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Our First Experience of Using Biodegradable Implants in Latarjet – Bristow Surgical Procedure at Chronic Posttraumatic Anterior Shoulder Instability

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Abstract
Background. Multi-layer spiral computed tomography shows that the main cause of shoulder instability is glenoid cavity bone defect. The aim of our research was to assess the effectiveness and safety of biodegradable implants in the treatment of patients with chronic posttraumatic anterior shoulder instability under conditions of bone defect of glenoid cavity margin by the restoration of anatomic shape and structure of scapula articular surface.
Materials and methods. We performed a pilot study based on the results of surgical treatment of 7 patients using 4.5 mm biodegradable compressing screws. In preoperative period, all patients had standard two-dimensional X-rays and MSCT with 3D-reconstruction. In postoperative period, all patients had check-up X-ray right after the surgery and MRI in 3 months after the surgery.
Results. The results of the treatment were assessed by common clinical criteria, functional criteria, X-ray evidence and intra- and postoperative complications. We registered strong functioning of an arm and an increase in the range of motions. Data from Rowe/Zarins and DASH questionnaires showed that the patients totally recovered. X-ray evidence showed consolidation of non-free autograft to the zone of scapula bone defect without osteolysis or widening of a drilled hole. We did not observe either a failure of union, or any formation of false joint, or any screw fractures in bone tissue. Beyond that, we did not observe any complication in postoperative period and early postoperative complications in particular.
Conclusion. Pilot study with use of modern biodegradable implants in osteoplastic stabilization of shoulder joint at recurring instability showed their effectiveness and safety in patients of young and active working age. However, considering small number of patients in pilot study we cannot extrapolate our results to all similar and analogue cases of using biodegradable implants. In this regard, it is necessary to perform major multicenter clinical randomized study for further long-term observation and detection of possible unwanted side effects.

Key words: *shoulder joint, instability, surgical treatment, biodegradable implant*

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Наш первый опыт применения биодеградируемых имплантов при хирургическом лечении хронической посттравматической передней нестабильности плечевого сустава по методике Бристоу – Летарже

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Резюме
Обоснование. По данным МСКТ-обследования пациентов, основной причиной, приводящей к нестабильности плечевого сустава, является костный дефект впадины лопатки. Цель исследования: оценить эффективность и безопасность применения биодеградируемых имплантов во время фиксации несвободного аутотрансплантата при лечении пациентов с хронической посттравматической передней нестабильностью плечевого сустава в условиях костного дефекта края впадины лопатки путём восстановления анатомической формы и структуры суставной поверхности лопатки.
Материалы и методы. Нами проведено пилотное исследование, основанное на результатах оперативного лечения 7 пациентов с использованием 4,5 мм биодеградируемых компрессирующих винтов. Всем пациентам в предоперационном периоде выполнялись стандартные рентгенограммы в двух проекциях и мультиспиральная томография с 3D-реконструкцией плечевого сустава. В послеоперационном периоде всем пациентам сразу после операции выполнялась контрольная рентгенография оперированного плечевого сустава, а спустя 3 месяца после операции – МРТ-сканирование.
Результаты. Оценка результатов хирургического лечения пациентов осуществлялась по следующим критериям: 1) общеклинические критерии; 2) функциональные критерии; 3) рентгенологические результаты хирургического лечения; 4) интра- и послеоперационные осложнения. Результаты данных опросников Rowe/Zarins и DASH свидетельствуют о полном восстановлении пациентов и их адаптации к повседневной жизни. Рентгенологические данные показали консолидацию несвободного аутотрансплантата к зоне костного дефекта лопатки без остеолиза или расширения высверленного отверстия. Нами не выявлены несращения

и случаи формирования ложного сустава несвободного аутотрансплантата, а также перелома винтов в костной ткани. Также не было выявлено никаких осложнений в послеоперационном периоде и ранних послеоперационных осложнений в частности.
Заключение. Пилотное исследование с применением современных биодеградируемых имплантов при костно-пластической стабилизации плечевого сустава при рецидивирующей нестабильности наглядно продемонстрировало его эффективность и безопасность у пациентов молодого и трудоспособного возраста. Тем не менее, учитывая небольшое количество пациентов в пилотном исследовании, невозможно полностью экстраполировать его результаты на все случаи использования биодеградируемых имплантов. В связи с этим для долгосрочного последующего наблюдения и выявления возможных нежелательных побочных эффектов необходимо проведение масштабных многоцентровых клинических рандомизированных исследований.

