

Apogee® / Perigee®

CLINICAL STUDY SUMMARY

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T A B L E O F C O N T E N T S

Study Summaries	3
Apogee.....	3
Perigee.....	7
Apogee and Perigee.....	14
Expanded Study Summaries	16
Apogee.....	16
Perigee.....	20
Apogee and Perigee.....	28
Bibliography	34

Transvaginal Graft Repair for Apical Prolapse: Comparison of Uterine versus Vault Suspension.

Harvie H, et al. *J Pelv Med Surg.* 2008; 14(2):126-7. Abstract 58.

Study Type Retrospective

Population 118 patients

Treatment
 Uterine suspension (UTS) 58% (68)
 Vault suspension (VS) 42% (50)

Graft Type	Overall	UTS	VS
Apogee / IntePro (PRO)	53%	63%	42%
Apogee / InteXen LP (XN)	46%	37%	58%

Follow up
 Mean.....22±16 weeks (6-104)

Previous Surgery.....15%

Concomitant Procedures
 Cystocele repair..... 99%
 Enterocele repair.....100%
 Rectocele repair.....100%
 Sling 95%
 Hysterectomy..... 26%
 (VS only)

Concomitant procedures did not vary between groups with the exception of hysterectomy.

Results
 Post-operative mean POP-Q values were improved from baseline and similar between groups.

Complications

Intra-operative
 Enterotomies with dissection.....1.7% (2)

Post-operative
 Dyspareunia
 Pre-operative33%
 Post-operative.....29%
 Resolution.....77%
 de novo.....11%

Graft Exposure
 Overall1.7% (2)
 UTS1.5% (1)
 VS.....2.0% (1)

Healing Abnormalities
 UTS9% (6)
 VS.....18% (9)

Recurrence
 Apical (> Stage II)2.5% (3)
 (UTS only)

Graft Failure
 XN3.7% (2)
 PRO.....1.6% (1)

Conclusion:

Transvaginal graft repair of apical prolapse appears to be safe and effective, utilizing either uterine or vault suspension techniques. Short-term follow-up does not appear to demonstrate advantage by graft type.

A Prospective Multi-Center Clinical Trial Evaluating the Apogee System for the Treatment of Posterior Vaginal Wall and Apical Prolapse.

Lukban J, et al. *Int Urogynecol J.* 2008; 19 (Suppl. I):S93. Abstract 90.

Study Type Prospective, multi-center

Population 200 patients with posterior vaginal prolapse
>Stage II and/or apical descent >Stage II

Treatment

Apogee with InteXen LP (PD)..... 13% (26)
Apogee with IntePro (PP)..... 87% (174)

Follow up

Mean..... 8.6 months (0.4-14.7)

Concomitant Procedures

Hysterectomy..... 24.0% (48)

Results

Objective Posterior Wall Cure	6 mos	12 mos
Overall	92.8%	92.2%
IntePro.....	91.4%	90.6%
InteXen LP.....	100.0%	100.0%

Objective Apical Cure	6 mos	12 mos
Overall	97.0%	93.3%
IntePro.....	96.5%	92.0%
InteXen.....	100.0%	100.0%

Quality of Life	6 mos	12 mos
Mean PFDI Improvement.....	69.4%	69.0%
Mean PFIQ-7 Improvement.....	68.9%	72.0%

Patient Satisfaction	6 mos	12 mos
Extremely satisfied.....	53.8%	50.0%
Very satisfied.....	88.1%	86.2%
Recommend procedure	97.0%	95.7%

Complications

Post-operative

Buttock discomfort.....	0.5% (1)
Dyspareunia.....	1.0% (2)
Extrusion	
IntePro.....	7.0% (14)
InteXen LP.....	0.0% (0)
Requiring revision surgery.....	3.0% (6)
Hematoma.....	0.5% (1)
Infection	0.5% (1)
Perineal discomfort.....	1.0% (2)
Rectal pain.....	0.5% (1)
Vaginal discomfort	0.5% (1)

Conclusion:

The Apogee System appears to be effective in the treatment of patients with posterior vaginal wall and/or apical prolapse, with good anatomic durability through 6 and 12 months. The risks and benefits of employing mesh in the posterior compartment should be thoughtfully considered.

A Prospective Multi-Center Clinical Trial Evaluating the Apogee System for the Treatment of Posterior Vaginal Wall and Apical Prolapse: A Sub-Analysis of Apical Extrusions With or Without Concomitant Hysterectomy.
 Lukban J, et al. *Int Urogynecol J.* 2008; 19 (Suppl. I):S98. Abstract 116.

Study Type Prospective, multi-center

Population 174 patients

Treatment Apogee with IntePro

Follow up
 Mean.....8.4 months (range 0.4-14.7)

Previous Surgery
 Hysterectomy..... 72.6% (93)
 (Apogee Only)

Concomitant Procedures
 Hysterectomy..... 26% (46)

Results

Posterior	Apogee % (n)	Apogee + Hysterectomy % (n)
Baseline ≥ Stage II	98.4% (125/127)	88.6% (39/44)
6 months ≤ Stage I	90.1% (91/101)	95.0% (38/40)
12 months ≤ Stage I	90.4% (47/52)	91.3% (21/23)

Apical	Apogee % (n)	Apogee + Hysterectomy % (n)
Baseline ≥ Stage II	20.5% (26/127)	43.2% (19/44)
6 months ≤ Stage I	96.0% (97/101)	97.5% (39/40)
12 months ≤ Stage I	90.4% (47/52)	95.7% (22/23)

Complications

Post-operative	Apogee %	Apogee + Hysterectomy %
Mesh Exposure	0.8% (NR)	2.2% (NR)
Mesh Extrusion	8.6% (11/128)	6.5% (3/46)
Surgical Management	3.1% (4/128)	4.3% (2/46)

Conclusion:

Incidence of apical extrusion seems to be infrequent in patients receiving Apogee with IntePro with or without hysterectomy at six and twelve months postoperatively.

Apical Prolapse Repair Using the Apogee System.Biller D, et al. *J Minim Invasive Gynecol.* 2007; 14 (Suppl. 6):35.

Study Type	Retrospective
Population	108 patients ≥Stage I apical prolapse
Treatment	Apogee with InteXen LP
Follow up	
Mean	28.9 weeks (6-126)
Previous Surgery	15%
Concomitant Procedures	
Anterior repair	54
Suburethral sling	66
Perigee (anterior prolapse repair)	11

Results

Objective failure rate.....	3.8% (4/104)
Recurrent cystocele.....	14.4% (15/104)
De novo cystocele.....	4.8% (5/104)
Subjective failure rate.....	7.7% (8/104)

Complications**Intra-operative**

Proctotomy (unrelated to trocar insertion)	1
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Post-operative

Dyspareunia	
Pre-operative	12
Post-operative.....	4
de novo	9
No longer sexually active.....	2
Pelvic hematoma (anticoagulated pt).....	1

Conclusion:

The Apogee System with InteXen LP biologic porcine dermis is an effective alternative for surgical treatment of apical prolapse. This cohort demonstrates durability and high objective and subjective cure rates with minimal complications and no graft erosions.

The Outcome of Transobturator Cystocele Repair Using Biocompatible Porcine Dermis Graft Our Experience with 32 Cases.

Mahdy A, et al. *Int Urogynecol J Pelvic Floor Dysfunction*. 2008; 19(12):1647-52.

Study Type	Retrospective
Population	32 patients
Stage II cystocele.....	25% (8)
Stage III cystocele.....	65.6% (21)
Stage IV cystocele	9.4% (3)
Treatment	Perigee with InteXen LP
Follow up	
Median	8.72 months (6-31)
Concomitant Procedures	
Transobturator tape.....	37.5% (12)
Enterocoele repair.....	43.75% (14)
Rectocoele repair.....	18.75% (6)
Perineorrhaphy	9.3% (3)

Results	
Success (Stage 0 or I)	96.1% (25)
Stage 0	54.0% (14)
Stage I.....	42.0% (11)
Stage II.....	3.8% (1)
Complications	
Intra-operative (total)	2.6% (2/32)
Bladder perforation.....	3.0% (1)
Incidental cystotomy	3.0% (1)
Post-operative	
Graft erosion.....	3.8% (1)
Wound dehiscence.....	3.8% (1)

Conclusion:

The short-term results of Perigee with the biocompatible matrix (InteXen) for cystocele repair showed a high success rate with lower graft-related morbidity, especially vaginal wall erosion.

Multi-Center Trial Evaluating the 6 and 12 Month Efficacy and Safety of the Perigee System with IntePro.
 Moore R, et al. *Int Urogynecol J.* 2008; 19 (Suppl. I):S86. Abstract 29.

Study Type	Prospective, multi-center
Population	112 patients
Treatment	Perigee with IntePro
Follow up	
Mean.....	15.25 ±7.7 months
Previous Surgery	
Hysterectomy.....	54.1%
Cystocele repair.....	22.9%
Concomitant Procedures	
Vault suspension.....	62.4%
Incontinence.....	69.7%
Rectocele.....	64.2%

Results			
Objective Success		6 mos	12 mos
(< Stage I, anterior prolapse)	93.8% (91/97)		90.5% (76/85)

Quality of Life	
PFDI.....	Improved
PFIQ-7.....	Improved
PISQ-12.....	Improved

Complications

Intra-operative

Bladder perforation.....	1
Hematoma requiring transfusion.....	1

Post-operative

de novo stress incontinence.....	3.6% (4)
Extrusion	
Overall.....	9.8% (11)
Requiring surgical intervention.....	6.25% (7/11)
Re-operation for failure.....	0.9% (1)

Conclusion:

Repair of cystocele with the Perigee system results in a high anterior prolapse success rate at 6 and 12 months, postoperatively. Intra- and post-operative complications have been minimal with improvement in all QOL measurements. Mid-term cure rates are very encouraging and 24 month follow up is ongoing.

Anterior Repair with Mesh: With or Without Prior Anterior Repair.

Moore R, et al. *J Pelvic Med Surg.* 2008; 14(4):276. Abstract 28.

Study Type Prospective, multi-center

Population 110 patients
 ≥Stage II anterior wall prolapse

Recurrent cystocele (PAR).....25
 No previous anterior repair (NPAR).....85

Treatment Perigee with IntePro

Follow up
 Average16.7± 7.8 months

Previous Surgery
 Prior hysterectomy was significantly greater in NPAR (p=0.0001)

Results

Success at 12 months
 PAR.....95.2%
 NPAR.....88.6%

Complications

Intra-operative (total)

Hematoma (NPAR).....1
 Bladder perforation (NPAR)1

Post-operative

Extrusion
 Overall10.9% (12)
 PAR.....20%
 NPAR8.2%

Conclusion:

Anterior repair of cystocele with mesh graft via transobturator approach seems to be a safe and effective procedure both in patients with primary cystoceles and those with recurrent cystoceles that have had previous attempt at repair. In the current study there was no significant difference in the extrusion rate or the anterior success rate between these groups of patients. Patients with recurrent cystoceles are thought to be at a higher risk of complications and failure, however in the current study with the use of the Perigee procedure this was not found to be the case through medium term follow up.

