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Presentation to Advisory Committee

February 12, 2019

Introduction and Boston Scientific's Devices

Dr. Ronald Morton, Jr., MD, FACS
VP Clinical Sciences, Boston Scientific

Agenda

- Introduction
- Therapeutic options for treatment of Pelvic Organ Prolapse (POP)
- Clinical evidence for Transvaginal Mesh (TVM)
- BSC 522 data
- Physician training and risk mitigation
- Benefit / Risk discussion
- Conclusion

Issues to be Addressed

- **Efficacy** of TVM for anterior/apical POP repair
- **Safety** of TVM for anterior/apical POP repair
- **Overall benefit/risk profiles** of BSC's TVM devices
  - Comparison to other surgical options for POP repair
- The **appropriate time-point(s)** for evaluation of TVM compared to Native Tissue Repair (NTR)
- **Whether TVM must be superior to NTR** to support its continued availability
- **Patient factors** impact safety and effectiveness outcomes and appropriate **patient populations** for TVM POP repair
- Impact of **surgeon training/experience** on safety and efficacy outcomes

Speakers & Representatives

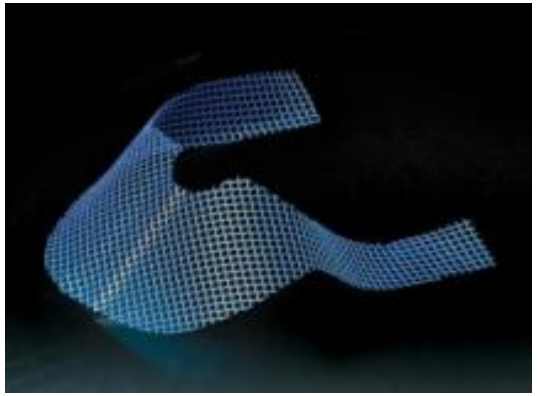
- Clinicians
  - **Suzette Sutherland, MD, MS, FPMRS** Director of Female Urology, UW Pelvic Health Center; Associate Professor, Department of Urology, University of Washington School of Medicine, Seattle, WA
  - **Miles Murphy, MD** Board Certified, Obstetrics & Gynecology and Female Pelvic Medicine & Reconstructive Surgery, Partner and Associate Medical Director-The Institute for Female Pelvic Medicine & Reconstructive Surgery, Chief – Division of Urogynecology, Department of Obstetrics and Gynecology, Abington-Jefferson Health
  - **Michael Kennelly, MD, FACS, FPMRS** Professor, Departments of Urology and Obstetrics & Gynecology, Carolinas Medical Center; Medical Director-Charlotte Continence Center at Carolinas Medical Center; Co-Director-Women's Center for Pelvic Health; Director of Urology, Carolinas Rehabilitation Hospital
- Study Design and Conduct
  - Ronald Morton, Jr., MD, FACS VP Clinical Sciences, Boston Scientific
- Regulatory
  - Donna Gardner, VP Regulatory Affairs, Urology and Pelvic Health, Boston Scientific
- Statistics
  - Dongfeng Qi, Ph.D. M.S. Director, Biostatistics and Data Management, Boston Scientific

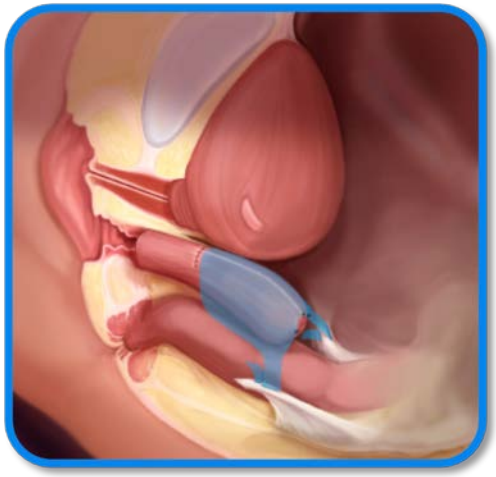
Boston Scientific Devices

- 2 marketed devices indicated for tissue reinforcement in women with pelvic organ prolapse, for the transvaginal repair of anterior and apical vaginal wall prolapse
  - Uphold LITE
  - Xenform
- Previously 510(k) cleared, now with pending PMA applications
  - Uphold LITE first cleared in 2011: 21,510 distributed for implantation in US and 47,992 worldwide
  - Xenform first cleared in 2005: 42,308 distributed for implantation in US and 43,650 worldwide

Uphold LITE

- Second generation, knitted Type 1, light-weight polypropylene mesh
- Anatomically sized
- Adjustable mesh legs for sacrospinous ligament attachment facilitate proper graft placement
  - Addresses both anterior wall and apex
- Single incision repair kit implanted with dedicated delivery instrument, Capio SLIM

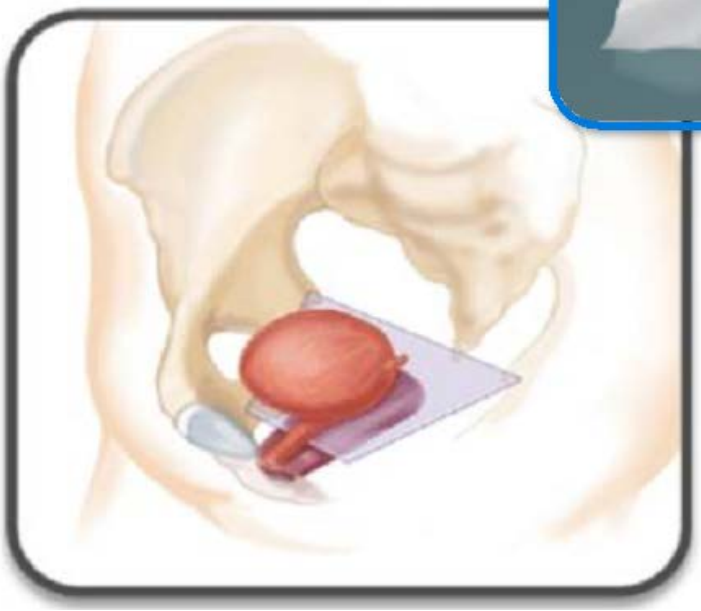




Uphold LITE is distinct from Uphold. Uphold is higher density mesh, no longer marketed, and not subject to a pending PMA

