Patch augmentation surgery for rotator cuff repair: the PARCS mixed-methods feasibility study

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The PARCS mixed-methods feasibility study

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Scientific summary

Background

A rotator cuff tear is a common, disabling shoulder problem. Symptoms include pain, weakness, lack of shoulder mobility and sleep disturbance. Many patients may require surgery to repair the tear; however, there is a high failure rate. There is a need to improve the outcome of rotator cuff surgery, and the use of patch augmentation to provide support to the healing process and improve patient outcomes holds new promise. Patches have been made using different materials (e.g. human/animal skin or intestine tissue and completely synthetic materials) and processes (e.g. woven or a mesh). Augmentation can be carried out in two main ways: on-lay (placing the patch on top of a completed repair) and bridging (using it to fill a defect that the repair could not address).

Objectives

The aim of the Patch Augmented Rotator Cuff Surgery (PARCS) study was to determine the design of a future definitive randomised controlled trial, assessing the clinical effectiveness and cost-effectiveness of a patch to augment surgical repair of the rotator cuff, that is both acceptable to stakeholders and feasible.

The study objectives were to:

1. review the existing evidence to identify candidate patches for use in a randomised controlled trial and the evidence relating to their clinical use
2. ascertain current NHS clinical practice relating to the use of patches to augment rotator cuff repair
3. explore the acceptability of the proposed trial to patients, surgeons and other stakeholders
4. assess the feasibility of a trial of patch-augmented rotator cuff repair
5. achieve consensus on the key elements of the design of a definitive randomised controlled trial to assess the use of patches to augment rotator cuff repair
6. confirm the scope of the health economic evaluation required in the trial to appropriately assess the cost-effectiveness of patches to augment rotator cuff repair
7. identify areas for further research related to the PARCS study.

Methods

The PARCS feasibility study was a mixed-methods study. It involved six stages: a systematic review of clinical evidence, a survey of the British Elbow and Shoulder Society's surgical membership, a survey of surgeon triallists, focus groups and interviews with stakeholders, a two-round Delphi study administered via online questionnaires and a 2-day consensus meeting. Various stakeholders (including patients, surgeons and representatives from industry) were involved across the six stages.

Systematic review

The MEDLINE, EMBASE and Cochrane databases were searched between April 2006 and August 2018, in accordance with a previously published search strategy for clinical studies of patch use for rotator cuff surgery. No restriction was placed on language. A risk-of-bias assessment was carried out on all comparative studies (Cochrane risk-of-bias tool version 2 for randomised controlled trials and Risk Of Bias In Non-randomized Studies – of Interventions tool for observational studies).

Surveys

An online survey was sent to the surgical membership of British Elbow and Shoulder Society. Questions covered the respondents' demographics, experience with patches, indications for patch augmentation and willingness to be involved in a randomised controlled trial of patch-augmented rotator cuff surgery. A second survey was directed at surgeons who had taken part in previous large, multicentre, UK shoulder trials. It focused on trial-specific implementation issues. The statistical analysis of the surveys was descriptive only.

Qualitative study

Four focus groups covering three stakeholder groups (patient/public, regulatory body and NHS-related administration, and industry representatives) were conducted, with the aim to access a broad range of views and opinions on the feasibility and acceptability of clinical research involving patches in cuff repair. The focus group transcripts were analysed by two members of the PARCS team, alongside data collection, using thematic analysis.

Consensus process

A two-stage online Delphi study, which was informed by the results of the systematic review, surveys and qualitative work, was conducted to develop a consensus on the best way to design a clinical trial of patch-augmented rotator cuff surgery. This was followed by a 2-day consensus meeting with stakeholder representatives and project members to review findings from stages 1–5 of the PARCS study, and to achieve consensus on the feasibility, acceptability and basic design of a randomised controlled trial to address patch use for rotator cuff repair.

Results

Systematic review

Of the 939 articles, 52 studies were included, which consisted of four randomised controlled trials, 11 observational comparative studies and 37 observational non-comparative studies. They varied in terms of study design, inclusion criteria, surgical approach, patch material [human allograft/autograft (46%), xenograft (33%) and synthetic (20%)] and outcome assessed.

