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THE ZUIDEX™ SYSTEM FOR THE TREATMENT OF STRESS URINARY INCONTINENCE: 36-MONTH FOLLOW-UP

Hypothesis / aims of study

Transurethral or periurethral injection of specific agents into the submucosa has been used for several decades in the treatment of female stress urinary incontinence (SUI). However, concerns have arisen relating to certain agents. One such problem is a lack of implant durability, leading to a requirement for multiple re-treatments. Despite this, there are very few data relating to the long-term efficacy of urethral injection therapy. The Zuidex™ system is an SUI treatment that was initially shown to significantly improve incontinence and quality of life (QoL) over 12 months (1, 2), with improvements sustained to 24 months in an extension phase (3). This study was undertaken to investigate whether Zuidex improves incontinence symptoms and QoL up to 36 months post-treatment.

Study design, materials and methods

This was an open, multicentre study approved by independent ethics committees and performed in accordance with the Declaration of Helsinki. Women with SUI were treated with Zuidex (4 x 1.0 ml or 4 x 0.7 ml injections of non-animal stabilised hyaluronic acid/dextranomer [NASHA/Dx gel] via the Implacer). Inclusion criteria included: age ≥18 years, history of SUI for ≥12 months, failure of previous non-invasive treatment, and no prior invasive therapy. Patients who were not improved to their satisfaction were offered a second treatment 1–2 months later. Patients who completed the initial 12-month follow-up were eligible for the extension phase. Extension efficacy assessments included only those patients entering the extension phase who were classified as responders (defined as ≥50% improvement in urine leakage by provocation test at 12 months compared with baseline). Efficacy assessments were performed at baseline, 1, 3, 6 and 12 months, 2 years and 3 years. Efficacy parameters included urine leakage by provocation test, number of incontinence episodes/24 hours and patient perception of bladder condition (six-category scale from ‘many severe problems’ to ‘no problems’). QoL was assessed using the King’s Health Questionnaire (KHQ).

Results

A total of 18 patients were included in the extension efficacy population. Median urine leakage by provocation test was significantly decreased compared with baseline at all timepoints from 3 months to 3 years following treatment ($p<0.0001$; Figure 1). Seventeen patients remained responders at 3 years (the remaining patient was a responder at 2 years and withdrew consent before the 3-year assessment). The number of patients with no urine leakage by provocation test increased from 4/18 at 3 months to 9/18 at 3 years post-treatment. Patients who required re-treatment had similar improvements in median urine leakage by provocation test to those who received only one treatment, but more were considered dry at 3 years (6/8 *vs* 3/10 patients, respectively). The median number of incontinence episodes/24 hours decreased significantly from 2.2 at baseline to 0.3 at 3 years post-treatment ($p=0.0003$; Figure 2).

Median KHQ domain scores were significantly improved compared with baseline in 7/10 domains at 12 months ($p\leq0.014$), and this improvement was sustained in six domains (incontinence impact, role limitation, physical limitation, social limitation, emotions and urinary symptoms) at 3 years ($p\leq0.011$). The median domain scores for personal relationship and sleep/energy were zero (indicating no impairment) at baseline and remained zero at all subsequent assessments. There was no significant change from baseline in general health perception or severity measures at 3 years. Patient perception of bladder condition was improved by at least one category compared with baseline in 14/18 patients at 3 years, with 13 patients reporting either minor or no problems.

Figure 1. Median urine leakage by provocation test following Zuidex treatment.

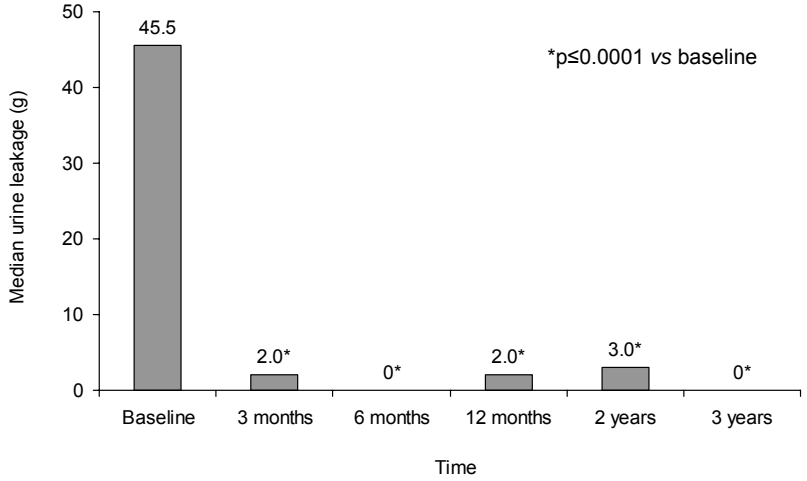
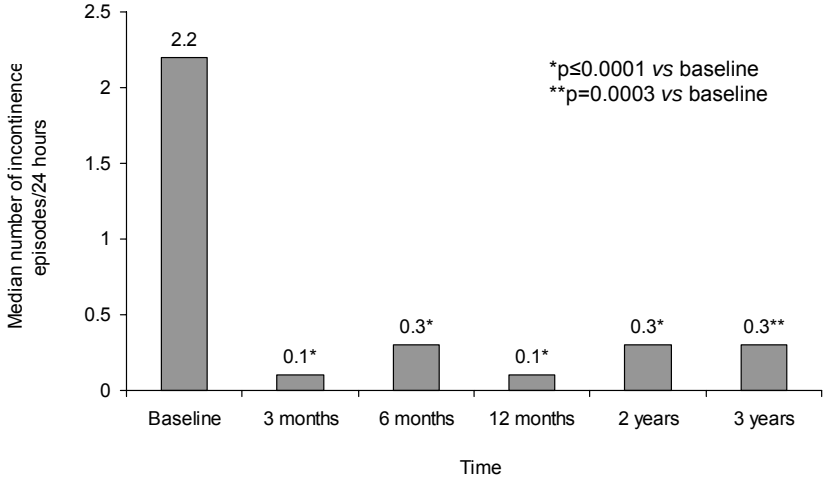


Figure 2. Median number of incontinence episodes/24 hours following Zuidex treatment.



There were no treatment-related adverse events during the extension study.

Interpretation of results

This is the longest follow-up study of Zuidex treatment of SUI to date, and shows that this therapy is well tolerated and produces sustained improvements in incontinence symptoms and QoL over at least 3 years. As all patients included in the efficacy extension population were responders at 12 months, the results indicate that the beneficial effects of Zuidex are sustained for at least 3 years in the vast majority of patients who demonstrate an initial improvement in symptoms.

Concluding message

This study has shown that the beneficial effect of Zuidex is sustained for at least 3 years in the majority of patients with SUI who have a positive response 12 months after treatment. These preliminary results suggest that durability problems associated with other injectable agents may not be applicable to Zuidex.

1 Efficacy and safety of a novel system (NASHA/Dx copolymer via the Implacer device) for the treatment of SUI. *Urology* 2004; **64**: 276–81.
2 Treatment of stress urinary incontinence using a copolymer system: impact on quality of life. *BJU Int* 2004; **94**: 1040–3.
3 The Zuidex™ system for the treatment of stress urinary incontinence: 24-month follow-up. Presented at the International Continence Society Congress 2004, Paris, France.

FUNDING: Q-Med AB, Uppsala, Sweden