Xenform Soft Tissue Repair Matrix

- Constructed from extracellular collagen material manufactured from bovine skins
  - Non crosslinked
  - Minimally absorbed
- Trimmed to fit patient anatomy
- Hydrated in sterile saline prior to implantation



Therapies for Repair of POP and History of Mesh

Suzette E. Sutherland, MD, MS, FPMRS

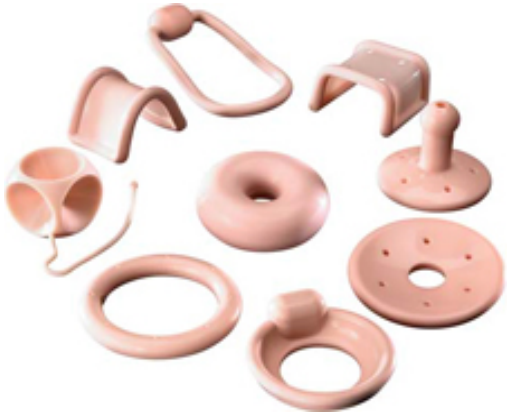
Director of Female Urology, UW Pelvic Health Center

Associate Professor, Department of Urology

University of Washington School of Medicine

Current therapies for POP

- **Non-surgical treatments**
  - Pelvic floor strengthening exercises and physical therapy
  - Pessaries: provide temporary support and symptom relief
    - Therapies require continued efforts by patients
    - Conservative therapies are most appropriate milder prolapse
- **Surgical interventions**
  - **Restore** anatomic **support** and **function** by re-suspending the prolapsed organ(s)
  - Abdominal and minimally-invasive transvaginal approaches available
    - Both with or without mesh
    - Considerations include:
      - Adequacy of support
      - Durability of the repair



Surgical Options for POP
Risks and Benefits

- **Sacrocolpopexy**
  - "Gold standard" for long term durability (≥ 5 years) of APICAL prolapse repair
  - Uses permanent mesh and suture in the abdomen; risk of mesh exposure/erosion and pain
  - Associated with longer surgery, general anesthesia; potential for serious abdominal complications such as bladder/bowel/vessel injury/obstruction and pain
- **Hysteropexy**
  - Abdominal or transvaginal approach
  - Uses permanent mesh or suture
  - Risks include suture and/or mesh exposure/erosion, bladder/bowel injury and pain
- **Transvaginal Native Tissue Repair (NTR): Ant Colporrhaphy / SSL or USL**
  - High rates of prolapse recurrence: anterior and apex

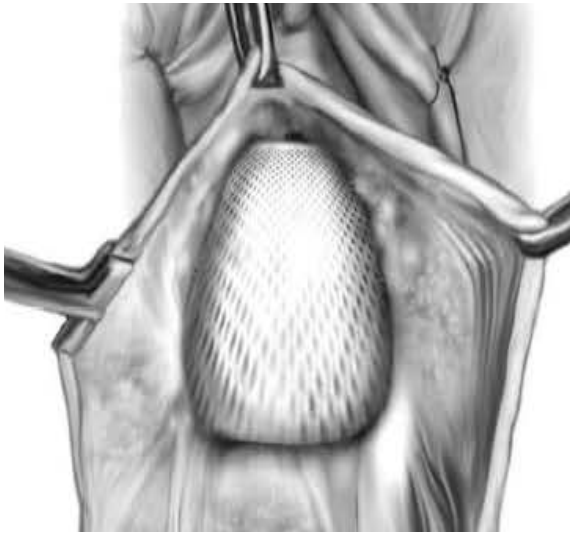
• Failure at 2 years:	Anterior repair	27% - 42%	(Maher Cochrane Rev 2017)
• Failure at 2 years	SSL 40%	USL 41%	
• Failure at 5 years:	SSL 61.5%	USL 70.3%	
• Retreatment at 5 years:	SSL 8%	USL 12%	(OPTIMAL JAMA 2014,2018)

  - Apical support usually utilizes permanent suture
- **Transvaginal mesh (TVM)**
  - Can address the ant/post compartment AND the apex
  - Increased anatomic durability
  - Mesh-related complications such as exposure/erosion and pain

Evolution of Transvaginal Mesh

- Earlier TVM products and surgical techniques were associated with high complication rates and poor efficacy resulting in POP recurrence
  - Larger mesh footprint
  - Higher density, thicker mesh (45-50 g/m^2)
  - Mesh inlay method where graft was placed to cover the entire bladder area
  - Split thickness dissection plane leaving mesh susceptible to exposure
  - Implantation with multiple incisions and trocars ("blind" transvaginal trocar passages)
  - Only an anterior wall repair without suspending apex

Mesh Inlay



NO LONGER* considered *standard of practice

Uphold LITE Represents a Contemporary TVM Product for Ant/Apical Repair

- Uphold LITE is a low-density, large pore mesh product
- Uphold LITE is implanted with a single incision technique without trocars
  - Utilizes known Capio device technique for SSL attachment
  - Detailed surgical implantation instructions and training provided by Boston Scientific
- Provides anterior AND apical support!
  - Isolated anterior or apical prolapse are RARE
  - Cystocele stage predicts apical prolapse
    - Stage 3 cystocele – 85% POP-Q apex-3
    - Stage 4 cystocele – 100% POP-Q apex-3

Current device designs and surgical technique designed to:

- ***Reduce complications***
- ***Improve outcomes***

Elliot, CS et al. J Urol 2013; 189:200-3

Contemporary Literature Addressing Boston Scientific's Uphold LITE

NICHD SUPeR Study of Uphold LITE

https://augs.confex.com/augs/2018/meetingapp.cgi/Paper/2081

- Prospective randomized trial across 8 sites –175 subjects
  - Mesh Hysteropexy (Uphold LITE) versus Vaginal Hysterectomy + Apical NTR (USL)
- Minimum 36 months follow up
- Results:
  - **No difference** in composite success through 48 months
  - **Anterior wall support better** with Uphold LITE hysteropexy at 36 month
    - POP-Q Ba -1.2 (=Stage I) vs -0.7 (=Stage II); p=0.030
  - **No difference** in patient reports of pain, dyspareunia, sexual function
  - **Operative time less** with Uphold LITE: 111.4 min vs 156.7 min
  - Mesh exposure: Hysteropexy 8% None required surgery
  - Suture exposure (12 wks): Hysteropexy 3% vs VHx/USL 20%
  - Excessive granulation tissue: Hysteropexy 1% vs VHx/USL 11%

