Int Urogynecol J (2009) 20:177–183
DOI 10.1007/s00192-008-0741-5

ORIGINAL ARTICLE

Effects of Macroplastique® Implantation System for stress urinary incontinence and urethral hypermobility in women

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Received: 17 June 2008 / Accepted: 25 September 2008 / Published online: 21 October 2008

Abstract A study was carried out to evaluate efficacy of Macroplastique® (MPQ) Implantation System (MIS) in women with urodynamic stress urinary incontinence (SUI) and urethral hypermobility after an unsuccessful conservative treatment. This is a prospective randomized controlled trial in women without previous incontinence surgery. Twenty-four women received MPQ. Twenty-one controls underwent a pelvic floor muscle exercises home program. Follow-up was at 3 months and the MPQ group also at 12 months. At 3 months, pad usage decreased significantly more in the MPQ group than in the control group (p= 0.015). According to physician and patient self-assessment, respectively, 71% and 63% women in the MPQ group were considered cured or markedly improved. This was significantly higher compared to controls. There was a significant higher increase of Incontinence Quality-of-Life questionnaire score in the MPQ group compared to controls (p= 0.017). Improvements in MPQ group at 3 months are sustained to 12 months. Adverse events were mild and transient. MIS is an acceptable option for women with SUI and urethral hypermobility.

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Keywords Hypermobility · Macroplastique® Implantation System · Polydimethylsiloxane · Quality of life · Randomized clinical trial · Stress urinary incontinence

Introduction

For the treatment of stress urinary incontinence (SUI) in adult women, there is a broad variety of therapies nowadays. They range from physiotherapy to surgical interventions. Injection therapy with urethral bulking agents is generally considered as a minimally invasive procedure for SUI [1]. However "minimally invasive" is a relative term and can be viewed as minimally invasive from the surgeon's perspective or the patient's. Acceptance for injection therapy as the least invasive of all surgical procedures is progressing [2, 3].

Injection therapy can be used for all types of SUI. Urethral hypermobility is thought to decrease the success of treatment with injectables [4]. However, published results of periurethral collagen injections for SUI caused by hypermobility indicate positive outcome [5]. No differences in success rates with and without hypermobility were reported [6].

Macroplastique® is a urethral bulking agent that has been used in the treatment of urodynamic stress incontinence (USI) in adult women for approximately 9 years [2, 7, 8]. In studies, success rates vary from 58% (long term) to 73% (short term) [9]. Macroplastique® is a bulking agent that consists of solid polydimethylsiloxane particles with a mean maximum diameter of 209 μm [10]. After injection, these particles seem to be nonmigratory and will be organized within 6 to 8 weeks in firm nodules with infiltrated collagen and surrounded by a fibrous sheath that is well developed at 9 months [11–14].

The aim of this study is to evaluate the efficacy and the quality of life in women using the Macroplastique® Implantation System (MIS), a novel guiding instrument for transurethral injection of Macroplastique®, as a minimally invasive procedure in adult women with USI and urethral hypermobility after an unsuccessful conservative treatment (i.e., no improvement of SUI after pelvic floor muscle exercises (PFME)).

Materials and methods

The study was approved by the Medical Ethical Committee of the University Hospital Maastricht, the Netherlands. Data out of this study and the informed consent forms were obtained complying with the applicable regulatory requirements, adhering to Good Clinical Practice and to the ethical principles that have their origin in the Declaration of Helsinki [15]. The study is designed to comply with the CONSORT statement and follows the CONSORT checklist registration study (www.consort-statement.org)

