A NEW WAY TO ASSESS SUPERFICIAL CHANGES TO LYMPHOEDEMA

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Abstract

Background: Appropriate management of lymphoedema requires an accurate diagnosis of the changes in fibrotic induration in order to target treatment. Tonometry is used to measure tissue's resistance to compression and provide an objective assessment of the stage of lymphoedema, tissue changes and treatment efficacy. The mechanical tonometer that is commonly used has some shortcomings, as the display is difficult to read and has to be read while in place on the limb. A new tool, the indurometer, has been designed to replicate the function of the tonometer, but overcome its shortcomings. *Aims:* This study compared a prototype indurometer with the original mechanical tonometer. *Methods:* A prototype indurometer and an original tonometer were used to measure fibrotic induration levels on 22 subjects with secondary arm lymphoedema taken at six points on each patient's body. The results were analysed for repeatability using a coefficient of variation and the usability of each device was considered. *Results:* The results from the indurometer had a similar repeatability to the tonometer. The tonometer had consistent repeatability at all measurement sites and, while similarly good, the indurometer's repeatability deteriorated for measurements at the anterior chest. *Conclusion:* Some changes will need to be made to the indurometer's design to make measurements more repeatable. *Declaration of interest:* Olivia Pallotta and Mark McEwen are employed by Flinders Biomedical Enterprises Pty Ltd.

Key words

Lymphoedema
Tonometry
Diagnosis and treatment efficacy
Indurometer

Lymphoedema occurs when the transport capacity of the lymphatic system is reduced while the lymph load remains within a normal range. The failure may be a result of:

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- Slow change in extracellular fluids and their contents (Piller and Birrell, 2004)
- A decrease in tissue oxygenation levels (Piller and Birrell, 2004)
- An increase in the distance between vascular lymphatic capillaries (Piller and Birrell, 2004)
- Change in cell functionality, e.g. adipocytes, microphages and fibroblasts (Piller and Birrell, 2004)

In the early stages of the disease (the latent or hidden phase), only subtle changes occur. Subjective signs are typically experienced such as heaviness, tension, bursting pain or aches, and changes in the limb during the day. Fluid begins to predominate in the lymphatic territories or within the whole limb or organ. This stage (stage 1) is reversible on elevation. The tissue is soft, pitting is present and there are minimal skin changes. As the condition progresses, a protein-rich fluid accumulates in the tissue which is gradually replaced by fibrous tissue. The build up of fibre results in external pressure on the lymph collectors and inhibition of pulsation and transport capacity. At this stage (stage 2), limb volume does not regress on elevation due to the tissue changes. The third stage — rarely seen — manifests as a significantly enlarged limb (or in some cases a small, hard, fibrous limb when the lower limb is involved), with significant sclerosis and skin changes (Piller and Birrell, 2004).

Once lymphoedema has developed, there is no cure, but there are a range of treatment options. These options involve reducing the lymphatic load by improving the integrity and functionality of vital physiological systems affected by the condition (vascular, cardiac and skin), improved wound and skin care, minimising risk of infection, examining factors that have a negative impact such as body mass index (BMI), and the use of support garments (Piller and Birrell, 2004). Halting the progression of the disease is regarded as a positive treatment outcome. Treatment goals aim to improve lymphoedema status by producing an increase in limb comfort and/or a reduction in limb size (Piller and Birrell, 2004). Treatment typically

begins after the latent phase (as the early stage is often missed) and during the clinically manifest stage, where there is significant change in limb size (a circumference difference of 2cm or more, or volume difference of 200ml or more) (Piller and Birrell, 2004). Early detection of the condition may yield better outcomes for the patient's lifestyle and for the management of the disease (Cornish et al, 2000; Piller et al, 2009; Piller, 2007). An instrument to detect lymphoedema during its early stages would be a powerful tool in the management and control of the condition. Furthermore, individual patients can respond differently to treatment and there is no particular combination of treatments that work successfully for all patients. Therefore, it is vital to use tools to monitor disease progression and efficacy of treatments (Piller and Birrell, 2004).