Anatomy and Visceral Function After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial.
 Nguyen J, et al. *J Pelvic Med Surg.* 2008; 14(4):238. Abstract 42.

Study Type Randomized, controlled

Population 76 patients
 (≥ Stage II anterior vaginal prolapse)

Treatment
 Anterior colporrhaphy (AC).....38
 Perigee with IntePro.....37

Follow up 2 years

Results

	AC	Perigee	P
Recurrent prolapse at 2 years	53% (20/38)	14% (5/38)	p=0.004

Quality of Life

Pre-operative	AC	Perigee
PFDI-20	109±58	108±45
PFIQ-7	82±54	82±54
Post-operative	AC	Perigee
PFDI -20	45±32	34±31
PFIQ-7	23±34	14±23

PISQ-12 were similar at baseline and did not change significantly after surgery

Complications

Post-operative	AC	Perigee
de novo dyspareunia	16% (4/26)	9% (2/22)
Extrusion	N/A	5% (2/37)

Conclusion:

Anterior vaginal prolapse repair with polypropylene mesh reinforcement offers lower anatomic recurrence than anterior colporrhaphy at two years. However, quality of life and sexual symptoms scores improved in both groups.

Outcome After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial.

Nguyen J, et al. *Obstet Gyn.* 2008; 111:891-8.

Study Type Randomized, controlled

Population 76 patients
(≥ Stage II anterior vaginal prolapse)

Treatment
Anterior colporrhaphy (AC).....38
Perigee with IntePro.....37

Follow up 1 year
(interim)

Previous Surgery

	AC	Perigee
Hysterectomy	31% (12)	43% (16)
Incontinence	8% (3)	8% (3)
Prolapse	16% (6)	22% (8)

Concomitant Procedures

Concomitant surgical procedures similar in the two treatment groups.

Results

	AC	Perigee
Optimal and satisfactory anterior vaginal support at 1 year	55% (21/38)	89% (33/37)
Recurrent POP-Q Stage II anterior vaginal prolapse and stress urinary incontinence at 6 months	3% (1)	0% (0)

Quality of Life

Pre-operative	AC	Perigee
PFDI-20	109±58	108±45
PFIQ-7	82±54	77±54
Post-operative	AC	Perigee
PFDI -20	45±32	34±31
PFIQ-7	23±31	14±23

PISQ-12 were similar at baseline and did not change significantly after surgery

Complications

Post-operative	AC	Perigee
Blood transfusion	3% (1)	3% (1)
Fever	8% (3)	5% (2)
de novo dyspareunia at 1 year	16% (4/26)	16% (4/26)
Extrusion	N/A	5% (2)
Transient leg pain	0%	3% (1)
Urinary retention requiring intervention	5% (2)	5% (2)
Urinary tract infection	18% (7)	11% (4)

Conclusion:

Our results demonstrated that although visceral and sexual functions were improved after both anterior colporrhaphy and polypropylene mesh-reinforced repair, the latter was associated with a significantly lower short-term anatomic recurrence rate in both primary and secondary repairs. Because the long-term durability and safety of mesh-reinforced repair is unknown, surgeons may consider using these procedures for recurrent prolapse or primary repairs in cases where there is a high risk of recurrence and after discussion of risks, benefits, and alternatives.

Prospective Study of the Perigee System for the Management of Cystoceles-Medium-term Follow up.
 Rane A, et al. *Aust N Z J Obstet Gynaecol.* 2008; 48:427-32.

Study Type	Prospective
Population	70 patients
Stage III cystocele.....	35
Stage IV cystocele.....	35
Treatment	Perigee
Follow up	18-36 months
Previous Surgery	
Cystocele repair.....	40% (28)
Vaginal hysterectomy.....	18
Total abdominal hysterectomy.....	20
Incontinence correction surgery.....	7
Concomitant Procedures	
Vaginal hysterectomy.....	8.6% (6)
Suburethral sling.....	41.4% (29)
Defect-specific posterior repair.....	27.1% (19)
Posterior mesh repair.....	4.3% (3)
Perineoplasty.....	11.4% (8)
Transvaginal sacrospinous fixation.....	1.4% (1)
Manchester procedure.....	1.4% (1)
Apogee posterior repair.....	17.1% (12)

Results

Satisfaction	
Completely satisfied.....	87.3% (48/55)
Not fully satisfied.....	12.7% (7/55)
Cure (subjective)	
Cured of symptoms.....	90.9% (50/55)
No improvement.....	4/55
Worsening symptoms.....	1/55
Stress Incontinence	
Cured.....	92.7% (51)
Worse.....	7.3% (4)

Complications

Post-operative	
Dyspareunia.....	1.4% (1)
Exposure.....	7.1% (5)
Perineal pain.....	1.4% (1)
Recurrence (Stage II).....	2.8% (2)
Urgency (de novo).....	7.1% (5)
Urinary incontinence.....	4.3% (3)
Vaginal narrowing.....	1.4% (1)

Conclusion:

The Perigee system seems to be an effective, minimally invasive, global operation for anterior wall prolapse with minimum morbidity in the long-term.

Transobturator Cystocele Repair: Short-term Retrospective Comparison of Xenograft Versus Polypropylene.
 Harvie H, et al. *J Pelvic Med Surg.* 2007; 13(5):286. Abstract 58P.

Study Type	Retrospective, comparative
Population	78 patients
Treatment	
Perigee with InteXen (X).....	60% (47)
Perigee with IntePro polypropylene mesh (S).....	40% (31)
Follow up	
Average.....	14.3 weeks (2-44)
Concomitant Procedures	
Hysterectomy.....	26%
Vault suspension.....	83%
Enterocoele repair.....	85%
Rectocoele repair.....	91%
Retropubic sling.....	50%
Transobturator sling.....	46%

Results	
Quality of Life	
Postoperative POP-Q values	No difference
Complications	
Post-operative	(X) (S)
Erosion	
At 6 weeks	0.0% (0) 1.4% (1)
Subsequent follow-up.....	0.0% (0) 3.6% (2)
SUI.....	<3.0% <3.0%
Voiding dysfunction	1.4% (1)

Conclusion:

Transobturator cystocele repair using grafts appears to be safe and effective during short-term follow-up. Results are similar between xenograft and polypropylene graft material.

Prospective, Multi-Center Trial Evaluating the Perigee System with Polypropylene Mesh for Cystocele Repair: Estrogenicity and Outcomes.

Moore R, et al. *J Minimally Invasive Gyn.* 2007; Abstract 204.

Study Type	Prospective
Population	104 patients > Stage II cystocele
High or moderate vaginal estrogenicity.....	80%
Treatment	Perigee with IntePro
Follow up	
Mean.....	35.7 ±18.4 weeks

Results	
Objective cure (anterior POP-Q < Stage I)	
At 6 months.....	90.9%
Quality of Life	
PFDI.....	Improved
PFIQ-7	Improved
PISQ-12	Improved
Complications	
Post-operative	
Extrusion	
Overall	6.7% (7)
Minor revision in the OR.....	4.8% (NR)
Re-operation (pain & urinary retention).....	(1)

Conclusion:

The Perigee System with polypropylene mesh is safe and effective resulting in a low extrusion rate in mostly post-menopausal population with mild atrophy (moderate estrogenicity). There does not seem to be a correlation between vaginal estrogen levels and the incidence of an extrusion.

Retrospective Multicentre Study of the New Minimally Invasive Mesh Repair Devices for Pelvic Organ Prolapse.
 Abdel-fattah M, et al. *BJOG*. 2008; 115:22-30.

Study Type	Retrospective, multi-center
Population	289 patients
Treatment	
Gynecare.....	76% (219)
Prolift anterior.....	76
Prolift posterior.....	70
Prolift combined.....	73
AMS.....	24% (70)
Perigee (anterior).....	30
Apogee (posterior).....	32
Perigee/Apogee.....	8
Follow up	3 months
Previous Surgery (Prolapse/TAH)	
Gynecare	
Prolift anterior.....	59% (45)
Prolift posterior.....	50% (45)
Prolift combined.....	52% (38)
AMS	
Perigee (anterior).....	88% (28)
Apogee (posterior).....	80% (24)
Perigee/Apogee.....	50% (4)

Results

Cure (≤ Stage I POP-Q or Grade 1 Baden and Walker POP.....)	95% (274)
Failed.....	5% (15)

Complications

Intra-operative	Overall	Gynecare	AMS
Bladder injury	1.6% (3/189)	1.6% (3/149)	0.0% (0/40)
Rectal injury	1.1% (2/181)	(3/143)	(1/38)
Bleeding > 400 ml	2.0% (6)	(4/219)	(1/70)

Post-operative	Overall	Gynecare	AMS
Erosion	10.0% (30)	(24/219)	(6/70)
Persistent erosion	1.3% (4)	NR	NR
Mesh removal	0.7% (2)	NR	NR
Dyspareunia	4.5% (13)	(8/219)	(3/70)
Recurrence	(15)	(11/219)	(4/70)
Re-operation	13% (37)	(25/219)	(12/70)

Conclusion:

The new mesh repair devices are associated with excellent short-term cure rates and low morbidity rates considering the surgically high-risk population involved. However, some of these uncommon complications are serious and can be life threatening and need highly specialized management. We, therefore, recommend that these procedures should only be performed by specialists with detailed knowledge and training in the anatomy of the pelvic sidewalls in well-equipped units especially with facilities for interventional radiology. Cystoscopy should be considered in all cases involving anterior mesh repair kits.

Follow-up after Polypropylene Mesh Repair of Anterior and Posterior Compartments in Patients with Recurrent Prolapse.

Gauruder-Burmester, et al. *Int Urogynecol J.* 2007; 18:1059-64.

Study Type	Retrospective
Population	120 patients with recurrent cystocele, and/or rectocele or with combined vaginal vault prolapse.
Treatment	
Apogee	40% (48)
Perigee	60% (72)
Follow up	1 year (±31 days)
Previous Surgery	
Hysterectomy.....	100%

Results	
Free of vaginal prolapse.....	93% (112)
Non-symptomatic Level 2 defect	7% (8)
Quality of Life and Satisfaction Significantly Improved (p=0.023)	
Complications	
Post-operative	
Erosion (anterior)	3% (4)
Healing defect.....	8% (10)
Recurrence (anterior)	7% (8)

Conclusion:

The interposition of a monofilament polypropylene mesh by the vaginal route seems to be an excellent procedure for definitive repair of recurrent anterior/posterior vaginal wall prolapse or combined vaginal vault prolapse. This new procedure is minimally invasive, reproducible, and efficient. It has low morbidity and is well tolerated by the patients.

