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Review

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Preoperative Planning Using 3D Printing as a Way to Improve the Outcomes of Surgical Treatment for Pilon Fractures

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RELEVANCE Despite the development of modern diagnostic methods, osteosynthesis instruments and rehabilitation, surgical management of distal tibia fractures remains a great problem due to the high complication rate leading to permanent disability, such as problems with soft tissue healing, infectious complications, post-traumatic arthrosis of the ankle joint.

These complications are associated with the high incidence of high-energy injuries, soft-tissue envelope features, and the wide range of movements in the ankle joint. At the same time, in the treatment for comminuted intra-articular pilon fractures, there is no clearly defined operation algorithm: choice of access, reduction and fixation techniques. Recently, when planning osteosynthesis, additive technologies have become increasingly widespread, in particular, 3D printing of full-size fracture prototypes.

AIM OF STUDY To analyze preoperative planning methods of osteosynthesis in pilon fractures and evaluate 3D-printing for the improvement of surgical treatment of pilon fractures.

MATERIAL AND METHODS The literature search was carried out in the databases of medical publications: PubMed, eLibrary, Cyberleninka. The search was performed using the following terms: pilon fractures, osteosynthesis, preoperative planning, 3D-printing, 3D-model, and the corresponding terms in Russian.

RESULTS According to various authors, the use of 3D printing in preoperative planning improves the parameters of operative duration, reduction quality, functional outcome, intraoperative blood loss, and reduces the number of complications.

CONCLUSIONS Evaluation of the long-term results of using 3D printing in preoperative planning for osteosynthesis in pilon fractures is ongoing. But even now we can draw conclusions about the prospects of the method and recommend it for widespread use in the routine practice of the orthopedic traumatologist.

Keywords: pilon fractures, osteosynthesis, preoperative planning, 3D-printing, 3D-model

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AO – Arbeitsgemeinschaft für Osteosynthesefragen - Association of Osteosynthesis
CAD – Computer-aided Design
CT – computed tomography
DICOM – Digital Imaging and Communications in Medicine
MRI – magnetic resonance imaging
PACS – Picture Archiving Communication System
STL – Stereolithography
VAS – Visual Analogue Scale

INTRODUCTION

Intraarticular fractures of the distal tibia, also known as pilon fractures, account for 5–7% of all tibial injuries [1, 2]. The term "pilon" was coined in 1911 by French surgeon Etienne Destot [3], and is translated as "pestle". Thus, Destot wanted to describe the mechanical action of the distal tibia on the talus, similar to the pressure of the pestle on the mortar. Pilon injuries are always unique; they represent "a complex intraarticular fracture covered by a thin and very sensitive soft tissue envelope" [4], so the choice of treatment tactics is always complex and individual.

Preoperative planning in a broad sense includes not only taking into account the characteristics of anatomical damage, destruction of bone and soft tissue structures, but also the severity of the patient's concomitant diseases, his functional activity. Factors such as gender, age, socioeconomic status, type of the patient's employment, and the relationship of injury to work also influence the determination of tactics and, ultimately, the outcome of treatment [5].

Specific features of fractures are presented in various classification systems. In clinical practice, the Rüedi–Allgöwer [6] and Association of Osteosynthesis (AO) [7] classifications, based on planar radiography data, are widely used. Rüedi and Allgöwer divide pilon fractures into groups depending on their nature and the position of bone fragments:

1. Fracture of the distal tibial metaepiphysis without significant displacement of bone fragments;
2. Fracture of the distal tibial metaepiphysis with significant displacement of fragments;
3. Comminuted fracture of the distal tibial metaepiphysis with significant displacement of bone fragments.

The AO classification suggests dividing fractures into groups according to the degree of damage to the articular surface:

Type A - extraarticular fracture of the distal tibial metaepiphysis. The identification of subgroups A1, A2 A3 is based on the number of fragments of the metaphyseal region and the degree of their fragmentation.

Type B - incomplete intraarticular fracture, in which the articular surface of the tibia splits, but part of it remains connected to the diaphysis of the bone. The division into B1, B2, B3 is determined by assessing the degree of impaction of the articular surface and the characteristics of the fragments.

Type C - intraarticular fracture of the tibia with complete separation of the articular surface of the tibia from the diaphysis by the fracture lines. The division into Cl, C2, C3 is associated with the assessment of the splintered nature of damage to the articular surface and metaphyseal part of the bone.

