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Author's Response to Letter to the Editor regarding paper JMIG-D-15-00731, "Synthetic Graft Augmentation in Vaginal Prolapse Surgery: Long-Term Objective and Subjective Outcomes"

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Response

To the Editor

We would like to thank Drs. Moen and Veronikis for their comments regarding our manuscript, "Synthetic Graft Augmentation in Vaginal Prolapse Surgery: Long-Term Objective and Subjective Outcomes" [1]. Prolapse surgery is challenging given the high recurrence rates. Transvaginal mesh was originally introduced as a more potentially durable minimally invasive surgical approach. Currently no "gold standard" approach exists as every prolapse case is unique. Our goal as surgeons is to offer individualized treatments with long-term objective and subjective benefits without adverse events.

There continues to be a lack of long-term outcome studies, especially regarding subjective outcomes on vaginal mesh. Patient enrollment in long-term studies is generally challenging. However, it appears more so for studies related to vaginal mesh partially because "mesh" has been under medico-legal, media, and public scrutiny over the last decade. Although our follow-up rate was low, "23%" was of patients who returned to clinic for physical examination (objective outcomes) and completed questionnaires (subjective outcomes). The follow-up rate is higher for those who completed the subjective portion of the study including the assessment of symptom severity, quality of life, adverse outcomes, satisfaction and retreatment. This limitation was further discussed in our manuscript.

The commenters focused on the negative aspect of the results; "15% dissatisfaction rate, 20% complaining of bulge symptoms, and 30% meeting the failure criteria". However, it depends on how one interprets the data presented. We would argue that both 85% treatment

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satisfaction and 80% of the subjects with the absence of vaginal bulge symptoms are not trivial. In addition, 70% cumulative success rate (meeting all 3 criteria) using the widely accepted composite success definition is at least comparable with the mid- to long-term success rates reported in the literature of prolapse surgical outcomes. Although the rest (30%) had failed at least one criterion, it is important to point out not all subjects with anatomical “failure” also met the symptomatic failure criteria, and vice versa. We agree with the commenters that adverse events related to vaginal mesh continue to occur over time and the importance on reporting the long-term rates of such events, which were discussed in our manuscript. Our reported rate of dyspareunia (36%) was the overall rate, not the actual de novo dyspareunia related to mesh augmentation as we did not explore the baseline rate of dyspareunia in this population. Dyspareunia is not unique to mesh augmentation, also occurs with native tissue prolapse surgery, and does not seem to be associated with patient dissatisfaction after pelvic surgery.

As prolapse surgery tends to deteriorate over time, and every prolapse is unique, it has been an on-going challenge for pelvic reconstructive surgeons to find the “magic wand” for the treatment of prolapse. Experts are yet to agree on the most durable approach combined with long-term improvements in symptoms and quality of life with limited adverse outcomes. Although limited by our high attrition rate, which we transparently discussed, we attempted to tackle the challenge and aimed to report long-term outcomes, as there is still a paucity of data. In addition, our manuscript was also intended to bring up the current issues related to enrollment in long-term outcome studies specifically involving vaginal mesh.

It is reassuring that the number and quality of studies assessing the efficacy and safety of vaginal mesh has been increasing. More studies now have consensus on evaluating both objective and subjective outcomes using a composite definition of treatment success. Multiple professional organizations have published statements regarding safety and clinical guidelines for the use of vaginal mesh. The American Urogynecologic Society has established a national registry for patients undergoing treatment for pelvic organ prolapse both with and without mesh to understand the role of transvaginal mesh in pelvic reconstructive surgery. It is not our intention to advocate the use of mesh in every case. However, the current literature suggests that transvaginal mesh may be useful in selected cases. There was no intent or any implication to suggest that mesh use should be generalized. Future goals should include finding strategies to overcome the obstacles to achieve more long-term high quality data to help women with this complex disorder.

REFERENCES

1. Meyer I, McGwin G, Swain TA, et al. Synthetic graft augmentation in vaginal prolapse surgery: long-term objective and subjective outcomes. *J Minim Invasive Gynecol*. 2016;614–621. [PubMed: 26922879]