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Changes in Prolapse Surgery Trends Relative to FDA Notifications Regarding Vaginal Mesh

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Abstract

Introduction and Hypothesis—In 2008 and 2011, the FDA released notifications regarding vaginal mesh. In describing prolapse surgery trends over time, we predicted vaginal mesh use would decrease and native-tissue repairs would increase.

Methods—Operative reports were reviewed for all prolapse repairs from 2008–2011 at our large regional hospital system. The number of each type of prolapse repair was determined per quarter

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year and expressed as a percentage of all repairs. Surgical trends were examined focusing on changes with respect to the release of 2 FDA notifications. We used linear regression to analyze surgical trends and Chi-square for demographic comparisons.

Results—1211 women underwent 1385 prolapse procedures. Mean age was 64+12 and 70% had stage III prolapse. Vaginal mesh procedures declined over time (p=0.001), comprising 27% of repairs in early 2008, 15% at the 1st FDA notification, 5% by the 2nd FDA notification, and 2% at the end of 2011. The percentage of native-tissue anterior/posterior repairs (p<0.001) and apical suspensions (p=0.007) increased, while colpocleisis remained constant (p=0.475). Despite an overall decrease in open sacral colpopexies (p<0.001), an initial increase was seen around the 1st FDA notification. We adopted laparoscopic/robotic techniques around this time, and the percentage of minimally invasive sacral colpopexies steadily increased thereafter (p<0.001). All sacral colpopexies combined as a group declined over time (p=0.011).

Conclusions—Surgical treatment of prolapse continues to evolve. Over a 4-year period encompassing 2 FDA notifications regarding vaginal mesh and the introduction of laparoscopic/robotic techniques, we performed fewer vaginal mesh procedures and more native-tissue repairs and minimally invasive sacral colpopexies.

Keywords

FDA Public Health Notification; FDA Safety Communication; Pelvic organ prolapse; Prolapse repair; Prolapse surgery trends; Surgical trends; Vaginal mesh

Introduction

Surgical techniques to treat female pelvic organ prolapse have changed drastically due to emerging technologies and techniques. Historically, surgeons have relied on patients' native tissue through vaginal reconstructive procedures such as the anterior and/or posterior colporrhaphy and apical suspension, including uterosacral ligament suspension and sacrospinous ligament suspension. All were performed both with and without hysterectomy. Due to high rates of prolapse recurrence with native-tissue repairs, the sacral colpopexy introduced mesh graft material to attach the vagina to the anterior sacrum in 1962.[1] However, higher success rates were tempered by longer operative times and slower return to normal activity with a laparotomy.[2] In an effort to merge the benefits of both techniques, surgical mesh was applied from a vaginal approach in the 1990's with the first product specific to pelvic organ prolapse repair approved by the Food and Drug Administration (FDA) in 2002. [3]

Vaginal mesh saw a sudden and drastic increase soon thereafter. The cases performed in the United States almost tripled between 2005 and 2010 and vaginal placement of mesh comprised 74.9% of the 60,152 mesh-augmented prolapse repairs during that time period.[4] Unfortunately vaginal mesh was not the panacea originally thought with a recent systematic review demonstrating complications such as erosion (10.3%), wound granulation (7.8%) and dyspareunia (9.1%).[5] More recent reports suggest exposure rates may be even higher.[6] These complications appear more frequently with vaginal than abdominal mesh and prompted 2 FDA notifications regarding vaginal mesh use in 2008 and 2011.[7,8] Current

recommendations in 2011 from the American College of Obstetricians and Gynecologists and the American Urogynecologic Society state that vaginal mesh should be reserved for high risk individuals after a thorough informed consent process.[9] Likewise, the International Urogynecological Association has published guidelines on patient selection and informed consent when placing vaginal mesh.[10,11] Other techniques have simultaneously evolved to make abdominal mesh placement less invasive including laparoscopic and robotic sacral colpopexy. Compared to abdominal sacral colpopexy, laparoscopy has longer OR times but less blood loss and shorter length of hospital stay.[12] Minimally invasive sacral colpopexies have been adopted more slowly because they require special equipment and are technically more challenging. The abdominal approach was almost 3.5 times more common in 2005, but by 2009 robotic and laparoscopic sacral colpopexies had surpassed this approach in frequency.[4] A final category of prolapse repair is obliterative, including total colpectomy and LeFort colpocleisis. These repairs result in superior anatomic results compared to the reconstructive procedures described above and yield 95% patient satisfaction.[13] They are reserved for women who will no longer pursue penetrating vaginal intercourse after surgery. The technique, surgical outcomes, and appropriate patient population have changed little since their description over a century ago.[14]

