OSTEOPLASTY OF VERTEBRAL BONE DEFECTS CAUSED BY PEDICLE SCREW LOOSENING USING ORTHOBIOLOGICAL APPROACHES: A PILOT STUDY OF CASE SERIES

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Objective. To analyze the effectiveness and safety of using an orthobiological product in osteoplasty of bone defects of the vertebrae with simultaneous reosteosynthesis.

Material and Methods. The results of screw augmentation technology using thrombogel-enriched allogeneic bone were studied in a retrospective, single-center, non-randomized study, which included 17 patients (10 women, 7 men) with instability of the hardware in the form of screw loosening and osteolysis around screws. Results within 12 months were followed up in 17 patients (100 %). We compared preoperative and postoperative instrumental data, clinical parameters in dynamics.

Results. The mean age of the patients was 59 (43–75) years. The distribution of patients, according to the primary pathology, was as follows: 11 patients (64.7 %) had a degenerative-dystrophic pathology of the spine, 4 patients (23.5 %) had a traumatic injury, and 2 patients had a kyphotic deformity on the background of Bechterew's disease (11.8 %). The mean time from primary to revision surgery was 7.06 months (3.1–12.1), mean CRP was 4.48 (0.5–15.0). When observing patients for 12 months, all patients showed a positive trend in the form of a statistically significant regression of back pain according to VAS from 7.0 (6.0; 7.3) to 1.0 (0.0; 1.0) points ($\chi^2 = 47.9$, df 3, $p < 0.0001$). A positive trend was also noted in the form of a decrease in ODI indicators and an improvement in the quality of life of patients from 63.8 (57.1; 69.1) to 3.0 (2.0; 7.5) at 12 months. When comparing the parameters (VAS and ODI), the obtained differences before/after the operation were statistically significant, while these changes have a pronounced correlation. Postoperative CT studies (3, 6, 12 months) showed no instability of the screws.

Conclusion. Osteoplasty of vertebral bone defects and screw augmentation using orthobiological approaches have demonstrated their primary efficacy and safety. Further studies with a large sample size are needed to confirm the obtained results.

Key Words: instability of the hardware, screw loosening, osteoplasty, orthobiology, thrombogel, platelet-rich plasma.

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Transpedicular fixation is widely used in the surgical treatment of a wide range of diseases and injuries of the spine. Instability of the installed hardware is found in 4–20 % of cases. Moreover, it is one of the main causes of decreased quality of life and efficiency in patients with impaired bone density and exceed 50 % of cases [1–6].

Hardware instability includes fractures of the fixing elements, migration and loosening of screws with the onset of osteolysis around them [7]. Loosening of the pedicle screws is the main cause of instability. The frequency of loosening in the case of rigid fixation of the thoracic and/or lumbar spine is 1–15 % with normal bone mineral density. This indicator is considerably higher and can reach 60 % in patients suffering from osteoporosis [8].

Risk factors for screw loosening are reduced bone mineral density, an inflammatory response to titanium microparticles, stress shielding, an incomplete bone block, implant-associated infection, the extension of the hardware, etc. [8, 9].

Nowadays, various techniques have been developed to increase the strength of screw fixation, including the use of expansion screws and augmentation techniques such as polymethyl methacrylate (PMMA) and bone chips [10, 11].

It should be noted that the proposed strategies for screw augmentation are mostly of a preventive nature, and the treatment strategy for patients with bone defects of the vertebrae due to pedicle screw loosening has not been practically developed. Lea et al. [12] proposed a technique for using revision screws with additional osteoplasty with allogeneic bone chips. The issues of osteoplasty for extensive defects and chronic implant-related bone infections are

poorly described in the literature. There is no data on the effectiveness of the use of allogeneic bone chips in combination with osteoinductive materials or stimulators of tissue regeneration. The lack of treatment strategies for patients with bone defects of the vertebra due to the destabilization of the transpedicular system results in the development of new techniques of osteoplasty using orthobiological approaches.

