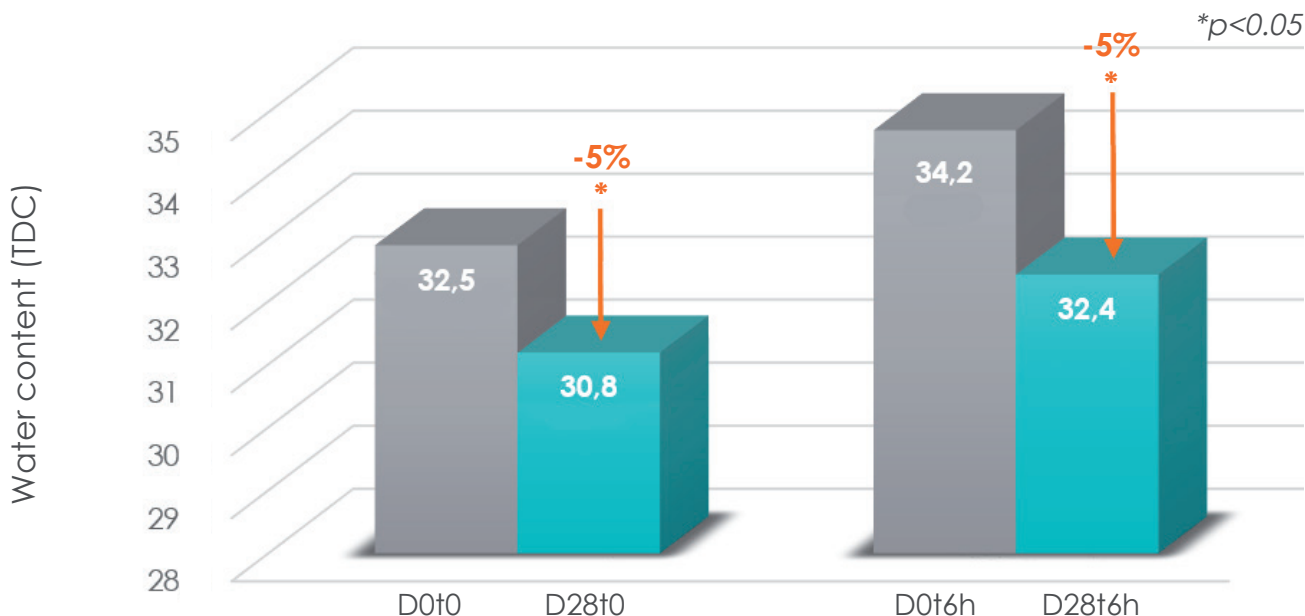
86%

73%

59%

Overall, the quality of life of subjects with venous insufficiency improved significantly after 28 days of use of **Drainastim® device**. The use of **Drainastim® device** during 28 days allowed to decrease significantly the pain, physical and psychological repercussions of venous insufficiency in a large majority of the subjects (from 73% to 86%). Social repercussions were also improved in 59% of the subjects