Ключевые слова: *плечевой сустав, нестабильность, хирургическое лечение, биодеградируемые импланты*

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BACKGROUND

By "chronic posttraumatic shoulder instability" we mean repeated episodes of shoulder dislocation due to the complication of acute traumatic dislocation and causing joint dysfunction [2, 3, 9, 12]. Main reason of recurring shoulder dislocation is primary injury of bony margin of anterior glenoid cavity, which occurs in 67–91 % of cases according to various estimates [5, 6, 10, 14, 15]. In course of time, this injury causes bone fragment lysis and consolidation of the remained fragment with scapula articular process in malposition. The latter predetermines formation of different-sized bone defect of scapula articular surface. Area of a bone defect is directly proportional to the number of micro-injuries occurring in the process of repeated dislocations of humeral head.

Injured structures can be repaired using surgical treatment that is aimed at the restoration of anatomical-functional stabilization of humeral head [1, 2, 3, 5, 8, 14]. At the present time, based on the bone defect visualization using multi-layer spiral computed tomography, the osteoplasty of marginal bone defect of scapula articular process is used. If the area of bone defect is less than 15 % of total area, the most reliable and safe surgical method is the Latarjet – Bristow procedure [6].

Traditionally, non-free autograft is attached to the bone defect by one or two metal screws. One of the causes of a repeated surgery is a removal of the screws due to a pain during shoulder joint movement, which is caused by the closeness of a screw-head and humeral head. Another disadvantage of using metal screws is a lifelong fixation of an autograft even after its compression to the bone defect of scapula articular process in order to achieve the consolidation. After the consolidation of an autograft, there is no need to use the screws and besides that, a metal screw can eventually widen bone canal causing problems in case of repeated shoulder surgeries. Finally, metal screws can become the artefacts while further magnetic resonance imaging.

To avoid these potential problems, we considered the possibility of using biodegradable screws for autograft fixation.

The **aim** of our research was to assess the effectiveness and safety of biodegradable implants in the treatment of patients with chronic posttraumatic anterior shoulder instability under conditions of bone defect of glenoid cavity margin by the restoration of anatomic shape and structure of scapula articular surface. Biodegradable screws should provide proper compression, maintain strong fixation of an autograft, be safe in the long term and completely fit into the bone tissue in the area of fixation.

MATERIALS AND METHODS

The pilot study included the patients admitted to the clinic of Irkutsk Scientific Center of Surgery and Traumatology from November 2014 to December 2015. According to the Good Clinical Practice protocol, all patients were qualified to be eligible for either inclusion or exclusion criteria. Representatives of the producers of biodegradable implants have all enabling documents presented on their official web site.

All patients included in the study were the citizens of the Irkutsk Region (average age – 25.18 ± 2.4 years

Table 1

Comparative analysis of patients with chronic posttraumatic shoulder instability with bone defect of glenoid cavity (M ± m)

Criteria	Treatment group (*n* = 7)
Age (years)	25.18 ± 2.4
Gender (abs., %)	Male – 6 (85.7 %) Female – 1 (14.3 %)
Injured side	Right – 5 (71.4 %) Left – 2 (28.6 %)
Number of shoulder dislocations	25.38 ± 2.2
Term of hospital stay (from the moment of the first dislocation), months	26.12 ± 12.6
Night shoulder dislocations (abs., %)	7 (100 %)
Bone defect of glenoid cavity (3D multi-layer spiral CT), %	12.2 ± 2.34

(from 18 to 30 years), 6 men and 1 woman; Table 1). Pilot study allowed us to determine the power of the research with 90 % confidential interval and to ascertain clinical effectiveness of this method of treatment.

The hospital period was the same for all the patients. They all were given similar recommendations at the discharge from the hospital. The next day after the discharge, a patient applied to the out-patient hospital at the place of his/her residence for further management and rehabilitation. In 3, 6 and 12 months after the surgery, a patient had a scheduled visit to the clinic of ISCST. In a year after the surgery, an Individual list of a patient was collected and statistical analysis was performed.

