Urolon™

12-month

Clinical Study Data

urolon™ *perspectives*

In September 2016, a European multicenter clinical trial was initiated to support the safety and efficacy of Urolon™, a bioresorbable urethral bulking agent (UBA) for the treatment of mild to moderate female stress urinary incontinence (SUI). 50 female subjects, recruited between September 2016 and July 2017, were treated by transurethral sub-mucosal Urolon™ injection. All subjects had attempted and failed prior pelvic floor muscle training.

SUI symptoms and treatment success (efficacy) were assessed with the Stamey Grading System (SGS), Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Improvement (PGI-I). Whilst SGS is used as an objective measure of efficacy, PGI-S and PGI-I represent subjective measures of efficacy. The PGI-S is a single question asking the patient to rate how their urinary tract condition is now on a scale of 1- Normal to 4- Severe. PGI-I is a transition scale from a single question asking the patient to rate their urinary tract condition now, as compared with how it was before beginning treatment, on a scale from 1 - Very much better to 7 - Very much worse.

Quality of life (QoL) was assessed using both the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) and Incontinence Quality of Life (I-QOL) scale. ICIQ-SF severity is divided into the following categories: slight (1-5), moderate (6-12), severe (13-18) and very severe (19-21). I-QOL is a disease-specific instrument designed to measure the impact of urinary incontinence on quality of life. QoL measures are an essential end-point in evaluating the efficacy of incontinence treatments. Safety was assessed via reported adverse events.

Figure 1 shows the distribution of SGS scores before treatment (baseline) and at 3-, 6- and 12-month follow-up. A higher grade indicates a higher SUI severity. Results show a shift to a lower grade and therefore an improvement in SUI after treatment with Urolon™.

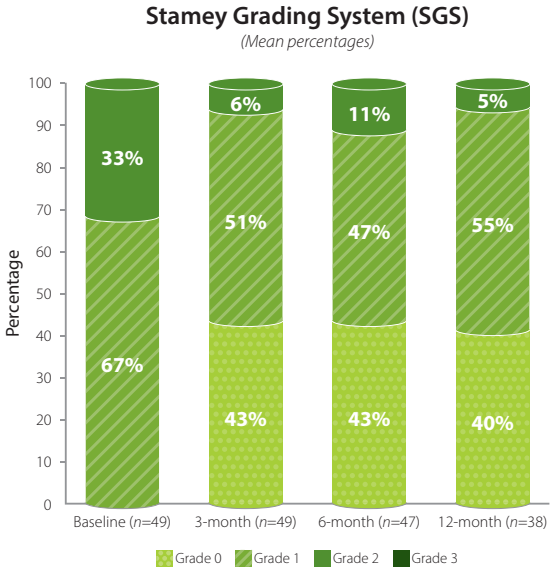

Figure 1: SGS at baseline, 3-, 6- and 12-month follow-up. A higher grade indicates a higher SUI severity. Results show a shift to a lower grade and therefore an improvement in SUI after treatment with Urolon™.

Figure 2 shows the total improvement of SGS at 3-, 6- and 12-month follow-up. Total improvement at 3-month follow-up was 63%, at 6-month follow-up 57% and at 12-month follow-up 58%. Of note is that the majority of subjects at baseline were SGS1 (mild) which is very difficult to reduce to a SGS0 (low sensitivity of SGS), therefore results are likely an underestimate of actual improvement.

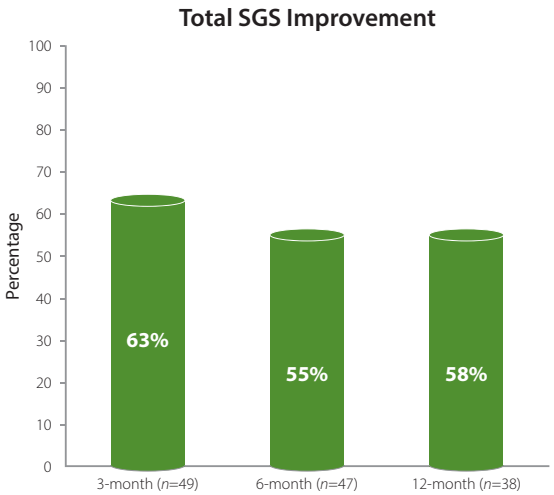

Figure 2: SGS total improvement results showing sustained improvement in SGS at both 3-, 6- and 12-month follow-up.

REFERENCES

1. Ford AA, et al. Cochrane Database Syst Rev. 2015;7:CD006375
2. Tamanini JT, et al. J Endourol. 2006;20(12):1082-1086
3. Pai A & Al-Singary W. Cent European J Urol. 2015;68(4):428-433
4. Futyma K, et al. Eur J Obstet Gynecol Reprod Biol. 2016;207:68-72

Figure 3 shows the results for the PGI-S improvement at 3-, 6- and 12-month follow-up as 76%, 72% and 63% respectively. While slightly decreased, this still represents sustained improvement up to 12-month follow-up.

Figure 4 shows the mean PGI-I improvement at 3-, 6- and 12-month follow-up as 86%, 75% and 79% respectively.

In addition to a reduction in severity of SUI symptoms and sustained efficacy, the data also show improvement in Quality of Life (QoL). Results show that the median ICIQ-SF score improved from "severe" at baseline to "moderate" at 3-, 6- and 12-month follow-up (figure 5). This improvement in QoL is further reflected in figure 6 which shows the improvement in I-Qol scores at the 3-, 6- and 12-month follow-up where subjects had an 88%, 91% and 90% improvement in I-QoL respectively.

