



Mesh Sprayer Device with Liquefied Mesh Delivery System: Proposed Alternative for Currently Available Meshes in Hernia Repair and Supplement to Abdominal Closure

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Introduction

Over 1 million hernia repairs are performed annually in the United States, including approximately 800,000 inguinal hernia repairs [1] and approximately 350,000 ventral/incisional hernia operations [2]. Inguinal and ventral/incisional hernia recurrence following mesh repair ranges from 0.5% to 10% with inguinal hernias [3] and 15% to 32% for ventral/incisional hernias [4]. These recurrence rates are improved when compared to historical tissue-based repairs. Prospective trials of mesh vs. primary repair have also demonstrated decreased postoperative pain and shorter hospital stay for mesh-based repairs [5]. Although different techniques of repair are practiced, no particular mesh-repair technique has proven to be superior to others, especially with tension free mesh-repairs.

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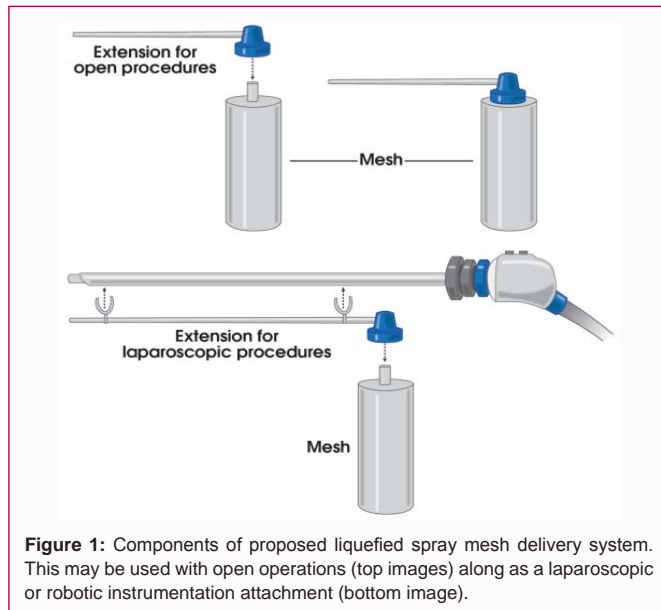
In addition to the utility of mesh for hernia repairs, proposals for prophylactic implantation of mesh following open abdominal surgeries, especially for the group of patients with a high risk of incisional hernia formation, open a whole new prospect of an increased use of mesh in the future [6]. The incentive for conducting an open-label, prospective randomized trial for evaluation of the impact of prophylactic implantation of mesh stems from observations of high frequency of hernia following abdominal surgeries and the fact that mesh is proven to be helpful with reducing the recurrence of hernia following incisional hernia repair [6]. Given the current well-intentioned trend toward limiting the use of mesh to forestall its complications, this voice for increasing the use of mesh for prophylaxis begs for a comparison of the risk of mesh complications vs. the risks posed by incisional hernias.

Current Mesh Limitations

Deficiencies of currently available meshes include operative factors such as handling time to sterilely handle, measure, and cut/modify meshes intra-operatively, variable incidence of mesh infections due to exposed mesh material to skin and outside environment, and difficulty with placement of mesh and its fixation. Additional logistical factors include wasted mesh as excessive mesh material is discarded, the shelf space requirements to stock different sizes and shapes of various meshes, and shelf life limitations. It is clear that we are far from having an ideal mesh material and application method. One solution for patient-specific hernia meshes have included the proposal of 3D printed meshes that allow for customization and even impregnation with drugs [7]. However, at writing, this technology has not been implemented in human studies.

