

Surgical treatment of patients with tumors of long bones of upper limbs using tailored 3D printed bone substitute implants

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Purpose To evaluate outcomes of surgical treatment of patients with tumors of long bones of upper limbs using a single-stage repair of bone defects with tailored bone substitute implants manufactured with 3D printing technique. **Materials and methods** Clinical and radiological assessment of 22 patients with tumors of long bones of upper limbs was produced after surgical treatment that included removal of neoplasm and one-stage bone plasty using a tailored implant manufactured with three-dimensional printing (Patent RU 2598769). Bone cement and Recost bone substitute (Patent RU 2518753) were used to produce an implant. All patients were evaluated preoperatively and at 12-month follow-up using the 36-item Short Form Health Survey (SF-36), Musculoskeletal Tumor Society (MSTS) Rating Scale and visual analogue scale (VAS). **Results** Postoperatively, all patients showed pain reduction and improved function of the upper limb. No radiographic evidence of implant migration was observed throughout the followup. Evaluation of benign patients at one year after surgical intervention showed average 71.4 ± 6.6 of SF-36, 2.5 ± 1.5 of VAS, and 65.1 ± 8.3 % of MSTS scoring system; malignant cases demonstrated average figures of SF-36 39.2 ± 4.3 , VAS 4.8 ± 1.4 , and 41.8 ± 5.2 % at MSTS rating scale. **Conclusion** Surgical treatment of patients with tumors of the humerus, ulna and radius using one-stage plasty of bone defects with tailored 3D-printed bone substitute implants has shown to be an efficient method in improving an affected upper limb function and patient's quality of life. The use of 3D printing to manufacture implants allows for precise and single-stage repair of bone defects of any shape, size and complexity with the technique making surgery easier to perform.

Keywords: 3D printing, tailored bone substitute implant, bone tumor, orthopaedic oncology, personalized medicine

INTRODUCTION

Management of patients with oncologic bone pathology has been one of the challenges of the contemporary medicine. The morbidity rates of both primary and metastatic tumour lesions of human bone and muscular systems have been growing each year. More than 2.900 cases of osteogenic sarcoma have been diagnosed annually [1–3]. Moreover, a number of malignant diseases develop metastasis in the bone tissue. Skeleton lesions were revealed in 65 to 73 % of mammary gland carcinoma cases, in 56 to 68 % of prostate adenocarcinoma and in 30 to 36 % of lung cancer cases [4, 5]. Most frequently (40 to 70 %), bone tumours develop in long bones [6]. In the upper limbs, the most frequent tumour locations are the proximal (more than 40 % of cases) and diaphyseal (about 15 % of cases) parts of the humerus, or distal radius (about 20 % of cases) [2].

Primary tumours and metastatic foci in the locomotor system impair considerably the patient's quality of life, result in disability or mortality in

many cases [7]. Mortality rates due to pathological fractures reach 32 % [8].

The main methods of bone tumour management is surgical. One-year survival was reported in only 8 to 13 % cases of multiple bone metastasis if no surgery was performed [6, 9]. Amputation of limbs was used in most bone oncological cases up to the 1970s. Limb salvage operations are a priority for such cases nowadays and include resection of new formations followed by plasty of the bone defect with autologous bone or implants fabricated from synthetic materials [4, 10, 11]. The use of 3D printing in the manufacture of such implants provides high precisions and personification, and a possibility to create any implant shape and size [12, 13, 16, 17].

The purpose of this study was to assess the results of surgical management of patients with an oncologic pathology in the upper limb long bones that included an immediate bone defect plasty with individual implants made of bone substance substitutes and fabricated with 3D printing technology.

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MATERIAL AND METHODS

We conducted a clinical and radiographic examination of 22 patients after surgical treatment for upper limb bones oncologic pathology. It included the removal of the neoplasm and an immediate bone plasty with an individual implant manufactured using 3D printing. There were 10 males in the mean age of 44.5 ± 3.8 years (range: 41–49; confidence interval: 95 %) and 12 females in the mean age of 56.3 ± 4.2 years (range: 51–62; confidence interval: 95 %). The pathological focus in 11 patients was in the humerus. In seven cases its location was in the radius, and in four cases it developed in the ulna. Benign neoplasms were identified in 13 (59 %) patients and malignant ones in 9 cases (41 %). All patients with benign tumors presented complaints of pain and functional impairment in the upper limbs. All patients with malignant neoplasms underwent a course of radiation- and chemotherapy at the prehospital stage. The diagnosis was confirmed by histological and immunohistochemical examination of the material after an open biopsy.

