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CARFAX

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A single transurethral Macroplastique® injection as primary treatment for stress incontinence in women

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Summary
The clinical records of 102 women were analysed to estimate the success rate of a single transurethral Macroplastique® (Uroplasty BV, Netherlands) injection for the treatment of stress incontinence. We then compared the results of those who had had the injection as primary treatment (71/102) with those women who had undergone previous failed incontinence surgery (31/102). The overall success rate was 68% following a single injection of Macroplastique at a mean follow-up period of 3·2 months; the success rate was obtained by including all patients who were either cured or markedly improved requiring no further intervention. The success rate of those who had had previous surgery was 71% and for the primary treatment group it was 66%. This difference was not statistically significant. These results suggest a potential role of Macroplastique transurethral injection as primary treatment for genuine stress incontinence in women.

Introduction

Urinary stress incontinence is a common problem which affects at least 3·5 million women in the United Kingdom (MORI Health Survey, 1991). Although it is a source of considerable economic, social and psychological morbidity (Kelleher *et al*., 1993), it is often neglected by patients and medical practitioners alike.

In women genuine stress incontinence may be due to abnormal descent of the bladder neck, intrinsic sphincter deficiency (poor urethral closure) or a combination of both. When urinary incontinence is due to urethral sphincter incompetence, the treatment is aimed at increasing urethral resistance to the outflow of urine. This may be achieved either by suburethral sling procedures, implantation of artificial urinary sphincter or injection of urethral bulking agents. Periurethral injection of a bulking agent has been proven to be appropriate treatment for patients with good pelvic support and intrinsic sphincter deficiency (Chaliha and Williams, 1995).

It has been suggested that patients who have undergone two or more previous operations to correct stress urinary incontinence have a particularly high prevalence of intrinsic sphincter deficiency at 75% (McGuire, 1981).

Although the concept of injecting material periurethrally to treat stress urinary incontinence was first documented nearly 50 years ago (Murless, 1938), the popularity of periurethral injections was only renewed in the early 1970s with the introduction of polytetrafluoroethylene (Polytef) as a relatively safe periurethral injectable (Berg, 1973; Politano, 1974). The earlier injectables were unfortunately associated with unacceptable cardiorespiratory complications due to particle migration (Murless, 1938; Sachse, 1963). Polytef is a highly viscous, biocompatible material which was associated with very encouraging short-term cure and success rates ranging from 70% to 90% (Politano, 1974; Schulman *et al*., 1983). The long-term cure rates declined rapidly ranging from 7% to 36% (Beckingham *et al*., 1992; Harrison *et al*., 1993; Buckley *et al*., 1994). In fact, experience with Polytef has been limited because of concerns regarding its safety: there have been reports regarding migration and distant emboli both in experimental and clinical studies (Mittleman *et al*., 1983; Malizia *et al*., 1984). Extensive scarring at the site of injection has also been reported (Boykin *et al*., 1989) and this can render subsequent continence surgery technically very difficult.

Autologous fat was introduced as an inexpensive, biocompatible periurethral bulking agent in 1989 (Gonzales de Garibay *et al*., 1989). Although success rates of up to 79% have been reported at 1 year follow-up (Blaivas *et al*., 1994), the main disadvantage of fat as a bulking agent is its resorption at unpredictable rates (Santarosa and Blaivas, 1994). The use of collagen as a bulking agent has also been extensively studied recently. This substance is also biodegradable and the majority of patients require more than one injection (Eckford and Abrams, 1991; Monga *et al*., 1995). Before treatment with collagen a skin test must be performed as hypersensitivity has been reported (Appell, 1994).

