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A Novel Non-Invasive Method for the Detection of Elevated Intra-Compartmental Pressures of the Leg

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TITLE:

A Novel Non-Invasive Method for the Detection of Elevated Intra-Compartmental Pressures of the Leg.

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KEYWORDS:

Compartment Syndrome, Non-invasive pressure monitoring, intra-compartmental pressure, tibia fracture, decompressive fasciotomy, ultrasound

SUMMARY:

An ultrasound probe coupled with a pressure sensor is used to assess the intra-compartmental pressure of the leg by directly measuring the compartment fascia flattening pressure (CFFP). This non-invasive protocol will provide reliable assessment of the pressure inside the anterior muscular compartment of the lower leg.

ABSTRACT:

Acute Compartment Syndrome is a devastating consequence of musculoskeletal trauma. Currently the diagnosis is based on clinical signs and symptoms, and while adjuncts such as invasive intra-compartmental pressure measurements are often used to corroborate the physical exam findings, there remains no reliable objective test to aid in the decision to perform a decompressive fasciotomy. In a cadaver model of compartment syndrome, an ultrasound (US) based method has been shown to be a reliable measurement of increased intra-compartmental pressure. An absolute pressure of > 100 mbar or a difference of 50 mbar in the CFFP between the legs can be considered pathologic. Using an ultrasound transducer, coupled with a pressure sensor, the pressure needed to flatten the superficial fascia of the anterior compartment of lower legs (Compartment Fascia Flattening Pressure [CFFP]) can be measured. The CFFP of the injured leg is compared to the CFFP of the uninjured leg. This US measured index can then serve as an adjunct to the physical exam in evaluating injured lower extremities and assessing the need for decompressive fasciotomy. The advantages of this protocol include: being a non-invasive method and an easily reproducible technique.

INTRODUCTION:

The purpose of this novel protocol is to evaluate the intra-compartmental pressure of the leg in

a non-invasive way by using an ultrasound transducer coupled with a pressure sensor. Compartment syndrome is a well-known complication in musculoskeletal trauma and is the result of elevated intra-compartmental pressures which compromise the perfusion of tissues leading to irreversible ischemic injury if not intervened upon. Its diagnosis is primarily based on clinical exam. Unfortunately, clinical exam alone has been shown to have poor sensitivity and specificity in the diagnosis of compartment syndrome[1]. Invasive intra-compartmental pressure measuring by needle manometry is commonly used in the assessment of compartment syndrome[2-4]. The disadvantage of needle manometry is that it is an invasive procedure, being quite uncomfortable for the patient and not amenable to serial measurements. Furthermore, invasive intra-compartmental pressure measuring measurement is not routinely performed by some surgeons due to considerable disagreement over the appropriate threshold pressure for diagnosis of ACS and the high (35%) false positive rate and variability of a single invasive measurement[5-7].

It has been previously demonstrated in artificial, animal, and human cadaver models that a rise in the intra-compartmental pressure results in a decreased elasticity of the fascia overlying the anterior compartment suggesting a correlation between the intra-compartmental pressure and compliance of the facial compartment as measured by ultrasound[8-10]. Further work has described using the pressure required to flatten the fascia of the anterior compartment as measured by ultrasound (Compartment Fascia Flattening Pressure [CFFP]) as a surrogate measure of the intra-compartmental pressure[11]. The anterior compartment fascia can be readily visualized with standard ultrasonography and, with the addition of a pressure sensor to the probe, CFFPs can be easily and reliably measured. This protocol offers a non-invasive diagnostic alternative for evaluating intra-compartmental pressures and can be performed quickly and serially with little to no patient discomfort.

PROTOCOL:

This experimental protocol has been reviewed and approved by our hospital's institutional review board (IRB) and follows all guidelines set forth by our institution's human research ethics committee.

1. Identify the fascia of the anterior compartment of the leg

1.1. Identify a starting site for the ultrasound probe. Place the probe directly over the anterior compartment, just lateral to the tibial crest and one handbreadth distal to the tibial tubercle.

1.2. Identify the fascia as the bright, white strip just below the subcutaneous tissue on the ultrasound. Move the probe until the fascia is seen at the point where it attaches to the tibial crest.

1.3. Note the geometry of the fascia. With minimal pressure applied, this should be a convex shape.

2. Measure the Compartment Fascia Flattening Pressure of the injured leg

2.1. Once the fascia of the anterior compartment is identified, apply slow and steady pressure to the ultrasound probe until the fascia changes shape from convex to completely flat. Make several attempts including passing the flattening point to produce a concave shape in an effort to gently hone in on the exact CFFP.

