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Efficacy and safety of polydimethylsiloxane injection (Macroplastique®) for the treatment of female stress urinary incontinence: results of a series of 85 patients with ≥3 years of follow-up

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Objective

To assess the long-term efficacy and safety of polydimethylsiloxane injection (Macroplastique®, Cogentix Medical, Orangeburg, New York, USA) for the treatment of female stress urinary incontinence (SUI), with a minimum follow-up of 3 years.

Patients and Methods

This is an observational analytical prospective cohort study conducted in a single uro-gynaecological unit. All consecutive women with urodynamically confirmed pure SUI treated with the Macroplastique procedure, were included. Data regarding patient outcomes (International Consultation on Incontinence Questionnaire–Short Form, Patient Global Impression of Improvement, and patient satisfaction scores), objective cure rates, and adverse events were collected during follow-up. Uni- and multivariable analyses were performed to investigate outcomes. Multiple logistic regression was performed to identify factors involved in the risk of failure of the procedures or recurrence of SUI.

Results

In all, 85 women had the Macroplastique procedure. At the 3-year follow-up, all 85 (100%) patients were available for the evaluation. We did not find any significant change in the surgical outcomes during this time. At 3 years after surgery, 42 of 85 patients (49%) declared themselves cured (P = 0.67). Similarly, at the 3-year evaluation, 40 of 85 patients (47%) were objectively cured. There was no significant deterioration of objective cure rates over time (P = 0.3). A history of radical pelvic surgery and a low surgeon's skill were significantly associated with the risk of failure of Macroplastique. The multivariate analysis confirmed these findings; a previous history of radical pelvic surgery and a low surgeon's skill independently predicted the subjective and objective failure of Macroplastique.

Conclusions

The 3-year results of this study showed that Macroplastique could be an acceptable alternative for the treatment of SUI with stable results over time and a negligible complication rate.

Keywords

bulking agents, injectable, long-term follow-up, stress urinary, #Incontinence

Introduction

Stress urinary incontinence (SUI) is the predominant form of UI in women. Depending on age, the prevalence ranges from 29% to 75%, with a mean of 48% [1]. When first-line conservative management fails, surgery is required and several surgical options for treating SUI are available. Retropubic and transobturator tension-free mid-urethral slings (MUS) are the most effective and commonly performed procedures for the surgical treatment of female SUI [2]. These techniques are currently the 'gold standard' treatment for SUI, even in comparison with Burch colposuspension, as they are characterised by a global cure rate of 84.4% at 12 months follow-up with long-lasting benefits [1,3,4]. After the 2008 USA Food and Drug Administration (FDA) warning on the transvaginal

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placement of surgical mesh for the treatment of pelvic organ prolapse, some criticisms also involved the adoption of prosthetic material in the treatment of SUI [5]. Very recently, the European Urology Association (EAU) stated a Consensus on the use of implanted materials for treating pelvic organ prolapse and SUI taking into account, amongst others, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report on the use of surgical mesh. A key message from this Consensus is that synthetic slings for SUI can be safely used, provided that patients are aware of the alternative available options including bulking agents, colposuspension, and autologous sling surgery [6,7].

Bulking agents can be effectively considered an alternative option in the management of female patients with SUI and they are currently considered the first-line surgical choice in selected populations of incontinent women (i.e., patients with comorbidities, high anaesthetic risk, in those who prefer a less invasive approach) [8]. The growing interest toward efficacy and safety of urethral injection therapy, as an alternative approach for the treatment of female SUI, is witnessed by the publication in the last few years of various systematic reviews and meta-analysis [8–11]. The Cochrane systematic review by Kirchin et al. [9] outlines that 'The available evidence base remains insufficient to guide practice'. Heterogeneity of agents studied, small number of cases, lack of comparison with other treatments or placebo, and short follow-up, represent the major limitations of available studies. At 12 months follow-up, a cure rate of 24.8% to 36.9% is reported but no data on a longer term are available [1]. Moreover, no data on the reproducibility and learning curve of the different materials and implantation techniques are reported in the literature. Interestingly, on the basis of the systematic review published by Riemsma et al. [1] on cure rates for the available treatment options for incontinence (UI and faecal), it becomes evident that in the elderly population none of the studies on UI reported cure rates beyond 3 months' follow-up. Particularly in this population, the advantages in terms of reducing postoperative voiding dysfunction and complication rates have to be clearly documented, even in the long term [1,7].

