Lymphology 57 (2024) 116-131

VALIDATION OF A NEW MEASUREMENT DEVICE (PeriKit®) FOR PERIMETRY AND VOLUMETRY OF THE LOWER LIMB: METROLOGICAL AND INTRA-OBSERVER COMPARATIVE STUDY

M. Louys, M. Mathieu, S. Harnie, N. Adriaenssens

Belgian Society of Lymphology, Young Lymphologists Group, Belgium (ML, MM); Medical Oncology Department, UZ Brussel, Brussels, Belgium (SH, NA); Rehabilitation Research, Vrije Universiteit Brussel, Brussels, Belgium (SH, NA).

ABSTRACT

Accurate quantitative assessments are crucial to understanding development of diseases and their effective treatments. Various validated perimetry and volumetry measurement methods for patients with lymphedema exist and each has its own advantages and limitations and choosing the right instrument is essential. PeriKit® (PK) is a new measurement device that requires validation. This single-blind, cross-sectional study compared three assessment methods for perimetry and volumetry of the lower limb: conventional tape measure (CTM); optoelectronic infrared volumeter (Perometer® (OS) as the gold standard); and PK. Correlation coefficients between measurements were "strong" to "very strong". The ICC of the lower limb was the highest for PK (0.995), followed by the CTM (0.986) and the OS (0.974). PK had the lowest dispersion of results for all segments. Despite its poor reliability, CTM is widely used because of its low cost and portability. The OS is simple, ergonomic, and doesn't require calibration, but suffers from imperfections such as the absence of distal extremities (i.e. feet, hands, fingers, etc.) as well as cost. PK has succeeded in reducing many of the problems associated with measurement thanks to its standardized methodology which offers high repeatability. PK can replace OS and CTM, but OS or CTM can't replace PeriKit® because they are more dispersed and less accurate.

Keywords: PeriKit®, perimetry, limb volume, optoelectronic scanner, conventional tape measure, lymphedema

Quantifying limb circumferences and volumes, especially in the lower limb which is more complex to measure, can generate conflicting results. There is a lack of longitudinal studies of sufficient size that assess the quality and measurement of edema, especially for the lower limb (1).

Little is known about the value of accurate circumference measurement (2). Volumetry is a valuable and non-invasive diagnostic aid for several disorders (3). However, circumference is most often the basis of volume measurements. When taking body measurements, it is important to get as close as possible to the most precise information in order to objectify the evolution of pathologies and treatments (4). The use of perimetry is therefore helpful in many fields e.g.: in neurology, where amyotrophy or hypertrophy must be identified (5,6); in nutrition, to monitor weight loss or gain (7); and in surgery, to quantify a blood effusion (8). The field of lymphology is not an exception to this need for

precise measurements (9-11) with volumetric monitoring recommended for patients at risk for breast cancer-related lymphedema (BCRL) treatment (12). Pre-operative measurement followed by regular post-treatment measurements could detect subtle variations in volume and enable rapid intervention allowing better management (13). Currently, each of these fields require accurate and reliable measurement tools that allows an analysis leading to results as close as possible to reality: the Gold Standard (GS). The GS unfortunately does not take into account many needed practical parameters (cost, size, weight, ease and time of use, adaptability, etc.) (4). For daily practice, a GS is not always the ideal method and further studies are needed to explore the effectiveness of potential tools in these specific applications.

The Optoelectronic scanner (OS) (considered as the GS in this study) allows the measurement of limbs in 3 dimensions by means of an infrared system integrated into a frame in which the entire limb is passed longitudinally (14,15). Another instrument used in our study is the conventional tape measure (CTM) which allows the limb to be reconstructed by comparing it to a series of stacked cones (the cone method), each corresponding to a cylindrical portion of the limb. The volume of the limb can then be calculated by summing the volumes of these individual cones whose dimensions are measured at regular intervals along the length of the limb (16-18).

PeriKit® (PK) is the third instrument in this study (Harfouche Methodology). It is a new circumferential measurement instrument that consists of the PeriBase (longitudinal tape measure) and the PeriTape (perpendicular tape measure). The PeriBase is attached to the root of the limb and its tape measure unrolls longitudinally along the limb being measured. It is then attached to the extremity of the limb (malleoli, styloid) on a bony landmark. This tape measure allows PeriTape to be attached perpendicularly to the limb being measured (19).

The aim of this study is to test a new device, the PK, for measuring lower limb volume changes and to define its intra-observer repeatability. This study also aims to observe whether PK is interchangeable with OS and CTM, two widely used techniques for monitoring limb volumetry.

MATERIALS AND METHODS

This study was carried out at the Oncology Revalidation Department of the UZ Brussel Hospital, between 22/02/2021 and 22/04/2021. The participants were recruited on a voluntary basis and met the following exclusion criteria: patients under 18 years of age (minors); incapacitated subjects; and patients with lower limb amputations or major deformities. A study on healthy subjects represented a first step in establishing the validity of the method (20). Once the method has shown convincing results under simplified conditions, studies can be envisaged on people with pathologies such as lymphedema, in order to validate the accuracy of the PK in complex clinical situations (21).

Studies of intra-observer variability are usually performed on about 25 "limbs" (22). This study is therefore above average since we recorded measurements on 33 lower limbs. The average age of the participants was 37.31 ± 24.26 years (range 18 to 93 years), with a body mass index (BMI) of 25.53 (kg/m^2) ± 4.04 (kg/m^2) (range 20.13 to 35.51 kg/m^2). Only 6.25% of the subjects were left-handed, but both dominant and non-dominant legs were analysed. 37.5% of the legs belong to women and 62.5% to men. For lower limb measurement, 3 devices were selected: a conventional rolling plastic tape measure with millimeter accuracy (+/-1mm), the Rollfix® model (Hoechstmass Balzer GmbH, Sulzbach, Germany); a mobile optoelectronic volumeter, Perometer® 1000M (Pero-System GmbH, Wupertal, Germany) whose results were recorded and analysed with Peroplus™ software (14); and the prototype No. PKPT7050001 of the PeriKit® (Just A New Health SRL, Beauvechain, Belgium).

