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# Assessing Long-Term Outcomes in Individuals Undergoing Fasciotomy for Chronic Exertional Compartment Syndrome of the Lower Leg

Nick Pasic, The University of Western Ontario

Supervisor: Dr. Dianne Bryant, *The University of Western Ontario* Joint Supervisor: Dr. Kevin Willits, *The University of Western Ontario* A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Kinesiology © Nick Pasic 2012

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#### Assessing Long-Term Outcomes in Individuals Undergoing Fasciotomy for Chronic Exertional Compartment Syndrome of the Lower Leg

(Spine title: Fasciotomy and Outcomes for CECS Patients)

(Thesis format: Monograph)

by

Nicholas Stefan Pasic

Graduate Program in Kinesiology

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science

The School of Graduate and Postdoctoral Studies The University of Western Ontario London, Ontario, Canada

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#### Abstract

This study was a case series of 46 patients (mean age 30 years (SD  $\pm$  13.0)) who underwent fasciotomy for treatment of chronic exertional compartment syndrome (CECS). We prospectively collected long-term patient-reported functional outcome using the Lower Extremity Functional Scale (LEFS) and used existing pre-operative intracompartmental pressure testing data prior to and following exercise to determine the association between the LEFS and pre-operative pressure measurements. At the time of follow-up, patients completed one LEFS questionnaire to assess their current health status, another to query their status at the time of best outcome, as well as a return-to-sport/satisfaction questionnaire.

In our sample of individuals who underwent fasciotomy for treatment of CECS, the immediate post-exercise pressure, 20 minute post-exercise pressure, and the number of months symptomatic prior to surgery were most predictive of functional outcome.

However, our model should be validated through confirmatory analysis before being adopted into clinical practice.

#### Keywords

*Keywords*: chronic exertional compartment syndrome, compartment pressures, long-term outcomes, fasciotomy, leg

## **Co-Authorship Statement**

With the assistance of Dr. Kevin Willits and Dr. Dianne Bryant, we designed a retrospective consecutive case series, in which I was solely responsible for identifying and recruiting patients. Dr. David Whitehead assisted me in creating the patient questionnaire. I wrote the original draft of the manuscript, including interpretation of the statistical results (with the assistance of Dr. Bryant) and sent the drafted manuscripts to committee members for their comments and suggestions for the critical revision of the manuscript.

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#### Glossary of Terms

**CECS** – chronic exertional compartment syndrome

**Deep vein thrombosis** – a blood clot in a deep vein in the leg

Dorsi Flexion – movement of the foot towards the shin bone in the sagittal plane

**Doppler ultrasound** – a diagnostic tool that uses sound waves to evaluate blood flow through the blood vessels

Dorsal/dorsum – of, or relating to, the upper side or back of a person

EMG – electromyography, the recording of the electrical activity of muscle tissues

Etiology – the cause of a disease or condition

**Fascia** – dense, regular connective tissue; creates compartments within the body, which can house muscles, nerves, arteries and veins

Fascial hernia – a bulging of muscle through a defect in its fascia

**Fasciectomy** – a variation of surgical fasciotomy, where some portion of the fascia is removed

**Fasciotomy** – surgical intervention for chronic exertional compartment syndrome, involves incising the fascia over the troublesome compartment and extending that incision the length of the compartment

Haemoglobin – the protein responsible for transporting oxygen in the blood

Hematoma – a localized swelling filled with blood

Hemorrhage – bleeding, or abnormal flow of blood

Hypertrophy – an increase in size of an organ or tissue

**ICP testing** – intracompartmental pressure testing, used for establishing a diagnosis of chronic exertional compartment syndrome

In vitro – taking place outside a living organism

**Ischemia** – inadequate blood supply

Kinins – any of a group of substances formed in body tissue in response to injury

Manometer – an instrument for measuring pressure

**MRI** – magnetic resonance imaging

**MTSS** – medial tibial stress syndrome, another term for shin splints, a condition characterized by dull, aching, diffuse pain along the posteromedial shin

**Nerve entrapment** – repeated and long-term nerve compression

**NIRS** – near infrared spectroscopy

NSAID – non-steroidal anti-inflammatory drug

Paresthesia - "pins and needles", often caused by pressure or damage to peripheral nerves

**Periosteum** – a dense layer of vascular connective tissue enveloping the bones, except at the surfaces of the joints

**Peripheral cutaneous nerve injury** – a type of nerve injury that can occur following fasciotomy

Plantarflexion – movement of the foot away from the shin bone in the sagittal plane

**Popliteal artery entrapment** – a rare case of exercise-induced leg pain, where the popliteal artery may become compressed behind the knee

**Post hoc** – occurring or done after the event

**Pressure normalization** – returning to within 10% of the baseline intracompartmental pressure at 15 minutes post-exercise

Stress fracture – a fracture of a bone caused by repeated mechanical stress

#### Chapter 1

#### 1 Introduction

Chronic exertional compartment syndrome (CECS) is defined as an overuse disorder, typically affecting athletic populations. About one in five individuals suffering from exercise-induced pain of the lower leg are afflicted with CECS.<sup>1,2</sup> Nearly all chronic exertional compartment syndromes occur in one of the four compartments of the lower leg.<sup>3</sup> Anterior compartment involvement is most common, and has received the most attention in the literature.<sup>3-6</sup>

Although the exact pathophysiology is unclear, CECS occurs when physical exertion produces substantially elevated intracompartmental pressures due to inelastic compartments.<sup>4,5,7,8</sup> Since cessation of precipitating activities is the only means of eliminating symptoms non-operatively, the current practice is to treat CECS patients surgically by incising the fascia over the problematic compartment and extending that incision over the length of the compartment.<sup>4,5,7,9-11</sup>

Making a diagnosis of CECS is primarily based on history, although intracompartmental pressure testing (ICP) is also used in centres where it is available. ICP testing is viewed throughout the literature as the gold standard for confirming a suspicion of CECS.<sup>4,5,5,7,10-</sup>

ICP testing has been demonstrated to be sensitive to changes in pressures and reliable in a test-retest scenario when used correctly. Measurement of in vitro models of known pressure demonstrate the accuracy of ICP testing, and a subsequent study revealed a high correlation (r = 0.997-0.999) between externally applied pressures of known amounts and ICP values of the tibialis anterior.<sup>13,14</sup>

There is some controversy, however, as to which ICP measurements are of greatest diagnostic importance. Some advocate for the use of a resting baseline ICP measurement,<sup>7,11,12,15,16</sup> while others believe that ICP testing should be used only to determine the time it takes pressure to return to baseline levels.<sup>3,6,7,9,10,17</sup>

A study conducted in the Netherlands in 2004 evaluated intracompartmental pressure values in CECS-positive individuals before and after surgical fasciotomy. Pressure values were collected at rest, immediately after exercise, and five minutes after exercise. Following fasciotomy, statistically significant reductions in pressure were found immediately following and five minutes after exercise, but not for resting pressure. Thus, the authors concluded that a diagnosis of CECS should be made using exercise-related pressures rather than baseline pressures.<sup>6</sup>

Similarly, a study conducted in Calgary in 2000 retrospectively evaluated outcomes in individuals who underwent ICP testing followed by fasciotomy for CECS. Individuals were asked to report their percent pain relief at the time of follow-up using a visual analog scale. The authors found no statistically significant association between percent pain relief following surgery and the immediate post-exercise pressure value.<sup>3</sup>

The majority of studies addressing chronic exertional compartment syndrome examine the effectiveness of ICP testing, or attempt to create sets of diagnostic criteria for CECS; however, no study presently exists that provides minimum ICP values above which fasciotomy can be recommended with confidence of a positive outcome. Additionally, no study has been able to establish which ICP value is of greatest diagnostic value.

There is ample evidence to support the use of fasciotomy for individuals suffering from CECS.<sup>3,5,9,10,18</sup> The majority of fasciotomies result in positive outcomes, with patients often able to return to, or exceed, pre-operative activity levels, and reporting reduced pain levels.<sup>3,5,9,10,18</sup>

However, not all individuals who undergo fasciotomy experience a return to full activity, and the need for revision surgery is relatively common.<sup>3,5,18</sup> Approximately one in 20 individuals who undergo a fasciotomy will require a revision procedure, although the reason(s) why these individuals fail are not yet clear to clinicians.<sup>3,18</sup> To date, no study has determined which pre-operative factors predispose an individual failure.

Thus, the purpose of our study was to determine which patient characteristics and pressure values best predict outcomes following fasciotomy. We hypothesized, that a less

than 10% change in pressure at 15 minutes post-exercise, deep posterior compartment involvement, and a low self-reported pain score (<7/10) on the treadmill run prior to ICP testing would be predictive of poor outcome following fasciotomy.

## Chapter 2

## 2 Literature Review

#### 2.1 Anatomy

Groups of muscles are separated by fascia, a type of dense regular connective tissue, that create compartments that house muscles, arteries, nerves, and veins. The lower leg is divided into four compartments: anterior, lateral, deep posterior, and superficial posterior.<sup>3,4,11</sup> Debate exists as to whether the tibialis posterior can be considered its own compartment independent of the deep posterior compartment.<sup>4,5,7</sup>

Muscles, arteries, veins, and nerves found in the anterior compartment include the tibialis anterior, extensor digitorum longus, extensor hallucis longus, peroneus tertius, anterior tibial artery/vein, and the deep peroneal nerve. The peroneus longus, peroneus brevis, superficial peroneal nerve, and a branch of the anterior tibial artery/vein are housed in the lateral compartment. The deep posterior compartment contains the aforementioned tibialis posterior, as well as the flexor digitorum longus, flexor hallucis longus, popliteus, posterior tibial artery/vein, and the tibial nerve. Lastly, the superficial posterior compartment houses the gastrocnemius, soleus, plantaris, and the sural nerve.<sup>4,7,11</sup>



## Compartments of Lower Leg



## 2.2 Patient Population and Risk Factors

Chronic exertional compartment syndrome (CECS) is classified as an overuse injury, with distance running serving as a major precipitating factor in its diagnosis.<sup>6</sup> Consequently, incidence is highest in active athletes, runners, and military personnel.<sup>4-</sup><sup>7,11,19</sup> Due to the historical composition of these populations, the literature suggests a trend towards men being diagnosed with CECS more often than women. As more females have become involved in sport this difference has begun to disappear.<sup>4,9,11,12</sup> The incidence of CECS in the general population is relatively unknown as it is strongly influenced by the demographics of the population being sampled.<sup>4,5,11,20</sup> Qvarfordt et al. (1983) found a 14% incidence of anterior CECS in an unselected sample of patients with lower leg pain.<sup>1</sup> While in 1988, Styf reported an incidence of 26.5% in a group of 98 patients with exercise-induced anterior leg pain.<sup>2</sup> However, in CECS positive individuals, symptoms occur bilaterally between 80-95% of the time.<sup>3,4,7</sup>

Risk factors for CECS include muscular hypertrophy, as the added muscle reduces intracompartmental space and increases compartment pressures.<sup>4,7</sup> Subsequently, anabolic steroids, due to their hypertrophy-inducing effects, can greatly increase one's risk of CECS.<sup>7,9,11</sup> Individuals with resistant or noncompliant fascia are particularly at risk, as they are significantly less capable of accommodating muscular hypertrophy.<sup>4,7</sup> Abnormal gait may also predispose individuals to CECS.<sup>7,11</sup>

A potential link has been proposed between fascial hernias and CECS.<sup>5,6,9-12</sup> It is unclear, however, whether fascial herniation causes CECS, or occurs as a result of it.

