Measurement of Lower Leg Compression In Vivo: Recommendations for the Performance of Measurements of Interface Pressure and Stiffness

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BACKGROUND   Interface pressure and stiffness characterizing the elastic properties of the material are the deciding parameters determining the dosage of compression treatment and should therefore be measured in future clinical trials.

AIM   The aim of this consensus paper is to provide some recommendations regarding the use of suitable methods for this indication.

METHOD   This paper was formulated based on the results of an international consensus meeting between a group of medical experts and representatives from the industry held in January 2005 in Vienna, Austria.

RESULTS   Proposals are made concerning methods for measuring the interface pressure and for assessing the stiffness of a compression device in an individual patient.

CONCLUSIONS   In vivo measurement of interface pressure is encouraged when clinical and experimental outcomes of compression treatment are to be evaluated.

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Compression of the lower leg is an effective intervention in the prevention and treatment of venous and lymphatic diseases, with its effects largely dependent on the amount of compression applied during rest and while walking. Although the amount of compression can be measured as an applied pressure in mmHg (or kPa), this is rarely measured clinically, leading to uncertainty over exactly how much compression has been applied on the leg. Typically clinicians rely on the manufacturer's listed class of compression when using compression stockings and their experience when using compression bandages. This consensus statement focuses on compression stockings and bandages, although its principles could also apply to the evaluation of intermittent compression devices. Although measurement of the compression applied by stockings, bandages, or velcro straps is relatively rare in clinical practice, a wide range of instruments for measuring the pressures underneath these devices have been described.[1–33] It would appear that there is uncertainty over which instrument to use and how the pressures should be both measured and reported. The purpose of the consensus group was to provide recommendations that help to reduce this uncertainty and so lead to more frequent recording of interface pressures under compression devices.

Definitions

In vivo measurement of pressures under these devices will quantify the compression of the leg both during rest and movement. The pressure measured under static (resting) conditions is termed *resting pressure*; that measured on the moving patient is known as *working pressure*. One further performance indicator is required to fully characterize the effect of compression; this is *stiffness*, defined by the increase of compression per centimeter increase in the circumference of the leg, expressed in hectopascals per centimeter and/or millimeters of mercury per centimeter.[34]

Indications

The measurement of pressures under the device and stiffness of each device cannot be routine for every patient who wears compression stockings or bandages. However, there are several areas where quantifying compression may be of value:

- quality control of (new) compression products and/or compression techniques,[4,8,11,14,27,35–44]

- proof of concepts (e.g., do we apply graduated compression?), [31,39,45,46]

- comparative clinical trials (to assess the "dosage" of compression applied to individual legs),[8,47]

- correlation with clinical outcomes or with physiological measurements,[6,24,38,48–56]

- documentation of clinical care (continuous monitoring),[8,19,43,57]

- training individuals how to apply compression bandages,[9,58–60]

- classification of compression bandages, compression stockings, velcro-straps, multi-layer compression systems,[8,71]

- validation of in vitro measurements,[20,30,56,61,62]

- compression of stockings to be indicated in mmHg instead of compression classes,[63]

- evaluation of the level of compression of a bandage, a stocking or a device over time.[8,19,41,43,44,57]

Contraindications

No contraindications have been described for measuring the pressure under the device. However, skin irritation because of the applied sensor may occur—and nonflexible pressure sensors may cause pressure damage if applied for long periods of time (over 30 minutes to 2 hours).

Suitable Measurement Techniques

A variety of different measurement techniques can be used to determine exact pressures under each device. No one system has been established or identified as the only or best way to measure these pressures. It is recommended, however, that any pressure sensor that is considered for use should satisfy or come close to the following key specifications[3,7,17,18,33,64,65]:

- The sensor should be thin and flexible. Based on theoretical model calculations that are mainly valid for flat areas, Ferguson-Pell suggests a maximal thickness of 0.5 mm.[7,64]

- The sensitive area of the sensor should be adjustable and optimized for different applications (leg, hand, toe) and different measuring regimes: for example, small areas for mapping of a circumferential pressure pattern, large sensor areas (over 5 cm²) for measuring the integral pressure of a larger area, taking advantage of the fact that the local pressure distribution will be averaged because of changing curvatures of the leg segment.

- The sensor should be able to be left in contact with the leg for extended periods of time without skin irritation and should keep its accuracy.

