

# Intraurethral cross-linked hyaluronic acid/dextranomer (DEXSUI<sup>®</sup>) injection versus mid-urethral sling for stress urinary incontinence: a comparative short-term outcome analysis

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**Objectives:** Stress urinary incontinence (SUI) is a prevalent condition that impairs quality of life; while midurethral sling (MUS) surgery is the standard treatment, intraurethral bulking injection offers a minimally invasive alternative. This study aimed to compare the efficacy and safety of intraurethral cross-linked hyaluronic acid/dextranomer (CLHA/Dx, DEXSUI<sup>®</sup>) injection with midurethral sling surgery in the treatment of stress urinary incontinence in women.

**Methods:** This retrospective study included women who presented with stress urinary incontinence to İzmir Bakircay University, Çiğli Training and Research Hospital between January 2024 and June 2025. Patients underwent either midurethral sling surgery or intraurethral CLHA/Dx (DEXSUI<sup>®</sup>) injection. Exclusion criteria included urge incontinence, urinary tract infection, and BMI > 35 kg/m<sup>2</sup>. Quality of life was assessed using the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF),

Urogenital Distress Inventory-6 (UDI-6), and Incontinence Quality of Life Questionnaire (I-QOL) questionnaires. Treatment success was defined by Patient Global Impression of Improvement (PGI)-I scores.

**Results:** Midurethral sling (MUS) was associated with significantly longer operative time (30.5 ± 7.8 vs. 11.4 ± 4.3 min,  $p < 0.001$ ) and longer hospital stay (median 1 vs. 0 day,  $p < 0.001$ ). At 1-month follow-up, complete dryness rates were similar (82.4% vs. 79.4%,  $p = 0.76$ ). Both groups demonstrated significant improvement in ICIQ-SF, UDI-6, and Incontinence Quality of Life Questionnaire (I-QOL) scores compared with baseline (all  $p < 0.05$ ), with slightly greater improvement observed in the MUS group; between-group differences were not statistically significant. Subgroup analysis by stress urinary incontinence (SUI) severity revealed consistently high dryness rates across mild, moderate, and severe categories, without significant intergroup differences.

**Conclusions:** Intraurethral CLHA/Dx injection achieved clinical outcomes comparable to MUS, offering a less invasive alternative for SUI treatment.

**Key Words:** stress urinary incontinence, midurethral sling, hyaluronic acid, dextranomer, minimally invasive therapy

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## Introduction

Stress urinary incontinence (SUI) is the most prevalent subtype of urinary incontinence in women, accounting for nearly one-third of cases and representing a significant global health problem. Beyond its physical implications, SUI can markedly impair

quality of life, leading to social restrictions, hygiene concerns, and psychological distress.<sup>1,2</sup> The condition is primarily attributed to insufficient support of the bladder neck and urethra during episodes of increased intra-abdominal pressure, often in combination with intrinsic sphincter deficiency (ISD).<sup>3,4</sup> Given this underlying pathophysiology, various surgical approaches have been developed to restore urethral support, among which midurethral sling (MUS) surgery has become the gold standard.

MUS surgery is widely regarded as the gold-standard treatment for female SUI, achieving high short- and medium-term cure rates. However, the use of synthetic mesh is associated with well-documented, albeit relatively infrequent, complications such as mesh exposure, infection, and chronic pelvic pain.<sup>5,6</sup> These risks have heightened interest in less invasive alternatives, particularly among patients who wish to avoid surgery or have contraindications to general anesthesia. In this context, periurethral bulking agents have re-emerged as a therapeutic alternative, with cross-linked hyaluronic acid/dextranomer (CLHA/Dx) injections representing a contemporary approach. Several previous studies have evaluated the efficacy and safety of hyaluronic acid gel matrix, providing a historical context for its use as a minimally invasive treatment option for stress urinary incontinence.<sup>7</sup> Among the currently available bulking agents, CLHA/Dx has attracted particular attention due to its favorable biophysical properties and long-term biocompatibility.

CLHA/Dx consists of dextranomer microspheres (80–250  $\mu\text{m}$ ) suspended within a cross-linked hyaluronic acid gel matrix. The dextranomer component provides a stable scaffold that promotes fibroblast infiltration and collagen deposition, while the hyaluronic acid serves as a biocompatible carrier that facilitates smooth injection and tissue integration.<sup>8</sup> By creating submucosal bulking at the mid-urethral level, the agent enhances urethral coaptation and outlet resistance, thereby reducing urine leakage during increases in intra-abdominal pressure. Compared with earlier bulking materials—such as non-cross-linked hyaluronic acid and polydimethylsiloxane—CLHA/Dx demonstrates improved tissue integration, lower migration potential, and fewer inflammatory reactions, contributing to a more stable and longer-lasting bulking effect. DEXSUI<sup>®</sup> is CE-marked and approved for clinical use in the treatment of SUI.

