

## DEFLUX®-INJECTIONS FOR THE TREATMENT OF INCONTINENCE AFTER RADICAL PROSTATECTOMY OR TUR-P

### Hypothesis / aims of study

Stress urinary incontinence after prostatectomy is a postoperative complication that can have a severe effect upon the patient's quality of life. The incidence of post-prostatectomy incontinence varies with the method used, the modality of data collection and the definition of incontinence used and can be found with an incidence of 0.4-40 %. Currently there are several methods available for treatment. One option is the implantation of an artificial sphincter. More minimal invasive methods include pro-ACT implantation, male sling procedures and the transurethral application of bulking agents. Throughout time various materials have been used as bulking agents. Newer materials are collagen, polytetrafluorethylene or macroplastique®. Deflux® is a dextranomer/hyaluronic acid copolymer that is successfully used in the treatment of vesicoureteral reflux. Recently Deflux® is also used as a bulking agent in the treatment of SUI. In the literature, no data about the application of Deflux® as bulking agents in males as treatment modality for SUI after prostatectomy are available at present. The aim of this study was to present our experience, results and complications after Deflux®-injections.

### Study design, materials and methods

Since 2004 13 patients (n=12 after radical prostatectomy and n=1 after TUR-P) with a mean age of 70.1 years have been treated with transurethral Deflux®-injections. Preoperative evaluation included urodynamic studies, cystoscopic examination and sonography to exclude residual urine. A total of 3 ml of Deflux® was injected submucosal into the sphincter. Average pad use per day preoperatively was 6.1. Evaluation visits took place 1 and 3 months after the first injection and again after 3 months after re-injection. Continence was defined as a maximum use of one pad during daytime for security reasons and no pad use at night.

### Results

Average pad use decreased to 4.1 after injection. Two patients were completely continent and 2 patients did not show any benefit, 1 patient suffered from temporary impairment due to urgency. Side effects were sterile abscess (n=1), transient intermittent catheterisation (n=1) and mild hematuria (n=6). Summarizing all patients, 62 % were improved and 15% were continent. A total of 3 (23%) patients had to be re-injected after 4-6 weeks.

### Interpretation of results

Similar to the observations in the studies on Macroplastique® injections in men and the studies on Zuidex® in women, we could observe an improvement in 77% and 15% continent. A total of 3 (23%) patients had to be re-injected after 4-6 months. No relation between the degree of SUI before injection and the postoperative result can be seen.

The side effects - like perineal abscess, urinary retention and mild macrohematuria - were comparable to the other investigations on Macroplastique® or Zuidex. Apart from the perineal abscess all other complications were only transient. Nevertheless, continence rates after Deflux®-injection cannot reach those after alloplastic sphincter or the male slings.

### Concluding message

The transurethral injection of Deflux® is a save and effective treatment option for SUI after prostatectomy. Concerning the overall improvement this method is not comparable to the male sling procedures or alloplastic sphincter implantation.

### References

**FUNDING:** None

**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study did not need ethical approval because approved therapy but followed the Declaration of Helsinki Informed consent was obtained from the patients.