PATIENT-SPECIFIC IMPLANTS IN SPINE SURGERY: SYSTEMATIC REVIEW

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Objective. To review the current clinical use of patient-specific implants in spinal surgery concerning a problem solved, a disease treated, patients age, distribution of cases and publications by countries.

Material and Methods. A systematic search in PubMed/Medline, Google Scholar, and eLibrary databases was conducted. Reference lists of included articles were screened for additional publications. All articles in English and Russian with available full text describing clinical use of patient-specific implants in spinal surgery were includeds.

Results. 41 articles were included in final review with a total of 340 patients. Problems solved with individual implants were as follows: 1) C1—C2 reconstruction; 2) C1—C2 stabilization; 3) concave side distraction in subaxial cervical spine; 4) anterior reconstruction of subaxial cervical, thoracic, and lumbar spine; 5) sagittal or frontal balance correction; 6) zero-profile of the implant; 7) anterior and 8) posterior stabilization under unfavorable conditions. Types of implants used were as follows: 1) reconstructive implants for upper cervical spine bearing docking sites for C0 or C1; 2) implant-template for transarticular C1—C2 arthrodesis; 3) spacers for concave side distraction; 4) congruent interbody implants; 5) congruent body-substitute implants; 6) personified anterior plates; 7) bridge-type anterior implants; 8) "monolith" implants which reproduce serial devices without connecting nodes.

Conclusion. Personified implants were used when serial devices did not match the task at hand or anatomical features of individual patient. Pathologies treated were primarily degenerative disease and tumors in elderly persons.

Key Words: patient-specific implants; 3D-printing; systematic review.

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Additive technologies, allowing the physical reproduction of virtual three-dimensional objects, have found application in a number of fields of surgery, including in the operative treatment of spinal diseases [1, 2]. If the advantages and disadvantages of non-implantable objects (reference models of the zone of interest and navigation templates) are well studied [3–5], then data on the application of personified implants are significantly fewer. Considering that the manufacturing of individual implantable objects requires significant time and financial costs [6–8] and also must comply with strict quality standards [9], in a "typical" clinical situation, when the goal of the operation can be achieved using serial products, the application of patient-specific implants seems irrational. At the same time, if the application of serial products is fraught with a high risk of intra- or postoperative complications, requires additional traumatic operative techniques, or in principle does not allow solving the task facing the operator, the use of a unique implant meeting the anatomical features of the patient and the specifics of the disease may turn out to be the best approach.

Objective of the study was summarizing the experience reflected in the literature on the application of patient-specific implants in spine surgery with an analysis of the tasks set before surgical intervention and variants of technical solutions, as well as pathology, patient age, distribution of cases and publications by country.

Material and Methods

Search strategy

A systematic search for publications in electronic databases PubMed/Medline, Google Scholar, eLibrary was performed using combinations of the following keywords: 3-Dimensional-Printed, Custom-Made, Customized, Individualized, Patient-Specific, Personalized, Spine, Spinal, Vertebral, individual, personified, 3D, implant, vertebra, spine, as well as the logical operators AND and OR, as of June 28, 2025. The decision on the compliance of the publication with the inclusion criteria was made based on the consensus of the first two authors. To identify publications meeting the inclusion criteria not found during the initial search, a study of lists of references of the articles selected for analysis was conducted.

Inclusion and exclusion criteria

The review included publications in English and Russian languages describing the clinical application of patient-specific implants during the surgical treatment of spinal diseases. Literature reviews, laboratory biomechanical studies, animal studies, reports on the application of serial implants manufactured by the 3-Dimensional printing method, publications on the application of individual pre-bent rods, articles with an inaccessible full text were excluded.

Data extraction and synthesis

When extracting data, the surname of the first author, the year of publication, the state affiliation of the institutions, the number and age of patients, pathology, the comparative or descriptive nature of the study, the material used, the task solved using the personified implant, the design of the individual product were taken into account. If authors from different countries participated in the study, the publication and the cases described in it were taken into account for each country. Upon repeated mention by the authors of previously published observations by them, the number of patients was correspondingly adjusted.

