



PARTICIPANT INFORMATION SHEET

A comparison between conventional absorbable sutures and knotless sutures in third molar surgery using a split-mouth study design.

Locality: Department of Oral Diagnostic and Surgical Sciences, School of Dentistry

Principal Researcher: Nigel Tan (Doctoral candidate)

Primary Supervisor: Professor Darryl Tong (Consultant in Oral and Maxillofacial surgery)

Contact number: (03) 479 8889

Ethics Committee Ref: Pending

Thank you for taking the time to go over this information sheet.

We would like to invite you to take part in a study comparing the performance of knotless absorbable sutures against normal absorbable sutures in wisdom tooth surgery. There is no pressure for you to participate and you are not required to justify your reasons for not taking part. There will be no impact whatsoever on the quality of care you receive should you not take part. You are allowed to change your mind, even if you initially agree.

This Participant Information Sheet will outline some information to help you decide if you would like to take part. It will go over why we are doing the study, what your involvement will be, what benefits and risks you may encounter, and what happens after the study ends. We will go over this information with you and would like to answer any queries you have along the way. You are under no pressure to come to a decision today regarding your participation. Before deciding, feel free to have a discussion with your friends, family, wider whanau, dentist or GP.

If you agree to take part in this study, we will need you to sign the Consent Form at the end of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form for your own records.

This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the aim of this research?

This research is being undertaken as part of a Clinical Doctorate in Oral Surgery at the University of Otago. The aim is to compare the performance of knotless sutures and conventional sutures, in terms of pain, swelling and irritation in wisdom tooth surgery. Both sutures we are comparing are absorbable (dissolving) sutures. The knotless suture is the 3-0 V-loc wound closure device by Covidien. The conventional suture we are comparing it against is the 3-0 Vicryl Rapide by Ethicon. Knotless sutures have performed well in other surgical specialties, by reducing surgical time without affecting post-operative wound complications. We would like to see if this material also improves outcomes in oral surgery. To help minimise any bias, the clinician performing the surgery will not know which side each suture material

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will be used on beforehand and the participant will not know which side is receiving each material. Everyone participating will receive both sutures, one material on each side.

Who pays for the study?

Participants will bear the cost of surgical treatment according to the fee guidelines of the School of Dentistry, University of Otago, and the post-operative medications prescribed. There will be no cost associated with the knotless suture material to the participant. The knotless sutures are funded by a Fuller Scholarship grant. This has been awarded through the Sir John Walsh Research Institute, University of Otago.

Who are we seeking to participate in the project?

People between 18 and 44 years of age requiring the removal of at least 2 impacted lower wisdom teeth are invited to participate. Participants must be healthy with no significant medical conditions and must not have any allergic reactions to anaesthetics/sedatives, painkillers, anti-inflammatory tablets, codeine or tramadol. Female patients who are pregnant or breastfeeding will not be able to participate.

What will participants be asked to do?

Should you agree to take part in this project, you will be asked to:

1. Complete a short questionnaire about basic things such as your age, gender, occupation, oral hygiene practice, pain and irritation associated with your wisdom teeth, and whether you experience anxiety during dental treatment.
2. Attend an appointment for the removal of your wisdom teeth. Before the removal of your wisdom teeth, we will take a few measurements of your cheeks to help us measure any swelling later on.
3. Complete your post-operative diary. This involves scoring your pain level every 6 hours (while awake) for the first 2 days after the surgery. You will also need to answer questions about the irritation experience on each side and whether you have had to take any additional pain-relief other than paracetamol and ibuprofen. It will take only a moment of your time.
4. Attend a review appointment with Nigel Tan 2 days after the surgery, at which time we will:
 - a. Assess the amount of facial swelling.
 - b. Take some pictures of the where the wisdom teeth have been removed.
 - c. Collect your pain diary; and
 - d. Ask you to complete a short questionnaire about to your experience of pain and irritation following your wisdom teeth surgery.
5. Attend a review appointment with Nigel Tan 7 days after the surgery, at which time we will:
 - a. Assess the amount of facial swelling.
 - b. Take some pictures of the where the wisdom teeth have been removed.
 - c. Ask you to complete a short questionnaire about to your experience of pain and irritation following your wisdom teeth surgery.

Benefits and risks of participating in this study

Surgical wisdom tooth removal is a common procedure performed at the School of Dentistry, University of Otago. The knotless sutures we are evaluating have been well established in

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human surgery. To date, there has been no reported allergic reaction to the material. The conventional suture material is what we would otherwise normally use in wisdom tooth surgery.

We will give you a prescription for painkillers. These painkillers are routinely prescribed to patients undergoing wisdom tooth removal at the School of Dentistry.

If you have any issues with discomfort, please feel free to contact us for additional no-cost reviews.

What if something goes wrong?

In the unlikely event you receive an injury in this study, you would be eligible for compensation under ACC. This is similar to any injury at work or home. You would, however, need to lodge a claim with ACC, which could take some time for ACC to assess. If your claim is successful, you should receive funding to assist your recovery.

If you have private health or life insurance, you might want to check with your provider to ensure that taking part in this study does not affect your cover.

What about anonymity and confidentiality?

