Participant Information Sheet
For Control Participants

Title: The neurophysiological drivers of shoulder muscle activation, and functional recovery, after total reverse shoulder replacement.

Lay title: Understanding deltoid muscle control with total reverse shoulder replacement

Researcher(s):
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Informed consent to participate

Thank you for your interest in participating in this research project. Please read the following information about the project, so that you can decide whether you would like to take part in this research. Please ask one of our research team any questions you might have about your involvement in the project.

If you decide to participate in this research, please keep in mind that your participation is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you can stop at any time. You would not need to give any explanation for your decision to stop participating. You can keep this copy of the Information sheet, and you will be given a copy of the signed Consent Form.

Who can participate?

You can participate in this study if you are aged between 55 and 90 years of age, and are able to physically perform the testing procedures. You are not eligible to participate in this study if you cannot understand spoken and written English.

You have been contacted because you have normal pain-free shoulder function.

To be eligible, in general, you must not have:

- a neurological (e.g., Parkinson's disease, motoneuron disease)
- musculoskeletal pain (e.g., whiplash disorder, pain in the neck, upper back or upper limbs that required medication or time off work/sporting activities in the previous 6 months)
- a condition that may affect the control of movement about the shoulder.

Please discuss any concerns that you may have about eligibility to participate in this study with the investigators.

What is this research about?

Appropriate control of human movement is critical for good health. For example, movement at the shoulder underpins many daily functions, e.g., self-care and sports activities. Healthy shoulder function depends on the coordination of many shoulder muscles. Our research team is trying to understand how shoulder muscles are controlled before and after total reverse shoulder replacement, with the long-term aim to advance post-surgical care and outcomes. To do this we also want to know how people with normal shoulder function use their shoulder muscles.

You can also watch an information video (link: www.kennethcutbush.com/linktodeltovideo) that describes the research project.

What will I need to do?

You will be asked to attend only one laboratory session of approximately one hour.

Assessments will be conducted at the St. Andrew's War Memorial Hospital, Dr Kenneth Cutbush shoulder clinic (457 Wickham Terrace, Spring Hill). You will be asked to wear comfortable clothes (i.e., a singlet can be worn) for the assessment. Although we will provide refreshments/water during the experiment, it is desirable that you have eaten your meal (breakfast or lunch, depending on the time of the experiment) and have hydrated prior to commencing the experiment.

Tasks

- To activate your deltoid muscle, your arm will be held in place to provide resistance to an arm elevation movement. Your shoulder is positioned with a maximum of 45 degrees shoulder elevation or less and is adjusted to your available range of motion. The amount of resistance or force you produce will be provided as feedback on a screen and you will be asked to match a target force that is also provided on the screen. We will give you time to perform a couple of practice trials before data collection. We will ask you to push in 3 different directions. For each direction there will be 4 contraction of 20s each. We will provide enough rest in between to avoid fatigue. Procedures will include practice repetitions to familiarise you with the task. The force will be measured by sensors. Force tasks will range from very small to medium effort.
- You will be asked to hold a small weight (if unable without a weight) in your hand and hold the arm in certain postures (same arm posture as above, and in a higher elevation angle only of possible) whereby you contract shoulder muscles to produce a force to hold the weight of your arm with or without additional small weight.

Assessment methods

- To measure the activity of the shoulder muscles, recording electrodes will be placed on the skin overlying the muscles. These sensors have the shape of a grid and contain multiple recording sites that measure your muscle activity through your skin. An example of these sensors is shown in the figure 1 below. Real-time ultrasound will be used to visualise the

structure of your muscles prior to placement of the electrodes.

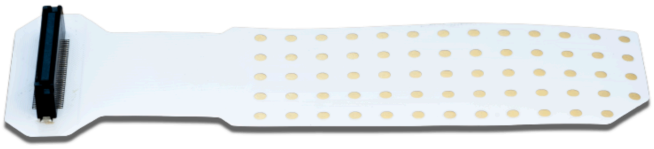

Figure 1. Example of a sensor that measures muscle activity. The sensor will be placed on top of the skin.

- Questionnaires: all participants will be asked to provide details about age, height and weight, pain history and physical activity, and general shoulder function. The completion of all questionnaires will take ~10 minutes. The following questionnaires are included:
    - Constant-Murley Questionnaire
    - American Shoulder and Elbow Surgeons Score.

What are the possible benefits of taking part?
Because this is a research project and not a treatment program, there is unlikely to be any direct benefit to you from your involvement. However, the findings may help us identify differences in muscle coordination in people with musculoskeletal shoulder issues, and subsequently advance post-surgical care and outcomes in the future. You will receive a $40 gift voucher towards the cost of your attendance for the assessment and reimbursement for your time.

What are the possible risks and disadvantages of taking part?
This study was designed to address our aims in such a manner that the research participants are exposed to the minimum possible degree of risk, inconvenience, and discomfort. However, there are some risks involved.

- We use tape to fix the electrodes to the skin, which may cause minor irritation in some cases.
- You might feel fatigued in the shoulder. To minimise fatigue appropriate rest between repetitions will be given and additional rest periods can be provided upon your request.

What will happen to the information about me?
All information collected about you will remain confidential. You will be assigned a number with which all data forms and files, pertaining to you, will be labelled. Data collected for this research will be stored electronically in a non-identified manner on The University of Queensland Research Data Manager server. For data collection and analysis purposes, data may be stored on local computers that are password protected so that only the investigators will have access. Forms will be kept in a locked filing cabinet in at Dr Cutbush's clinic. Data will be stored for at least 5 years. Collected data might be used for future research upon reasonable request, but your privacy will always be maintained.

It is anticipated that the results of this research project will be published and/or presented in a variety of forms. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your expressed permission.

What will happen if I decide to withdraw?

You will have the opportunity to withdraw from these procedures at any time should you wish to do so, without penalty. Your decision whether you take part, or not to take part, or to take part and then withdraw, will not affect your relationship with the researcher. If you choose to stop participating after the experiment has commenced, we will need to know if you are happy or not for us to retain the data that we have already collected. This is also described on the consent form.

Can I hear about the results of this research?
The overall outcomes of the study will be available at the completion of the research project. This can be in the form of a conference poster presentation or publication. Should you have any questions regarding the nature of the research, please feel free to contact Dr Wolbert van den Hoorn (w.vandenhoorn@qut.edu.au) or A/Prof Kylie Tucker (k.tucker1@uq.edu.au) who will be happy to provide you with more information.

Whom can I contact if I have any concerns about the project?
This study adheres to the Guidelines of the ethical review process of Local Research Ethics Governance Uniting Care Health, and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with the researcher contactable on (w.vandenhoorn@qut.edu.au / k.tucker1@uq.edu.au) if you would like to speak to an officer of the Uniting Care Health not involved in the study, you may contact the Ethics Coordinator on +617 3232 7500 / +617 3443 1656 or email HREC@ucareqld.com.au.