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Original article

Macroplastique outcome in women with stress urinary incontinence secondary to intrinsic sphincteric deficiency

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ABSTRACT

Objectives: To evaluate short-term outcomes of Macroplastique (MPQ) in women with stress urinary incontinence (SUI) using patient reported outcome and three-dimensional vaginal ultrasound (3DUS).
Materials and methods: After obtaining institutional review board approval, a chart review of non-neurogenic women that received MPQ for intrinsic sphincter deficiency (ISD) was extracted from a prospective database. Patients were divided into three groups: naïve (Group I), prior incontinence surgery (Group II), and both prior incontinence surgery and bulking agent (Group III). Women with urethral hypermobility were excluded. Baseline evaluation included a history, physical examination to confirm SUI, and questionnaires [Urinary Distress Inventory-6 (UDI-6), 1 quality of life (QOL) global score based on visual analog scale], and in select patients urodynamic studies and/or standing voiding cystogram. Patient follow up included repeat questionnaires scores and 3DUS to objectively assess MPQ volume. Success was defined as sufficient improvement after one injection so that a subsequent reinjection/different SUI operation was not requested at the last follow-up visit. It was hypothesized that Group I would fare best.
Results: Fifty-nine women met the inclusion criteria. Success rate was 83% for Group I, 70% for Group II, and 69% for Group III ($p = 0.54$) at 9 months mean follow up. Fifteen patients underwent a second 3DUS during follow up with a stable volume, compared to the first study (4.5 ± 1.5 vs. 4.4 ± 1.5, $p = 0.70$), which confirmed stable volumes over time. Among the failures ($N = 15$), nine patients proceeded with reinjection; four patients had fascial slings, and two patients had artificial sphincters.
Conclusion: As confirmed by 3DUS, Macroplastique appears efficacious as a primary treatment and as a salvage treatment for SUI due to ISD in the short-term.

1. Introduction

Urethral bulking agents (UBA) are an attractive option for treating stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD), especially for patients desiring a less invasive treatment. Macroplastique (polydimethylsiloxane) has been used for the treatment of SUI with demonstrable efficacy as early as 1991 in Europe.[1] In Macroplastique, silicone-based particles are incorporated within a polyvinylpyrrolidone (PVP) suspension and are > 100 μM in diameter, which effectively limits migration.

Similar to our experience using collagen as a urethral bulking agent, we have incorporated three-dimensional transvaginal ultrasound (3DUS) imaging and patient self-report questionnaires into our follow-up management algorithm[2,3] for Macroplastique injections. Three-dimensional vaginal ultrasound provides objective information about the volume of the bulking agent obtained and its configuration around the urethra. The use of 3DUS is not widespread or part of standard guidelines; however, it is a tool with low cost and no morbidity or invasiveness, which helps in deciding whether patients are suitable for observation, reinjection, or another modality of treatment for SUI. Three-dimensional vaginal ultrasound has been integral in our assessment of women receiving UBA such as Collagen since 3DUS became available at our center in 1999. Among the early studies reporting on Macroplastique, one series of 60 women included transurethral ultrasound findings in nine patients.[4] The ultrasound hyperechoic nature of

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Macroplastique was recognized at that time, and had a generally good outcome for at least 1 year after the procedure when it completely encircled the urethra.[5]

In line with these early reports, the aim of our study was to study the short-term outcomes of Macroplastique (MPQ) in women with SUI secondary to ISD by using validated questionnaires (i.e., patient reported outcome) and 3DUS imaging (i.e., objective outcome). Furthermore, the outcomes of three subgroups were analyzed to broaden the relevance of this new study. Group I comprised naïve patients. The remaining two groups were more complicated: Group II, comprised patients with a history of previous anti-incontinence surgery and Group III comprised patients with previous anti-incontinence surgery and failed prior collagen injection. We hypothesized that Group I would fare best.