The tumor was removed after the verification of the diagnosis, followed by substitution of the bone tissue defect formed with an individual implant which was manufactured according to the developed technology [14]. To do this, using patient's computed tomography image, a virtual 3D model of the damaged segment was created with the parameters (0–250) on the Hounsfield scale, characteristic of bone structures. Next, with the help of standard tools for computer modeling, the virtual tumor was removed within the limits of healthy tissues (**Fig. 1**).

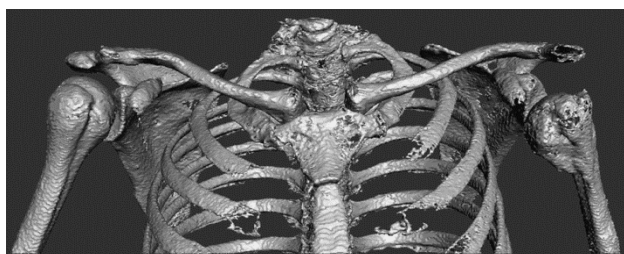


Fig. 1 Virtual three-dimensional model of bone tissue of the patient with a pathological formation in the left proximal humerus

Then, the missing bone tissue sections were reconstructed with the implant created using 3D modeling with the techniques of topological optimization and hybrid parametric modeling (**Fig. 2**).

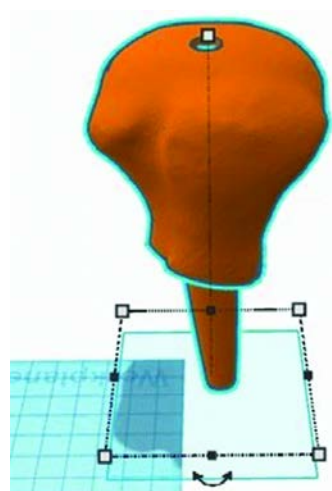


Fig. 2 The stage of hybrid parametric implant modeling

Then, based on the obtained data on the three-dimensional structure of the implant, a virtual model of the matrix was created which was subsequently used for implant production from bone-substituting materials. After that, the matrix model was sent (via a USB cable) to a FDM 3D printer for manufacture (**Fig. 3** and **Fig. 4**).

Upon three-dimensional printing completion, a liquid bone substituting substance was impregnated into the created matrix. When it solidified, the matrix was disassembled. As a result, there was an implant that was transferred to the operating room after sterilization.

With extensive defects (more than 5 cm²), crushed allograft chips were used along with the bone substitute material which was prepared according to standard techniques from allografts used at the institution. According to the indications, osteosynthesis was carried out with metal structures to reinforce the damaged area of bone tissue and prevent fractures in the postoperative period. For this, plates and intramedullary rods were used. Radical resection of neoplasm was checked using an express study of the tissues from the sawn bone ends.

Bone cement (polymethylmethacrylate) or bone substitute substance *Rekost* developed with the participation of FGBU Privolzhsky Federal Medical Research Center was used for fabrication of individual implants [15]. The implant material was chosen randomly using the method of even and odd numbers of medical case records (**Tables 1** and **2**).

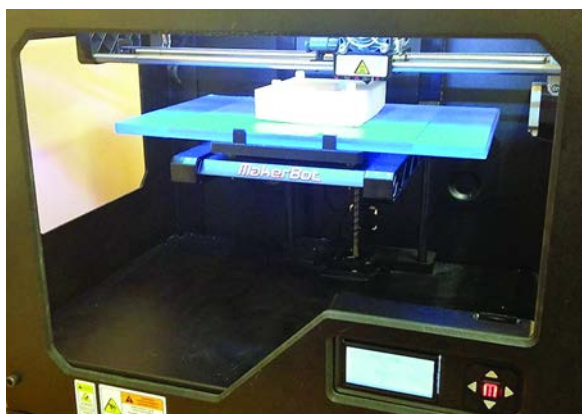


Fig. 3 Manufacturing of a matrix with the 3D printer (Makerbot replicator 2, USA)

