A single-center, phase IV, randomized, prospective study investigating the efficacy of various wound closure devices in reducing postoperative wound complications

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Study Product: Zipper wound closure device, Monocryl + Dermabond, Polyester mesh + Dermabond

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List of Abbreviations

TJA- Total joint arthroplasty

Study Summary

Title	**A single-center, phase IV, randomized, prospective study investigating the efficacy of various wound closure devices in reducing postoperative wound complications**
Short Title	Assessing various wound closure techniques; RCT
Protocol Number	i16-02020
Phase	4
Methodology	Randomized, control
Study Duration	7 months
Study Center(s)	Single-center
Objectives	To determine the efficacy of the experimental wound closure device in regards to reducing wound complications and costs
Number of Subjects	200 subjects
Diagnosis and Main Inclusion Criteria	Patients who are undergoing joint arthroplasty
Study Product, Dose, Route, Regimen	Zipper surgical skin closure device applied to the most superficial layer of skin following a joint arthroplasty
Duration of administration	Applied one-time to close the wound following joint arthroplasty. This device will be applied for up to 2-3 weeks
Reference therapy	Experimental treatment will be compared to two groups: 1) Monocryl + Dermabond 2) Polyester mesh + Dermabond
Statistical Methodology	Odd ratios will be used to determine which wound closure device is at higher risk of developing a wound complication

Introduction

1.1 Background

Today's healthcare climate continues to emphasize the need for high-quality of care while minimizing the financial burdens of the patient, hospital, and payer. This is particularly relevant in total joint arthroplasty (TJA) as payment models are shifting toward bundled, pay-for-performance episodes of care,[1, 2] and away from the current plan of payments for each separate service provided. Given that the demands for TJA are projected to increase substantially for decades to come,[3] it is imperative to identify potential factors that may improve clinical outcomes, so that ultimately, costs per episodes of care are minimized.

One such area of improvement involves gaining a better understanding of the optimal wound closure technique following TJA. Specifically, two measures, wound closure times and surgical outcomes, have been the focus of prior studies as they have been closely associated with avoidable healthcare expenditures. Common complications of failed wound closures include infection, dehiscence, edema, and arthrofibrosis.[4-15] Not only do these failures lead to exorbitant costs through poorer outcomes (i.e. delayed progress in physical therapy, increased length of stay, increased readmission, and reduced patient satisfaction), they are also known to have a significant impact on the overall long-term health of the patient.

The three common options for wound closure following TJA include sutures, staples, and skin adhesives. While conventional sutures and staples have been the mainstay techniques in TJA for some time, the barbed suture is a newer technique that has emerged as a popular option within the last decade. Reported advantages of this technique include the need for less material per incision, lower closure costs, shorter length of closure time, and a knotless application of the suture. [8-11, 16] Outcomes in regards to complications have been variable when compared to conventional sutures in TJA.[8-11] The skin adhesive that is most commonly used today includes a 2-octyl cyanoacrylate (OCA), high-viscosity, flexible glue.[7, 17] This technique has been associated with decreased wound closure times,[18] high satisfactory cosmetic results,[17, 19] and surgical outcomes comparable to conventional sutures.[17, 20] Other newer techniques such as the zipper technique[21] and variations of the OCA skin adhesives have also been sources of experimentation.

Wound closure techniques have been well-studied in a variety of surgical specialties, however, the level of evidence reported in the literature in regards to TJA is scarce. Thus, the current randomized, control trial study aims to investigate the perioperative outcomes and costs of various wound closure techniques including zipper technology, monocryl suture plus Dermabond, and polyester plus Dermabond wound closure techniques. The zipper wound technology is a new wound closure device that is an alternative to the commonly used conventional staples and sutures. The device acts like a scaffold to stabilize the adjacent sides of a wound in order to minimize forces that can disrupt normal healing of the skin. Monocryl suture plus Dermabond is a commonly used combination of wound closure techniques today. Finally, the polyester plus Dermabond closure techniques combines the OCA topical skin adhesive with a flexible, self-adhesive polyester mesh that has proven to reduce wound cosure times and have a significant greater skin holding strength than skin staples or subcuticular sutures in one study. Although there have been prior studies measuring the efficacy of these closure techniques individually, none have compared these three particular ones following TJA. Furthermore, in order to provide the highest level of evidence as possible for the study, it will be conducted in a randomized fashion.