Results

During the search, 347 publications were identified, 6 duplicates were removed, 312 articles were removed as irrelevant or non-compliant with the inclusion criteria. When studying the reference lists, 15 additional sources were identified, 3 publications were removed due to the inaccessible full text. The final analysis included 41 sources (Fig. 1; appendix*).

Distribution of the number of publications and patients by country

In six publications, the results of international collaboration are reflected (these works and the observations described in them are counted twice). The largest number of articles was prepared by authors from Australia, China and the United States of America. The experience of the majority of states (8 out of 14) is set forth in single reports (Fig. 2).

Researchers from the United States of America and China have the most significant number of observations. Among the other authors, only Australian, Italian and Russian ones provide data on ten or more patients (Fig. 3).

Comparative and descriptive studies

Only one study was of a comparative nature [10]. Two works cite previously published data as a comparison group [11, 12]. The overwhelming majority of articles provide only descriptive data.

Age of patients and pathology

Out of 340 observations described in the publications included in the review, the most numerous group was made up of older patients with degenerative diseases – 147 cases [6, 11, 13–17] (the age of one of the patients is not specified in the text of the article [16]). Significant groups are represented by tumor lesions of the spine – 88 observations (79 patients older than 18 years, 9 – younger) [8, 10, 18–36] and severe deformities in elderly individuals – 65 patients [12]. In 28 cases, the intervention was performed for a malformation, including in five adults [28, 30, 37–40]. In six patients, including one child, the indications for surgery were complications from previously installed implants [7, 24, 41–44]. The remaining cases are represented by traumatic injuries (2) [30, 45], neurofibromatosis (2, including 1 child) [9, 46], rheumatoid arthritis (1) [25], and Gorham's disease (1) [9].

Material used

In the overwhelming majority of studies, a titanium-aluminum alloy was used as the material for manufacturing implants. Two teams installed products made of polyetheretherketone (PEEK) [6, 35].

Tasks set and technical solutions

In the publications included in the review, technical solutions for following tasks were proposed:

1) reconstruction of C1– C2 vertebrae [8, 10, 18, 21–25, 27, 28, 32, 33]; 2) stabilization of C1–C2 vertebrae [14, 17, 30]; 3) distraction on the concave side of the deformity in the subaxial cervical spine [39]; 4) anterior reconstruction of vertebrae of the subaxial cervical, thoracic and lumbar spine departments [6, 7, 19, 20, 24, 26, 29, 31, 34–36, 44, 45]; 5) correction of sagittal or frontal balance [11–13, 15, 28, 37, 40]; 6) achieving a "zero" implant profile [41, 42]; 7) anterior [9, 38, 46] and posterior stabilization in unfavorable anatomical conditions [43].

Taking into account the absence of a generally accepted classification of patient-specific implants, the authors considered it possible to divide all the diversity of proposed technical solutions in the publications into eight types: 1) anterior upper cervical implants with docking sites for C0 or C1 vertebra [8, 10, 18, 21–25, 27, 28, 32, 33]; 2) implant-templates for transarticular arthrodesis of C1– C2 vertebrae [14, 17]; 3) unilateral distraction spacers [39]; 4) congruent interbody implants [11–13, 15, 16, 28, 37, 40]; 5) congruent body-replacing implants [6, 7, 10, 19, 20, 26, 29, 31, 34–36, 41, 44, 45]; 6) individual anterior plates [30, 38]; 7) bridge-like anterior implants [9, 46]; 8) "monolithic" implants reproducing elements of standard products without connecting nodes [42, 43].

It is necessary to note that there is no unambiguous correspondence between the tasks and technical solutions. Different teams of researchers used various types of implants to solve similar tasks.

