Implementing a novel splinting technique using 3D models for patients with scleroderma and arthritis

NCT Number: Not Yet Assigned

10/15/2021

Human Research Study Informed Consent and Authorization (Permission) to Use or Disclose (Release) Identifiable Protected Health Information (PHI)

Title of Research Study	Implementing a novel splinting technique using 3D models: For patients with scleroderma and arthritis: A Pilot Study
Principal Investigator	Christine Mulligan, OTD, OTR/L, CHT
Address	65 1st Street Troy, New York 12180
Phone Number	518-210-5086

Summary of Key Information

Invitation to Participate in Research	You are being asked to take part in a human research study. This form has information about the research. The researchers are studying the benefits and limitations of using a 3D model to fabricate splints for patients with scleroderma, osteoarthritis, and rheumatoid arthritis, as well as determine whether nighttime splint wear is effective in decreasing pain, maintaining range of motion, and increasing your ability to complete functional tasks. Where it says "See Below", there is more complete information later in this form. You and the research personnel will discuss this information so you can decide whether or not to take part in this research. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers to your questions or concerns about the research.
Informed Consent	This process is called informed consent. It is important that you understand this research so that you can decide whether or not you want to take part. To make your decision, you must consider all the information below. You should especially read and think about: • The purpose of this research. • How this research differs from standard medical care. • The procedures involved in this research. • The risks. • If the possible benefit of taking part in this research is worth the risk. • The alternatives to taking part in this research.
Voluntary Participation and Withdrawal (See Below)	You do not have to take part in this research. It is your choice whether or not you want to take part. You may "withdraw" or end the study early. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

Confidentiality and Privacy (See Below)	Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity such as de-identification of data, but the information collected about you can never be 100% secure. An "*Authorization (Permission) to Use or Disclose (Release) Identifiable Protected Health Information (PHI)*" section is below. Read this section carefully.
Purpose	The purpose of this research is to discover whether making a splint on a 3D model of a patient's hand is an effective method to provide patients with compromised skin integrity or deformities a custom-made hand splint. In addition, this study will determine whether wearing a splint(s) at night can result in decreased pain, increased hours of sleep, increased ability to complete daily activities, and maintain or increase range of motion within the wrist and fingers. The research does involve certain risks.
Description/ Procedures (See Below)	Experimental Parts of the Study: If you agree to participate in this study, the following will occur: Researchers will scan your forearm, wrist, and hand with an iPhone camera through the Comb O&P Scan App on the iPhone. The entire Comb O&P platform is HIPAA compliant. De-identified scans will be provided to Precision Valve & Automation (PVA) where a 3D model of your hand and partial forearm will be printed. After the study is complete the scans will be destroyed. Researchers will fit a splint to the 3D model and provide each you with either one or two custom-made hand splints. You will wear your splint(s) every night while you are sleeping. You will be required to visit St. Peter's Health Partners Hand Rehabilitation Center at Albany Memorial Hospital once every two weeks, where the researchers will assess your skin integrity through photographs and measure your range of motion in your wrist and fingers. In addition, each day you will report on your comfort level, number of hours you slept, and hours of splint wear through a protected Google Form Survey or hard copy version of the survey. Number of Participants: Approximately 20 people will take part in this study. Duration: You will be in this research study for about 14 weeks, with about 10 of the weeks requiring you to wear a splint while you sleep, and at least 8 clinic visits. Procedures: While you are in the study you will wear a splint while you sleep, complete a brief daily survey (log), and be evaluated which may involve certain risks.

