

**PARTICIPANT INFORMATION SHEET AND
CONSENT FORM**

CLINICAL TRIAL

Therapeutic Effects of Low Intensity Pulsed Ultrasound
(LIPUS) in Rotator Cuff Repair

Ethics Approval Number: HC 12561

Site: _____

Participant Number: _____



W.R. Walsh, Ph.D.
Professor
DIRECTOR
SURGICAL & ORTHOPAEDIC
RESEARCH LABORATORIES

Invitation

You are invited to participate in a research study to investigate the efficacy of using Low Intensity Pulsed Ultrasound (LIPUS) in Rotator Cuff Repair.

The study is being conducted by the Surgical and Orthopaedic Research Laboratories and UNSW by

Prof William Walsh

Dr Matthew Pelletier

Dr Jerome Goldberg

Dr Andrew Tasker

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose is to investigate whether the application of LIPUS after rotator cuff repair leads to improved outcome, or a faster recovery following surgery.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you will undergo rotator cuff repair in the near future.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

This study will be conducted over a one year period; however the treatment period will be for 6 weeks only.

The treatment being investigated in this study differs from the standard treatment offered in this institution because of the additional of LIPUS during the recovery period. No other post operative care will be altered.

This study will be conducted as a blind trial with placebo group. In a "blind trial" the study participants do not know which treatment group they are in. A placebo is a dummy treatment that looks like the genuine medicine but contains no active ingredient. Because the treatment cannot be felt you will not know which group you are in.

If you agree to participate in this trial, you will then be asked to apply a device to your shoulder for 20 minutes, 3 times a day. After surgery, you will be fitted for the device and instructed on its use. You will not be able to feel if the device is on or not so it is important to understand its operation. All other measures of shoulder function will be part of the standard treatment after rotator cuff repair.

5. 'How is this study being paid for?'

The study is being sponsored Ausmediic Australia. Sponsorship is in the form of instruction on using the device and loan of the device only. No money is paid directly to individual researchers.

6. 'Are there risks to me in taking part in this study?'

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

These risks are the same as those of associated with the use of the diagnostic ultrasound. Maximum temperature increase that the device is capable of is 0.1°C this will not produce clinically relevant or noticeable increase in tissue temperature. These risks are generally considered safe and are not associated with any harmful and adverse effects. There may also be risks associated with this trial that are presently unknown or unforeseeable.

7. 'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

The parties to this study agree to follow the Medicines Australia *Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial*. These Guidelines allow for some claims for compensation to be settled without the need for legal action to be taken. The fact that the parties have agreed to abide by these guidelines in respect of the clinical trial does not affect your rights to pursue a legal remedy in respect of any injury you may suffer as a result of participation. You can obtain a copy of these Guidelines from the Secretary of the Human Research Ethics Committee. A copy of these guidelines will be provided by the researchers if required.

8. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future treatment of rotator cuff repair; however it may or may not directly benefit you. If successful the treatment may lead to improved outcome following surgery.

9. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything. You will not be paid for your participation in this study. You will receive a device to provide the LIPUS treatment for the duration of the treatment period.

10. 'How will my confidentiality be protected?'

Of the people treating you, only your treating physician will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above, Dr. Goldberg and Dr. Tasker will have access to your

details and results. Coded results will be passed to Prof. Walsh and Dr. Pelletier where these results will be held at the Surgical & Orthopaedic Research Laboratories.

11. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss/publish the results as journal publications and presentations at scientific/clinical meetings. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

12. 'What happens to my treatment when the study is finished?'

The device will not be available after the study finishes. It is only intended to be used immediately following surgery for the prescribed time period.

13. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher Dr Goldberg will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on 02 93995333 or Dr Tasker, Shoulder Fellow, on 0450056073

14. 'Who should I contact if I have concerns about the conduct of this study?'

Complaints may be directed to the Ethics Secretariat, The University of New South Wales, SYDNEY 2052 AUSTRALIA (phone 9385 4234, fax 9385 6648, email ethics.sec@unsw.edu.au). Any complaint you make will be investigated promptly and you will be informed of the outcome.

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**

CONSENT FORM

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1. I,.....
.....
of.....
agree to participate in the study described in the participant information statement set out above (**or: attached to this form**).
2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Surgical & Orthopaedic Research Laboratories, University of New South Wales, or my medical attendants.
5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Goldberg on telephone 02 93995333 or Dr Tasker on 0450056073 who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Ethics Secretariat, The University of New South Wales, SYDNEY 2052 AUSTRALIA (phone 9385 4234, fax 9385 6648, email ethics.sec@unsw.edu.au). Any complaint you make will be investigated promptly and you will be informed out the outcome.

Signature of participant	Please PRINT name	Date
_____	_____	_____
Signature of witness	Please PRINT name	Date
_____	_____	_____
Signature of investigator	Please PRINT name	Date
_____	_____	_____

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REVOCAION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Surgical & Orthopaedic Research Laboratories, University of New South Wales, or the Prince of Wales Hospital or my medical attendants.

Signature of participant

Please PRINT name

Date

The section for Revocation of Consent should be forwarded to:

Prof. W.R. Walsh, Ph.D.
DIRECTOR
Surgical & Orthopaedic Research Laboratories
Level 1, Clinical Sciences Bld
Gate 6, Prince of Wales Hospital
Avoca St, Randwick NSW 2031
Sydney, Australia
ph : +61 2 9382 2663
fax : +61 2 9382 2660