Functional outcomes and patient satisfaction after fasciotomy performed for chronic exertional compartment syndrome.

By

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This study is in partial fulfilment of the requirements for the degree

Master of Medicine in Orthopaedic Surgery

University of Cape Town

Supervisor(s): Dr S Maqungo

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Declaration

I, Christoff de Villiers Marais, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever. I further declare the following:

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4. I have referenced all quotations and properly acknowledged other ideas borrowed from others.
5. I have not and shall not allow others to plagiarise my work.
6. I declare that this is my own work.
7. I am attaching the summary of the Turnitin match overview.

Signature: ………………………………………………... Date: ……………………………
Abstract

Study Rationale:
Chronic exertional compartment syndrome often forces patients to change their sporting activities or reduce their level of participation. Many undergo surgery with the aim to return to their activities symptom free. The aim of the study was to determine if fasciotomies for chronic exertional compartment syndrome are a reliable treatment option with a predictable outcome to allow patients to return to the same level of activities.

Objective:
The evaluation of the functional outcomes and patient satisfaction in an active population who had surgery, namely fasciotomies, for chronic exertional compartment syndrome (CECS) of the lower leg.

Design:
A retrospective descriptive cohort study with a telephonic follow-up interview.

Patients:
A consecutive series of 41 patients that were surgically treated for CECS by a single orthopaedic surgeon from July 2005 to October 2013.

Main Outcome Measures:
Patient records were reviewed to determine their presenting symptoms, diagnostic investigations and surgical procedures performed. A questionnaire was completed by each participant to assess pain and level of activity before and after surgery, level of improvement after surgery and patient satisfaction with surgical outcomes.
Results:

Twenty-one of the 41 patients that were included in the study were categorized as active sportsmen, participating at a competitive or a non-competitive level. The remaining 20 were experiencing symptoms during leisure activities. The majority of all the patients (63%) had to stop their activity due to their symptoms. After surgery 95% were able to return to participate in the same level of activities as before surgery. Ninety percent of the active sportsmen were able to return to participation at a competitive or non-competitive level, with 45% reporting an increase in the level of intensity that they could maintain. Overall satisfaction was reported by 80% of participants although only 46% were completely pain free.

Conclusions:

Fasciotomies are a viable surgical treatment option for chronic exertional compartment syndrome in active patients, including athletes. There is an 87% return rate to previous activities within 6 months and an 80% satisfaction rate reported by patients post-surgery.  

We do acknowledge that some of the data collected regarding symptomology is subject to recall bias due to the interval between surgery and completion of the questionnaire.
Part A: LITERATURE REVIEW

Objectives of literature review

Patients who are diagnosed with chronic exertional compartment syndrome have limited options for treatment if they wish to continue to participate in the activities or sport that led to their symptoms. Surgery is generally the only option that would allow them to return to the same level of participation as before.

The aim of our research was to study the outcomes after surgical fasciotomies for CECS with regards to patient satisfaction and the return to sports and activities, specifically for high level athletes or patients with physically demanding jobs like military personnel.

Literature search strategy

The objective of the literature review was to look at case series, retrospective reviews, cohort studies and review articles published during the past 15 years.

The focus was on articles that looked at outcomes after treatment for CECS, especially surgical treatment. Articles relating to both civilian and military populations were included.

The electronic database of the Health Science library of the University of Cape Town was used to access MEDLINE, PUBMED and Cochrane library for published articles. The MeSH terms and text words used were “chronic exertional compartment syndrome”, “treatment outcomes” and “patient satisfaction”.

Articles that were published in a language other than English were excluded. If the electronic version of the full text of a relevant article could not be located using the online database, the University of Cape Town library was used to find printed versions. The full text of all the articles was critically reviewed by the primary investigator.

Quality criteria

The literature search was limited to case series, retrospective reviews, cohort studies and review articles that were published between 2000 and 2015. These articles were critically reviewed to assess their relevance to our research.
Summary of literature

Compartment syndrome is the result of an increased pressure within a myofascial compartment that compromises the circulation to the tissue within the effected compartment and limits its function[1]. Two forms of compartment syndrome have been described, namely acute compartment syndrome and chronic exertional compartment syndrome. Acute compartment syndrome usually follows injuries like fractures, crush injuries or burns and can be limb threatening if not recognized early and treated as an emergency. Chronic exertional compartment syndrome (CECS) is most often seen in athletes and is due to exercise and overuse and results in pain and discomfort[2].