2. Materials and methods

After receiving approval from the UT Southwestern Institutional Review Board (IRB), we performed a review of prospectively collected data on women with SUI who received MPQ. Inclusion criteria were women with SUI secondary to ISD, a well-supported urethra, and at least one postoperative follow-up visit with questionnaires and 3DUS imaging. Exclusion criteria included neurogenic bladder, prior pelvic radiation therapy, and women with urethral hypermobility.

Success was defined as sufficient improvement after one injection so that a subsequent reinjection/different SUI operation was not requested by the patient at their last follow-up visit. "Cure"—the ability to remain dry and not wear any pads—was defined as a score of 0 on Question 3 of the Urinary Distress Inventory-6 (UDI-6) in relation to SUI.[6] Patients were divided into three subgroups: naïve (Group I), prior anti-incontinence surgery (Group II), and prior anti-incontinence surgery + collagen injection (Group III).

Baseline evaluation included medical history, physical examination, UDI-6, and one global quality of life visual analog scale (VAS) that asked "If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?" (with a "0" answer being "pleased" and "10" being "terrible.")[7] In addition, some patients received further workup such as office cystoscopy, voiding cystourethrogram and/or multichannel urodynamic studies if the patients were considered for MPQ reinjection or surgical sling placement. Women with SUI secondary to ISD and a well-supported urethra were identified primarily by examination findings (Aa point at −3) with demonstrable SUI during stress maneuvers. Other tools used to confirm a well-supported urethra in our practice included an angle of $\leq 30^{\circ}$ on a true lateral voiding cystourethrogram during straining views. A urodynamic study, when obtained, provided a Valsalva leak point pressure. The value of the Valsalva leak point pressure to confirm ISD is typically < 60 cmH2O; but higher values can occur, which indicates a lesser degree of ISD severity. Baseline urodynamics with a noninvasive flow test and a postvoid residual by bladder scan was obtained at baseline and in follow up. Of note, patients who had received previous collagen injections had a 3DUS prior to receiving MPQ, which provided collagen volume and configuration at baseline.

The MPQ injections were performed in an outpatient basis by the same urologist (PZ) with the patient under light anesthesia (i.e., intravenous sedation or laryngeal mask airway intubation). In general, in accordance with our prior protocol on Collagen injection, two injections (2.5 cc × 2 or approximately 5 mL) were delivered at the 3 o'clock and 9 o'clock positions to obtain luminal coaptation.

The first follow-up visit was 6–8 weeks after the MPQ injection procedure and included questionnaires and 3DUS imaging.[2] Subsequent follow up continued on an annual basis and included questionnaires with or without 3DUS.