These classifications, although simple and straightforward, are not always good in terms of reproducibility, which prevents their use for planning the volume of operations [8–11].

The computed tomography (CT) method significantly expanded the possibilities of visualizing pilon fractures. On its basis, studies were carried out to map pilon fractures; as a result, a typical Y-shaped fracture pattern was described with the formation of three key fragments (medial, including the inner malleolus and the maximally loaded part of the

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articular surface; anterolateral – the Chaput fragment; and posterolateral – the Volkmann fragment – with ligamentous attachments) [12].

Based on CT, classifications were created that describe the morphology of the fracture in more detail.

In order to facilitate the planning of osteosynthesis, Topliss et al. [13] when analyzing computer tomograms identified 6 fragments (they do not all have to be present in every case) – anterior, posterior, medial, anterolateral, posterolateral and intraarticular with impaction: fractures with a predominantly sagittal (higher trauma energy, more likely varus deformity) and with a predominantly coronal fracture line (lower trauma energy, more likely valgus deformity). (Fig. 1).

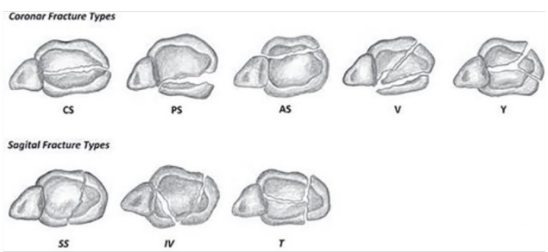

Fig. 1. Topliss classification system of pilon fractures [13]

Tang et al. [14] proposed a 4-column concept for the structure of pilon fractures, somewhat similar to the Topliss classification, without mentioning the central fragments. Understanding which column is predominantly affected allows surgeons to determine the access and location of the implant. (Fig. 2).

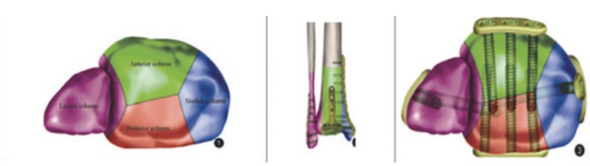
Fig. 2. Tang classification system of pilon fractures [14]

Leonetti and Tigani [15] published a classification system assessing four parameters: damage to the articular surface, displacement and number of intraarticular fragments, direction of the main fracture line and degree of comminution. (Fig. 3).

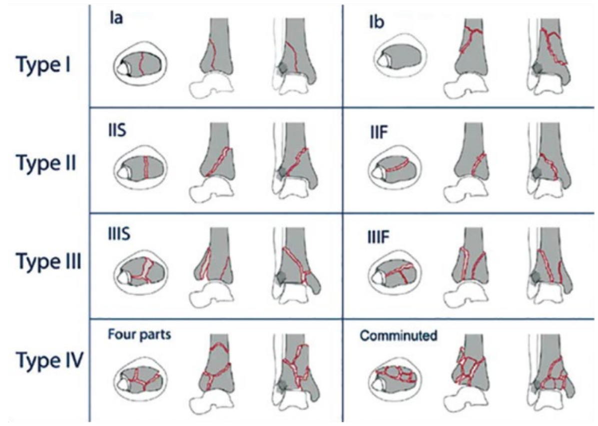

Fig. 3. Leonetti-Tigani classification system of pilon fractures [15]

A large number of studies examining different classifications of pilon fractures were carried out [16–18], and they demonstrated conflicting findings regarding the level of interrater agreement. Thus, Ramappa et al. asked five traumatologists-orthopedists to classify 47 CT images of various pilon fractures using the Ruedi–Allgower, AO and Topliss systems; in which case, the level of consistency of expert opinions turned out to be moderate [19]. Palma et al. [20] noted a high level of interrater reliability when using the Leonett–Tigani classification in 71 patients with pilon fractures; however, the results of a research by Xu-Sheng Qiu et al. [21] during which 70 fractures were classified using the Ruedi–Allgower, AO, Topliss, and Leonetti–Tigani systems, were not encouraging. The Topliss and Leonetti classifications were not recommended for use, and the AO classification showed good results only at the fracture group level.