Risks (See Below)	Taking part in this study involves certain risks. In addition to the risks described below, there may also be risks that are not known at this time. • Some of the more common and possibly serious risks are: Pain, discomfort, rash, irritation, soreness, stiffness, or blisters within the forearm, wrist or hand. The risk of experiencing pain or severe discomfort in this study is extremely low because of the efforts the researchers take to ensure the splints are comfortable and you can take your splint off at any point. • If you have any medical issues during this study, contact an investigator (see the Contacts section). **If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are participating in this study.** • There is also a risk of breach of confidentiality. HIPAA guidelines will be followed. If some of the questions during the interview may make you feel uneasy, you may choose to refuse to answer such questions. All forms and photographs will be kept on a password protected computer or in a locked cabinet in a secure office.
Benefits	By participating in this study, the potential benefits to you include maintaining or slowing down degression of range of motion of the fingers and wrist, increased hours of sleep, increased ability to complete occupation-based tasks, and decreased pain in the upper extremities. To maximize these benefits you will be strongly encouraged to continue wearing your splint(s) for the duration of the study. To ensure consistent splint use throughout the study, you will fill out a survey daily to ensure you are keeping track of your splinting regime and schedule, and to provide information on sleep quality and wrist/hand comfort.
Alternatives to Taking Part in this Study	As a potential participant in this study, you are urged to discuss all options/possible alternative treatments and their consequences with your doctor. The alternative to being in this study is to not take part.
Other Important Information (See Below)	Please read these additional sections below: Medical Issues/Injury, Costs of Participation, Payment for Participation, Researchers Disclosure of Financial Interest, New Information, Additional Information Available on the Internet, Study Contacts, and a Note from the St. Peter's Health Partners (SPHP) Institutional Review Board (IRB)

Continued Next Page - Additional Sections with More Detailed Information

Description of Study Procedures and Their Risks

You are being asked to consent to participate in this study because you have either a diagnosis of scleroderma, osteoarthritis, or rheumatoid arthritis. If you agree to participate in this study, the following will occur:

Early May 2022:

- Provide informed consent
- Researchers will complete an initial evaluation on your arms to ensure you meet the criteria to partake in this study
- Researchers will then complete the initial evaluations:
    - Range of motion of the forearm, wrist, and hand using a goniometer (at the Hand Center)
    - Photographs will be taken of your forearm, wrist, and hand
- You will then complete The Disability of the Arm Shoulder and Hand Questionnaire (DASH) which is a brief 30 item questionnaire.
- Your forearm, wrist, and hand(s) will be scanned by one of the researchers using an iPhone camera. The scans will be sent over to Precision Valve & Automation (PVA), where a 3D model will be printed. Only de-identified scans are sent to PVA to protect your privacy.

End of May 2022:

- You will come to the Hand Center and receive your custom-made hand splint
- You will be fitted appropriately
- You will be educated on splint wear and care

June- end of August 2022:

- You will wear your splint(s) every night while you sleep
- Every day you will complete a brief survey either online (Google Forms) or a hard copy where you will report on your comfort level, hours you slept, and the number of hours you wore your splint(s).
- Once every two weeks you will visit the Hand Center and the student researcher will assess your range of motion in your forearm, wrist, and hand using a goniometer. Photographs of your forearm, wrist, and hand will be taken once every two weeks as well by the researcher.
- If you are unable to come into the clinic once every two weeks, the student researcher will request that you send photographs of your affected hand via email if you feel comfortable doing so. Note: there is a security risk of e-mailing photographs if photographs are not encrypted. If not, the student researcher will request a video chat to assess any changes in skin integrity over video call. If this is not possible either, you will be requested to report any changes in skin integrity over the phone to the student researcher.

Middle of July 2022:

- You will be briefly interviewed by the student researcher to monitor how you are feeling about the study. This interview will ideally occur in person at the Hand Center, but is also possible by video chat or by phone.

End of August 2022:

- You will complete the Disability of the Arm, Shoulder, and Hand Questionnaire (DASH) again as a post assessment.
- You will be briefly interviewed by the student researcher again to collect subjective opinions on how the study went. This interview will ideally occur in person at the Hand Center, but is also possible by video chat or by phone.

Please note that additional tests and procedures may be needed to check on your health condition.

