Novel digital continuous sensor for monitoring of compartment pressure: a case report

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Abstract

Case: The American Academy of Orthopaedic Surgeons has recently identified continuous intracompartmental pressure monitoring as 1 of the few means to assist in ruling out acute compartment syndrome (ACS). There are very few methods that allow this measurement. This manuscript describes the use of a new digital monitoring system for ACS in 3 patients. This minimally invasive device, the MY01 (NXTSENS, Montreal, Canada) is capable of continuously and precisely measuring variations in intracompartmental pressure.

Conclusion: MY01 detected the occurrence of ACS at early-stage and expedited the timing of surgery for 2 patients. This tool also objectively excluded a suspected diagnosis of ACS in a medically comorbid patient, obviating the need for unnecessary fasciotomies and potential complications.

Keywords: acute compartment syndrome, continuous intracompartmental pressure, fasciotomy, pressure monitoring

1. Introduction

Acute compartment syndrome (ACS) is a limb-threatening condition and a true surgical emergency. It is characterized by increased intracompartmental pressure (ICP) compromising the microcirculation of the muscle.\[^{1,3}\] Tissue ischemia develops within a noncompliant myofascial compartment, which may subsequently lead to irreversible myonecrosis within hours from symptom onset.\[^{1,4}\] While the most common etiology is trauma, other less common etiologies such as burns, emboli, and iatrogenic injuries can be equally troublesome and make diagnosis challenging.\[^{1,3}\] Ischemic neuropathy, contractures, chronic infection or amputation are possible with devastating long-term complications.\[^{1,6}\] Therefore, compartment syndrome requires an early clinical recognition and accurate diagnosis, followed by an emergency decompressive fasciotomy.\[^{6}\] Early clinical findings often include pain out of proportion to injury, pain with passive stretch, and tensesness of the involved compartment.\[^{1,6}\] Neurological symptoms, pallor, and pulselessness are considered late findings.\[^{1,6}\] Currently, ACS is diagnosed based on physical examination or single point of time ICP measurement when evaluating unconscious patients.\[^{7–9}\] In order to improve diagnostic accuracy and precision, a minimally invasive tool that is capable of continuous intracompartmental pressure (cICP) monitoring has been advocated by the American Academy of Orthopaedic Surgeons.\[^{10}\] This case report highlights the use of a device that employs cICP to help the clinician accurately diagnose ACS.

MY01 (MY01 Inc., Montreal, Canada) is an indwelling sensor that can be inserted in a muscle compartment. It is a single use disposable device that stays in up to 18 hours and gives results on a display tethered to the compartment in question. It also can feed directly to the care provider through a cellphone application (Fig. 1). With its novel microelectromechanical sensors, MY01 has been shown to have superior ICP measurements accuracy over other existing devices.\[^{11}\] The MY01 device can be used to capture several single-point measurements from up to 5 different insertion sites. Clinical judgement is paramount to decision in which compartment the pressure is trended. It is meant to act as an aid to clinicians in monitoring ACS. The burden of a missed ACS is immense for both the patient and health care system. Although timely fasciotomy is generally well tolerated and inexpensive relative to other surgical procedures, unnecessary fasciotomies are not innocuous. The ability to more accurately diagnose ACS benefits patients by simultaneously avoiding missed compartment syndromes and avoiding unnecessary fasciotomies.\[^{12}\] This manuscript underlines the novel use of this digital continuous pressure monitoring sensor for the diagnosis of compartment syndrome. This device is approved by the Food and Drug Administration and Health Canada. All monitored data is encrypted and associated with a Health Insurance Portability and Accountability Act compliant database in the context of a prospective study approved by local ethics board. Each patient was informed that data concerning their case could be submitted for publication, and informed consent was provided.
2. Case report

2.1. Case 1

A 57-year-old male was involved in an accident where he was struck while driving a scooter. The patient was evaluated and managed as per Advanced Trauma Life Support protocol at a level 1 trauma center. He sustained an ipsilateral tibial plateau fracture combined with an open fracture-dislocation of the ankle (Fig. 2). The patient remained stable and showed no clinical signs of ACS when evaluated by the orthopedic trauma team. He was enrolled in the cICP study and the catheter was inserted in the anterior compartment. The initial pressure was within normal limits but increased after splint application. As a result, the splint was released resulting in lowering of the ICP. Repeated clinical assessments including examination and palpation were not suggesting a clear progression in ACS. The ICP continued to rise, and eventually was found to be greater than 30 mmHg, within 25 mmHg of the diastolic blood pressure and corresponding to an increase in pain. The patient was provisionally diagnosed with ACS and taken to the operating room for urgent fasciotomies (Fig. 3). The surgery was changed in order to release the compartment before addressing the open ankle injury. Intraoperative fasciotomy revealed patchy necrosis in the anterior compartment muscles of the leg. Muscles bulged upon fasciotomy suggesting there was increased pressure that had been released. The muscles of the anterior compartment contracted with mechanical and electrical stimulation and appeared healthy. The intraoperative assessment was that the patient indeed had ACS, but it was early enough in the course that the fasciotomy was timely and the muscle was still healthy. The tibial plateau was reduced and fixed appropriately as well as the fracture-dislocation of the ankle. Primary wound closure was performed. He had an excellent postoperative rehabilitation without any surgical site infection or wound complication. At 6 months follow-up, the patient had complete range of motion of the ankle and demonstrated good muscle strength on dorsiflexion against resistance.

