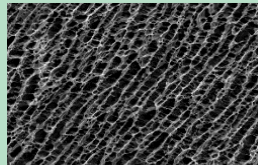




Why is Bulkamid different to other bulking agents?

Non-particulate homogenous gel

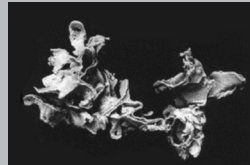


Bulkamid

non-particulate permanent homogenous hydrogel consisting of 97.5% water and 2.5% polyacrylamide



Predictable, controllable and precise urethral bulking due to volume of hydrogel¹



Particulate combination gel

Other bulking agents

mini-particles in a transient carrier gel, which is absorbed shortly after implantation



Inherent variability in urethral bulking due to absorption of transient gel and subsequent inflammatory response

Clinical benefits

		Macroplastique®	Durasphere®	Deflux®
Safety & efficacy at 12 months²⁻⁵	✓	✓	✓	✓
Long-term efficacy to 7 years⁶	✓	✗	✗	✗
Low acute complication rates (0 - 6%)*²⁻⁵	✓	✗	✗	✗
No long-term complications**⁷⁻¹⁰	✓	✗	✗	✗
No long-term tissue changes⁷⁻¹⁰	✓	✗	✗	✗

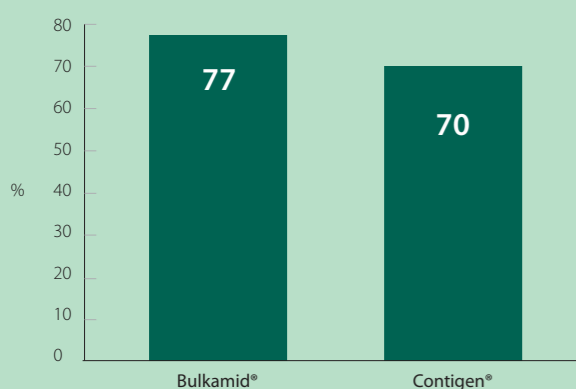
* urinary retention / urinary tract infection

** e.g. migration, calcification, cyst formation, urinary retention

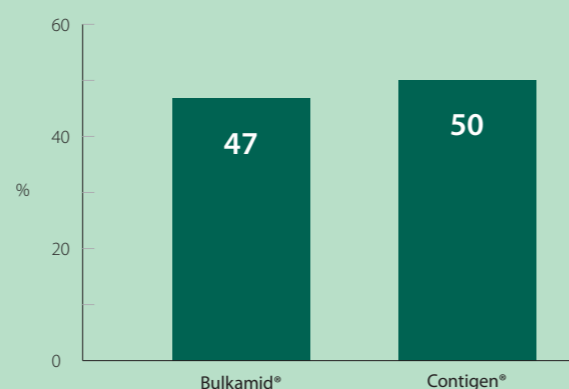
Safety and efficacy at 12 months²

Number of patients	345 (229 Bulkamid: 116 Contigen)
Study design	Randomised controlled trial, single blind
Previous incontinence surgery	25% of patients