Your participation in this study is strictly confidential. Any personal information such as your name, age, gender, and contact details will be strictly handled according to the institution's privacy policy. The information collected from you will be de-identified and used only by the researchers directly involved in this project. The de-identified study data will be stored securely at the University of Otago for a period of 10 years, after which time it will be destroyed.

The results of this study will be written up as a clinical doctoral thesis. This might later be summarised and published in a research journal, shared with other clinicians to benefit other patients receiving treatment. Nothing that could be used to identify you will be in anything we publish.

If I agree to participate, can I withdraw later?

You are able to change your mind at any time. Your participation is entirely voluntary and withdrawal will not disadvantage you or affect the standard of care you receive. To participate you will need to fill in the accompanying consent form. Should you wish to, you are welcome to request a copy of the final results of this research project. You have the right to access your personal data at any time.

What if I have any questions about the research project?

If you require additional information, please do not hesitate to contact Nigel Tan (tanni823@student.otago.ac.nz) or Professor Darryl Tong on (03) 479 8889 during business hours.

What if I have any problems or require additional pain relief following my wisdom teeth surgery?

If you need to contact the oral surgery team following your wisdom teeth surgery, you may do so during business hours on (03) 479 8889. For after-hours emergency, you may contact Dunedin Public Hospital on (03) 474 0999 and ask to be put through to the on-call Dental House Surgeon.

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For Māori health support, please contact Professor John Broughton, Associate Dean (Māori), Faculty of Dentistry, on (03) 479 7639.

For Health and Disability Advocacy Service, please contact 0800 555 050 or advocacy@advocacy.org.nz



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Contact number: (03) 214 7293

Ethics Committee Ref: Pending

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will be used on beforehand and the participant will not know which side is receiving each material. Everyone participating will receive both sutures, one material on each side.

Who pays for the study?

Participants will bear the normal cost of treatment in accordance with the Southland Hospital outpatient dental treatment fee guideline. Normal pharmacy or chemists' fees apply for prescriptions. There will be no additional cost associated with participating in this study. The knotless sutures are funded by a Fuller Scholarship grant. This has been awarded through the Sir John Walsh Research Institute, University of Otago.

Who are we seeking to participate in the project?

People between 18 and 44 years of age requiring the removal of at least 2 impacted lower wisdom teeth are invited to participate. Participants must be healthy with no significant medical conditions and must not have any allergic reactions to anaesthetics or sedatives, painkillers, anti-inflammatory tablets, codeine or tramadol. Female patients who are pregnant or breastfeeding will not be able to participate.

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Should you agree to take part in this project, you will be asked to:

6. Complete a short questionnaire about basic things such as your age, gender, occupation, oral hygiene practice, pain and irritation associated with your wisdom teeth, and whether you experience anxiety during dental treatment.
7. Attend an appointment for the removal of your wisdom teeth. Before the removal of your wisdom teeth, we will take a few measurements of your cheeks to help us measure any swelling later on.
8. Complete your post-operative diary. This involves scoring your pain level every 6 hours (while awake) for the first 2 days after the surgery. You will also need to answer questions about the irritation experience on each side and whether you have had to take any additional pain-relief other than paracetamol and ibuprofen. It will take only a moment of your time.
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 - a. Assess the amount of facial swelling.
 - b. Take some pictures of the where the wisdom teeth have been removed.
 - c. Collect your pain diary; and
 - d. Ask you to complete a short questionnaire about to your experience of pain and irritation following your wisdom teeth surgery.
10. Attend a review appointment with Nigel Tan 7 days after the surgery, at which time we will:
 - a. Assess the amount of facial swelling.
 - b. Take some pictures of the where the wisdom teeth have been removed.
 - c. Ask you to complete a short questionnaire about to your experience of pain and irritation following your wisdom teeth surgery.

Benefits and risks of participating in this study

Surgical wisdom tooth removal is a common procedure performed at the Southland Hospital. The knotless sutures we are evaluating have been well established in human surgery. To date,

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there has been no reported allergic reaction to the material. The conventional suture material is what we would otherwise normally use in wisdom tooth surgery.

We will give you a prescription for painkillers. These painkillers are routinely prescribed to patients undergoing wisdom tooth removal at Southland Hospital.

If you have any issues with discomfort, please feel free to contact us for additional no-cost reviews.

What if something goes wrong?

In the unlikely event you receive an injury in this study, you would be eligible for compensation under ACC. This is similar to any injury at work or home. You would, however, need to lodge a claim with ACC, which could take some time for ACC to assess. If your claim is successful, you should receive funding to assist your recovery.

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What if I have any questions about the research project?

If you require additional information, please do not hesitate to contact Nigel Tan (ext. 58313 at Southland Hospital) or Professor Darryl Tong on (03) 479 8889 during business hours.

What if I have any problems or require additional pain relief following my wisdom teeth surgery?

If you need to contact the oral surgery team following your wisdom teeth surgery, you may do so during business hours on (03) 214 7293. For after-hours emergency, you may contact Southland Hospital on (03) 218 1949 and ask to be put through to the on-call Dental House Surgeon.

For Māori health support, please contact Te Huinga Tahī, the Māori Health Unit at 03 218 1949 ext. 48309.

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