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An Automated Technique for the Measurement of Limb Occlusion Pressure During Blood Flow Restriction Therapy Is Equivalent to Previous Gold Standard



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Purpose: To evaluate the efficacy of an automated pneumatic tourniquet pump and its ability to automatically calculate the limb occlusion pressure (LOP), as compared with the manual Doppler ultrasound technique. **Methods:** Participants presenting to a Sports Medicine clinic were evaluated for study enrollment. Participants were fitted with a pneumatic tourniquet for the upper and lower extremity. LOP measurements were taken with a Doppler ultrasound or automated SmartCuffs PRO device in a randomized order. **Results:** Final analysis was performed on 96 limbs (48 upper extremities and 48 lower extremities). The study population had a mean age 37.1 ± 14.7 years old and a mean body mass index of 25.47 ± 3.80 . The mean measured LOP pressure on the upper extremity with Doppler ultrasound was 174.0 ± 48.7 mm Hg with a range from 120 to 282 mm Hg, whereas the mean measured LOP by the automated pump was 184.0 ± 44.9 mm Hg with a range from 135 to 266 mm Hg. There was no statistically significant difference found between the Doppler LOP and the Smart Cuff upper extremity LOP ($P = .29$). When evaluating LOP pressure on the lower extremity the mean LOP found with the Doppler ultrasound was 195.0 ± 31.9 mm Hg with a range from 160 to 272 mm Hg, whereas the automated pump the mean LOP was 205.0 ± 27.1 mm Hg with a range from 168 to 278 mm Hg. There was no statistically significant difference found between the Doppler LOP and the automated pump lower extremity LOP ($P = .09$). **Conclusions:** No difference in the personalized LOP measurement was found when comparing an automated pump with the current gold standard of manual Doppler ultrasound. No patients complained of pain or discomfort during the LOP measurement. **Level of Evidence:** Level II, diagnostic: prospective cohort study.

Blood flow restriction (BFR) therapies are becoming an increasingly used adjunct to physical therapy and rehabilitation protocols. BFR is a technique in which a pneumatic tourniquet system is placed around the most proximal portion of an extremity to occlude venous return while maintaining arterial flow.¹ Previously, pneumatic tourniquets were

inflated to a predetermined limb occlusion pressure (LOP) measured by Doppler ultrasound. The development of automatized pneumatic tourniquet technology has enabled personalized application of pneumatic cuffs without the difficulties of measuring LOP with a Doppler. Recently, this technology has demonstrated equivalent efficacy in measuring LOP as

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compared with the gold standard Doppler ultrasound, thus obviating the need for equipment, time, and distal limb pulse and oxygenation monitoring.² In addition, personalized LOP reduces the risks associated with excess inflation pressures, which can include nerve injuries and soft-tissue damage.³

Recent studies have suggested that BFR therapy invites several benefits over traditional rehabilitative therapy. These benefits include the production of muscular strength and hypertrophy without the risk of high-resistance loads. Although the exact mechanism is unknown, current thought suggests that BFR induces the musculoskeletal system's response to fatigue, muscle tension, reactive hyperemia, and metabolic stress with tourniquet application.^{1,4-10} Current literature suggests that patients undergoing postoperative or acute injury rehabilitation also may benefit from BFR therapies, since low-resistance exercise allow patients to stay within their weight-bearing restrictions while receiving the benefits of exercise, such as minimizing atrophy and strength loss, and improved functional outcomes.^{9,11-14}

To maximize the therapeutic benefit of BFR therapy, accurate assessment of LOP and application of appropriate inflation pressures are paramount. While previous studies compared automated pneumatic cuff devices with Doppler ultrasound in their ability to measure LOP, there continues to be an emergence of new devices on the market for the purposes of BFR therapy.^{2,15-17} Doppler ultrasound calculation of LOP continues to be the gold standard; however, it requires trained personnel and specialized equipment. As BFR therapy continues to expand and its use is increasingly explored, patient use of BFR therapy outside a clinic with automated devices may be adopted. The purpose of the present study is to evaluate the efficacy of an automated pneumatic tourniquet pump and its ability to automatically calculate the LOP as compared with the Doppler ultrasound technique. It is hypothesized that the automated LOP measurements would not be significantly different when compared with measurements taken using Doppler ultrasound.

