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OPERATIVE TECHNIQUE FEATURES IN APPLICATION OF BIOABSORBABLE IMPLANTS FOR LIMB FRACTURES TREATMENT

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Bioabsorbable screws and rods were used for treatment of different types and locations of limb fractures in the CCH of RAS orthopedic trauma department between 2014 and 2016 for 120 patients. Interfragmentary fixation with bioabsorbable implants was applied as a single fixation method for 53 patients (44%), and in 67 (56%) cases it was combined with metallic plates and screws. Bioabsorbable implants were recognized as effective devices for interfragmentary fixation. Generally, bioabsorbable screws and rods did not require particular skills for the surgeon`s team and were in accordance with AO principles of fracture management. However, certain features are revealed, such as possible screw destruction when using an unsuitable instrument or applying excessive force; difficulties in defining the position and length of fixing devices due to their X-ray transparency, as well as visual transparency in the wound; the ability to adapt the length of implant; the desired insertion of screws through two corticals and the use of full or partially threaded screws in pairs. Also, it is desirable to fix implants in two cortices, and to use fully threaded and lag-screws together in a pair.

Key words: fracture, cannulated screws, bioabsorbable screws, operative treatment.

Introduction

A recent problem related to operative treatment of fractures is the need for implant removal, which is often done in several steps and also often more traumatic than the insertion of the implant, which includes all the risks of surgical intervention. This intervention is accompanied by complications and could lead to an increase in the total cost and total duration of treatment, as well as the expenditure of medical institution resources. The main reason for implant removal (from 20% to 46%) is the patient's insistence when there are no other symptoms [1, 2, 3, 4, 5]. This necessitates the minimization of re-operative activity, including through the use of implants that do not require removal, for example, when making interfragmentary compression and temporary fixation as one of the stages of multi-stage operative fixation of the fracture, with self-binding of the fragments with screws (including directed outside the main structure), and with fixation of apophyseal fractures [1, 6-8].

The improvement of polymer materials and the technology of their production was developed during the last years. It is now possible not only to produce biodegradable materials that have sufficient mechanical strength and are optimal for the treatment of fractures with a good degradation profile, but also to make it possible to produce devices that are close to the classic metallic ones in form, properties and operational techniques, allowing us to consider the most advanced biodegradable devices as a full-fledged alternative [9, 10-18]. Most of the studies on the use of biodegradable materials in traumatology and orthopedics, as well as the use of biodegradable devices for osteosynthesis, are related to the study of structures made from materials of previous generations, such as polylactic (PLA, PLLA) or polyglycolic (PGA) acids [11, 12, 16, 17, 19-24]. To date, one of the most advanced and promising materials is an oriented copolymer of polylactic (85%) and polyglycolic (15%) acids, PLGA [13, 15, 19, 25-28].

Obviously, due to differences in the characteristics of the materials, even with all possible congruency, the technique of using biodegradable implants will inherently have some distinctive features in comparison with the use of analogous products made out of metal [13, 29-31].

Purpose of the study

To determine the technical features of the use of modern biodegradable devices as a means of optimizing functionally stable osteosynthesis for bone fractures of the extremities, to facilitate the mastery of the technique by practicing physicians.

Materials and methods

This study was prepared in the framework of a study approved by the Committee for the Ethics of Scientific Research of the City State Educational Institution of Higher Education of the Russian Academy of Education (Moscow).

During the period from 2013 to 2016 in the traumatology department of the FSHI Central Clinical Hospital of the Russian Academy of Sciences, operative treatment with biodegradable devices was performed in 120 patients with closed limb fractures of various types and localization. The patients age ranged from 18 to 80 years, with an average age of 48.4 years. There were 53 men (44%) and 67 women (56%). According to the localization of the fracture, the patients were distributed as follows: humerus – 9 cases (7.5%), forearm – 13 (10.8%), condyle of the tibia – 16 (13.3%), ankle – 60 (50%), foot – 15 (12.5%), others (patella, talus, wrist bones, metatarsal bones) – 7 (5.8%). Interfragmentary fixation with biodegradable implants as the only means of osteosynthesis was performed in 53 patients (44%), in 67 patients (56%) biodegradable osteosynthesis were used together with metal plates and screws, and in 6 cases (5%) of tibia condyles fracture, osteosynthesis was supplemented using various bone substitutes. The type and method of surgical treatment were selected in accordance with the principles to reach functionally stable osteosynthesis [8, 32, 33]. Biodegradable screws and pins were used for interfragmentary fixation and compression using the same principles as for metal screws of a similar designation, with the exception of insertion them through metal plates or intramedullary nails.

