Clinical characteristics associated with successful use of a novel Vaginal Bowel Control (VBC) System for the treatment of fecal incontinence

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Introduction

Fecal incontinence (FI), also known as accidental bowel leakage (ABL), is a debilitating condition and a significant unmet need in women’s health. Recent studies of community-dwelling women in the U.S. report the prevalence to be 19-25%. Current treatment options have limitations in efficacy, morbidity, and cost. The Vaginal Bowel Control (VBC) System (Eclipse™, Pelvacon) was designed to offer a low risk, non-surgical treatment option. It consists of a vaginal insert and pressure-regulated pump. The insert, consisting of a silicone-coated stainless steel base and posteriorly-directed balloon, is designed to reversibly deflect the rectovaginal septum and interrupt the passage of stool.

The primary study outcome, reported separately, demonstrated 79% (48/61) of intent-to-treat subjects (86%, or 48/56, of per protocol subjects) achieving treatment success, defined as 50% or more reduction in Fecal Incontinent Episodes (IEs)/week. There were no serious device-related adverse events experienced by any patients involved in any portion of the study. Use of the VBC significantly improved Quality of Life scores across all subscales of the FIQOL and MIMHQ.

In addition, we sought to understand the clinical characteristics associated with overall device success, including ability to fit the insert and the insert’s influence on the range of bowel symptomology. The objectives of this secondary analysis were to evaluate factors that predict successful insert fitting and to assess the interaction between baseline FI characteristics and treatment efficacy.

Methods

This was an IRB-approved, multi-center, prospective, open-label clinical study in women with FI. Inclusion criteria included: age 19-75, history of FI ≥6 months, ≥4 fecal IEs during 2-week bowel diary, and successful fitting. Subjects were seen for a baseline study visit, consisting of a comprehensive history and baseline pelvic examination. Subjects then completed a 2-week baseline diary, including entries for: continent bowel movements, staining, minor FI episodes, and major FI episodes. All major FI episodes (both solid and liquid, per subject) were recorded as proportional to their total number of bowel movements. Data from the subject’s background and pelvic examination were compared across successful and unsuccessful fitting groups. Multivariate, logistic regression analysis was performed. Paired T-tests were used to characterize the difference in FI symptoms from baseline to treatment.

Results

Six clinical sites in the U.S. recruited from August 2012 through October 2013. Overall, fitting was attempted in 112 women and 61/112 (54.5%) were successfully fitted and entered the treatment portion of the study. Multivariate, logistic regression analysis revealed that only previous prolapse surgery (p=0.008), shorter vaginal length (p<0.042), and vaginal atrophy (p=0.012) were associated with unsuccessful fitting. Women who have not undergone previous prolapse surgery have 5.7 times the odds (95% CI 1.93, 16.85) of a successful fit.

Conclusion

Shorter vaginal length, worsening vaginal atrophy and previous prolapse surgery were associated with increased risk of fitting failure. This information can be used to counsel patient expectations regarding the VBC fitting experience. Some women with each of these conditions did achieve a successful fit, so it is warranted to attempt fitting in these women given the low-risk nature of the therapy. This information is also valuable in guiding new size offerings to fit a higher percentage of patients in the future.

Previous prolapse surgery may cause changes to the shape or quality of the vaginal walls, possibly explaining the increase in unsuccessful fittings. However, a larger sample size is needed to truly assess this predictor, as only 22 subjects of 112 in whom fitting was attempted had previous prolapse surgery.

A shorter vagina may provide less proximal space for the insert to dwell, causing it to slip downwards and create discomfort, as shown in Figure 1. However the small (8%) difference between the two mean lengths as well as the wide standard deviation indicates that some women with shorter vaginas may still achieve a good fit.

Vaginal atrophy, shown in Figure 2, is naturally associated with discomfort upon vaginal agitation. Use of intravaginal estrogen should be considered for those women with vaginal atrophy.

Once successfully fit, as illustrated in Figures 3 and 4, the insert reduced IEs regardless of FI characteristics, including episode size, urgency, and consistency. Of particular note is the improvement in episodes with loose stool, as the device mechanism (temporary occlusion of the rectum) may not have been expected to protect as well against liquid events.

References


Table 1. Baseline FI Characteristics and treatment success

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline*</th>
<th>1 mo†</th>
<th>% Change in # of FI episodes</th>
<th>p-value‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major FI soiling episodes</td>
<td>3.2±(1.1)</td>
<td>0.6±(1.2)</td>
<td>-81%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Minor FI soiling episodes</td>
<td>8.4±(7.5)</td>
<td>1.5±(2.3)</td>
<td>-82%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>All FI episodes associated with urgency</td>
<td>6.6±(6.8)</td>
<td>1.1±(2.1)</td>
<td>-83%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>All FI episodes not associated with urgency</td>
<td>4.8±(5.5)</td>
<td>0.9±(1.8)</td>
<td>-81%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>All FI episodes with loose stool (Bristol Score 6-7)</td>
<td>5.1±(8.5)</td>
<td>1.2±(2.4)</td>
<td>-76%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>All FI episodes with normal stool (Bristol Score 1-5)</td>
<td>6.1±(7.4)</td>
<td>0.9±(1.6)</td>
<td>-86%</td>
<td>&lt;0.0001</td>
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Figure 1. Vaginal Bowel Control (VBC) System (Eclipse™, Pelvacon). The insert, consisting of a silicone-coated stainless steel base and posteriorly-directed balloon, is designed to reversibly deflect the rectovaginal septum and interrupt the passage of stool.

Figure 2. Unsuccessfully fit inserts: Shorter total vaginal length (L), illustrated here in the case of a hysterectomy, may not allow sufficient space for the insert to dwell comfortably or to provide rectal occlusion. Hysterectomy alone was not a predictor of unsuccessful fitting. Allopecic tissue (R) may not be compliant enough to allow for comfortable placement, complete balloon expansion or rectal occlusion.

Figure 3. A successfully fit insert: deflated (top), inflated (bottom). Dynamic occlusion above the sphincter complex results in a reduction in incontinent episodes, including across stool presentations.

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