All but one study looked at functional outcome measures. The Constant Scale, American Shoulder and Elbow Surgeons and University of California, Los Angeles, Shoulder Scale scores were most commonly used (range 27–48%). Although several studies demonstrated an improved function following patch augmentation, no consistent trends to support a particular patch type or brand were observed. Over two-thirds of studies investigated repair failure, with only one of four randomised controlled trials showing significant reduction in re-tears after patch augmentation. Complications were reported in 21 studies, with a similar complications rate after patch augmentation or non-augmented repair. Only one study in this review had a low risk of bias.

Surveys

For the British Elbow and Shoulder Society surgical membership survey, 105 responses (21%) were received, with over half (58%) stating that they had used a patch to augment rotator cuff surgery and 70% of patch users having undertaken an augmented repair within the last 6 months. A wide surgical experience in augmentation was reported, ranging from 1 to 200 implanted procedures. However, most surgeons reported low-volume use, with a median of five rotator cuff augmentation procedures performed. At least 10 different products were reported as having been used. Most of the patches derived from decellularised dermis tissue, although porcine-derived and synthetic-based patches had also been used. Only 3–5% of respondents stated that they would undertake an augmented repair for small tears across ages, whereas 28–40% and 19–59% would do so for large and massive tears, respectively. When assessing patient suitability, patient age seemed more relevant when considering those with large and massive tears. Half of the surgeons reported an interest in taking part in a randomised controlled trial evaluating the role of patch augmentation for rotator cuff surgery, with a further 22% of respondents undecided.

For the surgeon triallists survey, 24 responses (77%) were received. In total, 20 (83%) used a patch or would be willing to do so in a trial. Views on the importance of assessing the subscapularis state regarding the potential use of a patch were evenly split, with 11 respondents (55%) stating that they considered it. Typical patch used was evenly split between 'on-lay' (45%) and 'bridging' (55%). Responses for age and tear size and revision operation for two- and three-arm trial scenarios regarding willingness to randomise a patient were very similar. With regard to the running of a definitive trial, almost all respondents supported having a standardised operative technique ($n = 18$, 90%) and a standardised postoperative rehabilitation regime ($n = 19$, 95%). Most respondents ($n = 11$, 55%) supported randomising in the operating room, with 12- and 24-month follow-ups supported by almost all respondents ($n = 18$, 90%).

Qualitative study

The four focus groups involved 24 stakeholders. Stakeholders held differing views on a number of aspects, including the appropriate patient population to participate in a trial. For example, some stakeholders felt that all patients having rotator cuff repair surgery should be offered a patch, whereas others felt that the patient population needed to be more specific. There were also differing views on which treatment and control arms to include in a trial and whether or not randomisation was appropriate.

Consensus process

Of the individuals invited to the Delphi study, 29 participated (67%). Initial agreement on five out of six domains was met. The initial proposal based on the Delphi study was revised in the light of discussions at the consensus meeting, which 22 participants attended. The outlines of two potential randomised controlled trials were developed at the consensus meeting. The first related to the use of a patch as an on-lay for patients with a completed rotator cuff repair and the second related to patients with a partial rotator cuff repair using a bridging approach. The two comparisons could potentially be within one more comprehensive trial or conducted separately. In addition, the need for an observational safety study was identified.

Conclusion

Although several experimental and observational studies have demonstrated a decreased failure rate and improved outcome scores following augmented rotator cuff repair, rigorous clinical evaluation of this technology is currently lacking, which prevents firm recommendations for practice. We identified that a variety of patches for rotator cuff repair are available and in clinical use, although few have published evidence for their clinical effectiveness.

Areas for further research identified were randomised comparisons of on-lay patch use where rotator cuff repair has been completed and bridging patch use for partial rotator cuff repairs. The value of a registry was also highlighted.

Study registration

The systematic review is registered as PROSPERO CRD42017057908.

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This report

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