2.2. Once the anterior compartment fascia is perfectly flat, record the pressure sensor measurement.

2.2. Repeat the CFFP measurement 2 more times. Record and average all 3 pressures to define the final CFFP.

3. **Calculate the delta CFFP compared to the uninjured (contralateral) leg**

3.1. Measure and record the CFFP in the contralateral leg in the same manner described above.

3.2. Calculate the delta CFFP by taking the difference between the CFFP of the injured leg the well leg.

REPRESENTATIVE RESULTS:

This technique has been used to measure 10 consecutive patients with injured legs without evidence of compartment syndrome and 3 patients with a clinical diagnosis of compartment syndrome necessitating decompressive fasciotomies. The average delta CFFP for patients without compartment syndrome was 10.7 ± 10.6 mbar compared to 157 ± 51.7 mbar for patients with compartment syndrome and single-tailed t-test identified the differences in pressures between the groups as being statistically significant ($P<0.02$).

FIGURE AND TABLE LEGENDS:

Figure 1: Ultrasound image of anterior compartments. The bright white fascia overlying the anterior compartment is demonstrated with the white arrows. Note the convex appearance of the fascia (**A**) with gentle pressure with the ultrasound probe versus the flattened appearance of the fascia (**B**) seen with applying increased pressure.

DISCUSSION:

This article demonstrates a novel, clinically applicable technique for the non-invasive measurement of intra-compartmental pressures in the leg using an ultrasound coupled with a pressure sensor. This technique only requires a hand-held ultrasound and a commercially available pressure sensing transducer. It is quick and easy to perform and is well tolerated by patients. The entire diagnostic procedure can be performed in under 5 minutes with no additional resources. The calculated delta CFFP may then be used in conjunction with the physical exam to assess the need for decompressive fasciotomy in an injury leg.

The critical step of this protocol requiring the greatest attention to detail is capturing the pressure value at the point where the fascial layer is completely flat. Subtle convexity or concavity may

markedly inflate or deflate the CFFP value. Obtaining 3 serial measurements will aid in improving the accuracy of the test. Additionally, practicing the technique will improve reproducibly and reliability of this exam.

The next step, which is currently underway, is prospectively evaluating the utility of this noninvasive ultrasound method for assessing intra-compartmental pressures. We are collecting a prospective series of patient without compartment syndrome to obtain a baseline reference for CFFPs. We are also collecting prospective data on patient clinically diagnosed with compartment syndrome to identify a delta CFFP threshold for predicting the need for decompressive fasciotomy.

ACKNOWLEDGMENTS:
None.

DISCLOSURES:
The authors have nothing to disclose

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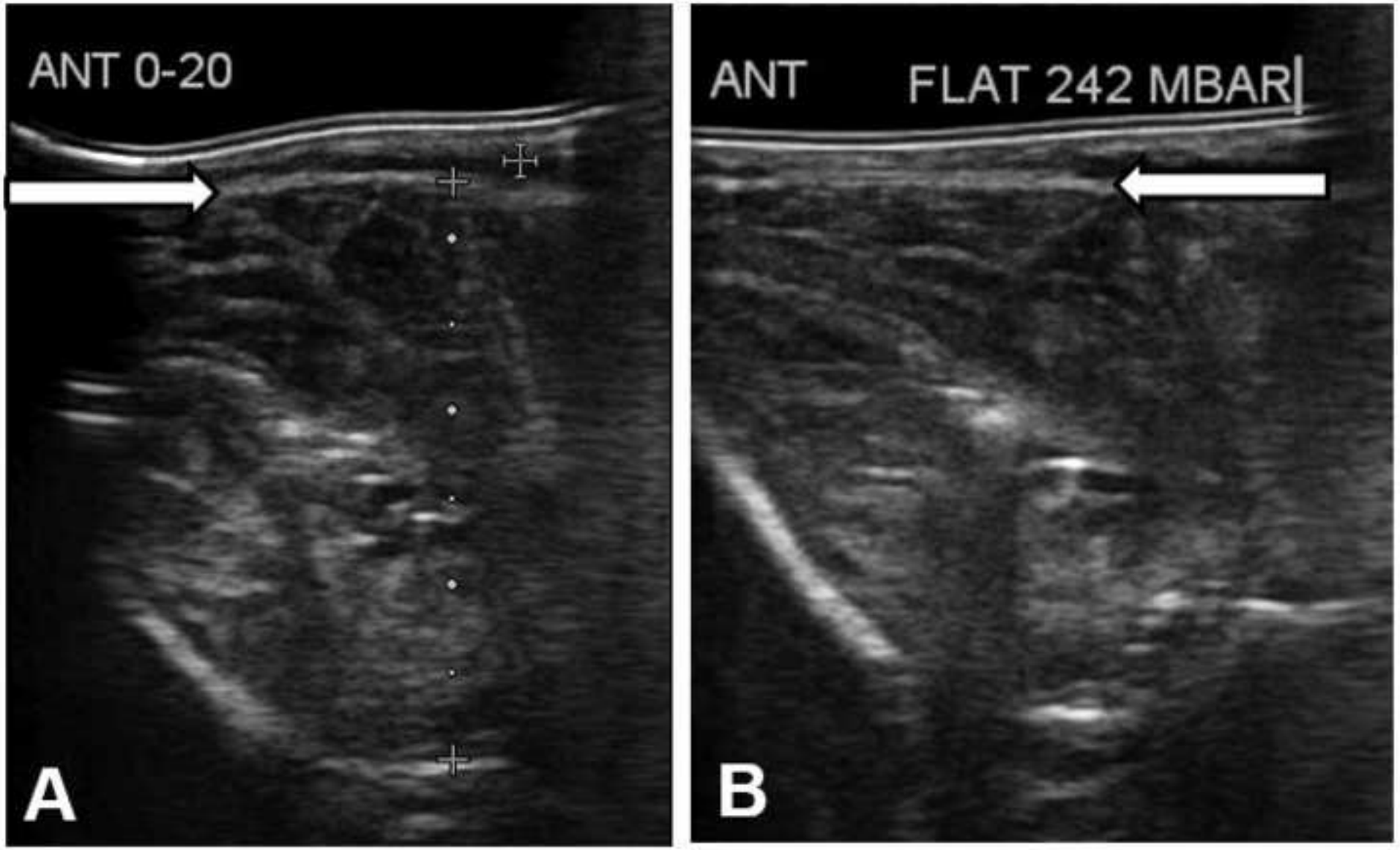
Figure 1

