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Patient Information Sheet

The Fibula Nail vs. Plate and Screws for the Fixation of Ankle Fractures

You have been asked to participate in a study that is designed to help us to determine which method of fixing ankle fractures is the best. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of this study?

Ankle fractures are one of the most common fractures that we treat with an operation. The currently most widely used surgery for many of these fractures is a plate and screws on the fibula (lateral ankle bone). Although this traditional method of plates and screws has proven to be a satisfactory way of treating these fractures, there may be complications, most commonly related to the wound.

A new implant has been developed called a fibula nail. This is device is a metal rod that is inserted through a small incision on the outside of your ankle into the fibula. This has been shown to be an excellent way of stabilising fractures with minimal wound complications.

Unfortunately, we have no good way of knowing which method is the best for fixing ankle fractures, and the only scientific way to find out is through a clinical trial that compares the two techniques carefully.

2. Why have I been chosen?

You have been asked to consider participating in this study because you are over the age of 18 and have an ankle fracture that can benefit from operative repair.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without. giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

4. What happens to me if I take part?

If you agree to take part in the study you will be randomised to either treatment with a fibula nail or with screws and a plate. This is called a randomised trial. Sometimes when we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected at random, i.e. by chance. Patients in each group have a different treatment and these are compared. You have a 50/50 chance of having your ankle fixed with screws and plates, or a fibula nail.

Follow up visits to the outpatient orthopaedic clinic will occur at regular intervals. The schedule is as follows:

Two weeks after surgery: your cast will be changed and new x-rays obtained.

Six weeks after surgery: your cast will come off and another set of x-rays will be obtained.

Three months from surgery: Another set of x-rays will be obtained and your progress evaluated.

Six months from surgery: X-rays of your ankle will be obtained and we ask you to fill in a questionnaire regarding your progress and return to pre injury level of activity.

Two years from surgery: We will ask you to fill in a questionnaire.

The schedule for follow up visits to the outpatient clinic is similar whether or not you choose to participate in the study. Participation does not require you to come to the clinic more often or to have additional x-rays. We ask that you fill in the questionnaire, which should take no longer than 5 minutes.

5. What do I have to do?

There are no lifestyle changes you will need to make if you decide to participate in the study. You can continue on your regular medications.

6. What is the medical device being tested?

We are comparing two products that are currently available for treating ankle fractures. One is a fibula nail that has been in use for several years and has been shown to be an effective way to treat ankle fractures. The other is a system of screws and plates that has been used for over 20 years and has also been very effective at treating ankle fractures.

7. What are the alternatives for treatment?

The other alternative would be non-operative treatment of your ankle fracture. Studies have shown that patients do not have a good outcome with non-operative treatment (i.e. – more pain in their ankle and a higher risk of arthritis developing). Therefore, we recommend operative treatment for your type of fracture.

8. What are the side effects of any treatment received when taking part?

As far as we are aware there are no side effects from either method of treatment.

9. What are the possible disadvantages and risks of taking part?

As far as we are aware, there are no likely disadvantages to taking part in the study. Both methods of treatment have proven successful. There are general risks associated with undergoing surgery including but not limited to infection, damage to blood vessels and nerves and complications associated with anaesthesia. There should be no increase in these general surgical risks whether or not you choose to take part in the study. Some patients go on to develop wear and tear (arthritis) in their ankle after a fracture, but again we do not expect this to be either more or less likely with either type of treatment.

10. What are the possible benefits of taking part?

There is no clinical or financial benefit to you taking part in the study.

11. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism is available to you.

12. Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital / surgery will have your name and address removed so that you cannot be recognised from it. Your GP will be informed that you are participating in the study.

13. What will happen to the results of the research study?

The results of this study will be submitted to an orthopaedic journal and may be presented at a meeting. You can obtain a copy of the published results by writing to the principle investigator listed below. You will not be identified in any publication or report.

14. Who is organising and funding the research?

The study is being organised by the principal investigator. He will not be paid for including you in this study. There are no financial incentives for completing the study.

15. Who has reviewed this study?

The Research Ethics Committee has reviewed and approved this study.

16. Contact for further information:

If you wish to discuss this study at any time you can contact the primary researcher at:

Mr T White
Consultant Orthopaedic Trauma Surgeon
Royal Infirmary of Edinburgh
Little France
Edinburgh
EH16 4SU
Tel 0131 242 3435

Or, if you prefer, you can discuss this study with someone who knows and understands the study but is not directly involved:

Mr J Keating
Consultant Orthopaedic Trauma Surgeon
Royal Infirmary of Edinburgh