

Participant Information Sheet



Study Title: Surgical and Patient-Reported Outcomes following Surgical Procedures
Undertaken by Orthosports Surgeons

Study Title: Orthosports Prospective Surgical Outcomes (OPSO) Study

Locality: Orthosports North Harbour, 17 Antares Place, Auckland

Ethics Committee Reference: 17/NTA/269

Lead Investigator: Dr Matthew Brick **Contact Phone Number:** +64 9 477 2080

Tēnā koutou katoa!

We are asking you to take part in a continuing study of outcomes following Orthosports surgery. If you agree to participate, you'll be asked to complete questionnaires about your pain and disability before and after surgery and to release medical information relating to your surgical treatment and care.

What is the Purpose of the Study?

The purpose of our research is to learn more about the best treatments for orthopaedic conditions treated by Orthosports North Harbour surgeons. The goals of the surgical procedures are to restore normal anatomy whilst maintaining stability and function. These can help prevent further deterioration and improve your quality of life.

Primarily, we collect data from you to help the surgeons do a better job of treating patients. We combine the accurate, standardised feedback you provide with their knowledge of diagnoses and treatments. Sometimes, the information we collect may be of wider medical interest. In those circumstances, fully anonymised data may be published in the scientific literature, or presented at medical conferences. Analysing and sharing our surgical outcomes helps add knowledge to surgical science and ensure that our care is in line with the best international standards. There will be no way to identify any individual from these external presentations. Your individual data are kept entirely confidential at all times.

What Will My Participation in the Study Involve?

The information you provide is collected into the Orthosports research database and includes:

- Basic non-personal information, for example age, gender, height, weight, surgical funding;
- Pertinent medical history and diagnoses;
- Specific surgical findings and procedure details, e.g. length of procedure, degree of tissue damage noted, surgical techniques and equipment applied;
- Radiological evaluations and findings;
- Pre- or post-surgical rehabilitation information and relevant clinical assessments;
- Results of questionnaires you complete, normally online, routinely before and at specified time points after surgery, the first being at 6 months and then annually from 1 year;

- Serious post-operative complications, such as the need for a reoperation, revision or joint replacement.

If you are unable to complete the questionnaires, we'd still like you to take part in the study. That is because information about other outcomes, such as the need for revision or joint-replacement surgery, is also very important.

What Are the Possible Benefits and Risks of this Study?

The procedure of the study, completing questionnaires and allowing access to your health and surgical information, poses no risk to your health as a participant. There are minimal direct benefits to you personally for taking part, although the surgeons may review the questionnaire results you have completed as part of your follow-up clinical assessments. Knowledge gained from this study can benefit future Orthosports patients or orthopaedic patients more widely.

You may be concerned about the risk that people outside of the research team will see your research information. Your data are kept on the same nationally approved secure computer system that contains your medical notes. The IT company that runs our service specialises in the secure storage of medical notes and is used by many medical practices around Auckland. Every effort will be made to protect your privacy and confidentiality. All identifying information will be stored in a secured place and only the Orthosports research team will have access.

Who Pays for the Study?

Orthosports funds the data acquisition and management processes, but unfortunately you will not be paid for completing the questionnaires or taking part in this study. If you are unable to access the questionnaires online, Orthosports will pay for postage costs.

What are my Rights?

You can choose whether or not you would like to be included in this study. You can stop participating and/or withdraw your data from future research at any time. If you decide not to take part, you don't have to give a reason. You have the right to access your information collected as part of the study.

Importantly, the care you personally receive for your condition and the surgical procedures that are performed will not be affected in any way by your decision about whether or not to take part. This study assesses the outcomes of our best practice care that we aim to provide to all our patients.

The study investigators may also decide to stop or suspend the study if necessary. You will be informed if any new information becomes available that could affect your willingness to be in the study.

What Happens After the Study or If I Change My Mind?

The study findings and results will be available to you free of charge. Check our website, www.orthosports.co.nz, for updates about the results of this study.

Who Do I Contact for More Information or If I Have Concerns?

If you have any questions at any time, you can email the research manager at research@orthosports.co.nz. You can also contact Mat Brick or any of the Orthosports surgeons directly.

Dr Matthew Brick, Sports Orthopaedic surgeon and Lead Investigator

Phone: +64 9 477 2080
Fax: +64 9 477 2091
Mobile: +64 21 485 940
Email: mat@orthosports.co.nz; matbrick@xtra.co.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the Auckland and Waitematā District Health Boards Māori Research Advisor on:

Phone: (09) 4868920 ext. 3204
Email: helen.wihongi@waitematadhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that reviewed this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form



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I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.

I have had the opportunity to ask questions and I am satisfied with the answers I have received.

I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.

I understand that my decision about whether or not to take part will not affect my treatment and care by Orthosports staff in any way.

I freely agree to participate in this study and understand that I may withdraw if I change my mind without this affecting my medical care.

I consent to the research staff collecting and processing my information, including relevant information about my health.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I understand that no information from which I could be personally identified will be accessible to anyone outside of the Orthosports research and clinical teams, or used in any reports about the study.

I know who to contact if I have any questions about the study in general, or any particular concerns.

I have been given a copy of the Participant Information Sheet and Consent Form to keep, which may be electronic.

Declaration by participant:

I hereby consent to take part in this study.

Check Box

Yes

Yes, but I am not able to or don't want to complete the questionnaires

No

Participant's Name:

Date:

I confirm that I am over the age of 16 years

Check Box

Yes

No

If no, you must obtain parental authorisation to take part.

I confirm that I am the parent of legal guardian of the above-named participant, that I have read and understand the Participant Information Sheet, agree with all items in the Consent Form and grant my permission for participation

Check Box

Yes

No