Comparative study on the accuracy of Biosculptor's Bioscanner system in transtibial residual limb circumference measurement

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Purpose: This study aimed to examine the accuracy and validity of the Biosculptor's Bioscanner shape capturing system as a portable measuring device by analysing the changes in transtibial residual limb circumference parameters while walking. Assessment on an amputee could also allow for the clinical usability of the digital scanner to be studied. *Methods*: To verify the accuracy of the system, the Bioscanner method was compared to the widely used standard anthropometric manual measurement technique (i.e., tape measure). One transtibial prosthetic user was recruited to conduct a walking activity at a normal walking pace for 5 to 15 minutes. Circumferential profiles of the participant were obtained digitally and manually during 2–5 minutes of resting walking intervals. The mean differences between the two methods were compared and percentage differences were calculated. The means were used to calculate the standard error measurement (SEM) and the 95% confidence intervals. Study of the limit of agreement between the two method was also used to validate the accuracy of Bioscanner. *Results*: The findings showed that both measurements gave a general comparable linear pattern. The averaged results from both methods resulted in only small distinctive differences especially at circumference near the mid-patella tendon. Similarly, the pressure-sensitive areas of the limb resulted in only an average of 2.28% differences between the two measurement techniques. The system showed high reliability and SEM with <1 of 95% CI values and repeatability study gave ICC >0.9. *Conclusions*: Bioscanner appeared to be comparable with the standard manual method. The Biosculptor system provides the portability, fast, reliable, and high accuracy measurements of the transtibial residual limb circumference, thus, it can be considered as a valuable tool for daily measurement of amputee's residual limb and pre-prosthetic training.

Key words: anthropometry; computer aided design; digital scanner; prosthetics; rehabilitations; transtibial

1. Introduction

The loss of a lower limb, transtibial or transfemoral amputation, has a significant impact on a person's agility and ability to carry out daily tasks [3], [14], [25]. That being so, the objective of rehabilitation is to ensure persons with loss of a limb to ambulate effectively with a prosthesis. A successful rehabilitation relies on the type of techniques and equipment used. Anthropometric measurement of the residual limb is routinely carried out by practitioners after limb amputations, particularly for pre-prosthetic trainings [11]. Thus, practitioners are highly reliant on their experience and the accuracy of the measurement tools used. The accuracy and reliability of the measuring tools influences the type and prescription timing of prosthetics following limb amputation [4]. Measuring tools are also used to assess morphological changes on an amputee's residual limb, such as muscle strength deficit, especially during the process of rehabilitation [17], [20], [46]. This is crucial as prior studies have shown that a significant

number of amputees were reluctant to don their prosthetic devices due to pain and discomfort that resulted from a poor rehabilitation plan [30], [42].

Consequently, pre-prosthetic exercises are important to not only maintain amputees' range of movement (ROM) but also to improve their lower limb muscle strength [29], [31]. The practice considers the amputee's physical abilities, level of amputation and other pre-existing medical conditions. Any changes of the residual limb during the first few months after amputation must be monitored to ensure that sockets are fitted properly and limb volume does not decrease rapidly; thus, ensuring that subsequent problems such as pain and postoperative oedema are under control [16], [21]. Researchers studies long-term residual limb shape changes have also done ground-breaking work in identifying guidelines for prosthetists in determining the timeline for amputees to switch from a temporary socket to a definitive socket. Studies by Lilja et al. [21]–[23] early highlighted the importance of managing the volume changes of the residual limb. Moreover, a much more recent study conducted by Ahmadizadeh et al. [2] continued to emphasize that the current management systems are still challenging.

Morphological changes of the residual limb can be difficult to manage; hence, recording the shape and volume changes until it stabilizes are clinically essential as it would lead to timely fabrication of definitive sockets. These characteristics and stabilization of the residual limb shape must be accurately measured to acquire a successful fitting. The measurement tools used by practitioners must be reliable and able to offer high accuracy to estimate the anthropometric measurement of the residual limb [36], [44]. There are numerous considerable efforts conducted on new devices that have the potential in giving accurate representation of human's limb and have been extensively compared between the various measurement techniques [28]. One of the promising tools in measuring the changes on the residual limb is the "hands-off" technique using a laser or an electromagnetic digital scanning system [33]. Low-cost 3D scanners may assure the price advantage; however, the accuracy is highly debatable and require further examination [32]. Meanwhile, a study on novel systems, such as the BODYTRONIC 600, proved that it can be considered a valuable measurement tool on measuring lower limb circumference and volume. The comparison study between data from BODYTRONIC 600 with computed tomography (CT) showed that a 3D volumetric system has the potential of high-level reliability and accuracy [45]. However, many similar studies were not conducted specifically on transtibial amputees [8], [12], [19], [41]. Earlier

work by Sanders et al. [39] discussed the potential of Computer Aided Design and Computer Aided Manufacturing (CAD/CAM) in measurement comparison between transtibial residual limb shape particularly after an activity that may strongly affect prosthetic socket fit. The process of digitization of the residual limb shape can offer much more sophisticated structural analysis. With the advance of today's computer, the residual limb geometry, one of which is the circumferential measurement, can be easily obtained and the data can certainly be used to monitor the changes during pre-prosthetic trainings [15].