Water retention measurements



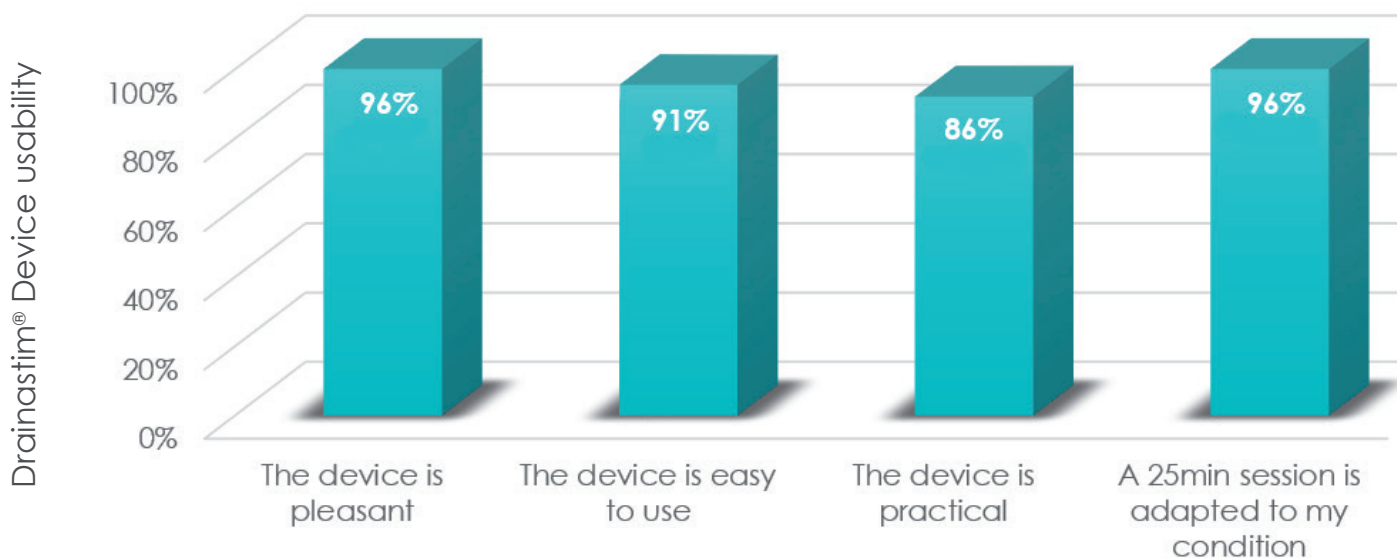
Subjects with an improvement



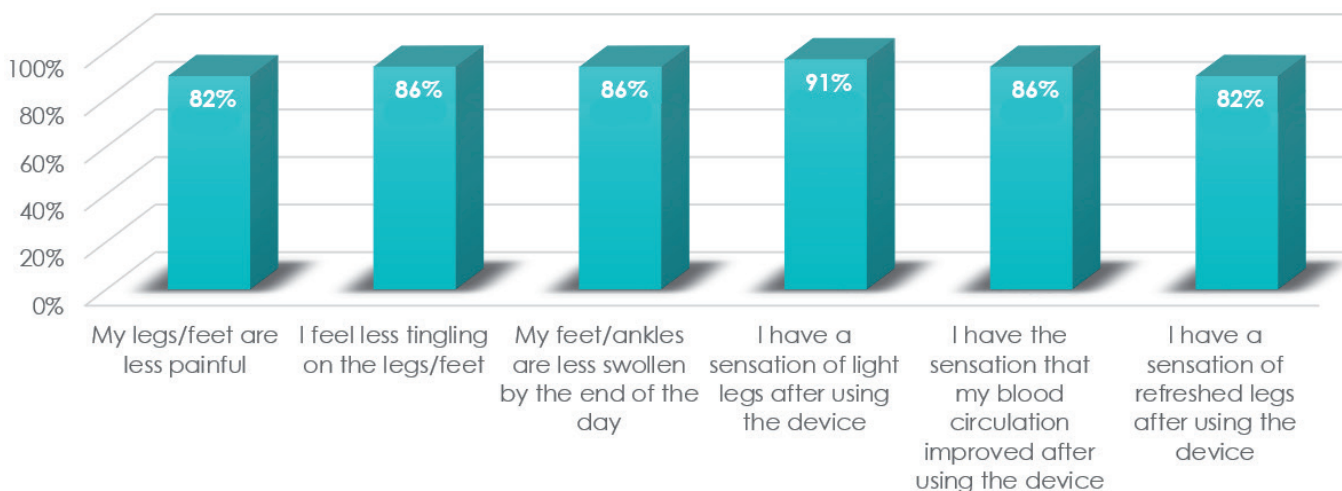
The baseline measurements before device use, on D0, confirmed that the subjects included in this study presented naturally an oedema at the ankle level by the end of the day. Indeed, the water content at ankle level increased from t0 to t6h of 5,5%.

After 28 days of daily use of **Drainastim® device**, the majority of the subjects presented a draining effect, visible from the beginning of the day for 73% of subjects until the end of the day for 86% of subjects. We observed a significant decrease of water content on D28t0 and D28t6h of 5% on average compared to the baseline.

