PARENTAL CONSENT FORM

COMPARISON OF SCAR FORMATION IN SYNDACTYLY RELEASE SURGERY WITH FULL THICKNESS SKIN GRAFT VERSUS SKIN GRAFT SUBSTITUTE

Your child is invited to participate in a research study because he/she has been given a referral for syndactyly release surgery. This study is being conducted by Ann Van Heest, MD Deborah Bohn at Gillette Children's Specialty Healthcare, 200 University Avenue, St. Paul, MN 55101.

This form contains a full explanation of the study that your child is being invited to participate in. You will be asked to sign this form if you decide to have your child participate in this study. Additionally, this consent may have words you do not understand. Please ask the study doctor or the staff to explain anything you do not understand.

BACKGROUND

Syndactyly is the most common hand abnormality in children. During development, two or more fingers do not separate in the usual way and remain connected by skin. Surgery is needed to separate the fingers. Usually, it is performed between 6 months and 3 years of age, depending on the severity of the syndactyly. During the surgery, the fingers are separated; however, there isn't enough skin to completely cover the fingers once they are separated. There are two areas on the fingers that need to be covered after separation, and there is a standard method, and now a new technique to cover these areas.

Skin Graft

The current technique that surgeons use to cover the newly separated fingers is to apply a small section of the patient's own skin taken from a different area of their body (*this is known as a* skin graft).

Skin Graft Substitute

A new technique called Hyaluronic acid matrix (Hyalomatrix®) is a U.S. Food and Drug Administration (FDA) approved, commercially available, skin graft substitute that is currently being used both in the US and in Europe. The Hyalomatrix (or skin graft substitute) is sutured into place using a stitch on each corner, over the areas left without skin covering during the surgery. Hyalomatrix is not commonly used for treatment of syndactyly.

STUDY PURPOSE

The purpose of this study is to compare effectiveness, wound healing, scar formation and potential associated complications of the current skin graft technique with the new technique called Hyalomatrix (or skin graft substitute) following surgery.

STUDY DESIGN

This is a randomized, single-blind, within-subject controlled study. We expect to enroll a total of 40 participants at Gillette Children's Specialty Healthcare. In addition to standard of care procedures that would typically take place prior to, during and following syndactyly surgery, participants who agree to participate in this study will also complete the research study procedures outlined below. Participation in this study will last approximately 24 months.

STUDY PROCEDURES

Research study procedures will be incorporated into the 7 standard of care/clinic visits that are standard procedure prior to, during and following syndactyly surgery. You and your child will also be asked to participate in a *research-only* 2-year post surgery assessment.

Visit 1:Pre-Surgery

At the pre-surgery visit, in addition to the typical standard of care clinic visit information and surgical data that is collected the research consent will be reviewed and signed. Demographics (age, date of birth and address, etc.) will also be obtained.

Visit 2: Syndactyly surgery:

If you agree to participate in this study, each web on your child's hand(s) that requires surgery and is operated on will have both a skin graft placed **and** the Hyalomatrix (or skin graft substitute) placed. The skin graft will be placed on one open area and the Hyalomatrix (or skin graft substitute) on the other open area at the end of the surgery. The open area where the skin graft is placed will be randomly assigned using computer software, much like tossing a coin. The Hyalomatrix (or skin graft substitute) will be placed on the other remaining open area. Consequently, one side of each web will have the skin graft and the other side will have the Hyalomatrix (or skin graft substitute).

We will not tell you or your child which side of the web the doctor(s) placed the skin graft and which side they placed the Hyalomatrix (or skin graft substitute). However, the study doctors can obtain this information quickly if needed for the care of your child. Both the skin graft and the Hyalomatrix (or skin graft substitute) will be stitched into place with the same type of dissolvable stitches. A cast is placed, after surgery, while your child is still asleep. Research-only photographs of the hands will be taken both pre and post operatively for the study.

Visit 3: 0-4 weeks Post-Op:

The cast and bandages will be removed by the surgeon or nurse at the0-4 week post-op visit. The surgeon or nurse will then remove the outer layer of the Hyalomatrix device known as the silicone membrane. You will be instructed on how to care for your child's surgical wound. Photographs taken at the 0-4 weeks post–op visits will be used to monitor healing.