Methods

Participants

Institutional review board approval was granted (#14126) by Henry Ford Hospital. Participants were enrolled and consent was obtained before initiation in the study. All patients presented to an ambulatory sports medicine clinic for one visit. Healthy patients older than the age of 18 years old were evaluated for study enrollment. Patients received no compensation for study involvement and were made aware of the potential risk of tourniquet usage during the informed consent process. Risk presented to patients included but

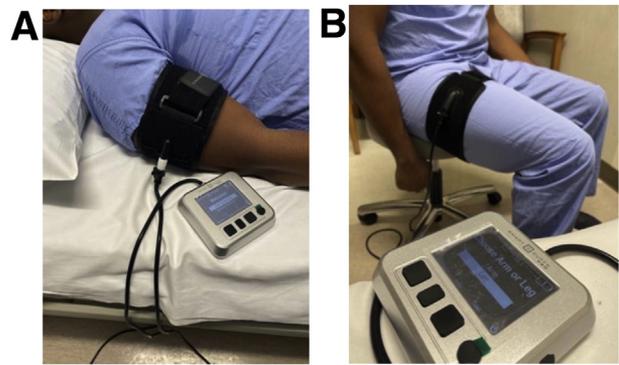


Fig 1. (A) Photograph of the upper extremity cuff placed distal to the axilla. Cuff is connected to pneumatically to the Automated SmartCuffs PRO for the calculation of the limb occlusion pressure. (B) Photograph of the lower extremity cuff placement was just distal to the gluteal fold. Cuff is connected to pneumatically to the Automated SmartCuffs PRO for the calculation of the limb occlusion pressure.

where not limited to the possibility of deep vein thrombosis, pulmonary embolism, and pain from the pressure of the cuff during measurements. Exclusion criteria was modeled off a previously published study, which consisted of a medical history significant for cardiovascular disease or more than 1 cardiovascular risk factor, blood clots or bleeding disorders, any diagnosed neurologic condition, any known musculoskeletal disorder, and/or any history of significant injury or surgery to the extremity.¹⁸ All patient data were kept in a password-encrypted digital database during the duration of the study and was deleted following completion.

Tourniquet Design

The automatized tourniquet (Smart Tools Plus, Strongsville, OH) used for this study contains a ring-shaped single-chamber bladder in which the inner portion of the bladder is not constrained during inflation. This bladder design allows the tourniquet to conform to a patient's extremity during inflation. This is a similar design as other devices investigated in the literature, which enables the tourniquet to self-detect LOP without the need of a pulse or oxygen monitoring device on the distal limb. Tourniquets used are available in 3 sizes: size 1 tourniquets are designed to fit extremities that are 17 inches or smaller, size 2 tourniquets fit extremities ranging from 17.5 to 23 inches, and size 3 tourniquets fit extremities over 23.5 inches.

The automated SmartCuffs PRO (Smart Tools Plus, Strongsville, OH) pneumatic device calculates LOP by inflating the tourniquet in increments of 10 mm Hg in a stepwise fashion. At each increment, the automated pump evaluates the tourniquet bladder for pneumatic pulsations from the subject's arterial pulse, which

Table 1. Patient Demographic Variables (N = 48)

Variable	Mean (SD)	Range
Age, y	37.1 (14.7)	20-68
Weight, lbs	163.8 (35.2)	105-277
Height, inches	67.1 (4.12)	60-76
BMI	25.5 (3.8)	18.1-33.5
UE circumference, inches	30.6 (5.2)	21-44
LE circumference, inches	54.3 (7.6)	39-70
Sex		
Male		33%
Female		67%
Race		
White		58%
African American		22%
Hispanic		12%
Other		8%

BMI, body mass index; LE, lower extremity; UE, upper extremity; SD, standard deviation.

determines the inflation pressure at which occlusion has been achieved.

Protocol

Following patient enrollment into the study, demographic characteristics such as height and weight were obtained. Patients were asked to lie on a clinic bed and measurements of the circumference of the thigh (15 cm proximal to the superior most aspect of the patella) and arm (halfway between acromion process and olecranon) were collected. Subsequently, the participants were fitted with a BFR cuff for both their upper and lower extremities. The same BFR cuff was used for both the automated and manual pumps. LOP measurements were taken in a randomized order. For the upper extremity, the cuff was placed just distal to the axilla (Fig 1A) whereas lower-extremity cuff placement was just distal to the gluteal fold (Fig 1B). Manual occlusion pressure was obtained using a manual hand pump (Smart Tools Plus) and Doppler ultrasound at the radial pulse (upper extremity) and dorsalis pedis pulse (lower extremity). There was a 5-minute rest period between the manual pressure and automated LOP measurements. The automated occlusion pressure was obtained with the automated pump (Smart Tools Plus). All pressure measurements were recorded in mm Hg and collected by a single orthopaedic surgery resident physician (M.E.D.).