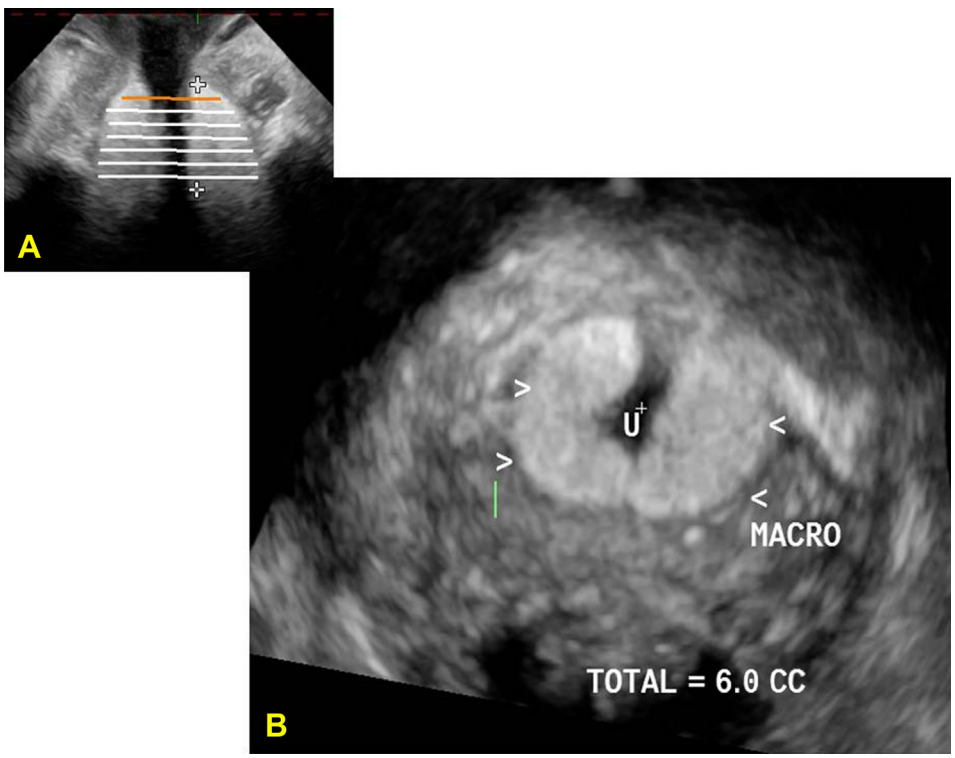

Fig. 1. Macroplastique on 3DUS has a very hyperechogenic appearance along the urethra (U) on (A) longitudinal and (B) transversal images in a naïve patient who was dry after one injection. 3DUS = three-dimensional vaginal ultrasound.

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The 3DUS was performed by the same imaging team consisting of a senior ultrasound technician and a radiologist with longstanding experience with collagen measurements by ultrasound.[7]

A small finger-size vaginal probe was introduced in the patient in supine position. The probe was positioned underneath the urethral meatus and moved alongside the vaginal wall in longitudinal and transversal directions. The MPQ is very echogenic and easy to identify (Fig. 1) on each side of the urethral lumen using the Philips iU22 ultrasound system (Philips, Andover, MA, USA) and a broad band 3D volume probe (V9-3) with frequency range of 9 mHz−3 mHz. This mechanical 3D probe performs automatic acquisition of volume data sets. Measurements are performed transversally and axially to provide a volume calculation. The data collected from the 3DUS included the total UBA volume (including MPQ and Collagen, if previously injected) and the configuration (i.e., circumferential versus asymmetric).

Descriptive statistics were provided using the mean and standard deviation for continuous variables and frequencies and percentages for categorical variables. Fisher's exact test (for categorical variables), the Student *t* test (for continuous variables, 2 subgroups), and analysis of variance (ANOVA; for continuous variables, 3 subgroups) were used to determine differences between subgroups. *Post hoc t* tests were completed for any significant ANOVA comparisons. The paired *t* test was used to find if there were any differences between the pre- and postoperative VAS-QOL scores and the 3DUS volume changes between the first and second visit after injection. A mixed model was used to ascertain whether the 3DUS volume after final injection decreased significantly over time after being controlled for by the subgroups and number of injections. All statistics were completed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

3. Results

From a prospective database of 72 patients from July 2011 to December 2013 who received MPQ, 59 women met inclusion criteria (Table 1). No serious adverse effects were reported. Early urinary retention lasting < 48 hours occurred in five women. At a mean follow up of 8.5 ± 7.2 months, the success rate was 83% for Group I, 70% for Group II, and 69% for Group III. The cure rate was 17% for Group I, 9% for Group II, and 38% for Group III. The mean age ($p = 0.21$) and BMI ($p = 0.28$) were comparable across the three groups, as was the mean duration of follow up ($p = 0.46$; Table 1). Group II had a significantly higher parity than Group I ($p = 0.046$). For naïve patients, the mean volume of MPQ injected was 4.43 mL (range, 2.5−5 mL) with the mean volume measured on first 3DUS after MPQ at 3.85 (range, 1.77−5.91). This gave a volume retention rate of 87%. At this first 3DUS study, 72% of studies indicated a circumferential configuration for MPQ.

