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Avulsion Fractures Osteosynthesis in Patients with Normal Bone Mineral Density and Osteoporosis

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Abstract

Objective: to compare the effectiveness of osteosynthesis for avulsion fractures using bioabsorbable versus titanium implants in patients differing in bone mineral density. ***Materials and Methods.*** In the experimental phase of study, two groups of bone blocks were singled out from patients' femoral heads to assess the anchoring properties of the implant in osteoporotic and healthy bone. The first group included blocks of 31 patients with osteoporosis, the second one — 27 blocks of patients without osteoporosis. In the first group, cortical bioabsorbable Poly-L-Lactic/co-glycolic acid (PLGA) screws were implanted into 13 bone blocks, titanium screws — into 10 bone blocks, and bioabsorbable pins (PLGA) — into 8 bone blocks. In the second group, 10 titanium screws, 10 bioabsorbable screws and 7 bioabsorbable pins were implanted. The anchorage of the implant in bone was evaluated by a pull-out test. Then, depending on the anchorage used, the studied bone blocks with osteoporosis, newly obtained from the first group, were divided into three groups for the purpose of evaluating the resistance to the damaging effects of the implant. In experiment, the osteosynthesis for avulsion fracture was simulated on these bone blocks. In the first group (11 bone blocks), the transosseous osteosynthesis of the bone fragment was carried out with a titanium screw, in the second group (9 bone blocks) with a bioabsobable screw, in the third group (11 bone blocks) with a bioabsorbable pin. The results of osteosynthesis were assessed based on how often a small bone fragment was damaged by an implant and on stability of the anchored implant. In the clinical phase of study, a comparative analysis of 65 surgical interventions (38 people with osteoporosis and 27 without osteoporosis) in patients with avulsion fractures was performed. In 24 cases, bioabsorbable screws were used for osteosynthesis, AO/ASIF titanium screws were used in 31 cases, and pins were used in 10 cases. ***Results.*** Experimental studies showed that the resistance to pull-out test of a bioabsorbable screw anchored in osteoporotic bone is 25.7% higher than a titanium screw. No statistically significant difference was found in bone without osteoporosis. Resistance to pull-out test of a bioabsorbable pin is 3% higher than a titanium screw. The model-based experiment with an avulsion fracture in osteoporotic bone using a titanium screw showed lower effectiveness of osteosynthesis: in 27.2% of cases the cortical titanium screw damaged a small bone fragment. Based on the clinical trial findings, no negative results were obtained using bioabsorbable anchorage. In 12.5% cases of osteosynthesis with a titanium screw, migration of a bone fragment was noted. The data obtained during the clinical study correlated with the experimental data. This makes the use of bioabsorbable implants advantageous. ***Conclusion.*** For avulsion fracture osteosynthesis in patients with normal bone mineral density, it is possible to use both titanium and biodegradable fixators with equivalent strength of fragment fixation. In osteosynthesis of fractures in patients with osteoporosis it is preferable to use bioabsorbable implants.

Keywords: avulsion fractures, osteosynthesis, osteoporosis, bioabsorbable screws, titanium screws, anchoring strength.

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Introduction

Metal implants made of titanium, tantalum, zirconium, cobalt and steel alloys [1–3] are mainly used for internal fixation of various fractures. Above implants feature certain disadvantages like tissues reaction to metal (metallosis) [4–6], instability [7–9], risk of infection complications [10, 11], implant breakage [12, 13], need for subsequent implants removal and related difficulties [14–16]. Treatment of small fragments fractures often results in unsatisfactory outcomes due to the further splitting of bone fragments during fixation and screws migration [17, 18]. Internal fixation of medial malleolus fractures, hand and foot fractures, shoulder epicondyles fractures and the like in patients with osteoporosis are also challenging due to impossible stable fixation of metal implant in the bone [19–23]. Currently a need for introduction of new internal fixation materials and techniques into the clinical practice is recognized such as bioabsorbable implants made of poly(lactic-co-glycolic) acid (PLGA) [10, 24, 25]. Biophysical features of those implants are maximally similar to the bone tissue parameters and their linear load strength is similar to the metal implants [24, 26]. In contrast to metal implants that create various artifacts the PLGA bioabsorbable implants do not impact visualization of bone regenerate during MRI examination [27]. Enhancement of internal fixation stability in patients with local and systemic osteoporosis when it's impossible to use metal fixations is the key purpose of the present study.

