Point-of-Service Device for Idetification of Dyssynergic Defecation

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The Clinical Need

Motivation

- Each year, 63 million Americans are affected by chronic constipation, and less than half of this constipation population seeks medical treatment.
- Of this treatment population, roughly half will improve with conventional dietary/laxative therapies while the other half of this population will not.
- The reason why this particular group does not improve with dietary/laxative therapies is because they suffer from a specific type of constipation known as dyssynergic defecation (DD).

Problem

- DD arises from muscle coordination issues in the anorectum, meaning problems with anal sphincter relaxation, puborectalis muscle relaxation, and/or intrarectal pressure generation during defecation.
- While DD cannot be treated with dietary/laxative therapies, studies have shown that biofeedback therapy—a type of physical training regimen—has an 80% positive response rate in DD patients.
- The current gold standard tool for diagnosing DD is anorectal manometry but its drawbacks include:
  1.) high start-up and maintenance costs often exceeding $75,000 and $300,000 respectively
  2.) complicated data analysis
  3.) inability to assess puborectalis muscle activity and intrarectal pressure
- As a result of the high costs and expertise required to operate ARM, fewer than 200 clinics across the United States house ARM technology

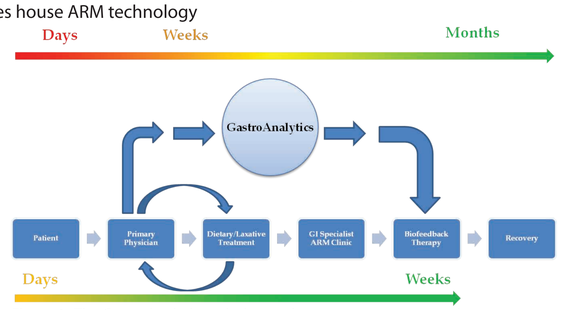


Figure 1. The GastroAnalytics solution to the current treatment pathway.

Critical Design Requirements

Requirement	Specification
Finger-based	≤ 3 mm thickness
Maintain finger function	≥90° flexion
Maximize patient comfort	Optimize through testing
Calibration of device	Yes
Interface with personal computer	Windows XP, Vista, or 7®
Relay data	≤ 200 ms delay
Interpret data	Yes
Low manufacturing cost	Less than $75 per use
Temperature performance	15-45°C
Electrical safety	Meet IEC 60601-1 standards
Biocompatibility	Meet AAMI/ANSI/ISO 10933 standards

Table 1. Critical design requirements that GastroAnalytics set out to meet for the final clinical prototype.

Basic System Overview

Our finger device will capture data from the patient which will be then be passed through our conditioning circuitry into a PC laptop. Diagnostic algorithms will interpret the signals and output a diagnostic recommendation to the user.

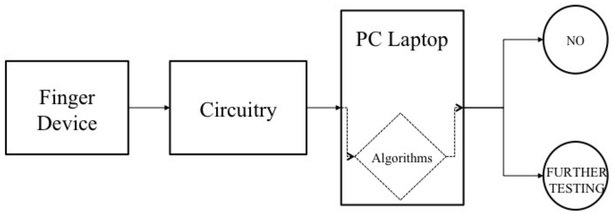


Figure 2. A system block diagram depicting the flow of information in our device.

Detailed Design

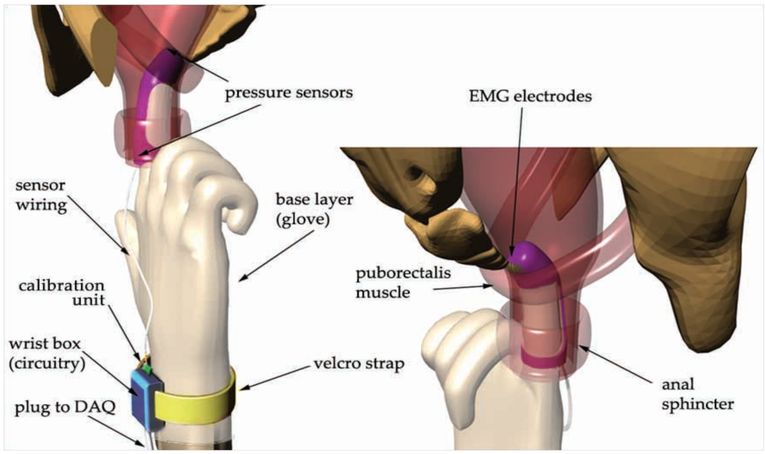


Figure 3. A model depicting how the device housing will integrate with relevant pelvic anatomy. The finger portion of the device will be capable of simultaneously obtaining EMG biopotentials from the puborectalis muscle, fluid pressure in the intrarectal region, and contact pressure in the anal sphincter region.

Inner Layer

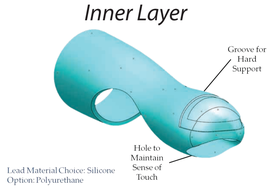


Figure 4. (left) The inner layer will interface directly with the physician's finger and provide a form-fitting structure that will allow a secure fit yet maintain the physician's range of motion.