Among the 15 failures, there was no significant difference between the groups—four failures were from Group I; seven failures from Group II, and four failures from Group III ($p = 0.59$) (Table 2). The pretreatment UDI-6 scores for Question 3 in the success group were generally more favorable than those of the failure group. Among the failures, nine patients proceeded with reinjection; four patients with slings; and two patients with artificial urinary sphincters. The mean time between the first and the repeat injection was 10 months (range, 3−19), whereas the mean time between the first injection and a secondary sling was 8.5 months (range, 2−16).

Fifteen patients underwent a second 3DUS during the follow up (mean interval of 9 months after the first 3DUS) with a stable volume, compared to first study (4.5 ± 1.5 vs. 4.4 ± 1.5, respectively; $p = 0.70$). Four patients with a prior collagen injection also underwent a second 3DUS with similar findings (5.3 ± 1.3 vs. 4.9 ± 1.4; $p = 0.35$). In a mixed model that controlled for the number of injections and prior urological history, time since the last injection was not a significant factor in ultrasound volume after the last injection (mean follow up, 6.5 months; $p = 0.46$).

Parameters related to voiding such as Question 5 of the UDI-6, maximum flow, or postvoid residuals were not affected by MPQ injection across the three groups.

Of patients that had VAS-QOL recorded during their pre- and postoperative visits, there was significant improvement whether

Table 1
Baseline group comparison, based on prior stress urinary incontinence surgical history.

	Naïve ($n = 23$)	Prior surgery ($n = 23$)	Prior surgery + collagen ($n = 13$)	*p*
Age (y)	64.1 ± 8.1	65.0 ± 11.3	70.1 ± 10.2	0.21
Parity	1.9 ± 1.0	2.8 ± 1.3	1.9 ± 1.3	0.046
BMI	26.0 ± 5.3	28.6 ± 6.3	27.2 ± 3.9	0.28
Duration of follow up (mo)	7.2 ± 5.9	8.7 ± 7.4	10.3 ± 8.8	0.46
Preoperative VLPP				
Mean ± SD	53.6 ± 17.2	75.1 ± 40.4	65.4 ± 28.5	0.22
<60	4/13 (31)	8/13 (62)	4/7 (57)	0.29
≥60	9/13 (69)	5/13 (38)	3/7 (43)	
	($n = 19$)	($n = 18$)	($n = 9$)	
Qmax	15.5 ± 7.7	13.8 ± 8.5	20.1 ± 15.8	0.30
Postvoid residual				
No residual	16/19 (84)	15/18 (83)	6/9 (67)	0.56
Residual	3/19 (16)	3/18 (17)	3/9 (33)	
UDI6 Total score	11.4 ± 3.6	10.4 ± 3.9	9.5 ± 4.2	0.59
UDI6 Q2 − Urge Incontinence				
0 or 1	2/10 (20)	5/18 (28)	3/8 (38)	0.79
2 or 3	8/10 (80)	13/18 (72)	5/8 (63)	
UDI6 Q3 − Stress incontinence				
0 or 1	0/10 (0)	1/19 (5)	2/8 (25)	0.17
2 or 3	10/10 (100)	18/19 (95)	6/8 (75)	
UDI6 Q5 − Emptying				
0 or 1	5/10 (50)	15/19 (79)	6/8 (75)	0.29
2 or 3	5/10 (50)	4/19 (21)	2/8 (25)	

Data are presented as *n*/*N* (%) or mean ± SD.
UDI6 score of 0, 1 = none or rare; Score of 2, 3 = moderate or severe.
BMI = body mass index; Q2 = Question 2; Q5 = Question 5; Qmax = XX; UDI6 = Urinary Distress Inventory-6; VLPP = Valsalva leak point pressure.

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Table 2
Differences between the patients that only received one injection and had no other surgery versus patients that had a repeat injection or reoperation.