Purpose — to compare the effectiveness of internal fixation of avulsion fractures with bioabsorbable versus titanium implants in patients differing in respect of bone mineral density.

Materials and Methods

The authors conducted an open prospective comparative multicenter study on fixation rigidity of titanium screws and biodegradable implants in the bone of various bone density characteristics. The study was conducted in accordance with requirements of WMA Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects 2013.

Experimental study

The authors simulated internal fixation in the experiment in accordance with theory of avulsion fracture. As the null hypothesis the authors considered a theoretical availability of advantages in case of bioabsorbable implants use for fixation of porotic bone in contrast to titanium implants based on the effect of self-compression of bioabsorbable implants and absence of substantial efforts to obtain fragments adaptation during internal fixation.

Bone blocks of femoral heads of the patients who underwent hip joint arthroplasty were used to evaluate anchor properties of implants.

Obtained bone blocks were divided into two groups: first one included 31 blocks from female patients with osteoporosis, second one — 27 blocks from patients with normal mineral bone density. Osteoporosis diagnosis in patients was confirmed by dual-energy X-ray absorptiometry (DEXA) in the program "femoral neck" in the contralateral joint and lumbar spine with T-criteria ≤-1.5.

Immediately after removal femoral heads were placed into normal saline for the mean term of 2 hours ± 25 minutes at room temperature. Parallelepiped block with length of 5 cm, width 1±0.2 cm and thickness of 0.5±0.2 cm was formed out of the femoral head. The superior pole of the block preserved a cortical layer which approximated the experimental model to the anatomical. To compare implants fixation strength during the experiment the following implants were used: bioabsorbable PLGA screws 3.5 mm in diameter, 40 mm long, with screw pitch of 2 mm and flat head (PLGA pins) as well as titanium self-threading screws 3.5 mm in diameter, 40 mm long, with screw pitch of 2 mm and flat head.

In the first group 13 blocks were fixed with cortex bioabsorbable screws, 10 blocks — with titanium screws, 8 blocks — bioabsorbable pins. For comparison 10 titanium, 10 bioabsorbable screws and 7 bioabsorbable pins were implanted into bone blocks of normal density (T-criteria not exceeding -1 SD). Strength of screw fixation was examined by pull-out test using tensile-testing machine (RM-0,5) designed for tensile testing of materials with breaking load of 500 kgf-m² and speed of 20 mm/min. Sample fixation was done at the screw head and at bone block. Testing was done to evaluate force needed to pull-out the screw from "implant-bone" complex. The data was recorded using force measuring unit calibrated in kilonewton (kN).

Considering the obtained data the authors again harvested bone blocks from femoral bones of 31 female patients of the first group with proven osteoporosis and simulated internal fixation of avulsion fracture. For this purposes cubical bone blocks of 4×4 cm were cut from femoral heads; one of the angles of bone block was cut off in a pyramidal shape with preserved cortex. The size of cut off pyramidal fragment was 1,5 cm^3 which corresponded to the model of avulsion fracture (Fig. 1).

The experimental criterial for efficiency of internal fixation was obtaining of stable fragment fixation without its breakage during compression.

The bone blocks in experiment were divided into 3 groups. In the first group (11 bone blocks) internal fixation was performed after preliminary drilling according to AO recommendations [31] by titanium cortex screw with the full thread and in certain cases was accompanied by bone block fragmentation (Fig. 2). In the second group (9 bone blocks) the internal fixation was performed with bioabsorbable screw inserted by dynamometric screwdriver with torque of 0,8 Nm. In the third group (11 bone blocks) internal fixation was done with bioabsorbable pin (Fig. 3).

Fig. 1. Model of avulsion fracture on a cubic bone block

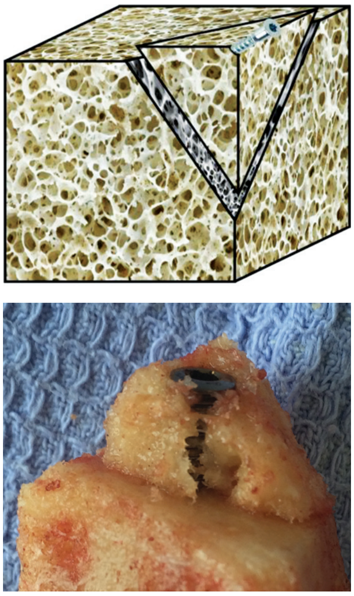

Fig. 2. Osteosynthesis with a metal screw resulted in bone fragmentation

Fig. 3. Schematic representation and model of the fracture osteosynthesis with a bioabsorbable pin

Clinical study

The clinical stage of the study included the outcomes of internal fixation of 65 patients, where 38 patients had a proven osteoporosis (T-criteria not exceeding -2,5 SD) and 27 patients without osteoporosis. The study included patients with avulsion fractures of 44A1-44A2, 44B2 types by AO classification, where 47 had medial malleolus fractures and 18 — fractures of lateral malleolus below the syndesmosis.