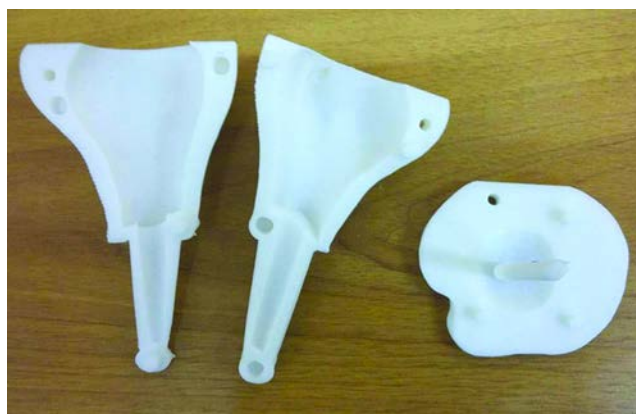


Fig. 4 Matrix for an individual implant

Table 1

Distribution of patients depending on the disease and the materials used to fabricate implants

Classification	Diagnosis	Material used	
		Bone cement	Rekost
Benign formations	Enchondroma	1	5
	Osteoblastoclastoma	1	1
	Non-osteogenic fibrosis	1	1
	Solitary bone cysts	2	1
Malignant formations	Osteogenic sarcoma	1	1
	Metastasis of mammary or prostate gland and lung cancer	5	2
Total		11	11

Table 2

Distribution of patients depending on the location of the lesion and the implant materials

Lesion location	Material used		Total
	Bone cement	Rekost	
Humerus	7	4	11
Ulna	2	2	4
Radius	2	5	7
Total	11	11	22

The following questionnaires were used for clinical examination of patients: Short Form-36 [18], Musculo-skeletal Tumor Society (MSTS) [19] and Visual analog scale (VAS) [20].

All patients were examined and interviewed before the operation and at a 1-year follow-up after it.

The study was carried out in accordance with the ethical principles laid down by the *Helsinki Declaration of the World Medical Association* (the World Medical Association Declaration of Helsinki (1964, and 2011 amend-

ments)) and the *Rules of Clinical Practice in the Russian Federation* approved by the order No. 266 of the ministry of health of the Russian Federation dated June 19, 2003.

The statistical processing of the data was carried out using the Statistica 6.1 software. The results are presented as $M \pm \sigma$ where M is the arithmetic mean and σ is the standard deviation. Assessment of the reliability of differences between the groups was carried out using the Mann-Whitney U-test. Differences with a probability level of $p < 0.05$ were accepted as reliable data.

RESULTS

When examined one year after surgical treatment, all the patients had a positive postoperative dynamics such as decrease or absence of pain, increase in the range of movements in the joints of the affected upper limb, and improvement of their quality of life.

Patients who underwent operative treatment for malignant tumors resumed their habitual life and labor activity in 44 % of cases (4 patients). A partial restoration of the upper limbs functions was observed in 5 (56 %) patients. The Short Form-36 results for physical functioning were 18.4 ± 2.1 points as compared with 4.9 ± 1.7 points before surgery. The mental health score

was 20.9 ± 2.3 points while it was 5.3 ± 2.2 points prior to surgery.

The results of the examination of patients with benign tumors according to Short Form-36 were 30.3 ± 7.4 points for physical functioning (11.6 ± 2.9 points before surgery) and 40.7 ± 6.2 points for mental health (16.5 ± 3.3 points before the operation). All the patients were able to resume normal life and work activities.

Statistically significant ($p < 0.05$) improvement in the parameters after the surgical treatment was also observed in all groups according to the results of the VAS and MSTS questionnaires (**Table 3**).

Table 3

Results of patients' questionnaires before and after surgery

Questionnaire		Benign formations		Malignant formations	
		Before surgery	12 months after surgery	Before surgery	12 months after surgery
Short Form-36	Rekost	30.6 ± 6.9	73.7 ± 7.2	9.1 ± 3.5	37.0 ± 3.2
	Bone cement	25.3 ± 5.1	69.2 ± 5.9	11.2 ± 4.2	41.4 ± 5.3
	Mean in the group	28.1 ± 6.1	71.4 ± 6.6	10.2 ± 3.8	39.2 ± 4.3
MSTS	Rekost	27.1 ± 5.4	61.9 ± 6.5	10.2 ± 5.1	39.5 ± 6.9
	Bone cement	24.2 ± 3.6	68.3 ± 10.2	13.1 ± 7.7	44.1 ± 3.5
	Mean in the group	25.7 ± 4.3	65.1 ± 8.3	11.7 ± 6.5	41.8 ± 5.2
VAS	Rekost	5.3 ± 1.2	2.1 ± 1.8	8.1 ± 1.3	5.3 ± 1.1
	Bone cement	6.1 ± 2.3	2.8 ± 1.1	7.2 ± 1.2	4.2 ± 1.6
	Mean in the group	5.7 ± 1.8	2.5 ± 1.5	7.7 ± 1.3	4.8 ± 1.4

Note. Short Form-36 and VAS estimate the results in points. The outcome is estimated in % by MSTS.