Retrospective Analysis of Efficacy and Safety of Perigee and Apogee in Patients Undergoing Repair for Pelvic Organ Prolapse.

Davila, G, et al. et al. *J Minimal Invas Gyn.* 2006; 13(Suppl. 5):S27. Abstract 56.

Study Type	Retrospective, multi-center
Population	299 patients
Treatment	
Perigee	122
Apogee	82
Perigee and Apogee	95
Follow up	1-8.7 months

Results	
Perigee	
Grade 0	93.3%
Grade II.....	6.7%
Apogee	
Grade I	
Prior enterocele.....	100.0%
Prior rectocele.....	97.7%
Prior vault prolapse.....	88.0%
Perigee and Apogee	
Grade 0	
Prior cystocele.....	95.7%
Prior enterocele.....	100.0%
Prior rectocele.....	100.0%
Prior vault prolapse.....	95.5%
Complications	
Post-operative	
Exposure (overall).....	9.7% (29/298)
Perigee	4.1% (5/121)
Apogee	12.2% (10/82)
Perigee/Apogee.....	14.7% (14/95)

Conclusion:

POP repair with Perigee and/or Apogee systems with polypropylene or porcine dermis grafts are effective in treating POP with few postoperative complications.

Transvaginal Graft Repair for Apical Prolapse: Comparison of Uterine Versus Vault Suspension

Harvie H, et al. *J Pelv Med Surg.* 2008; 14(2):126-7. Abstract 58.

Objective: To compare outcomes of transvaginal graft repair of apical pelvic organ prolapse (POP) using either uterine (UTS) or vault suspension (VS) techniques.

Methods: Retrospective cohort study evaluating all women who underwent repair of POP using a transvaginal graft procedure with the Apogee system (American Medical Systems) from October 2005 to August 2007 with a minimum of 6 weeks of follow-up. Two graft types were used: polypropylene mesh (PRO) and noncross-linked porcine dermis (XN).

Results: One hundred eighteen women were treated, 68 (58%) with UTS and 50 (42%) with VS. Graft type used was 54 (46%) XN (37% UTS, 58% VS), and 62 (53%) PRO (63% UTS, 42% VS). Mean age was (60 ± 11 yrs), parity (2.6 ± 1.4), and BMI (27 ± 5). Seventy-nine percent were postmenopausal and 15% had prior POP surgery. Preoperative demographics, UDS findings, and symptoms were similar between groups and by graft type, except that the XN group was older (63 ± 11 years, $P = 0.01$). Relevant preoperative mean POP-Q measurements did not differ between groups: Ap (-0.11 ± 1.59, $P = 0.99$), Bp (0.08 ± 2.12, $P = 0.76$), C (-2.13 ± 3.48, $P = 0.29$), and D (-4.04 ± 3.60, $P = 0.62$). Concomitant procedures did not differ except for hysterectomy; they included: cystocele repair (99%), enterocele repair (100%), rectocele repair (100%), sling (95%), and hysterectomy (26% VS only). Intraoperative complications were 2 (1.7%)

enterotomies with dissection, mean EBL was 125 ± 89 cc, and median hospital stay was 2 days. Mean follow-up was 22 ± 16 weeks (6-104). Postop mean POP-Q values were similar between groups: Ap (-2.91 ± 0.36, $P = 0.95$), Bp (-2.91 ± 0.36, $P = 0.95$), and for vault comparison: C (-8.44 ± 0.98, VS) versus D (-8.79 ± 1.33, UTS) ($P = 0.13$). Apical recurrence, defined as > stage 2 prolapse, occurred in 3 (2.5%) overall; all in the UTS group (4.4%) but did not reach statistical significance ($P = 0.14$). Failures by graft type were: 2 (3.7%) XN and 1 (1.6%) PRO ($P = 0.47$). There were 2 (1.7%) graft exposures, 1 (1.5%) UTS and 1 (2.0%) VS ($P = 0.83$); one with each graft material ($P = 0.95$). These were successfully treated with conservative measures. Healing abnormalities consisting of granulation tissue and adhesions occurred in 6 (9%) UTS and 9 (18%) VS ($P = 0.13$), with no difference by graft material ($P = 0.65$). Fifty-seven percent were sexually active preoperatively, with a dyspareunia rate of 33%. At 6 months postoperatively, 51% were sexually active with an overall dyspareunia rate of 29%, a dyspareunia resolution rate of 77%, and a de novo dyspareunia rate of 11% with no differences between groups ($P = 0.91$) or graft type ($P = 0.44$). In the UTS group there was 1 patient who required a subsequent hysterectomy due to abnormal uterine bleeding and another who required a trachelectomy for cervical hypertrophy.

Conclusion: Transvaginal graft repair of apical prolapse appears to be safe and effective, utilizing either uterine or vault suspension techniques. Short-term follow-up does not appear to demonstrate advantage by graft type.

A Prospective Multi-Center Clinical Trial Evaluating the Apogee System for the Treatment of Posterior Vaginal Wall and Apical Prolapse

Lukban T, et al. *Int Urogynecol J*. 2008; 19 (Suppl. I):S93. Abstract 90.

Objective: To evaluate the safety and efficacy of the Apogee® System (AMS Minnetonka, MN) in pelvic organ prolapse.

Methods: In an ongoing, prospective, multi-center study involving 13 US sites, women with posterior vaginal prolapse (>Stage II) and/or apical descent (>Stage II) were enrolled for primary posterior mesh implant.

Each patient underwent placement of polypropylene mesh (Apogee with IntePro) or porcine dermis (Apogee with InteXen® LP) employing a bilateral transgluteal approach. Primary endpoint was the percent of patients with Stage < I ("cure") at follow-up, with clinical evaluations performed by an unblinded practitioner.

Results: Two-hundred women underwent the procedure with a mean follow-up of 8.6 months (range 0.4 - 14.7). Baseline demographics included a mean age of 60.8 years (range 33 - 90), mean BMI of 28.5 (range 18.0 - 53.1), and mean parity of 3.1 (range 0 - 9). The majority were postmenopausal (88.3%). Just less than half (49.2%) were on estrogen replacement therapy for at least 4 weeks prior to surgery. At baseline, 96.4% of patients presented with posterior vaginal prolapse, 52.5% had posterior enterocele, and 25.8% had apical or uterine descent. Hysterectomy was performed at the time of Apogee placement in 48 (24.0%) patients. Additional reconstructive procedures were preformed as indicated with the exception of concomitant repairs in the same vaginal segment. Polypropylene (PP) was used in 174 (87%) patients and 26 (13%) received porcine dermis (PD). Average procedure time for Apogee only was 45.8 + 20.8 minutes. Mean EBL was 69.7 + 63 cc and no patient required transfusion. No intra-operative complications were attributed to the Apogee trocars including trauma to the rectum or the bowel. Six and twelve month follow-up data were available on 169 (84.5%)

and 90 (48.0%) patients, respectively. Objective posterior wall cure rates at 6 and 12 months were 92.8% and 92.2% (91.4% and 90.6% for PP; 100% and 100% for PD), with apical cure rates of 97.0% and 93.3% (96.5% and 92.0% for PP; 100% and 100% for PD). Extrusions (vaginal exposure of mesh) were seen in 14 (7.0%) PP patients, with none reported in those receiving PD. Six (3.0%) patients with extrusion required revision in the operating room while the remaining patients were treated conservatively (local estrogen and/or trimming in the office) or observed. With respect to extrusion sites, mesh exposure occurred along the midline incision in 42.8%, distal vagina in 57.1%, and at the apex in 14.3%. One (0.5%) erosion (mesh into viscus) was reported involving the anterior rectum, 2 cm proximal to the anal verge. The site was managed surgically by trimming a 3–4 mm corner of visible polypropylene mesh and closing the defect in two layers. No anatomic or functional compromise was incurred following correction.

Other device-related complications occurred at or below 1%, with the following complications reported by number of patients: infection of the apical incision in 1 (0.5%), buttock discomfort in 1 (0.5%), perineal discomfort in 2 (1.0%), vaginal discomfort in 1 (0.5%), dyspareunia in 2 (1.0%), hematoma in 1 (0.5%), and rectal pain in 1 (0.5%). QOL questionnaires (PFDI, PFIQ-7) showed improvement, with percent improvements of 69.4% and 69.0% for the mean PFDI summary score; and 68.9% and 72.0% for the mean PFIQ-7 summary score.

Regarding patient satisfaction, 99.4% and 98.9% of patients had an overall feeling of "a lot" (83.4% and 85.1%) or "some" (16.0% and 13.8%) improvement"; 88.1% and 86.2% were "very" (34.3% and 36.2%) or "extremely" (53.8% and 50.0%) satisfied; and 97.0% and 95.7% would recommend the procedure to a friend at 6 and 12-months, respectively.

Conclusion: The Apogee System appears to be effective in the treatment of patients with posterior vaginal wall and/or apical prolapse, with good anatomic durability through 6 and 12 months. The risks and benefits of employing mesh in the posterior compartment should be thoughtfully considered. Follow-up through 24 months is ongoing.

A Prospective Multi-Center Clinical Trial Evaluating the Apogee System for the Treatment of Posterior Vaginal Wall and Apical Prolapse: A Sub-Analysis of Apical Extrusions With or Without Concomitant Hysterectomy

Lukban J., et al. *Int Urogynecol J.* 2008; 19 (Suppl. I):S98. Abstract 116.

Objective: To describe the incidence of apical extrusions (vaginal exposure of mesh) in patients receiving the Apogee® System (AMS, Minnetonka, MN, USA) in pelvic organ prolapse repair with or without concomitant hysterectomy.

Methods: A sub-analysis was performed to evaluate patients who received a concomitant hysterectomy versus those who did not receive hysterectomy at the time of Apogee insertion. Each subject underwent placement of an apical polypropylene strip with a 5x14 cm (approximate) cape of polypropylene mesh (Apogee with IntePro) employing a bilateral transgluteal approach. Patients were seen postoperatively at 6 weeks, 3 months, 6 months and 12 months, and will be followed prospectively through 2 years.

Results: 174 women underwent the procedure with a mean follow-up of 8.4 months (range 0.4–14.7). Forty-six (26%) had concomitant hysterectomy and 128 (74%) had Apogee alone.

Overall rates of extrusion were similar in both groups ($p=0.763$). Vaginal exposure of mesh was seen apically in 0.8% of those receiving Apogee alone and in 2.2% of those receiving a concomitant hysterectomy.