Polydimethylsiloxane (Macroplastique®, Cogentix Medical, Orangeburg, New York, USA) is a minimally invasive bulking agent, with reported efficacy in the short-term (1-year) ranging from 34.8% to 80% [10]. Very limited data are available on the long-term follow-up, with Ghoniem et al. [12] reporting 67% objective cure rate at 24 months follow-up of 75 women and Tamanini et al. [13] in a smaller study (21 patients) claiming a cure/improvement rate of 73.3% at 60 months.

The aim of the present study was to prospectively evaluate long-term efficacy and safety of Macroplastique with a minimum follow-up of 3 years. Moreover, we assessed the possible risk factors associated with a lower efficacy of this procedure.

Patients and methods

This was an observational analytical prospective cohort study performed in a single Urogynecological Unit, between 2008 and 2014. We enrolled all consecutive women with pure SUI symptoms and urodynamically confirmed urodynamic SUI, who received the Macroplastique procedure. Patients were counselled between Macroplastique and MUS procedure; the choice of the surgical method was based on the patient's preference.

Exclusion criteria were: preoperative clinically significant voiding dysfunction, a postvoid residual urine volume (PVR) of >100 mL, documented recurrent UTIs, concomitant vaginal prolapse > stage 1 according to the pelvic organ prolapse quantification (POP-Q) system, overactive bladder (OAB) symptoms, urodynamically confirmed detrusor overactivity (DO). We also included women with previous history of radical pelvic surgery. We excluded patients with a concomitant relevant POP because these patients can present several confounding variables, such as increased rate of concomitant OAB, DO, and/or voiding dysfunction. Preoperative evaluation included: medical history, physical examination, a voiding diary, urine analysis, and complete urodynamic testing. Physical examination was performed with the patient in lithotomy and POP was described during a maximal Valsalva manoeuvre according to the POP-Q system [14]. All women were evaluated with urodynamic studies as previously described [15] (including uroflowmetry, filling cystometry, Valsalva leak-point pressure [VLPP] measurement, and pressure/flow study) by a trained urogynaecologist, using a standardised protocol in accordance with the *Good Urodynamic Practices* guidelines of the ICS [16]. We evaluated the objective severity of SUI using the '1-3-5 cough test' during urodynamics [17]. Urethral hypermobility was defined by a Q-tip test >30°. Patients were included regardless of Q-tip test and VLPP values. All methods, definitions, and units were updated in agreement with the last version of the ICS standardisation of terminology [18]. All patients also completed the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) questionnaire [19] and Urogenital Distress Inventory (UDI). One experienced urogynaecological surgeon, according to the original technique, performed all the urethral injections of Macroplastique. The 'Macroplastique Implantation System' included: the Macroplastique implantation device (MID) and two needles; the MID is a sterile, 25 F, single-use device with a fluid drainage channel and three fixed needle entry ports. A measuring scale for determining urethral length during the procedure is printed on MID. We inserted the MID tip into the urethra and

advanced the tip into the bladder until fluid flowed from the fluid drainage channel. Then, we withdrew the MID 15 mm and we injected 2.5 mL Macroplastique in the 6 o'clock position, 1.25 mL in the 10 o'clock position, and 1.25 mL in the 2 o'clock position [20,21]. Patients were allowed to go home the same day when comfortable and voiding. If the patient was unable to pass urine spontaneously within 3–4 h of the procedure, 'in and out catheterisation' with a catheter was performed to relieve any symptoms of urinary retention. If PVRs of >100 mL were detected, the patient was followed-up in the hospital until voiding. All procedures were performed under general anaesthesia.

