# Comparison of Three Devices to Measure Pressure for Acute Compartment Syndrome

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**ABSTRACT** Introduction: Acute compartment syndrome (ACS) is a well-recognized and common emergency. Undiagnosed ACS leads to muscle necrosis, limb contracture, intractable pain, and may even result in amputation. Methods: Three devices (Synthes, Stryker, and MY01) were compared in a pre-clinical rat abdominal compartment syndrome simulation. Simultaneous measurements of intracompartmental pressures allowed concurrent comparison among all devices. Results: Large variations from the reference values are seen with the Synthes and Stryker devices. Variances are large in these two devices even under ideal conditions. The MY01 device was the truest indicator of reference pressure in this ACS model (over 600% more accurate). Conclusions: The MY01 device was the most accurate device in tracking pressure changes in this rat model of abdominal compartment syndrome.

## INTRODUCTION

Acute compartment syndrome (ACS) remains a clinical problem for all trauma victims. High-energy trauma causes swelling and increased pressure within the affected muscle compartments resulting in reduced blood flow. ACS is a well-recognized and common emergency.[1] The usual cause of this condition is trauma. Undiagnosed ACS leads to muscle necrosis, contracture, and could eventually result in chronic infection or amputation. The only way to avoid these complications is early recognition and attendant decompression of the affected muscle with a large incision to release the fascial containment of the compartment.[2] Missed compartment syndromes are an issue in combat situations.[3] A failure to release the supra-physiological pressure within a few hours will result in muscle death and severe intractable pain, paralysis, or sensory deficits.[4,5] A reliable method for the accurate and reproducible diagnosis of ACS, especially in the obtunded, polytrauma, or distracted patient, has yet to be developed. Currently, the diagnosis of ACS is made on the basis of physical exam and repeated needle sticks over a short timeframe to measure intracompartmental pressures. Existing technology for continuous pressure measurements is insensitive,[6] particularly in the deep tissues and compartments,[7] and their use is restricted to highly trained personnel.[8] They are of little use in field conditions. Consequently, resolution or clarification of the diagnosis of ACS would be a great asset. Although newer technologies are being tested,[7,9–12] many newer techniques seem to have major diagnostic problems and/or interfere with complete care of the patient. There is therefore a need for an always-on minimally invasive device that does not interfere with transportation or total care of the patient. An insert and forget technique for continuous monitoring is also desirable. Newer technology needs to monitor all potential areas of interest without being labor-intensive, relying on highly educated technicians, or be excessively user dependent.

Over the past several years, tremendous advances in silicon microfabrication techniques have led to the development of miniaturized sensors (including but not limited to pressure, temperature, acceleration, flow, angular acceleration, touch) that are finding many applications in video gaming devices, automotive and aerospace industries, process control and industrial monitoring, and medical monitoring. A newer device based on this technology is being brought to the market that seems to have the potential of fulfilling these criteria. MY01 (NXTSens Inc., Montreal, Canada) is a temporary, indwelling compartment-based sensor that can be accurately inserted by technical personnel with minimal training via a single needle syringe. The authors represent an academic-corporate relationship with interests in the corporate entity in the form of ownership and future possible stock holdings. The device is currently undergoing FDA regulatory approval. The device is capable of single point measurements or continuous real-time monitoring. The goal of this project was to compare its performance against two currently used technologies (Stryker [Stryker Inc., Kalamazoo, MI, USA] and Synthes [Depuy-Synthes Inc., West Chester, PA, USA] compartment pressure measurement devices). Building on prior laboratory work, a preclinical pilot study was carried

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out in a rat model. The null hypothesis was that there would be no difference in precision or sensitivity between the three devices.

