

## TEST RE-TEST RELIABILITY OF A NOVEL WIRELESS INTRA-VAGINAL PRESSURE DEVICE.

### Hypothesis / aims of study

Recent clinical evidence has shown that Australian women have a 19% lifetime risk of requiring surgery for pelvic organ prolapse (1). Following surgery, patients are often advised to restrict their activity based on the assumption that increases in intra-abdominal pressure will adversely affect the tissue healing process. However, little empirical evidence is available to assist clinicians make decisions about the type and period of physical restrictions that should be followed. As a result there is substantial variability in post-operative and convalescent recommendations, with little knowledge on the necessity and validity of such information.

Previous studies which have used pressure devices to infer increases in intra-abdominal pressure during movement use either intra-vaginal or rectal catheters. However limitations have been identified in the shape and type of pressure transducer used, and that many suffer from displacement during activity (2). Moreover, all but one of these devices required a catheter connection to a machine in order to record pressure variation.

Thus the aim of this study was to design and produce a reliable, novel intra-vaginal pressure device with wireless communication that would minimally distort the surrounding tissue that was in contact the pressure transducer. It had to be easy to use and remain *in situ* during activity

### Study design, materials and methods

The shape of our intra-vaginal pressure device is based on a vaginal support device (VSD), typically used post surgery, which was developed from silicon moulds of the vaginal anatomy (3). Our pressure device is smaller than the VSD and designed to be located in the proximal vagina above the levator ani muscles. Unlike previous pressure sensors, our device is relatively flat and compliant so it does not mechanically distort the surrounding anatomy (Figure 1). Two soft medical grade silicon sheets of appropriate shape were formed through a moulding process. These were then fashioned into a 'balloon' with a small entry tube to allow insertion of the pressure catheter. A 1mm diameter (3 French) micro-tipped solid-state Millar pressure catheter was threaded through a silicon tube to protect the catheter and facilitate connection to the 'balloon' The balloon was filled with 5 ml of sterile water with the sensor tip of the pressure catheter secured to sit within the fluid, and then sealed. A second silicon tube was attached to the pressure device to aid removal. The silicon balloons and tubes were disposable. The wireless pressure measuring unit (TR83P, Telemetry Research®) is situated outside the body, and allows data transmission of pressure measurements to a wireless data receiver using the 2.4 GHz bandwidth similar to blue tooth devices. The system can measure pressures from -200 Kpa to 1000 KPa (-60 mmHg to 300 mmHg), has a sampling rate of 2 kHz, and a transmission range of 10 metres.

Calibration of the device was achieved using a calibration rig and a set of masses, which were cumulatively added and then subtracted. The resultant pressures were recorded and graphed against the known applied load to calibrate the pressure sensor.

Reliability and repeatability of the device was assessed in 15 volunteers performing a set of well-defined activities (cycles), which were sequentially repeated three times. Each cycle was the same and consisted of 19 activities including: coughing; Valsalva manoeuvres; walking on a treadmill (2 km/hr, 4 km/hr, 6 km/hr); running on a treadmill (7 km/hr) star jumps; squatting; lifting of weights (2 kg and 5 kg) above the head; sit-ups and lying down for a baseline pressure. None of the participants had had vaginal surgery, or any contraindications for using an intra-vaginal device. All participants were able to insert the device themselves. Subjects 1-6 performed cycles 1 and 2 consecutively, then removed the device and re-inserted it for cycle 3 (termed Order 1). The remaining subjects performed cycle 1, then removed the device and re-inserted it for cycles 2 and 3 (termed Order 2). This design removed the effect of 'time' and 'position' as being confounders for reliability of measurement. Statistical analyses used SAS V9.2. Reliability was assessed using Cronbach's alpha ( $\alpha$ ) across cycles, over all 19 independent variables in all subjects. A nested Split-Plot, factorial ANOVA determined the effect of 'time' using both 'mean' and 'peak-to-peak amplitude' as dependent variables.

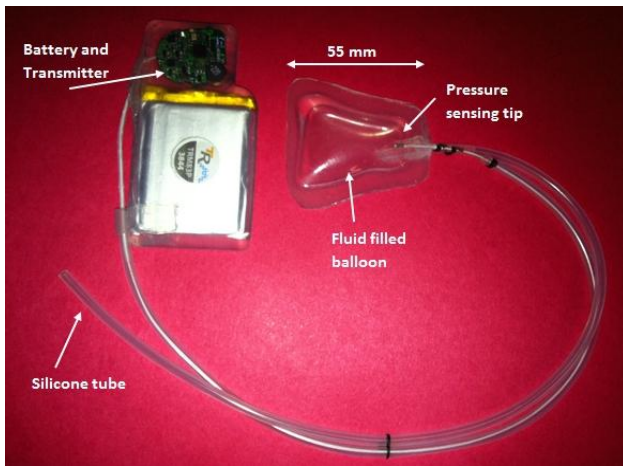


Figure 1: Components of the intra-vaginal pressure device.