In the preparation of prosthetic sockets, it is essential that the first contact of the CAD/CAM system, which is the scanner, can capture the subject's residual limb accurately. The progression of new techniques and studies have enabled several measurement techniques to detect errors on CAD/CAM systems in the market. There are vast numbers of literature on monitoring of activity of able-bodied individuals [13], [26]. However, only a small number looked at measuring the rate of activity of people with prostheses, whereas CAD studies on capturing transtibial residual limb were mostly conducted on theoretical models [10], [43]. This study was designed to preliminary assess the reliability of the Biosculptor CAD system's Bioscanner on the circumferential measurement of a transtibial amputee. The Bioscanner was used to examine an inactive participant (non-accommodator) and the accuracy of the circumferential measurements was compared with those taken manually, ultimately aiming to suggest the use of the Biosculptor CAD system's Bioscanner as one of the measurement tools for capturing the changes of residual limbs with regards to pre-prosthetic rehabilitation. In order to examine the accuracy of the Bioscanner, an activity such as walking on a leveled walkway was chosen as the ambulation activity that may affect the movement of fluid out of the residual limb, thus decrease its volume and shape [40].

2. Materials and methods

2.1. Participant

The participant was a female participant at the age of 68 with body mass index (BMI) of 33.3 kg/m^2. In 2017, the participant had a unilateral transtibial (left) amputation due to a diabetic ulcer. The study was conducted with the approval of the National Medical

Research Register Secretiat 37912 and the experiment was carried out under the guidance and supervision of a Certified Prosthetist and Orthotist (CPO) of the International Society of Prosthetics and Orthotics (ISPO) Category 2. The participant has been using patellar tendon bearing socket (PTB) with an expanded polyethylene liner together with neoprene suspension sleeve for the past two years and was categorised as K-2 functional level ambulator with the ability to ambulate on low barriers and uneven surfaces [5]. The participant had a long cylindrical residual limb (junction of lower and middle 1/3rd length) with small muscle volume, but, due to participant's health condition (diabetes and high blood pressure), was only asked to conduct the activity when she is well-rested and fit to walk. Prior to the investigation, the participant's prosthetic was carefully checked by the certified CPO to be well aligned, and the skin condition of the residual limb was also examined to ensure the absence of swelling, no phantom pain, skin ulceration or sores on the skin of the residual limb. A set of practice sessions were conducted before the data collection to familiarise the participant with the room condition and critically to assure the participant of any possible incidents.

2.2. Experiment protocol

During the week of the experiment and after obtaining consent from the participant, the participant was informed to go about her daily life as normal as possible without any out-of-routine activities. This was to ensure that the changes in the participant's residual limbs were not affected by other laborious actions. The experiment was conducted for 5 days continuously and during the exercise, the participant was instructed to walk at her self-selected walking speed for approximately 200 metres on a leveled floor. Measurements of the residual limb before the exercise were taken manually and digitally at 0 minutes. While walking, the participant was under constant supervision during the entire exercise to ensure the participant walked consistently at her self-selected speed. Subsequently, measurements and scans were performed at 5, 10, and 15 minutes of walking intervals separated by 2–5 minutes rests. At each interval, the participant was instructed to sit and doff off prosthesis before the measuring took place.

Measuring tape was used to measure the limb manually and Biosculptor's Bioscanner (FastSCAN, Polhemus) was used to capture the shape of the residual limbs digitally. For manual measurements, the participant's residual limb was marked starting from the mid-patella tendon as the most proximal point (point 0 cm) and the following points were 2 cm increments downwards towards the distal end of the residual limb (point 2 cm to 14 cm). Bioscanner is an electromagnetic non-contact capturing device that captures the residual limb by simply sweeping the handheld camera over the limb at a 45° angle [7], [19]. The device has a characteristic of a dual-camera with a line laser [19], and is equipped with a transmitter that the user can attach to the object. It acts as a guide connected to the motion-tracking device integrated in the scanner for the device to track each sweep profile [18]. Each sweep profile was uploaded directly into a FastScan software as 3D images with an accuracy of 0.178 mm. This process required very minimal preparation and the scanner's optical stylus mode enabled the user to locate landmarks and alignment marks, for example,
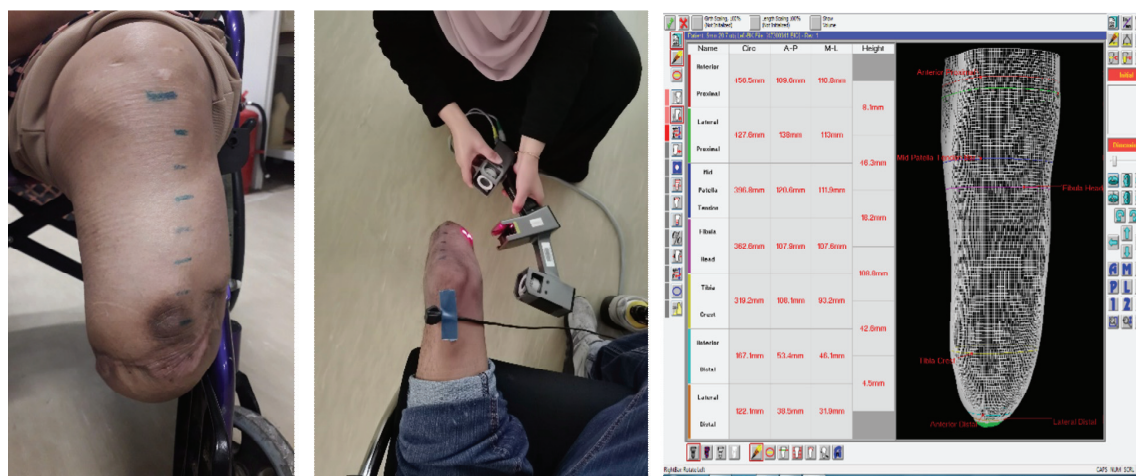

