Appendix I Study protocol (2023.03.10)

Objective of the scoping review

A variety of composite meshes reducing adhesion have been developed and the number of animal experiments exploring an optimal composite mesh for incisional hernia repair is increasing. However, to our knowledge there is no study investigates the experimental methodology of those studies. Our review analyses the variability in this area of in vivo testing of incisional hernia composite mesh. By doing so, it will help identify the need, if any, for standardization in the field and the areas in which this is most urgently required.

Eligibility Criteria

The eligibility criteria related to study characteristics: 1) Study design: controlled studies, with no restriction on whether they were randomly grouped; 2) Participants: animal models of abdominal wall defect, with no limitations on the animal species nor modeling methods; 3) Intervention/Comparison: composite mesh (comprised of a permanent synthetic mesh material on the parietal side and an adhesion barrier layer on the visceral side) implanted in the abdominal wall. Studies that compare different fixation techniques, adjuncts that are not meshes, or new pharmacological products were excluded; 4) Outcomes: tissue-to-mesh adhesions, regardless of measurements used.

The eligibility criteria related to the report characteristics: 1) publication language: English or Chinese and 2) publication status: abstracts of studies were excluded.

Searching

We will conduct a systematically search of following eight national and international databases, including PubMed, Ovid-Embase, Web of Science, China National Knowledge Infrastructure Database (CNKI), Chinese Scientific Journals Full-Text Database, Wanfang Database, and China Biological Medicine Database (CBM). The free words and medical subject heading (MeSH) of three groups search terms, including “abdominal wall defect”, “adhesion”, and “search filters of animal studies” [1] are combined. To identify potential additional studies, we will also search relevant reviews [2] and the references cited in included studies.

Screening

All search results of electronic databases will be exported to the EndNote X8 software the removal of duplicates. Two authors will independently screen titles and abstracts based on the

eligibility criteria. Studies were subcategorized into three groups (included, excluded, and unsure) in this step. Then, two authors will independently examine the full text of potentially eligible and unclear studies to reach the final decision of inclusion or exclusion. Any disagreements between the two authors will be resolved by discussion or through consultation with a third author.

Charting the data

Two of three authors will extract the data from the included studies using a standardized, predefined data collection form prepared Microsoft Excel 2016, and another author will check the extracted data. Any discrepancies will be resolved by consensus or through consultations with the fourth author. The four authors from our group previously collaborated on a similar project [3], which created a good understanding of the process. Before the final extraction, a pretest using a random sample of ten included studies will be carried out to revise the form, and its final version will be consulted with medical device inspector and general surgeon.

The extracted information included the following: 1) general study characteristics (first author and year of publication); 2) animal species, weight, age, sex; 3) number of animals used; 4) type of animal model; 5) whether reported the modeling method; 6) whether cited published standard animal models; 7) whether reported the surgical procedure; 8) barrier layers and mesh layers of composite mesh; 9) product name for marked composite mesh; 10) time points of mesh and tissue explanation; 11) methods of assessing adhesions.

Critical appraisal of studies

Two authors will independently assess the inherent risk of bias of included studies using SYRCLE's risk of bias tool for animal studies [4]. The two authors will cross-check their evaluation results. Any disagreements were resolved through consultation with a third author.

Data analysis

Results from the data extraction tool will be collated and summarized to provide a narrative review of how published literature reports on the experimental methodology in vivo testing adhesion for composite mesh used in incisional hernia repair. Tabular and graphical representations of the data will be used to illustrate the identified results, and will be supported by narrative descriptions of data.

Reference

[1] van der Mierden S, Hooijmans CR, Tillema AH, Rehn S, Bleich A, Leenaars CH. Laboratory animals search filter for different literature databases: PubMed, Embase, Web of Science and PsycINFO [published online ahead of print, 2021 Sep 24]. Lab Anim. 2021;236772211045485. doi:10.1177/00236772211045485

[2] Liu H, van Steensel S, Gielen M, et al. Comparison of coated meshes for intraperitoneal placement in animal studies: a systematic review and meta-analysis. Hernia. 2020;24(6):1253-1261. doi:10.1007/s10029-019-02071

[3] Yang J, Kang Y, Zhao W, et al. Evaluation of patches for rotator cuff repair: A systematic review and meta-analysis based on animal studies. Bioact Mater. 2021;10:474-491. Published 2021 Aug 28. doi:10.1016/j.bioactmat.2021.08.016

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