PARCS | PATCH AUGMENTED ROTATOR CUFF SURGERY

PARCS Study Survey (BESS Membership)

Introduction

A survey of current practice and opinions on using patches to enhance rotator cuff surgery.

The aim of this survey is to get BESS members' views on the use a patch to augment Rotator Cuff Surgery, and to explore current practice. It is part of a larger study (called the PARCS feasibility study) which is looking at the feasibility and design of a randomised trial to assess the clinical and cost effectiveness of patch augmented surgery in the NHS. Studies, such as the UKUFF trial, have indicated a failure rate of up to 40% for cuff repairs. There is growing interest amongst surgeons in the use of patches to provide a support structure or "scaffold" for the repair, to improve tendon fixing to the bone and healing. Various patches have been developed using different materials (e.g. animal heart or synthetic materials), processes and sizes. It is unclear to what extent they have been used in the NHS, which patients are best suited to patch augment, and the degree of support amongst surgeons for a randomised trial.

This survey addresses these uncertainties and will help inform future trials in this area of research. Findings will be circulated to BESS membership, presented at a BESS meeting and published in an academic journal.

We would be extremely grateful if you could take the time (approximately 10 minutes) to complete this short survey.

About you

What is your position? * *Required*

Please select exactly 1 answer(s).

- [ ] Consultant Shoulder Surgeon
- [ ] Orthopaedic Trainee
- [ ] Other

Other, please state:

About you

Where do you work? * *Required*

Please select between 1 and 4 answers.

- [ ] District General Hospital
- [x] University/ Teaching Hospital
- [ ] Private Hospital
- [ ] Other

Other, please state:

About you

What is your surgical practice regarding rotator cuff repair? * *Required*

Use of a patch to augment rotator cuff surgery

Have you used a patch to augment rotator cuff surgery? * *Required*

Use of a patch to augment rotator cuff surgery

How many rotator cuff operations have you performed using a patch? * *Required*

Please enter a whole number (integer).
The number should be 1 or greater.

Which patches have you used? * *Required*

Why did you use these specific patches? * *Required*

Please use this space to add any further comments relating to choice of patch for using to augment rotator cuff repair.

Patinet suitability for a patch augmented rotator cuff repair

It is unclear in which patients patch augmented surgery would be considered appropriate. We would like to know your views on when patch augmentation is, or might be, suitable.

Age and tear size have been suggested to be the two main factors affecting outcome after rotator cuff repair surgery. The table below shows 16 combinations of age and tear size. If you think a patient with a particular combination would be suitable please choose 'yes'. If you would never consider such a patient to be suitable then choose 'no'. If you are unsure about whether they would be suitable choose 'unsure'.

In the example below patients with small tears are never considered suitable whereas those with large and massive tears always are. The suitability of those with a medium sized tear in uncertain. Age did not affect the decision for any size of tear.

Tear Size/ Patient Age	Yes	No	Unsure
50 year old, small		X	
60 year old, small		X	
70 year old, small		X	
80 year old, small		X	
50 year old, medium			X
60 year old, medium			X
70 year old, medium			X
80 year old, medium			X
50 year old, large	X		
60 year old, large	X		
70 year old, large	X		
80 year old, large	X		
50 year old, massive	X		
60 year old, massive	X		
70 year old, massive	X		
80 year old, massive	X		

Your response

Please don't select more than 1 answer(s) per row.

Please select exactly 16 answer(s).

	Yes	No	Unsure
50 year old, small	☐	☐	☐
60 year old, small	☐	☐	☐

70 year old, small	☐	☐	☐
80 year old, small	☐	☐	☐
50 year old, medium	☐	☐	☐
60 year old, medium	☐	☐	☐
70 year old, medium	☐	☐	☐
80 year old, medium	☐	☐	☐
50 year old, large	☐	☐	☐
60 year old, large	☐	☐	☐
70 year old, large	☐	☐	☐
80 year old, large	☐	☐	☐
50 year old, massive	☐	☐	☐
60 year old, massive	☐	☐	☐
70 year old, massive	☐	☐	☐
80 year old, massive	☐	☐	☐

Please feel free to use this space to add any further comments relating to suitability of a patient for a patch augmented rotator cuff repair.

