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Throughout science, digitization is occurring in shorter waves than ever before. Digital transformation can reduce operational costs and inefficiencies, and puts the technology of scientific studies/research at the center of scientific strategy. Highly complex interactions between many technologies, activities, and people make up modern scientific work.

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Scholars, professionals and experts whose work is related to the digital transformation of modern socio-economic and engineering systems in the digital age are the target audience of this book.

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CONTENT

The Use High-Porosity Cellular Carbon to Replace Bone Defects from Children

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Abstract. The results of surgical treatment of 8-16-year-old children with extensive bone defects after pathological tissue resection with the use of high-porosity cellular carbon in isolation (9 patients) and in combination with autografts (3 patients) are presented. Children with lesions of long bone segments – the tibia, humerus, and femur (10 patients) predominated. The Musculo Skeletal Tumor Society Score was used as the basis for outcome assessment, and clinical and radiological data were assessed. The results in 100% of treated patients were rated as good in terms of 7 to 12 years after surgery. There were no complications in the operated patients. The efficacy of treatment according to the ISOLS system was + 56.8% after treatment in the group after carbon plastic surgery, the postoperative score became higher by more than 1.5 times, there were no recurrences of the defects, full integration of the implanted materials with good clinical and radiological results were registered. High-porous cellular carbon is suitable for effective plasty of bone defects in children and when properly applied leads to good results and no complications.

Keywords: bone replacement materials, high-porous cellular carbon, tumor and tumor-like diseases.

1. Introduction

The search for implantable materials for the replacement of defects formed as a result of the removal of tumors, tumor-like or affected by dysplastic or systemic disease areas of bone continues to this day [1–4]. A persistent study of bone formation processes and bone reaction to the introduction of implantable materials is continuing [5–9]. Conservative and mainly operative treatment methods are being improved, using various innovations of advanced transplantation materials [10].

In general, all materials except autologous bone are non-autogenous grafts. No doubt, the patient's own bone material is ideal. However, donating one's own bone, especially at an early age, involves additional trauma. Children's donor resources are limited. In the area where autografts are taken, there is a risk of infection or even a fracture at the site of the graft and the appearance of cosmetic defects. More than 15-20% of complications can occur, which is why the search for bone replacement materials is so active.

In the literature available to us, when studying the use of various implantable materials, we did not find reports on the use of carbon-carbon composite material in children, the boundaries of its use are not clear, and indications and contraindications for its applying are not outlined. The aim of our study is to investigate the long-term results of treatment of children using high-porosity cellular carbon (HPCC) for the replacement of tumor and tumor-like bone defects of the type of extensive cysts in children after resection of pathologically altered tissues. This paper presents the results of surgical treatment of 12 children aged 8-16 years.

2. Literature Review

Biocomposite grafts have recently been competing quite well with their predecessors. The application of composite materials is an entire trend [11–16]. In our opinion, the use of carbon materials to substitute for bone cavities is particularly developing [17–19]. Bone replacement structures made of carbon-carbon material "Uglekon-M" have not found use in pediatric practice due to the difficulty of reconstructing the material [20]. In this regard, high-porosity cellular carbon has great prospects. We have not found any reports on the use of such materials in pediatric practice. The advantage of the implant is the closeness of its elastic modulus to that of the native bone and inertness in relation to the living tissues, but there are no reports on the experience of such implant application in children [3, 19]. The effectiveness of the HPCC turned out to be quite high with clearly defined boundaries of application of this material in children as well [21].

3. Data and Methodology

We observed 12 children aged 8 to 16 years with bone defects in the form of bone cysts of tumor-like and tumor-like genesis (fibrous dysplasia, aneurysmal cyst, unassociated bone fibroma, solitary bone cyst). All children were operated with resection of the contents of the cystic cavities, treatment of compact bone sections using osteotomes and cutters to healthy tissues, followed by replacement of the resulting bone defects with HPCC with a porosity of 70-90% [21]. In all cases, the patient and their representatives were informed and given reasons, and in all cases, consent was obtained for the use of this still little-used material. The localisation of replaceable defects and the nature of the method used are shown in Table 1.

Table 1. The localisation of replaceable defects and the nature of the method used

The segment on which the postresection defect was replaced by the HPCC	Isolated use of HPCC	The use of autobone in combination with HPCC
Clavicle	1	--
Humerus	2	1
Femur	2	--
Tibia	3	2
Calcaneus	1	--

In the combined approach, we aimed to isolate the growth plate from the bone affected by the tumor or tumor-like process. The affected areas were removed during surgery with preservation of the bone walls and with appropriate treatment. In the immediate vicinity of the fissure zone, spongy autologous bone was used; the rest of the post-resection defect was replaced with an HPCC (certificate for the rationalization proposal No. 2655 dated 15.09.2014). HPCC is a lightweight material, practically pure carbon. It is easily processed and can be cut with a knife, and this allows you to give the implants any shape corresponding to the formed bone defect (Figure 1).