Forty-seven adult women with USI and urethral hypermobility after an unsuccessful conservative treatment and no history of previous incontinence surgery were included in this prospective, randomized, controlled and single-center clinical trial between April 2002 and May 2007. Prior to participation of this study, each woman completed dipstick urinalysis, a Quality-of-Life Questionnaire (QoL), Patient Questionnaire including Stamey incontinence rating [16]. Stamey rating is as follows. Grade 0: The patient is continent (dry). Grade 1: The patient will lose urine with sudden increases in abdominal pressure (stressful activities such as lifting weights, coughing, or sneezing) but never in bed at night. Grade 2: The patient's incontinence worsens with lesser degrees of stress such as walking, standing erect from a sitting position, or sitting up in bed. Grade 3: The patient has total incontinence and urine is lost with any activity, irrespective of position. Also, a frequency–volume chart (FVC) and 1-h International Continence Society pad test [17] in addition to routine urogynecological workup including detailed physical examination with assessment of bladder neck excursion measurement and pelvic organ prolapse [18] and urodynamic assessment were performed. The Incontinence Quality-of-Life (I-QoL) Questionnaire was used in this study for the assessment of QoL [19]. The Dutch-translated and validated version is a reliable instrument for the assessment of QoL in women with urinary incontinence. The mean score lies theoretically between 1 and 5 and, the higher the score is, the more satisfied patients are about their continence condition. The 22 I-QoL item scores can be divided in three domains: "avoidance and limiting behavior," "psychosocial impacts," and "social embarrassment". Measurement of bladder neck mobility was assessed by the Q-tip test [20]. Independently, Valsalva leak point pressure was measured. This measurement provides a validated tool to assess urethral function allowing an estimation of the relative contributions of intrinsic sphincter deficiency and urethral hypermobility [21].

Women, who met the primary inclusion and exclusion criteria (Table 1), were considered candidates for randomization. Written informed consent was obtained from all women. The women were randomized for Macroplastique® injection utilizing the Macroplastique® Implantation Device (MID) or a control PFME home training program. Randomization process was performed using sealed envelopes containing the treatment assignment. A table of random numbers was used; all 0–4 were assigned to MPQ and all 5–9 were assigned to control PFME home training program. The control group was offered written instruction material for the maintenance of the PFME home training program.

The transurethral injection was performed using the MIS. The MIS consists of a set of two syringes of Macroplastique® (2.5 ml each), the implantation device (MID), and two special needles. The MID is used to standardize the location of periurethral injection, as described by Henalla et al. [22]. The initial injection was placed 10 mm from the bladder neck. The procedure was performed under sterile conditions and was carried out under local anesthesia in day case setting. Although only women with negative urinalysis and urine culture were allowed to undergo the intervention, postoperatively, 250 mg ciproxin twice daily was given for 5 days as prophylaxis. If the patient was unable to pass urine spontaneously up to 3 or 4 h following the procedure, "in and out catheterization" with a catheter Ch12 was performed to relieve any symptoms of urinary retention. If residuals of more than 100 ml were detected, the patient was instructed to perform clean intermittent self-catheterization (CISC) with a catheter Ch12.

Both patient groups were followed up to 3 months from the moment of injection and the Macroplastique® group also up to 12 months after treatment. The 3- and 12-month follow-up visit included an FVC, I-QoL Questionnaire, Patient Questionnaire, and a pad test. A further Macroplastique® implantation procedure was scheduled after the 3-month follow-up, if clinically indicated or requested by the patient. A reimplantation was performed at a new level, in the midurethral position as defined by location with the MID. After repeat Macroplastique® implantation, women were again followed up at 3 and 12 months. Objective assessments of treatment outcome are the results of pad testing and FVC. Subjective assessments of treatment outcome are the results of I-QoL Questionnaire with Stamey incontinence rating, side effects, and complications, investigator Stamey incontinence rating, and subjective investigator stress incontinence cure rating. Treatment

Table 1 Inclusion and exclusion criteria

Inclusion
Female and at least 18 years of age
Urodynamic stress urinary incontinence and urethral hypermobility
Urodynamic assessment of SUI and VLPP >60-cm water
SUI did not show defined improvement after PFME therapy
No more than stage 0, 1, or 2 pelvic organ prolapse (Bump classification)
Negative dipstick urinalysis
Postvoid residual urine ≤100 ml
Not pregnant or within 12 months postpartum
Understanding of the Dutch language
Written informed consent document
Exclusion
Any prior solid particle UBA treatment or any surgical anti-incontinence procedure
A form of urinary incontinence other than SUI contributing substantially to their symptoms
A neurogenic bladder
Urinary incontinence due to an anatomical defect, fibrotic urethral mucosa (preventing Macroplastique® bolus formation), tissue damage due to injury, pelvic radiotherapy, or other therapy affecting the bladder neck and/or urethral tissues
A history of intermittent or long-term use of intraurethral continence devices
Voiding difficulties
A history of unexplained hematuria
Cystitis, urethritis, or evidence of possible infection, which would preclude safe penetration of the urethral wall with the implantation needle
An incurable malignant disease or other form of disease that is advancing rapidly and causing deterioration of the patient's physical condition
Any condition that could lead to serious postoperative complications (e.g., current infection or uncontrolled diabetes)
Lactating within 12 months postpartum or planning to become pregnant in the next 12 months
Morbidly obese (i.e., body mass index; BMI>40 kg/m^2)
Unable or unwilling to perform clean intermittent self-catheterization if the need arises (e.g., lack of manual dexterity, arthritic hands, dementia, etc.)