The first reported description of CECS was by Edward Wilson who described his symptoms in 1912 during an Antarctic expedition[3]. The first true report of CECS was reported by Mavor in 1956 in a professional soccer player who was successfully treated by surgically widening the fascia of the anterior compartment of the lower leg[4]. However, elevated compartment pressures as the cause for CECS was only documented in 1962 by French and Price[5].

The most widely accepted theory is that during exercise fluid accumulates in the interstitial space of skeletal muscles leading to an increase in mass of up to 20%[6]. With the increase in mass the pressure within the muscle compartment increases, resulting in impaired tissue perfusion, ischemia and pain[3]. This theory has been challenged and using SPECT scanning it has been demonstrated that there is no significant difference in the relative perfusion of the muscle compartment of patients with confirmed CECS and a control group[7]. This study has led to the theory that it is not a reduction in perfusion to the compartment, but rather an imbalance between oxygen supply and demand[3], [8]. Others theorize that with the increase in the muscle mass during exercise, pressure sensitive nerve fibres within the muscles and fascia are stimulated leading to pain[3], [7].

Although CECS can theoretically occur in any myofascial compartment and has been described in the forearm, thigh and erector spinae muscles[9][10][11], up to 95% of CECS occur in the lower leg[1]–[3]. This is due to the particular anatomy of the regions, as well as the fact that the legs are used in virtually all sports[1], [2]. Symptoms are usually described as pain and a feeling of tightness in the lower legs after a set volume of exercise (distance, time or intensity). Other symptoms may include weakness of involved muscles or paraesthesia. Clinical examination is usually normal if the patient has been resting and is asymptomatic. However, if a patient is examined when symptomatic after exercise abnormal finding may be found, such as pain on passive stretch of involved muscles or paraesthesia and numbness[2], [3], [12][13].
Due to the vague nature of the symptoms and often normal examination there is frequently a delay of between 22 and 28 months between onset of symptoms and treatment[13][14], [15]. Measurement of intracompartmental pressures during exercise and recovery is required to confirm the diagnosis of CECS. This is performed by using indwelling, flexible catheters that are placed within the muscle compartment and portable transducers that allow pressure monitoring and recording during exercise. There is, however, no validated pressure measurement protocol that describes the position, depth and angle of catheter insertion[16] and there is also no consensus on diagnostic values. Multiple diagnostic criteria have been suggested (Table 1). A survey of orthopaedic surgeons based in the United Kingdom showed that 83% of those that regularly see patients with CECS use intracompartmental pressure monitoring to confirm the diagnosis. Pedowitz criteria were only used by 35%, while 42% used maximal intracompartmental pressure during exercise of greater than 35 mmHg as confirmation of diagnosis[17].

Table 1: Diagnostic criteria of intracompartmental pressure measurement[2]