In clinical practice, this technique aims to increase urethral closure resistance by injecting the agent around the urethra, thereby reducing urine leakage

during episodes of stress. The procedure is minimally invasive, performed under local anesthesia without hospitalization, and offers a shorter recovery period—features that make it particularly appealing to patients contraindicated for surgery or those preferring non-surgical solutions.<sup>7,8,9</sup> Clinical guidelines recognize the utility of bulking agents in selected patients who are not ideal candidates for operative interventions.<sup>10</sup> Understanding the underlying mechanism of bulking therapy is essential to optimize patient selection and treatment outcomes.

The therapeutic rationale for urethral bulking in the treatment of SUI is to enhance urethral coaptation and increase outlet resistance, particularly in patients with ISD.<sup>11</sup> Bulking agents create localized submucosal volume, strengthening mucosal apposition and helping to maintain urethral closure during episodes of increased intra-abdominal pressure.<sup>11</sup> In contrast, MUS procedures primarily target urethral hypermobility by providing mechanical support to the mid-urethra, thereby restoring its anatomical position and function. These two treatment modalities act through different yet complementary mechanisms: bulking therapy compensates for sphincteric insufficiency, while sling surgery corrects structural mobility.<sup>11</sup>

However, it should be acknowledged that the early improvements observed following bulking injections may, in part, result from transient tissue edema or inflammatory reactions induced by the procedure rather than the durable mechanical effect of the material itself.<sup>12</sup> These transient effects may contribute to the short-term efficacy observed in early follow-up but may diminish over time as edema subsides.<sup>12</sup> Therefore, the long-term durability of continence outcomes after bulking therapy remains an important concern, and repeat injections are often required to maintain clinical effectiveness.<sup>13</sup> Given these limitations, ongoing research continues to focus on the development of next-generation bulking agents with improved biostability, longer duration of action, and more durable clinical outcomes.

DEXSUI<sup>®</sup>, as a urethral bulking agent, is positioned in the treatment algorithm for female SUI according to both guidelines as an option for patients who are not ideal candidates for surgical interventions, such as those with significant comorbidities, contraindications to anesthesia, or a preference to avoid surgery. While MUS remains the gold-standard treatment due to higher long-term efficacy, urethral bulking offers a minimally invasive alternative with favorable perioperative safety and short-term symptom improvement.<sup>14</sup> The therapeutic mechanism of CLHA/Dx involves submucosal urethral bulking to

enhance coaptation and outlet resistance, thereby reducing urine leakage. Although long-term durability may be lower compared to MUS and repeat injections may be necessary, urethral bulking is recommended for selected patient subgroups where surgical risk is elevated, or patient preference dictates a less invasive approach.

Nevertheless, long-term success rates for bulking agents are generally lower than those for MUS, and repeated treatments may be necessary to maintain symptom improvement.<sup>15,16</sup> Despite these limitations, some patients prioritize the lower procedural risk and faster recovery of bulking therapy over the higher—but more invasive—success rates of surgery. High-quality comparative studies evaluating both objective and patient-reported outcomes between MUS and CLHA/Dx injections remain scarce. In light of the increasing demand for minimally invasive treatments, this study compares the short-term efficacy, safety, and patient satisfaction of MUS and CLHA/Dx in women with SUI. The purpose of this study was to directly compare the short-term efficacy, safety, and patient-reported outcomes of MUS and intraurethral bulking therapy in women with SUI. We hypothesized that intraurethral CLHA/Dx injection would achieve short-term results comparable to MUS, with a potentially more favorable perioperative safety profile.

## Methods

### *Study design and setting*

This retrospective cohort study was carried out in the Department of Obstetrics and Gynecology, İzmir Bakırçay University, Çiğli Training and Research Hospital, between 01 January 2024 and 01 June 2025. Ethical approval was obtained from the Izmir Bakircay University Ethics Committee (approval No. 2437/2425). Women diagnosed with SUI and treated with either an MUS procedure or intraurethral CLHA/Dx (DEXSUI®, Ekspo-Farma, Istanbul, Turkey) injection were included. Patients who underwent intraurethral injection were matched with those undergoing MUS in terms of age and body mass index (BMI).

### *Inclusion and exclusion criteria*

Eligible participants were women with SUI due to urethral hypermobility, confirmed by a positive Marshall–Marchetti test, urinary leakage during the Valsalva maneuver, and post-void residual urine volume  $\leq 100$  mL. Patients with ISD, prior anti-incontinence surgery, or those receiving repeat

bulking injections were excluded. Additional exclusion criteria comprised transient urinary incontinence, active urinary tract infection, urge incontinence, nocturnal enuresis, impaired bladder compliance or detrusor overactivity on urodynamic evaluation, BMI  $> 35$  kg/m<sup>2</sup>, current use of medications affecting bladder function, and severe psychiatric disorders such as major depression or anxiety.

