

Cystoscopic and periurethral Bulkamid for post-obstetric fistula repair stress incontinence: a pilot study

Kenneth M Peters¹, MD, Michael Breen², MD, Aidan Kennedy¹, MD; Nikta Rezakahn Khajeh¹, MD; Bernadette M.M. Zwaans¹, PhD; Larry T Sirls, MD¹

¹Corewell Health William Beaumont University Hospital, Royal Oak, MI; ²Freedom From Fistula Clinic, Analankininina University Hospital Center, Tamatave, Madagascar

534

Introduction

- Post-obstetric fistula repair incontinence (POFRI): persistent urinary leakage after technically successful obstetric fistula closure
- 19–35% of fistula repair patients develop stress urinary incontinence (SUI) postoperatively
- Surgical management is challenging due to urethral loss, reduced bladder capacity, and severe vaginal scarring
- Standard of care is autologous pubovaginal sling — invasive, with ~20% risk of bladder/urethral injury
- Bulkamid is safe, effective, and durable for primary SUI;
 - less invasive, faster recovery, and significant cost savings in low-resource settings
- Only one prior report of polyacrylamide hydrogel in POFRI (n=4, no validated outcome measures)

Objective

- Evaluate feasibility and efficacy of Bulkamid for POFRI-associated SUI using two techniques:
 - Cohort 1: Cystoscopic-guided urethral injection (standard technique)
 - Cohort 2: Periurethral injection without cystoscopy (novel technique)

Methods

- Prospective pilot study; Freedom from Fistula unit, Tamatave, Madagascar
- Cohort 1 (n=11): Cystoscopic injection, January 2025
- Cohort 2 (n=17): Periurethral injection without cystoscopy, June 2025
- Exclusion criteria: urethral scarring preventing 14 Fr catheter passage, or bladder capacity <50 mL

Preoperative Evaluation

- Waldijk fistula classification, bladder capacity, urethral length, vaginal length, urethral/vaginal scarring

Outcome Measures

- Primary: Patient Global Impression of Improvement (PGI-I) at discharge (2–3 days) and 3 months
- Secondary: QUID and ICIQ-UI-SF

Results

Table 1. Baseline Demographics

Number of patients	Cohort 1 (N=11)	Cohort 2 (N= 17)	All (N=28)
Age	35.9 years (14.3; 32)	29.1 years (13.0; 25)	31.8 (13.7; 30.5)
# VVF repairs	2 (1.8; 1)	1.8 (1.0; 1)	1.9 (1.4; 1)
Prior surgeries			
1 or more surgeries	N =11 (100%)	N =10 (59%)	N = 22 (78.6%)
2 or more surgeries	N = 7 (64%)	N = 5 (29%)	N = 12 (42.9%)
Bladder capacity	150.9 cc (78.5; 100)	151.2 cc (85.5; 120)	151.1 (81.3; 115)
Urethral length	2.7 cm (0.78; 3)	3.38 cm (0.49; 3.5)	2.3 (0.8; 2.2)
Urethral Scarring			
No	N = 0	N = 5 (29.4%)	N = 5 (17.9%)
Mild	N = 2 (18.2%)	N = 4 (23.5%)	N = 6 (21.4%)
Moderate	N = 4 (36.4%)	N = 3 (17.6%)	N = 7 (25%)
Severe	N =5 (45.5%)	N =5 (29.4%)	N =10 (35.7%)
Urethra mobile			
Yes	N = 2	N = 4	N = 6
No	N = 9	N = 13	N = 22
Vaginal length	4.7 cm (3.2; 4)	4.5 cm (2.1; 4)	4.6 (0.8; 2.2)
Vaginal Scarring			
No	N = 1 (9.1%)	N = 1 (6%)	N = 2 (7.1%)
Mild	N = 2 (18.2%)	N = 5 (29.4%)	N = 7 (25%)
Moderate	N = 1 (9.1%)	N = 5 (29.4%)	N = 6 (21.4%)
Severe	N = 7 (63.6%)	N = 6 (35.3%)	N = 13 (46.4%)

Primary Outcome (PGI-I Success)

- Combined discharge success: 19/28 (67.8%)
- Combined 3-month success: 8/15 (53.3%)
- Cohort 1: 72.7% at discharge → 40% at 3 months (5 patients with data)
- Cohort 2: 64.7% at discharge → 60% at 3 months (10 patients with data)

Safety

- 2 patients (1 per cohort) developed recurrent vaginal fistulas; both successfully repaired with Martius flap
- No other significant complications reported