A range of tools are available to monitor lymphoedema. Each may measure different aspects of the condition, but all provide information to assist in the diagnosis and monitoring of treatment progress. These tools include:

- Lymphoscintography detects reduced lymph transport capacity by observing dye movement. It is an invasive and costly procedure, and is not practical for day-to-day monitoring of the condition (Piller and Birrell, 2004)
- Magnetic resonance imaging (MRI) and ultrasound can be used to assess structural changes. MRI can detect pooling of fluid, lymphatic anatomical structures and the level of fibre within the tissues. However, MRI is not able to detect subtle changes in fluid (Piller and Birrell, 2004). Ultrasound is ideal for assessing fibrotic induration, distances between deep tissue layers and changes in tissue thickness (Piller and Birrell, 2004). Both of these methods are relatively expensive and are not always easily accessible to lymphoedema clinics
- Bioimpedance measures the amount of fluid in the limb segments of the body (arms, legs and trunk). The devices come in a range of sizes including large stand-on whole body units (Bio-Space, Korea) to smaller hand-held units (ImpediMed, Australia). They are generally less expensive than imaging techniques. While bioimpedance devices can measure fluid content within a limb, they cannot pinpoint the areas or territories within the limb where pooling is occurring. In this situation, the extent of fluid pooling (identified as areas where pitting occurs) needs to be accessed with finger pressure (Piller and Birrell, 2004)
- Tonometry monitors the amount of fibrotic induration within a limb. It does this by measuring the tissue's resistance to compression by an applied weight at the lymphatic territories. The higher the resistance to compression, the higher the fibrotic induration. Tonometry provides a comparative (not absolute) measure of fibre, hence the results must be compared with contralateral limb territories, or to measurement changes over time (Piller and Birrell, 2004).

An instrument to detect lymphoedema during its early stages would be a powerful tool in the management and control of the condition.

While all of these tools provide a means of assessing the progression of the disease and treatment efficacy, each tool monitors a different aspect of the condition: fluid, fibre, transport capacity or structural changes. Lymphoscintograms are the gold standard measure assessing functional changes in the lymphatic system. The other tools measure lymphatic failure. Bioimpedance and tonometry are typically used within a clinic due to their availability, low cost, transportability and small size. This article focuses on the use of tonometry in lymphoedema management and considers a prototype of a new form of tonometer which has been produced to avoid the problems associated with the design of the original mechanical tonometer.

Figure 1. Mechanical tonometer, manufactured by Biomedical Engineering, Flinders Medical Centre, Australia. The black reference plate of the device rests on tissue.

Tonometry

Tonometry has been used since 1976 to monitor tissue changes (Clodius et al, 1976). It measures the resistance of the tissue above the deep fascia to compression by using a 200g mass and a displacement gauge. Tonometry was designed to provide an objective measure of tissue's induration (Piller and Birrell, 2004) and can be used to replace the subjective measure of a finger press (Stanton, 2002), or the pinch and roll technique (Piller, 2007). Research has shown that tonometry can indicate the degree of fibrosis and the impact of treatment when used over the major lymphatic territories (Piller and Clodius, 1976; Chen et al, 1988; Kar et al, 1992; Liu and Olszewski, 1992; Stanton et al, 2000; Stanton, 2002; Rockson, 2006; Piller, 2007; Moseley and Piller, 2008).

The original mechanical tonometer, based on the Clodius et al design of 1976 (Clodius et al,

1976) (manufactured by Biomedical Engineering, Flinders Medical Centre, Australia) is a mechanical device. It uses a 200g mass and a plunger to apply the compression force to the tissue. The degree of compression is read from an analogue dial gauge with 0.1mm resolution (*Figure 1*).

While used in many studies and shown to correlate with fibrous tissue, its design does present problems such as:

- A difficult-to-read dial (Bates et al, 1994; Chen et al, 2008)
- The dial must be read while the device is held *in situ*, which can be cumbersome to use at some measurement sites
- It can only be used in a vertical position (Bates et al, 1994; Chen et al, 2008)
- The user must balance the 200g weight at the measurement site due to the top-heavy nature of the design (Bates et al, 1994; Chen et al, 2008)
- It requires user training to improve technique (Bates et al, 1994; Chen et al, 2008)
- When pitting is present the user must make sure that they take a reading at a fixed time after the 200g is applied, because the reading changes with time as the tissue pits (Bates et al, 1994; Chen et al, 2008).

A new tonometry device called the indurometer (*Figure 2*) is under development by FBE Pty Ltd, Australia, in an attempt to overcome the shortcomings of the mechanical tonometer. Prototype devices have been supplied for trial purposes.

The prototype indurometers exert the same force as the mechanical tonometer — compression of the tissue by a plunger to 200g. However, the device is electronic with a digital screen displaying the result with 0.01mm resolution. The readings are stored on the device until the user clears them. Unlike the mechanical tonometer, this means that the display does not have to be read *in situ*. The indurometer takes readings at the instant in time when 200g is applied (reducing the effect of pitting on the measurement). In addition, it can be used in non-vertical positions because it does not use a mass to apply the 200g, but rather a constant force spring pushes into the tissue.