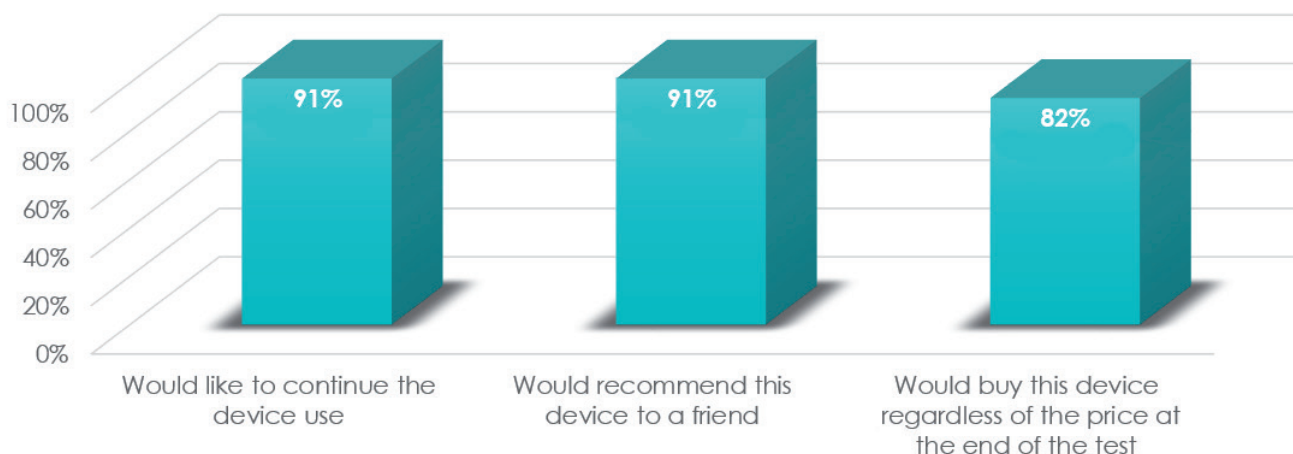
Subjective evaluation questionnaire



Drainastim® Device efficacy



Drainastim® Device future use



CONCLUSION

After 28 days of daily use of **Drainastim® device**, the quality of life of subjects suffering from venous insufficiency significantly increased. **Drainastim® device** permitted to significantly reduce the water retention for a majority of subjects, probably by improving their blood circulation at lower limb due to the daily stimulation of the muscle contraction during 28 days. The majority of subjects appreciated the device for its practicality, its efficacy on symptoms related to venous insufficiency.

91% of subjects would like to continue the device use.

STUDY PROTOCOL

This was an open, intra-individual study; each subject is her own control.

PANEL

The study was conducted on 22 healthy women, aged between 26 and 70 (average age: 46±3 years), suffering from venous superficial insufficiency (presenting at least telangiectasia on legs) and presenting an oedema (water retention) of ankles at the end of the day.

INSTRUCTIONS OF USE

Daily use at home, during 28 days in normal condition of use. A cycle of stimulation lasted 25 minutes. The intensity of stimulation had to be adapted everyday by the subject himself. The subject had to increase the intensity until he felt some contraction/relaxation of the muscles of feet and calves.

STUDY DESIGN



MEASUREMENT PRINCIPLE

Quality of life measurements

The subjects evaluated their quality of life thanks to a validated questionnaire for subjects suffering from venous insufficiency Civiq-14. This questionnaire was developed by Prof LAUNOIS with an educational grant from SERVIER.

Different dimensions are represented in this questionnaire: Psychological repercussions, Pain repercussions, Physical repercussions, Social repercussions and an overall score of quality of life. The scale ranges from 0 to 100. The lower the score is, the better the quality of life is.

Water retention measurements

The Moisturemeter® D (Delfin Technologies) allows measure locally and non-invasively the water content of skin layers. The device generates a 300 MHz electromagnetic wave that propagates in the skin. The di-electric constant measured by the probe is proportional to the total amount of water (free water and bound water) contained in the analyzed tissues. The probe M25 used in this study has an exploration depth of 25mm (until the hypodermis). The results are expressed as dielectric constant values (TDC: Tissue Dielectric Constant). Measurements were done on the inside part of each ankles, on a zone situated between the start of muscle and the malleolus, where the oedema is the most measurable.

Subjective appreciation by the subjects

On D28, a questionnaire was filled in by the subjects to subjectively evaluate the properties of the studied device, its global efficacy and its future use.

