Appendix 1. Native Tissue Repair Patients from the AUGS PFD Registry, by Study

Study	Patients
Boston Scientific, Xenform 522 study (A Prospective, Non-Randomized, Parallel Cohort, Multi-Center Study of Xenform vs. Native Tissue for the Treatment of Women with Anterior/Apical Pelvic Organ Prolapse)	146
Acell, MatriStem 522 study (Evaluation of the Use of Transvaginal Resorbable Biologic Mesh as Compared to Traditional Non-Mesh Surgical Repair for Treating Pelvic Floor Disorder)	69
Coloplast, Restorelle 522 study (Restorelle® Transvaginal Mesh Versus Native Tissue Repair for Treatment of Pelvic Organ Prolapse)	206

Kahn B, Varner RE, Murphy M, Sand P, Thomas S, Lipetskaia L, et al. Transvaginal mesh compared with native tissue repair for pelvic organ prolapse. Obstet Gynecol 2022;139.
The authors provided this information as a supplement to their article.

Appendix 2. Data Collection at Study Time Points

	Time Point								
Measure	Baseline	Procedure	Discharge	2 months	6 months	12 months	18 months	24 months	36 months
POP-Q measurement*	•			•	•	•	•	•	•
PFIQ-7	•				•	•	•	•	•
PISQ-12	•				•	•	•	•	•
PFDI-20	•			•	•	•	•	•	•
TOMUS pain scale	•			•	•	•	•	•	•
Analgesic use	•			•	•	•	•	•	•
EQ-5D	•					•		•	•
Cystoscopy		•							
Estimated blood loss		•							
Anesthesia type		•							
Procedure duration		•							
Adverse events		•	•	•	•	•	•	•	•

Kahn B, Varner RE, Murphy M, Sand P, Thomas S, Lipetskaia L, et al. Transvaginal mesh compared with native tissue repair for pelvic organ prolapse. Obstet Gynecol 2022;139.
The authors provided this information as a supplement to their article.

Infection			•	•	•	•	•	•	•
Voiding status			•						
Pelvic exam with vaginal length measurement	•			•	•	•	•	•	•
Assessment of risk factors	•			•	•	•	•	•	•
PGI-I for Prolapse					•	•	•	•	•
SSQ-8					•	•		•	•

Abbreviations: EQ-5D, EuroQol; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; PFDI-20, Pelvic Floor Distress Inventory; PFIQ-7, Pelvic Floor Impact Questionnaire; PGI-I for Prolapse, Patient Global Impression of Improvement for Prolapse; POP-Q, Pelvic organ prolapse quantification system; SSQ-8, Surgery Satisfaction Questionnaire; TOMUS, Trial of Mid-Urethral Slings

* Post-procedure POP-Q assessments were completed by the primary surgeon and were not blinded.

Appendix 3. Safety Summary of Device-Related, Procedure-Related, or Device and Procedure-Related Serious Adverse Events in Participants in the Intent-to-Treat Group