The objective is to analyze the effectiveness and safety of using an orthobiological product in the osteoplasty of bone defects in the vertebrae with simultaneous reosteosynthesis.

Material and Methods

The outcomes of screw augmentation technique using platelet gel enriched allogeneic bone were studied in a retrospective, single-center, non-randomized study, which included 17 patients (10 women and 7 men) with instability of the hardware in the form of screw loosening and osteolysis around screws. The mean age of patients was 59 (43–75) years; the outcomes were followed up within 12 months in 17 patients (100 %).

This study was conducted in accordance with the provisions of the Helsinki Declaration (2013) and approved by the Ethics Committee of the Research Institute – Regional Clinical Hospital No. 1 n.a. Prof. S.V. Ochapovsky. Informed consent was obtained from all the patients.

Inclusion criteria:

1) age: 18–80 years;

2) clinically significant bone defects in the vertebral body and pedicles of more than 1 mm associated with the pedicle screw loosening;

3) back pain of more than 5 points according to VAS (on a scale of 0–10);

4) disability index of more than 40 (on a scale of 0–100).

Exclusion criteria:

1) pedicle fracture;

2) any oncological diseases;

3) end-of-life situations;

4) signed refusal of the surgery.

Neurological and clinical examinations were used for objective assessment of the patient's condition. The pain intensity was evaluated by VAS prior to surgery, 1, 6 and 12 months after it. The degree of vital activity impairment was assessed according to the Oswestry questionnaire (ODI) before surgery and 1, 6 and 12 months after it.

In order to visualize pedicle screw loosening and osteolysis areas around them and for postoperative control, CT study was performed with a smart metal artefact reduction (MAR) at 3, 6 and 12 months after surgery.

The criterion for screw loosening was the presence of radiotransparent area around the screw of at least 1 mm and a Double halo sign. The areas of bone defect around the screws were assessed according to the following formula: the size of the largest around-screw bone defect in axial CT scans minus the diameter of the screw thread. Depending on the data obtained, the zones of bone defects were divided as follows: small (1–2 mm), medium (2–4 mm) and large (more than 3 mm).

Obtaining of allogeneic bone tissue. Bone tissue was obtained by preserving the femoral head excised during endoprosthesis replacement. Initially, mechanical treatment of the femoral head was performed to clean it from hyaline cartilage using a reamer (Fig. 1).

Subsequently, the Marburg Bonebank System was introduced for bone tissue thermal disinfection [13]. Bone chips were prepared intraoperatively from the femoral head and mixed with platelet gel.

Preparation of platelet gel. In order to obtain a platelet gel, peripheral blood underwent exfusion into a hemacon with 150 ml of CFDA-1 anticoagulant solution. Platelet gel was prepared according to the technique described by O.I. Sharipov et al. [14] with our own modification. The first step was to separate platelet-rich plasma (PRP) from peripheral blood using the double centrifugation technique. The final volume of PRP was 20 ml; it was divided into 2 components: 5 ml of PRP was stored at the initial concentration (the first component of platelet gel) and 15 ml was used to prepare thrombin. For this purpose, 15 ml of PRP was mixed with a solution of 100 μl of $CaCl_2$ (20:1 ratio) in a Petri dish, after which it was left at a temperature of +37 °C for 15–60 minutes until the clot formation was completed. After clot retraction, the remaining liquid with a high thrombin content and a final volume of 5 ml (the second component of the platelet gel) was collected in a Petri dish. The finished tubes with PRP (5 ml) and thrombin (5 ml) were transferred to the general operating room in a sterile package (Fig. 2a). Immediately before use, 5 ml of PRP and 5 ml of thrombin were mixed in a 20 ml syringe; the plunger was pushed to the extreme position and the resulting platelet gel was used 15 seconds after the clot was formed (Fig. 2b).

