THE EFFECT OF A PHYSIOTHERAPY EXERCISE PROGRAM ON PELVIC FLOOR MUSCLE STRENGTH IN WOMEN UNDERGOING PROLAPSE SURGERY.

Hypothesis / aims of study
Pelvic floor muscle training (PFMT) has been shown to be effective in the treatment of stress and mixed urinary incontinence (UI) in women. In clinical practice, PFMT is often also advised as part of a pre- and/or post-operative pelvic surgery physiotherapy intervention, as it is considered beneficial to the surgical outcome in the short term [1], however little is known regarding the effectiveness of this intervention in the long term. Several studies have shown that a large proportion of women with pelvic organ prolapse (POP) have PFM defects and muscle avulsions [2, 3]. Hence, this group of women may not respond as well to PFMT as do women with UI. This randomised controlled trial (RCT) aimed to investigate the effect of a pelvic floor physiotherapy exercise program on the pelvic function of women undergoing vaginal gynaecological surgery at 3, 6 and 12 months post-operative.

Study design, materials and methods
The study design was a single-blind RCT, comparing physiotherapy-supervised pre- and post-operative pelvic floor exercises, as part of a ‘package’ of conservative therapy, to ‘usual care’ provided by the surgeon and the hospital. Included were women of any age undergoing gynaecological vaginal or laparoscopic-assisted vaginal surgery for either pelvic organ prolapse repair, and/or hysterectomy. Exclusion criteria were surgery for cancer or surgery for UI. Recruitment commenced in July 2002 and ceased in April 2005. A sample size calculation based on one of the primary outcome measures, UI, indicated that a sample size of 50 women would be required to detect a 20% difference in bladder control between the treatment group (TG) and control group (CG), with 80% power and an alpha of 0.05. A total of 244 women were screened for eligibility to the trial; 58 agreed to participate. Fifty-one women completed the 12 month follow-up appointment. Three women underwent hysterectomy alone, for reasons other than POP, so the data presented relates to the 48 women who underwent surgery for POP. Twenty-four women were in each of the TG and CG. The physiotherapy intervention comprised one pre-operative instruction session, and eight post-operative physiotherapy appointments; at day 3 post-operative, week 6, 7, 8, 10 and 12, and a final appointment at 9 months post-operative. A PFMT strength training protocol was given to the women in the TG. Physiotherapy assessments of PFMT strength were performed by a blinded investigator at 4 time points: pre-operatively prior to randomisation, and at 3, 6 and 12 months post-operatively. Pelvic floor muscle strength was assessed by manometry, using a Peritron™ unit, and by digital muscle strength grading. Manometry measures included the peak score recorded over a 3 second maximum voluntary contraction (MVC), and the total work generated throughout the 3 second hold. Digital muscle testing was recorded using the modified Oxford grading scale over a 3 second MVC. Data were analysed using a 2-way repeated measures ANOVA. Analysis was done by intention-to-treat.

Results
The PFMT strength scores measured at each time point are presented in Table 1, and the changes in strength over time are presented graphically in Figure 1.

Table 1. Results of manometry and digital muscle testing (DMT) for the control group (CG) and the treatment group (TG).

<table>
<thead>
<tr>
<th>PFM strength test</th>
<th>Pre-operative (mean ± SD)</th>
<th>3 months post-operative (mean ± SD)</th>
<th>6 months post-operative (mean ± SD)</th>
<th>12 months post-operative (mean ± SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CG</td>
<td>TG</td>
<td>CG</td>
<td>TG</td>
<td></td>
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<tr>
<td>Manometry MVC (cm H2O)</td>
<td>22.8 ± 23.1</td>
<td>22.9 ± 18.2</td>
<td>22.8 ± 16.7</td>
<td>23.6 ± 16.1</td>
<td>0.6</td>
</tr>
<tr>
<td>Manometry total work (cm H2O)</td>
<td>52.2 ± 65.6</td>
<td>53.5 ± 48.1</td>
<td>66.7 ± 48.8</td>
<td>67.1 ± 49.2</td>
<td>0.5</td>
</tr>
<tr>
<td>DMT (grade 0 – 5)</td>
<td>2.1 ± 1.2</td>
<td>2.1 ± 1.3</td>
<td>2.1 ± 1.3</td>
<td>2.4 ± 1.1</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Figure 1. PFM strength scores: changes over time, between groups.
Interpretation of results
Despite the tendency towards improvement in the TG over time, the present results did not find a significant difference in strength scores between the CG and the TG at any time point. Previous studies have shown that POP is associated with PFM weakness [2, 3], and that weaker PFM are associated with higher rates of recurrence of POP symptoms post-surgery and higher re-operation rates. However this study did not show a significant difference in PFM strength between TG and CG. Negative findings in this study may be due to a small sample size, the large variability in the data, too low a dosage of supervised PFMT, muscle avulsion injuries or a combination of these and other factors. As women in the CG were also being measured for PFM strength, this may have had an effect on their exercise awareness and encouraged a level of PFM exercising beyond ‘usual care’ guidelines.

Concluding message
The present PFMT program failed to improve PFM strength in women undergoing surgery for POP or hysterectomy beyond that achieved by surgery alone. Further studies with a larger sample size are needed to see if a higher training dosage can increase PFM strength in women undergoing surgery for POP, and to investigate the role of possible injuries on PFM strength in women with POP surgery.

References

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the University of Melbourne, Cabrini Hospital Malvern, Cliveden Hill Private Hospital East Melbourne, Freemasons Hospital East Melbourne, Cabrini Hospital Brighton, Mercy Private Hospital East Melbourne, Waverley Private Hospital Mt Waverley and followed the Declaration of Helsinki. Informed consent was obtained from the patients.