## MATERIALS AND METHODS

Abdominal compartment syndrome was chosen as a surrogate for extremity ACS. This is because of the easier positioning of the study devices in the same position. The Synthes device uses a membrane sensor that will perform regardless of position in tissue or fluid but is more accurate in fluid. The Stryker device uses a standing column of water to read pressure and therefore will be most accurate in a fluid environment like inside the peritoneal cavity. Adult male Sprague-Dawley rats, weighing 600 g, were used from the retired breeders maintained at the Charles River facility (Wilmington, MA). The study was approved by the McGill Facility Animal Care Committee, in keeping with the guidelines of the Canadian Council on Animal Care. The animals were sedated with carprofen and anesthetized by breathing isoflurane in an induction box and mask. The animals were immobilized in supine position on a heating plate. Anesthesia was maintained with isoflurane throughout the entire surgery and observation. The abdomen was shaved allowing a perimeter of at least 1 cm around the surgical site and washed with 2% chlorhexidine solution. The rat's vital signs and temperature were continuously monitored during the entire experiment. An abdominal puncture in the left flank of the animals was performed, and an intraperitoneal catheter (no. 12 catheter) was placed and exteriorized at the lower end of the incision. To provide a waterproof closure of the abdominal cavity, an additional suture of the above-mentioned layers encircling the intraperitoneal catheter was performed, and finally, the skin was sutured. Retroperitoneal implantation of the pressure sensors for continuous monitoring of the intraperitoneal pressure (IAP) was accomplished using an adjacent entry portal. A retroperitoneal position was chosen to ensure that the MY01 device could measure transmitted pressures, mimicking the conditions in an extremity muscle. It avoids the position of being directly in the pool of fluid in the abdominal cavity and therefore just being a measurement of whatever pressure what artificially induced. The incision was carefully closed with a single interrupted suture, including all muscle layers and the fascia. Three sensors were used for this study: Quick pressure Stryker monitor set, compartmental pressure monitoring system by Synthes, and the experimental advanced sensor microsystem from MY01. The MY01 is a high-precision implantable pressure sensor that is capable of measuring the compartment pressure as accurate 0.1 mmHg. It was placed directly into the abdomen. MY01 is calibrated within the physiological pressure range by an extremely precise pressure chamber that can provide the accuracy of ±0.008 mmHg. The Micro-Electrical-Mechanical System (MEMS) pressure sensor is a parallel plate capacitor with a 20 μm diaphragm made of single crystal silicon, separated by a 1 μm vacuum gap. Any pressure changes cause the diaphragm to deflect and changes the MEMS capacitance. The capacitance value of the MEMS is accurately measured and translated to pressure. MY01 is calibrated within the physiological pressure range by an extremely precise pressure chamber that can provide the accuracy of ±0.008 mmHg. The measured pressure by MY01 is broadcasted to a cloud storage database and to a MY01 cellphone application.


**FIGURE 1.** Image showing a screenshot of a recorded video indicating different pressure monitors in place during the experiment. The Stryker, Synthes, and MY01 were in the retroperitoneal space not in direct communication with the fluid or peritoneal cavity. The Ashcroft device was in line with the infuser providing reference for infusion pressure. The METEK device was in the peritoneal space communicating through a standing column of water.

An inline industrial pressure monitor was used as a control to measure the peritoneal space pressure (Fig. 1). The IAP was measured directly and independently via a high precision reference gauge (METEK). The METEK was attached to an IV-line filled with IV solution. The IV-line then was connected to a catheter that was inserted into the abdomen, right next to all three Stryker, Synthes, and MY01 devices. The high precision and factory-calibrated gauge called METEK (METEK Crystal 15PSIXP2i-S2) was to directly measure the IAP pressure in the fluid-filled cavity. The precision of the METEK is as high as ±0.15 mmHg in the range of 0 to 750 mmHg. The recorded values of all the devices (MY01, Synthes, Stryker, and the reference gauge METEK) were demonstrated with respect to time (Fig. 2) as well as the reference gauge METEK (Fig. 3) to be able to see and compare how accurate each device can trace the pressure. The IV-line and METEK were placed on a table with the same height as the rat abdomen to avoid false reading due to liquid head pressure at different heights. The input pressure of the supply was usually slightly higher than the reference gauge METEK since there was a small water leakage at high pressure from the sutured wound where the devices were inserted. In the data analysis only, the high precision reference pressure Gauge METEK was used as a reference. The relationship is seen in Figure 4.

To generate a raised IAP, warmed (37°C) normal saline (NS) solution was infused to a rat. A standard intravenous infusion set was connected to the bag of the 1,000 mL NS and attached to a stopcock connected to the exteriorized intraperitoneal catheter. The NS bag was elevated well above the animal to provide a pressure gradient. A digital pressure trans-

