

A Global Orthopedic Surgery Outcome Registry

Reinhold Schmieding, President & Founder, Arthrex Inc.

What motivated you to begin the development of a global surgical outcomes registry?

Arthrex's mission is helping surgeons treat their patients better. Historically, our focus has been on product and technique innovation in arthroscopy and less invasive orthopaedics. The responsibility of designing and manufacturing the highest quality products grew into a responsibility in providing surgeons a surgical skills learning environment using the latest technology. This responsibility has now evolved into aligning experienced scientists, software and multimedia design talent into providing the most comprehensive global, web-based surgical outcomes registry in orthopaedics that is paperless, time and cost efficient and data secure for orthopaedic surgeons. Outcomes data collection and analysis is not only important for surgeons to quantify and validate their treatment outcomes for their patients, peers, publishers and payers, it's ensuring that our products have safe and effective patient outcomes long after they are used or implanted.

It's taking our quality assurance responsibility to the highest level.

Data privacy is important to patients and surgeons. How do you protect it?

Arthrex's SOS program is a service to meet the global research and quality assurance needs of orthopaedic surgeons. Extensive measures have been taken to ensure the security of patient's protected health information (PHI) according to HIPAA privacy and security rules. SOS only collects the minimum necessary PHI and all information is encrypted and transferred over secure data communication lines. Arthrex actively performs due diligence with regards to third-party validation of information security controls. Following industry best practices, Arthrex strives to meet the highest level of security and privacy protection possible. SOS is IRB approved and a leading surgeon group monitoring board oversees all SOS policies and procedures to verify patient and surgeon data privacy protection. Each surgeon or site enrolled in SOS owns their own data and has exclusive, private access to their identifiable data. This is secured with a binding legal agreement with SOS and Arthrex. Arthrex does not access or utilize surgeons' identifiable data, unless it is for a technical or maintenance purpose. In fact, identifiable data is immediately transformed and de-identified or anonymized prior to any aggregation of the shared global average. All surgeon and site subscribers enrolled in the SOS registry have shared access to de-identified global averages on treatment outcomes, allowing for patient education and benchmarking for medical decision-making. SOS must adhere to individual country privacy laws for data collection with written approval from government authorities in that country. Additionally, as a privately held corporation without outside investors, our core mission is scientific with an unwavering commitment to surgeons, scientific principles and evidence-based medicine for over 33 years.

How much time does the surgeon need to monitor patients' outcomes with SOS?

The preoperative data field is streamlined and takes approximately 30 seconds for the surgeon or designated staff member to enroll a patient. The post-op data fields are intuitively designed and on average require less than 1 minute to enter relevant post-op data. The "favorites" option allows selecting a customized template, a preprogrammed surgical technique created by the surgeon,



which takes seconds to enter the post op data field. That's it. The SOS system automatically contacts the patient via email at predetermined intervals with relevant surveys that can be viewed on any device including smartphone, tablet or PC coming from their surgeon. Data is tabulated in real time and allows continuous, up-to-date monitoring of a patient's post-op results and well-being up to 2 years to 15 years post op for total joint arthroplasty.

What patient compliance pearls are recommended with SOS?

It's important that the surgeon explain to the patient that SOS allows them to monitor their post-operative progress and well-being. It's in the patient's best interest that their surgeon is monitoring their postoperative progress. Being educated that SOS is an integral part of their post op recovery, no matter where they live or how often they visit their surgeon after treatment, is reassuring and comforting for patients and motivates them to complete surveys on time. SOS automatically contacts patients with a follow-up email if they are late in responding to surveys and flags the surgeon or staff member to contact them should they become non-compliant. A phone call at that time is usually enough to achieve compliancy. SOS provides another opportunity for the patient to stay connected with their surgeon throughout the entire treatment and rehab period. With proper patient communication and a single staff member monitoring compliance, sites can achieve a higher patient compliance.

How does SOS help surgeons market their practice?

Many surgeons lose patients through second or third opinions from other surgeons. How powerful is presenting real time patient outcomes data on surgical options during treatment discussions? Just a few clicks on SOS compares one treatment option over another, such as ACL reconstruction with autograft or allograft. Real time outcome data from thousands of other patients in the global average comparing one treatment option versus another or against the surgeon's own outcomes, if desired, can make the difference in building evidence-based confidence in patients to move forward without second or third opinions that don't have access to real time outcome data. With the shift in healthcare to bundled payments, those providers who have evidence-based data to prove performance will be ahead of the curve. It is in the best interest of the physician to begin tracking their patient outcomes now.

How can outcomes be compared with the de-identified data?

The global de-identified data is fully accessible to all SOS subscribers. Arthrex will provide a comparative analysis study service in which SOS surgeons can request a comprehensive comparison of one technique variable from another from the global data. SOS scientists will create a customized study report within 24 hours at a cost of \$25 upon request as a comparative analysis research service.

Is EMR integration complexity, time, significant cost and PHI exposure really necessary? Why is a surgical device company better than a software company as a partner?

SOS is a service for surgeons that evolves rapidly and is enhanced daily by an internal web development and research team who are nimble, innovative and can respond to a question or system enhancement promptly. When subscribers have a question on functionality of SOS, they are speaking with the SOS research and technical staff members or their local field support.



A modern, low cost, easy to use and evolving, web-based global registry will obsolete other data collection software systems over time as orthopedic societies adopt the SOS registry for their members at significant less cost to them with a growing power of thousands of surgeons and patients in the global registry, strengthening the power of outcomes data collection and analysis in the future.

What countries currently have SOS approval?

SOS is data protection authority (DPA) approved in over 15 countries. All currently approved countries have been updated on the global map located on the SOS Marketing Page: <https://surgicaloutcomesystem.com>. SOS patient surveys have been translated for our approved countries. Arthrex is seeking data protection authority approvals in additional countries globally.

What have we learned from SOS post op data analysis to date?

With an exponentially growing patient population in the SOS registry, 2 year comparative data reveals some interesting outcome comparisons:

- BTB vs hamstring ACL reconstruction
- ACL preservation with InternalBrace augmented primary repairs versus ACL reconstruction
- HTO versus UKA versus TKA
- Double row versus single row RCR
- Orthobiologic enhanced procedures
- InternalBrace Brostrom and Achilles repairs versus traditional methods.

You can view all global de-identified clinical outcomes reports here: <https://surgicaloutcomesystem.com/clinical-outcomes>. The results can help validate new technology and less invasive procedures in comparative outcome analysis.

Having access to all the global data on most orthopaedic procedures provides surgeons the outcomes evidence they need to educate their patients, peers, publishers and payers on the quality and reliability of their treatments.

It's evidence-based medicine at the highest level.