The hypothesis of the study is that there will be reduced complications rates, improved outcomes, and overall cost reduction for the zipper technology versus the other two closure techniques.

1.3 Clinical Data to Date

A recent meta-analysis[22] compared this surgical zipper technique to conventional sutures in closing surgical wounds based on 4 randomized, control trials. The study showed that there was a similar incidence of postoperative complications, less time for incision closure, less cost for personnel involved in the procedure as well as total operating times, and higher levels of patient comfort for the zipper technique cohort.

Research Risks and Benefits

Risks

There are low associated risks with all three closure techniques. Commonly documented complications associated with all closure techniques include infection, abscess formation, hematoma formation, dehiscence, prolonged discharge, and allergic reactions. These risks are minimal overall with minimal risk differences between each technique. Thus, at worst, there will be minimal change in risks whether patients are randomized or have the option to choose a specific technique.

Benefits

There may be no direct benefit from agreeing to participate in this study. It is hoped that the knowledge gained will be of benefit to others in the future.

1.4 Primary and secondary objectives:

Primary objective: to identify the rate of complications associated with each type of wound closure technique. Some of these complications will include infection, abscess formation, dehiscence, prolonged drainage, allergic reactions, among others.

Secondary objective: to determine the cost effectiveness of each of these wound closure techniques, which will be calculated by the differences in supply costs, total lengths of operation, and postoperative complications.

2 Study Design

2.1 General Design

A single-center, phase IV, randomized, prospective study. Patients will be expected to participate for about 4 months. Please refer to section 4 for a summary description of the sequence and duration of all trial periods including follow-up.

2.2 Primary Study Endpoints

Each complication will be documented for every patient. The rates of complication will be analyzed individually for each technique, and risk ratios will be conducted between techniques to determine which technique has the lowest risk of developing a complication. Complications include infection, abscess formation, dehiscence, prolonged drainage, allergic reactions, among others.

2.3 Secondary Study Endpoints

Cost effectiveness will be determined by the increased LOS, readmissions, cost of supplies, and differences in wound closure time between the differences in wound closure techniques. Each of these variables will be calculated based on the associated hospital costs and analyzed to determine the most cost effective wound closure technique.

2.4 Inclusion Criteria

Following IRB approval, all patients who are scheduled for joint arthroplasty at NYULMC will be eligible to take part in this research study. Inclusion criteria includes:

- All patients ≥18 years of age treated with joint replacement surgery at our institution
- Patients who are willing to participate in post-operative surveys

2.5 Exclusion Criteria

- Treatment of total joint replacement surgery at an outside institution
- Patients younger than 18
- Pregnant women, prisoners, adults unable to consent.

Vulnerable Subjects: No vulnerable subjects will be included within this study

2.6 Subject Recruitment and Screening

All participants will be initially identified by participating surgeons among a large patient population scheduled for joint arthroplasty.

This study will be discussed with eligible patients by their surgeon at one of their pre-operative clinic visits. Research assistants working for the orthopaedics department will meet with patients during their pre-op visit to explain the study and obtain written informed consent using the IRB-approved consent form. A study log of consented patients will be maintained in a de-identified manner.

3 Study Treatment

3.1 Description

The zipper wound technology is a new wound closure device that is an alternative to the commonly used conventional staples and sutures. The device acts like a scaffold to stabilize the adjacent sides of a wound in order to minimize forces that can disrupt normal healing of the skin. The other treatment groups include monocryl + Dermabond (conventional sutures and skin adhesive glue) and polyester mesh + Dermabond. All products have been FDA approved.

3.2 Method for Assigning Subjects to Treatment Groups

Names of patients who are consented for the study will be inputted into a computer and randomized to one of the three treatment groups based on an alternating method. A randomized control trial will provide the highest level of evidence without altering the potential risks to the patient as all three wound closure techniques have been found to have comparable complication rates.

3.3 Preparation and Administration of Study Product

The three different treatment devices will be administered following the normal standard of care. All three wound closure devices are currently being used at NYULMC. No modifications to the normal standard of practice other than the randomization process will be implemented.

