Compartment Syndrome Management: What is the State of the Art?

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Disclosure Information

Andrew H. Schmidt, M.D.

Conflicts of Commitment/ Effort

Current research supported by DOD / Army grants.

PI of METRC PACS study

PI of current US DOD study on Tissue Filtration in ACS

Co-Chair of AAOS/OTA/SOMOS CPG group for management of acute compartment syndrome

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Disclosure of Off-Label and/or investigative Uses

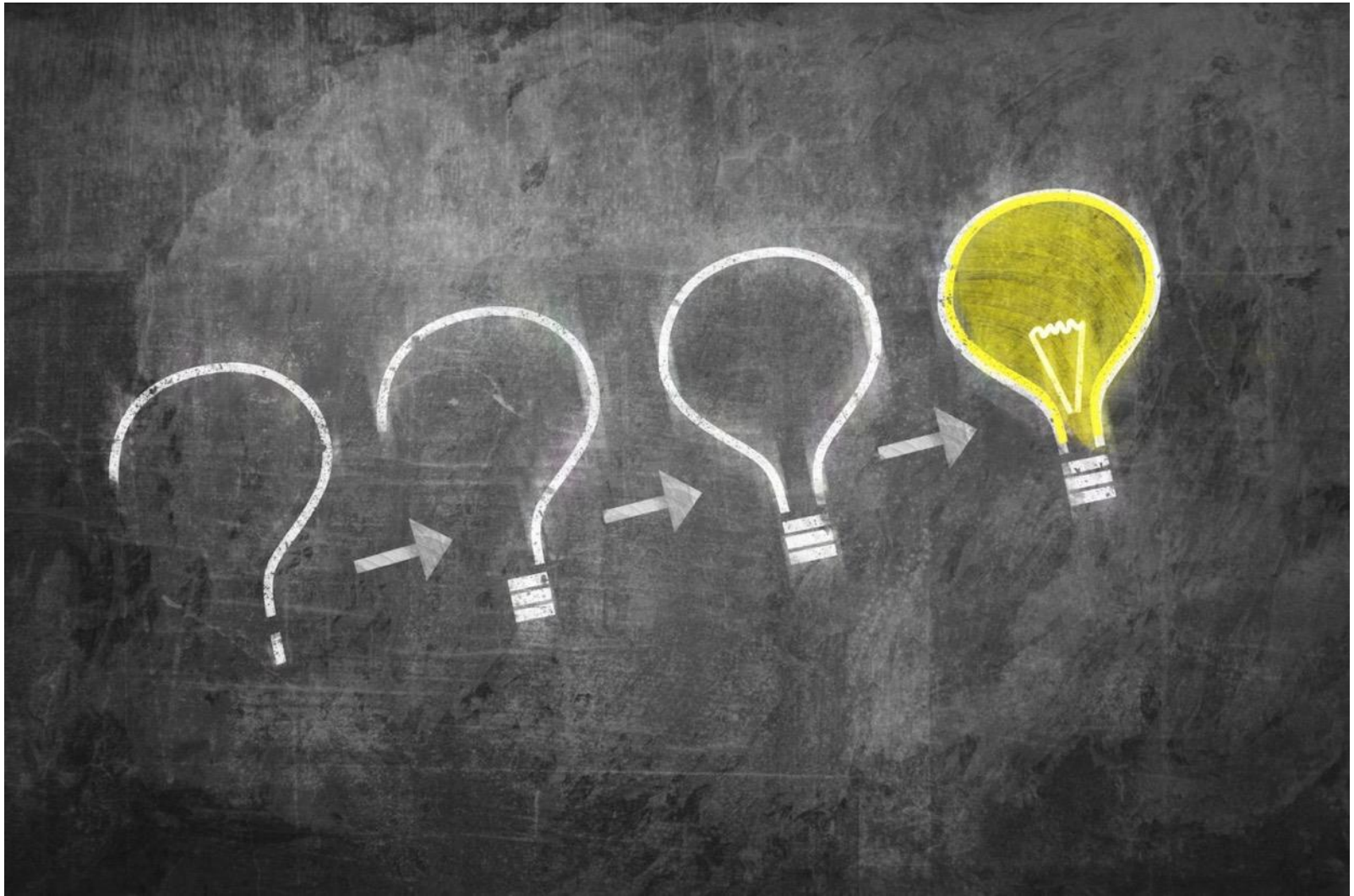
I will not discuss off label use and/or investigational use in my presentation.

Acute Compartment Syndrome

- Academically "understood"

- A clinical conundrum…
  - No one ever feels confident in the diagnosis
  - No confirmatory "test" (a test with high PPV)
  - No definitive treatment shy of fasciotomy

What do we really know about acute compartment syndrome?



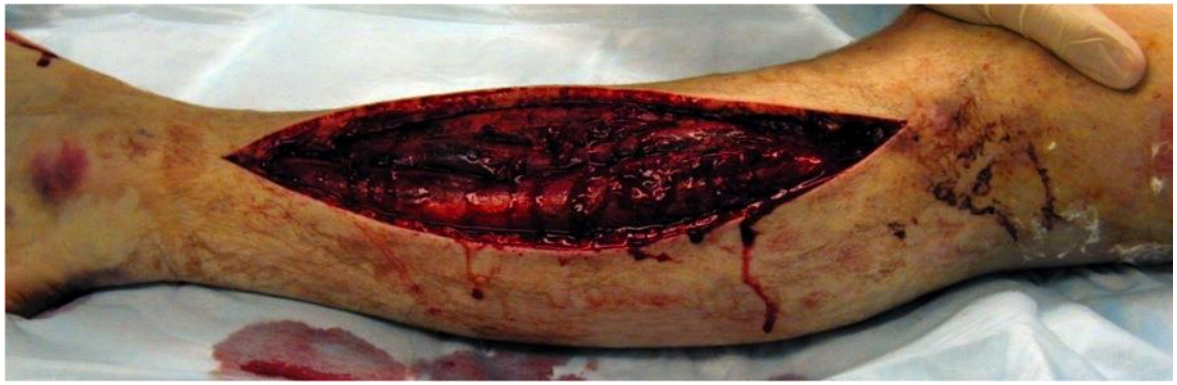
“Dogma”

A principle or set of principles laid down by an authority as incontrovertibly true.

“eminence- based medicine”

Regarding ACS, what is dogma and what is truly evidence-based?

Truth or Dogma ?

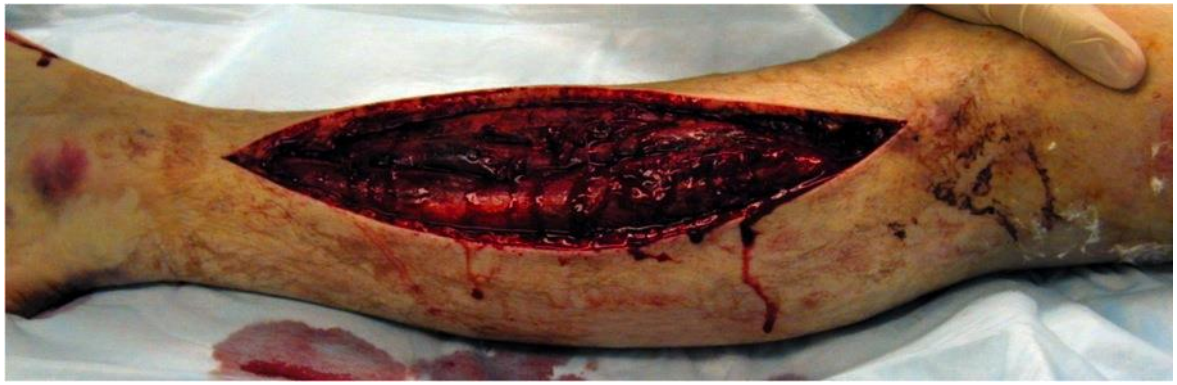


When acute compartment is present, early fasciotomy is critical to achieve the best outcome.

How do we know “when acute compartment is present” ?

How do we know what compartments are involved, or how severe the muscle damage is?

Truth or Dogma ?



When acute compartment is present, early fasciotomy is critical to achieve the best outcome.

Are there ever circumstances when the treatment is worse than the disease?

