

Reply

We thank Prof. Kohl for his interest in our study¹. The large group of authors encompasses proponents of both open fetal and fetoscopic spina bifida aperta (SBA) repair and we aimed to be as objective as possible in assessing the learning curve of current surgical methods. Our systematic review and meta-analysis was conducted in accordance with international guidelines^{2–4}.

We agree with Sotiriadis and colleagues that the quality of a product is heavily dependent on the quality of its ingredients⁵. Therefore, we contacted the corresponding authors of all eligible full-text manuscripts to obtain (missing) outcome data as well as raw chronological data¹. To our knowledge, this is the best approach to retrieve additional information^{2–4}. Analysis of such data received first hand using the validated group-splitting method suggested that competency of Prof. Kohl's fetoscopic SBA repair technique was not achieved after 81 consecutive cases^{1,6–8}. In this process, we also invited Prof. Kohl to provide missing data, but we did not receive a response¹. Therefore, we could not determine precisely his team's learning curve using cumulative sum analysis. We acknowledged this as a limitation of our study and noted that the lack of raw data might have led to '... an unfair comparison to the MOMS trial standard-hysterotomy results'. With respect to Prof. Kohl's data, we could only resort to the quality of the ingredients in his papers^{1,9}, but we hope that we can refine our analysis when complete outcomes of his impressive cohort of 240 cases are published.

In our study, the simplified denomination of 'percutaneous single-layer fetoscopy' was used for Prof. Kohl's fetoscopic SBA repair technique. This classification was made because the technique used was not standardized and repair consisted of a single layer of Surgisis® skin patch in 67.6% (48/71) of the cases^{9,10}. To our knowledge, the efficacy of single-layer fetoscopic repair has not yet been confirmed in well-conducted clinical or animal studies^{1,11}. In contrast, clinical studies have shown the benefits at 12 months of age of prenatal multilayer repair, either by open^{12–15} or exteriorized-uterus fetoscopic¹⁶ approach as compared to prenatal single-layer repair. The animal study of Herrera *et al.* was not designed to compare the neuroprotective effects of the simplified fetoscopic technique involving coverage of the defect with those of the open surgical approach¹⁷. This study has several limitations including: (1) utilization of fetal lambs in which surgical creation and repair of the SBA-like defect were performed during the same surgery, hence, lacking any neurodegenerative effects of *in-utero* exposure; (2) a different repair technique in two layers (cellulose and skin) via an open approach as compared to Prof. Kohl's single-layer fetoscopic repair technique; (3) preterm sacrifice of the fetal lambs and lack of functional assessment; and (4) insufficient numbers to achieve statistical power^{11,17}.

Prof. Kohl also suggests that postnatal leg function is significantly better preserved following fetoscopy than after open fetal surgery. However, this is based on data from a subjective congress abstract which describes incompletely neuromuscular outcomes of a small ($n = 30$) and heterogeneous group of patients managed either postnatally or by open fetal or fetoscopic repair in three different centers¹⁸.

We acknowledge that Prof. Kohl currently has the single largest personal experience with percutaneous fetoscopic SBA repair and we share his opinion that this technique requires advanced endoscopic dissection and suturing skills and adequate training. Our meta-analysis aimed to translate these requirements into number of cases needed to reach competency, which exceeds the level of eminence-based statements¹. We performed this study to provide valuable information to some of our centers that are transitioning from open to fetoscopic repair and to institutions looking to establish a new fetal center. In that process, we aim to follow the IDEAL recommendations for surgical innovation¹⁹. We concur with Prof. Kohl that candidate fetoscopic surgeons should undergo a multistep training program. We (L.J., P.D.C., W.E.W., M.A.B., F.V.C. and J.D.) have chosen to use valid training models for fetoscopic repair to avoid or limit training on clinical subjects, to determine and shorten the learning curve and retain our operative skills^{19–21}. We have paired this training with off- and onsite clinical training and guidance from established fetal centers, similar to the process followed by some of our centers for open fetal surgery^{22,23}. Given the rarity of the condition and the need for data aggregation, we hope that all fetal centers offering fetal SBA repair will track outcomes in a central registry and maintain transparency in experience and outcome reporting, as advocated by the fetal myelomeningocele Maternal-Fetal Management Task Force, the International Fetal Medicine and Surgical Society (IFMSS) and the North American Fetal Therapy Network (NAFTNet)^{22,24,25}.

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