Measurement Methodology

Protocols for taking perimetry (for limbs, except hands and feet) and volumetry (for hands an feet) measurements have been

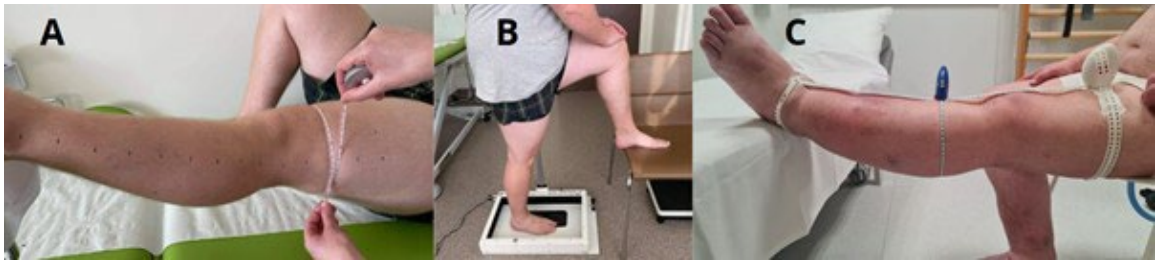

Fig. 1. *Characteristic findings of 3D NMRL include the early Mist pattern (left) and the advanced Spray (middle) and Inky (right) patterns.*

defined by some national or regional health social security agencies in order to ensure the assessment and follow-up of treatments for lymphedema (LO). Since no internationally validated protocol exists, the protocol used was based on the protocol established by the INAMI/RIZIV (Belgian health social security). For the lower limb, the practitioner starts by making an erasable mark at the top of the lateral malleolus, followed by other marks every 4cm in a distal-to-proximal direction up to the knee (at the top of the head of the fibula) or up to the proximal part of the thigh (at the antero-superior iliac spine) (1,23), depending on the segment of interest. The circumferences are then measured at each marker using a flexible CTM and perpendicular to the axis of the measured segment. The operation must be repeated 3 times (at least) so that the average of the measurements (rounded to the nearest centimeter per INAMI/RIZIV, but this study utilized millimeter- see below) at each segment can be used for the volume calculation, which will be done using specific software. Obtaining measurements of the foot was not developed in this study because the OS was not capable of such measurements (24).

Our study was cross-sectional and single-blinded. No participant was diagnosed with lymphatic pathology. Each lower limb is measured with the 3 devices in a randomly defined order to avoid remembering the values (14). The major investigator took the total measurements 5 times with each device, switching devices after each set of measurements. Moving and repositioning between each measurement avoided potential bias in the study based on the individual's position (25). The secondary investigator read the measurements taken, observed any measurement errors/difficulties, and reported them in data log (26). We rounded the measurements to the nearest millimetre (unlike the INAMI/ RIZIV protocol) to ensure greater reliability. This approach is more appropriate in a method validation study and reduces precision bias (27).

Procedure

The three devices are pictured in *Fig. 1*. To define the highest point of the thigh, we have used the following: For PK and CTM, the largest multiple of 4cm, 5cm below the inguinal crease for women and below the bursa for men. For OS, the largest multiple of 4cm below the bursa and the same on the inguinal fold. As the measurements were randomised, the highest measurement was the one defined by the first measurement.

Conventional Tape Measure: The participants were measured in underwear, supine on the examination table, with knee straight and the heel resting high on a lower limb support. The foot is relaxed to avoid straining the muscle structures and thus affecting the total volume of the limb (23). A Micropore® is placed along the length of the lower limb, from the malleolus to the highest point of the thigh as described above, and markings perpendicular to the axis of the lower limb are made every 4cm with a dermographic pencil on the Micropore®. The maximum length was noted for retaking measurements. Circumferences are then measured above each line using

as similar pressure as possible. After measurement, the Micropore® is removed. We calculated volumes from the perimetry measurements using the truncated cone formula.

Optoelectronic Scanner: The participant is in their underwear and standing with foot in the OS frame on a marker on the associated support. Standing upright, the other foot is placed on a chair in front. The knee is then bent and hands placed on it. A perimeter marker is then placed around the ankle at the level of the malleoli, which will be used to define the start of the measurement during the analysis (28). The device is then moved along the axis of the lower limb until it reaches the most proximal part of thigh as possible (close to the root of the limb) and then returned to its initial position (28). Care should be taken to ensure that the person being measured does not touch any part of the frame at any time and that there is no rotation or tilting of the limb (28), which can lead to volume change (23). In order to prevent a volume change that may be due to an upright position, participants were asked to stand only during the measurement of the OS and to return to the horizontal position for the rest of the measurements. The OS uses its own formula for calculating the volume and it is not possible to take measurements every 4cm as the OS takes measurements every 0.4cm ±0.1cm. We therefore had to take the closest measurement to 4cm. The impossibility of taking measurements at strict 4 cm intervals with the OS is not an obstacle because the device is used on the same patient by the same observer. Regardless of the exact intervals, a device can be repeatable with intra-observer consistency (29). However, this limitation can cause problems when comparing the OS with other measurement methods, as it is necessary to obtain standardised intervals for optimal data consistency between techniques.

PeriKit®: The participant is placed in the same position as for the CTM. According to the Harfouche Methodology (4), the PeriBase (PB) is aimed to eliminate positioning errors when taking circumferential measurements and prevent marking the skin of the patient with ink. It is attached at the highest point of the thigh by the large strap(s), as described above. The PB tape is perforated each 1 cm. It is unrolled along the limb and attached to the instep of the foot just below the malleoli by the thin strap, forming the "Reference Point". As the PB tape measure is inextensible, one "Confirmation Point" is defined (4). This confirmation point is unique and steady on each limb (i.e., mole, scar, tattoo, etc.). It is then defined and encoded using a photography attached to the participant's file. This fixed distance between the confirmation and reference point ensures the repeatability of all the measurements each 4cm. The PeriTape (PT) is the precision circumference measuring instrument. It is equipped with an isotonic spiral that delivers a constant tension insuring its precision and repeatability. The PT pin is inserted in each 4 cm holes of the PB. No pressure must be applied on the skin when the measurements are taken. Thanks to the perpendicular superposition of the PB tape and the PT tape, the perpendicular of the PT tape is easily achieved. We calculated the volumes from perimetry measurements using the truncated cone formula.

RESULTS

In order to have identical limb measurements to facilitate accurate comparison and to meet the INAMI standard of taking measurements every 4 cm, we established that the lower volume ends at 40 cm from measurement 0 (which, in retrospect, corresponds to the average measurement of the knee fossa in our participants), and that the upper volume is defined from 40 cm to the most proximal part of the lower limb. We defined the total volume as going from measurement 0 to the most proximal measurable point (sum of the two previous volumes).

