

Research studies at AUGM

"TVT-Secur in office sling procedure under local anesthesia: a prospective two year analysis" Khandwala S . -*Female Pelvic Medicine & Reconstructive Surgery* May 2012.

This study was conducted in an office setting entirely under local anesthesia in awake patients undergoing the sling procedure for urinary incontinence. The results were excellent and a complex subjective and objective score was assessed. Complications were minimal.

Experience with TVT-SECUR sling for stress urinary incontinence: a 141-case analysis. Khandwala S - *Int Urogynecol J Pelvic Floor Dysfunct* - 01-JUL-2010; 21(7): 767-72

This paper evaluated patients who underwent a minimally invasive sling procedure for urinary stress incontinence. Patients who had the sling procedure showed significant improvement in their symptoms and also noticed improvement in urge incontinence.

Medium-term clinical outcomes following trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh. Milani, A.L., Hinoul, P., Gauld, J., Jones, P., Reisenauer, C., Lobodasch, K., Cosson, M., Khandwala, S., Van Drie, D., Lucente, V. IUGA Abstract 2012.

This paper assessed the role of a special type of vaginal mesh -- partially absorbable-- for the management of uterovaginal prolapse. This was an international Clinical Trial with Investigators from the United States, United Kingdom, Germany and Italy.

The TVT Worldwide Observational Registry for Long-Term Data: A Prospective Evaluation of the Safety and Efficacy of 3 Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women. Tincello, D.G. , Botha, T. , Grier, D. , Jones, P. , Subramanian, D. , Urquhart, C. , Kirkemo, A. , Khandwala, S. - *The Journal of Urology* Dec 2011; pp 2310-2315 Vol 186(6).

This is a worldwide record of the different type of slings done for the management of stress urinary incontinence. the paper shows that the third generation slings pose the least problems and have satisfactory success.

Two Year Clinical Outcomes of a Trocar-Guided Transvaginal Mesh Repair Utilizing a New Light-Weight Synthetic Mesh. C Urquhart, P Hinoul, A Milani, C Reisenauer, M Cosson, V Lucente, Khandwala, S. *IUGA* 2011.

This paper follows patients for at least 2 years after undergoing a prolapse surgery. The success rate was very good with minimal complications.

Medium-term clinical outcomes following surgical repair for vaginal prolapse with a tension-free mesh and vaginal support device. Van Drie, D., Lim, J.L. , Hinoul, P. , Gauld, J. , Sayer, T.R. , Jones, P. , Franco, N. , Slack, M. , Khandwala, S. - *Female Pelvic Medicine & Reconstructive Surgery* - September/October 2011; 17(5) Supplement 2 and IUGA 2011.

This paper explores a newer mesh technique called the Prosima. The major advantage is the ease of placement of the mesh with good results. This was an International study.

Clinical outcomes of an observational registry utilizing a trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh

Khandwala, S., Lucente, V., Van Drie, D., Gauld, J., Hinoul, P. - *Female Pelvic Medicine & Reconstructive Surgery* - September/October 2011; 17(5) Supplement 2

This paper reviewed the initial analysis of vaginal reconstruction surgery with the Prolift + M system. The results are very encouraging and complications are limited.

A trocar-free procedure for vaginal prolapse repair using mesh and a vaginal support device – an observational registry. Khandwala, S., Slack, M., Hinoul, P., Urqhart, C., Al-Salihi, S. - *Female Pelvic Medicine & Reconstructive Surgery* - September/October 2011; 17(5) Supplement 2

Transvaginal Mesh surgery for Pelvic Organ Prolapse Prolift + M: A prospective Clinical trial
Khandwala S, Jayachandran C: *Int Urogynecol J Pelvic Floor Dysfunct* October 2011 1482-4

This was a 6 month prospective analysis of the Prolift + M system for the management of prolapse. There were minimal complications and the success was very high.

Investigator: Trocar guided mesh repair for vaginal prolapse using partially absorbable mesh: 1 year outcomes Milani, A. , Hinoul, P. , Gauld, J. , Sikirica, V. , Van Drie, D. , Cosson, M. , Khandwala, S. *Am J Obstet Gynecol.* Jan 2011; pp 74.e1-74.e8 vol 204(1).

One-year clinical outcomes after prolapsed surgery with nonanchored mesh and vaginal support device. Zyczynski, H. , Carey, M. , Smith, A. , Gauld, J. , Robinson, D. , Sikirica, V. , Reisenauer, C. , Slack, M. , Khandwala, S. *Am J Obstet Gynecol.* Dec 2010; pp 587.e1-587.e8 vol 203(6).

