Blood flow restriction therapy: The essential value of accurate surgical-grade tourniquet autoregulation

T. Lai MASc[1] L. Hughes PhD[2] and J.A. McEwen PhD[1,3]

[1] Western Clinical Engineering Ltd., Vancouver British Columbia, Canada
[2] Sport, Exercise and Rehabilitation Department, Northumbria University, Newcastle UK
[3] School of Biomedical Engineering and Departments of Orthopedics and Electrical and Computer Engineering, University of British Columbia, Vancouver British Columbia Canada

Abstract **Blood flow restriction (BFR) therapy, in which arterial blood flow into a subject's limb is restricted by a pressurized tourniquet cuff during prescribed therapy, has been shown to induce significant improvements in muscle strength, hypertrophy and endurance. However, differences in equipment and methodology have led to inconsistent restrictions of blood flow ('inconsistent BFR pressure stimuli'). This prevents meaningful comparisons of results and identification of optimal therapy protocols and outcomes. We conducted a pilot study to evaluate the ability of five common BFR systems to accurately maintain and autoregulate the actual BFR cuff pressure near target BFR pressure throughout prescribed exercise periods. For effectiveness and safety, accurate autoregulation for BFR was defined to be the same as for surgical tourniquet systems: automatic and rapid self-regulation of cuff pressure to within ±15 mmHg of the target pressure, within one second in the presence of transient pressure changes associated with exercise. Fifteen subjects (8 male; 7 female) completed a standard 30/15/15/15 BFR protocol at 2-second eccentric and 2-second concentric cadence on a horizontal leg press for each BFR system. Target pressures followed manufacturers' recommendations and actual BFR cuff pressures were recorded at 100 samples per second for the duration of BFR exercise periods. The percentage of time BFR systems provided accurate surgical-grade autoregulation of BFR cuff pressure were: 36.6% ± 41.9% (B Strong), 100% ± 0.0% (Delfi), 45.2% ± 33.6% (Saga), 35.3% ± 34.6% (Smart Tools), and 62.1% ± 26.7% (Suji). At the end of prescribed exercise periods, actual BFR cuff pressures in 3/5 systems differed from target pressures among subjects by more than 15 mmHg and 4/5 systems demonstrated standard deviations of more than 15 mmHg. In view of the pilot results, it is recommended that BFR systems having accurate surgical-grade autoregulation be used to achieve consistent, safe and effective BFR therapy.**

Keywords— **BFR, Blood Flow Restriction, Tourniquet, Surgical-Grade, Autoregulation**

I. Introduction

Blood flow restriction (BFR) therapy, in which arterial blood flow into a subject's limb is restricted to a target level by a pressurized tourniquet cuff during prescribed periods of limb exercise, has been shown to induce significant improvements in muscle strength, hypertrophy and endurance [1, 2]. However, differences in equipment and methodology have led to inconsistent restrictions of blood flow ('inconsistent BFR pressure stimuli') [3, 4]. This prevents meaningful comparisons of results and identification of optimal therapy protocols and outcomes [3, 4].

We conducted a pilot study to evaluate the ability of five common BFR systems to accurately maintain and autoregulate the actual BFR pressure measured in the cuff near target BFR pressure stimulus levels throughout prescribed exercise periods. For effectiveness and safety, accurate autoregulation for BFR was defined to be the same as for surgical tourniquet systems: automatic and rapid self-regulation of cuff pressure to within ±15 mmHg of the target pressure, within a one second in the presence of transient pressure changes associated with exercise. For reference, the design, function, accuracy, safety and reliability of modern surgical tourniquet systems, including both tourniquet cuffs and instruments, are described elsewhere [5-13]. Also, for reference, aspects of the effectiveness and safety of non-autoregulated and autoregulated BFR systems are described elsewhere [14-18]

II. Method

A. Participants

Fifteen subjects (8 male; 7 female) were recruited for the study which was conducted at the Medical Device Development Centre (MDDC) in Vancouver, BC. Subjects were asked whether they meet any standard contraindications to tourniquet use and were excluded if they had answered yes to one or more of the contraindications. All procedures performed in the study involving human participants were in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

B. BFR Systems

Five common BFR systems were evaluated in the study: (1) B Strong Training System (B Strong, Utah, USA), (2) Delfi PTS for BFR (Delfi Medical Innovations, Vancouver, Canada), (3) The BFR Cuffs (Saga Fitness, Newstead,

Australia), (4) SmartCuffs (Smart Tools, Ohio, USA) and (5) Suji (Suji, Scotland, UK). The systems were modified to allow for an external pressure sensor to record actual pressures in the cuffs at 100 samples per second.

