My Experience in the Treatment of Stress Urinary Incontinence (SUI) using the Viveve Monopolar Radiofrequency System

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BACKGROUND

Stress urinary incontinence (SUI) is a major challenge for many women particularly those who have experienced child birth or are menopausal. Upwards of 55% of women with a previous vaginal delivery may exhibit signs and symptoms of SUI[1]. The overarching effects of SUI impact a women's health and quality of life and have been shown to result in depression, social stigma and lack of self-confidence. The need to use an external pad to absorb urine leakage from even normal daily activities, such as laughing or coughing, is unsatisfactory and can be extremely inconvenient, and often embarrassing for women.

Currently available treatment options for women are limited. Pelvic floor exercises (such as Kegels) offer some benefit to a percentage of women but compliance and sustained benefit can be issues. More aggressive approaches to manage SUI include pelvic surgery, slings and mesh. These invasive options involve more risk and recovery time and are a last resort for many patients.

The void between conservative and invasive treatment options for SUI represents an opportunity to address an enormous unmet healthcare need for women. Minimally invasive treatments for SUI would be a highly appealing solution provided they offered a safe, consistent improvement in symptoms without significant time commitment or recovery. Any effective treatment would represent a major advance in women's health.

In my search for other options for my patients, I evaluated the Viveve cryogen-cooled monopolar radiofrequency system to determine how it could be used to improve the symptoms of SUI. The Viveve system already has a well-documented safety and efficacy profile for the treatment of vaginal laxity,[2,3,4] and I have used the system in my practice for the past 5 years.

The Viveve system employs a proprietary pulsed radiofrequency energy in combination with simultaneous cooling to protect the upper layers of tissue. This combined cooling and heating approach enables safe delivery of thermal energy to much deeper tissue levels than other available technologies. The deep heating capability targets the connective tissue that plays a role in the structural integrity of the vagina and urinary systems.

PILOT STUDY RESULTS

Based upon an initial feasibility assessment, 10 premenopausal subjects were enrolled in a pilot study to evaluate the potential of a novel treatment protocol using the Viveve system. Subjects were split into 2 treatment groups. Group 1 received a single SUI treatment and Group 2 received a 2nd SUI treatment approximately 6 weeks following the initial treatment. All subjects were required to fill out assessment questionnaires at baseline, 4 months and 6 months post treatment. The questionnaires used to evaluate the status of the patient's SUI were UDI-6 (Urogenital Distress Inventory Short Form), IIQ-7 (Incontinence Impact Questionnaire), and ICIQ-UI (International Consultation on Incontinence Questionnaire).

In this pilot study, we observed a dramatic improvement in SUI symptoms in this cohort of patients. Patients reported a response within four to twelve weeks following the initial treatment, and several patients reported the improvements as "life-changing". The subjects in our study showed an impressive response rate with durability of results lasting out to 9 months in most subjects (Table 1).

Table 1: Percentage of Patients with Improvement in their SUI Symptoms*

Treatment Group	UDI-6			IIQ-7			ICIQ-UI		
Timepoint (Months)	**4**	**6**	**9**	**4**	**6**	**9**	**4**	**6**	**9**
Group A (1 Tx)	100%	100%	100%	100%	100%	100%	100%	100%	89%
Group B (2 Tx)	100%	90%	100%	100%	100%	100%	89%	100%	100%

*Response rate (i.e., an improvement in SUI symptoms and quality of life) is based upon a decrease in composite score for validated questionnaires UDI-6, IIQ-7 and ICIQ-UI from Baseline; N = 9 at 9-month time point.

SUI TREATMENT PROTOCOL

The treatment was delivered in pulses from the electrode on the end of a treatment tip. The Geneveve protocol for sexual function was modified to provide additional energy to support the improvement of stress urinary incontinence. Each treatment consisted of 220 pulses, with each pulse delivering approximately 90 J/cm^2, as outlined below:

- **Position 1:** *0-2 cm beyond hymenal ring*
  - **Treatment tip placement beyond hymenal ring:** proximal edge 0 cm, distal edge 2 cm
  - The first set of 100 pulses was applied to the area just behind the hymenal ring using the quadrant approach. Each quadrant was treated with 5 consecutive passes of 5 locations of pulses for a total of 25 pulses/quadrant. Pulses were applied in a clockwise fashion with an overlap of ~0.5 cm. Once a quadrant was fully treated with 25 pulses, the next quadrant was treated until all 4 quadrants were treated.
- **Position 2:** *1-3 cm beyond hymenal ring*
  - **Treatment tip placement beyond hymenal ring:** proximal edge 1 cm, distal edge 3 cm
  - The second set of 100 pulses were applied in a similar fashion to the first set but at ~ 1 cm deeper than Position 1. This provided an ~1 cm overlap of treatment pulses.
- **Position 3:** *2-4 cm beyond hymenal ring*
  - **Treatment tip placement beyond hymenal ring:** proximal edge 2 cm, distal edge 4 cm
  - The third depth of treatment involved positioning the proximal edge of the treatment tip window ~2 cm behind the hymenal ring. Five pulses were applied directly to the right of the urethra and five pulses were applied directly to the left of the urethra.
- **Position 4:** 3-*5 cm beyond hymenal ring*
  - **Treatment tip placement beyond hymenal ring:** proximal edge 3 cm, distal edge 5 cm
  - The fourth depth of treatment was applied in a similar fashion to the third pass but with the proximal edge of the treatment tip window positioned ~3 cm behind the hymenal ring.

