1. What is the major research question addressed by this study? What was the study design used by the authors, and what are the strengths and limitations of this study design? Would a randomized, controlled trial be a better study design to answer this research question?

Multiple surgical procedures have been designed to correct apical pelvic organ prolapse (POP). A Cochrane review and previous imaging studies have demonstrated that abdominal sacrocolpopexy (ASC) provides more durability and restores normal pelvic anatomy. Vaginal POP surgery is certainly less invasive than ASC. Given recent concerns with the use of various mesh kits, it behooves us to develop and rigorously investigate new surgical techniques for vaginal POP repair. Our study looks at a new surgical technique that introduces mesh vaginally to suspend the apex: bilateral sacrospinous fixation with synthetic mesh arms (bSSVF). In this first study of bSSVF, our research question was: “Does bSSVF restore nulliparous pelvic anatomic relationships?” We investigated this with pelvic magnetic resonance imaging (MRI) in patients after bSSVF. The study design we used was a case series. Among the strengths were prospective data collection, the use of control data of anatomic measurements in nulliparous women and the use of the same protocol for pelvic MRI measurements in the bSSVF group as in controls. We were limited by a small sample size and funding for the MRI scans. However, we knew from the control group data, which was normally distributed, that measurements had good interrater variability and thus eleven MRI scans were sufficient to determine nulliparous pelvic parameters. Similarly, we had measurements that were normally distributed and our ranges and
95% confidence intervals (CI) were fairly similar to the control measurements. With a sample size of ten, based on the 95% confidence interval for the mean, we are confident for example that the mean average direct distance vector between vault and spine would be within 0.5 cm of the true mean (direct vector $5.2\pm0.5$). Given our data, our sample size was sufficient to determine anatomic pelvic relationships of the bSSVF procedure.

Since there is no previously published data on this procedure, we need to collect preliminary information before we can plan a randomized controlled trial of clinical success. The current study is an important first step in the validation of bSSVF. We believe our research question was adequately addressed by our research design. We plan to invest our future efforts in demonstrating clinical success of bSSVF with a randomized controlled trial with clinical outcomes. Such a trial will likely involve large numbers of patients; performing MRI scans on all would not be feasible, because of time, MRI availability and cost issues, and would also not be clinically useful. Although restoration of normal anatomy is important, it does not necessarily translate into adequate patient subjective and objective improvement. This needs to be established in further clinical trials before bSSVF can be widely adopted in the armamentarium of pelvic reconstructive surgeons.

2. The authors used a two-samples t-test to compare differences in anatomical distances between the bSSVF group and the control group. Why did they choose this statistical test? What test would be appropriate if they wanted to compare differences in a dichotomous variable, such as the prevalence of women with diabetes, between the groups?

A two-sample t-test is appropriate for comparing means of a variable between two groups. One crucial assumption is that the underlying distribution of the data should not significantly depart from the normal distribution. Our decision on using the t-test for the current study is based upon careful examination of the data to rule out any significant departure from the normality assumption. In contrast, Wilcoxon rank-sum test can be used if the data is highly skewed or it is suspected that the normality assumption may not hold for the data. In terms of comparing dichotomous outcome between groups, various methods are available, ranging from the simple Fisher’s exact test or Chi-square test to a more advanced method like logistic regression. The method of choice will be data and study dependent, for example logistic regression might be used if one wants to adjust for potential confounders.

3. Is the authors’ conclusion about mesh contracture rates supported by their data? What is known about mesh contracture and time since surgery? Was the timing of the MRI measurements in this study appropriate to detect post-operative mesh contracture?

Our MRI scans were performed at least one month postoperatively, with a range of 1-13 months postoperatively. After one month, inflammation and proliferation stages of wound healing are complete and wounds enter maturation and remodeling phases. One would think most mesh contractures would happen in the initial inflammatory phase.
One of the most interesting findings of this study was that the average length of the direct vector between cervicovaginal junction and ischial spine was 5.2 cm, which is very close to the 5 cm length of the mesh arms we routinely measure and insert intraoperatively during bSSVF (with small variations depending on intraoperative vaginal length). There are very few comparable studies measuring the length of polypropylene mesh after vaginal insertion. One study evaluated Prolift via ultrasound postoperatively. Given that Prolift uses a much larger piece of mesh, it is presumably harder to lay flat behind the vaginal tissues and folding can occur. In addition, the more foreign material is used right against the vaginal wall, the more inflammation and thus more scarring and contracture may occur. The authors noted different mesh lengths intraoperatively and at 4 days and 3-5 months postoperatively (9.0 vs. 5.7 vs. 4.8 cm respectively). Because most change occurred early, they postulated that it might be due to folding rather than contracture. Our results seem to indicate that if vaginal mesh is inserted deep and away from the vaginal mucosa incision, as well as laid down flat and tension free, contracture may not occur. As contracture is normally associated with vaginal pain, it will be interesting to investigate if the lack of mesh contracture noted with the bSSVF procedure translates into improved clinical outcomes for vaginal pain postoperatively.