To test the hypothesis of improving the scores on all the scales after surgical treatment, the Mann-Whitney U- test was used. In the group as a whole and in the subgroups formed according to the material used for implants, a statistically significant increase in the MSTS and Short Form-36 indices and a decrease in the VAS score ($p < 0.05$) were revealed. There were no statistically significant differences by comparing the subgroups depending on the material used ($p > 0.05$).

Migration of the implants was not detected by radiography of the upper extremities in patients at long-term postoperative period. According to computer tomography, the presence of marginal osseointegration was revealed in 4 (36 %) patients who underwent replacement of the defects using an implant from the developed bone-substituting material Rekost. Among them, two patients had an operation for the enchondroma, one had a bone cyst, and one had metastasis of breast cancer.

We present two clinical cases to demonstrate the results of surgical treatment of upper limb oncopathology with the use of personified implants from bone substitute substance using the developed technology.

Clinical case 1 Patient K., 58 years old. Diagnosis: metastatic lesions in the upper third of the right humerus. Adenocarcinoma of the prostate. Complaints of pain, impaired right upper limb function. The range of motion in the right shoulder joint: extension/flexion – 5° / 0° / 30°; abduction / adduction – 30° / 0° / 10°; rotation external/internal – 5° / 0° / 10°. Results of a pre-surgery examination: 8 points (VAS), 38 points (Short Form-36), 25 % (MSTS). According to roentgenographic findings: pathological formation in the upper third of the right humerus (**Fig. 5**).

Segmental resection of the pathological focus was carried out followed by bone grafting of the resulting defect with an individual implant from bone cement and fixation with intramedullary UHN nail (**Fig. 6**).

The postoperative period proceeded without complications. Follow-up study was performed 1 year after the operation with the results: 3 points (VAS), 70 points (Short Form-36) and 75 % (MSTS). The range of movements in the right shoulder joint: extension / flexion – 5° / 0° / 90°; abduction / adduction – 70° / 0° / 20°; rotation external/internal – 20° / 0° / 20°.