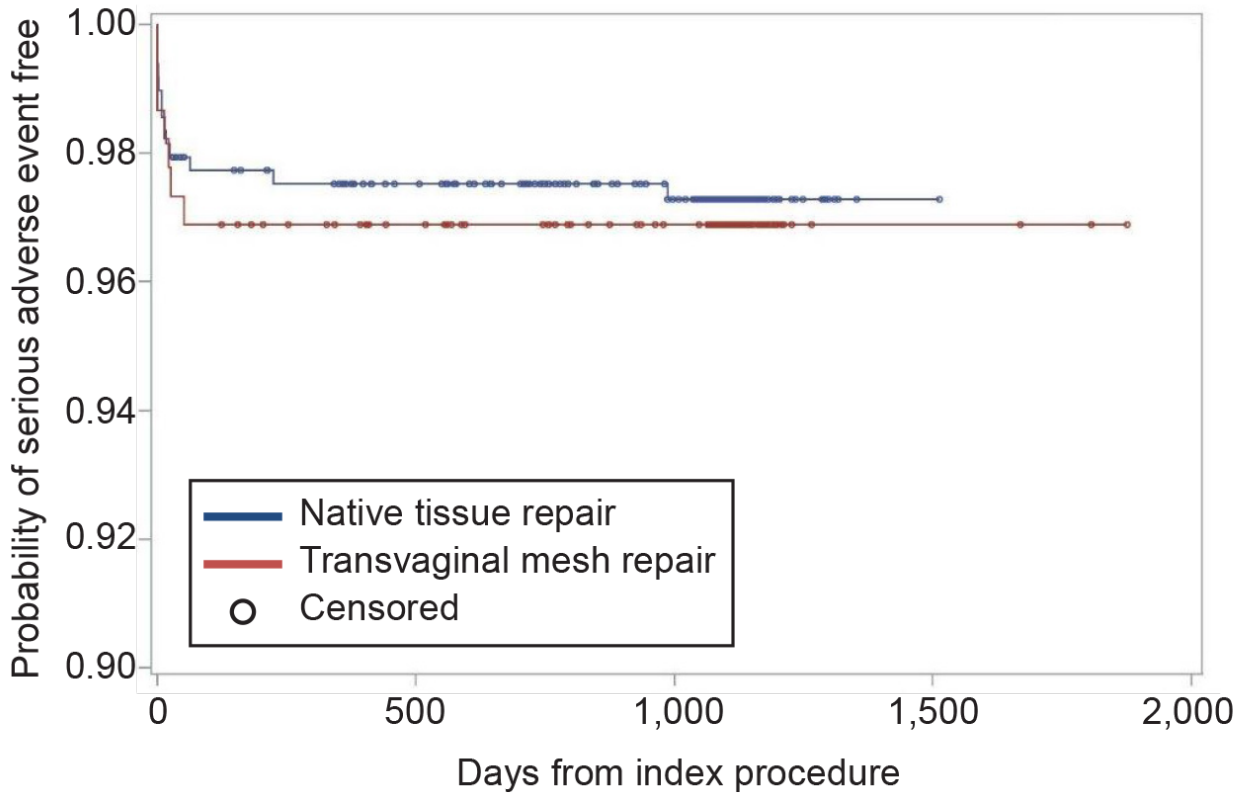
	TVM Intent-to-Treat Subjects (N=225)				NTR Intent-to-Treat Subjects (N=485)	
	Events	Proportion of Subjects with ≥ 1 Event	Proportion of Subjects with ≥ 1 Device-Related Event	Proportion of Subjects with ≥ 1 Procedure-Related Event	Events	Proportion of Subjects with ≥ 1 Event*
Infection - Other, specify type	1	0.4% (1/225)	0.4% (1/225)	0.4% (1/225)	3	0.6% (3/485)
Ureteral Kink / Injury	1	0.4% (1/225)	0.4% (1/225)	0.4% (1/225)	2	0.4% (2/485)
Ileus / Bowel Obstruction	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	2	0.4% (2/485)
Pelvic Infection / Abscess	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	2	0.4% (2/485)
Urinary Tract Infection (UTI), Lower	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	2	0.4% (2/485)
Bleeding	1	0.4% (1/225)	0.0% (0/225)	0.4% (1/225)	0	0.0% (0/485)
Bleeding Requiring Blood Transfusion	1	0.4% (1/225)	0.0% (0/225)	0.4% (1/225)	0	0.0% (0/485)
Cardiac Event - NEW	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	1	0.2% (1/485)
Constipation - Worsening	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	1	0.2% (1/485)

	TVM Intent-to-Treat Subjects (N=225)				NTR Intent-to-Treat Subjects (N=485)	
	Events	**Proportion of Subjects with ≥ 1 Event**	**Proportion of Subjects with ≥ 1 Device-Related Event**	**Proportion of Subjects with ≥ 1 Procedure-Related Event**	**Events**	**Proportion of Subjects with ≥ 1 Event***
Fever	1	0.4% (1/225)	0.0% (0/225)	0.4% (1/225)	0	0.0% (0/485)
Mesh Exposure in Vagina	1	0.4% (1/225)	0.4% (1/225)	0.4% (1/225)	0	0.0% (0/485)
Mixed Incontinence	1	0.4% (1/225)	0.4% (1/225)	0.4% (1/225)	0	0.0% (0/485)
Other, Specify	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	1	0.2% (1/485)
Pulmonary Event, Specify - Worsening	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	1	0.2% (1/485)
Thrombotic Event	0	0.0% (0/225)	0.0% (0/225)	0.0% (0/225)	1	0.2% (1/485)
Total	7	3.1% (7/225)	1.8% (4/225)	3.1% (7/225)	16	2.7% (13/485)