Uphold LITE provides durable long-term (3-year) success with uterine-sparing hysteropexy

Contemporary Literature Supporting Uphold LITE

- **Gutman et al. (2017) – 1-year** prospective multi-center parallel cohort study comparing vaginal (Uphold LITE) (VMHP) and laparoscopic sacrocolpopexy (LSHP) mesh hysteropexy
  - Total operating times significantly shorter for VMHP (112 min vs 239 min)
  - **No difference** in composite, anatomic, or symptomatic cure
  - Patient Satisfaction (per PGII) was **95%** in each group
  - Mesh exposure in both arms: **6.6%** (VMHP), **2.7%** (LSHP)

- **Rahkola et al. (2017) – 5-year** prospective multi-center single cohort study
  - Success defined as POP-Q stage ≤2 and no vaginal bulge symptoms
  - Objective Apical Success in **83.5%** Subjective QOL improvement in **78.8%**
  - Mesh exposure: **1.4%** (3 pts – no surgery needed)

Contemporary Literature Summary - Complications

- Most mesh exposure were clinically **MILD**
- Treated conservatively; No subsequent surgery needed

Study	# of Subjects	Follow-Up Duration	Anatomic Success	Exposure Rate
Uphold LITE				
Rahkola et al. 2017	207	60 months	83.5%	1.4%
Gutman et al. 2017	74	12 months	80%	6.6%
NICHD SUPeR Study 2018	175	36 months	aHR vs NTR 0.65*	8%
Lo et al. 2018	89	12 months	95.5%	0%
Xenform				
Goldstein 2010	45	12 months	88%	0%

*comparison of composite efficacy endpoint with NTR

Mesh exposure rates are lower for BSC's devices (0-8%) compared to FDA-reported data (11-18%) encompassing outdated mesh products

Contemporary Literature Summary - Clinical Benefits

Study	# of Subjects	Follow-Up Duration	Anatomic Success	Subjective Results
Uphold LITE				
Rahkola et al. 2017	207	60 months	83.5 %	91%
Gutman et al. 2017	74	12 months	80 %	95%
Lo et al. 2018	89	12 months	95.5 %	94.3%
NICHD SUPeR Study 2018	175	36 months	aHR 0.65 vs NTR*	
Xenform				
Goldstein 2010	45	12 months	88%	72%

*comparison of composite efficacy endpoint with NTR

Long-term durability consistently noted with anatomic success to 5 years!

QoL scores note clinical benefit (91-95%) based on validated questionnaires

Data Supporting Boston Scientific's Devices

Dr. Ronald Morton, Jr., MD, FACS
VP Clinical Sciences, Boston Scientific

522 Postmarket Surveillance Studies

- BSC is conducting prospective studies in response to 522 study orders
- Parallel cohort with comparison to traditional NTR
  - Uphold LITE: 225 subjects across 23 sites (35% academic and 65% private practice)
  - Xenform: 228 subjects across 19 sites (32% academic and 68% private practice)
  - NTR: 482 subjects from 36 sites and AUGS registry
- Follow-up at 2, 6, 12, 18, 24, and 36 months
- Study currently ongoing; patients to be followed out to 36 months
  - At FDA's request, PMAs based on pre-defined hypothesis testing at 12 months

522 Postmarket Surveillance Studies

- Study population
  - Broad diversity of women
    - Various stages of POP
    - Smokers, diabetics, estrogen use
    - Primary and secondary POP repair
    - Concomitant procedures without placement of additional mesh
  - Potential imbalance in patient baseline characteristics between treatment groups accounted for with propensity score stratification