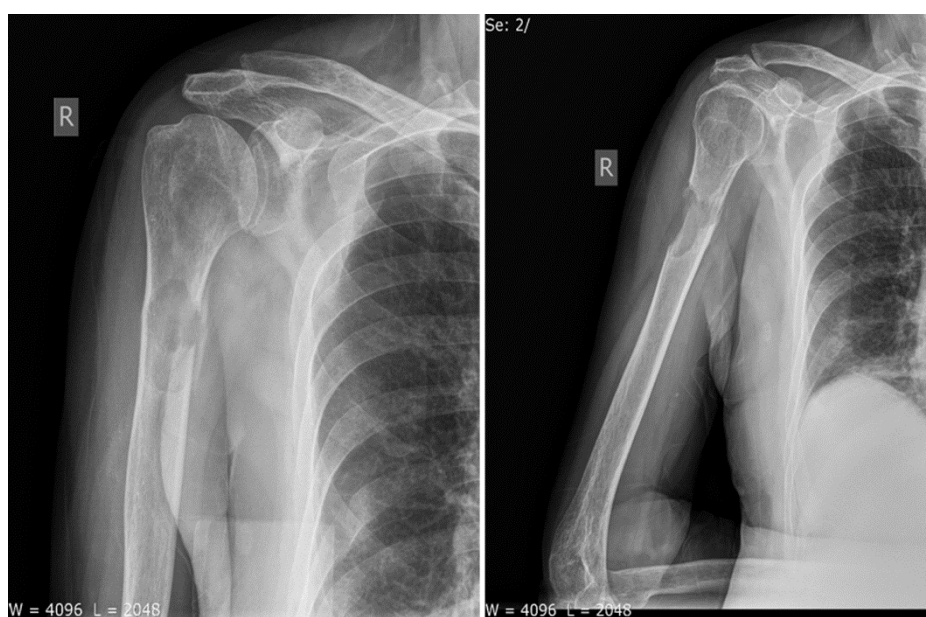


Fig. 5 Radiographs of the right humerus taken before operation

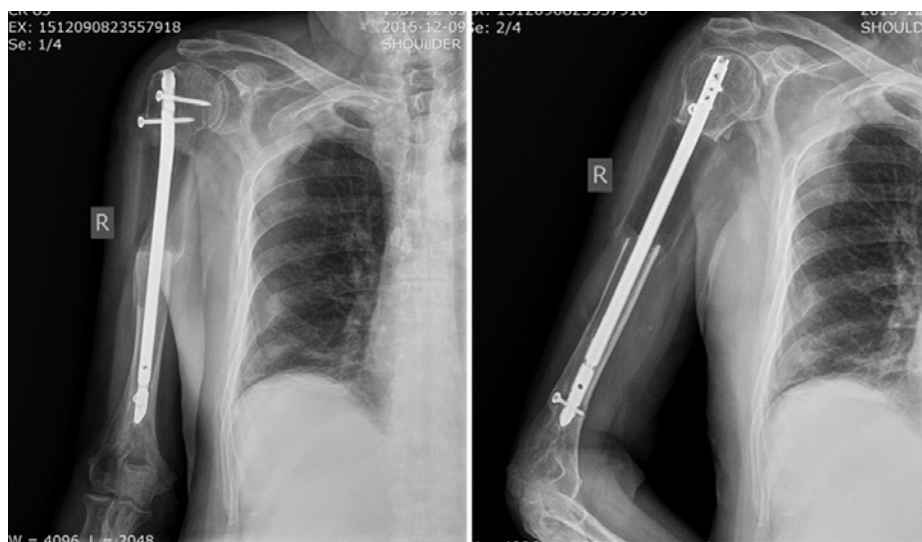


Fig. 6 Radiographs of the right humerus taken one year after the operation

Clinical case 2 Female patient B., 55 years old. Diagnosis: pathological fracture of the left humerus. Metastasis of right breast cancer. Complaints on admission: pain, impaired function of the left upper limb. Injury was not in her history. The results of the questionnaires conducted before the operation: 8 points (VAS), 39 points (Short Form-36), and 15 % (MSTS). Movements in the left shoulder were not possible due to severe pain. According to radiographic study: a pathological fracture at the border of the upper and middle third of the diaphysis of the left humerus (**Fig. 7**).

The pathological focus was removed, followed by bone grafting of the defect with an individual implant from the bone-substituting substance *Rekost* which is X-ray negative. The UHN intramedullary nail was used for fixation (**Fig. 8**).

The postoperative period proceeded without any complications. At a 1-year follow-up, the patient's scores were 3 points (VAS), 71 points (Short Form-36), and MSTS was 67 %. The range of movements in

the left shoulder was: extension / flexion – 5° / 0° / 80°; abduction / adduction – 60° / 0° / 20°; rotation external / internal – 15° / 0° / 20°.

