EFFECTS OF CHRONIC PELVIC PAIN, SECONDARY TO VAGINAL MESH PLACEMENT INCLUDING TRANS-VAGINAL TRANS-OBTURATOR (TVT-O) MESH AND MONARC TRANS-OBTURATOR TAPE (TOT) MESH

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Abstract

Extreme controversy surrounds the uncertainty of pelvic mesh and sling devices to essentially cure patients of stress urinary incontinence (SUI). A relatively new product that has taken the market by storm is the tension free Vaginal Tape- Obturator (TVT-O) mesh by Ethicon, Gynecare. It has obtained Center for Disease Control approval and labeled a “clinically proven, safe product with a 90% cure rate for urinary incontinence,” according to the manufactures website (Ethicon, Gynecare)[4, 8]. One side effect that is known about this particular device is its ability to leave patients post surgery with unbearable, chronic pelvic pain[2]. Although the mesh is needed to prevent urinary incontinence, it is pivotal that the quality of life of our patients does not suffer appreciably with elective, non-life threatening procedures. Another common mesh product is the pelvic sling by Monarc. One-study reports more than 95 percent of patients who underwent elective surgery with the insertion of Monarc sling achieved complete dryness and did not require the use of pads following the procedure[22]. These are successful outcomes, but what occurs with the minority of patients that have unfavorable outcomes such as chronic pain[12, 15, 16]? A retrospective study was completed to deduce the onset of pain and severity of pain caused by the TVT-O mesh and Monarc mesh-utilizing data from Dr. Hibner’s patients. There were 19 chronic pelvic pain patients with an average age of 50, standard deviation of 11 years, seen by Dr. Hibner and his colleagues. These patients completed the International Pelvic Pain assessment form upon their first visit to the office and SF-36 scores of physical and mental scores were obtained. Results found physical scores of 29.5 and mental scores of 36 in pelvic pain patients, which were higher than certain other chronic, medical diseases[1]. We were able to conclude that patients with pelvic pain from mesh have lower physical and mental SF-36 scores than patients with other chronic diseases representing a decreased quality of life overall.

Table Of Contents:

Table of Figures:

Introduction

Pelvic mesh is a topic of discussion heard around every practice utilizing these products. What is the true efficacy of mesh, does it improve the quality of life for patients that elect to undergo procedures of installment? Previous literature suggests that many different types of mesh are the root cause of chronic pelvic pain[12, 15, 16]. Upwards of 30% of patients that under mesh placement have been found to develop pelvic pain[10]. With almost 1/3 of patients sustaining injury or chronic pain from mesh, it is pivotal that we in the medical community take action in researching why this is a frequent occurrence. The Food and Drug Administration (FDA) has posted a warning in July of 2011 about TVT-O mesh and other such products stating that these is a risk of "severe pain involved as well as erosion of the mesh," that can cause serious harm to patients and require multiple surgical procedures to remedy the effects[7]. It is also important to give accurate information to patients who are thinking of undergoing pelvic mesh surgery, so they can make informed decisions on accurate adverse reaction, percentages and data.

