#337 A decade of experience with urethral bulking injections Deflux® (NASHATM/Dx) in women with stress urinary incontinence

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INTRODUCTION

Urinary incontinence is prevalent and debilitating, affecting up to 52% of all women

- **Stress urinary incontinence** is the involuntary leakage of urine on physical effort or exertion
- More common in women than urge urinary incontinence

Current treatment options are limited in women who are:

- High surgical risk
- Of child-bearing age
- Looking for minimally invasive low risk option

Deflux® is a non-animal stabilised hyaluronic acid/dextranomer (NASHATM/Dx) gel.

- It is injected under direct vision via a cystoscope Bulking is achieved by the dextranomer microspheres of 80-200µm with hyaluronic acid acting as the transport compound.

However – **no long-term data** on the duration of efficacy is available

METHODS

All women with SUI who underwent urethral bulking with Deflux between 2001 – 2007 were identified

Only women with mild to moderate incontinence (<3 pads per day) selected

- SUI was diagnosed clinically via reported symptoms
- Patients with mixed incontinence underwent urodynamics - only those with predominately SUI were selected

Intra-operative method

- Deflux® was applied cystoscopically under direct vision at the level of the bladder neck in 2 or 3 injection sites via a cystoscopic needle.
- Up to 2ml of gel was used
- Aim was to achieve coaptation of the urethra.
- A prophylactic dose of Gentamicin antibiotic was given intravenously at anaesthetic induction

Outcome measure

- Treatment was deemed successful if the patient was dry at their initial 3 months follow up or the patient described minor residual incontinence for which they do not desire further treatment.
- Treatment was deemed a failure if the patient felt there was no significant improvement to their incontinence.

Follow up protocol

- Long term outcomes were ascertained from subsequent medical records. If a patient had subsequent definitive surgical treatment for SUI this was defined as an end point and no further follow up was examined.
- If a woman was lost to follow-up she was contacted by phone or, if unable to contact them by phone, by post, to determine whether symptoms of SUI had returned, when, and whether she had sought any further treatment and if there were any delayed complications.

RESULTS

142 women (average age 57, range 33 – 87)

- **90% (128/142) women followed up**
- 14 women lost to follow up after their initial clinical appointment three months post-operatively.

