Article

MEMS Sensors Driven Scientific Process to Solve Acute Compartment Syndrome

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Background   Sensor usage in the classical scientific process has allowed new experimentation in medicine. We report on the design process of a MEMS sensor being used for muscle trauma evaluation in diagnosing acute compartment syndrome (ACS), a medical ailment costing society billions of dollars per year.

Objectives   Modeling the disease with scientific process allows a more complete understanding of the disease. The goal was to formulate a hypothesis that could be tested to aid in making the diagnosis of ACS accurately.

Methods   Scientific process was observed throughout the disease modelling process. Background information was improved and clarified, new pre-clinical models were designed and verified, a hypothesis built on pressure measurement with MEMS sensors was carried out, and the testing of the model as verified against previous clinical data was accomplished.

Results Scientific process resulted in hypothesis generation around the relationship of intracompartmental pressure measurement and the disease process and therapy. This resulted in new understanding of ACS, accurate modelling, and sensor. Design resulting in a MEMS device that has an extremely high sensitivity and specificity (over 99%) in treating and diagnosing the disease.

Conclusion   MEMS sensor technology defines the new gold standard of implanting a sensor in a muscle compartment that allows accurate diagnosis of ACS with continuous trends in pressure.

Keywords: Acute Compartment Syndrome, MEMS, scientific process; biomarker, pressure, diagnosis, medical device, bioengineering, medicine.

1. Introduction

Sensors are the pen and paper of the next wave of medical data acquisition. Although medicine is a very conservative industry, adoption of this new wave of medicine is underway. Early sensor products, that are now coming to market, will change the way we think about diagnosis and outcomes. A combination of broadband internet, micro electrical machine systems (MEMS), and wireless communication standards is facilitating this approach. Several medical sensors have emerged for the purpose of monitoring medical conditions. There are many reasons for this. Uniquely, remote reliable sensing technology allows a new look into old problems. Conditions we previously had difficulty diagnosing and treating can now be more completely explored [1-7]. Continuous monitoring offered by sensors can help early detection of emergency medical conditions

and improve communication in those situations. Our research group has developed several early sensor concepts in the search for more information on important medical conditions [8-13]. One of the goals of this series of studies was to establish a scientific process to better understand acute compartment syndrome (ACS). ACS is a surgical emergency most commonly occurring in the extremities after trauma with resultant swelling within a closed compartment. This closed compartment may result in death of the confined muscle. Release of the muscle with extensive surgery is the treatment. Timely diagnosis with surgery will save the muscle from dying. Unfortunately, many more releases or fasciotomies, are performed than are needed. This results in large costs to the system and significant morbidity to the patient. The concept of compartment pressure and its disease analogue of ACS remained a vexing issue for all trauma surgeons [14-21]. There was a knowledge gap regarding the pathophysiology, diagnosis, treatment, and outcome for ACS. For a disease associated with a financial burden to society that represents billions of dollars worldwide, the literature did not have established baseline diagnostic tools to predict treatment and outcomes [22]. Modeling the disease with scientific process allows a more complete understanding of the disease. Following scientific process (Figure 1), a MEMS sensor (Figure 2) was developed capable of monitoring tissue trauma in muscle. This was accomplished through a design principle process to allow direct insertion of the sensor assembly into the muscle that is being monitored. Other methods in the literature relied on a standing water column and an external sensor [19, 23]. The goal of the process was to formulate a hypothesis that could be tested to aid in answering the overall question of making the diagnosis of ACS accurately. The hypothesis tested here was that pressure monitoring, in particular continuous data, was important for diagnosis of ACS.

