

Official Title: Bovine Carotid Artery Biologic Graft and Expanded Polytetrafluoroethylene for Permanent Hemodialysis Access

NCT03300024

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If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **A Prospective Randomized Study of Bovine Carotid Artery Biologic Graft and Expanded Polytetrafluoroethylene for Permanent Hemodialysis Access**

Application No.: **IRB00069002**

Principal Investigator: **Thomas Reifsnyder, MD**
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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on <http://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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to compare two different types of materials used to create an arteriovenous (AV) graft.

In order to start hemodialysis treatment a person needs an access to their bloodstream. This is called a vascular access. The access allows the patient's blood to travel to and from the dialysis machine. One type of access point commonly used in hemodialysis treatment is called an arteriovenous (AV) graft.

An arteriovenous (AV) graft is created by connecting a vein to an artery using a tube. After the graft heals, hemodialysis is performed by placing one needle in the arterial side and one in the venous side of the graft. The graft allows for increased blood flow.

In this study we want to compare two different types of AV grafts. Synthetic grafts such as those made from expanded polytetrafluoroethylene (ePTFE) are the most common in current use. Alternative grafts made out of vessels transplanted from cows (bovine carotid artery or BCA) are also used. There is very limited information as to which type of graft is better. Our goal is to learn more about how each type performs in an actual patient.

Both treatment options offered in the study are considered standard of care for your specific condition.

In a recent study that was conducted with 6 month follow-up in small number of patients, the BCA graft was an excellent option for patients on hemodialysis that were not candidates for AV fistulas. The patients who received the bovine carotid grafts required fewer interventions than the ePTFE grafts. However, due to the short duration of the study and the small number of people enrolled in the study, one graft was not found to be better than the other. People requiring hemodialysis access may join.

How many people will be in this study?

About 100 participants will be enrolled in this study at Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Screening

You will be tested to see if you are fit for surgery and graft placement per standard of care. A physical exam will be done and a venous ultrasound (taking pictures of your veins), if necessary, will be obtained to make sure you are a good candidate for the procedure. If you are a woman capable of having children, a urine pregnancy test will be done per standard of care to rule out pregnancy. If you are pregnant or plan on becoming pregnant for the duration of the study, you will be excluded from taking part.

AVG Placement

If you qualify you will be randomly (by chance, like a flip of a coin) assigned to receive either a BCA or standard ePTFE graft. You will undergo surgery and receive the randomized graft according to standard of care guidelines for AVG creation. The graft will be placed either in the arm (brachial artery to axillary vein) or forearm (brachial artery to cephalic or suitably sized vein) depending on which location works best in your particular case.

Post-operative assessment and use

You will be monitored postoperatively (after the operation) per standard of care regardless of the graft you have received.

Follow-ups will be scheduled at 2 weeks and 4-6 weeks following graft placement, during which you will undergo a physical examination by the surgeon or the surgery fellow.

Subsequently, the graft will be monitored for its functionality (how well it works) during dialysis sessions three times weekly by a nephrologists or trained dialysis nurse. Difficulty during dialysis (disruptions in flow pattern or increased bleeding) or the absence of a thrill or bruit will warrant surgical evaluation. A duplex ultrasound or fistulogram will then be obtained to evaluate the graft and the cause of any problems.

Follow-up

The standard surgical follow up following this procedure is outlined above. Once all of your sutures have been removed and we have cleared you to use your graft at dialysis normally we would not see you back in clinic unless there was a problem. However, as part of this study you will be contacted by the study staff every three months for up to two years to assess unction of the graft and to monitor outcomes of interest.

How long will you be in the study?

You will be in this study for 2 Years

4. What are the risks or discomforts of the study?

You will sign a separate clinical consent form that will cover the risks of AVG Placement.

It is unknown known, which type of AV graft provides a better outcome. It is possible that, as a result of being in the study, you will be randomized to an arm that may offer less favorable outcome and have more side effects.

5. Are there risks related to pregnancy?

Pregnant patients are excluded from the research. If you are pregnant or plan to become pregnant, you should inform the study staff immediately and you will not be able to participate in this research.

6. Are there benefits to being in the study?

There may be no direct benefit to you by joining the study. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

. You or your insurance company will be responsible for the costs associated with AVG placement.

9. Will you be paid if you join this study?

No.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment]).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study. If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Thomas Reifsnyder at 410-550-4335. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

Approved October 27, 2015

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Principal Investigator: Thomas Reifsnyder, MD

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c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Thomas Reifsnyder, MD at 410-550-4335 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Mahmoud Malas, MD at 410-550-4335 during regular office hours and at 410-507-2131 after hours and on weekends.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

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16. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant (Print Name) Date/Time

Signature of Person Obtaining Consent (Print Name) Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

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DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time
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Signature of Participant	(Print Name)	Date/Time
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NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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