Proposed Mesh Sprayer Innovation

Given the limitations of currently available mesh and its placement, we propose a mesh delivery model and a liquid, paste-like mesh. The current design includes a self-spraying device that delivers liquid, paste-like, pressurized, sterile mesh in a controlled fashion (Figure 1 and 2). The mesh would solidify shortly after exposure to the outside environment. The design allows for



attachments to laparoscopic and robotic-assisted instruments or as a free-standing attachment for open techniques. The liquefied mesh reservoir can be deployed through the sprayer device, delivering the solidifying compound in the place of the conventional placement of currently available meshes for the repair of hernias. Additionally, the spray device can be used prophylactically to facilitate fascial closure for all abdominal surgical incisions. Of note, this technique requires closure of fascia and, as such, cannot be used for bridging. The contents of the spray reservoir are customizable, with the ability to deliver permanent or bio-absorbable plastics, adhesives compounds, or bioactive compounds. In our prior proof of concept publication, we showed a novel system for attachment of a talc sprayer device to the thoracoscopic camera which eliminated the angle which exists in the current available systems between the camera and the sprayer device (alpha angle). Eliminating this angle mitigates the uncertainty and reduced accuracy when spraying talc during the thoracoscopic procedures [8]. The same concept would apply to mesh spraying devices.

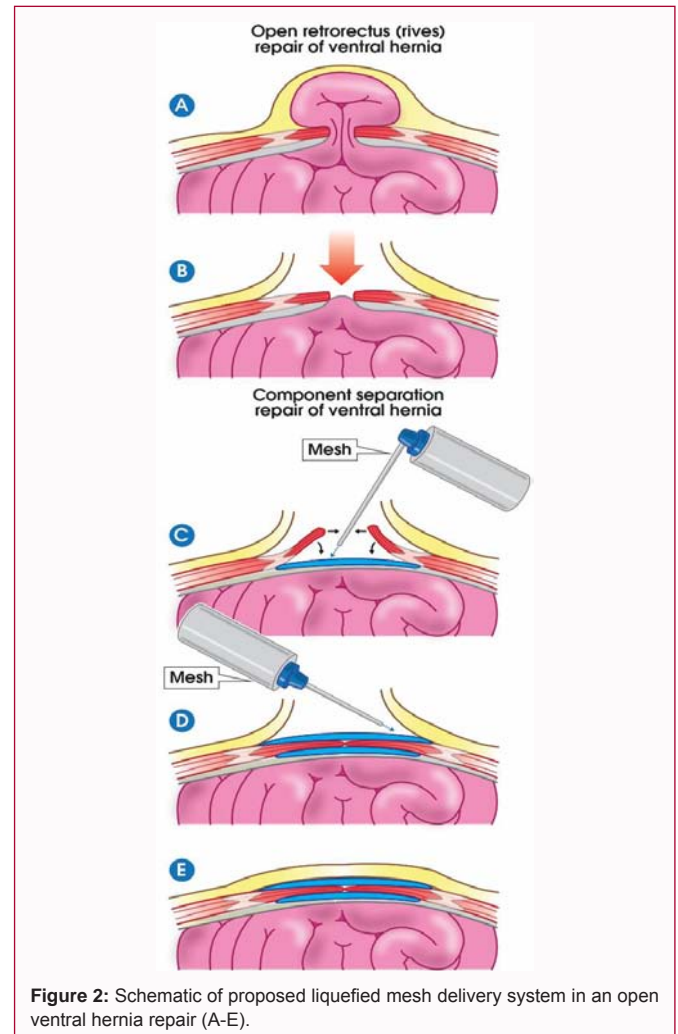
This system may reduce mesh handling time, storage requirements, infections, operative times, cost, and incisional hernias in both primary incisions and hernia repairs. Specific to prophylactic use of this system compared to the use of traditional meshes, this system would require no additional dissection for placement. Data are needed to substantiate these claims. Unanswered questions and potential limitations of this proposed system include if it can serve as a replacement or unnecessary replacement to fascial closure, if the solid layer will result in an unnatural sensation compared to perforated currently available meshes, and if the application of the liquid mesh layer would complicate an abdominal exposure in future operations. The authors are freely proposing research and development of this liquid/paste mesh and delivery system without future intellectual property claims.

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