A LaRue Company

NIH SBIR Phase 1 Specific Aims

A. LaRue, C. LaRue

2 SPECIFIC AIMS

There were 365,000 breast augmentations performed in 2021. In addition, 148,000 women had implants removed and replaced (+32% from 2020), and 71,000 had their implants removed and not replaced (+47%).[1] The rate of removal procedures has increased dramatically in the last year, trends are showing it will remain high. Breast augmentation with silicone implants remains one of plastic surgery's most common cosmetic and reconstructive procedures. There is an increasing awareness among implant patients of the health risks associated with these medical devices.[2] These risks include breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a rare form of non-Hodgkin lymphoma.[3] Modern breast implants typically contain either saline or a viscous silicone gel- 88% of breast augmentations in the U.S. are silicone implants. The FDA removed its approval of PIP saline implants in 2000 and published several reports linking Allergan's textured, saline-filled implants to BIA-ALCL. Silicone implants consist of an outer membrane of vulcanized silicone elastomer filled with a medical-grade silicone gel made of a heterogenous mixture of silicone (poly-dimethylsiloxane) compounds with differing numbers of dimethylsiloxane units. Although there have been concerns over the potential endocrine disruptor effects of the cyclic silicones D4 and D5 present in very low concentrations in medical-grade silicone gels,[4] current evidence does not support these concerns.[5,6] Silicone is widely considered to be non-toxic and biocompatible. However, there is growing evidence that low levels of silicone leakage into the body can have autoimmune effects, leading to what is known as breast implant illness (BII) or autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA) due to silicone incompatibility.[7-11] Given the accumulating evidence for BII/ASIA in patients with intact implants, acute leakage of larger volumes of silicone into the breast pocket due to implant rupture that may be exacerbated during removal is likely to represent an acute risk factor for BII/ASIA. Best practice therefore demands the thorough removal of the implant, any leaked silicone gel, and capsular tissue. Currently, removal methods lead to cross-contamination of silicone back to the patient via surgeon's gloves or instruments, have safety issues, and require longer, more involved surgeries. Therefore, there is an unmet need for a device that can more safely remove implants and the associated capsular scar tissue that forms around them.

A LaRue Company was co-founded in 2019 by Angela LaRue, an experienced Registered Nurse specializing in aesthetic surgery, to develop a novel surgical evacuator (the LaRue Surgical Evacuator, or LSE) that can be used in breast implant removal procedures to ensure the thorough and safe removal of silicone and capsular tissue from the patient. The device is designed to be attached to a standard vacuum line and to safely contain the evacuated materials. Using the LSE reduces the possibility of reintroducing silicone into the breast pocket by keeping the surgeon from touching the implant or leaked silicone. The LSE also minimizes exposure of the surgical team to harmful biohazards, including capsular tissue and blood. The device has additional surgical applications, for example, in the removal of hematomas, in abdominal bowel perforation surgery, and treating infections after total joint replacement. We have produced early 3D-printed prototypes of the basic LSE design that have been tested in two surgeries (breast implant and hematoma removal). In this SBIR Phase I project, we will engineer and test a fully functional prototype with enhanced functionality.

Aim 1. Engineer a second-generation prototype of the LaRue Surgical Evacuator with enhanced functionality and control features. We have developed initial designs for two additional attachments for the LSE unit that will i) enhance its functional capabilities in silicone implant removal and other surgical procedures, and ii) allow for control of suction at the device to improve usability. In Aim 1, we will prototype a second-generation LSE device with these attachments and conduct benchtop performance testing, quantifying suction pressures for all device configurations under standard suction line pressures, calibrating the control mechanism for each configuration or clinical application, and quantifying between-device variability for multiple prototype units. Milestone: A calibrated prototype surgical evacuator that achieves the optimal flow rate for silicone extraction with standard operating room suction (≤-350 mmHg) and maintains its physical integrity.

Aim 2. Gather end-user feedback on the features and usability of the LaRue Surgical Evacuator. The perceptions of surgeons who will be the end users of the device are of key importance in understanding the usability of the second-generation prototype, potential improvements to the design, and its surgical applications. We will recruit a group of 12 surgeons who will view a demonstration of the features of the device and its intended applications and who will handle a prototype device. The surgeons will then complete a questionnaire comprising a set of Likert-scale questions on the functionality, usability (including ergonomics and practicality), perceived safety, and acceptability of the LSE, and a set of open-ended questions designed to obtain insight into their perceptions and possible uses of the device. The resulting analyzed data will inform the design of the final device. Milestone: i) A completed analysis of Likert-scale data using non-parametric statistical methods showing a positive perception of the LSE versus existing surgical tools and techniques; ii) a completed thematic analysis of coded responses to open-ended questions and a corresponding set of updated considerations for the final LSE design.

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