Macroplastique® which is one of the more recently developed injectables consists of solid textured silicone macroparticles (vulcanised polydimethylsiloxane) suspended in a polyvinyl-pyrolidinone (PVP) gel. This relatively viscous material heals within a thin fibrin capsule which is fully formed approximately 6 weeks following implantation (Allen, 1992) (see Figure 1). Once formed, this fibrous capsule remains stable. Hence, long-term success with this injectable has been more promising. Indeed, several authors have reported high cure and improvement

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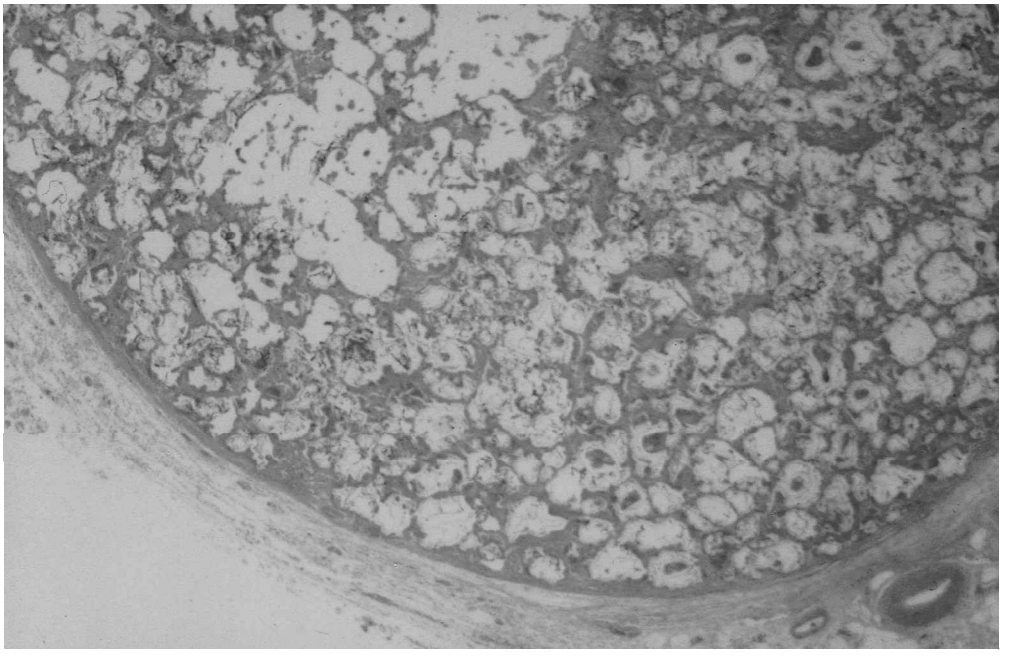

Figure 1. Macroplastique heals within a thin capsule which is fully formed approximately 6 weeks following implantation.

rates with microparticulate silicone (Buckley *et al.*, 1993; Iacovous *et al.*, 1993; Harris *et al.*, 1996).

In this report, we present the subjective outcome of patients who have had transurethral Macroplastique injection with particular emphasis on those who underwent the procedure as primary treatment for stress urinary incontinence.

Patients and methods

We analysed retrospectively the clinical data of 102 patients who had undergone periurethral Macroplastique injection for stress urinary incontinence at Barnsley District General Hospital from December 1992 to February 1996. Their mean age was 58·8 years (range 33–83 years). Genuine stress incontinence had been proven urodynamically by performing provocative cystometry before the Macroplastique injection for 88 women. In the remaining 14 patients, the diagnosis of genuine stress incontinence had been made after obtaining a very suggestive clinical history and demonstrating stress incontinence during physical examination. The pre-operative mean maximum detrusor pressure was 7 cmH_2O (range 0 to 30); only three patients had a maximum detrusor pressure between 16 and 30 cmH_2O.

Of the 102 women, 31 had previously undergone failed incontinence operations; these included anterior colporrhaphy with or without bladder neck buttressing and two failed Stamey procedures. None of these 31 patients had undergone a Burch colposuspension. The remaining 71 patients had undergone the periurethral Macroplastique injection as the primary procedure for stress urinary incontinence; they had not had any previous incontinence surgery. All 102 procedures had been carried out under a general anaesthetic. Cystourethroscopy was performed initially; an open bladder neck had been documented in all cases. An average of 5 ml of Macroplastique were injected transurethrally into the submucosal tissue under direct cystoscopic control. The Macroplastique was placed below the bladder neck at 6, 3 and 9 o'clock positions to achieve urethral apposition. The bladder was then emptied using a 14F gauge catheter. The patient was allowed to leave the hospital when spontaneous voiding had established. All patients had been requested to complete a 5-day course of antibiotics on discharge.