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Diagnostically relevant pressure values</th>
</tr>
</thead>
<tbody>
<tr>
<td>French and Price</td>
<td>1962</td>
<td>Post exercise fall time &lt;30 min in normal subjects, &gt;100 min in patients</td>
</tr>
<tr>
<td>Reneman</td>
<td>1975</td>
<td>At six minutes post exercise pressure &gt;15 cm H₂O (11 mm Hg) above resting pressure</td>
</tr>
<tr>
<td>Puranen</td>
<td>1981</td>
<td>Mean pressure of 50 mm Hg during running. Resting of no value, but did observe slow post exercise fall</td>
</tr>
<tr>
<td>McDermott</td>
<td>1982</td>
<td>Mean pressure of 85 mm Hg during running</td>
</tr>
<tr>
<td>Mubarak and Hargens</td>
<td>1982</td>
<td>Resting pressure &gt;15 mm Hg. Exercise pressure &gt;75 mm Hg. Pressure remains &gt;30 mm Hg for &gt;5 min after exercise</td>
</tr>
<tr>
<td>Qvarfordt et al</td>
<td>1983</td>
<td>Pressures raised before, during, and after exercise. Post exercise decline 40 min. T₁/₂ 6 min</td>
</tr>
<tr>
<td>Wallensten</td>
<td>1983</td>
<td>No difference at rest, still raised 10 min post exercise (anterior), returned to normal &lt;10 min (deep posterior)</td>
</tr>
<tr>
<td>Detmer et al</td>
<td>1985</td>
<td>At rest, normal pressure &lt; 15 mm Hg</td>
</tr>
<tr>
<td>Styf and Korner</td>
<td>1986</td>
<td>Muscle relaxation pressure</td>
</tr>
<tr>
<td>Styf and Korner</td>
<td>1986</td>
<td>Post exercise pressure &gt;35 mm Hg remained raised for &gt;6 min (Also muscle relaxation pressure was raised during exercise, &gt;20 min to return to normal)</td>
</tr>
<tr>
<td>Allen and Barnes</td>
<td>1986</td>
<td>Exercise pressure &gt;50 mm Hg anterior, &gt;40 mm Hg deep posterior No difference in resting pressures</td>
</tr>
</tbody>
</table>
The incidence of CECS in the general population is unknown as it is a self-limiting condition and many potential patients may simply adjust their activities rather than seek medical advice[2]. However, CECS has been reported as the cause in up to 27% of athletes being investigated for chronic lower leg pain. Despite the relative high incidence in athletes an average delay of 22 to 28 months from presentation to correct diagnosis has been reported[14][15]. This is due to the fact that chronic leg pain is a very common problem in athletes[6][18][12]. Up to 82.4% of athletes will seek medical consultation at least once for activity-related lower leg pain[13]. As definitive testing for CECS is invasive, other causes are usually excluded first. The differential diagnoses (Table 2) are varied as the lifestyle of athletes predisposes them for multiple conditions that would cause lower leg pain and successful diagnosis and treatment can be challenging. However, if a high clinical suspicion exists, testing for CECS should be pursued[3]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Findings</th>
<th>Confirmatory Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress fractures</td>
<td>Localized tenderness directly over tibia; pain with torsional and bending stress</td>
<td>Plain radiographs, bone scan, MRI</td>
</tr>
<tr>
<td>Medial tibial stress syndrome</td>
<td>Manual resistance to plantar flexion and insertion leading to pain along distal posteromedial aspect of the tibia</td>
<td>Bone scan, MRI</td>
</tr>
<tr>
<td>Complex regional pain syndrome</td>
<td>Allodynia and trophic skin changes</td>
<td>Triple-phase bone scan, thermography, sympathetic block.</td>
</tr>
<tr>
<td>Peripheral nerve</td>
<td></td>
<td>EMG, nerve conduction study</td>
</tr>
</tbody>
</table>
Symptoms of CECS only occur when athletes perform activities above a certain threshold. Therefore, the easiest conservative treatment is to limit activities to below the volume (length or intensity) that lead to the symptoms. Multiple other conservative treatment modalities have been suggested and tried, such as anti-inflammatory drugs, physiotherapy, ultrasound, heat and ice. All had some degree of success in relieving symptoms, but none were curative. Non-operative treatment can only be successful if the patient stops the causative activity or stops participating at the intensity level that causes symptoms. In the case of competitive athletes this is not possible.

Surgical treatment, a fasciotomy, consists of release of the fascial compartments of the lower leg. High success rates have been reported, but it is not without risk and potentially prolonged recovery time.

In the literature, there is also a disparity between reported success rates of fasciotomies as treatment in civilian and military study populations. In the military population the younger candidates generally have a higher dissatisfaction rate and discharge rate from military service on medical grounds, while in the civilian population the younger patient group generally appears to respond better with surgical treatment. This may be due to the higher and rigid fitness standards military personnel must adhere to and the relative ease for civilians to modify their level of activity to suit their symptoms and lifestyle, rather than a better response to surgical treatment.
We proposed a review of 41 patients diagnosed with chronic exertional compartment syndrome who received fasciotomies by a single surgeon. The aim of the study was to determine patient satisfaction and outcomes specifically for the high demand civilian population.
References


PART B: MANUSCRIPT IN ARTICLE FORMAT.

Title page:

Functional outcomes and patient satisfaction after fasciotomy performed for chronic exertional compartment syndrome.

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\textit{Consultant}

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\textit{Consultant}

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\textsuperscript{2} Vincent Palotti Hospital, Cape Town, South Africa
Abstract

Study Rationale:
Chronic exertional compartment syndrome often forces patients to change their sporting activities or reduce their level of participation. Many undergo surgery with the aim to return to their activities symptom free. The aim of the study was to determine if fasciotomies for chronic exertional compartment syndrome are a reliable treatment option with a predictable outcome to allow patients to return to the same level of activities.