Interest in participating in a randomised trial

Would you be interested in taking part in a randomised controlled trial of patch augmented surgery? (i.e. your patients being approached to take part, and you would perform the study operations, etc.) * *Required*

- ○ Yes
- ○ Maybe
- ○ No

Interest in participating in a randomised trial

Is there anything that would make you more interested in taking part in such a study?
*Required

- Yes
- No

Yes, please give details:

Final Questions

Please feel free to use this space to comment on any aspect related to this topic or survey that you feel is important.

Final Questions

Would you be happy for us to contact you if we have further questions? * *Required*

- ○ Yes
- ○ No

If Yes, please provide your e-mail address

Please enter a valid email address.

Thank you

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY!

YOUR HELP IS GREATLY APPRECIATED.

If you have any queries about this survey or about the PARCS Study please contact: Andrew Carr on (01865) 223404 or at rcrstudies@ndorms.ox.ac.uk

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Key for selection options

3 - What is your surgical practice regarding rotator cuff repair?

All/ predominantly arthroscopic rotator cuff repair
All/ predominantly open rotator cuff repair
Substantial amount of both arthroscopic and open repairs

4 - Have you used a patch to augment rotator cuff surgery?

No
Yes, in the last 6 months
Yes, but not in the last 6 months

PARCS Surgeon Triallist Survey

Introduction

Dear Surgeon Colleagues

Currently we are developing a trial looking at the use of patches for rotator cuff tears in the NHS setting. This work is within a project called PARCS (Patch Augmented Rotator Cuff Surgery). Professors Andy Carr, Amar Rangan, Jonathan Rees and Mr Mike Thomas, along with Professor Jonathan Cook are involved in the study, amongst others.

You may have answered a survey related to this earlier last year. As a further step in designing a rotator cuff patch trial, we are asking you to complete a survey related to how such a trial could be designed.

This survey should take about 10 minutes to complete.

Please note: this survey needs to be completed in one-sitting to avoid losing data.

All data analysed will be anonymous. However, we do request your contact details if you would like to be involved in future PARCS work (a Delphi study).

If you have any queries please contact Cushla Cooper at rcrstudies@ndorms.ox.ac.uk.

Many thanks from the PARCS team

The PARCS project is funded by National Institute for Health Research's Health Technology Assessment Programme (15/103/03).

https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/parcs

Patch use for rotator cuff repair

Do you currently use a patch to augment a rotator cuff repair on any of your patients?

If you do use a patch, how do you typically use it?

If you selected Other, please specify:

Would the state of the subscapularis muscle affect your decision to use a patch?

Please explain your answer:

A trial of patch augmented rotator cuff

Please consider which patients **you would be prepared to randomise** to each trial scenario.

Tick all that apply

(we realise not everyone within a category would be considered the same but we are interested in *which patient subgroups you would consider using a patch*)

Randomised Controlled Trial comparing a rotator cuff repair *plus a Patch* **versus** a standard cuff repair *with No-Patch* (2-arm study)

- [ ] Medium tear
- [ ] Large tear
- [ ] Massive tear
- [ ] Revision
- [ ] 50-60 years
- [ ] 60-70 years
- [ ] 70-80 years
- [ ] 80+
- [ ] Would not randomise any patients into such a study

Randomised Controlled Trial of standard rotator cuff repair *plus Patch A* **versus** standard rotator cuff repair *plus Patch B* **versus** standard rotator cuff repair *with No-Patch* (3-arm study)

- [ ] Medium tear
- [ ] Large tear
- [ ] Massive tear
- [ ] Revision
- [ ] 50-60 years

- [ ] 60-70 years
- [ ] 70-80 years
- [ ] 80+
- [ ] Would not randomise any patients into such a study

Please consider each patient characteristic below in turn, and confirm whether you think **any of the subgroups should be excluded** from a trial of patch augmented rotator cuff repair.

