1. Briefly describe the rationale for the study with respect to the tissue injury that occurs during surgery and the effect of pelvic floor physical therapy (PFPT) on neuromuscular function.

Thank you for the opportunity to clarify this point. Pelvic reconstructive surgery done transvaginally will involve incising tissue, sharp dissection, blunt dissection and suture reapproximation of the fibromuscular layers supporting the vagina. In the case of apical suspension, our approach is a bilateral uterosacral ligament fixation using delayed absorbable sutures through the uterosacral ligaments, and tied internally in the vagina to elevate this segment. All components of this repair may thus result in nerve compression or stretch, muscular inflammation or pain and dysfunctional coordination.

Prior studies involving lateral vaginal dissection at the time of paravaginal repair have suggested latency of the pudendal nerve.¹ Pelvic pain, muscle guarding and poor relaxation can result in symptoms of voiding dysfunction or defecatory dysfunction as well as dyspareunia after surgery. Studies done in women following pregnancy have likewise documented pudendal latency for several months after vaginal delivery;² these population cohorts have shown improvements using physical therapy postpartum to a multitude of symptoms.³ Furthermore, physical therapy is often cited as a treatment modality for urinary incontinence, pain and sexual dysfunction.⁴⁵
Therefore pelvic floor physical therapy and its neuromuscular reeducation may be an adjunctive treatment to improve coordination and control of the pelvic floor.

2. **Why were patients undergoing vaginal reconstructive surgery with mesh, other than midurethral slings, specifically excluded?**

We appreciate this question. In our patient population in order to reduce confounders we selected only subjects undergoing native-tissue vaginal repairs without mesh. Additionally, this is the preferred surgical approach by our group for primary repair of prolapse.

3. **The authors state, “PFPT can be beneficial for complaints after vaginal reconstructive surgery”. What common complaints do patients report after vaginal reconstructive surgery? What complaints were assessed in the study?**

Reassuringly, complaints are uncommon following vaginal reconstructive surgery. Nevertheless, some patients present with dyspareunia, voiding complaints, stress incontinence, urgency/urge incontinence or constipation and defecatory dysfunction after their repair. In this present study “complaints” were not assessed independently, rather we utilized validated indices: the World Health Organization Quality of Life-BREF Scale (WHOQOL-BREF), the General Health Survey (SF-12), the Surgical Pain Scale (SPS), the Activities Assessment Scale (AAS), the Female Sexual Function Index (FSFI), the Prolapse and Incontinence Sexual Questionnaire (PISQ-12), the Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Floor Incontinence Questionnaire-7 (PFIQ-7) as surrogates for evaluating symptoms of distress and bother in order to improve the reliability of this data, and reduce subjective bias. As described in the methods these were assessed at baseline and 2, 6 and 12 weeks after surgery.

4. **Were controls given the same educational information that test subjects received? If not, why not? Comment on the possible impact education can have independent of the provider-based portion of the PFPT program.**

Controls were allocated our ‘standard of care’ in the postoperative period with respect to counseling and education. Since educational information/handouts are not ‘standard’ this group was not provided such information. However our physical therapists routinely utilize educational handouts in treating all patients that seek physical therapy. Therefore they were given the opportunity to utilize the same tools that they would typically use in their treatment plan. On this basis, the educational information the test subjects received were not shared with the controls.
We acknowledge that education and provider care is an important component of healing and recovery. To attempt to minimize this 'treatment effect' confounder we maintained the same physician visit schedule for both groups.

Education provided by physical therapy may have led to better outcomes in this group, and thus should be detected via scores on the many validated quality of life indices as provided. Unfortunately, in this study, no significant differences between the groups were noted.

5. The control subjects attended postoperative visits with the physician at 2, 4, 6, 8, and 12 weeks. Are these intervals part of standard postoperative care? How might frequent postoperative visits influence the patient's overall perception of well being after surgery?