#### 2.3 Pathophysiology

Relatively little is known about the pathophysiology of CECS, and much debate exists over the underlying cause of pain. Much of what is currently known has been extrapolated from analysis of the acute condition, which may not be an accurate model of CECS.<sup>4,5</sup> Many believe that the characteristic elevated intracompartmental pressures associated with CECS restricts blood flow and causes ischemic pain.<sup>4,5,7,9-11,19</sup> However, uniform agreement does not exist throughout the literature, and no studies have directly demonstrated this effect.<sup>4,11,17</sup> Those who remain skeptical of the ischemic pain model attribute pain to factors such as the presence of metabolites, sensory stimulation of fascial nerves, the stimulation of pain receptors in the fascia or periosteum, or the local release of kinins.<sup>4,5,7</sup>

Additionally, it is well-established that muscle volume can increase up to 20% with exercise.<sup>4,5,7,10,11</sup> This increase in muscle volume causes pressure within the fascial

compartment(s) to rise, making tissue perfusion difficult, thus contributing to the proposed ischemic effect.

Elevated intracompartmental pressures in CECS positive individuals is found throughout the literature;<sup>4,5,10,11</sup> however, no study exists demonstrating a cause-and-effect relationship between elevated pressures and the perception of pain. Consequently, CECS does not have a clearly defined etiology, and appears to be complex and multifactorial in nature.

#### 2.4 Diagnosis

A diagnosis of CECS based solely on clinical findings has tremendous potential to result in unnecessary fasciotomies being performed.<sup>6</sup> A diagnosis of CECS is not confirmed after performing intracompartmental pressure (ICP) testing up to 70% of the time.<sup>6,9</sup> Many authors suggest that an absence of clinical findings at rest are a primary symptom of CECS, which illustrates the difficulty clinicians face in recognizing it.<sup>5,10,11</sup> Sensory deficits can occur as a result of CECS, with the affected area suggestive of the involved compartment. Anterior compartment involvement is associated with paresthesia to the first web space of the foot, lateral compartment involvement with paresthesia to the dorsum of the foot, and deep posterior compartment involvement is associated with paresthesia to the plantar aspect of the foot.<sup>5,9,11</sup>

In 2006, a survey was sent to 206 UK orthopaedists, who were members of one of six specialist medical societies (60% response rate). This survey indicated that most clinicians thought the following criteria were indicative of a positive diagnosis: pain on exercise that is relieved within minutes of rest, tightness of the affected compartment(s), and sensory deficits. Limitations of this study include the uncertainty regarding the representativeness of the surveyed population, as well as the specific method of selection for inclusion in the survey (affiliation with one of six specialist associations). Strengths of this survey include its unbiased wording of questions regarding diagnosis and treatment of CECS, and its generalizability to other countries.<sup>20</sup>

#### 2.4.1 Intracompartmental Pressure Testing

Intracompartmental pressure testing (ICP) testing requires a needle attached to a manometer to be inserted into the problematic compartment, and a measurement is typically taken at rest or baseline. The patient then performs some type of exercise, which can range from resisted plantar/dorsiflexion to treadmill walking/running to a specific activity that is symptomatic for the patient. Immediately following exercise, various ICP values are obtained at varying intervals; 0, 1, 5, 10, and 15 minute measurements are common.<sup>3,4,6,7,9-12,15,21,22</sup>

The technique for obtaining ICP measurements is not consistently defined, and it is a user-dependent test, as protocols and subsequent values may vary with the investigator.<sup>4,5,17,22</sup> Since it has been demonstrated that pressure measurements can vary with ankle and knee position, the use of standardized protocols by testing centres is recommended.<sup>4,17,23</sup>

Due to difficulties associated with making a correct diagnosis of CECS based exclusively on clinical findings, a diagnostic test is recommended to achieve the highest diagnostic certainty. ICP testing is viewed throughout the literature as the gold standard for confirming a suspicion of CECS.<sup>4,5,7,10-12</sup> In the aforementioned 2006 survey of UK clinicians, 91% stated that they use ICP measurements to confirm a CECS diagnosis when it is available.<sup>20</sup>

The effectiveness of ICP testing as a diagnostic tool has been corroborated in the literature, where it has been demonstrated to be sensitive and test-retest reliable when used correctly. Measurement of in vitro models of known pressure demonstrated the accuracy of ICP testing, and subsequent study revealed a high correlation (r = .997-.999) between externally applied pressures of known amounts and ICP values of the tibialis anterior.<sup>13,14</sup> Estimates for the sensitivity and specificity of ICP testing range from 77-93% and 74-83% respectively.<sup>21,22</sup>

Debate exists, over when to obtain ICP measurements and which test values are of the greatest diagnostic importance. Some advocate for the use of a resting baseline ICP

measurement when making a CECS diagnosis.<sup>7,11,12,15,16</sup> Other experts believe that a resting ICP value is of little merit, and ICP testing should be used only to determine the time it takes pressure to return to baseline levels.<sup>3,6,7,9,10,17</sup>

The major disadvantage to ICP testing is that it is an invasive test.<sup>4,6,21</sup> Noninvasive procedures such as near-infrared spectroscopy (NIRS) and magnetic resonance imaging (MRI) appear to be emerging as potential alternatives. NIRS testing measures the haemoglobin saturation of lower leg muscle tissue, and relies on the ischemic model of CECS. Clinicians use NIRS to determine the tissue oxygen saturation (StO<sub>2</sub>). Percentage change in StO<sub>2</sub>, or a StO<sub>2</sub> value below a cut-off point, can be used to arrive at a diagnosis of CECS. To achieve greater significance from clinicians, definitive evidence is required to prove that ischemia is an etiologic factor in CECS.

MR images are used to establish a diagnosis of CECS by using the relaxation constants T1 and T2, which are prolonged in abnormal tissue. Both T1 and T2 values reach a peak post-exercise and return to baseline levels similar to pressure curves. CECS positive individuals demonstrate a greater percentage increase in T1 and T2 values post-exercise compared to healthy individuals. Despite high sensitivity values, specificity is poor for MRI at these cut-off points; further research is needed to establish threshold values. Additionally, long wait times for MR imaging in Canada may deter clinicians from using it as a diagnostic tool.<sup>4,5,7,11,17,21</sup>

A 1990 prospective, double-blind study by Amendola and colleagues investigated the usefulness of MRI in diagnosing CECS. Twenty consecutive patients with chronic leg pain and suspected CECS constituted the patient population, and an additional five normal volunteers were used as a control group. All individuals underwent clinical examination, ICP testing, MRI, and nuclear blood flow testing. ICP testing, MR images, and nuclear blood flow images were all analyzed independently of each other. The gold standard for diagnosis of CECS was classic clinical symptoms in conjunction with elevated compartment pressures. The number of individuals considered CECS positive varied with the diagnostic test used; clinical findings identified 9 individuals as having CECS, compartment pressure testing confirmed 5 of these cases, only 4 individuals had

CECS diagnosed using MR images (all of whom were identified both clinically and through ICP testing), while the nuclear blood flow images were inconclusive in the patient and control population. Amendola and colleagues advocate for further investigation into the use of MRI as a diagnostic tool for CECS. Advantages of MRI include its ability to visualize all four compartments with one test, and its potential as a noninvasive alternative to ICP testing. Strengths of this study include its rigorous use of blinding and independent analysis of tests, while its greatest limitation is the absence of reported ICP data in the control group.<sup>17</sup>

Van den Brand et al. (2005) examined the diagnostic value of ICP testing, MRI, and NIRS for CECS. Of the 45 patients who completed the study, all underwent fasciotomy, ICP testing, MRI, and NIRS. The decision to proceed with fasciotomy was based solely on clinical findings. Patients were considered CECS positive if they had a compartment pressure of  $\geq$ 35 mm Hg immediately following exercise. Patients were assessed six weeks after fasciotomy and underwent ICP testing and NIRS once again, with an absence of exercise-related complaints serving to retrospectively confirm CECS diagnosis. Sensitivity and specificity values, using a cut-off point of ICP  $\geq$  35 mm Hg immediately after exercise, demonstrated that ICP and NIRS were the best diagnostic options; however, the sensitivity value for ICP was lower than what is found in the literature (77%) [95% CI, 67-86] vs. 93%) perhaps due to the fact that all 50 participants faced diagnostic uncertainty in this study unlike previous studies whose samples consisted of known groups, a method known to overestimate the validity of diagnostic tests. Also, sensitivity values were calculated using an immediate post-exercise pressure of  $\geq$ 35 mm Hg as the only cut-off point for diagnosis. ICP values considered diagnostic of CECS vary across studies, which can contribute to the disparity in sensitivity values. In addition, diagnoses were only confirmed if there was an absence of exercise-related complaints at six weeks following fasciotomy. Exercise-related complaints after surgery could be due to a number of factors, such as poor surgical release, the formation of scar tissue, or a failure to extend the fascial incisions far enough in either direction. To only confirm a patient's CECS diagnosis if he/she was no longer symptomatic may be inappropriate due to the potential for confounding explanations.<sup>21</sup>

Due to the invasiveness of the ICP procedure, it is useful for a clinician to rule out differential diagnoses before directing a patient to undergo ICP testing. Differential diagnoses for CECS include stress fracture, medial tibial stress syndrome (MTSS), popliteal artery entrapment, and nerve entrapment.<sup>4,5,7,10,11</sup> Consequently, additional diagnostic tests should be performed if a differential diagnosis is suspected. A bone scan can be used to diagnose MTSS, while MRI can aid in a diagnosis of stress fracture. Electromyogram (EMG) is useful for determining the presence of nerve entrapment syndromes, while Doppler ultrasound can be used to detect cases of popliteal artery entrapment.<sup>4,5,11,16</sup> If none of these diagnoses are suspected or confirmed, ICP testing should follow.<sup>11</sup>

A 1990 study by Pedowitz and colleagues established ICP values that most clinicians have used for diagnostic purposes the past two decades. In their study, 120 patients suspected of CECS underwent ICP testing. When the study began, baseline pressures of  $\geq$ 10 mm Hg or 5-minute post-exercise pressures of  $\geq$ 25 mm Hg were considered CECS positive results. Seventy-five individuals were classified as CECS negative and forty-five were considered CECS positive. Two standard deviations were added to the mean pressures in CECS negative individuals at baseline, 1-minute post-exercise, and 5minutes post-exercise to create the Pedowitz criteria. Pedowitz et al. (1990) reasoned that by adding two standard deviations to the mean ICP values of CECS negative individuals, there should be less than a 5% chance of a false positive diagnosis. The Pedowitz criteria state that one or more of the following criteria, in conjunction with appropriate clinical findings, are indicative of a diagnosis of CECS: 1) a pre-exercise pressure of  $\geq$ 15 mm Hg, 2) a 1-minute post-exercise pressure of  $\geq$  30 mm Hg, or 3) a 5-minute post-exercise pressure of  $\geq 20$  mm Hg. However, Pedowitz and colleagues admit that their criteria are conservative, and that some individuals in the CECS negative group should have had CECS diagnosed. Other limitations of this study include the high proportion of patients lost to follow-up and no mention of the validity of the questionnaire used. Strengths of this study include its large sample size and the use of a population facing diagnostic uncertainty.<sup>12</sup>

While most clinicians consider the Pedowitz criteria as acceptable for diagnostic purposes,<sup>4,5,10-12,22</sup> a 2006 survey of UK clinicians treating CECS demonstrated that a variety of different criteria were being used for diagnostic purposes.<sup>20</sup> Additionally, significant confusion exists as to what ICP values distinguish if patients are likely to benefit from fasciotomy.