	Success group ($n = 44$)	Failure group ($n = 15$)	p
Prior History			
Naïve	19/23 (83)	4/23 (17)	0.59
Prior surgery	16/23 (70)	7/23 (30)	
Prior surgery + prior collagen	9/13 (69)	4/13 (31)	
Preoperative VLPP (cm H_2O)			
Mean ± SD	62.6 ± 31.4	71.9 ± 31.3	0.49
<60	11/16 (69)	5/16 (31)	0.22
≥60	15/17 (88)	2/17 (12)	
	($n = 36$)	($n = 10$)	
Qmax (mL/s)	15.8 ± 10.5	15.5 ± 8.8	0.94
Postvoid residual (mL)			
No residual	29/37 (78)	8/37 (22)	1.00
Residual	7/9 (78)	2/9 (22)	
UDI6 Total	10.2 ± 4.0	11.2 ± 3.4	0.44
UDI6 Q2 – Urge Incontinence			
0 or 1	8/10 (80)	2/10 (20)	0.69
2 or 3	18/26 (69)	8/26 (31)	
UDI6 Q3 – Stress Incontinence			
0 or 1	3/3 (100)	0/3 (0)	0.54
2 or 3	23/34 (68)	11/34 (32)	
UDI6 Q5 – Emptying			
0 or 1	19/26 (73)	7/26 (27)	0.70
2 or 3	7/11 (64)	4/11 (36)	

Data are presented as n/N (%) or mean ± SD.
UDI6 score of 0 or 1 = "none" or "rare"; UDI6 score of 2 or 3 = "moderate" or "severe."
Q2 = Question 2; Q5 = Question 5; Qmax = XX; UDI6 = Urinary Distress Inventory-6; VLPP = Valsalva leak point pressure.

the procedure was classified as a failure or success. The success group reported a 3.3 ± 3.7 ($p = 0.0003$) improvement in the absolute value score. The failure group reported a 2.7 ± 3.4 ($p = .03$) improvement. The difference between the VAS-QOL scores for the success and failure groups were significantly different at the preoperative visit (7.2 ± 2.6 vs. 9.4 ± 1.3, respectively; $p = 0.002$) and postoperative visit (3.8 ± 2.9 vs. 6.7 ± 3.2, respectively; $p = 0.02$), although the improvement in the score was not significantly different ($p = 0.65$).

There was no loss to follow up. Twenty-three patients had a follow up > 1 year. Of these, 13 of 23 (56%) patients only had one injection and were observed because of cure or significant improvement that did not require additional therapy. By contrast, seven of 23 (30%) patients had a repeat injection, two of 23 (9%) patients had a sling placed, and one of 23 (4%) patients had an AUS.

4. Discussion

We report our early experience with MPQ, which indicates an overall success rate of nearly 70% and a slightly higher success rate in the naïve subgroup. In a subset of women who underwent repeat 3DUS testing over time, no significant loss of volume was noted. Even though absolute cure or strict dryness after MPQ is only achieved in a minority of patients, MPQ provided durable SUI symptom improvement in most of our patient population. No changes in Question 5 of UDI-6 related to voiding, maximum flow, or postvoid residual were noted, which implies no effect on voiding function.

Several series on bulking agents have been reported in the literature such as a recent large series of 514 women treated with a variety of bulking agents within the past 13 years.[8] However, limited data is available on Macroplastique and the use of an objective outcome measure such as the one employed in this study with 3DUS. A study by Hegde et al,[9] which used 3DUS to evaluate MPQ outcomes at 15 minutes after the procedure, demonstrated that a better clinical outcome was associated with MPQ location in the proximal urethra and with a circumferential periurethral distribution. In the Hedge study ($N = 100$) divided treatment-naïve patients into groups based on their clinical outcomes: patients with a good outcome (Group A; $N = 72$) and patients who either worsened or did not improve after injection (Group B; $N = 28$). The mean follow up was 19.32 weeks in Group A and 17.77 weeks in Group B.