Co-primary efficacy and safety endpoint

Primary endpoint

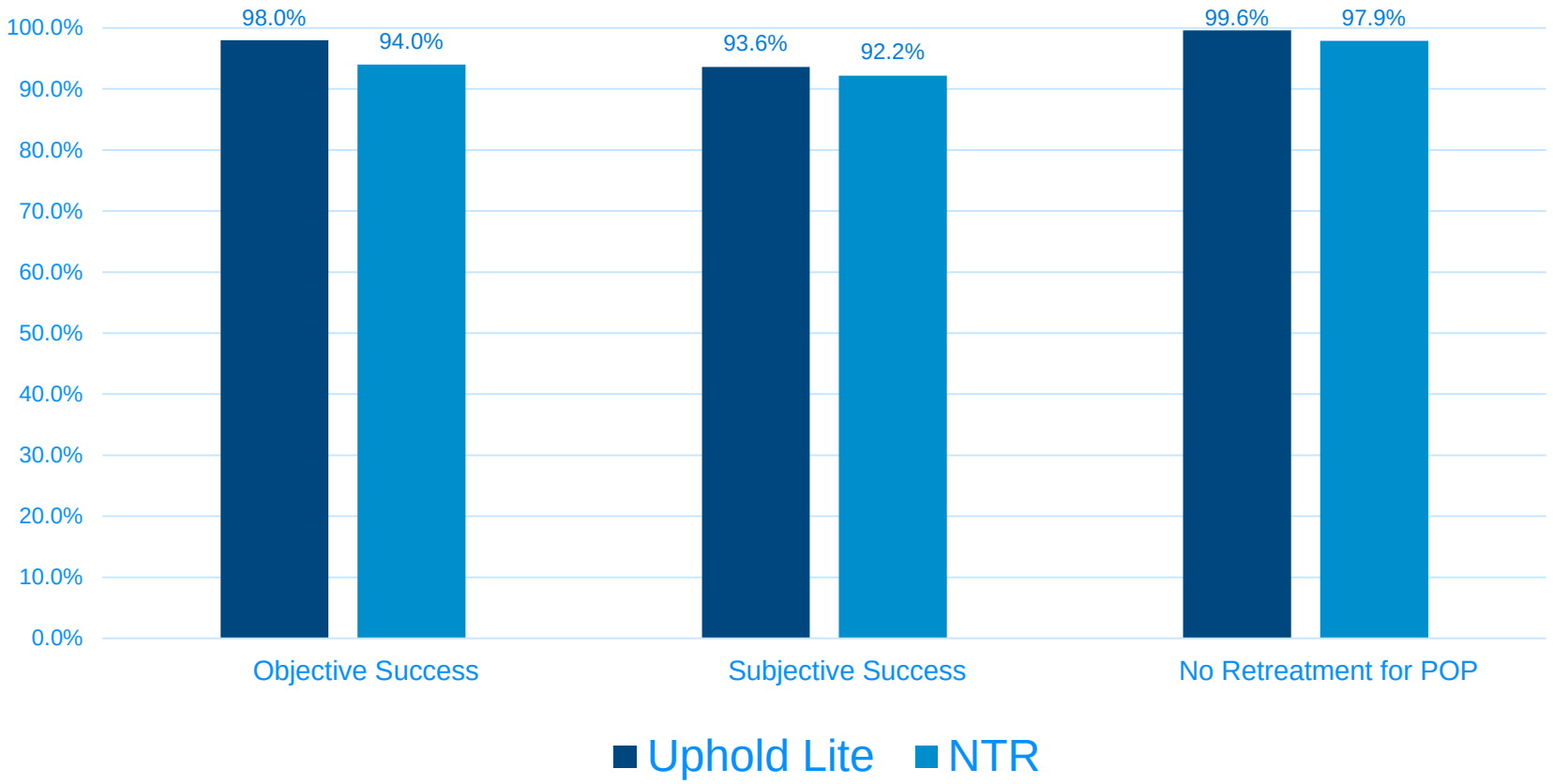
Efficacy	Objective Success	Leading edge of prolapse at or above the hymen in the operated compartment	Anterior: Leading edge of at or above the hymen or POP-Q point Ba ≤ 0
			Apical segment: Vaginal apex does not descend more than one-half into the vaginal canal (i.e., POP-Q point C < -1/2 TVL for multi-compartment prolapse or POP-Q point C ≤ 0 for single compartment apical prolapse)
	Subjective success	No symptoms of bulge or bulge not bothersome	
	No retreatment for POP	No surgery or pessary	
Safety	Serious device- and/or serious procedure-related AEs		

Secondary composite efficacy endpoint: Same except objective success is defined as leading edge of prolapse above the hymen in the operated compartment*

*Other secondary endpoints include pelvic specific AEs and QOL instruments

Uphold LITE Data

Uphold LITE
Components of Primary Endpoint -12 Months



- Objective success included very high rates of both anterior and apical success
  - Anterior compartment: 98.5% (Uphold LITE) vs. 93.5% (NTR)
  - Apical compartment: 98.0% for both Uphold LITE and NTR

Uphold LITE
Primary Efficacy Composite Endpoint -12 Months

	Treatment Success Uphold LITE	Treatment Success NTR	Propensity Score Adjusted Treatment Difference (TVM - NTR)	
			Estimate (90% CI)	P-value*
Multiple Imputation				
Intent-to-Treat	91.4% (206/225)	87.1% (420/482)	3.8% (-1.3%, 9.0%)	0.112
Per Protocol	91.3% (199/218)	87.0% (415/477)	3.4% (-1.9%, 8.8%)	0.147
Available Case Analysis				
Intent-to-Treat	91.6% (185/202)	87.3% (379/434)	3.4% (-1.9%, 8.8%)	0.146
Per Protocol	91.3% (179/196)	87.2% (376/431)	3.1% (-2.4%, 8.6%)	0.179

* Non-inferiority is met; p-value is for superiority test

Uphold LITE comparable to NTR across all analyses for composite efficacy endpoint comprised of (1) anatomic success, (2) subjective success, and (3) no retreatment for POP