We developed and used the "Individual list of the estimation of functional outcomes of surgical treatment" as a method of documentation of objective and subjective evidence of patients who participated in the study. It included estimation of range of motions in surgically operated arm, Visual Analogue Scale (VAS) of pain, integral estimation of functional outcomes using Rowe/Zarins scale and DASH.

Statistical analysis was conducted using Russian version of Statistica for Windows 10.0 (StatSoft Inc., USA, license № AXAR301F643210FA-C; the rightsholder: Scientific Center of Surgery and Traumatology). To determine statistical significance of functional outcomes, we used nonparametric Wilcoxon test. Differences between the groups were statistically significant at $p \leq 0.05$.

Biodegradable screws

We used 4.5 mm *Activa screw* biodegradable compressing screws composed of conjoint polymer L-lactic / conjoint glycolic acid (PLGA 85L/15G) (*Figure 1*). Screws were inserted in accordance with the producer's instruction and they are supposed to maintain strong fixation during first 8 weeks after the insertion with full degradation within about 2 years. These polymers dissolve *in vivo* during hydrolytic degradation into α-hydroxyacids, which are excreted metabolically. The screws are compatible with AO instruments and have metal single-use adaptor for insertion.

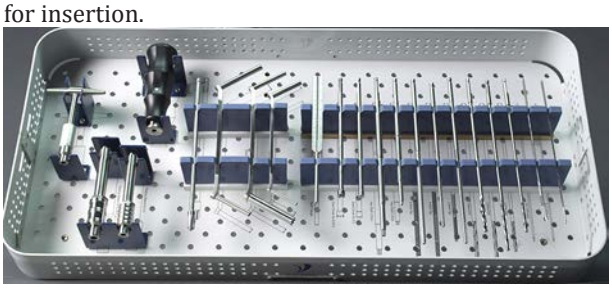


Fig. 1. Instruments for biodegradable compressing screws (Activa screw).

Surgical technique

In aseptic conditions, under regional anesthesia and with a patient's "beach chair" position, surgical incision up to 5 cm from the apex of scapula coracoid process towards axillary fold is made. Acromial and clavicular portions of deltoid muscle are expanded by blunt dissection. Surgical approach to subdeltoid spatium and coracoid process of left shoulder is performed. Using scoop, we dissect away *processus coracoides* apex (v-shaped, inverted, 1.0 × 1.0 × 2.0 cm) and attached muscles (short head of biceps and coracobrachial muscle). Cortical layer of the lower part of a bone is removed using oscillating saw to make a flat surface of cancellous bone; muscles are fixed by the retaining fibers and are retracted downwards and medially. Shoulder is rotated outwards. Longitudinal dissection of subscapular muscle at the levels of middle and lower thirds was performed routinely. Vertical arthrotomy is made, joint is examined. Found: bone fragment of anteroinferior glenoid cavity margin 1.0 × 0.5 × 0.5 cm consolidated in malposition; absence of glenoid labrum of scapula; when inward surgical release a bone defect of scapula articular surface is detected. When abduction 90° and external rotation 90°, free anteroinferior humeral head luxation occurs. Bone defect of anterior scapula articular surface is skeletonized up to slight bleeding. Non-free autograft was fixated to the bone defect zone in parallel to scapula articular surface and diafixated by two 1.0 mm Kirschner wires. A hole in central part of coracoid process of scapula was made using 3.2 mm burr. The hole was finished with 4.5 mm tap drill and multiflute drill. The autograft is fixated with 3.5 mm biodegradable wire (*Activa screw*) 35 mm long. Apex of coracoid process is moved and fixated with 3.5 mm screw. Defect of the capsule is cut down, and free part of capsular graft is fixated to the moved apex of coracoid process with absorbable polyester suture 3/0. Wound is flushed with Ringer's solution, Redon drainage is set, and wound is cut down in layers. Hemostasis control during the surgery – dry. Aseptic dressing is applied. Left arm is fixed with Desault's bandage.