This is a 1 year postoperative follow up in patients who had the Prosima procedure. The results showed significant improvement in the prolapse and also minimal complications. The incidence of mesh exposures were low.

One year results from a worldwide registry of Tension free vaginal tapes in women with stress urinary incontinence. Khandwala S, Lucente V, Tincello et al: *Female Pelvic Medicine & Reconstructive Surgery* - September/October 2009; pp 261 vol 12(5)

This paper assessed the worldwide results of the mini sling procedure. The results showed significant improvement following the sling procedure with minimal complications.

Light weight mesh system for transvaginal mesh repair: Interim 3 month results: Lucente, Milani, Khandwala et al: *Female Pelvic Medicine & Reconstructive Surgery* - September/October 2009; pp 359 vol 12(5).

Clinical Experience of a novel vaginal support device and balloon used in a trocar-less vaginal approach of mesh placement for prolapse repair. : M Carey, H Zyczynski, Khandwala et al : *Female Pelvic Medicine & Reconstructive Surgery* - September/October 2009; pp 364 vol 12(5) .

National Institute of Health (NIH) Clinical studies performed at AUGM

A Randomized Trial of Urodynamic Tests Before Stress Incontinence Surgery. Nager, C., Brubaker, L., Litman, H., Zyczynski, H., Varner, R., et al. *The New England Journal of Medicine*. This paper assesses the role of urodynamic testing for patients with incontinence.

"Urinary Incontinence Treatment Network"-MIMOSA study- NIH-sponsored multicentric randomized clinical trial to compare medication and behavioral therapy versus surgery for mixed urinary incontinence

This study aimed to assess the impact of pelvic floor therapy versus medications on the management of overactive bladder conditions

- **BE-DRI (Behavior Enhances Drug Reduction of Incontinence)** This study investigated if the addition of behavioral treatment to drug therapy for the treatment of urge incontinence makes it possible to discontinue the drug and still maintain a reduced number of accidents.

Behavioral therapy to enable women with urge incontinence to discontinue drug treatment: a randomized trial. *Ann Intern Med*. 2008;149(3):161-9.

-ValUE study

The ValUE Study is designed to determine the appropriate amount of pre-surgical urinary testing that is necessary for a patient.

- **Anticholinergic versus Botulism toxin-a comparison trial for the treatment of urgency urinary incontinence: the ABC randomized trial** Visco AG, Brubaker L, Richter HE, Nygaard I, Paraiso MF, Menefee SA, Schaffer J, Lowder J, Khandwala SS, Sirls L, Spino C, Wallace D, Meikle S for the Pelvic Floor Disorders Network (NIH)

TOMUS (Trial Of Mid-Urethral Slings)

Trial of Midurethral Sling (TOMUS): A Randomized Controlled Trial of Retropubic versus Transobturator Midurethral sling for stress urinary incontinence *New Engl J of Medicine*.

2010 Jun 3;362(22):2066-76

Trial of Midurethral Sling (TOMUS): Design and Methodology *Journal of Applied Research* Vol 8, no 1, 2008.

The TOMUS trial is a randomized study comparing the retropubic sling to the transobturator sling for the management of stress urinary incontinence. This was a National Institute of Health study. The study was conducted by several centers across the country. The results showed that the trans-obturator system is comparable to the retropubic system. Stringent subjective and objective criteria were used to determine success following the surgical intervention. Complications with both the procedures were minimal and comparable.

Ongoing Clinical Trials at AUGM

- **Follow up on patients with the suburethral mini sling procedure for urinary incontinence -- a long term follow up**

This study reviews all the patients who have had the third generation sling procedure and reviews the complications, success and failures.

- **Role of Interstim for the management of fecal incontinence**

This paper assesses the subjective success of the Interstim procedure in patients suffering from fecal incontinence.

- **Is hysterectomy necessary for the management of uterovaginal prolapse? The role of uterine preservation – a retrospective analysis of 126 cases**

This study looks at the ability to preserve the uterus at prolapse surgery. Patients with prolapse of the cervix greater than stage II were considered for the study.

- **A comparison of in office and operating room sling procedure for the management of urinary incontinence**

This study looks to see if there are any risks or differences in doing the procedure in the office as compared to the operating room.

- **Long term follow up of vaginal reconstructive surgery for uterovaginal prolapse -- reviewing the role of Prolift + M surgery**

Patients who underwent Prolift + m surgery for prolapse and were at least 12 months out are considered for the outcome analysis.

- **Pelvic floor therapy for the management of incontinence**

Patients who underwent pelvic floor therapy for incontinence management are surveyed by way of validated questionnaires prior to and after the intervention.