Data were compared by calculating the mean and standard deviation (SD), 95% confidence interval (CI), and coefficient of variation (CV). For all results, a p-value < 0.001 was considered highly significant (30). For the 3 volumes (total, lower, and upper segment), in most cases (75%), we observed the largest mean SD (161.53ml) for OS and

TABLE 1
Standard Deviation and Coefficient of Variation Values for Total Volume (Lower Limb + Thigh), Lower Volume (Lower Limb), and Upper Volume (Thigh) for Each of the Three Devices

Measuring devices	Mean SD (ml)	Mean CV (%)	[Min:Max] SD (ml)	[Min:Max] CV (%)
CTM (Total)	110.92	1.41	[20.00: 367.17]	[0.38: 4.11]
PK (Total)	55.18	0.82	[9.22: 88.81]	[0.12: 1.48]
OS (Total)	161.53	2.05	[49.19: 501.94]	[0.29: 7.89]
CTM (Lower)	34.00	1.06	[3.86: 86.50]	[0.14: 3.02]
PK (Lower)	24.89	0.81	[11.29: 49.07]	[0.32: 1.72]
OS (Lower)	52.06	1.41	[11.96: 139.20]	[0.50: 3.27]
CTM (Upper)	88.38	1.91	[16.30: 357.44]	[0.47: 7.09]
PK (Upper)	40.24	1.10	[14.02: 82.86]	[0.44: 1.87]
OS (Upper)	122.72	2.97	[34.10: 482.13]	[0.71: 14.49]

TABLE 2
Intraclass Correlation Coefficient (ICC), 95% Confidence Interval (CI), and P-Value for Total Volume (Lower Limb + Thigh). Lower Volume (Lower Limb) and Upper Volume (Thigh) Measured by the Three Devices. By Convention. Repeatability is Judged to be Very Good if ICC Values are ≥ 0.91 (14)

Measuring devices	ICC	CI	p-value
CTM (Total)	0.985640	[0.98: 0.99]	< 0.00001
PK (Total)	0.995384	[0.99: 1.00]	< 0.00001
OS (Total)	0.973577	[0.96: 0.94]	< 0.00001
CTM (Lower)	0.991718	[0.99: 1.00]	< 0.00001
PK (Lower)	0.995960	[0.99: 1.00]	< 0.00001
OS (Lower)	0.985537	[0.98: 0.99]	< 0.00001
CTM (Upper)	0.979767	[0.97: 0.99]	< 0.00001
PK (Upper)	0.995569	[0.99: 1.00]	< 0.00001
OS (Upper)	0.972648	[0.95: 0.99]	< 0.00001

TABLE 3
Interchangeability of the Measurements by the Three Devices Evaluated by the Pearson Correlation Coefficient Comparing PK and CTM, PK and OS, and CTM and PK

Matching measuring instruments	r-value	p-value
PK - CTM	0.980090	< 0.00001
PK - OS	0.779511	< 0.00001
CTM - OS	0.811128	< 0.00001

the smallest mean SD (55.18ml) for PK, and the largest CV (2.05%) for OS and the smallest CV for PK (0.82%). For the CTM, the dispersion values are generally halfway between the OS and the PK (*Table 1*). PK thus shows the smallest dispersion results.

The intraclass correlation coefficient (ICC) was also calculated to obtain the repeatability. Repeatability is evidence of reliability. For all measurements, the ICCs are above 0.91, which is equivalent to very good repeatability for all devices (31). Based on the 95% CI and the ICC, the PK has better repeatability *(Table 2)* (32). Also, the Pearson correlation coefficient (r), which allows to see if two series are correlated or not was calculated (33). The correlation coefficient is very strong between the PK and the CTM (0.980090), and strong between the PK and the OS (0.779511), and between the CTM and the OS (0.811128) *(Table 3)* (34).

Examining interchangeability using Bland-Altman plots resulted with the largest dispersion for total volume for OS ([-18.46: 6.18]) and smallest for PK ([-2.12: 3.69]). For volume measured in the lower limb, the largest dispersion is for the OS ([-3.30: 5.49]). The values obtained by the CTM ([-2.09: 3.21]) and the PK ([-2.27: 3.11]) are similar. For the volume measured in the thigh, the largest dispersion for the OS ([-37.15: 8.56]) and smallest for the PK ([-3.28: 4.55]). The CTM ([-7.84: 4.42]) is between the two measurements, about 5% more dispersed than the PK *(Table 4; Fig. 2)*.

TABLE 4
Interchangeability of the Measurement (Bland-Altman values) for CTM. OS, and PK for Total Leg, Upper Leg, and Lower Leg Comparing Average (%), 95% Confidence Interval, and [Min: Max]

Measuring devices	Average (%)	CI 95% (%)	[Min: Max] (%)
CTM (Total)	0.15	[-3.38: 3.68]	[-5.04: 3.85]
PK (Total)	0.32	[-2.25: 2.88]	[-2.12: 3.69]
OS (Total)	-0.21	[-8.41: 7.99]	[-18.46: 6.18]
CTM (Lower)	0.37	[-2.15: 2.88]	[-2.09: 3.21]
PK (Lower)	0.46	[-2.23: 3.14]	[-2.27: 3.11]
OS (Lower)	0.21	[-3.45: 3.87]	[-3.30: 5.49]
CTM (Upper)	-0.02	[-5.33: 5.28]	[-7.84: 4.42]
PK (Upper)	0.18	[-3.34: 3.70]	[-3.28: 4.55]
OS (Upper)	-0.52	[-15.37: 14.32]	[-37.15: 8.56]