Fig. 1. Marking of landmarks on participant's residual limb with 2-cm interval during manual measurements (left).
Bioscanner was used to scan the residual limb (middle) and a digital model of patient's residual limb in Bioshape
with each 2-cm interval marked starting from mid-patellar tendon (right)

the patella, tibial tuberosity, and the fibular head on the scanned images. 5–8 sweeps were taken to capture the whole residual limb over 2-second intervals. During the image acquisition, the room had to be dimmed or darkened to ensure no other light source were affecting the accuracy of the device. The participant's residual limb was also measured and scanned without the socks/stockinet that might impede accurate measurement of the residual limb. Once all the scans were done, 3D images of the patients' residual limb were exported to a CAD software called Bioshape.

Bioshape software was developed specifically to cater prosthetists to analyse residual limb. The in-built guide assists the users based on the type of residual limb they are working on. Once the images were gathered in FastScan, Bioshape software was used to obtain the circumferential measurement for the data analysis. Circumferential measurements of each patient were obtained by marking the limb and the digital images of the limb at 2-cm intervals. In order to compare the manual and digital measurements, no modifications were required for this study. In Figure 1, the processes of digitally measuring the participant's residual limb are specifically summarised.

2.3. Data analysis

The study was conducted for 5 days and both measurement techniques were used and recorded consecutively. Once the participant successfully completed the 5 days, all results were analysed and the accuracy of the Bioscanner was compared with the manual measurement technique. The results obtained on the transtibial residual limb were analysed to address the questions of how precise and consistent were the digitally obtained measurements compared with the manually obtained ones, of what are the percentage of differences between manual and digital measurements, whether is Bioscanner reliable as a tool to obtain circumferential measurement of the patient's residual limb, and of how did the validity and reliability compared to a similar study using optical or electromagnetic scanner.

The differences in percentage between the two methods were calculated using Eq. (1).

$$\text{Percentage of differences (\%)}$$
$$= \frac{\text{Difference between digital and manual}}{\text{manual measurement}} \times 100\%. \quad (1)$$

To measure the consistency for each measurement taken, the mean and standard deviation (SD) were ob-

tained for each measurement site for both manual and digital measurements. Subsequently, the mean and SD values were used to obtain the standard error measurements (SEM), to express the measurement error, which were then used to calculate the 95% confidence intervals (CI) for the results. The SEM values were obtained using Eq. (2).

$$\text{Standard error measurement (SEM)} = \sigma\sqrt{1-r} \,, \quad (2)$$

where σ represents the standard deviation and r represents the reliability coefficient.

95% CI is a useful tool to measure the reliability of the tools used in gathering the true values of the residual limb. The 95% CI was calculated based on Eq. (3).

$$\text{Confidence level (CI)} = \bar{x} \pm z\frac{\sigma}{\sqrt{n}}, \quad (3)$$

where $\bar{x}$, z, σ and n represent the sample mean, confidence coefficient, standard deviation, and sample size, respectively.

Validity study on the limits of agreement were also calculated based on Bland–Altman methods [41]. Finally, to quantify the reliability (repeatability) of the Bioscanner scans, the repeated scanned data was used to calculate the intra-class correlation coefficients (ICCs). A two-way mixed model with absolute type ICCs were performed using SPSS®.

3. Results

Due to the physical and health conditions of the participant, the participant required a longer time than expected to complete the activity. Nevertheless, the participant was able to maintain her walking pace throughout the period under investigation. To assess the overall performance of the participant, the mean of the circumferential measurements from the 5 days of walking were calculated for both manual and Bioscanner measurement techniques, as shown by curved line graphs in Fig. 2. Analysis of the mean circumference over the residual limb lengths which makes up the limb's circumferential profiles, showed that the residual limb measurements of the participant from the manual and digital measurements generally had produced the same pattern of results. The manual assessment of the limb, shown in Fig. 2A, measured the starting points (0 cm) of the mid-patella tendon to be slightly lower than the recorded by the Bioscanner's measurement illustrated in Fig. 2B. According to the manual meas-
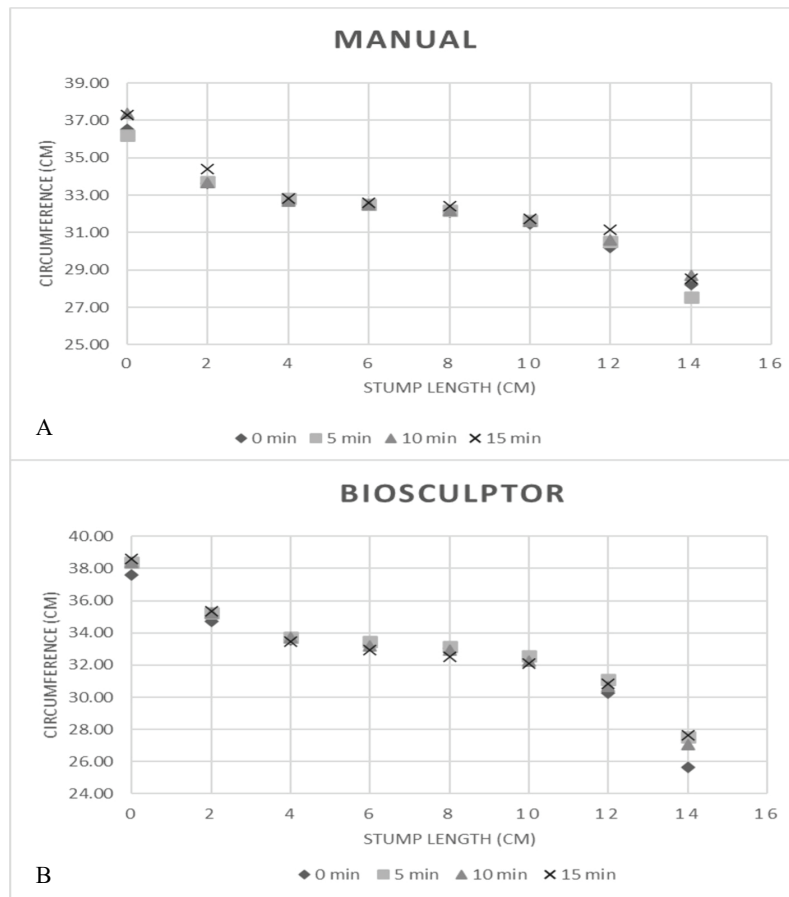
Fig. 2. Residual limb circumferences (mean *n* = 5) at the different residual limb lengths against time/duration of the walking.
Each plot represented the location of the circumferential profiles at which the measurements were taken manually (A)
and digitally using the Bioscanner (B)