### *Treatment selection and shared decision-making*

Prior to the initiation of any intervention, all patients received comprehensive, structured counseling regarding the available treatment options—specifically, MUS surgery and intraurethral CLHA/Dx injection. The treating physician systematically explained the anticipated benefits, expected success rates, potential risks, likelihood of complications, degree of invasiveness, expected recovery timelines, and the possibility of requiring additional procedures, particularly in the case of bulking agent therapy. The transobturator tape (TOT) procedure, performed using the outside-in technique, was offered to patients as the mid-urethral sling (MUS) option during treatment counseling.

Patients were encouraged to actively engage in the decision-making process, taking into account their clinical profiles, treatment expectations, and lifestyle considerations. The final treatment decision was made collaboratively, ensuring consistency with both clinical indications and patient-centered values. This shared decision-making model aimed to optimize treatment satisfaction while preserving patient autonomy throughout the therapeutic selection process.

All patients underwent a single treatment procedure, either MUS or CLHA/Dx injection. Repeat injections were not permitted during the study period, ensuring that all outcomes reflected the effect of a single intervention.

### *Data collection*

Demographic and clinical data were extracted from electronic medical records. Collected parameters included BMI, parity, menopausal status, comorbid conditions (diabetes mellitus, hypertension, chronic obstructive pulmonary disease), alcohol and tobacco use, and educational status. Obstetric and gynecological history covered the number and mode of deliveries and previous pelvic surgeries.

Incontinence-specific parameters comprised the duration of incontinence, daily leakage frequency, number of pads used per day, results of the Valsalva stress test, and the degree of pelvic organ prolapse when present.

Procedural data included the type of intervention (MUS or CLHA/Dx), concurrent surgical interventions, operation time, hospital stay (recorded as zero for CLHA/Dx cases), perioperative complications, postoperative urinary retention or dysuria, and postoperative residual urine volume.

Postvoid residual urine volume (RUV) was measured at the first postoperative follow-up (day 1 for MUS, same day for CLHA/Dx). After complete voluntary voiding, RUV was assessed within 5 min using a portable bladder ultrasound scanner in the supine position. If the reading exceeded 100 mL or was inconclusive, sterile single-use urethral catheterization was performed for exact measurement.

### *Patient-reported outcome measures*

Patient-reported outcomes were assessed using validated, disease-specific questionnaires evaluating urinary incontinence symptom severity, distress, and health-related quality of life. The following instruments were used: International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), Urogenital Distress Inventory-6 (UDI-6), Incontinence Quality of Life Questionnaire (I-QOL), and Patient Global Impression of Improvement (PGI-I). All PROMs were administered at baseline and 1-month postoperatively. Questionnaires were self-completed by patients, and all assessments were conducted by trained, blinded study personnel.

**ICIQ-SF:** A brief, structured questionnaire designed to quantify the frequency, severity, and impact of urinary incontinence on daily activities. The total score ranges from 0 to 21, with higher scores indicating greater symptom severity. For this study, severity categories were defined as follows: Mild SUI: ICIQ-SF score 1–7; Moderate SUI: ICIQ-SF score 8–13; Severe SUI: ICIQ-SF score  $\geq 14$ . Patients completed the ICIQ-SF during the preoperative evaluation, and categorization was performed prior to any intervention. This classification was used for subgroup analyses of treatment outcomes.

**UDI-6:** This six-item questionnaire assesses the level of distress caused by lower urinary tract symptoms, particularly those associated with incontinence. Responses are scored on a 4-point Likert scale, providing a total score between 0 and 100, where higher scores reflect greater distress.

**I-QOL:** A comprehensive 22-item tool specifically developed to measure the impact of urinary incontinence on quality of life across emotional, social, and physical domains. Scores range from 0 to 100, with higher scores representing a better quality of life.

**PGI-I:** A single-item global assessment tool used to capture the patient's subjective perception of

improvement following treatment. The PGI-I is a 7-point Likert scale ranging from 1 ("very much better") to 7 ("very much worse").

All instruments were administered at baseline and at the 1-month postoperative follow-up to evaluate changes in symptom severity, distress levels, and quality of life outcomes. These measures allowed for a multidimensional assessment of treatment efficacy from the patient's perspective. Internal consistency reliability was assessed for all patient-reported outcome measures. In our study population, Cronbach's alpha coefficients were 0.88 for the ICIQ-SF, 0.86 for the UDI-6, and 0.93 for the I-QOL, indicating high internal consistency for all instruments.

The primary outcome of this study was the change in the ICIQ-SF score from baseline to the 1-month postoperative follow-up, representing the objective measure of continence improvement. Secondary outcomes included changes in UDI-6 and I-QOL scores, PGI-I responses, perioperative complications, postoperative urinary retention or dysuria, need for re-treatment, and operative metrics such as operation time and hospital stay.