- Pressure measurement systems that allow continuous pressure measurement during active or passive patient movement (e.g., muscle pump test or tilt test) are preferred.

- Easy sensor calibration is desirable before each measurement.

- Multiple sensors allowing concurrent measurement of pressures under the device at several anatomical sites may be preferred over single sensors.

Some characteristics of an "ideal" pressure sensor are shown in Table 1 to recognize that, in every case, selection of a pressure

TABLE 1. Characteristics of an "Ideal Sensor"
•Size–insensitive to force concentrations
•Flexibility–insensitive to bending, but not distensible
•Durability
•Reliability
•Overload tolerance
•Electronic simplicity
•Low cost
•Low hysteresis
•Little creep
•Insensitive to temperature and humidity changes
•Continuous output
•Linear response to applied pressure
•High sampling rate–locomotion studies
•Operating range consistent with biological parameters
•Accuracy
•Resolution (time<0.1 sec, amplitude<0.1 mmHg)
•Thin
•Variable sensor sizes

sensor involves a series of compromises given that no ideal sensor currently exists.

Table 2 shows a wide variety of pressure sensors (many of them commercially available, with their advantages and limitations illustrated in Table 3).

Where to Measure Pressures Under a Compression Device?

The pressure sensors are positioned on the leg before the compression device is applied. Where the sensors should be placed is a matter of controversy.

It is recommended that the identification of anatomical locations described in the European document on normalization[34] be used to define the position upon the leg along with recording the exact position of each sensor (ventral, medial, dorsal, lateral).

- B: ankle at point of minimum girth.

- B1: area at which the Achilles tendon changes into the calf muscles ($\sim$10–15 cm proximal to the medial malleolus).

- C: calf at its maximum girth.

- D: just below the tibial tuberosity.

- E: center of the patella and over the back of the knee.

- F: between K and E (mid-thigh, between patella and groin).

- G: 5 cm below the center point of the crotch.

- H: greatest lateral trochanteric projections of the buttock.

- K: center point of the crotch.

Interface pressure should not be measured over bony prominences or tendons, as the hardness of the underlying structures will greatly influence the measured pressure.[65] The curvature of the leg at the position of the sensor and how

TABLE 2. Types of Interface Pressure Sensors

Pneumatic, pneumatic-electric or pneumatic-piezoelectric	Oxford Pressure Monitor (Talley Ltd, Ramsey, Hampshire, UK)
	Talley Pressure Evaluator (Talley Ltd)
	MST MKIII Salzmann (Salzmann Medico, St Gallen, Switzerland)
	Digital Interface Pressure Evaluator (Next Generation Co., Temecula CA, USA)
	Scimedics Pressure Evaluator Pad (Vista Medical, Winnipeg, MB, Canada)
	Kikuhime (Meditrade, Soro, Denmark)
	Juzo Tester (Elcat, Wolfratshausen, Germany)
	Sigat Tester (Ganzoni-Sigvaris, St. Gallen, Switzerland)
Piezoelectric	MCDM-I (Mammendorfer Inst. Physik, Munich, Germany)
Fluid-filled, fluid-filled-resistive	Strathclyde Pressure Monitor, (University of Strathclyde, Scotland)
	FlexiForce (Tekscan, South Boston, MA, USA)
	Skip Air pack Analyzer (AMI Co., Japan)
Resistive, and strain gauge	FSR, FSA (Vista Medical, Winnipeg, MB, Canada)
	Fscan, Iscan (Tekscan, South Boston, MA, USA)
	Rincoe SFS (Rincoe and Associates, Golden, CO, USA)
	MCDM (Mammendorfer Inst. Physik, Munich, Germany)
	Fontanometer (Gaeltec Ltd, Dunvegan, Isle of Skye, Scotland)
	Diastron (Diastron Ltd, Andover, Hampshire, UK)
Capacitive	Kulite XTM190 (Kulite Semiconductor Products, Leonia, NJ, USA)
	Precision (Precision Measurement Co., USA)
	Xsensor (Crown Therapeutics, Belleville, IL, USA)
	Pliance (Novel, Munich, Germany)

circumference changes during movement must be taken into consideration. The B segment, which is a reference point for stocking manufacturers, remains a challenging location for in vivo measurement[46] because of the following facts:

- Stocking manufacturers use a wooden leg model to measure the pressure of their garments. This model has a circular circumference and does not contain the irregularities of the human leg.