Our goal was to describe the trends in surgical approach for female pelvic organ prolapse at our large regional hospital system. We specifically describe this evolution as it pertains to the release of 2 separate FDA notifications regarding vaginal mesh and the simultaneous introduction of both laparoscopic and robotic techniques. We hypothesize that the following will occur as a result of these events:

1. Native tissue repairs will increase due to patient and/or physician reaction to the FDA notifications despite the specific focus of the notifications on vaginal mesh and not all mesh-augmented prolapse repairs.
2. Colpocleisis will remain constant as it is a specific subset of the population with excellent outcomes despite no recent technique innovations.
3. Vaginal mesh placement and open abdominal sacral colpopexies will decline while laparoscopic and robotic sacral colpopexies will increase.
4. Overall, total sacral colpopexies (open, laparoscopic, and robotic combined) will decline as women and surgeons are less likely to select a mesh-augmented repair.

Materials and Methods

We conducted a retrospective study examining all prolapse repairs performed by Urogynecologists at the University of Pittsburgh Medical Center from January 2008 through December 2011. The research plan was approved by the University of Pittsburgh Institutional Review Board. We identified all patients who underwent prolapse repairs by one of 7 staff Urogynecologists through use of the division's surgical calendar. Operative reports were reviewed to confirm the date of surgery and to determine the exact surgical procedures that were performed. Data collection was performed by physicians in order to ensure accurate recording of the surgical procedures. Current Procedural Terminology

(CPT) codes were not used because this coding scheme does not capture all of the distinct prolapse repairs that were performed and because individual chart review is more accurate. De-identified patient demographic information was also recorded including age, race, body mass index (BMI), prolapse stage prior to surgery, and smoking history.

For data analysis, prolapse procedures were grouped by type. Native-tissue apical suspensions included uterosacral ligament vaginal vault suspensions (through vaginal, open, laparoscopic, and robotic approaches) and vaginal sacrospinous ligament fixations. Anterior and posterior repairs (colporrhaphies) were grouped together as single-compartment non-apical native-tissue repairs. The vaginal mesh category included a variety of vaginal mesh kits including Gynecare Prolift™ and Prosima™ (Gynecare, Somerville, NJ) and Boston Scientific Uphold™ and Pinnacle™ (Boston Scientific, Natick, MA). Minimally invasive sacral colpopexies (laparoscopic and robotic approaches) were grouped together. Open sacral colpopexies were considered separately, and colpocleisis procedures, including total colpectomy and LeFort, were also a separate category.

The number of each type of prolapse repair was determined per quarter year and then expressed as a percentage of all prolapse repairs performed in that quarter. Concurrent prolapse procedures during the same surgical case were treated independently, since the purpose of this project was to identify trends in individual prolapse procedures. We anticipated that a small number of women would undergo repeat prolapse repair during the data collection time period. Because we expected this number to be insignificant, these cases were treated independently in the analysis. Surgical trends were examined over time focusing on changes with respect to the release of the FDA notifications regarding vaginal mesh in October 2008 and July 2011. Linear regression was used to analyze surgical trends.

For the demographic analysis, women who underwent 2 types of prolapse procedures at the time of their surgery (primary prolapse procedure plus anterior and/or posterior repair), were included in the group of their primary prolapse repair. For example, a subject who underwent a native tissue apical suspension and an anterior repair was only considered as part of the apical suspension group for the demographic analysis. This was done in order to avoid double-counting subjects. BMI categories for the demographic analysis were based on the World Health Organization classification. Age was broken down as follows: ≤ 49 years-old, 50–59 years-old, 60–69 years-old, 70–79 years-old, and ≥ 80 years old. These categories were chosen based on the age distribution of the patient population. Smoking history was classified as current, never, or prior. Chi-square test was used to analyze demographic factors.