What if it's only the deep posterior compartment that's involved?

The ACS literature is of very poor quality

- There is no “gold standard” for diagnosis
- The treating surgeon’s decision to perform fasciotomy has been accepted as equivalent to a diagnosis of ACS.
  - Even though we know that the surgeon’s decision is highly biased towards doing fasciotomy.

The ACS literature is of very poor quality

- What's in the literature as criteria for a positive diagnosis of ACS:
  - Pressure in any compartment > 30mmHG (Blick 1986)
  - Muscle escape during fasciotomy (McQueen 2000)
  - Unable to close the fasciotomy wounds primarily at forty-eight hours (McQueen 2013)
- No paper uses histopathology for confirmation of diagnosis.

When is the Correct Time for Fasciotomy ?

- Too early – maybe it wouldn't have been needed.
- Too late – then it won't help and has more morbidity.

Fasciotomy

- 15% of patients complain of pain at rest
- 27% reported pain on exertion.
- A significant reduction of torque and work compared to uninjured leg.

Injury 52 (2021) 2914–2919

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Bacterial infection of fasciotomy wounds following decompression for acute compartment syndrome

Elizabeth Magdelin Hines[a,b,*], Samantha Dowling[a,c], Fergus Hegerty[a], Anita Pelecanos[d], Kevin Tetsworth[c,e,f]

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[e] Orthopaedic Research Centre of Australia, Brisbane, QLD, Australia
[f] Limb Reconstruction Centre, Macquarie University Hospital, Sydney, NSW, Australia

- 370 fasciotomies
- Overall infection rate was 16.7%.
- Most prevalent organism was *Pseudomonas aeruginosa*,
- Ten patients required amputation for infection control.
  - Six of these were secondary to *Pseudomonas* infection
  - One patient died.

J Orthop Trauma • Volume 30, Number 7, July 2016

Infection and Nonunion After Fasciotomy for Compartment Syndrome Associated With Tibia Fractures: A Matched Cohort Comparison

James A. Blair, MD, Thomas Kyle Stoops, MD,† Michael C. Doarn, MD,‡ Dan Kemper, MD,§ Murat Erdogan, MD,‖ Rebecca Griffing, BS,† and H. Claude Sagi, MD¶*

TABLE 2. Comparison Between All Patients With ACS/Fasciotomies and Case-Matched Patients Without ACS/Fasciotomies

	Groups 1 + 3 Plateau + Shaft Fx With ACS (n = 46)	Group 2 + 4 Plateau + Shaft Fx Case Matches (n = 138)	*P*	*P**	OR (95% CI)
Smoker	21 (46%)	27 (20%)	<0.001		
Infection	9 (20%)	6 (4.3%)	<0.001	0.009	4.59 (1.5–14.3)
Nonunion	9 (20%)	7 (5%)	0.003	0.009	4.34 (1.5–13.0)
Delayed union	10 (22%)	30 (22%)	NS	NS	
Mean weeks to union (SD)	26.8 (17.0)	21.5 (14.4)	0.06	NS	

*Statistical comparison after binary logistic regression analysis to control for smoking status.
CI, confidence interval; Fx, fracture; SD, standard deviation.

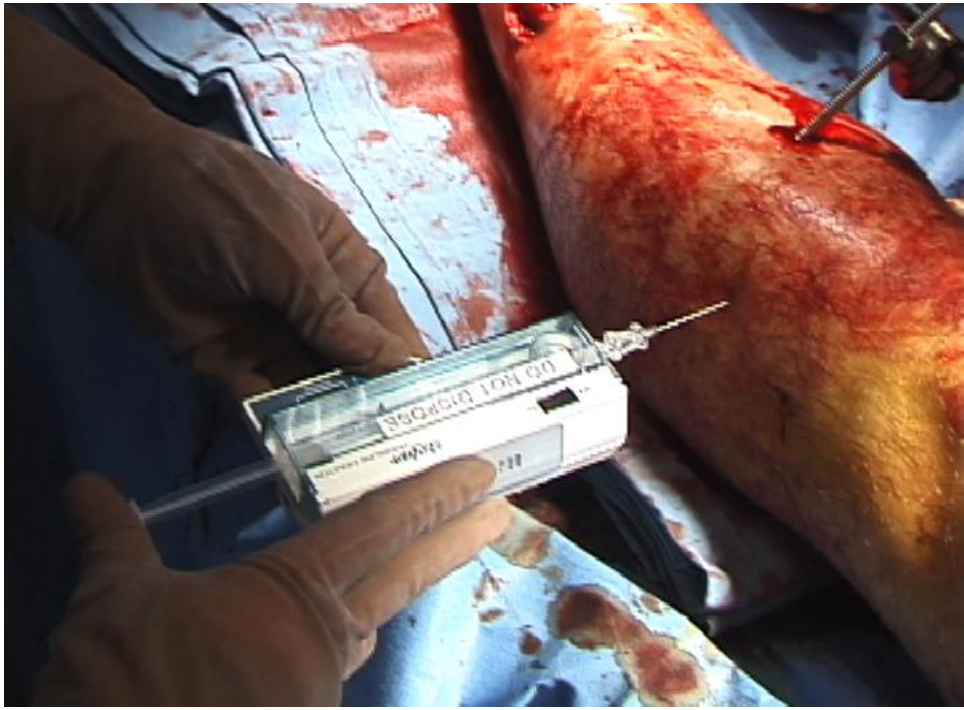
Diagnosis of compartment syndrome begins with suspicion and ends with vigilance

Diagnosis of compartment syndrome begins with suspicion and ends with vigilance

- Suspicion = Understanding who's at-risk
- Vigilance = Repeated Clinical Exam
- Progression of Objective Findings
  - Compartment Pressures
  - Oximetry
  - Lab Values

Intramuscular Pressure Measurement

- Used for years, but still considered an adjunct to clinical examination and role uncertain.
- Represents the only data available in comatose or otherwise non-evaluable patient:
  - Anesthesia
  - Head Injury
  - Sedated
  - Intoxicated



How to Interpret Pressure Measurements ?

J Bone Joint Surg [Br] 1996;78-B:99-104.

COMPARTMENT MONITORING IN TIBIAL FRACTURES

THE PRESSURE THRESHOLD FOR DECOMPRESSION

M. M. McQUEEN, C. M. COURT-BROWN

From the Royal Infirmary of Edinburgh, Scotland

In our series, the use of a differential pressure of 30 mmHg as a threshold for fasciotomy led to no missed cases of acute compartment syndrome. We recommended that decompression should be performed if the differential pressure level drops to under 30 mmHg.

The Estimated Sensitivity and Specificity of Compartment Pressure Monitoring for Acute Compartment Syndrome

Margaret M. McQueen, MD, FRCSEd(Orth), Andrew D. Duckworth, MSc, MRCSEd, Stuart A. Aitken, MRCSEd, and Charles M. Court-Brown, MD, FRCSEd(Orth)

Investigation performed at the Edinburgh Orthopaedic Trauma Unit, Royal Infirmary of Edinburgh, Edinburgh, Scotland

TABLE IV The Estimated Diagnostic Performance Characteristics of Compartment Pressure Monitoring in the Diagnosis of Acute Compartment Syndrome Following a Tibial Diaphyseal Fracture

Diagnostic Performance Characteristic	Value*
Sensitivity	0.940 (0.890 to 0.968)
Specificity	0.984 (0.972 to 0.991)
Positive predictive value	0.928 (0.875 to 0.959)
Negative predictive value	0.987 (0.976 to 0.993)
Positive likelihood ratio	59.818 (33.236 to 107.661)
Negative likelihood ratio	0.061 (0.032 to 0.115)

J Bone Joint Surg Am. 2013;95:673-77 • http://dx.doi.org/10.2106/JBJS.K.01731

ORIGINAL ARTICLE

J Trauma Acute Care Surg 2014;76: 479–483.

Do one-time intracompartmental pressure measurements have a high false-positive rate in diagnosing compartment syndrome?