Uphold LITE
Secondary Efficacy Composite Endpoint -12 Months

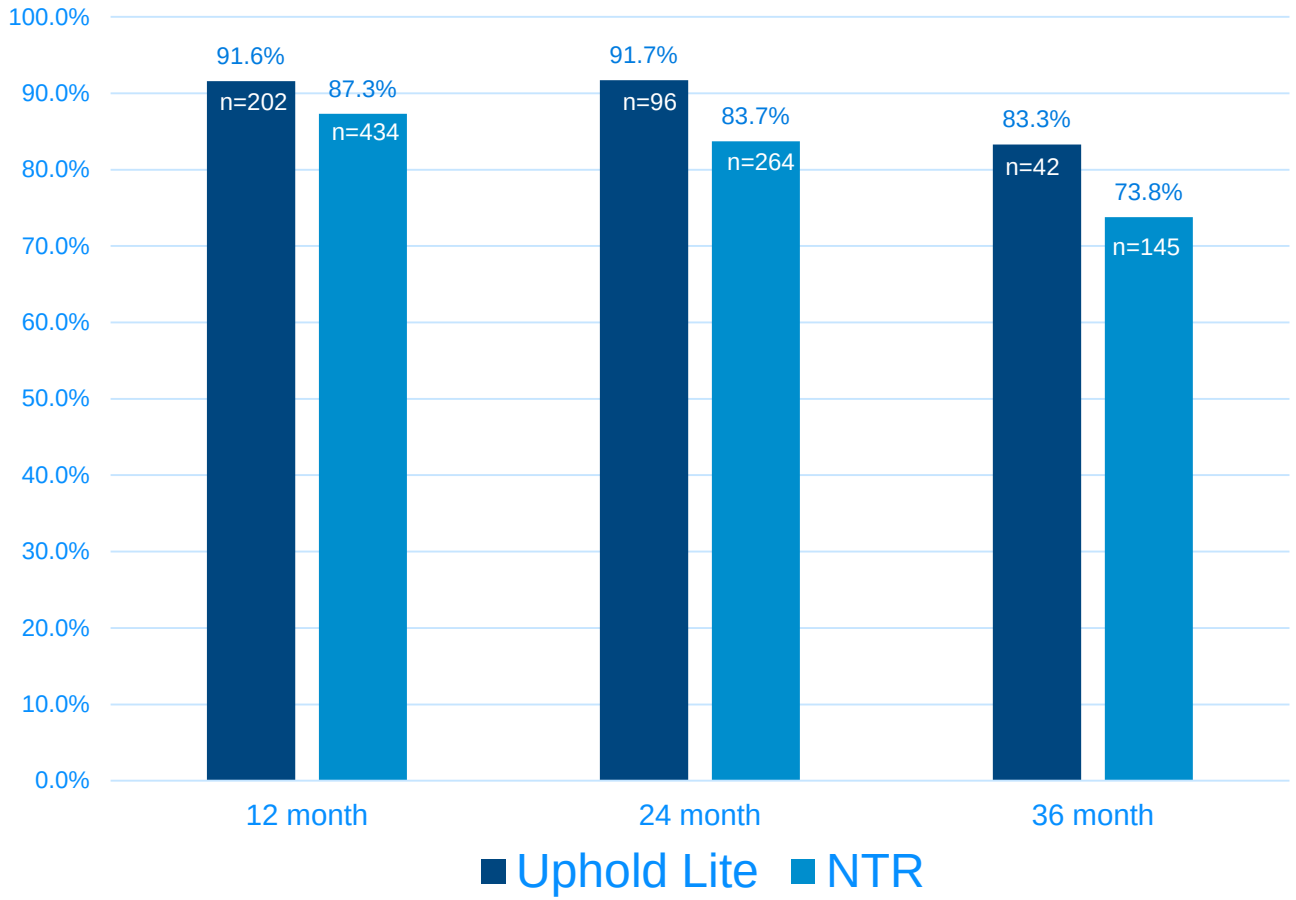
	Treatment Success Uphold LITE	Treatment Success NTR	Propensity Score Adjusted Treatment Difference (TVM - NTR)	
			Estimate (90% CI)	P-value*
Multiple Imputation				
Intent-to-Treat	85.8% (193/225)	78.4% (378/482)	9.5% (3.5%, 15.5%)	0.005
Per Protocol	85.3% (186/218)	78.2% (373/477)	8.9% (2.8%, 15.0%)	0.008
Available Case Analysis				
Intent-to-Treat	86.1% (174/202)	78.1% (339/434)	10.0% (3.9%, 16.1%)	0.004
Per Protocol	85.7% (168/196)	78.0% (336/431)	9.6% (3.3%, 15.8%)	0.006

*p-values for superiority test, not adjusted for multiplicity

Treatment success is higher in Uphold LITE compared to NTR for the composite secondary efficacy endpoint with more stringent assessment of anatomic success

Uphold LITE
Primary Efficacy Outcome Over Time

- Data available as of March 10, 2018; follow-up ongoing



Sustained benefits over time;
Available 36 month data shows potential benefit over NTR

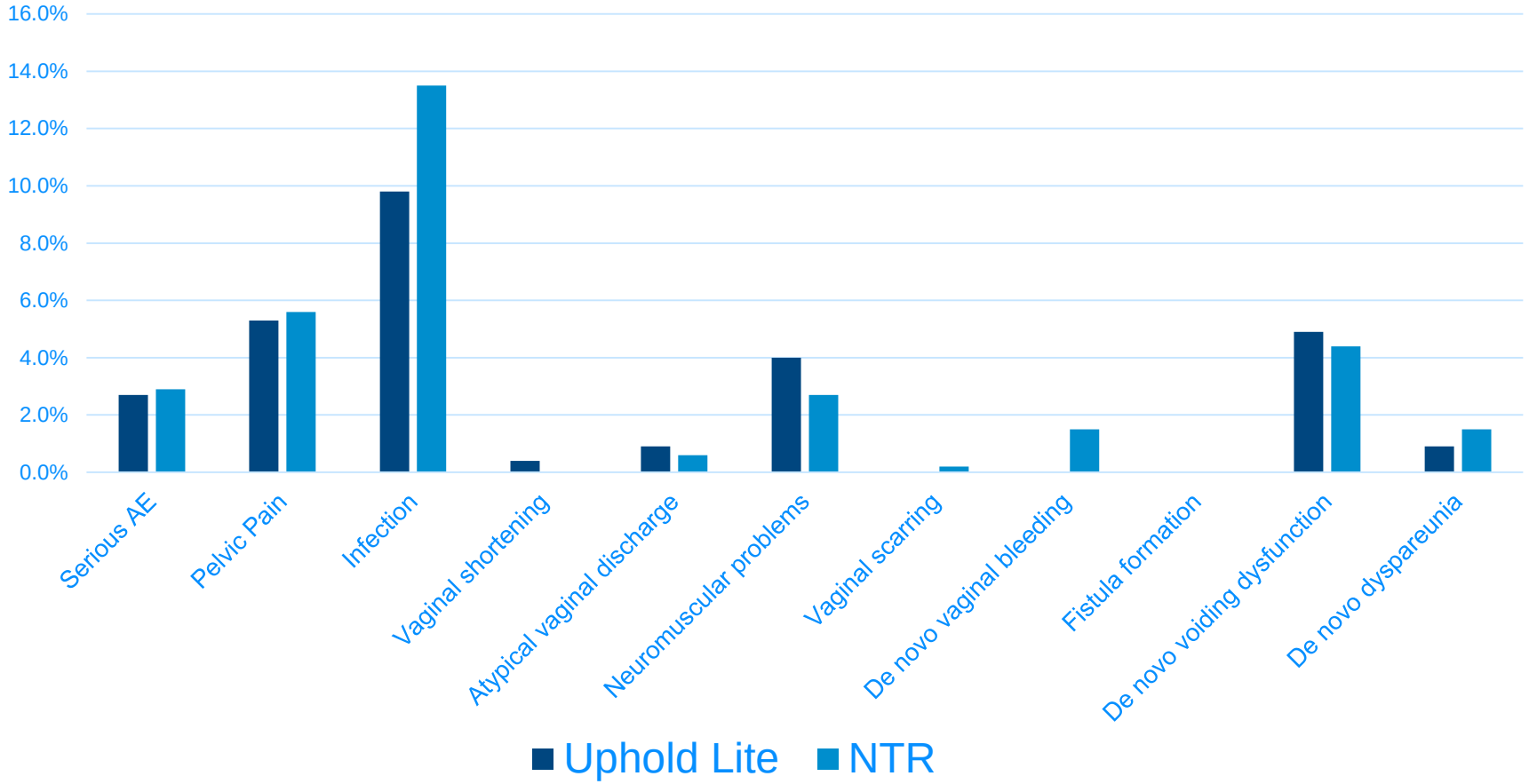
Uphold LITE
Quality of Life Outcomes – 12 Months