Results

1301 surgical cases for prolapse were performed from January 2008 through December 2011. These surgical cases represent patient-level admission records where each patient may have undergone multiple different prolapse procedures during one surgical case. The following procedures were excluded from the analysis due to low numbers: trachelectomy (7 procedures), sacrohysteropexy (2 procedures), and paravaginal defect repairs (6 procedures). This resulted in 3 surgical cases being excluded from the analysis because the women in

these cases had only undergone one of these low-volume procedures (2 women underwent sacrohysteropexy and 1 underwent trachelectomy without additional prolapse procedures).

1211 surgical cases (93.3%) involved a single prolapse procedure and 87 (6.7%) involved 2 (primary prolapse procedure plus concurrent anterior and/or posterior repair during the same surgical case). This yielded 1385 prolapse repairs for analysis. Women had a mean age of 64+12, 70% had stage III prolapse, and the majority (96%) were Caucasian.

We identified 15 women (1.2% of the study population) who underwent repeat prolapse surgery during the study time period. This insignificant percentage of repeat surgeries justified our decision to include them as independent events for analysis. All patients with the exception of one underwent different prolapse repairs than their original surgery. Repeat surgeries included: 1 colpocleisis, 12 anterior/posterior repairs (one patient underwent anterior and posterior colporrhaphy twice), 5 native-tissue apical suspensions, 5 vaginal mesh procedures, 4 open sacral colpopexies, and 5 laparoscopic or robotic sacral colpopexies. The mean time between the first and second surgical case was 9.9 ±7.2 months (range=3–30 months).

Vaginal mesh procedures declined over time (slope= −0.013, p=0.001), comprising 27% of prolapse repairs in early 2008, 15% at the time of the 1st FDA notification regarding vaginal mesh, 5% by the 2nd FDA notification, and 2% at the end of 2011 (Figure 1). The percentage of native-tissue anterior/posterior repairs (slope=0.015, p<0.001) and apical suspensions (slope=0.006, p=0.007) increased, while the percentage of colpocleisis procedures remained constant (slope=0.002, p=0.475). Despite an overall decrease in open sacral colpopexies (slope= −0.036, p<0.001), an initial increase was seen near the time of the 1st FDA vaginal mesh notification. We adopted laparoscopic/robotic techniques around this time to provide an additional minimally invasive option for our patients, and the percentage of laparoscopic/robotic sacral colpopexies steadily increased thereafter (slope=0.029, p<0.001).

We also combined all sacral colpopexies together as a single group encompassing open, laparoscopic, and robotic approaches to minimize the confounding effect of our adoption of minimally invasive techniques around the same time as the FDA notifications regarding vaginal mesh. All sacral colpopexies combined as a group declined over time (slope= −0.01, p=0.011).

Demographic factors were analyzed by prolapse repair type. Compared to other prolapse procedures, elderly women (age ≥ 70) most often underwent colpocleisis (p<0.001), while younger women (age ≤ 49) underwent a greater percentage of sacral colpopexies (p<0.001), anterior/posterior repairs (p=0.007), and apical suspensions (p=0.004, Figure 2). Vaginal mesh procedures were less common in women younger than age 50 and older than age 80 (p<0.001), compared to women age 50–80.

Obese women (BMI≥30) were more likely than other BMI groups to undergo isolated anterior/posterior repairs (p=0.003) and native-tissue apical suspensions (p=0.019), and less likely to undergo minimally invasive sacral colpopexy (p<0.001, Figure 3). Underweight women (BMI<18.5) were most likely to undergo colpocleisis (p=0.019). BMI was not

associated with vaginal mesh repair (p=0.256) or open sacral colpopexy (p=0.140). Vaginal mesh (p=0.038) and colpocleisis (p=0.023) procedures were less common in current smokers. Smoking status was not significantly associated with the other types of prolapse repairs that were analyzed.

