414

Schell A[1], Budgett D[1], Nielsen P[1], Smalldridge J[1], Hayward L[2], Dumoulin C[3], Kruger J[1]
1. University of Auckland, 2. Counties Manukau District Health, 3. University of Montreal

DESIGN AND DEVELOPMENT OF A NOVEL INTRA-VAGINAL PRESSURE SENSOR ARRAY

Hypothesis / aims of study

The measurement of the vaginal pressure profile is likely to be a desirable metric for both the monitoring and assessment of effective pelvic floor muscle training (PFMT), and the assessment of change in the vaginal pressure profile pre- and post-surgical correction of pelvic organ prolapse (POP) [1].

There are several commercially available 'pelvic floor trainers' but none have the ability to simultaneously measure abdominal pressure and PFM pressure, and is feasible to be worn during everyday activities [2, 3]. The aim of this project was to design and develop a wireless intra-vaginal device which would conform to the anatomical shape of the vagina; could be used during everyday activities; measure changes in the pressures exerted along the length of the vagina without distorting the vaginal walls; remain in position; display the pressures measured on a user friendly interface and have a recording frequency fast enough to capture rapid changes in pressure. The pressure sensor array had to also show good repeatability and reproducibility of the pressure profiles.

Study design, materials and methods

The intra-vaginal pressure sensor device (IVPSD) contains an array of eight pressure sensors (MS5803-02BA, Measurement Specialties, United States) which are mounted onto a flexible printed circuit (FPC) board to allow the device to conform to the anatomy of the vagina. The device went through several iterative shape designs to determine the most suitable for comfort and retention. The final design has a total length of 80 mm and a maximum width of 20 mm (Figure 1). The contoured edges cover a distance of 55 mm and are designed to sit within the rugae of the vaginal wall to reduce device movement. The cover is made out of a soft, biocompatible silicone (MED-4901, NuSil, United States), and cast using a silicone transfer press. The electronics module uses a nRF52832 (Nodic Semiconductor) low energy Bluetooth radio system. Data is transmitted to an Android tablet for data logging and realtime display and user feedback. Each pressure sensor sampled at a rate of 140 Hz.
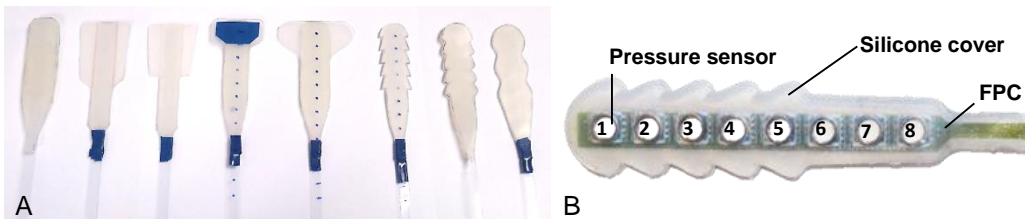

Figure 1: A) Prototypes of different shape designs for trialling. B)The IVPSD. The head of the device is sitting deep within the vagina. The top sensors measure abdominal pressure. The lower end of the device is located at the introitus. The sensors measure near atmospheric pressure.

Bench testing was performed to verify the performance of the device. It included the assessment of: pressure sensor drift, response to rapid pressure changes, bending and flexing of the device, hysteresis, hydration of the silicone encapsulation and temperature sensitivity. In order to validate the repeatability of the device, pressure profile measurements were obtained from four subjects (no symptoms of POP) across four different tasks: maximum PFM contractions (3x 5s), rapid PFM contractions (15s), Valsalva (3x 5s) and coughing (5x). For each test the device was self-inserted with the sensors facing towards the pubic bone (anterior). The order of tasks was random. After each set of tasks the device was removed and re-inserted to evaluate the repeatability of the pressure profiles. Data was analysed using MATLAB.

Results

Bench testing identified that bending and the effect of body temperature dominated the accuracy of the pressure measurements and their combined effect could introduce an error of approximately 5 mmHg.