Apparently, the reason for the inconsistency and problems with reproducibility of the Leonetti and Topliss classifications was their complexity: an abundance of components that must be taken into account, as well as different capabilities of computed tomographs in different clinics and programs for viewing them. Thus, the availability of CT does not make it possible to create a universal, simple and at the same time complete classification of fractures of this location, which facilitates planning their surgical treatment.

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The location of the fracture line beyond the cortical layer, the position of intraarticular fragments, and the extension of the fracture to the metadiaphyseal region determine the place of implant installation and, accordingly, surgical access. Moreover, in addition to assessing the bone injury, a thorough analysis of the condition of the soft tissues is necessary to determine the soft tissue window, identify (or assume) soft tissue interposition, take into account previous and possible subsequent surgical interventions on the segment – all these details significantly influence the planning of the operation. At the same time, the role of magnetic resonance imaging (MRI) in preoperative planning of surgical treatment for pilon fractures remains limited [5], since it has an auxiliary value with the main role assigned to CT.

One should also take into consideration the presence of concomitant injuries in the patients (abdominal injuries, spinal injuries, etc.), which may affect the patient's position on the operating table.

The choice of method and timing of surgical intervention depends on the general condition of the patient, the condition of the soft tissues, the morphology of the fracture, and the experience of the surgeon. The goals of treatment are reconstruction of the articular surface of the tibia, restoration of the axis, length and rotation of the limb, protection of the soft tissue envelope, as well as stable fixation allowing early rehabilitation training in the ankle joint [3, 22–24].

Surgical treatment options for pilon fractures include internal fixation [16], external fixation with limited or no internal fixation [25–27], or primary arthrodesis [2]. The "gold standard" in the treatment for pilon fractures since the publication of Helfet [28], Patterson et al. [29], and Sirkin et al. [30] became a two-stage treatment strategy consisting of the application of an external fixation device on an emergency basis and transition to submersible osteosynthesis after the edema has subsided and the skin has healed. This approach in the English-language literature is called "span, scan, plan" [31], and reflects the need to plan final fixation based on CT data of the pilon fracture strictly after applying a distraction device [32].

Currently, despite an established protocol for the treatment of pilon fractures and a wide choice of surgical techniques, there is no optimal strategy of the first level of evidence [33]. At the same time, the need for its planning, especially reduction, is an extremely important element. The likelihood of a poor reduction result with a particular type of treatment is an indication for choosing another one [34]. Clinical guidelines with flowcharts of decision making during planning were published [1, 35]. When analyzing the early and long-term outcomes of surgical treatment for pilon fractures, a large number of complications are still recorded. Duckworth et al. reported a complication rate of 27.5%, including primarily infection (17.6%), as well as loss of reduction, compartment syndrome, complex regional pain syndrome, and infected nonunion [36].

Pollak et al. [37] used the SF-36 questionnaire [38] to study the quality of life of patients after treatment for pilon fractures. The authors noted that 43% of previously employed patients were forced to give up working, and 68% of them associated this fact with the previous fracture. More recent studies have only confirmed these data: at least 75% of patients who underwent surgical treatment for pilon fractures complained of a noticeable deterioration in ankle function, and two-thirds of the respondents experience ankle pain on a daily basis [39–43]. Moreover, these patients take a very long time to return to their previous activities: 12 months after surgery, only 57% of patients return to work [44]. Within 2 years after surgery, 50% of the patients develop post-traumatic arthrosis of the ankle joint [28].

Improving understanding of fracture morphology and optimizing treatment planning is the key to success [45].

In a broad sense, planning is a set of measures necessary to achieve the main goal in the treatment of patients with a pilon fracture: consolidation in optimal terms and preservation of articulation in the ankle joint. It includes anatomical reduction with stable fixation and prevention of complications - secondary displacement of bone fragments and purulent infection.

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Michael Leslie [46] identifies five stages of planning: 1) determining the specific objectives of the operation (usually there are several of them); 2) determination of surgical approaches; 3) assessment of the condition of soft tissues; 4) selection of implant(s); 5) development of postoperative management.