- In the human leg the radius at the ankle varies widely because of the bony prominences and tendons prevailing in this segment.

- The retromalleolar fossae correspond to a negative radius and can only be compressed using pads.

Leg segments E, H, and K are not suitable.

It is proposed that location B1 should always be included in future pressure measurements, with the exact location of the sensor situated at the segment that shows the most extensive enlargement of the leg circumference during dorsiflexion or by standing up from the supine position.[66,71] Although B1 should always be included as a measurement location, other sites could be included in any measurement of pressures.

TABLE 3. Some Advantages and Disadvantages of Sensors

	Advantages	Limitations
Pneumatic transducers	Thin and flexible probes, Cheap, easy, and handy	Dynamic measurement is only possible with additional special equipment. Sensitive for temperature and hysteresis.
Fluid filled	Flexible, dynamic measurements	Thick when filled, problems during motion
Resistance	Thin sensors, dynamic measurement	Sensitive to curvature, stiff and thick, not useful for long-term measurements

Special Situations

It may be desirable to measure pressures over specific areas (e.g., a venous ulcer, lipodermatosclerotic areas or over varicose veins). This may be of interest because it may dictate the extent and location of local pads or rolls in order to increase the local pressure.[67]

Body Positions to Measure the Pressures Under the Devices

After application of the compression device, pressures should be measured with the patient in both supine and standing positions.[8,19,35,42,45,68] Pressures may also be measured when the calf muscle and ankle joint pump are activated.[13,15,19,27,28,48,66] Possible movements include the following:

- Dorsal and plantar flexion.

- Walking, for example on a treadmill.

- Adopting a "tip-toe" stance, or flexing of the knees.

- Passive ankle movement.

Documentation and Reporting

- The digital output of pressure transducers without continuous recording can be recorded either visually (eg, Kikuhime®, Meditrade, Soro, Denmark; Talley Oxford system®, Talley Ltd., Ramsey, UK) or printed (eg, MST tester®, Salzmann Medico, St Gallen, Switzerland). The value of continuous measurements in addition to static measurements includes the abil-

ity to obtain a pressure profile of the device during ambulation. The output can be directly plotted or sent to computer-based digital data capture systems. As a minimum the following pressure data should be reported (illustrated in Figure 1):

- Resting pressure, supine and standing.

- Working pressure during movement.

- Maximal pressure peaks (systolic working pressure).

- Minimal pressure (diastolic working pressure).

- The measurements from adjacent sensor locations at one leg segment can be averaged to describe the pressure at a particular level in that leg.

In addition to the pressure measurements, other information that should be recorded includes

- the location of the sensors (distance from the heel or from malleoli),

- the movements carried out by the patient,

- circumference of the leg segment where the sensors are placed,

- smallest circumference of the leg,

- room temperature,

- exact time after application of the compression device when pressure measurements are performed, and

- time of the day when pressure measurements are performed.

Stiffness

Stiffness can be defined as the increase in compression per centimeter increase in the circumference of the leg, expressed in
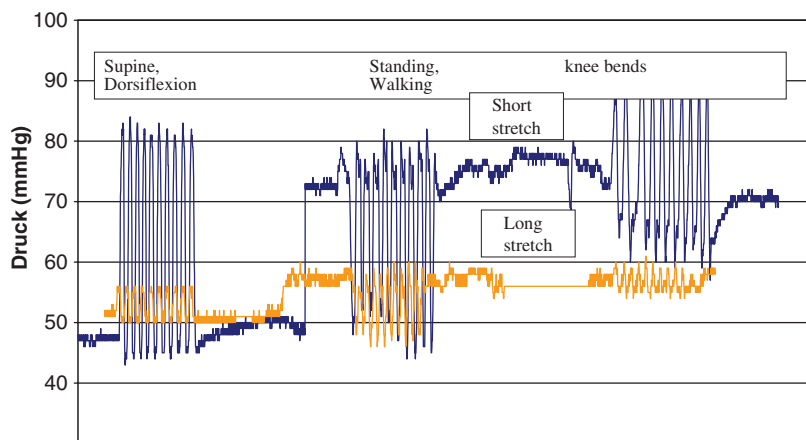

Figure 1. Resting and working pressure measurement on both legs, using the large Kikuhime probe at B1 and a date logger for continuous registration. Upper curve: multilayer short-stretch bandage on one leg; lower curve: long-stretch bandage on the other leg. The higher stiffness of the short stretch bandage is characterized by the higher pressure amplitudes during movement, and also by the higher increase of the pressure by standing up from the supine position.

hectopascals per centimeter and/ or millimeters of mercury per centimeter.[34] This parameter characterizes the distensibility of a textile, which plays an important role concerning the performance of a compression device during standing and walking.

