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### Abstract Reproduction Form B-1

Author(s):	J. Grosse, P. Walter, B. Mandalka, G. Gaul, G. Kramer, M. Stöhrer
	Double Spacing
Institution	Department of Urology and Urodynamic Unit, Berufsgenossenschaftliche
City	Unfallklinik Murnau, Murnau, Germany
Country	Double Spacing
Title (type in CAPITAL LETTERS)	<b>TREATMENT OF FEMALE NEUROGENIC INCONTINENCE BY A RE-INSERTABLE RESTERILISABLE INTRAURETHRAL SPHINCTER PROSTHESIS (In/Flow™)</b>

#### Aims of study

The first clinical experiences using the self-secured In/Flow™ prosthesis with a self-contained urinary pump in females with neurogenic lower urinary tract dysfunction demonstrate a limited acceptance because of the high incidence of bacteriuria and urinary tract infection. Therefore a home sterilisation unit was produced that can be used by the patient overnight, in combination with an exchangeable, self-insertable device. The efficacy of this method in reducing the incidence of infections and in increasing the acceptance of the In/Flow™ prosthesis is investigated.

#### Patients and methods

Since September 1996, 23 patients (20 spinal cord lesion; 3 genuine stress incontinence) with a mean age of 38 years (range 26 to 80 years) were treated with the In/Flow™ catheter that was exchanged monthly in the office. Since October 1997 six further patients use and exchangeable self-insertable system. All patients failed earlier conservative or surgical incontinence treatments. Initial evaluation included history, physical examination, cystoscopy and urodynamics. Post-treatment symptom questionnaire, urine culture, residual urine and urodynamics after 6 and 12 months follow up were performed.

#### Results

All women emptied the bladder completely. From the first group of 23 patients, twelve were dry, satisfied and still use the In/Flow™ with a mean follow up of 18 months (range 3-27 months). The other 11 patients did not tolerate the prosthesis for a longer period than one month. The reasons were (multiple nominations possible): vegetative dysreflexia in four cases, bladder discomfort in five, recurrent urinary tract infections in four cases and ulceration of the external meatus in two patients. Asymptomatic bacteriuria occurred in 16 patients after a mean follow-up of 4 months.

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Author(s):

J. Grosse, P. Walter, B. Mandalka, G. Gaul, G. Kramer, M. Stöhrer

Four out of the six patients who use the self-insertable In/Flow™ were free of infection after 4 months, transient asymptomatic bacteriuria occurred in two patients. Two prototypes had to be replaced within two months of application because of technical problems. One of these patients had a mild ulceration of the bladder neck. The overall patient satisfaction with this new system is very high in both groups.

Conclusions

In selected cases, in particular for patients who are unable to practice intermittent self catheterization, this prosthesis is safe, effective and improves quality of life. It is a convenient solution for treatment of incontinence in females with underactive detrusor function during voiding. Detrusor hyperreflexia should be treated additionally with anticholinergic drugs to avoid urinary leakage around the prosthesis and to prevent vegetative dysreflexia. The high incidence of bacteriuria and urinary infections is still a limiting factor in the use of intra-urethral prosthesis, in particular in patients with neurogenic lower urinary tract dysfunction. This warrants further improvements in the design of these prosthesis. For long-term application the daily exchangeable self-insertable In/Flow™ catheter in combination with a sterilisation unit for home use appears advantageous in the prevention of urinary tract infections.