Numbers are count, % (Count/Sample Size)

*All events in the NTR control arm are procedure-related, device/delivery system relatedness is not applicable to control patients

Appendix 4. Kaplan-Meier curve of serious adverse event free comparing transvaginal mesh and native tissue repair in intent-to-treat participants.



Kahn B, Varner RE, Murphy M, Sand P, Thomas S, Lipetskaia L, et al. Transvaginal mesh compared with native tissue repair for pelvic organ prolapse. Obstet Gynecol 2022;139.
The authors provided this information as a supplement to their article.

Appendix 5. Secondary Safety Endpoint - Device-Related and/or Procedure-Related Adverse Events in Intent-to-Treat Patients at 6, 12, 18, 24 and 36 Months

	TVM	NTR	Group Difference (95% CI)	
			No Propensity Score Adjustment	With Propensity Score Adjustment
De novo Dyspareunia				
Occurred Within 6 Months	0.4% (1/225)	0.8% (4/485)	-0.4% (-1.6%, 0.8%)	-0.5% (-1.2%, 0.3%)
Occurred Within 12 Months	0.4% (1/225)	1.2% (6/485)	-0.8% (-2.1%, 0.5%)	-1.0% (-2.2%, 0.1%)
Occurred Within 18 Months	0.4% (1/225)	1.2% (6/485)	-0.8% (-2.1%, 0.5%)	-1.0% (-2.2%, 0.1%)
Occurred Within 24 Months	0.9% (2/225)	1.2% (6/485)	-0.3% (-1.9%, 1.2%)	-0.8% (-2.1%, 0.4%)
Occurred Within 36 Months	0.9% (2/225)	1.2% (6/485)	-0.3% (-1.9%, 1.2%)	-0.8% (-2.1%, 0.4%)
Pelvic Pain				
Occurred Within 6 Months	2.7% (6/225)	3.5% (17/485)	-0.8% (-3.5%, 1.8%)	-2.0% (-4.0%, 0.1%)
Occurred Within 12 Months	3.6% (8/225)	4.1% (20/485)	-0.6% (-3.6%, 2.4%)	-2.0% (-4.2%, 0.1%)
Occurred Within 18 Months	4.0% (9/225)	4.9% (24/485)	-0.9% (-4.2%, 2.3%)	-2.3% (-4.7%, 0.0%)

Kahn B, Varner RE, Murphy M, Sand P, Thomas S, Lipetskaia L, et al. Transvaginal mesh compared with native tissue repair for pelvic organ prolapse. Obstet Gynecol 2022;139.
The authors provided this information as a supplement to their article.

	TVM	NTR	Group Difference (95% CI)	
			No Propensity Score Adjustment	With Propensity Score Adjustment
Occurred Within 24 Months	4.4% (10/225)	5.4% (26/485)	-0.9% (-4.3%, 2.4%)	-2.0% (-4.8%, 0.8%)
Occurred Within 36 Months	4.9% (11/225)	5.8% (28/485)	-0.9% (-4.4%, 2.6%)	-1.8% (-4.8%, 1.2%)
Infection				
Occurred Within 6 Months	6.2% (14/225)	11.1% (54/485)	-4.9% (-9.1%, -0.7%)	-4.9% (-10.6%, 0.8%)
Occurred Within 12 Months	8.9% (20/225)	12.4% (60/485)	-3.5% (-8.2%, 1.3%)	-3.6% (-9.7%, 2.5%)
Occurred Within 18 Months	9.3% (21/225)	13.2% (64/485)	-3.9% (-8.7%, 1.0%)	-4.2% (-10.3%, 2.0%)
Occurred Within 24 Months	9.3% (21/225)	13.6% (66/485)	-4.3% (-9.1%, 0.6%)	-4.5% (-10.7%, 1.7%)
Occurred Within 36 Months	10.2% (23/225)	14.0% (68/485)	-3.8% (-8.8%, 1.2%)	-4.4% (-10.7%, 1.9%)
Vaginal Shortening				
Occurred Within 6 Months	0.4% (1/225)	0.0% (0/485)	0.4% (-0.4%, 1.3%)	0.4% (-0.4%, 1.1%)
Occurred Within 12 Months	0.4% (1/225)	0.0% (0/485)	0.4% (-0.4%, 1.3%)	0.4% (-0.4%, 1.1%)