To assess the outcome following the Macroplastique injection, patient records were scrutinised for documentation at follow-up visits.

Statistical analysis

We used contingency table analysis in which the observed values are compared to the values expected on the basis of the totals. A chi-squared test was then used to determine the level of significance of any differences between the observed and expected values.

Results

The patients' feedback at follow-up visits was analysed and the following symptomatic categories were identified: (A) cured—no further treatment required; (B) marked improvement—no further treatment required; (C) slight improvement—further treatment required; (D) no improvement—further treatment required. The mean follow-up period was 3·2 months (range 3–5 months). Using this criterion, there was a 33% cure rate and a success rate of 68% following a single injection of Macroplastique; the success rate was obtained by including all patients who were either cured or markedly improved requiring no further intervention and therefore considered their operation a success (Table I).

The overall success rate of those who had had previous surgery was 71% and for those who had not it was slightly less at 66%. This difference however was not statistically significant. A single Macroplastique injection was unsuccessful in nine of the 31

Table I. Subjective outcome for mean follow-up of 3·2 months following a single treatment with Macroplastique

	Total	Cured	Marked improvement	Success	Slight improvement	No improvement	Failure
Primary	71	21 (30%)	26 (37%)	47 (66%)	5 (7%)	19 (27%)	24 (34%)
Secondary	31	13 (42%)	9 (29%)	22 (71%)	3 (10%)	6 (19%)	9 (29%)
Total	102	34 (33%)	35 (34%)	69 (68%)	8 (8%)	25 (25%)	33 (32%)

Table II. Comparison of outcome of patients in primary and secondary groups and for those with or without a cystocele

	Primary			Secondary		
	Cystocele	No cystocele	Total	Cystocele	No cystocele	Total
Cured	6	15	21	5	8	13
Improved-NFT	6	20	26	1	8	9
Improved-FT	1	4	5	0	3	3
No change	5	14	19	2	4	6
Total	18	53	71	8	23	31

Table III. Subjective outcome for mean follow-up of 17·6 months following a single treatment with Macroplastique

	Total	Cured	Marked improvement	Success	Slight improvement	No improvement	Failure
Primary	56	13 (23%)	14 (25%)	27 (48%)	11 (20%)	18 (32%)	29 (52%)
Secondary	28	4 (14%)	9 (32%)	13 (46%)	6 (21%)	9 (32%)	15 (54%)
Total	84	17 (20%)	23 (27%)	40 (48%)	17 (20%)	27 (32%)	44 (52%)

women (29%) who had had previous incontinence surgery (i.e. these nine women were either in the slight or no improvement categories) while 34% (24/71) of women who had not had previous surgery were unsuccessful (Table I). Again these differences in the unsuccessful outcome were not statistically significant. $\{\chi^2 = 0{\cdot}24995$, including Yates' correction for integer data; $\nu = 2$; $\chi^2_{0{\cdot}95} = 5{\cdot}99\}$.

Association with cystocele

In the group of patients who had not had previous incontinence surgery (primary treatment group) 18 of the 71 patients in this group had a documented mild cystocele. Twelve of these 18 patients achieved success following a single Macroplastique injection. In the secondary group (patients who had had previous incontinence surgery), eight of the 31 patients in this group had a documented mild cystocele and six of these eight patients were successful following a single Macroplastique injection (Table II). There was no statistically significant difference in the outcome of these two groups (Primary group: $\chi^2 = 0{\cdot}05741$, including Yates' correction for integer data; $\nu = 1$; $\chi^2_{0{\cdot}95} = 3{\cdot}84$. Secondary group: $\chi^2 = 0{\cdot}02573$, including Yates' correction for integer data; $\nu = 2$; $\chi^2_{0{\cdot}95} = 3{\cdot}84$).

Of the 33 patients for whom a single injection of Macroplastique was unsuccessful, six patients reported success after a second Macroplastique injection and two women required a third injection before achieving relief of urinary symptoms. Hence, following a second or third Macroplastique injection, the overall success rate increases to 75% (69 + 8/102). Six women subsequently had Burch colposuspension and two underwent bladder neck buttressing with anterior vaginal wall repair. The rest of the patients are currently under review.

