

Multi-Site Study Reveals Vibrance Pelvic Trainer (VPT) Improves Urinary Incontinence, Pelvic Prolapse and Sexual Experience As Reported By Patients

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Executive Summary

Upwards of 50% of midlife women report pelvic symptoms such as urinary incontinence, prolapse, and pelvic pain (The Women's Health Foundation, SG₂, The Advisory Board), and 33% report decreased sexual satisfaction (Giebink and Alexander, 2015). The medical costs associated with treatment can be greater than \$25,000 if surgery is indicated, not to mention the emotional costs involved with disorders that are embarrassing and often considered taboo. Many studies over the past two decades have shown that pelvic floor muscle training (Kegel exercises) and biofeedback have independently demonstrated improvement in women's pelvic symptoms (Delgado and Drake, 2010). The Vibrance Pelvic Trainer (VPT) integrates both pelvic floor muscle training with biofeedback in order to work synergistically to improve pelvic symptoms in women. A convenience sample of twenty-one (21) women trialed the VPT over a four week period and reported improvements in urinary incontinence, pelvic prolapse and sexual experience. The highlights of this study are reported in this white paper.

Need

Women utilize more health services than men at every age across the lifespan (Service Line Strategy Advisor, 2011), and midlife women are the fastest growing population in the US (US Census Bureau, 2009). Women over the age of 45 are projected to grow by 42% by 2020. With the high prevalence of pelvic/sexual symptoms in midlife women, the cost of care could be staggering. Currently, SG₂, 2014 reports that there are approximately 7.6 million urogynecology outpatient procedures annually in the US and this volume is projected to increase by 21% over the next decade. The majority of these procedures are office based with an average cost of \$400 - \$600/visit and \$2,500 for the total treatment. If surgery is necessary, it could cost upwards of \$25,000/case. If this traditional medical care could be supplemented with self-managed home care with the VPT, it could decrease the cost of care, accelerate treatment results and possibly avoid the more aggressive treatment of surgery.

Study Design

The original research demonstrating the clinical efficacy of the VPT was completed in 2011 by Ting and associates. This study sought to obtain women's perceptions of the VPT and their self-assessed clinical outcomes. A convenience sample of twenty-one women were recruited from two medical practices, one in Western Pennsylvania and one in South Florida, to participate in this study. Both providers in the medical practices were board certified in obstetrics and gynecology and were trained on the VPT and the study protocol. Participants were seen weekly over the course of the four week study. Following the trial, participants completed an anonymous survey on line. The results of this survey are presented below.

Results

The results were overwhelmingly positive, >70%, regarding clarity of instructions, packaging, ease of use and comfort of the VPT. Sixty-five percent (65%) of the participants felt the biofeedback (audio guided feature) of the VPT was useful. The participants were asked to rank the clinical impact of the VPT on a scale from 1 to 5, with 1 having no impact and 5 having significant improvement. The participants reported significant improvements in orgasm intensity, quality of intimate experience and urinary incontinence with an average score of 4.38 out of 5. They also reported good improvements with prevention/management of pelvic prolapse with an average score of 3.90. Refer to Table 1 and Figure 1 for an illustration of the distribution of the results.

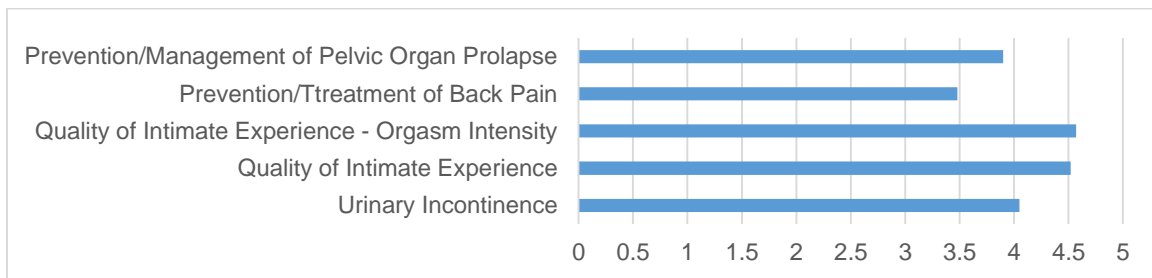
Table 1. Clinical Impact of VPT

	1	2	3	4	5	Total	Weighted Average
Urinary Incontinence	9.52% 2	9.52% 2	4.76% 1	19.05% 4	57.14% 12	21	4.05
Quality of Intimate Experience	0.00% 0	4.76% 1	4.76% 1	23.81% 5	66.67% 14	21	4.52
Quality of Intimate Experience – Orgasm Intensity	0.00% 0	4.76% 1	4.76% 1	0.00% 6	66.67% 14	21	4.57
Prevention/ Treatment of Back Pain	14.29% 3	14.29% 3	14.29% 3	23.81% 5	33.33% 7	21	3.48
Prevention/ Management of Pelvic Organ Prolapse	0.00% 0	19.05% 4	14.29% 3	23.81% 5	42.86% 9	21	3.90

Key:

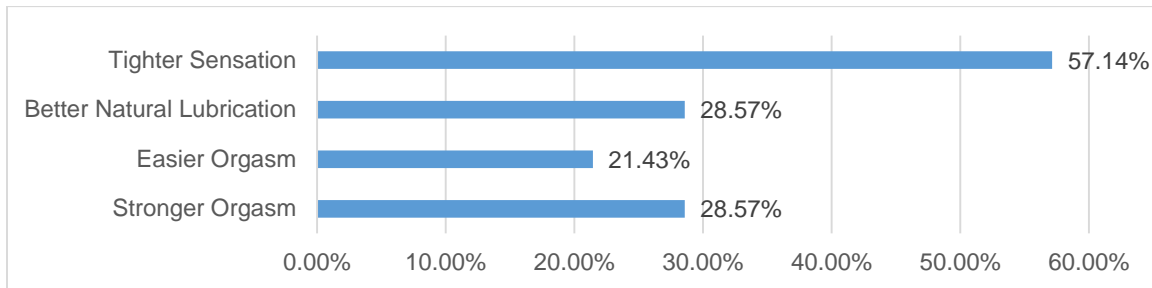
- 1 = No Impact
- 2 = Low Impact
- 3 = Moderate Impact
- 4 = Good Improvement
- 5 = Significant Improvement

Figure 1. Clinical Impact of VPT



Sixty-two percent (62%) of the participants responded that their sexual experience improved after using the VPT. When asked specifically about the improvements in their sexual experience, 57% noted a tighter sensation. Refer to Figure 2 for a display of the specific improvements in sexual experience.

Figure 2. Sexual Experience Improvements with VPT



Conclusions and Implications

The VPT was successful in improving pelvic symptoms such as urinary incontinence and pelvic prolapse, and in improving sexual experience as reported by the participants. It is a cost effective and effective first line treatment for women with pelvic symptoms and sexual satisfaction concerns. The VPT is also appropriate as an adjuvant therapy with medical or surgical management. The device should help accelerate the therapeutic responses from medical management, and should accelerate the rehabilitative course in surgical management patients. The VPT is appropriate for preventive care in an effort to prevent, delay or mitigate the onset of pelvic symptoms as women age. With the Affordable Care Act of 2013, the cost of care is shifting to the providers and the patients. Thus the VPT will play an important role in the maintenance of women's pelvic and sexual health with demonstrated high quality, cost effective outcomes.

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