Are open-toe antithromboembolic compression stockings safe?

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Introduction

Medical compression stockings (MCS) prevent venous thromboembolic diseases (VTED) from arising on bedridden or hospitalized patients.[1,2] Open-toe MCS (OTMCS) allow nurses to check toes, anticipating adverse-effects due to either stockings or the underlying pathology, mainly caused by surgery. In 2016, the French medical device vigilance system reported foot skin lesions occurring on at least 10 elderly patients, aged more than 80 years old, who had been prescribed with OTMCS for post-surgery VTED prevention. Most of the lesions were caused by an inadequate wearing and/or inadequate stockings. In spite of this explanation, we carried out an inquiry aiming to evaluate the effective pressure level that was exerted by these antithromboembolic OTMCS (ATE OTMCS), on the lateral aspect of the metatarsa-phalangeal joints.

Materials and Methods

We analysed each item of a set of 4 sizes from the previously mentioned reported cases of OTMCS. Local exerted pressure is linked to the local limb radius, complying to the Laplace's law. Due to the very small radius of the concerned areas where measurements had to be done, interface pressure devices were not suitable for this kind of measurement. In order to study the effective pressure applied over the foot, especially at the toe joint zones, we involved an innovative approach: the *ex-vivo protocol*. This methodology, a hybrid protocol combining *in-vivo* and *in-vitro*, provides reliable local pressure figures with a minimum of operator dependency. We also involved a new portable dynamometer, which is highly correlated to any usual dynamometer in textile laboratory dynamometers.[3]

Firstly, we evaluated the constitutive law (force *vs* elongation properties of the elastic material) of the OTMCS fabric within the area of the metatarsa-phalangeal. From this material specific properties, we elaborated an algorithm enabling to calculate effective local pressure on any location of the limb according to the considered local radius (fifth metatarsa-phalangeal joints).

In a second phase, thirty patients between 75 to 85 years old from the phlebological consultation were prospectively included in our survey, and toe-joint shape measurements were performed using a tape meter for the forefoot circumference and a caliper for the thickness of the metatarsal phalangeal joints (Figure 1). The caliper is to be used by pressing firmly on the skin to reflect the true local radius of the forefoot and not the theoretical one as it has already been demonstrated.[4] Oral consent was obtained since this study is, on a legal point of view, considered as a vigilance inquiry.

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Results

Thirty patients - aged 80±3.4 years old - were included in the survey program. Circumference of forefeet, great and fifth metatarsal phalangeal joints were 235.8±13.2 mm, 32.3±3.8 mm and 21±2.2 mm as respectively mean and standard deviation (SD). Considering these patients being equipped with a French ATE OTMCS (15 to 20 mmHg pressure at the ankle), the effective local mean ± SD pressure that would have been applied would be 40±13.7 mmHg at the first metatarsa-phalangeal joint and 62±21.1 mmHg at the fifth (Figure 2).

Discussion and Conclusion

The results demonstrate that at least one brand of ATE OTMCS applies, whichever the sizing and the dimensions at the toe

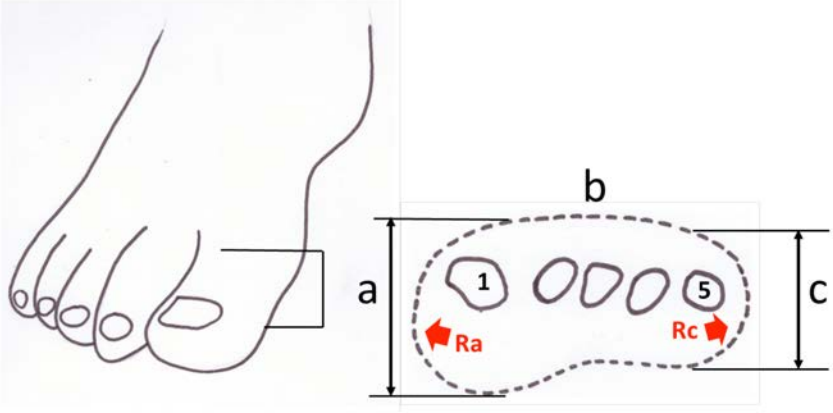

Figure 1. Parameters to be measured before being introduced in the calculator: a, b) thickness of the fist and fifth metatarsa-palangeal joint measured using a caliper; c) tape measurement of the foot circonference including the first and fifth metatarsa-phalangeal joints (dotted line). Ra is the local limb radius of the first metatarsa-phalangeal joint and Rc the local limb radius of the first metatarsa-phalangeal joint.

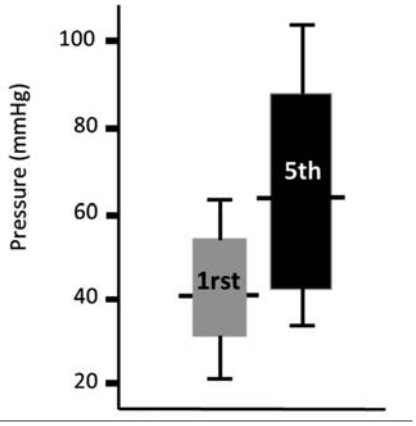

Figure 2. Pressure values on the fifth and first metatarsal phalangeal joint on 30 patients. Boxes represent 25th to 75th quartiles, horizontal bar is mean and vertical bars represent the range.

level are, an elevated pressure at the base of the toes, due to the Laplace's law consideration. This pressure could be the cause of pain, skin injuries or discomfort that can alleviate compliance. Opposite to many other ATE OTMC, whose characteristics are variables[5,6] the ones we tested are certified graduated stockings and then correspond to the recommended stockings by the HAS (French Health Authorities) and the last international consensus on MTEV prevention.[7,8]

OTMCS can be used not only for bedridden but on hospitalized patients. They are also used to increase compliance to MCS in Summer time, if one wants to enjoy flip flops, sandals and peep toe heels. OTMCS are more comfortable for patients with very long feet and for toe comfort in case of long toes or toenail problems. Therefore, this study should be extended to any OTMCS and not only ATE OTMCS. Apart from the pressure the shape of the foot could have been played a non-negligible role on patient's injuries. Egyptians shape foot are more often reported as related to inadequate adaptation of OTMCS. Consequently and generally speaking, it has to be repeated that compression therapy is a treatment that needs education, expertise and medical follow-up whatever the compression medical devices are.

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