As biodegradable implants, we used cannulated screws 3.5 mm, 4.0 mm, and 4.5 mm in diameter and pins 1.5 mm and 2.0 mm in diameter made of PLGA (polylactic and polyglycolic acid copolymer, PLGA 85L/15G), manufactured by Bioretec (Fig. 1). When necessary, metal implants of the Synthes, Konigsee, Smith & Nephew, and Medin were also used. The implantation was used as recommended by the manufacturer (Fig. 2). In general, the recommended procedure differs little from the standard technique of inserting an interfragmentary screw and consists of inserting a wire, reaming a bone with a cannulated drill, threading the channel by tap and inserting the screw into the prepared channel with a screwdriver (Fig. 3). The pins were inserted by a special applicator after reaming with a drill or wire. The cutting of the inserted devices was also included in the permissible actions.

Examination and treatment of patients were carried out in accordance with the current standards and included clinical examination, laboratory and instrumental studies indicated in accordance with the nature of the injury, anesthesia, prevention of TEC (thromboembolic complication), prevention of infectious complications (usually a single administration of an intravenous broad-spectrum antibiotic before the operation), bandaging of postoperative wounds, and treatment of concomitant pathology, if applicable. Early movements in the joints of the injured limb after surgery were generally allowed. External immobilization by a cast is used in order to relieve pain and edema and to encourage the healing process of soft-tissue wounds and was generally continued for no more than 2-3 weeks.

Fig. 1. General view of a biodegradable screw with an attached metal adapter head and container

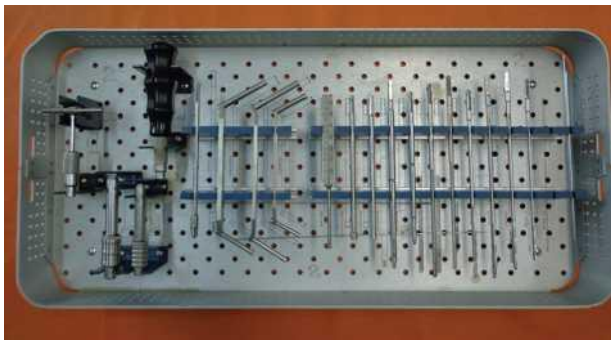

Fig. 2. An original set of tools for installation of biodegradable screws with a diameter of 3.5 mm, 4.0 mm and 4.5 mm

Also, in the course of mastering the technique of using biodegradable screws, the testing laboratory of orthopedic and traumatological items of FSBI Central Research Institute of Traumatology and Orthopaedics of N.N. Priorov (Accreditation Certificate of the Laboratory under the Federal Agency for Technical Regulation and Metrology No.ROSS RU.0001.22IM21) carried out a comparative study of the primary fixation strength of the fracture model type 41-B1.1 (by AO) on a artifical fracture of the tibia (SYNBONE AG, Switzerland) using the servohydraulic universal test machine LFV10-T50 (Walter + Bai AG, Switzerland). The fracture model was fixed with a pair of cannulated biodegradable partially threaded screws 4.0 mm in diameter and a pair of cannulated titanium partially threaded screws 4.0 mm in diameter (Synthes, Switzerland) according to the procedure recommended in the AO manuals (Fig. 4) [32].