Target pressure for each BFR system was determined following manufacturer's instructions, see Table 1. If the BFR system had the capability to measure the subject's limb occlusion pressure (LOP), the target pressure was set to 80% of the LOP, which is commonly recommended for lower limb BFR exercises. LOP is the minimum pressure required, at a specific time in a specific tourniquet cuff applied to a specific patient's limb at a specific location, to stop the flow of arterial blood into the limb distal to the cuff.

Table 1 Target Pressures

BFR System	Target Pressure
B Strong	Standard pressure based on cuff size used, per instructions for use
Delfi	80% of LOP as measured by the system
Saga	80% of LOP as calibrated by the system
Smart Tools	80% of LOP as calibrated by the system
Suji	80% of LOP as calibrated by the system

C. BFR Exercise

A horizontal single-leg leg press exercise was chosen for the study as it is a common rehabilitation exercise for BFR therapy. Exercise was performed on a leg press machine set up with the platform parallel to the ground with three resistance bands attached (Weider Ultimate Body Work Exercise Machine WEBE15911). A standard 30/15/15/15 BFR exercise protocol was followed (75 repetitions over 4 sets, separated by 30-second rest periods). Subjects followed an audio cue to maintain a 2-second eccentric and 2-second concentric cadence for each repetition.

D. Experimental Procedure

Each subject was asked to lie on the horizontal leg press machine. Adjustments were made such that the subject's lower leg was parallel to the ground and knee was bent at 90 degrees during the starting position of the leg press exercise. For familiarization, each subject was instructed to perform a few repetitions following the audio cue to maintain a 2-second eccentric and 2-second concentric cadence for each repetition.

After familiarization, the first BFR system was applied to the subject's lower limb while in a supine position. Randomization of BFR system order and starting limb was completed using a computerized random number generator to create a numbered list of random allocation sequences. Participants were assigned in consecutive order to the randomized sequences on the list The target pressure was determined according to manufacturer's instructions and the cuff was inflated to the target pressure in the supine position. Each subject then entered the starting position of the leg press exercise. Cuff pressure recording was initiated until the subject completed the 30/15/15/15 BFR exercise time period. After the completion of the BFR exercise time period, the BFR system was removed, and the procedures repeated for the remaining 4 BFR systems, alternating limbs.

E. Data Analysis

To determine the BFR system's ability to deliver consistent BFR pressure stimuli, two metrics were evaluated.

1.) Percentage of total BFR time during which accurate surgical-grade autoregulation is provided. This is calculated by subtracting the number of cuff pressure samples during which the measured cuff pressure deviates by more than ± 15 mmHg from the target pressure for 1 or more seconds continuously from the total number of cuff pressure samples:

$$\% = \frac{\text{Samples}_{\text{total}} - \text{Samples}_{\text{outside 15 mmHg}}}{\text{Samples}_{\text{total}}} \quad (1)$$

2.) Pressure change in the BFR cuff, by comparison of the target pressure to the measured pressure at the end of the BFR exercise period:

$$P_{change} = P_{end} - P_{target} \quad (2)$$

III. Results

The mean percentage of the total BFR time period during which each BFR system provided accurate surgical-grade BFR pressure autoregulation is summarized in Fig. 1 and Table 2. The standard deviation for each system is also summarized in Figure 1 and Table 2.

Pressure change is defined as the measured cuff pressure at the end of the exercise minus the target pressure. As such, a negative difference indicates the cuff pressure dropped from the target pressure at the end of the BFR exercise. The mean pressure change, and the standard deviation (SD) for each BFR system is presented in Table 3.