% of patients cured or improved at 12 months



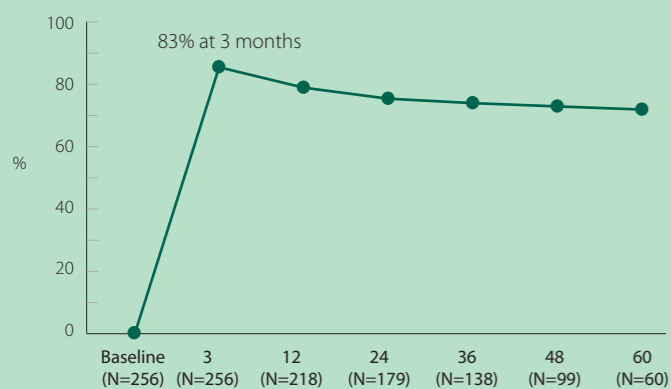
No SUI episodes at 12 months



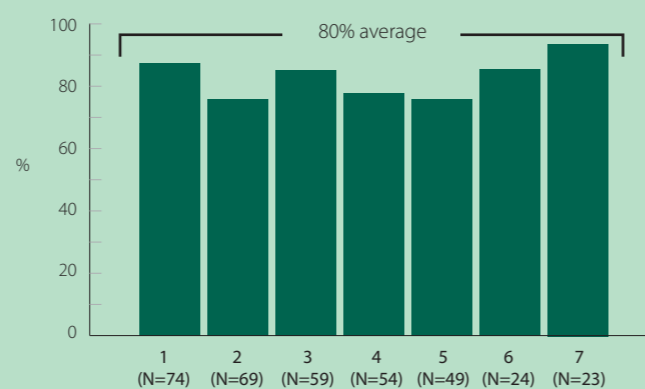
Durability at 5 and 7 years^{11,16}

Number of patients	256	352
Study design	Observational	Longitudinal observational
Previous incontinence surgery	None	None
Follow up period	5 years	7 years

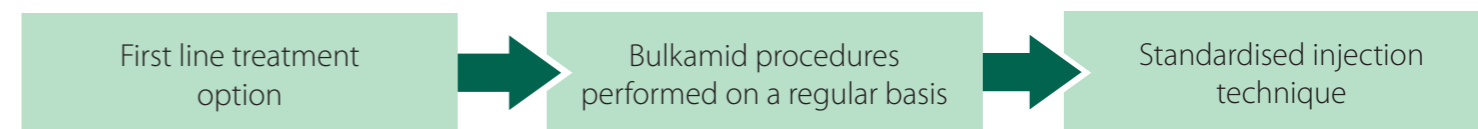
% of patients cured or improved at 5 years (subjective)



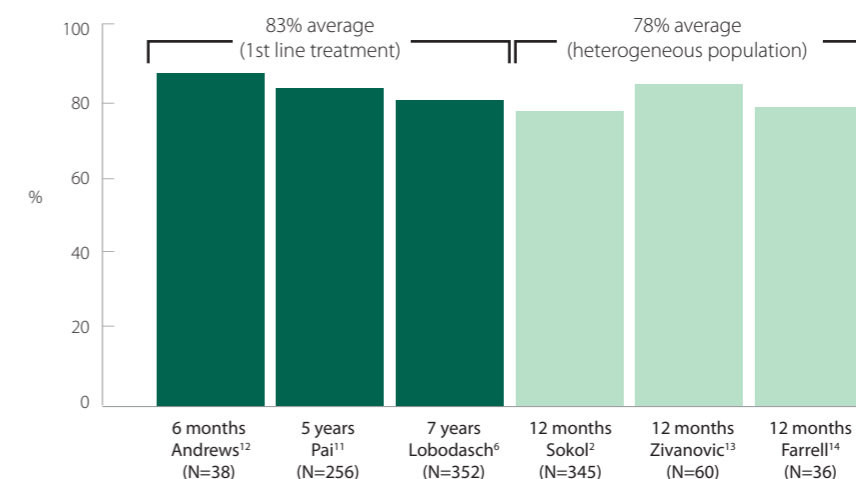
% of patients cured or improved at 7 years (subjective)