Rehabilitation

We recommended the patients to fixate the operated arm with Desault's bandage for 4 weeks. From the 2nd day after the surgery, isometric exercises were advised. In 4 weeks after the surgery, the fixation of the operated arm ceased. A patient was referred to the rehabilitation therapy that included therapeutic massage of collar zone, exercise therapy, physiotherapeutic procedures (electrostimulation of supraspinatus and infraspinatus tendons) up to 10 sessions aimed at the gain of motions in arm and shoulder in particular and at restoration of tone in shoulder girdle muscles. In 3 months after the surgery, a patient had a scheduled visit to the clinic of ISCST and basing on the clinical and X-ray evidences a physician permitted him to return to sport activities.

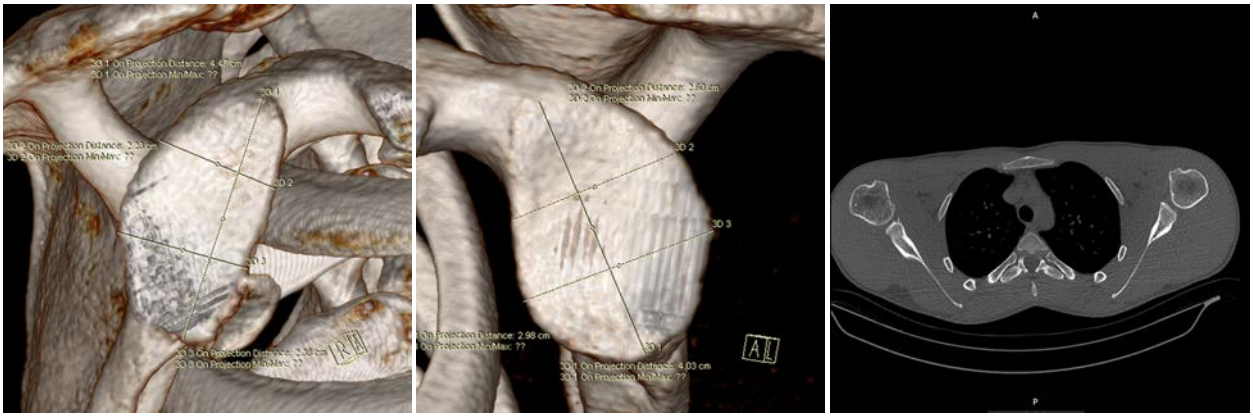
X-ray diagnostics

In preoperative period, all patients had standard two-dimensional (frontal and lateral) roentgenograms (*Figure 2*), multi-layer spiral computed tomography with 3D-reconstruction of shoulder joint from both intact (*Figure 3*) and injured sides. This examination allowed us to estimate and to plan the extent of surgical procedure. The patients included in this study had marginal bone defect of scapula articular process less than 15 % of total area in comparison with intact arm. In postoperative period, all patients had check-up X-ray of operated shoulder right after the surgery (*Figure 4*). In 3 months after the surgery, the patients had MRI (*Figure 5*) in order to examine the consolidation of an autograft to the zone of bone defect.

RESULTS

a **b**

Fig. 2. Patient S. X-rays of left shoulder joint: **a** – frontal; **b** –axial.



a **b** **c**

Fig. 3. Patient S. Multi-layer spiral computed tomography with 3D-reconstruction of shoulder joints: **a** – 3D-reconstruction of articular surface of injured scapula; **b** – 3D-reconstruction of articular surface of intact scapula; **c** – axial section of injured shoulder joint.

Fig. 4. Patient S. Check-up X-ray of the left shoulder joint after the surgery.

a **b** **c**

Fig. 5. Patient S. MRI of left shoulder joint in 6 months after the surgery: **a** – axial; **b** – frontal; **c** – lateral.

The results of surgical treatment of patients were assessed by the further criteria: 1) common clinical criteria – duration of surgical procedure, extent of intra- and postoperative blood loss, total blood loss, terms of inpatient treatment; 2) functional criteria – range of motions in surgically operated arm, functional scales; 3) X-ray evidence; 4) intra- and postoperative complications.

Dynamics of range of certain types of motions in shoulder joint (*Table 2*) from the 3rd month after the surgery shows strong functioning of an arm along with minimum changes which do not affect life quality. In the following observation periods, an increase in the range of motions is evident: the patients are able to have full range of motions due to the restoration of congruence of scapula articular surface and without a risk of recurrence of dislocation.

