

Results from the START:REACTS study

Plain English Summary

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What was the problem?

Many people get shoulder pain. For some, this can be because of a tear in the muscles that keep the shoulder joint stable (rotator cuff tears). These rotator cuff tears are very common. Some people with a painful rotator cuff tear with pain and loss of function that is not improved by simple treatments, may need surgery.

For many people who have surgery, the rotator cuff tear is repaired. However, some tears cannot be repaired, and we do not know the best treatment when this happens.

What treatments were we testing?

One option is to use keyhole surgery to clear space around the tendons and allow the shoulder to move better. This is called arthroscopic debridement.

As well as arthroscopic debridement, surgeons have been using a device called the InSpace balloon, to try to provide some cushioning between the bones in the shoulder as it was thought this would help. The InSpace balloon is a dissolvable device, filled with water, which is placed by the surgeon just above the shoulder joint after an arthroscopic debridement.

In this study, we compared the standard operation, arthroscopic debridement, to the same procedure with the InSpace balloon inserted.

What did we do?

We invited people from 24 NHS hospitals with rotator cuff tears that could not be repaired; 117 people took part. People either had arthroscopic debridement surgery, or arthroscopic debridement surgery with the InSpace balloon. A computer decided, at random, which treatment people would have to ensure it was a fair comparison. We did not tell people which treatment they had as this also helps ensure the results are fair.

We asked people questions about their shoulder pain and function, and about their general health. These were done with questionnaires taken three, six and twelve months after the

operation. Some people also had their movement and strength assessed (we could not do this after covid restrictions started).

We used a new method for doing this study. We set some statistical rules at the start of the study to decide whether to stop early or to continue. We monitored the results that were coming in and stopped entering people into the study if the statistical rules told us that we already had enough people taking part.

What did we find out?

By using our new set of statistical rules, we only needed 117 people to take part in the study. This is about half the number of people we would normally expect to need to get a result, which means we were able to finish around a year earlier than expected.

Twelve months after their operation, most people felt better than they did before the surgery. People who had the arthroscopic debridement surgery alone, without the balloon, had better results. They felt less pain and were able to use their shoulder more than people who had surgery with the balloon.

The questionnaires give a score for how much people are affected by their shoulder problems (it is scored out of 48). At the start of the study the average score was 22.4. On average, people who had an arthroscopic debridement alone improved by 12.6 points over a year, using our main score. People who had an arthroscopic debridement with the InSpace balloon improved by 7.2 points over a year. In both groups, some people improved by more and some by less. The difference between the two treatments was very unlikely to be due to chance.

We did not see any differences for whether people needed any extra treatments, visits to hospital, or further surgery.

In Summary

On average, people improved with both treatments, but they improved more when the balloon was not inserted. We do not recommend the InSpace balloon for people with a rotator cuff tear that cannot be repaired.

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The company that makes the InSpace balloon was previously called Ortho-Space but they were purchased by Stryker (based in the USA) in 2019. They provided some free balloons for the study and contributed to some of the costs of training surgeons. The study team had legal agreements to ensure they were independent.

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