

Prosthetic Material Exposure After Remeex System Implantation for Female Stress Urinary Incontinence: A Retrospective Cohort Study

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Research Article

Keywords: Stress urinary incontinence, Reemex system, midurethral sling, mesh exposure, prosthetic material, female urology

Posted Date: October 15th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11133229/v1>

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Additional Declarations: No competing interests reported.

Abstract

Background

The Remeex system is a readjustable midurethral sling used for the management of complex or recurrent female stress urinary incontinence (SUI), particularly in patients with intrinsic sphincter deficiency. Although favorable functional outcomes have been reported, evidence regarding prosthetic material exposure and its associated factors remains limited. This study aimed to evaluate the frequency and factors associated with prosthetic material exposure after Remeex system implantation.

Methods

This retrospective cohort study included 76 women who underwent Remeex System implantation for SUI at a tertiary referral center in Mexico between 2018 and 2023. Clinical characteristics, previous surgical history, and preoperative factors were compared between patients with and without prosthetic material exposure. Quantitative variables were compared using the Mann-Whitney U test and categorical variables using Fisher's exact test. Associations were expressed as odds ratios (Ors) with 95% confidence intervals (Cis). A p-value < 0.05 was considered statistically significant.

Results

Prosthetic material exposure occurred in 17 of 76 patients (22.4%). Among patients with exposure, 10/17 (58.8%) developed exposure within the first 12 months. Vaginal hysterectomy was associated with prosthetic material exposure (OR 7.92, 95% CI 1.46–46.21; p = 0.04), as was a contaminated preoperative urine culture (OR 13.62, 95% CI 1.81–178.7; p = 0.02). Other evaluated clinical characteristics were not significantly associated with exposure. Conservative management was the most frequently used treatment among patients with exposure.

Conclusions

Prosthetic material exposure occurred in approximately one-fifth of women undergoing Remeex system implantation in this cohort. Vaginal hysterectomy and a contaminated preoperative urine culture were associated with exposure, although the wide confidence intervals indicate uncertainty regarding the magnitude of these associations. These findings support further investigation of factors associated with prosthetic material exposure in larger cohorts.

Background

Stress urinary incontinence (SUI) is a common condition in women and can substantially affect quality of life and daily functioning [1, 2]. Midurethral slings are widely used for the surgical management of SUI;

however, treatment of recurrent SUI and cases associated with intrinsic sphincter deficiency remains challenging [2]. In these settings, readjustable sling systems have been developed to allow postoperative modification of suburethral tension and potentially improve incontinence while reducing the risk of excessive or insufficient tension [3, 4].

The Remeex system is a readjustable midurethral sling that allows modification of sling tension after implantation. It has been used particularly in women with recurrent or complex SUI, intrinsic sphincter deficiency, and voiding dysfunction [3–5]. Previous studies have reported favorable continence outcomes and the possibility of postoperative readjustment across different patient populations including voiding dysfunction and obesity [5–8]. Nevertheless, complications such as voiding dysfunction, urinary tract infection, wound complications, and prosthetic material exposure have also been described [3, 5–8].

Prosthetic material exposure is particularly relevant because it may cause vaginal symptoms, infection, discomfort, or the need for additional treatment, including partial excision or removal of the implanted material [9]. Reported exposure or erosion rates after Remeex implantation have varied across published series, and evidence regarding factors associated with this complication remains limited [3, 9–11]. Differences in patient characteristics, previous pelvic surgery, local tissue conditions, and postoperative follow-up may contribute to variability in reported rates.

Evidence regarding Remeex-related complications in Latin American populations, particularly in Mexico, remains scarce [12–15]. Identifying clinical and preoperative characteristics associated with prosthetic material exposure may help characterize patients who develop this complication and inform postoperative surveillance. Therefore, the aim of this study was to evaluate the frequency of prosthetic material exposure and the clinical, surgical, and preoperative factors associated with its occurrence in women undergoing Remeex system implantation for SUI at a tertiary referral center in Mexico.