- Procedure/Test/Evaluation: The Disability of the Arm Shoulder and Hand Questionnaire (DASH)
- Description of Procedure/Test/Evaluation: The DASH is a 30-item self-report questionnaire designed to assess disorders of the upper limbs. It assesses one's pain and ability to complete functional tasks with their hands.
- Risks of Procedure/Test/Evaluation: No risk

- Procedure/Test/Evaluation: Range of Motion using a goniometer
- Description of Procedure/Test/Evaluation: The aim of this is to measure the flexibility of the joints of the wrist and fingers.
- Risks of Procedure/Test/Evaluation: Minimal risk, possibly pain or discomfort

- Procedure/Test/Evaluation: Google Form daily questionnaire
- Description of Procedure/Test/Evaluation: You will report comfort level in your hand(s), hours you slept, hours you wore your splint the night before, and leave any comments or concerns
- Risks of Procedure/Test/Evaluation: No risk

- Procedure/Test/Evaluation: Photographs of the forearm, wrist, and hand
- Description of Procedure/Test/Evaluation: To allow the researchers to assess your skin integrity to ensure the splint is not causing any harm to the skin.
- Risks of Procedure/Test/Evaluation: No risk

- Procedure/Test/Evaluation: Scans of the forearm, wrist, and hand
- Description of Procedure/Test/Evaluation: To allow the researchers to send de-identified scans of your hands, wrists, and forearms to PVA so that 3D model(s) can be printed for custom splint fitting.
- Risks of Procedure/Test/Evaluation: No risk

Potential Risks of Research Procedures

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- The study procedures may not be better, and could possibly be worse, than the usual approach for your condition
- The procedures used in this study may affect how different parts of your body work such the hands and fingers.

There is also a risk that you could have side effects from the study procedures.
Here are important points about side effects:

- The study researchers do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.

- Here are important points about how you and the researchers can make side effects less of a problem:
  - Tell the study researchers and your rheumatologist if you notice or feel anything different so they can see if you are having a side effect.
  - The study researchers may be able to treat some side effects.

The bullet below outlines the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about.

- **Risks**. Wearing a custom splint at night may cause side effects. These side effects are: Pain, discomfort, rash, irritation, soreness, stiffness or blisters within the forearm, wrist or hand. The risk of experiencing pain or severe discomfort in this study is extremely low because of the efforts the researchers take to ensure the splints are comfortable and you can take your splint off at any point.

Additional Risks

There is a risk of breach of confidentiality. HIPAA guidelines will be followed. All paper and electronic forms and digital recordings will be kept on a password protected computer or in a locked cabinet in a secure office. Some of the questions during the interview may make you feel uneasy. You may refuse to answer such questions.

Reproductive Risks, Risks to Pregnant Women and, Risks to Unborn or Nursing Children

Reproductive Risks: There are no known reproductive risks associated with this research study.

Withdrawal from Voluntary Participation

Even after agreeing to take part in this research study, you may withdraw from the study at any time. If you do decide to withdraw from the study, there will be no penalty or loss of benefits to you. After withdrawal, you will be offered all available care that suits your needs and medical condition. Before withdrawing from this study, you should notify one of the persons involved with this research that you wish to withdraw. This notice will allow that person or someone else supervising the research to inform you if there are any medical risks associated with withdrawal.

You may also have to stop the study early even if you do not want to. The researchers may discontinue the study treatment at any time if it appears to be in your best interest such as if your hands fail to respond to treatment or if excessive side effects occur. You and the research personnel will discuss the reasons if this becomes necessary. If you do leave the study early, you may still be asked to have some of the evaluations/procedures described in this form and information may still continue to be collected on your condition.

Medical Issues/Injury

There is the possibility that you could have a physical injury or illness that is directly caused by wearing a splint that is different from your standard medical care. If this happens, you will receive the necessary and available medical care. If physical injury occurs due to any study related intervention properly given according to the study plan, medical expenses for treating the injury will be billed to your insurance carrier.

Costs of Participation

There are no costs to you for participating in this study except for your time and transportation to and from the Albany Memorial Hand Center. Your custom splint(s) will be provided to you free of charge.

If you receive a bill that you think is wrong, please contact the investigator or research personnel.

Payment for Participation

You will not receive payment for taking part in this study.

There is no plan to compensate you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

Please Note: If this research or the information or specimens you provide result in commercial profit, you will not receive any money.