4. Why did the authors need to use trigonometry to calculate vector distances? (Note: Did they actually use geometry?).

According to the Merriam-Webster dictionary, trigonometry deals with “relationships between the sides and angles of a triangle”, and has an “application that extends far beyond geometry”. Trigonometry was used to calculate vector distances for two main reasons. First, we used the same protocol as for the control group. Second, surgical anatomy is three-dimensional, and trigonometry allowed us to reflect this by describing the locations of vaginal apex and ischial spines in three dimensions. This is useful spatial information for a surgeon. 

5. The authors added 1 cm to the direct and right/left distances in the 6 women who underwent bSSVF post-hysterectomy. Why? How might this bias their results? Would it be more informative to see the data both with and without this modification?

The control data of nulliparous women with normal support was collected by measuring the cervicovaginal junction (CVJ) as a landmark because it is well seen on MRI. We sought to make the measurements comparable in our post bSSVF patients who did not have a uterus and were measured from lateral fornix (LF) to spine. Looking at MRIs of women with uterine preservation, it was apparent that the LF and CVJ constitute 2 separate points. The distance between LF and CVJ was measured in order to make the measurements more accurate. When looking at the distance between CVJ and LF in patients with uterine preservation, it was consistently 1 cm. The bias comes from the fact that the number of bSSVF women with a uterus was 4. A larger number of patients would improve the validity of this measurement, but we were reassured that the distance was consistent in all 4 patients. The data without adding the 1 cm was not included because it constituted a different measurement all together.
6. The authors note that prospective studies are underway to compare clinical subjective and objective outcomes after bSSVF when compared with other apical support procedures such as sacrocolpopexy. How would you design such a study? How would you quantify objective success and failure?

We have collected clinical data prospectively on bSSVF with a control group of sacrocolpopexy. Based on this, we can determine clinical success of bSSVF. Since both objective and subjective outcomes are important to us and to our patients, we would likely define clinical success as a composite outcome of subjective symptoms of bulge (likely extracted from answers on a validated questionnaire such as the Pelvic Floor Distress Inventory), objective POPQ measurements and retreatment with surgery or pessary for recurrent POP. More and more studies use such composite outcomes rather than just POPQ measurements as a primary outcome defining success versus failure of pelvic reconstructive procedures. Once we determine the clinical success rate of bSSVF, we can then determine a sample size for a randomized controlled trial comparing bSSVF with another method of apical POP correction.

7. Why did the authors choose the control group they chose? What if they had chosen to use a control group from a study of MRI evaluations of postoperative pelvic anatomy after abdominal sacral colpopexy instead? Would you find the results more or less useful?

The control group of young nulliparous women was chosen because it represents gold standard pelvic anatomy. The length of the mesh arms used during BSSVF was determined based on the measurements of this control group. Indeed, parous, older women with good support could also make a good control group. It would be interesting to study their anatomy as well, and see how it compares to nulliparous women. We are definitely interested in seeing how postoperative in vivo BSSVF pelvic anatomy compares to ASC. Unfortunately, MRI scans are prohibitively expensive and we suspect it would be challenging to convince granting agencies of the clinical necessity to make such a comparison.

8. Based on this study, are you likely to offer this surgery to your patients? Why or why not?

This study shows bSSVF recreates normal pelvic anatomy, which is usually one of the goals of pelvic reconstructive surgery. This is encouraging but restoration of normal anatomy does not necessarily translate into restoration of normal function. Proof of clinical success is needed before bSSVF can be widely implemented. Until then, we continue to offer bSSVF to our patients as an experimental procedure and as part of research studies ongoing at our institution.
References