### *Statistical analysis*

Prior to data collection, a priori sample size estimation was conducted using G\*Power software (version 3.1.9.7). Assuming a medium effect size (Cohen's  $d = 0.5$ ), a power of 80%, and a type I error rate ( $\alpha$ ) of 0.05 for detecting differences in primary outcome measures (quality of life scores), the minimum required sample size was calculated as 27 participants per group. To account for potential attrition or incomplete data, a final target of 34 patients per group was established to ensure adequate statistical power for between-group comparisons. Handling of missing data and loss to follow-up: Missing data were managed using a complete-case analysis approach. Patients lost to follow-up were excluded from the final analysis, and no imputation methods were applied. The attrition rate was minimal ( $<5\%$ ). Analysis population: All analyses were performed on a per-protocol basis, including only participants who completed the study as planned.

All statistical analyses were performed using IBM SPSS Statistics version 24.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as means  $\pm$  standard deviations or medians with interquartile ranges, depending on data distribution assessed by the Shapiro-Wilk test. Categorical variables were presented as frequencies and percentages. Between-group comparisons were conducted using the independent samples *t*-test or Mann-Whitney U test, as appropriate. Paired samples *t*-test or Wilcoxon

signed-rank test assessed within-group changes. One-way ANOVA or Kruskal-Wallis test was used for comparisons among multiple groups. Correlations were analyzed using Pearson or Spearman coefficients. Categorical variables were compared with the Chi-squared or Fisher’s exact test. A  $p$ -value  $< 0.05$  was considered statistically significant.

## Results

A total of 68 women with SUI were included in the analysis, with 34 patients in each treatment group (MUS vs. CLHA/Dx). Baseline demographic and clinical characteristics were comparable between the two groups (Table 1). In addition to age, BMI, parity, menopausal status, and baseline SUI severity, we explicitly report symptom duration, daily leakage episodes, daily pad use, and presence of pelvic organ prolapse  $\geq$  stage 2. All parameters were comparable between the two treatment groups (all  $p > 0.05$ ), confirming balanced baseline characteristics. The median symptom duration was over seven years in both groups (MUS:  $7.6 \pm 3.1$  years vs. CLHA/Dx:  $7.3 \pm 3.0$  years,  $p = 0.68$ ).

### Perioperative and postoperative outcomes

Perioperative parameters are summarized in Table 2. The operative time was significantly longer in the MUS group compared with CLHA/Dx ( $30.5 \pm 7.8$  vs.

$11.4 \pm 4.3$  min,  $p < 0.001$ ). Similarly, hospital stay was longer after MUS [median (IQR): 1 (1–2) days] compared with CLHA/Dx [0 (0) days  $p < 0.001$ ]. The rates of perioperative complications, postoperative urinary retention, and postoperative dysuria did not differ significantly between groups (all  $p > 0.05$ ). Perioperative complications were limited to intraoperative bleeding, all of which were successfully controlled during the procedure. No patients developed *de novo* urge incontinence, and in cases of transient urinary retention, normal voiding function was restored after 24 h of catheterization. Mean postoperative residual urine volume was slightly higher in the MUS group, but the difference was not statistically significant ( $35.2 \pm 12.4$  vs.  $30.5 \pm 11.8$  mL,  $p = 0.37$ ). At 1-month follow-up, complete dryness rates were high and comparable between groups (MUS: 82.4% vs. CLHA/Dx: 79.4%,  $p = 0.76$ ).

### Patient-reported outcomes

Patient-reported outcome measures are presented in Table 3. At baseline, ICIQ-SF, UDI-6, and I-QOL scores were similar between groups ( $p > 0.05$ ). At 1 month, both treatments resulted in significant improvements from baseline in symptom severity and quality of life. In the MUS group, mean ICIQ-SF score decreased from  $16.8 \pm 2.1$  to  $5.3 \pm 2.2$  ( $p = 0.002$ ), and UDI-6 score decreased from  $72.5 \pm 8.4$  to  $21.8 \pm 9.2$  ( $p = 0.007$ ). Corresponding improvements were also observed in the CLHA/Dx group,

TABLE 1. Baseline demographic and clinical characteristics of patients undergoing midurethral sling (MUS) or intraurethral CLHA/Dx injection