We appreciate this astute point. In fact, our standard postoperative regimen includes visits at 2, 6 and 12 weeks with 4 and 8 weeks added if there are concerns. For this study we applied standard assessments at 4 and 8 weeks after surgery for all subjects. As physical therapy sessions were to occur at these intervals, in order to improve consistency and to reduce confounders associated with contact with a provider we requested all subjects follow the same schedule for postoperative visits. Physical therapy subjects were seen by the physician and the physical therapist at the scheduled times and control subjects saw the physician only. In this manner all groups were influenced by contact with the physician at the same frequency.

6. Test subjects attended postoperative PFPT visits at 2, 4, 6, 8, and 12 weeks. How often did test subjects have a physician visit?

As noted above in Question 5, test subjects had physician visits at the same times as physical therapy visits and followed the same schedule.

7. What postoperative instructions and/or restrictions are commonly given to patients undergoing pelvic reconstructive surgery? What is the practice of the authors? How do the authors address the issue of the impact of postoperative recovery on postoperative activity?

Our standard instructions following surgery include: no heavy lifting or strenuous activity for 6 weeks which would include lifting over 10 pounds; No driving for 2 weeks; pelvic rest at least until 6 weeks or until instructed by the physician. These directions regarding postoperative recovery were consistent for both groups.
As part of this study our patients completed the validated Activity Assessment Scale and the Surgical Pain Scale at both 2 and 6 weeks postoperatively. Nevertheless, it may have been useful to include these indices at the 12 week time point as well given certain activities were omitted by patients as a result of their postoperative restrictions. We accounted for these eliminated behaviors by adjusting the AAS scoring methodology. This adjustment to the scoring was done based on a personal communication by the validated questionnaire author Dr. McCarthy.

8. Did the authors assess adherence to the PFPT home regimen in test subjects? Describe ways that adherence can be assessed. Use examples from other studies, if applicable.

This is an excellent point. We are aware that adherence can be assessed by a variety of measures including patient’s home diaries or journals to measure compliance and adherence with home regimens. Indeed, our initial study methodology did include a patient home adherence data sheet. However, inconsistent communication and directions by the physical therapists rendered this data very sparse and was eliminated from our analysis. We agree that this information would have been useful and hope that it can be provided in the future.

9. What is meant by the term, “effect size” and where does the number 0.917 derive from?

In an interventional study such as ours the effect size is an indicator of the magnitude of the intervention’s influence. The effect size noted in our sample size calculation, 0.917, represents the expected difference in means divided by the expected standard deviation (i.e., Cohen’s $d$). In the context of study design, the combination of power (80%), significance level (.05) and effect size yields the number of subjects needed in each group.

10. Was there a difference in the Surgical Pain Scales (SPS) between the two groups?

Surgical pain scales were not significantly different between the control and test groups as noted in the Results section, paragraph 2. The summary statement at the end of paragraph 2 applies to both SPS and AAS scores (data not shown).

11. These data indicate improved neuromuscular function in the PFPT group however no difference in any of the quality of life indices compared to
controls subjects. 

Explain the rationale for continued perioperative use of PFPT in women undergoing vaginal reconstructive surgery?

Although no quality of life changes were noted in the physical therapy group compared to control, we believe that improved muscular coordination and neuromuscular function in treated subjects show an impact by the physical therapy. It is possible that the 12-week time frame was not long enough to note subsequent difference on the quality of life measures. We also believe that our regimen, although more rigorous than that previously studied following gynecologic surgery is less involved than schedules employed by orthopedic surgeons after their surgical treatments. More frequent visits, twice a week or for a longer period after surgery may have led to a greater difference in quality of life. Furthermore future studies selecting those subjects that have complaints after surgery in the areas of voiding or defecatory dysfunction, pain or sexual dysfunction may see a greater role for physical therapy in a standardized manner. Nevertheless, we are speculating, as we are not able to conclude this information from our results.

References: