HOW CAN PERSONALIZED TOURNIQUET SYSTEMS ACCELERATE REHABILITATION OF WOUNDED WARRIORS, PROFESSIONAL ATHLETES AND ORTHOPAEDIC PATIENTS?

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INTRODUCTION

Rehabilitation of wounded warriors, professional athletes and orthopaedic patients has profound health, economic, psychological, and social implications. This has motivated development and investigation of a new technique, Personalized Blood Flow Restriction Training (PBFRT), which may substantially reduce recovery time and improve rehabilitation, Figure 1.

Figure 1: PBFRT system in clinical use for accelerated rehabilitation

Periods of reduced activity are common following surgery or injury. Physical inactivity leads to muscle atrophy, and inactivity caused by an unloading of body weight is associated with numerous health consequences including changes in the quality and quantity of muscle and bone and a reduced ability for exercise [1].

Resistance training is used to recover muscle size and strength following injury or surgery. Typically a person is required to lift loads at or above 65% of their one repetition maximum to have noticeable increases in muscle size and strength [2]. However during rehabilitation from injury patients may be limited to performing low-load resistance exercises in which strength and size benefits are less evident compared with high-load resistance exercise.

A technique which applies Blood Flow Restriction (BFR) to a limb during low intensity exercise has been shown to increase both muscle size and strength across different age groups. Although the exact mechanism is not fully understood, many studies have shown beneficial effects of BFR training on skeletal muscle form and function, and preliminary evidence suggests it may also promote bone formation [3].

The benefits of BFR training has been investigated in a large number of studies in recent years and is a topic of continuing investigation [1]. A review of BFR training literature shows that inconsistencies exist in the levels of pressure used and the types and sizes of cuffs used, making it difficult to compare the results of different studies and determine which have the most effective BFR training protocols. For example Jessee et al. [4] summarized fifteen recently published BFR studies in the upper body and cuff pressures ranged widely. Some studies used a fixed cuff pressure, other studies based the tourniquet pressure on systolic blood pressure and still other studies used a pressure that was a percentage of the Limb Occlusion Pressure (LOP). To help standardize a cuff pressure that will allow participants to receive a similar stimulus, Jessee et al. [4] suggested that BFR should be applied at a relative percentage of the LOP.

This recommendation of basing BFR pressure as a function of LOP has been supported in other BFR studies [5] [6]. Specifically, these studies demonstrate that setting BFR pressure as a function of blood pressure or at a fixed pressure do not provide a consistent stimulus across patients because these methods of setting pressure neglect important factors that affect LOP such as limb circumference and cuff width. Providing a consistent stimulus through a BFR pressure that is a relative percentage of the LOP is important to enable the outcomes and results of various BFR studies to be compared on a meaningful basis.

Previously the most commonly used method for determining LOP prior to setting the BFR pressure was through the use of a Doppler ultrasound probe. Alternatively, Jessee et al. [4] developed equations to

predict a patient's LOP, taking into account some of the determinants of LOP investigated in the study. Although these methods may provide an accurate estimate of LOP they require expertise to determine LOP and can be cumbersome and time consuming. As such these methods may be impractical for implementation in clinical use.

To overcome these obstacles we have developed a clinically-usable novel simplified method of standardizing the tourniquet pressure used for BFR training through the use of Personalized Blood Flow Restriction Training (PBFRT). PBFRT is a personalized method of BFR training that uses a standardized tourniquet pressure, based on a patient's LOP, known as the Personalized Restrictive Pressure (PRP). Advances in the development of modern tourniquet systems made within our group in Canada allow PBFRT to be performed with optimal safety and repeatability, establishing a PRP that automatically accounts for important variables including individual limb shape and size, muscle tone, blood pressure, tourniquet cuff characteristics, and application technique.

This paper describes a Personalized Tourniquet System for BFR specially designed for PBFRT and outlines reasons why this system should be used as the standard for PBFRT clinical protocols based on its inherent simplicity, safety, accuracy, and repeatability.

PERSONALIZED TOURNIQUET SYSTEM FOR BFR OVERVIEW

Limb Occlusion Pressure (LOP):

Definition:

LOP can be defined as 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. LOP is affected by variables including the patient's limb characteristics, characteristics of the selected tourniquet cuff, the technique of application of the cuff to the limb, physiologic characteristics of the patient including blood pressure and limb temperature, and other clinical factors (for example, the extent of any elevation of the limb during LOP measurement and the extent of any limb movement during measurement) [7][8]. Automatic measurement of LOP takes into account these variables and also other variables that could affect LOP such as gender and race [4]. In order for PBFRT to be performed with a consistent and safe stimulus, the cuff pressure applied should be a PRP that is a predetermined relative percentage of the LOP.

