

## BEAT THE LEAK: A NEW DEVICE TO MEASURE THE VAGINAL PRESSURE PROFILE

### Hypothesis / aims of study

Pelvic floor disorders, such as stress urinary incontinence (SUI) and pelvic organ prolapse (POP), are costly in both psychosocial and economic terms and affect more than 25% of the female population [1]. Although the exact mechanisms of POP and SUI are poorly understood, the development of such conditions are likely to alter the pressures acting on the vaginal wall, and thus change the vaginal pressure profile. There is little research on the change in the vaginal pressure profile in response to either surgical correction of POP or as a consequence of pelvic floor muscle training. Recent reviews suggest that pelvic floor muscle training (PFMT) is an effective first line treatment for women with stress urinary incontinence, and mild POP [2]. However, more than 30 % of women are unable to effectively contract their pelvic floor muscles and PFMT is contingent on the exercises being performed correctly [3]. This means increasing the pressure in the region of the pelvic floor muscles (PFM), while keeping abdominal pressure low. This study aimed to develop and test a novel compliant and wireless intra-vaginal pressure sensing device (IVPSD) which is able to record the vaginal pressure profile at rest, during PFMT and everyday activities. Vaginal pressure profiles could be used as biofeedback for PFMT, being able to measure both abdominal and PFM pressure simultaneously, in addition to assessing the vaginal pressure profile pre- and post-surgery.

### Study design, materials and methods

The IVPSD contains an array of eight pressure sensors (MS5803-02BA, Measurement Specialties, United States) to accurately measure the pressure along the length of the vagina. The sensors are mounted on a flexible printed circuit (FPC) board to allow the device to conform to the anatomy of the vagina, without distorting the vaginal walls. A soft biocompatible silicone (MED-4901, NuSil, United States) is used as the encapsulating material. The array of sensors has a total length of 80 mm and a maximum width of 20 mm. 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 (Figure 1). The 250 mm long lead of the FPC connects to a small electronics module which is located outside the body. For bench-top and preliminary in-vivo testing, the device was connected to an SPI bus (USB-8452, National Instruments, United States) and a computer. LabVIEW served as the user-interface. Each pressure sensor samples at a rate of 140 Hz.

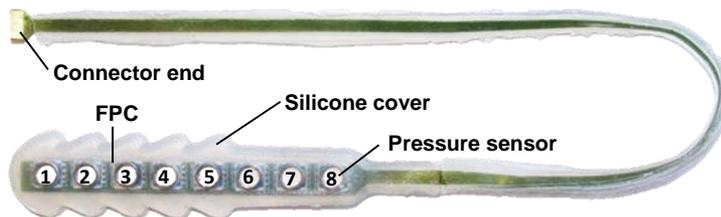


Figure 1: The IVPSD. The head of the device is sitting deep within the vagina. The top sensors measure abdominal pressure. The lower end of the device is located at the introitus. The sensors measure near atmospheric pressure.

Bench-top testing 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. Four devices were constructed for preliminary in-vivo testing. Each subject knew how to contract their pelvic floor muscles and had no symptoms of POP. The IVPSD was self-inserted and the following tasks performed: maximum PFM contractions (3x 5s), as many as possible rapid PFM contractions (15s), Valsalva (3x 5s) and coughing (5x). Vaginal pressures profiles were recorded for all tasks. Baseline pressures were recorded prior to each task, and the raw data was analysed using MATLAB. For each task the maximum and mean pressures were calculated. For selected tasks the rate of pressure change was also computed.

### Results

Bench-top testing indicated that bending and temperature may introduce an error of approximately 5 mmHg. Drift was negligible during the testing period. All subjects were parous (2 vaginal, 2 caesarean). Mean age 49.2 years  $SD \pm 8.5$ . The IVPSD was easy to insert and comfortable. Downward displacement of the IVPSD occurred only during cough or Valsalva, more so in the vaginally parous women. Each resting baseline pressure profile was unique, although a drop in pressure in the region of the PFM was recorded for all subjects, reaching near atmospheric pressure at the introitus. Distinctive vaginal pressure profiles were measured for each task and each subject (Figure 2). During PFM contractions the greatest increase in pressure was in the region of the PFM, shown by the sensors placed approximately 3.5 cm from the introitus (for 3 out of the 4 subjects). Pressure increases ranged from 23 mmHg to 120 mmHg. Pressure profiles for cough and Valsalva showed the greatest pressure increase at the most distal sensors which would be measuring abdominal pressure. Maximum abdominal pressures were in the range of 70 mmHg to 120 mmHg for cough and 30 mmHg to 85 mmHg for Valsalva. The greatest rate of pressure change was 605 mmHg/s recorded for cough. Due to the small sample size, no statistical analysis could be performed.

