Trial record **1 of 1** for: NCT03891004

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# Skin Closure With Tissue Adhesives vs. Subcuticular Suture After Robotic Urogynecologic Procedures



ClinicalTrials.gov Identifier: NCT03891004

Recruitment Status : Completed
First Posted : March 26, 2019
Last Update Posted : April 4, 2019

**Sponsor:**
St. John Hospital & Medical Center

**Information provided by (Responsible Party):**
Sunetris Fluellen, St. John Hospital & Medical Center

Study Details | Tabular View | No Results Posted | Disclaimer

How to Read a Study Record

## Study Description

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Brief Summary:
To compare skin closure via subcuticular suture versus tissue adhesive (Dermabond) in urogynecological robotic surgeries. The primary outcome is incision cosmesis at the 12 week follow up visit. Secondary outcome is the operative

time between the two methods of closure.

| Condition or disease | Intervention/treatment | Phase |
|---|---|---|
| Surgical Wound<br>Tissue Adhesion | Procedure: Subcuticular Skin Closure<br>Device: Tissue Adhesives | Not Applicable |

Detailed Description:

The purpose of this study is compare skin closure via suture versus tissue adhesive (Dermabond) in urogynecological robotic surgeries. The primary outcome is incision cosmesis. Therefore, if the tissue adhesive is cosmetically comparable to that of sutures, that will be reason to use tissue adhesives over traditional sutures. In these surgeries, there are five to six port sites (compared to fewer for usual laparoscopic procedures) and the procedures are lengthy procedures (average duration about 300 minutes as per recent AUGS/ACOG committee opinion), so if the investigators can show significant time reduction for closure, that should reduce operative time and costs. To the investigators' knowledge, this will be the first study of its kind to make this comparison for urogynecologic robotic procedures.

## Study Design

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|---|---|
| Study Type : | Interventional (Clinical Trial) |
| Actual Enrollment : | 47 participants |
| Allocation: | Randomized |
| Intervention Model: | Parallel Assignment |
| Intervention Model Description: | This will be a randomized controlled trial comparing skin closure after robotic urogynecologic surgery with tissue adhesive versus subcuticular suture. |
| Masking: | Double (Participant, Outcomes Assessor) |
| Masking Description: | The evaluators of cosmesis will be blind to the group assignment. The person who will evaluate the scars will be a nurse or medical assistant. |
| Primary Purpose: | Treatment |
| Official Title: | Skin Closure With Tissue Adhesives vs. Subcuticular Suture After Robotic Urogynecologic Procedures |
| Actual Study Start Date : | March 20, 2018 |
| Actual Primary Completion Date : | December 31, 2018 |
| Actual Study Completion Date : | December 31, 2018 |

## Arms and Interventions

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| Arm | Intervention/treatment |
|---|---|
| Experimental: Tissue Adhesives Only<br>For the tissue adhesive, we will use Dermabond, which was FDA approved for skin closure in 1998. We will record the length of time of each closure method for comparison, and have patients follow- | Device: Tissue Adhesives<br>No subcuticular closure will be done. Only tissue adhesives applied to the approximated skin |

| | |
|---|---|
| up at two, six and 12 weeks. At the 12 week visit we will score the appearance of the incision. | |
| Active Comparator: Subcuticular Suture Closure Method Only<br>For the suture arm we will only close the subcuticular layer. We will record the length of time of each closure method for comparison, and have patients follow-up at two, six and 12 weeks. At the 12 week visit we will score the appearance of the incision. | Procedure: Subcuticular Skin Closure<br>We will only close the subcuticular layer with suture |

## Outcome Measures

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Primary Outcome Measures :

1. Incision Cosmesis [ Time Frame: 12 weeks ]

   Our primary outcome measure is to compare incision cosmesis between the two closure methods at the 12 week postoperative visit. The Stony Brook Scar Evaluation scale is used. A point is awarded in each of the following categories: width, height, color, hatch/suture marks, overall appearance. Poorer cosmesis is indicated by a lower score. Highest score possible is 5 points.

Secondary Outcome Measures :

1. Incision closure time [ Time Frame: 30 minutes ]

   The time of each closure method will be recorded and compared.

## Eligibility Criteria

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**Information from the National Library of Medicine**

*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.*

| | |
|---|---|
| Ages Eligible for Study: | 18 Years to 99 Years (Adult, Older Adult) |
| Sexes Eligible for Study: | Female |
| Gender Based Eligibility: | Yes |
| Gender Eligibility Description: | Only females as this pertains to skin closure of robotic urogynecology procedures |
| Accepts Healthy Volunteers: | Yes |

**Criteria**

Inclusion Criteria:

- Women, ages 18 years and older, undergoing any urogynecologic robotic procedure at St. John Hospital and Medical Center from March 19, 2018 - November 30, 2018.

Exclusion Criteria:

- We will exclude women with active skin infections as they may contribute to poor wound healing and infections. We will also exclude procedures that are converted to laparotomy.

## Contacts and Locations

Go to

**Information from the National Library of Medicine**

*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number):* ***NCT03891004***

**Locations**

**United States, Michigan**

St. John Hospital & Medical Center
Detroit, Michigan, United States, 48236

**Sponsors and Collaborators**

St. John Hospital & Medical Center

## More Information

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| | |
|---|---|
| Responsible Party: | Sunetris Fluellen, Principal Investigator, St. John Hospital & Medical Center |
| ClinicalTrials.gov Identifier: | NCT03891004 History of Changes |
| Other Study ID Numbers: | StJohnHMedCtr |
| First Posted: | March 26, 2019 Key Record Dates |
| Last Update Posted: | April 4, 2019 |
| Last Verified: | April 2019 |

| | |
|---|---|
| Studies a U.S. FDA-regulated Drug Product: | No |
| Studies a U.S. FDA-regulated Device Product: | Yes |

Additional relevant MeSH terms:

| | |
|---|---|
| Tissue Adhesions | Fibrosis |
| Surgical Wound | Pathologic Processes |
| Cicatrix | Wounds and Injuries |

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For Patients and Families | For Researchers | For Study Record Managers

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