In 24 cases bioabsorbable screws were used for internal fixation, in 15 patients with osteoporosis and in 9 — without osteoporosis. In 31 cases AO/ASIF titanium screws were used: in 16 patients with osteoporosis and in 15 — without osteoporosis. In 10 cases the PLGA pins were used: in 7 patients with osteoporosis and in 3 cases — without osteoporosis. Primarily the evaluation of internal fixation efficiency was performed visually during the surgery. The present study also evaluated the adaptation and integrity of bone fragments. Displacement of bone fragment after fixation, breakage or delayed healing was evaluated in dynamics by X-rays in standard views.

Results

Bench biomechanical testing of cortex titanium screws stability proved that maximal displacement of titanium screw (1.1–1.2 mm) in the bone with decreased mineral density occurs at 0.26 kN, of bioabsorbable screw (1.0–1.1 mm) at 0.36 kN which is at 25.7% higher as compared to titanium screw, $t = 0.325$, $p = 0.749$. Migration of bioabsorbable screw occurred gradually with reduction of motion in the interval 1.2–1.3 mm and at force of 0.14 kN. The migration of titanium screw occurred almost in a single step. Test completion at zero force for titanium screw occurred at 1.8 mm displacement and for bioabsorbable screws — at 1.7 mm displacement (Fig. 4).

When evaluating resistance to pull-out force during fracture fixation by titanium screw and PLGA screw in bone blocks without osteoporosis (T-criteria not exceeding -1) the authors did not obtain any statistically significant differences ($p<0.05$). Pull-out force for maximal displacement of titanium screw from healthy bone (T-criteria ≥-1.5) was 0,44 kN, which was 2.8% higher that for PLGA screw, Student's test = -1.698, $p = 0.133$ (Fig. 5). Test completion at zero force for titanium screw occurred at 1.8 mm displacement, for bioabsorbable screw — at 1.7 mm.

Comparative studies of pull-out resistance tests for titanium screws and bioabsorbable pins demonstrated that the difference of breaking load for pulling out the pin from porotic bone did not exceed 0.106 kN which is 3% higher than for titanium screw ($t = -1.017$, $p = 0.324$) (Fig. 6).

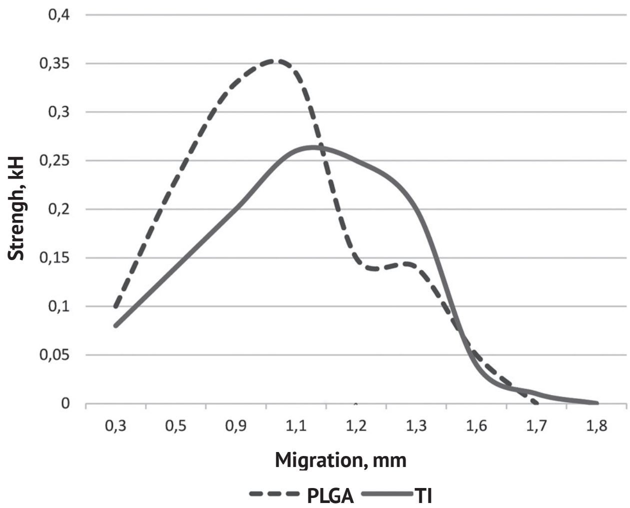

Fig. 4. Breaking strength for the titanium and bioabsorbable screw migration (T-score ≤-1.5 — osteopenia and osteoporosis)