Discussion

Our findings indicate that surgical trends in the treatment of pelvic organ prolapse have evolved in recent years. Over a 4-year time period (2008–2011) that encompassed 2 FDA notifications regarding vaginal mesh in October 2008 and July 2011, our institution performed fewer vaginal mesh procedures and more native-tissue repairs. During this period, we broadened our surgical armamentarium to include laparoscopic and robotic techniques, and we performed more minimally invasive sacral colpopexies and fewer open sacral colpopexies. When examined as a group, the percentage of sacral colpopexies performed from all approaches declined over time. The percentage of colpocleisis procedures remained constant, which was anticipated, as this type of repair involves a specific subset of women with excellent outcomes despite no recent innovations in technique. These findings were all consistent with our original hypotheses which were generated prior to any data collection.

Our use of vaginal mesh started to decline in the months preceding the 1st FDA notification, as we became increasingly more aware of the potential complications of vaginal mesh from our own clinical experience. We saw an initial increase in the number of open sacral colpopexies around this time as we sought to offer patients a surgical option with comparable durability to mesh-augmented vaginal repairs. We believe that use of native-tissue repairs increased over time due to both patient and surgeon reactions to the FDA notifications. Although these notifications were meant to specifically address the risks associated with vaginally placed mesh and not all mesh-augmented repairs (i.e. sacral colpopexy), it has been our experience that many patients have difficulty accepting this distinction and prefer to avoid the use of mesh in general. Indeed, the percentage of sacral colpopexies from all approaches combined declined over the course of our study. New long-term data suggests that the risk of mesh exposure with sacral colpopexy may be higher than previously thought which may also be influencing these trends.[15] In light of the FDA notifications, we have found it to be more important than ever to provide patients with appropriate counseling regarding surgical procedure selection. We believe that minimally invasive sacral colpopexy provides patients with a durable repair without the added risks associated with laparotomy (open sacral colpopexy) which has been supported by a recent randomized trial.[16] Further studies are needed to determine if these minimally invasive approaches reduce the mesh exposure rate seen with vaginally placed mesh. At the end of the study period in December 2011, laparoscopic and robotic sacral colpopexies were the most frequent procedures that were performed at our institution. A recent randomized controlled trial showed equivalent anatomic results for laparoscopic sacral colpopexy when compared to the open approach with decreased blood loss, hospital stay, and 3-day morphine use with laparoscopy.[16] Another recent randomized trial showed that both laparoscopic and robotic sacral colpopexies “demonstrated significant improvement in vaginal support and functional outcomes 1 year after surgery with no differences between groups.” [17]

A recently published population-based analysis by Jonsson Funk et al showed that vaginal mesh surgeries represented the majority of mesh-augmented prolapse repairs utilizing mesh from 2005–2010, and that the rate of vaginal mesh procedures increased from 2005 to 2008 and then plateaued from 2008–2010.[4] Our study differs in that it included all prolapse repairs performed during the time period including obliterative and reconstructive procedures as well as mesh-augmented and native tissue repairs. Whereas Jonsson Funk et al only showed trends for mesh-based procedures, we demonstrated that native-tissue repairs were increasing while vaginal mesh was declining. Another large database study showed that use of surgical mesh for prolapse peaked in 2006 and declined slightly in 2010.[18] This study, however, did not distinguish between route of mesh insertion (i.e. vaginal or abdominal). We believe the route of placement is particularly relevant to the discussion of mesh use in prolapse surgery, a fact which is highlighted by the 2011 FDA notification.[8] Additionally, the 2nd FDA notification regarding vaginal mesh which was much more direct in its recommendations and notifications occurred after the completion of both of these other studies, making it difficult to draw comparisons with our study as they are unable to capture changes in reaction to the 2nd notification. We expect that there would be a national trend toward decreased vaginal mesh procedures following the 2nd FDA notification, although this decrease may be more gradual over time in a population-based study due to variation in practice patterns on a national level. Limited data is available at this time.

Jonsson Funk et al showed that the national rate of minimally invasive sacrocolpopexy was higher than the rate of open sacral colpopexy by 2009 and was relatively equal in 2008.[4] We did not begin to offer laparoscopic and robotic procedures until the end of 2008, but minimally invasive techniques were more common than open sacral colpopexy by the first quarter of 2010. We recognize that our relatively late adoption of minimally invasive techniques may make our findings less generalizable to institutions that offered these surgical approaches earlier on.