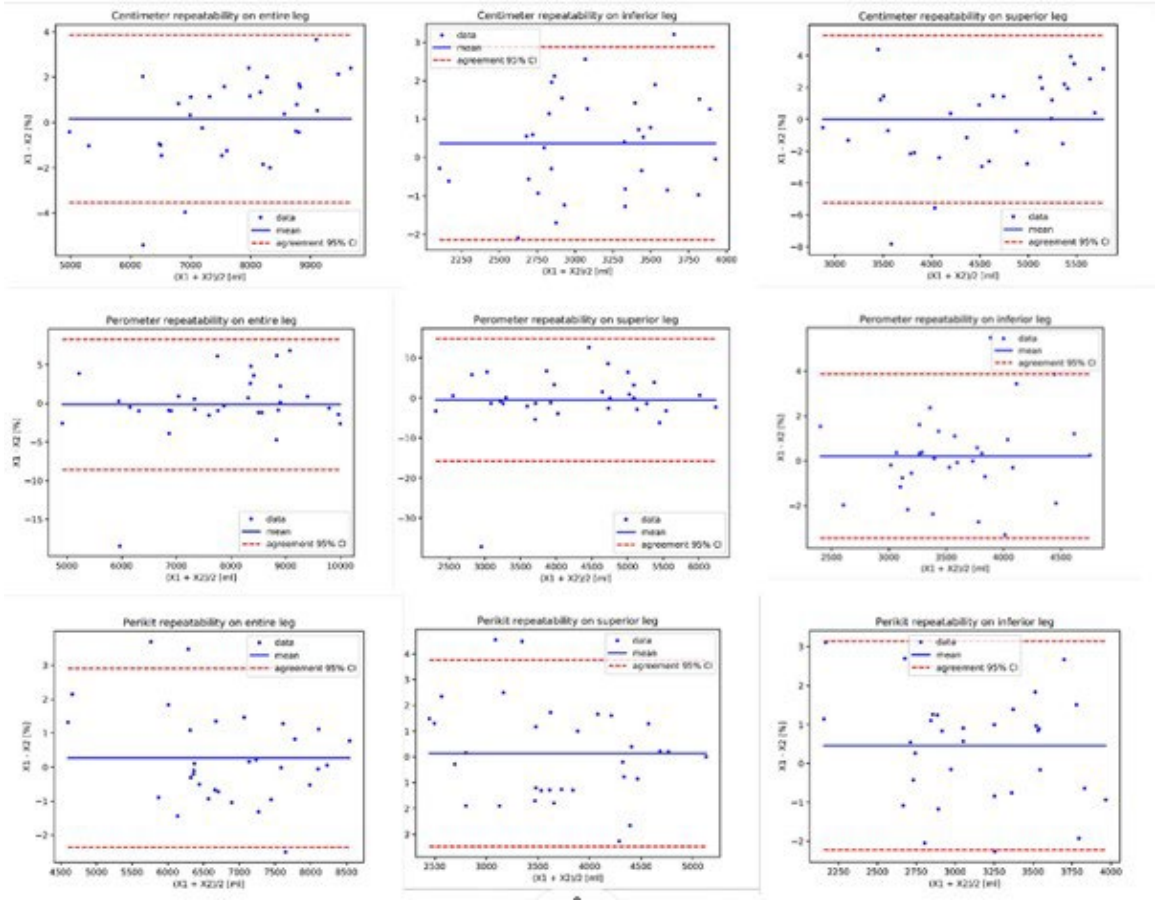

Fig. 2. *Schematic diagrams of the 3D NMRL image patterns based on characteristic 3D NMRL findings. The 3D NMRL stage of thigh and lower leg was determined based on the number of segments with Advanced patterns and Early patterns. The 3D NMRL stage was determined using the total numbers of the thigh and lower leg stages and the foot stages.*

Each device was then compared to the others, two by two (Table 5; Fig. 3). For the lower limb-only comparison, the PK versus CTM results appears to be comparable and therefore interchangeable (186.01ml). This was in contrast to comparisons between the PK and OS (-869.77ml) and between the CTM and OS (-1055.77ml). However, PK seems to have similar results to the OS than CTM, with a smaller 95% CI, despite the larger minimum and maximum. For the thigh comparison only, no results are interchangeable. The PK appears to be much closer to OS values (-417.82ml) than CTM (-589.82ml). Both PK and CTM underestimate the values given by the OS with underestimation by CTM being much bigger. For the total volume of the lower limb, the values are comparable as for the thigh.

DISCUSSION

Circumferences and Volumes

Concerning volume measurements, the ICC's calculated for the three devices are high, similar, and have very good repeatability. But good repeatability of volume does not

TABLE 5
Comparison of Measurements (Bland-Altman) between CTM, OS, and PK for Total Leg, Upper Leg, and Lower Leg for Average (ml), 95% Confidence Interval, and [Min: Max] Comparing 2 devices to each other

Measuring devices	Average (ml)	CI 95% (ml)	[Min: Max] (ml)
PK VS CTM (Total)	186.01	[-314.14: 686.16]	[-110.83: 1117.91]
PK VS OS (Total)	-869.77	[-1629.11: -110.42]	[-1950.46: -290.94]
CTM VS OS (Total)	-1055.77	[-1915.77: -195.78]	[-2056.61: -269.43]
PK VS CTM (Lower)	14.00	[-165.67: 193.68]	[-170.72: 226.77]
PK VS OS (Lower)	-451.95	[-778.58: -125.32]	[-929.30: -177.82]
CTM VS OS (Lower)	-465.95	[-802.04: -129.86]	[-881.96: -133.60]
PK VS CTM (Upper)	172.00	[-201.70: 545.70]	[-78.08: 940.06]
PK VS OS (Upper)	-417.82	[-935.46: 99.82]	[-1059.44: 14.00]
CTM VS OS (Upper)	-589.82	[-1208.98: 29.33]	[-1425.52: -135.83]

mean that the device is really repeatable in terms of circumference. PK, CTM, and OS are basically perimetric devices. Even the OS, often mistakenly called a volumeter, has circumference measurements based on ellipses, which are more reliable because they are easier to measure with fatty or muscular limbs (35,36).

The OS has other important qualities, including absence of contact between the device and patient's skin. This eliminates difficulties associated with "classic" measurement with CTM, i.e. inconsistent tension (often too big, especially in the case of LO) placed on the tape measure (23) and stigma of notations on the skin, etc. However, PK also manages to eliminate some of these disadvantages by using an isotonic tension by means of a calibrated spring, and because it does not require markings on the skin. OS is not capable of analysing a whole limb (distant extremities cannot be measured) with difficulties for the upper thigh (37) in the classical vertical position. In addition, segmental analysis remains inaccurate in terms of circumferences. On the contrary, one advantages of perimetry is the ability to segment the limb and to assess variations in volume, even small ones, over relatively small areas (impossible with the current GS since it only considers the complete volume).

Unfortunately, CTM results always show strong and inconsistent volumetric over- or underestimations, probably due to volume approximation formula used to calculate circumferences to volume, and by regular measurement errors (28,38). There are several types of calculations for moving from circumferences to volume. Each type of formula can cause different variations depending on the type of limb morphology (limb size, dominance, amount of fat, etc.) (14). The cylinder formula would be more efficient but would overestimate the values (39,40). The more widely used truncated cone formula underestimates values up to 300ml and its results are higher than the standard error of measurement (15,41,42). However, the shorter the limb, the less underestimation there will be. Perhaps the 4cm height defined by INAMI/RIZIV should then be lowered to further increase the value of perimeter methods (43). This will inexorably