Methods

Study design and setting

This retrospective cohort study included women who underwent Remeex system implantation for stress urinary incontinence between 2018 and 2023 at the Gynecological Urology Service of Centro Médico Nacional 20 de Noviembre, a tertiary referral center in Mexico City, Mexico. Patients were identified from the institutional database and were followed through review of their medical records to assess the occurrence of prosthetic material exposure and associated clinical, surgical, and preoperative factors.

Participants and eligibility criteria

Women aged 35–85 years who underwent Remeex system implantation for stress urinary incontinence between 2018 and 2023 were eligible for inclusion. Indications for Remeex implantation included

recurrent stress urinary incontinence and stress urinary incontinence associated with intrinsic sphincter deficiency. Patients were required to have at least 12 months of postoperative follow-up.

Patients with incomplete medical records that prevented assessment of the primary outcome or relevant study variables and those with less than 12 months of postoperative follow-up were excluded. All eligible patients identified during the study period were included in the analysis. No formal sample size calculation was performed because all eligible patients treated during the study period were included.

Outcome definition and study variables

The primary outcome was prosthetic material exposure after Remeex system implantation. Prosthetic material exposure was defined as visualization of any portion of the Remeex prosthetic material through the vaginal epithelium during pelvic examination. The diagnosis was identified from postoperative follow-up records, and the time from Remeex implantation to the diagnosis of exposure was recorded.

Clinical variables included age, age at menopause, type 2 diabetes mellitus, arterial hypertension, hypothyroidism, radiculopathy, voiding dysfunction, smoking, constipation, and recurrent urinary tract infection. Previous surgical procedures included vaginal hysterectomy, abdominal hysterectomy, anterior colporrhaphy, previous anti-incontinence sling procedures, and Burch colposuspension. Preoperative variables included urine culture results, vaginal culture results, and vaginal atrophy. Vaginal atrophy severity was categorized as mild, moderate, severe or absent.

Data Collection

Clinical data were retrospectively obtained from the patient's medical records using a standardized data collection form. Information collected included demographic and clinical characteristics, comorbidities, previous pelvic and anti-incontinence surgical procedures, preoperative urine and vaginal culture results, vaginal atrophy, SUI severity, and postoperative follow-up findings.

During postoperative follow-up, medical records were reviewed for the occurrence of prosthetic material exposure, time from Remeex implantation to exposure, and subsequent management. Patients were classified into two groups according to the presence or absence of prosthetic material exposure.

Statistical analysis

Continuous variables were summarized using means and standard deviations or medians and interquartile ranges, as appropriate. Categorical variables were presented as frequencies and percentages. Comparisons between patients with and without prosthetic material exposure were performed using the Mann-Whitney U test for continuous variables and Fisher's exact test for categorical variables. The association between vaginal atrophy severity and prosthetic material exposure was evaluated using the Fisher-Freeman-Halton exact test for the 4 x 2 contingency table.

Associations between categorical clinical, surgical, and preoperative variables and prosthetic material exposure were expressed as odds ratios (Ors) with 95% confidence intervals (CIs). Given the limited number of exposure events, analyses were considered exploratory and no multivariable logistic regression model was performed. All tests were two-sided, and a p value < 0.05 was considered statistically significant. Statistical analyses were performed using GraphPad Prism, version 9 (GraphPad Software, San Diego, CA, USA).

Ethical considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Institutional Research and Ethics Committees of Centro Médico Nacional 20 de Noviembre. Patient information was handled confidentially, and data was analyzed in anonymized form.

Results

Study population and prosthetic material exposure

A total of 76 who underwent Remeex system implantation between 2018 and 2023 were included in the analysis. The mean age was 61.7 ± 10.8 years, and the mean age at menopause was 47 ± 5.2 years. The most frequent comorbidities were hypertension (33/76, 43.4%) and type 2 diabetes mellitus (28/76, 36.8%), followed by voiding dysfunction (7/76, 9.2%), hypothyroidism (5/76, 6.6%), and radiculopathy (4/76, 5.3%) (Table 1).