Augusta Whitney, MD, Robert V. O'Toole, MD, Emily Hui, MPH, Marcus F. Sciadini, MD, Andrew N. Pollak, MD, Theodore T. Manson, MD, W. Andrew Eglseder, MD, Romney C. Andersen, MD, Christopher LeBrun, MD, Christopher Doro, MD, *and* **Jason W. Nascone, MD,** *Baltimore, Maryland*

- 48 consecutive patients with tibial shaft fxs not suspected of having compartment syndrome based on physical examinations.
- Pressure measurements were obtained in all 4 compartments at a single point in time immediately after induction of anesthesia.
- Preop and intraop blood pressures recorded
- 6 month follow-up with detailed clinical examinations

- No clinical evidence of compartment syndrome was observed postoperatively or during follow-up until 6 months after injury.
- Using the accepted criteria of delta P of 30 mm Hg from preoperative diastolic blood pressure, 35% of cases (n = 16; 95% confidence interval, 21.5Y48.5%) met criteria for compartment syndrome.
- Raising the threshold to delta P of 20 mm Hg reduced the false-positive rate to 24% (n = 11; 95% confidence interval, 11.1Y34.9%). Twenty-two percent (n = 10; 95% confidence interval, 9.5Y32.5%) exceeded absolute pressure of 45 mm Hg.

TABLE 2. Compartment Pressure Measurements

Compartment	Average Absolute Compartment Pressure	Average Delta Preanesthesia*	Average Delta Postanesthesia*
	Mean (Range), mm Hg		
Anterior	26 (6–62)	47 (3–81)	32 (−7 to 70)
Lateral	26 (7–71)	47 (19–82)	32 (−12 to 73)
Deep posterior	27 (7–64)	46 (10–77)	31 (−6 to 69)
Superficial posterior	20 (5–47)	53 (18–87)	38 (7 to 67)

*Diastolic blood pressure minus compartment pressure.

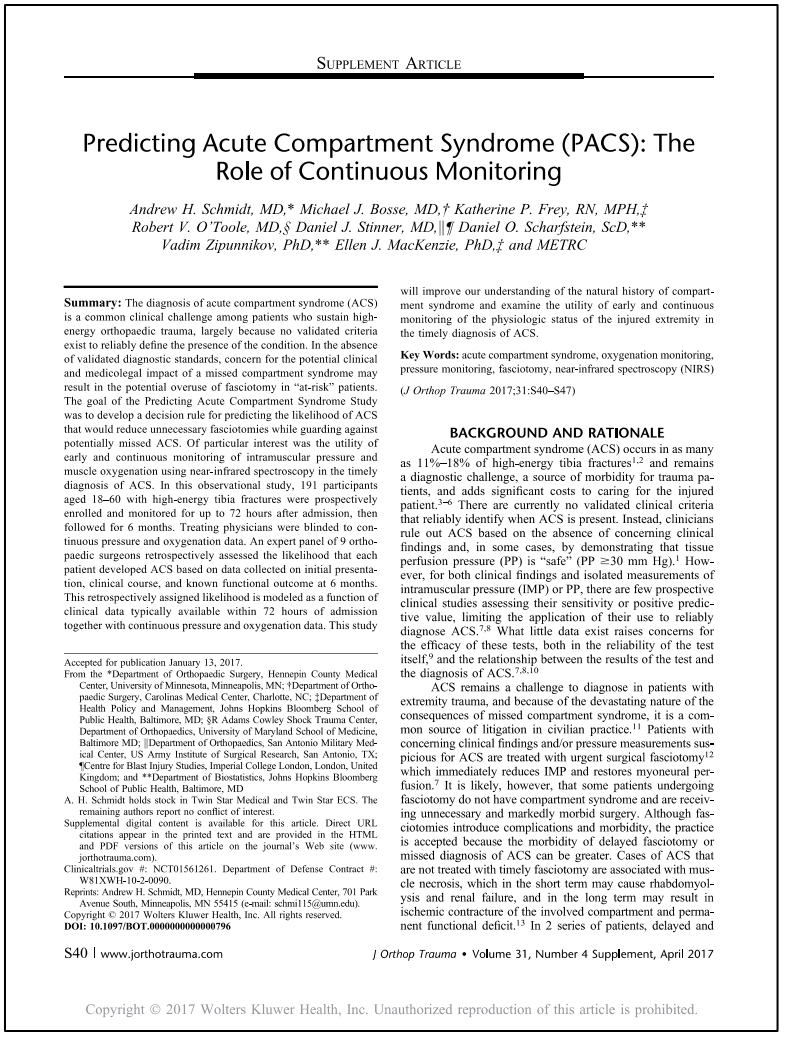
TABLE 3. Compartment Pressure Measurements Compared With Diagnostic Criteria for Recommended Fasciotomies

	Absolute Pressure ≥ 30 mm Hg	Absolute Pressure ≥ 45 mm Hg	Delta* < 30 mm Hg Preoperative DBP	Delta* < 20 mm Hg Preoperative DBP	Delta* < 30 mm Hg Intraoperative DBP	Delta* < 20 mm Hg Intraoperative DBP
	n (%)					
Anterior	18 (39)	7 (15)	10 (22)	7 (15)	21 (46)	17 (37)
Posterior	17 (37)	5 (11)	12 (26)	6 (13)	22 (48)	13 (28)
Deep posterior	17 (37)	6 (13)	12 (26)	3 (7)	22 (48)	13 (28)
Superficial posterior	9 (20)	2 (4)	3 (7)	1 (2)	16 (35)	6 (13)
Patients with at least one compartment meeting criteria	22 (48)	10 (22)	16 (35)	11 (24)	28 (61)	22 (48)

*DBP minus compartment pressure.
DBP, diastolic blood pressure.

THE PACS STUDY

- Observational study of adult patients with severe lower leg injuries at risk for ACS
- Performed at 7 METRC sites



SUPPLEMENT ARTICLE

Predicting Acute Compartment Syndrome (PACS): The Role of Continuous Monitoring

Andrew H. Schmidt, MD, Michael J. Bosse, MD,† Katherine P. Frey, RN, MPH,‡ Robert V. O'Toole, MD,§ Daniel J. Stinner, MD,‖¶ Daniel O. Scharfstein, ScD,** Vadim Zipunnikov, PhD,** Ellen J. MacKenzie, PhD,‡ and METRC*

Summary: The diagnosis of acute compartment syndrome (ACS) is a common clinical challenge among patients who sustain high-energy orthopaedic trauma, largely because no validated criteria exist to reliably define the presence of the condition. In the absence of validated diagnostic standards, concern for the potential clinical and medicolegal impact of a missed compartment syndrome may result in the potential overuse of fasciotomy in "at-risk" patients. The goal of the Predicting Acute Compartment Syndrome Study was to develop a decision rule for predicting the likelihood of ACS that would reduce unnecessary fasciotomies while guarding against potentially missed ACS. Of particular interest was the utility of early and continuous monitoring of intramuscular pressure and muscle oxygenation using near-infrared spectroscopy in the timely diagnosis of ACS. In this observational study, 191 participants aged 18–60 with high-energy tibia fractures were prospectively enrolled and monitored for up to 72 hours after admission, then followed for 6 months. Treating physicians were blinded to continuous pressure and oxygenation data. An expert panel of 9 orthopaedic surgeons retrospectively assessed the likelihood that each patient developed ACS based on data collected on initial presentation, clinical course, and known functional outcome at 6 months. This retrospectively assigned likelihood is modeled as a function of clinical data typically available within 72 hours of admission together with continuous pressure and oxygenation data. This study will improve our understanding of the natural history of compartment syndrome and examine the utility of early and continuous monitoring of the physiologic status of the injured extremity in the timely diagnosis of ACS.