#### 2.5 Treatment

#### 2.5.1 Conservative Treatment of CECS

Conservative treatment for CECS includes modification of activity, massage therapy, stretching, ultrasound, non-steroidal anti-inflammatory drugs (NSAIDs), or the use of orthoses.<sup>7,11,17</sup> However, outside of cessation of precipitating activities conservative treatment has not shown promising results.<sup>4,5,7,9-11</sup> There have been no documented cases demonstrating long-term pain relief using conservative treatment.<sup>3</sup> Consequently, fasciotomy has evolved as the treatment of choice for CECS positive individuals.

Despite this lack of evidence, 91% of clinicians would opt for, or at least consider, conservative management for CECS according to the results obtained from the 2006 survey of UK clinicians. The prevailing belief is that information regarding the effectiveness of conservative treatment for CECS is largely anecdotal, and that more scientific data is required. However, fasciotomy is the surgical treatment of choice for 93% of these clinicians.<sup>20</sup>

#### 2.5.2 Fasciotomy and Outcomes

Fasciotomy involves release of the fascia in the CECS affected compartment(s). This surgical release is accomplished by incising the troublesome fascia and extending this opening both proximally and distally. Failure to extend the incision as far as possible in both directions increases the chance of suboptimal outcomes following surgery.<sup>5,15,18</sup> However, the majority of fasciotomies performed for CECS produce positive outcomes, with patients often able to return to, or exceed, pre-operative activity levels, and reporting reduced pain levels.<sup>3,5,9,10,18</sup>



# Figure 2: Incising the fascia over the anterolateral compartments at the proximal lateral incision

Verleisdonk et al. (2004) studied long-term outcomes of 106 active individuals with exertional pain in the lower leg using a diagnostic validity study design. ICP testing was done on all patients. Individuals were considered CECS positive if they met one of the following criteria: 1) tissue pressure immediately after exercise >50 mm Hg, 2) tissue pressure immediately after exercise between 30 mm Hg and 50 mm Hg and >30 mm Hg five minutes later, or 3) tissue pressure at rest >20 mm Hg and >30 mm Hg immediately after physical activity. Using these criteria, 56 patients were diagnosed with CECS and 50 were not. Of those positive for CECS, 53 underwent anterior compartment fasciotomy, while 18 of 50 patients with normal tissue pressures underwent fasciotomy. ICP testing at three months postoperatively in CECS patients undergoing fasciotomy demonstrated a statistically significant decrease in both pressure immediately after

exercise, and pressure five minutes after exercise, suggesting the importance of these values in diagnosing CECS. Pressure at rest did not demonstrate a statistically significant difference before and after fasciotomy, leading Verleisdonk and colleagues to conclude that a diagnosis of CECS must be confirmed by exercise-related pressure measurements. Of the 53 CECS positive individuals who underwent fasciotomy, 44 had strongly decreased complaints at two year follow-up. Of the 18 CECS negative individuals who underwent fasciotomy, 12 were reported to be asymptomatic two years later, while the remaining six experienced no change in symptoms. Similarly, the complaints of the three CECS positive individuals who refused fasciotomy were unchanged three years after pressure measurement. Of the CECS negative patients who did not have fasciotomy, they fared essentially no different than the CECS negative individuals who did have fasciotomy, as 21 of the 32 experienced decreased complaints. Limitations of this study include lack of postoperative pressure measurement in CECS negative individuals who underwent fasciotomy, no mention of blinding, and incomplete description of the questionnaire used making it impossible to judge the validity of the instrument. Strengths include the selection of the control population, the representativeness of the study population, and the length of follow-up. Further research is required to establish a minimum tissue pressure following exercise above which fasciotomy will provide a successful outcome.<sup>6</sup>

Detmer et al. (1985) assembled a consecutive operative series of 100 patients treated between 1974 and 1984. All 100 patients received fasciotomy; follow-up was complete to one week on 99 patients, and complete to two months on 97 patients. Fasciotomy was shown to be tremendously effective, with 91 patients describing a functional improvement, and 93 citing pain relief. Only four patients experienced no improvement following surgery. Additionally, patient satisfaction was high, 89 patients indicated they would have the procedure again. Statistical analyses showed no significant correlation between duration/severity of symptoms, functional impact, or resting compartment pressures with outcomes. Detmer and colleagues believed this to be attributable to individual variation in pain thresholds/tolerance. Only five patients developed a recurrence of symptoms, and a repeat procedure was at least partially successful in four of these individuals. No reliable indicators could be found as to what precipitated recurrences. Limitations of this study include poor description of diagnostic ICP criteria used and the short length of follow-up. Strengths include the completeness of follow-up and statistical analysis attempting to identify patients who would benefit from early operative care.

Cook and Bruce (2002) retrospectively studied fourteen military patients who underwent fasciotomy between December 1997 and December 2000, who had their diagnosis of CECS confirmed by ICP testing and clinical examination. A questionnaire was designed to assess pre- and post-surgical symptoms, as well as ability to pass a military fitness test. Resting compartment pressures of  $\geq 15$  mm Hg and post-exercise pressures >40 mm Hg were considered diagnostic of CECS, with post-exercise pressures between 30 and 40 mm Hg considered highly indicative of CECS. Following fasciotomy, 11 of the 14 patients experienced full relief of symptoms and expressed satisfaction with the procedure. However, the remaining three reported no improvement, and two of these three reported being worse off following the fasciotomy. Cook and Bruce (2002) conclude that fasciotomy is an effective surgery for CECS positive individuals, particularly if conservative treatment has offered no improvement. Limitations of this study include its small sample size and poor description of the ICP diagnostic criteria used, as it is unclear what distinction is made between patients with pressure values considered diagnostic of CECS and patients with pressure values considered highly indicative of CECS. Strengths of this study include the functional outcome measure (military fitness test) and that all fasciotomies were performed in a consistent manner by one surgeon.<sup>24</sup>

Raikin, Rapuri, and Vitanzo (2005) undertook a retrospective review of 19 patients who had fasciotomy for management of CECS between 2000 and 2003. Diagnoses were established using the Pedowitz criteria, with 18 patients meeting these thresholds. Sixteen patients elected to undergo bilateral surgery, one of whom was lost to follow up, while three patients opted for staged fasciotomies. Follow-up interviews were conducted by a blinded physician, on average, four months following fasciotomy to determine patient outcomes. Thirteen of the fifteen bilateral surgery patients returned to their previous levels of activity, while the other two did not return to their previous activities due to extenuating circumstances (graduation from high school/college). All fifteen patients expressed satisfaction with the procedure and that they would have it again if required. Twelve of the 15 patients had a self-reported pain score of 0 out of 10 during sports participation at final follow-up, while the remaining three reported experiencing mild, but significantly decreased, pain during sports activity (ranging from 3-5 out of 10), all three of whom had deep posterior compartment involvement. The three patients who underwent staged fasciotomy all returned to their previous activity levels without complaints. However, patients who opted for bilateral surgery returned to full activity, on average, three months earlier than those who underwent staged fasciotomies. The authors advocate for the bilateral procedure as it not only reduces patient exposure to anesthetic and is more cost-effective, but also appears to return patients to full activity more quickly. Limitations of this study include its small sample size and relatively short length of follow-up, while strengths include a blinded outcome assessor and representative sample.<sup>25</sup>

Edmundsson, Toolanen, and Sojka (2007) prospectively studied 63 consecutive patients seen for a suspicion of CECS. Diagnosis was confirmed in 36 patients, as ICP values met the Pedowitz criteria. Fasciotomy was performed on 32 of these individuals (3 refused surgery, and 1 was lost to follow-up), 25 of whom had bilateral surgery. Results were scored by patients as good or excellent in 41 of 57 legs at one-year follow-up on a four-point Likert scale. Of the 27 patients without CECS, 22 reported no change of symptoms at one-year follow-up. This study was unique in that most patients had sedentary lifestyles, which is atypical for CECS populations, leading the authors to conclude that it is more common in non-athletic populations than previously thought. Limitations of this study include no mention of the validity of the questionnaire used and the uncertainty surrounding the external validity, while strengths include the comparison with prognostically similar controls and completeness of follow-up.<sup>26</sup>

A 2001 Spanish study sought to determine long-term outcomes in adolescents who underwent fasciotomy for CECS. Between 1992 and 1999, 23 adolescents were confirmed to have CECS of the lower leg. A diagnosis of CECS was established through clinical findings, and confirmed via measurement of ICP values using the following criteria: pressure at rest >10 mm Hg, >20 mm Hg at 1-minute post-exercise, >20 mm Hg at 5-minutes post-exercise, and >15 minutes to achieve ICP normalization. Based on their results, the authors felt that a failure to achieve normalization was the most reliable criteria. Fasciotomy was performed in 22 of the 23 adolescents, with one individual rejecting surgical treatment and opting for modification of activity. All 22 patients expressed satisfaction with the procedure, reporting excellent results and full symptomatic relief following surgery on four-point Likert scales. Return to sports activities took place within six weeks in all 22 cases, and no revision surgeries were required at the time of publication. Six patients underwent ICP testing again at one year following surgery, with great reductions in pressure being seen in all values post-exercise. The biggest limitation of this study was no mention of blinding during the collection of outcomes, thereby the potential for clinician or interviewer bias exists. Strengths of this study include its length of follow-up (mean of 4.8 years), and thorough patient evaluation to ensure all included adolescents were truly CECS positive.<sup>9</sup>

Rorabeck, Fowler, and Nott (1988) examined the results of fasciotomy in the management of CECS using a case series design. Twenty-five patients with CECS underwent fasciotomy and were followed up for a minimum of two years. Thirteen individuals had anterior compartment involvement only, eight had deep posterior compartment involvement only, and four presented with involvement of both compartments. A diagnosis of CECS was made if resting pressure was >12 mm Hg and immediate post-exercise pressure was >15 mm Hg, or if the return to baseline resting pressure was delayed. However, the authors emphasize that clinicians cannot rely solely on ICP values to make a diagnosis of CECS, and that ICP testing must supplement clinical examination. Patients who had only anterior compartment involvement all experienced a relief of symptoms at follow-up, with 10 of the 13 being able to increase their activity levels following surgery based on a four-point Likert scale. All thirteen individuals indicated they were satisfied with the procedure. Among the remaining twelve patients, who all had some level of deep posterior compartment involvement, three reported they were not satisfied with the procedure, and only six of the twelve were able to increase their postoperative activity levels. This led Rorabeck and colleagues to conclude that fasciotomy is more effective in treating CECS of the anterior compartment, rather than of the posterior compartment. Strengths of this study include its minimal subject dropout and standardization of the fasciotomy procedure. Limitations include the small sample size and the use of a yes/no scale for satisfaction with surgery, which lacks the sensitivity to change of a visual analog scale or four-point Likert scale found in most other studies on CECS.<sup>15</sup>

