**Introduction:**
Vaginal tissue laxity has been understudied and overlooked as a contributing etiological factor to female sexual dysfunction. This study investigates the use of a patented cryogen-cooled monopolar radiofrequency (CCMRF) system that uses surface cooling and energy delivery to provide a non-ablative, minimally-invasive approach to create heat deep within vaginal tissue.

**Methods:**
- **VLQ: Vaginal Laxity Questionnaire**
  How would you rate your current level of vaginal laxity/looseness during intercourse?
  - 1: Very Loose
  - 2: Moderately Loose
  - 3: Slightly Loose
  - 4: Neither Loose Nor Tight
  - 5: Slightly Tight
  - 6: Moderately Tight
  - 7: Very Tight

- **FSFI: Female Sexual Function Index**
  Areas of Focus: No. Questions
  - Sexual Desire/Interest
  - Sexual Arousal
  - Lubrication
  - Orgasm
  - Satisfaction
  - Pain

**Subject Disposition:**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Randomized &amp; Treated Subjects</th>
<th>Per Protocol w/ Vaginal Laxity (VSQ)</th>
<th>Per Protocol w/ Sexual Dysfunction (FSFI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>108</td>
<td>103</td>
<td>71</td>
</tr>
<tr>
<td>Sham</td>
<td>56</td>
<td>52</td>
<td>32</td>
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</tbody>
</table>

**Month 6 Follow-Up:**

<table>
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<th>Treatment</th>
<th>Randomized &amp; Treated</th>
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<td>41</td>
<td>26</td>
</tr>
</tbody>
</table>

**Conclusions:**
- Achieved primary endpoint: NO laxity at 6 months (active vs placebo), statistically significant at 95% confidence level
- Achieved statistically significant difference at 95% confidence level for change from baseline to 6 months (active vs placebo): Sexual function (FSFI) and Vaginal laxity (VLQ)
- The Viveve system is a safe and effective treatment for vaginal laxity.