In order to minimize the confounding effect of our adoption of laparoscopic and robotic techniques during the same time period as the FDA notifications, we analyzed all sacral colpopexies as a group and showed a decline over the study period. Since the decision to perform a sacral colpopexy is relatively similar for open, laparoscopic, and robotic approaches, we feel that this decline is a patient and/or surgeon response to the FDA notifications. While the notifications stated that “mesh placed abdominally for [prolapse] repair appears to result in lower rates of mesh complications,” perception regarding mesh from any route has changed dramatically.[8] This is also reflected in the increasing number of native-tissue repairs performed over the study period.

Our demographic analysis showed that vaginal mesh procedures were less common in current smokers, and that smoking status was not significantly associated with other types of prolapse repairs, including sacral colpopexy. Smoking has been associated with an increased risk of vaginal mesh exposure in several studies involving both transvaginal and transabdominal mesh placement.[19–22] We suspect that this difference in smokers was seen in vaginal mesh procedures but neither open nor minimally invasive sacral colpopexies because transvaginal mesh already confers a higher baseline risk of exposure compared to abdominally placed mesh.[23]

Araco et al [20] showed that age greater than 60 years conferred a 2.2-fold increase in the risk of developing a mesh erosion, but not all studies have been able to associate age with mesh exposure.[21,24] We found that vaginal mesh procedures were less common in women younger than age 50 and older than age 80, compared to women age 50–80. Colpocleisis was by far the most common surgical procedure performed in women age 80 and older in our study. This procedure is ideal for elderly women who do not desire preservation of coital function, has excellent success rates, and has been associated with high patient satisfaction.[13] Compared to other prolapse procedures, younger women (age ≤ 49) underwent a greater percentage of sacral colpopexies, anterior/posterior repairs, and apical suspensions. Colpocleisis is obviously not appropriate for this age group, and we suspect that surgeons were less eager to offer these women vaginal mesh procedures out of concern for potential complications over their comparatively longer remaining lifetime.

We found that BMI was not associated with vaginal mesh repair or open sacral colpopexy, but that obese women (BMI≥30) were more likely than other BMI groups to undergo isolated anterior/posterior repairs and native tissue apical suspensions, and less likely to undergo minimally invasive sacral colpopexy. It is difficult for us to explain these findings and limited data exist on the relationship of BMI and prolapse procedure selection. We imagine that surgeons performed a greater number of native tissue repairs in women with a BMI≥30 in an attempt to avoid mesh placement, out of concern for the possibility of increased risk of complications. One study showed that BMI≥30 conferred a 10.1-fold increase in the risk of developing a mesh erosion after transvaginal mesh placement, but not all studies have confirmed this relationship.[20,21] Underweight women (BMI<18.5) in our study were most likely to undergo colpocleisis.

The greatest strength of our study was the ability to capture trends of the individual types of surgical procedures that are used to correct prolapse. Every operative report was manually reviewed by a physician and we did not relying on coding. Coding schemes often fail to capture all of the distinct repairs that a surgeon performs. Although national database publications surpass our study in terms of numbers, our data are unique in that we were able to analyze the specific procedures that a surgeon performs in the operating room and not just information that has been entered by medical coders. Another strength of our study is that we recorded demographic factors and were able to analyze their impact on surgery selection.

Although this study was performed at a single institution, the limitation inherent to this is tempered by the fact that our data represent more of a regional study. We believe that our institution is uniquely situated to track the evolution of trends in procedures for pelvic organ prolapse based on geographic location and surgeon volume. As one of the largest Urogynecology groups in the nation, we serve a geographic area that extends from Cleveland to Philadelphia and from the Canadian border through West Virginia. This geographic region consists largely of the 29 counties in Western Pennsylvania with a total population of approximately 4.0 million people and 2.0 million females. Since Urogynecology has only recently been recognized as a subspecialty, we do not have detailed market share data. However, our Gynecologic Oncology colleagues have a similar structure with few competing physicians in the region and they provide care to 63.5% of the region based on inpatient admission data. Our 11 clinical sites around a central hub in Pittsburgh

make our experience more similar to regional data than a single institution. Seven different Urogynecologists translates into a very large aggregate surgical volume which is not as biased by a single surgeon's preferences. We do recognize, however, that surgeon preference could still impact our results more than a national study given that regional and institution-specific surgical styles may exist.