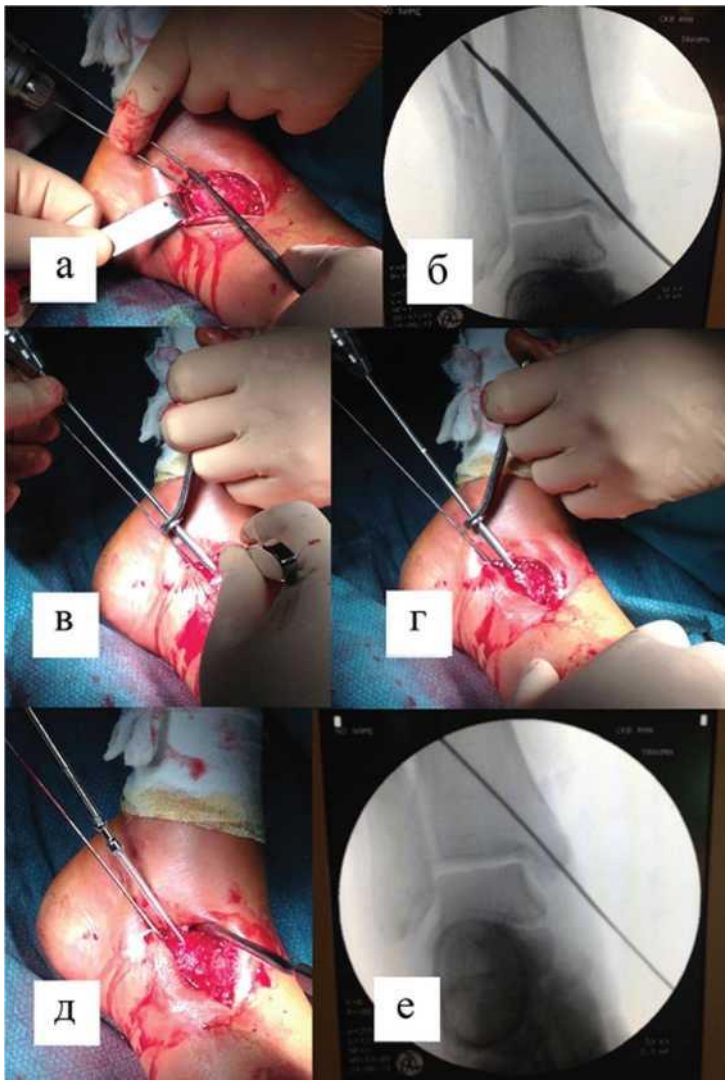

Fig. 3. Stages of the standard technique for inserting a biodegradable screw: а - fragment repositioning, fixation with wires, б - X-ray fluoroscopy (wires held to the opposite cortical bone layer), в - reaming the channel for the screw with a cannulated drill, г - tapping in the channel, д- insertion of the screw (partially threaded), е - X-ray check by intensifier, the screw is not visualized due to X-ray transparency

Results

When comparing the strength characteristics of the primary fixation of the fracture model with biodegradable and titanium cannulated screws, the results were fairly close. In particular, the ultimate strength for the fracture model fixed by biodegradable screws was 729.67 MPa, the destructive load was 0.75 kN (which roughly corresponds to a body weight of 76.5 kg), and displacement of fragments by 1 mm occurred at an application of force of 0.56 kN (~ 57.1 kg).