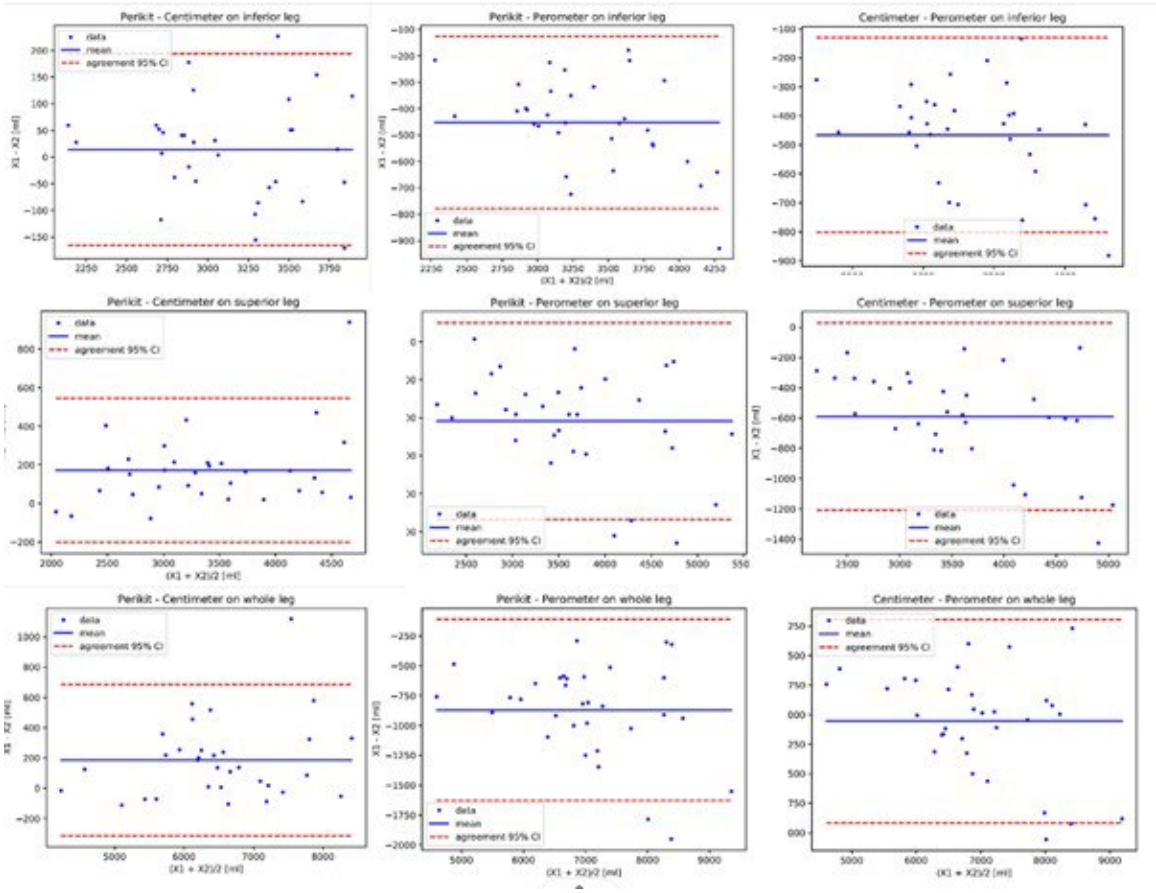

Fig. 3. *The prevalence of fluid infiltration on NMRL. The total prevalence of each pattern in all areas (P < 0.001) (A). The prevalence of Mist (B), Spray (C), and Inky (D) patterns according to the ICG-L stage (P < 0.001). The association between the prevalence of predominant NMRL findings and the ICG-L stage (P < 0.001) (E) and between the prevalence of the NMRL stage and the ICG-L stage (P < 0.001) (F).*

increase the time of the measurement.

PK is also affected by underestimations, which are less scattered and much lower than CTM. It is therefore necessary to choose the formula that best fits the clinical situation. Usually, the frustrum or disc method is used. Fixed reference points may compromise accuracy of the frustrum method as the measured segment may not be a true truncated cone, but it greatly facilitates the comparison between different measurement techniques. With such criteria, studies have shown that the disc method is more accurate and efficient, and that the frustrum method is too inaccurate for clinical situations with an r=0.72 for water displacement (WD) compared to an r=0.90 for the disc method (23,37). A study in LO diagnosis showed that the frustrum method diagnoses 63.4% of LO, compared to 85.3% for the disc method and OS, and 90.3% for WD (14). It appears that no one formula is good to use in all cases, but the same formula should be used in evaluation of the same patient- they are clearly not interchangeable within one patient. We should choose the best formula depending on the situation that best correlates with the shape of the lower limb (44). Moving from an edematous to a healthy lower limb

makes the measurement even more complex as it requires 2 different calculations which causes measurement bias. The frustrum method would be better than the disc method (23), but accuracy of each model depends on the shape of the limb segment: an edematous lower limb or upper limb would be better suited to the disc method, and the thigh or healthy limb to the frustrum method. The more deviation there is from an assumed truncated cone shape, the bigger is the measurement error. In this context, the truncated cone method was used in this study since the study focuses on healthy people and includes the thigh. One study also defined that the truncated cone would be more effective for the lower limb while the arm would appear to be more uniformly edematous and therefore more cylindrical than the lower limbs (45).

Interchangeability of Measurement

A 10% difference in volume appears to confirm the presence of pathology (diagnostic threshold) (2,46), so perhaps this order of magnitude and the definition of interchangeability criteria should be reviewed? A diagnostic criterion of 10% seems too close to the measurement error of 10% or more measured between different devices, so there could be pathology with one device and no pathology with another. The accuracy of a device seems unavoidable to define whether or not there are volume variations.

There are strong correlations between CTM and OS (r=0.95) (47), but little agreement between OS and CTM, as the latter would overestimate limb volumes (25,38), concluding that there is no interchangeability between these 2 methods. PK is the device with the least over- and/or underestimation of the measurement compared to WD, ahead of, respectively, the CTM and OS (30). There would be a close agreement between the OS and GS (3% difference) while the indirect methods (disc and frustrum) would differ between 8-12% (37). However, there is a lack of studies conducted on the vertical OS, which we used in this study. Other studies confirm good results of the horizontal OS (15,48) and point out underestimation of volume measurements of the CTM. The statistical indices of the horizontal OS are therefore often generalised to the vertical version when in fact (35), volume measurements differ when there are differences in knee angle. This is due to misalignment of the thigh and lower limb axes with respect to the longitudinal axis of the OS, e.g., during postural sway, and due to the tensioning of certain muscle chiefs via the foot resting on the floor. This implies that the results obtained on the horizontal OS are not generalizable to the vertical OS. This may explain the lower ICCs measured for the OS compared to those cited in literature. The measurements established in this study for OS are similar, but a bit lower than previous studies (15,38), around 0.99, but the measurement error of this method would only be clinically "acceptable", by too large 95% CIs (-934ml to 519ml) and too big SD (38). Indeed, most studies only focus on the lower limb up to 36 or 40cm in length, at knee level (25), as they use a horizontal OS, not easily allowing for higher measurements. Here, the study was also done on the thigh, and the ICC is lower. The OS would therefore be a good device for the limbs, but only for the distal parts and those less fatty or muscular. It is less reproducible than PK. The differences in measurement between the OS and the CTM are small, but still significant (1).