- Baseline pain scores were low and comparable improvements in TOMUS pain score were seen in both arms
- Significant improvements over baseline per the PFIQ-7 and PFDI-20 scores
- Significant improvement in PISQ-12 scores (sexual function)
- Most subjects reported feeling “much better” or “very much better” after surgery per PGI-I
- Stability of quality of life improvements out to 36 months shown in available data

Uphold LITE and NTR subjects reported comparable improvements in QoL metrics on validated scales at 12 months

Uphold LITE
Safety Results

- Comparable rate of SAEs to NTR at 12 months
- Comparable rate of overall AEs
- Comparable rate of pelvic floor specific AEs of interest



Uphold LITE
Safety Results - Mesh-Specific

- No reported visceral mesh erosions
- Mesh exposure documented in 4 subjects (1.8%) at 12 months
- Exposure documented in 9 subjects (11 events) within 36 months; 10 events fully resolved*
- Kaplan-Meier estimate at 36 months of mesh exposure is 6.2%

	Surgical Intervention	Office Procedure/Med	No Intervention
# Mesh Events	5	2	4
# Mesh Subjects	4	2	3

*This includes up to date safety information beyond the 12-month data included in PMA

Uphold LITE
Safety Results - Mesh-Specific

- Summary of exposure subject narratives
  - No mesh removals
  - 5 subjects taken to OR for trimming of mesh exposure
    - 1 ~ “dime size”
    - 4 ≤ 1cm required mild trimming
  - 2 subjects had <1cm exposure trimmed in office under local anesthesia
  - 3 resolved without intervention
  - 1 yet to resolve after 206 days duration, palpable but not visible on examination, managed conservatively

Mesh exposures were rare and predominately mild, without lasting sequelae

Xenform Data

Xenform
Primary Efficacy Composite Endpoint -12 Months

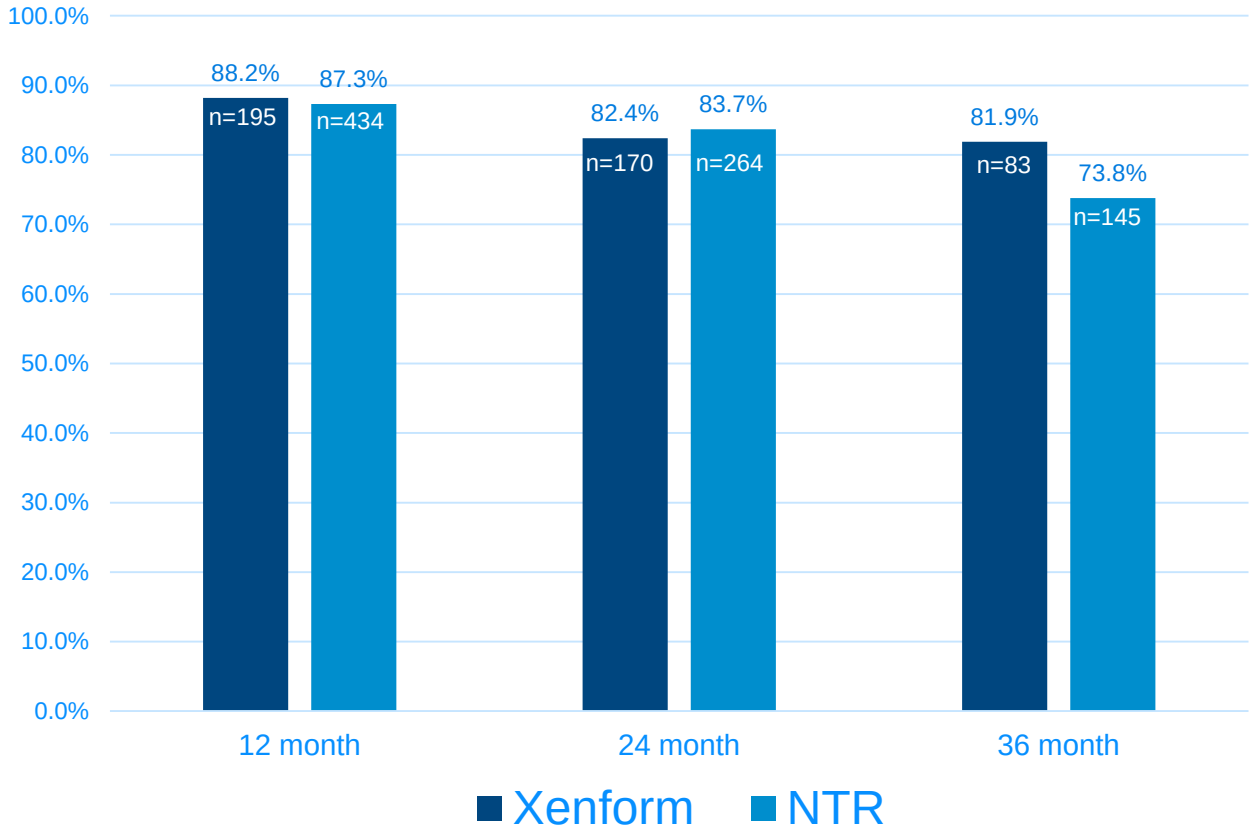
	Treatment Success Xenform	Treatment Success NTR	Propensity Score Adjusted Treatment Difference (TVM - NTR)	
			Estimate (90% CI)	P-value
Multiple Imputation				
Intent-to-Treat	88.9% (203/228)	87.0% (419/482)	0.6% (-4.5%, 5.6%)	0.427
Per Protocol	88.0% (187/213)	87.0% (415/477)	-0.1% (-5.1%, 4.9%)	0.515
Available Case Analysis				
Intent-to-Treat	88.2% (172/195)	87.3% (379/434)	-0.5% (-5.5%, 4.5%)	0.565
Per Protocol	87.4% (160/183)	87.2% (376/431)	-0.9% (-6.1%, 4.3%)	0.613