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The evaluation of the functional outcomes and patient satisfaction in an active population who had surgery, namely fasciotomies, for chronic exertional compartment syndrome (CECS) of the lower leg.

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Patient records were reviewed to determine their presenting symptoms, diagnostic investigations and surgical procedures performed. A questionnaire was completed by each participant to assess pain and level of activity before and after surgery, level of improvement after surgery and patient satisfaction with surgical outcomes.
**Results:**

Twenty-one of the 41 patients that were included in the study were categorized as active sportsmen, participating on a competitive or a non-competitive level. The remaining 20 were experiencing symptoms during leisure activities. The majority of all the patients (63%) had to stop their activity due to their symptoms. After surgery 95% were able to return to participate in the same level of activities as before surgery. Ninety percent of the active sportsmen were able to return to participation at a competitive or non-competitive level, with 45% reporting an increase in the level of intensity that they could maintain. Overall satisfaction was reported by 80% of participants, although only 46% were completely pain free.

**Conclusions:**

Fasciotomies are a viable surgical treatment option for chronic exertional compartment syndrome in active patients, including athletes. There is an 87% return rate to previous activities within 6 months and an 80% satisfaction rate reported by patients after surgery.

*We do acknowledge that some of the data collected regarding symptomology is subject to recall bias due to the interval between surgery and completion of the questionnaire.*
Main Text of Article:

Chronic exertional compartment syndrome (CECS) is one of the causes of exercise-induced lower leg pain in active people. Unlike the other common causes, it seldom resolves with nonsurgical management unless the patients stop their activities or participate at a lower level of intensity. This means that surgical intervention by the means of facial releases of the lower leg compartments, fasciotomies, are the only means of treatment for active patients. Like all surgical interventions, it is not without risks or complications. We proposed a review of a series of patients diagnosed with CECS to determine the functional outcome and patient satisfaction following surgical fasciotomies by a single orthopaedic surgeon. The aim is to gather information to enable surgeons to more accurately inform patients what to expect following fasciotomies regarding their symptoms and their ability to return to their activities.

Methods:

A retrospective cohort study design was used to evaluate outcomes using a subjective patient questionnaire and a review of patient records. Approval was obtained from our institution’s Departmental Research and Ethics Committee prior to contacting the patients to obtain verbal consent. The questionnaire was completed during a telephonic interview and their medical records reviewed.

The purpose of this study was to evaluate the outcomes of a fasciotomy for chronic exertional compartment syndrome in active patients. We also aimed to determine the effect on their performance after surgery, based on time to return to activities and if they return to the same level of activity.

A questionnaire was designed based on the questionnaires used by Schepsis et al and Howard et al[1]. The questionnaire consisted of multiple-choice questions, short answer responses and visual analogue pain scores. The aim was to determine level of activity, symptoms, impact on activities prior to
surgery, and after surgery the return to activities, symptoms and patient satisfaction.

We identified 53 patients from theatre records who received fasciotomies of the lower limb by a single orthopaedic surgeon from 2005 to 2013. After review of medical records 12 patients were excluded due to incomplete data or follow-up. The remaining 41 patients meeting the inclusion criteria were contacted telephonically for a short interview to complete the questionnaire after the purpose of the study was explained and verbal consent taken. The interval between surgery and the interview was on average 6 years (range 3-12 years).

Once all the patients were interviewed and the necessary data collected, the data was entered in to an Excel spreadsheet and the Excel statistical package was used to analyse the data.

**Pressure Measurements:**

All patients received compartment pressure testing as part of their diagnostic work-up. The pressure testing was performed at the Sports Science Institute of South Africa using an indwelling pressure catheter and an ambulatory recording device. A standardized regime was used that tested compartment pressures at rest sitting, while standing, during resisted contracture, during exercise and during the recovery period.