Variable	MUS (n = 34)	CLHA/Dx (n = 34)	$p$ value
Age (years), mean $\pm$ SD	$54.3 \pm 8.2$	$56.7 \pm 8.5$	0.21
BMI (kg/m <sup>2</sup> ), mean $\pm$ SD	$26.1 \pm 3.2$	$27.4 \pm 3.5$	0.11
Parity, median (IQR)	3 (2–4)	3 (2–4)	0.91
Postmenopausal, n (%)	20 (58.8%)	19 (55.9%)	0.81
Diabetes mellitus, n (%)	6 (17.6%)	7 (20.6%)	0.76
Hypertension, n (%)	10 (29.4%)	9 (26.5%)	0.79
COPD, n (%)	2 (5.9%)	1 (2.9%)	0.55
Alcohol use, n (%)	2 (5.9%)	1 (2.9%)	0.55
Smoking, n (%)	8 (23.5%)	7 (20.6%)	0.77
Education $\geq$ high school, n (%)	7 (20.6%)	6 (17.6%)	0.76
Symptom duration, years, mean $\pm$ SD	$7.6 \pm 3.1$	$7.3 \pm 3.0$	0.68
Daily leakage episodes, mean $\pm$ SD	$3.8 \pm 1.4$	$3.7 \pm 1.3$	0.76
Daily pad use, mean $\pm$ SD	$2.7 \pm 1.0$	$2.6 \pm 1.1$	0.69
Pelvic organ prolapse $\geq$ stage 2, n (%)	5 (14.7%)	6 (17.6%)	0.74

Abbreviations: MUS, Midurethral Sling; CLHA/Dx, Cross-Linked Hyaluronic Acid/Dextranomer; COPD, Chronic Obstructive Pulmonary Disease; BMI, Body Mass Index.

TABLE 2. Perioperative and postoperative outcomes

Outcome	MUS (n = 34)	CLHA/Dx (n = 34)	p value
Operative time, min, mean $\pm$ SD	30.5 $\pm$ 7.8	11.4 $\pm$ 4.3	<b>&lt;0.001</b>
Hospital stay, days, median (IQR)	1 (1–2)	0 (0–0)	<b>&lt;0.001</b>
Perioperative complications, n (%)	3 (8.8%)	1 (2.9%)	0.30
Postoperative urinary retention, n (%)	2 (5.9%)	1 (2.9%)	0.55
Postoperative dysuria, n (%)	4 (11.8%)	3 (8.8%)	0.69
Postoperative residual urine volume, mL, mean $\pm$ SD	35.2 $\pm$ 12.4	30.5 $\pm$ 11.8	0.37
Complete dryness at 1 month, n (%)	28 (82.4%)	27 (79.4%)	0.76

Note. Bold *p*-values indicate the statistical significance. Abbreviations: IQR, Interquartile Range; SD, Standard Deviation; MUS, Midurethral Slings; CLHA/Dx, Cross-Linked Hyaluronic Acid/Dextranomer.

TABLE 3. Patient-reported outcome measures (baseline and 1-month follow-up)

Variable	Time point	MUS (n = 34)	CLHA/Dx (n = 34)	p-value (between groups)	p-value (within group)
ICIQ-SF (0–21, higher = worse)	Baseline	16.8 $\pm$ 2.1	16.5 $\pm$ 2.0	0.54	—
	1 month	5.3 $\pm$ 2.2	6.0 $\pm$ 2.5	0.12	0.002/0.005
UDI-6 (0–100, higher = worse)	Baseline	72.5 $\pm$ 8.4	71.8 $\pm$ 8.1	0.67	—
	1 month	21.8 $\pm$ 9.2	25.4 $\pm$ 10.1	0.09	0.007/0.014
I-QOL (0–100, higher = better)	Baseline	38.7 $\pm$ 10.2	39.1 $\pm$ 10.5	0.82	—
	1 month	83.9 $\pm$ 8.7	80.1 $\pm$ 9.4	0.08	0.001/0.009
PGI-I (1–7, lower = better)	1 month	1.7 $\pm$ 0.5	1.9 $\pm$ 0.6	0.10	—

Note. ICIQ-SF, International Consultation on Incontinence Questionnaire–Short Form (0–21, higher scores indicate worse symptoms); UDI-6, Urogenital Distress Inventory–Short Form (0–100, higher scores indicate greater distress); I-QOL, Incontinence Impact Questionnaire–Short Form/Incontinence Quality of Life Scale (0–100, higher scores indicate better quality of life); PGI-I, Patient Global Impression of Improvement (1–7, lower scores indicate greater improvement); Between-group comparisons indicate differences between the MUS and CLHA/Dx groups, while within-group comparisons represent changes from baseline to the 1-month follow-up within each respective group. Abbreviations: MUS, Mid-Urethral Slings; CLHA/Dx, Cross-Linked Hyaluronic Acid/Dextranomer injection.

although post-treatment scores remained slightly less favorable compared to MUS (ICIQ-SF: 16.5  $\pm$  2.0 to 6.0  $\pm$  2.5,  $p = 0.005$ ; UDI-6: 71.8  $\pm$  8.1 to 25.4  $\pm$  10.1,  $p = 0.014$ ). I-QOL scores increased markedly in both groups, from 38.7  $\pm$  10.2 to 83.9  $\pm$  8.7 in MUS ( $p = 0.001$ ) and from 39.1  $\pm$  10.5 to 80.1  $\pm$  9.4 in CLHA/Dx ( $p = 0.009$ ). At 1 month, the median PGI-I score indicated high patient satisfaction in both groups, with slightly more favorable scores in the MUS arm (1.7  $\pm$  0.5 vs. 1.9  $\pm$  0.6,  $p = 0.10$ ).