Fig. 1. Scalpel treatment of the HPCC material. The cellular structure of carbon facilitates its processing and promotes the integration of osteons into hollow cells. The volume of voids in the material reaches 90%

To assess long-term results, the ISOLS system proposed by the International Society of Organ-preserving Surgery was used. All similar significant clinical signs of Musculo Skeletal Tumor Society Score (MSTS) were also present in the system used. The scoring systems evaluated 6 clinically relevant parameters on a 5-point scale. The clinical result was represented by the sum of points. An excellent outcome ranged from 23 to 30, a good outcome from 15 to 22, a satisfactory outcome from 8 to 14, and an unsatisfactory outcome from 0 to 7. In our conclusions, we categorised excellent and good results as 'good', since the differences in outcomes were not significant. Based on these tables, we evaluated the effectiveness of treatment, which was presented as a percentage, reflecting the change in the score relative to the initial condition of the patient, which was conditionally assumed to be 100%. Thus, 30% efficiency means that the increase in the score after surgery was 30% of the patient's baseline score before surgery.

All clinical data had radiological verification, which was important in assessing the integration of implantable materials into the bone [22]. The Wilcoxon rank sign criterion (a nonparametric criterion for comparing paired observations) was used for small samples [23].

4. Results

In nine cases, replacement of bone defects was performed exclusively with a carbon-carbon composite implantable material consisting of bioinert carbon with a porosity of 70-90% (HPCC). For three patients with extensive defects, the replacement was performed in combination with autografts. In the latter, the material was used to reduce the amount of autologous bone used (for 2 patients) and for 1 patient, HPCC was used in the metaphyseal area of the tibia in combination with spongy autograft to isolate it from the growth zone. The use of the material did not imply further axial load on the replacement material, therefore, 2/3 of the patients had a temporary limitation of the total load on the limb for 4-6 weeks, and for the rest, there was no such need.

During the intervention, whenever possible, we used at least some part of a suitable cortical wall after appropriate treatment to close the implant (Fig. 2).

(a) (b)

Fig. 2. Patient P. 8 years. A part of the suitable wall of the diaphyseal section of the bone (b) was used to close the implanted block of the HPCC (a)

The maximum length of the replaced defect was noted on the tibia when the fibrous dysplasia nidus was removed. It was 11 cm (Figure 3).

Fig. 3. Patient P. 8 years old. Treatment and replacement of the defect of the humerus with HPCC. The bone wall is unsuitable for plastic surgery. The carbon material is covered by the periosteum

The process of substitution with HPCC material was not fundamentally different from other methods. The options of covering the outer wall with a preserved part of the cortical wall were used, or the material was covered with periosteum. There was no fundamental difference in the use of these methods of placing and fixing the material.

The indications for the use of combined bone grafting with HPCC when the use of the patient's own bone is required should be specifically mentioned. The situation was difficult when there was a large part of the bone affected, directly connected to the epimetaphyseal bone growth zone. We managed to catch the process at a stage where the cystic mass did not grow through the growth plate. We believed that in all cases the fissure plate should be isolated from the diseased bone and from the implant with autologous tissue. We used this approach irrespective of the material used to fill the remaining cavity formed after resection of the pathological tumor-like cysts tissue. For combined bone grafting, high-porous cellular carbon was used in 3 children (certificate for rationalization proposal No. 2655 dated 15.09.2014). In one case, the cavity was filled with HPCC in combination with autografts on the humerus. In two other cases, a similar filling was performed on the tibia with extended bone defects exceeding 10 cm.

It should be noted that the transition to combined plastic surgery, in which bone autografts and any material are combined in order to fill the cavity, was due not only to the large size of the defect but also to the presence of the disease relapses. For example, we observed a patient with two relapses of an extensive shoulder cyst (Figure 4).