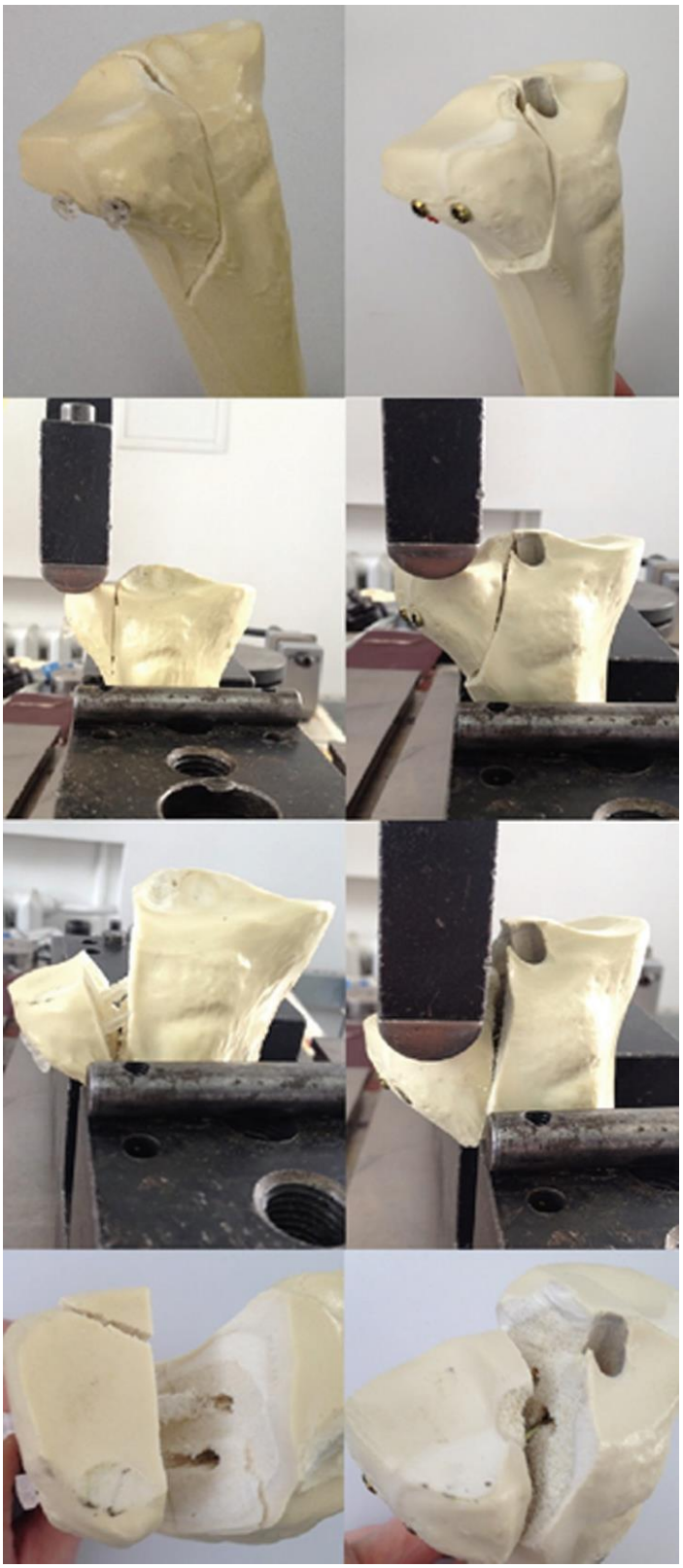

Fig. 4. Investigation of primary fixation strength of fracture model 41-B1.1 with cannulated biodegradable (left) and titanium (right) screws.

For the fracture model fixed with cannulated titanium screws, these values were 904.33 MPa, 0.9 kN (~ 91.8 kg) and 0.58 kN (~ 59.1 kg), respectively. The ultimate strength, when fixation was done with biodegradable screws, was 80.7% of titanium screw (analogous index), the destructive load was 83%, and the displacement of fragments by 1 mm occurred at an almost equal force (96.7% compared with titanium fixation).

According to the experience of our clinic, biodegradable screws proved to be a successful solution for the implementation of interfragmentary fixation, which is applicable in a significant number of clinical situations and is practically equivalent to metal screws for the use of positional, compression and temporal (intermediate) fixation of fragments in multi-stage reconstruction of complicated multi-fragmentary fractures. There were no local or general reactions to the implants. In the postoperative period there were three episodes of fixation loss and repeated displacement of fragments resulting from mistakes in the choice of surgical procedure, incorrect selection of the sizes of implants and the direction of their insertion. In particular, there was a repeated displacement of fragments of the distal meta-epiphysis of the radius due to an incorrect pre-operative evaluation of the fracture configuration and, as a consequence, the choice of the wrong osteosynthesis technique. Migration of a fragment of the large tubercle of the humerus due to an incorrect evaluation of the necessary screw length and the loss of direction of their insertion in an older patient with reduced bone density. Migration of fragments after osteosynthesis of the patella related to the use of too thin screws only partial threaded. There were also three episodes of intraoperative implant failure when inserting them, associated with the violation of the prescribed operative technique by the surgeon. This, however, was corrected by inserting the implants and the quality of the osteosynthesis was not affected at all. All of the above mistakes refer to the initial stage of mastering the technique, and they occurred during the first 4 months of using biodegradable implants. Delayed consolidation and non-unions were not observed in the remaining cases. After fracture union, the removal of biodegradable devices was not required, which either completely eliminated repeated surgical interventions or significantly reduced the volume of operations to remove the implants (also eliminating the risks involved in searching for separately inserted screws and the radiation load in such a situation) in cases of combined use of metallic and biodegradable fixatives.