Tick all that apply

Degree of atrophy present

- [ ] Grade 0 - normal muscle
- [ ] Grade 1 - some fatty streaks
- [ ] Grade 2 - less than 50% fatty muscle atrophy
- [ ] Grade 3 - 50% fatty muscle atrophy
- [ ] Grade 4 - greater than 50% fatty muscle atrophy

Optional comments on degree of atrophy present:

Degree of glenohumeral osteoarthritis present (Kellgren Lawrence Classification)

- [ ] Grade 0 - No radiographic evidence of osteoarthritis
- [ ] Grade 1 - Marginal osteophytes of doubtful importance
- [ ] Grade 2 - Definite osteophytes
- [ ] Grade 3 - Moderate joint space narrowing, subchondral sclerosis
- [ ] Grade 4 - Severe joint space narrowing cyst formation

Optional comments on degree of glenohumeral osteoarthritis present:

Presence of cuff arthropathy:

- Yes
- No

Optional comments on cuff arthropathy:

Trial procedures

When to randomise

When would it be most practicable for a patient to be randomised to a treatment allocation?

- Prior to the day of surgery (eg: pre-surgery assessment)
- In the anaesthetic room
- In the operating room (at the start of the operation)
- In the operating room (once the shoulder pathology has been assessed)
- Other (please explain)

If you selected Other, please specify:

Consider what you would be willing to do in a trial.

For a trial, we would work with surgeons to agree a standardised repair technique suitable to the trial patient population. Within a trial, would you be willing to:

- Use an agreed standardised repair technique
- I would not want to use a standardise repair technique, I prefer to use my own repair technique

Optional comments on use of a standardised repair technique: *Optional*

Would you be willing to only use a specific patch? (i.e: a brand of patch, not a generic type)

- Yes
- No

Optional comments on using a specific patch within a trial:

Would you be able to use a standardised post-operative rehabilitation regime for patients in a trial?

- Yes
- No

Optional comments on standardised post-operation rehabilitation regime within a trial:

What length of patient follow up is requried post rotator cuff repair to assess the outcome of the operation?

- 6 months
- 12 months
- 24 months
- Other

If you selected Other, please specify:

Further contact

If you would be interested in being involved in the Delphi study seeking consensus on the key aspects of the design of the RCT on this topic, please enter the best email address to contact you about this below:

Thank you for completing this survey.

Any further comments

Thank you for completing this survey

Thank you for completing the PARCS Survey!

Key for selection options

1 - Do you currently use a patch to augment a rotator cuff repair on any of your patients?

Yes
No, but I would be willing to for a trial of patch augmentation with suitable support.
No, and I would not be interested in being involved in a trial where I would have to carry out patch augmentation.

2 - If you do use a patch, how do you typically use it?

Bridge (used to fill a persistent defect after a standard repair)
On-lay (used to reinforce a standard repair)
Other, please state

3 - Would the state of the subscapularis muscle affect your decision to use a patch?

Yes
No

PARCS Delphi Questionnaire Round 1

Page 1: Introduction

We are developing a randomised trial looking at the use of patches for rotator cuff tears in the NHS setting. This work is within a project called PARCS (Patch Augmented Rotator Cuff Surgery). Professor Jonathan Cook is leading the project in collaboration with Professors Andy Carr, Amar Rangan, Jonathan Rees and Mr Mike Thomas.

You may have previously answered a survey or attended a focus group as part of the PARCS project. To continue designing a randomised trial of patch use when repairing a rotator cuff tear, we are asking you to complete this first of two surveys, as we begin to reach a consensus on how such a trial could be designed.

For the purposes of our work, a patch is defined as:

"An implantable human, synthetic, or animal material which is used with the aim of improving tissue healing and/or patient outcome via some form of mechanical support."

This survey should take about 10-15 minutes to complete. Please note: this survey needs to be completed in one sitting to avoid losing data.