Osteoplasty technique using platelet gel enriched allogeneic bone. The patient's position on the operating table is prone. A sequential approach to the hardware is performed. The nuts are unscrewed, the bone trabeculae are removed and the screws are unscrewed; after that a thorough curettage of post-screw bone defects is performed. The contents of the screw bed are sent for bacteriological examination. Then, a tube port with an exterior diameter of 6 mm (45° bevel at one end) is placed into post-screw defect through the vertebral pedicle to the greatest depth possible and positioned in such a way as the port's bevel was within the vertebral body. The placement of the tube port is monitored by radiographs in direct and lateral views (Fig. 3a). The soft material is introduced in small doses through the port into the defect; each new portion of the material is tamped with an impactor and a hammer, with a gradual reverse withdrawal of the port until the material first filled the entire defect over the body and then the pedicle (Fig. 3b, 3c).

Bone defects are filled completely and have a radiological picture presented in Fig. 4.

After filling the defect the port is removed and then new screws with the same diameter are placed. The rods are mounted on the screw heads and fixed with nuts. Henceforth, the wound is sutured with the installation of active drains.

Statistical processing of results. The obtained clinical outcomes were processed using IBM SPSS 16.0. Since the total number of patients was 17, and the distribution of numerical values in part of the sample was substantially different from the normal distribution (the hypothesis of the normality of the distribution was tested using the Kolmogorov-Smirnov test), additionally, a nonparametric test of statistical analysis was used: Friedman χ^2 test. The value of statistical significance of $p < 0.05$ is accepted as the lower limit of reliability. During the presentation of the study results, the data obtained on a sample with a distribution other than normal were recorded in the form of the median – Me [25 and 75 percentiles].

Results

The treatment outcomes of 17 patients were analyzed. The distribution of patients by primary pathology was as follows: 11 (64.7 %) with degenerative spine diseases; 4 (23.5 %) with traumatic spinal injuries and 2 (11.8 %) with kyphotic deformities associated with Bechterew's disease. The mean time from the primary to the revision surgery was 7.06 months (3.1–12.1) and the mean CRP value was 4.48 (0.5–15.0). Culture from the bed of a loose screw showed no growth of microflora in 15 (88.2 %) cases and gramme-positive flora with scant growth, sensitive to levofloxacin and clindamycin was found in 2 (11.8 %) patients. In the postoperative period after receiving the culture data antibacterial therapy (levofloxacin 500 mg: 1 tablet twice a day) was performed in these patients for 6 weeks with dynamic control of the CRP findings.

Medium and large defects near the screw were detected in 12 (70.6 %) cases, and 5 (29.4 %) patients had clinically significant small defects.

Under follow-up for 12 months, all patients showed improvement in the form of statistically significant regression of back pain syndrome according to VAS from 7.0 (6.0; 7.3) to 1.0 (0.0; 1.0) points ($\chi^2 = 47.9$, df 3, $p < 0.0001$; Table, Fig. 5).

There was also an improvement in the form of decreased ODI indicators and improved patients' quality of life for patients, from 63.8 (57.1; 69.1) to 3.0 (2.0; 7.5) after 12 months (Table, Fig. 6). When comparing the parameters (VAS and ODI), the differences obtained before and after surgery are statistically significant, while these changes have a pronounced correlation.

Postoperative CT findings showed the absence of instability of the installed screws; the integration of allogeneic bone tissue was noted.

Case history. Patient L., 74 years old, was admitted to a neurosurgical inpatient unit with complaints of severe lumbar spine pain (VAS: 7 points out of 10, ODI: 67). Hypertension and type 2 diabetes mellitus were in the patient's past medical history. In 2021, the patient underwent decompression and stabilization surgery in the volume of TLIF of L3–L4–L5–S1 for degenerative stenosis at the level of L3–L4 (type C according to Schizas), L4–L5 (type D according to Schizas), L5–S1 (type C according to Schizas) and unstable spondylolisthesis of L4 (grade 2 by Meyeding). After surgery, the patient noted a significant improvement in the condition such as regression of pain in the lower extremities and in the lumbar spine (VAS: 2 points out of 10). After 4 months, the patient reported a progressive increase in lumbar spine pain resistant to non-surgical therapy. Seven months after surgery, a CT examination of the lumbar spine was performed during control examination (Fig. 7). The instability of hardware was revealed in the form of its loosening in the L4 vertebra (more than 1 mm for the right screw), L5 vertebra (more than 1 mm for both screws), S1 vertebra (more than 2 mm for both screws). In addition, frontal and axial images showed Grade 1 bone block according to Tan at the level of L3–L4, Grade 2 at the level of L4–L5, Grade 4 at the level of L5–S1 and cage subsidence at the level of L5–S1.