Statistical Analysis

Sample size for this study was based on previous literature with similar methodology. Previous studies have demonstrated a sample size of 20 to be sufficiently powered to determine the statistical difference between LOP measurement in 2 groups.^{19,20} A sample size of 50 was selected for this study to increase statistical confidence in the results and account for a potential dropout

rate due to possible pain or discomfort during measurements.

In an effort to evaluate the accuracy of the proposed automated technique for determining LOP, the mean difference, range, standard deviation, and 95% confidence interval of the LOP measurement between the automated and manual system were calculated for each extremity. Histogram and Bland–Altman plots were used to present the distribution of difference for the LOP measurements of each extremity.

All continuous data were described using means and standard deviations. Categorical data were described using counts and column percentages. Wilcoxon rank sum test was carried out to assess univariate 2-group comparisons for continuous variables; Fisher exact tests were used for categorical variables. The relation between continuous variables was examined using a Spearman correlation. Statistical significance was set at $P < .05$. All analyses were performed using SAS software (version 9.4; SAS Institute, Cary, NC).

Results

Patient Demographics

A total of 50 consecutive patients were assessed for participation in the study. Two patients were excluded from statistical analysis due to measurements being greater than 2 standard deviations from the mean. No patients declined to participate, and no patients were excluded due to a history of blood clots or bleeding disorders. Final analysis was performed on 96 limbs (48 upper extremities and 48 lower extremities). The study population had a mean age 37.1 ± 14.7 years old and a mean body mass index (BMI) of 25.47 ± 3.80 . A total of 33% of the study population was male. A total of 72% of patients required a size 3 cuff on the lower extremity and 100% required a size 1 cuff for the upper extremity. All demographic characteristics of the study population are presented in Table 1. No patients complained of pain or discomfort during the LOP measurement.

Upper-Extremity LOP

When evaluating LOP pressure on the upper extremity, the mean LOP found with the Doppler ultrasound was 174.0 ± 48.7 mm Hg (range: 120-282 mm Hg). When LOP was calculated using the automated pump, the mean LOP was 184.0 ± 44.9 mm Hg (range: 135-266 mm Hg). There was no statistically significant

Table 2. Limb Occlusion Pressure Difference

Variable	N	Minimum Difference	Maximum Difference	Mean Difference	Standard Deviation	Paired <i>t</i> -Test
Upper	48	-16	34	13	14	0.29
Lower	48	-48	48	9	20	0.09

NOTE. Values are in mm Hg.

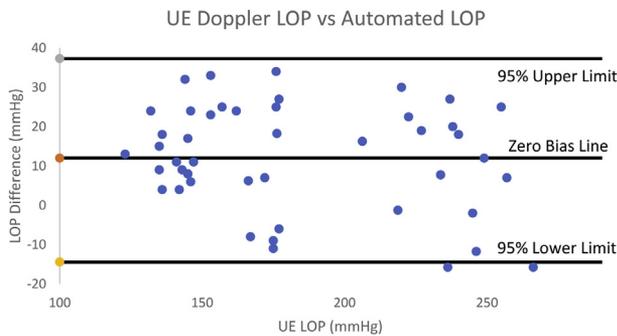


Fig 2. Bland–Altman plot of limb occlusion pressure (LOP) difference between proposed technique and manual Doppler technique for the upper extremity (UE). Mean difference is shown (zero bias line) plus or minus 2 standard deviations (95% confidence interval).

difference found between the Doppler LOP and the Smart Cuff upper extremity LOP ($P = .29$) (Table 2). The LOP differences between both systems are demonstrated in Figure 2, and a histogram is provided in Figure 3.

Lower-Extremity LOP

When evaluating LOP pressure on the lower extremity, the mean LOP found with the Doppler ultrasound was 195.0 ± 31.9 mm Hg (range: 160–272 mm Hg). When LOP was calculated using the automated pump, the mean LOP was 205.0 ± 27.1 mm Hg (range: 168–278 mm Hg). There was no statistically significant difference found between the Doppler LOP and the Smart Cuff LOP ($P = .09$) (Table 2). The LOP difference between both systems are demonstrated in Figure 4, and a histogram is provided in Figure 5.