success and failure are defined as follows: success is "cured" (dry) or "markedly improved" (no further incontinence treatment needed), and failure is "slightly improved" (requires further incontinence treatment) or "unchanged" (requires further incontinence treatment).

Statistical analysis

The sample size was determined using the following power calculation. Given $p1=30\%$ (success rate of control), $p2=75\%$ (success rate of Macroplastique®), $\alpha=0.05$, and $\beta=0.05$ results in a value of 25.5 for n. The number of patients of each group should be a least 26. Metric variables are first inspected for normality of statistical distribution by the Kolmogorov–Smirnov test. If normally distributed, means and standard deviations are given for univariate variables; if not, medians and ranges are also provided. Categorical data are represented by frequencies and percentages (or proportions). Patient demographical characteristics and clinical data are broken down for the randomization arm (Table 2): Macroplastique® group or control group. For normally distributed variables, Student t test is used to verify similarity of means for baseline characteristics; for nonnormally distributed variables, the Mann–Whitney test is used. For categorical data, the log-likelihood chi-squared test is applied. For the pad test on the data, a 10-log transformation is also done to ensure normality of distribution for the performance of Student t test. The analysis of I-QOL data is performed at two levels: first, a general total scale is calculated on all 22 items and next the three subscales (the avoidance and limiting behavior, psychosocial impacts, and social embarrassment items) are constructed. To test changes in I-QoL data at 3 months after baseline measurements, repeated-measures analysis of variance is done and to control these changes for baseline factors or variables repeated-measures analysis of covariance is performed. To control for baseline measurements (and other confounding variables or factors) in nonnormally distributed changes in outcome variables measured at 3 months, a Mann–Whitney test is performed on the Studentized residuals of these outcomes found in regression analysis.

According to intention-to-treat principles in data analysis, missing values are imputed by general mean substitution. A p value of less than 0.05 is considered to be statistically significant. All data were analyzed with SPSS-pc, version 15.0 [23].

Results

The MPQ group contained 24 women and the control group 21. Two patients had to be excluded because they did not

Table 2 Patient's characteristics

	MPQ group (n=24)	Control group (n=21)	p value
Mean age, years (SD; range)	54.7 (8.9; 41–76)	55.6 (8.9; 40–73)	0.73
Mean BMI, kg/m^2 (SD; range)	26.6 (4.3; 20–40)	28.3 (8.3; 19–38)	0.41
Menstrual cycle (normal/perimeno/meno)	6/3/15	7/2/12	0.81[a]
Parities (median)	2	2	0.23[a]
Duration of incontinence, months (range)	142 (36–360)	118 (36–360)	0.35
VLPP, cm water (SD; range)	102 (28; 70–172)	93 (21; 63–136)	0.28

SD standard deviation
[a] Log-likelihood chi-squared test (other p values: Student's t test)

fulfill inclusion criteria (one was accidentally included twice and one had mainly frequency and urgency complaints). Mean age was 55 years (range 40–76). Baseline characteristics of both groups were similar as shown in Table 1. The injected volume of MPQ was 5 ml in all women. An additional injection of 5 ml MPQ was performed in two women after the 3-month follow-up. The treatment was well tolerated according to the women treated and considered acceptable and easy to perform by the physician. The following adverse events of 26 transurethral Macroplastique® injection using Macroplastique® Injection System in 24 women were reported: retention 19 (73.1%)*, mild pain 2 (7.7%), hematuria 2 (7.7%), dysuria 12 (46.2%), leakage implant 2 (7.7%), infection 0 (0%). Duration of retention (>100 ml) and dysuria complaints was 1–2 days, except in one woman with persistent retentions because of a "de novo" prolapse of the anterior vagina wall. The women experienced these events as acceptable and mild. Product-related side effects were not seen. There were no dropouts at the 3-month follow-up (Fig. 1).

