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**Title:** KEY FACTORS IN IMPROVING THE RESULTS OF THE TRANSVAGINAL RADIO FREQUENCY BLADDER NECK SUSPENSION PROCEDURE

**Aim of Study:**

: The results of several transvaginal radio frequency (RF) bladder neck suspension studies for the treatment of genuine stress incontinence have been previously presented. We report on the importance of several variables related to surgical technique and their contribution to the success of the procedure.

**Methods:**

A prospective IDE approved comparative study was conducted at ten (10) centers in the US to evaluate the RF bladder neck suspension procedure. A system (SURx, Inc., Livermore, CA) that consisted of a disposable single use RF “applicator”, a RF generator and a computerized automatic data collection unit was used in the study. Electronic data for temperature, power, impedance and time was collected by the data collection unit continuously during treatment for all patients. A total of 120 patients with genuine stress incontinence (GSI) confirmed by urodynamic evaluation were enrolled in this study. All patients had positive valsalva leak point pressures (VLPP). Patients averaged  $49.5 \pm 9.9$  years old and experienced symptom duration for  $6.4 \pm 5.9$  years. The technique was performed using transvaginal paraurethral or “U” shaped incisions, and reflection of the vaginal epithelial surface to directly visualize the endopelvic fascia (EPF). Bipolar RF energy was applied directly to the EPF with the applicator causing it to heat and shrink. At six-month follow-up, success rates were determined using five criteria including urodynamic testing and valsalva manoeuvres. Data from 95 patients was extensively analysed comparing 26 treatment parameters with individual clinical outcomes. Key parameters to significantly improve clinical success were identified and related to treatment techniques using a series of laboratory experiments.

**Results:**

The success rate for all patients at 6-month follow-up (N=94) was 71.6%. The total RF treatment time for the procedure was approximately 2 minutes. Analysis of 39 patients showed that outcome success when more than 25 seconds was spent with the applicator tip immersed in blood or fluid was 60% and when less than 25 seconds was spent immersed in blood or fluid was 85% (55 patients). Also, when less than 40% of the total treatment time was spent with the applicator tip making correct contact with the tissue, success was 50% (N=11), but increased to greater than 70% (N=82) when more than 40% of total treatment time was spent in correct contact with the endopelvic fascia. Laboratory data to confirm these findings were consistent with these observations. These observations on tissue showed that tip fluid immersion and poor tip/tissue contact reduce the depth of penetration of the RF energy into the endopelvic fascia by approximately 50%. This reduces the effective treatment depth and the amount of total tissue volume

treated which may result in poorer outcomes.

**Conclusions:**

The data indicates that there are two variables that can greatly influence the clinical success of the procedure. These are 1) the amount of time spent with the RF applicator tip immersed in blood or fluid and 2) the amount of time the applicator tip is in correct contact with the endopelvic fascia. These findings have important implications for the treatment of stress incontinence using the RF bladder neck suspension procedure. Reducing the amount of time the tip is immersed in blood or fluid and assuring good tissue contact by maintaining a moderate amount of pressure between the applicator tip and endopelvic fascia improve clinical outcomes. These variables can be easily controlled using standard surgical techniques. Confirmation of the importance of these variables in clinical trials is ongoing.

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