Cronbach's alpha(r) across cycles (C)  
**MEAN**

	C 1	C 2	C 3
C 1	1.000	0.943	0.935
C 2	0.943	1.000	0.955
C 3	0.935	0.955	1.000

Cronbach's alpha(r) across cycles (C)  
**AMPLITUDE**

	C 1	C 2	C 3
C 1	1.000	0.964	0.964
C 2	0.964	1.000	0.975
C 3	0.964	0.975	1.000

Table 1: Cronbach's alpha across Mean and 'peak-to-peak' amplitude values

**Results**

The mean age of the participants was 35.9 years (range 20-51 years), BMI 22.6 kg/m<sup>2</sup> (range 18.6-26.7 kg/m<sup>2</sup>). Four were nulliparous, eleven multiparous with the median number of vaginal deliveries being 2. Twelve sets of data were available for analysis; two participants could not complete all three exercise cycles, and one set of data was unable to be analysed. Correlation coefficients for the calibration curves ranged from 0.995 to 0.998 showing an excellent perfect linear relationship between masses applied and pressures recorded. Reliability between cycles demonstrated excellent correlation cycles across all variables, with  $r > 0.935$  using the 'mean' and  $r > 0.964$  using peak-to-peak amplitude (Table 1).

Whereas there was large variation of peak-peak amplitude across Activities, there was no statistically significant effect of 'Order' (i.e. whether the pressure device was removed and replaced between Cycles 1&2 or between Cycles 2&3)

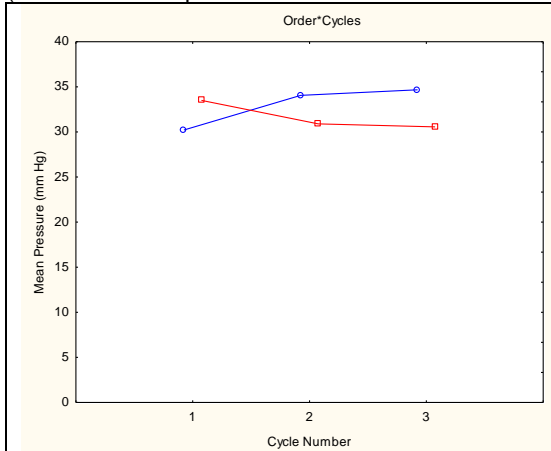


Figure 2: Effect of 'order' using Mean values across cycles

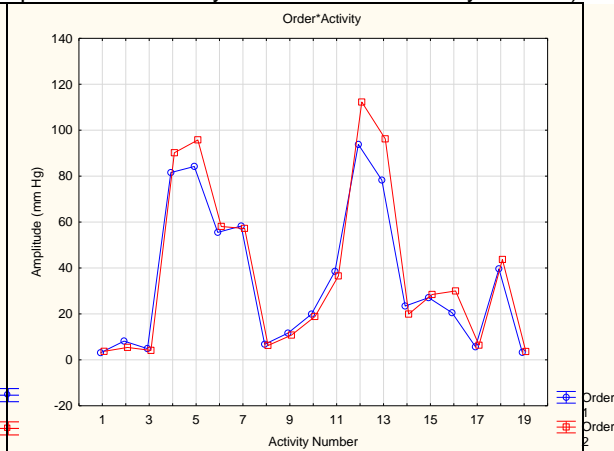


Figure 3: Effect of 'order' using Amplitude across activities.

**Interpretation of results**

Statistical analysis demonstrates excellent reliability of the measurements with  $r > 0.9$  in all cases. The effect of time and repositioning of the device were also negligible which offers confidence in the interpretation of data.

**Concluding message**

The intra-vaginal device has proved reliable and consistent across a range of activities and repetitions of those activities. Future work will include measurements of intra-abdominal pressure variation due to more intense exercise regimes and as a possible alternative to rectal pressure measurement in urodynamics.

**References**

1. Smith, 2010
2. Rosenbluth, 2011
3. Carey, 2008.

**Disclosures**

**Funding:** J Kruger was supported by a Rutherford Foundation postdoctoral fellowship through the Royal Society of New Zealand **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** University of Auckland Human Participants Ethics Committee 2011/275 **Helsinki:** Yes **Informed Consent:** Yes