Pressure measurements results:

<table>
<thead>
<tr>
<th>Pressure Readings</th>
<th>Mean mmHg</th>
<th>Range mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Rest</td>
<td>13</td>
<td>1-58</td>
</tr>
<tr>
<td>Resisted Contraction</td>
<td>28.5</td>
<td>1-70</td>
</tr>
<tr>
<td>Standing</td>
<td>22.2</td>
<td>3-48</td>
</tr>
<tr>
<td>At Onset of Symptoms</td>
<td>58</td>
<td>5-133</td>
</tr>
<tr>
<td>Peak Pressures</td>
<td>74.2</td>
<td>22-166</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recovery Pressures</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 minute</td>
<td>49.3</td>
<td>5-117</td>
</tr>
<tr>
<td>2 minutes</td>
<td>43.5</td>
<td>3-116</td>
</tr>
<tr>
<td>5 minutes</td>
<td>38</td>
<td>1-100</td>
</tr>
<tr>
<td>10 minutes</td>
<td>33.4</td>
<td>0-98</td>
</tr>
</tbody>
</table>
All patients experienced symptoms consistent with exertional compartment syndrome and needed on average 4 minutes and 45 seconds of exercise to become symptomatic. The majority of the patients experienced a combination of symptoms and most commonly experienced pain and discomfort (n=35) combined either with paraesthesia and numbness (n=14) or a feeling of tightness and pressure (n=14).

Despite experiencing symptoms consistent with CECS only 68% met at least one of the Pedowitz diagnostic criteria[13].

<table>
<thead>
<tr>
<th>Pedowitz Criteria</th>
<th>mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-exercise</td>
<td>&gt;15</td>
</tr>
<tr>
<td>Post exercise</td>
<td></td>
</tr>
<tr>
<td>1 minute</td>
<td>&gt;30</td>
</tr>
<tr>
<td>5 minutes</td>
<td>&gt;20</td>
</tr>
</tbody>
</table>

**Surgical Procedures:**

All patients included in the study received fasciotomies by a single orthopaedic surgeon between July 2005 and October 2013.

Fasciotomies were performed using a mini open technique, by making a 4 cm longitudinal incision centred over the midpoint of the fibula through which the myofascial compartments are released.

Thirty-six patients (86.8%) had bilateral procedures done. The majority (61%) had a single compartment released. The antero-lateral compartment in 23 cases and posterior compartment in 2 cases. Combined antero-lateral and posterior compartment releases were performed in 16 cases.

**Results:**

**Demographics:**

The study population consisted of 41 patients of which 27 were female (66%) and 14 males, aged between 15 and 57 years (mean 31 years). Of the 41 patients, just over half were classified as active athletes (51%), participating at either a competitive level (n=19) or a non-competitive level.
(n=2). The remaining 49% of the patients experienced symptoms during leisure activities.

**Impact of Symptoms on activities:**

Participants were asked to rate the severity of their pain as a score out of 5, with 0 being pain free and 5 as most severe. Thirty-one patients (73%) reported scores of 4 or 5 out of 5. These included all 21 patients that were classified as active athletes. Twenty-six patients (63.4%) had to stop participating due to symptoms, while 14 patients were able to continue to participate, though at a lower level of intensity. One patient reported that despite being symptomatic it didn’t affect his participation in leisure activities.

**Response to surgery:**

All the patients continued to live active lives after the surgery and 92.7% (n=38) continued to participate in the same activities as prior the surgery. Of the group categorized as active athlete prior to surgery, 85% (n=19) returned to participate in the same sport as prior to surgery at a competitive or non-competitive level. Of the 3 patients that did change their sport, 1 continued to participate at a competitive level and 1 participates at a non-competitive level. At the time of completing the questionnaire 19 of the 21 patients that were participating as active athletes at either competitive or non-competitive level prior to surgery were still participating in the active athlete category. It was noted that 8 patients changed from competitive level to non-competitive level. This could be attributed to the normal aging process or change in demands of daily living. However only 3 patients downgraded to leisure activity level.

Thirty-six patients (87.7%) reported that they could maintain the same or a greater level of intensity than before surgery. Though, only 19 patients (46.3%) reported that they were completely symptom free. A further 15 patients (29.3%) experienced significant improvement, but still had some residual symptoms.
All patients participated in a rehabilitation programme after surgery and 87.7% returned to their activities within 6 months.

The overall satisfaction rate was 80.5% (n=33), though only 71% (n=15) of the active athletes were satisfied with the results after fasciotomies. Of the 6 athletes that were not satisfied with the results, 3 still returned to competitive sport at the same level of intensity than before.

**Complications:**

Of the 41 patients who received fasciotomies 11 experienced complications (26.8%). The majority of these were minor complications that resolved with time and none required surgical intervention.