urement data, the mid-patella of the participant was in the range of 36.2 cm to 37.73 cm at 0 cm for each walking interval. Bioscanner recorded the circumference of the mid-patella tendon to be in the range of 37.60 cm to 38.6 cm, slightly higher than the manual measurement. The middle portion of the limb, between limb length at 4–8 cm, the circumference measured does not deviate much when both the manual and Bioscanner measurements were compared. An average of 2.28% difference of the circumference from those techniques were observed at 4 to 8 cm points of the circumferential profiles. However, a discernible difference can be noted at point 14 cm below the mid-patella at 0 minute. At this point, a difference of 9.65%, which is the highest percentage difference, was recorded between both measurements, meanwhile the smallest difference of 0.12% was reported at the same point after 5 minutes of walking. Overall, the Bioscanner obtained generally higher circumferential measurements than the recorded measurements from the manual technique.

To further elaborate the percentage differences between the two methods at each walking duration,

box plot configuration was used, as displayed in Fig. 3. At 0 minutes, the box plots are comparatively shorter than the ones reported at 5, 10 and 15 minutes. The upper and lower quartiles are relatively similar indicating that there are minute differences in percentage between the two measuring techniques at 0 minutes. The upper whisker extended to 6.6% difference between the maximum difference and the upper quartile. Based on the graph, the fmedian values at 0 and 5 minutes are not significantly different (2.82% at 0 minutes and 2.87% at 5 minutes). The median value at 5 minutes is the same as plotted at 0 minutes indicating about 50% of the measurements taken from manual and Bioscanner techniques were in accordance and comparable with each other, which is also reflected by the even distributions of the box plots at these durations. The box plots at 10 and 15 minutes are broader than the ones plotted at 0 and 5 minutes, suggesting that many of the measurements between the manual and Bioscanner contradicted. About 75% of the measurement values fell below the upper quartile at 10 and 15 minutes. However, the box plots are even, thus, suggesting that there were not much of
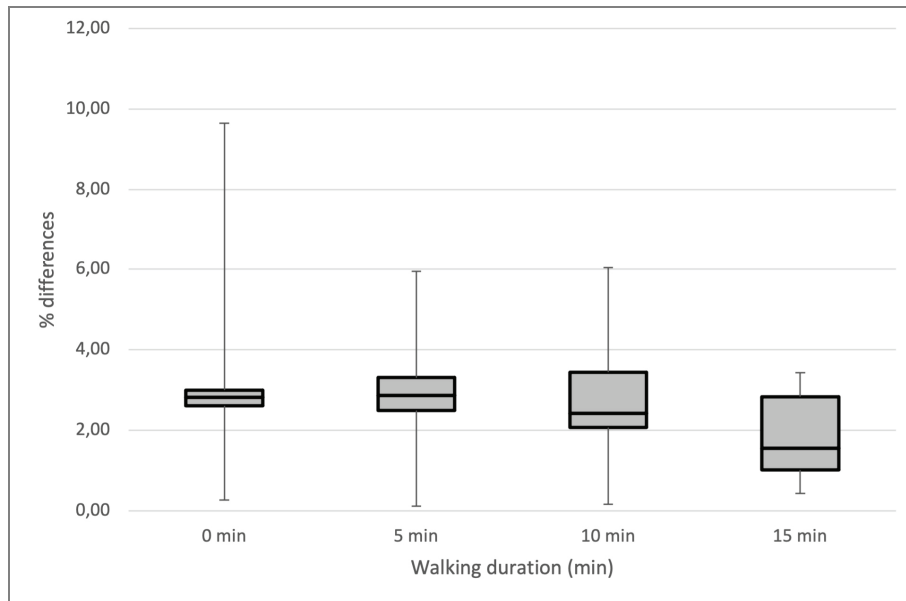
Fig. 3. Box plot graph to represent the percentages of differences in circumference
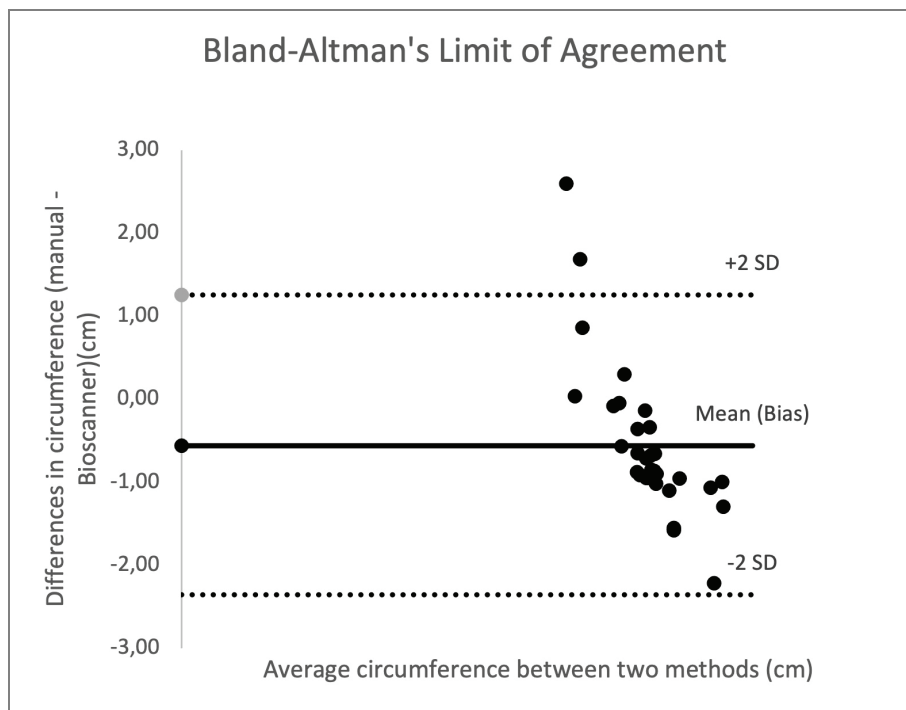between the manual and Bioscanner measurements

