

Version Date: 30 November 2022

CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: Suture Repair of Lacerations in the Emergency Department: Comparison between Absorbable and Non-absorbable Suture Material

Principal Investigator: Kenneth Taylor, MD

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Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?

We are asking you to take part in this voluntary research study because you presented to the Emergency Department with a hand laceration that requires repair with sutures.

What is the purpose of this research study?

The purpose of this voluntary research study is to evaluate the use of absorbable and non-absorbable suture material in hand lacerations and to compare differences in outcomes, if they exist.

How long will the research study last?

The expected duration of involvement will be about 12 weeks from initial encounter in the Emergency Department. A total of three follow up visits will be scheduled over that time period.

What will I need to do?

Part of this research involves following up in our Hand Surgery Clinic for a total of three visits over the next 12 weeks. Follow-up appointments after having a laceration are standard of care practices and would be a typical part of your care regardless of involvement in the research study.

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What are the main risks of taking part in the study?

For this study, the main risks to know about are largely related to laceration (wound) repair, which you would face regardless of involvement in the study. Such risks include hematoma, infection and wound healing breakdown or dehiscence (separation of the wound).

What are the possible benefits to me that may reasonably be expected from being in the research?

We cannot promise any benefits to you from taking part in this study. However, possible benefits include improved wound healing (i.e., reduced healing time and improved cosmetic result). Results of the study may benefit other people in the future by helping us learn more about laceration repair healing.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Instead of being in this research study, you will be treated with one of the two suture materials, at the discretion of the treating physician and resident, as both are current standard of care practices.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?

This research is being done to determine whether laceration repairs performed with absorbable suture material or non-absorbable suture material result in better wound healing.

You will be randomly assigned (assigned at random, like flipping a coin) to receive one of two study groups.

Group 1: Absorbable sutures

Group 2: Non-Absorbable sutures

This means whichever study treatment you receive will be determined purely by chance. You will have an equal chance of being in either group. Both absorbable and non-absorbable sutures are typically used depending on provider (attending and resident) preference; as such, both types of sutures are not deviations from standard of care practices.

Approximately 32 participants will be enrolled in the study; 16 will receive absorbable sutures and 16 will receive non-absorbable sutures.

2. What will happen in this research study?

Initial Visit – Emergency Department

- After you have read through this consent form, all of your questions have been answered to your satisfaction, and you have agreed to participate by signing this form, it will be determined by reviewing your medical history if you meet all of the criteria to continue in the study.
- If you are eligible to be in the study, you will be randomly assigned to receive either the absorbable or non-absorbable sutures.

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- You will have your wound evaluated and classified according to the surgical wound classification system. The laceration will be thoroughly cleaned with 1 liter of normal saline to irrigate the wound. This is standard of care procedure and would be done regardless of your participation in the research study.
- After repair, you will be sent home with a 1-week course of antibiotics. The antibiotic of choice is Keflex. If you have a known allergy to Keflex, another antibiotic will be given instead. Antibiotic administration status post laceration repair is standard of care practice and would be given regardless of participation in the research study.

Follow-Up Visits

Follow-Up Visit # 1: Two weeks after initial encounter, sutures will be removed in the Outpatient Hand Clinic per standard care practice. The wound will be assessed. The following will be completed by you and the blinded single observer together as part of the research study.

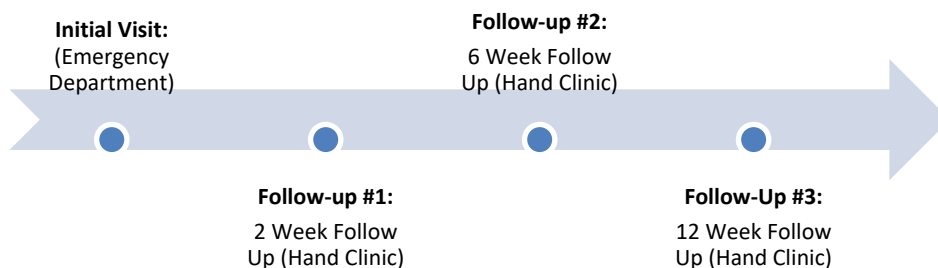
- The Patient and Observer Scar Assessment Scale (POSOS)
- Visual Analog Scale (VAS)

Follow-Up Visit # 2: Six weeks following initial visit, you will be seen in the Outpatient Hand Clinic for a wound assessment per standard care practice. The following will be completed by you and the blinded single observer together as part of the research study.

- The Patient and Observer Scar Assessment Scale (POSOS)
- Visual Analog Scale (VAS)

Follow-Up Visit #3: Twelve weeks following initial visit, you will be seen in the Outpatient Hand Clinic for your final wound assessment per standard care practice. The following will be completed by you and the blinded single observer together as part of the research study.