Table 1
Demographic and clinical characteristics of the study population

Characteristic	Value (n = 76)
Age (years), mean $\pm$ SD	61.7 $\pm$ 10.8
Age at menopause (years), mean $\pm$ SD	47.0 $\pm$ 5.2
Comorbidities, n (%)	
Type 2 diabetes mellitus	28 (36.8)
Arterial hypertension	33 (43.4)
Hypothyroidism	5 (6.6)
Radiculopathy	4 (5.3)
Voiding dysfunction	7 (9.2)
Data are presented as mean $\pm$ standard deviation (SD) or n (%), as appropriate.	

Prosthetic material exposure occurred in 17 of 76 patients (22.4%) during postoperative follow-up.

Time to prosthetic material exposure

Among the 17 patients who developed prosthetic material exposure, 5 (29.4%) presented exposure within the first 6 months after Remeex implantation and 5 (29.4%) between 6 and < 12 months. Two patients (11.8%) were diagnosed at 12 months, 4 (23.5%) between > 12 and < 24 months, and 1 (5.9%) at 24 months (Table 2).

Table 2
Time to prosthetic material exposure after Remeex system implantation

Time to exposure	n (%)
< 6 months	5 (29.4)
6 to < 12 months	5 (29.4)
12 months	2 (11.8)
> 12 to < 24 months	4 (23.5)
24 months	1 (5.9)
Total	17 (100)
Percentages were calculated among the 17 patients who developed prosthetic material exposure.	

Clinical characteristics associated with prosthetic material exposure

No statistically significant associations were observed between prosthetic material exposure and the clinical characteristics evaluated (Table 3). Type 2 diabetes mellitus showed an OR of 2.00 (95% CI 0.67–5.64, $p = 0.25$), while hypertension showed an OR of 1.40 (95% CI 0.47–4.02; $p = 0.58$). Smoking was associated with an OR of 2.57 (95% CI 0.76–8.69; $p = 0.15$), although the confidence interval was wide and the association did not reach statistical significance. Constipation and recurrent urinary tract infection were also not significantly associated with prosthetic material exposure ($p > 0.05$).

Table 3
Clinical characteristics associated with prosthetic material exposure

Clinical characteristic	OR (95% CI)	p-value
Type 2 diabetes mellitus	2.00 (0.67–5.64)	0.25
Arterial hypertension	1.40 (0.47–4.02)	0.58
Hypothyroidism	0*	0.58
Smoking	2.57 (0.76–8.69)	0.15
Constipation	1.36 (0.44–4.69)	0.75
Recurrent urinary tract infection	0.92 (0.18–4.87)	> 0.999
OR, odds ratio; CI, confidence interval. Associations were evaluated using Fisher's exact test. *The OR for hypothyroidism could not be reliably estimated because no exposure events occurred in one of the comparison cells.		

Previous surgical history

Among previous surgical procedures, vaginal hysterectomy was significantly associated with prosthetic material exposure (OR 7.92, 95% CI 1.46–46.21; $p = 0.04$) (Table 4). No statistically significant associations were observed for abdominal hysterectomy, anterior colporrhaphy, previous anti-incontinence sling procedure, or Burch colposuspension (all $p > 0.05$).

Table 4
Previous surgical history and prosthetic material exposure

Previous surgical procedure	OR (95% CI)	p-value
Vaginal hysterectomy	7.92 (1.46–46.21)	0.04
Abdominal hysterectomy	2.25 (0.73–6.31)	0.16
Anterior colporrhaphy	1.92 (0.60–5.93)	0.31
Previous anti-incontinence sling	2.76 (0.77–9.61)	0.21
Burch colposuspension	4.07 (0.85–18.49)	0.11
OR, odds ratio; CI, confidence interval. Associations were evaluated using Fisher's exact test. A p -value < 0.05 was considered statistically significant.		

Preoperative factors

Among the preoperative factors evaluated, contaminated urine culture was significantly associated with prosthetic material exposure (OR 13.62, 95% CI 1.81–178.70; $p = 0.02$) (Table 5). No statistically significant associations were observed for vaginal culture results or vaginal atrophy ($p > 0.05$).