Visits4-6: 8 weeks, 6 months and 12-months Post-Op:

Research-only photographs will be taken of the hand(s) for the study. Additional *research-only* assessments will include: *Patient/Parent and Observer Scar Assessment Scale (PSAS and OSA)*, the *Hamilton* assessment, and the Web Creep Assessments will also be completed. And clinical data will be obtained as per typical standard of care procedures at these visits. In the event that your child is unable to come to his/her standard of care visit, you will be given two options to complete the assessments as outlined in the participant timeline below. Specifically, the assessments will be sent through the mail with postage paid return envelopes, or complete the assessments online using a secure web link to REDCap. A study team member may call you to check in on the status of completion.

REDCap 24-month Post-Op follow-up:

If you are unable to attend your 24-month post-op visit in clinic; we will ask you to take photographs of your child's hand(s) and to complete a final set of *research-only* assessments which will be administered electronically using a secure data collection tool called REDCap. The photos of your child's hand(s) will also be electronically uploaded to the REDCap tool.

Unblinding

Once the 24-month questionnaires are complete, the study doctors will send or give you a letter to let you know where on your child's fingers(s) they placed the skin graft and where they placed the Hyalomatrix (or skin graft substitute). If you decide not to complete the study, we will still send the unblinding letter to you immediately revealing the locations of the skin graft and Hyalomatrix (or skin graft substitute).

ASSESSMENTS

Patient/Parent and Observer Scar Assessment Scale (PSAS and OSAS)

The PSAS and the OSAS will be used to assess overall satisfaction with scar quality at 8 weeks, 6 months, 12 months and 24 months post-surgery. The Patient/Parent Scar Assessment Scale (PSAS) will be completed and scored independently for each side of each web that has undergone syndactyly surgery as well as the donor site scar. The patient scale contains six items (characteristics of the scar including color, pliability, thickness, relief, itching, and pain).

The Observer Scar Assessment Scale (OSAS) will be completed by the surgeon and contains five items (scar vascularization, pigmentation, pliability, thickness, and relief).

The Modified Hamilton burn scar rating

For photographic analysis, we will use the Hamilton burn scar rating at 8 weeks, 6 months, 12 months and 24 months to assess scar thickness, regularity, vascularity (blood flow) and color/pigmentation.

Web Creep Assessment

Using the photographs of your child's hand(s), one of the clinicians will use a modified version of the Web Creep Assessment to evaluate how much web creeping has occurred during healing.

STUDY TIMELINE

	Visit 1 Pre-Surgery	Visit 2 Surgery	Visit 3 0-4-week Post-Op	+Visit 4 8-week Post-Op	+Visit 5 6 month Post-Op	+Visit 6 12 month Post-Op	*24-month Post Op REDCap Assessments
Consent	X						
Demographics	X						
Randomization		X					
++Photographs of the Hands		Pre and Post Op	X	X	X	X	X
Clinic visit and Surgical Data Collection	X	X	X	X	X	X	
Patient/Parent Scar Assessment (PSAS)				X	X	X	X
Optional Observer Scar Assessment (OSAS)				X	X	X	**X
Hamilton Assessment				X	X	X	X
Web Creep Assessment				X	X	X	X
		Following completion of the 24-month post op assessments, a letter containing the unblinding information will be mailed to participants home.					

+ In the event that your child is unable to come to his/her standard of care visit, you will be given two options to complete the assessments as stated above.

++ In the event that your child is unable to come to his/her standard of care visit, you will be asked to submit photographs of your child's hands according to the Family instructions in the photography manual

* This final set of assessments will be administered electronically using REDCap (you will not need to bring your child to the clinic to complete the 24-month follow-up).

** Completion of the Observer Scar Assessment is dependent upon patient/parent/family compliance with the submission of a usable photograph via REDCap of their child's hand at 24 months post-operatively.

RISKS OF STUDY PARTICIPATION
The Hyalomatrix (or skin graft substitute) is a sterile, commercially available, relatively inexpensive skin graft substitute. The FDA has approved it as safe for use in children. However, as with any medication, drug or synthetic device, there could be unforeseen problems. Potential problems could include infection, slow wound healing, allergic reaction, need for reoperation (for infection, wound breakdown), discoloration and scarring. In addition to the possible risks or side effects described above, your child may experience problems or an injury that we could not predict. It is possible that a problem or injury could require unanticipated medical and/or surgical treatment.

Research may include risks to your child which are not currently foreseeable. If you decide to have your child participate in this study, there is a small risk for loss of privacy. By agreeing to be in this study, you will be allowing researchers to access your child's private medical records for study related purposes. Although the risk of loss of privacy is small, by allowing this access, it is still possible.