(a)

(b)

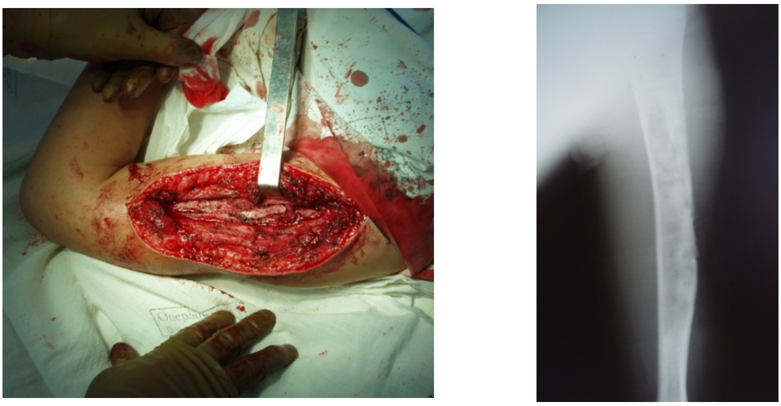
Fig. 4. Patient L. The picture on the left (a) is an extensive bone cyst with a fracture of the bone wall, the picture on the right (b) is a recurrence of the cyst after the first bone alloplasty

The patient had been operated on twice in other institutions. The patient had undergone extensive alloplasty for histologically established fibrous dysplasia 3 years before admission to our clinic (the last operation before admission). However, the performed surgical intervention did not guarantee the possibility of relapse, despite the seeming radical nature of the operation (Fig. 5).

(a) (b)

Fig. 5. The same patient. The two pictures on the left (a) show the condition after extensive alloplasty of the upper and middle third of the shoulder. The two pictures on the right (b) show a repeated relapse after alloplasty when the patient was admitted to the clinic at the age of 14

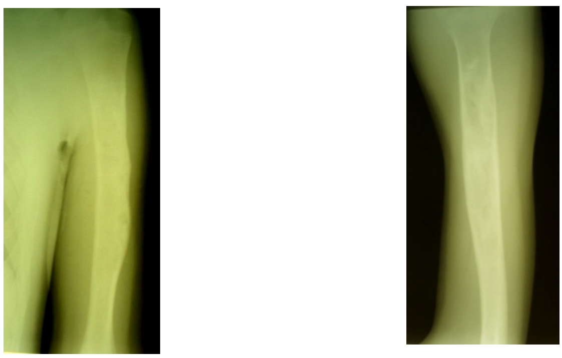
Thus, patient L., 14 years old, underwent surgical treatment in a combined manner for repeated recurrence of fibrotic formation. High-porous cellular carbon and autologous bone from the iliac crest were used to fill the cavity after removal of the cyst and formation of the defect (Figure 6).



(a) (b)

Fig. 6. The same patient L., 14 years old. The cavity is filled; the moment the operation is completed (a) and the immediate result (b)

The result after 3 years: bone structure restored (Fig. 7).



(a) (b)

Fig. 7. Radiographs of patient L. 3 years after the last surgical intervention (a). There are no signs of relapse (b)

Contractures of the elbow and shoulder joints were not formed, the result was assessed as good.

With combined interventions, when taking bone autografts, we did not observe any complications at the site of the donor bone collection. Meanwhile, this is a known risk when taking significant reserves of autografts [24]. The maximum size of the transplant from the HPCC was 11 cm in length. In all the observed patients, no specific complications were noted when using these materials. The complete reconstruction of the transplants took place within a period of 6 months to 1 year. There were no further recurrences.

The clinical results, conducted as an additional study, completely coincided with the applied assessment systems in accordance with the MSTS schemes. Overall, the results in 100% of treated patients were evaluated as good. There were no complications in the treated patients. All the results were tracked in terms of 7 to 12 years. The effectiveness of treatment according to the ISOLS system was +56.8%. These data are not inferior to the effectiveness of treatment using other artificial materials and approach the results with the use of autologous bone alone.

The aim of our study was to study the long-term results of the replacement of cystic bone defects with the help of HPCC in childhood. All defects were the result of extensive resection of the pathological cystic tissue, with a histological examination in all cases.

To our knowledge, the use of HPCC in pediatric traumatology and orthopedics is not covered in the literature. There are reports of the use of carbon materials only in the form of nanostructured carbon implants during foot surgery, but there is no evidence of the formation of a true bone-carbon block [25]. The loaded bone area and the features of the implant structure did not give the expected results, however good clinical results were obtained and bone fouling of sufficiently inert implants was achieved. The porosity of the materials used reached 70-90%, so we did not count on their strength and relied on the biocompatibility of the carbon itself. The successful application of this material in the practice of adult patients [26–28] has given us confidence in the possibility of its use in children. Nevertheless, we were quite cautious about this material at the beginning of its clinical application and limited its use in the plastic of extensive bone defects in the metaphyseal, metadiaphyseal and diaphyseal regions of the long bones.