Discussion

The present study found that personalized LOP measurements with the automated pump were not statistically different from the current gold standard of Doppler ultrasound for both upper and lower extremities. No patients complained of pain or discomfort during the LOP measurement. Advantages of this technology in a clinical setting include atomization, obviating the need for technical proficiency using a Doppler ultrasound, the lack of distal limb monitoring for oxygen saturation or pulse, the potential time-saving benefits of using less equipment, and the ability of the cuff to change LOP to meet the dynamic needs of the patient in a rehabilitation setting.

Achieving appropriate LOP when using tourniquets should be individualized to each patient to reduce risks associated with improper tourniquet inflation. The ability to personalize inflation pressures based on patient-specific LOP allows clinicians to adequately occlude arterial supply to the distal limb while avoiding the risks associated with excessive inflation.

Tourniquet-related nerve injury and increased risk of injuries associated with greater tourniquet pressures has been the impetus for developing methods to use lower tourniquet pressures.^{3,21,22} In an investigation of the impact of tourniquet width on LOP, Graham et al.²³ evaluated tourniquets with a width range from 4.5 to 80 cm and found that wider cuffs can be used to diminish the LOP. Specifically, when LOP was calculated using a Doppler in their study, the ratio of tourniquet width to limb circumference was inversely related to the LOP. This finding is further corroborated by Pedowitz et al.,²⁴ who determined that curved and wider cuffs were associated with lower tourniquet inflation pressures required for limb occlusion. The proposed benefits of personalized arterial occlusion pressures have not translated directly to clinical applications such as surgery, due to the fact that the methodology of using Doppler signals at the distal extremity has several practical difficulties and time inefficiencies.^{2,25} In an effort to curtail the practical shortcomings associated with using a Doppler ultrasound to measure LOP, several automated pneumatic cuff devices have been developed.

Several studies have evaluated the various automated pneumatic cuff devices in an effort to validate their accuracy to the gold standard. Masri et al.² examined the use of an automated system (US Patent 8425,551), which similarly increased cuff pressure in 10-mmHg stepwise increments, and evaluated the pneumatic pressure pulsation in the tourniquet bladder at each increment as compared with Doppler ultrasound. The device they evaluated demonstrated a mean difference of 1 ± 8 mm Hg for the upper extremity and -1 ± 13 mm Hg for the lower extremity, and there was no significant difference between the Doppler and automated system ($P = .45$). McEwen et al.¹⁷ evaluated the use of an automated dual-sensor technique for calculation of LOP compared with Doppler ultrasound across 39 lower extremities. Their study found that the mean

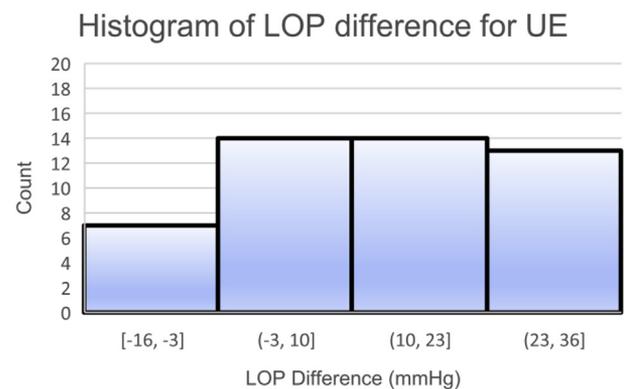


Fig 3. Histogram of limb occlusion pressure (LOP) difference between proposed technique and manual Doppler technique for the upper extremity (UE).