	Apogee without Hysterectomy (n = 128)	Apogee with Hysterectomy (n = 46)
Mean Age (range *)	62.5 (33.0 – 90.0)	54.4 (34.0 – 87.0)
BMI (range)	28.4 (18.0 – 46.9)	29.1 (20.4 – 53.1)
Mean Parity (range)	3.2 (0 - 9)	2.9 (0 - 6)
Menopause, n(%*)	122 (96.9%)	27 (60.0%)
Estrogen Replacement, >4 weeks pre-op, n (%)	67/128 (52.3%)	17/45 (37.8%)
Prior Hysterectomy, n (%)	93 (72.6%)	—
Procedure (min) – Apogee (mean + SD)	46.95±21.62	45.02±19.92
EBL (cc), Apogee (mean + SD)	69.3±63.0	70.4 ±71.9
Posterior Prolapse, % (n)		
Baseline (>/=Stage II)	98.4% (125/127)	88.6% (39/44)
6-mo (</=Stage I)	90.1% (91/101)	95.0% (38/40)
12-mo (</=Stage I)	90.4% (47/52)	91.3% (21/23)
Apical Prolapse, % (n)		
Baseline (>/=Stage II)	20.5% (26/127)	43.2% (19/44)
6-mo (</=Stage I)	96.0% (97/101)	97.5% (39/40)
12-mo (</=Stage I)	90.4% (47/52)	95.7% (22/23)
Extrusion Rate, % (n)	8.6% (11/128)	6.5% (3/46)
Surgical Mgmt.	3.1% (4/128)	4.3% (2/46)
Conservative Mgmt.**	5.5% (7/128)	2.2% (1/46)
Extrusion Location, % (n)		
Midline Incision	4.7% (6/128)	2.2% (1/46)
Apex	0.8% (1/128)	2.2% (1/46)
Distal Vagina	4.7% (6/128)	2.2% (1/46)

*Statistical difference across the treatment groups ($p<0.05$).

**Includes those who received local estrogen and/or trimming in the office or observed.

Conclusion: Incidence of apical extrusion seems to be infrequent in patients receiving Apogee with IntePro with or without hysterectomy at 6 and 12 months postoperatively. Follow-up through 24 months is ongoing.

Apical Prolapse Repair Using the Apogee System

Billir D, et al. *J Minim Invasive Gynecol.* 2007; 14 (Suppl. 6):35.

Objective: To report on the success rate, safety and complications associated with the Apogee system for vaginal apical suspension and posterior wall support.

Methods: One hundred eight (108) patients with Stage 1 or greater prolapse underwent an Apogee procedure with porcine dermis graft. Significant postoperative prolapse was defined as any POP-Q value of -1 or greater. Subjective failure rate was defined as patient's complaint of palpable prolapse, vaginal pressure, or vaginal heaviness.

Results: One hundred four (104) patients are reported on—all using biologic porcine dermis. Three were lost to follow up, and one had incomplete data set. Mean age was 64.9 years (34-84), and median parity was 3 (0-6). Mean follow

up was 28.9 weeks (range 6-126). Concomitant procedures performed included anterior repair (54), suburethral sling (66), Perigee procedure (11). Intraoperative complications included 1 proctotomy unrelated to trocar insertion. Post-operative complications included one pelvic hematoma in an anticoagulated patient. Mean total vaginal length was 8.1 cm (6-11) and mean POP-Q Point C was -6.9 [1-(-11.0)]. Median POP-Q Point Ba was -2.5 [(-3.0) -4]. Objective failure rate was 3.8% (4/104). Recurrent cystocele occurred in 14.4% (15/104), and de novo cystocele in 4.8% (5/104). Subjective failure rate was 7.7% (8/104). Of the 12 patients who reported dyspareunia pre-operatively, 6 resolved, 4 persisted, and 2 were no longer sexually active. De novo dyspareunia occurred only in 9 cases.

Conclusion: The Apogee system with biologic porcine dermis is an effective alternative for surgical treatment of apical prolapse. This cohort demonstrates durability and high objective and subjective cure rates with minimal complications and no graft erosions.

The Outcome of Transobturator Cystocele Repair Using Biocompatible Porcine Dermis Graft Our Experience with 32 Cases

Mahdy A, et al. *Int Urogynecol J Pelvic Floor Dysfunction*. 2008; 19(12):1647-52.

Objective: This study aims to evaluate the outcome of cystocele repair using Perigee® with biocompatible matrix (InteXen®).

Methods: After IRB approval, a retrospective chart review of patients who underwent Perigee®/InteXen® repair was done. Success was defined as a postoperative anatomical stage 0 or I using POP-Q system.

Results: Thirty two patients were included in this study with a mean age of 64 (32–85) years, a mean BMI of 26.4 (18.3–34.8) kg/m², and a mean parity of 2.5. All patients had lateral defect either unilateral or bilateral with or without central defect.

Ten (31.25%) of the 32 patients in this study underwent only Perigee®/InteXen® repair with a mean operative time of 72 (65–80) min; the remaining 22 (68.75%) patients underwent one or more concomitant procedures, including transobturator tape in 12 (37.5%), enterocele repair in 14 (43.75%), rectocele repair in six (18.75%), and perineorrhaphy in three (9.3%).

A total of 26 patients (81.25%) satisfied the inclusion criterion of a minimum of 6 months follow up. Those patients were available for a median follow up period of 8.72 (6–31) months. Twenty five patients (96.1%) had successful repair: 14 (54%) were stage 0 and 11 (42%) were stage I cystocele after surgery (Table 1). There was a tendency towards stage I (versus stage 0) postoperative prolapse with older age and with failed previous repairs. Of the 11 patients with postoperative grade I cystocele, seven (63.6%) had previous failed repairs and nine (81.8%) were 70 years of age or older. None of the patients in this study had vaginal length less than 9 cm after surgery, neither any of them developed postoperative voiding difficulty.

Intraoperative complications in the 32 patients who underwent the procedure included bladder perforation, detected by cystoscopy, in one (3%) and incidental cystotomy during dissection in another (3%).

Mesh-related postoperative complications occurred in two (7.7%) patients; one developed erosion and dyspareunia while the other had wound dehiscence. The patient who developed erosion had recurrent grade III cystocele and grade III enterocele after failed previous surgery. The erosion site was incidentally discovered and related to the upper left (Riv Fix) part of the mesh, which connects the synthetic arms to the biocompatible graft. This patient was successfully treated with trimming of the exposed part and application of silver nitrate. The patient with wound dehiscence was conservatively treated and healed by secondary intention with no further surgical intervention.

Operative Data and Postoperative Results

Operative Procedure	Number (%)
Perigee alone	10 (31.25)
Perigee with concomitant procedure(s):	22 (68.75)
TOT	12 (37.5)
Enterocele repair	14 (43.75)
Rectocele repair	6 (18.75)
Perineorrhaphy	3 (9.3)
Intraoperative complications	2 (6)
Bladder perforation	1 (3)
Incidental cystotomy	1 (3)
Postoperative complications	2 (7.7)
Graft erosion	1 (3.8)
Wound dehiscence	1 (3.8)
Postoperative POP-Q staging (26 cases):	
Stage 0	14 (54)
Stage I	11 (42)
Stage II	1 (3.8)

Discussion: In our study, the success rate was 96.1%, which is relatively higher than the aforementioned studies. This higher success rate can be attributed to various aspects; first, we used the Perigee® mesh fixation system in which the mesh is secured by four arms to the arcus tendineus fascia pelvis through the transobturator approach. This provides a more efficient fixation mechanism than the free mesh cystocele repair, which is based on fibrotic tissue reaction after mesh implant. Second; we provided the option of graft repair to all patients with symptomatic cystocele, regardless of the prolapse stage. This is in opposition to Wheeler's study in which the authors limited the use of graft only to cases with poor tissue support and Gomelsky's study wherein use of the graft was limited to high grade cystocele. Third, is the short-term median follow up (8.72 months) in our study compared with others (17–24 months). This is in addition to the smaller number of cases in our study in comparison to previous studies. On reference to measures of success in the aforementioned studies, only Handel et al. have clearly defined cure being grade 0 cystocele and improvement being grade I or less cystocele. In the other two studies, the authors considered that grade II cystocele as recurrence. Therefore, we could not find an impact of success measures on our outcome compared with others.

In our study, no cases of graft infection have been encountered, which may likely be due to the technical steps we have developed to avoid this complication. Specifically, the graft is routinely soaked in antibiotic solution for a period of at least 15 min prior to interposition. In addition, we meticulously control as many visible bleeding points as possible, either by cauterization or by suture ligation prior to mesh application. Thorough irrigation with antibiotic solution is also done immediately before and after final

Conclusion: The short-term results of Perigee® with the biocompatible matrix (InteXen®) for cystocele repair showed a high success rate with lower graft-related morbidity, especially vaginal wall erosion. Long-term prospective studies comparing the outcome of various graft materials in prolapse repair are required.

reposition of the graft and, finally, during vaginal mucosal closure, we partially close the vaginal wound in continuous manner, leaving the last 2 cm of vaginal incision to be closed in an interrupted manner in order to provide a window for drainage of blood that may have collected during or early after the procedure. Another important factor to consider is the use of a "ready-to-wear" kit that facilitates the procedure with minimal tissue manipulation and trauma. This has been corroborated by Debodinance et al. who concluded that the use of full kits in prolapse surgery are safer, easier to use, and minimize complications.

Mesh retraction is an important issue related to mesh interposition techniques, which may affect vaginal length. Although we did not evaluate mesh retraction in our study, none of our patients had vaginal length less than 9 cm after the procedure.

Multi-Center Trial Evaluating the 6 and 12 Month Efficacy and Safety of the Perigee System with IntePro

Moore R, et al. *Int Urogynecol J.* 2008; 19 (Suppl. I):S86. Abstract 29.

Objective: The purpose of this study was to evaluate the 6 and 12 mo efficacy and safety of mesh placement along the anterior vaginal wall.

Methods: Each patient underwent placement of Type I, polypropylene mesh (Perigee System with IntePro™, American Medical Systems, Inc., Minnetonka, MN, USA) employing a transobturator approach. At the time of implant, the cystocele was not reduced nor repaired under the mesh. Patients were seen post-operatively at 6 weeks, 3 mos, 6 mos, and 12 mos and will be followed prospectively through 24 mos.

Results: 112 patients were implanted. Currently, 99 patients have completed their 6 mo follow-up, and 85 have reached their 12 mo follow-up (mean follow-up: 15.25±7.7 mos). Patient demographics include: ethnicity (Caucasian: 96.3%, Hispanic: 2.8%, African American: 0.9%), age: 60.7 years (27, 87), BMI: 27.5±6.0, gravida: 3.2±1.7, para: 2.8±1.5, prior cystocele repair: 22.9%, menopausal: 87.1%, prior hysterectomy: 54.1%. The Perigee only procedure time was 29.2±13.2 min; total procedure time (skin-to-skin) was 86.6±44.1 min. Concomitant repairs included vault suspension (62.4%), incontinence (69.7%), and rectocele repair (64.2%). Estimated blood loss for Perigee, only, was 69.0±74.1 cc. Hematocrit at baseline, immediately following the procedure, and at postop day 1 was: 39.7±3.5, 33.2±3.9, and 33.0±3.8.