Postoperative evaluations were scheduled at 3-months, 1-, 2-, 3-years, and then every year. Every follow-up visit included medical history, physical examination, voiding diary, stress test, and evaluation of subjective satisfaction. A stress test was performed in the lithotomy and upright positions with a full bladder (ultrasonographic measurement >400 mL). Objective cure was defined as the absence of urine leakage during the stress test. To define the subjective outcomes, all patients completed the ICIQ-SF, the Patient Global Impression of Improvement (PGI-I) Scale (a 7-point scale, with a range of responses from 1, 'very much improved,' through to 7, 'very much worse') [22], and a Patient Satisfaction Scale (a single, self-answered, Likert-type scale of 0–10 that grades the patient's degree of satisfaction regarding continence: 0 represents 'not satisfied,' and 10, 'satisfied') [23]. Subjective success was indicated both by 'very much improved' or 'much improved' (PGI-I ≤2) and by a patient satisfaction score ≥8, as previously described in 2011 by Abdel-Fattah et al. [24]. All other patients were considered as failures. Patients also completed the ICIQ-SF and UDI at the 3-month and 3-year follow-up visits. The Declaration of Helsinki was followed, and preoperative written informed consent for Macroplastique injection was obtained from all patients. A local Institutional Review Board approval was obtained (o.g.Va02/08). Data were prospectively collected into a specifically designed digital database.

Statistical analysis

Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS®), version 17 for Windows (SPSS Inc., IBM Corp., Armonk, NY, USA). Continuous variables were reported as median and interquartile range (IQR). We used the chi-squared test and chi-squared test for trend to analyse and compare the surgical outcomes during follow-up. The chi-squared test for trend can better assess if the success of the surgical procedure tends to decrease over time, comparing the cure rates at the different follow-up visits (3-months, 3-years, and last follow-up). The null hypothesis is that there is not an association between the cure rate of Macroplastique and the time. One-way ANOVA was used to compare continuous series of variables in the comparison of the scores used to measure the subjective outcomes. Multiple logistic regression was performed to identify factors involved in the risk of failure of the procedures or recurrence of SUI. The multivariate model included those variables that achieved significance ($P < 0.05$) or association ($P \leq 0.10$) in the univariate analysis. Statistical significance was considered achieved when $P < 0.05$.

Results

During the study period, 85 women with confirmed SUI, who fulfilled the inclusion criteria, had Macroplastique urethral injections. Baseline characteristics of the study are summarised in Tables 1 and 2. At the 3-year follow-up, 85 (100%) patients were available for evaluation. The mean (SD; median) follow-up was 58 (22; 48) months. Subjective and objective cure rates are summarised in Table 3. Table 4 reports the trend of the subjective outcomes scores over time. Long-term data showed no significant deterioration of either subjective or objective outcomes. No patients received a second injection of Macroplastique, as we preferred to offer a MUS in case of failure and not a second bulking procedure. Therefore, in the 12 cases of failure at the 3-month follow-up, we performed a transobturator sling procedure 6 months after Macroplastique injection, with objective and subjective cure of SUI in all patients. Looking at factors influencing the

Table 1 Baseline characteristics.

Characteristic	Value
Number of patients	85
Age, years, median (IQR)	64 (40–76)
BMI, kg/m^2, median (IQR)	25.3 (23–28)
Obese (BMI ≥30 kg/m^2), *n* (%)	13 (11)
Menopausal, *n* (%)	36 (42)
Previous vaginal deliveries, *n*, median (IQR)	1 (1–2)
Operative delivery (vacuum/forceps), *n* (%)	4 (5)
Previous radical pelvic surgery, *n* (%)	8 (9.4)
Previous anti-incontinence surgery, *n* (%)	9 (11)

BMI, body mass index.

Table 2 Preoperative urodynamic data.