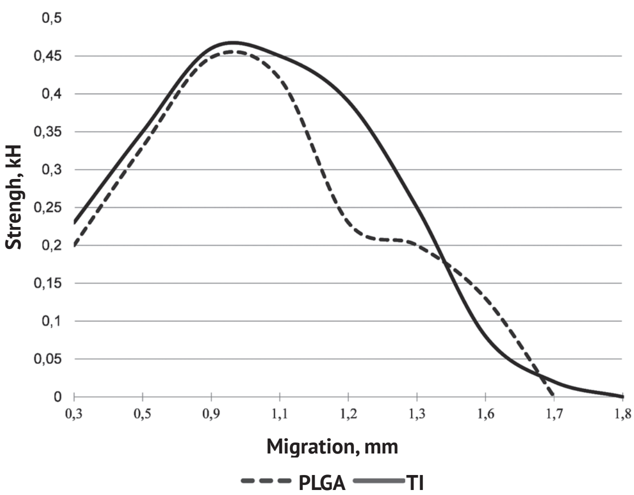

Fig. 5. Breaking strength for the titanium and bioabsorbable screw migration (T-score ≥ -1.5)

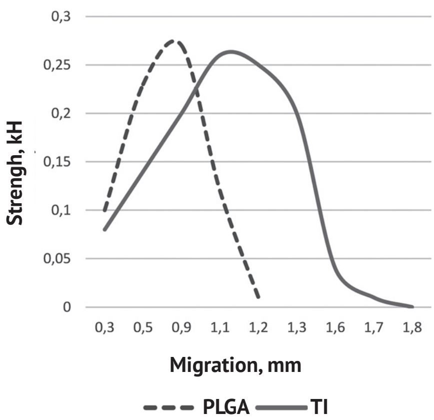

Fig. 6. Breaking strength for the titanium screw and bioabsorbable pin migration (T-score ≤-1.5 — osteopenia and osteoporosis)

Maximum displacement of titanium screw (1.2–1.3 mm) in the bone with decreased mineral density occurs at force of 0.26 kN, of bioabsorbable screw (0.8–0.9 mm) — at force of 0.28 kN. Pin migration occurred almost in a single step while for titanium screw the process was gradual. Test completion for titanium screw occurred at 1.8 mm displacement, for bioabsorbable pin — at 1.2 mm.

During experiment the authors evaluated the efficiency of internal fixation for avulsion fracture by signs of fragment breakage and observed that in 27.2% (3) cases the cortical titanium screw was breaking the bone fragment (table 1).

Comparative outcomes of various internal fixation techniques in the clinical practice from 2015 to 2017 were evaluated roentgenologically in terms from 2 to 6 weeks postoperatively. When assessing X-rays in terms shorter than 2 weeks posteopratively the primary importance was given to preservation of adaptation and anatomical structure of bone fragments (malleolus).

In terms up to 6 weeks the authors assessed consolidation process and status of screw canal after insertion. Table 2 presents comparative outcomes after various fixation procedures on weaker bones.

Table 1

Efficiency of internal fixation for marginal fragments

Criteria	Implant type		
	titanium screw	bioabsorbable pin	bioabsorbable screw
Number of internal fixation simulations	11 (100%)	10 (100%)	9 (100%)
Breakage of bone fragment	3 (27,2%)	0	0
Stable fixation	8 (72,72%)	10 (100%)	10 (100%)

Table 2

Outcomes of internal fixation of marginal fragments in clinical practice (*n*)

Outcome	Implant type					
	titanium screw		bioabsorbable pin		bioabsorbable screw	
	osteo-porosis	healthy bone	osteo-porosis	healthy bone	osteo-porosis	healthy bone
Stable fixation	12	14	7	3	15	9
Breakage of fragment and Weber fixation procedure	2	1	0	0	0	0
X-ray confirmed pseudarthrosis	1	0	0	0	0	0
Bone fragment displacement after fixation and early screw migration	1	0	0	0	0	0

Clinical studies demonstrate absence of bone fragment splitting and migration of implants in the area of fixed fracture, preservation of fragments adaptation and regeneration in the area of porotic bone fracture (Fig. 7).

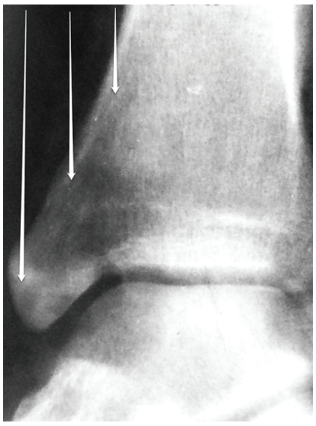

Fig. 7. X-ray of the medial ankle 2 weeks after osteosynthesis with a bioabsorbable screw

The analysis of outcomes after use of metal implants demonstrated risks of fragments breakage and secondary displacement (Fig. 8a) which required revision fixation and another technique — Weber procedure (Fig. 8b).

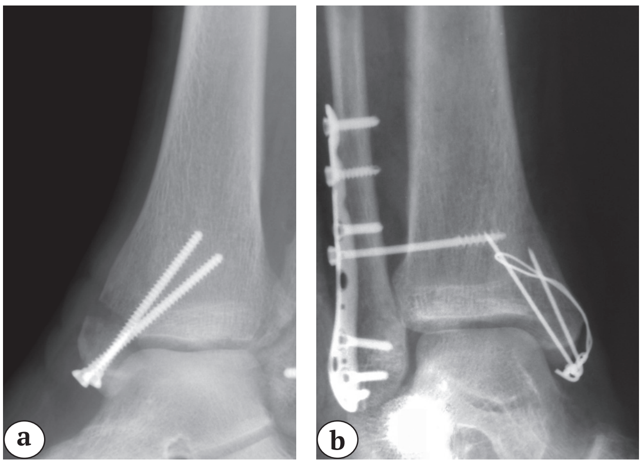

Fig. 8. X-rays of the medial ankle after osteosynthesis with a metal screw:
a — fracture and migration of bone fragment;
b — refixation by Veber in osteoporosis

In 12,5% (2) patients with avulsion malleolar fractures and osteoporosis the authors reported splitting and migration of bone fragment which required revision fixation (χ^2 Pearson df = 1, 1,41, p = 0.23, Mc Nemar χ^2 11.53, p = 0.007).

Discussion

Many authors report a growing number of avulsion malleolar fractures, first of all in elderly patients with low mineral density of bone and small fragments challenging for fixation which worsens surgery outcomes [18, 19]. The important predicting factor of stable fixation is the screw fixation strength in the bone. For 3.5 mm AO titanium screws O.C. Thiele et al demonstrated the dependency of strength fixation in the bone on osteoporosis degree where results of pull-out test for cortical bone decreased from 2500N in patients without osteoporosis to 1300N — with osteoporosis of severe degree [32]. Thus, conventionally applied fixation with screws of various thread types does not justify itself in trauma surgery for treatment of fractures in porotic bone.

Results of pull-out test obtained by authors during bench testing correspond to the data of Y.V. Lartsev et al on multi-stage migration pattern of metal AO screw during mechanical separation of fixed fragments at force of 0.09–0.14 kN [22]. Obtained experimental data on resistance of fixed fragments to pull-out forces after fixation by bioabsorbable screws as compared to titanium screws correlate to data of M.W. Kroeber et al study [33], where properties of bioabsorbable implants were significantly higher in cancellous bone fixation (68.5±3.3 N) versus titanium screws (3±1.4 N, p<0.05). Above allows to conclude about the advantages of bioabsorbable screws for some types of internal fixation. Described advantages of bioabsorbable pins and screws are explained by alterations in bioabsorbable implant size with arising geometry transformation, namely diameter increase with simultaneous shortening due to molecular hydratation which leads to secure fixation of pins and screws in the bone [26, 28]. Uniplanar force pattern without any rotation during pin insertion into small fragments significantly decreases the risk of their breakage [30, 31].

Small volume of analyzed data is the limitation of performed study. However, the obtained statistically significant results confirm the hypothesis on anchorage insufficiency of metal screw for internal fixation of avulsion malleolar fractures in patients with disturbance of mineral bone density and decrease of fragmentation risk of the already small fragments along with osteoporosis when using bioabsorbable fixators ($t = -1.017$, $p = 0.324$). At the same time in the healthy bone the fixation strength of fragments by titanium screws was comparable with parameters of bioabsorbable implants ($p = 0.133$). The obtained data allows to recommend bioabsorbable pins and screws for internal fixation of porotic bone.

However, bench testing doesn't allow to evaluate comparative dynamics of fixation properties depending on rate of dioabsorption and resistance to various types of mechanical loads, which needs further research.

Conclusion

Metal and bioabsorbable implants can be used for internal fixation of avulsion fractures of 44A1-44A2, 44B2 types by AO classification in cases of normal mineral bone density.

For internal fixation of bones with altered biomechanical properties it's preferential to use bioabsorbable implants while metal fixators can cause splitting and migration of bone fragments. This is confirmed by experimental and clinical stages of the present study.

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