There were two device related perioperative complications: a bladder perforation and a hematoma. The bladder perforation was (1 cm) lateral to the ureteral orifice, occurred during dissection, and was immediately repaired. The surgery resumed and the Perigee was implanted without any postop sequelae. The hematoma formed behind the vaginal incision and required intraoperative drainage. The patient did require transfusion,

and was the only patient that required transfusion out of the 112 patients for an overall rate of <1%. There were no erosions into the surrounding viscera. Eleven patients (9.8%) did experience a mesh extrusion into the vagina with an average time to onset of 211.2 days, post-op (38–686). 7/11 (6.25%) patients required surgical intervention and the others (3.6%) healed with conservative intervention or observation. Only two (1.8%) extruded patients had low vaginal estrogenicity (determined from a cytological vaginal wall maturation index); the remaining extruded patients (8.0%) had moderate (7/11, 6.25%) or high (2/11, 1.8%) vaginal estrogenicity. Two (1.8%) patients reported de novo urge, with incontinence; both have resolved. De novo stress incontinence was reported in 4 (3.6%) patients. Two patients were treated with a subsequent Monarc. The other 2 patients both received concomitant incontinence slings at the time of the Perigee implant: one failed and was replaced; the other patient is being treated with medication.

All other device-related complications occurred at a rate less than 1%, including pain. Objective success rates (<Stage I, anterior prolapse) at 6 and 12 mos are 93.8% (91/97) and 90.5% (76/85), respectively. Only 1 (0.9%) patient, to date, has had a reoperation for symptomatic failure (Aa: -2.0; Ba: 0.0). A small piece of mesh was resected and imbricated to reduce the recurrent cystocele. Improvement was seen on all quality of life questionnaires (PFDI, PFIQ-7, and PISQ-12). PFDI scores improved across all subscales at 6 and 12 mos, with greatest mean improvement on the urinary (UDI) and POP (POPDI) subscales. PFIQ-7 scores improved across all subscales at 6 and 12 mos, with greatest mean improvement on the urinary (UIQ) subscale. The PISQ-12 displayed improvement at 6 and 12 mos, in score, over baseline by 7.4±6.2 and 5.8±5.5 points (out of a possible 48 points).

Conclusion: Repair of cystocele with the Perigee System results in a high anterior prolapse success rate at 6 and 12 mos, postoperatively. Intra- and post-operative complications have been minimal with improvement in all QOL measurements. Mid-term cure rates are very encouraging and 24 mo follow up is ongoing.

Anterior Repair with Mesh: With or Without Prior Anterior Repair

Moore R, et al. *J Pelvic Med Surg.* 2008; 14(4):276. Abstract 28.

Objective: To compare outcomes of patients with primary versus recurrent cystoceles undergoing anterior repair with mesh via a transobturator route.

Methods: Each patient underwent placement of Type I, polypropylene mesh (Perigee System with IntePro™, American Medical Systems, Inc., Minnetonka, MN, USA) employing a transobturator approach. At the time of implant, the cystocele was not reduced nor repaired under the mesh.

Results: 110 subjects (anterior vaginal wall prolapse (≥ Stage II)) were implanted; 25 had previous anterior repair (PAR) with recurrent cystocele and 85 had no previous anterior repair (NPAR). There was no significant difference in demographics (age, bmi, gravidity, parity), but prior

hysterectomy was significantly greater in the NPAR ($p = 0.0001$). Average follow-up was 16.7 ± 7.8 mos. Two intraoperative complications only occurred in NPAR hematoma and bladder perforation. There was no significant difference on the 12 mo anterior staging success rates between the two groups (PAR: 95.2%; NPAR: 88.6%, $p = 0.253$). Overall, 12 extrusions were seen for an overall extrusion rate of 10.9%. There was no significant difference in extrusions between the two groups (PAR: 20%; NPAR: 8.2%, $p = 0.097$). Average onset of extrusions was 240.8 days (PAR, 38–124) and 177.6 days (NPAR, 48–426). There was no significant difference between other complication rates such as de novo urge with incontinence or pain.

Conclusion: Anterior repair of cystocele with mesh graft via transobturator approach seems to be a safe and effective procedure both in patients with primary cystoceles and those with recurrent cystoceles that have had previous attempt at repair. In the current study there was no significant difference in the extrusion rate or the anterior success rate between these groups of patients. Patients with recurrent cystoceles are thought to be at a higher risk of complications and failure, however in the current study with the use of the Perigee procedure this was not found to be the case through medium term follow up.

Anatomy and Visceral Function After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial

Nguyen J, et al. *J Pelvic Med Surg.* 2008; 14(4):238. Abstract 42.

Objectives: To report 2-year outcomes of a randomized controlled trial comparing polypropylene mesh reinforced anterior vaginal prolapse repair to anterior colporrhaphy.

Methods: Seventy-six patients, mean age 60 years and BMI 28 kg/m², with stage II or greater anterior vaginal prolapse were recruited from the urogynecology clinic and randomly assigned to either anterior colporrhaphy (AC) or Perigee polypropylene mesh repair

Results: Thirty-eight women had anterior colporrhaphy and 37 had polypropylene mesh repair. One patient allocated to mesh repair withdrew from the study prior to surgery. Clinical and demographic data did not differ significantly between the two treatment groups. Recurrent stage II anterior vaginal prolapse (primary outcome) at two years occurred in 20/38 (53%) of anterior colporrhaphy and 5/38 (14%) of

the mesh group ($p = .004$). Operative time and length of hospitalization were similar in both groups. Postoperative day one hemoglobin change was higher in the mesh group (2.4 vs. 1.8 g/dl, $p = .02$) but there was no difference in transfusion rates (3%). Quality of life (PFDI-20, PFIQ-7) symptom scores improved in both the AC (109 ± 58 vs. 45 ± 32 , 82 ± 54 vs. 23 ± 34) and mesh (108 ± 45 vs. 34 ± 31 , 82 ± 54 vs. 14 ± 23) groups two years after surgery ($p = .0001$). Sexual symptom (PISQ-12) scores were similar between groups at baseline and did not change significantly after surgery. The rates of de novo dyspareunia were 4/26 (16%) and 2/22 (9%) in the colporrhaphy and mesh groups respectively. Two of 37 women (5%) had vaginal mesh extrusions and were treated without recurrence. Neither serious adverse events nor deaths occurred in either group.

Conclusion: Anterior vaginal prolapse repair with polypropylene mesh reinforcement offers lower anatomic recurrence than anterior colporrhaphy at two years. However, quality of life and sexual symptoms scores improved in both groups.

Outcome After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial

Nguyen, J, et al. *Obstet Gyn.* 2008; 111:891-8.

Objective: To report 1-year outcomes of a randomized controlled trial comparing polypropylene mesh-reinforced anterior vaginal prolapse repair with anterior colporrhaphy.

Methods: Seventy-six patients with stage II or greater anterior vaginal prolapse were randomly assigned to either colporrhaphy or polypropylene mesh repair. The primary outcome was recurrent stage II anterior vaginal prolapse, and secondary outcomes were effects on quality of life and sexual symptom scores, operative time, blood loss, length of hospitalization, and adverse events.

Results: Thirty-eight women had anterior colporrhaphy, and 37 had polypropylene mesh repair. One patient allocated to mesh repair withdrew from the study before surgery. Clinical and demographic data did not differ significantly between the two treatment groups. One year after surgery, optimal and satisfactory anterior vaginal support were obtained in 21 of 38 (55%) of the colporrhaphy group and 33 of 38 (87%) of the mesh group ($P=.005$). Patients in both groups reported less bother after surgery in both prolapse and urinary symptoms. The rates of de novo dyspareunia were 4 of 26 (16%) and 2 of 23 (9%) in the colporrhaphy and mesh groups, respectively. Two of 37 (5%) patients had vaginal mesh extrusion. Nine anterior colporrhaphy patients would have to have recurrent anterior vaginal prolapse to prevent one vaginal mesh extrusion. Neither serious adverse events nor deaths occurred in either group.

Two of 37 (5%) polypropylene mesh repair patients had asymptomatic 2- to 3-mm mesh extrusions along the anterior vaginal incision at their 6-month examination. Both were postmenopausal and not using either vaginal or oral estrogen. In both patients, there was no granulation tissue or evidence of infection, and the extrusions were successfully treated with in-office local excision and vaginal estrogen cream. There were no vaginal healing defects in either patient at one year.

Given the 5% vaginal mesh extrusion rate, the number needed to harm would be 20. Given the 45% failure rate after anterior colporrhaphy, nine anterior colporrhaphy patients would have recurrent anterior vaginal prolapse to prevent one polypropylene mesh repair vaginal mesh extrusion.

Conclusion: Our results demonstrated that although visceral and sexual functions were improved after both anterior colporrhaphy and polypropylene mesh-reinforced repair, the latter was associated with a significantly lower short-term anatomic recurrence rate in both primary and secondary repairs. Because the long-term durability and safety of mesh-reinforced repair is unknown, surgeons may consider using these procedures for recurrent prolapse or primary repairs in cases where there is a high risk of recurrence and after discussion of risks, benefits, and alternatives.

Baseline Demographic and Clinical Data of the Two Surgical Groups

	AC (n=38)	Perigee (n=37)	P
Mean age ± SD (y)	59 ± 9.5	61 ± 10.5	.73
Median (range) vaginal parity	3 (0-6)	3 (0-5)	.72
Mean BMI ± SD (kg/m ²)	27 ± 4	28 ± 3	.59
Previous hysterectomy	12 (31)	16 (43)	.42
Previous prolapse surgery	6 (16)	8 (22)	.56
Previous incontinence surgery	3 (8)	3 (8)	.99
Menopausal status			.64
Premenopausal	7 (18)	7 (19)	
Postmenopausal with HT	7 (18)	10 (27)	
Postmenopausal without HT	24 (64)	20 (54)	
Urodynamic stress incontinence	24 (64)	20 (54)	.57
Overactive bladder	12 (32)	10 (27)	.86
Anterior vaginal POP-Q stage			.44
Stage II	23 (61)	18 (49)	
Stage III	14 (37)	16 (43)	
Stage IV	1 (2)	3 (8)	
Concomitant surgical procedures			
Vaginal hysterectomy	20 (53)	17 (46)	.71
Salpingo-oophorectomy	11 (29)	9 (24)	.86
Uterosacral vaginal suspension	30 (79)	26 (70)	.33
Midurethral sling*	28 (74)	25 (68)	.54
Site-specific rectocele repair	9 (24)	8 (22)	.75
Perineoplasty	6 (16)	8 (22)	.67
Apogee prolapse repair	1 (3)	3 (8)	.35
Median (range) operative time (min) [†]	120 (60-150)	135 (65-210)	.50
Median (range) hemoglobin change (g/dL) [‡]	1.8 (1.0-2.5)	2.4 (0.5-3.7)	.02
Median (range) hospitalization length (d)	2 (1-3)	2 (1-3)	.33
Postoperative adverse events			
Fever	3 (8)	2 (5)	1.00
Blood transfusion	1 (3)	1 (3)	1.00
Urinary retention requiring intervention [§]	2 (5)	2 (5)	1.00
Urinary tract infection	7 (18)	4 (11)	.51
Transient leg pain	0	1 (3)	.49
Vaginal mesh exposure	0	2 (5)	.24

AC, anterior colporrhaphy; Perigee, polypropylene mesh repair; SD, standard deviation; HT, hormone therapy; POP-Q, pelvic organ prolapse quantification.