Xenform was non-inferior to NTR for this composite primary efficacy endpoint comprised of (1) anatomic success, (2) subjective success, and (3) no retreatment for POP

Also non-inferior for composite secondary efficacy endpoint

Xenform
Primary Efficacy Outcome Over Time

- Data available as of March 10, 2018; follow-up ongoing



Sustained benefits over time;
Available 36 month data shows potential benefit over NTR

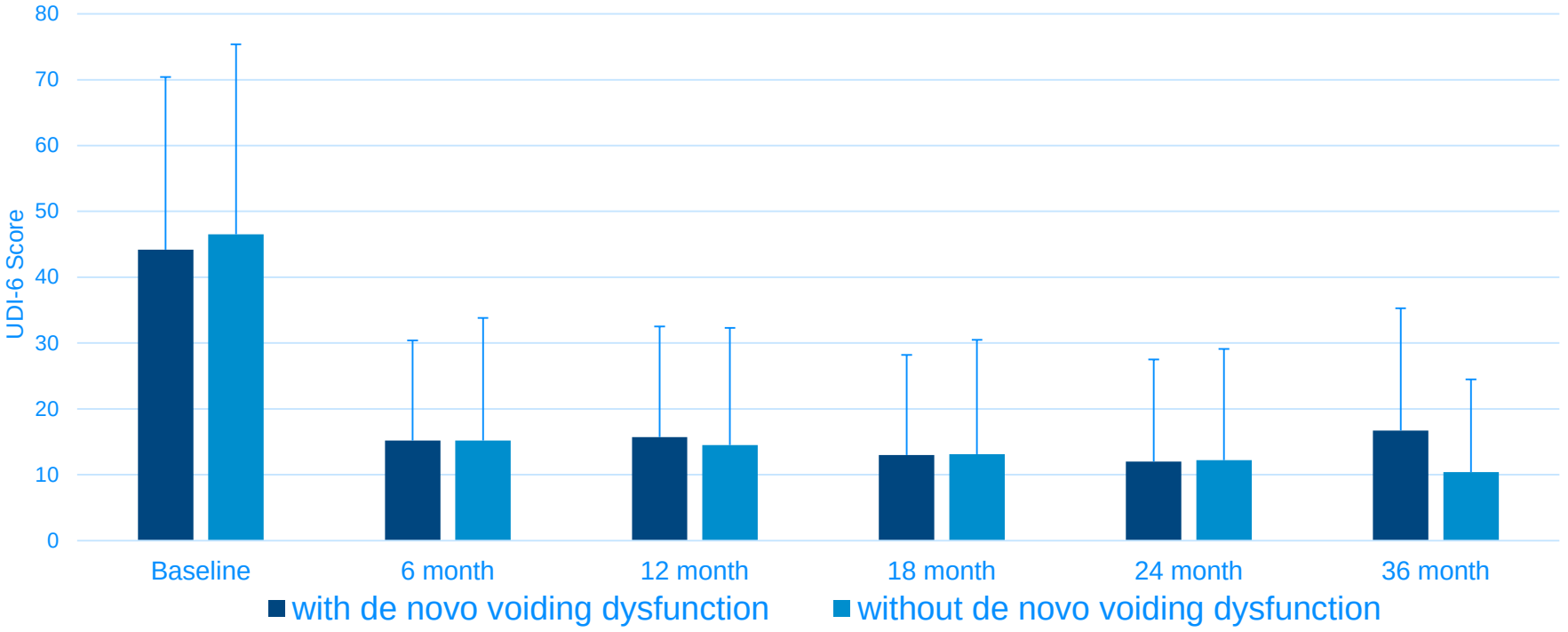
Xenform
Quality of Life Outcomes – 12 Months

- Baseline pain scores were low and comparable improvements in TOMUS pain score were seen in both arms
- Significant improvements over baseline per the PFIQ-7 and PFDI-20 scores
- Significant improvement in PISQ-12 scores (sexual function)
- Most subjects reported feeling “much better” or “very much better” after surgery per PGI-I
- These quality of life improvements showed stability out to 36 months for those subjects who reached that follow-up.

Xenform and NTR subjects reported comparable improvements in QoL metrics

Xenform
Safety Results

- Comparable rate of SAEs to NTR at 12 months
- No higher rate of pelvic floor specific complications except for post operative obstructive voiding symptoms (11% vs 3%)
  - Higher rates of de novo difficulty in emptying bladder; little impact on QoL per UDI-6 (Urinary Distress Inventory)



Xenform
Safety Results - Graft-Specific

- No reported visceral graft erosions
- Graft exposure documented in 2 cases (0.9%) at 12 months
  - Small incisional dehiscence
  - No additional exposures documented for patients out to 24 or 36 month follow-up
- Both graft exposures were mild in severity, did not require any surgical intervention and have fully resolved

Graft-related complications were rare, mild, and without lasting sequelae

Clinical Evidence Summary

- POP treatment with Uphold LITE and Xenform achieve a high rate of objective and subjective success
  - Non-inferior to NTR at 12 months on composite efficacy outcome
    - Objective success rates numerically higher for Uphold LITE compared to NTR
    - Uphold LITE demonstrates greater efficacy compared to NTR when success is defined as above the hymen
  - Quality of life improvements comparable to NTR at 12 months
  - Sustained benefits supported by literature and 522 study data out to 36 months
- Risks are comparable to NTR for overall and serious adverse events
  - Low rates of mesh exposures not leading to significant complications
  - Rates of surgical intervention for all complications: Uphold LITE 4.9%, Xenform 5.3%, NTR 6.6%