#### Subgroup analysis by SUI severity

Subgroup analysis by preoperative ICIQ-SF severity classification showed comparable complete dryness rates across treatment groups (Table 4). In mild SUI, dryness was achieved in 90.9% of MUS and 90.0% of CLHA/Dx patients ( $p = 0.94$ ). Moderate SUI

patients had identical dryness rates of 80.0% in both groups ( $p > 0.99$ ). In severe SUI, MUS patients had slightly higher dryness rates compared with CLHA/Dx (75.0% vs. 66.7%), though the difference was not statistically significant ( $p = 0.69$ ).

## DISCUSSION

This study compared short-term outcomes of MUS and urethral bulking with CLHA/Dx in women with SUI. Our principal finding is that both MUS and CLHA/Dx achieved high and comparable subjective success at one month, with MUS showing a trend toward slightly superior symptom improvement, while CLHA/Dx offered a markedly more favorable perioperative profile, including shorter

TABLE 4. Subgroup analysis according to SUI severity

Severity	MUS–Complete dryness at 1 month, n/N (%)	CLHA/Dx–Complete dryness at 1 month, n/N (%)	p value
Mild SUI	10/11 (90.9%)	9/10 (90.0%)	0.94
Moderate SUI	12/15 (80.0%)	12/15 (80.0%)	
Severe SUI	6/8 (75.0%)	6/9 (66.7%)	0.69

Note. Severity classification was based on preoperative ICIQ-SF scores: mild (1–7), moderate (8–13), severe (≥14). Abbreviations: SUI, Stress Urinary Incontinence; MUS, Mid-Urethral Sling; CLHA/Dx, Cross-Linked Hyaluronic Acid/Dextranomer injection.

operative time and same-day discharge. No early adverse events were observed in either group, and patient-reported outcomes (ICIQ-SF, UDI-6, I-QOL, PGI-I) improved substantially in both arms.

Stress urinary incontinence remains a highly prevalent condition that significantly impairs women’s quality of life. Over recent decades, the surgical treatment landscape has continued to evolve, aiming to optimize the balance between efficacy and invasiveness. The mid-urethral sling procedure has undeniably established itself as the gold standard surgical intervention, supported by robust long-term efficacy data. However, its inherent invasiveness and associated perioperative morbidity have continuously driven the search for effective, minimally invasive alternatives.

Among these, urethral bulking agents such as cross-linked hyaluronic acid/dextranomer (CLHA/Dx) have emerged as a compelling, office-based option—particularly appealing for patients seeking a less invasive approach or those presenting with elevated surgical risks. This retrospective comparative study contributes to the ongoing discourse by presenting short-term outcomes of two conceptually distinct treatment modalities—the established gold-standard MUS and the minimally invasive challenger, CLHA/Dx—in a homogeneous cohort of women with SUI.

Our key finding was that both techniques achieved high and comparable subjective success rates at one month. However, they represent a classic clinical trade-off: MUS demonstrated a trend toward superior symptom improvement, whereas CLHA/Dx provided a markedly more favorable perioperative profile with minimal recovery time.

When short- and mid-term outcomes are examined, the randomized non-inferiority trial by Itkonen et al. conducted in Helsinki compared Tension-Free Vaginal Tape (TVT) with polyacrylamide hydrogel injection (PAHG). At one year, both patient satisfaction and objective cure rates favored TVT, although

complications were more common in the TVT arm.<sup>17</sup> The three-year follow-up of the same cohort confirmed that superiority persisted in favor of TVT.<sup>18</sup> In our cohort, similar dryness rates at one month for both arms suggest that the early “symptom-silencing” effect of bulking can be strong. However, with extended follow-up, the divergence observed in prior studies may re-emerge in favor of MUS.<sup>17,18</sup>

In a two-year, patient-preference-based Finnish cohort (n = 391), Särkilahti et al. reported retreatment rates of 0.9% for TVT and 27.0% for PAHG. While overall complication rates were comparable, the severity of complications was higher in the TVT group.<sup>19</sup> These findings align with our observation that short-term equivalence and procedural advantages with CLHA/Dx may shift toward sling durability in the long term.

Campanella et al. followed 159 women for 29 months in a prospective study comparing PAHG with a single-incision sling. Both groups demonstrated significant improvements in ICIQ-UI-SF and PGI-I scores; however, groin pain and *de novo* urgency were more frequent in the sling arm, while no pain was reported in the bulking group.<sup>20</sup> In our series, the short operative time (~11 min) and same-day discharge are fully consistent with the minimal invasiveness and early recovery profile of CLHA/Dx.