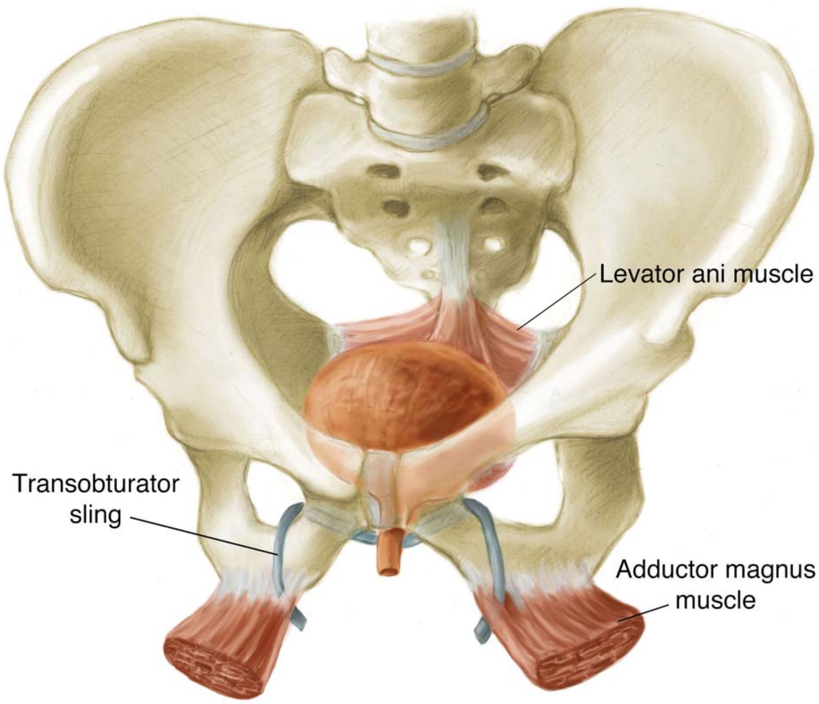

Figure 1: Pelvic anatomy with transobturator suburethral sling

The stress and embarrassment women suffering from stress urinary incontinence is in itself an issue that should be addressed. In one study, it reported that 87% of female patients that underwent TVT-O mesh placement were indeed cured of their urinary incontinence, with only a 7% failure rate. However, the study also reported that TVT-O mesh placement was accompanied with higher complications[20]. For a surgery that is non-life threatening and not emergent, products such at TVT-O, carry higher risks of adverse side effects. Other studies have also reported utilizing other mesh products on the market, such as SIMS Ajust, is just as successful in curing SUI, but with lessened hospital stays, shorter recovery period and less severe post operative pain with a faster return to work[19, 20]. If other mesh products have been proven to provide similar outcomes, but with less side effects, why is TVT-O still utilized?

Another mesh product by AMS is the Monarc trans obturator tape (TOT) mesh, and is a contender for causing chronic pelvic pain and side effects such as erosion in patients. The data currently published on this product report high success rates upwards of 95% for curing stress incontinence[8]. However, the studies don't focus on the subset of patients that do not receive relief from the mesh and actually report poor prognosis and multiple complications such as erosion, or chronic pain. Our study will aim to look at the minority of patients that indeed suffer from chronic pain after mesh placement, as it is important to recognize patterns, if any, in the subset of patients who respond poorly to these products.

Research Question

1. **To determine the efficacy of TVT-O mesh vs. Monarch mesh for bladder SUI patients by reviewing their 2008 International Pelvic Pain Society history and physical sheet, and correlating severity and onset of pain post surgical procedure.**

We will be utilizing the data provided by each patient during the first visit to Dr. Hibners' office directly obtained from the 2008 International Pelvic Pain Society form. This includes an elaborate eleven-page history and physical evaluation, provided by the International Pelvic Pain Society assessment questionnaire[13] (Document 1 Link in Appendix). The data collected on this survey includes the quality, severity, onset, if the pain alters daily living and other such questions important to the quality of life of the patient.

<u>Hypothesis:</u> We hope to see correlation in decreased pain status post mesh removal in both the TVT-O and Monarc mesh groups. We also hope to observe a trend in positive outcomes after mesh removal, including greater satisfaction in daily living tasks and other such markers.

2. **Determine if there is a subset of patients with common histories or backgrounds that do not respond well to TVT-O mesh or Monarch mesh and therefore, should not qualify as prime candidates for this elective procedure.**

We will be looking at past medical, surgical and social history, including ethnicity and age, to determine if there is a correlation between chronic pain caused by these separate mesh products and their efficacies in certain populations of patients. This will extend the recommendations of this product to decrease the likelihood of side effects, such as chronic pelvic pain.

Hypothesis: Although our sample size is not large, we hope to see correlations in patients who experience pain and seek surgical removal. Between prior abdominal surgeries, ethnicity, age or risk factors (i.e. diabetes, obesity, etc.) we expect to see higher correlations with increased severity of pain, in comparison to those in good health with only mesh insertion surgery.

Methods

1. Study Population and Study Design

Data was collected via a retrospective chart review from Dr. Hibners' practice at Saint Josephs Medical Center in Phoenix, Arizona. It has been standard practice for several years that new patients to the office completed two pre-operative questionnaires in clinic prior to their initial consultation. These two forms included the International Pelvic Pain Society (IPPS) Questionnaire and an SF-36 Questionnaire[13]. These forms were uploaded to the electronic medical record and retrieved for this study. Each questionnaire was reviewed for completeness and if questions were left blank, the patients were not included in the study population. This information was collected and compiled within an Excel document.

