#446 FLUX trial: 3-month outcome of female urethral bulking with Deflux bulking agent

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Hypothesis / aims of study

Stress urinary incontinence (SUI):
Sudden, involuntary leakage of urine during activities that increase intra-abdominal pressure, such as laughing, sneezing, coughing, or exercising

Urethra bulking is a well-established endoscopic intervention for female stress incontinence. Current bulking agents include Bulkamid and Macroplastiue®.

Deflux® is a Non-Animal Stabilised Hyaluronic Acid (NASHA) and Dextranomer (Dx) agent used commonly in paediatric vesicoureteral reflux, with proven good safety profile and clinical effectiveness. Following the injection of Deflux gel, fibroblast cells infiltrate the implant and migrate between dextranomer microspheres. A matrix of collagen is then generated, which surrounds the microsphere. This collagen matrix effectively replaces the hyaluronic acid component of the implant.

However, though licensed in the UK, clinical data on its role in adult urethral bulking is lacking. In this study, we investigated the efficacy and safety of Deflux as urethral bulking a in treatment of adult female stress incontinence.

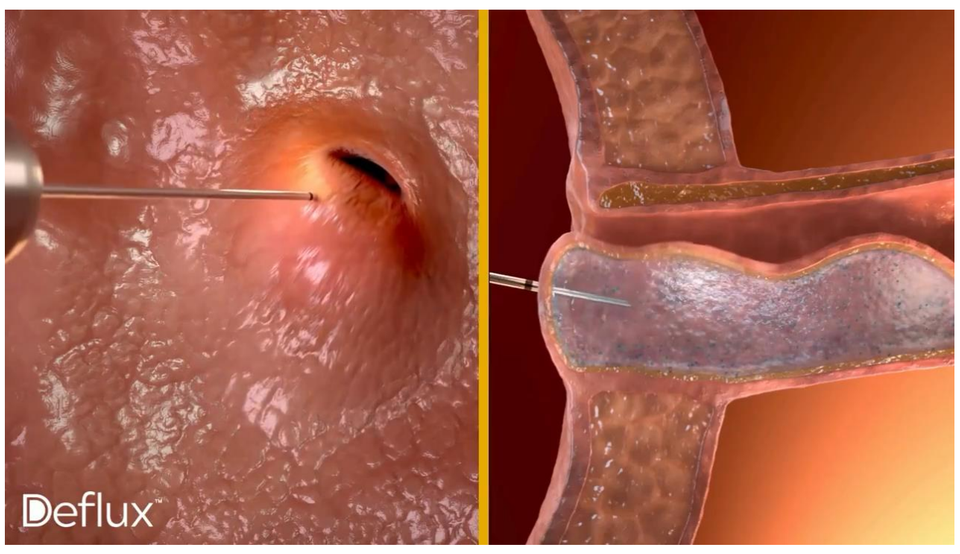

Figure 1: Illustration of the effect of deflux injection submucosally in treatment of VUR.[1]

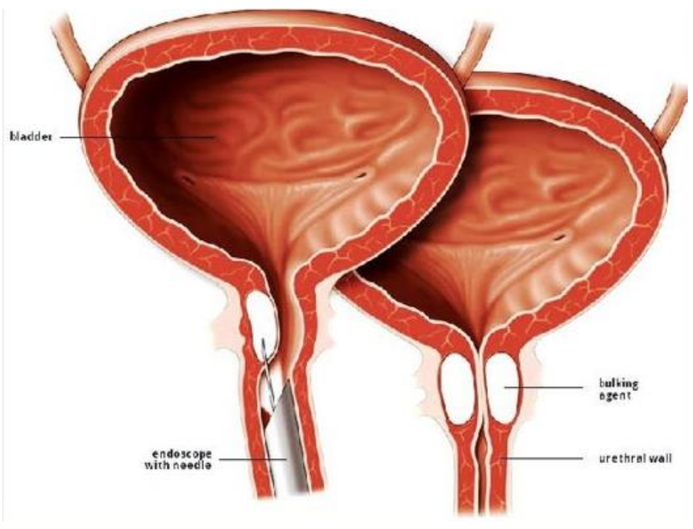

Figure 2: Illustration demonstrating the effect of urethral bulking agent injection.[2]

Study design, materials and methods

51 female patients, with urodynamics proven stress incontinence received urethral bulking with Deflux from 2021 to 2023, with follow up planned for 12 months. In lithotomy position under general anaesthetic, with intravenous Gentamicin prophylaxis, 2 millilitres of Deflux was injected endoscopically at the bladder neck, using a 22-gauge flexible needle via a rigid cystoscope.

Treatment success (dry) was defined as using ≤1 pad for reassurance only per day. Clinical effectiveness was determined by comparing pre- and post-procedure ICIQ-UI (Short form) scores, number of pads used in 24 hours, and weight of leaked urine, by measuring the sum of pad weight within 24 hours.