In the large seven-year series by Brosche et al., the “cure/improvement” rate in primary cases was 67.1%, 19.5% of patients required a subsequent incontinence procedure, and ICIQ-UI-SF improved by –8.6 points.<sup>21</sup> Similarly, in Lose’s multicenter 12-month study, a 35% re-injection rate was reported alongside substantial gains in symptom severity and quality of life;<sup>22</sup> Toozs-Hobson’s two-year extension confirmed maintenance of mid-term durability.<sup>23</sup> Together, these data indicate that our one-month equivalence results should not be directly extrapolated to the long term and underscore the importance of discussing the potential need for re-injection during patient counseling.<sup>21–23</sup>

Within the dextranomer/hyaluronic acid family, multicenter randomized trials using Zuidex™ failed to demonstrate equivalence to collagen (Contigen®), and adverse events such as pseudo-abscess formation and urethral obstruction were reported.<sup>24,25</sup> These findings highlight that differences in formulation (CLHA/Dx vs. NASHA/Dx), particle size, cross-linking, and injection technique can result in distinct efficacy and safety profiles. In our series, no serious early adverse events occurred with CLHA/Dx; nonetheless, ongoing education and vigilance for rare late complications remain essential.<sup>24,25</sup>

A hyaluronic acid–dextranomer (HA/Dx)–based product was previously used for the treatment of SUI; however, it was withdrawn from the market due to insufficient long-term efficacy and safety concerns. In contrast, the CLHA/Dx used in our study is structurally distinct from this earlier formulation and was designed as a more stable and effective biomaterial. In CLHA/Dx, hyaluronic acid chains are stabilized through chemical cross-linking, forming a three-dimensional network via covalent bonds. This structure enhances the material's biomechanical strength, tissue stability, and durability of volumetric effect, thereby ensuring a longer-lasting therapeutic response. Furthermore, this cross-linked configuration promotes a more homogeneous distribution of dextranomer microspheres within the HA matrix, potentially reducing particle migration, localized inflammatory reactions, and sterile abscess formation. Owing to these properties, CLHA/Dx demonstrates a theoretically superior safety and efficacy profile compared with previous HA/Dx-based formulations.<sup>26</sup> Due to its slower biodegradation rate and prolonged volumetric effect, CLHA/Dx represents a next-generation bulking agent that may reduce the need for repeated injections in the management of SUI.

In our study, among patients with mild to moderate SUI, one-month complete dryness rates were nearly identical between both modalities. In contrast, among women with severe SUI, a clinical—though not statistically significant—trend favored MUS. The Cochrane review has similarly concluded that while injection therapy can improve SUI, surgery remains more effective in most scenarios, with substantial heterogeneity among bulking agents.<sup>27</sup> For slings, a large randomized controlled trial demonstrated that single-incision mini-slings are non-inferior to standard MUS surgery in patient-reported success at 15 months and up to 3 years.<sup>28</sup> Collectively, these data reinforce that MUS offers greater predictability for women with severe SUI or those seeking a durable single-session cure, whereas bulking represents a

rational alternative for women who wish to avoid surgery, have medical comorbidities, or present with mild to moderate symptoms.<sup>27,28</sup>

A more in-depth analysis elucidates the biological and mechanical underpinnings of the performance differences between mid-urethral slings (MUS) and urethral bulking agents. Bulking agents are primarily designed to augment the submucosal urethral space, thereby enhancing urethral coaptation and increasing outlet resistance.<sup>29</sup> Injection of the material elicits a localized inflammatory and fibroblastic tissue response, characterized by fibroblast activation, neo-collagen deposition, and capsule formation around the injected particles.<sup>30</sup> This controlled inflammatory reaction confers procedural stabilization of the implant; however, over time, macrophage-mediated resorption, tissue remodeling, and potential material degradation may lead to volume loss.<sup>31</sup> This mechanism provides a biological rationale for the comparatively limited durability of bulking agents relative to MUS.<sup>28</sup> Additionally, physicochemical properties—including particle size, degree of cross-linking, biological inertness, and tissue migration potential—critically influence long-term efficacy.<sup>32</sup>

In contrast, MUS exerts its therapeutic effect predominantly via mechanical support and urethral suspension.<sup>33</sup> Polypropylene mesh integrates with surrounding connective tissue, forming a durable fibrotic scaffold. This mechanism relies on tension redistribution rather than volumetric augmentation. The resulting tissue integration and long-term fibrotic response account for the superior long-term efficacy observed with MUS.<sup>34</sup> However, this permanent incorporation is also associated with increased risk of complications, such as pain, erosion, mesh exposure, and voiding dysfunction.<sup>35</sup>