Figure 2. Indurometer, manufactured by FBE Pty Ftd, Australia. The transparent reference plate of the device rests on tissue.

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This study investigates the new indurometer. The indurometer and the mechanical tonometer are compared for ease of use and the repeatability of their results.

Methods

Both the mechanical tonometer and indurometer were used to assess tissue compliance in subjects with lymphoedema of the arms. Twelve subjects were recruited from the Lymphoedema Assessment Clinic at Flinders Medical Centre and 10 from the Lymphoedema and Laser Therapy Clinic, both in Adelaide. Potential subjects were informed of the nature of the study and provided with an information sheet. Informed written consent was obtained. The inclusion criteria were:

- Aged between 18 and 75 years
- General health described as satisfactory by the patient
- Had lymphoedema in one arm
- Was able to give informed written consent for entry into the study.

Patients were excluded if they:

- Were taking diuretic medications
- Had undertaken excessive exercise within two hours of measurement
- Had consumed large amounts of alcohol or caffeinated drinks within six hours of the measurements
- Were in the fourth week of their menstrual cycle
- Were currently pregnant or breast-feeding
- Had a fever at the time of screening.

The following data was collected:

- Medical history, dates and nature of surgeries, current and previous lymphoedema treatments, current lymphoedema symptoms and limb condition
- Limb volume (arm circumference or measured by perometry, Perosystems Wuppertal, Germany) of both arms
- Limb fluid (Using bioimpedence SFB7, ImpediMed, Australia at the Lymphoedema Assessment Clinic and L-Dex U400, ImpediMed, Australia at the Lymphoedema and Laser Therapy Clinic)
- Tonometry readings with the mechanical tonometer and indurometer at the anterior chest, upper arm and lower arm, all bilaterally.

Subjects were instructed to lie on their backs on a treatment plinth with their arms resting on pillows on either sides of their torso during the measurements. They were required to remain stationary, breathe normally and to avoid muscle contraction for five minutes after which measurements were taken.

Six measurement sites for each subject were marked on the patient's

Table 1

Number of data points removed from the study due to inaccurate measurement technqiue

	Total number of data points collected	Number of data points removed	Number of data points with IR>IU	Number of data points with IR<0
Operator 1	180	2	2	0
Operator 2	108	2	1	1
Operator 3	108	2	2	0

Table 2

Coefficient of variation for all the data

	Coefficient of variation, all data		
	Mechanical tonometer	Indurometer IU	Indurometer IR
Operator 1	8%	16%	22%
Operator 2	7%	7%	16%
Operator 3	21%	14%	16%
All operators	11%	14%	19%

skin with a water-based marker to ensure the same site was used for repeated measurements. The measurement sites used were:

- Site 1: anterior surface of lower arm, midway between the distal wrist crease and the elbow crease
- Site 2: anterior surface of the upper arm, midway between the elbow crease and the armpit crease
- Site 3: anterior surface of the chest between the second and third ribs in the mid-clavicular line
- Sites 4–6 were identical to sites 1–3 but on the opposite side of the body.

Measurements were taken at each site with the mechanical tonometer and the indurometer. The order in which the sites were measured was as listed above, starting with the right arm. The order of device used was randomised for each subject (by the toss of a coin).

Three measurements where taken at each site with the randomised device. To ensure that the 'pitting effect' had minimal influence on subsequent readings, all six sites were measured in turn and this process was then repeated twice. The same method was applied to the other device.

At the Lymphoedema Assessment Clinic two operators undertook measurements on six subjects each. Both operators were given instructions and 30 minutes' practice in the use of the mechanical tonometer and the indurometer. They were followed in their first groups of measurements by an observer to check their technique. At the Lymphoedema and Laser Therapy Clinic the same operator undertook measurements on all 10 subjects. The operator was experienced in lymphoedema management and in the use of the mechanical tonometer. An instruction manual was provided for the indurometer.

To determine the repeatability of both the mechanical tonometer and the indurometer, the coefficient of variation (COV) for each device and for each user was calculated using equation 1 (Bland and Altman, 1999; British Standards Institute, 1979).

$$\text{Coefficient\_of\_Variation, COV} = \left\{\frac{Sw}{\text{total\_mean}}\right\} * 100$$

Equation 1: Calculation used for COV. (sw = within subject standard deviation).