<table>
<thead>
<tr>
<th>Complications</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seroma</td>
<td>3</td>
</tr>
<tr>
<td>Neuropraxia</td>
<td>3</td>
</tr>
<tr>
<td>Toe paraesthesia</td>
<td>1</td>
</tr>
<tr>
<td>Keloid formation</td>
<td>1</td>
</tr>
<tr>
<td>Peroneal tendonitis</td>
<td>1</td>
</tr>
<tr>
<td>Wound sepsis</td>
<td>1</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1</td>
</tr>
</tbody>
</table>

**Discussion:**

The results of this study show that the majority of most patients with lower limb CECS experience significant pain relief and were satisfied with the results of the surgery.
A satisfaction rate greater than 80% has been reported in the literature that compares well with the satisfaction rate of 81% for this study. However, for the active athletes the satisfaction rate was significantly lower with only 71% of the patients reporting that they were satisfied with the result. This lower satisfaction rate is comparable with the literature regarding other active populations such as military personnel[17].

There is, however, a big disparity between the return to pre-surgery activity levels when comparing military personnel with athletes. In our study 85% of athletes returned to their pre-surgery activity levels and Rorabeck et al and Detmer et al reported a return rate of 83% and 71% respectively[18][19], but in the military population a return rate as low as 41% has been reported[17]. This has been attributed to the more rigorous fitness standards in the military, as well as civilians being able to adjust their type of activities to compensate for symptoms. Higher ranking military personnel also showed a greater return to duties than their younger counterparts. It has been postulated that the motivation to keep benefits and pension options for the higher ranks may have influenced the higher ranks, and the enticement of programmes to help with further education once discharged, may have influenced younger, lower ranking personnel [16][17][20].

This disparity between active civilian athletes and military personnel highlights the major impact that patient motivation and expected gain from the surgery have on satisfaction and return to activity rates.

**Conclusion:**

On completion of the study we can conclude that offering fasciotomies as treatment option for patients with chronic exertional compartment syndrome, including active athletes, is a viable option with proven benefits. The majority of patients will be able to return to their previous activities within 6 months and most can expect to maintain the same or greater intensity, but may not necessarily be completely symptom free.

_We do acknowledge that some of the data collected regarding symptomology is subject to recall bias due to the interval between surgery and completion of the questionnaire._
Contribution of Authors, Competing Interests and Funding:

The author of this dissertation, Dr C de V Marais, was responsible for compiling the research protocol and Human Research Ethics application and also for gathering the necessary data for analysis. Dr S Maqungo provided a supervisory role during the writing of the dissertation. Dr B Bernstein kindly allowed access to his patient files and theatre notes once consent was obtained from the participants.

There are no competing interests among the authors.

The project was self-funded by the author.
References


Part C: Addenda

A. Questionnaire:

CECS - QUESTIONNAIRE

You were diagnosed with chronic exertional compartment syndrome and underwent surgery in our clinic. To give us an idea of the overall outcome of your operation we ask that you answer the following questions given in this questionnaire. The questions deal with two blocks. In block A we will ask you about your activity level and the pain you felt before the operation. In block BB, we will ask you about your level of activity and how you manage after the operation.

Block A: Before Operation

A 1: During what type of sport or which activity you developed the pain that required surgery?

A 2: Please specify the level of your sport / activity (mark the most appropriate answer):


A 3: Please line out the level of severity of your leg pain with a vertical slash in the scale below

A 4: How did the pain affect your performance? (Mark the most appropriate answer)

1. Same activity despite pain / 2. Lower level of activity / 3. Had to stop activity

Block B: After Operation

B 1: What type of sport / activity you do at present? If no sport at all, proceed to B 5!
If the same as in A 1, proceed to B 2!

If different, is that because of leg pain when practicing?

Yes / No

If No, please specify and proceed to B 2:

_________________________________________________________________

If Yes, how long after surgery you experienced leg pain when practicing?

1. 0-6 months / 2. 6-12 months / 3. >12 months

If yes, please line out the level of severity of your leg pain with a vertical slash in the scale below

![Scale of pain severity](image)

**B 2:** Please specify the level of your sport / activity (mark the most appropriate answer):


**B 3:** Please specify your present level of maximum activity compared to before surgery. (Mark the most appropriate answer)

1. Same as before / 2. Less than before / 3. More than before

**B 4:** At what time after surgery you started your sport / activity again? (Mark the most appropriate answer)

1. <3 months / 2. 3-6 months / 3. 6-9 months / 4. 9-12 months / 5. >12 months

**B 5:** Did you take part in a special rehabilitation programme?

Yes / No
**B 6**: How would you evaluate your overall status after the surgery? (Mark the most appropriate answer)


**B 7**: Overall, are you satisfied with the result of the surgery?

Yes / No
B. Consent form and Patient information sheet.