Objective findings: the patient had hypersthenic body type, walked with the support of a cane and with body bent forward. Local findings: pronounced tenderness of the paravertebral muscles of the lumbar spine was greater on the left.

Fig. 1
Treatment of the femoral head: **a** – femoral head with hyaline cartilage; **b** – mechanical cleaning from cartilage using a reamer; **c** – final appearance after processing

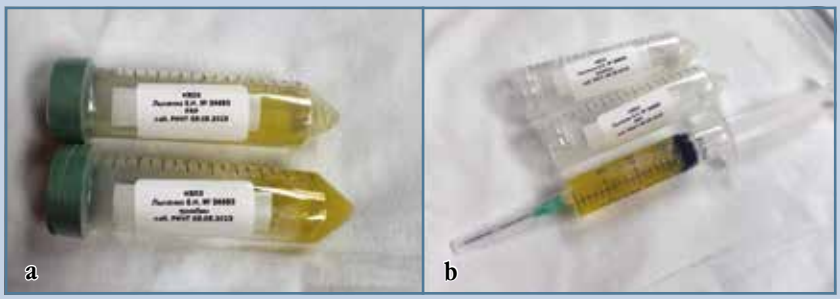

Fig. 2
Tubes with thrombin and PRP **(a)** and mixed components in a syringe **(b)**

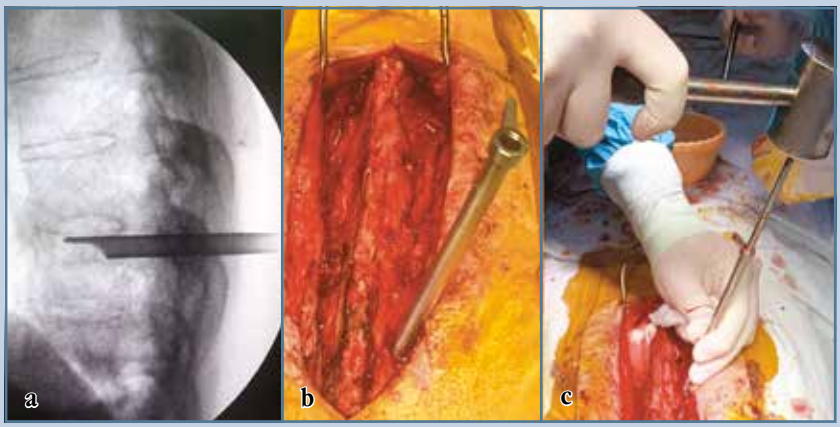

Fig. 3
Installation of a tube port in a post-screw vertebral defect and the stage of osteoplasty: **a** – radiological control; **b** – intraoperative picture; **c** – process of tamping soft material