After this population had undergone surgery, patients were asked to complete a follow up SF-36 questionnaire post operatively, to deduce if symptoms improved or resolved. Again, these forms were reviewed and only those patients with complete forms were a part of the study population. Once our patient population was established, and scores were gathered, patients were de-identified and the data was kept within an encrypted Excel file on the Saint Josephs network drive. Each patient's SF-36 score was calculated to reach both a physical and mental quality of life score. After completing the medical record review, these SF-36 scores were compared to other published, chronic medical diseases[1]. For the SF-36 scores, both the physical and mental quality of life scores were identified.

Utilizing a published article from Alonso et al, we compared our patient population SF-36 scores with other chronic, medical conditions. Both the physical and mental scores were taken into account and direct analysis was completed between these two groups. There were a total of 19 patients that qualified for this study based on the mesh that was removed, and the completeness of each questionnaire.

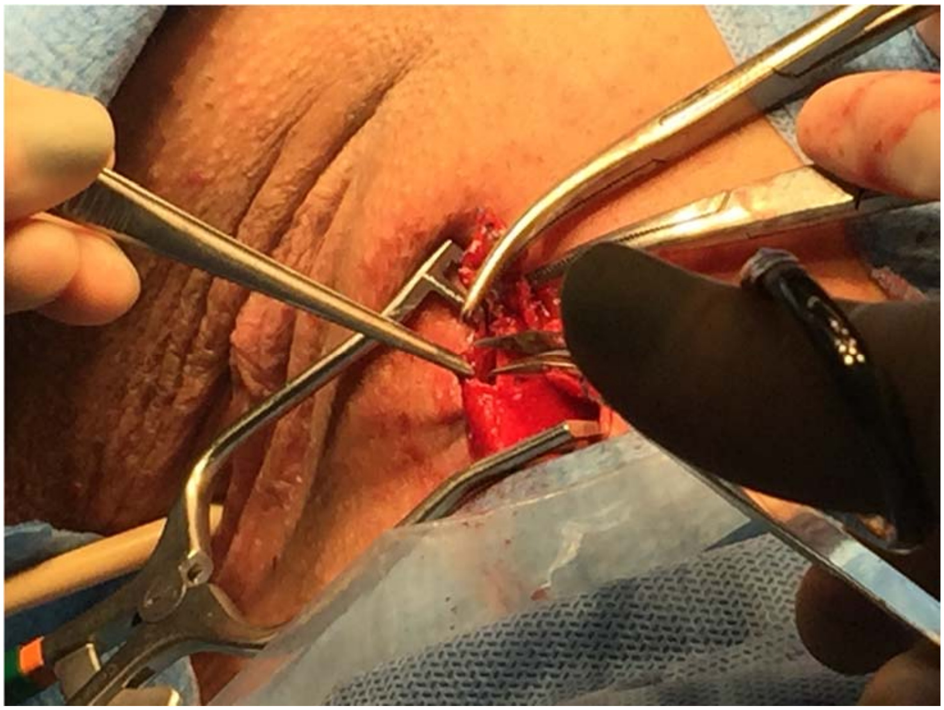

Figure 2: Groin incision for dissection to explant TVT-O mesh

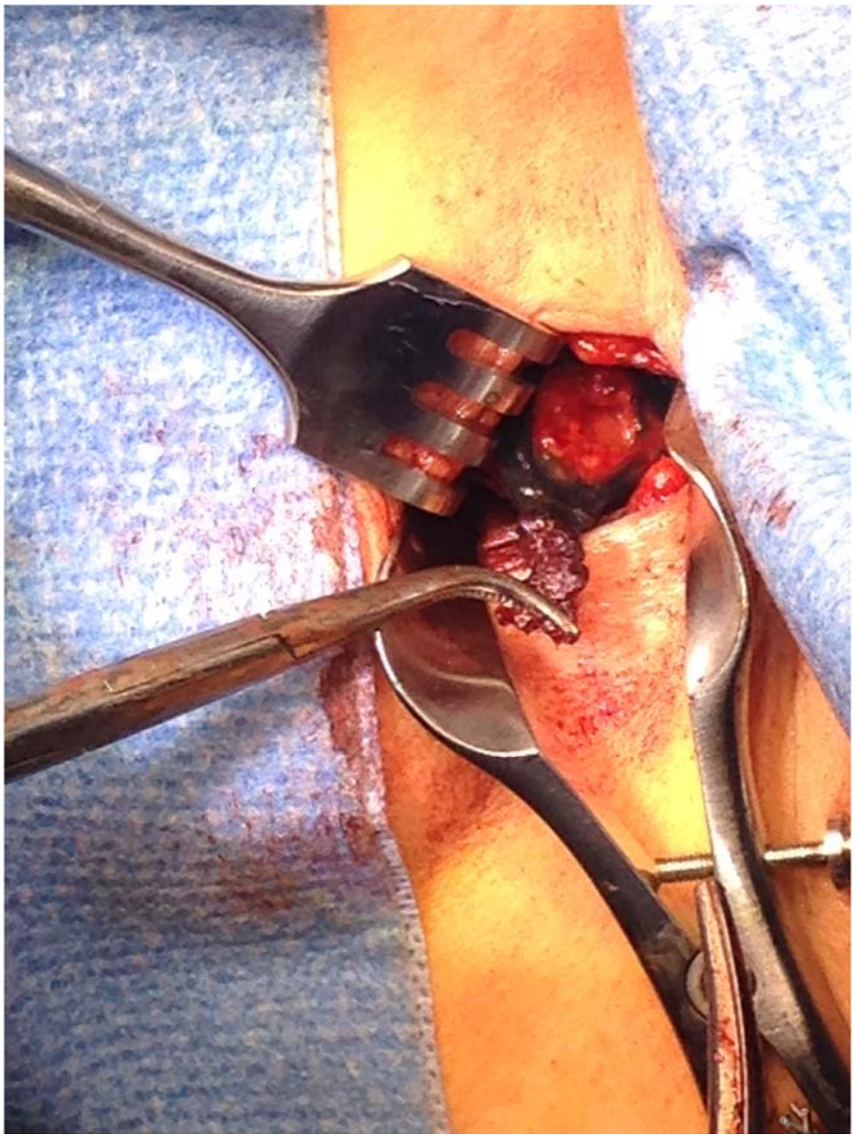

Figure 3: Mesh explant – groin region

2. Statistical Analysis

Consent was obtained during the first visit to Dr. Hibner's practice and is on file. First and foremost, the patients' identifying history was de-identified using a numerical system for confidentiality (Patient 1, Patient 2 etc.). All identifiable information utilized in our statistical analysis was kept in an Excel Spreadsheet and saved on Saint Joseph's network drive.

It was anticipated that we would complete statistical analysis on our data vs. other published SF-36 scores, however, we were unable to obtain the raw data from other studies, and therefore could not complete statistical analysis. For our analysis we directly compared our patients' SF-36 physical and mental quality of life scores to other chronic disease SF-36 scores.

3. Complications

We found that obtaining raw data for our statistical analysis from other prior published articles was difficult. This limited the analysis that we could complete. It was also difficult because there were quite a few patients that did not fully complete their SF-36 forms and IPPS forms, so they were excluded from the study. This decreased our total number of patients for our study.

Results

The patient population was compiled of 19 females average age of 50 years old with a standard deviation of 11 years. All patients were considered if they had placement of a TVT-O or Monarch mesh, and no clinically distinguishing factors were noted between these two products. Baseline symptoms these patients experiences were chronic, lower pelvic pain, dyspareunia and discomfort with daily activities.

Patients with pain resulting from transobturator synthetic suburetheral slings scored 29.5 on the physical component and 36.0 on the mental component of the SF-36 questionnaire. The median age for our population was 50 years old. There were eight patients that reported their pain was completed resolved after mesh removal, seven reported improved pain symptoms, two reported unchanged and two were lost to follow up.