Fig. 4. Limits of agreement between the manual tape measure and the Bioscanner measurement

a difference (~50%) between the circumference measurement and they were in range of the inter-quartile range (IQR).

Meanwhile, study on Bland–Altman's limits of agreement presented in Fig. 4 showed that most of the collected measurements were closed to the mean for both techniques (within the limits of agreements), and only 2 data can be classified as outliers.

In addition, the validity study of the Bioscanner measurements resulted in values of SEMs and CIs that were both <1, indicating a high accuracies and validity of the measurement taken (Table 1). In final analysis of reliability/repeatability of the Bioscanner, the ICC was measured to be >0.90, which showed that the Bioscanner showed high levels of intra-rater reliability.

Table 1 na leżąco

4. Discussion

The Biosculptor's Bioscanner was proposed as one of the measurement tools to measure the residual limb's change during pre-prosthetic trainings [1]. To validate and accurately quantify the reliability of the Bioscanner in measuring real patients is important in the decision making for limb shape management [34]. Data on the circumferential profiles may give practitioners useful information in designing prosthetic sockets and subsequently as a useful guideline for amputees on their volume and shape changes during certain activities. As stated by Kofman et al. [19], Bioscanner, as one of the non-contact scanners studies, had systematic differences in volume measurement that were in 97% explained by the system when measuring residual limb model. Therefore, a small error of variance of ~3% would permit the system to be tested on amputees to assess it clinical usability. Based on the results, the manual methods recorded lower circumference measurement than that from the Bioscanner. This may be due to the limb muscles being pressed slightly when measurements were taken. However, the differences in percentage were not significant, as can be seen in Figs. 2 and 3, especially at 0 and 5 minutes after walking. The figures also denoted that Bioscanner circumferential profiles deviate at the beginning of the residual limb (mid-patella tendon) compared to the manual circumferential profiles. Further deviation can be clearly seen near the distal end of the residual limb, which is the pressure-sensitive area. The pressure-tolerant areas, which are between 4 and 10 cm, displayed a more stable measurement. In addition, a prior study done on measuring the volume of transtibial limbs reported comparable outcomes when comparing Bioscanner results with a conventional method of water displacement. The mean percentage in circumference (2.76%) between the Bioscanner scanned image and the manual measurement technique compares well with the results reported by Mehmood et al. [24].

According to results displayed in Fig. 2, the circumference of the residual limb reduced and may be due to the increased fluid transport from the interstitial space into the venous vasculature. Comparable results can be observed from a study conducted by Sanders et al. [37], where the authors produced a comparable pattern of residual limb changes from a K2-ambultor through a bioimpedance study [37]. However, compared to the bioimpedance study, the Bioscanner requires no preparation of electrodes and zero attachment is needed, thus, making Bioscanner a far simpler equipment to use. Further understanding of the difference between the manual and Bioscanner measurements showed that there is a small percentage of differences between the two techniques. The mean percentage of circumference difference from the two techniques, as shown in Fig. 3, were less than 1%. The plotted box plots for each walking interval were comparatively short, which suggested that the values have a greater level of agreement between each other. The results were also in agreement with the recent study conducted by Mehmood et al. [24], who presented that the mean percentage between a Biosculptor socket and a conventional socket were 0.59 and 0.60%, respectively. The short-term increase in the circumferential measurements seen in Bioscanner's result may possibly be the results of venous pooling and arterial vasodilation or arterial pressure following the release of compression of the residual limb from the prosthetic socket and the accumulation of metabolites after the first intervals of walking [47]. Nevertheles, according to Sanders et al. [35], walking exercise with transtibial amputees affected only 39.3% of the total session fluid volume change.