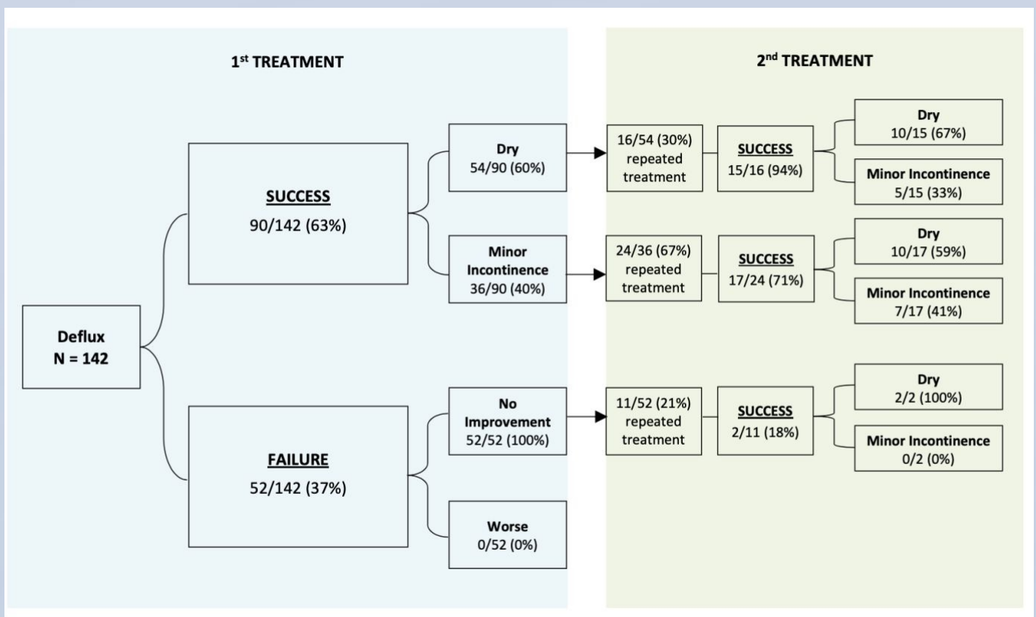
Duration

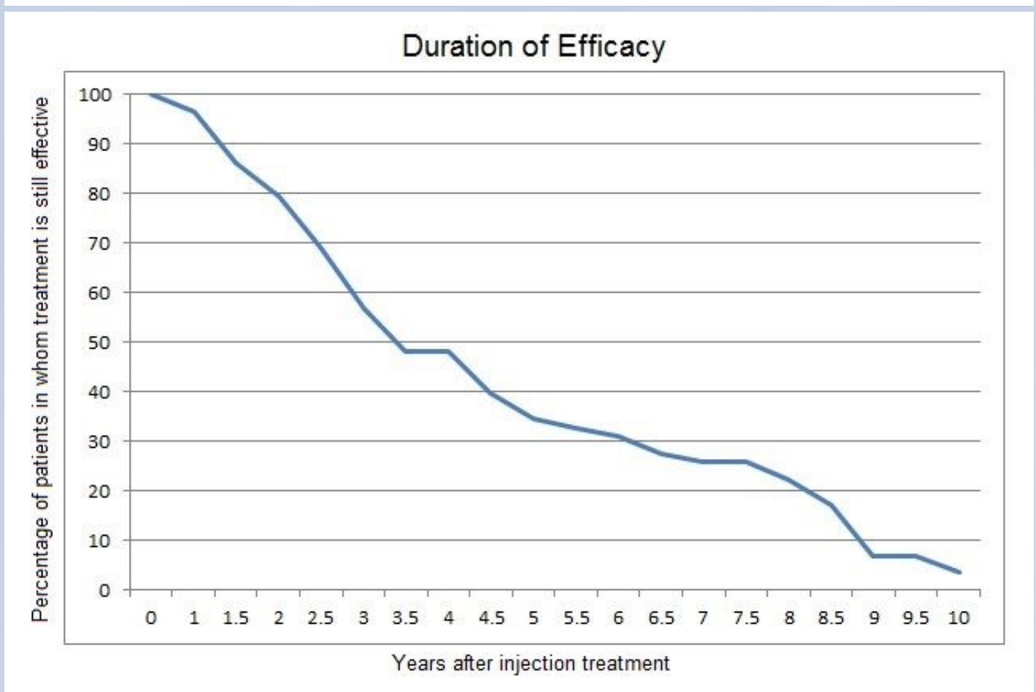
- 13 years (mean 8.8 years, median 8.7 years) from initial treatment.

51 women underwent repeat urethral bulking procedures

- Either insufficient initial symptom relief (n=35)
- or due to recurrence of symptoms after a period of good symptom control (n=16)

Total of 209 treatments
60/142 (42%) progressed to further definitive SUI treatments





SIDE EFFECTS

45/209 (22%) Clavien-Dindo classified complications post urethral bulking injection.

21 (10%) reported episodes of lower urinary tract symptoms (dysuria, frequency and urgency) within the first 2 weeks post urethral bulking injection.

- All symptoms resolved by three months follow up. None required pharmacological treatment - Clavien-Dindo I.

7 (3%) developed UTI post treatment

- All treated with oral antibiotics, none required hospital admission
- No cases of recurrent UTIs post treatment - Clavien-Dindo II

12 (6%) developed urinary retention

- All performed ISC until spontaneous voiding resumed
- All resolved within 2 weeks post injection - Clavien-Dindo II

11 (5%) developed pseudocyst formation

- All treated successfully via I&D
- 3 under GA, 2 under LA - Clavien-Dindo III

CONCLUSIONS

Deflux® urethral bulking injections appears to be an effective treatment option in women with mild to moderate (no more than three pads in 24 hours) SUI with minimal morbidity

Overall full incontinence was achieved in 46% (66/142) of patients

- 65% (92/142) had marked improvement in their continence

Duration of effect beyond 24 months show that the efficacy of Deflux® appears to reduce in a linear fashion, reaching a satisfaction rate of 48% at 48 months, 31% at 72 months and 22% at 96 months.

Conflict of interest: BY has received reimbursement of study/conference expenses from CJ Medical SF is an international trainer for Urethral bulking in men and women