Variable	Median (range)
FDTV, mL,	180 (50–430)
CC, mL	480 (220–500)
$Pdet_{Max}$ during filling phase, cmH_2O	8.4 (3–15)
Q_{max}, mL/s	21 (7–77)
Intravesical opening pressure, cmH_2O	23.4 (9–66)
$Pdet_{Max}$ during voiding, cmH_2O	31.5 (10–75)
$PdetQ_{Max}$, cmH_2O	24.4 (8–60)
VLPP, cmH_2O	64 (24–91)

CC, cystometric capacity; FDTV, first desire to void; $Pdet_{Max}$, maximum detrusor pressure; $PdetQ_{Max}$, detrusor pressure at maximum urinary flow; Q_{max}, maximum urinary flow.

Table 3 Cure rates at 3-months, 1-, 2-, 3-years and at last follow-up visit.

Cured at 3-months, % (*n*/*N*)	Cured at 1-year, % (*n*/*N*)	Cured at 2-years, % (*n*/*N*)	Cured at 3-years, % (*n*/*N*)	Cured at last follow-up (≥3 years), % (*n*/*N*)	*P*
Objective outcomes					
53 (45/85)	51 (43/85)	48 (41/85)	47 (40/85)	47 (40/85)	0.9* HR (95% CI) 1.3 (0.7–2.3) 0.4†
Subjective outcomes					
53 (45/85)	51 (43/85)	51 (43/85)	51 (43/85)	49 (42/85)	0.67* HR (95% CI) 1.1 (0.6–2.0) 0.44†

**Chi-squared test; †Chi-squared test for trend.*

Table 4 Subjective outcomes scores at the 3-month, 3-year and at last follow-up visit.

Variable	Baseline	3-months	3-years	Last follow-up ≥3-year	*P*
ICIQ-SF, median (IQR)	17 (16–17)	6 (0–17)	7 (0–17)	7 (0–17)	0.01*
'Very much better' or 'much better' on PGI-I, *n*/*N* (%)		55/85 (65)	54/85 (64)	51/85 (60)	
Patient satisfaction scale, median (IQR)		8 (3–10)	8 (2–10)	7 (2–10)	
80% reduction in UDI score, *n*/*N* (%)		56/85 (66)	54/85 (64)	51/85 (60)	

**One-way ANOVA.*

Macroplastique failure rate, we found that a previous history of radical pelvic surgery and a low surgeon's skill (≤20 procedures, on the basis of the learning curve) were significantly associated with the risk of failure of Macroplastique (Table 5). The multivariate analysis confirmed these findings; previous history of radical pelvic surgery and a low surgeon's skill independently predicted the subjective (odds ratio [OR] 12.2, 95% CI 1.4–16.6, $P = 0.02$ and OR 3.8, 95% CI 1.3–11.0, $P = 0.01$, respectively) and objective failure of Macroplastique (OR 11.8, 95% CI 1.6–17.2, $P = 0.02$ and OR 3.6, 95% CI 1.2–10.2, $P = 0.01$, respectively).

Only one patient at the 3-month follow-up reported the onset of *de novo* OAB symptoms. We administered antimuscarinics treatment for 3 months with a total resolution of the symptoms. The Clavien–Dindo Classification of the complications is shown in Table 6. We found only one case of voiding dysfunction with a spontaneous resolution 3 days after the procedure. Finally, one patient reported postoperative urethral pain cured successfully with analgesic drugs. No significant POP or *de novo* dyspareunia were registered in our study population.

Discussion

A durable effect over time after the Macroplastique procedure, for the treatment of SUI, is the most striking finding in our present study: women objectively and subjectively cured after 3 months were still continent 3 years later and remained dry even with protracted follow-up.

