Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

There is no funding for this study.

Key Information About This Research Study

Principal Investigator:	Mark Miller, MD 545 Ray C. Hunt Dr. Charlottesville, VA 22903 (434) 243-7778

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

This study is trying to find out if there is one method of surgical incision closure is better than another. The three different wound closure methods in this study are currently used in standard of care. The three methods being compared are standard stitches and the wound closure devices, Clozex, and Zipline. All of these methods are approved by the FDA.

You are being asked to take part in this study because you are having an outpatient surgery, in which your surgical incision can be closed with any of these three methods. Several criteria will be used to determine which method is better including an assessment scale to evaluate several aspects of the surgical scar, a survey of your satisfaction as the patient, a survey of your surgeon's satisfaction in applying each method and the incidence of adverse events.

Why would you want to take part in this study?
You will not be helped by being in this study, but the information gained by doing this study may help others in the future.
Why would you NOT want to take part in this study?
You might not want to take part in this study because you may not want to be randomly assigned to receive a surgical incision closure method. You may rather have your doctor choose which method they will use to close your incision.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form.
If you take part in this study you will:

- Be randomly assigned to the product or method used to close your surgical incision
- Fill out a satisfaction questionnaire at your post-operative follow up visits with your doctor

What is the difference between being in this study and getting usual care?
If you take part in this study, the following things will be done differently than if you do not take part in this study.

- As part of usual care, your doctor would choose which product or method is used to close your surgical incision. In this study, your doctor cannot choose.
- As part of usual care, you would not have to answer questions about your incision/scar at your follow up visits

Up to 60 people will be in this study at UVA.

How long will this study take?

You will be in this study from the time of your surgery until your second follow up visit, which will occur 10-14 weeks after surgery. This study will add 10 minutes to each of the two follow up visits done as part of your standard care.

What will happen if you are in the study?

SCREENING

Visit 1 (this add 30 minutes to your standard of care visit)
If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, we will review your inclusion/exclusion criteria, to make sure you are a good candidate for the study

If this review shows you are eligible, you will return for your surgery, to being study procedures.

RANDOMIZATION

Visit 2

On the date of your surgery, you will be randomly assigned into one of three groups. This randomization will determine how your doctor closes your surgical incision.

You will be randomly assigned (like the flip of a coin) to 1 of 3 study groups. Each method used in this study is currently being done here at UVA by your doctor. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor can choose which group you are assigned.

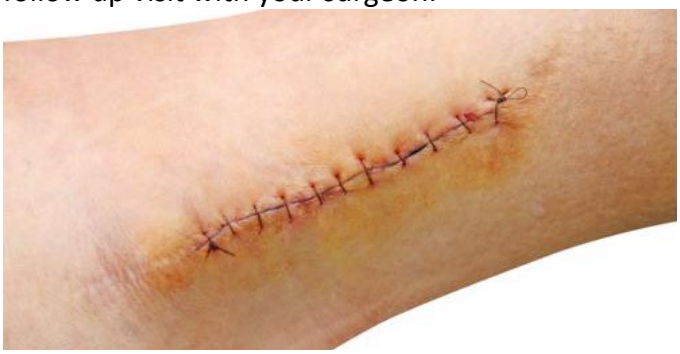
GROUP 1: 3-0 Prolene stitches (control group)

GROUP 2: Clozex surgical skin closure

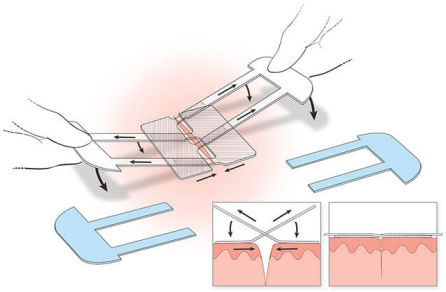
GROUP 3: Zipline surgical skin closure

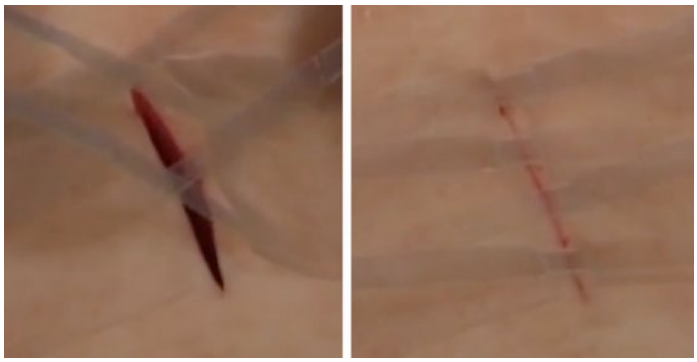
Depending which group you are randomized to, your surgeon will close your wound with the method you were assigned to.

