

RESEARCH CONSENT FORM

Protocol Title: Craniofacial Applications of 3D (three-dimensional) printing

Study No.: HP-00071854

Principal Investigator: Arthur J. Nam MD, MS, 410-328-3058

Sponsor: Division of Plastic Surgery, R Adams Cowley Shock Trauma Center, University of Maryland Medical System.

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- This is a research study and participation is voluntary. You can ask questions at any time. If you are consenting for someone else – a child or someone unable to provide consent themselves – then the word “you” means that person.

PURPOSE OF STUDY

- 3D (three-dimensional) printing is technology that allows for creation of custom physical models of body parts based on CT scan images of the body. Repair of facial fractures usually requires bending and shaping of hardware to fit the unique individual bone contour and fracture pattern. This keeps the fractured bone stable while it heals. Currently, bending and shaping is done by free hand based on the surgeon’s estimation of what best fits the fracture.
- We are studying whether 3D printed custom plastic models, rather than free hand for bending and shaping of the hardware can improve results of facial fracture reconstruction. 60 people will take part in this study.

PROCEDURES

- Before you participate in the study, you will have exams, tests and imaging of your face. These exams, tests and imaging are part of regular care for your injury and may be done whether or not you participate in the study. If they show that you have facial fracture(s) that need surgical repair, and you choose to take part, you will be “randomized” into one of the two groups: “Arm A” or “Arm B”.
- Randomization means that you are put into a group by chance, like flipping a coin. A computer program will place you in one of the study groups. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.
- You will be taken to surgery where your facial fracture(s) will be repaired and stabilized with metal hardware across your fracture to stabilize the bone pieces while they heal. If you were randomized to Arm A, your fractures will be stabilized using hardware that is bent and shaped by freehand. This method of bending and shaping hardware is the regular method that is used even if you do not participate in the study. If you were randomized to Arm B, your fractures will be stabilized using hardware that is bent and shaped with the aid of 3D printed custom plastic model of parts of your facial bones. The design and printing of the custom plastic model and its use for bending and shaping the metal hardware to match your anatomy will be the only differences in your treatment, compared with patients in Arm A, or patients that are not taking part in this study. If this plate does not appear to fit well on your bone for whatever reason, we will choose another plate which will be formed at the time of your operation.
- After surgery, we will obtain CT scan images to confirm that the fracture has been adequately repaired. The CT scan is a regular part of treatment and is obtained whether or not you participate in the research study.

We will also monitor your progress after surgery just like we do regularly. This usually involves one routine clinic follow-up visit one to two weeks after surgery. Additional follow-up visits may be necessary depending on your condition, even if you were not participating in a research study. We will collect information about your health just like we regularly do. However, some of the information collected will be used for research purposes. Specific information that will be used for research purposes includes: Billing and payment information and the medical information justifying it, Clinical images (i.e. CT scans), Protected health information such as name, date of birth, medical record number, and demographic information (age, sex, ethnic group), clinical information related to the procedure and follow-up visits.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

- No additional responsibilities are necessary to take part in the research.

POTENTIAL BENEFITS

- Patients assigned to Arm B may benefit from a custom model with less time in surgery compared to those in Arm A and patients who are not taking part in this study.
- Taking part in this study may help researchers determine if using the 3D plastic model yields (1) cost saving by decreasing the operative time, (2) improved fracture reduction and repair.
- There may not be any actual benefits to you.
- You need to decide if your child's participation in this research study is in your child's best interest.

POTENTIAL RISKS/DISCOMFORTS:

- Potential risks of participating in this study include breach of confidentiality and privacy. Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet. As for privacy, discussions will take place in a private exam room during your routine appointments to minimize risks associated with a breach in privacy.
- There may be risks in this study which are not yet known.

ALTERNATIVES TO PARTICIPATION

- Your alternative is to not take part in this study. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected and your facial fractures will be repaired without using the 3D plastic model.

COSTS TO PARTICIPANTS

- It will not cost you anything to take part in this study
- The University Of Maryland Division Of Plastic Surgery will incur all costs related to this research. Participants in this study will not incur any additional costs.

PAYMENT TO PARTICIPANTS

- Participants will not be paid for participation in this study
- Medical staff will be on hand to treat any research related injuries that occur.
- There will be no compensation for research related injury.

CONFIDENTIALITY AND ACCESS TO RECORDS

- This study will involve accessing confidential information in the participant's medical record. This information will be de-identified and kept in a locked office on a password-protected computer. Only the study investigators will have access to this information.
- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

- Any paper records (i.e. consent forms) will be kept securely in a locked cabinet in the office of our research staff. Only they will have access to these records.
- 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.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. If you decide to withdraw early, there is no risk, side effects or discomfort. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. You do not give up your right to seek additional compensation if you are harmed as a result of being in this study. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator: Dr. Arthur Nam, MD at 410-328-3058. After you decide that you no longer wish to participate, we will remove you from the study and all of the data related to your care will be removed from this study. Any records related to this study will be destroyed.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff or if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

Participant's Signature

Date: _____

Signature of Parent/Guardian

Relationship: _____

Date: _____

Investigator or Designee Obtaining Consent
Signature

Date: _____

Witness

Date: _____