Slimmon et al. (2002) hypothesized that incorporating a fasciectomy with fasciotomy for CECS would be more effective in alleviating pain and symptoms in the long-term. Fasciectomy is a surgical technique not utilized in the traditional fasciotomy procedure, and involves the removal of some portion of the fascia. In this study, a 10 cm long window of fascia was removed during anterior compartment surgeries, while a 15 cm long portion was excised for posterior compartment surgeries. A retrospective cohort was assembled of patients who underwent a fasciotomy with partial fasciectomy between January 1992 and June 1997. A diagnosis of CECS was established if compartment pressures met the Pedowitz criteria and appropriate clinical findings were present. Sixtytwo patients completed the study questionnaire, which sought information regarding symptoms prior to surgery, at perceived best outcome, and at the time of follow-up, as well as outcomes following surgery such as pain reduction and return to previous sport/activity. At the time of follow-up patients who underwent anterior or deep posterior compartment surgeries were more likely to report a satisfactory surgical outcome (scoring excellent or good on a five-point Likert scale) than those who underwent combined anterior/posterior compartment surgery. Additionally, individuals who underwent deep posterior compartment surgeries experienced significantly less pain during running, as scored on a 10 cm visual analog scale, than the other two surgical groups (deep posterior compartment: 1.3 [SD 2.3], anterior compartment: 3.4 [SD 3.0], combined: 5.1 [SD 2.7]) at the time of follow-up. However, all groups showed a reduction in pain from one week before surgery to time of follow-up on the 10 cm visual analog scale (anterior compartment: 8.2 [SD 2.2] to 3.4 [SD 3.0]. posterior compartment 8.8 [SD 1.2] to 1.3 [SD 2.3], combined 9.1 [SD 0.9) to 5.1 [SD 2.7]). At the time of follow-up, 13 individuals indicated a return of compartment syndrome(s), causing them to exercise at a lower level than before injury. These study results were contrary to most other CECS studies in that anterior compartment fasciotomy was less effective than

posterior compartment fasciotomy. Slimmon et al. (2002) suggest this may be the result of publication bias in the CECS literature. Additional explanations for the surprising success of the posterior compartment procedure include the longer period of follow-up, misdiagnosis, or duration of pre-operative symptoms. However, the authors conclude that the reasons for the differences seen between groups remain unclear. Furthermore, Slimmon et al. (2002) found that including a fasciectomy with fasciotomy for CECS is effective in the short-term, but does not appear to provide notably better long-term results than a traditional fasciotomy. Limitations of this study include risk of recall bias and the use of post hoc explanations. Strengths of this study include the duration of follow-up (minimum two years, average 4.25 years), the methods taken to reduce a response bias, the use of a visual analog scale and the collection of outcomes at perceived best outcome, as well as at the time of follow-up.<sup>19</sup>

A 2000 study by Howard, Mohtadi, and Wiley sought to retrospectively evaluate outcomes in individuals who underwent a fasciotomy to relieve CECS. The patient population encompassed all individuals who were surgically treated for CECS at one sports medicine clinic between January 1991 and December 1997. Sixty-two individuals were identified, only 39 (62.9%) of whom completed and returned the study questionnaire. To be considered CECS positive, an immediate post-exercise compartment pressure of  $\geq$ 30 mm Hg and an elevated pressure (>15 mm Hg) at three minutes postexercise was required. Fasciotomy was shown to provide an average of 68% (95% CI, 54-82%) pain relief based on visual analog scale responses. Twenty-six of 32 patients who underwent anterior/lateral fasciotomy showed a clinically significant improvement based on a five-point Likert scale, compared to only three of six patients with deep posterior compartment involvement. However, 8 of 36 patients reported that their postoperative level of maximal activity was lower than before the operation. This study also found no correlation between percent pain relief and immediate post-exercise compartment pressures (r = -0.07). This suggests that individuals with greater immediate post-exercise compartment pressures cannot be guaranteed more favourable outcomes following fasciotomy. The authors conclude that while fasciotomy is usually effective, inherently not all patients can expect pain relief and some will require revision surgery. Limitations of this study include the risk of recall bias, its poor patient response rate to

the questionnaire, as well as its small sample size. Strengths of this study include the use of a responsive outcome measure, the method of item generation and testing on the questionnaire, and the standardization of the fasciotomy procedure and ICP testing.<sup>3</sup>



Figure 3: A view of the superficial peroneal nerve as it exits the fascia

#### 2.5.3 Fasciotomy and Outcomes: Summary

Throughout the literature, success rates have been demonstrably greater in the anterior and lateral compartments compared to the deep posterior compartment.<sup>4,5,7,10,11,15</sup> The reasons for lower success rates in the deep posterior compartment are not entirely known. It has been hypothesized that it could be a consequence of the more complex anatomy of this compartment, the presence of subdivisions within this compartment, poor visualization, the difficulty in diagnosing CECS in the posterior compartments, or any combination of these factors.<sup>4,5,7,11</sup> Additionally, chronic exertional compartment syndromes occur much more frequently in the anterior and lateral compartments compared to the posterior compartments, which may contribute to this disparity in surgical outcomes by virtue of clinicians having greater expertise in releasing the fascia of the anterior and lateral compartments.<sup>3-6</sup>

Complications following fasciotomy are relatively benign and are uncommon. Howard et al. (2000) demonstrated a complication rate of 13%, while Detmer et al. (1985) report a complication rate of 11%. Complications described in the literature include hematoma, arterial injury, hemorrhage, peripheral cutaneous nerve injury, nerve entrapment, and deep venous thrombosis.<sup>3,18</sup> Due to the possibility of nerve damage during fasciotomy of the anterior and lateral compartments, the superficial peroneal nerve must be identified and protected by the surgeon.<sup>4,15</sup> Similarly, when operating on the posterior compartments, surgeons must identify and protect the saphenous nerve and vein.<sup>4</sup>

While fasciotomy is typically an effective surgical treatment for CECS positive individuals, outcomes are not uniformly positive, and the need for revision surgery is recognized in the literature.<sup>3,5,18</sup> Reasons for individuals requiring revision fasciotomy can include inadequate release of the affected fascia, or the formation of scar tissue following initial fasciotomy, which reduces the amount of space available for muscular expansion during exercise. Individuals undergoing revision fasciotomy because of inadequate compartment release benefit from extension of the fascial split from the previous operation, while partial fasciectomy is recommended for those who experienced postoperative scarring from the initial operation.<sup>4,5</sup> Moreover, it appears that only 5-6% of patients fail to achieve adequate outcomes from the original fasciotomy and require revision surgery.<sup>3,18</sup> Consequently, despite the fact that no study exists that explains the postoperative decrease in pain, fasciotomy has been demonstrated to be largely effective in treating CECS positive individuals and remains the standard for surgical treatment.<sup>5</sup>

#### 2.5.4 Surgical Rehabilitation

The protocol for post-surgical rehabilitation protocol following fasciotomy has been well discussed in the literature. Most authors place a strong emphasis on early mobilization of the affected limb(s) to prevent the formation of scar tissue on the incised fascia.<sup>5,7,15</sup>
Range-of-motion exercises of the knee and ankle should commence immediately postoperatively. For three to five days, limited weight bearing using crutches is recommended, graduating to full weight bearing as tolerated. After the superficial incisions have healed, transitional activities, such as cycling and swimming can be started, and will progress to jogging/running at 3-6 weeks postoperatively.<sup>4,5,7,11</sup> The general consensus on return to full sports participation has been reported to range from 6-12 weeks;<sup>4,5,7,9,11</sup> however, return to full activity has been reported as early as the 3-4 week mark.<sup>4</sup>

### 2.6 Summary

CECS is known to occur most often in active individuals. The etiology and pathophysiology is not yet well defined and much debate exists over the true cause of pain. Symptoms typically occur bilaterally and in the anterior compartment. Diagnosis should not rely solely on clinical findings as this can lead to unnecessary fasciotomy, and thus should be confirmed by intracompartmental pressure testing prior to and following exercise. The Pedowitz criteria are currently widely accepted within the literature as sufficient for diagnosing CECS. Conservative treatment methods have demonstrated poor outcomes, with cessation of precipitating activity the only non-surgical method capable of alleviating symptoms. Fasciotomy is the recommended treatment and has been shown to be largely beneficial for CECS positive individuals. Surgical outcomes are best in the anterior and lateral compartments and worst in the deep posterior compartment. The complication rate is believed to be between 11% and 13%, and the need for revision surgery is only about 1 in 20. Individuals undergoing fasciotomy typically can expect to return to full activity 6-8 weeks postoperatively. Continued research is required to establish diagnostic ICP values that can be used to predict successful outcomes in CECS positive individuals undergoing fasciotomy.

## Chapter 3

## 3 Objective

The primary objective was to identify which patient characteristics and pressure values best predict outcomes, as measured using lower extremity functional scale (LEFS) score, for individuals who underwent fasciotomy for chronic exertional compartment syndrome. Secondary outcomes include the proportion of patients who: required revision surgery, returned to sport following fasciotomy, returned to pre-operative activity levels, and who were satisfied with their outcome following fasciotomy.

We suspected that individuals whose compartment pressures showed a failure to normalize (return to within 10% of resting pressure) at 15 minutes post-exercise will experience better outcomes. Additionally, we hypothesized individuals who had a lower self-reported pain score and had posterior compartment involvement would have a greater chance of requiring a revision surgery.

## Chapter 4

## 4 Methodology

This was a single-centre case series conducted in London, Ontario involving 46 consecutive patients who underwent intracompartmental pressure (ICP) testing preoperatively, surgical fasciotomy for treatment of chronic exertional compartment syndrome (CECS) of the lower leg and prospective long-term follow-up. The study took place from September 2011 to August 2012 at the Fowler Kennedy Sport Medicine Clinic (FKSMC), with the fasciotomies being performed at the London Health Sciences Centre, University Hospital in London, Ontario between September 2001 and January 2012.

## 4.1 Eligibility Criteria

Patients between 14 and 80 years of age, who underwent ICP testing followed by fasciotomy by a FKSMC orthopedist for treatment of CECS of the lower leg from September 2001 to January 2012, were eligible to participate in this study. Patients were excluded if they were unable to complete the follow-up questionnaires.

## 4.2 Subject Recruitment

A total of 89 patients were screened for eligibility. Of these, 20 did not meet eligibility requirements (see Figure 1). Eligible patients were mailed a letter of information (Appendix B) explaining the study. The letter of information made clear that participation in the study was voluntary and that patients were free to discontinue participation at any time. A username and password was provided within the letter of information to allow patients to complete the three questionnaires on a secure online database. If the patient had not completed the questionnaires online within one week of receiving the letter of information in the mail, a telephone interview was conducted by a member of the research team.



Figure 4: Flow of patients through the trial

## 4.3 Intracompartmental Pressure Testing

Compartment pressure measurement of the most symptomatic compartment was undertaken for all 46 participating patients (35 anterior, 0 lateral, 11 deep posterior, 0 superficial posterior) using the Synthes Compartmental Pressure Monitoring System (West Chester, PA). First, the patient was placed supine with his/her ankle relaxed. Three to four milliliters of 1% lidocaine was used to anesthetize the local tissue superficially. Next, a 14 gauge intravenous cannula was inserted into the compartment. The angle at which the needle was inserted varied depending on the compartment being tested; an angle of 30° parallel to the tibia is ideal for measurements of pressure within the anterior compartment and an angle of 45° to the tibia and 45-60° to the skin is ideal for pressure measurements within the deep posterior compartment. The trocar was removed, the probe

(with unicrystalline piezoelectric semiconductor tip) was inserted through the cannula into the compartment, and the cannula was retracted to expose the tip of the probe. To confirm that the probe was properly inserted into the compartment, light pressure was applied to the compartment, if the probe was properly inserted, the pressure reading increased simultaneous to the applied force. Once the probe has been appropriately adjusted, the patient's baseline (resting) pressure was recorded. The probe was then taped against the patient's leg, and a stocking was applied to the lower leg to cover the insertion site and bandage. Patients then ran on an inclined treadmill until their symptoms were reproduced or they became too symptomatic to continue. Typically this took 10-15 minutes. Patients were asked to reproduce symptoms to at least an 8/10 on a self-reported pain score, with 10/10 serving to represent symptoms at their worst. Upon completing the treadmill exercise, patients were quickly returned to the supine position and the immediate post-exercise pressure (P 0) was recorded. Additional pressure measurements were obtained at 5, 10, 15, and 20 minutes post-exercise, after which the cannula was removed.