Discussion

The analysis of the distribution of publications and observations by country was conducted to obtain data on the place currently occupied by the use of patient-specific implants in spine surgery and where the technology is applied most actively. Despite a significant number of observations among American and Chinese authors, on the scale of the populations of these countries and the number of vertebrological operations performed annually (in the United States of America – more than a million [47]), the proportion of interventions using personified products remains negligibly small. Nevertheless, the experience of using congruent interbody implants, summarized in two multicenter studies of American authors [11, 12], covers 200 observations and has no equals. The achievement of Chinese researchers is 38 cases of using reconstructive implants for the upper cervical spine [8, 10, 22–24, 27, 32, 33], as well as the development and application in 22 patients of individual interbody spacers for distraction of the concave side of the deformity in cervical hemivertebrae [39]. Publications by Australian authors [13–15, 17, 19, 25, 28, 29, 37, 41, 43–45], the

* *The appendix is available at: https://www.spinesurgery.ru/jour/issue/current*

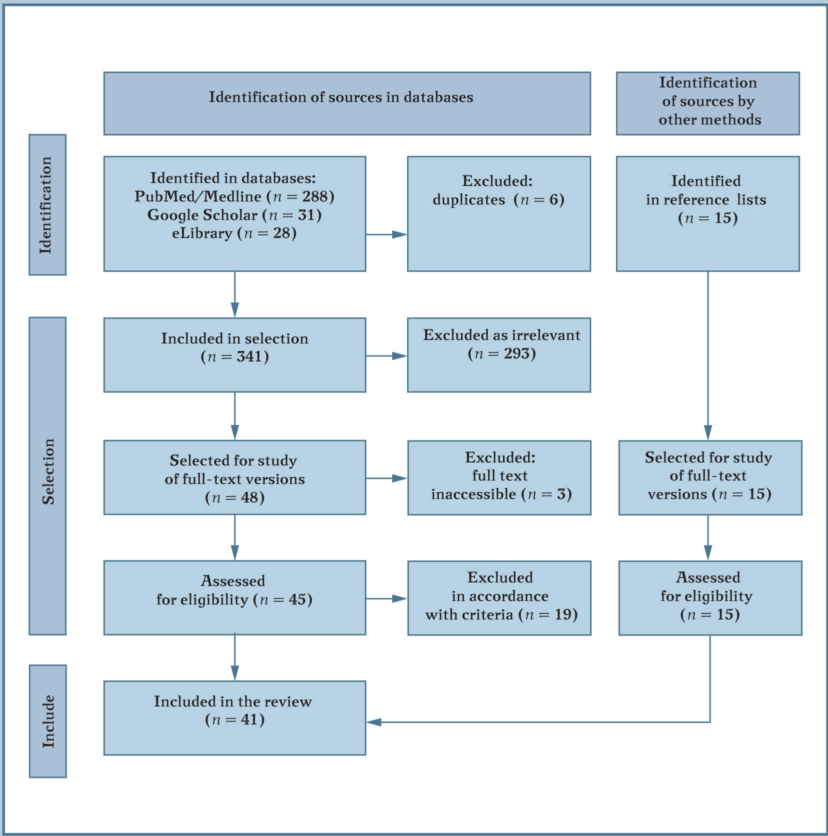

Fig. 1
Systematic review diagram

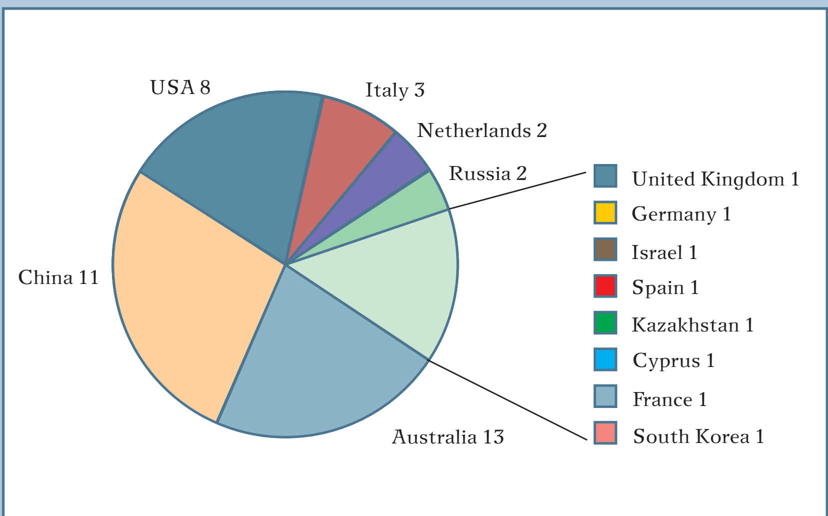

Fig. 2
Distribution of the number of publications by country

most numerous with a small number of patients, draw attention to the variety of solutions used (five types of patient-specific implants). Reports from other countries, describing small series or even single cases, allow hoping for a wider spread of the technology in the future.

Anterior upper cervical implants