Data are n (%) unless otherwise specified.

* Transvaginal or transobturator tape.

† For all operative procedures combined.

‡ Preoperative hemoglobin minus hemoglobin obtained on the morning of the first postoperative day.

§ Patients returned to the operating room for sling mobilization. All voided successfully after the procedure.

|| Two- to 3-mm exposure occurring at the previous anterior vaginal incision site.

Prospective Study of the Perigee System for the Management of Cystoceaes-Medium-term Follow up

Rane A, et al. *Aust N Z J Obstet Gynaecol.* 2008; 48:427-32.

Objective: To prospectively study the safety and efficacy of the Perigee system in the management of anterior vaginal wall prolapse.

Methods: All patients who had undergone surgery with the Perigee system between March 2004 and December 2005 were included in this study. All the surgeries were either performed by the senior surgeon (AR) or under his direct supervision. Follow-up period was 18-36 months.

The initial assessment of the patients involved detailed history-taking, examination using the International Continence Society Pelvic Organ Prolapse Quantitation (ICS POPQ) prolapse scoring system and administration of the Modified Bristol Lower Urinary Tract Symptoms Questionnaire for quality of life. Preoperative urodynamics were performed by the senior surgeon (AR) and the average operative time for Perigee was 18.4 minutes with the range of 11-26 minutes.

Operative technique and difficulties, intraoperative complications and other concomitant procedures performed were carefully documented. Bladder and urethral damage were excluded by routine urethroscopy. Rectal examination was also performed as a routine to exclude rectal injuries.

Patients were reviewed at six weeks, three months, six months, 12 months and biannually thereafter to assess any complications including mesh infections, satisfaction with the procedure and recurrence. Mesh infection was defined as offensive vaginal discharge complained of by the patient.

Results: A total of 70 patients underwent surgery with the Perigee system between March 2004 and December 2005.

Twenty-eight (40%) patients had a previous cystocele repair procedure done. Of the 28 patients, 24 patients had an anterior vaginal repair with either conventional colporrhaphy or defect specific repair. Eighteen patients had had a previous abdominal hysterectomy. Seven patients had previous incontinence correction surgery done.

There were no life-threatening or major intraoperative complications documented. These include significant or excessive haemorrhage, bladder perforations, urethral injuries or other major vessel or organ injuries.

At six weeks follow up, one patient had a stage 1 cystocele and two patients had developed de novo stage 2 rectoceaes. These three patients complained of a lump sensation. On the second review visit at three months, two more patients were noted to have recurrence of a stage 1 cystocele. On subsequent reviews, the cystoceaes remained at the same level. The recurrence rate for anterior prolapse in this study was 4.28%, of which 1.42% was symptomatic and the rest were asymptomatic. The posterior compartment prolapse became obvious and symptomatic in 2.85% of patients. There were no apical prolapses noted.

Five patients (7.1%) had mesh exposure postoperatively. Of the five patients, two patients were found to have small mesh exposures, less than 1 cm in diameter, during the second review at three months. Both were treated with trimming in the outpatient clinic and were prescribed local oestrogen cream. On subsequent visits the exposures

were no longer evident. The other three patients had mesh exposures centrally and also less than 1 cm in diameter on the third review. These patients were treated conservatively with oestrogen cream and were not evident subsequently. There were no documented cases of mesh infection during any of the visits. None of the patients required mesh excision or trimming under anaesthesia.

One patient complained of dyspareunia after a combined Perigee and posterior repair. This was successfully treated with oestrogen cream and dilators.

Fifty-five (78.5%) patients answered the subjective quality of life questionnaire completely following surgery. Fifteen other questionnaires were not included in the analysis as they were either incorrectly filled or incomplete. Forty eight (87.3%) patients were completely satisfied with the surgery performed, and seven (12.7%) patients were not fully satisfied with the surgery. Fifty (90.9%) patients were cured of their symptoms of prolapse, four patients had no improvement and only one patient had worsening of symptoms subjectively.

Discussion: The 70 cases we are presenting here are our medium-term follow up. The lessons we have learnt over the three years using this operation are to perform full thickness vaginal dissection, palpate the entry points before insertion of the needles, keep the tail as short as possible, fix the proximal and distal portions of the graft with PDS sutures, avoid excessive trimming of the vaginal mucosa and avoid 'tensioning' the graft too tight. Tensioning the graft tightly to get an immediate visual impact may lead to a small percentage of women developing vaginal 'ridging' causing dyspareunia.

The rate of mesh exposure or extrusion in our study was about 7%. Mesh exposures from 5% to 30% have been described using polypropylene meshes but with variable surgical techniques and follow-up times. In an attempt to reduce this, we now keep the fascia attached to the vagina during the dissection of the bladder. This provides a thicker layer of vaginal skin and may reduce further the incidence of mesh exposure. In menopausal patients with evidence of urogenital atrophy, a course of local vaginal oestrogen prior to the surgery was prescribed to help reduce the incidence of exposures. These findings are our personal views and are not scientifically corroborated. Mesh exposures, however, were generally easy to treat either conservatively with oestrogen creams and/or with trimming if required.

The minimal recurrence rate of 4.28% after surgery has shown the effectiveness of this surgical procedure in the follow-up period of 18-36 months. The surgical design of the procedure only surmises safety, but effectiveness and longevity of the procedure can be gauged by follow up, preferably by an independent surgical audit in single surgeon series.

Conclusion: The Perigee system seems to be an effective, minimally invasive, global operation for anterior vaginal wall prolapse with minimum morbidity in the medium term. Whether a randomized controlled trial can be performed ethically and by strict standardization of the repair arm remains to be seen. Our unit intends to follow up these patients for a minimum of five years.

Transobturator Cystocele Repair: Short-term Retrospective Comparison of Xenograft Versus Polypropylene

Harvie H, et al. *J Pelvic Med Surg.* 2007; 13(5):286. Abstract 58P.

Objective: To compare short-term outcomes of transobturator cystocele repairs using either polypropylene or porcine dermis collagen grafts.

Methods: A retrospective comparative series evaluating all women who underwent anterior repair using a transobturator approach with either porcine collagen dermis or polypropylene with Perigee system (American Medical Systems MN, USA) from 12/05 to 2/07.

Results: A total of 78 women were treated, 47 (60%) with xenograft (X) and 31 (40%) with synthetic material (S). The group demographics were similar except the X group was older (mean age 58.5 versus 51.9, $P=0.01$). Preoperative mean POP-Q examination did not differ between groups (see table). Concomitant procedures included hysterectomy (26%), vault suspension (83%), enterocele

repair (85%), rectocele repair (91%), retropubic sling (50%), and transobturator sling (46%). Rates of concomitant procedures did not differ between groups. There were no intraoperative complications, mean EBL was 155+/-88 mL, and mean hospital stay was 2.9+/-4.2 days, with no differences between groups. Follow-up averaged 14.3 (2-44) weeks. There were no anterior recurrences in either group at all time periods and no differences in postoperative POP-Q values (see Table). At 6 weeks there was 1 (1.4%) and at subsequent follow-up 2 (3.6%) graft erosions in group S. Both were successfully treated with conservative measures. Postoperative SUI was <3% in both groups and urinary symptoms were similar. Mean PVR was 48+/-66 mL preoperatively and 37+/-36 at 6 weeks, with no differences between groups. There was 1 patient with postoperative voiding dysfunction in group S which was corrected with urethrolisis.

Conclusion: Transobturator cystocele repair using grafts appears to be safe and effective during short-term follow-up. Results are similar between xenograft and polypropylene graft material.

Prospective, Multi-center Trial Evaluating the Perigee System with Polypropylene Mesh for Cystocele Repair: Estrogenicity and Outcomes

Moore R, et al. *J Minimally Invasive Gyn.* 2007; 14(6):S75. Abstract 204.

Objective: To evaluate the safety and effectiveness of the Perigee System with IntePro and whether there is a correlation between vaginal estrogen levels and extrusion rate.

Methods: 104 Women with > Stage II cystocele (Ba > 1) underwent placement of Type I, polypropylene mesh (Perigee System with IntePro™, American Medical Systems, Inc., Minnetonka, MN, USA) employing a transobturator approach. At the time of implant, the cystocele was not reduced nor repaired under the mesh.

Results: 104 Women with > Stage II cystocele (Ba > 1) were treated with Perigee with a mean follow-up of 35.7 + 18.4 weeks. Patients were 62 years [27-87], bmi (27.0 + 6.0), parity (2.9 + 1.5), and menopausal or post-menopausal

(89%). 80% of subjects had high or moderate vaginal estrogenicity by means of a vaginal maturation index and the baseline vaginal pH showed no or mild atrophy in 76.5% of subjects. Mesh extrusion occurred in 6.7% (n=7) of subjects with mean time to onset at 81 days (38-180). 4.8% of extrusions required minor revision in the O.R.; 1.9% were treated in the clinic. Of the 7 extruded subjects, only 1 had low vaginal estrogenicity. One subject returned to the O.R. for reasons other than an extrusion—vaginal pain and urinary retention. The pain could not be determined to be secondary to the sling or the Perigee—both were removed at <1 mo, po. Quality-of-life PFDI, PFIQ-7, and mean PISQ-12 scores improved. Overall objective cure rate (Anterior POP-Q < Stage I) was 90.9% at 6 mos.

Conclusion: The Perigee System with polypropylene mesh is safe and effective resulting in a low extrusion rate in a mostly post-menopausal population with mild atrophy (moderate estrogenicity). There does not seem to be a correlation between vaginal estrogen levels and the incidence of an extrusion.

Retrospective Multicentre Study of the New Minimally Invasive Mesh Repair Devices for Pelvic Organ Prolapse.

Abdel-fattah M, *BJOG*. 2008; 115:22-30.

Objective: To assess the complications and short-term outcomes of prolapse repair mesh devices used in the management of female pelvic organ prolapse (POP).

Methods: A total of 302 case notes were successfully traced during the study period of March to May 2007. An independent clinician in each unit performed a case notes review with the main outcome measures being the operative, postoperative and mesh-related complications. The secondary outcomes were the short-term cure at 3-month follow up (defined as ≤stage I prolapse as classified on POP-Q or Baden Walker scoring systems), and re-operation rates for other compartment prolapse and/or urodynamic stress incontinence (USI) up to May 2007.