'Nothing last forever?' was the incipit of Peter Dwyer's Editorial, commenting on the first report 17 years after a TVT procedure [25,26]. Contrary to what is consistently reported for MUS, with its durability further confirmed in the very long term [27], the success rate of bulking agents is considered to be associated with a relevant deterioration over time [10]. Zivanovich et al. [28], in a study adopting polyacrylamide hydrogel (Bulkamid®) in 60 women with previously failed MUS reported a decrease in objective efficacy from 56.7% at 1 month to 43.3% and 25.4% after 6 and 12 months, respectively. Similarly, Zullo et al. [29], reported on 27 patients treated with Macroplastique and reported a decrease in objective cure rate from 55% at 6 months to 44% at 1 year. In addition, methodological defects of the available studies on bulking agents are evident and more stringent criteria for objective assessment have been recommended [9,10]. Consequently, the concept of bulking agents as a low efficacy and transient cure for SUI has been incorporated into guidelines [6]. Our present results disprove this concept showing a not negligible and stable effect over time of Macroplastique injections. In our present study, only one highly trained surgeon performed the Macroplastique injections, and this reduced the risk of failures due to technical variation and different surgical experience.

We are quite confident in the results of our present study due to its methodological strength: we included a relevant number of women in a monocentric single-operator prospective study; women underwent a structured objective and subjective follow-up with a 100% follow-up rate at 3 years. Objective cure was considered as the absence of urine leakage during a stress test with a documented full bladder. Under these circumstances, out of 85 women with confirmed SUI, 53% were objectively and subjectively cured after 3 months. At

Table 5 Univariable analysis of variables potentially involved in the risk of failure of Macroplastique at 3 years.

Variable	Subjective failure Univariable analysis*		Objective failure Univariable analysis*	
	HR (95% CI)	*P*	HR (95% CI)	*P*
Elderly (age ≥65 years)	0.41 (0.23–1.14)	0.13	2.12 (0.84–5.73)	0.2
Obese (BMI ≥30 kg/m^2)	1.84 (1.13–5.12)	0.05	1.53 (0.52–4.61)	0.5
Number vaginal deliveries (n ≥2)	0.42 (0.11–1.23)	0.3	0.80 (0.31–2.34)	0.8
Macrosome (≥4000 g)	0.71 (0.15–3.14)	0.6	0.63 (0.12–2.83)	0.5
Operative delivery	2.12 (0.63–7.62)	0.2	0.53 (0.07–3.91)	0.6
Menopausal	0.23 (0.03–1.70)	0.17	2.92 (0.34–4.33)	0.4
Previous anti-UI procedures	1.89 (0.44–8.11)	0.5	2.14 (0.64–9.7)	0.4
Previous radical oncological surgery	**13.39 (1.66–18.4)**	**0.04**	**12.1 (1.32–13.45)**	**0.04**
Surgeon's skill (≤20 procedures)	**3.51 (1.19–10.28)**	**0.02**	**1.52 (1.06–7.50)**	**0.03**
Urethral mobility (Q-tip <30°)	1.53 (0.34–8.23)	0.8	1.41 (0.03–2.12)	0.3
VLPP <60 cmH_2O	1.41 (0.39–6.88)	0.7	2.62 (0.81–3.42)	0.09
FDTV (≤180 mL)	3.1 (0.3–29.8)	0.32	4.2 (0.5–16.9)	0.20
CC (>480 mL)	1.9 (0.2–13.2)	0.52	2.8 (0.5–16.9)	0.25
$Pdet_{Max}$ during filling phase (>9 cmH_2O)	4.7 (0.5–45.5)	0.17	6.4 (0.7–57.1)	0.11
Q_{max} (≤24 mL/s)	5.6 (0.3–28.7)	0.95	5.6 (0.3–28.7)	0.95
Intravesical opening pressure (≤22 cmH_2O)	6.2 (0.3–28.3)	0.95	2.6 (0.1–8.2)	0.95
$Pdet_{Max}$ during voiding (≤29 cmH_2O)	5.0 (0.1–14.2)	0.94	7.2 (0.8–64.4)	0.07
$PdetQ_{Max}$ (>28 cmH_2O)	0.95 (0.1–9.1)	0.96	1.8 (0.3–11.2)	0.48
Severity at UDI score	1.87 (0.56–4.32)	0.3	2.11 (0.91–3.22)	0.11
Severity at '1-3-5 cough test' during UDS	1.4 (0.81–5.3)	0.5	1.2 (0.77–4.5)	0.62