In our study, we did not perform ultrasound to determine immediate results, but to evaluate the durability of the injection in volume and configuration around the urethra in different clinical subgroups of women. All studies were performed approximately 6–8 weeks after the injection procedure as part of the first follow-up visit. We have previously reported on the use of 3DUS, and focused on evaluating the mid- and long-term results of Collagen injections for SUI.[2,3] These studies together demonstrate that circumferential distribution of an injectable agent is a more important predictor of favorable outcome than the injected volume and that 3DUS is a simple tool to serially and objectively evaluate UBA distribution.

Variable improvement and cure rates for MPQ have been reported in contemporary literature (Table 3)[12–14]. A recent meta-analysis by Ghoniem and Miller[10] described cure rates of 45% (short-term outcome) and 36% (long-term outcome), whereas the improvement rates were 75% (short-term outcome) and 65% (long–term outcome). Variability between reports is associated with indications, success definition, and duration of follow up. Our

Table 3
Literature review on Macroplastique.

Study	Design	Follow-up period (mo)	N	Improvement rate (%)	Cure/dry rate (%)	Success determinant	Adverse effects
Ghoniem et al[15]	Randomized, single-blind	12 mo	247	61.5	36.9	Stamey grade	24% UTI, 9% dysuria, 9% urgency, 8% frequency, 7% retention
Ghoniem et al[13]	Case series	24 mo	67	84	67	Stamey grade	None reported
Maher et al[14]	Randomized controlled trial	12 mo	23	60	n/a	Patient report	5% voiding dysfunction
Plotti et al[16]	Case series	12 mo	24	42	42	Urodynamic assessment	None reported
Tamanini et al[12]	Case series	60 mo	15	33.3	40	Urodynamic assessment	10.3% transient urinary retention; 4.8% loss of PDMS through injection site
Zullo et al[17]	Prospective cohort study	12 mo	27	33	44	Urodynamic assessment	None reported

PDMS = XX.

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present short-term findings of improvement ranging 69–83% are consistent with these literature findings.

The MPQ deserves special attention as a salvage treatment post–anti-incontinence procedure because it has been under-reported in the literature. Lee-Lewis and Anderson[11] reported a 34.8% cure rate and a 77% improvement rate in women treated for recurrent SUI after a prior mid-urethral sling (MUS). In a study by Gumus et al,[1] which compared women with and without a history of an anti-incontinence operation, the women who had undergone a prior procedure for SUI were more satisfied with their condition post-MPQ in a long-term follow up. Different expectations between the two groups may have affected their response rates. Our own study suggests the same adaptation of women to their incontinence condition after a prior failed anti-incontinence procedure with improvement but not complete cure being well accepted.

Long-term favorable outcome has been reported by Tamanini et al[12] at 12 months, 24 months, and 60 months, which indicated the relative durability and stability of the MPQ. Ghoniem et al[13] likewise reported that 84% of patients maintained significant Stamey grade improvement at their 12–24 month assessments.[11] However, Maher et al[14] reported a continence rate of only 22% post-MPQ at the 60-month follow up; however, these lower values for long-term findings were obtained from a nonvalidated questionnaire.

Our study has unique strengths. It was a prospective study on women with different SUI backgrounds ranging from naïve to prior sling procedure with or without an additional bulking agent. The data was collected and analyzed by a neutral investigator not involved in patient care. The 3DUS procedure was performed by the same team of technicians and radiologists with longstanding expertise of more than a decade in 3DUS interpretation after collagen injection.

The limitations of this study include its short-term follow-up period and its relatively limited study size. However, it is one of the largest cohorts reported to date. In addition, because 3DUS was not performed immediately at the time of the injection under anesthesia, it was not possible to determine if failures were because of substance migration or extrusion, or operative/technical failure.

5. Conclusion

MPQ is apparently an effective treatment option in the short-term in women with naïve or complicated ISD-related SUI. A complete cure is only achieved in a minority of patients, although a significant improvement was observed by many women. Three-dimensional vaginal ultrasound can be used to assess and monitor MPQ injection results over time, and has demonstrated stable volumes in a subset group.

Conflicts of interest

None.

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