Key Words: acute compartment syndrome, oxygenation monitoring, pressure monitoring, fasciotomy, near-infrared spectroscopy (NIRS)

(*J Orthop Trauma* 2017;31:S40–S47)

BACKGROUND AND RATIONALE

Acute compartment syndrome (ACS) occurs in as many as 11%–18% of high-energy tibia fractures[1,2] and remains a diagnostic challenge, a source of morbidity for trauma patients, and adds significant costs to caring for the injured patient.[3–6] There are currently no validated clinical criteria that reliably identify when ACS is present. Instead, clinicians rule out ACS based on the absence of concerning clinical findings and, in some cases, by demonstrating that tissue perfusion pressure (PP) is "safe" (PP ≥30 mm Hg).[1] However, for both clinical findings and isolated measurements of intramuscular pressure (IMP) or PP, there are few prospective clinical studies assessing their sensitivity or positive predictive value, limiting the application of their use to reliably diagnose ACS.[7,8] What little data exist raises concerns for the efficacy of these tests, both in the reliability of the test itself,[9] and the relationship between the results of the test and the diagnosis of ACS.[7,8,10]

ACS remains a challenge to diagnose in patients with extremity trauma, and because of the devastating nature of the consequences of missed compartment syndrome, it is a common source of litigation in civilian practice.[11] Patients with concerning clinical findings and/or pressure measurements suspicious for ACS are treated with urgent surgical fasciotomy[12] which immediately reduces IMP and restores myoneural perfusion.[7] It is likely, however, that some patients undergoing fasciotomy do not have compartment syndrome and are receiving unnecessary and markedly morbid surgery. Although fasciotomies introduce complications and morbidity, the practice is accepted because the morbidity of delayed fasciotomy or missed diagnosis of ACS can be greater. Cases of ACS that are not treated with timely fasciotomy are associated with muscle necrosis, which in the short term may cause rhabdomyolysis and renal failure, and in the long term may result in ischemic contracture of the involved compartment and permanent functional deficit.[13] In 2 series of patients, delayed and

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A. H. Schmidt holds stock in Twin Star Medical and Twin Star ECS. The remaining authors report no conflict of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.jorthotrauma.com).

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How to Ascertain Diagnosis of ACS

SUPPLEMENT ARTICLE

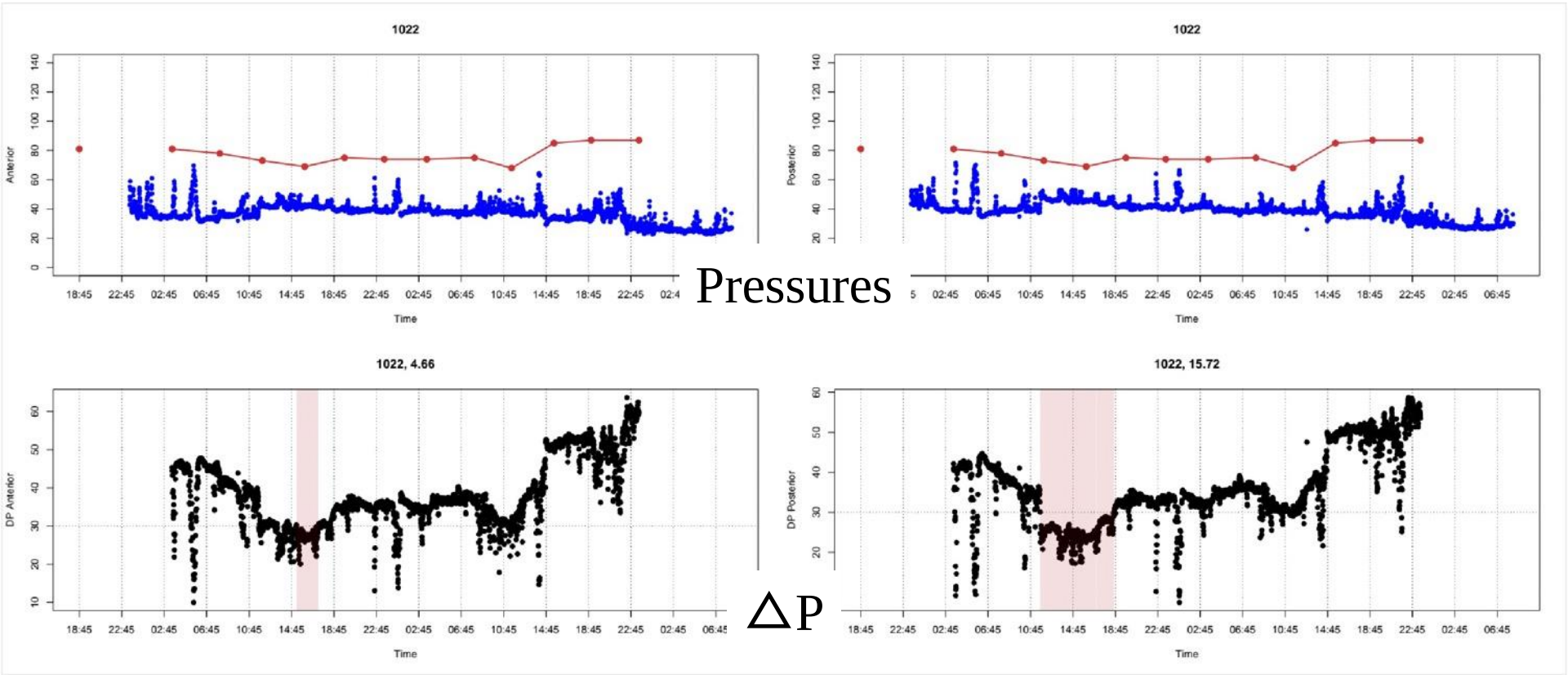
J Orthop Trauma • Volume 36, Number 1 Supplement, January 2022

Defining Incidence of Acute Compartment Syndrome in the Research Setting: A Proposed Method From the PACS Study

Andrew Leroux, PhD,[a] Katherine P. Frey, PhD, RN,[b] Ciprian M. Crainiceanu, PhD,[c] William T. Obremskey, MD, MPH,[d] Daniel J. Stinner, MD, PhD,[d] Michael J. Bosse, MD,[e] Madhav A. Karunakar, MD,[e] Robert V. O'Toole, MD,[f] Eben A. Carroll, MD,[g] David J. Hak, MD,[h] Roman Hayda, MD,[i] and Dana Alkhoury, MPH,[b] Andrew H. Schmidt, MD,[j] on behalf of METRC

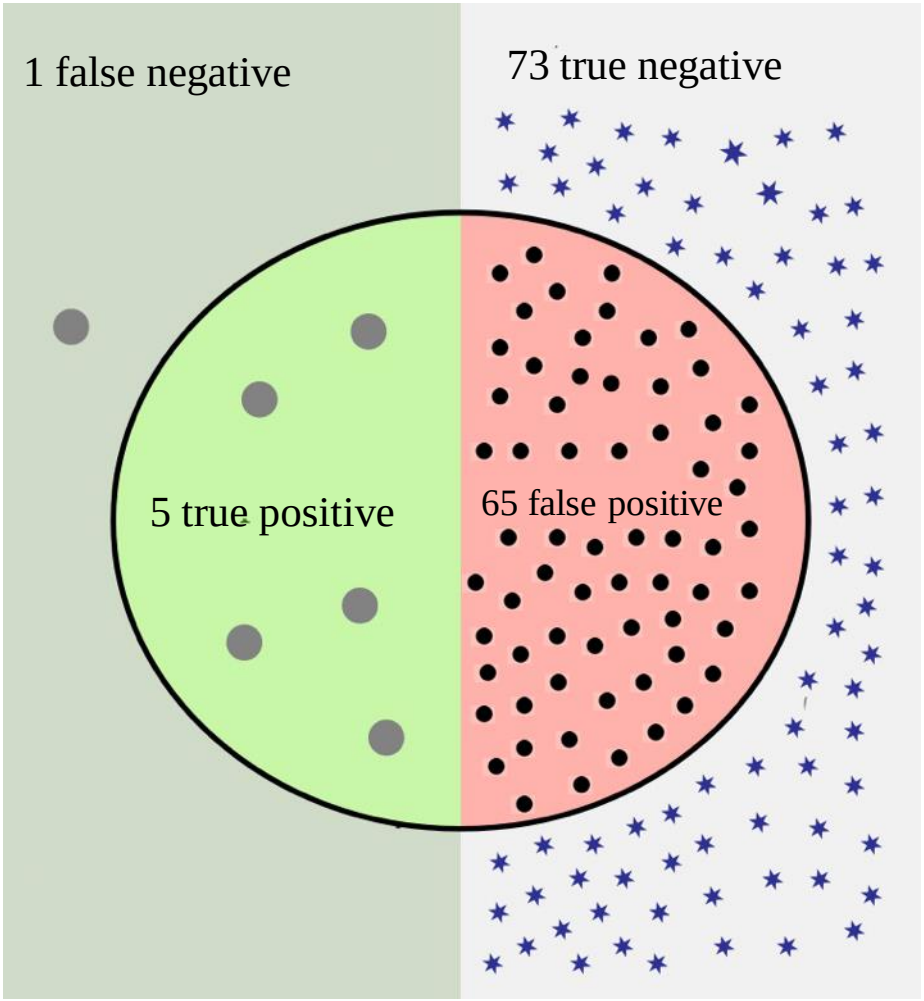
We convened a panel of expert orthopaedic trauma surgeons to review each patient's complete data as well as known 6-month clinical outcomes, to assess the likelihood that each patient had ACS.