Further analysis on the accuracy of the Bioscanner using 95% CI values resulted in overall CI values of within the acceptable range (< 1). Analysis on 95% CI values resulted in CI values within the acceptable range (<1) to test the reliability of the techniques. The 95% CI values have been used in a related study done by Boonhong et al. [9] and it is used to determine the estimation of the reliability and validity of a measurement tool in observing residual limb shape changes. In this study, the SEM served as an addition statistical measure and both SEM and the 95% CI yielded high accuracy and reliability for both Bioscanner and manual methods. Similarly, the limits of agreement revealed that both manual and Bioscanner method may be interchangeable to one another as the most of the measurements taken were within the limits of agreement. Additionally, ICC also reflected a high reliability and repeatability of the Bioscanner method in measuring amputee patient. Similarly to the Bioscanner, other hand-held laser devices, such as the Omega Tracer, has also reported high reliability coefficient results, thus affirming the technique's accuracy and effectiveness and by the evidence presented, it could be a reliable method for measuring change in residual shape in clinical practice [12]. Based on the results, it can be stated that the Bioscanner provides useful information for understanding whether the prosthetic socket is meeting the needs of the participant and offering the specified physical changes on daily prosthesis wear [6], [38]. In addition, daily monitoring from a certain type of activity might assist on early signs of changes in socket fit and residual limb tissue health.

Similar remarks made by Chadwell et al. [10] also emphasized the need for more community-based daily activity monitoring which can benefit in collecting amputee data to be used in designing better prosthesis. Further study on other types of amputation, for example the upper limb, is recommended. The benefit of the Bioscanner as a mobile non-contact scanner may also make it possible to be used to assess limb shape changes for other activities (e.g., running or climbing). Bioscanner also could be recommended to track changes of the body/residual limb response towards prosthesis [27].

5. Conclusion

Bioscanner as a circumference measurement tool for transtibial residual limbs was presented in this study. Its accuracy and reliability were demonstrated by taking daily measurements of a transtibial residual limb after undergoing walking activity. The preliminary study compared the measurements taken using the Bioscanner with the conventional method. The results of the Bioscanner are comparable with the manual measurements and may be used as a complementary method of prosthetic socket fitting, checking, and assessing. The difference in percentage between the two techniques (less than 1%) were not significant and the results presented in this study are consistent with multiple similar prior studies. The application of 95% CI test and SEM are sufficient in stating the accuracy and reliability of Bioscanner. Thus, based on the study conducted, Bioscanner provides the useful clinical insight towards understanding and managing limb shape change with transtibial amputation. Further investigations can be conducted by using Bioscanner to compare residual limb shape changes based on other variables, such as body mass index, walking cadence, limb length and cause of amputation.

Acknowledgement

References

[1] AGRAWAL V., GAILEY R., O'TOOLE C., GAUNAURD I., FINNIESTON A., *Influence of gait training and prosthetic foot category on external work symmetry during unilateral transtibial amputee gait*, (in Eng.), Prosthet. Orthot. Int., Oct. 2013, Vol. 37, No. 5, 396–403.

[2] AHMADIZADEH C., POUSETT B., MENON C., *Towards Management of Residual Limb Volume: Monitoring the Prosthetic Interface Pressure to Detect Volume Fluctuations – A Feasibility Study*, APPL SCI-BASEL, Oct. 2020, Vol. 10, No. 19, Art. no. 6841.

[3] AMTMANN D., MORGAN S.J., KIM J., HAFNER B.J., *Health-Related Profiles of People With Lower Limb Loss*, Arch. Phys. Med. Rehabil., Aug. 2015, Vol. 96, No. 8, 1474–1483.

[4] ARMITAGE L., KARK L., CZERNIEC S., KWAH L.K., *Reliability and validity of measurement tools for residual limb volume in people with limb amputations: A systematic review*, Phys. Ther., Review, 2019, Vol. 99, No. 5, 612–626.

[5] BALK E., GAZULA A., MARKOZANNES G., KIMMEL H.J., SALDANHA I., RESNIK L.J. et al., *Lower Limb Prostheses: Measurement Instruments, Comparison of Component Effects by Subgroups, and Long-Term Outcomes* ((Comparative Effectiveness Review, 2018, No. 213) ed.). Available: https://www.ncbi.nlm.nih.gov/books/NBK531523/

[6] BALKMAN G.S.M.C., VAMOS A.C.M., SANDERS J.E.P., LARSEN B.G.M., HAFNER B.J.P., *Prosthetists' Perceptions of Information Obtained from a Lower-Limb Prosthesis Monitoring System: A Pilot Study*, J. Prosthet. Orthot., Article, 2019, Vol. 31, No. 2, 121–132.

[7] BIOSCULPTOR. *Biosculptor Orthotic and Prosthetic CAD/CAM system*. Available: http://biosculptor.com/

[8] BOLT A., DE BOER-WILZING V.G., GEERTZEN J.H.B., EMMELOT C.H., BAARS E.C.T., DIJKSTRA P.U., *Variation in measurements of transtibial stump model volume: A comparison of five methods*, Am. J. Phys. Med., Article, 2010, Vol. 89, No. 5, 376–384.