Examing the correlation coefficient can be misleading: a high r does not mean that 2 methods agree, which is why one should also look at the limits of agreement (49). Even a high correlation coefficient (r=0.93) between the GS and extrapolation of data obtained by the circumferential measurement with a truncated cone can show that there is a huge gap between 2 methods, as there is an unacceptable degree of agreement reflecting large variations in measurements (3,50). The r indicates whether two series are correlated or not (51). However, correlation does not mean agreement, so care should be taken when drawing conclusions from the Pearson coefficient even if it is close to 1. In this study, the techniques studied are highly correlated, but the Pearson coefficient is not the most appropriate method

to attest to agreement if used alone (37,52).

About Inter-rater Reliability?

Assessing intra-observer repeatability is a crucial methodological step in establishing accuracy of a device or method under controlled conditions where the same observer performs multiple measurements under identical conditions (53,54). Repeatability is considered the first step in method validation studies because it ensures consistency of measurements by a single observer before introducing variability due to different observers or conditions (inter-observer reproducibility) (52). This approach reduces the risk of differences in results being attributed to basic methodological inconsistencies and strengthens the validity of the instrument (29). The next stage may focus on reproducibility, providing an insight into the robustness of the instrument in more realistic clinical situations (55). Testing repeatability first therefore provides a reliable and accurate basis for studying reproducibility with greater confidence, ensuring that the variations observed are due more to differences between observers or to measurement conditions, and not to intrinsic inconsistencies in the method (20). Future inter-observer studies are needed and are in preparation.

Other Issues

The CTM has a wider distribution of minimum and maximum values. The CTM is less precise than PK and OS due to uncertainty about the measurement location and this can lead to significant volume variations, so repeatability is not assured.

The OS is a non-contact device, but it is sometimes necessary to place a physical marker on the skin to isolate a limb segment. This makes it difficult to compare it with other devices, as the reference point at the malleoli is not constant and varies from one measurement to another. This also could be influenced by the mobility of the skin in relation to the bony landmark. Additionally, the design of the device makes it difficult to choose a similar starting value for each measurement. The procedure described in the OS manual is to place plasticine around the ankle so it does not match with the INAMI/RIZIV method. In all cases, if a measuring device is used intra-observer with its own measurement methodology and repeatable starting points, this constitutes a kind of measurement 'standardisation' for that device. However, during patient follow-up, repeatability is rarely guaranteed and there is no validated inter-clinical or inter-observer methodology (general standardisation of measurement). With PK for example, the methodology for taking measurements is completely standardised with predefined confirmation points and reference points, allowing standardisation and better reproducibility of measurements (54). However, this needs to be refined through more clinical studies. The use of such a methodology reduces heterogeneity associated with different clinical practices and ensures greater consistency of measurements between different care sites. In all cases, whatever the device used, the same method must be used each time for the same patient, which improves repeatability.

The OS would become the future GS due to its many qualities during measurements (1,15,37,56). However, its cost remains an absolute obstacle for many practitioners and its lack of accessibility is a problem for everyday practice. Also, the OS presents the impossibility of taking measurements every 4 cm accurately, which leads to measurement errors especially in the fatter or more muscular segments. Although it has more segments measured, which explains its higher accuracy. Selecting a specific area in the lower limb or thigh is difficult. The software does not offer recognition of "irregular" points and the delineation of a body segment must be done manually. The analysis of the volume of this segment does not always correspond to the selected markers, which can vary by several millimeters and therefore induce a summation of the error. It does not measure hands/feet and has difficulty measuring the ankle and thigh (37). It measures an overall volume (it is necessary to add manipulations to have a precise segment) without differentiating between a decreasing LO and/or an increasing

muscle size. If the lower third of the leg contains reduced muscle mass and there is a decrease or increase in the lower third, it can only be attributed to edema. However, the upper third occupied by muscle can fluctuate. In this case, circumferential measurements have the advantage of being able to isolate the lower third from the upper third.

One essential quality that a LO measuring device must have is its ability to be sensitive to changes in volume (43). Monitoring must be able to show the slightest change in volume to best anticipate and prevent the occurrence of LO. The sensitivity of CTM to volume variations is 8%, OS is 6% and that of PK is 4% (43). Summing volumes will increase the measurement error and mask the segmental inconsistency that may exist (43). This increases the value of taking circumferential measurements.

CONCLUSION

Volumetric measurements calculated from perimetric measurements are considered reliable, repeatable, and reproducible. The choice of one technique over another depends on access to the equipment, the operator, pathology, and limitations of each method. PK is the only device that can address all three of these issues with the participant being his own comparator for every technique (57). Several points appear to be essential for measuring a limb: using the right equipment in the right situation; using the right formula to convert circumferences to volumes; and not only focusing on the volume, but also on the circumferences which give essential information on the progression/regression of volume. But it's also essential to select the right segment to measure and to always use the same technique in the same patient for a correct follow-up.

Concerning intra-observer repeatability, PeriKit® seems sufficiently repeatable to allow the monitoring of lower limb volumetry. PK therefore provides consistently very similar intra-observer measurements. Examing interchangeability between 2 methods for monitoring lower limb volumetry, in terms of measurement capabilities, OS or CTM can't replace PK, but PK can replace OS and CTM *(Table 6)*. It is not possible to find identical measurements between PK, CTM, and OS, among other things because of the impossibility for the OS to measure hands/feet.

For the measurement of lower limb volume, a fast, reliable, repeatable, and reproducible method is needed today to make it as accurate and patient friendly as possible (58). Some practitioners have regular access to minimal equipment and the more empirical methods therefore play an essential role in daily practice (44). A precise measurement is useful for the patient to improve compliance with treatment as well as to the practitioner, who can make an early diagnosis, improves therapy, or even compares several treatments (16). A standardised assessment method based on a tape is reliable and reproducible for leg circumference (59) and volume calculated from circumferences is the best measurement method in terms of reliability, cost, time, and limitation of use, etc (26).

