Early promising outcome following arthroscopic implantation of the subacromial balloon spacer for treating massive rotator cuff tear

R. S. M. Piekaar1 · I. C. E. Bouman2 · P. M. van Kamppen3 · F. van Eijk3 · P. E. Huijsmans3

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Abstract

Background Massive rotator cuff tear (RCT) can result in disability and severe pain. When conservative treatment fails, surgical treatment should be considered, as various surgical options can provide relatively satisfactory results. However, choosing an optimal treatment remains controversial. A relatively new treatment for irreparable RCT is the arthroscopic implantation of a biodegradable balloon spacer into the subacromial space. Here, we examined whether placement of this balloon spacer reduces pain and improves functional outcome in patients with an irreparable RCT. Patients were followed for 1 year following implantation.

Methods In this prospective single-arm study, a biodegradable balloon spacer was implanted into the subacromial space of patients with a massive RCT. Pain was evaluated using a numeric rating scale (NRS), and functional outcome was evaluated using the Oxford shoulder score (OSS) and the Constant–Murley shoulder score (CMS). Five follow-up visits were performed during the first postoperative year.

Results Forty-six shoulders in 44 patients with massive RCT were treated by surgical implantation of the subacromial balloon spacer. The mean reduction in NRS score was 3.5 points (95% CI 2.5–4.4), and 74% of patients achieved the minimal clinically important difference of 2 points by the 1-year follow-up visit. Functional outcome improved significantly based on OSS and CMS scores, and 80% of patients reported that they were satisfied with their outcome. No surgical or postoperative medical complications due to implantation of the balloon spacer were reported.

Conclusions Our results suggest that arthroscopic implantation of a biodegradable balloon spacer in the subacromial space significantly reduces pain and improves activities of daily living in patients with massive RCT during 1 year of follow-up. The specific contribution of the balloon with respect to improved clinical outcome needs further study, ideally in a randomized controlled trial.

Keywords Massive rotator cuff tear · Subacromial spacer · Balloon spacer · Arthroscopic surgery · Pain reduction · Functional outcome

Abbreviations

RCT Rotator cuff tear
CMS Constant–Murley shoulder score
OSS Oxford shoulder score
NRS Numeric rating scale
MCID Minimal clinically important difference
MRI Magnetic resonance imaging

Introduction

Rotator cuff tear (RCT) is one of the most common shoulder injuries among middle-aged and elderly orthopedic patients, leading to disability and severe pain [1]. The prevalence of RCT increases with age, occurring in approximately 50% of patients 70–90 years of age [2]. In the case of massive RCT, the head of the humerus can migrate superior due to direct force of the deltoid muscle when the force exerted by the supraspinatus and infraspinatus muscles is lost. Normally, the acromiohumeral interval is approximately 7–14 mm, and
massive RCT can reduce this distance, serving as the radiographic sign of a severe cuff tear [2–4]. When conservative treatment fails, a variety of minimally invasive surgical procedures are available, including arthroscopic surgery [5–10]. If the tendon is reparable, postsurgical subjective outcome is generally good [11–13]. In some patients, however, the tear is irreparable. Whether an RCT can be repaired can depend on several factors, including the location of the tear, fatty infiltration, tendon retraction, muscle atrophy, and whether the injury is chronic or acute [3, 12, 14].

Currently, no surgical “Gold Standard” exists for treating an irreparable RCT. Moreover, current salvage procedures such as reverse total shoulder replacement arthroplasty and tendon transfer are associated with a relatively high risk of complications and a prolonged rehabilitation period [5, 9, 10, 15].

A relatively new method for treating massive irreparable RCT is the arthroscopic implantation of a biodegradable balloon spacer in the subacromial space between the acromion and the head of the humerus [16–20]. In principle, implantation of such a spacer can restore shoulder biomechanics by reducing subacromial friction during shoulder movement by lowering the head of the humerus and simultaneously facilitating humeral gliding. The biodegradable spacer is composed a polylactide and ε-caprolactone copolymer and is believed to biodegrade over a period of 12 months [18]. The first published results by Senekovic et al. [16, 17] are promising, even after the balloon has dissolved.

The implantation procedure is described as relatively easy, reproducible, and less invasive than other currently available options such as tendon transfer, reverse total shoulder replacement arthroplasty, and (partial) cuff repair with anchors; moreover, the procedure has a short rehabilitation period and low risk of complications [16, 17]. In addition, balloon implantation may serve as a “bridging” option in patients who have a massive, irreparable tear and would normally be considered a candidate for reverse total shoulder arthroplasty. Importantly, if the procedure fails, all other salvage options remain.