- 138 patients were judged with high –consensus to have had a low likelihood of having had acute compartment syndrome
- 65 of them (47%) had delta P < 30 mm Hg in at least one compartment for more than 2 hours.



Compartment Syndrome

Present Absent



6 compartment syndromes

138 without ACS

Sensitivity = 5/6 (.83)
Specificity = 73/138 (.53)
PPV = 5/70 = .07
NPV = 73/74 = .99

False positives greatly outnumber true positives.

Lower number of ACS cases means much greater uncertainty in the sensitivity than the specificity.

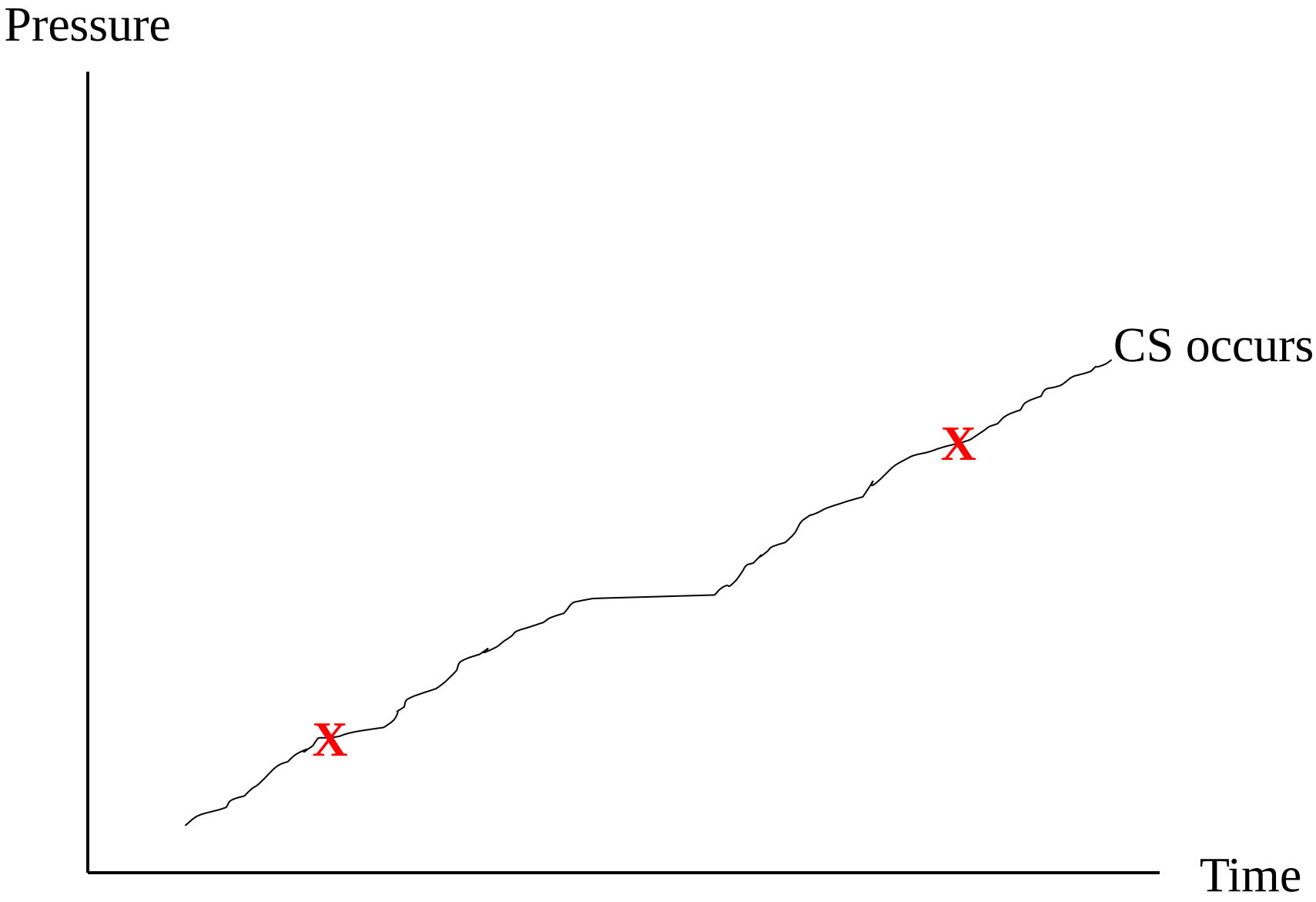
The concept of a pressure-based threshold for fasciotomy has limitations…

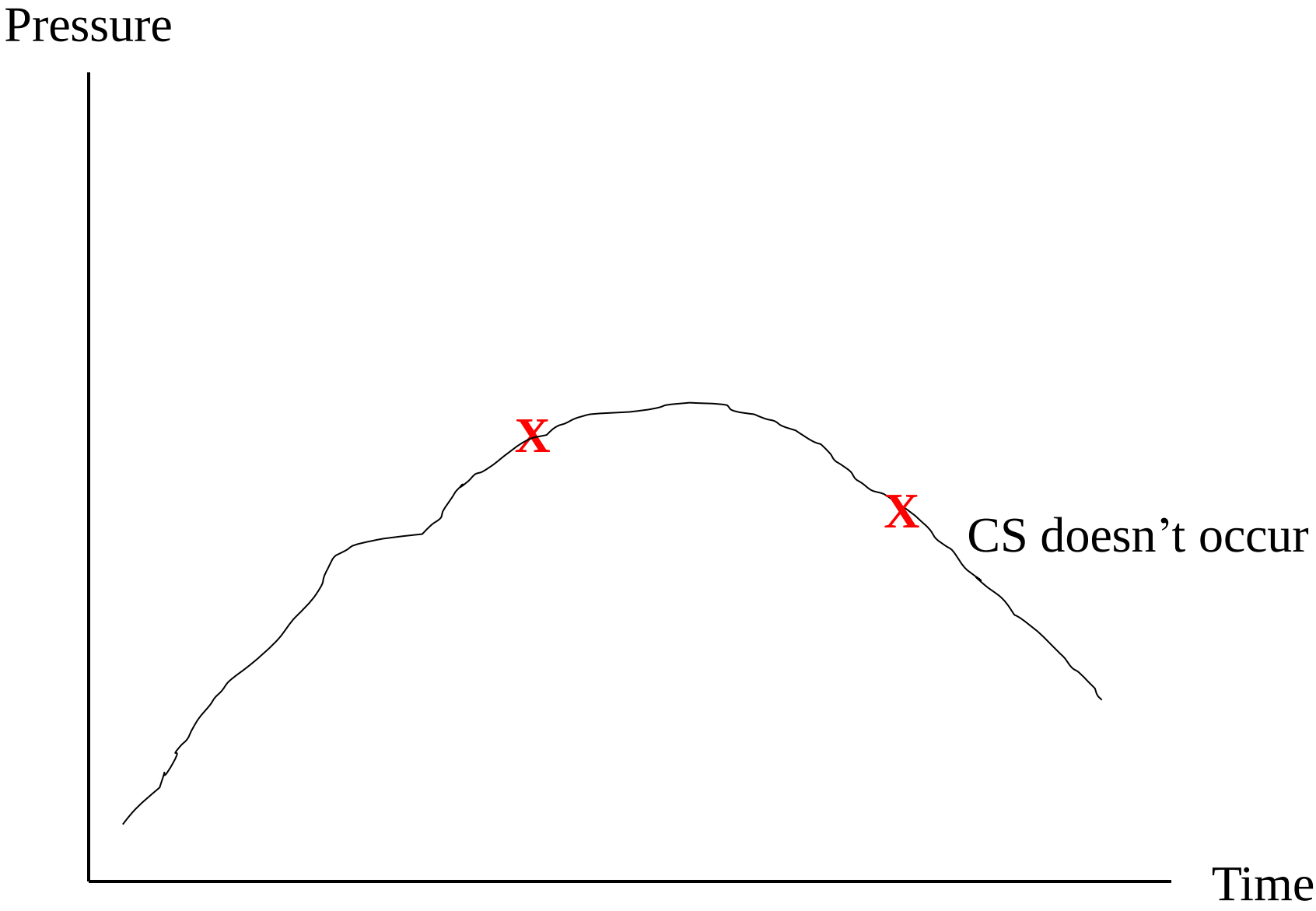
- We don't know where in the compartment to measure or how many "samples" we need.
- We don't know if the measurements we obtain are accurate/ representative
- We don't have any criteria that tells us what a given pressure means for a specific patient.