Table 2

Range of motions in operated patients, ˚(M ± m)

Criteria	Treatment group (*n* = 7)
flexion	
Before the surgery	93.97 ± 7.15
3 months after the surgery	110.29 ± 5.64
6 months after the surgery	117.94 ± 3.14
2 months after the surgery	119.2 ± 1.05
extension	
Before the surgery	47.35 ± 5.12
3 months after the surgery	40 ± 5.36
6 months after the surgery	50.88 ± 3.49
2 months after the surgery	56.76 ± 3.04
abduction	
Before the surgery	94.41 ± 8.85
3 months after the surgery	103.23 ± 5.98
6 months after the surgery	113.82 ± 4.32
2 months after the surgery	118.82 ± 2.07
external rotation	
Before the surgery	13.52 ± 5.50
3 months after the surgery	13.52 ± 4.49
6 months after the surgery	27.64 ± 6.02
2 months after the surgery	38.82 ± 6.67

Subjective evidence about postoperative recovery is presented by the data from Rowe/Zarins and DASH questionnaires. In 3 months after the surgery functional results were assessed by Rowe/Zarins scale – 98 ± 1.02 points, and by DASH – 3.29 ± 3.29 points. These results show that the patients totally recovered and got back to normal life.

X-ray evidence analysis showed consolidation of non-free autograft to the zone of scapula bone defect without osteolysis or widening of a drilled hole. All bone autograft are positioned edge-to-edge with the joint (a proper position).

We did not observe any failure of union or any formation of false joint of non-free autograft in our research. Besides, we did not observe any screw fractures in bone tissue.

Beyond that, we did not observe any complication in postoperative period, in particular there were no cases of early postoperative complications, such as hematomas, infections, synovitis, which testifies to the safety of the implants.

DISCUSSION

One of the modern trends in orthopedic surgery is using biodegradable implants. First, this is because no repeated surgeries for the implant removal are required (which is good from economic point of view) as the composition of biodegradable implants causes its full absorption in biological tissue. Second, an affection of metal on biological tissue and on bone tissue in particular causes osteolysis and implant migration in a long-term period. Third, metal screws can become the artefacts in further magnetic resonance imaging and can cause restricted visualization of an operated segment.

Unfortunately, an experienced orthopedic surgeon often deals with patients who were previously operated in this segment, and in case of repeated injures of an operated segment, previously fixed metal implants can cause some technical difficulties (i.e. bone canals from the screws, possible latent infection in the area of metal implants etc.).

Following on from the results of the pilot study, we can make a preliminary conclusion that the use of biodegradable implants with a set of instruments helps increasing accuracy of adaptation of a bone implant in the zone of bone defect:

1. Cannulated drill and tap drill make it possible to minimize the misalignment of an autograft along guide wire in the area of bone defect of scapula articular process.

2. Cannulated hole in the screw helps fixating an autograft without removal of guide wire.

3. Compressing form of the screw helps to achieve primary fixation of an autograft to the zone of bone defect.

In our opinion, using biodegradable screws helps increasing economical effectiveness of medical technologies owing to the decreasing injury rate at the repeated surgeries on account of the removal of metal implants.

Using biodegradable screws in surgical treatment of patients with chronic posttraumatic anterior shoulder instability under conditions of bone defect of scapula articular surface has high compliance.

Besides, biodegradable screws, according to the producer, were constructed with the mechanism of internal dynamic compression (autocompression). This makes it possible to achieve additional compression in the formed bone canal for account of the characteristics under hydrolysis conditions: increase in its diameter and decrease in its length for 1–2 % from the initial size guarantees stable compression in the period of bone regeneration. Unfortunately, we had no opportunity to test these characteristics of the screws that is why we cannot comment on these data.

Absence of postoperative complications along with consolidation of an autograft allows us to make a conclusion about the safety of modern biodegradable implants.

CONCLUSION

Pilot study with use of modern biodegradable implants in osteoplastic stabilization of shoulder joint at recurring instability showed their effectiveness and safety in patients of young and active working age. However, considering small number of patients in pilot study we cannot extrapolate our results to all similar and analogue cases of using biodegradable implants. In this regard, it is necessary to perform major multicenter clinical randomized study for further long-term observation and detection of possible unwanted side effects.

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