Results: A total of 302 case notes were reviewed and 13 women (4%) who used the Bard device were excluded because the numbers were too small to draw any conclusions. In total, 289 women were included: 219 women (76%) used the Gynaecare device; 76 anterior, 70 posterior and 73 combined. Seventy women (24%) used the AMS devices: 32 posterior, 30 anterior and 8 combined. The choice of device used was primarily according to the surgeons' preference for exclusively two indications: previous failed pelvic floor repair in the same compartment and/or severe prolapse (POP-Q stage III/IV or grade 3-4 Baden and Walker).

All women (n = 289) attended their first follow-up visit at 10–12 weeks. Twenty-four women (8.3%) initially declined pelvic examination due to various reasons (anxiety, n = 11; pain, n=4 and undocumented reasons, n = 6) but were re-examined in a further follow up 2–4 weeks later. The short-term cure rate at 3 months was 95% with 274 women showing stage I POP-Q or grade 1 Baden and Walker POP. Fifteen women (5%) were considered failures, out of which 10 women (3.4%) had further surgery.

Fourteen women (4.8%) developed postoperative USI and all underwent surgical treatment (transobturator tape, n = 10 and colposuspension, n = 4). Twenty-one women (7.3%) represented with symptomatic prolapse in another compartment within a period of 4–22 months after the initial operation (mean 8.4 months), out of which 17 (6%) underwent further surgical treatment.

Operative complications included three bladder injuries (3/189, 1.6%) and two rectal injuries (2/181, 1.1%). The three bladder injuries occurred during insertion of the superior trocars of an anterior Gynecare mesh device.

The two rectal injuries occurred during the initial dissection of the rectum from the posterior vaginal wall due to presence of extensive scar tissue and therefore they were not related to mesh insertion by any particular device.

Patient Demographics, Previous Prolapse Surgery and Associated Procedures at Time of Mesh Repair

	Gynaecare device			AMS device		
	Combined	Anterior	Posterior	Combined	Anterior	Posterior
Number of women	73	76	70	8	32	30
Mean age, years (range)	63 (34-84)	56 (39-81)	60 (42-71)	64 (62-71)	59 (45-73)	65 (46-80)
Mean parity (range)	3 (1-5)	3 (0-6)	3 (1-5)	2 (2-3)	3 (1-7)	2 (2-4)
Mean BMI (range)	28 (19-40)	27 (23-37)	28 (22-38)	29 (21-34)	30 (26-33)	29 (24-38)
Smokers, n (%)	9 (12)	4 (5)	11 (16)	0	2(6)	4 (13)
Postmenopause, n (%)	61 (84)	60 (79)	54 (77)	6	24 (75)	21 (70)
HRT	8 (11)	7 (9)	6 (9)	0 (75)	3 (10)	3 (10)
Previous surgery for Prolapse/TAH, n(%)	38 (52)	45 (59)	36 (50)	4 (50)	28 (88)	24 (80)
Previous repeated surgery, n (%)	18 (25)	16 (21)	22 (31)	2 (25)	13 (41)	8 (27)
Associated procedures, n (%)	34 (47)	28 (37)	21 (30)	3 (38)	8 (25)	17 (57)
Vaginal hysterectomy	27	20	10	2	2	6
Anterior colporrhaphy	N/A	N/A	5	N/A	N/A	9
Posterior colporrhaphy	N/A	8	N/A	N/A	6	N/A
Manchester repair	1	0	1	1	0	0
SSF	0	1	0	0	0	0
TOT	7	7	9	0	2	9
Others	2	1	1	0	0	2

BMI, body mass index; HRT, hormone replacement therapy; N/A, not applicable; TAH, total abdominal hysterectomy; TOT, transobturator tape; SSF, sacrospinous fixation.

Six women (2%) had blood loss of over 400 ml, although three of these women were associated with vaginal hysterectomies, which may have contributed to the extra blood loss. In two of these women, it was caused by serious vascular injuries and one woman had a right internal pudendal artery injury following insertion of a posterior Gynecare mesh by a general gynaecologist working in the tertiary centre. In the second case, the woman had left vaginal artery and right uterine artery injuries following an anterior Gynecare mesh insertion performed by a general gynaecologist in a district general hospital.

Postoperative complications included fever in 24 women (8.3%), urinary tract infection in 7 (2.4%), voiding dysfunction (>48 hours) in 26 (9%), perineal haematoma in 3 (1%), vaginal adhesions in 3 (1%), buttock pain in 15 (5.2%), dyspareunia in 13 (4.5%) and vaginal erosion in 30 (10%) Fisher's exact test showed no significant differences between both devices in all operative and postoperative complications.

All vaginal erosions were detected on pelvic examination between 6 and 22 weeks postoperatively. All women except one were symptomatic with offensive vaginal discharge (29) and dyspareunia (8). In 28 women, erosions were less than 1 cm in size and were initially managed conservatively with local estrogen and antiseptic treatment, although they all

subsequently required partial excision of the eroded mesh. Four women (1.3%) had persistent erosion requiring further excision. Two women (0.7%) had large erosions (4 and 8 cm) and presented with signs of local infection and pelvic pain. Both of them were managed with total removal of the mesh under anaesthesia 8 and 11 weeks postoperatively. The procedures were relatively easy as the infected meshes were not integrated into the surrounding tissues. One patient presented with severe bladder pain and recurrent urinary tract infections at 3 months postoperatively following combined anterior and posterior Gynecare mesh.

Serious systemic infection occurred in two women (0.7%), both within 2 weeks of the operation. One case of systemic infection with *Staphylococcus aureus* occurred following an anterior Gynecare mesh insertion and was treated by intravenous antibiotics and total surgical removal of the mesh under general anaesthesia. The second woman developed necrotizing fasciitis following vaginal hysterectomy and posterior Gynecare mesh insertion.

In this study, the rate of women who presented with persistent/ recurrent prolapse in the same compartment is low at 5% and only 3.5% required further surgery. The total re-operation rate was 13%, but this was mainly for prolapse of another compartment (6%) or unmasked stress incontinence (3.5%).

Operative, Post Operative and Mesh-Related Complications

	Gynecare device			AMS device		
	Combined	Anterior	Posterior	Combined	Anterior	Posterior
Number of women	73	76	70	8	32	30
Operative complications						
Bladder injury	1	2	0	0	0	0
Rectal injury	0	0	1	0	0	1
Haemorrhage (>400ml)	1	2	2	1	0	0
Blood transfusion	0	1	1	0	0	0
Postoperative complications						
Fever	7	4	5	0	2	6
UTI	4	1	0	0	1	1
Voiding dysfunction	11	8	3	1	3	0
Duration (days)	4-22	4-15	5-11	4	8-13	
CISC	1	2	0	0	0	0
Duration (weeks)	4	8-12				
Perineal haematoma	1	0	2	0	0	1
Vaginal adhesions	2	0	0	1	0	0
Buttock pain at follow-up	6	0	8	0	0	1
Dyspareunia	3	1	4	0	1	2
Mesh complications						
Vaginal erosion	11	8	5	1	2	3
Bladder erosion	1	0	0	0	0	0
Local infection	2	1	1	0	0	1
Systemic infection	0	1 <i>(Staphylococcus aureus)</i>	1 <i>(necrotising fasciitis)</i>	0	0	0
Partial mesh excision	10	7	3	1	2	2
Total mesh excision	1	1	2	0	0	1

UTI, urinary tract infection; CISC, clean intermittent self catheterization.

Retrospective Multicentre Study of the New Minimally Invasive Mesh Repair Devices for Pelvic Organ Prolapse.

Abdel-fattah M, *BJOG*. 2008; 115:22-30.
continued

Complications of Gynecare Device Versus AMS Devices

	Gynecare device	AMS device	Fisher's exact test
Bladder injuries	3/149	0/40	0.48 (NS)
Rectal injuries	3/143	1/38	0.37(NS)
Bleeding>400 ml	4/219	1/70	0.65 (NS)
Vaginal erosions	24/219	6/70	0.069 (NS)
Buttock pain	14/219	1/70	0.085 (NS)
Dyspareunia	8/219	3/70	0.74 (NS)
Same compartment Prolapse	11/219	4/70	0.48 (NS)
Reoperation rates	25/219	12/70	0.92 (NS)

NS, non significant.

The biomechanical properties of the mesh material and pore size have a major influence on the postoperative tissue healing and consequently mesh infection. However, both AMS and Gynecare devices use monofilament low-weight macroporous polypropylene meshes and therefore they fulfill the criteria of type I mesh according to Amid's classification and are associated with good tissue incorporation and low rates of infection. In almost all the women we encountered or were referred to us, the infection was mild and localized.

The vaginal erosion rate (10%) in our study is comparable to the 12.7% reported by Collinet et al., yet significantly higher than the recently reported 4.7% by Fattouh et al. The conservative management of these women was disappointing and all women proceeded for partial/total excision of the mesh.

Discussion: In this study, the total short-term cure rate was excellent at 95% and was comparable to other studies.

Our study has demonstrated a comparable rate of bladder injuries (1.6%); however the authors now recommend cystoscopy after insertion of all trocars during these anterior procedures.

Cadaver studies have shown considerable anatomical variation in the relationship of the sacrospinous ligament to the adjacent nerves and vessels. In view of the above studies and our experience, we now emphasize the importance of inserting the posterior Gynecare trocars into the sacrospinous ligament 3 cm medial and 2 cm lower than the level of ischial spine to avoid the pudendal and inferior gluteal bundles. The posterior AMS trocars pass through the ileococcygeus muscle rather than the sacrospinous ligament and, therefore, have a lower risk of injuring the above structures; however, this may be at the expense of the strength of support provided. In the case where the vaginal and uterine vessels were injured, it seems that the inferior trocars of the anterior Gynecare mesh were inserted quite deep and posterior in an attempt to pass through the arcus tendineus. It is our experience that in such cases we pass the inferior trocars through the levator ani fibres.

Conclusion: The new mesh repair devices are associated with excellent short-term cure rates and low morbidity rates considering the surgically high-risk population involved. However, some of these uncommon complications are serious and can be life threatening and need highly specialized management. We, therefore, recommend that these procedures should only be performed by specialists with detailed knowledge and training in the anatomy of the pelvic sidewalls and in well-equipped units especially with facilities for interventional radiology. Cystoscopy should be considered in all cases involving anterior mesh repair kits.

Follow-up after Polypropylene Mesh Repair of Anterior and Posterior Compartments in Patients with Recurrent Prolapse.

Gauruder-Burmester, et al. *Int Urogynecol J.* 2007; 18:1059-64.

Objective: To retrospectively analyze the outcome of surgery in women followed up for 1 year after vaginal repair with the Apogee® (support of posterior vaginal wall) or Perigee® (support of anterior vaginal wall) system.