**Chronic Exertional Compartment Syndrome Consent Form for Retrospective Review**

**INFORMATION:**
You have been invited to participate in a retrospective review of patients with chronic exertional compartment syndrome conducted by Dr Bernstein, Dr Marais and Dr Maqungo. This is a research project for a master’s degree for Dr Marais training at Groote Schuur Hospital and not part of the normal after-care following surgery. Information will be gathered by reviewing your medical records and chart. As this is not an interventional study you will not have any alteration in your care or procedures. The purpose is to evaluate your overall satisfaction with the procedure and its ability to relieve your pain.

**PURPOSE:**
Chronic exertional compartment syndrome is a challenging diagnosis for many healthcare workers. By reporting on patients such as you, we hope to expose more orthopaedic surgeons to the condition.

**TYPE OF RESEARCH INTERVENTION:**
This is a retrospective study meaning that your records will be reviewed. Additionally, you will be asked to complete a questionnaire telephonically pertaining to your current health condition and satisfaction with the surgery.

**PARTICIPANT SELECTION:**
You have been chosen for this study because you had chronic exertional compartment syndrome that was treated surgically.
**VOLUNTARY PARTICIPATION:**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change.

**DURATION:**

The telephonic questionnaire you will be asked to complete will be approximately 20 minutes. You will not be required to do anything in addition.

**RISK:**

This study is not interventional and will not affect your treatment course for this condition.

**BENEFITS:**

There will be no direct benefit to you, but your participation is likely to help us better understand chronic exertional compartment syndrome and improve the diagnosis and treatment of this condition.

**CONFIDENTIALITY:**

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone. You will not be identified personally in the study to ensure privacy.
PRIMARY INVESTIGATOR:

Dr C de V Marais

Tel: 0731458001

Email: Christoff_marais@yahoo.com

Dr S Maqungo

Email: sithombo@msn.com

If there are any further questions or concerns please do not hesitate to contact the investigator.

Ethical Clearance:

To be able to perform this research project it has been submitted to and passed by the Human Research Ethics Committee of the University of Cape Town

Reference 649/2015

Tel: 021 406 6338
Certificate of consent

I have been invited to participate in research about chronic exertional compartment syndrome and outcomes of surgery.

The foregoing information sheet has been read to me and I have had the opportunity to ask questions about it. Any questions I have asked have been answered to my satisfaction. I telephonically give consent voluntarily to be a participant in this study.

Print Name of Participant __________________________

Telephone number __________________________

Date ________________

Day / month / year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. Review of their medical records.

2. Telephonic questionnaires to be completed.

3. Information gathered will be analysed and presented as a scientific article.

4. A copy of the article would be provided on request.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.
A copy of the information sheet and consent form is available for the participant on request if requested.

Print Name of Researcher / person taking the consent
___________________________

Signature of Researcher / person taking the consent
___________________________

Date
___________________________

Day / month / year
C. Research Protocol

Functional outcomes and patient satisfaction after fasciotomy performed for chronic exertional compartment syndrome.
Dr CdeV Marais, Dr S Maqungo, Dr B Bernstein

Introduction and Objective

Chronic exertional compartment syndrome is a common cause for lower limb pain and deterioration in performance in a physically active population. Diagnosis of chronic exertional compartment syndrome can be difficult and would involve a detailed history, examination and measurement of compartment pressures at rest and after exercise. These patients respond poorly to nonsurgical treatment modalities other than ceasing the causative activity. This is often not a feasible option for athletes. Satisfactory results with fasciotomies have been reported, although this procedure is not without risk.

We propose a review of the data of the patients who were diagnosed with chronic exertional compartment syndrome and who underwent fasciotomies by Dr Bernstein at Vincent Palotti Hospital from 2005 to 2013. The review would consist of a folder review and a telephonic questionnaire. The aim is to determine the functional outcome and patient satisfaction after the procedure and identify predictive factors for satisfactory outcomes.