	TVM	NTR	Group Difference (95% CI)	
			No Propensity Score Adjustment	With Propensity Score Adjustment
Occurred Within 18 Months	0.4% (1/225)	0.0% (0/485)	0.4% (-0.4%, 1.3%)	0.4% (-0.4%, 1.1%)
Occurred Within 24 Months	0.4% (1/225)	0.0% (0/485)	0.4% (-0.4%, 1.3%)	0.4% (-0.4%, 1.1%)
Occurred Within 36 Months	0.4% (1/225)	0.0% (0/485)	0.4% (-0.4%, 1.3%)	0.4% (-0.4%, 1.1%)
Atypical Vaginal Discharge				
Occurred Within 6 Months	0.9% (2/225)	0.4% (2/485)	0.5% (-0.9%, 1.8%)	0.2% (-0.7%, 1.2%)
Occurred Within 12 Months	0.9% (2/225)	0.6% (3/485)	0.3% (-1.1%, 1.7%)	-0.2% (-1.5%, 1.1%)
Occurred Within 18 Months	0.9% (2/225)	0.6% (3/485)	0.3% (-1.1%, 1.7%)	-0.2% (-1.5%, 1.1%)
Occurred Within 24 Months	0.9% (2/225)	0.6% (3/485)	0.3% (-1.1%, 1.7%)	-0.2% (-1.5%, 1.1%)
Occurred Within 36 Months	0.9% (2/225)	0.6% (3/485)	0.3% (-1.1%, 1.7%)	-0.2% (-1.5%, 1.1%)
Neuromuscular Problems				
Occurred Within 6 Months	4.4% (10/225)	1.6% (8/485)	2.8% (-0.1%, 5.7%)	1.7% (-0.7%, 4.2%)

	TVM	NTR	Group Difference (95% CI)	
			No Propensity Score Adjustment	With Propensity Score Adjustment
Occurred Within 12 Months	4.4% (10/225)	2.1% (10/485)	2.4% (-0.6%, 5.4%)	1.4% (-1.1%, 3.9%)
Occurred Within 18 Months	4.4% (10/225)	2.5% (12/485)	2.0% (-1.1%, 5.0%)	0.8% (-1.8%, 3.5%)
Occurred Within 24 Months	4.4% (10/225)	2.7% (13/485)	1.8% (-1.3%, 4.8%)	0.6% (-2.1%, 3.3%)
Occurred Within 36 Months	4.4% (10/225)	2.9% (14/485)	1.6% (-1.5%, 4.6%)	0.4% (-2.3%, 3.2%)
Vaginal Scarring				
Occurred Within 6 Months	0.0% (0/225)	0.2% (1/485)	-0.2% (-0.6%, 0.2%)	-0.2% (-0.6%, 0.2%)
Occurred Within 12 Months	0.0% (0/225)	0.2% (1/485)	-0.2% (-0.6%, 0.2%)	-0.2% (-0.6%, 0.2%)
Occurred Within 18 Months	0.0% (0/225)	0.2% (1/485)	-0.2% (-0.6%, 0.2%)	-0.2% (-0.6%, 0.2%)
Occurred Within 24 Months	0.0% (0/225)	0.2% (1/485)	-0.2% (-0.6%, 0.2%)	-0.2% (-0.6%, 0.2%)
Occurred Within 36 Months	0.0% (0/225)	0.2% (1/485)	-0.2% (-0.6%, 0.2%)	-0.2% (-0.6%, 0.2%)