If you have any queries please contact Molly Glaze or Cushla Cooper at rcrstudies@ndorms.ox.ac.uk.

Many thanks from the PARCS team

By completing this survey you consent to the PARCS team using the information you provide in the study.

Page 2: User Details

Please complete the following details about yourself.

1. How would you describe yourself?

Please select between 1 and 3 answers.

- [ ] Project member
- [ ] Industry representative
- [ ] Funder representative
- [ ] Shoulder surgeon
- [ ] Allied health professional
- [ ] Medical researcher
- [ ] Other

1.a. If you selected Other, please specify:

1.b. Where do you work?

Please select between 1 and 4 answers.

- [ ] District general hospital
- [ ] Teaching hospital
- [ ] Private hospital
- [ ] Commercial company
- [ ] Funding body
- [ ] University
- [ ] Other

1.b.i. If you selected Other, please specify:

Page 3: Patient Population

The following questions relate to characteristics of the patient population who should be involved in a randomised trial of patches in rotator cuff surgery.

2. How much do you agree with the following inclusion criteria for the trial? 1 = Completely disagree, 2 = Somewhat disagree, 3 = Neutral, 4 = Somewhat agree, 5 = Completely agree

	1	2	3	4	5	Don't know
No clinically significant OA present (e.g: patients with Kellgren Lawrence Classifications Grades 3 & 4 will be excluded)	☐	☐	☐	☐	☐	☐
Less than 50% muscle atrophy present (patients with 50% or more will be excluded)	☐	☐	☐	☐	☐	☐
Medium, Large and Massive tears (patients with small tears will be excluded)	☐	☐	☐	☐	☐	☐
Primary repairs only (patients with re-tears/revisions will be excluded)	☐	☐	☐	☐	☐	☐

2.a. Please comment to clarify any disagreement:

3. How strongly do you agree with these groups of patients taking part in a randomised trial? 1 = Completely disagree, 2 = Somewhat disagree, 3 = Neutral, 4 = Somewhat agree, 5 = Completely agree

	1	2	3	4	5	Don't know
Patients less than 50 years old	☐	☐	☐	☐	☐	☐
Patients aged between 50 and 70 years old	☐	☐	☐	☐	☐	☐
Patients with other shoulder conditions, not just rotator cuff problems, that affect their muscles, joints, bones, tendons etc (eg osteoarthritis)	☐	☐	☐	☐	☐	☐
Patients older than 70 years old	☐	☐	☐	☐	☐	☐

3.a. Please comment to clarify any disagreement:

Page 4: Patch details

The following questions relate to the surgical use of a patch in the randomised trial.

4. For those who use patches, how much do you agree with the following surgical approaches to using a patch? 1 = Completely disagree, 2 = Somewhat disagree, 3 = Neutral, 4 = Somewhat agree, 5 = Completely agree

	1	2	3	4	5	Not relevant to me
Use On-lay approach only - where a patch overlies a successful primary repair	☐	☐	☐	☐	☐	☐
Use Bridge approach only - used to fill a residual defect for tears that cannot be repaired at or near their anatomical insertion site.	☐	☐	☐	☐	☐	☐
Depends on patient characteristics - allow the operating surgeon to vary the approach depending upon the patient in front of them	☐	☐	☐	☐	☐	☐

4.a. Please comment to clarify any disagreement:

5. How much do you agree to the following types of patches being used in a trial? 1 = Completely disagree, 2 = Somewhat disagree, 3 = Neutral, 4 = Somewhat agree, 5 = Completely agree

	1	2	3	4	5	Don't know
Patches made from animal products	☐	☐	☐	☐	☐	☐
Synthetic patches (eg made from plastic type of material)	☐	☐	☐	☐	☐	☐
Allograft patches (made from another human's tissue)	☐	☐	☐	☐	☐	☐
Autograft patches (made from the patient's own tissue)	☐	☐	☐	☐	☐	☐

5.a. Please comment to clarify any disagreement:

5.b. Which patches do you think should be used as part of a randomised trial?

