

ORTHOSPORTS



Jerome Goldberg - Shoulder Surgeon

PATIENT NOTES FOR LIPUS STUDY

Dear patient,

The Prince of Wales Hospital Orthopaedic Research Laboratory, with which I am associated, is involved in clinical research projects to advance medical science. In order to do this we need to ask for patient involvement.

I am asking you to consider being involved in a study to see whether Low Intensity Pulsed Ultrasound (LIPUS) improves Rotator Cuff healing. This study has been approved by the Ethics Committee of The University of New South Wales.

We have shown in animal studies that LIPUS promotes the healing of the Rotator Cuff quite dramatically. It is safe, painfree and has no complications. Enclosed is a copy of our animal research which was recently published.

The study involves selected patients applying Ultrasound via a small portable machine to the shoulder for 20 mins, three times a day for 6 weeks. This is painless and there are no known side effects of the ultrasound. You will be instructed on usage and the application of the machine before you leave the hospital.

There will be 50 patients in the study, and half of the patients will have a functioning ultrasound machine and half the patients will have a non functioning or "sham" machine. Both you and I, will not know if you have a functioning or non functioning machine. The decision as to who gets which machine will be made by a special computer program which randomises the patient group.

If selected, and the ultimate decision will be made if the surgery shows you have a Rotator Cuff tear without any other significant shoulder problems, like arthritis, you will be entered into the study. There is no compulsion to be involved in the study and you should not feel pressured to be involved. It is a VOLUNTARY decision.

If involved you will be asked to

- Use the ultrasound machine for 6 weeks
- Answer a questionnaire preoperatively , at 6 months and at 12 months
- Possibly have an ultrasound or MRI at 12 months

There is no charge for any of these services and there will be no payment to you for being in the study

You will be asked to sign a document to indicate that you are agreeable to participate in the study.

A week before surgery you will be called by my fellow, Dr Tasker, to ask whether you agree to be involved. If you have any questions please ask them at that time.

Please note that if you agree to be involved, the ultimate decision as to whether you qualify for the study, will be made at the time of the surgery and depends to whether your Rotator Cuff tear falls into the study parameters.

Thank you for considering being in the study

JEROME GOLDBERG