A polycaprolactone-based bioresorbable collagen stimulator for mild to moderate SUI

Koldewijn, Evert L.[1§], De Wachter, Stefan[2], Oerlemans, Dennis J.A.J.[3], De Wildt, Michel J.[1], Vandoninck, Vera[2]

CONCLUSION

Preliminary results show this polycaprolactone-based bioresorbable collagen stimulator (BCS) to be a promising safe and effective treatment for women with mild to moderate SUI.

INTRODUCTION AND AIM OF THE STUDY

A polycaprolactone-based BCS is evaluated for safety and efficacy in female patients with mild to moderate SUI who attempted or failed prior pelvic floor muscle training. A long-lasting clinical effect is expected due to polycaprolactone induced neocollagenesis, forming a scaffold of natural collagen (types I and III) around the microspheres. Polycaprolactone has been used successfully in numerous FDA approved and CE-marked medical devices and is fully bioresorbable.

MATERIALS AND METHODS

50 female patients will be treated by transurethral sub-mucosal injection with a novel polycaprolactone-based BCS. At the time of writing, 39 have been treated, 11 completed the 3-month follow-up and 4 completed the 6-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 (PGI-S) and Patient Global Impression of Improvement (PGI-I).

RESULTS

SGS improvement was 63.6% at 3-month follow-up (n=11), including a 27.3% cure rate. The PGI-S was improved in 72.7% of the patients including a 36.4% cure rate. In 90.1% of the patients improvement was shown with the PGI-I. Both ICIQ-SF and I-QoL improved. One mild treatment related Adverse Event was reported (transient urinary retention).

INTERPRETATION OF RESULTS

The intermediate analysis shows that the treatment is safe and effective, resulting in improvements in SUI severity and QoL. Preliminary 6-month follow-up data shows sustained (compared to baseline) and further improvement (compared to 3-month follow-up data), without any reported safety issues. The study is ongoing and the amount of data and follow-up period will be expanded up to 5 years, providing additional safety and efficacy data. (See ADDITIONAL CLINICAL DATA)

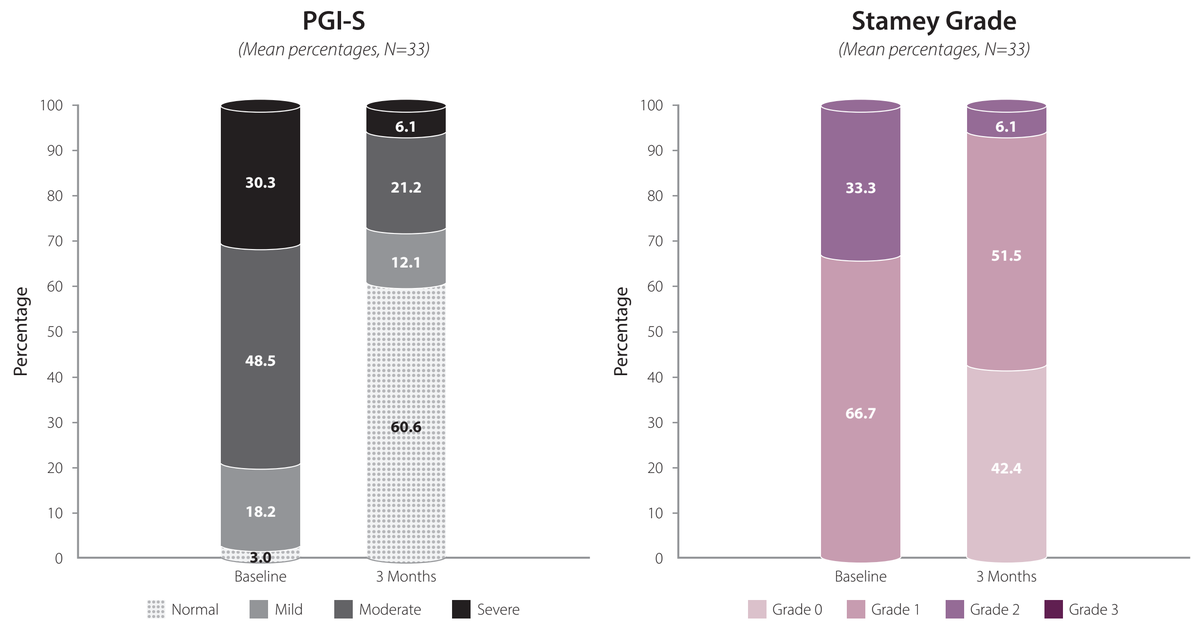
ADDITIONAL CLINICAL DATA

Since abstract submission a further 11 patients have been treated. Out of 50 patients treated, 33 completed the 3-month follow-up and 4 have completed the 6-month follow-up.

This additional data shows:

- SGS improved in 63.6% of patients at 3-month (n=33) including a 42.4% cure rate
- PGI-S improved in 78.8% of patients including a 60.6% cure rate
- PGI-I improved in 84.8% of patients
- ICIQ-SF and I-QoL both improved
- Of all patients treated (n=50), 3 reported mild Adverse Events;
  - 2 reported treatment related transient urinary retention
  - 1 reported transient urge incontinence.

3-MONTH FOLLOW-UP (N=33)



AUTHORS

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

§ Corresponding author • E-mail: evert.koldewijn@catharinaziekenhuis.nl

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