An additional limitation is that subjects who underwent more than one prolapse surgery during the study time period were treated as independent samples and not as correlated data. However, this pertains to only 15 surgical cases (1.2% of the study population). All patients, with the exception of one, underwent different prolapse repairs than their original surgery. We believe that the bias from treating these dependent records as independent samples is very small.

In summary, this study demonstrates that the surgical treatment of prolapse continues to evolve, particularly in response to FDA notifications regarding vaginal mesh. Future research is needed to analyze the ongoing changes that will inevitably occur as our subspecialty sees continued evolution in both technology and surgical techniques.

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Brief Summary

Over a 4-year period encompassing 2 FDA notifications, our institution performed fewer vaginal mesh procedures and more native-tissue repairs and minimally invasive sacral colpopexies.

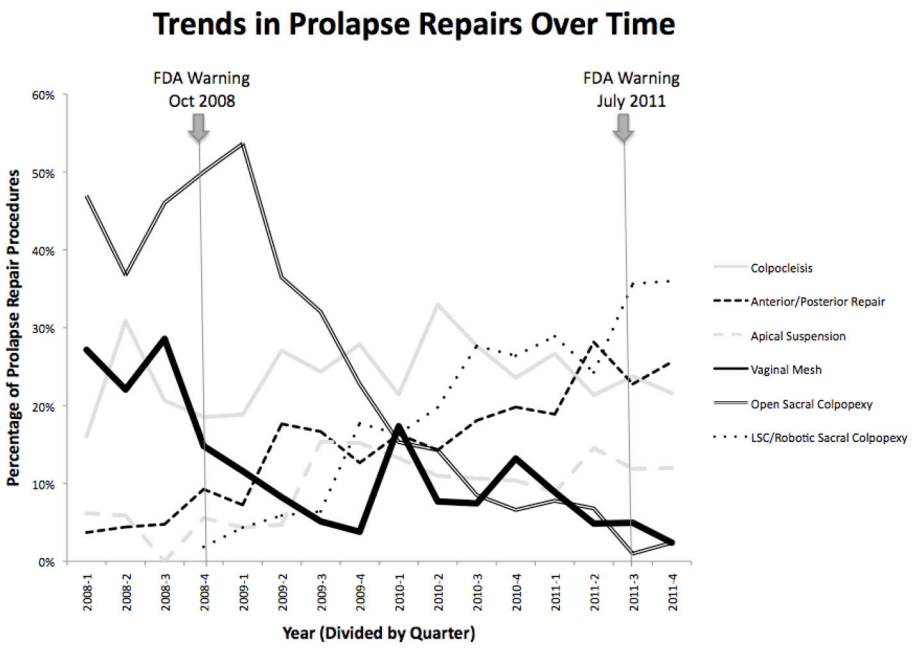

Figure 1.

Trends in prolapse repairs from 2008–2011 at the University of Pittsburgh Medical Center (n=1385 prolapse repairs)