Fig 1. Periurethral Injection Locations

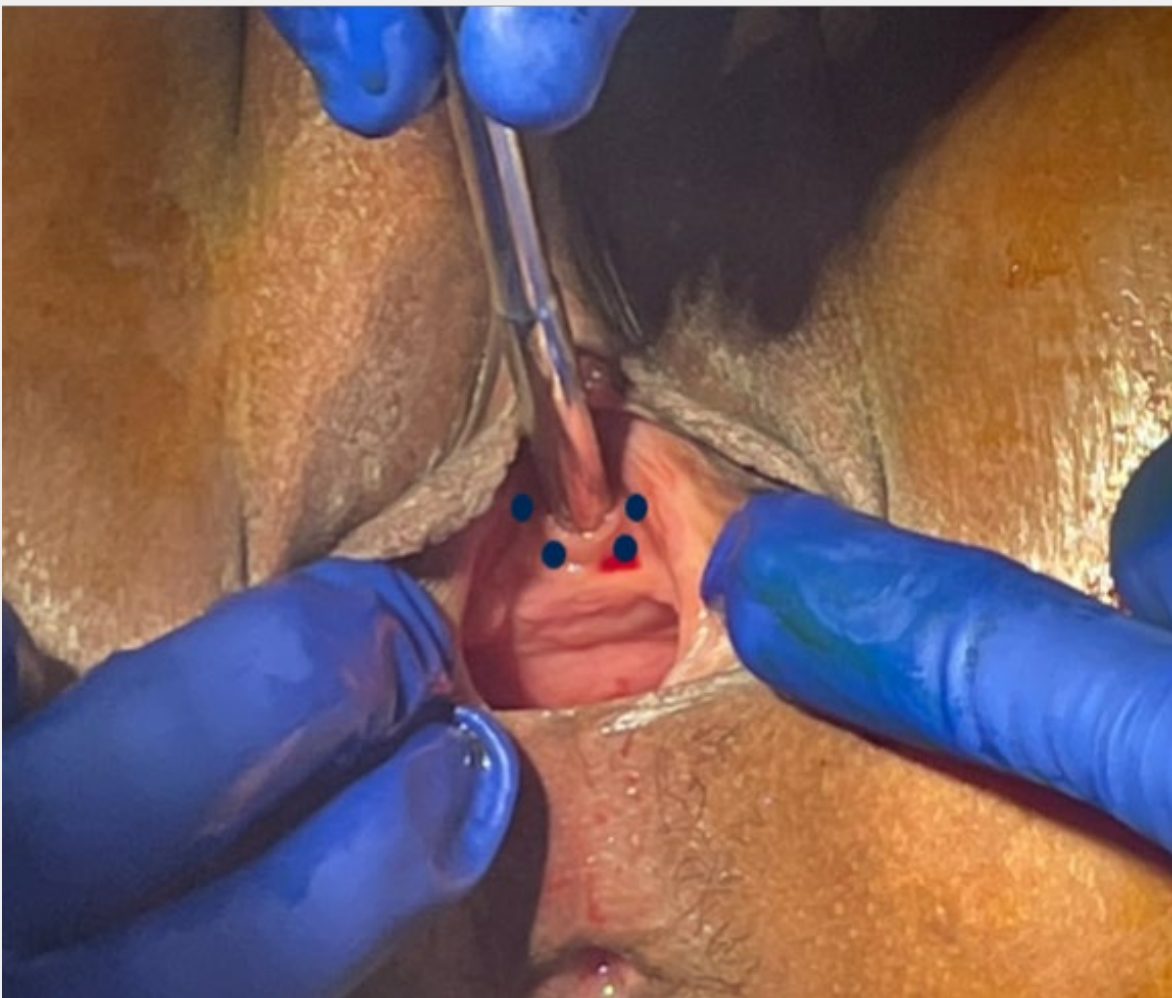


Fig 2. Surgical Equipment Comparison

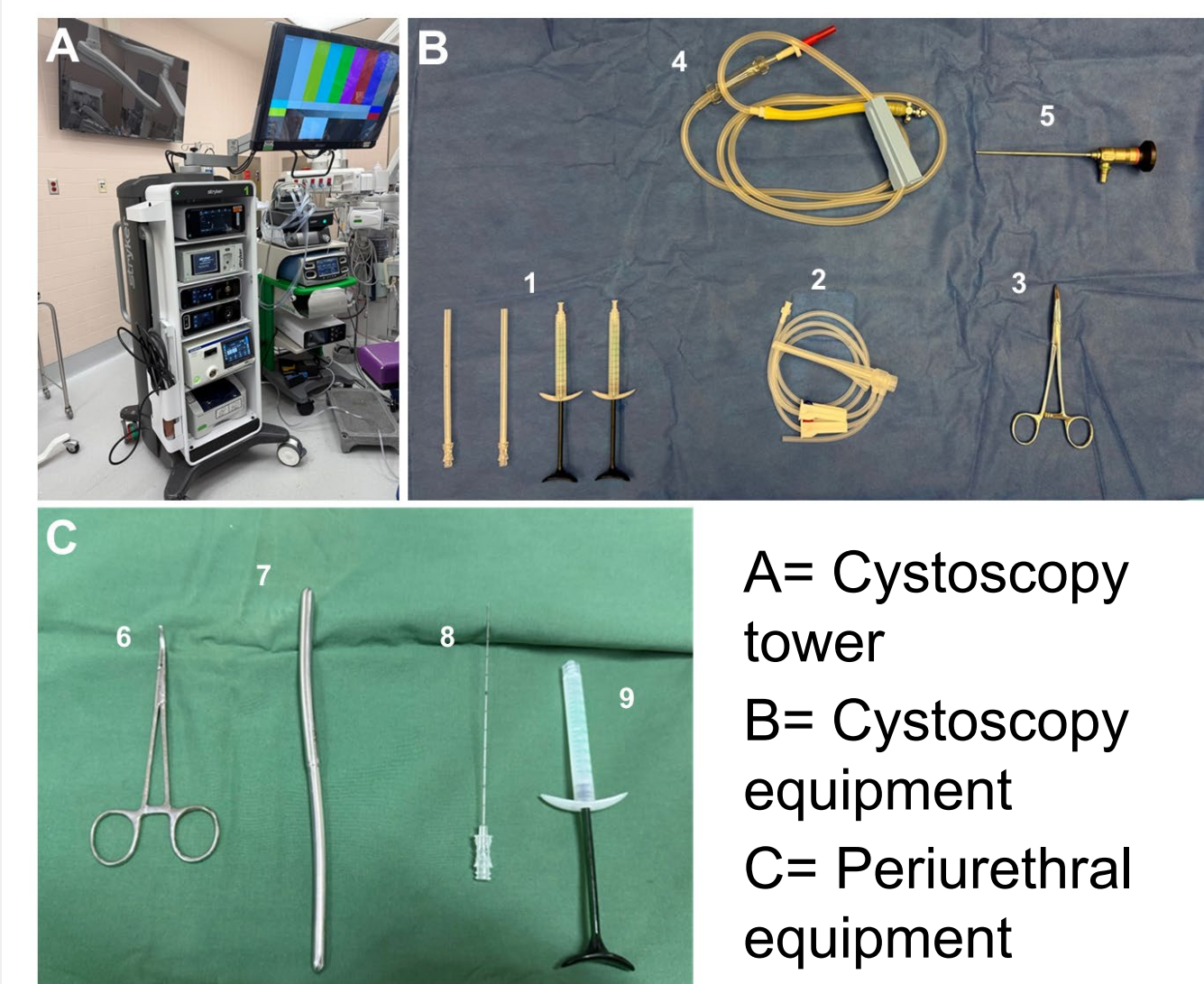


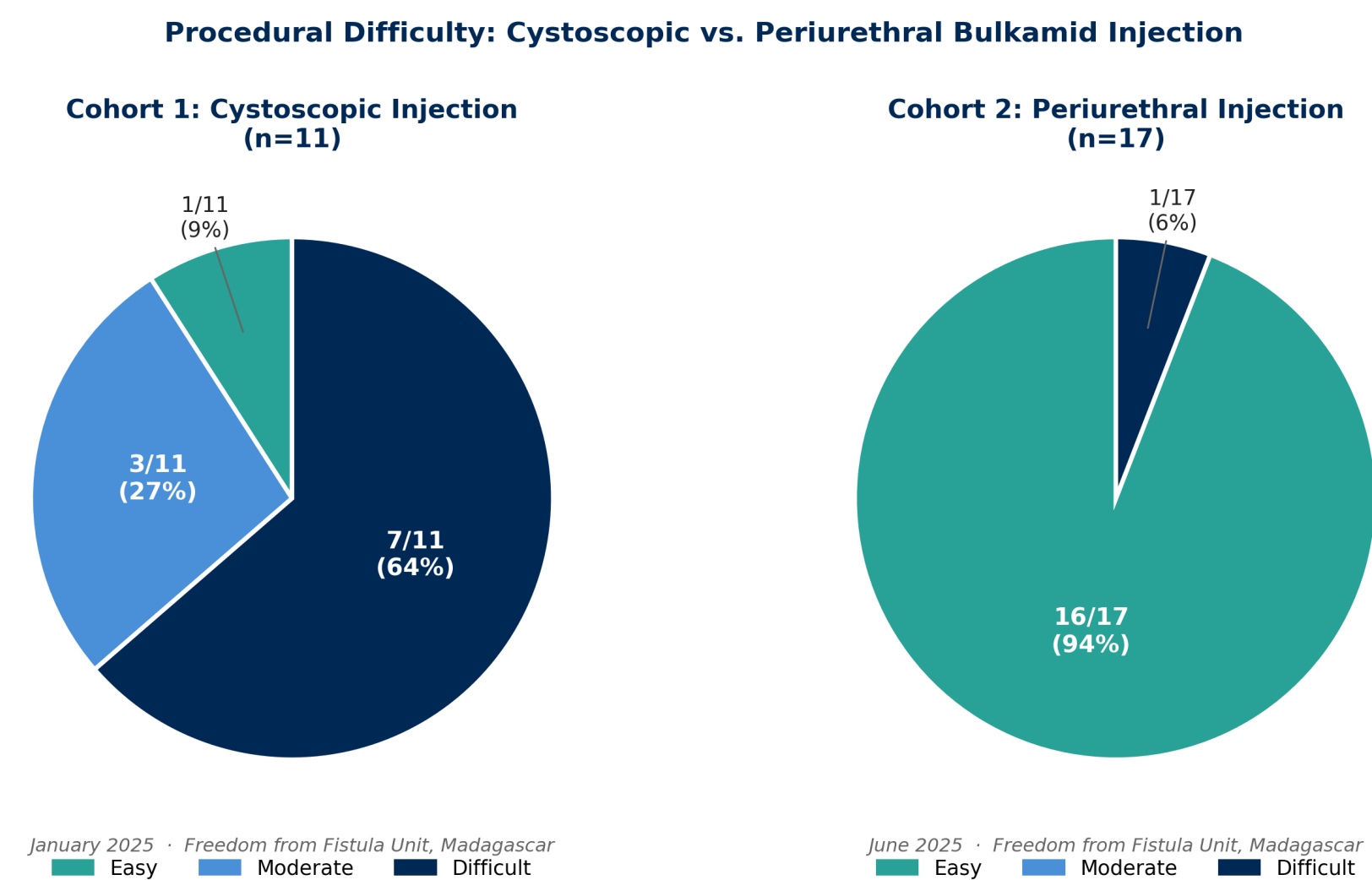
Table 2. PGI-I & Symptom Outcomes

	Cohort 1	Cohort 2	All
PGII	N = 11	N = 17	N = 28
Success at Discharge	N = 8 (72.7%)	N = 11 (64.7%)	N = 19 (67.8%)
Success at Follow-up	N = 2 (40%)	N = 6 (60%)	N = 8 (53.3%)
QUID			
Baseline	29 (2.1; 30)	20.6 (5.5; 20)	24.15 (6.03; 25)
Discharge	14.9 (10.1; 17)	10.1 (9.3; 5)	12.15 (9.76; 11)
Change in QUID BL - D	-14.1 (9.8; -8) (p< 0.001)	-10.5 (10.8; -13) (p< 0.001)	-12 (10.3; -12.5) (p< 0.001)
Follow-up	16 (11.4; 23)	13.4 (9.2; 17)	14.3 (9.6; 18)