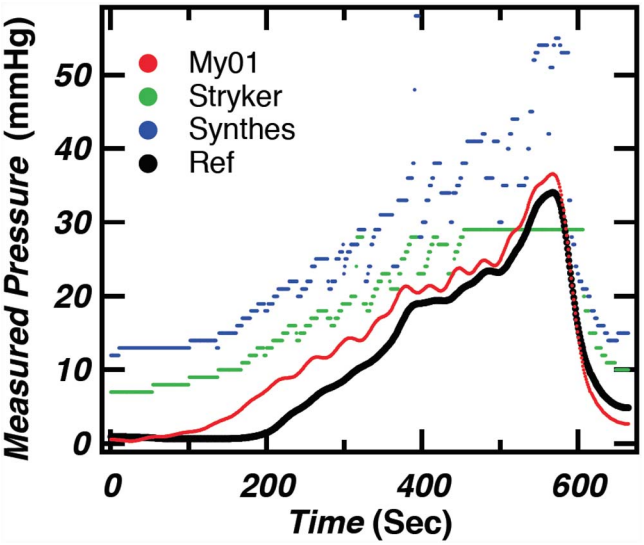


**FIGURE 2.** Bottom line represents pressure device inside abdomen (METEK). Three other lines show test device responses. Solid line closely tracking actual pressure is MY01 device. Stryker device regularly quit working after 400 seconds often near 30 mmHg as measured by that device (Flat line on graph).

ducer (METEK Inc., Taiwan) was placed inside the abdomen to ensure pressure was rising as per our model. This sensor was able to measure rough changes in pressure. Another sensor (Ashcroft Inc., Stratford, CT, USA) was connected inline to the catheter to measure externally the pressure applied through the catheter. The Ashcroft device was placed on the IV solution supply line connected to the IV-bag to monitor the pressure of the supply line. The stopcock was then opened to the intraperitoneal catheter to fill the peritoneal cavity and kept open throughout the experiment to ensure a constant pressure even in the presence of minor fluid resorption and leakage. The IAP was gradually stepwise increased to 35 mmHg. Comparison measurements were also taken with abdominal decompression. To decompress the abdomen, the NS bag was brought below the level of the animal and the intraperitoneal fluid was allowed to drain back into the bag. At the end of the experiment, euthanasia was performed.

## RESULTS

The result and measured pressure via different devices were plotted in representative Figures 2 and 3. Figure 2 demonstrates the pressure measured by all three devices as well as the METEK reference gauge vs. time. The MY01, Stryker, Synthes, and METEK data are indicated as red, green, blue, and black dots, respectively. The MY01 and METEK devices automatically sent their real-time readings (as fast as 1 data point/s) to a personal computer through Bluetooth and a RS232 communication port, respectively—while the Stryker and Synthes readings needed to be manually recorded. To be able to track down the readings of the Stryker and Synthes devices and reduce possible human error, both devices were video-recorded throughout the experiment to record the measurements at the appropriate time points. Figure 1 presents a screenshot of one of the videos recorded during the experiment displaying the Stryker, Synthes METEK, and Ashcroft device. The recorded videos were synchronized with MY01 and METEK via personal computer clock and a stopwatch.

IAP was raised up to about 35 mmHg by injecting NS into the abdomen of the rat during the first 500 seconds and was lowered by allowing the NS to drain out of the rat. We observed that the MY01 device was able to adequately trace the pressure variations and closely followed the reference gauge (METEK). The Stryker and Synthes devices were also able to detect the pressure variations qualitatively although their precision suffered from different types of drifts and offsets. We expected that such pressure drifts might occur in the tracings of the Stryker and Synthes devices due to formation of blood clots, dielectric, and/or temperature variations. The experiment was repeated three times independently on each animal and all the results were consistent. In a few cases, the Stryker device was observed to stop tracking pressure between 25 and 30 mmHg. The Synthes device also showed some initial reading shift immediately after it was inserted into rat, although the manufacturer's instructions were carefully followed. This may be due to dielectric or temperature variations picked up at the sensor surface. The MY01 device did not show any significant pressure drift. It is designed and fabricated to be insensitive to dielectric changes and has an integrated thermometer to measure the temperature as precise as 0.1°C. The measured temperature is used as part of the calibration software of the MY01 sensor, making it robust against temperature variations.

Figure 3 presents pressure measured by all the devices versus the METEK (dashed line) pressure gauge. It shows the convergence of the MY01 and METEK values, as an independent reference, while also indicating the pronounced deviation of the Stryker and Synthes readings. The error bar on the readings of the different devices is exhibited in Figure 3 (right graph). The MY01 has an error bar as small as 0.1 mmHg, while the Stryker and Synthes have minimum error bars of 1 mmHg under even these optimized conditions (no movement, no angular changes).

Based on a linear regression analysis, the MY01 device showed at least 670% superior precision in comparison to Synthes and Stryker, taking into account the precision limitation of the reference gauge itself. The on-bench (in vitro) preliminary experiment with more controlled conditions and using a sophisticated pressure monitor and gas supply suggests that MY01 is at least one order of magnitude more precise than the other devices.