The rather weak mechanical properties of the material did not allow it to be used as a support structure, so the calculation was primarily related to the osteoconductive effect, due to the high porosity of the material as well as its inert, biocompatible nature. This created the possibility of its application at the level of the bone marrow and spongy areas of the metaphysis. The features of access without weakening the supporting, undamaged compact part of the bone ensured its sufficient strength in the postoperative period and were a technical feature of this intervention. This circumstance also determined the localisation – of metaphyseal, metadiaphyseal parts, especially in marginal lesions, and mainly in the medullary cavity at the level of the diaphysis. With a limited cortical defect, we relied on the subsequent reconstruction of the periosteum over the implanted material, which we subsequently observed.

In our subsequent practice, we have successfully applied HPCC predominantly for extensive diaphyseal, metaphyseal or metadiaphyseal bone defects. In the text below, we highlighted the indications for the combined plasty of a bone defect with HPCC and autologous bone. The following circumstances and conditions must be taken into account for this method to be used:

- A significant size of the defect, in which additional stimuli for regeneration are required (in this case, such a source may be autologous tissue);
- There are areas of bone tissue with critical nutrition conditions or areas with reduced blood supply, when it is advisable to use musculoskeletal tissue complexes or spongy bone due to the difficulty of restoring the bone structure, in particular, due to the proximity of the physical zones. The germinal zone should be isolated from contact with the implantable material by autologous bone;
- The use of artificial materials alone can weaken the bone tissue to a critical state, reducing the possibility of reconstructing your own bone if the defect is significant.

In general, the use of artificial materials to replace bone cavities justifies itself, which we observed in our patients, although the number is relatively small. The porous structure of the HPCC makes it an osteoconductive material that allows the sprouting of the patient's own bone with true osseointegration.

In our opinion, the penetration of blood elements into the porous bone areas is the basis for this structural rearrangement. According to our data, the success of the use of these materials in metaphysical, metadiaphysical, diaphyseal defects, replacement of the bone marrow cavity, is an indisputable fact. In our opinion, the use of combined bone autoplasty and HPCC in the replacement of extensive bone defects, provides the possibility of using osteoinductive and osteoconductive properties of transplants.

The safety of using HPCC is that it consists almost entirely of carbon, which is inert to the human body. The material is easy to work with, can be cut with a knife, and the implant can be shaped to fit the bone defect. The porosity of the material reached 90%, and even more. The germination of osteones into the cavity formations of the implant has also been proven in early studies, the material does not give any autoimmune and allergic reactions, which our experience has also shown.

A single observation with the treatment of recurrent fibrotic dysplasia should not be definitive, but it can be assumed that in some cases of extensive defects, allografts may be ineffective, insufficiently effective and prone to recurrence. In this case, the use of a HPCC may be the choice.

The further wider application of this material to replace lower limb defects presents certain challenges and requires a number of engineering and clinical problems to be solved. First of all, attention should be paid to the fact that the segments of the lower limb are subjected to significant functional stresses that may cause implant failure. Therefore, it is very important to assess the biomechanical consequences of the choice of material, size and shape of the implant, the scope and nature of the intervention already at the preoperative stage. In our view, a promising way of solving this problem is to use computer modelling methods, as a digital twin of the limb segment of interest can be used to perform a computational experiment and calculate the stress and strain fields occurring in the bone. The use of digital twins (computer models) to solve clinical problems (calculation of biomechanical consequences of the choice of implantable material) has been demonstrated by us in [29, 30].

It should also be emphasized that the mechanical properties of carbon-carbon composite materials can vary in a wide, clinically relevant range, and the technologies for manufacturing implants (grafts) from this material allow creating specimens with a pre-designed, non-uniform distribution of mechanical properties. Determination of individual loads on lower limb segments and engineering calculations will make it possible to avoid possible clinical complications associated with the failure of the implanted structure during bone grafting of limb segments. Thus, the above allows us to consider this material as promising from the point of view of manufacturing individualized implants, and the use of this technology (bone grafting with using carbon-carbon composite materials of various porosity and strength) can be generalized to bone grafting of the lower extremities, after appropriate engineering calculations.

5. Conclusion

The use of high-porous cellular carbon for the replacement of tumor and tumor-like bone defects by the type of extensive cysts after resection of pathologically altered tissues has shown its effectiveness in children aged 8 to 16 years. All children had good results between 7 and 12 years postoperatively. No complications were reported with the isolated and combined use of these implants. The effectiveness of treatment according to the ISOLS system after plastic surgery with the use of HPCC was +56.8%, which was confirmed by the radiological studies and improved quality of life. The abovementioned allows us to conclude that the surgical treatment method developed and applied in the clinic is effective and promising.

The biomechanical behavior of the implanted material of the HPCC requires further study using computer models. This will expand the possibility of wider use of such implants in the native bone, improve the conditions of their vitalization, and reduce the risk of negative biomechanical consequences of their use.

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