Compartment Syndrome is a pressure-time phenomenon

- Tissue doesn't become irreversibly damaged until it has been ischemic for 6 -8 hours.

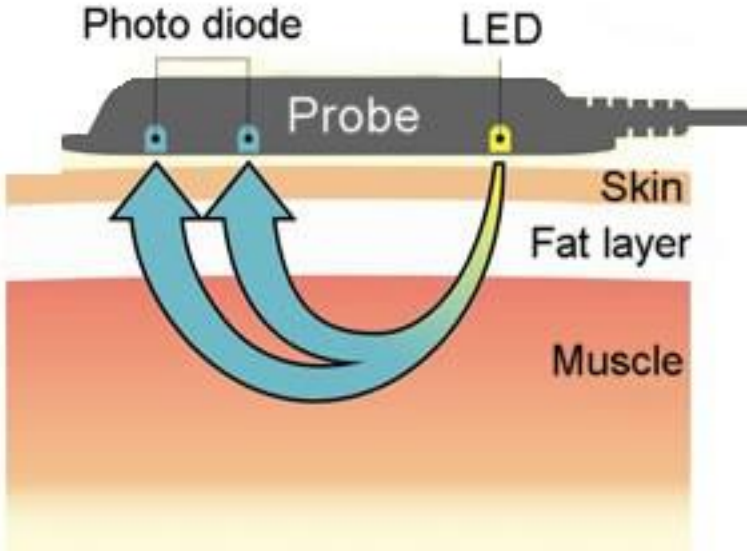
- In patients with extremity injury, you don't know when the clock started.


Pressure
CS occurs
X
X
Time


Pressure
X
X
CS doesn’t occur
Time

Near-Infrared Spectroscopy

- Measures tissue oxygenation.
- Limb trauma is associated with a rapid hyperemic response.
- Sudden drop in tO2 relative to a control limb may reflect sudden compromise in perfusion.
- Oxygenation correlates with tissue pressure in patients with ACS.



J Bone Joint Surg Am. 2010;92:863-70

Correlation Between Muscle Oxygenation and Compartment Pressures in Acute Compartment Syndrome of the Leg

By Michael S. Shuler, MD, William M. Reisman, MD, Tracy L. Kinsey, MSPH, Thomas E. Whitesides Jr., MD, E. Mark Hammerberg, MD, Maria G. Davila, MD, and Thomas J. Moore, MD

Investigation performed at Grady Memorial Hospital, Atlanta, and Emory University, Atlanta, Georgia

- 14 patients with clinical dx ACS
- Mean IMP 79 mmHg (21-176)
- 38/56 compartments had PP < 10mmHg
  - Of those, all had NIRS values at least 10% less than opposite control limb, and magnitude of difference correlated with magnitude of IMP.

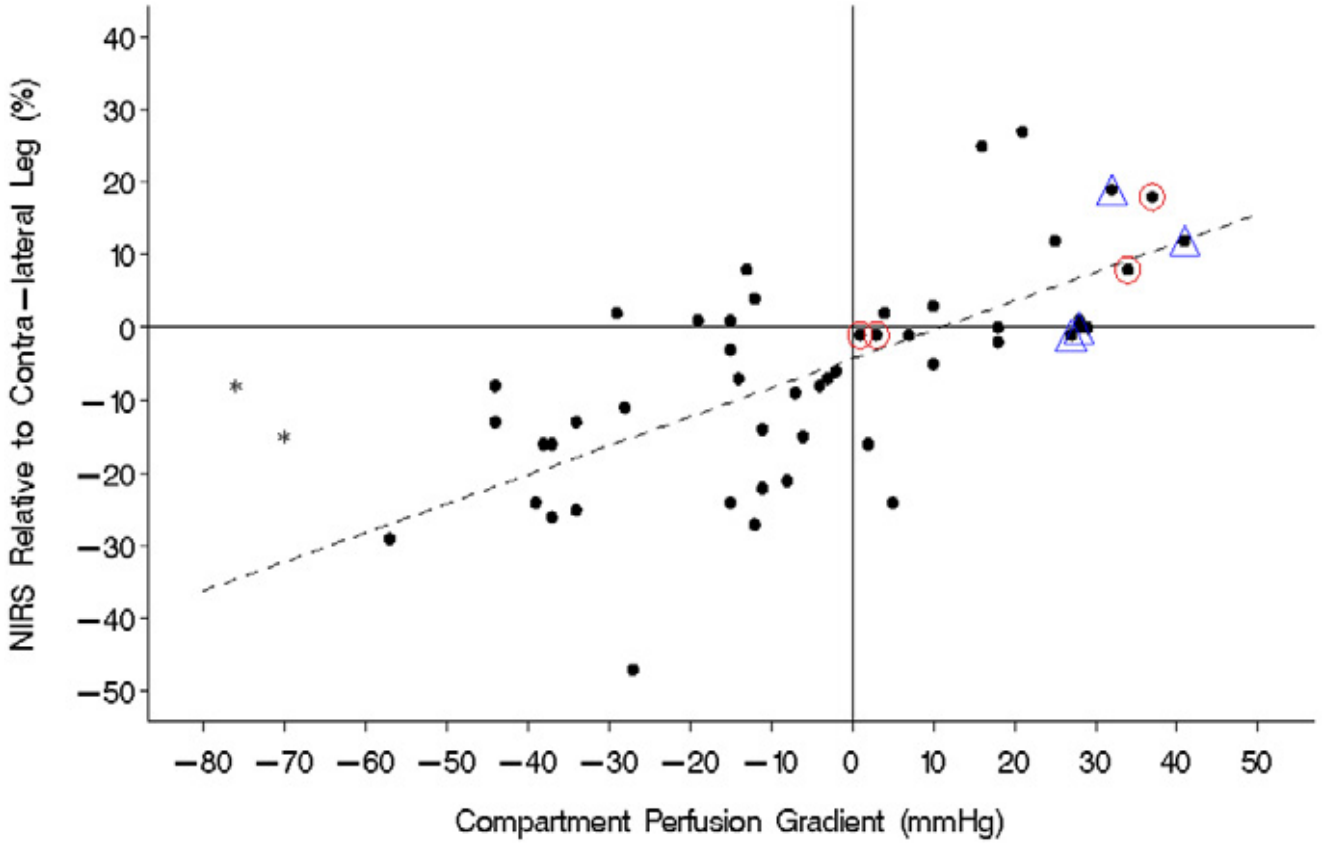
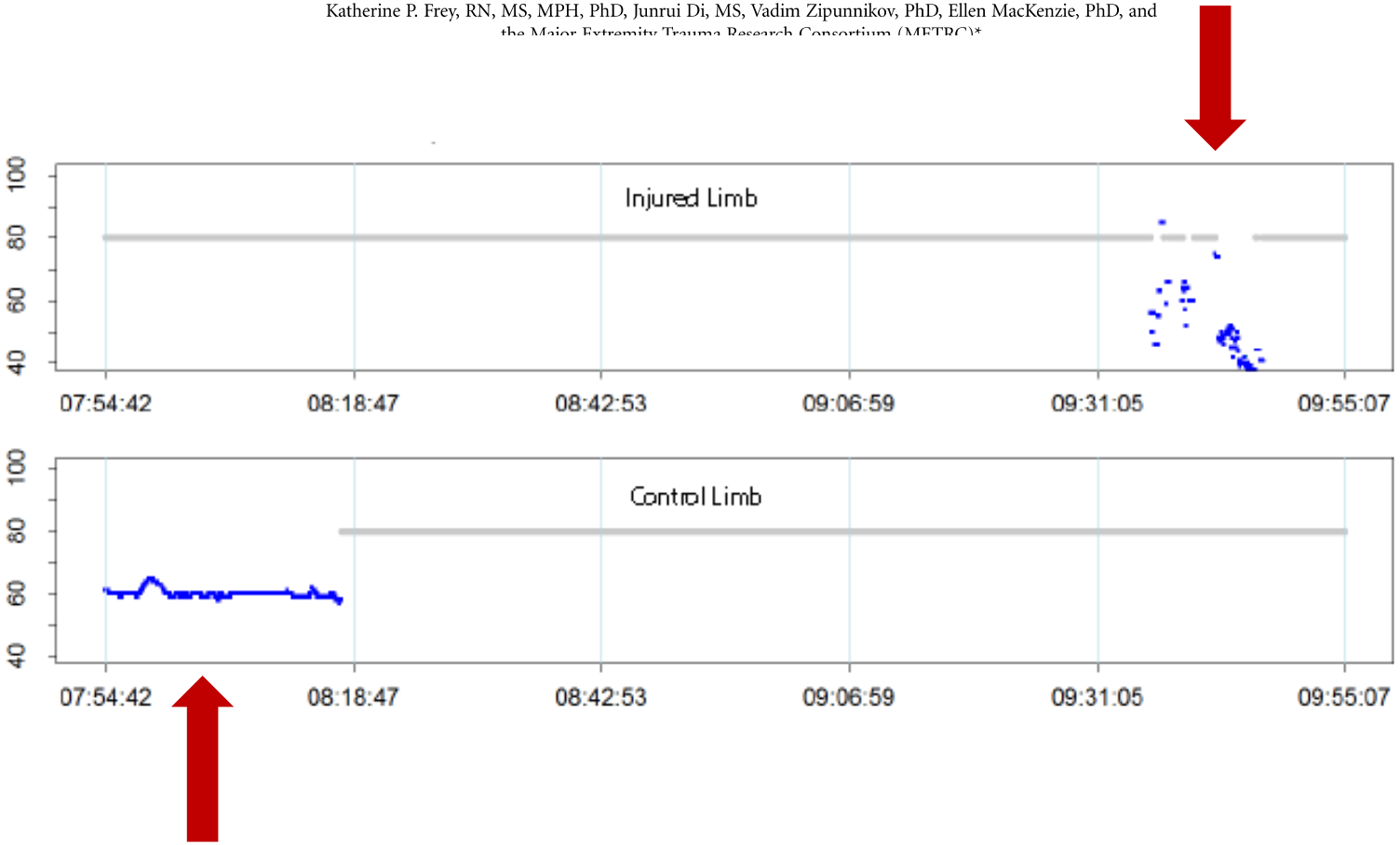