## DISCUSSION

All of these devices showed linear tracking with pressure changes in this model of ACS. All these devices were tested in a model to maximize their ability to monitor pressure.

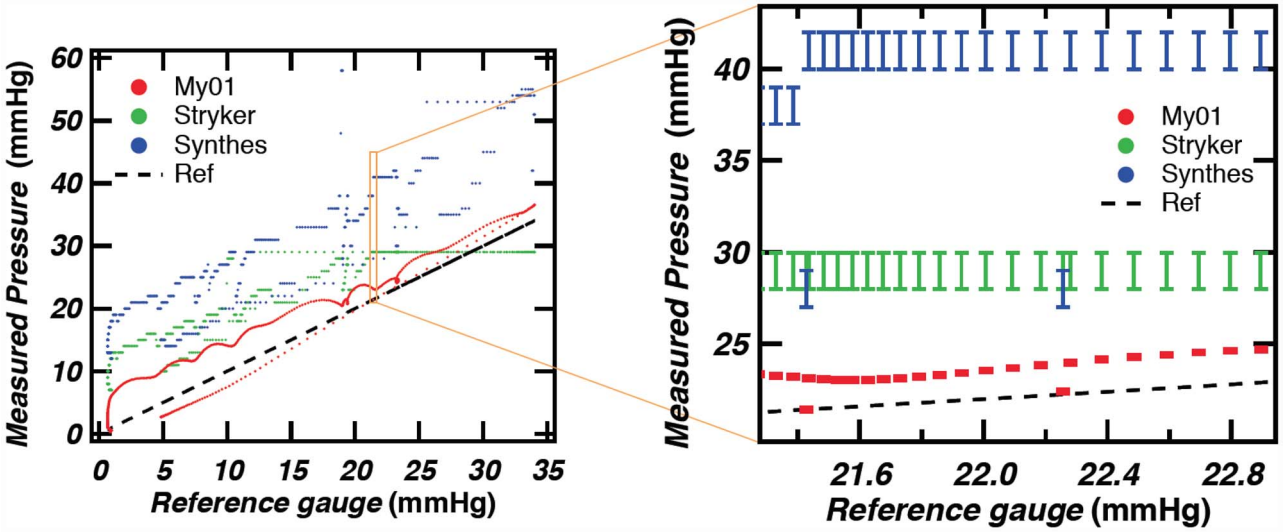


**FIGURE 3.** Best result would be one-to-one relationship with reference device. Graph on left shows reference line at bottom. Red line closest to reference line is MY01 device. Graph on right illustrates small subset of results before the critical pressure of 30 mmHg. Line at bottom is reference values. The Stryker device (middle error bars) stopped working before the critical pressure was reached. MY01 device was most accurate to the reference device (dashed line nearest reference line). Measurements were taken during pressure-driven inflow and the gravity defined outflow.