2. Materials and Methods

Scientific process was applied to the disease process of acute compartment syndrome (Figure 1). Strict scientific process entails formulation of a question based on current knowledge. Background information was compiled, and the English literature was reviewed for pertinent diagnostic criteria that would allow a question on diagnosis to be formulated (Figure 1 – Areas 1 and 2). Over 350 papers were examined. It was obvious from these readings that two major deficiencies in the literate existed. There was incomplete understanding of the epidemiology of ACS and there was no common classification that allowed review of disparate studies. Studies were then carried out [9, 10, 13, 19, 21-28] to fill these deficiencies. This allowed hypothesis generation around the findings – in particular that pressure was relevant to ACS progression and possibly diagnosis (Figure 1 – Area 3). A new device was produced to test the hypothesis (Figures 2 and 3) Several experiments were then designed to determine if accurate pressure measurement was possible (Figure 1 – Area 4) and then applied to pre-clinical and clinical modeling (Figure 1 – Area 5). These results were examined then used to fine tune the hypothesis (Figure 1 – Area 6 and 7) before being communicated and changing the diagnosis of ACS (Figure 1 – Area 8 and 9).
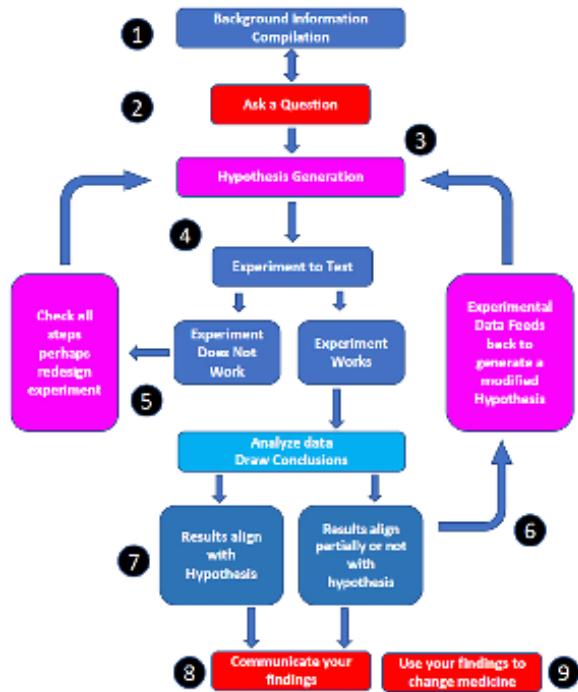
Figure 1. Scientific process and the accompanying action areas designated by the numbers in the schematic.
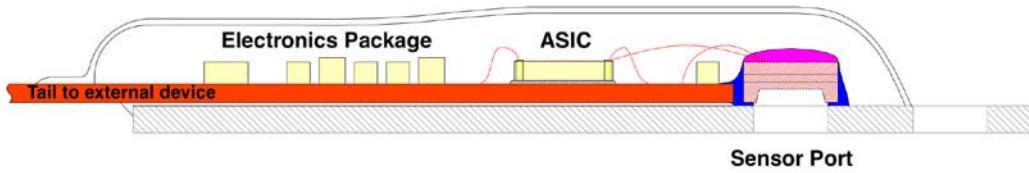

Figure 2. MEMS Sensor- the implanted portion of the device**.**

Figure 3. MY01 ™ compartment syndrome sensor- Designed to allow real time cloud-based data retrieval and display in a smartphone application, the electronic health record, and at the bedside.

3. Results

A big data approach (Figure 1 area 1) was used to better understand the clinical problem [22, 24]. A common grading system was also validated (in press, 2023) to compare the papers. Several