TABLE 6
Comparison Summary Among the Three Different Measurement Devices. The Best Method for each Comparison of Devices is Presented

Measuring devices	Measurement of extremities	Measurement accuracy	Ease of taking measurements
PK VS CTM	PK	PK	PK
PK VS OS	PK	PK	PK
CTM VS OS	CTM	CTM	CTM

CONCLUSION

Volumetric measurements calculated from perimetric measurements are considered reliable, repeatable, and reproducible. The choice of one technique over another depends on access to the equipment, the operator, pathology, and limitations of each method. PK is the only device that can address all three of these issues with the participant being his own comparator for every technique (57). Several points appear to be essential for measuring a limb: using the right equipment in the right situation; using the right formula to convert circumferences to volumes; and not only focusing on the volume, but also on the circumferences which give essential information on the progression/regression of volume. But it's also essential to select the right segment to measure and to always use the same technique in the same patient for a correct follow-up.

Concerning intra-observer repeatability, PeriKit® seems sufficiently repeatable to allow the monitoring of lower limb volumetry. PK therefore provides consistently very similar intra-observer measurements. Examing interchangeability between 2 methods for monitoring lower limb volumetry, in terms of measurement capabilities, OS or CTM can't replace PK, but PK can replace OS and CTM *(Table 6)*. It is not possible to find identical measurements between PK, CTM, and OS, among other things because of the impossibility for the OS to measure hands/feet.

For the measurement of lower limb volume, a fast, reliable, repeatable, and reproducible method is needed today to make it as accurate and patient friendly as possible (58). Some practitioners have regular access to minimal equipment and the more empirical methods therefore play an essential role in daily practice (44). A precise measurement is useful for the patient to improve compliance with treatment as well as to the practitioner, who can make an early diagnosis, improves therapy, or even compares several treatments (16). A standardised assessment method based on a tape is reliable and reproducible for leg circumference (59) and volume calculated from circumferences is the best measurement method in terms of reliability, cost, time, and limitation of use, etc (26).

PK is a sensitive, accurate, and reproducible device that solves most of the issues cited in this study (43,58). Its results are better than those of CTM and OS. Several tools exist, all with benefits and limitations. The OS, as a « direct » measurement method, is widely accepted as the GS, and many studies have proven its validity, sensitivity, and specificity. But in clinical practice, the PK can potentially serve as an equal alternative based on results from this study.

CONFLICT OF INTEREST AND DISCLOSURE

All authors declare no competing financial interests exist.

REFERENCES

1. Stanton, AW, C Badger, J Sitzia: Non-invasive assessment of the lymphedematous limb. Lymphology 30 (2000), 122–135.
2. Gardner, GC, JP Nickerson, R Watts, et al: Quantitative and morphologic change associated with breast cancer-related lymphedema. Comparison of 3.0T MRI to external measures. Lymphat. Res. Biol. 12 (2014), 95–102.
3. Kaulesar, Sukul, PT den Hoed, EJ Johannes, et al: Direct and indirect methods for the quantification of lower limb volume: Comparison between water displacement volumetry, the disk model method and the frustum sign model method, using the correlation coefficient and the limits of agreement. J. Biomed. Eng. 15 (1993), 477–480.
4. Louys, M, M Mathieu, S Harnie, et al: How to quantify limb volume: A new overview of measurement methods. The European Journal of Lymphology 34 (2023), 11-18.
5. Léger, B, C Gobelet: Schweizerische Zeitschrift. Sportmedizin Und Sporttraumatologie. 59 (2011), 14–17.
6. Franchi, MV, DP Fitze, J Hanimann, et al: Panoramic ultrasound vs. MRI for the assessment of hamstrings cross-sectional area and volume in a large athletic cohort. Sci. Rep.-UK 10 (2020).
7. González-Ruíz, K, M Medrano, J Correa-

Bautista, et al: Comparison of bioelectrical impedance analysis, slaughter skinfold-thickness equations, and dual-energy x-ray absorptiometry for estimating body fat percentage in Colombian children and adolescents with excess of adiposity. Nutrients. 10 (2018), 1086.
8. Loyd, BJ, AJ Kittelson, J Forster, et al: Development of a reference chart to monitor postoperative swelling following total knee arthroplasty. Disabil. Rehabil. 42 (2019), 1767–1774.
9. Petlund, CF: Volumetry of limbs. In: Lymph Stasis: Pathophysiology, Diagnosis and Treatment. CRC Press, 2019, 443–452.
10. Warren, AG, H Brorson, LJ Borud, et al: Lymphedema. Ann. Plas. Surg. 59 (2007), 464–472.
11. Zuccarelli, F, A Bérard: Test-retest reliability study of a new improved Leg-O-Meter, the Leg-O-Meter II, in patients suffering from venous insufficiency of the lower limbs. Angiology. 51 (2000), 711–717.
12. Cormier, JN, RL Askew, KS Mungovan, et al: Lymphedema beyond breast cancer: A systematic review and meta-analysis of cancer-related secondary lymphedema. Cancer. 116 (2010), 5138-5149.
13. Ridner, SH: Quality of life and a symptom cluster associated with breast cancer treatment-related lymphedema. Support. Care Cancer 13 (2005), 904-911.
14. Adriaenssens, N, R Buyl, P Lievens, et al: Comparative study between mobile infrared optoelectronic volumetry with a perometer® and two commonly used methods for the evaluation of arm volume in patients with breast cancer related lymphedema of the arm. Lymphology 46 (2013), 132–143.
15. Czerniec, SA, LC Ward, KM Refshauge, et al: Assessment of breast cancer-related arm lymphedema—comparison of physical measurement methods and self-report. Cancer Invest. 28 (2009), 54–62.
16. Auvert, JF, M Vayssairat: La volumétrie: Un examen complémentaire indispensable en lymphologie. La Revue de Médecine Interne. 23 (2002), 388s–390s.
17. Ramsey-Goldman, R: Measurements of extremity volume in systemic sclerosis: Comparison of four methods. Arthritis Rheum. 36 (1993), 1504-1510.
18. Földi E, M Földi, L Clodius: Földi's Textbook of Lymphology: For Physicians and Lymph-edema Therapists. Urban & Fischer, 2003.
19. Harfouche, J, N Daoud, T Velu: The PeriKit®: Reproductibility and accuracy of an innovative portable device to measure the limb perimeter through a blinded study. The European Journal of Lymphology 28 (2016).
20. Bollen, KA, PJ Curran: Latent Curve Models: A Structural Equation Perspective. John Wiley & Sons, 2006.
21. International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema: 2023 consensus document of the International Society of Lymphology. Lymphology 56 (2023), 133-151.
22. Damstra, RJ, EJ Glazenburg, WCJ Hop: Validation of the inverse water volumetry method: A new gold standard for arm volume measurements. Breast Cancer Res. Tr. 99 (2006), 267–273.
23. Stanton, A, J Northfield, B Holroyd, et al: Validation of an optoelectronic limb volumeter (Perometer®). Lymphology 30 (1997), 77–97.
24. La nomenclature de kinésithérapie [Internet]. INAMI. (2020).
25. Labs, K-H, M Tschoepl, G Gamba, et al. The reliability of lower limb circumference assessment: A comparison of spring tape measurements and optoelectronic volumetry. Vasc. Med. 5 (2000), 69–74.
26. De Vrieze, T, N Gebruers, WA Tjalma, et al: What is the best method to determine excessive arm volume in patients with breast cancer–related lymphedema in clinical practice? Reliability, time efficiency and clinical feasibility of five different methods. Clin. Rehabil. 33 (2019), 1221–1232.
27. Hutchinson, TA. Precision and reliability of measurement in medicine. BMJ Open 320 (2000), 54.
28. Pero-System mess geraete GmbH. Manual Perometer®. Perometer® Software PeroPlus; (2017).
29. Atkinson, G, AM Nevill AM: Statistical methods for assessing measurement error (reliability) in variables relevant to sports medicine. Sports Med. 26 (1998), 217-238.
30. Symons, F : Mémoire : Comparaison d'un nouvel outil de mesure volumétrique (PeriKit®) avec des outils de mesure habituels. Haute École Bruxelles-Brabant, Unité structurelle paramédicale, Kinésithérapie ISEK. (2017).
31. Walter, SD, M Eliasziw, A Donner: Sample size and optimal designs for reliability studies. Stat. Med. 17 (1998), 101–110.
32. Bravo, G, L Potvin: Estimating the reliability of continuous measures with cronbach's alpha