2.2. Case 2

A 37-year-old male that fell backwards off a 10-foot ladder. He sustained severe elbow injuries. On the right, he had a transolecranon fracture-dislocation of the elbow and on the left, a terrible triad injury (Fig. 4). On presentation he showed no clinical signs of compartment syndrome when evaluated by the orthopedic team. However, due to the nature of his injury, he was enrolled in the study and the insertion of the catheter in the right elbow extensor mass showed an immediate ICP at the upper limit of normal. He was kept under observation in the emergency room due to these findings. Overnight cICP data showed a concerning increasing trend, with measurements within 20 mmHg of diastolic blood pressure, resulting in prompt re-evaluation for possible urgent surgery (Fig. 3). With a cICP near 40 mmHg, splint opening and examination showed tense compartments in the forearm and marked tenderness on passive
stretch (Fig. 5). The patient was expeditiously brought to the operating room for release of the forearm. Release of the fascia showed a bulging extensor mass without any signs of myonecrosis. The fixation of both his fractures was completed, and by the end of the surgery, the skin was closed over a healthy and contractile muscle mass. This patient had a normal postoperative course completing a full course of physical therapy without any complications. Distal examination remained intact with normal strength, no signs of neurapraxia, full forearm pronation-supination and wrist flexion-extension.

2.3. Case 3
A 70-year-old male with multiple comorbidities including end-stage liver disease with evaluation for liver transplant. He sustained a fall while admitted on the medical ward resulting in a bi-malleolar ankle fracture. The orthopedics team was consulted. The medical team had diagnosed ACS; the clinical exam was concerning due to severe pain, significant swelling and hemorrhagic blisters (Fig. 6). There was worry about complications if the patient was taken for immediate fasciotomies. This patient was enrolled in the cICP study and the initial measurement reassured the clinicians with values stable around 10 mmHg (Fig. 7). After reduction and splinting, the orthopedics team followed the trend closely and no increase was detected. The patient eventually had a standard surgical fixation of his fracture after skin wrinkling had occurred and recovered without any complications. The patient did not develop signs of missed compartment syndrome, kept intact muscle strength and foot sensitivity. The use of the cICP avoided an unnecessary fasciotomy for this medically fragile patient who was at high-risk of complications.

3. Discussion
Early decompressive fasciotomy is used to minimize long-term complications of an ACS. In fact, it has been shown that a delay of more than 6 hours is the most significant risk factor for developing long-term complications. There is continuous challenge in the precision, sensitivity, specificity or overall validity of the current diagnostic tools. One possible avenue to overcome these challenges is the MY01 cICP system, a minimally invasive device that can continuously and precisely measure ICP variations. Recently, the precision of its modern miniaturized sensors was deemed to be superior to present alternative intermittent ICP measurement tools in precisely detecting pressure changes.

This manuscript presents 3 situations where cICP had a significant impact in the management of trauma patients (Fig. 3). There were no complications with the device pressure readings, usability, or data-transfer. For the first patient, who sustained an ipsilateral tibial plateau and open ankle fracture, the use of cICP expedited the timing of surgery where the fasciotomies showed early myonecrosis despite absent classic clinical features. Further delays would have caused irreversible complications. For the second patient, the use of cICP immediately warned the clinicians, indicated intrahospital overnight observation, and subsequently detected the development of ACS. This sequence of events shortened the delays to necessary surgical myofascial...
decompression in a patient with injuries often managed as an outpatient. The last case of this manuscript showed an example on how cICP can help avoid unnecessary fasciotomies. This is even more poignant for this medically comorbid patient where every surgical procedure is associated with higher perioperative risk. Overall, cICP is a powerful adjunct in the management of ACS. The continuous assessment of ICP provides increased granularity in depicting the global clinical picture compared to intermittent ICP measurements. Simple intermittent measurements, either over or below the 30-mmHg diagnostic cut-off, can mask important overall trends, resulting in inappropriate care and undesired complications. We do not know if the patients diagnosed with compartment syndrome by this technique would have developed a severe form of ACS. We also do not know if the patient diagnosed as no compartment syndrome would have erroneously been diagnosed with compartment syndrome by standard techniques. Finally, we do know that the patient diagnosed as no compartment syndrome did not subsequently develop signs of compartment syndrome or sequelae of missed compartment syndrome.

One cannot emphasize enough the importance of the early diagnosis of ACS and subsequent decompressive fasciotomies for the clinical evolution of a trauma patient. Nonetheless, value-based health-care assessment of cICP by hospital administrators would incentivize the use of this technology despite its added cost. Avoiding unnecessary fasciotomies has a direct impact on operative room demand and may reduce the number of days that patients are admitted on surgical units. Furthermore, it could reduce the cost and burden associated with the management of fasciotomy wounds. Conversely, the individual morbidity and economic burden associated with missed ACS is also colossal. Groups estimated health services cost of missed ACS to be close to 50,000$ during the first year following diagnosis compared to less than 10,000$ if early diagnosis is made. Ultimately, additional devices can be cost-effective if used correctly by avoiding progression to late stages and unneeded surgeries. Preventing some of these undesirable outcomes and devastating complications with the use of cICP would greatly serve our healthcare system and will be the focus of future investigation.

This is the first case report describing the feasibility and safety of a new cICP monitoring device (MY01 Inc., Montreal, Canada). We encountered no complications like infection, bleeding, nerve injury or device breakage at removal. Our experience highlights 2 important clinical implications: (1) cICP can help avoid unnecessary fasciotomies in cases at risk of ACS and (2) cICP can alert care givers to ACS before clinical signs which can help salvage the affected limb and significantly decrease the risk of debilitating complications. Continuous clinical monitoring remains paramount and standard in this difficult diagnosis. The successful application of a device capable of cICP monitoring in this case series highlights an important step towards what is needed clinically for the accurate diagnosis of ACS and successful management. This preliminary clinical data has important implications for the management of ACS not only in level 1 trauma centers but also in remote areas where
continuous clinical monitoring cannot be delivered. Ultimately, cICP monitoring has the potential to be an important tool for both the traumatologist and trauma patient alike.

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