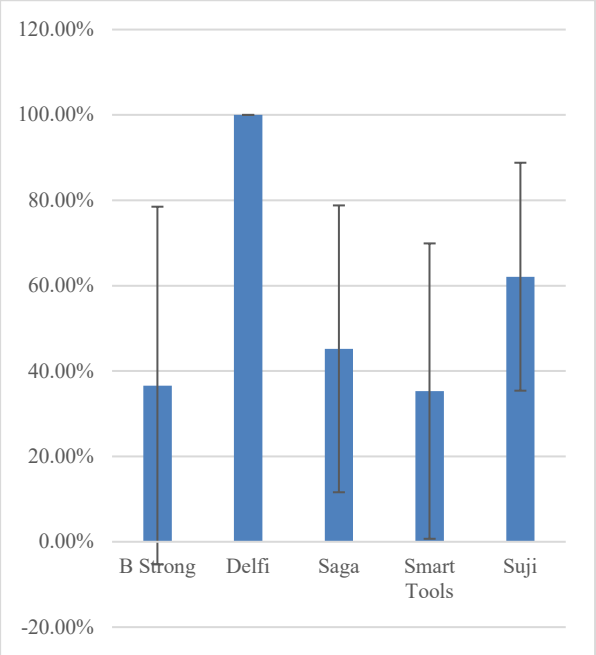

Fig. 1 Percentage of total BFR time period during which each system provides accurate BFR cuff pressure autoregulation meeting surgical-grade standard.

Table 2 Mean percent of total BFR exercise time period during which each system provides accurate autoregulation of BFR cuff pressure, including standard deviation as a percent of total BFR time period.

BFR System	% Total BFR Time	Standard Deviation (%)
B Strong	36.6	41.9
Delfi	100.0	0.0
Saga	45.2	33.6
Smart Tools	35.3	34.6
Suji	62.1	26.7

Table 3 Mean change in actual BFR cuff pressure from target pressure at the end of the BFR exercise period.

BFR System	Change from Target		Standard Deviation	
	mmHg	%	mmHg	%
B Strong	-32	-11%	22	7%
Delfi	2	2%	4	3%
Saga	-25	-13%	23	13%
Smart Tools	-19	-12%	18	12%
Suji	-7	-5%	21	15%

IV. Discussion

Differences in BFR equipment and study methodology have led to inconsistent restrictions of blood flow [3, 4]. This prevents meaningful comparisons of results and identification of optimal therapy protocols and outcomes [3, 4]. In this pilot study, for BFR therapy we have defined accurate surgical-grade tourniquet autoregulation to be equivalent to surgical tourniquet systems: automatic and rapid self-regulation of actual BFR cuff pressure to within ±15 mmHg of the target pressure during 1-second periods in the presence of transient pressure changes in BFR tourniquet cuffs.

The results shown in Fig.1 and Table 2 show that 4/5 BFR systems evaluated do not provide accurate surgical-grade cuff pressure autoregulation necessary to achieve consistent, safe, and effective BFR therapy. Additionally, results for the same 4/5 systems demonstrate large standard deviations, indicating wide fluctuations of actual BFR cuff pressures from target pressures during exercise periods. At the end of BFR exercise periods, actual BFR cuff pressures in 3/5 systems differed from target pressures by more than 15 mmHg.

Standard deviation is a key metric when assessing the safety and efficacy of a BFR system as it indicates whether a consistent and reliable BFR pressure stimulus can be provided across a range of subjects and exercise sessions.

It was noted during the pilot study that only 2/5 BFR systems displayed actual BFR cuff pressures. The ability of a BFR system to indicate to the user actual applied pressures, as opposed to only intended target pressures, may be critical in identifying when an incorrect or unsafe BFR pressure stimulus is applied. In addition, clinicians and therapists who are required to document treatments should be documenting accurate values of applied BFR pressure stimuli.

This pilot study presents a repeatable method for evaluating BFR systems on their ability to deliver a consistent BFR pressure stimulus throughout the entire BFR exercise period. However, there are some limitations to this study. While the leg press exercise is one of the most commonly utilized exercises for BFR rehabilitation, other exercises should also be evaluated, such as ones for rehabilitating upper limbs. We utilized 3 resistance bands for all subjects because of time constraints but it would be beneficial to repeat the study with each subject exercising at a load relative to their 1 repetition-maximum. Finally, as with any study of this nature, the number of subjects should be increased to improve confidence in the results.

V. Conclusions and Recommendatiions

The results of this pilot study indicate that, without accurate surgical grade autoregulation, target pressures did not

accurately indicate the BFR pressure stimuli delivered to subjects during exercise periods. Additionally, standard deviations showed wide variations in pressure during BFR time periods.

At a minimum, it is recommended that the actual BFR pressure stimuli used for therapy and in future studies be accurately measured and documented.

It is further recommended that in future BFR systems having accurate surgical-grade autoregulation be used to provide consistent, safe, and effective BFR therapy. This will allow meaningful comparisons of results, which will help to identify optimal therapy protocols and outcomes.

Acknowledgement

The authors gratefully acknowledge the assistance of Julie Kerr in organizing and editing the manuscript.