Subjects experienced equivalent results compared to NTR subjects at 12 months, without overall higher risk of complications

Training, Patient Selection, and Benefit/Risk of TVM

Dr. Miles Murphy

Board Certified, Obstetrics & Gynecology and Female Pelvic Medicine & Reconstructive Surgery

Partner and Associate Medical Director-The Institute for Female Pelvic Medicine & Reconstructive Surgery

Chief – Division of Urogynecology, Department of Obstetrics and Gynecology, Abington-Jefferson Health

Importance of Training and Experience

- Surgical technique for TVM improved over time
  - Surgeons must understand contemporary surgical technique, instructions for use, patient selection and response to complications
  - Training and surgeon experience critical to success of procedure
- FDA cited mesh exposure rates of 11-18% in the overall literature; in contrast Uphold LITE literature and 522 data shows 0-8%
  - Attributed to improved material properties, delivery system design, implantation techniques, and training
- Published recommendations from professional societies (i.e., AUGS) regarding the type of experience and training for surgeons performing TVM procedures[1]

Proper surgical technique, experience, and training have led to improved outcomes

[1]AUGS Guidelines Development Committee "Guidelines for providing privileges and credentials to physicians for transvaginal placement of mesh for pelvic organ prolapse" FPMRS 2012;18(4):194-7.

Patient Factors

- Patients should have a choice, shared decision making
- Therapy must always be specific to the patient's individual needs
  - Patient preferences
  - Preferred type of anesthesia
  - Severity and location of prolapse
- TVM mesh/graft may be the best options for specific populations of women:
  - Seeking uterine preservation
  - Previously failed NTR
  - Injury to the pelvic floor musculature, e.g., significant Levator Ani injury
  - Connective tissue disorders
  - High (III/IV) stage POP, especially anterior compartment defects
  - Higher risk for NTR failure
  - Medical or surgical issues compromising abdominal access

Availability of mesh is critical to optimizing the treatment of all patients

TVM Benefit / Risk

- Robust data exists in literature and clinical data to support the **safety** and **efficacy** of TVM devices
- Clinically significant improvements reflected in **anatomic** and **subjective** measures
  - Effective in restoring anatomical position; statistically superior results compared to NTR
  - Sustained benefits in both anatomic repair and quality of life
  - Multiple, independent systematic reviews/meta-analyses report not only superior anatomic, but also subjective outcomes (such as less symptoms of bulge) with anterior mesh as compared to NTR[1,2]
  - Re-operation rates for POP recurrence lower than NTR[1]
- Overall risks are comparable to other surgical treatment options
- Removal from the market would promote off-label use, de-standardize techniques, and decrease surveillance-impacting patient safety

[1] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J. Surgery for women with anterior compartment prolapse. Cochrane Database of Systematic Reviews 2016, Issue 11. Pg. 21.
[2] Schmiph MO, Abed H, Sanses T, et. al. Graft and Mesh Use in Transvaginal Prolapse Repair: A systematic Review. Obstet Gynecol 2016: 128:81-91

Benefit / Risk Summary

- Benefits established at 12 months for both anatomic and subjective success
  - Anatomic success, which may ultimately support superiority over long term
  - Clinically relevant improvements in subjective measures
- Safety profile at 12 months shows low rates of mesh-related complications, overall complication rate comparable to NTR
- Literature reports consistent outcomes
  - TVM for anterior prolapse shown to have lower rate of anatomic recurrence,[1,2] lower rate of recurrent symptoms of bulge/prolapse,[1,2] and lower reoperation for prolapse recurrence[1]
- BSC's devices present different benefit/risk profiles compared to historical mesh products attributed to design and improved surgical technique
- BSC's devices offer option of durable repair without increased risk compared to NTR
  - May be the most appropriate clinical option for certain populations

Clinicians require full scope of demonstrated therapeutic options such as Uphold LITE and Xenform

[1] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J. Surgery for women with anterior compartment prolapse. Cochrane Database of Systematic Reviews 2016, Issue 11. Pg. 21.

[2] Schmiph MO, Abed H, Sanses T, et. al. Graft and Mesh Use in Transvaginal Prolapse Repair: A systematic Review. Obstet Gynecol 2016: 128:81-91

BSC Conclusions

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VP Clinical Sciences, Boston Scientific

12 month Non-Inferiority Provides Sufficient Safety and Efficacy Information

- The 522 data shows clinical benefit at 12 months
- The trending data beyond 12 months shows potential for durable benefit without increased risk compared to NTR
- **Superiority** at 12 months for TVM compared to NTR was ***NOT*** **anticipated** and should ***NOT*** **be required** for assessment of benefit/risk
  - Comparable rate of overall complications experienced with BSC's devices compared to NTR
  - The majority of mesh related complications as reported in the 522 studies and contemporary literature are mild to moderate
  - The overall risk for TVM is not greater than NTR

- **Non-inferiority at 12 months appropriate because of comparable risk**

BSC-provided labeling and training

- Detailed labeling and training consistent with contemporary patient management for TVM POP repair
- Patient and physician labeling to help facilitate discussion of risks in clinical care decisions
- BSC has an extensive physician education and training program:
  - Performance characteristics of BSC's devices
  - Patient selection
  - Proper surgical technique for implantation
  - Management of complications
- Comprehensive and diverse training options:
  - Didactic lectures
  - Physician proctors
  - Physician preceptors
  - Training simulators
  - Cadaver labs (large and small group)

Training to contemporary surgical techniques offered by BSC is supplemental to residency and fellowship training programs

Conclusion

- Both Uphold LITE and Xenform represent viable clinical alternatives for the treatment of POP
- Our 522 studies and literature show:
  - Comparable clinical success for TVM compared NTR
  - Overall complication profile is comparable to NTR
  - Low rates of mesh-related AEs; generally mild and not requiring mesh excision
  - Rates of surgical intervention for all complications: Uphold LITE 4.9%, Xenform 5.3%, NTR 6.6%
- TVM may be the most appropriate clinical option for certain populations

Uphold LITE and Xenform present therapeutic options that should remain available to women in consultation with their physicians

Thank You