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MACROPLASTIQUE® IMPLANTATION SYSTEM FOR THE TREATMENT OF URODYNAMIC STRESS URINARY INCONTINENCE CAUSED BY URETHRAL HYPERMOBILITY IN ADULT WOMEN AFTER NON-SUCCESSFUL CONSERVATIVE TREATMENT: A RANDOMIZED CLINICAL TRIAL

Hypothesis / aims of study
To evaluate the efficacy and the quality of life in women using the Macroplastique Implantation System, a novel guiding instrument for transurethral injection of Macroplastique (MPQ), as a minimally invasive procedure in adult women with urodynamic stress urinary incontinence caused by urethral hypermobility after non-successful conservative treatment

Study design, materials and methods
A prospective randomized controlled, single centre, clinical trial comparing a group with MPQ injection(s) in the submucosa of the urethra utilizing the MPQ Implantation Device with a control group receiving written instruction about a pelvic floor muscle exercises home training program.
After informed consent women with no previous incontinence surgery answered a Quality of Life Questionnaire and Patient Questionnaire including Stamey incontinence rating. Frequency/volume chart, 1-hour ICS pad test, routine urogynecological work-up and urodynamic assessment including Valsalva leak point pressure were performed. All women were diagnosed with urodynamic stress urinary incontinence caused by urethral hypermobility and Valsalva leak point pressure > 60 cm water. Women were followed up till 3 and only the MPQ group also up till 12 months. Data analysis was done according to intention-to-treat principle.

Results
Forty-seven women were included between April 2002 and May 2007. Eventually, the MPQ group contained 24 women and the control group 21. Two had to be excluded because they did not fulfil inclusion criteria. Mean age was 55 years (40-76). Baseline characteristics of both groups were similar. The injected volume of MPQ was 5 ml in all women. An additional injection of 5 ml MPQ was performed in two women after 3-month follow-up. There were no dropouts at the 3 months follow-up. At 3 months, the pad test showed an improvement in both groups, although this was not statistically significant (p=0.328). In the MPQ group, the number of pads used decreased statistically significant more than in the control group (p=0.015). According to the physician and patient self-assessment, 17 (71%) and 15 (63%) women in the MPQ group were considered to be cured or markedly improved, respectively. This was both significantly higher compared to the control group (6; 29%, 4; 19%), respectively (p=0.029 and p=0.002). The increase of the Dutch validated I-QOL score in the MPQ group was significantly higher compared to the control group (p=0.035). For the three subgroups (avoidance and limiting behaviour, psychosocial impacts and social embarrassments items), a statistically significant higher improvement was noted in the MPQ group compared to the control group (p=0.024, 0.010, 0.007, respectively). At 3 months follow-up, 5 women received other continence treatment because of treatment failure. At 12 months, physician and patient self-assessment cure and markedly improved rate was 66.7% and 58.3% in the MPQ group, respectively. Two women out of nineteen were recorded as a failure. The treatment was well tolerated according to women treated, and considered acceptable and easy to perform by the physician. The adverse events of 26 procedures (n;%) were retention (19; 73.1%), mild pain (2; 7.7%), hematuria (2; 7.7%), dysuria (12; 46.2%), leakage of implant (2; 7.7%), and were mild and transient.

Interpretation of results
At 3 months, within group results of the pad test results showed improvement, but no significant difference between the two groups could be shown. More clearly, the decrease in number of pads used in the MPQ group at 3 months was significant different from the control group. Also, the subjective parameters were significantly better in the MPQ group compared to the control group. These results of MPQ treatment of stress urinary incontinence in patients with urethral hypermobility are in line with data from literature in patients without hypermobility. Comparing the results with other more invasive surgical treatments the MPQ shows a slightly lower success rate with a lower risk of complications. The improvement in the quality of life is in the same range as surgical interventions and confirms the trend in patient's preference to have a procedure with a lower risk of complications. The cure and markedly improved rates were sustained in the MPQ group at 12 months.

Concluding message
This study indicates that the bulking agent Macroplastique can also be used for stress urinary incontinence caused by urethral hypermobility and in the treatment algorithm of stress urinary incontinence this bulking agent implanted with the MPQ Implantation Device is a suitable candidate as first line surgical treatment. The procedure was easy to perform, safe and well accepted by women and physician. The success rates are satisfactory and the patient's quality of life increases significantly. The results were sustained at least for a year.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**

What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of University Hospital Maastricht, Maastricht, the Netherlands**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**