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© Zagorodni N.V., Belyak E.A., Lazko F.L., Kubashev A.A., Prizov A.P., Lazko M.F., Grigoryev I.V., Skipenko T.O., Zakirova A.R., 2019

DOI 10.18019/1028-4427-2019-25-3-272-276

### ***Experience of using subacromial balloon in combined treatment of patients with rupture of the rotator cuff***

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**Introduction** Rotator cuff tears is still a complex and unresolved problem, which solution requires a comprehensive approach and choosing the optimal way of treatment. Frequently, the results of surgical treatment do not satisfy both patient and surgeon. **Objective** Improve the results of treatment of patients with rotator cuff ruptures of the shoulder. **Material and methods** Results of arthroscopic treatment of rotator cuff tears in 15 patients (mean age,  $54 \pm 4$  years) with combined technique are presented. None of the cases had severe muscle atrophy of the rotator cuff (supra- and infraspinatus muscles), according to Goutallier classification less than 3 grade. All patients underwent shoulder arthroscopy with rotator cuff repair by single or double row stitching and subacromial balloon InSpace implantation. **Results** The mean score according UCLA scale before the operation was  $16 \pm 2$  (13–18), the mean score 12 months after the operation was  $30 \pm 3$  (26–35); in most cases good and excellent results were obtained. **Conclusion** Preliminary results characterize the proposed method as a relatively easy, law-traumatic and effective procedure for pain relief and shoulder function recovery in this group of patients.

**Keywords:** shoulder rotator cuff, rotator cuff tear, arthroscopy, shoulder joint, InSpace balloon

## INTRODUCTION

Rotator cuff tear is a common pathology in the practice of an orthopedic surgeon and is accompanied by pain and restriction of shoulder movements, which reduces daily activity and the quality of life of patients. Currently, the suture of the rotator cuff has taken a firm place in the arsenal of surgical techniques, has established itself as an effective and reproducible method for treating patients with tears of the rotator cuff with good short-term and long-term results [1, 2].

However, in some cases, patients feel pain and movement restrictions after surgery; sometimes there is a repeated rupture of the rotator cuff and suture failure, which significantly impairs the function of the shoulder joint and patient's satisfaction with treatment [3]. Pronounced pain in the postoperative period frequently does not allow for the timely and adequate start of the rehabilitation protocol, which worsens the results of treatment [4].

In April 2012, a description of a new method of managing unrecoverable tears of the rotator cuff

using the biodegradable subacromial spacer InSpace (Orthospace, Israel) was presented [5]. This implant is placed between the acromion and the head of the humerus, due to which the subacromial space increases and the head of the humerus gets reduced. It results in an increase in the range of movements in the shoulder joint and decrease in pain. Further on, there were reports of a successful use of the subacromial balloon in addition to the suture of the rotator cuff, when it acts as a “ptotector” of the rotator cuff suture, reduces pain and improves shoulder biomechanics, facilitating rehabilitation exercises for the patient [6].

Since January 2014, we have been using the InSpace subacromial balloon in addition to the suture of the rotator cuff in patients with poor tendon quality, severe retraction, as well as in a significant decrease in shoulder joint function in the preoperative period (shoulder pseudo-paralysis and persistent pain).

✉ Zagorodni N.V., Belyak E.A., Lazko F.L., Kubashev A.A., Prizov A.P., Lazko M.F., Grigoryev I.V., Skipenko T.O., Zakirova A.R. Experience of using subacromial balloon in combined treatment of patients with rupture of the rotator cuff. *Genij Ortopedii*, 2019, T. 25, No 3, pp. 272-276. DOI 10.18019/1028-4427-2019-25-3-272-276. (In Russian)

## PATIENTS AND METHOD

From August 2014 to September 2017, fifteen patients (9 women, 6 men) were underwent rotator cuff suture and installation of the subacromial spacer at the Buyanov hospital. The average age of patients was  $54 \pm 4$  years. All patients were diagnosed with a rupture of the rotator cuff (supraspinatus and supraspinous tendons). Patients with a concomitant rupture of the subscapularis muscle were excluded from the study. The degree of retraction of the tendon of the rotator cuff was of Patte grade 1 to 2 [7]. Patients with fatty atrophy of the muscles according to the Gutalle classification less than grade 3 were included [8]. An isolated rupture of the supraspinous muscle was revealed in 8 patients, and a combined detachment of the supraspinous and subspinous tendons in 7 patients. The concomitant conditions was pathology of the tendon of the long head of the shoulder biceps in 9 patients (60 %) with tendinitis and degenerative changes, which required the tenotomy in 7 cases and tenodesis in 2 cases. In 7 cases (47 %) degenerative changes in the anterior fibrocartilaginous labrum were found, which required debridement. Manifestations of arthrosis were detected in 8 patients (53 %), classified according to the Outerbridge scale as grade 1 in 6 patients, grade 2 in one patient, and grade 3 in one patient [9]. Bone acromioplasty with burr was needed in 6 cases (40 %). The patients underwent arthroscopy of the shoulder joint, suture of the rotator cuff and implantation of an InSpace balloon into the subacromial space. In 10 cases (66 %), a single-row suture of the rotator cuff was used and a double-row suture was used in 5 cases (33 %).