- ○ Only a specific patch (eg: only a particular brand of patch)

- Only one type of patch (eg: only synthetic patches)
- What's readily available in the NHS irrespective of type or brand (eg: "off the shelf")
- Other

5.b.i. If you selected Other, please specify:

Page 5: Trial Design

The following items relate to how the trial will be designed.

6. To what extent do you agree with the following trial designs? 1 = Completely disagree, 2 = Somewhat disagree, 3 = Neutral, 4 = Somewhat agree, 5 = Completely agree

	1	2	3	4	5
Randomised trial of standard repair with a patch versus standard repair with no patch	☐	☐	☐	☐	☐
Randomised trial of standard repair with Patch A versus Standard repair with Patch B versus Standard repair alone	☐	☐	☐	☐	☐

6.a. Please comment to clarify any disagreement:

7. In the randomised trial, we will follow up participants to assess and compare outcomes. We will use patient reported outcome measures collected in a questionnaire to do this. At what time point do you think the primary outcome should be measured in a randomised trial?

- ○ 12 months after the surgery
- ○ 18 months after the surgery

- 24 months after the surgery
- Other

7.a. If you selected Other, please specify:

Page 6: Further comments

8. Please let us know if you have any further comments relating to the design of this study.

Page 7: Final page

Thank you for completing the first round of the PARCS Delphi Study.

The answers you have submitted will be analysed and will inform the second round of this questionnaire. We will be sending this out in December. Both of these surveys will contribute to the design of a randomised trial using patches in rotator cuff surgery.

Many thanks from the PARCS team

The PARCS project is funded by National Institute for Health Research's Health Technology Assessment Programme (15/103/03).

https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/parcs

PARCS Delphi Questionnaire Round 2

Page 1: Page 1

We are developing a randomised trial looking at the use of patches for rotator cuff tears in the NHS setting. This work is within a project called PARCS (Patch Augmented Rotator Cuff Surgery). Professor Jonathan Cook is leading the project in collaboration with Professors Andy Carr, Amar Rangan, Jonathan Rees and Mr Mike Thomas.

You may have previously answered a survey or attended a focus group as part of the PARCS project. To continue designing a randomised trial of patch use when repairing a rotator cuff tear, we are asking you to complete this second of two surveys, as we move towards a consensus on how such a trial could be designed. The questions we are asking are based on the answers given in the first survey. We will summarise these at the start of every question.

For the purposes of our work, a patch is defined as:

"An implantable human, synthetic, or animal material which is used with the aim of improving tissue healing and/or patient outcome via some form of mechanical support."

This survey should take about 10-15 minutes to complete. Please note: this survey needs to be completed in one sitting to avoid losing data.

If you have any queries please contact Molly Glaze or Cushla Cooper at rcrstudies@ndorms.ox.ac.uk.

Many thanks from the PARCS team

Page 2: User Details

1. How would you describe yourself?

- [ ] Project member
- [ ] Industry representative
- [ ] Funder representative
- [ ] Shoulder surgeon
- [ ] Allied health professional
- [ ] Other

1.a. If you selected Other, please specify:

2. Where do you work?

- [ ] District general hospital
- [ ] Teaching hospital
- [ ] Private hospital
- [ ] Commercial company
- [ ] Funding body
- [ ] University
- [ ] Other

2.a. If you selected Other, please specify:

Page 3

Answers from the first round of the survey suggested that adults with a rotator cuff tear suitable for primary repair with or without a patch should be included in the randomised trial.

Within this population it was indicated the following should be excluded: small or partial tears, patients unfit for surgery, patients with clinically significant OA, patients with more than 50% muscle atrophy, patients needing revision surgery.

3. What do you think about including these patients in the trial?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

3.a. Please explain your choice.

Page 4

Answers from the first round of the survey indicated preference for patches being used according to their manufacturer guidelines and to clinical indication, rather than according to pre-specified instructions for the trial. This was also linked to whether the rotator cuff repair was complete or incomplete before a patch was used.