3.4 Blinding of Study Product

Given the nature of the application of the wound closure device, which will be visible to the surgeon at the time of application and the patient postoperatively, the study will not be blinded to either the surgeon or the patient. Prior to discharge, a blinded plastic surgeon will be asked to assess the wound based on comesis and overall quality of wound healing.

4 Study Procedures

Patients who are eligible for the study will be notified on a preoperative visit via a tool on the electronic medical record system (Epic). At this time, surgeon research assistant will ask the patient if they would like to be involved in the study. If consent to participate in the study is given, the surgeon will go ahead with the randomization process, which will dictate what type of wound closure device will be used at the time of the surgery. All of the wound devices are currently being used at the institution. The study will follow normal standard of care for the application of these devices. The only different will be the randomization process that will take place prior to the surgery. Data will be collected regarding the primary outcomes at the time of discharge as well as at their normally scheduled postoperative visits. Patients will be followed up to their 3rd postoperative visit. Prior to discharge, a plastic surgeon, who will be blinded to the type of wound closure technique that the patient received, will assess the wound for the quality of wound healing. At their postoperative visits, the physician will document whether a complication had occurred. Patients will also be given patient-reported outcome questionnaires, including VAS scores and HWES, that will measure the level of satisfaction of their wound healing at the time of these visits.

The following table shows the visits and procedures/ observational data collection that will occur during the study:

Activity	Pre-operative assessment	Date of surgery	Prior to discharge	**Postop visit #1**	**Postop visit #2**	Postop visit #3
Study team procedures						
Consent	X					
Medical History	X			X	X	X
Physical Exam	X		X	X	X	X
Height	X			X	X	X
Weight	X			X	X	X
Vitals signs	X		X	X	X	X
Record of			X	X	X	X

complications						
Perioperative costs – cost of supplies, time to wound closure, operative times, length of stay, readmissions		X	X			
Randomization		X				
Study treatment dispensation		X				
Subject Survey – VAS score, HWES score			X	X	X	X

5 Statistical Plan

5.1 Sample Size Determination

Based on an 80% power analysis, incidence rates reported from past studies, and a ratio of 1:1:1 cohort size between the different treatment groups involved, a total of 200 patients will be included in the study. Given an estimated 700 total hip and knee replacements done in a quarter each year at NYULMC, the project is scheduled to take a total of 7 months. It is estimated that 50% of all patients will be approached to be consented from these 700 patients (a total of 350 patients will be enrolled to reach the target number of participants), and an estimated 60% of these patients will agree to follow through with the study.

5.2 Statistical Methods

Data on patient baseline characteristics, procedural characteristics, perioperative outcomes, functional outcomes, and costs will be collected. Single variable and multivariate statistical analysis will be performed to assess the aforementioned data points. Dichotomous data outcomes will be analyzed using odd ratios and chi-squared tests while continuous data points will be analyzed using Student t-tests. Each complication will be documented for every patient. The rates of complication will be analyzed individually for each technique, and risk ratios will be conducted between techniques to determine which technique has the lowest risk of developing a complication. Complications include infection, abscess formation, dehiscence, prolonged drainage, allergic reactions, among others. Cost effectiveness will be determined by the differences in quality metrics such as LOS, readmissions, cost of supplies, and differences in wound closure time between the different wound closure techniques. Each of these variables will be calculated based on the associated hospital costs and analyzed to determine the most cost effective wound closure technique.

6 Safety and Adverse Events

6.1 Definitions

Unanticipated Problems Involving Risk to Subjects or Others

Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

Adverse Event

An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

Serious Adverse Event

Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

Adverse Event Reporting Period
The study period during which adverse events must be reported is normally defined as the period from the initiation of any study procedures to the end of the study treatment follow-up. For this study, the study treatment follow-up is defined as 30 days following the last administration of study treatment.

Preexisting Condition
A preexisting condition is one that is present at the start of the study. A preexisting condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

General Physical Examination Findings
At screening, any clinically significant abnormality should be recorded as a preexisting condition. At the end of the study, any new clinically significant findings/abnormalities that meet the definition of an adverse event must also be recorded and documented as an adverse event.