*CC, cystometric capacity; FDTV, first desire to void; $Pdet_{Max}$, maximum detrusor pressure; $PdetQ_{Max}$, detrusor pressure at maximum urinary flow; Q_{max}, maximum urinary flow. Significant values in bold. *Univariate Cox proportional hazard model.*

Table 6 Clavien–Dindo classification of complications.

Clavien–Dindo complication grade	*N* (%)(*N* = 85)	Action
Grade I		
Voiding dysfunction	1 (1.2%)	Observation
Grade II		
De novo OAB	1 (1.2%)	Antimuscarinics
Urethral pain	1 (1.2%)	Analgesic drugs.

3 years, the cure rate was 47%, which is not significantly different and remained the same both objectively and subjectively, and also at a more prolonged follow-up with a mean observation time of 58 months. In cases of failure, our clinical policy was to propose a MUS and not a second Macroplastique injection, with the aim to offer the most effective treatment on the basis of the available studies in the literature and to reduce the risk of a second failure.

Also, the role of the learning curve is worth commenting upon in our present case series, as there was significantly inferior efficacy for the first 20 procedures. It is likely that, with experience, the surgeon improves in ability to place the material at the correct depth and length in the urethra Injectable agents are commonly considered as a second-line surgical treatment, limited to frail women not fit, or not willing to receive a traditional surgical procedure. Based on these considerations, injectables tend to be adopted in few cases, sometimes with different materials and procedures. The scant quality of published data further supports the impression of a non-systematic adoption of this surgical approach [9]. As we documented, this aspect can have an impact on the low efficacy rate reported for bulking agents [1,6].

In our present study, previous radical pelvic surgery was the other predictor associated with a higher failure rate. These women normally are considered to have a severe form of UI with deficient sphincter mechanism, commonly identified as a fixed urethra via a direct or indirect neurologically mediated injury. Interestingly, in our present study, we failed to demonstrate a correlation of failure with urethral mobility, VLPP and severity of UI. Finally, a very low complication rate has been confirmed in our present study. Also, other previously published studies demonstrated that Macroplastique could also be equally effective in women with a fixed urethra [30]. We acknowledge that a possible limitation of the present study could be that we included procedures performed by only one highly trained surgeon and therefore that our findings could be not applicable to every other group. However, we also demonstrated that even an expert surgeon requires a learning curve period to really offer a good cure rate after a Macroplastique injection procedure. Another possible limitation could be the lack of pad-weight test and of the postoperative voiding diary results; however, in this study we used many validated tools to evaluate and describe the subjective and objective outcomes.

Conclusion

In an era when major surgery for SUI is under scrutiny due to being too invasive or associated with an excessive

complication rate, alternative strategies for the surgical treatment of SUI are welcome. Bulking agents can be considered a realistic alternative, but the quality of the evidence concerning their effectiveness, durability over time, and associated morbidity is scant. With rigorous methodological criteria, half of the women treated for SUI were dry after a Macroplastique injection, with stable results over time and a negligible complication rate. Our present results are encouraging and suggest that bulking agents could be an acceptable option in the treatment of female SUI.

Conflict of Interest

None declared.

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Abbreviations: DO, detrusor overactivity; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; IQR, interquartile range; MID, Macroplastique

implantation device; MUS, mid-urethral slings; OAB, overactive bladder; OR, odds ratio; PGI-I, Patient Global Impression of Improvement; POP(-Q), pelvic organ prolapse (quantification); PVR, postvoid residual urine volume; (S)UI, (stress) urinary incontinence; UDI, Urogenital Distress Inventory; VLPP, Valsalva leak-point pressure.

