Alan M. Hirahara, MD, FRCSC
Orthopaedic Surgeon | Specialist in Sports Medicine

2801 K Street, #330, Sacramento, CA 95816, USA
Phone: (916) 732-3000 Fax: (916) 732-3022
www.HiraharaMD.com

Research Using Surgical Outcomes System (SOS)

What is Surgical Outcomes System (SOS)?

Surgical Outcomes System (SOS) is an online, web-based registry that is designed to track your outcome after your procedure on a variety of different scales. Through simple, easy-to-complete surveys accessible through your email, I will be able to compare your condition at certain time-points to where you started preoperatively. SOS is maintained by Arthrex, Inc. (Naples, FL). The system is utilized by doctors worldwide and allows comparison to regional and global averages for the assorted outcome measures.

While the consent form for signing up on the system talks about a variety of medical information that will be on the system, **we only input your date of birth, email address (where surveys will be sent), and relevant medical history to the joint of interest**. We **WILL NOT** use or distribute your name, face, or other personal identifying information.

How & Why do I use SOS?

The information gathered on the system allows me to monitor your progress after undergoing a procedure. If the scores to the surveys fall out of the expected range, I am alerted and able to address the situation as necessary. I also travel nationally and internationally teaching other doctors about the techniques I use in the clinic and operating room. SOS provides critical information on my patient outcomes that allows me to constantly update my techniques and philosophies to ensure I am providing the best care. As seen on my website, I am very active in research and have been published numerous times. The SOS database allows me to collect patient data for my research and publications.

Insurance companies and hospitals are beginning to analyze physician performance based on patient satisfaction alone through evaluations like the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS, pronounced “H-caps”) or the Press Ganey patient experience surveys. These methods have not been validated as reliable measures to determine surgeon competence and ability; whereas SOS does use validated measures to assess patient outcome. Therefore, I have implemented the SOS system to objectively track my patient outcomes and to evaluate my performance.

INFORMED CONSENT AND HIPAA AUTHORIZATION

Orthopaedic sports medicine, arthroscopy, and related surgery registry using the web-based Surgical Outcomes System (SOS).

'You' refers to you or your child.

INTRODUCTION AND PURPOSE

You are being asked to participate in a global registry for orthopedics and sports medicine using the web based Surgical Outcomes System (SOS). The purpose of this research study is to create a large clinical database to collect information on patients undergoing orthopaedic and sports medicine related surgery and treatment, and to look at the outcomes and cost-effectiveness associated with treatment procedures. Approximately 3000 doctors will participate in this worldwide research study. Each doctor will be able to include 800 patients ages 12 and older, each a year.

Your participation in this study will involve that you complete outcome surveys that ask questions such as your level of pain, how you feel, and your ability to perform certain activities in your daily life. Through your completion of these surveys, your doctor has the opportunity to monitor your progress after treatment, even when you may not be scheduled to see him/her. Your doctor is also able to compare your outcomes to the average de-identified global data.

Your participation in the SOS study is voluntary and will not change your treatment in any way. Please read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

PROCEDURES

Your participation will involve completing surveys on your level of pain, function and well- being before and after treatment for at least five years on a web based secure site. Data collection time points are before treatment, multiple times after treatment during the first 6 months, 6 months, and 1,2,3,4 and 5 years after treatment. Depending upon your type of surgery or treatment, you may be requested to complete these same surveys up to 15 years. Completion of these surveys will take approximately 15 minutes or less to complete.

You will be asked to complete these surveys by providing your email address and/or phone number. An email or text reminder that has a secure link to the survey will be sent to you. If you do not complete the surveys online, you will be sent another reminder. Your information will be kept secure and confidential. You will be provided the opportunity to unsubscribe. If you do not have access to a computer or internet, or do not have an email address or cell phone, your doctor or designated study staff has the option to collect the survey information over the phone or at the office and enter it into SOS on your behalf.

Before and after your treatment or surgery, your doctor will enter your medical information (for example, your name, medical record number, age, date of birth, medical history, diagnosis and procedures, financial charges) ,email address and phone number into the registry. Your name, email address, phone number and medical record number will be the only information that directly identifies you and these will be stored encrypted.

POTENTIAL RISKS AND DISCOMFORTS AND ANTICIPATED BENEFITS

There are no known physical risks associated with being in this study; however the privacy of your health information cannot be guaranteed. You will be told about anything new that might change your decision to be in this study, such as how the data will be collected and used. You may not receive a direct benefit if you agree to participate; however participation gives your doctor the opportunity to remotely monitor your health progress and outcomes. Future patients may benefit from the information obtained from this study.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not participate.