A number of properties affecting biodegradable implant use emerged; specific features in operational technique, necessary equipment and surgeon's actions in procedure. These features include: less hardness compared to their metallic counterparts, greater elasticity, deformability, X-ray transparency, visual translucency and almost complete transparency when wetted. An important feature is the thread pitch, which corresponds to the same in cancellous and cannulated but not cortical metal screws (Fig 5).

In addition, it is necessary to remember both the limited shelf life and the specific requirements for the implant storage conditions. Attention should also be paid to the effect of Auto-Compression, which consists of implant shortening within 1-2% of the length with simultaneous widening to a similar value within 24-48 hours after insertion (Fig 6) [13].

Fig. 5. The configuration and thread pitch of the biodegradable screw and the corresponding tap are close to those of the cannulated and cancellous screws and do not correspond to the threads of the cortical screws

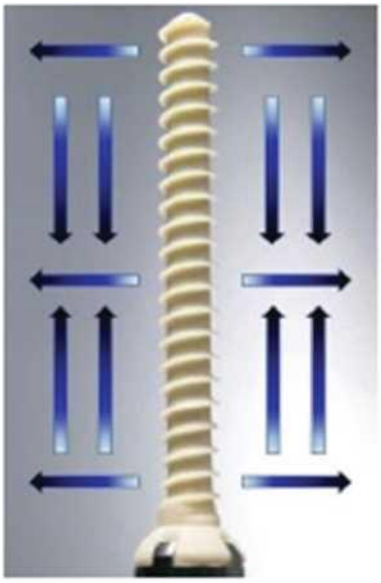

Fig. 6. Diagram of the phenomenon of Auto-Compression: shortening and widening of the screw when wetted within 1-2% of the initial linear dimensions during the first 24-48 hours

As a consequence of these particulars, we can consider the following. Biodegradable screws are not self-tapping, so the screw channel must be made with a tap that strictly corresponds in size before the implantation. Otherwise, the screw may collapse with the insertion attempt. Unlike metallic screws, PLGA biodegradable screws are not prone to self-centering in the prepared channel; the loss of direction (for example, when inserting in a tubular bone or in a metaphyseal zone with a reduced density) can involve excessive efforts when twisting and also breakage of the screw (Fig 7). Biodegradable screws can be drilled with standard drills and can be tapped. They can be cut by coagulating and cutting tools. When excessive force is applied, the screws can be destroyed and deformed. This is also possible when trying to unscrew an already inserted screw, and even a successfully turned out screw can have thread damage, making a repeat insertion pointless or impossible (Fig. 8). The screws have X-ray transparency; only the removable metal cap on the screw head and the guidewire (when present) are visualized. It is not possible to determine the screw tip position by intraoperative X-ray examination directly. When wetting the surface of the implant, it becomes visually almost transparent, which requires a good visualization of the installation zone (Fig. 9).