Clinical Implications of Stiffness

Although compression devices may apply similar resting pressures, materials with no stretch (zinc paste or velcro straps) or short-stretch bandages produce higher peak pressures when standing or walking compared with the effects obtained with long-stretch devices (Figure 2). In patients with chronic venous insufficiency, it has been shown that this results in a more pronounced reduction of edema,[54] venous volume and reflux,[44,52,69] and may even lead to a reduction of ambulatory venous hypertension.[51] Multilayer elastic bandages, even consisting of rather long-stretch material, may also exhibit greater stiffness than single-layer long-stretch material. This is also true when two compression stockings are applied over each other.[8,20,70] In general, compression device materials that have a high stiffness combine high working pressure with a relatively low, tolerable resting pressure when lying.

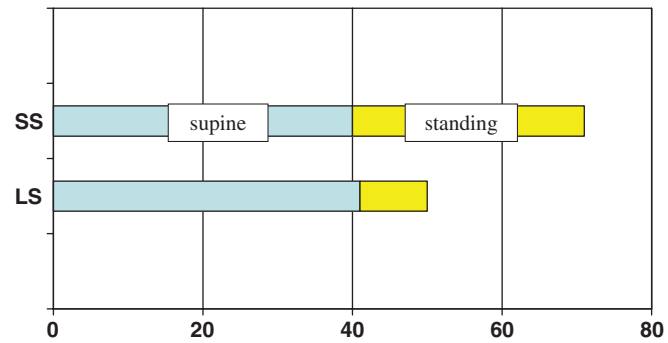For practical purposes, stiffness indices should be able to inform us about the performance of the

Figure 2. Pressure at B1 measured with a small Kikuhime probe with a short-stretch (SS) on one leg and a long-stretch bandage (LS) on the other leg in the supine and in the standing position. Starting from a resting pressure of about 40 mmHg, SS shows a more pronounced pressure increase than LS by standing up. (Difference of standing-supine = "static stiffness index")

compression device during walking. When, for instance, a pressure range between 20 and 30 mmHg is declared by the manufacturer of a class II stocking, it would be of clinical interest to see how much the pressure rises during standing and walking.

Measurement of Stiffness In Vivo

Measurement of dynamic stiffness[66] may require sophisticated laboratory equipment, including strain gauge plethysmography (to record changes in limb volume) and a treadmill (to allow ambulation under controlled circumstances). However, static stiffness measurements may be relatively simple and can also be performed in patients with restricted mobility. Several methods of calculation are available, for example, the difference between the standing and supine pressures at level B1.[6,8,11,40,68,71] Active standing can be considered to be a "snap-

shot" in the course of one step (Figure 1), leading to an increase of the leg circumference. The pressure difference between standing and supine position may be called "absolute resting pressure difference" (aRPD), and corresponds to what has been described as the "static stiffness index" (SSI).[71] The pressure difference can also be expressed as a percentage of the standing pressure ["relative resting pressure difference," (rRPD) or (SSI%). Other approaches to characterizing stiffness include the amplitude (difference) between the maximum and minimum working pressures or the pressure increase observed during one dorsiflexion. One further approach would be to describe stiffness as the product of working pressure divided by resting pressure, and this has been shown to correlate with an improvement in venous refilling time among patients with chronic venous insufficiency[41,48]

It has to be stressed that the outcome of the different approaches to characterizing stiffness will depend upon the physical characteristics of the pressure sensors (predominantly their flexibility and dimensions). Stiffness measures will also vary with the exact positioning of the sensor(s), the shape of the leg segment (local radius) and the consistency of the underlying tissue.