[9] BOONHONG J.O.M., WERAWATGANON T., *Validity and reliability of girth measurement (circumference measurement) for calculating residual limb volume in below knee amputees*, Chula Med. J., 2007, Vol. 51, No. 2, 77–88.

[10] CHADWELL A., DIMENT L., MICÓ-AMIGO M., MORGADO RAMÍREZ D.Z., DICKINSON A., GRANAT M. et al., *Technology for monitoring everyday prosthesis use: A systematic review*, J. Neuroeng. Rehabil., Review, 2020, Vol. 17, No. 1, Art. No. 93.

[11] CHUI K.K.J.M., YEN S., LUSARDI M.M., *Orthotics and prosthetics in rehabilitation* 4th Edition ed. St. Louis, MO: Elsevier, 2020.

[12] DE BOER-WILZING V.G., BOLT A., GEERTZEN J.H., EMMELOT C.H., BAARS E.C., DIJKSTRA P.U., *Variation in results of volume measurements of stumps of lower-limb amputees: A comparison of 4 methods*, Arch. Phys. Med. Rehabil., Article, 2011, Vol. 92, No. 6, 941–946.

[13] DIAS R., DA SILVA J.M., *A flexible wearable sensor network for bio-signals and human activity monitoring*, [in:] Proceedings – 11th International Conference on Wearable and Implantable Body Sensor Networks Workshops, BSN Workshops 2014, 2014, 17–22.

[14] DILLINGHAM T.R., PEZZIN L.E., *Rehabilitation setting and associated mortality and medical stability among persons with amputations*, (in English), Arch. Phys. Med. Rehabil., Article, Jun. 2008, Vol. 89, No. 6, 1038–1045.

[15] GEIL M.D., *Consistency, precision, and accuracy of optical and electromagnetic shape-capturing systems for digital measurement of residual-limb anthropometrics of persons with transtibial amputation*, J. Rehabil. Res. Dev., Article, 2007, Vol. 44, No. 4, 515–524.

[16] HACHISUKA K., NAKAMURA T., OHMINE S., SHITAMA H., SHINKODA K., *Hygiene problems of residual limb and silicone*

liners in transtibial amputees wearing the total surface bearing socket, Arch. Phys. Med. Rehabil., Article, 2001, Vol. 82, No. 9, 1286–1290.

[17] HEITZMANN D., GUENTHER M., BECHER B., ALIMUSAJ M., BLOCK J., DRONGELEN S. et al., Integrating strength tests of amputees within the protocol of conventional clinical gait analysis: A novel approach, Biomed. Tech. (Berl.), 03/02 2013, Vol. 58, 1–10.

[18] JOHNSTON R.A., Use of a hand-held laser scanner in palae-ontology: a 3D model of a plesiosaur fossil, 01/01 2004.

[19] KOFMAN R., BEEKMAN A.M., EMMELOT C.H., GEERTZEN J.H.B., DIJKSTRA P.U., Measurement properties and usability of non--contact scanners for measuring transtibial residual limb vol-ume, Prosthet. Orthot. Int., Jun 2018, Vol. 42, No. 3, 280–287.

[20] LI F., CHEN H., MAO K., Computational simulation analysis for torus radius of edge contact in hip prostheses, Acta Bioeng. Biomech., 2015, Vol. 17, No. 3, 67–73.

[21] LILJA M., HOFFMANN P., ÖBERG T., Morphological changes during early trans-tibial prosthetic firing, Prosthet. Orthot. Int., Conference Paper, 1998, Vol. 22, No. 2, 115–122.

[22] LILJA M., JOHANSSON S., ÖBERG T., Relaxed versus activated stump muscles during casting for trans-tibial prostheses, Prosthet. Orthot. Int., Article, 1999, Vol. 23, No. 1, 13–20.

[23] LILJA M., ÖBERG T., Proper time for definitive transtibial prosthetic fitting, J. Prosthet. Orthot., Review, 1997, Vol. 9, No. 2, 90–95.

[24] MEHMOOD W., ABD RAZAK N.A., LAU M.S., CHUNG T.Y., GHOLIZADEH H., ABU OSMAN N.A., Comparative study of the circumferential and volumetric analysis between conven-tional casting and three-dimensional scanning methods for tran-stibial socket: A preliminary study, Proc. Inst. Mech. Eng. H., Feb. 2019, Vol. 233, No. 2, 181–192.

[25] MOO E.K., ABU OSMAN N.A., PINGGUAN-MURPHY B., ABAS W., SPENCE W.D., SOLOMONIDIS S.E., Interface pressure profile analysis for patellar tendon-bearing socket and hydrostatic socket, Acta Bioeng. Biomech., 2009, Vol. 11, No. 4, 37–43.

[26] MUKHOPADHYAY S.C., Wearable sensors for human activity monitoring: A review, IEEE Sens., Review, 2015, Vol. 15, No. 3, 1321–1330, Art. No. 6974987.

[27] NELSON E.C., SOOLS A.M., VOLLENBROEK-HUTTEN M.M.R., VERHAGEN T., NOORDZIJ M.L., Embodiment of wearable technology: Qualitative longitudinal study, JMIR mHealth uHealth, Article, 2020, Vol. 8, No. 11, Art. No. e16973.

[28] OZEN M., SAYMAN O., HAVITCIOGLU H., Modeling and stress analyses of a normal foot–ankle and a prosthetic foot–ankle complex, Acta Bioeng. Biomech., 2013, Vol. 15, No. 3, 19–27.