- Standard stitches: if you are randomized to this group, you will have stitches sewn in your skin, and tied, to close your surgical incision. These will stay in your skin until your follow up visit with your surgeon.

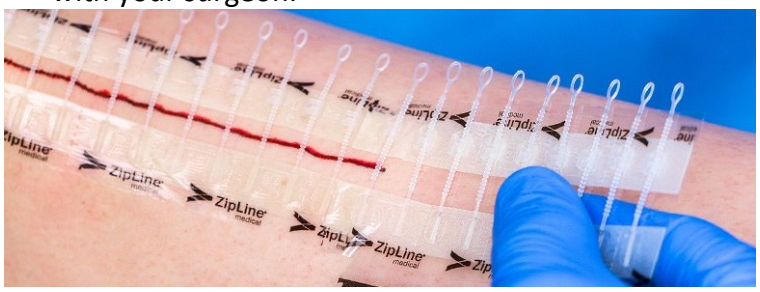


- Clozex- This is a wound closure method that uses adhesive strips to close your surgical incision. Your doctor will place adhesive strips on either side of the wound, then pull tabs to pull the wound together and lay the additional adhesive strips over top of the wound to keep it closed. You will keep this on your wound until your follow up visit with your surgeon.





- Zipline- This is a wound closure method that uses adhesive strips and zip ties to close your surgical incision. Your doctor will place adhesive strips on either side of the wound, then pull zip ties along your incision until both edges of the incision meet, and the incision is completely closed. You will keep this on your wound until your follow up visit with your surgeon.



After your incision closure is completed, your surgeon will fill out a survey on their satisfaction, and report any complications that may have occurred.

For research purposes, the study team will calculate the total cost for the incision closure materials used in your surgery, the cost of time from start of wound closure application to end, and the cost of total time in the OR (in minutes). We will gather this information both during surgery, and from your medical chart.

FOLLOW UP:

This will add about 10 minutes to your standard of care visit
After your surgery, you will follow up with your surgeon as part of your standard of care. Your first follow up visit will be about 2 weeks after surgery. At this time, your incision closure material will be removed if determined appropriate by your doctor. Your doctor will measure and examine your incision, and you will fill out a satisfaction questionnaire about your incision/scar.

You will then follow up with your surgeon 10-14 weeks after surgery as part of your standard of care. During this visit, your surgeon will measure and examine your scar, and ask you to rate your satisfaction with your scar for research purposes.

Study Schedule

	Visit 1 Pre-Op	**Visit 2** Surgery	**Visit 3** 2-weeks	**Visit 4** 10-14-weeks
Informed Consent	X			
Review study eligibility	X			
Randomization		X		
Wound Closure Application		X		
Wound Closure Removal			X	

Scar Evaluation			X	X
Satisfaction Questionnaire		X Surgeon only	X	X
Review of Complications		X	X	X

END OF STUDY:

Once your surgeon determines that you no longer need to come to clinic for follow up visits after your surgery, you will have completed you participation in the study.

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You must come to each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the Prolene Stitches include:

Likely

- Pain in stitches

Less Likely

- Ripping of stitches (breakage)
-

Rare but serious

- Infection under your stitches
- Skin reaction to stitch material

Risks and side effects related to the Clozex include:

Less Likely

- Skin reaction to adhesive material (such as allergic reaction, hypopigmentation or hyperpigmentation)
- Skin stripping upon removal

Rare but serious

- Wound infection
- Loss of product adhesion

Risks and side effects related to the Zipline include:

Less Likely

- Skin reaction to adhesive material (such as allergic reaction, hypopigmentation or hyperpigmentation)
- Skin stripping upon removal

Rare but serious

- Wound infection
- Loss of product adhesion
- Zip device breaks

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Your surgeon using the wound closure method of his choice, rather than it being randomly assigned to you

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

The following procedures, which are being done for research purposes, will be provided at no cost to you or your health insurance: completing the satisfaction survey and having your incision measured during your visits.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study.
Some of the reasons for doing so may include

a) Your study doctor is concerned about your health
b) Your disease/condition gets worse
c) The side effects are too dangerous for you
d) New information shows the study will not work or is not safe for you
e) You do not follow your doctor's instructions
f) The study doctor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we will ask you to let the study team know that you wish to withdraw.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study will not be used in future research.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study

- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Mark Miller
Address: 545 Ray C. Hunt Drive
Charlottesville, VA 22903 Telephone: 434-924-6187

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.
The follow up information will be collected by:

- Obtaining information from my medical records

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE