The rotator cuff is a group of muscles and tendons that surround the shoulder joint and help to keep it stable. A tear in 1 or more of the rotator cuff tendons can cause pain and limit movement of the arm, and may lead to arthritis. When inserting a biodegradable subacromial spacer, a balloon-shaped device is implanted inside the shoulder joint. It creates a physical barrier between the bones (the acromion at the top of the joint and the humerus below). The aims are reducing pain, improving shoulder function and delaying more invasive surgery. The spacer dissolves after about 1 year.

The National Institute for Health and Care Excellence (NICE) is examining inserting a biodegradable subacromial spacer for rotator cuff tears and will publish guidance on its safety and efficacy to the NHS. NICE’s Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about inserting a biodegradable subacromial spacer for rotator cuff tears.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE’s formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.
The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.

The Advisory Committee will then prepare draft guidance which will be the basis for NICE’s guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE’s duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 22 February 2016

Target date for publication of guidance: May 2016

1 Provisional recommendations

1.1 Current evidence on the efficacy and safety of inserting a biodegradable subacromial spacer for rotator cuff tears is limited in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research may include collaborative data collection. Patient selection should be clearly documented. Outcomes of interest

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include measures of shoulder function, pain relief and quality of life. All complications should be reported. Follow-up should be for a minimum of 2 years.

2 Indications and current treatments

2.1 Patients with rotator cuff tears may have shoulder pain and weakness accompanied by functional limitation leading to a reduced quality of life. Rotator cuff tears can be caused by an injury or can develop gradually. They can be minor or severe depending on the degree of damage to the tendon. Minor tears to the rotator cuff are very common and may not cause any symptoms at all. Diagnosis is usually by ultrasound or MRI.

2.2 Conservative treatment may include physical therapy, pharmacological treatments (including pain relief and topical or oral non-steroidal anti-inflammatory drugs) and corticosteroid injections. If the tear is severe or has not responded to other treatments, surgical interventions such as debridement, rotator cuff repair, subacromial smoothing, tendon transfer, or shoulder arthroplasty may be needed.

3 The procedure

3.1 Inserting a biodegradable subacromial spacer aims to improve pain symptoms and restore shoulder function in patients who have irreparable rotator cuff tears. The intention is to reduce subacromial friction by lowering the humeral head during shoulder abduction. It aims to be a less invasive and potentially safer alternative to tendon transfer or shoulder arthroplasty, with shorter procedure and rehabilitation times.
3.2 Inserting a biodegradable subacromial spacer is done with the patient under general or regional anaesthesia. The subacromial space is visualised using either arthroscopy or minimal access open surgery. A surgical clearance of the damaged area is carried out. Measurements are made to determine the required size of the biodegradable spacer. The balloon-like spacer is then inserted into the subacromial space and inflated with saline solution. Once sufficient volume is reached, the balloon is sealed and left in situ. The balloon spacer is made from a biodegradable polymer and resorbs over a period of about 1 year.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview [add URL].

4.1 A prospective case series of 20 patients with massive irreparable rotator cuff tear reported a significant increase in total Constant score (0–100, from worst to best outcomes) of 31.54 points 3 years after the procedure (p<0.0001). No improvement in the total Constant score was reported in 10% (2/20) of patients; MRI of these 2 patients 3 years after implantation showed suspected synovitis without cystic formation.

4.2 The prospective case series of 20 patients reported a significant increase in activity of daily living score (0–20, from worst to best) of 9.24 points 3 years after the procedure (p<0.0001).
4.3 The prospective case series of 20 patients reported a significant increase in range of motion score (0–40, from worst to best) of 8.1 points 3 years after the procedure (p<0.0001).

4.4 The prospective case series of 20 patients reported a significant increase in power score (0–25, from worst to best) of 7.19 points 3 years after the procedure (p<0.0001).

4.5 The prospective case series of 20 patients reported a significant increase in subjective pain score (0–15, from worst to best) of 6.44 points 3 years after the procedure (p<0.0001).

4.6 The prospective case series of 20 patients reported a significant increase in night pain score of 1.05 points (scale not given) 3 years after the procedure (p<0.0001).

4.7 The specialist advisers listed key efficacy outcomes as decrease in pain (particularly at night), increase in range of movement and improvement in shoulder function.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Suspected synovitis without cyst formation was reported in 2 patients 3 years after implantation (seen on MRI) in a prospective case series of 20 patients with massive irreparable rotator cuff tear (no further details given). Local inflammation/suspected aseptic synovitis were reported in 6% (3/50) of patients in a prospective
case series of 50 patients with massive rotator cuff tear (no further details reported).

5.2 Deterioration in shoulder function was reported in 1 patient in the prospective case series of 50 patients with massive rotator cuff tear; the device was removed (no further details reported).

5.3 Displacement of the device was reported in 1 patient in the prospective case series of 50 patients (no further details given).

5.4 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers reported bursting of the balloon as an anecdotal adverse event. They considered that the following were theoretical adverse events: nerve injury, balloon rejection and inflammatory response, infection, increased pain, and secondary bony changes (erosion).

6  Committee comments

6.1 The Committee noted that current evidence is from small numbers of patients and is restricted to patients with massive, full thickness rotator cuff tears.

7  Further information

7.1 For related NICE guidance, see the NICE website.

Tom Clutton-Brock
Chairman, Interventional Procedures Advisory Committee
January, 2016