Therefore, the project team propose that randomisation will take place in theatre after the primary repair has taken place. At this point the surgeon will know which technique is needed for the repair, and this can be used to stratify the patients.

4. What do you think about randomising patients in theatre after their initial repair?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

4.a. Please explain your choice.

Page 5

Answers from the first round of the survey showed most people were happy to use all types of patches, although patches made from animal products were more contentious.

There was also comparable agreement to use both an 'off-the-shelf' patch and a specific type of patch in a randomised trial. However, there was no consensus as to which type of patch should be used.

Therefore, the study team propose using an 'off-the-shelf' patch as part of the randomised trial. The patches used must fall into the subtypes: synthetic, animal product, allograft, autograft. A non-animal patch should be available in case of surgeon or patient preference.

5. What do you think of using an 'off-the-shelf' patch, including the option of a non-animal patch?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

5.a. Please explain your choice.

Answers from the first round of the survey showed agreement with both a two-arm trial comparing patch with no patch, and a three-arm trial of specific patch type, general patch and no patch.

Given there was no clear consensus for which specific patch type to use, the study team propose a two-arm trial comparing A) rotator cuff repair with an 'off-the-shelf' patch and B) repair without patch.

6. What do you think about a two-arm randomised controlled trial comparing A) rotator cuff repair augmented with an 'off-the-shelf' patch and B) repair without a patch.

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

6.a. Please explain your choice.

Page 6

Answers from the first round of the survey suggested that both 12 months and 24 months are appropriate timepoints to measure key outcomes. It was also indicated that both imaging and Patient Reported Outcome Measures (PROMS) would be valuable.

Therefore the project team propose for imaging (specifically MRI) and PROMS to be collected at 12 and 24 months post randomisation as key outcomes for the study.

7. What do you think about collecting imaging and PROMS as key outcomes for the trial at 12 and 24 months post randomisation?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

7.a. Please explain your choice.

Page 7: Final page

Thank you for completing the second round of the PARCS Delphi Study.

The answers you have submitted will contribute to the design of a randomised trial using patches in rotator cuff surgery. The final consensus for this trial design will be reached at a meeting in Oxford on 29-30 January 2019. Please contact us at rcrstudies@ndorms.ox.ac.uk if you would like to attend and have not yet let us know.

Many thanks from the PARCS team

The PARCS project is funded by National Institute for Health Research's Health Technology Assessment Programme (15/103/03).

https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/parcs

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PARCS Delphi Questionnaire

Page 1: Page 1

Earlier this year, you kindly took part in a focus group with us, either in Oxford or in Middlesbrough. You may remember that we're planning a clinical research study which will look into how good a "patch" is when used as part of a shoulder operation called a rotator cuff repair. Having studied other methods, we do not know the best way to repair tears in patients' shoulders, so we are exploring new technology.

Over the past 18 months we've completed a large review of existing research evidence about the use of patches for a shoulder operation called rotator cuff surgery. We've also conducted surveys with surgeons. We've completed focus groups with patients and carers like you, people from commercial companies who manufacture patches, and people who are involved in reviewing clinical research carried out in the NHS.

With input from patients, surgeons and research reviewers we have been able to draft some ideas about what a research study looking at the use of a patch when carrying out a rotator cuff repair operation might look like. You may recognise some of the ideas, as we discussed these in the focus groups. We'd now like to ask your thoughts on some of these ideas. Below is a quick survey (it may take around 10 minutes to complete) asking your opinion on some possible aspects of the study. We're asking you to state how strongly you agree or disagree with the questions in each section.

There are optional comments boxes after each question in this survey; you can use these for anything you wish to tell us, or not use them at all.

Please note: this survey needs to be completed in one sitting to avoid losing your responses.

If you have any queries please contact Molly Glaze or Cushla Cooper at rcrstudies@ndorms.ox.ac.uk.

Many thanks from the PARCS team

Page 2

You may recall from the focus group, that the main aim of PARCS is to design a study to see whether the use of a patch could help the repair of a tear in the rotator cuff in the shoulder. It is important that the study is one that patients and surgeons (along with other relevant parties) would support. Additionally, it should be one that can run in the NHS.

