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#14	Development of a Translational Porcine Hiatal Hernia Model for Evaluation of Reinforced Repair Devices	Darcy Gagne	Becton Dickinson	Abstract

Development of a Translational Porcine Hiatal Hernia Model for Evaluation of Reinforced Repair Devices

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Introduction

Porcine hiatal hernia models are limited in the published literature despite the need for clinically relevant preclinical platforms to evaluate novel repair devices. The objective of this study was to develop and assess the feasibility of a translational porcine hiatal hernia model that mimics the clinical repair of a hiatal defect reinforced with a medical device. Secondary objectives included evaluating implant-tissue interactions through macroscopic, histologic, and mechanical assessments following a 12-week implantation period.

Methods

Following observation of clinical hiatal hernia repair procedures and evaluation of relevant anatomy, a series of human and porcine cadaver studies were conducted to optimize the surgical approach and establish a survival model. After iterative refinement, a pilot in vivo study was performed.

In this preliminary study, three animals were anesthetized and positioned in reverse Trendelenburg prior to abdominal insufflation and placement of four laparoscopic trocars. An additional incision was created to facilitate placement of a Nathanson liver retractor for improved visualization of the hiatus. Laparoscopic dissection was performed to expose the diaphragmatic hiatus, and the esophagus was mobilized to permit retraction and creation of a simulated hiatal hernia defect. The defect was repaired and reinforced with a hiatal hernia repair device using clinically relevant implantation techniques.

Following recovery from anesthesia, animals were managed with a staged postoperative nutritional regimen consisting of a liquid diet followed by gradual transition to solid food. Animals were maintained for 12 weeks before necropsy. Explanted tissues underwent macroscopic evaluation, histologic analysis, and mechanical assessment using a ball burst test.

Results

The surgical procedure was successfully performed and closely replicated clinical hiatal hernia repair techniques. All animals recovered from surgery without major complications and tolerated the postoperative dietary progression. Animals maintained normal health status and demonstrated continued weight gain throughout the 12-week survival period. At study completion, tissues and implants were successfully harvested and evaluated using macroscopic, histologic, and mechanical testing methodologies. The model provided adequate access to assess device performance and tissue integration, supporting its feasibility as a platform for future evaluation of novel hiatal hernia repair technologies.

Conclusions

A clinically relevant porcine hiatal hernia model was successfully developed through a translational process that included clinical observation, anatomical assessment, cadaver feasibility studies, and iterative procedural refinement. The model enabled laparoscopic creation and repair of a simulated hiatal hernia defect with device reinforcement and supported comprehensive post-implantation evaluation over a 12-week period. These findings demonstrate the feasibility of the model and its potential utility for preclinical assessment of innovative hiatal hernia repair devices and surgical techniques.