[29] PITKIN M., What can normal gait biomechanics teach a designer of lower limb prostheses?, Acta Bioeng. Biomech., 2013, Vol. 15, No. 1, 3–10.

[30] POLJAK-GUBERINA R., ŽIVKOVIĆ O., MULJAČIĆ A., GUBERINA M., BERNT-ŽIVKOVIĆ T., The amputees and quality of life, Coll. Antropol., Article, 2005, Vol. 29, No. 2, 603–609.

[31] RAU B., BONVIN F., DE BIE R., Short-term effect of physio-therapy rehabilitation on functional performance of lower limb amputees, (in English), Prosthet. Orthot. Int., Sep. 2007, Vol. 31, No. 3, 258–270.

[32] REDAELLI D.F., GONIZZI BARSANTI S., FRASCHINI P., BIFFI E., COLOMBO G., Low-cost 3D devices and laser scanners com-parison for the application in orthopedic centres, in Interna-tional Archives of the Photogrammetry, Remote Sensing and Spatial Information Sciences – ISPRS Archives, 2018, Vol. 42, 953–960.

[33] RYNIEWICZ W.I., RYNIEWICZ A.M., WIŚNIEWSKA G., The evalua-tion of the accuracy of shape imaging of prosthetic abutment, Acta Bioeng. Biomech., 2016, Vol. 18, No. 2, 43–50.

[34] SAFARI R., Lower limb prosthetic interfaces: Clinical and technological advancement and potential future direction, Prosthet. Orthot. Int., Dec. 2020, Vol. 44, No. 6, 384–401 (in English).

[35] SANDERS J.E., CAGLE J.C., ALLYN K.J., HARRISON D.S., CIOL M.A., How do walking, standing, and resting influence transtibial amputee residual limb fluid volume?, J. Rehabil. Res. Dev., 2014, Vol. 51, No. 2, 201–212.

[36] SANDERS J.E., FATONE S., Residual limb volume change: Systematic review of measurement and management, J. Rehabil. Res. Dev., Review, 2011, Vol. 48, No. 8, 949–986.

[37] SANDERS J.E., HARRISON D.S., ALLYN K.J., MYERS T.R., Clinical utility of in-socket residual limb volume change meas-urement: Case study results, Prosthet. Orthot. Int., Dec. 2009, Vol. 33, No. 4, 378–390.

[38] SANDERS J.E., REDD C.B., LARSEN B.G., VAMOS A.C., BRZOSTOWSKI J.T., HAFNER B.J. et al., A novel method for assessing prosthesis use and accommodation practices of people with transtibial amputation, J. Prosthet. Orthot., Article, 2018, Vol. 30, No. 4, 214–230.

[39] SANDERS J.E., SEVERANCE M.R., SWARTZENDRUBER D.L., ALLYN K.J., CIOL M.A., Influence of prior activity on resid-ual limb volume and shape measured using plaster casting: Results from individuals with transtibial limb loss, J. Rehabil. Res. Dev., Article, 2013, Vol. 50, No. 7, 1007–1016.

[40] SANDERS J.E., YOUNGBLOOD R.T., HAFNER B.J., CIOL M.A., ALLYN K.J., GARDNER D. et al., Residual limb fluid volume change and volume accommodation: Relationships to activity and self-report outcomes in people with trans-tibial amputation, Prosthet. Orthot. Int., Aug. 2018, Vol. 42, No. 4, 415–427.

[41] SEMINATI E., TALAMAS D.C., YOUNG M., TWISTE M., DHOKIA V., BILZON J.L.J., Validity and reliability of a novel 3D scanner for assessment of the shape and volume of ampu-tees' residual limb models, PLoS One, Article, 2017, Vol. 12, No. 9, Art. No. e0184498.

[42] SHERMAN R.A., Utilization of prostheses among US veterans with traumatic amputation: A pilot survey, J. Rehabil. Res. Dev., Article, 1999, Vol. 36, No. 2, 100–108.

[43] SUYI YANG E., ASLANI N., MCGARRY A., Influences and trends of various shape-capture methods on outcomes in trans-tibial prosthetics: A systematic review, Prosthet. Orthot. Int., Review, 2019, Vol. 43, No. 5, 540–555.

[44] TANTUA A.T., GEERTZEN J.H.B., VAN DEN DUNGEN J.J.A.M., BREEK J.K.C., DIJKSTRA P.U., Reduction of residual limb volume in people with transtibial amputation, J. Rehabil. Res. Dev., Article, 2014, Vol. 51, No. 7, 1119–1126.

[45] TISCHER T., OYE S., WOLF A., FELDHEGE F., JACKSTEIT R., MITTELMEIER W. et al., Measuring lower limb circumference and volume – introduction of a novel optical 3D volumetric measurement system, (in English), Biomed. Tech. (Berl.), Apr. 28 2020, Vol. 65, No. 2, 237–241.

[46] WESTEBBE B., THIELE J., KRAFT M., A Mobile Gait Analysis System for Optimization of Prosthetic Alignments, Biomed. Tech. (Berl.), 2013, Vol. 58, Suppl 1.

[47] ZACHARIAH S.C., SAXENA R., FERGASON J.R., SANDERS J.E., Shape and volume change in the transtibial residuum over the short term: Preliminary investigation of six subjects, J. Rehabil. Res. Dev., Sep.–Oct. 2004, Vol. 41, No. 5, 683–694.