The mean pad test at baseline showed a 19.6-g (median 7.5, range 0–115) and 24.9-g (median 13.8, range 2–84) urinary loss in the control group and MPQ group, respectively. After 3 months, the mean pad test showed an 11.9-g (median 4, range 0–66.6) and 15.1-g (median 3, range 0–133) urinary loss in the control group and MPQ group, respectively. This improvement was not statistically significant between the two groups (p=0.328).

The mean number of pads used per day at baseline was 2.7 (median 3, range 0–6) and 3.4 (median 3, range 0–6) in the control group and MPQ group, respectively. After 3 months, the mean number of pads were 2.5 (median 2, range 0–6) and 1.9 (median 1, range 0–11) in the control group and MPQ group, respectively. The number of pads used at 3 months in the MPQ group decreased statistically significantly compared the number used in the control group (p=0.015).

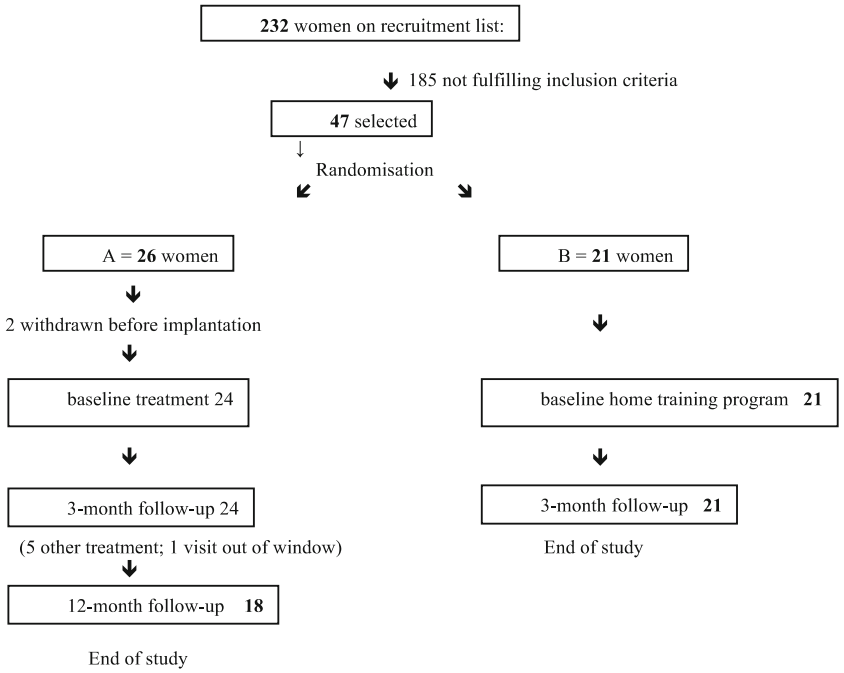
After the 3-month follow-up, five women in the MPQ group received other continence treatment because of treatment failure. The incontinence condition of women was rated by Stamey rating. At baseline and 3-month follow-up, the frequencies in grading for both groups as well as the 12-month follow-up of the MPQ group are shown in Table 3. At 3-months follow-up, the Stamey grading showed a statistically significant difference compared to baseline scores (p=0.020).

The physician's global impression of the incontinence condition of women was rated by the final surgeon incontinence rating (Table 4). The number of women (17; 70.8%) that was "cured" or "markedly improved" at 3 months was statistically significantly higher than that in the control group (6; 28.5%; p=0.029).

The subject's global impression of the incontinence condition was rated by patient self-assessment of the incontinence problem and is presented in Table 4. There was a statistically significant difference in the number of women (15; 62.5%) "cured" or "markedly improved" at 3 months in the MPQ group compared to that in the control group (4; 19.0%; p=0.002).