### 4.4 Intervention: Fasciotomy

Fasciotomies were performed in a similar fashion to the technique described by Rorabeck and colleagues.<sup>27</sup> All of the procedures were performed with the patient under general anaesthesia and in the supine position. A tourniquet was applied to the operative limb. The limb was prepped and draped in a standard and sterile fashion. The tourniquet was then elevated to 250 mm Hg. Depending on the clinical scenario, all four compartments of both legs were released under the same anaesthesia.



#### **Figure 5: Surgical Incision Sites**

Two four-inch incisions, proximal and distal, were made midway between the anterior crest of the tibia and the fibula. The superficial peroneal nerve was identified and protected. Through each incision, the deep fascia was divided on either side of the intermuscular septum, releasing the anterior and the lateral compartments.

A four-inch incision was made over the middle third of the posteromedial border of the tibia. The long saphenous nerve and vein were identified and protected. The deep fascia was divided, releasing the superficial posterior compartment. The origin of the soleus muscle was elevated, and then the muscles of the posterior compartment were bluntly dissected off the posterior surface of the tibia, releasing the deep posterior compartment.

The tourniquet was deflated. Haemostasis was achieved. The subcutaneous fat was closed with a 2/0 absorbable braided suture. The skin was closed with a 3/0 absorbable suture.

Local anaesthetic was infiltrated into the wounds. Simple dressings and a compression bandage were applied to the leg. Once the incisions healed, the patient is encouraged to return to their pre-operative level of activity.

### 4.5 Outcomes

Patients were asked to complete a total of three questionnaires: a 20-item standardized return-to-sport and satisfaction questionnaire created for this study (Appendix E); and two versions of the 20-item lower extremity functional scale (LEFS) (Appendices C and D), the first was to represent the patient's current functional outcome and the second was to represent the patient's self-perceived time of best outcome. Additionally, the graduate student (NSP) abstracted demographic information (Appendix F) from the patient's hospital chart.

### 4.5.1 Return-to-Sport and Satisfaction Questionnaire

We (orthopedic fellow (DJW) and graduate student (NSP)) designed this questionnaire to assess symptomatic relief, return to sport/occupation, and satisfaction with the fasciotomy procedure. Eight items were dedicated to pre-operative demographics, eight items were related to outcome, and the remaining four items queried patient satisfaction with the surgery. Three of the outcome-related items, queried return to sport, return to occupation, and return to previous activity levels; including asking patients to recall the timeline for return to activities. Items were evaluated through yes/no responses and the use of fourpoint ordered categories.

### 4.5.2 Lower Extremity Functional Scale Questionnaire (LEFS)

The Lower Extremity Functional Scale is a 20-item, self-administered functional scale for patients with lower extremity orthopedic conditions. Each item has five possible response options ranging from zero (extreme difficulty or unable to perform) to four (no difficulty). The scale could be completed in less than two minutes online, or less than five minutes over the phone. A LEFS score was calculated by adding the responses for all items (each item has maximum score of four), for a maximum overall score of 80, which represents the highest possible functional level. The LEFS has been shown to be a valid

measure of function, is responsive to change, and is highly reliable. A minimal detectable change and minimal clinically important difference is nine points.<sup>28</sup>

#### 4.5.3 Chart Abstraction Sheet

The chart abstraction sheet contained 14 items including basic demographic information such as sex and age. Additionally, the affected compartment(s), compartment being tested, self-reported pain score (1-10), and compartment pressures that were collected during pre-operative ICP testing were recorded on the chart abstraction sheet.

### 4.6 Plan for Analysis

The SPSS version 20 (SPSS Inc., Chicago, IL) was used to perform analyses of the data. Tables reporting the demographic characteristics of the patient population were provided using means and standard deviations for continuous variables and proportions for nominal variables. We used Pearson's correlation coefficient (continuous variables) and Spearman's rho (ordered variables) to determine the magnitude and direction of the correlation between single predictor variables and LEFS score. Since many of the potential predictor variables were highly correlated, we used univariate logistic regression to measure the strength of the association between predictor variables and our primary outcome of LEFS score. If any of the univariate tests were found to be predictive, our plan was to use backward regression to determine their significance while adjusting for the other potential predictors. If the compartment being tested is shown to be a confounder, we will split the data in groups by whether testing was performed in anterior or deep posterior compartment. As we performed a univariate regression we reported Pearson's correlation coefficient, beta (with 95% confidence interval), and the p value for each potential predictor variable. All significant tests were two-sided with  $p \le 0.10$  being significant, as our research is hypothesis generating, not hypothesis testing.

## Chapter 5

## 5 Results

## 5.1 Flow of Patients

Of the 89 patients screened for this study, 20 were ineligible, 10 were unable to be contacted (contact information was not updated), and 13 could not be contacted (unable to reach patient). Patients were deemed ineligible because they did not undergo intracompartmental pressure (ICP) testing (n=11), had an acute compartment syndrome (n=5), had a compartment syndrome somewhere other than the lower leg (n=2), or were deceased (n=2).

Beginning in April 2012 until May 2012, 69 patients were recruited to participate in this study. Forty-six patients completed all three follow-up questionnaires (LEFS for time of follow-up and best outcome, and a return to sport/satisfaction questionnaire). Five patients had missing values from their ICP testing.

## 5.2 Demographic Information

Our sample had an even distribution of males and females, with a mean age of 30 years  $(SD \pm 13.0)$  at surgery. Thirty-eight patients had bilateral surgery, five had only a right leg surgery, and the remaining three had left leg fasciotomy only. The precipitating activity was primarily running (19 patients), and the average length of time symptomatic prior to surgery was 47.5 months (minimum (0 months), maximum (252 months)). The vast majority of patients were employed or students (n=26 and n=14 respectively).

## Table 1: Patient Demographics

	Eligible and
	Completed
<b>Characteristics</b>	Ouestionnaires (n =
	46)
Gender (number female, % female)	23 (50%)
Mean age at surgery (yrs.) (mean ± SD)	$30 \pm 13.0$
Time Symptomatic Prior to Surgery (months) ((mean) (minimum, maximum)	47.5 (0, 252)
Bilateral surgery (number Yes, % Yes)	38 (83%)
Compartment Tested	
-Anterior	35
-Deep Posterior	11
Affected compartment(s) (# of legs)	
-Anterior	80
-Lateral	80
-Superficial Posterior	42
-Deep Posterior	42
Precipitating Activity	
-Running	19
-Basketball	1
-Prolonged Standing	3
-Other	24
WSIB (number Yes, % Yes)	0,0%
Self-Reported Pain Score (mean ± SD)	8.1 ± 1.2
Self-Reported Health Status	
-Excellent	18
-Good	25
-Fair	3
-Poor	0
Employment Status	•
-Employed	26
-Unemployed	$\frac{1}{2}$
-Retired	4
-Student	14
Length of Follow-Up (months)	
((mean) (minimum, maximum))	54.9 (3.9, 127.3)

### 5.3 Primary Outcome Measure

#### Lower Extremity Functional Scale (LEFS):

At the time of follow-up, the mean LEFS score was 70.4 (SD  $\pm$  11.2). While the mean LEFS score for the patient-perceived time of best outcome was 72.3 (SD  $\pm$  11.2). The mean for the time of best outcome was at 14.3 months (minimum (0.5 months), maximum (84 months)) following surgery.

### 5.3.1 Regression

We performed three sets of univariate regressions using the raw pressure values, absolute change from baseline pressure values, and percent change from baseline pressure values as the independent variable. We present the association (r), beta with 95% confidence interval and probability value for the univariate regressions using raw pressure values. Because the results of the univariate regression tests were similar for the change from baseline data, we did not present these results. The analyses using percent change from baseline pressure values showed no association with the outcome and thus, we do not present those results. Significance was found at the immediate post exercise pressure and absolute change from rest to immediate post exercise (refer to Table 2). Additionally, when cases were grouped by what compartment pressure testing was performed in (anterior or deep posterior), opposite effects were observed; consequently, we separated these two groups. Because of our small sample size with respect to the deep posterior compartment (n=9), we dealt exclusively with the 33 anterior compartment cases with complete testing data. Next we undertook a backward regression including all the raw pressure values (P rest, P 0, P 5, P 10, P 15, P 20), as well as age at surgery, number of months symptomatic prior to surgery, self-reported pain score during pressure testing, and time since surgery. Including all the raw pressure values lead to a collinearity problem, thus we subsequently included the P 0 value with only one other pressure value (as well as age at surgery, number of months symptomatic prior to surgery, self-reported pain score during pressure testing, and time since surgery) in a backward regression model. The best model we created included the P 0 pressure value as a predictor, while

controlling for the effects of the P 20 pressure value , and the number of months symptomatic prior to surgery (refer to Table 5).

	LEFS (current status)				
Variable	r	B (95% CI)	p value		
P rest	.03	.05 (4858)	.86		
P 0	.27	.11 (0223)	.08		
P 5	.20	.01 (0625)	.20		
P 10	.16	.09 (0927)	.32		
P 15	.10	.07 (1427)	.53		
P 20	.04	.03 (2430)	.81		

 Table 2: Univariate Regression for Raw Pressure Values (All Cases)

	LEFS (current status)				
Variable	r	B (95% CI)	p value		
P rest	.12	.21 (4385)	.52		
P 0	.31	.12 (0226)	.08		
Р 5	.26	.13 (0530)	.16		
P 10	.19	.11 (0131)	.29		
P 15	.12	.08 (1631)	.51		
P 20	.07	.06 (2536)	.72		

 Table 3: Univariate Regression for Raw Pressure Values (Anterior Compartment Cases only)

 Table 4 - Univariate Regression for Raw Pressure Values (Deep Posterior Compartment Cases only)

	LEFS (current status)					
Variable	r	B (95% CI)	p value			
P rest	.35	54 (-1.7366)	.33			
P 0	.13	11 (8765)	.74			
P 5	.15	15 (9867)	.68			
P 10	.09	11 (-1.0887)	.81			
P 15	.11	14 (-1.0678)	.74			
P 20	.23	34 (-1.5183)	.50			

	LEFS (current status)				
Variable	B (95% CI)	p value			
P 0	0.36 (0.15 - 0.58)	0.00			
P 20	-0.47 (-0.890.05)	0.03			
# Months Symptomatic	-0.07 (-0.14 - 0.00)	0.04			
$R^2 = 0.30$	· · ·				

 Table 5: Backwards Regression for Anterior Compartment Cases (n=33)

## 5.4 Secondary Outcome Measures

### 5.4.1 Revision Surgery

At the time of follow-up, nine of the 46 patients (19.6%) had required a revision surgery for their chronic exertional compartment syndrome (CECS). Four of these patients had their revision fasciotomy performed at the Fowler Kennedy Sport Medicine Clinic (FKSMC), and their original fasciotomy elsewhere, while the other five had both their original and revision fasciotomy performed at the FKSMC. At the time of follow-up, the average LEFS score of this subgroup was not significantly different from the other 37 patients.

