

This form is not valid without a TTUHSC IRB stamp on each page.

CONSENT TO TAKE PART IN A MEDICAL RESEARCH STUDY

This is a research study for people who **voluntarily** choose to take part. Please **take your time** to make a decision, and discuss the study with anyone you think could help you with your decision. If you decide not to take part you will not lose access to benefits you would normally get.

STUDY TITLE: Evaluating the Efficacy of Blood Flow Restriction Therapy in a Randomized Clinical Trial for Postoperative Rehabilitation Following Ankle Ligament Reconstruction

INVESTIGATOR(S): Jerry Grimes, MD; Kenneth Stephenson, MD

CONTACT TELEPHONE NUMBER(S):

You should contact the investigator(s) at the number(s) listed below if you have any concerns or unexpected complications. If it is a medical emergency, please seek medical care immediately and notify the investigator(s) above when you are safely able to do so.

Jerry Grimes, MD
806-743-2465

INSTITUTION(S):

Clinic sites

- Texas Tech Physicians Orthopedic Surgery Medical Pavilion Clinic

Surgical sites

- University Medical Center
- The Center for Orthopedic Surgery

Physical therapy sites

- Physical Therapy Today (PTT)

OVERVIEW

What you need to know:

- Blood flow restriction (BFR) therapy is a physical therapy (PT) treatment where therapists limit the amount of blood that reaches your arm or leg while lifting light weights
- This lack of blood makes muscles work harder while lifting less weight. This allows physical therapists to mimic the effects of high intensity training without the use of heavier weights
- By using lighter weights, this helps reduce the risk of reinjury after surgery. This also allows the patient to strength train earlier than would be possible with the current

standard of care.

What you will be asked to do while in the research study:

- You will be randomly assigned to one of two groups (like flipping a coin).
 - Group 1) physical therapy (PT) with blood flow restriction (BFR)
 - Group 2) traditional physical therapy (traditional PT)
- If assigned to the BFR group, you will be asked to perform exercises as you normally would in PT. However during visits you will have inflated blood pressure cuffs on your lower limbs.

Most common risks include:

- Delayed onset muscle soreness after the first and second sessions. It is expected that the amount of muscle soreness will decrease over time
- Bruising where the blood pressure cuffs are placed. This risk is reduced by having them placed by your physical therapist.

If you are interested in learning more about the study and participation, the rest of this form will be reviewed and discussed with you.

DETAILED INFORMATION

1. What is the purpose of this study?

The purpose of this study is to evaluate blood flow restriction (BFR) as a treatment for patients after ankle ligament reconstruction. The goal is to determine if BFR therapy is the same as or better than traditional physical therapy (PT). We will be seeking to enroll 84 participants total. These patients will do their PT at University Medical Center (UMC) or PT Today in Lubbock, Texas.

The BFR device we are using is the Smarttools SmartCuffs. If you decide to enroll and are in the BFR group, the device will be placed over your injured limb's upper thigh. You will then perform the prescribed exercises during the session with the BFR device inflated.

2. How long will I be in this study?

If you decide to enroll in the study, you will receive 6-weeks of PT. The baseline data will be taken on the first day of PT. You will then complete the PT course prescribed by your physical therapist. Data will be collected again at the end of your 6-week PT visit or upon completion of your PT program.

3. What will happen in this study that is different than my usual care?

Your surgical treatment will not change if you decide to enroll in the study.

If you are randomly assigned to the traditional PT group, you will undergo a 6-week course of PT designed by your physical therapist.

If you are randomly assigned to the BFR treatment group, you will undergo a 6-week course

of PT designed by your physical therapist. However, during your sessions, a BFR device will be placed on your injured limb's upper thigh.

Data will be taken for both groups at the first PT visit and at the end of your 6-week PT course or upon your final PT session.

The data we are collecting includes:

- Demographic information: age, race, ethnicity, sex, BMI, and insurance status
- Change in muscle size by measuring the circumference of your calf and your thigh
- Functional outcomes to see how your surgery and recovery affect your daily life
- Pain scores using a scale of 0-10
- Impact of BFR on your heart rate and blood pressure

When the study is done, we will keep your unidentifiable recorded medical information to use in our future research, or in research done by our colleagues. If your unidentifiable medical information is used in future studies, we will not ask for your consent again before using it. You will not know when or if that information is used for research, and no one will be able to tell you any results of research that used your information. By agreeing to participate in this study, you also consent to the use of your unidentifiable recorded medical information to use in our future research, or in research done by our colleagues.

4. What about confidentiality and the privacy of my records?

We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center (TTUHSC) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research. A copy of this document may be placed in your medical record.

Study results that are used in publications or presentations will not use your name.

5. What are my choices if I decide not to take part in this study?

If you choose to not take part in this study, you will still receive the current standard of care. This includes ankle ligament reconstruction, a period of immobility to protect your ankle while it heals, and a period of PT when you would strengthen your lower leg to get back to normal. The only difference between our study and the current standard of care would be performing the exercises under blood flow restriction (BFR) if you are randomized into that group.

6. What risks are expected based on what we know now?

There have been individuals who have performed BFR therapy against the advice of healthcare professionals which resulted in injury. In these cases, use of BFR without

medical supervision has resulted in rhabdomyolysis, a condition where muscle cells break down. To our knowledge, no cases of rhabdomyolysis have been observed in a clinical setting.