Methods: In a 1-year period (2004-2005), 145 women underwent vaginal repair with the implantation of an Apogee® or Perigee® (monofilament polypropylene meshes from American Medical Systems). Seven women did not present at follow-up. Another 18 patients were excluded because no urodynamic findings were available (n=8) or the data on POP-Q staging were incorrect (n=10); thus, 120 women were included in the analysis. Forty-eight (40%) women underwent apical posterior repair (Apogee®) and 72 (60%) anterior wall repair (Perigee®). All patients had previously undergone hysterectomy. All patients received two 8-12-week courses of local estrogen therapy, one before and one after surgery.

The mean age of the patients was 66 (±6) years. Most of the patients (n=84, 70%) had undergone vaginal hysterectomy before anterior or posterior mesh repair. All women had a prior hysterectomy and some had a history of other types of repeat interventions, the most common being sacrospinal fixation (38%).

Preoperative POP-Q grading demonstrated recurrent rectocele in 48 (40%) of the women (Bp stage 3). Sixteen of these patients (13%) with additional vaginal vault descent had a point C stage 2. Seventy-two (60%) women had isolated recurrent cystocele with point Ba stage 3. Preoperative vaginal estrogenization was good in 81 patients (68%) with a pH of 4.3 (±0.3), moderate in 34 (28%) with a pH of 4.9 (±0.5), and poor in 5 (4%) with a pH of 5.5 (±0.2).

Results: None of the patients had any peri- or intraoperative complications. The mean duration of surgery was 35 min (±4.5 min).

At follow-up after 1 month and 1 year, 112 women (93%) were anatomically cured of prolapse, whereas 8 women (7%) had recurrent level-2 defects of the anterior compartment (Ba stage 2) but with no clinical symptoms. The average vaginal length after the intervention was 7.6 cm (±1.2 cm). The preoperative symptoms reported by the patients were cured or improved postoperatively in the majority of cases.

Ten women (8%) who were treated by local estrogen therapy showed defect healing after 4 weeks. Four women had mesh erosions (3%) requiring revision. All erosions occurred in women with anterior mesh placement. No mesh infections were observed.

Retraction was significant for both mesh types (p=0.032) but did not correlate with the patient's vaginal length, and there was no association with either compartment.

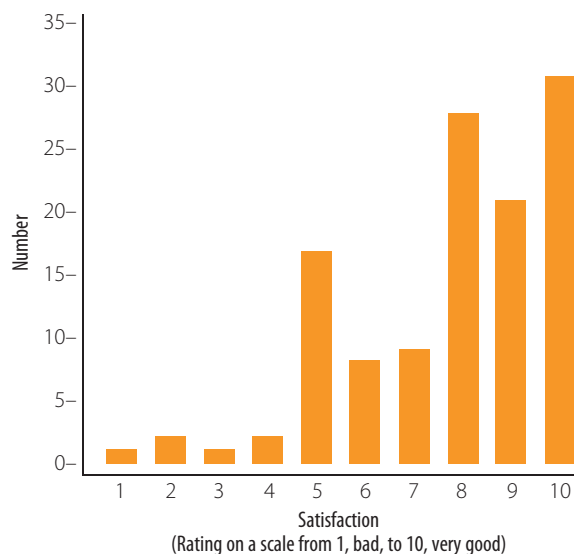
Thirty-four patients (28%) had stool obstruction before surgery compared to only six (5%) patients after surgery. The preoperative evaluation of the pelvic floor contractility demonstrated grade 0 in 58 women (48%), grade 1 in 4 (3%), grade 2 in 17 (14%), and grade 3 in 35 women (2%). None of the women had grade 5 (0%), and only 6 (5%) had grade 4.

Symptoms Before and After Mesh Placement

Symptoms	Before mesh placement	After mesh placement
Dyspareunia	15	0
Stress urinary incontinence	29	5
Urge incontinence	21	13
Stool obstruction	34	6
Prolapse-related problems	24	2
Disturbed bladder voiding	3	0
Recurrent UTI	8	0

Pelvic floor contractility had no significant effect on the outcome of surgery or patient satisfaction after surgery. Sexual exploration revealed that 80 (67%) women were sexually active, whereas 40 (33%) suffered from sexual dysfunction secondary to partner problems. There was no association with dyspareunia in these cases. The patients were explored by a colleague trained in sexual medicine. None of the 15 patients who reported dyspareunia before the mesh procedure did so after the intervention. In these cases dyspareunia was due to prolapse. These findings agree with the answers given in the validated questionnaire on sexuality that identified neither sexual disturbances nor partner problems in any of these 15 women.

Rating of Satisfaction



Follow-up after Polypropylene Mesh Repair of Anterior and Posterior Compartments in Patients with Recurrent Prolapse.

Gauruder-Burmester, et al. *Int Urogynecol J.* 2007; 18:1059-64.
continued

Discussion: The very low mesh erosion rate of 3% achieved in our study after 1 year justifies the long-term estrogen treatment of 8–16 weeks administered to our patients. Our results do not confirm that inverted T colpotomy increases the risk of erosion as reported by Belot et al. We routinely performed T colpotomy in 50% of our patients. However, mesh erosion in our study may be explained by the fact that three of the four patients had manifest type II diabetes mellitus. Diabetes impairs wound healing and should be considered when establishing the indication for mesh repair in the future. Another factor that may contribute to mesh erosion is the status of the vaginal mucosa that is difficult to predict before surgery and may not be optimal despite local estrogen therapy. The low erosion rate achieved in our study may be attributed to the small size of the mesh graft. The fact that all patients in our study underwent fascial repair before mesh placement may have caused reduced perfusion and, thus, contributed to the defects observed in our patients. Early disturbance of wound healing does not seem to be a problem because it can be successfully treated by estrogen therapy. These cases are probably due to poor tissue quality and reduced perfusion that may occur as a result of the intervention and in spite of estrogen therapy. The erosion rates reported in the literature are approximately 10%. We think that the improved rate achieved in our study is due to very strict patient selection, no simultaneous hysterectomies, and two experienced surgeons performing all interventions.

The absence of infections in our patients is mainly due to the type of mesh material used and intra- and postoperative antibiotic prophylaxis. The recurrence of anterior compartment level II–stage 2 cystocele in eight patients

in our study population was associated with a suboptimal anatomical outcome, whereas the clinical symptoms resolved. We assume that, in these cases, the foreign material provided adequate support to eliminate the symptoms.

The mean postoperative vaginal length was 7.6 cm (± 1.2 cm) in our study patients. This is adequate given the fact that all patients were women with repeated prior surgery. The high rate of dyspareunia reported in the literature were not confirmed in our study population. We obtained a comprehensive preoperative sexual history by means of validated questionnaires and could, thus, exclude underlying sexual disorders and partner problems. The 15 cases of dyspareunia reported preoperatively had anatomical causes and were, therefore, eliminated by mesh repair in all cases.

Despite their rather high mean age, most of the patients included in our study still engaged in vaginal sexual activities. This is why the authors of this study are against colpopoiesis as an alternative surgical approach in these patients. Moreover, colpopoiesis constitutes a violation of female physical integrity.

Additional problems such as stool obstruction, prolapse-related symptoms, disturbed bladder voiding with secondary recurrent urinary tract infection improved significantly or were completely eliminated. The six patients (5%) with persistent stool obstruction had a history of additional factors including chronic constipation, diverticulosis and hemorrhoids. In these cases, we assume that the complex interaction of these factors is responsible for the patients' persistent symptoms and that these cannot be eliminated just by repairing the anatomical defect.

Conclusion: Our findings suggest that the interposition of a monofilament polypropylene mesh by the vaginal route seems to be an excellent procedure for definitive repair of recurrent anterior/posterior vaginal wall prolapse or combined vaginal vault prolapse. This new procedure is minimally invasive, reproducible, and efficient. It has low morbidity and is well tolerated by the patients.

Retrospective Analysis of Efficacy and Safety of Perigee and Apogee in Patients Undergoing Repair for Pelvic Organ Prolapse.

Davila, G, et al. *J Minimal Invas Gyn.* 2006; 13(Suppl. 5):S27. Abstract 56.

Objective: To assess outcomes following pelvic organ prolapse (POP) repair with a transobturator anterior prolapse repair system (Perigee; AMS, Minnetonka, MN, USA) and/or vaginal vault and posterior repair system (Apogee) using polypropylene mesh or porcine dermis grafts.

Methods: Reviews of 299 patient charts were conducted. Investigators collected data on a maximum of their first 7 patients in each category: Apogee only, Perigee only, or combined Apogee and Perigee.

Results: Follow-up ranged from 1-8.7 months. The Perigee system was used in 122 patients (mean age, 61.4 years). Preoperatively, 78.7% had grade III and 21.3% had grade II prolapse. Significant improvement (grade 0) was seen in 93.3%; the remaining 6.7% achieved grade I. Of the 82 Apogee patients (mean age, 64.0 years), preoperatively,

56.1% had grade III and 43.9% had grade II prolapse. 100% had prior enterocele, 97.7% had prior rectocele, and 88.0% had prior vault prolapse achieved grade 0, and 12.0% with prior vault achieved grade I prolapse. Of the 95 undergoing repair with both Perigee and Apogee, preoperatively, 63.9% had grade III prolapse and 36.1% had grade II prolapse. Final postoperative evaluation showed that 95.7% had prior cystocele, 100% had prior enterocele, 100% had prior rectocele, and 95.5% with prior vault were noted to have grade 0 prolapse. Device-related complications, including pain, were demonstrated in < 1% of patients. Mesh exposure rates were low (overall, 29/298 [9.7%]; Perigee, 5/121 [4.1%]; Apogee, 10/82 [12.2%]; and Perigee and Apogee combination, 14/95 [14.7%]). Of these 29 patients, 9 (31.0%) required in-office therapy; and 9 (31.0%) required surgical treatment.

Conclusion: POP repair with Perigee and/or Apogee systems with polypropylene or porcine dermis grafts are effective in treating POP with few postoperative complications.

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American Medical Systems, Inc.
World Headquarters
10700 Bren Road West
Minnetonka, MN 55343 USA
Phone: 952 930 6000
Fax: 952 930 6157
www.americanmedicalsistemas.com

**American Medical Systems
Europe B.V.**
Straatweg 66H
3621 BR Breukelen
THE NETHERLANDS
Phone: 31 346 258 100
Fax: 31 346 258 130

**American Medical Systems
Australia Pty. Ltd.**
Unit 39, Building F
16 Mars Road
Lane Cove 2066
NSW AUSTRALIA
Phone: 61 2 9425 6800
Fax: 61 2 9427 6296

**American Medical Systems
Canada Inc.**
P.O. Box 461
Guelph, Ontario
N1H6K9 CANADA
Phone: 519 826 5333
Fax: 519 821 1356