Click here to access/download;Figure;Figure 1.tiff



Name of Material/ Equipment	Company	Catalog Number
Pressure sensor: Venous pressure measurement device	Vein press	VP 2014
Ultrasound probe: Vscan Extend R2 Dual Probe DICOM Base Package	GE Healthcare	H8038VP

Comments/Description

A peripheral venous measuring device used in conjuction with an ultrasound to measure peripheral venous pressure.

Any ultrasound probe will be sufficent for this test. Using the narrow tranducer will function best when coupled to the pressure sensor

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AUTHOR RESPONSE: Completed. Image submitted as a .tif in maximum pixels available.

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AUTHOR RESPONSE: Completed. JBJS changed to journal of bone and joint surgery. Line 165

4. Please revise the table of the essential supplies, reagents, and equipment. The table should include the name, company, and catalog number of all relevant materials in separate columns in an xls/xlsx file. Please sort the Materials Table alphabetically by the name of the material.

AUTHOR RESPONSE: Completed. Only two devices are required and these are listed in alphabetical order.

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AUTHOR RESPONSE: Completed.

Line 68-71 “Ethics Statement: This experimental protocol has been reviewed and approved by our hospital’s institutional review board (IRB) and follows all guidelines set forth by our institution’s human research ethics committee.”

Reviewers' comments:

Reviewer #1:
Manuscript Summary:
Overall an innovative approach to a challenging clinical problem with severe down stream effects if missed. Compartment syndrome is a challenge with no real solution outside of clinical exam. This offer a promising possibility to diagnose and monitor the tissue.

Major Concerns:
None

Minor Concerns:
none

AUTHOR RESPONSE: We appreciate the review and agree that the diagnosis of compartment syndrome remains elusive. It is our hope this technique may ultimately prove to be a reliable means of diagnosing compartment syndrome.

Reviewer #2:
Manuscript Summary:
A compartment syndrome is a severe potential threat in trauma patients, and can occur at any age, any anatomical compartment and can be provoked by different mechanism.

However, missed diagnosis of an acute compartment syndrome can provoke a severe soft tissue necrosis with unacceptable consequences up to live threatening complications.
A very wide range of minimal invasive and non-invasive techniques were published in the last decades. All of them lack due to their reliability and there is in deed a need for further developments.
The authors present a novel technique of measuring the elasticity of the muscle compartment in vitro (Sellei et al. 2015 in Patient Saf Surg), a cadaver model, which was published previously in 2015 (Sellei et al. in Eur J Trauma Emerg Surg) using a ultrasound probe connected with a pressure measurement and in 2018 (Bloch et al) in an animal model. The authors should refer to these publications. The results should decribe the method of statistical calculation.
The aspect of measuring the flattening pressure of the fascia seems to be a promising access. Overall a well written manuscript with potential clinical impact.

Major Concerns:
none

Minor Concerns:
a) please refer to the above mentioned authors

AUTHOR RESPONSE: We have added the above requested references:

> **Line 56-59:"It has been previously demonstrated in artificial, animal, and human cadaver models that a rise in the intra-compartmental pressure results in a decreased elasticity of the fascia overlying the anterior compartment suggesting a correlation between the intra-compartmental pressure and compliance of the facial compartment as measured by ultrasound.8-10"**

b) please describe the statistical method

AUTHOR RESPONSE: Descriptive analysis included mean, median, and standard deviation was performed on the compartment pressure data. A single-tailed t-test was used to evaluate for a difference between the compartment pressures of those who had fasciotomies performed for compartment syndrome and those who were not diagnosed with compartment syndrome.

> **Line 110-113: "The average delta CFFP for patients without compartment syndrome was 10.7 ± 10.6 mbar compared to 157 ± 51.7 mbar for patients with compartment syndrome and single-tailed t-test identified the differences in pressures between the groups as being statistically significant (P<0.02)."**