Post-study Adverse Event
All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

Abnormal Laboratory Values
A clinical laboratory abnormality should be documented as an adverse event if <u>any one of the following</u> conditions is met:

- The laboratory abnormality is not otherwise refuted by a repeat test to confirm the abnormality
- The abnormality suggests a disease and/or organ toxicity

- The abnormality is of a degree that requires active management; e.g. change of dose, discontinuation of the drug, more frequent follow-up assessments, further diagnostic investigation, etc.

Hospitalization, Prolonged Hospitalization or Surgery

Any adverse event that results in hospitalization or prolonged hospitalization should be documented and reported as a serious adverse event unless specifically instructed otherwise in this protocol. Any condition responsible for surgery should be documented as an adverse event if the condition meets the criteria for and adverse event.

Neither the condition, hospitalization, prolonged hospitalization, nor surgery are reported as an adverse event in the following circumstances:

- Hospitalization or prolonged hospitalization for diagnostic or elective surgical procedures for a preexisting condition. Surgery should ***not*** be reported as an outcome of an adverse event if the purpose of the surgery was elective or diagnostic and the outcome was uneventful.
- Hospitalization or prolonged hospitalization required to allow efficacy measurement for the study.
- Hospitalization or prolonged hospitalization for therapy of the target disease of the study, unless it is a worsening or increase in frequency of hospital admissions as judged by the clinical investigator.

6.2 Recording of Adverse Events

At each contact with the subject, the investigator must seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events should be recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results should recorded in the source document, though should be grouped under one diagnosis.

All adverse events occurring during the study period must be recorded. The clinical course of each event should be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period must be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study treatment or study participation should be recorded and reported immediately.

6.3 Reporting of Serious Adverse Events and Unanticipated Problems

Investigators and the protocol sponsor must conform to the adverse event reporting timelines, formats and requirements of the various entities to which they are responsible, but at a minimum those events that must be reported are those that are:

- related to study participation,

- unexpected, and
- serious or involve risks to subjects or others

For Narrative Reports of Safety Events

If the report is supplied as a narrative, the minimum necessary information to be provided at the time of the initial report includes:

- Study identifier
- Study Center
- Subject number
- A description of the event
- Date of onset
- Current status
- Whether study treatment was discontinued
- The reason why the event is classified as serious
- Investigator assessment of the association between the event and study treatment

6.3.1 Investigator reporting: notifying the IRB

Federal regulations require timely reporting by investigators to their local IRB of unanticipated problems posing risks to subjects or others. The following describes the NYULMC IRB reporting requirements, though Investigators at participating sites are responsible for meeting the specific requirements of their IRB of record.

Report Promptly, but no later than 5 working days:

Researchers are required to submit reports of the following problems promptly but no later than 5 working days from the time the investigator becomes aware of the event:

- ***Unanticipated problems including adverse events*** **that are unexpected and related**
  - *Unexpected: An event is "unexpected" when its specificity and severity are not accurately reflected in the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document and other relevant sources of information, such as product labeling and package inserts.*
  - *Related to the research procedures: An event is related to the research procedures if in the opinion of the principal investigator or sponsor, the event was more likely than not to be caused by the research procedures.*
  - *Harmful: either caused harm to subjects or others, or placed them at increased risk*

Other Reportable events:

The following events also require prompt reporting to the IRB, though ***no later than 5 working days***:

- ***Complaint of a research subject*** when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team.

- ***Protocol deviations or violations*** (includes intentional and accidental/unintentional deviations from the IRB approved protocol) for any of the following situations:
  - *one or more participants were placed at increased risk of harm*
  - *the event has the potential to occur again*
  - *the deviation was necessary to protect a subject from immediate harm*
- ***Breach of confidentiality***
- ***Incarceration of a participant*** when the research was not previously approved under Subpart C and the investigator believes it is in the best interest of the subject to remain on the study.
- ***New Information indicating a change to the risks or potential benefits*** of the research, in terms of severity or frequency. (e.g. analysis indicates lower-than-expected response rate or a more severe or frequent side effect; Other research finds arm of study has no therapeutic value; FDA labeling change or withdrawal from market)

Reporting Process
The reportable events noted above will be reported to the IRB using the form: "Reportable Event Form" or as a written report of the event (including a description of the event with information regarding its fulfillment of the above criteria, follow-up/resolution and need for revision to consent form and/or other study documentation).