Automatic LOP measurement with distal sensor:

Automatic distal-sensor based measurement of LOP was first developed by McEwen et al. [9]. In this technique, a special-purpose tourniquet controller finds LOP by

adjusting cuff pressure while detecting a distal pulse using a photoplethesmographic sensor temporarily clipped onto a digit (finger or toe) of the limb on which the tourniquet is applied, Figure 2. The measurement routine takes about 30 seconds, and the sensor can be removed immediately after LOP is displayed. The accuracy of this measurement technique has been validated extensively with the gold-standard Doppler ultrasound technique and shown to have a clinically acceptable level of accuracy, e.g. [10].
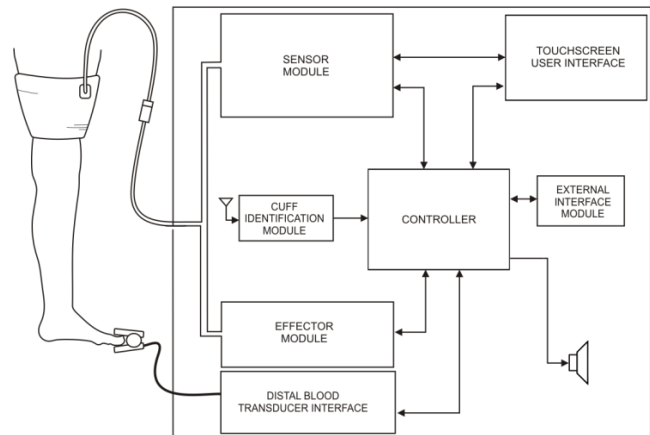

Figure 2 Block diagram of a modern tourniquet system with distal-sensor based LOP measurement. Distal sensor shown attached to toe.

Automatic LOP measurement without distal sensor:

Background:

The clinical use of personalized tourniquet settings based on LOP has been limited by practical difficulties of manual LOP determination using Doppler ultrasound, and because of limitations inherent in the distal bloodflow sensor technique described above. LOP determination using Doppler ultrasound is awkward, time consuming, and requires considerable operator skill to be accurate and precise. Limitations of distal bloodflow sensor LOP measurement include added cost, complexity and time; and the success rate of LOP measurement is dependent on variables affecting measurement of low peripheral bloodflow.

A new technique for measuring LOP has been successfully developed in an effort to overcome these limitations, using a Personalized Tourniquet System for BFR. Many limitations of present techniques of LOP measurement are overcome with the new technique. For example: no distal bloodflow sensor or Doppler ultrasound sensor is required, reducing the complexity and time required to measure LOP; and the success rate of LOP measurement should be substantially greater because the new technique is not dependent on variables affecting

measurement of low bloodflow distal to the cuff such as cold digits or poor peripheral circulation.

Components of the Personalized Tourniquet System for BFR:

The Personalized Tourniquet System for BFR consists of a unique dual-purpose personalized tourniquet cuff and a personalized tourniquet instrument containing LOP calculation sensors and software.

The personalized tourniquet cuffs surround and conform closely to a range of underlying limb shapes. In contrast with standard tourniquet cuffs these personalized cuffs have the dual purpose of LOP measurement and act as a tourniquet to safely restrict arterial blood flow during PBFRT.

The instrument connected to the tourniquet cuff increases the cuff pressure in stepwise increments, analyzes the pneumatic pressure pulsations induced in the cuff bladder by the arterial pressure pulsations at each cuff pressure increment, and uses these characteristics to determine the LOP [11]. After determining the LOP the instrument automatically recommends a PRP that is a percentage of the determined LOP. When the personalized tourniquet cuff is pressurized during exercise, the instrument regulates the pressure at the PRP.

The Personalized Tourniquet System for BFR differs from tourniquet systems used for surgery in that it contains safety and performance features unique to PBFRT. One important PBFRT-specific feature is a programmable lockout period during which the instrument automatically depressurizes the personalized tourniquet cuff from the PRP to 0mmHg and prevents inflation for the duration of the lockout period. This important feature is embedded into the instrument to improve compliance to the PBFRT protocols specified by qualified professionals. A second feature is the capability of embedding recognized PBFRT protocol parameters such as activity and rest times, activity description, and number of intervals (repetitions and sets) into the instrument to assist with training and ensure compliance to the specified PBFRT protocols [12].