PRIVACY AND SECURITY

The SOS registry is maintained by the study sponsor, Arthrex, Inc. or another qualified company working with Arthrex. Arthrex manufactures orthopedic medical products that may be used in your treatment; however, Arthrex does not participate in your doctor's selection of medical device or provision of treatment to you. Both your doctor and the study sponsor have taken precautions to protect the data collected for this research. These precautions include for example developing and using unique user ids and passwords to access the registry, not sharing that information with other people, special security clearance for your email address in the database, and using an electronic data storage system that is designed to ensure the security of patient health information according to HIPAA regulations. The information collected about you for this research may be shared with others such as the study staff, sponsor, other researchers, and federal and foreign government agencies as fully described below.

If you give permission and sign this consent, you are allowing your study site, Alan M. Hirahara, MD, FRCSC and your doctor and staff to use and release certain kinds of protected health information about you. This includes all health information in your medical and billing records that is related to the research study. For example, your name, medical record number, email address, phone number, date of birth, medical history, diagnosis and medical procedures, medical device(s), other medical data collected by the doctor and study staff and other healthcare providers as part of your normal clinical care, financial charges, and any survey data.

Your protected health information may be used by and released to the following: The research study staff and affiliated clinic/hospital/ambulatory surgery center employees, the research sponsor Arthrex, Inc., other companies that work for or with Arthrex, such as database administrators, and the Institutional Review Board that approved this study.

Your protected health information may be used and/or released for the following purposes: To conduct the research and establish a registry called the Surgical Outcomes System (SOS); (2) To host and provide technical support for the SOS database or other databases that contain the collected data; (3) To review the quality and security of the research; (4) To carry out statistical analyses, and prepare reports which may be provided to your doctor; (5) To remove from your health information any information that could be used to identify you, and (6) for other uses/disclosures required by laws or regulations.

Your de-identified data may additionally be used by your doctor and designated study staff, other doctors and study staff participating in the registry and Arthrex to (1) help other researchers and scientists carry out other studies or to draft reports for scientific publications relating to these outcomes; (2) to prepare analyses for governments and health insurers; (3) or for marketing purposes about surgical and non-operative benefits, cost-effectiveness and patient outcomes; (4) to make reports to government agencies that oversee Arthrex and the other people involved with the studies; and (5) to support future product development and improvements to products and surgical procedures. Publications or presentations that result from this study will not contain personal information that may identify you.

Protected health information, if released outside of your study site, may not be protected by federal privacy laws. Your decision to be in this study is voluntary. You will not be penalized or lose benefits if you decide not to participate or if you decide to stop participating. You may withdraw from this study at any time by contacting your doctor. When you withdraw your permission, no new health information will be entered into SOS after that date. Information that has already been gathered may still be used and given to others. If you leave the study before the planned final survey, you may be asked by your doctor to consider completion of a final survey. Your part in this study may be stopped at any time by your doctor or the sponsor without your permission.

FINANCIAL OBLIGATION

Responsibility for treatment payment is in no way different from responsibility for payment for patients who do not participate in the study. You will not be paid for your participation.

QUESTIONS AND CONCERNS

Contact your doctor at 916-732-3000 for questions about the study or if you think you have been harmed as a result of joining this study. Contact Salus IRB if you have questions about your rights as a research subject: 855-300-0815. Salus IRB is a group of people who perform independent review of research.

SIGNATURE

Your signature tells us read and understand this consent and all your questions have been answered. It also means that you want to participate and to authorize the use and disclosure of your personal health. You will be given a signed copy of this consent.

_____ _____

Signature of Research Participant Date

_____

Print Name of Research Participant

For Personal Representative of the Research Participant *(if applicable)*

_____ _____

Signature of Personal Representative Date

_____

Print Name of Personal Representative

_____

Personal Representative Relationship or Authority

****

The signature lines below are required when minor participants are involved.

_____

Printed Name of Minor Participant

_____

Printed Name of Parent or Legal Guardian Granting Permission for Minor Participant

_____ _____

Signature of Parent or Legal Guardian Granting Permission for Minor Participant Date

Study Site Name: _____

_____

Printed Name of Person Explaining Informed Consent Document

_____ _____

Signature of Person Explaining Informed Consent Document Date

FOR SALUS IRB USE ONLY
Initial draft mys: 18May18