Here, we performed a prospective single-arm study to determine whether implantation of the balloon spacer in the subacromial space results in minimal clinically important differences in terms of reducing pain and improving functional outcome during the first postoperative year. In addition, we compared outcome between patients who underwent balloon implantation together with a conventional arthroscopic partial repair of the torn tendon and patients who underwent only the implantation procedure.

Materials and methods

Design

This study was reviewed by the Medical Ethics Committee of South-West Holland (14-019), who determined that the study was not subject to the Dutch Medical Research Involving Human Subjects Act. The study was approved by the board of directors of the Haga Hospital (The Hague, The Netherlands). During the arthroscopic procedure, the surgical team decided whether the RCT was directly reparable or not. When direct repair was not deemed feasible, implantation of the spacer was performed.

All patients were assessed preoperatively and at their outpatient follow-up visits conducted 3, 6 weeks, 3, 6, and 12 months after surgery.

Participants

All patients participated voluntarily and did not receive any compensation for their participation. Before participation, each patient provided written informed consent.

The following inclusion criteria were used: shoulder pain due to irreparable massive RCT confirmed initially with ultrasonography or MRI and re-confirmed during arthroscopy; prior failure of conservative treatment or a failed attempt at surgical (partial or complete) repair; 18 years of age or older; and the ability to sufficiently understand the Dutch language and complete the questionnaires. The exclusion criteria included the presence of severe glenohumeral osteoarthritis, rupture of the subscapularis muscle, and prior participation in a medical research study involving the affected shoulder. The balloon spacer is contraindicated for use in patients with a known allergy to the device’s materials (polylactide and/or ε-caprolactone) and in patients with an active or latent infection or signs of tissue necrosis in the subacromial area.

Variables

Prior to surgery and during the five follow-up visits, subjective pain was scored using a numeric rating scale (NRS), with scores ranging from 0 to 10 [21]. To measure functional outcome, we used the Constant–Murley shoulder score (CMS) [22, 27] and the Oxford shoulder score (OSS) [22–24]. The CMS is based on a 100-point scale and is used to measure the role of pain, activities of daily living, strength, and range of motion in performing daily activities. We adjusted the CMS score for age and gender [25]. The OSS has a maximum score of 48 and was used to measure the patient’s subjective improvement in daily living and the experience of pain. At the 1-year follow-up, patient
satisfaction was assessed using a three-point scale (very satisfied, satisfied, or not satisfied).

Based on published literature, 1.4 points is the minimal clinically important difference (MCID) for a visual analog scale (VAS) measuring pain in patients treated for a rotator cuff injury [21]. Because the NRS score uses whole integers, an MCID of 2 points was used in our analysis. The reported MCID for the OSS is 4.8 points [26]; however, because the answers in this questionnaire are scored from 0 to 4 points, we used an MCID of 5 points. The reported MCID for the CMS is 11 points [27].

Any complications associated with the biodegradable balloon spacer were recorded in the patient’s personal health record.

**Surgical technique**

Arthroscopic insertion of the biodegradable spacer (Orthospace InSpace system, Implant Service BV, Vlaardingen, the Netherlands) into the subacromial space was performed by two experienced shoulder surgeons (authors PH and FvE) at the Haga Hospital in The Hague, the Netherlands from March 2014 through December 2015. We are the first clinic in the Netherlands to perform this new procedure. All procedures were performed using two arthroscopic portals (one anterior and one lateral) with the patient in the lateral decubitus position. During examination (under general anesthesia and/or with a local regional interscalene nerve block), the size of the tear and any other lesions were inspected carefully. After inspection of the glenohumeral joint for additional pathology, arthroscopic bursectomy and debridement was performed. Tenotomy of the long head of the biceps was performed if the biceps tendon was still intact.

If the rotator cuff was deemed to be irreparable, the surgeon proceeded with insertion of the balloon spacer. To enable insertion in the subacromial space via the lateral portal, the balloon spacer was folded and placed into a cylinder-shaped insertion tube, which was removed once the spacer was positioned beneath the acromion [18]. This surgical technique for implantation of a spacer has been used previously and is considered to be simple, safe, and reproducible [16–19].

After the balloon was inserted, it was expanded using a sterile saline solution (0.9% NaCl). The total volume of saline solution used to expand the balloon depended on the size of the balloon and the manufacturer’s recommendations. Afterward insertion and expansion of the balloon, to ensure stability the shoulder was moved through the full range of motion [18, 19]. Correct positioning of the balloon was confirmed by performing a final arthroscopic examination in the subacromial space.

**Postoperative protocol**

Following surgery, the patient’s shoulder was immobilized for 2–3 weeks with a shoulder immobilizer. The patients were instructed to perform active finger, wrist, hand, and elbow movements directly after implantation. Later, active assisted shoulder exercises were initiated in order to train the deltoid muscle and shoulder depressor muscles. In addition, patients were advised to strengthen their shoulder and increase the shoulder’s range of motion until maximum improvement was achieved.

**Statistical analysis**

All continuous baseline characteristics are presented as the group mean with 95% confidence interval. Nominal data are presented as individual counts. Box plots, with median values and the upper and lower quartiles, were generated to visualize pain reduction and improvement in daily activities during the first postoperative year. Preoperative and postoperative NRS, OSS, and CMS scores were compared using linear mixed model analysis in SPSS version 22.0. The one-sample Student’s t test was used to compare preoperative and postoperative NRS, OSS, and CMS differences with their respective MCID. A linear mixed model was used to compare the preoperative and postoperative NRS, OSS, and CMS differences between patients who received a balloon spacer implantation and patients who underwent simultaneously a partial repair. Differences with a p value < 0.05 were considered to be statistically significant. Complications are described, and patient satisfaction is presented as a percentage.

**Results**

**Participants**

Fifty-two patients underwent an arthroscopic shoulder procedure. Two patients were excluded because the rotator cuff could be sufficiently repaired during arthroscopy, and implantation of a balloon spacer was therefore not necessary. Two patients underwent debridement instead of balloon implantation because of the perioperative finding of intact rotator cuff tendons. One patient was excluded due to severe glenohumeral osteoarthritis. Of the 47 patients who received the balloon spacer, one patient was lost to follow-up due to receiving chemotherapy, one patient died 2 months after surgery due to cardiac disease, and one patient underwent a repeat arthroscopy. In total, 44 patients (with 46 shoulders) with a massive tear of the rotator cuff met the inclusion criteria for arthroscopic implantation of a subacromial spacer and
completed the follow-up period (Fig. 1). The characteristics of the patient cohort are summarized in Table 1.

Twenty-five patients (57%) were male, and 19 (43%) were female; the mean age of all 44 patients at the time of the implantation procedure was 66 years (95% CI 63.7–68.33). In 17 out of 46 shoulders (37%), tenotomy was performed on the long head of the biceps. In 11 shoulders (24%), a partial repair was performed on part of the torn rotator cuff using a simple suture technique. Finally, one shoulder (2%) underwent a distal clavicle resection before the balloon spacer was inserted. Acromioplasty was not performed in any of our patients.

### Pain and functional outcomes

The preoperative (baseline) and postoperative pain (NRS) and functional status (CMS and OSS) scores are summarized in Table 2 and are illustrated graphically in Figs. 2, 3, and 4. Implantation of a subacromial balloon spacer resulted in a significant reduction in pain, with a mean decrease in NRS score from 6.84 points (95% CI 6.19–7.49) at baseline to a mean score of 3.27 points (95% CI 2.41–4.14) at the 12-month follow-up visit. Mean OSS score increased from a preoperative value of 21.80 points (45% of the maximum score; 95% CI 19.58–24.02) to a mean score of 32.43 points (68% of the maximum score; 95% CI 29.25–35.60) after 12 months. The mean CMS score also increased significantly from 37.06 points (95% CI 32.46–41.66) at baseline to 60.15 points (95% CI 53.43–66.87) at the 12-month follow-up visit.

One year after surgery, pain measured using the NRS score was significantly improved compared to baseline ($p < 0.01$). The mean reduction in NRS score was 3.46 points (95% CI 2.52–4.39), and 74% of patients achieved the MCID of 2 points ($p = 0.01$).

The OSS was also significantly improved at the 1-year follow-up visit ($p < 0.002$), with a mean increase of 10.46

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**Table 1** Patient characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients/shoulders</td>
<td>44/46</td>
</tr>
<tr>
<td>Gender, male/female</td>
<td>25/19</td>
</tr>
<tr>
<td>Mean age, years (95% CI)</td>
<td>66 (63.7–68.3)</td>
</tr>
<tr>
<td>Minimum age</td>
<td>45</td>
</tr>
<tr>
<td>Maximum age</td>
<td>85</td>
</tr>
<tr>
<td>Side, right/left</td>
<td>25/21</td>
</tr>
<tr>
<td>Involvement of the dominant arm, %</td>
<td>61%</td>
</tr>
<tr>
<td>Mean duration of shoulder complaints, months (95% CI)</td>
<td>54 (28–63)</td>
</tr>
<tr>
<td>Minimum duration</td>
<td>3</td>
</tr>
<tr>
<td>Maximum duration</td>
<td>360</td>
</tr>
<tr>
<td>Anesthesia, number of patients</td>
<td></td>
</tr>
<tr>
<td>General anesthesia</td>
<td>23</td>
</tr>
<tr>
<td>With interscalene block</td>
<td>16</td>
</tr>
<tr>
<td>Without interscalene block</td>
<td>7</td>
</tr>
<tr>
<td>Interscalene block alone</td>
<td>21</td>
</tr>
<tr>
<td>Procedure</td>
<td></td>
</tr>
<tr>
<td>Number of implanted balloon spacers</td>
<td>46</td>
</tr>
<tr>
<td>Biceps tenotomy, n (%)</td>
<td>17 (37%)</td>
</tr>
<tr>
<td>Partial repair, n (%)</td>
<td>11 (24%)</td>
</tr>
<tr>
<td>Distal clavicle resection, n (%)</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

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**Excluded: n = 5**
- Rotator cuff repair, n=2
- Debridement, n=2
- Glenohumeral osteoarthritis, n=1

**Lost to follow-up: n=3**
- Death, n=1
- Lost to follow-up due to chemotherapy, n=1
- Repeat arthroscopy, n=1

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Total: n = 52 patients

Included in the final analysis: n = 46 shoulders in 44 patients

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Fig. 1 Flowchart for the inclusion and exclusion of patients

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points (95% CI 7.63–13.28); 78% of patients achieved the MCID for OSS. We also measured a significant improvement in CMS scores after 1 year ($p < 0.05$), with a mean increase of 21.58 points (95% CI 16.06–27.10); 65% of patients achieved the MCID. A subscore analysis of the CMS data revealed improvement in all four categories, including pain, activities of daily living, range of motion, and strength (Fig. 5).

One year after implantation of the balloon, 35 of the 44 patients (80%) reported that they were either satisfied or very satisfied with the outcome of the surgical procedure; the remaining nine patients (20%) reported that they were not satisfied with the outcome after 1 year. We found no significant correlation between satisfied and dissatisfied patients with respect to age, sex, pain score, or functional outcome (data not shown).

**Partial repair**

In 24% of the cases (i.e., 11 shoulders), a partial repair was performed while implanting the balloon spacer. Therefore, we compared the patients who had a partial repair with the patients who did not. As shown in Table 3, we found no significant difference between these two groups with respect to either pain ($p = 0.82$) or functionality measured with the OSS ($p = 0.91$) and CMS ($p = 0.79$).

**Complications**

No surgical or postoperative medical complications due to implantation of the balloon spacer were reported. One of the original 47 patients who underwent balloon implantation but was subsequently excluded from the final analysis.

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**Table 2** Preoperative (baseline) and postoperative pain and functional status scores

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>3 weeks</th>
<th>6 weeks</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS</td>
<td>6.84 (6.19–7.49)</td>
<td>1.91 (1.31–2.51)</td>
<td>3.17 (2.39–3.95)</td>
<td>4.08 (3.26–4.89)</td>
<td>3.28 (2.49–3.97)</td>
<td>3.27 (2.41–4.14)</td>
</tr>
<tr>
<td>OSS</td>
<td>21.80 (19.58–24.02)</td>
<td>25.93 (22.63–29.22)</td>
<td>28.40 (25.22–31.58)</td>
<td>29.63 (25.95–33.30)</td>
<td>34.00 (30.84–37.16)</td>
<td>32.43 (29.25–35.60)</td>
</tr>
<tr>
<td>CMS</td>
<td>37.06 (32.46–41.66)</td>
<td>Not determined</td>
<td>Not determined</td>
<td>49.34 (42.73–55.94)</td>
<td>60.56 (54.47–66.64)</td>
<td>60.15 (53.43–66.87)</td>
</tr>
</tbody>
</table>

Values are presented as the mean score (95% CI)

NRS numeric rating scale, OSS Oxford shoulder score, CMS Constant–Murley shoulder score

* $p < 0.05$ versus baseline

** $p < 0.01$ versus baseline
Fig. 3  Oxford shoulder score

Fig. 4  Total constant shoulder score
due to repeat arthroscopy developed superficial wound erythema postoperatively, which suggested perioperative infection. Oral antibiotics were not administered. This patient underwent a repeat arthroscopy 7 months after the initial procedure, which revealed no internal signs of infection except for synovitis. At the time of the repeat arthroscopy, the balloon had nearly completely dissolved. During the repeat arthroscopy, cultures were taken but were negative. Another patient dislocated the shoulder with the implant 6 weeks after implantation due to acute trauma.

Discussion

The aim of this prospective cohort study was to evaluate pain, shoulder function, and quality of life following implantation of a biodegradable balloon spacer for massive rotator cuff tear. In general, this new treatment modality led to a significant and clinically important reduction in pain and improved functional outcome by the 12-month follow-up visit, with 80% of patients reporting satisfaction with their outcome. No severe medical complications were reported. The described results are the early (1 year) results after balloon implantation.

This study has several limitations that warrant discussion. First, this study included a relatively small number of patients and did not include a control group. Second, outcome was assessed for only 1 year following surgery; however, it is important to note that the biodegradable implant is designed to dissolve within this follow-up time. Third, possible confounders may have affected our results; possible confounders may include concomitant bursectomy and debridement, biceps tenotomy, and/or partial repair of the rotator cuff during implantation of the subacromial spacer. Given that some patients underwent additional interventions, we cannot exclude the possibility that the reported outcomes were attributed solely to the balloon implant; moreover, previous studies reported similar outcome after these interventions were performed alone [28–30].

The results with respect to reduced pain are consistent with the results of previous prospective studies by Senekovic et al. [16, 17], who found significantly decreased pain in 20 patients during 3–5 years of follow-up. The functional improvement in daily activities measured in our study using the CMS and OSS was significant, despite the fact that the tendon was not repaired. Nevertheless, the CMS subgroup strength did only slightly improve, not significantly. Moreover, we found no significant difference between patients who had a partial tendon repair prior to implantation of the spacer and patients who did not receive a partial repair. One year after the balloon spacer was implanted, 80% of patients were satisfied or very satisfied with their outcome from the procedure. This rate of satisfactory outcome is similar to—or even slightly better than—the outcome following other minimally invasive procedures for rotator cuff repair [31–33].

| Table 3 | Preoperative (baseline) and postoperative NRS, OSS, and CMS scores in all patients, the patients who underwent a partial repair prior to implantation, and the patients who did not undergo a partial repair |
|----------------------|----------------------|----------------------|----------------------|----------------------|
|                      | Preoperative         | 3 months             | 6 months             | 12 months            |
| Pain (NRS)           |                      |                      |                      |                      |
| Partial repair       | 6.92 (5.46–8.37)     | 4.01 (2.44–5.58)     | 3.10 (1.51–4.69)     | 3.00 (1.41–4.60)     |
| No repair            | 6.75 (5.91–7.60)     | 4.15 (3.31–4.99)     | 3.31 (2.45–4.17)     | 3.39 (2.52–4.25)     |
| Total                | 6.84 (6.19–7.49)     | 4.08 (3.26–4.89)     | 3.28 (2.49–3.97)     | 3.27 (2.41–4.14)     |
| OSS                  |                      |                      |                      |                      |
| Partial repair       | 22.75 (17.18–28.32)  | 29.52 (23.55–35.49)  | 33.51 (27.44–39.58)  | 32.65 (26.56–38.75)  |
| Total                | 21.80 (19.58–24.02)  | 29.63 (25.95–33.30)  | 34.00 (30.84–37.16)  | 32.43 (29.25–35.60)  |
| CMS (total)          |                      |                      |                      |                      |
| Partial repair       | 37.73 (24.83–50.63)  | 45.38 (32.48–58.28)  | 51.96 (39.01–64.86)  | 56.58 (43.20–69.95)  |
| No repair            | 39.46 (32.60–46.33)  | 49.85 (43.06–56.65)  | 62.67 (55.72–69.63)  | 61.06 (54.26–67.85)  |
| Total                | 37.06 (32.46–41.66)  | 49.34 (42.73–55.94)  | 60.56 (54.47–66.64)  | 60.15 (53.43–66.87)  |