NIRS Relative to Contra−lateral Leg (%)
40
30
20
10
0
−10
−20
−30
−40
−50
−80 −70 −60 −50 −40 −30 −20 −10 0 10 20 30 40 50
Compartment Perfusion Gradient (mmHg)

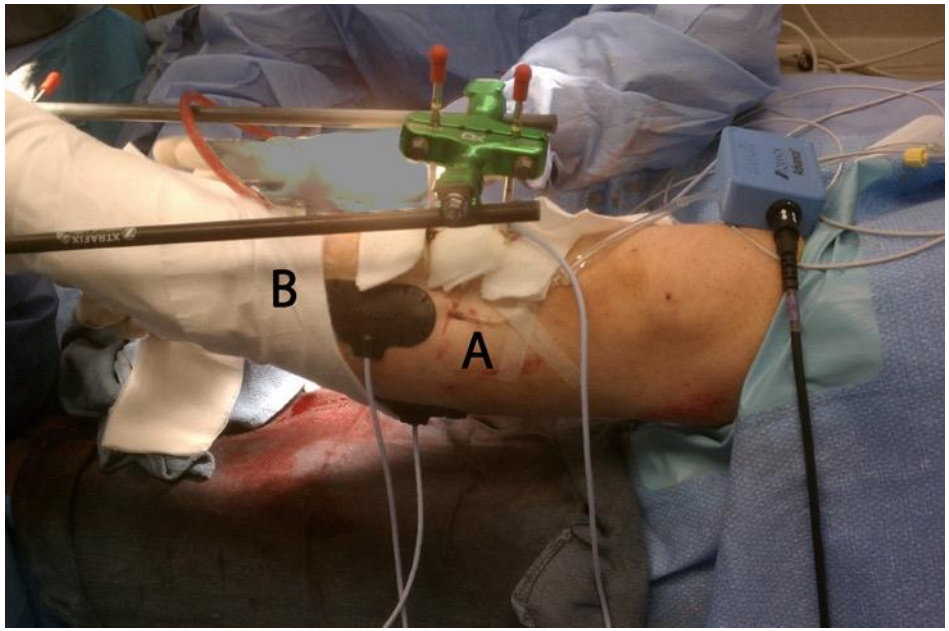
Fig. 2

Continuous Near-Infrared Spectroscopy Demonstrates Limitations in Monitoring the Development of Acute Compartment Syndrome in Patients with Leg Injuries

Andrew H. Schmidt, MD, Michael J. Bosse, MD, William T. Obremskey, MD, MPH, Robert V. O'Toole, MD, Eben A. Carroll, MD, Daniel J. Stinner, MD, David J. Hak, MD, Madhav Karunakar, MD, Roman Hayda, MD, Katherine P. Frey, RN, MS, MPH, PhD, Junrui Di, MS, Vadim Zipunnikov, PhD, Ellen MacKenzie, PhD, and the Major Extremity Trauma Research Consortium (METRC)*



NIRS



- Not ready for prime time…

How else might we diagnosis acute compartment syndrome?

- Objective measurement of "pathophysiologic state":
  - Evidence of ischemia / altered metabolism

Tissue pressure is not itself a direct marker of muscle injury

- Might one sample biomarkers from the injured muscle or the patient's serum?
- Candidate markers would be anything indicating impaired perfusion or metabolic "exhaustion" of the muscle.

Fri., 10/11/13 Knee/Tibia, PAPER #68, 3:50 pm OTA 2013

Acute Compartment Syndrome: Where Pressure Fails, pH Succeeds

Kirsten G.B. Elliott, FRCS (Ortho), MD; Alan J. Johnstone, FRCS;
Aberdeen Royal Infirmary, Aberdeen, United Kingdom

- 51 Patients at risk for leg CS had both indwelling pressure and pH monitors
- CS diagnosed by clinical or pressure criteria

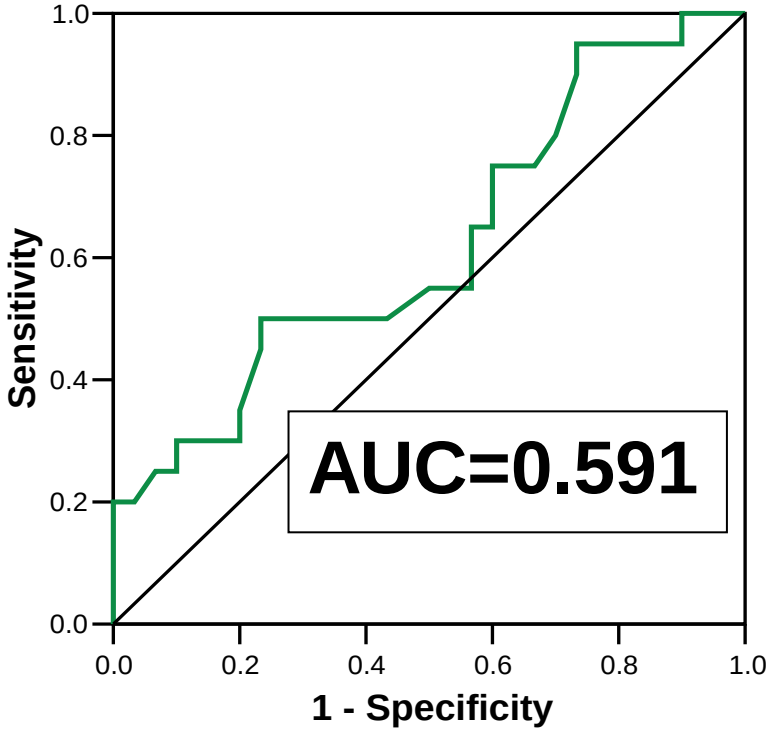
Initial	Follow-up
13 cases CS	7 missed CS