The Dutch-validated overall 22-item I-QoL showed a mean total score at baseline for the control group and MPQ group of 2.96 (SD=0.62) and 2.59 (SD=0.61), respectively, and at 3 months this mean total score was 3.03 (SD=0.66) and 3.20 (SD=0.73), respectively (Table 5). The increase in the MPQ group was significantly higher compared to the control group (F ratio=9.83:1 and 43 df, p=0.003). When the I-QoL scores are corrected for baseline values, the difference remained statistically significant (F ratio=6.15:1 and 42 df, p=0.017). The mean scores and standard deviations of the domain scales are also shown in Table 5. In all three scales and controlled for their respective baseline measurements, there was a statistically significant improvement in the means of the MPQ group compared to the ones of the control group (F=4.57:1 and 42 df, p=0.038, F=4.85:1 and 42 df, p=0.033, F=7.99:1 and 42 df, p=0.007, respectively). The increase in mean scores was the highest on the "social embarrassment" subscale after correction for possible differences in baseline values between the control and MPQ group. In contrast to the control group, the I-QoL for the MPQ group was again measured at 12 months after treatment. If—outside the trial data analysis—a cohort trend analysis for just these 18

Fig. 1 Flow diagram of study



patients who had a successful MPQ treatment at 3 months is done, the improved mean overall and subscale scores in I-QoL at 3 months turns out to be sustained to the 1-year follow-up. The overall score and the subscale score social embarrassment seem even to improve statistically significant compared to the 3-month scores (F=4.87:1 and 17 *df*, p=0.041, F=7.77:1 and 17 *df*, p=0.013, respectively; Table 5).

At 12 months, physician and patient self-assessment "cure" and "markedly improved" rate was 88.9% (16/18) and 82.4% (14/17) in the MPQ group, respectively (Table 4). After treatment, five women presented with symptoms of de novo urgency but only one needed medical treatment.

Discussion

To our knowledge, this is the first randomized clinical trial comparing transurethral Macroplastique® injection with a control pelvic floor muscle exercise home training program in adult women with urodynamic SUI and urethral hypermobility after an unsuccessful conservative treatment. The enrollment time was long (5 years); this could be due to the strict inclusion and exclusion criteria. Also, in this period of time, the suburethral slings became popular and could have been of influence on the patient's choice of treatment.

Table 3 Stamey rating frequencies (n) for the control and the MPQ group at baseline and at 3-month follow-up and at 12 months for the successful part of the MPQ group only

Grade		0	I	II	III	p value
Baseline	Control (n=21)	0	14	7	0	
	MPQ (n=24)	1	15	8	0	
3 months	Control (n=21)	1	16	4	0	
	MPQ (n=24)	8	15	1	0	0.020
12 months	MPQ (n=18)	10	7	1	0	

The exact mechanism of achieving continence with urethral bulking agents is unknown. It is commonly thought that they increase urethral resistance at the level of the bladder neck by adding "bulk" or provide internal support to the urethral mucosa and creating urethral coaptation when injected submucosally [14].

At 3 months, results of the pad test results showed improvement, although no significant difference between the two groups could be shown. We have used the 1-h pad test as recommended by the International Continence Society [17]. However, a number of studies have reported poor reproducibility for the 1- and 24-h pad test [24–27]. In a study by Simons et al., the test–retest reliability of the 1-h pad test was shown to be inadequate, with the first and second tests differing by −44 to +66 g, despite the women having similar bladder volumes [27]. Lower anxiety levels at the second test may account for this finding. The 1-h pad test is a useful baseline measure of incontinence, but the poor repeatability suggests that is not an optimal measure of posttreatment.

More clearly, the decrease in number of pads used in the MPQ group at 3 months was significantly different from the control group. Also, the subjective parameters were significantly better in the MPQ group compared to the

Table 4 Final surgeon's subjective cure rating and the patient self-assessment of patient's incontinence condition (*n*) for the control and the MPQ group at 3-month follow-up and at 12 months for the successful part of the MPQ group only

	Final surgeon's subjective cure rating						Patient self-assessment					
	n	Cured	Markedly improved	Slightly improved	Unchanged	*p* value	*n*	Cured	Markedly improved	Slightly improved	Unchanged	*p* value
Control 3 months	21	2	4	4	11		21	0	4	3	14	
MPQ 3 months	24	8	9	1	6	0.029	24	7	8	2	7	0.002
MPQ 12 months	18	9	7	1	1		17[a]	6	8	2	1	