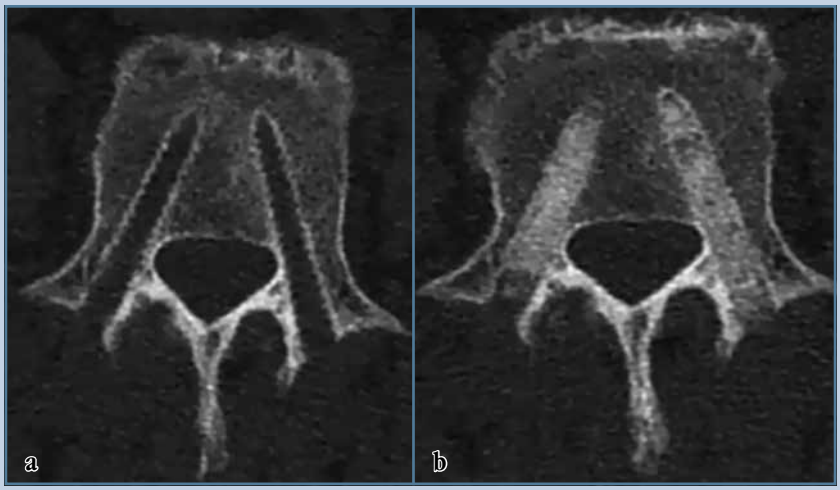

Fig. 4
CT scans before **(a)** and after **(b)** osteoplasty

There were no signs of inflammation in the postoperative scar. Tendon reflexes from the lower extremities were reduced from the point of view of neurological status. Muscle strength in the extremities was 5 points in all muscle groups. There were no pelvic organ dysfunctions. There was no sensory disturbance.

Based on the clinical and radiological data, the following surgery was performed: removal of the hardware, osteoplasty of the screw channels in L3–L4–L5–S1 (platelet gel + allograft bone), and reinstallation of the 8-screw system.

In the postoperative period, an improvement was found in the form of pain syndrome regression; the patient was mobilized on the first day after surgery. In the postoperative period, a CT of the lumbar spine was performed on the 3rd day to assess the treatment outcomes. According to CT findings, previously identified areas of bone rarefaction around the screws were totally filled with bone chips; the hardware was stable (Fig. 8).

The patient was discharged in a satisfactory condition on the 7th day after surgery, without complications. He moved independently without additional support devices. The wound was subsequently healed by primary tension. The control examination of the patient was performed 3, 6 and 12 months after surgery. The patient had no complaints; he returned to work. According to CT findings of the lumbar spine after 12 months, there were no signs of hardware instability; there was a bone block of Grade 1 according to Tan at the level of L3–L4, Grade 1 at the level of L4–L5, and Grade 2 at the level of L5–S1 (Fig. 9).

Discussion

Nowadays, the treatment strategy of patients with vertebral bone defects due to osteolysis and pedicle screw loosening is practically not developed. The most common treatment techniques are larger-diameter screws and cement augmentation of the vertebral body using perforated screws; an alternative technique is augmentation of the revision screw with

Table
VAS and ODI points before and after surgery

Scales	Before treatment, Me (25 %; 75 %)	1 month after treatment, Me (25 %; 75 %)	6 months after treatment, Me (25 %; 75 %)	12 months after treatment, Me (25 %; 75 %)	Friedman χ^2
VAS, points	7.0 (6.0; 7.3)	4.0 (3.0; 4.0)	2.0 (2.0; 3.0)	1.0 (0.0; 1.0)	$\chi^2 = 47.9$, df 3, $p < 0.0001$
ODI, points	63.8 (57.1; 69.1)	32.8 (29.5; 39.7)	13.6 (12.0; 15.0)	3.0 (2.0; 7.5)	$\chi^2 = 40.8$, df 3, $p < 0.0001$

bone chips or osteoinductive material [11, 16, 17].

Cement augmentation considerably enhances the rigidity and strength of the pedicle screw. Nevertheless, polymethyl methacrylate (PMMA) has a number of substantial drawbacks: exothermic properties, risk of injury to nerve structures during extravasation, pulmonary artery thromboembolia, accessibility of augmentation of the vertebral pedicle and development of vertebral osteonecrosis [17].

Bone chips were suggested as a material for screw augmentation in 1994. The initial outcomes of bone chips application suggested that it was less effective than the technique using PMMA [10]. On the contrary, it has been proven in an experimental study by Shen et al. [18] that the bone chip osteoplasty technique is more effective than revision screws.