In addition, study patients are at increased risk of blood clots in their legs or lungs. However, this is due to their ankle-reconstruction surgery which is not part of the study itself. That being said, BFR helps prevent clots and the number of people who experience clotting issues is lower in BFR subjects than in the general population.

It is important to note these are not expected risks but are included here for completeness.

The only expected risks are potential bruising at the site of cuff placement. This risk may be reduced by proper cuff placement and inflation. There is also a risk of delayed onset muscle soreness after the first few sessions.

There are no other known risks beyond what is stated in the overview at the beginning of this form.

7. What happens if I am injured because I take part in this study?

Texas Tech University Health Sciences Center, University Medical Center, The Center for Orthopaedic Surgery, and PT Today, does not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.

If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

8. Are there any benefits to me?

Subjects randomized into the BFR group may experience faster and more complete recovery post ankle ligament reconstruction.

Results of this study may help standardize use of BFR in the future and improve outcomes for other patients.

9. Will I receive anything for taking part in this study?

You will not be paid for participating in this study.

10. Will it cost me anything to take part in this study?

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only, or that are covered by the study. These include: BFR device, study specific surveys, and study specific evaluations.

Any procedures that are considered standard of care are your or your insurance provider's responsibility.

Talk to your insurance provider and the study staff to make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

Ask your researcher/doctor for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

11. Does anyone on the research staff have a personal financial interest in this study?

No one on the research staff has a financial interest in this study.

12. If I decide to take part in this study can I stop later?

Yes, your participation is voluntary. You can decide to stop taking part in the study at any time. However, any data about you that has been collected up to that point in time cannot be removed.

If you decide to stop, let your researcher/study doctor know as soon as possible. This will help to ensure your needs related to this research are met. It's important that you stop safely.

If you decide to stop the study intervention(s), you can decide if you want to keep letting the researcher know how you are doing or if you want to completely withdraw from participation.

Your researcher/study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

13. Are there any other reasons why I might stop being in the study?

Yes. The researcher/study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by Institutional Review Board (a committee that reviews and approves research), the Food and Drug Administration or study sponsor, Texas Tech University Health Sciences Center.

14. What if I have questions?

For questions about this study, contact the Investigator, Dr. Jerry Grimes, at 806-743-2465. In the event you believe an emergency may affect your participation in this study, contact the investigator as soon as you are safely able to do so.

If you would like to speak to someone who is not involved in the study about your rights as

a participant, research-related injuries, or any other matter, including emergencies, related to the study, you can call the TTUHSC EthicsPoint Hotline: 1-866-294-9352, or you can file an Ethics Point report online:

<https://secure.ethicspoint.com/domain/media/en/gui/12958/index.html>. Please choose the "Regulatory Compliance" option when making an online report.

[SIGNATURE PAGE FOLLOWS]

You will be given a signed and dated copy of this form. By signing this form, I acknowledge that I have reviewed the information contained in this document, that I have had an opportunity to have all of my questions answered to my satisfaction, and I agree to participate in the study as it is described.

Printed Name of Study Participant

Signature of Study Participant Date

Signature of Guardian/Authorized Representative Date

I have discussed this research study with the study participant and his or her authorized representative (if applicable), using language that is understandable and appropriate. I believe I have fully informed the study participant of the possible risks and benefits, and I believe the study participant understands this explanation. I have given a copy of this form to the study participant.

Signature of authorized research personnel who conducted the informed consent discussion Date

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**TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER
AUTHORIZATION TO USE AND/OR DISCLOSE
YOUR PROTECTED HEALTH INFORMATION for a RESEARCH STUDY**

STUDY TITLE: Evaluating the Efficacy of Blood Flow Restriction Therapy in a Randomized Clinical Trial for Postoperative Rehabilitation Following Ankle Ligament Reconstruction

This form is intended to tell you about the use and/or disclosure (sharing) of your personal **Protected Health Information (PHI)** if you decide to participate in the research study described on the previous pages. The health information about you that may be used or disclosed is described below. This information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached Informed Consent document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.
2. If you choose to cancel this Authorization, please give notice in writing to:
**Institutional Privacy Officer
Office of Institutional Compliance
3601 4th St MS 8165
Lubbock TX 79430**

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

- your treating physicians and healthcare providers and their staff,
- associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC Notice of Privacy Practices.

The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:

<ul style="list-style-type: none">• hospital records and reports• admission history, and physical examination	<ul style="list-style-type: none">• immunizations• allergy reports
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<ul style="list-style-type: none"> • X-ray films and reports; operative reports • laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS) • any other Protected Health Information needed by the research personnel listed above <p><i>(*use separate form for disclosure of psychotherapy notes)</i></p>	<ul style="list-style-type: none"> • prescriptions • consultations • clinic notes • mental health records • alcohol/substance abuse records
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For the purposes of this study, your Protected Health Information may need to be reviewed or disclosed to individuals or organizations within and/or outside of TTUHSC who sponsor, approve, assist with, monitor or oversee the conduct of research studies. This includes, but is not limited to, the TTUHSC Institutional Review Board, TTUHSC compliance reviews, the US Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services, or governmental agencies in other countries. Some of these individuals or organizations may share your health information further, and your health information may not be protected by the same privacy standards that TTUHSC is required to meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your Protected Health Information. When we receive your request, you may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about you that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form, your regular health care will not be affected. However, not signing this form will prevent you from participating in this research study and prevent you from receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

Printed Name of Study Participant

Signature of Individual or Authorized Representative

Date

If applicable, Relationship of Authorized Representative or Authority to Sign