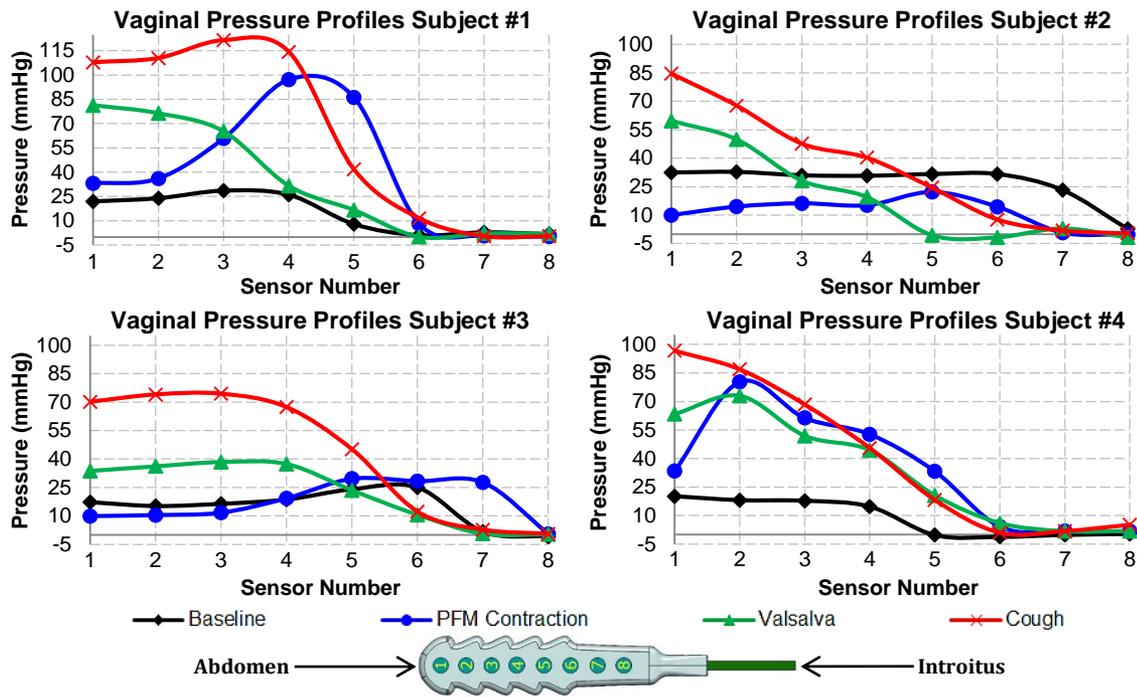


Figure 2: The vaginal pressure profiles of different tasks for all four subjects. Atmospheric pressure has been subtracted for the baseline pressure. The baseline pressures have been subtracted from the profiles.

#### Interpretation of results

The IVPSD is able to accurately measure the vaginal pressure profile and preliminary evidence suggests there are distinctive pressure profiles for the baseline and for each task. In-vivo movement of the device needs to be accounted for, which may be done using signal processing or through changes to the physical shape design. A sampling frequency of 140 Hz appears to be sufficient to capture rapid pressure changes, as experienced for coughing.

#### Concluding message

The simultaneous measurement of abdominal pressure and PFM pressure, producing a vaginal pressure profile, has great potential for the IVPSD to be used as both an effective and novel PFMT tool, and as an aid for clinician to define pre and post-surgical vaginal pressure profiles.

#### References

1. Obstetrics & Gynecology, (2014) 123 (1) 141-8
2. International Consultation on Incontinence 5th Edition; (2013) Conservative management Chapter 12. 1103-1229
3. Acta Obstetrics Gynecology Scandinavia (2001); 80 (10) 883-887

#### Disclosures

**Funding:** J Kruger -Aotearoa Postdoctoral Fellowship **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** University of Auckland Human Participants Ethics Committee. Ref no: 010994 **Helsinki:** Yes **Informed Consent:** Yes