Statistical analyses were performed with R (version 4.3.0). Paired t-test was used to compare the outcome variables pre-procedure and at follow-up. Logistics regression was performed to delineate relationship between baseline characteristics and outcome variables.

Results and interpretation

At 3 months:

28 in 51 patients (55%) dry

Mean number of pad use
3.2 → 1.4 ↓ 56% (p≤0.001**)

Average 24-hour leaked urine weight
225g → 54g ↓ 76% (p = 0.05*)

Mean ICIQ
15.7 → 7.8 ↓ 50% (p≤0.001**)

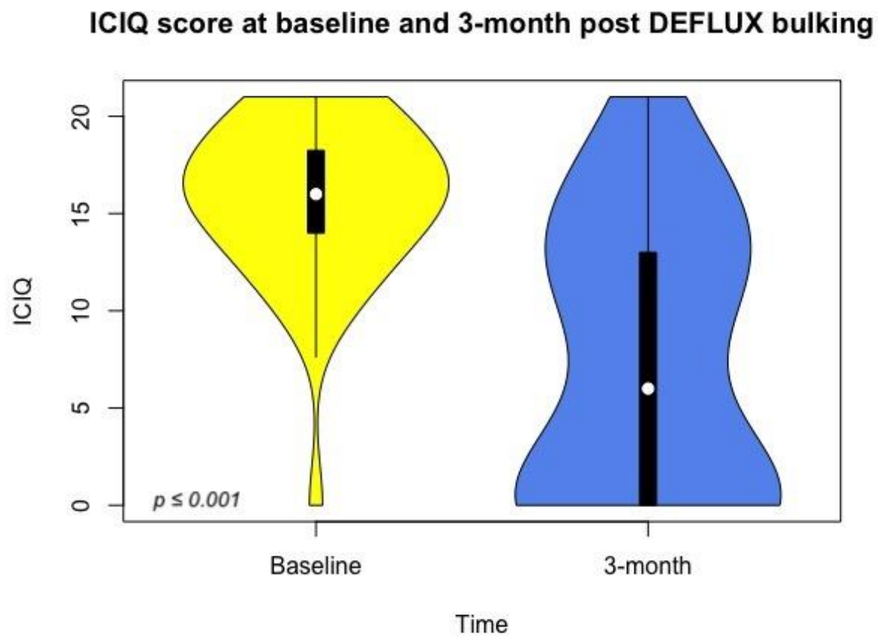

Figure 2: Violin plot showing distribution of ICIQ at baseline and 3-month.

Logistic regression of baseline characteristics shows the number of pads pre-procedure and baseline ICIQ are both statistically significant predictors of treatment success (p≤0.01 and p=0.04, Figure 3).

Univariate logstic regression on prediction of treatment success

Variable	Coef (SD)	*p*
Age	0.02 (0.03)	0.39
BMI (kg/m2)	0.04 (0.05)	0.42
Number of vaginal deliveries	-0.14 (0.32)	0.66
Number of pads use at baseline	-0.68 (0.25)	≤ 0.01**
24-hour urine weight at baseline (g)	-0.00057 (0.0019)	0.77
Baseline ICIQ	-0.26 (0.11)	0.04*

* $p \leq 0.05$, ** $p \leq 0.01$
Abbreviation: BMI= Body Mass Index, ICIQ = International Consultation on Incontinence Questionnaire

Figure 3: Univariate logistic regression result on baseline variables on the prediction of treatment success at 3 months.

A complication rate of 6% was observed, namely urinary tract infections (n=2, treated with antibiotics) and urinary retention (n=1, treated by temporary catheter). These are minor complications which affected only a small group of patients in our study.

Conclusions

A significant proportion of patients remain dry after 3 months of Deflux injection, showing its short-term clinical efficiency. This treatment success is further proven by the statistically significant improvement of weight of urine leakage and mean ICIQ at follow-up.

Patients with lower number of pads and ICIQ at baseline have less bothersome stress urinary incontinence, and thus a better treatment response is expected from such group of patient.

Deflux is a clinically effective and safe bulking agent in female stress incontinence treatment. By utilising a flexible needle with rigid cystoscopy which is already readily available in most Urology departments, Deflux is thus a cost-effective choice of bulking agent. Longer term follow up for 12 months is ongoing to confirm longevity of efficacy as well as safety profile.

References

1. Deflux Endoscopic Injection - Method of Action (Online Video). Palette Life Sciences.
2. Lemperle, Gottfried & Lemperle, Stefan. (2017). Injectable Bulking Agents for the Treatment of Stress Urinary Incontinence. SM Gerontology and Geriatric Research. 1. 1-9. 10.36876/smggr.1005