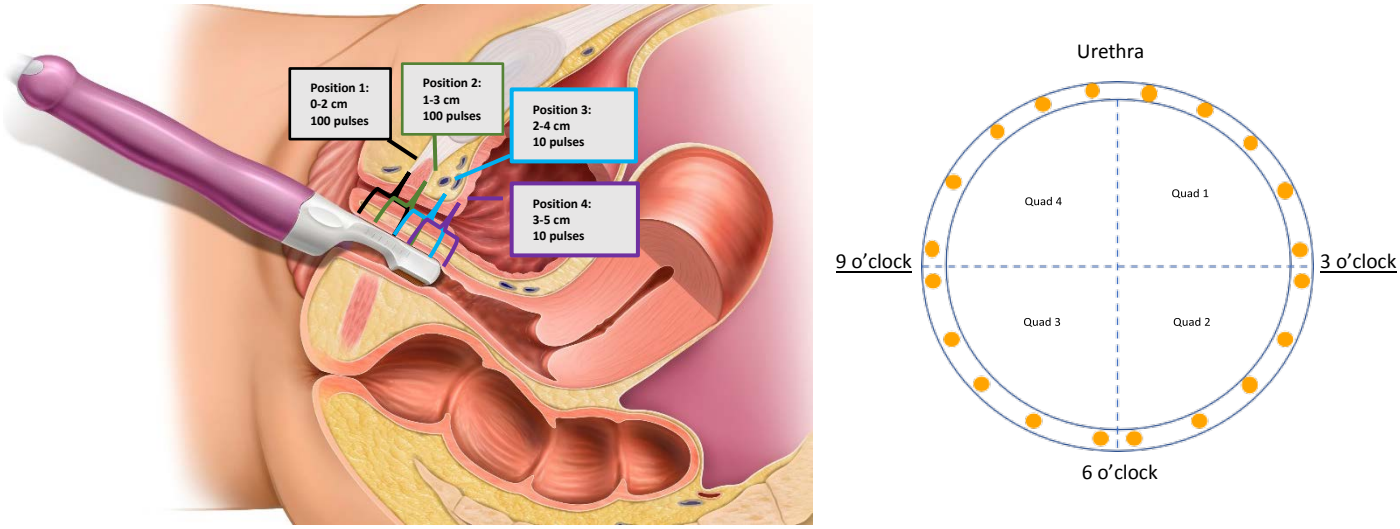

Figure 1: Proposed SUI Protocol Schematic

CONCLUSIONS

While this report is only on a small cohort of subjects in our study, this treatment for SUI shows promise as a viable option for patients searching for a minimally invasive non-surgical treatment option. Our initial experience merits a larger scale study to investigate this treatment for SUI, therefore we have initiated a more comprehensive, investigator-sponsored clinical study to expand our initial findings to a larger treatment group.

REFERENCES

[1] Tahtinen R, Cartwright, R, Tsui, J, Aaltonen R, Aoki Y, Ca´rdenas J, El Dib R, Joronen K, Al Juaid S, Kalantan S, Kochana M, Kopec M, Lopes L, Mirza E, Oksjoki S, Pesonen J, Valpas A, Wang L, Zhang Y, Heels-Ansdell D, Guyatt G, Tikkinen K. Long-term Impact of Mode of Delivery on Stress Urinary Incontinence and Urgency Urinary Incontinence: A Systematic Review and Meta-analysis. J Eur Uro; 2016; 70: 148-158.

[2] Krychman M, Rowan CG, Allan BB, DeRogatis L, Durbin S, Yacoubian A, Wilkerson D. Effect of single-treatment, surface-cooled radiofrequency therapy on vaginal laxity and female sexual function: the VIVEVE I randomized controlled trial. J Sex Med. 2017 Feb;14(2):215-25.

[3] Millheiser LS, Pauls RN, Herbst SJ, Chen BH. Radiofrequency treatment of vaginal laxity after vaginal delivery: nonsurgical vaginal tightening. J Sex Med. 2010;7(9):3088-95.

[4] Sekiguchi Y, Utsugisawa Y, Azekosi Y, Kinjo M, Song M, Kubota Y, Kingsberg SA, Krychman ML. Laxity of the vaginal introitus after childbirth: nonsurgical outpatient procedure for vaginal tissue restoration and improved sexual satisfaction using low-energy radiofrequency thermal therapy. J Womens Health (Larchmt). 2013;22(9):775-81.

[5] Wiegel M, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. J Sex Marital Ther. 2005 Jan-Feb;31(1):1-20.