BENEFITS OF STUDY PARTICIPATION
Your child may not directly benefit from participating in this study. However, your child's participation in this study may help the way surgeons treat future children who require syndactyly surgery.

ALTERNATIVES TO STUDY PARTICIPATION
Participation in this study is completely voluntary. The alternative to participating in this study is to simply decline to participate. Your child will still receive standard medical care.

STUDY COSTS/COMPENSATION
There is no compensation to you for participation in this study. The costs associated with the Hyalomatrix (or skin graft substitute) will be borne by Gillette at no cost to you or your child's insurance company if you choose to participate. The costs of the standard of care or routine medical and surgical care and procedures will be billed to you or your child's insurance.

RESEARCH RELATED INJURY
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your child's insurance company. If you think that your child has suffered a research related injury, let the study team know right away. You and your child are not giving up any of your legal rights by signing this form.

CONFIDENTIALITY
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify your child as a participant. Your child's medical record for the study may be, however, reviewed by the departments that regulate research at the University of Minnesota or Gillette Children's Specialty Healthcare who are responsible for oversight of safe research practices. Your child will be assigned a study ID

number that is linked to your child's name and medical record number. To help protect your child's confidentiality, we will store the information separately and as securely as possible. Paper or hard copy information will be stored within a secure location at Gillette. Electronic information will be stored on a secure network drive and/or a secure REDCap database, only the study team at Gillette will have access to this information. Any personal identifying data will be kept separate from the study data (this means that none of the researchers can look at the data and know which data belongs to your child). If necessary, the researchers can look up this information.

PROTECTED HEALTH INFORMATION (PHI)
Your child's PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

VOLUNTARY NATURE OF THE STUDY
Participation in this study is completely voluntary. Your decision whether or not to have your child participate in this study will not affect your child's current or future care with Gillette Children's Specialty Healthcare. If you and your child decide to participate, you are free to withdraw at any time without consequence to your child's clinical care.

CONTACTS AND QUESTIONS
The investigators of this study are Ann Van Heest, MD and Deborah Bohn, MD. If you have questions or concerns at any time, or if you need to report an injury related to the research, you are encouraged to contact them at:

Ann Van Heest, MD.	651-578-5061
Deborah Bohn, MD.	651-312-3113

You may also contact the research study coordinator Jamie Price at 651-325-2316.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), contact *Patient Representative of the Quality Improvement Resources Department* at Gillette Children's Specialty Healthcare, 200 East University Avenue, St. Paul MN 55101, Telephone 651-229-1706 or 1-800-719-4040 (toll free) or e-mail qualityrep@gillettechildrens.com. You may also send feedback by going to: https://www.gillettechildrens.org/contact-us/ and completing the feedback form.

RIGHTS AS A RESEARCH SUBJECT
You are free to withdraw your consent and stop your child's participation in this study at any time. If you withdraw consent, there will be no penalty, and your child will not lose any benefits to which he/she is entitled. If you decide to withdraw consent to have your child participate in this study for any reason, you should contact the study doctor(s) listed above. If you withdraw consent, we will not collect any additional information without your permission. We will use

the information collected from the time your child was enrolled in the study up to the time of withdrawal.

Also, if new information becomes available during the study that may affect your willingness to continue in the study, we will discuss this information with you. The study doctors may stop the study, or your child's participation at any time such as if your child's medical condition changes and/or it is in your child's best interest.

STATEMENT OF CONSENT

I have read the above information. I acknowledge I have been given an opportunity to ask questions regarding this study to help me understand what my child's participation will involve. All of my questions have been answered to my satisfaction. I consent to my child's participation in this study. I will be offered a copy of this consent form for my records. I am not giving up any legal rights by signing this form.

By signing this document, I agree to have my child participate in this study.

_____

Printed Name of Participant

_____

Printed name of Parent/guardian Relationship to study participant

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Signature of Parent/guardian Date

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Email address of Parent/guardian

STATEMENT OF PERSON WHO OBTAINED CONSENT

As a representative of this study, I have explained to the participant and/or the participant's legally authorized representative, the purpose, the procedures, the possible benefits, and the risks of this research study. I have also explained the alternatives to being in the study, and how the participant's health information will be collected, used and shared.

_____

Name of Person obtaining Consent

_____ _____

Signature of Person obtaining Consent Date and Time Signed