Values are presented as the mean score (95% CI)

NRS numeric rating scale, OSS Oxford shoulder score, CMS Constant–Murley shoulder score
Compared to other minimally invasive treatment options such as arthroscopic debridement and decompression [29, 31], our results obtained using a biodegradable balloon spacer were similar with respect to reducing pain and improving functional outcome. Liem et al. [29] treated 31 patients with massive RCT using debridement and bursectomy; after 47 months of follow-up, the average pain score (measured on a VAS ranging from 0 to 10) was reduced from 7.8 to 2.9 points. Lee et al. [30] reported a similar reduction in pain scores (from 7.0 to 3.3) following decompression with acromioplasty and tuberoplasty. Moreover, the beneficial effects of biceps tenotomy should not be overlooked. For example, Boileau et al. [28] reported that 78% of patients with massive RCT were satisfied and had improved outcome 3 years after undergoing simple biceps tenotomy or tenodesis. Our results were similar with respect to functional improvement [28, 29]. Although the benefits of these interventions are similar, implantation of a balloon spacer is associated with higher costs, and this should not be trivialized. Nevertheless, these higher costs may be justifiable if the reduced pain and improved functional outcome can be attributed to the spacer.

In addition, the reduction in pain in our cohort was similar to results obtained with more invasive surgery. For example, Birmingham et al. [34] performed a latissimus dorsi transfer in 18 patients and observed a reduction in the average pain score from 7.0 to 3.1 after 24 months. Moreover, Mulieri et al. [35] performed reverse shoulder arthroplasty in 58 patients with irreparable RCT and observed a reduction in average pain score from 6.3 to 1.9 measured using a VAS.

An extended surgical procedure and/or general anesthesia may be contraindicated in patients who have a massive RCT with a comorbid condition. For these patients, this arthroscopic intervention may be a viable solution for achieving pain relief, particularly given the lack of complications in our study cohort. In addition, the ability to perform the procedure under local anesthesia is a considerable advantage [36]. Finally, even if the balloon spacer does not provide sufficient results, all salvage procedures remain possible and most importantly no bridges are burned.

In the patient who underwent a repeat arthroscopy at 7 months, the balloon spacer had already dissolved, which is faster than the stated biodegradability time of 12 months. This finding raises questions regarding the duration of the effect of the spacer in the subacromial space. Further studies are therefore needed in order to determine the sustainability of this effect. To the best of our knowledge, whether shoulder biomechanics can be restored by lowering the head of the humerus has not been investigated previously; therefore, whether placement of a balloon spacer can provide results similar to other arthroscopic interventions such as debridement and decompression remains to be investigated. Moreover, whether the observed benefits in our cohort were due to a direct effect of the balloon spacer or the additional interventions (e.g., debridement, tenotomy) remains unclear. Although our results suggest that this relatively new surgical procedure is promising, further research is needed in order to investigate long-term outcome and compare the results with other treatment options.

Conclusions
Our results suggest that arthroscopic implantation of the biodegradable InSpace balloon spacer in the subacromial space can significantly reduce pain and improve activities of daily living in patients with a massive rotator cuff tear, with low risk of severe complications. Importantly, at their 1-year follow-up visit, 80% of our patients reported that they were satisfied or very satisfied with their outcome. Nevertheless, the precise contribution of the balloon spacer to this improvement in clinical outcome should be investigated further, ideally in a randomized controlled study in which the results can be directly compared with other interventions.

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Author contributions RP and IB collected the patient data. PH and FvE performed the surgeries. RP and IB analyzed the patient data. PvK supported RP and IB with analyzing and interpreting the data. RP wrote the manuscript. All authors helped write the manuscript and have read and approved the final version.

Compliance with ethical standards
Conflict of interest The authors declare no conflict of interest.

Ethical approval This study was reviewed by the Medical Ethics Committee of South-West Holland (14-019), who determined that the study was not subject to the Dutch Medical Research Involving Human Subjects Act. The board of directors of the Haga Hospital (The Hague, the Netherlands) approved the study.

Informed consent All patients in this case report provided written informed consent authorizing the use and disclosure of their protected health information.

References