Validation:

A study was performed to determine the accuracy of this new technique of measuring LOP compared to LOP measured using a gold standard Doppler ultrasound technique [9]. Through a randomized crossover multicenter trial, the study investigated if the LOP measured by the new technique was statistically or clinically different from the LOP measured by the gold standard Doppler technique.

The study enrolled 143 pre-surgical and post-surgical patients aged 17-86 (54 ± 15, mean ±SD) in three surgical clinics located in Vancouver British Columbia, Canada.

Each patient was asked to lie on a clinic bed and an appropriately sized dual-purpose tourniquet cuff with underlying matching limb protection sleeve was applied to the non-surgical upper arm and thigh, in a sequential manner by an experimenter.

252 pairs of LOP measurements were taken from upper and lower limbs of each patient in a randomized order using the new technique and the Doppler technique. LOP difference was defined as the new technique reading minus the Doppler technique reading.

The mean LOP difference (new-Doppler) ± SD mmHg was +0.56 ± 11.73 for all limbs (252 limbs), +0.99 ± 7.79 for upper limbs (134 upper), and +0.08 ± 15.03 for lower limbs (118 lower). The measured LOP was not clinically nor statistically different from the one measured using the gold standard Doppler technique.

These results demonstrate that the new technique of LOP measurement has clinically acceptable accuracy that is comparable to LOP measurement by Doppler ultrasound, and that the new technique is feasible for incorporation into Personalized Tourniquet Systems for BFR. The accuracy is closely comparable to the accuracy of the distal-sensor-based automatic method of LOP measurement as determined by McEwen et al. [10].

Application in PBFRT:

The Personalized Tourniquet System for BFR provides an elegant solution for the problem of standardizing BFR training by allowing users to quickly, easily, and accurately determine a PRP based on the LOP. Using a PRP based on LOP will ensure PBFRT with a safe tourniquet pressure below LOP as well as a consistent tourniquet pressure that will enable different users to receive a consistent stimulus. This will enable an accurate comparison of results from different PBFRT studies.

The Personalized Tourniquet System for BFR is a medical device, thus meeting all required medical device safety regulations. To minimize risk of injury and for a desirable clinical outcome, it is important that BFR training be conducted using a medically approved device and that training is performed by qualified professionals who have received appropriately recognized educational training in PBFRT.

PERSONALIZED TOURNIQUET SYSTEM FOR BFR IN USE

Our Personalized Tourniquet System for BFR has been used successfully by the US Army to improve recovery of more than 300 wounded warriors to date, and routine use continues. Also, therapists in thirteen professional teams in the NFL, NBA, NHL and MLB are currently using and evaluating the potential of PBFRT to improve recovery of

injured high-value professional athletes. Several clinical studies in the civilian and military sector with approved funding of over $5 million are ongoing, involving use of PBFRT on 450 patients having a wide range of orthopaedic diagnoses and treatments. Table 1 provides an overview of important studies assessing the efficacy of BFR training.

Table 1 Studies assessing the efficacy of personalized BFR training

Name	Status	No. of Pat's	Study
Anterior Cruciate Ligament Reconstruction	Currently Enrolling	80	Randomized prospective trial assessing patient outcomes after anterior cruciate ligament surgery following either standard of care or blood flow restriction rehabilitation.
Chronic Thigh Weakness After Surgery	Currently Enrolling	60	BFR on patients with persistent thigh weakness after 6 months post-op.
REPAIR Study	Proposed Start Date: 1st quarter 2016	250	Very large BFR trial assessing clinical outcomes after femur fractures. This is a multi-center randomized prospective trial.
Distal Radius Fractures	Currently Enrolling	40	Prospective randomized controlled trial assessing the use of BFR to improve strength, hypertrophy and functional outcomes after wrist fractures. A secondary aim is to assess improved bone healing (less non-unions) and faster bone healing times.
Meniscus Repairs	Proposed Start Date: 1st Quarter 2016	60	Prospective randomized control trial comparing outcomes after meniscal repair with standard of care or BFR.
Regenerative Medicine and BFR	Awaiting IRB Approval	10	Study will assess a novel new regenerative medicine technique combined with BFR to potentially restore lost soft tissues.
Achilles tendinopathy:	Awaiting IRB Approval	40	Study will assess tendon morphologic changes after standard of care eccentric loading Achilles tendinopathy protocol vs eccentric loading with the addition of PBFRT
Total Knee Arthroplasty	Awaiting IRB Approval	60	Randomized prospective trial assessing strength training after total knee arthroplasty vs strength training under PBFRT.

CONFLICT OF INTEREST STATEMENTS

J.A. McEwen, J. Jeyasurya, and J. Owens have financial interests in companies that develop and distribute tourniquet systems.

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