Results and discussion

Performance

The prototype indurometer displayed two results for each test. The first was a measurement in induration units (IU), representing the displacement of the plunger into the skin at 200g. The second, denoted induration rate (IR), represented the displacement of the plunger into tissue as the force increased from 150 to 200g and was calculated by equation 2:

$$IR = \frac{\text{Displacement}_{200g} - \text{Displacement}_{150g}}{(200 - 150)} \times 200$$

Equation 2: Calculation used for the Induration Rate (IR).

As can be seen from equation 2, if the relationship between displacement and force was linear, the IR and IU value would be equal. However, due to the non-linear nature of tissue, the amount of plunger displacement per gram of force tends to decrease as the overall displacement increases.

Therefore, the IR value can be

Table 3

Coefficient of variation with the anterior chest data removed

	Coefficient of variation, anterior chest data removed	
	Mechanical tonometer	Indurometer IU
Operator 1	8%	12%
Operator 2	7%	6%
Operator 3	20%	9%
All operators	11%	10%

Table 4

Change in coefficient of variation between all data and data without the anterior chest measurement

	Difference in coefficient of variation (COV all data — COV anterior chest removed)	
	Mechanical tonometer	Indurometer IU
Operator 1	0	4%
Operator 2	0	1%
Operator 3	1%	5%
All operators	0	4%

expected to be less than the IU value when tests are performed on tissue. In addition, the IR value was always expected to be greater than zero, because the displacement of the plunger into tissue was expected to increase as the applied force increased from 150 to 200g.

The IR value can be used as a check of the operator's technique. An IR reading which is negative or greater than the corresponding IU reading, suggests that the operator had a poor measurement technique. This could result from tilting the reference plate during the measurement rather than placing the entire reference plate surface onto the skin and maintaining this position during the test.

A check for IR>0 and IU>IR was performed on all of the data collected in the study before it was analysed. Any points failing to meet this criterion were removed. *Table 1* shows the number of discarded data points for each operator and the reason for removal.

A small number of points were removed from the data set, suggesting that for the most part, the operators were applying the indurometer correctly near the end of the measurement process (i.e. the reference plate was evenly applied to tissue at all times).

For the remaining data points at all sites, the coefficient of variation (COV) for both the indurometer and the mechanical tonometer were calculated for each operator and overall (*Table 2*).

While the IR value was used to assess user technique, the measure itself is related to the tonometry measurement (displacement) and hence may be used to monitor the tissue's resistance to compression. Therefore, it was included in the repeatability analysis to determine if there was any additional value in monitoring IR values as well as, or instead of IU values. *Table 2* shows that the repeatability of the indurometer's IR measurement was worse than both the mechanical tonometer's output and the indurometer IU measurement. This pilot data suggests that the IR measurement may not be a reliable measure of tissue compliance and was not considered in any further data analysis reported in this paper.

Table 2 shows that, overall, the COV for the indurometer was similar to the COV for the mechanical tonometer and that there was smaller variability in the indurometer's COV between operators. The COV ranged from 7% to 21% for the mechanical tonometer, and 7% to 16% for the indurometer (IU). At an individual level, operator 2 had the most consistent results with both devices, operator 1 performed better with the mechanical tonometer and operator 3 performed better with the indurometer. This indicates that both devices can give varying results depending on the operator.

It was noted by all users that the anterior chest was a difficult site to measure with both the mechanical tonometer and the indurometer. Hence, the coefficient of variation analysis was repeated with the anterior chest data removed (*Table 3*).

When the anterior chest data was removed, the overall COV reduced for the indurometer, but remained unchanged for the mechanical tonometer (*Table 4*). This suggests that the mechanical tonometer had similar repeatability across all

Table 5

COV for each measurement site

	Mechanical tonometer			Indurometer (IU)		
	Forearm	Upper arm	Anterior chest	Forearm	Upper arm	Anterior chest
Operator 1	9%	7%	7%	13%	12%	18%
Operator 2	8%	6%	8%	7%	5%	9%
Operator 3	25%	16%	22%	8%	10%	17%
All operators	13%	9%	11%	10%	9%	16%

the measurement sites, while the indurometer was more variable at the anterior chest. To perform a closer examination of this result, the COV was calculated for each individual measurement site (*Table 5*).