- The Patient and Observer Scar Assessment Scale (POSOS)
- Visual Analog Scale (VAS)



You are free to skip any questions you do not wish to answer.

3. What are the risks and possible discomforts from being in this research study?

- There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality

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of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

- You will be assigned to a treatment group by chance. The treatment you receive may prove to be less effective or to have more side effects than the other research treatment.
- Risks related to laceration repairs include hematoma, infection, and wound healing complications, including wound breakdown or dehiscence (separation of wound). These risks you would have with or without the research.
- Non-absorbable suture risks: Adverse reactions associated with the nylon suture material include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in transmission of bloodborne pathogens.
- Absorbable suture risks: Adverse reactions of the plain and chromic suture material include wound dehiscence, calculi formation in urinary and/or biliary tracts and prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Patients with allergy or hypersensitivity to collagen or chromium may experience reactions resulting in inflammation, tissue granulation, fibrosis, wound suppuration, bleeding, sinus formation, secondary infection or inflammatory response characteristic of foreign body response.

This suture may have variable rates of absorption over time (depending on such factors as the type of suture used, the presence of infection, and the tissue site). This may result in failure to provide adequate wound support in closure of sites where expansion, stretching or distension etc. may occur, unless additional support is supplied through the use of nonabsorbable suture material. Failure to provide adequate wound support in elderly, malnourished, or debilitated patients or in patients suffering from cancer, anemia, obesity, infection or other conditions may delay wound healing.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include improvement in wound healing (i.e., reduced time, improved cosmetic result) and reduction in complications related to suture repair.

4b. What are the possible benefits to others?

The results of this research may guide the future treatment of lacerations by determining the most effective suture material for wound healing.

5. What other options are available instead of being in this research study?

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could receive care for repair of your laceration following standard of care practices without being part of this research study. Before you decide if you want to be in this research, we will

discuss the choices that are available to you. We will tell you about the possible benefits and risks of these choices.

6. How long will I take part in this research study?

If you agree to take part, it will take you approximately 12 weeks from your visit to the Emergency Department to complete this research study. You will be asked to visit the research site (Outpatient Hand Clinic) a total of three visits. All visits are part of your routine standard of care.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

In our research files at Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: names, phone number, a code number, date of emergency department visit, and dates of follow up appointments to the Hand Clinic.

- A list that matches your name with your code number will be kept in a locked file in Dr. Kenneth Taylor's research office.
- Your research records will be labeled with: your code number and your initials and will be kept in a safe area in Dr. Kenneth Taylor's research office.
- A copy of this signed consent form will be included in your PSH medical record. This means that other PSH healthcare providers will know you are in this study.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. What will happen to my research information and/or samples after the study is completed?

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all your identifiers are removed.

7c. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. We will use and disclose your information only as described in this form and in the PSH Privacy Notice.

The research team may use the following health information:

- Past, present, and future medical records, including identifiable information
- New health information from procedures, visits, interviews, or forms filled out as part of this research study.

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The following people/groups may see, use, and share your identifiable health information:

- PSH/PSU research staff involved in this study
- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Research Protection Program (HRPP)
- The PSH/PSU Research Quality Assurance Office
- Non-research staff within PSH/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original PSH/PSU records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

For costs of tests and procedures that are only being done for the research study:

The research-related tests and procedures that will be provided at no cost to you include:

- The Patient and Observer Scar Assessment (POSAS)
- Visual Analog Score for Pain (VAS)

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

N/A

9. Will I be paid to take part in this research study?

You will be paid \$25.00 for your participation in this research study. This money covers your time needed to complete the surveys at your visits. This payment will be made only if all study visits are completed and will be payable at the final 12-week follow-up visit.

This reimbursement will be issued by an external company called Greenphire. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process the reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.

When your final visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto a ClinCard, Greenphire will need your Study/Subject ID, Name, Address, Date of Birth, and Social Security Number.

You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send your messages, Greenphire will need your mobile phone and/or email.

Payment received as compensation for participation in research is considered taxable income. If payments from Greenphire exceed \$600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of Penn State.

10. Who is paying for this research study?

Funds from the Department of the Orthopaedics and Rehabilitation will be used to support this research.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

During the course of the research, you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Kenneth Taylor at (717) 531-5638 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the PSU Human Research Protection Program (HRPP) at (814) 865-1775 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at <http://med.psu.edu/clinical-research/faqs> for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HRPP at (814) 865-1775.

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A description of this clinical trial will be available on <https://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name
(Only approved investigators for this research may explain the research and obtain informed consent.)			

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name