Treatment with a Polycaprolactone-Based Bioresorbable Urethral Implant for Mild to Moderate Stress Urinary Incontinence

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E.L. Koldewijn[1], S. De Wachter[2], D.J.A.J. Oerlemans[3], M.J.A.M. de Wildt[1], V. Vandoninck[3]

AIM OF THE STUDY

The aim of the ongoing study is to support the safety and efficacy of a CE-marked polycaprolactone (PCL)-based bioresorbable urethral implant (Urolon™) for the treatment of mild to moderate female stress urinary incontinence (SUI).

STUDY DESIGN, MATERIALS AND METHODS

50 female subjects, recruited between September 2016 and July 2017, were treated by transurethral sub-mucosal injection of the PCL-based bioresorbable urethral implant. The mean (± sd) initial injection volume was 1.5 ± 0.5 cc with a median of 1.6 cc. 34% of the subjects were re-treated. Total mean injection volume (initial volume + re-treatment) was 1.9 ± 0.9 cc with a median of 1.6 cc. All subjects had attempted and failed prior pelvic floor muscle training. SUI symptoms and treatment success (efficacy) were assessed with the Patient Global Impression of Severity (PGI-S), Patient Global Impression of Improvement (PGI-I) and International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF).

SAFETY RESULTS

Six subjects reported a total of 8 transient adverse events (AE) which were mild in nature and resolved following relevant medication and/or temporary catheterization. At 12-month follow-up, all subjects received an additional cystoscopic examination. No abnormalities were found at the injection sites.

SUSTAINED IMPROVEMENT UP TO 18-MONTH FOLLOW UP

An important endpoint of the study is the PGI-S showing that 76%, 72%, 63% and 71% of the subjects were improved at 3-, 6-, 12- and 18-month follow-up, respectively. *Figure 1* represents sustained improvement up to 18-month follow-up.

Furthermore, PGI-I results show that 86%, 75%, 80% and 79% of the subjects were satisfied with the treatment at 3-, 6-, 12- and 18-month follow-up, respectively. This shows that the treatment was experienced with high satisfaction by the subjects (*Figure 2*) up to 18-month follow-up.

Median ICIQ-SF scores improved from "severe" at baseline to "moderate" at 3-, 6-, 12- and 18-month follow-up (*Figure 3*).

CONCLUSION

In summary, the current intermediate analysis shows that the CE-marked PCL-based bioresorbable urethral implant (Urolon™) is a safe and effective treatment option for females with mild to moderate SUI who have attempted or failed pelvic floor muscle training. Results show a sustained efficacy and subject satisfaction to at least up-to 18-month follow-up with only 6 subjects with treatment-related mild AE's, which supports a high safety profile. As the study is ongoing (up to 2 years follow-up), additional data will become available.

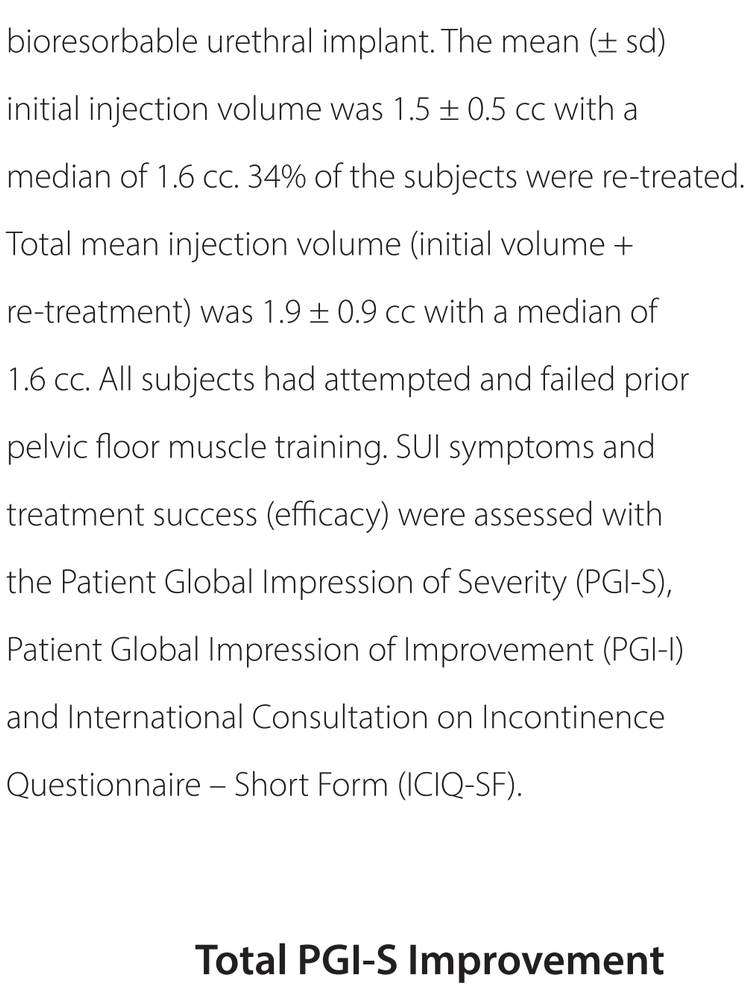

FIGURE 1: PGI-S total improvement shows sustained improvement up to 18-month follow-up (per-protocol analysis).