Hak et al. [47] distinguish three stages of preoperative planning of orthopedic operations: 1) work with diagnostic images; 2) direct surgical tactics: step-by-step operation plan; 3) logistics of the operating room: requirements for the operating table and instruments, features of anesthesia, necessary instruments and implants. The transition from film radiographs to digital imaging, in the opinion of many, could symbolize the end of the era of classical preoperative planning [48]. However, standard office software (Adobe PhotoShopTM, Microsoft OfficeTM, Apple KeyNoteTM) is currently available for preoperative planning [49, 50]. In addition, more and more specialized programs are being created for planning orthopedic surgeries, such as TraumaCADTM, MediCADTM, OrthoViewTM, OrthoplanTM, Click2CorrectTM and others. Operating principle of these programs is the possibility to import PACS (picture archiving communication system) diagnostic image files from a local diagnostic workstation, identify individual fracture fragments and virtual reduction, and use the implant database to select an implant of the appropriate shape and length [51].

Despite the obvious advantages of using software for preoperative planning, it is necessary to note the limitations of the method: 1) organizational – requirements for computer equipment installed in the hospital, the need to purchase and renew a software license, train doctors; 2) software limitations – the need to update the implant database against the backdrop of a changing situation in the procurement market, the lack of possibility of individual modeling of the implant for the characteristics of a particular fracture, and the difficulty in extrapolating fracture reduction on a monitor screen to actual actions in the operating room. In this regard, there is a need to search for new methods of operation planning, for example, the use of additive technologies.

Aim of the study: To analyze methods for preoperative planning of osteosynthesis of tibial fractures using software, and to evaluate the possibilities of 3D printing for improving the outcomes of surgical treatment of distal tibia fractures.

MATERIAL AND METHODS

The search for sources was carried out using electronic databases of scientific literature – PubMed, eLibrary, Cyberleninka.

The following keywords were used: pilon fractures, osteosynthesis, preoperative planning, 3D-printing, 3D-model, and the corresponding terms in Russian. The depth of information search was 10 years. To analyze and evaluate literature data, criteria for including sources in the analytical study were determined.

The criterion for including sources in the study was the availability of the full text of the article or the structured one indicating specific quantitative data of the abstract.

Exclusion criteria: clinical examples, abstracts of reports, unpublished works, studies with signs of "duplication" (similar research protocol, groups, number of patients, etc.). In case of detecting duplicate articles, we chose a source that was later in date of publication.

RESULTS

The use of 3D printing in traumatology and orthopedics has increasingly become part of routine practice over the past 10 years [52–67]. There are more and more studies devoted to its use, primarily for preoperative planning [68]. Three-dimensional (3D) printing is a rapidly developing technology that allows surgeons to create a real physical object that has all the characteristics of its digital prototype. During printing, a 3D printer creates an object layer by layer without any distortion. 3D printing was invented and patented by American engineer Charles Hull (USA Patent No. 4575330, 1986) [69] and was intended for use in industry and architecture. However, the technology quickly found its application in medicine.

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Pal et al. [61] distinguish the following stages of 3D printing:

1. Creation of computer-aided design (CAD). A digital 3D model is developed by "stitching" a series of CT or MRI slice images using professional CAD programs. Images obtained from ultrasound, positron emission tomography, and some other examinations are saved in the DICOM (Digital Imaging and Communications in Medicine) format and are then post-processed in CAD programs that create a 3D model.
2. Conversion to stereolithography (STL) file is a critical stage in the 3D model creation process. Information about the object in STL format is stored as a list of triangular faces that describe its surface. The higher the resolution of the file, the more triangular faces, and the larger the file size. Before loading, the STL file must be cleared of interference, the model's dimensions must be corrected, its orientation in space must be made, the file is then transferred to the printer.
3. 3D printer settings, calibration, print speed setting, print material setting.
4. The actual printing. On most modern printers this process is completely automatic and only requires monitoring if a printing error occurs.
5. Post-processing. The removed 3D model is cleared of its casing, polished, and prepared for use.

The resulting full-size three-dimensional prototype of the fracture provides excellent visualization of the fracture in all planes, allows the operating team to evaluate all the specific characteristics of the fracture, confirm its type, the nature of the displacement of fragments, the location of the fracture line, the number of fragments, damage to the columns, and the presence of a bone defect. At the same time, the 3D model creates the conditions for individual, accurate and rational planning. The surgeon has access to simple visualization of all details of the fracture before surgery, which is an obvious advantage and the basis for developing an optimal surgical plan. The ability to simulate osteosynthesis on a 3D model can improve the accuracy of reduction and stability of fixation [70]. The use of 3D models in the treatment of ankle joint fractures demonstrates unique advantages, such as accurate reduction, correct selection of implants [71], minimizing operating time and intraoperative blood loss.