### 5.4.2 Return to sport/pre-operative activity levels

At the time of follow-up, 35 of 46 (76.1%) patients reported they were (or would have been) able to return to their chosen sport following fasciotomy. Additionally, 29 of these 35 patients reported they were (or would have been) able to return to their pre-operative activity levels.

### 5.4.3 Satisfaction

At the time of follow-up, 35 of 46 (76.1%) patients reported that their expectations were met after surgery. Forty of 46 (87.0%) patients indicated that, knowing what they know now, they would have chosen to undergo the fasciotomy. Forty-two of 46 (91.3%) patients responded that they would recommend fasciotomy for someone else suffering from chronic exertional compartment syndrome. Lastly, 36 of 46 (78.3%) patients reported feeling either satisfied (n=14) or very satisfied (n=22) with their outcome at the time of follow-up.

Secondary Outcome	Proportion of Patients (X/Y,
	(%))
Patients requiring revision fasciotomy	9/46 (19.6%)
Patients able to return to sport/pre-operative activity levels	Sport: 35/46 (76.1%)
	Activity: 29/35 (82.9%)
Patients satisfied with their outcome	36/46 (78.3%)

#### **Table 6: Secondary Outcomes**

## Chapter 6

### 6 Discussion

The purpose of this thesis was to identify which pre-operative factors are most predictive of functional outcome as measured by the Lower Extremity Functional Scale (LEFS) for individuals at least one year post-fasciotomy for chronic exertional compartment syndrome (CECS). Additionally, we reported the percentage of patients who: required revision surgery, returned to their sport, returned to or exceeded their pre-operative activity levels, and were satisfied or very satisfied with their outcome. We found that the immediate post-exercise pressure value, 20 minute post-exercise pressure value, and the number of months symptomatic prior to surgery were most predictive of functional outcome.

Five studies, all consecutive case-series, have examined the outcomes of CECS-positive individuals following fasciotomy. One of these five studies examined the effect of fasciotomy on compartment pressure values,<sup>6</sup> while Howard and colleagues (2000) sought to determine the relationship between pre-operative compartment pressure values and pain relief.<sup>3</sup>

Verleisdonk and colleagues (2004) measured compartment pressures before and after surgery in 46 CECS-positive individuals. At three months post surgery, there was no statistically significant difference between the pre- and postoperative P rest pressure values. However, they did demonstrate a statistically significant decrease in postoperative compartment pressures both immediately and five-minutes following exercise. They concluded that compartment pressure at rest (P rest) was not an integral aspect of CECS, and even suggested that this pressure value is unrelated to CECS.

In their study, Verleisdonk and colleagues attempted to establish accurate diagnostic criteria for CECS, meaning that individuals who met these criteria were likely to experience a better outcome following surgery. Similarly, our data indicated that the immediate post-exercise pressure is the most useful value in predicting outcome in

individuals undergoing fasciotomy. However, in our study, we did not find a significant association between outcome and the five minute post-exercise pressure value.

Notable differences between the Verleisdonk et al. study and our study is that Verleisdonk focused specifically on anterior compartment CECS (although our final model also focused specifically on the anterior compartment), had no measure of overall patient satisfaction/outcome besides symptomatic improvement, had a younger study sample, and a fixed length of follow-up (2 years). According to the CECS literature, the inclusion of compartment syndromes of the deep posterior compartment in our study should have meant worse outcomes compared to Verleisdonk's study; however, symptomatic improvement was comparable between the two studies (76% vs. 83%).<sup>6</sup>

Howard, Mohtadi, and Wiley (2000) compiled a retrospective case series of 39 CECS patients and measured their outcome at the time of follow-up. Primary outcome measures included: pain (before and after surgery), level of improvement, level of maximum activity, satisfaction level, and the occurrence of reoperations. The average time of follow-up was 3.4 years, and data was complete. They found no significant association between percent pain relief and the immediate post-exercise pressure (P 0) value (r = -0.07) which is contrary to our findings. In our study, the pressure value immediately post-exercise was the most valuable compartment pressure testing value for predicting a patient's functional outcome. Since we did not measure pre-operative function, we could not assess the effect of surgery on functional change, which may explain the difference in findings between our study and the study by Howard et al. Further, we measured function not pain, which may also explain the difference in findings.

In the study by Howard et al, patient satisfaction following surgery was high (78%), and similar to our findings (79%). A slightly greater proportion of patients in the study by Howard and colleagues (2000) were able to achieve activity levels equal or greater to their pre-operative levels compared to those in our study (78% versus 63% respectively). This difference in findings could be related to the greater number of patients in our study that required a revision fasciotomy. Additionally, our findings suggest that surgical fasciotomy may fail at a greater rate than suggested by the literature.

In a study conducted by Garcia-Mata and colleagues (2001), a different approach was taken whereby 22 adolescents were followed for an average of 4.8 years following fasciotomy for CECS. They used a composite outcome and ability to return to sport as their primary outcome measures. The composite outcome was adapted from another study where an excellent outcome was indicated if the individual had no exercise related pain, no limitation of activity, and considered themselves "cured." <sup>29</sup> Surprisingly, they found that all 22 patients experienced an excellent outcome, and were able to return to sports activities within six weeks of fasciotomy. These results are considerably more favorable than those found elsewhere in the literature and may be related to the sample (young and active patient population) that was studied. Additionally, there may have been some element of confirmation bias since the primary author was also the surgeon who performed the fasciotomies.

Following their study, Garcia-Mata et al. suggested new criteria for arriving at a diagnosis of CECS: a resting pressure value of >10 mm Hg, a one and five minute postexercise pressure value of >20 mm Hg, and an intracompartmental pressure (ICP) normalization time of longer than 15 minutes. Particular emphasis was placed on the ICP normalization time. During the planning phases of our study we hypothesized that the pressure value at 15 minutes post-exercise would be most predictive of a patient's outcome. However, we did not find a significant association between functional outcome (LEFS score) and either the pressure value at 15 minutes post-exercise, the change in pressure from pre exercise to 15 minutes post-exercise, or the percent change in pressure from pre exercise to 15 minutes post-exercise. We did however; find that both the immediate and 20 minute post-exercise pressure values were predictive. If one accepts that the immediate post-exercise pressure value is essentially the same as the pressure value one minute following exercise, and the twenty minute post-exercise pressure value encompasses the concept of ICP normalization, then our results support some of the suggestions made by Garcia-Mata et al. We did not however find a significant relationship between the resting compartment pressure and patient outcome.

The fourth study, by Slimmon and colleagues study (2002), was a consecutive case series where 62 CECS-positive patients were given a self-administered questionnaire to assess

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surgical outcome and activity levels an average of 4.25 years following surgery. A slightly different surgical approach was undertaken, where a fasciectomy was performed in addition to the fasciotomy. Outcomes were found to be worse compared to patient outcomes reported in other studies. In the Slimmon study, only 60% of those who did not require a revision surgery reported an excellent or good outcome, and 13 of the 62 patients reported reduced activity levels because of either a return of their compartment syndrome, or the development of a new compartment syndrome of the lower leg. Additionally, the proportion of patients requiring a revision surgery was roughly four times higher than what is reported elsewhere. Other interesting findings included better outcomes for patients who underwent isolated anterior or posterior compartment surgeries compared to those who had anterior and posterior combined surgeries. More surprising was the finding that patients who underwent only posterior compartment release fared significantly better than the other two groups, this is contrary to the trend seen in the CECS literature.<sup>19</sup>

The primary difference between the Slimmon et al. study and ours was the surgical technique. Fasciectomies were only included as part of the surgical procedure in our study for those undergoing a revision surgery. Consequently, it is possible the inclusion of the fasciectomy precipitated the difference in satisfactory outcomes between this study and ours (60% vs. 78%). Another potential explanation for this difference was the minimum two year follow-up in the Slimmon et al. (2002) study. Multiple patients in our study indicated that they initially experienced a period of symptomatic relief with subsequent return of symptoms that were as bad as, or worse than, before their surgery. Our study included eleven patients who were within two years of their surgery. If a stable outcome cannot be expected until at least two years following surgery, the inclusion of these patients may have influenced our results. However, when we conducted a sensitivity analysis by removing these eleven individuals, the beta values for the model did not appreciatively change.

The fifth study, by Detmer et al. (1985), investigated the pain relief, functional improvement, and satisfaction experienced by 100 patients receiving fasciotomy for CECS. One patient withdrew from the study within one week, and two others withdrew

within two months. The average length of follow-up was 10 months. Overall results were positive. Only four patients described no improvement in symptoms following fasciotomy. Ninety-three patients experienced pain relief, while 91 patients described functional improvement, 73 of whom reported a complete functional cure. Eighty-nine of 95 patients indicated that they would undergo the procedure again if a new CECS developed. These results parallels our findings, where 40 of 46 patients indicated that, knowing what they know now, they would have the surgery again.

Additional statistical analyses by Detmer et al. showed no appreciable relationship between the duration/severity of symptoms, functional impact, or resting compartment pressures with outcome. Our study sought to determine which, if any, variables were predictive of outcome following fasciotomy for CECS patients and also failed to demonstrate a relationship between the resting pressure value and outcome. However, we did find that the duration of symptoms prior to surgery was an important factor in predicting outcome. This difference may be attributable to the significantly shorter duration of symptoms prior to surgery of patients in the Detmer and colleagues study (22 months, minimum 0.3 months, maximum 46.8 months) compared to our study (47.5 months, minimum 0 months, maximum 252 months).

It is also important to note the difference in mean time of follow-up between this study (10 months) and ours (4.6 years), as the shorter timeframe may have contributed to the more positive results for the reasons mentioned previously. Additionally, when discussing the posterior compartments, Detmer and colleagues describe five compartments rather than the traditional two. Despite this distinction, surgical technique is similar to that used in our study, and it is thus unlikely that this would explain any differences between the two studies. The apparent discrepancy in patients experiencing symptomatic relief following surgery could be explained by the vague description of the pain measure used in the Detmer et al. study. They noted that ninety-three of the 100 patients experienced pain relief; applying these criteria, 43 of 46 patients in our study experienced a complete functional cure (73% vs. 63%), the inclusion of the four patients in our study who had a failed original fasciotomy elsewhere before visiting

our clinic for a revision may play a role. However, when we conducted a sensitivity analysis removing these four individuals, the proportion of patients who experienced a complete functional cure was unchanged. Furthermore, our study did not directly ask patients to grade their functional improvement. Consequently, for the purposes of comparing results between studies, we considered a complete functional cure to be indicated by a response of 'yes' when patients were asked if they were able to return to their pre-operative levels of activity. It is worth noting that 76% of patients indicated that they were able to return to their chosen sport following fasciotomy.