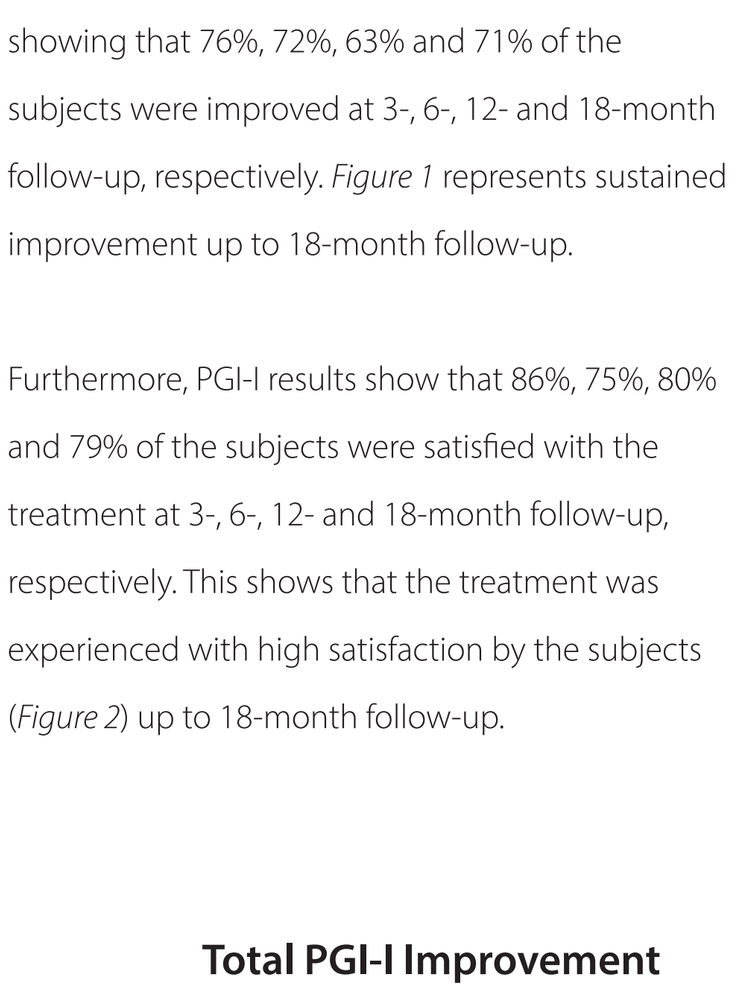

FIGURE 2: PGI-I total improvement shows sustained efficacy up to 18-month follow-up (per-protocol analysis).

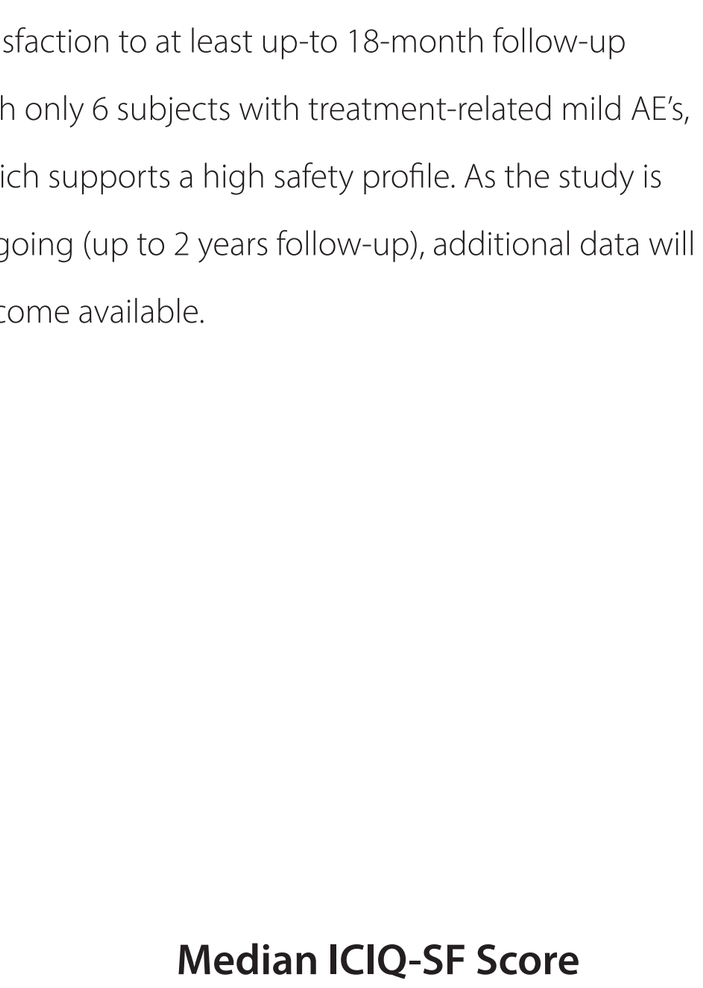

FIGURE 3: Results show an improvement in median ICIQ-SF scores from "severe" at baseline to "moderate" at 3-, 6-,12- and 18-month follow-up (per-protocol analysis).

AUTHORS

1. Catharina Hospital, Eindhoven, The Netherlands
2. University Hospital Antwerp (UZA), Edegem, Belgium
3. Laurentius Hospital, Roermond, The Netherlands

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