or the intraclass correlation coefficient: Toward the integration of two traditions. J. Clin. Epidemiol. 44 (1991), 381–390.
33. Fermanian, J : Validation des échelles d'évaluation en médecine physique et de réadaptation: Comment apprécier correctement leurs qualités psychométriques. Annales de Réadaptation et de Médecine Physique. 48 (2005), 281–287.
34. Schober, P, C Boer, LA Schwarte: Correlation coefficients. Anesth. Analg. 126 (2018), 1763–1768.
35. Man, IOW, KL Markland, MC Morrissey: The validity and reliability of the Perometer® in evaluating human knee volume. Clin. Physiol. Funct. I. 24 (2004), 352–358.
36. Fialka-Moser, V, M Korpan, E Varela, et al: The role of physical and rehabilitation medicine specialist in lymphedema. Annals of Physical and Rehabilitation Medicine. 56 (2013), 396–410.
37. Tierney, S, M Aslam, K Rennie, et al: Infrared optoelectronic volumetry, the ideal way to measure limb volume. Eur. J. Vasc. Endovasc. 12 (1996), 412–417.
38. Tan, C-W, F Coutts, C Bulley: Measurement of lower limb volume: Agreement between the vertically oriented Perometer® and a tape measure method. Physiotherapy. 99 (2013), 247–251.
39. Lilja, M, T Ober: Volumetric determinations with CAD/CAM in prosthetics and orthotics: Errors of measurement. J. Rehabil. Res. Dev. 32 (1995), 141–148.
40. Tewari, N, PG Gill, MA Bochner, et al: Comparison of volume displacement versus circumferential arm measurements for lymphedema: Implications for The Snac Trial. ANZ J. Surg. 78 (2008), 889–893.
41. Szuba, A, JP Cooke, S Yousuf, et al: Decongestive lymphatic therapy for patients with cancer-related or primary lymphedema. Am. J. Med. 109 (2000), 296–300.
42. McNeely, ML, DJ Magee, AW Lees, et al: The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: A randomized controlled trial. Breast Cancer Res. Tr. 86 (2004), 95–106.
43. Watteyne, M: Mémoire : Comparaison de 3 outils de mesure volumétrique que sont le mètre ruban, le PeriKit® et le scanner. Haute École Bruxelles-Brabant, Unité structurelle paramédicale, Kinésithérapie ISEK. (2017).
44. Sitzia, J: Volume measurement in lymphedema treatment: examination of formulae. Eur. J. Cancer Care 4 (1995), 11–16.
45. Casley-Smith, JR: Measuring and representing peripheral edema and its alterations. Lymphology 27 (1994), 56–70.
46. Armer, JM, BR Stewart: A comparison of four diagnostic criteria for lymphedema in a post-breast cancer population. Lymphat. Res. Biol. 3 (2005), 208–217.
47. Tunc, R, A Caglayan-Tunc, G Kisakol, et al: Intraobserver and interobserver agreements of lower limb circumference measurements by tape measure based on 3 reference points. Angiology 58 (2007), 593–596.
48. Deltombe, T, J Jamart, S Recloux, et al: Reliability and limits of agreement of circumferential, water displacement, and optoelectronic volumetry in the measurement of upper limb lymphedema. Lymphology 40 (2007), 26–34.
49. Desquilbet, L: Guide pratique de validation statistique de méthodes de mesure: Répétabilité, reproductibilité, et concordance. HAL Open Science. (2020).
50. Müller, R, P Büttner: A critical discussion of intraclass correlation coefficients. Stat. Med. 13 (1994), 2465–2476.
51. Walter, SD, M Eliasziw, A Donner: Sample size and optimal designs for reliability studies. Stat. Med. 17 (1998), 101–110.
52. Bland, JM, DG Altman: Statistical methods for assessing agreement between two methods of clinical measurement. Int. J. Nurs. Stud. 47 (2010), 931–936.
53. Shrout, PE, JL Fleiss: Intraclass correlations: Uses in assessing rater reliability. Psychol. Bull. 86 (1979), 420.
54. Koo, TK, MY Li: A guideline of selecting and reporting intraclass correlation coefficients for reliability research. J. Chiroprac. Med. 15 (2016), 155-163.
55. Hopkins, WG: Measures of reliability in sports medicine and science. Sports Med. 30 (2000), 1-15.
56. Jain, M, J Danoff, S Paul: Correlation between bioelectrical spectroscopy and perometry in assessment of upper extremity swelling. Lymphology 43 (2010), 85–94.
57. Boulon, C, F Becker, S Vignes: Comment quantifier un œdème des membres. J. Mal. Vascul. 35 (2010), 163–168.
58. Harfouche, J: The periKit: An innovative connected portable device with high level of accuracy and reliability in taking circumferential limb measurements. Veins and Lymphatics 6 (2017); 14-15.

59. te Slaa, A, P Mulder, D Dolmans, et al: Reliability and reproducibility of a clinical application of a simple technique for repeated circumferential lower limb measurements. Phlebology 26 (2010), 14–19.

Maxime Louys, PT
5 Avenue Winston Churchill,
1180 Brussels, Belgium
Email: maximelouys@hotmail.com
Phone: +32(0)476421981