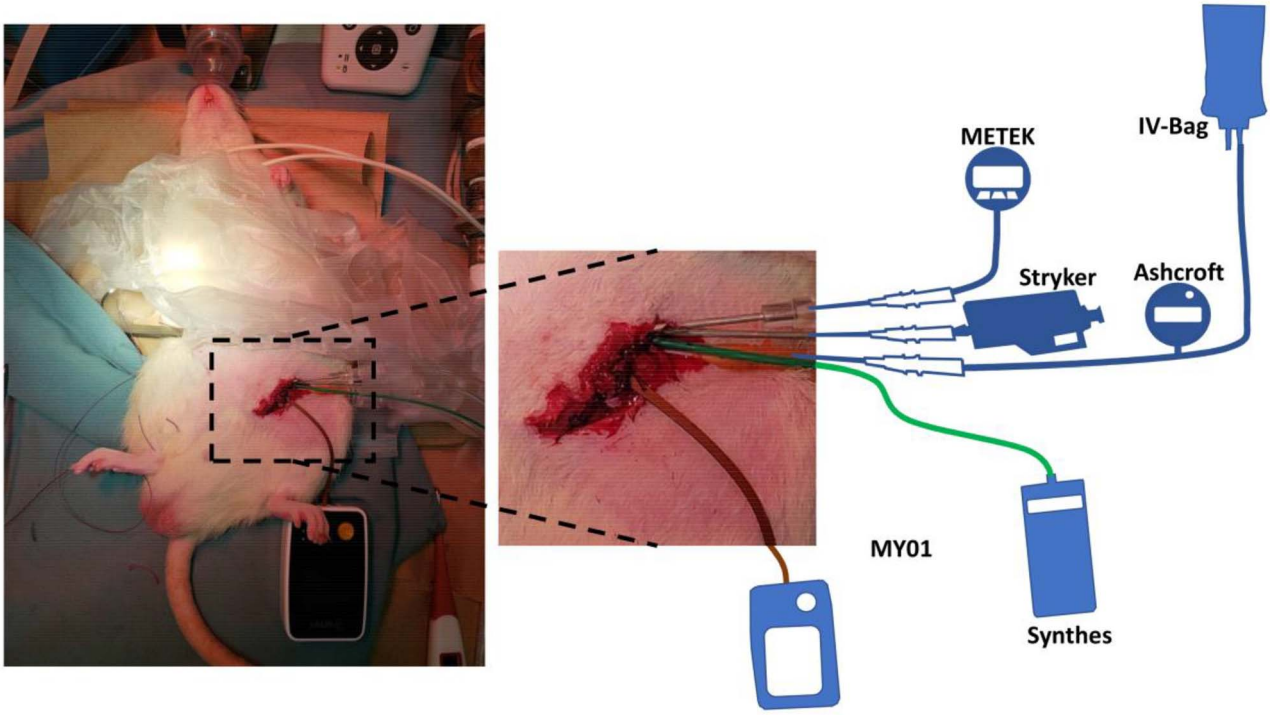


**FIGURE 4.** Apparatus schematic showing relationship between all measuring devices.

There are no literature references to substantiate abdominal compartment syndrome as an identical process as limb compartment syndrome. This model implemented ensures that all three sensors could be tested simultaneously. The limb ACS model in the rodent was of insufficient volume to accept all three sensors. The position was of short enough distance to allow all sensors to be introduced in a normal fashion and to have the entire sensing portion of the device to be within the high-pressure zone. No movement or angular changes were inserted into the testing conditions for the data reported here. When moved or rotated, these two devices had large variances in values not seen in the MY01 device. It is well documented that the Stryker device although in common usage does not respond to real-life situations with accuracy.[6] Certainly in the real-life clinical setting (moving patient limb, transport conditions), the Stryker and Synthes devices fail to meet

the standard needed for accurate measurement. The Stryker and Synthes devices were used exactly according to their instructions and user manuals. Stryker was calibrated right before insertion and showed 0 mmHg as per its instruction. Synthes has an automated calibration that it executes upon plugging and turning on its sensor. It showed 0 mmHg prior to insertion as well according to its user manual. The Stryker and Synthes devices were also able to detect the pressure variations qualitatively, although their precision suffered from different types of drifts and offsets. The Synthes device also showed some initial reading shift immediately after it was inserted into rat, although the manufacturer's instructions were carefully followed. This may be due to dielectric or temperature variations picked up at the sensor surface.

MY01 was also the only device that is designed for indwelling continuous ACS measurements in the clinical setting. The other devices are single use designs but the Stryker device has been used in experiments for continuous monitoring in the past.[13] The MY01 device showed at least 670% superior precision by linear regression modeling in comparison to Synthes and Stryker. There is actually some evidence that the MY01 was more accurate than the actual reference gauge itself. Calibration of the reference gauge had error bars larger than the MY01 device. The on-bench (in vitro) experiment with more controlled conditions and using a sophisticated pressure monitor and gas supply suggests that MY01 is at least one order of magnitude more precise than the other devices.

Measurement bias may be present because of the small number of animals in this pilot study ($n = 6$). The tests were run three times in each rat in order to diminish that effect (18 events). Because of the primary outcome score being a measurement of pressure, this was a desirable method to decrease cost and decrease the number of animals sacrificed. Previous work had been done with multiple events in an ex vivo pressure chamber model and had the same results (unpublished data). This animal pilot study was performed to ensure that all three devices would work in an animal model and not be different from the ex vivo results. Bias may have potentially been introduced into this study because corporate sponsors funded it. The lead authors have no ties to the corporate sponsors and the clinical investigators who performed the actual tests. The senior author does have shares in the company. The MY01 device was the best at detecting pressure changes. It is a single use wireless compatible device that gives local results on a display at the wound site as well as wireless connection to the care provider. This is a step towards what is needed clinically in not just the hospital-controlled setting but in more austere prolonged field care environments where continuous monitoring or time demanding one-on-one care cannot be delivered.

## FUNDING

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