Table 5
Preoperative factors associated with prosthetic material exposure

Preoperative factor	OR (95% CI)	p-value
Contaminated urine culture	13.62 (1.81–178.70)	0.02
Vaginal culture	2.71 (0.44–14.10)	0.28
Vaginal atrophy	0.55 (0.11–2.56)	0.71
OR, odds ratio; CI, confidence interval. Associations were evaluated using Fisher's exact test. A p-value < 0.05 was considered statistically significant.		

Vaginal atrophy severity

No statistically significant association was observed between vaginal atrophy severity and prosthetic material exposure ($p > 0.81$). Exposure occurred in 2 of 14 patients (14.3%) with mild atrophy, 12 of 44 (27.4%) with moderate atrophy, 2 of 12 (16.7%) with severe atrophy, and 1 of 6 (16.7%) without vaginal atrophy (Table 6).

Table 6
Vaginal atrophy severity according to prosthetic material exposure

vaginal atrophy severity according to prosthetic material exposure					
Vaginal atrophy	Exposure, n	No exposure, n	Total, n	Exposure, %	p-value
Mild	2	12	14	14.3	0.81
Moderate	12	32	44	27.3	
Severe	2	10	12	16.7	
No atrophy	1	5	6	16.7	
Total	17	59	76	22.4	
Data are presented as n (%). Percentages were calculated within each vaginal atrophy category. The p-value corresponds to the overall comparison using Fisher's exact test (Fisher-Freeman-Halton extension).					

Management of prosthetic material exposure

Of the 17 patients who underwent prosthetic material exposure, conservative management was used in 11 (64.7%), surgical flap repair in 3 (17.6%), and 3 (17.6%) required Remeex system removal.

Discussion

This retrospective cohort study evaluated prosthetic material exposure after Remeex system implantation and explored clinical, surgical, and preoperative factors associated with its occurrence. Prosthetic material exposure was identified in 17 of 76 patients (22.4%). Previous vaginal hysterectomy and contaminated preoperative urine culture were significantly associated with exposure, whereas the other clinical and surgical characteristics evaluated showed no statistical significance associations.

These findings provide additional evidence regarding a relatively understudied complication of the Remeex system, particularly in women with complex or recurrent SUI.

The 22.4% frequency of prosthetic material exposure observed in our cohort was higher than that reported in most previous Remeex series. Errando-Smet et al., in a long-term study of 205 patients, reported urethral or vaginal erosion and infection requiring prosthesis removal in approximately 3.4% of patients, whereas Park et al. reported wound infection in 5.9% of 102 women treated with the Remeex system, with prosthesis removal required in only two cases [3, 10]. Although these findings suggest a lower frequency of device-related complications than that observed in our cohort, direct comparisons should be interpreted cautiously because definitions of exposure, erosion, and infection, as well as follow-up duration and patient characteristics, differ across studies. This variability is also evident in the broader synthetic midurethral sling literature, in which reported rates of vaginal mesh exposure or erosion vary considerably depending on the type of sling, definition of the complication, and duration of follow-up [9].

Previous vaginal hysterectomy was significantly associated with prosthetic material exposure in our cohort. This finding is consistent with evidence from the broader sling literature suggesting that previous hysterectomy may be associated with subsequent mesh-related complications. In a large population-based cohort, Chughtai et al. reported that a history of hysterectomy was associated with an increased hazard of sling erosion (HR 1.62, 95% CI 1.36–1.92) [16]. Previous pelvic surgery may alter vaginal tissue integrity, vascularization, and local anatomy, potentially affecting tissue healing and incorporation of prosthetic material. However, the magnitude of the association observed in our study (OR 7.92, 95% CI 1.46–46.21) should be interpreted cautiously because of the small number of exposure events and the wide confidence interval.

A contaminated preoperative urine culture was also significantly associated with prosthetic material exposure. Although contamination does not indicate urinary tract infection or bacteriuria, this finding may identify a subgroup requiring closer preoperative assessment. The association observed in our cohort was substantial (OR 13.62, 95% CI 1.81–178.70), but the markedly wide confidence interval indicates considerable uncertainty in the effect estimate. Therefore, this finding should be considered exploratory and requires confirmation in larger studies.