Middle Layer

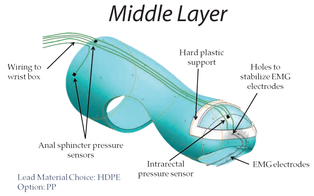


Figure 5. (right) The middle layer contains all the sensors and electrodes as well as the hard plastic support structure. The plastic support will provide mechanical integrity to the overall housing and maintain proper sensor placement.

Outer Layer

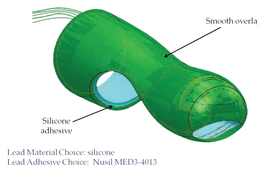


Figure 6. (left) The outer layer will interface directly with the patient's rectum. It will consist of a silicone overlay, which encases the device circuitry and ensures patient comfort and physician range of motion.

Graphic User Interface in LabVIEW

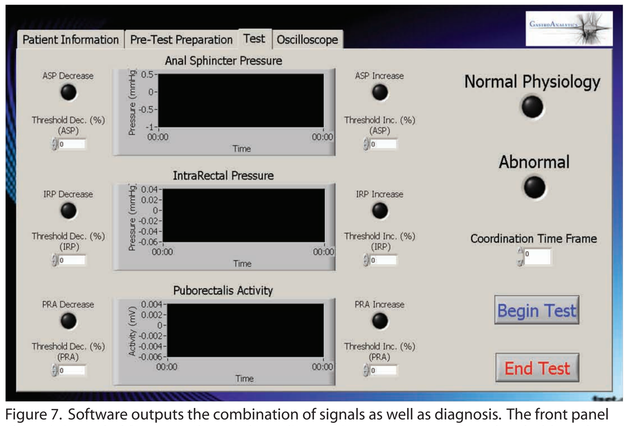


Figure 7. Software outputs the combination of signals as well as diagnosis. The front panel above is intended for research use where diagnostic parameters, such as thresholds and coordination times, are controlled by the physician.

Rapid Prototype

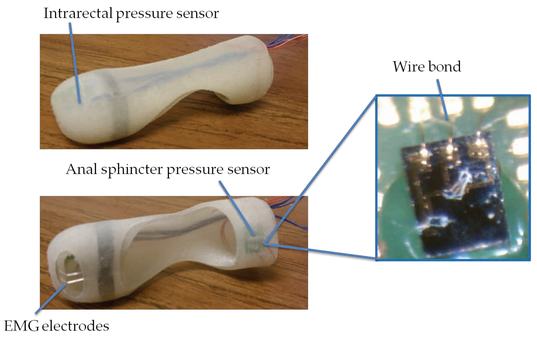
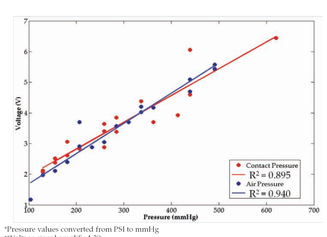


Figure 8. The rapid prototype above was printed out at the Medical Innovation Center using silicone-like material and was outfitted with two pressure sensors and two EMG electrodes. Additionally, the micro pressure sensors were mounted onto protoboards and then wire-bonded to larger pads.

Validation Testing Results



*Pressure values converted from PSI to mmHg
**Voltage signal amplified 20x

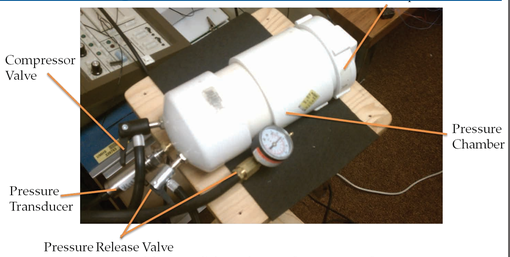
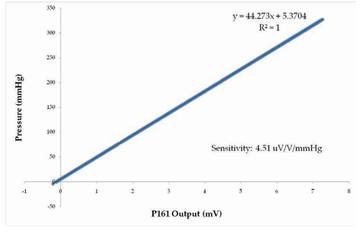


Figure 9. Utilizing a pressure chamber to test our sensors, we were able to validate the performance of our pressure sensors. Data suggested that our hypothesis of air pressure transduction through silicone was valid.

Calibrated Pressure Sensors

Intrarectal Pressure Sensor



Anal Sphincter Pressure Sensor

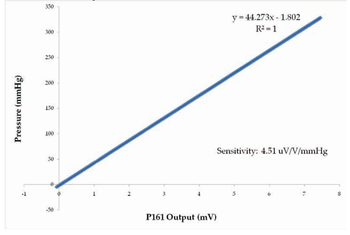


Figure 10. Using Microbridge technologies, we were able to calibrate both pressure sensors with a high level of precision.

Summary

Conclusion

- Defined clinical problem and design requirements
- Refined consensus design concept
- Validated device subsystems
  1.) Calibrated pressure sensors
  2.) Developed software interface and algorithms
  3.) Awaiting IRB approval for EMG

Future Steps

- First clinical prototype
- Raise capital ($50-$100k) for production and testing
- Complete Business Feasibility Study
- Look for potential licensee or acquisition

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