A control group was 20 patients in who only suture of the rotator cuff was used. The group was comparable by sex, age and nature of the pathology with the main group. It included 13 women (65 %) and 7 men (35 %) who underwent a rotator cuff suture; the average age of the patients was  $52 \pm 3$  years. The nature of damage to the rotator cuff, the degree of retraction and fatty atrophy were similar to the parameters in the first group. In 16 cases, a single-row suture was performed (80 %) and a double-row suture in 4 cases (20 %).

The InSpace assembly consists of a conductor and a balloon made of polilactic acid (L-lactide-co-ε-caprolactone) (Fig. 1).



Fig. 1 InSpace system with an attached syringe

The material is biodegradable (5–6 months). Moreover, cicatrice bags and “interlayers” are not formed in the area of its installation. We conducted a histological study of the tissues formed in the area of the balloon installation and found rough fibrous scar tissue (Fig. 2).

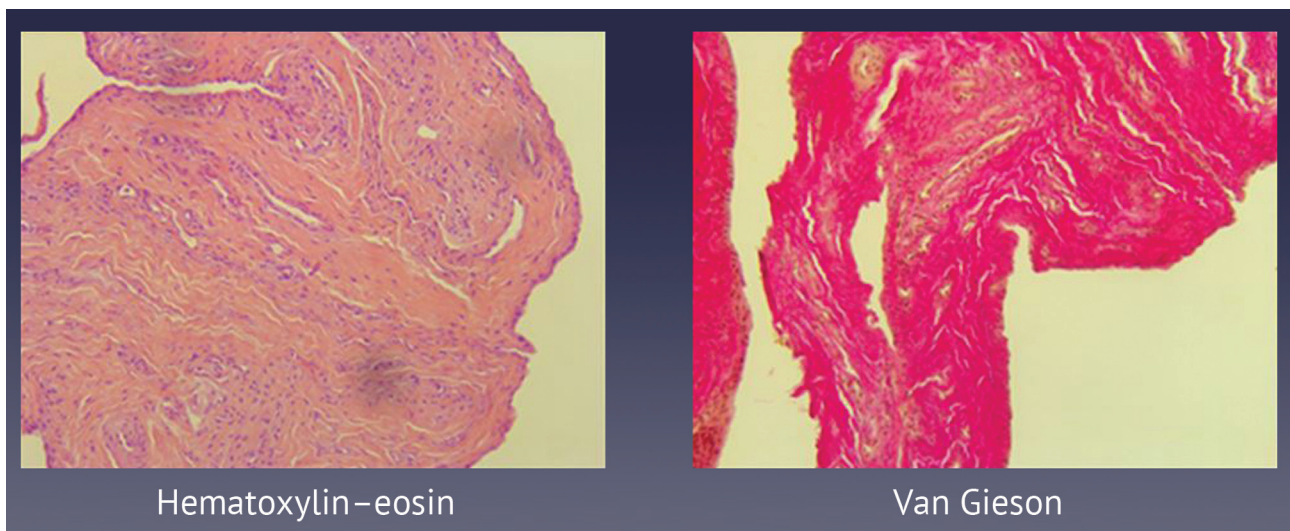


Fig. 2 Histological preparations: staining with hematoxylin and eosin and Van Gieson. Rough fibrous small-cell connective tissue is seen

**Arthroscopic intervention technique** The surgery runs under combined anesthesia (conduction + endotracheal anesthesia) with the patient in the position of "lying in a chaise longue." The operation consisted of several stages. *Stage 1* Through a standard posterior arthroscopic approach, we performed a survey arthroscopy of the shoulder joint, revealed the nature of the rupture of the rotator cuff, the pathology of the biceps tendon, the articular labrum, and the severity of arthrosis. If necessary, tenotomy or intra-articular tenodesis of the biceps tendon of the shoulder was conducted. *Stage 2* The arthroscope was transferred to the subacromial space and the external portal was performed. *Stage 3* Subacromial decompression, acromioplasty, bursectomy, removal of scar and adipose tissues were performed using a shaver and ablator; the nature of tendon rupture was determined, its release and mobilization was carried out. *Stage 4* The rotator cuff tendon was stitched with a single- or double-row suture. *Stage 5* Using an arthroscopic probe with a laser graduation, the

required size of the InSpace balloon was determined. *Stage 6* A balloon of a defined size was installed in the subacromial space and filled with the necessary amount of saline. *Stage 7* Range of motion, viability of the suture of the cuff and stability of the implant were checked (Fig. 3).

