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EXPERIENCE WITH THE ZUIDEX™ SYSTEM IN CLINICAL PRACTICE: INTRODUCTION OF A MODIFIED INJECTION TECHNIQUE

Hypothesis / aims of study

The Zuidex™ system is designed for urethral injection in the treatment of stress urinary incontinence (SUI) in women. It comprises four syringes filled with non-animal stabilized hyaluronic acid/dextranomer (NASHA/Dx) gel, and an Implacer™ device for guided injection without the need for cystoscopy. Urethral injection of NASHA/Dx gel has been shown in several clinical studies to be effective and well tolerated, providing significant improvement in urinary leakage that is in many cases sustained for up to 6–7 years (1,2).

We have used a modified injection technique, whereby the needles are mounted such that the desired depth of injection is determined when the device is assembled. Thus, the needles only need to be pushed forward during treatment, and there is no need for a back-and-forward motion to determine the appropriate injection depth. This simplifies the treatment procedure, makes it more reproducible, and should reduce the risk of complications such as urinary retention.

We report the efficacy and safety of NASHA/Dx injection for SUI in clinical practice, firstly using the original injection technique and subsequently using the modified technique.

Study design, materials and methods

A total of 105 female patients with SUI were treated between February 2003 and March 2006. Of these, 96 patients had at least 3 months' follow-up and are included in this study.

Eighty-two patients were treated up until August 2005 using the original technique, and the remaining 14 patients were treated from April 2005 using the modified approach. For patients not improved to their satisfaction after their first Zuidex™ treatment procedure, up repeat treatment (up to a total of three procedures) was permissible. Two patients who were initially treated using the original technique underwent re-treatment using the modified technique.

Treatment success was assessed based on pad usage, 24-hour pad test and standardized provocation test. Patients who did not require any pads, or had 24-hour pad test leakage less than 8 g, or had no measurable provocation test leakage were classified as cured. Patients with a pad test or provocation test leakage reduction of at least 50% versus baseline were classified as improved, and the remaining patients were classified as unchanged. (Patients could be classified as cured or improved if they satisfied the relevant criteria in any tests that were completed).

Results

Patients' mean age at first Zuidex™ treatment was 60 years (range: 31–83 years). Complicating factors included prolapse (7 patients), asthma (4), and uterine enlargement due to fibroids (2). Eighty-five patients (89%) were assessed as having pure SUI and 11 (11%) had mixed incontinence. Nine out of the 11 patients with mixed incontinence were treated with anticholinergics prior to Zuidex™ treatment. Mean leakage at baseline was 114.7 g (range: 8–1290 g).

Twenty-nine patients received two treatments (two of these using the modified technique), and four patients received three treatments.

Treatment outcomes in the two patient groups, at a mean follow-up of 8.8 months after the last Zuidex™ treatment (range: 3–37 months), are summarized in Figure 1. The percentage of patients cured or improved was 78% among those treated with the original technique, and 100% in those treated with the modified approach.

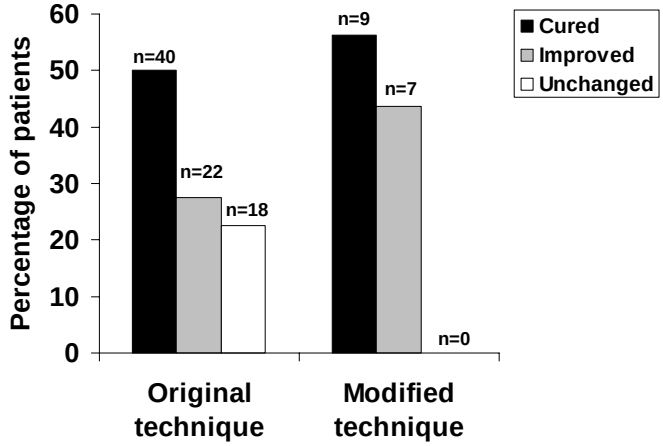

Figure 1. Treatment outcomes after Zuidex treatment (original *vs* modified technique, as used for last treatment procedure) for stress urinary incontinence.

Among the patients classified as improved (both treatment groups), only one later opted for a mid-urethral sling, while 11 of the unchanged patients chose that option.

Following initial treatment with the original technique, urinary retention was reported by seven patients (9%); catheterization was needed by seven (9%); and urgency was reported by nine patients (11%). These data were for the first treatment procedure, and were similar to the corresponding results following the second procedure (two patients [7%], three [11%] and two [7%], respectively). All of these events were transient in nature. In the group treated with the modified technique, urinary retention was reported by two patients (14%) after the first treatment, and one patient (50%) had urinary retention after the second treatment procedure (there were no cases of urgency). Five patients treated with the original technique developed pseudocysts which were treated successfully, but there were no such reports in those treated with the modified approach. In the longer term (3 months post-treatment), two patients in the original group (2%) reported some voiding difficulties and 12 (14%) reported urgency problems; in the modified group, one patient (7%) reported urgency.

Interpretation of results

These data show that the vast majority of patients treated with the Zuidex™ system are cured or improved following treatment, and that the procedure is well tolerated. The results suggest that the modified injection technique may improve the effectiveness of treatment, and that it may reduce the incidence of adverse events such as urgency and pseudocyst.

Concluding message

Further data with this promising, modified technique for administering Zuidex™ treatment are awaited with interest.

References

1. *Int Urogynecol J Pelvic Floor Dysfunct* 2003; **14**: 335-8.
2. Data presented at the International Continence Society (ICS) Congress 2004, Paris, France. Abstract no. 667.

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HUMAN SUBJECTS: This study did not need ethical approval because Approval not required for clinical practice studies in Sweden and did not follow the Declaration of Helsinki - with approval by the ethics committee - in the sense that The study was performed in the context of clinical practice as opposed to a clinical trial setting Informed consent was obtained from the patients.