Researcher's Disclosure of Financial Interest

This research is funded by the Steffens Scleroderma Foundation (non-commercial or “not for profit”) and Precision Valve & Automation (PVA, commercial or “for profit”). The clinical investigator(s) or the investigator’s office receives no money or other payment for recruitment, enrollment, or follow-up in this study.

New Information/Clinically Relevant Results Arising from Research

New information or clinically relevant research results may come out during this study. You will be given any new information that could change your decision to take part. You will be given any individual research results that could affect your health.

Additional Information Available on the Internet

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.

Confidentiality

Your privacy and research records will be kept confidential, and your identity will be protected to the extent permitted by law. However, authorized research investigators and agents of the US Food and Drug Administration (FDA) and St. Peter's Health Partners Institutional Review Board (IRB) have the right to inspect the records involving you.

The principal investigator, student researcher, and co-investigators will have access to the data collected. The student researcher will be checking the data collected daily. The quantitative data will be stored on Google Sheets and shared amongst the PI and co-investigators on password protected laptops. All the researchers will ensure their laptop is password protected at all times and data is reviewed in private. The photos will be stored on the student researcher's password protected laptop. All data will be de-identified and associated with your subject ID number. All documents shared amongst researchers will not include any identifiable information. In addition, you will not have access to your data nor to other participant's data at any time. All data collected during the experiment will be treated as confidential. Data will be stored separately from patient identifiers. Researchers will have access to the data and photos for three years after completion of the project. After that time all data will be destroyed, except already published work. Please note that if you have any identifiable features from your elbow to your fingertips (ie. tattoos, birthmark, etc.) people may be able to identify your upper extremity in publications. Also note that there is a potential for you to be recognized as a study participant when observed by other patients or staff at the Hand Center.

The entire Comb O&P platform is HIPAA compliant. The app automatically deidentifies patients names and automatically deletes all scans on the iPhone after they are sent to the portal which can only be accessed on laptop devices through a secure login. The data is encrypted when it moves to the computer from the iPhone. The researchers are responsible for the security of the log-on information. After the completion of the study all scans will be destroyed.

By signing this form, you consent to this review and to the release of medical records, imaging studies, and laboratory and pathology specimens as necessary for evaluation of your disease and therapy.

Privacy Authorization

Authorization (Permission) to Use or Disclose (Release) Identifiable Protected Health Information (PHI) for Research – HIPAA – Health Insurance Portability and Accountability Act

In order to take part in this study, we need to obtain your protected health information (PHI) from your medical providers. We are committed to respecting your privacy and to keeping your personal and health information confidential.

1. What is the purpose of this authorization?

St. Peters Health Partners in collaboration with Russell Sage College is doing research to learn about a novel splinting process for patients with scleroderma, rheumatoid arthritis, and osteoarthritis. Researchers would like to use your protected health information for research. This information may include data that identifies you and reveals specific facts about your medical condition. Please carefully review the information below. By signing this form you agree that researchers can use your protected health information as outlined in the paragraphs below.

2. What protected health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record needed for their research. If you enter this research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

Note: You may request a blank copy of the data forms from the study researchers to learn what information will be shared.

3. Why do the researchers want my protected health information?

St. Peters Health Partners will collect your protected health information and share it with the researchers on this study if you enter this research study, or to evaluate your eligibility for a study. The researchers will use your information for this research study: Implementing a novel splinting technique through the use of 3D models for patients with scleroderma and arthritis.

4. Who will be able to use my protected health information?
St. Peters Health Partners and the study researchers will use your protected health information for research. As part of this research, they may give your information to the following Groups taking part in the research. They may also permit staff from these Groups to review your original records as required by law for audit purposes:

- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- St. Peter's Health Partners Institutional Review Board (IRB)

5. How will information about me be kept private?
St. Peters Health Partners will keep your protected health information private to the extent possible. Only researchers working on this study will have access to your information.
St. Peters Health Partners will not release protected health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot 100% assure you that the information will remain protected. Additionally, the information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

6. What happens if I do not sign this permission form?
If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I be entered into the research study?
Yes, since this is a Consent and HIPAA authorization, the intent is to enroll you in the research study. You should not sign this form or be entered into any research study until after you have had a discussion with the researchers and had all of your questions and concerns answered. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research Consent and HIPAA authorization form.