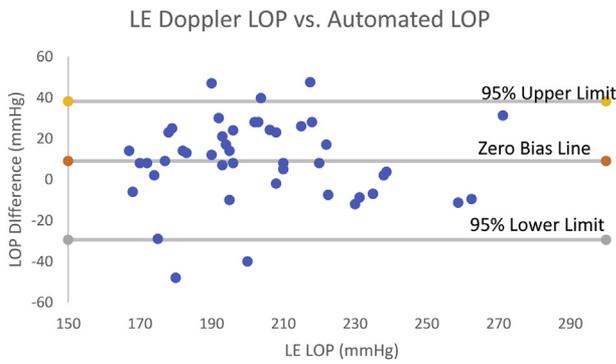


Fig 4. Bland–Altman plot of limb occlusion pressure (LOP) difference between proposed technique and manual Doppler technique for the lower extremity (LE). Mean difference is shown (zero bias line) plus or minus two standard deviations (95% confidence interval).

difference between the automated method and Doppler ultrasound was 1.7 ± 8.9 mm Hg ($P > .05$). The present investigation demonstrated that when compared with Doppler ultrasound, the automated pump had a mean difference of 8.09 ± 21.39 mm Hg on the upper extremity and 10.85 ± 38.65 mm Hg on the lower extremity, which are greater differences than those found by McEwen et al. However, neither study reported metrics related to patient BMI, body habitus, or extremity circumference. It is possible that these differences could account for the discrepancy between studies in mean variation of LOP measurements taken using automated pumps and the gold standard Doppler technique.²⁶ For both upper- and lower-extremity measurements in the present study, the personalized LOP measured by the automated pump did not differ statistically from measurements taken using the Doppler ultrasound, thereby supporting the application of this technology as an efficacious alternative to Doppler ultrasound in the clinical setting. Furthermore, the automated pumps are an easy to use and cost-effective mobile solution that can be sent home with patients for rehabilitation needs, rather than limited use at rehabilitation centers.²

Applying a pneumatic cuff in the clinical setting must be done in a manner that is safe for the patient, adequate for the purposes of occluding arterial supply, that does not compromise work flow. Automated systems may provide a quick and pragmatic application, without the risks of exceeding inflation pressures or distal limb monitoring in an otherwise sterile field. For the purposes of rehabilitative practices, BFR must be applied in a purposeful manner. In a systematic review of the application of BFR after knee surgery, DePhillipo et al.²⁷ demonstrated that rehabilitation protocols typically begin as early as 2 days postoperatively and use 80% of LOP in the lower extremity. These protocols normally incorporated BFR use twice a week during isometric

quad contractions, straight leg raises, and leg press. In a randomized controlled trial evaluating the application during upper extremity rehabilitation, Bowman et al.²⁸ used pneumatics cuffs inflated to 60% LOP. Their protocol consisted of BFR usage twice weekly and demonstrated improvement in strength both proximally (flexion [23% increase], and abduction [22% increase]) and distally (grip strength [13% increase]) when compared with the non-BFR group ($P < .05$). The proposed benefits of BFR during the postoperative period highlights the need for automated pneumatic BFR cuff systems, as they provide standardized assessments of LOP and less room for user error.

Limitations

The present study is not without limitations. While a sample size was determined by a power analysis conducted before initiating the investigation, it must be noted that due to the nature of this type of investigation and sample size, representative of the entire patient population is not feasible, and it was not possible to account for all anthropometric variation in limb dimensions, which could impact the performance of automated LOP measurements taken. In addition, the mean BMI for patients participating in the study was 25.47 ± 3.80 with a range of 18.1 to 33.5, and for this reason results might not be generalizable to patients with a body habitus on either end of the BMI spectrum. Furthermore, only the reliability of the personal pressure setting on the automated pump was evaluated in this analysis. These results may not be applicable to the ischemic preconditioning and manual pressure setting present on the device.

Conclusions

No difference in the personalized LOP measurement was found when comparing an automated pump with the current gold standard of manual Doppler ultrasound. No patients complained of pain or discomfort during the LOP measurement.

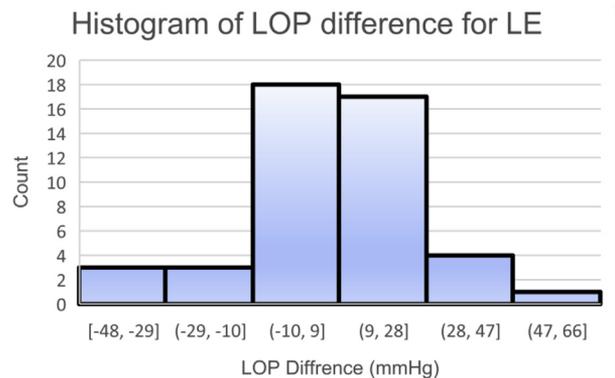


Fig 5. Histogram of limb occlusion pressure (LOP) difference between proposed technique and manual Doppler technique for the lower extremity.

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