Table 5 shows that all operators generally achieved a more consistent COV between measurement sites with the mechanical tonometer than with the indurometer. Using the indurometer, operators achieved similar COV for the forearm and upper arm, but much larger COV occurred with the anterior chest measurement. This supports the previous finding that, overall, the mechanical tonometer was able to operate consistently across the measurement sites, while the indurometer's performance was less reliable at the anterior chest. It is important to note, however, that while this was the case for the overall result (all operator data combined), the results were dependent on the operator. Examination of individual operator's COV demonstrates that operator 3 had a larger range in COV results for the mechanical tonometer across the sites, while more consistent results were achieved by operator 3 with the indurometer. Operator 1 had a large range in COV results with the indurometer across the sites, but was more consistent with the mechanical tonometer, and operator 2 was consistent across all sites with both devices. This may indicate that the relatively large COV from measurements at the anterior chest may be related to technique.

The reason for the indurometer's overall poor repeatability with the anterior chest measurements in this study is unknown. It is hypothesised by the authors to be due to the difficulty in applying the reference plate evenly onto the skin throughout the measurement procedure. The reason the mechanical tonometer performed fairly consistently across all the measurement sites in this study is also unclear. It is hypothesised by the authors to be a result of the difference in weight between the two devices. The mechanical tonometer was significantly heavier than the indurometer, which may have assisted operators in applying the reference plate evenly onto the skin. The indurometer's lighter weight required users to consciously exert and control force onto the device to ensure that the reference plate was evenly applied to tissue during measurements.

The purpose of the indurometer is to make it easy for an operator to take reliable and objective tonometry measurements.

The IR measurement, as mentioned earlier, can be used to investigate the user's application of pressure and movement of the indurometer onto the tissue during the measurement. In the indurometer prototype, the IR measurement was only performed near the end of the measurement (the last 50g of force). A check during the whole duration of the measurement may be advantageous. For instance, this could be performed by calculating the rate of plunger penetration at each 20g increment from 0 to 200g. Furthermore, if the user applied a smooth increase in force from 0 to 200g, the displacement would always increase or stay the same for each increment in force. A decrease in the displacement with an increase in force would indicate that the user may have lifted the reference plate from the tissue, or tilted the device during the measurement. A future version of the indurometer could include more advanced user technique checks in software, and hence be capable of indicating to the user when their measurement technique is poor and instruct them to retake the measurement. This may help to educate users in correct measurement technique.

The results reported here are based on data from a pilot that will form a larger investigation of the indurometer. The results of the pilot study have indicated that the next stage of the investigation may be improved by:

- Providing operators with a detailed set of instructions that highlight correct measurement technique
- Modifying the indurometer's software to check the user's technique.

Useability

During the study, feedback was collected from the operators regarding the use of the two devices. Overall, the operators rated the indurometer easier to use but said that it was possibly a little too large for an operator with small hands. More specific comments included:

- Placing the indurometer onto a measurement site was easier than placing the mechanical tonometer due to its transparent reference plate
- The final measurement on the indurometer's digital display was easier to read than the result from the mechanical tonometer's analogue scale

- Reading the mechanical tonometer's display *in situ* was more difficult than reading the indurometer result, which remained on the display after the device was removed from the test site
- Users felt unsure of when to read the dial gauge on the mechanical tonometer when pitting was present, because the reading continually changed as the fluid moved within the tissue. This difficulty was not found with the indurometer.

Conclusion

The purpose of the indurometer is to make it easy for an operator to take reliable and objective tonometry measurements. This pilot study indicated that the indurometer had a similar repeatability to the mechanical tonometer and was successful in overcoming some of the mechanical tonometer's shortcomings. The study also showed that the IR measurement could be used as an assessment of the user's technique, and could be both expanded upon and built into future software.

The study also showed deterioration in repeatability by the indurometer at the anterior chest measurement site. While the reason for this is unclear, it is hypothesised that better repeatability may be achieved by improving the user technique. This could be attained through educating the operator, or ideally by changing the design of the indurometer to avoid the possibility of 'bad' measurement techniques.

The next generation of indurometers could include software intelligence to verify smooth and even application of force from 0 to 200g, and immediately inform users when measurements should be retaken. JL

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Key points

- The original mechanical tonometer had a display that was difficult to read, the results were not stored and had to be read while held upright, in place on the limb.
- The indurometer is intended to make it easy for an operator to take reliable and objective tonometry measurements.
- This pilot study indicated that the indurometer had a similar repeatability of results to the mechanical tonometer, and was successful in overcoming some of the mechanical tonometer's shortcomings.
- The study showed that the induration rate measurement could be used as an assessment of the user's technique and could be both expanded upon and built into accompanying software in the future.

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