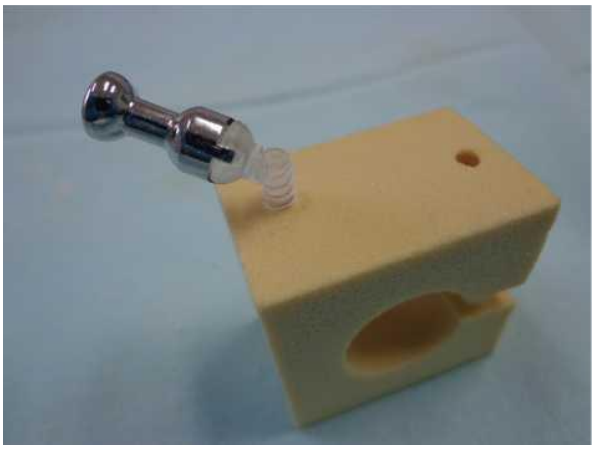

Fig. 7. Screw failure when applying excessive force in twisting

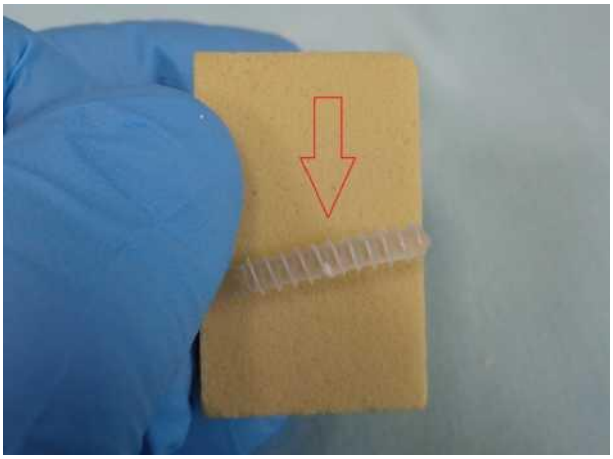

Fig. 8. Damage and deformation of the threaded part (marked by an arrow) after unscrewing with excessive force

A screw with full thread also performs the compression function due to the phenomenon of Auto-Compression, unlike the metal screws with full thread, which are mainly positional.

Thus, the common features of operational technique are as follows: the manufacturer's recommended procedure for the implantation must be strictly followed, and special attention should be given to matching the used drill and tap to the diameter of the screws. During provisional fixation of fragments, it is important to use wires that correspond in size to the tools for inserting screws. Using an inappropriate wire size will make it impossible to form a correct channel for the screw, or it can lead to clogging of the drill and/or tap with a bone plug.

The bone must be drilled and tapped for the entire length. It is possible to lose direction due to the "drilling" of the wire and its unintended removal together with the drill or tap (especially if their clear opening is partially blocked with a bone chip), which can lead to a failed insertion of the device. It's better to tap the channel by hand if possible or with the drill at a low speed. Tapping at a higher speed instead of cutting the internal thread can destroy the walls of the bone channel, making them unusable for implantation of the implant. Removal of the tap is performed strictly by reversing the drill

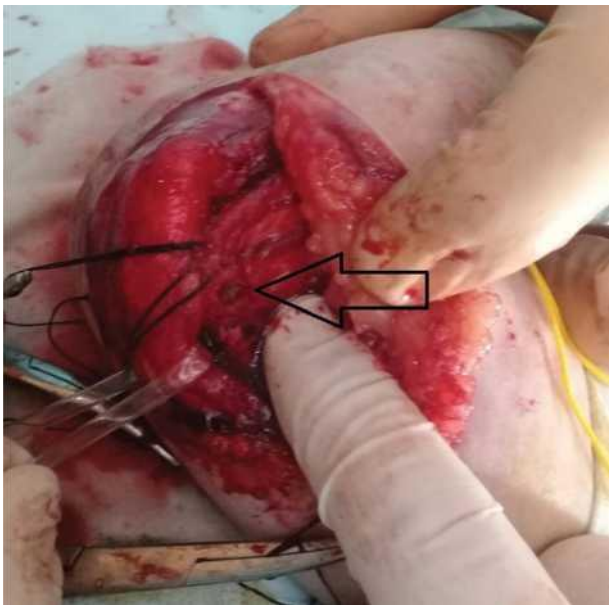

Fig. 9. The arrow indicates the head of the inserted screw. In the wetted state it is visually practically transparent

at low speed without applying additional force, or manually for the same reason. In very exceptional cases, a cancellous (cannulated) screw of the same diameter can be used as a tap, provided that the pitch of the thread is matched.

It is necessary to visualize the bone surface when inserting the screw and/or to perform thorough X-ray monitoring of the position of the head to ensure that it is set to a sufficient depth.

Do not try to unscrew the inserted implant or re-insert it, and do not apply excessive force in case of difficulty when inserting the screw, as it could be destroyed.

The implant can be cut at any stage if needed. The screw is cut with a coagulator (including an authorized tool) or forceps after insertion and from the side of the screw head (Fig. 10). Attempting to cut the threaded part of the screw with forceps will lead to deformation of the thread and the product itself (up to its cracking); also, the thread on the tip can be deformed by cutting it with a coagulator. Therefore, if necessary, shorten the threaded part of the cannulated screw using the "lathe machine" method: attach the cutting tool to the screw being turned by the drill, into the channel of which the guide wire is inserted (Fig. 11).

