

Treatment of Mild to Moderate Stress Urinary Incontinence using a PCL-based Bioresorbable Urethral Bulking Agent

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Aim of the Study

Here we evaluate the safety and efficacy of an injectable poly(ϵ -caprolactone) (PCL)-based bioresorbable bulking agent in the treatment of female subjects with mild to moderate stress urinary incontinence (SUI). A high safety profile and sustained clinical efficacy are foreseen, as PCL is bioresorbable and has been shown to induce neo-collagenesis [1,2].

Study Design, Materials and Methods

50 female subjects (mean age 47.5 ± 12.2 yrs.) with mild to moderate stress urinary incontinence (SUI) were treated by transurethral sub-mucosal injection of a novel urethral bulking agent consisting of PCL microspheres dispersed in a gel (Urolon™, AQLANE Medical, The Netherlands). In this study designed to last 24 months, to date 49 subjects have completed the 3-month follow-up, 47 the 6-month follow-up and 13 the 12-month follow-up.

Safety assessment was based on reported adverse events.

Efficacy was assessed with the Stamey Grading System (SGS), the Patient Global Impression of Severity (PGI-S) and the Patient Global Impression of Improvement (PGI-I). Quality of life (QoL) was assessed with the Incontinence Quality of Life (I-QoL) scale and the International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF).

Results

Initial mean treatment volume was 1.5 ± 0.5 mL (n=49), 14/49 (28.6%) subjects were re-treated with a mean re-treatment volume of 1.29 ± 0.44 mL.

Safety

7 out of 49 subjects (14.2%) reported mild post-treatment related adverse events (AEs) which were resolved by providing relevant medication and/or catheterization. Three AEs occurred directly post-treatment (hematuria, dysuria and urinary retention) and four AEs between treatment and the 6-month follow-up (urinary tract infection, urge incontinence, psoriasis and severe coughing). One AE of urinary retention, recorded as serious due to hospitalization, was resolved with a catheter.

Efficacy

See Table 1.

SGS improvements were 63.3% (cure-rate 42.9%) and 55.3% (cure-rate 42.6%) at 3- (n=49) and 6-month (n=47) follow-up, respectively.

PGI-S improvements were 75.5% (cure-rate 53.1%) and 72.3% (cure-rate 44.7%) at 3-month (n=49) and 6-month (n=47) follow-up, respectively.

Results from the PGI-I show a high treatment success of 85.7% at 3-month (n=49) follow-up and 74.5% at 6-month (n=47) follow-up.

The median ICIQ-SF scores [3] improved from 13 (“severe”) initially to 7 and 6 (“moderate”) at 3- and 6-month follow-up, respectively. See Figure 1.

Interpretation of Results

The results indicate that treatment with this injectable PCL-based bulking agent is safe and effective, resulting in improvements in SUI severity and QoL. The rate of adverse events is low. The study is ongoing, the follow-up period will be extended to 5 years and provide additional safety and efficacy data.

Conclusions

It can be concluded that this injectable PCL-based bulking agent is a safe and effective treatment option for women with mild to moderate SUI who attempted and failed prior pelvic floor muscle therapy. Additionally, its bioresorbability is an attractive safety feature when compared to permanent non-degradable bulking agents.

- References:** 1) Nicolau PJ, & Marijnissen-Hoftsé J. Eur J Aesth Med Dermatol. 2013; 3(1):19-26
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3) Klovning A, et al. Neurourol Urodyn. 2009; 28(5): 411

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Table 1. Efficacy of PCL-based bioresorbable injectable urethral bulking agent at 3- and 6-month follow-up

	3-month follow-up	6-month follow-up
SGS		
Grade 0 (dry)	21 of 49 subjects (42.9%)	20 of 47 subjects (42.6%)
Total improvement (incl. dry)	31 of 49 subjects (63.3%)	26 of 47 subjects (55.3%)
PGI-S		
Grade 1 (normal)	26 of 49 subjects (53.1%)	21 of 47 subjects (44.7%)
Total improvement (incl. normal)	37 of 49 subjects (75.5%)	34 of 47 subjects (72.3%)
PGI-I		
Improvement	42 of 49 subjects (85.7%)	35 of 47 subjects (74.5%)
ICIQ-SF^{a)}		
Median at baseline	13	13
Median at follow-up	7	6
I-QoL		
Improvement	43 of 49 subjects (87.8%)	32 of 47 subjects (70.0%)

^{a)} ICIQ-SF severity of incontinence: slight (score 1–5), moderate (score 6–12), severe (score 13–18), very severe (score 19–21) [3]

Figure 1. Median ICIQ-SF scores showing severity of incontinence at baseline, 3-month and 6-month follow-up.