The average stay in hospital was 2·7 days (range 1–12 days).

Post-operative complication

Dysuria and slight haematuria were universal for the first 24–48 hours. Seven (6·8%) of the 102 patients in the study group experienced postoperative urinary retention lasting between 2 and 7 days. A suprapubic catheter was inserted in all these patients. A long-term indwelling catheter was not required in any patient. Five of these seven women were completely dry following the Macroplastique procedure, one patient's symptoms improved markedly and she required no further treatment and the final patient had found no change in her symptoms. One patient had a urinary tract infection immediately following the procedure and her treatment was subsequently unsuccessful.

Longer term outcome

Further data was also available for 84 of the 102 women studied. The mean follow-up period was 17·6 months (range 11–44 months). The patients' notes were analysed and the subjective outcome was subdivided in the symptomatic categories as described before (Table III). The level of success in the primary and secondary group was again very similar at 48%.

and 46% respectively. There was however a decline in the overall success rate from 68% to 48% over the period studied.

Discussion

In our retrospective analysis the overall subjective success rate of 69% at 3-months follow-up period is in agreement with the short to medium-term results reported by other authors (Iacovous *et al*., 1993; Buckley *et al*., 1993).

The findings of several authors suggest that periurethral bulking agents have better outcome in women who have intrinsic sphincter deficiency with a stable bladder. The prevalence of intrinsic sphincter deficiency (low urethral closure pressures) has been reported to be high in women who have undergone previous failed incontinence surgery (McGuire, 1981; Hilton and Stanton, 1983). However, in these two retrospective series, the authors did not determine whether the low urethral closure pressure caused or resulted in failure of the prior operations. In our retrospective analysis there was no statistically significant difference in outcome when the overall success rate was compared for the primary and secondary treatment groups. If the outcome is assessed subjectively only, the success of the procedure may be slightly overestimated as has been demonstrated by Monga *et al*. (1995) and Eckford and Abrams (1991) i.e. slightly higher success rates were reported when the objective and subjective outcome measures were compared following collagen para-urethral injections. Nevertheless, even if it is assumed that there is a slight overestimation of success rates in our analysis, it would have been reflected in both study groups and therefore, we may infer that the difference in outcome for the primary and the secondary groups would still not be statistically significant. The clinical implications of these findings are that Macroplastique periurethral injections may be used as a primary treatment for stress urinary incontinence in women. Furthermore, a periurethral injection of Macroplastique (in contrast to Teflon) is not associated with local tissue scarring (Allen, 1992). Hence, further surgery if required will not be complicated by local fibrosis.

We also found that of the 71 patients in the primary treatment group, 18 patients had been recorded as having a mild cystocele. Of these 18 women, 12 had successful outcome and of the eight women who had a cystocele in the secondary treatment group, six had successful outcome. We did not find any statistically significant difference in the outcome of women who either did or did not have a cystocele before the procedure. Although the numbers were small in this subgroup of patients, two possibilities might explain this finding. Firstly, intrinsic sphincter weakness may be present with a mild cystocele without significant abnormal bladder wall descent. Secondly, should the degree of bladder neck descent be sufficient to cause stress urinary incontinence, they may have co-existent weak sphincters to allow a bulking agent like Macroplastique to significantly improve their symptoms of incontinence.

Conclusion

The transurethral Macroplastique injection is a minimally invasive procedure which requires a short hospital stay and is associated with low postoperative morbidity. The findings of this study support the use of Macroplastique transurethral injection as a primary procedure for the treatment of genuine stress incontinence in women. Furthermore, those who have a mild cystocele on examination may still be suitable for a Macroplastique injection.

Further work is required to establish the true incidence of intrinsic sphincter deficiency in women who have not had any previous incontinence surgery and to further investigate the mechanism whereby different bulking agents achieve continence. We also feel that success following transurethral Macroplastique injections may be further increased if the patients are appropriately investigated and selected prior to treatment.

We are now conducting a longitudinal prospective study to evaluate objectively the efficacy of transurethral Macroplastique injections as a primary procedure for stress urinary incontinence in women.

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