Fig. 10. Cutting the excess part of the inserted screw with a cutting tool

Fig. 11. Cutting the excess part of the screw thread before inserting by the "lathe machine" method

Biodegradable fixatives located in the bone after insertion can be reamed or drilled, which allows the device to be passed through each other (including the insertion of metal implants over biodegradable ones) without a conflict between the implants (Figure 12).

It is preferable to fix fragments with at least two screws (except for "provisional" fixation, or when it is impossible to use a pair of screws due to the limited space available for insertion).

If possible, the implant should be fixed in at least two cortices (as shown in Fig 3).

A combination of screws with partial and full threads is optimal: first, a screw with a partial thread is inserted to create a primary compression effect, and then a screw with full thread is inserted in order to achieve subsequent interfragmentary compression and to improve the fixation of the fragment due to the thread of the screw.

If the screw with full thread has passed beyond the fracture line and met an obstacle to its further insertion, it can be cut without compromising the quality of fixation (Fig 10) [34].

It is necessary to use screws with the greatest possible thickness.

Biodegradable screws cannot be inserted through the holes of metal plates or pins.

It is prohibited:

To use implants when the integrity of the packaging is broken.

To sterilize and re-sterilize, reuse devices.

To use expired implants.

To use implants that were not stored in accordance with storage conditions, for example, when there is a reaction from the thermo-index label.

The particular features of the use of biodegradable implants for osteosynthesis in fractures of limb bones are the following. Biodegradable screws are most effective in the treatment of metaphyseal fractures, including intraarticular and partial intraarticular (according to AO) fractures. They are most useful in the treatment of the following fractures: the proximal humerus, especially for fixing the large tubercle; the condyles of the humerus, especially type C according to AO for the reconstruction of the articular block of the humerus; the condyles of the tibia; fractures of the ankle (inner ankle, posterior border of tibia, syndesmosis lesions of the external ankle, fixation of the distal tibiofibular syndesmosis); and fractures of the heel bone. When fixing the large tubercle of the humerus and the inner malleolus, it is worthwhile to aim the screws through the opposite cortical layer of the bone to increase the reliability of fixation (Fig. 3). The same applies to the condyles of the humerus and shin bones. It is also possible to use biodegradable screws as augments when there are defects or a reduced quality of bone tissue for osteosynthesis with the plates of the tibial condyles or the external malleolus.

The possibility of fixing parts of the fracture with PLGA devices and use for the main part of the fracture fixation with plates without disturbing biodegradable implant is beneficial. Particularly positive is the possibility of using plates and PLGA devices during reconstruction of complex fractures of the condyles of the shoulder and tibial bone without the risk of conflict between the devices and the obstacles on their part for intraoperative X-ray control (Fig. 12). In the treatment of fractures of the calcaneus, biodegradable screws can be used both for fixing the main fragments, fragments of the articular surface of the calcaneus (including in combination with the pin for osteosynthesis of the calcaneus), and for primary arthrodesis of the subtalar joint.

Discussion of the results

Based on the experience gained, it is possible to identify the positive and negative properties of biodegradable implants for osteosynthesis in fractures of the limb. The positive features, besides no need for removal, include the possibility of adapting the implants before and after their insertion, the lack of conflict between implants, the ability to pass them through each other, no risk of secondary damage to the bone with a device, and compliance with the requirements of the AO principles (in particular, gentle impact on soft tissues and sufficient stability of fixation, which allows early weight bearing)