Final view after the intervention is given in Figure 4.

The rehabilitation protocol consisted of four stages. The first stage was immobilization with a splint in abduction for up to 6 weeks; passive movements in the joint were allowed from the 3rd week. The second stage was stretching exercises and restoration of the passive range of motion after removing the immobilization splint (weeks 6–9). The third stage was static strengthening of the muscles of the shoulder joint, and training of active movements (weeks 9–12). The fourth stage was strengthening the muscles of the shoulder joint with the help of weights and a gradual return to sports loads (from week 12 up to 6 months.)



Fig. 3 Schematic image of balloon installation into the subacromial space

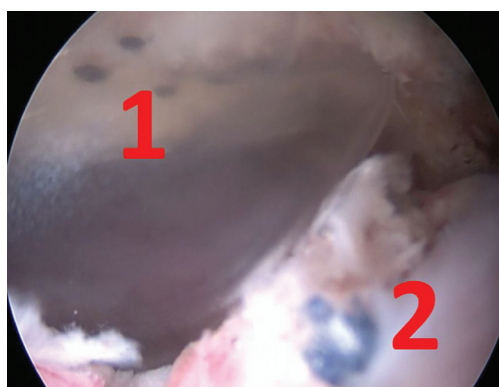


Fig. 4 Final view after the operation:  
1 — the balloon installed, 2 — the suture of the rotator cuff

## RESULTS

To assess the results and function of the shoulder joint, we used the scale of the shoulder joint function assessment of the University of California, Los Angeles (UCLA), according to which the score of 0 to 20 points is a bad result, from 21 to 27 a satisfactory one, 28–33 is good and above 33 is an excellent outcome (maximum

score is 35 points). The average score in the study group before the operation was  $16 \pm 2$  (13–18) points and 12 months after the surgery it scored  $30 \pm 3$  (26–33) ( $p < 0.005$ ). In the control group, the score before the surgery was  $17 \pm 3$  (14–19) and 12 months post-surgery grew up to  $26 \pm 3$  (23–30). Statistical analysis used



Student's test. Patients in the group with the installation of a subacromial spacer reported a sharp decrease in pain the next day after surgery; their rehabilitation was easier and faster. There were no complications in the early and late postoperative periods. Wounds healed by primary intention, the sutures were removed on average after 10 days. All patients adhered to the

rehabilitation protocol run at our outpatient clinic. Upon completion of rehabilitation, patients returned to household activities and, if necessary, to sports. The range of motion increased: bending was  $73 \pm 4^\circ$  and  $170 \pm 6^\circ$ , abduction was  $81 \pm 5^\circ$  and  $173 \pm 6^\circ$ , external rotation was  $10 \pm 3^\circ$  and  $37 \pm 4^\circ$ , before the surgery after surgery respectfully.

## DISCUSSION

A normally functioning rotator cuff provides dynamic stabilization of the humeral head in the shoulder joint. If coordinated work of the tendons suffers due to their damage, the head of the humerus is decentralized, pain appears and movements in the joint become restricted [10]. The suture of the rotator cuff tear is an effective treatment method; however, in some cases, the function of the shoulder joint cannot be fully restored, and pain persists. A. Kilinc et al., first reported on their successful experience of combining the rotator cuff suture and installation of a subacromial balloon and showed good clinical results [6]. In 2014, Lafos et al. reported on long-term results of using this technique and demonstrated good results [11]. A group of researchers from Turkey under the head of M. Bozkurt reported on the experience of the combined use of the rotator cuff stitching along

with the installation of the subacromial balloon with good results [12]. We have experience of using the subacromial balloon for treating patients with massive non-repairable ruptures of the rotator cuff, where the suture of the cuff was not possible [13]. However, in the domestic literature there are no reports about the use of the combination of a rotator cuff suture and installation of a subacromial balloon. Our first experience of using the InSpace balloon in conjunction with a rotator cuff suture can be regarded as successful, since it allowed us to achieve good and excellent results in the long-term period, to restore the function of the shoulder joint to a greater degree as compared to the control group. However, given the small group of cases, it is necessary to analyze the results on a larger sample of patients with a longer follow-up period.

## CONCLUSION

The method of installing the InSpace balloon in conjunction with the suture of the rotator cuff is simple, low invasive and effective, allowing recovery of the shoulder joint function and pain relief to a greater

degree in comparison with rotator cuff stitching only. However, given the small number of cases, this technique requires further study and evaluation of the results on a larger sample of patients.

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Received: 14.02.2019

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