Conflict of Interest declarations

L. Hughes has nothing to declare. T. Lai and J. McEwen have financial interests in companies that evaluate, develop, and commercialize tourniquet systems for surgery and BFR therapy.

References

1. Hughes, L., Paton, B., Rosenblatt, B., Gissane, C., & Patterson, S. D. (2017). Blood flow restriction training in clinical musculoskeletal rehabilitation: a systematic review and meta-analysis. British journal of sports medicine, 51(13), 1003-1011.
2. Mattocks, K. T., Jessee, M. B., Mouser, J. G., Dankel, S. J., Buckner, S. L., Bell, Z. W., ... & Loenneke, J. P. (2018). The application of blood flow restriction: lessons from the laboratory. Current sports medicine reports, 17(4), 129-134.
3. McEwen, J. A., Owens, J. G., & Jeyasurya, J. (2019). Why is it crucial to use personalized occlusion pressures in blood flow restriction (BFR) rehabilitation?. Journal of Medical and Biological Engineering, 39, 173-177.
4. Kerr, J., & McEwen, J. A. (2019). Personalizing Tourniquet Pressures–SBP-Based Estimation Methods are Unsafe, Unreliable, and Inconsistent. CMBES Proceedings, 42.
5. Tourniquet Cuff Technology. (n.d.). Retrieved from https://tourniquets.org/tourniquet-cuff-technology/
6. McEwen, J. A. (1981). Complications of and improvements in pneumatic tourniquets used in surgery. Medical instrumentation, 15(4), 253-257.
7. Noordin, S., McEwen, J. A., Kragh Jr, C. J. F., Eisen, A., & Masri, B. A. (2009). Surgical tourniquets in orthopaedics. JBJS, 91(12), 2958-2967.
8. McEwen, J. A., & Casey, V. (2009). Measurement of hazardous pressure levels and gradients produced on human limbs by non-pneumatic tourniquets. CMBES Proceedings, 32.
9. Younger, A. S., McEwen, J. A., & Inkpen, K. (2004). Wide contoured thigh cuffs and automated limb occlusion measurement allow lower tourniquet pressures. Clinical Orthopaedics and Related Research®, 428, 286-293.
10. Masri, B. A., Day, B., Younger, A. S., & Jeyasurya, J. (2016). Technique for measuring limb occlusion pressure that facilitates personalized tourniquet systems: a randomized trial. Journal of Medical and Biological Engineering, 36, 644-650.
11. Hughes, L., & McEwen, J. (2021). Investigation of clinically acceptable agreement between two methods of automatic measurement of limb occlusion pressure: a randomised trial. BMC Biomedical Engineering, 3(1), 1-8.
12. Delfi Medical Innovations Inc. (n.d.). Delfi PTS ii Personalized Tourniquet System Operator & Maintenance Manual. Retrieved from https://www.delfimedical.com/wp-content/uploads/2022/11/4-2200-025-PTSii-Tourniquet-System-9-Series_IFU-Rev-7-sm.pdf
13. Tourniquets.org. (n.d.). Zimmer A.T.S. 4000TS Operator / Service Manual Revision: E. Retrieved from https://tourniquets.org/wp-content/uploads/PDFs/ATS-4000-IFU-EN.pdf
14. Brandner, C. R., May, A. K., Clarkson, M. J., & Warmington, S. A. (2018). Reported side-effects and safety considerations for the use of blood flow restriction during exercise in practice and research. Techniques in Orthopaedics, 33(2), 114-121.
15. Rolnick N, Licameli N, Moghaddam M, Marquette L, Walter J, Fedorko B, Werner T. (2023). Accute central stiffness and muscle morphological responses following blood flow restricted resistance exercise with autoregulated and non-autoregulated pressure application. Sportrxiv.
16. Patterson SD, Hughes L, Warmington S, Burr J, Scott BR, Owens J, et al. (2019). Blood flow restriction exercise position stand: Considerations of methodology, application, and safety. Frontiers in Physiology. 10, 553.
17. Jessee M, Mattocks K, Buckner S, Dankel S, Mouser J, Abe T, Loenneke J. (2018). Mechanisms of Blood Flow Restriction: The New Testament. Techniques in Orthopaedics 33(2):p 72-79
18. Hughes L, Rosenblatt B, Gissane C, Paton B, Patterson SD. Interface pressure, perceptual, and mean arterial pressure responses to different blood flow restriction systems. Scand J Med Sci Sports. 2018 Jul 1; 28(7):1757-65.