TREATMENT WITH A POLYCAPROLACTONE (PCL)-BASED BIORESORBABLE URETHRAL BULKING AGENT FOR MILD TO MODERATE STRESS URINARY INCON TinENCE (SUI)

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INTRODUCTION: A CE-marked polycaprolactone-based biodegradable bulking agent is evaluated for safety and efficacy in female patients with mild to moderate SUI who attempted and failed prior pelvic floor muscle training. Polycaprolactone has been used successfully in numerous FDA approved and CE-marked medical devices and is fully biodegradable.

MATERIALS AND METHODS: 50 female subjects (Median age 47) were treated by transurethral submucosal injection. 49, 47 and 39 completed the 3-, 6- and 12-month follow-up. Efficacy was assessed with the Stamey Grading System (SGS), International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), Patient Global Impression of Severity and improvement (PGI-S, PGI-I) and Incontinence-Quality of Life (I-QoL).

RESULTS: For the subjects that completed the 3-, 6- and 12-month follow-up visits, total SGS improvement (improvement + cure) was shown for 31/49 (63.27%), 25/46 (54.34%) and 22/38 (57.89%) subjects, respectively; total PGI-S improvement was shown for 37/49 (75.51%), 34/46 (73.24%) and 24/38 (63.16%) subjects, respectively; PGI-I results showed a treatment success for 42/49 (85.71%), 35/47 (74.47%) and 31/39 (79.49%) subjects, respectively. Baseline median ICIQ-SF scores were moderate/severe (12/13) which were improved to moderate ICIQ-SF scores of 7, 6 and 6 (3-, 6- and 12-month follow-up, respectively. A mean difference (improvement follow-up vs baseline) of 15.31%, 15.88% and 15.56% at 3-, 6- and 12-month follow-up, respectively, in I-QoL values were found.

Eight out of 50 subjects reported mild post-treatment related adverse events (AE) and 1 serious AE (SAE) to treat urinary retention (also mild in nature but recorded as an SAE due to required hospitalization).

CONCLUSION: The study shows that the polycaprolactone-based biodegradable bulking agent treatment is safe and effective for women with mild to moderate SUI, resulting in improvements in both SUI severity and QoL.

As the study is ongoing (up-to 2 years follow-up), data is subject to change.