Only 6 out of 49 subjects reported post-treatment related adverse events (AE) which were mild in nature and resolved spontaneously by providing relevant medication and/or catheterization (2 additional recorded AEs were not related to Urolon™; psoriasis and severe coughing). One AE was recorded as serious due to required hospitalization. However, it was also mild in nature (urinary retention) and resolved with the use of a catheter. Three AE's occurred directly post-treatment (hematuria, dysuria and urinary retention) and 2 AE's between treatment and the 6-month follow-up (urinary tract infection, urge incontinence). In summary, this demonstrates the high safety profile for Urolon™.

Initial data show 29% of subjects were re-treated, which is favorable when compared to other currently available UBA's which show re-treatment rates of 35%-77%[1-4]. Whilst re-treatments have often been listed as a negative aspect of UBA's, of note is that subjects during the clinical study requested re-treatment due to a low treatment-impact and desired to further sustain and/or improve treatment effect. Mean injection volume at treatment was 1.5ml with a mean re-injection volume of 1.3ml (corrected for a priming volume of 0.4ml).

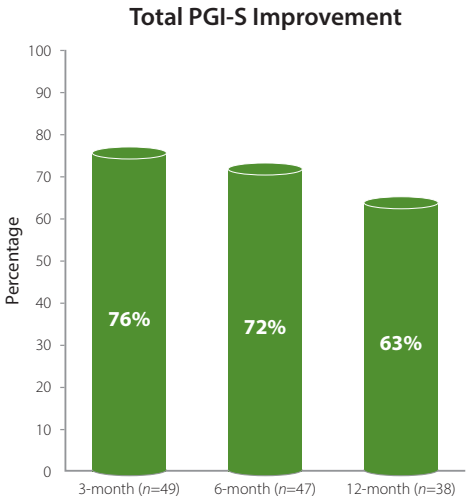

Figure 3: PGI-S total improvement shows sustained improvement up to 12-month follow-up

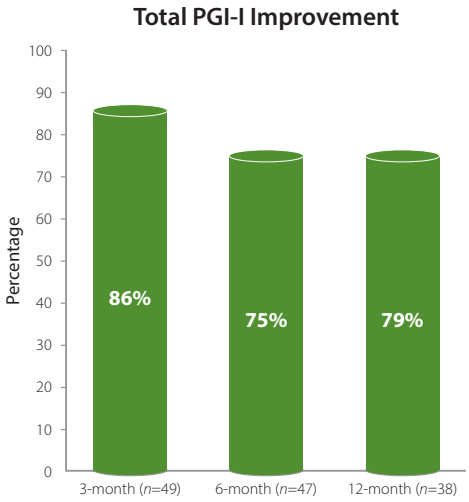

Figure 4: PGI-I total improvement showing sustained efficacy.

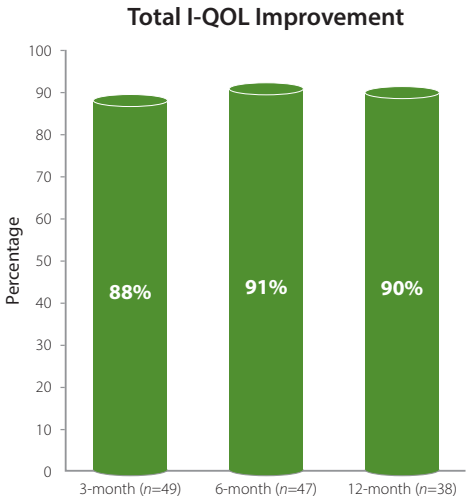

Figure 6: Total I-QOL improvement at 3-, 6- and 12-month follow-up

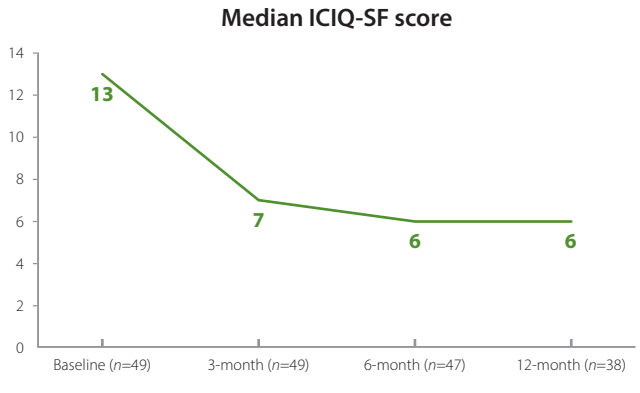

Figure 5: Results show an improvement in median ICIQ-SF scores from "severe" at baseline to "moderate" at 3-, 6- and 12-month follow-up

In summary, the intermediate analysis shows Urolon™ as a safe and effective treatment option for females with mild to moderate SUI who have attempted or failed pelvic floor muscle training. Results show improvements in SUI severity and QoL with only 6 out of 49 mild treatment-related AE's which supports a high safety profile. Anecdotal reports from all clinical study sites confirms the performance of Urolon™ as superior in comparison to other UBA's on the market. The bioresorption profile of Urolon™ is an attractive characteristic and feedback from urologists, gynecologists and urogynecologists alike, suggest this is a highly sought-after feature of a UBA. As the study is ongoing additional data will be provided at 24-month follow-up to further confirm the safety and efficacy profile of Urolon™.

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