8. What happens if I want to withdraw my permission?
You can change your mind at any time and withdraw your permission to allow your protected health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new protected health information will be used for research. However, researchers may continue to use the protected health information that was provided before you withdrew your permission.
If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.
To withdraw your permission, please contact either of the persons below. She will make sure your written request to withdraw your permission is processed correctly.

Christine Mulligan
65 1st Street

Troy, NY 12180
(518) 210-5086
mullic@sage.edu

Giovanna Fichera
65 1st Street
Troy, NY 12180
845-416-8639
ficheg@sage.edu

9. How long will this permission last?
If you agree by signing this form that researchers can use your protected health information for the study. Your personal information will be used as long as necessary for this study. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my protected health information?
You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your protected health information kept by St. Peters Health Partners. You do not have the right to review and/or copy records kept by other researchers associated with the research study.

Future Research
No identifying information will be used for future research.

Contacts
Important: If you are having a medical emergency, call 911 or go to an emergency room right away. Please let emergency personnel/providers know that you are taking part in this study.

For Questions About:	Person or Office	Contact Information
Study or Research related Medical Issues	Main Investigator: Christine Mulligan Research Staff: Giovanna Fichera	 (518) 210-5086 (845) 416-8639
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	St. Peter's Health Partners Institutional Review Board (SPHP IRB)	(518) 525-6273

NOTE FROM THE IRB

This protocol, its risks and benefits, and this informed consent were reviewed by the Institutional Review Board (known as the IRB) of St. Peter's Health Partners. The IRB is a regularly convened committee of voluntary medical professionals and non-medical civilian volunteers both affiliated and non-affiliated with St. Peter's Health Partners whose mission is to review human subject research protocols to guarantee, among other things, that the research under review satisfies the qualities of respect for autonomy (your rights as a human subject), beneficence (the apparent benefits outweigh the apparent risks), and justice (the selection of study participants who also suffer from your disease and may share in the benefits of this study is fair) as outlined by the Belmont Report of 1979. The IRB finds that this research study satisfies these criteria. If you have questions about this protocol or your rights as a research subject, please contact the IRB at (518) 525-6273.

Signatures for Informed Consent/Authorization Use or Disclose Identifiable PHI

Patient/Subject - By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.
- You have been given a signed copy of this form, which is yours to keep.
- You understand that you are being asked to participate in research. You have been told the risks and benefits involved in participating in this research, and you freely give your consent to participate in the research project outlined in this form, under the conditions indicated in it.
- You understand that you may refuse to participate in the research project or may withdraw at any time without penalty.
- I agree that my protected health information (PHI) may be used for the research purposes described in this form.

_____	_____	_____
Your Name	Your **Signature**	Date
_____	_____	_____
Name of Person Obtaining/ Assisting with Consent	Signature of Person Obtaining/ Assisting with Consent	Date
_____	_____	_____
Name of Investigator	Signature of Investigator	Date
_____	_____	_____
Name of Witness	Signature of Witness	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/LAR**

Optional Teach-Back Questions – These questions can be asked to help ensure that the patient understands the study.

☐ Check this box if these questions were reviewed with the patient.

We have gone over a lot of information. I would like to ask you a few questions to make sure I have done a good job explaining the study to you.

1. In your own words, please answer these questions about this study:
    a. Why are we doing this study (what are we trying to learn)?
    b. What things (including tests and procedures) will you have to do in this study?
    c. What are some of the risks of being in this study?
    d. What is the benefit of being in this study?
    e. How will being in this study be different than usual medical care?
    f. How long will you be in this study?
2. Taking part in this study is voluntary. What does that mean to you?
    a. If you don't want to be in this study, what are your other choices?
    b. What will happen if you chose not to be in this study?
3. What will we do to make sure your information remains confidential?
4. What other questions do you have about this study?