In our study, allogeneic bone enriched with platelet gel was used for osteoplasty of vertebral bone defects associated with the screw loosening. In this regard, allogeneic chips are the focus of regeneration and platelet gel is a stimulator of osteogenesis.

According to a number of researchers [19–21], the use of platelet-collagen concentrates accelerates the restoration of a segmental defect of bone tissue, and autogenous PRP is a safe, justified, and reliable healing stimulant.

It has been proven that the stimulating effect of PRP manifests itself at a platelet concentration of 1,000,000/μl in a small amount of plasma [22]. An increased number of platelets in plasma also enhances the concentration of growth factors affecting cell migration and proliferation, stimulating the formation of extracellular matrix, suppressing

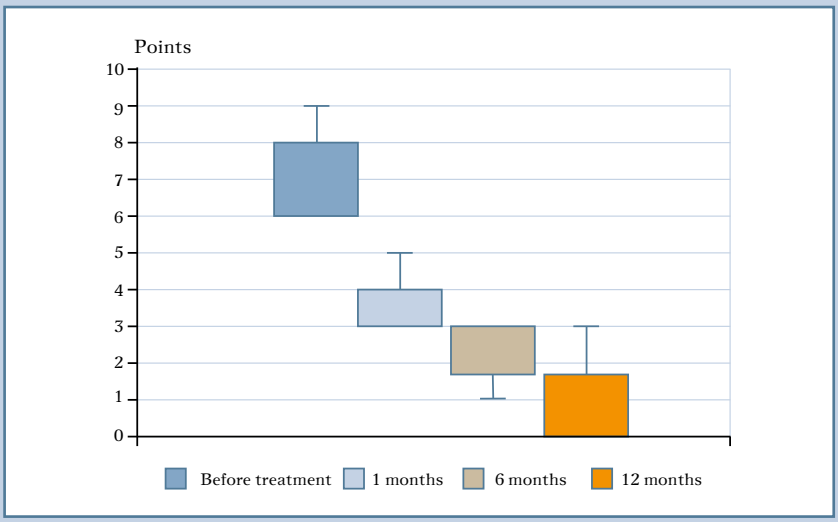

Fig. 5
Dynamics of changes in back pain according to VAS before treatment and 1, 6, 12 months after surgery

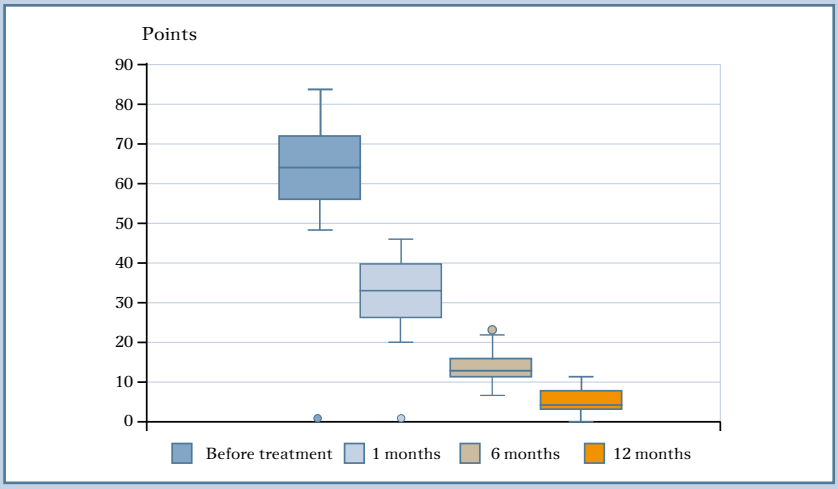

Fig. 6
Dynamics of changes in ODI points before treatment and 1, 6, 12 months after surgery