Change in QUID BL - FU	-13.5 (10.9; -7) (p< 0.001)	-8.4 (9.0; -7.5) (p< 0.001)	-10.1 (9.6; -7) (p< 0.001)
ICIQ			
Baseline	17.2 (1.7; 17)	17.7 (6.9; 16)	17.5 (5.26; 17)
Discharge	9.5 (5.4; 11)	8.9 (5.6; 11)	9.15 (5.44; 11)
Change in ICIQ BL – D	-7.6 (5.5; -8) (p< 0.001)	-8.9 (7.0; -9) (p< 0.001)	-8.3 (6.3; -8) (p< 0.001)
# of patients that met MID	7 (63.6%)	11 (73.3%)	18 (69.2%)
Follow-up	10.8 (7.9; 13)	11.1 (6.6; 13)	11.0 (6.8; 13)
Change in ICIQ BL – FU	-6.4 (7.9; -4) (p< 0.001)	-4.5 (6.5; -4) (p< 0.001)	-5.1 (6.8; -4) (p< 0.001)
# of patients that met MID	2 (40%)	5 (50%)	7 (46.7%)
Pad Weight	N = 11	N = 16	
Baseline	93 (49.2; 79.5)	379.4 (196.4; 367.5)	269.3 (210.3; 185.5)
Discharge	76.5 (72.6; 67)	66.4 (86.9; 31.5)	70.5 (80.0; 45)
Follow-up	42.5 (37.6; 32)		42.5 (37.6; 32)

Procedural Difficulty

- Cystoscopic injection "moderate" or "difficult" in 10/11 (91%) cases
- Periurethral injection "easy" in 16/17 (94%) cases
- Cystoscopy required more injection sites (7.1 vs 3.9, p<0.001); total Bulkamid volume similar (2.4 vs 2.5 cc)

Fig 3. Procedural Difficulty



Conclusions

Bulkamid provides promising short-term outcomes for SUI in POFRI women

Both cystoscopic and periurethral approaches were effective; periurethral technique was substantially easier and avoids cystoscopy equipment

Periurethral technique is teachable, generalizable, and well-suited for low-resource environments