Adding more layers to a bandage or putting on several stockings, one above the other, will not only increase the pressure but will also increase stiffness, mainly because of changes in the friction between the layers.[20,70,72]

The stiffness indices should allow a differentiation between short-stretch (extensibility <100%) and long-stretch material (extensibility >100%), which is an end characteristic difficult to predict in multilayer bandages consisting of different materials.[8]

Using devices with continuous pressure readings, the best discrimination between long-stretch and short-stretch material could be demonstrated at level B1 using the pressure difference between standing and supine, dorsiflexion and relaxed ankle position and between systolic and diastolic working pressures. Figure 3 shows examples for different stiffness parameters measured using the Sigat transducer® (Ganzoni-Sigvaris, St Gallen, Switzerland).
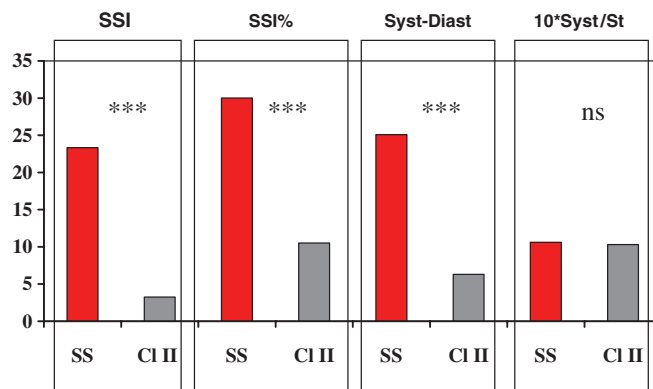

Figure 3. Stiffness parameters calculated from interface pressure measurements at B1 in 12 healthy volunteers using the Sigat tester. Comparison of multilayer short-stretch bandages (SS) on one leg and medical compression stockings class II on the other leg. (SSI = static stiffness index = standing−supine pressure, SSI% = SSI in percent of standing pressure, Syst-Diast = pressure amplitude during walking, Syst/St = systolic peaks/standing pressure). To keep the numeric range of the y-axis, the quotient Syst/St was multiplied by 10. ***$p<0.001$, Mann–Whitney test.

Calibration and Orientation Regarding the Plausibility of Measured Values

A zero adjustment to correct for atmospheric pressure should be performed before each measuring period. Each pressure sensor should be calibrated according to the manufacturer's recommendations.

As a rough guide to the pressures, it is recommended that one compares the pressure sensor output and the pressures applied by a blood pressure cuff. In this test the sensor should be positioned on the leg (eg, at level B1) and a 12-cm-wide blood pressure cuff placed centrally over the sensor. Wrinkles and folds of the cuff in the region of the sensor must be avoided and only one layer of the pressure cuff should cover the sensor. The cuff is then connected to a calibrated pressure gauge (preferably a mercury column). By inflating the blood pressure cuff in steps of 10–20 mmHg repeatedly, the accuracy and variability of the pressure transducer can be assessed.[1,9,19,25,71,73]

Accuracy and reproducibility should be given for each measuring technique.

Conclusions

A standardized measurement of pressure between the skin and the medical compression device makes it possible to evaluate objectively the biophysical impact of a compression product, which in turn determines its hemodynamic efficacy. It is essential that these measurements are carried out in vivo, especially when new compression products are being developed.

Compression therapy is a very potent treatment modality whose effects mainly depend on the amount of compression applied and on the elastic properties of the material used. In future studies comparing different compression devices, these two influential characteristics (pressure and stiffness) should be quantified.

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COMMENTARY

It is with pleasure that I read the consensus statement regarding measurement of lower leg compression by Partsch and colleagues. A world-class group representing phlebology and lymphology was assembled to generate these much-needed guidelines that will advance the basic science of compression as therapy. The inter-relationships between the calf muscle pump and in vivo external compression are well accepted, but study outcomes have not always been measured accurately. The consensus statement allows for comparison of therapeutic protocols using agreed upon standards. As with the recent unification of anatomic nomenclature of the venous system of the lower extremities, this consensus is welcome. I recently had the opportunity to observe a demonstration and discussion of various compression modalities with measurement of each. To see Dr. Partsch wrap his model, Dr. Cornu-Thenard, while explaining long versus short stretch, as well as the concept of stiffness, was compelling. The introduction of a new compression term, hectopascals per centimeter, will require some getting used to as we are more familiar with millimeters of mercury per centimeter. I also agree that, for the use of graduated compression hosiery, the amount of pressure is preferable to a class system. The included bibliography is extensive and provides reference, both recent and historic. Overall, this consensus statement on compression will set international standards for study reporting and comparison that will be highly useful for years to come.

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