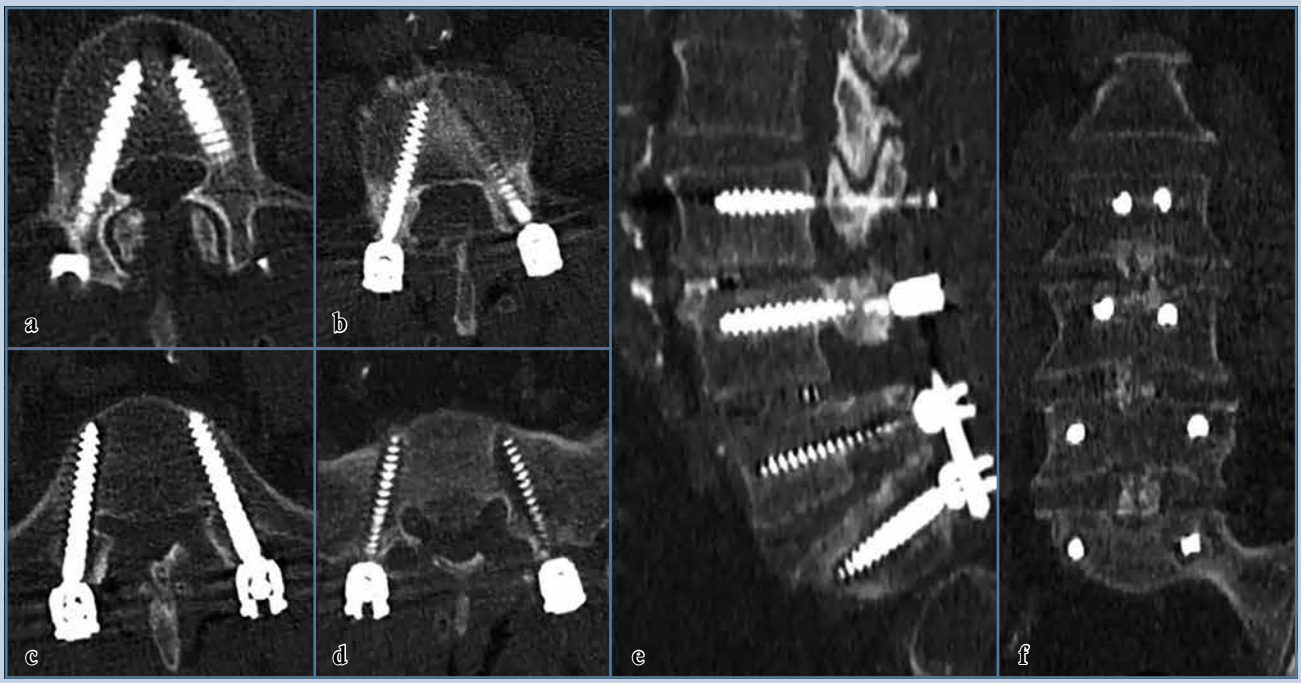

Fig. 7
Axial CT scans of patient L., 74 years old, at the level of L3 **(a)**, L4 **(b)**, L5 **(c)**, S1 **(d)**, sagittal and frontal CT image reconstructions of the operated area **(e, f)**

the release of proinflammatory cytokines and limiting inflammation by interacting with macrophages that is essential for the integration of bone tissue [22, 23].

Oyama et al. [24] compared the outcomes of osteoplasty of the alveolar defect with autogenous bone and osteoplasty in combination with PRP in 7 patients. As a result the authors found a considerable increase in bone content in the alveolar defect after the use of platelet gel ($p < 0.05$) compared with the control group.

V.G. Samoday et al. [25] used an antibiotic-rich PRP in the treatment of pseudoarthrosis and infected bone tissue defects; spongy autogenous bone graft was used as a focus of regeneration. The authors noted the stimulant and antibacterial effects of this combination on bone regeneration.

In our study we obtained PRP at the first stage and platelet gel in the operating room. According to the postoperative CT findings, there were no signs of instability in the reinstalled hardware. No implant-associated infection was found in any patient in the postoperative period.

Limitations of the study. A small group of patients was analyzed (a case series study). There is no control group in our study. Risk factors for screw loosening have not been analyzed due to a small sample.