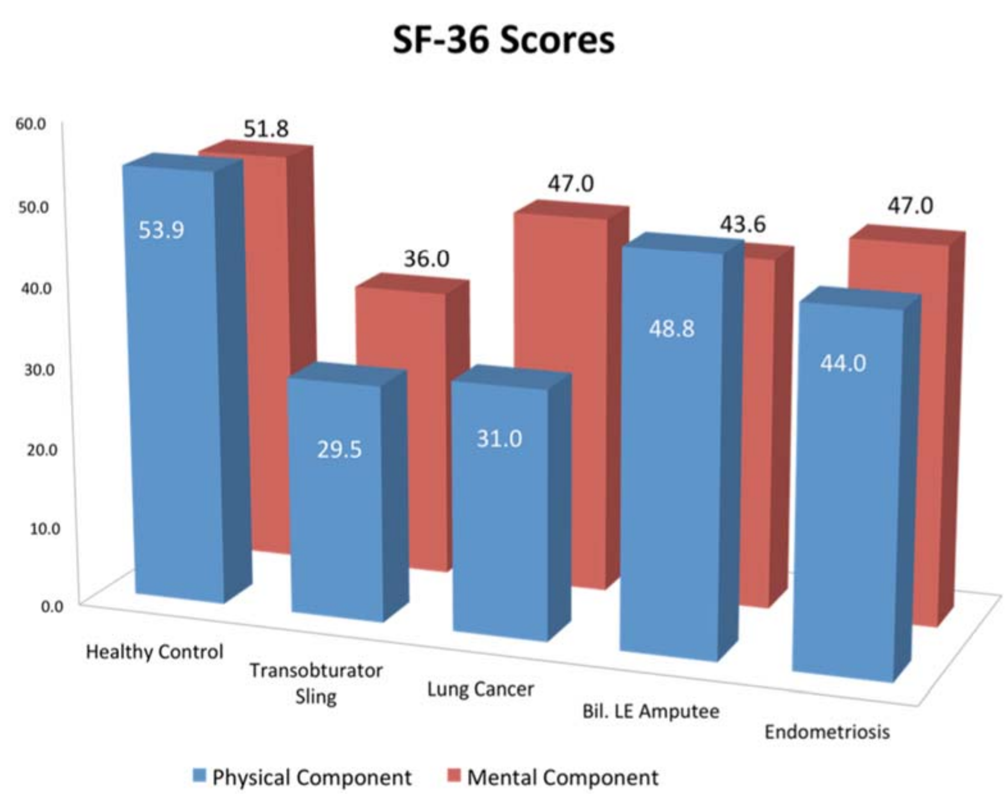

Figure 4: Physical and mental SF-36 scores for healthy controls vs. patients with mesh pain and patients with serious chronic medical conditions[1]. SF-36 scores for mesh patients had physical component score of 29.5 and a mental component score of 36. These scores were much lower, indicative of severe debilitation both physically and mentally in comparison to healthy controls. It was also noted that other chronic medical conditions, including endometriosis patients, had higher SF-36 scores vs. mesh patients indicating that these patients have a higher quality of physical and mental health in regards to their diagnosis.

	Years
Average Patient Age	**50**
Standard Deviation (Age)	**11**

Figure 5: Table representing the average patient age and standard deviation of age within all 19 patients included in this study.

Discussion

If you turn on the television today, you are guaranteed to find legal ads flooding the circuits in regards to chronic pelvic pain, secondary to placement of pelvic mesh. This topic is controversial and at the forefront of gynecological surgery. It has been found that chronic pelvic pain, secondary to pelvic mesh effects upwards of 30% of patients that undergo pelvic mesh placement[10]. This 30% result indicates that the mesh has high risk of adverse reaction, and may result in lowering the quality of life for patients.

From the data it is clear that patients with chronic pelvic pain experience severe disability. Their SF-36 scores are lower than patients with other chronic serious medical conditions. Not only is the physical pain severe, but the mental disability that accompanies their pain is also severe. Chronic pelvic pain patients have notably lower SF-36 scores when compared to lung cancer, bilateral lower amputee and endometriosis patients. This study shows that pelvic pain is indeed a serious disability in this population and should be treated as such. It should also serve as warning of potential serious complications of mesh to patients and physicians.

Conclusions

From the data it is clear that patients with chronic pelvic pain experience severe disability. Their SF-36 scores are lower than patients with other chronic serious medical conditions. Not only is the physical pain severe, but the mental disability that accompanies their pain is also severe. Chronic pelvic pain patients have notably lower SF-36 scores when compared to lung cancer, bilateral lower amputee and endometriosis patients. This study shows that pelvic pain is indeed a serious disability and this population should be treated as such. Focusing on not only the physical aspect of pain, but ensuring to support the mental affliction that also accompanies. It should also serve as warning of potential serious complications of mesh to patients and physicians.

Future Direction

Through this research many different avenues can be pursued to explore the effects of pelvic mesh. It is clear from the data that certain patients do not tolerate mesh, and decreases their quality of life both physically and mentally. It is important to attempt to identify these patients to exclude them as surgical candidates for this procedure. The second leg of this project will expand the data to include patients that have recently been seen for mesh explant in the pelvic pain office. This will expand the data and increase the number of patients within this study.

Appendix

<u>Document 1 Link</u>*: International Pelvic Pain Society pelvic pain assessment form (The International Pelvic Pain Society, 2014)*

http://pelvicpain.org/docs/resources/forms/history-and-physical-form-english.aspx

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