Many patients will go on to have a rotator cuff repair to treat their shoulder condition after first receiving other treatments such as physiotherapy and painkillers. Unfortunately, a substantial number of these repairs fail within 12 months. Therefore, various ways to improve the operation's success have been explored. The use of a patch to enhance the repair appears promising, though it is unclear if doing so is indeed better than the standard operation.

Work for PARCS so far suggests that four types of patches are used in the NHS and there isn't an overall preference for one type of patch compared to another. These types are: synthetic patches, patches made from animal products, patches made from human (donor) tissue and patches made from your own tissue. All these patches are already used clinically in the NHS and have been approved as a safe implant to insert into the human body.

Given there is no clear evidence to support one type of patch over another we would like to allow the different types of patches to be used in the study. This would reflect current practice in the NHS. In the study, a participant could then receive any of the different types. There would be an alternative (e.g. synthetic) to patches made from animal products for participants who do not want them.

1. What do you think of all of the different types of patches being available for use in a study? The option of a non-animal based patch would be available to all participants.

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

1.a. Please explain your choice.

Findings from the PARCS study so far suggest that a reasonable way to look at the use of patches in rotator cuff repair surgery within a study is to compare the following two groups of patients:

Group 1 - this group would have their rotator cuff tear repaired without a patch

Group 2 - this group would have their rotator cuff tear repaired with a patch

2. What do you think about comparing these two groups?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

2.a. Please explain your choice.

Page 3

As was explained at the focus group, patients in a study are given a treatment at random from those available. This is done because it is the best way to fairly compare different treatments. All patients in the study will be allocated a treatment in this way. Whatever group participants are in, they will still be under the care of their doctor and followed up regularly.

Randomisation can happen at any point between entering the study and receiving the treatment. Findings from the PARCS study so far suggest that the best time to randomise participants may be in the operating theatre. This would mean that, going into the operation, the participant would not know whether a patch would be used. The participant could expect to have their rotator cuff repaired, although this would depend on the nature of the shoulder problem which can be more easily assess during the operation. We would like to know whether patients would be comfortable with this idea.

3. What do you think about participants being randomised in the operating theatre as described above?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

3.a. Please explain your choice.

Often in studies, patients are "blinded" to their randomised group. This term means that they do not know which group they are in while the study is running. This is done in order to get a more scientifically reliable result from the study. For PARCS, this means a participant would not know whether their shoulder was repaired with a patch or not, unless there was a significant safety issue that meant they needed to know.

4. What do you think about participants in the study not routinely knowing whether their shoulder was repaired with a patch while the study is running?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

4.a. Please explain your choice.

Page 4

To find out whether using a patch helps to repair the rotator cuff tear, it would be useful to follow-up participants for 24 months after entering the study. For example, they might be asked to complete a questionnaire at 6, 12 and 24 months about their shoulder symptoms and related care.

5. What do you think about participants completing questionnaires up to 24 months after joining the study?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral
- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

5.a. Please explain your choice.

Other findings in the PARCS study suggest that an MRI scan would be a helpful way to see how tsuccessful the operation has been. This could mean coming to the hospital up to 24 months after joining the study to get a scan in addition to your routine visits.

6. What do you think about participants coming to hospital 24 months after joining the study for a study-specific visit?

- 1 = Completely disagree
- 2 = Somewhat disagree
- 3 = Neutral

- 4 = Somewhat agree
- 5 = Completely agree
- Don't know

6.a. Please explain your choice.

Page 5: Final page

Thank you for completing the second round of the PARCS Delphi Study.

The answers you have submitted will contribute to the design of a randomised trial using patches in rotator cuff surgery. The final decision for this trial design will be reached at a meeting in Oxford on 29-30 January 2019. Please contact us at rcrstudies@ndorms.ox.ac.uk if you would like to attend and have not yet let us know.

Many thanks from the PARCS team

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https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/parcs