Therefore, the “inflammation–fibrosis hypothesis” offers a biological explanation for the differential durability profiles observed between these treatment modalities. While bulking agents achieve stabilization through a transient and limited inflammatory response, MUS provides mechanical reinforcement via a sustained fibrotic reaction.<sup>36</sup> Clinically, this distinction underpins the higher long-term continence rates observed with MUS, whereas bulking agents, although minimally invasive and generally safe, are associated with a higher likelihood of repeat interventions.<sup>37,38</sup>

In light of these mechanistic insights and the existing literature, patient selection and counseling are of critical importance. For women with mild to moderate SUI, those who prefer to avoid surgery or mesh, or those with significant comorbidities, urethral bulking agents such as CLHA/Dx may represent a reasonable

and more comfortable option. However, it should be clearly communicated that the long-term durability of these agents may be lower than that of MUS, and the likelihood of requiring repeat injections may be higher.<sup>39</sup> Conversely, for women with severe SUI, those seeking a single-session, durable treatment, or those unwilling to accept the burden of repeat procedures, MUS remains the most predictable option, as recommended in current guidelines.<sup>40,41</sup> Although our study demonstrated nearly equivalent subjective success rates at one month, the short follow-up period limits the ability to draw conclusions regarding long-term durability.

In our cohort, we observed marked decreases in ICIQ-SF and UDI-6 scores, substantial improvements in I-QOL, and high patient satisfaction on PGI-I. Randomized and prospective studies similarly demonstrate significant improvements in both quality of life and symptom severity following sling and bulking procedures.<sup>16,19,21,22</sup> Therefore, in the early postoperative period, both interventions can be considered to exceed the threshold of clinical meaningfulness regarding quality-of-life improvement.<sup>42-44</sup>

The 2023 SUFU and 2024 EAU guidelines continue to recommend MUS as the first-line surgical treatment owing to its high and durable efficacy, while endorsing urethral bulking agents as a minimally invasive, outpatient, and repeatable option—particularly suitable for patients who decline mesh or carry surgical/anesthetic risk—within a shared decision-making framework.<sup>45,46</sup> Furthermore, the 17-year TVT follow-up reinforces the long-term durability of sling procedures.<sup>47</sup> Our findings are in full agreement with these guideline recommendations.<sup>41-46</sup>

### *Strengths, limitations, and future directions*

We acknowledge that our study has inherent limitations, including its retrospective design, single-center setting, limited sample size, short one-month follow-up, and potential selection bias. While our findings provide important short-term insights, they do not establish medium- or long-term equivalence to MUS.

Future prospective studies with follow-up periods of 6–12 months or longer, incorporating comprehensive quality-of-life assessments and cost-effectiveness analyses, are warranted. Treatment decisions should be individualized, taking into account SUI severity, patient comorbidities, expectations, and willingness to undergo surgery. Although our results support urethral bulking agents such as CLHA/Dx as a reasonable option for selected patients, the potential limitations in long-term durability and the need for

repeat injections should be clearly communicated to patients.

## Conclusions

In this study, both MUS and urethral bulking with CLHA/Dx demonstrated comparable short-term subjective success at one month, with MUS showing a trend toward slightly greater symptom improvement. However, bulking agents offered a favorable perioperative profile, including shorter operative time and same-day discharge. These findings suggest that urethral bulking may be a reasonable, minimally invasive option for selected patients—particularly those with mild to moderate SUI, significant comorbidities, or a preference to avoid surgery. Nonetheless, clinicians should be cautious in extrapolating these results to the long term, as bulking agents are likely associated with higher rates of repeat procedures compared to MUS. Therefore, while these data support the use of CLHA/Dx in carefully selected patients, MUS remains the preferred option for those seeking durable, long-term continence.

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None.

## Author Contributions

Mehmet Adıyeke: Literature Review, Data Collection, Writing—Review & Editing. Suna Yıldırım Karaca: Conceptualization, Methodology, Supervision, Writing—Original Draft. S. Anıl Arı: Data Curation, Formal Analysis, Visualization, Writing—Review & Editing. Rüyam Ercenk: Resources, Project Administration, Visualization. Mücahit Furkan Balcı: Investigation, Software, Validation. İbrahim Karaca: Methodology, Supervision, Funding Acquisition, Final Approval of the Manuscript. All authors reviewed and approved the final version of the manuscript.

## Availability of Data and Materials

The authors declare that data supporting the findings of this study are available within the article. The data sets used or analyzed during this study are available from the corresponding author on reasonable request.

## Ethics Approval

This study was approved by the Izmir Bakircay University Ethics Committee (approval No. 2437/2425).

## Informed Consent

The requirement for informed consent was waived due to the use of anonymized retrospective data. This study utilized de-identified patient data. The ethics committee waived the requirement for informed consent due to the retrospective and anonymized nature of the research.

## Conflicts of Interest

The authors declare that they have no conflicts of interest in connection with this article.

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