All 20 cases would have been picked up by pH

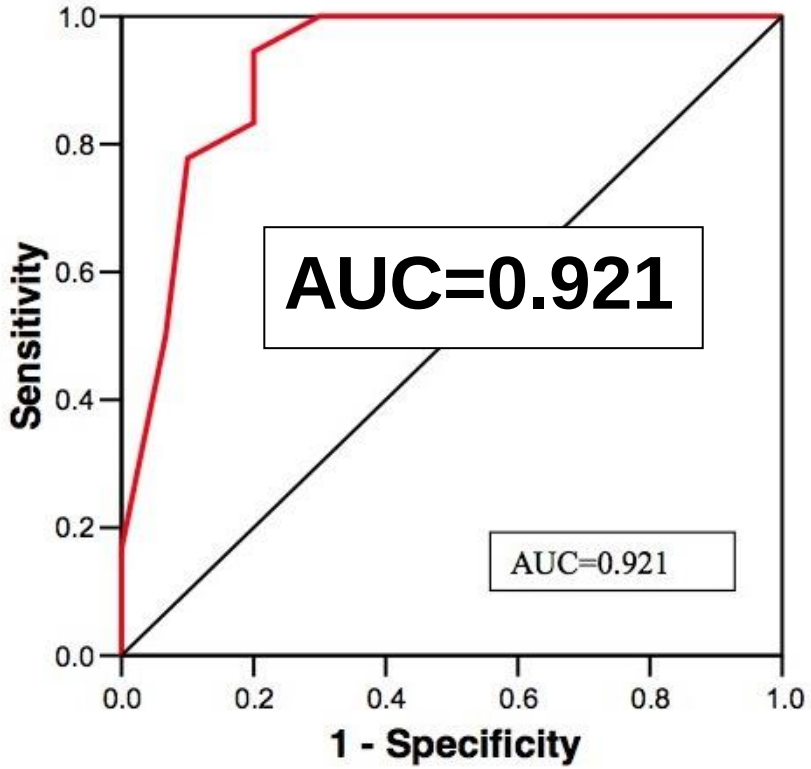
Slide courtesy of Alan Johnstone

1: ROC curve for pH

Delta pressure (dP)



pH



Area under the curve = .73 pressure, .92 pH

Slide courtesy of Alan Johnstone

Results - Critical levels

(Sustained for 60 minutes)

Criteria	Sensitivity	Specificity
pH < 6.4	95%	80%
ICP > 40mmHg	65%	60%
dP < 20mmHg	53%	60%

Slide courtesy of Alan Johnstone

Treatment of Compartment Syndrome is (a properly timed) Fasciotomy

- Longitudinal skin incision that extends the *entire length* of the compartment.
- Leg – 2 incisions safest.
- Release fascia of involved muscle.
- Skin left open.

"Found Down" Compartment Syndrome

Experience from the Front Lines of the Opioid Epidemic

Lydia Parzych, MD, Jacob Jo, BA, Amna Diwan, MD, and Eric Swart, MD

Investigation performed at the Department of Orthopaedic Surgery, University of Massachusetts, Worcester, Massachusetts

Background: With the worsening of the opioid epidemic, there has been an increasing number of cases in which patients are "found down" following a drug overdose and develop a crush injury resulting in muscle necrosis, rhabdomyolysis, and elevated compartment pressures in a unique presentation of compartment syndrome. The purpose of the present study is to summarize our experience at a trauma center in a region with a high endemic rate of opiate abuse to provide guidance for the management of patients with "found down" compartment syndrome.

Methods: We performed a retrospective review of the records of patients who had been found unconscious as the result of overdose, with findings that were concerning for compartment syndrome, and had been managed with fasciotomy or observation at the discretion of the surgeon. The patients were divided into 3 groups based on presentation (partial deficits, complete deficits, or unexaminable), and the operative findings, hospital course, laboratory values, and functional status were compared between the groups.

Results: Over 12 years, we identified 30 "found down" patients who had an examination that was concerning for compartment syndrome. Twenty-five patients were managed with fasciotomy; this group required an average of 4.2 operations and had a 20% infection rate and a 12% amputation rate. Lactate, creatine phosphokinase, and creatinine levels typically were elevated but did not correspond with muscle viability or return of function. At the time of initial debridement, 56% of patients had muscle that appeared nonviable, although muscle function returned in 28% of the patients who had questionable viability. Four patients had no motor or neurological function on initial examination, and none had meaningful return of function at the time of the latest follow-up. Of the 10 patients who had partial neurological deficits at the time of presentation and underwent fasciotomy, over half (70%) had some improvement in ultimate function.

Conclusions: Patients who are "found down" following an opiate overdose with crush injuries resulting in compartment syndrome have a high surgical complication rate and poor recovery of function. The limited data from the present study suggest that those with absent function at the time of presentation are unlikely to gain function after fasciotomy, and the risk-benefit ratio of fasciotomy in this patient population may be different from that for patients with traumatic compartment syndrome.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Opioid abuse continues to be a major public health issue in the United States and around the world. It is estimated that 2.1 million Americans suffer from substance use disorders related to prescription opioid pain relievers and that 467,000 are addicted to heroin[1]. With opiate abuse rising, the number of people found unconscious from opiate overdose is also increasing. Of particular concern to the orthopaedic surgeon, these patients can present with rhabdomyolysis and a crush injury resulting from limb compression for a prolonged period of time, which can lead to a clinical compartment syndrome. This presentation differs from that of acute traumatic compartment syndrome, and there are no clear guidelines for the treatment of "found-down" patients with crush injuries and a concern for compartment syndrome.

The management of patients who are admitted after being found down from substance overdose is challenging; patients are often unexaminable because of sedation, making definitive diagnosis of compartment syndrome, which is

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25 of 30 patients with possible extremity compartment after being found down treated with fasciotomy

4 operations
20% infection rate
12% amputation rate

Minneapolis Experience

31 patients with rhabdomyolysis following event not occurring within 6 hours of admission.

Drug use most common etiology
45 anatomic regions affected.

64% of affected muscles had fasciotomy

87% of affected limbs had sensory dysfunction and 76% had motor deficits at last follow up.
42% of our patients required short-term dialysis. All had normal kidney function at avg follow-up of 200 days
2% amputation rate

Table 4. Complications			
Affected extremities	**Total (n=45)**	**Fasciotomy (n=29)**	**Non-operative (n=16)**
Sensory dysfunction at final follow up	39 (87%)	25 (86%)	14 (88%)
Motor dysfunction at final follow up	34 (76%)	25 (86%)	13 (81%)
Deep infection	2 (4%)	2 (7%)	0 (0%)
Superficial infection	1 (2%)	1 (2%)	0 (0%)
Amputation	1 (2%)	1 (2%)	0 (0%)
Deep vein thrombosis	1 (2%)	0 (0%)	1 (6%)
Pulmonary embolus	0 (0%)	0 (0%)	0 (0%)
Affected individuals	**Total (n=31)**		
Dialysis	13 (42%)	7 (23%)	6 (19%)
Mortality	3 (10%)	1 (3%)	2 (6%)

Summary

- Current diagnosis for ACS is based on ruling it out rather than making a definitive diagnosis.
- For a specific patient, changes in pressure or other metabolic measure with time are most helpful when correlated with other information.
- More precise methods to diagnose ACS are available, but we are still hampered by the lack of a gold standard, both in the clinical and research settings.

Thank you !