Offered as a first line treatment



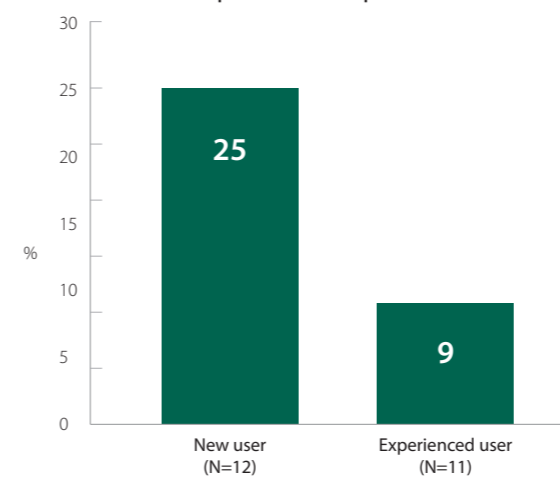
Patients reported as cured or improved



Reduction in repeat injections

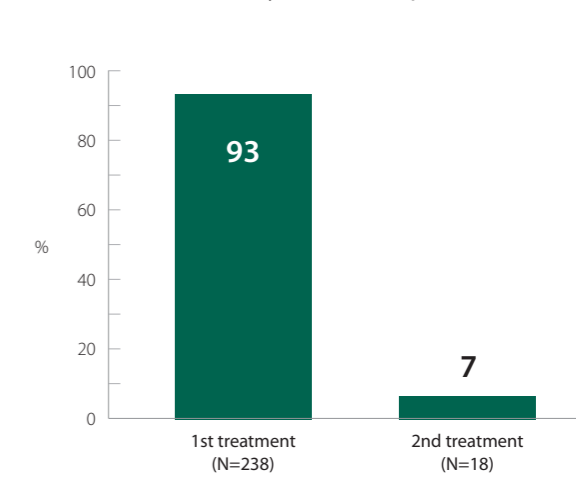
Learning curve

% of repeat injections required for a new vs. experienced implanter*¹⁵



Experienced user and first line treatment

% of patients requiring 1 or 2 treatments (5 year follow up)¹¹



* Average follow up 5 months (1-12 months)

Emerging risks of mid-urethral slings¹⁶

Reported complications in review (337 publications)

Reported complications in review (337 publications)	Incidence
Urethral obstruction*	2.3%
Vaginal, bladder and / urethral erosion*	1.8%
Refractory chronic pain	4.1%
Vesicovaginal fistulas	<1%

* Requiring surgery

“Considering the additional risks of refractory overactive bladder and bowel perforations, amongst others, the overall risk of a negative outcome after SMUS implantation surgery is**

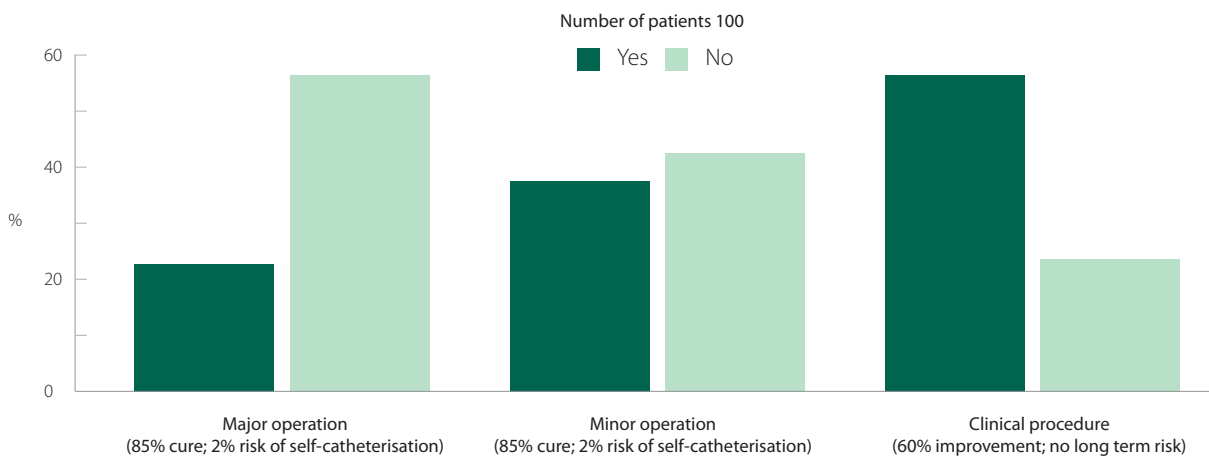
≥15%”

Blaivas et al

** Synthetic mid-urethral slings

Most women would prefer a bulking agent to a mid-urethral sling

Acceptability of treatments¹⁷



Is it now time to think about Bulkamid as a first line treatment?

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