Vaginal atrophy severity was not significantly associated with prosthetic material exposure in our cohort. Although the highest proportion of exposure was observed among women with moderate vaginal atrophy (27.3%), compared with mild (14.3%), severe (16.7%), or no atrophy (16.7%), the overall comparison was not statistically significant ($p = 0.81$). Given the small number of patients within some atrophy categories, these findings should be interpreted cautiously and do not exclude a potential relationship between local tissue characteristics and prosthetic material exposure.

Several factors previously associated with mesh-related complications, including diabetes and smoking, were not significantly associated with prosthetic material exposure in our cohort [9]. Smoking showed an OR of (2.57 95% CI 0.76–8.69), while type 2 diabetes mellitus showed an OR of 2.00 (95% CI 0.67–5.64);

however, neither association reached statistical significance. The absence of statistically significant associations should not be interpreted as evidence of no effect, particularly given the limited sample size and the small number of exposure events. Larger studies are needed to determine whether these and other patient-related factors contribute to prosthetic material exposure after Remeex implantation.

Most cases of prosthetic material exposure were managed conservatively, while a smaller proportion required surgical intervention, including flap repair or removal of the Remeex system. Conservative and surgical approaches have both been described for vaginal mesh exposure, with treatment depending on factors such as the extent of exposure, symptoms, and response to initial management [9]. Accordingly, prosthetic material exposure does not invariably require complete device removal, and management should be individualized according to the clinical presentation.

This study provides additional evidence on prosthetic material exposure after Remeex system implantation, a complication for which data remain limited, particularly in Latin American populations. However, several limitations should be acknowledged. The retrospective, single-center design may limit the generalizability of the findings and relies on the completeness of medical records. In addition, the relatively small sample size and the limited number of exposure events resulted in wide confidence intervals and restricted the ability to perform adjusted multivariable analyses. Therefore, the associations identified, particularly those involving previous vaginal hysterectomy and contaminated preoperative urine culture, should be considered exploratory. Finally, differences in follow-up duration may have influenced the detection of late exposure events. Larger prospective studies with standardized definitions and longer follow-up are needed to confirm these findings.

Conclusions

Prosthetic material exposure was observed in 22.4% of women undergoing Remeex system implantation in this cohort. Previous vaginal hysterectomy and a contaminated preoperative urine culture were significantly associated with prosthetic material exposure, although the magnitude of these associations should be interpreted cautiously given the limited number of events and wide confidence intervals. Most exposure cases were managed conservatively. These findings provide additional information on factors associated with prosthetic material exposure after Remeex implantation and support the need for larger prospective studies to confirm these associations.

Abbreviations

- **Remeex** : External mechanical regulator
- **SUI** : Stress urinary incontinence
- **DIE** : *Intrinsic sphincter deficiency*
- **DM2** : Type 2 Diabetes Mellitus
- **95% CI** : 95% confidence interval.

- **ICS** : *International Continence Society* .
- **IUU** : Urge urinary incontinence.
- **UTI** : Urinary tract infection.
- **SLE** : Systemic lupus erythematosus.
- **mL** : Milliliters.
- **mL /s** : Milliliters per second.
- **OR** : *Odds Ratio* .
- **POP** : Pelvic organ prolapse.
- **MUS** Mid-urethral SLings
- **BMI** Body Mass Index

Declarations

Ethics approval and consent to participate.

This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the institutional Research and Ethics Committees of Centro Médico Nacional 20 de Noviembre. Given the retrospective nature of the study and the use of existing medical records, the requirement for informed consent was waived by the institutional Ethics Committee. Patient confidentiality was maintained throughout the study, and all data were analyzed anonymously.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Author's contributions

GGR and VABV contributed to the conception and design of the study, data collection, and manuscript drafting. AGG and RHV contributed to the study methodology and interpretation of the results. MMRC contributed to data collection and clinical data interpretation. RGG contributed to the statistical analysis, interpretation of the results, and critical revision of the manuscript. HETR contributed to data interpretation and critical revision of the manuscript. OTC supervised the study, contributed to its conception and design, and critically revised the manuscript. All authors read and approved of the final manuscript.

Acknowledgements

Not applicable.

Clinical Trial Number

Not applicable.

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