Unique to our study was the outcomes of patients who had deep posterior compartment involvement as part of their fasciotomy. The predominant viewpoint in the CECS literature is that these patients will fare significantly worse than those with anterolateral compartment involvement only. However, our results showed no appreciable differences between the two groups with respect to outcome (LEFS score or satisfaction measures), length of time symptomatic prior to surgery, or the time at which patients were experiencing their best outcome following surgery. Furthermore, these two groups had similar pre-operative demographics, leading us to believe that CECS patients with deep posterior compartment involvement fare better than reported in the literature. A similar claim is made in the Slimmon et al. study, where publication bias is cited as a potential explanation as to why this is not reported elsewhere in the literature. Additional explanations for this discrepancy between our results and the prevailing view on CECS could stem from surgeon expertise with the fasciotomy technique. It is well established that a deep posterior compartment release is a more difficult procedure than an anterior or lateral compartment release, due to the complex anatomy, poor visualization, and presence of subdivisions within the deep posterior compartment.

The original goal for this study was to create a regression model that incorporated intracompartmental pressure (ICP) values to predict an individual's outcome following fasciotomy. The data from the univariate regressions demonstrated that the only significant ICP value for predicting outcome was the immediate post-exercise pressure value. Interestingly, the magnitude and direction of predictors differed for anterior and deep posterior compartments, and our final model is specific to the anterior compartment.

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Our sample size for the deep posterior compartment (n=9) was inadequate to produce a reliable prediction model. The three variables that were shown to be most important for predicting outcome, when pressure testing was done in the anterior compartment, were the immediate post-exercise pressure value, the twenty minute post-exercise pressure value, and the number of months symptomatic prior to surgery, with the immediate postexercise pressure value being most important. The immediate post-exercise pressure showed a positive correlation with LEFS while the twenty minute post-exercise pressure value and number of months symptomatic prior to surgery demonstrated a negative correlation. Fasciotomy is performed to allow patients to accommodate increased compartment pressures, thus the positive correlation between the immediate post-exercise value and outcome makes intuitive sense. However, it is surprising to see a negative correlation between the twenty minute post-exercise pressure value and outcome, as patients with elevated pressure values at 20 minutes post-exercise would be considered prototypical CECS cases. If compartment pressures remain elevated for as long as twenty minutes following exercise, perhaps patients require a procedure beyond a fasciotomy to achieve a full recovery. As for the negative correlation between the number of months symptomatic prior to surgery and outcome, the possibility exists that irreversible damage is done to the fascia if one suffers from CECS for an extended period of time.

### 6.1 Strengths

The strengths of this study include its sample size. Complete follow-up on 46 patients following fasciotomy makes this one of the larger studies conducted on patients with CECS. In addition, this is the first study to utilize the validated Lower Extremity Functional Scale (LEFS) to measure outcome in this patient population. It is also one of the first studies to examine the relationship between the percent change in pressure during intracompartmental pressure (ICP) testing and outcome. This analysis provided a more comprehensive understanding of the effect of compartment pressures on self-reported outcome. Furthermore, the creation of a model to predict outcome following fasciotomy in individuals suffering from CECS makes this study unique, and has provided a rudimentary model that should be tested and refined through future research.

Another strength of our study was the standardization of both the ICP testing procedure and surgical technique. All of the ICP testing was performed at one site by one of two clinicians following a standard procedure with the same equipment, thereby reducing the variability from multiple raters or measurement techniques. Also, 42 of the 46 surgeries were performed by the same surgeon, reducing the opportunity for the results to be influenced by surgical technique or variability in surgeon expertise.

## 6.2 Limitations

One of the greatest limitations of this study was that it was retrospective in nature. Of the patients contacted, fasciotomies were performed as early as 2001. Consequently, it is possible that these individuals struggled to accurately recall how long they had been symptomatic prior to surgery or how quickly they were able to return to activity following surgery. Another limitation of our study was the inherent variability and error related to compartment pressure measurement, as occasionally a patient will register a tremendously high pressure value that is not consistent with physical findings. Furthermore, it is often difficult to differentiate between the anterior and lateral compartments when performing ICP testing.

Additionally, analysis demonstrated that the LEFS scores did not show a standard normal distribution, as scores were skewed towards the upper (higher functioning) boundary of 80, with 14 patients scoring a perfect 80/80 at the time of follow-up. Contrarily, the ICP values did demonstrate a standard normal distribution. Thus, the ceiling effect noted in the distribution of LEFS scores means that we have to assume the 14 individuals with a score of 80 experienced identical outcomes when in reality some likely fared better than the LEFS was able to reflect. However, there is no questionnaire or outcome measure that has been validated specifically for the CECS population.

We recognize that our model must be validated through confirmatory analysis before being adopted into clinical practice. Moreover, if our model was utilized in a prospective study it may be useful to collect a baseline LEFS score prior to fasciotomy, as the effect of surgery on functional change could be directly assessed. Lastly, FKSMC uses the Synthes Compartment Pressure Monitoring System to test ICP pressures, which uses a semiconductor to evaluate compartment pressure. Contrarily, the machine frequently mentioned in the literature, the Stryker Pressure Monitor, uses either wick-catheter or side-ported needle technology. Although there is no reason to believe that these different technologies would yield different pressure values, we are unaware of any study that has evaluated the agreement between these instruments. Finally, there is no standardized exercise protocol for patients undergoing ICP testing. Consequently, the variability between studies in the exercise protocol used to evoke symptoms could explain some of the differences in findings between studies; it is possible that our protocol reproduces true CECS symptoms better or worse than those used at other centres.

FKSMC has earned a reputation for providing surgical treatment for patients suffering from CECS. As such, the orthopedist responsible for performing these surgeries has far greater exposure to this patient population and greater experience with the surgery. This means that these results may not be representative of smaller centres with less exposure to the CECS patient population. Similarly, this reputation meant that some patients who were dissatisfied with the results from a fasciotomy performed elsewhere visited FKSMC for a revision procedure. For some of these patients ICP values were collected after a fasciotomy was already performed, which may have resulted in lower pressure values for this group.

## Chapter 7

## 7 Conclusion

Predictors of outcome are different for patients who undergo anterior versus deep posterior fasciotomy for CECS. Analysis of the data for those who had testing performed in the anterior compartment suggest importance in the immediate post-exercise pressure value, twenty-minute post-exercise pressure value, and the number of months symptomatic prior to surgery. Confirmatory analysis on new data is required before we can make definitive conclusions or make recommendations for clinical practice.

## 7.1 Directions for Future Research

- A. Obtain a new data set (either prospective or retrospective) to test our prediction model for patients undergoing fasciotomy of the anterior compartment
- B. Prospective comparison of the characteristics, pressure values and outcomes of patients diagnosed with CECS who underwent ICP testing and underwent fasciotomy to those patients who underwent ICP testing but did not undergo fasciotomy
- C. The creation and validation of an outcome measurement tool specific to individuals who suffer from CECS
- D. A prospective reproduction of this study where a baseline LEFS score was also obtained to better elicit the effect of surgery on patients

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## Appendices

#### **Appendix A: Ethics Approval Form**

web Western	Use of Human Participan	ts - Ethics Approval	Notice
Principal Investigator: Dr. Kevin Willits File Number: 102027 Review Level:Delegated Approved Local Adult Participants: 11 Approved Local Minor Participants: 0 Protocol Title:Assessing Long-Term O Syndrome of the Lower Leg - 18644E Department & Institution: Schulich Scf Sponsor: Ethics Approval Date:April 25, 2012 E Documents Reviewed & Approved &	o utcomes in Individuals Ur nool of Medicine and Dent xpiry Date:August 31, 20 Documents Received fo	ndergoing Fasciotomy listry\Surgery,Wester 114 r Information:	y for Chronic Exertional Compartment n University
Document Name	Comments	Version Date	
Western University Protocol			
Letter of Information		2012/03/07	
Other	Telephone Script		
This is to notify you that The University Subjects (HSREB) which is organized a Involving Humans and the Health Canar and regulations of Ontario has reviewed date noted above. The membership of t of the Food and Drug Regulations. The ethics approval for this study shall n	of Western Ontario Resea nd operates according to dar/ICH Good Clinical Pra- and granted approval to his REB also complies wil remain valid until the expli-	arch Ethics Board for the Tri-Council Polic ctice Practices: Cons the above referenced th the membership re	Health Sciences Research Involving Human y Statement: Å Ethical Conduct of Research olidated Guidelines; and the applicable laws d revision(s) or amendment(s) on the approval squirements for REB's as defined in Division 5 assuming timely and acceptable responses to
the HSREB's periodic requests for surve time you must request it using the Unive Members of the HSREB who are named discussion related to, nor vote on, such	eillance and monitoring in rsity of Western Ontario I d as investigators in resea studies when they are pro	formation. If you requ Updated Approval Re arch studies, or decla esented to the HSRE	uire an updated approval notice prior to that equest Form. re a conflict of interest, do not participate in B.
The Chair of the HSREB is Dr. Joseph under the IRB registration number IRBÅ	Gilbert. The HSREB is reg 00000940.	gistered with the U.S.	Department of Health & Human Services

F	Ethics,	Officer to Contact for Further Information	
Janice Sutherland	(gra	Grace Kelly	Shantel Walcott
(jsutherl@uwo.ca)		ce.kelly@uwo.ca)	(swalcot@uwo.ca)

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#### **Appendix B: Letter of Information**



#### Letter of Information

<u>Title of Research</u>: Assessing Long-Term Outcomes in Individuals Undergoing Fasciotomy for Chronic Exertional Compartment Syndrome of the Lower Leg

#### Principal Investigator

Dr. Kevin Willits, Fowler Kennedy Sports Medicine Clinic, 3M Centre, UWO, London, Ontario, N6A 3K7

Phone: : Ext.

The pronouns 'you' and 'your' should be read as referring to the participant, and not to the parent / guardian who is reading this letter

The purpose of this letter is to provide you with the information you require to make an informed decision about participating in this research.

#### **Procedure**

You have been identified as having undergone intracompartmental pressure (ICP) testing at Fowler Kennedy Sport Medicine Clinic to confirm a diagnosis of chronic exertional compartment syndrome (CECS) and receiving surgical fasciotomy during, or after, 1990.

If you agree to participate, you will be asked to complete a questionnaire assessing your level of activity, quality of life, and satisfaction with the fasciotomy procedure. You have the option to complete this form online using the username (johndoe@empower.ca) and password (CECS2011) provided. If you do not to complete this form online, you will receive a phone call approximately one week from receipt of this letter. If you agree to participate, we will administer the questionnaires over the telephone. Completion of the questionnaire will take approximately 10-15 minutes.

With your consent, we will look in your medical chart obtain your preoperative pain levels, ICP values at time of testing, date of birth (to calculate your age at surgery), BMI at surgery, and sex.

#### Risks

There are no known health risks associated with participation in this study. The data that is collected from you is protected by a username and password. It travels in a scrambled format to

1 of 3 Page

Patient Initials: \_\_\_\_

Version: January 23, 2012

a server (storage computer) that is located in Toronto. The company that houses the server is a professional company with extremely high standards of physical and virtual security. We want to let you know however, that even with this high level of security, there is always a remote chance that your information could be accessed or "hacked" by someone who is not supposed to have your information. If we became aware that this had happened, we would inform you immediately.

#### Benefits

There are no known benefits to you for participating in this study; however, participation may benefit future patients suffering from CECS by enabling clinicians to establish post-exercise ICP value thresholds for surgical intervention. This has the potential to allow clinicians to recommend surgical intervention with greater confidence of a positive outcome.

#### Compensation

There are no known expenses associated with participation in this study.

