

## Hypothesis / aims of study

We have previously published the outcomes of polydimethylsiloxane (Macroplastique®) in patients suffering from urine leakage from their Mitrofanoff channels. Macroplastique® has now been replaced by Bulkamid® hydrogel in our clinical practice. We present the outcomes of Bulkamid® injection in the last 5 years and compare it to the previous usage of silicone bulking agents in our department.

## METHODS

We retrospectively analysed data from 2016-2021 for patients who had previously undergone Mitrofanoff channel formation of any type, who received Bulkamid® injections due to incontinence from their channels. Effectiveness was assessed based on the number of pads used before and after the injection. Outcomes were classified as complete success (dry), partial success (>50% reduction in incontinence pads) and failure. We also calculated success rates for type of channel (appendix, Monti, double Monti), for type of reservoir (native bladder, cystoplasty, neobladder) and for number and volumes of injections per treatment. Statistical analysis was performed to compare success rates of our previous Macroplastique® outcomes published in 2015, with Bulkamid® using chi-square tests, with  $p < 0.05$  as significant.

## RESULTS

Results are shown on Table 1. Eleven female patients had Bulkamid® injection to their Mitrofanoff channels due to urinary leakage. Mean age was 45.9 (range 21-67) and median follow-up was 16 weeks (range 1-44 weeks). Nine patients received Bulkamid® injections once, whilst two patients received injections twice. One patient was lost to follow up. Initial injection was partially successful in 4/10 patients (40%) and a second injection in one patient (cumulative success rate 45%), but only one patient was completely dry (9%). Of the five known failures, two had surgical revision of their Mitrofanoff channels with success. The five successful first injections were given to 4 patients with Monti channel and one patient with appendiceal channel (3 patients with ileocystoplasty and 1 patient with ileal neobladder). None of the injections given to native bladders were successful. The mean volume of the injected Bulkamid® gel was 1.9mls (range 0.5ml to 4ml). Greater volumes did not necessarily imply higher success rates, as 3/4 successful first injections had a volume less than 1.9 ml. The volume of the two other successful (first and repeat) injections were higher than the mean injected volume. Comparison to the outcomes of Macroplastique® showed no statistical difference in the success rates between the two injectable bulking agents.

Table 1. Success rates for each type of bulking agent

PARAMETER		MACROPLASTIQUE® (N=24), n(%)	BULKAMID® (N=11), n(%)	P value	
<b>Complete success</b>		3 (12.5)	1 (10)	0.83	
<b>Partial success</b>		9 (37.5)	3(30)	0.98	
<b>Indication for CCUD</b>	<b>Neuropathic</b>	4 (44.4)	1 (50)	0.89	
	<b>Atonic Bladder</b>	3 (50.0)	0(0)	0.20	
	<b>Complex incontinence</b>	3 (75.0)	1 (25)	0.15	
	<b>Cancer</b>	2 (100)	1 (50)	0.24	
	<b>Bladder pain</b>	0 (0)	NA	-	
<b>Type of Conduit</b>	<b>Appendix</b>	4 (66.7)	1 (50)	0.67	
	<b>Monti</b>	4 (44.4)	3 (50)	0.83	
	<b>Double Monti</b>	4 (50.0)	0 (0)	0.19	
<b>Type of reservoir</b>	<b>Native bladder</b>		2 (33.3)	0 (0)	0.19
	<b>Neobladder</b>	<b>Ileum</b>	0 (0)	1 (33.3)	0.36
		<b>Colonic</b>	2 (100)	-	-
		<b>Ileocolonic</b>	4 (80.0)	-	-
	<b>Clam cystoplasty</b>	<b>Ileum (native tunnel)</b>	2 (28.6)	1 (33.3)	0.25
<b>Colon (native tunnel)</b>		2 (100)	-	-	
<b>Total volume of Bulkamid®</b>	<b>&lt; 1.9 ml (1/5 lost in follow-up)</b>	n/a	Failure 1/4 (25)	Success 3/4 (75%)	
	<b>≥ 1.9 ml</b>	n/a	Failure 5/6 (83.3)	Success 1/6 (16.7)	
<b>Number of injections</b>	<b>2</b>	n/a	Failure 1/2 (50)	Success 1/2 (50)	
	<b>4</b>	n/a	Failure 5/8 (62.5)	Success 3/8 (37.5)	

## Interpretation of results

Bulkamid® injection to Mitrofanoff® channel has a partial response rate (40% with the first injection and 45% if a second one is given) in the management of incontinence through a Mitrofanoff channel, but was curative in only 9%. Bulking may, at least, defer the necessity for major surgical revision. Ultimately, the small number of patients included in our study, constitute one of the major limitations.

## Concluding message

Success rates for Bulkamid® seem to be comparable to the ones reported for Macroplastique® injections. Further randomised prospective studies with larger populations are required to assess the effectiveness of different bulking agents.