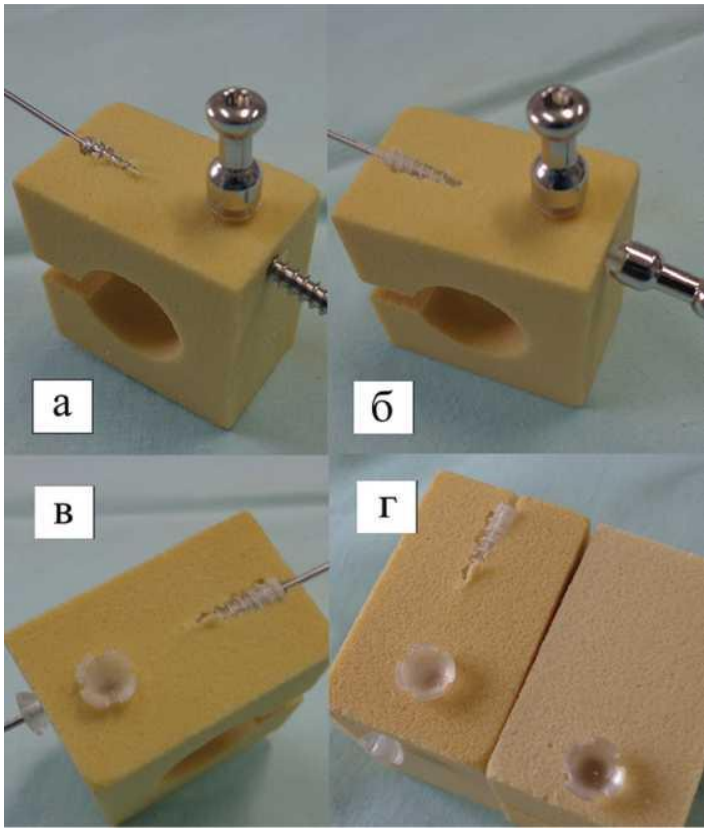

Fig. 12. "Screw through the screw": a - reaming of the inserted screw, б - holding a new screw in the formed channel, в, г - the inserted screw is observed through the semitransparent head of the first screw

The negative features include the following: less hardness and strength, greater fragility and deformability (especially the threaded part of the screws) as compared to metal products, difficulty of visualization due to X-ray transparency, limited shelf life and special requirements for storage conditions, and generally a more complex operational technique compared with similar metal implants. This leads to the idea of ways to improve this kind of device, in particular, making marks on the tip of the screw, increasing the strength of implants, strengthening the thread and, if possible, making the screws self-cutting.

The obtained results generally correspond to the published data of Russian and foreign authors on the experience of using biodegradable implants in traumatology [9-11, 13, 17, 19, 22, 23, 26, 35, 36]. However, I would like to note that we do not share the opinion about the need for additional external immobilization of the operated limb due to doubts about the fixation strength [35]. Also, it does not seem obligatory to expose the bone surface when inserting cannulated biodegradable screws for visual control of the screw head position, although, due to design features, this is required when pins are inserted, which reduces their value as a minimally invasive osteosynthesis device [13].

Conclusion

Biodegradable implants can be widely used in the complex operative treatment of limb fractures – in particular, practically in all cases (and stages of operations) when the insertion of interfragmentary screws is indicated (but not in combination with a plate). In this case, the combined use of metal structures with biodegradable implants is not only possible and expedient, but in a number of cases it is actually preferable.

The surgical technique for working with biodegradable screws is based on the generally accepted technique of inserting screws, but it has its own important features that require a surgeon to know them, and it requires heightened attention. In general, this technique is somewhat more demanding for the surgeon.

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OPERATIVE TECHNIQUE FEATURES IN APPLICATION OF BIOABSORBABLE IMPLANTS FOR LIMB FRACTURES TREATMENT

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Bioabsorbable screws and rods were used for treatment of different types and locations of limb fractures in the CCH of RAS orthopedic trauma department between 2014 and 2016 for 120 patients. Interfragmentary fixation with bioabsorbable implants was applied as a single fixation method for 53 patients (44%), and in 67 (56%) cases it was combined with metallic plates and screws. Bioabsorbable implants were recognized as effective devices for interfragmentary fixation. Generally, bioabsorbable screws and rods did not require particular skills for the surgeon`s team and were in accordance with AO principles of fracture management. However, some features were discovered of that implant type application, such as the possibility of implant destruction when incorrect instrumentation was used, X-ray and visual transparency while implanted that led to some difficulties in length measurement and implant position assessment, a possibility of implant length adaptation, drilling through implanted device that eliminates risks of implants conflict, and an opportunity for augmentation of bone defects by screws. Also it is desirable to fix implants in two cortices, and to use fully threaded and lag-screws together in a pair.

Key words: fracture, cannulated screws, bioabsorbable screws, operative treatment.