Conclusion

Osteoplasty of vertebral bone defects and screw augmentation with the use of orthobiological techniques have proven to be primarily effective and safe. Additional investigation with a large sample size is required to verify the results.

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The authors declare that they have no conflict of interest.
The study was approved by the local ethical committee of the institution.
All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.

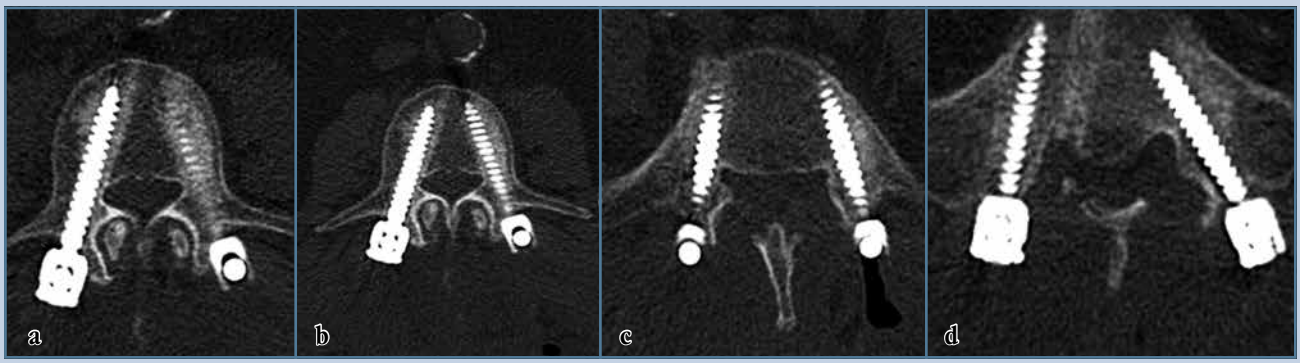

Fig. 8
Axial CT scans of the lumbar spine of patient L., 74 years old, at the levels of L3 **(a)**, L4 **(b)**, L5 **(c)**, S1 **(d)**: dense filling of the initial defects, absence of the Double halo sign around the reinstalled screws

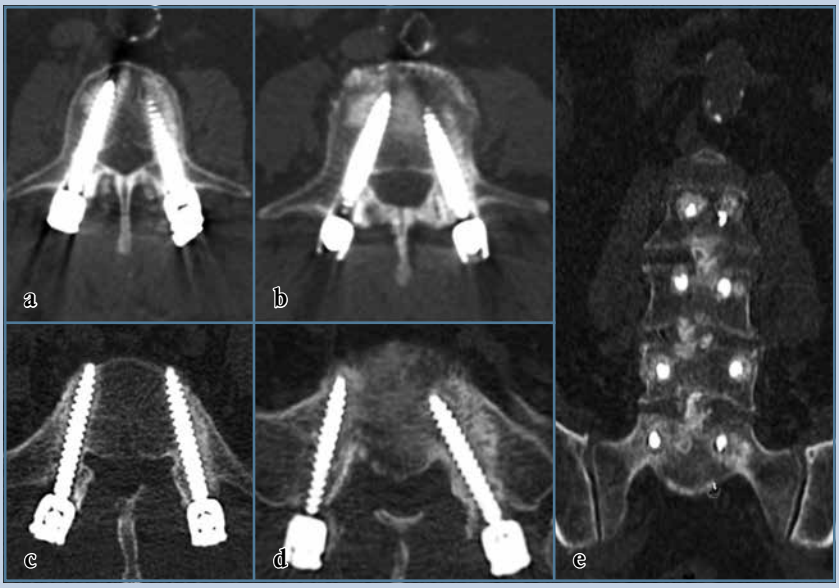

Fig. 9
Axial CT scans of the lumbar spine of patient L., 74 years old, at the levels of L3 **(a)**, L4 **(b)**, L5 (c), S1 **(d)**: no signs of the hardware instability; frontal scan of the lumbar spine with signs of bone block at all levels **(e)**

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