	TVM	NTR	Group Difference (95% CI)	
			No Propensity Score Adjustment	With Propensity Score Adjustment
De novo Vaginal Bleeding				
Occurred Within 6 Months	0.0% (0/225)	0.8% (4/485)	-0.8% (-1.6%, -0.0%)	-0.7% (-1.4%, -0.0%)
Occurred Within 12 Months	0.0% (0/225)	1.4% (7/485)	-1.4% (-2.5%, -0.4%)	-1.5% (-2.6%, -0.3%)
Occurred Within 18 Months	0.0% (0/225)	1.4% (7/485)	-1.4% (-2.5%, -0.4%)	-1.5% (-2.6%, -0.3%)
Occurred Within 24 Months	0.0% (0/225)	1.4% (7/485)	-1.4% (-2.5%, -0.4%)	-1.5% (-2.6%, -0.3%)
Occurred Within 36 Months	0.0% (0/225)	1.4% (7/485)	-1.4% (-2.5%, -0.4%)	-1.5% (-2.6%, -0.3%)
De novo Voiding Dysfunction				
Occurred Within 6 Months	5.8% (13/225)	3.3% (16/485)	2.5% (-1.0%, 5.9%)	0.8% (-2.3%, 4.0%)
Occurred Within 12 Months	5.8% (13/225)	3.5% (17/485)	2.3% (-1.2%, 5.7%)	0.6% (-2.6%, 3.8%)
Occurred Within 18 Months	5.8% (13/225)	4.3% (21/485)	1.4% (-2.1%, 5.0%)	-0.0% (-3.3%, 3.2%)
Occurred Within 24 Months	6.7% (15/225)	4.7% (23/485)	1.9% (-1.8%, 5.7%)	1.1% (-2.7%, 4.9%)

	TVM	NTR	Group Difference (95% CI)	
			No Propensity Score Adjustment	With Propensity Score Adjustment
Occurred Within 36 Months	7.6% (17/225)	4.7% (23/485)	2.8% (-1.1%, 6.8%)	2.2% (-1.8%, 6.2%)

Appendix 6. Mesh Exposure in Vagina in Participants in the Intent-to-Treat Transvaginal Mesh Group

Days to Event	Serious	Study Device Related	Study Delivery Device Related	Procedure Related	Vaginal Compartment Related	Pelvic Floor Related	Action Taken/ Additional Treatment	Hospitalized	Outcome
1119	No	Yes	No	No	Anterior	No	None	No	Not recovered/not resolved (continuing)
723	No	Yes	No	Yes	Anterior	Yes	None	No	Resolved/recovered with no sequelae
370	No	Yes	Yes	Yes	Anterior	Yes	None	No	Resolved/recovered with no sequelae
749	No	Yes	Yes	Yes	Anterior	Yes	None	No	Resolved/recovered with no sequelae
1669	No	Yes	Yes	Yes	Anterior	Yes	Medication; Other Action Taken	No	Not recovered/not resolved (continuing)

421	No	Yes	Yes	Yes	Anterior	Yes	Office procedure intervention; Medication	No	Resolved/recovered with no sequelae
169	No	Yes	No	Yes	Anterior	No	Office procedure intervention	No	Resolved/recovered with no sequelae
204	No	Yes	Yes	Yes	Unable to be Determined or Cannot be Specified	Yes	Office procedure intervention	No	Resolved/recovered with no sequelae
103	No	Yes	Yes	Yes	Anterior	No	Office procedure intervention; Outpatient Surgical intervention	No	Resolved/recovered with no sequelae
756	No	Yes	Yes	Yes	Anterior	Yes	Outpatient Surgical intervention; Medication	No	Resolved/recovered with no sequelae
272	No	Yes	No	Yes	Anterior	Yes	Outpatient Surgical intervention	No	Resolved/recovered with no sequelae

523	No	Yes	Yes	Yes	Anterior; Apical	Yes	Outpatient Surgical intervention	No	Resolved/recovered with no sequelae
22	Yes	Yes	Yes	Yes	Anterior	Yes	Outpatient Surgical intervention	No	Resolved/recovered with no sequelae