Zheng et al. [72] compared surgical treatment of pilon fractures according to modern AO standards with a treatment method supplemented with 3D printing assistive technology in 100 patients, dividing them into two groups of 50 people in the control and 3D groups. In these circumstances, statistically significant results in improving the quality of anatomical reduction according to Burwell-Charnley [73], reducing operating time, intraoperative blood loss, the number of intraoperative X-rays, and a higher proportion of good and excellent outcomes were found in the 3D group compared with the control group. However, in both groups there were no significant differences in the proportion of complications.

Bai et al. [55] in a meta-analysis of randomized trials of 486 patients treated for pilon fractures (there were 242 patients in the 3D groups) noted a statistically significant advantage of the 3D group in terms of reduction in surgical time, blood loss, as well as improvement in postoperative functional results, visual analogue scale (VAS) data, the proportion of good and excellent outcomes, and the quality of anatomical reduction. Some of the meta-analysis studies also noted the advantage of the 3D group in such indicators as the incidence of infectious complications [74, 75], fracture healing time [76, 77], the incidence of post-traumatic arthrosis [77] or malunion of fractures [72, 79]. However, the meta-analysis included many studies that only performed intraoperative assessment without analyzing long-term outcomes, so the effect of 3D modeling on long-term outcomes of treatment for pilon fractures remains to be studied.

In a meta-analysis by Yang S [78], based on 12 clinical studies, including 641 patients, the author noted the undoubted advantage of using 3D modeling in osteosynthesis in terms of the duration of surgery, reducing intraoperative blood loss and radiation exposure during surgery, as well as a larger number of excellent outcomes, and even a reduction in the average fracture healing time compared to conventional operations without the use of 3D

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models. The author associates this with the possibility to create the most realistic picture of the fracture, assess the number and direction of displacement of fragments, the condition of the articular surface, and the presence of bone defects. The knowledge gained is embodied in the surgical strategy, a deeper analysis of fixation methods with an understanding of the size and location of implants, which has a positive effect on the quality of reduction.

Other researchers also testify to a reduction in intraoperative blood loss and operating time when using 3D models in planning osteosynthesis [48, 79, 80].

Kang HJ [81] noted in his work that the use of 3D models of intraarticular pilon fractures in 56% of cases led to a change in the choice of plate relative to the one selected only based on CT data.

Oki et al. [82] report the successful use of 3D planning for surgical treatment of a pilon fracture in combination with fibular head dislocation: given the absence of a fibular deficiency, the dislocation was not diagnosed, however, 3D planning revealed tibial deficiency, which contributed to the detection of fibular head dislocation. The operation was performed in two stages: first, elimination of the dislocation and fixation of the fibula, then osteosynthesis of the pilon fracture.

Nonetheless, the use of 3D models has some limitations. Firstly, when producing a 3D model, CT information about bone structures without data on the state of soft tissues and their blood supply is used. Also, the absence of "soft tissue" in the 3D model can disorient the surgeon in terms of the location of the plate and the direction of the screws, as described in the article on 3D modeling of osteosynthesis of the acetabulum and wrist joint [83, 84]. Secondly, the actual printing of one 3D model takes, on average, 10–12 hours, which makes it difficult to use in emergency cases; and, taking into account the software processing time, a longer process of preoperative preparation somewhat disavows time savings during surgery [85]. Moreover, 3D printing technology requires the use of specific software, qualified personnel, availability of 3D printers and consumables, which can increase the cost of treatment; although over time, the cost of using this technology is gradually decreasing [86]. There is an opinion that 3D printing, although certainly useful in planning osteosynthesis of complex fractures, should not be used routinely in 100% of cases [87]. Of course, when introducing the use of 3D models, it is necessary to take into consideration the learning curve of personnel, which can affect the production time of models and their quality [88].

CONCLUSION

The use of 3D models in planning surgical treatment for distal tibia fractures can reduce surgical time and simplify the selection and adaptation of appropriate implants for osteosynthesis. The technique of creating 3D prototypes itself continues to develop. There are publications about the use of artificial intelligence in the creation of these models: information has appeared about the so-called 4D printing, in which the mechanical properties of the bone are imparted to the prototype material [89–91].

Evaluation of long-term outcomes continues, and more and more studies are emerging confirming the positive impact of using this high-tech method. This allows us to conclude that it is promising and recommended for widespread use in the routine practice of the traumatologist-orthopedist.

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