All subjects for intra-vaginal testing were parous (2 vaginal, 2 caesarean). Mean age 49.2 years SD± 8.5. Due to the small sample size, no statistical analysis could be performed. The vaginal pressure profiles were distinctive for each task and subject. Figure 2 shows the profiles in blue for the initial insertion and in red for the re-inserted device. The overall reproducibility of the profiles was good. However, for some subjects the profiles of the second insertion were shifted. This was likely due the difference in device positioning for the re-inserted device. Retrospective data processing could compensate for the shift.
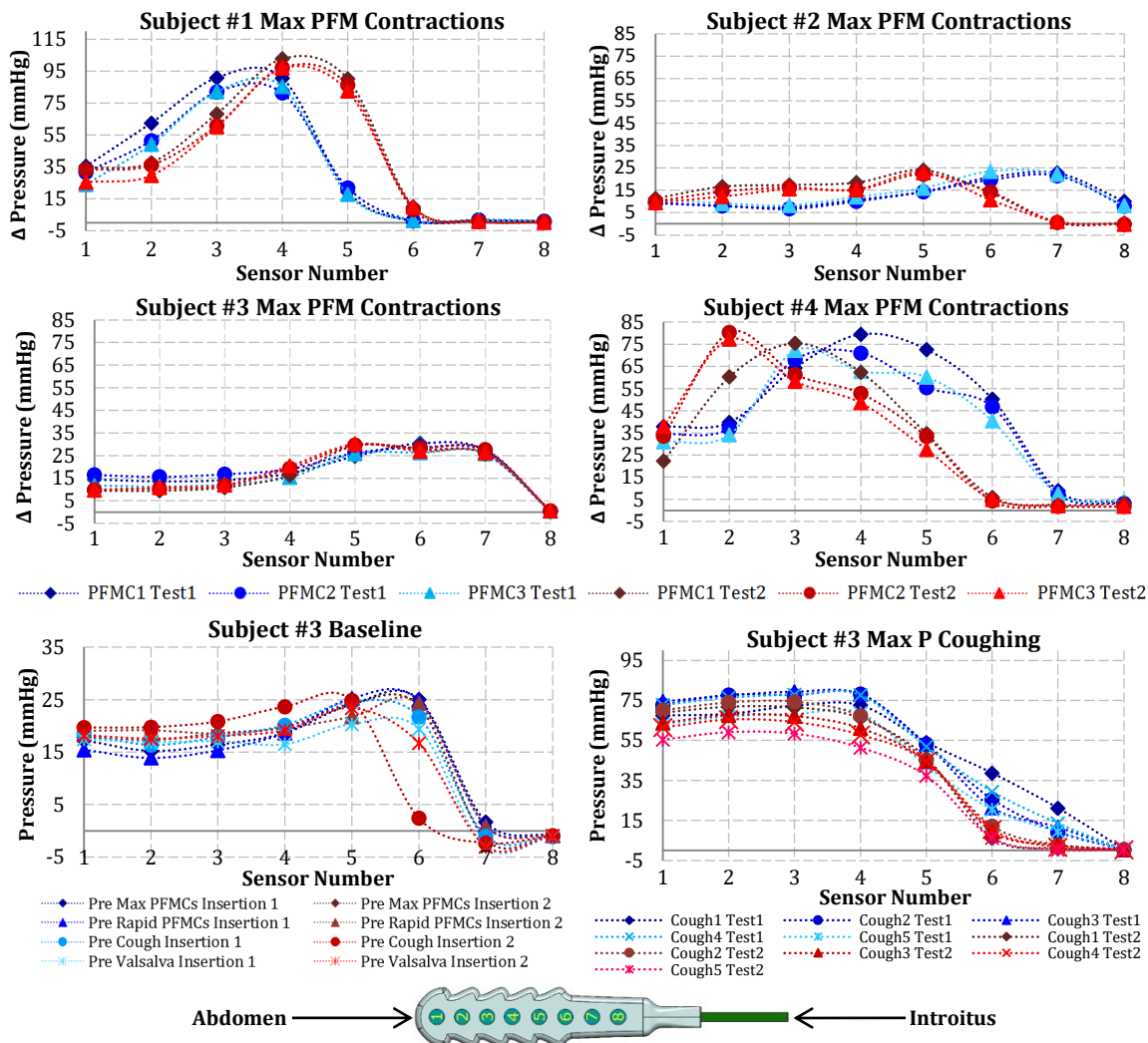
Figure 2: The vaginal pressure profiles of different tasks and subjects. Atmospheric pressure has been subtracted for the baseline pressure. The baseline pressures have been subtracted from all other profiles. Blue graphs show the profiles of insertion one, red graphs of insertion two.

Interpretation of results

The reproducibility of the vaginal pressure profiles appears to be good. When comparing data from different sessions, it seems the position of the device can vary, particular during tasks such as cough. This data provides confidence that the magnitude of the pressure differences generated when performing PFMT tasks is much larger than the magnitude of the error.

Concluding message

Bench-top and in-vivo testing verified that the IVPS device is reliable and repeatable when measuring the pressure profile along the length of the vagina at rest and during exercise.

References
1. Neurourol. Urodyn., vol. 24, no. 3, pp. 243–247, 2005.
2. "PeriCoach." Online. Available: http://www.pericoach.com/. Accessed: 24-Feb-2016.
3. "M!NNA kGoal." Online. Available: http://www.minnalife.com/products/kgoal. Accessed: 24-Feb-2016.

Disclosures