Reference List


Relevance of the study

Chronic exertional compartment syndrome is a challenging condition to treat due to the high demand population group in which it commonly occurs. Many are competitive athletes that wish to return to their activities without delay. Accurate information is essential for athletes to plan training programmes.

Study aim and objective

By reporting on this series of patients we aim to highlight the correct indications for surgical treatment, to establish preoperative prognostic and predictive parameters and also a timeline to expected recovery to normal activities. This would enable surgeons to give more accurate information to patients.

Study population

With the permission of Dr Bernstein an audit was performed of his surgical logbook for his private practice at Vincent Palotti Hospital, to identify patients who received fasciotomies for chronic exertional compartment syndrome (ICD 10: M79 A2) Fifty-three theatre cases were identified.

Patient recruitment:

The secretary from Dr Bernstein’s practice, who has an established relationship with the patients, will contact the patients identified to introduce the investigators and ask their permission to be contacted.

Study Design

Retrospective folder review with a telephonic follow-up interview.
Study Method

Patient record will be reviewed to collect data as outlined in section 8. Focus would be on symptomatology, investigations, surgical interventions and recovery after surgery.

Patients would also be contacted telephonically to complete a questionnaire to compare their severity of symptoms before surgery and the response of any surgical intervention. The questionnaire is similar to the one used in previous internationally published studies, Schepsis et al and Howard et al. The answers to the questionnaire are descriptive in nature and not a scoring system that would require formal validation. Copy of the questionnaire is attached.

Data Sheet

Proposed parameters to be investigated:

1. Age
2. Sex
3. Presenting symptoms
4. Compartment Pressures Testing
   a. Pressures at rest, during resisted contracture, while standing, during exercise
   b. Symptoms during testing
   c. Time till symptomatic
   d. Recovery pressures at 1 minute, 2 minutes, 5 minutes and 10 minutes
5. Details of surgical procedure
   a. Date of surgery
   b. Compartments released
   c. Side operated on
   d. Complications noted
6. Follow-up period
7. CECS questionnaire

Ethical Considerations:

Participation in the study would be voluntary and patients who are willing to participate would be asked to give telephonic consent and will be provided with an information sheet outlining the method and the purpose of the study. The information sheet would be verbally explained to the patients and copies will be sent by email on patients’ request.
All patients’ records would be kept confidential and only the investigators will have access to it. No personal information will be entered in the data stream, but anonymous identifiers will be used.

If it happens that a poor outcome or previously unidentified complications are uncovered while conducting the study, it would be brought to the attention of Dr Bernstein. As primary treating surgeon, he would follow up the patients and address the problem.

**Statistical Analysis**
The data collected will be statistically analysed using STATSTICA. A 1 way ANOVA design will be used to explore multiple group comparisons. A power analysis has shown that a population of 44 would be sufficient to power the study.

**Report of findings**
Results will be submitted for publication in peer reviewed journals. Results will also be discussed at national or international orthopaedic conferences and research or faculty meetings. Participants who wish to receive a copy of the publication would be provided with one.

**Budget and funding**

**Costs not requiring funding:**
- Departmental and personal computer usage.
- Paper and photocopying supplied by the Orthopaedic Department of the University of Cape Town.
- Stationery, telephone and postal services, if required, will be funded by the Orthopaedic Department.
- Researchers will not be remunerated.

**Costs possibly requiring funding:**
- Travel and accommodation expenses expected to present at the national or international conferences R7500.
- Costs expected in publication process: R500
D. Human Research Ethics Committee Approval Letter

HREC REF: 649/2015

Dr S Maqungo
Department of Orthopaedic Surgery
H49, OMB

Dr Maqungo

PROJECT TITLE: FUNCTIONAL OUTCOMES AND PATIENT SATISFACTION AFTER FASCIO TOMY PERFORMED FOR CHRONIC EXERTIONAL COMPARTMENT SYNDROME (MMed candidate – Dr C Marais)

Thank you for your response letter dated 05 January 2016, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study.

Approval is granted for one year until the 30th December 2016.

Please submit a progress form, using the standardised Annual Report Form if the study beyond the approval period. Please submit a Standard Closure form if the study completed approval period.
(Forms can be found on our

Please quote the HREC REF in all your correspondence.

We acknowledge that the following student, Dr Christoff Marais will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH HREC 649/2015

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95 and FDA Code Federal Regulation Part 50, 56 and 312.