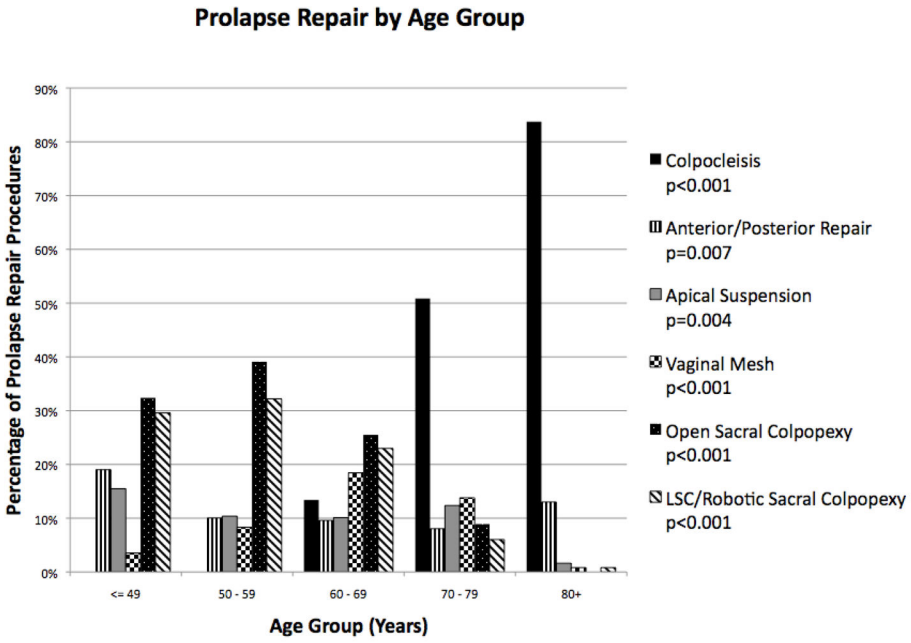

Figure 2.
Demographic analysis of prolapse repair by age group (n=1298 subjects)

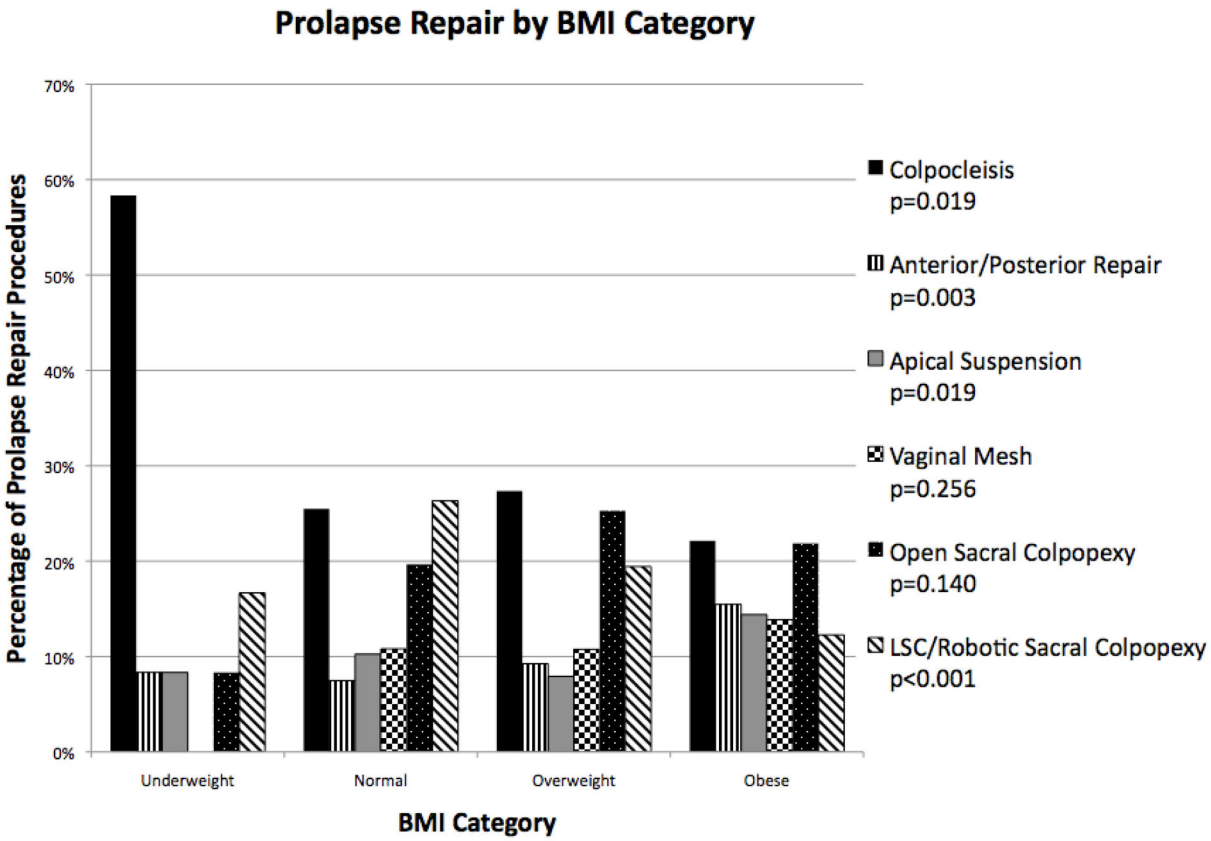

Figure 3.
Demographic analysis of prolapse repair by BMI category (n=1298 subjects)