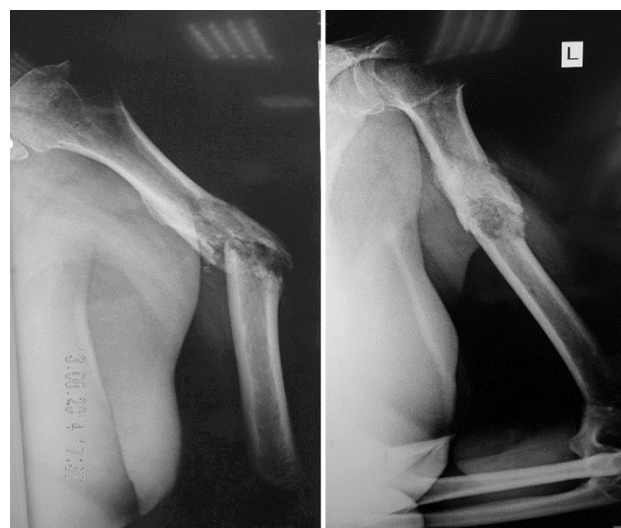


Fig. 7 Radiographs of the left humerus taken before surgery

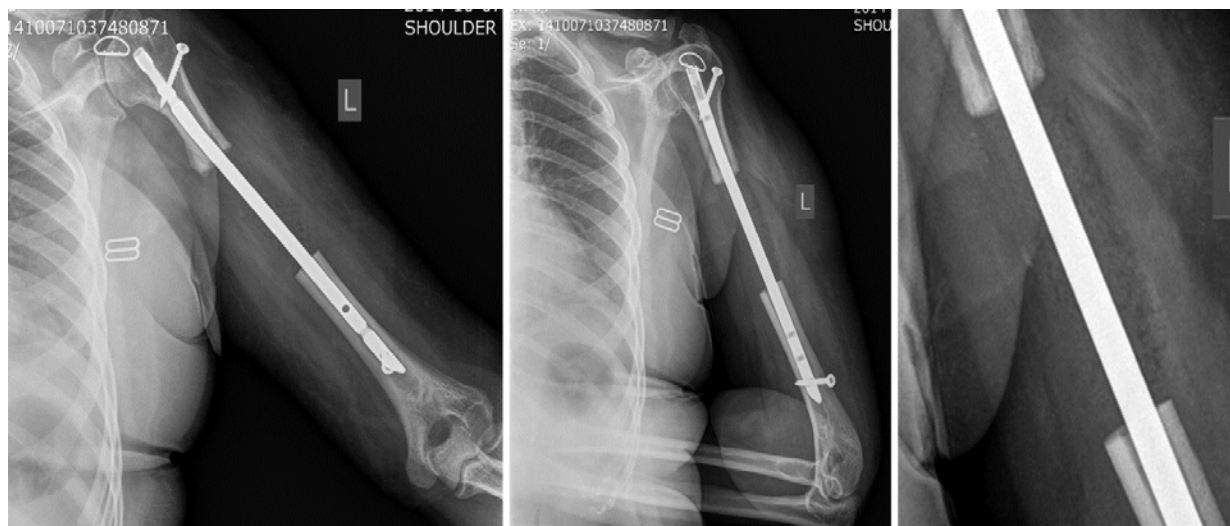


Fig. 8 Radiographs of the left humerus taken 1 year after the operation

DISCUSSION

One of the main problems in bone oncopathology management is the replacement of the defect formed after tumor resection. The use of autografts for this purpose is restricted by the need for an intraoperative modeling, limited graft volume, and traumatization of the donor site. The use of xeno- and allografts necessitates the presence of a bone bank and has a high probability of histological incompatibility of tissues. Also, the nonunion rate reaches 33 % with at their use. In addition, the use of biological grafts requires a long-term immobilization, and there is no possibility of early functional treatment [1, 3, 21–23]. Also, oncological endoprotheses can be used but their application is associated with a high risk of developing aseptic instability or necrotic processes at the site of their contact with the bone resulting in revision surgery [22, 24]. The existing techniques and technologies for manufacturing serial implants do not provide for the possibility of their modeling and topological adaptation with a precise correspondence to the physical and volumetric sizes of the defect or their creation from osteosubstitut-

ing material for surgical treatment of bone oncopathology with a large limb segment lesion [16, 17]. The developed technology of individual implants has assisted to avoid these shortcomings.

The use of matrices in the production of implants from bone cement ensured the absence of thermal damage to the patient's bone tissue which occurs when this material solidifies.

Given the absence of statistically significant differences in the evaluation of the clinical outcomes of patients with the use of implants from bone cement or bone substitute and the presence of marginal osseointegration in 4 (36 %) cases, we believe that *Rekost* can be a priority in the choice of material for individual implants.

The absence of radiographic signs of implant migration, in our opinion, is due not only to stable fixation with metal structures but also to elastic compression by the patient's bone tissue. Bone defect can be precisely replaced thanks to the developed technology of implant manufacturing.

CONCLUSION

Personalized implants fabricated with three-dimensional printing according to the developed technology allow for a precise and simultaneous replacement of bone defects of any shape, complexity and size that arise after removal of the tumor and simplify the technique of surgical intervention. The use of matrices makes it possible to create implants from any bone-substituting materials that have a liquid stage during solidification and to avoid thermal damage to the body tissues with bone cement. In all patients, we observed a positive dynamics

after operative treatment: decrease in the intensity or total absence of pain, better results of MSTS, Short Form-36 and VAS questionnaires. Surgical treatment of patients with oncopathology of the humerus, ulna and radius with the use of one-stage bone plasty of the defects formed by their substitution with individual implants made from bone substitute material and manufactured using 3D printing technologies is one of the effective methods for improving the function of the affected upper limb and the quality of patients' life.

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