interesting new correlations were found in the big data study but the finding that hypertension was protective for ACS led the author s to believe that pressure measurement in the compartments was an important biomarker. This allowed the formulation of the question of how accurate pressure measurement in diagnosing ACS and the hypothesis was that accurate pressure measurement would be an important tool (Figure 1- Area 2 and 3). Accurate MEMS sensor-based device was designed and compared to other devices (Figure 1 – Area 4). Results showed that the new device (MY01 Inc) was 600% more accurate than current technology. It was also the only device that allowed continuous pressure sensing. Experiments to test this device were carried out (Figure 1 – Area 5) [10, 13, 23, 25, 26]. Feedback allowed us to modify the hypothesis to incorporate continuous pressure measurements as a more accurate tool (Figure 1 – Area 6). Eventual results aligned with the hypothesis allowing a change in diagnostic criteria for ACS (Figure 1- Areas 7,8,9 and Figure 4).
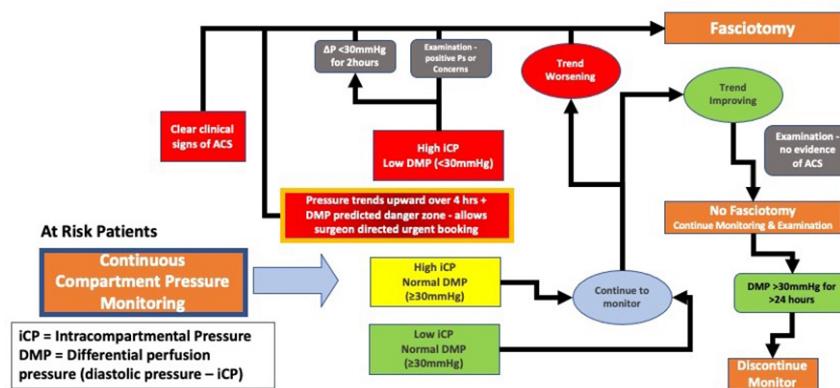

Figure 4 Algorithm from the scientific process around MEMS pressure sensing. This represents incorporation of the new literature on pressure sensing that allows modification of the classic literature.

4. Discussion

Acute Compartment Syndrome (ACS) is a surgical emergency most commonly occurring in the extremities because of trauma and resultant swelling within a closed compartment. It is ultimately the result of increasing pressure leading to circulatory compromise, tissue ischemia, and necrosis [16, 28-31]. Monitoring of objective continuous pressure values has been difficult. Micro electrical machine systems (MEMS) techniques can be used to design biomedical sensors to obtain objective data. MEMS are transducers, either sensors or actuators, which convert one type of signal into another type of signal. MEMS devices are advantageous, due to their small size, closely related to characteristics such as ease of integration, light weight, low power consumption. Other advantages include reduced fabrication costs due to high mass production and high accuracy, sensitivity, and throughput. The MY01 device (Figure 2 and 3) was designed with these advantages in mind. This MEMS sensor product was designed to aid in the diagnosis of acute compartment syndrome [23]. The device represents a true transition to digital health monitoring as it was combined with a smartphone application for real time data study. This allowed cloud-based storage and integration with electronic health records. The research groups involved [9, 19, 22, 23, 27, 32, 33] have also used the device for the scientific process (Figure 1 – Area 4) to better understand ACS disease process – an example of how new technology and information can be used to better define medical diseases.

It is now understood that abnormally elevated pressure within a compartment is an early and important marker of ACS [29, 34]. Continuous pressure monitoring of the affected compartment is a desired marker for the progression or resolution of ACS and this sensor driven information provides the basis for recommendations regarding the need for fasciotomy (Figure 3). This information now allows the treating physician to deploy a diagnostic sensor proactively with early use aiding care management.

5. Conclusions

What do we get from sensor proliferation? We get better recording of disease progression – whether through medical record amplification or wellness quantification. This example showed how accurate MEMS sensing platforms can permit better disease understanding. MEMS sensor technology has defined a new gold standard of diagnosing acute compartment syndrome. Implantation of a sensor in a muscle compartment allows accurate diagnosis of ACS with continuous trends in pressure.

Author Contributions: For research articles with several authors, a short paragraph specifying their individual contributions must be provided. The following statements should be used "Conceptualization, GM and EJH.; methodology, GM, APH, EJH.; formal analysis, GM and EJH.; investigation, GM, APH, EJH.; resources, GM and EJH.; writing—original draft preparation, EJH.; writing—review and editing, GM, APH, EJH.; project administration, GM EJH.; funding acquisition, GM EJH. All authors have read and agreed to the published version of the manuscript."

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Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to proprietary sensor technology.

Conflicts of Interest: Dr EJ Harvey is a founder of MY01 Inc, a paid employee and founder of NXTSens Inc, and founder of Stathera. He is a paid consultant at CMAJ Medical publications (Editor in Chief of Canadian Journal of Surgery)

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