[a] One missing data

control group. The "cure" and "markedly improved" rates were sustained in the MPQ group at 12 months. These results of MPQ treatment of SUI in patients with urethral hypermobility are in line with data from literature in patients without hypermobility [28]. Comparing the results with other more invasive surgical treatments, the MPQ shows a slightly lower success rate, however, with a lower risk of complications [29]. In this study, the retention rate seems rather high. This can be explained by strict control of women after the procedure. The duration of retention was 1 to 2 days and treated by CISC, except in one woman with a body mass index of 40 kg/m^2, who had persistent retention because of a "de novo" prolapse of the anterior vagina wall unrelated to the procedure. Surgical correction of this prolapse was necessary. CISC may influence the results of injection therapy by possible dislocation and/or loss of the bulking agent. However, a small-sized catheter (Ch 12) was used to minimalize this risk as much as possible. The improvement in the quality of life is in the same range as with surgical interventions and confirms the trend in patient's preference to have a procedure with a lower risk of complications [30]. In a recent study of Robinson et al., the majority of women have realistic expectations regarding outcome hoping for improvement so that their quality of life increases. In general, they are able to tolerate the inconvenience of minor lower urinary tract symptoms. Women would appear to prefer a minor procedure with a lower risk of complications and are content to accept a lower success rate [30].

An advantage of Macroplastique® implantation using the MID is that it is performed following an outpatient treatment protocol requiring local anesthesia only. Also, the instrument is easy to handle in comparison to the cystoscope, with predetermined and consistent depth of

Table 5 (A) Mean (sub)scale scores and standard deviations (SD) of the I-QoL at baseline and 3 months for both treatment groups (overall mean imputed data; n=45). Scores will lie between 1.00 (worst possible QoL) and 5.00 (best possible QoL). (B) Mean (sub)scale scores and standard deviations (SD) of the I-Qol at baseline and at 3 and 12 months for patients who had a successful MPQ treatment after 3 months (n=18). Scores will lie between 1.00 (worst possible QoL) and 5.00 (best possible QoL)

Subscale	Treatment	Number	Baseline	3 months	12 months	*p* value	*p* value controlled for baseline values
A							
Overall	Control	21	2.96 (0.62)	3.03 (0.66)			
	MPQ	24	2.59 (0.61)	3.20 (0.73)		0.003[a]	0.017[c]
Avoidance and limiting behavior	Control	21	2.86 (0.72)	2.99 (0.71)			
	MPQ	24	2.55 (0.65)	3.26 (0.86)		0.012[a]	0.038[c]
Psychosocial impacts	Control	21	3.27 (0.66)	3.31 (0.65)			
	MPQ	24	2.76 (0.70)	3.37 (0.74)		0.003[a]	0.033[c]
Social embarrassment	Control	21	2.53 (0.66)	2.59 (0.87)			
	MPQ	24	2.31 (0.68)	2.95 (0.81)		0.004[a]	0.007[c]
B							
Overall		18	2.58 (0.64)	3.38 (0.70)	3.85 (0.81)	0.041[b]	0.006[d]
Avoidance and limiting behavior		18	2.47 (0.58)	3.37 (0.80)	3.65 (0.73)	0.185[b]	0.093[d]
Psychosocial impacts		18	2.76 (0.77)	3.60 (0.66)	3.94 (0.78)	0.157[b]	0.058[d]
Social embarrassment		18	2.35 (0.71)	3.13 (0.73)	3.77 (0.97)	0.013[b]	0.008[d]

[a] ANOVA results (time × group) effects
[b] Paired *t* test
[c] ANCOVA results (time × group) effects
[d] Wilcoxon paired test

needle penetration and consistent implant placement at three predetermined locations.

Conclusions

In the treatment algorithm of stress urinary incontinence, the bulking agent Macroplastique® using MPQ Implantation Device seems to be a suitable option as a first-line surgical treatment. The procedure is 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 appear to be sustained at least for 1 year postoperatively.

Acknowledgment This study was funded by an unrestricted grant of Uroplasty BV.

Conflicts of interest None.

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