#### Voluntary Participation:

Your participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. Should you choose to withdraw from this study, we will keep all data obtained up to the point that you chose to withdraw.

Participation in this study does not prevent you from participating in any other research studies at the present time or future. If you are participating in another research study, we ask that you please inform of us of your participation. You do not waive any legal rights by signing the consent form.

#### Request for Study Results:

Should you decide to participate and want to receive a copy of the study results, please send an email to **service and an email** to **service and an email** to **service and an email** once the study has been published, you will be notified via email and arrangements can be made to get you a copy. Please note that the results of this study may not be available for a few years. Should your email change, please let us know.

#### Confidentiality:

All information will be kept in strict confidence. Upon agreeing to participate in this study, you will be assigned a unique number that will be used for all your information and data collection. Data that is collected will be username and password protected and stored on a server located in Toronto through a scrambled format. Your identifying information will not appear on the database used to analyze data. In any publication, presentation or report, your name will not be used and any information that discloses your identity will not be released or published. Representatives of The University of Western Ontario Health Sciences Research Ethics Board

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Patient Initials: \_\_\_\_

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may require access to your study related records or may follow up with you to monitor the conduct of the study.

#### Questions:

If you have questions about your rights as a research participant, or the conduct of the study, you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at

If you have questions or concerns about your surgery, please contact your orthopaedic surgeon. If you have any questions about this research, please contact Nick Pasic at or ext. Dr. Dianne Bryant at ext. or

, or Dr. Kevin Willits at

If you are attempting to fill out the questionnaire online and experience technical difficulties, please contact Nick Pasic at or ext. or Stacey Wanlin at ext.

Completion of this questionnaire indicates your consent to participate. If you do complete this questionnaire you also provide your consent for us to perform a chart review. If you do not wish to have us review your chart, please do not complete this questionnaire

This letter is yours to keep.

Sincerely,

Dr. Kevin Willits, BPE, MA, MD, FRCSC Dr. Dianne Bryant, BSc, BA, MSc, PhD Dr. David Whitehead, BSc, MBChB, FRACS Nick Pasic, BHSc, MSc Candidate

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Patient Initials: \_\_\_\_

Version: January 23, 2012

#### **Appendix C: LEFS for Current Health Status**

https://secure.empowerhealthresearch.ca/secure/survey/print/form\_t...

CECS

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Lower Extremity Functional Scale (LEFS) - Current Health Status

We are interested in knowing whether you are **currently** having any difficulty at all with the activities listed below because of your previous lower limb problem. Please provide an answer for each activity.

<b>Τοdav</b> . do vou or would νοι	have anv d	lifficulty at al	I with.
------------------------------------	------------	------------------	---------

	Extreme difficulty or unable to perform	Quite a bit of difficulty	Moderate difficulty	A little bit of difficulty	No difficulty
1. Any of your usual work, housework, or school activities	0	0	0	$\bigcirc$	0
2. Your usual hobbies, recreational or sport activities	0	$\bigcirc$	0	0	0
3. Getting into or out of the bath	0	0	0	0	0
4. Walking between rooms	0	0	0	0	0
5. Putting on your shoes or socks	0	$\bigcirc$	0	0	0
6. Squatting	0	0	0	0	0
7. Lifting an object, like a bag of groceries from the floor	0	0	0	0	0
8. Performing light activities around your home	0	0	0	0	0
9. Performing heavy activities around your home	0	0	0	0	0
10. Getting into or out of a car	0	0	0	0	0
11. Walking 2 blocks	0	0	0	0	0

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https://secure.empowerhealthresearch.ca/secure/survey/print/form\_t...

12. Walking a mile	0	0	0	0	0	
13. Going up or down 10 stairs (about 1 flight of stairs)	0	0	0	0	0	
14. Standing for 1 hour	0	0	0	0	0	
15. Sitting for 1 hour	0	0	0	0	0	
16. Running on even ground	0	0	0	0	0	
17. Running on uneven ground	0	0	0	0	$\bigcirc$	
18. Making sharp turns while running fast	0	0	0	0	0	
19. Hopping	0	0	0	0	0	
20. Rolling over in bed	0	0	0	0	0	

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### **Appendix D: LEFS for Best Outcome**

 $https://secure.empowerhealthresearch.ca/secure/survey/print/form\_t...$ 

CECS

#### Lower Extremity Functional Scale (LEFS) - Best Outcome

We are interested in knowing whether at your **best outcome** following surgery you would have experienced any difficulty at all with the activities listed below because of your lower limb problem. Please provide an answer for each activity.

# At your **best outcome** following surgery, would you have experienced any difficulty at all with:

	Extreme difficulty or unable to perform	Quite a bit of difficulty	Moderate difficulty	A little bit of difficulty	No difficulty
1. Any of your usual work, housework, or school activities	0	0	0	0	0
2. Your usual hobbies, recreational or sport activities	0	0	0	0	0
3. Getting into or out of the bath	0	0	0	0	0
4. Walking between rooms	0	0	$\bigcirc$	0	0
5. Putting on your shoes or socks	0	0	0	0	0
6. Squatting	0	0	$\bigcirc$	0	0
7. Lifting an object, like a bag of groceries from the floor	0	0	0	0	0
8. Performing light activities around your home	0	0	0	0	0
9. Performing heavy activities around your home	0	0	0	0	0
10. Getting into or out of a car	0	0	0	0	0

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11. Walking 2 blocks	0	0	0	0	0	
12. Walking a mile	0	0	0	0	0	
13. Going up or down 10 stairs (about 1 flight of stairs)	0	0	0	0	0	
14. Standing for 1 hour	$\bigcirc$	0	0	0	0	
15. Sitting for 1 hour	$\bigcirc$	0	0	0	0	
16. Running on even ground	0	0	0	0	0	
17. Running on uneven ground	0	0	0	0	0	
18. Making sharp turns while running fast	0	0	0	0	0	
19. Hopping	0	0	0	0	$\bigcirc$	
20. Rolling over in bed	0	0	0	0	$\bigcirc$	

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# Appendix E – Return-to-Sport and Satisfaction Questionnaire

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Patient Questionnaire Current Health Status
1. What activity caused your chronic exertional compartment syndrome?
ORunning
OProlonged Standing
OBasketball
Other (specify)
2. Was your chronic exertional compartment syndrome part of a WSIB claim?
Oyes
$\bigcirc_{No}$
3. In general, would you say your health is:
OExcellent
OGood
OFair
OPoor
4. What is your employment status?
OEmployed
OUnemployed
ORetired
Ostudent
5. Do you suffer from:
Hypertension (High Blood Pressure)
Diabetes
Vascular Disease
None of the Above
6. Prior to surgery, how long had you been symptomatic?
Years Months
7. Prior to surgery, did you experience pain with sporting activities?
$\bigcirc_{\mathrm{Yes}}$

⊖<sub>N₀</sub>

8. Prior to surgery, did you experience pain with activities of daily living?

<b>Yes</b>	
$\bigcirc_{N_0}$	

9. Were you (or would you have been) able to return to your chosen sport after the surgery?

$\frown$	L
U.	Yes
$\sim$	ries

How long after your surgery could you return to your chosen sport? Within 3 Months 3-6 Months 6-9 Months

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$\langle \rangle$	Л	Ιo

10. Were you (or would you have been) able to return to your chosen occupation after the surgery?

**V**Yes

How long after your surgery could you return to your chosen occupation?

Within 3 Months
3-6 Months
O6-9 Months
>9 Months

>9 Months

### ⊖<sub>№</sub>

11. Were you (or would you have been) able to return to the same level of activity after the surgery?



How long after your surgery could you return to your previous level of activity?

С	Within 3 Months
С	3-6 Months
С	-9 Months
С	>9 Months

⊖**‰** 

12. Did your symptoms improve after surgery?

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ιz	v	-	-
$\sim$	1	e	s

Yes, but only with a decrease in the level of activity

 $\bigcirc_{N_0}$ 

13. Have your symptoms returned?

QYes; my symptoms are worse than before surgery

Yes; my symptoms are about the same as before surgery

Yes; my symptoms are not as bad as they were before my surgery

⊖N₀

14. Were your expectations met after surgery?

() Yes

 $\bigcirc_{\mathbf{No}}$ 

15. Knowing what you know now, would you have chosen to have the surgery?

⊖<sub>Yes</sub>

 $\bigcirc_{N_0}$ 

16. Would you recommend your surgery to someone else suffering from chronic exertional compartment syndrome?

⊖<sub>Yes</sub>

 $\bigcirc_{N_0}$ 

17. Did you have a complication as a result of the surgery?

Ves Please specify:

 $\bigcirc_{N_0}$ 

18. Have you had any further surgery on the same leg for any reason?

Ves Please specify:

 $\bigcirc_{N_0}$ 

19. Overall, after the surgery you were:

OVery Satisfied

Satisfied

Uncertain

Dissatisfied

20. At what point following your surgery were you experiencing your best outcome?

Years Months

## **Appendix F - Chart Abstraction Sheet**

## CECS

Chart Abstraction 1. Date of birth:
2. Date of surgery:
3. Sex: OMale OFemale
4. Height feet inches Weight: Okgs Olbs
5. In what compartment was testing performed?
Anterior
DLateral
Deep Posterior
Superficial Posterior
5. Bilateral Surgery? OYes ONo
7. Involved compartment(s) (check all that apply)
Anterior
Lateral
Deep Posterior
Superficial Posterior
8. Self-Reported Pain Score (1-10)

9. Insertional ICP (P rest)

10. Immediate ICP (P 0)

11. ICP 5 Minutes Post-Exercise (P 5)

12. ICP 10 Minutes Post-Exercise (P 10)

13. ICP 15 Minutes Post-Exercise (P 15)

14. ICP 20 Minutes Post-Exercise (P 20)

## NICK PASIC

#### CURRICULUM VITAE

#### **EDUCATION:**

**Master of Science** 

#### Honors Bachelor of Health Sciences Health Sciences Dean's Honours List

Graduated with Distinction

#### **RESEARCH EXPERIENCE**

University of Western Ontario London, ON **Thesis Project** Status: In Progress 2011-2012 Sports Medicine University of Western Ontario, London, ON September 2011-Present

Honors Specialization in Health Sciences University of Western Ontario, London, ON Class of 2011

Assessing Long-Term Outcomes in Individuals Undergoing Fasciotomy for Chronic Exertional Compartment Syndrome of the Lower Leg Role: Co-Investigator; responsible for Collecting and analyzing all data, and contacting all patients

#### PUBLICATIONS, PAPERS AND PRESENTATIONS

University of Western Ontario London, ON January 2012, July 2012

#### **TEACHING EXPERIENCE**

University of Western Ontario London, ON Fall 2011

University of Western Ontario London, ON Winter 2012 **Presentation: Fowler Kennedy Sport Medicine Clinic – Research Rounds** Assessing Long-Term Outcomes in Individuals Undergoing Fasciotomy for Chronic Exertional Compartment Syndrome of the Lower Leg

**Teaching Assistant – Kinesiology 1088A** 

**Teaching Assistant – Kinesiology 2236B** 

## AWARDS, DISTINCTIONS, CERTIFICATIONS

2011-2012

July 2012 December 2008

2007-2011

University of Western Ontario Graduate Research Scholarship Emergency First Aid, CPR Level C Michael Kirkley Memorial Football Award *Value:* \$1,250 University of Western Ontario Continuing Admission Scholarship *Value:* \$10,000 (\$2,500 for 4 years)