Copies of each report and documentation of IRB notification and receipt will be kept in the Clinical Investigator's study file.

Data and Safety Monitoring Plan

7 Data Handling and Record Keeping

7.1 Confidentiality

While PHI will temporarily be seen, none will be collected, stored, or recorded for this study. All de-identified data will be stored securely. The database will be stored securely in a password-protected electronic spreadsheet and only accessible to those individuals granted access to it by the research staff. No other individuals beyond those identified within the study protocol will be permitted to view, handle, or possess the data. The research data will be de-identified to protect confidentiality. No PHI will be recorded.

7.2 Confidentiality and HIPAA

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

7.3 Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

7.4 Case Report Forms

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

7.5 Records Retention

The Principal Investigator and other researchers must ensure that all Research Data is maintained in accordance with this Policy for the longer of (i) three (3) years after the final project close-out or (ii) six (6) years after any reporting, publication, presentation, or use in any grant application by the researcher of such Research Data, or self-citation of the same in such manner that may be of benefit to such researcher.

8 Data and Safety Monitoring Plan

8.1 Data and Study Monitoring Plan

The Investigator will allocate adequate time to monitor the activities of the study. The Investigator will ensure that the monitor or other compliance or quality assurance reviewer is given access to all the above noted study-related documents and study related facilities (e.g. pharmacy, diagnostic laboratory, etc.), and has adequate space to conduct the monitoring visit. The Investigator is able to stop the study whenever they see fit. However, this is not anticipated as the level of safety associated with the study has minimal to no differences in risk compared to the normal standard of care. Written reports will be submitted to the IRB if any concerns regarding the monitoring plan arise.To further ensure safety, the other study members will monitor the participants on an ongoing basis. Each member will be trained in the definition, monitoring, and reporting of adverse events, as well as both anticipated and unanticipated problems.

Study data and safety monitoring will focus on several areas and will be periodically reviewed to ensure that the study is meeting study expectations. These areas will be reviewed biweekly:
- Safety – to assess the mechanisms used to protect the safety and privacy of the study participants as well as the extent and magnitude of adverse events.
- Performance – to assess performance with respect to participant recruitment, retention, and follow-up, Case Report Form (CRF) tracking, protocol adherence, and quality of data
- Intervention effects – to assess whether the study should continue based on safety and efficacy data (if applicable).

8.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits as frequently as necessary, and inspections by the IRB, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.). Written reports will be submitted to the IRB if any concerns regarding auditing and/or inspection arise.

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

9 Ethical Considerations

This study is to be conducted accordance with applicable US government regulations and international standards of Good Clinical Practice, and applicable institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted Institutional Review Board (IRB) in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study. The investigator should provide a list of IRB members and their affiliate to the sponsor.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the IRB-approved consent form, must be obtained before that subject undergoes any study procedure. The consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

In addition, it will describe who will obtain consent and how the process of informed consent will be structured to be conducive to rational and thoughtful decision making by the subject/subject's legally authorized representative. If children and/ or cognitively impaired adults will be subjects, include a specific plan to assess comprehension during assent or the subject's agreement Individuals who are authorized to obtain consent must be listed on the protocol (or FDA form 1572) and consent form document. If necessary to use 'Auditor/Witness' and/or translator, these roles would be described in this section.
Include a plan for assessing subject capacity in cognitively impaired subjects. Describe the anticipated degree of impairment relative to their ability to consent and the anticipated direct benefits to the subjects.

10 Study Finances

10.1 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULMC investigators will follow the applicable University conflict of interest policies.

10.2 Costs and payments

Patients will not be financially reimbursed throughout this study. Also, there will be no funding necessary for this study as all three wound closure techniques are currently and regularly in use at the institution and there are no supply cost differences between them.

11 Publication Plan

Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the sponsor for the purposes of performing the study, will be published or passed on to any third party without the consent of the study sponsor. Any investigator involved with this study is obligated to provide the sponsor with complete test results and all data derived from the study.

12 References

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