These products are intended for the reconstruction of anterior structures after partial or complete removal of the C2 and/or C1 vertebra and represent a prismatic construct relying on the body of the underlying vertebra and bearing a docking site for connection with the anterior arch of the atlas (Fig. 4) or the base of the skull.

The minimal variant of using such a product is unilateral prosthetics of the lateral mass of the atlas [8]. Two methods of fixing the implant to the C1 vertebra are described: a saddle-shaped notch combined with the inferior surface of the anterior arch [18, 21], and a T-shaped expansion that is attached to the anterior surface of the lateral masses with screws [8, 10, 22–25, 32]. After the removal of the C1 vertebra, screws were installed into the clivus [28] or into the occipital condyles [23]. The base of the implant, as a rule, relies on the superior surface of the body of the C3 vertebra, to which it is fixed with two screws. With the spread of the process to the subaxial region, constructs relying on the bodies of the C4, C5 and T1 vertebrae were used [22, 23, 27]. Most often, the implants were installed in combination with a posterior construct, with some teams performing posterior fixation as the first stage [10, 18, 22, 23, 28, 32], others – as the second [8, 21, 25, 27], however Girolami et al. [21] achieved a satisfactory mechanical result using anterior stabilization only. Three groups of authors, during the resection and reconstruction of the axial vertebra, found it possible to abandon occipitospondylodesis [10, 25, 32]. Of note, out of 45 operations (including 7 with atlas reconstruction) almost all were carried out from an anterolateral submandibular incision, the transoral approach was required only in two cases [10, 28]. The study by Hu et al. [10] showed a tendency towards a higher rate

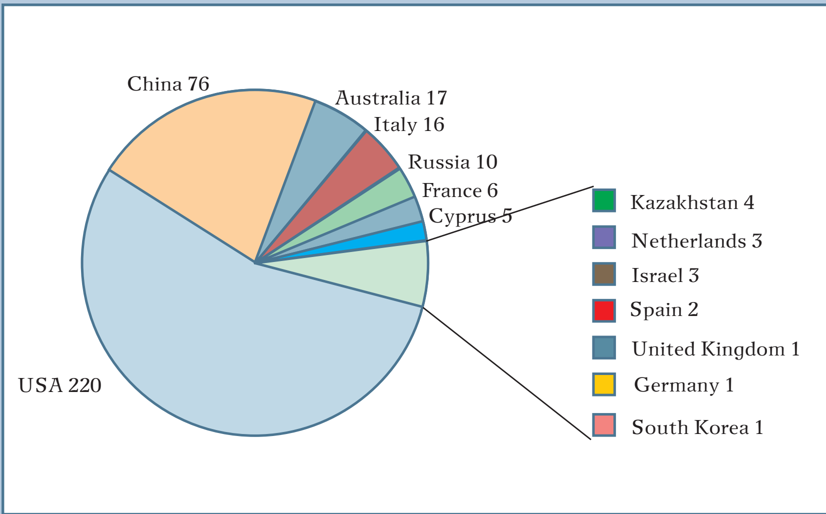

Fig. 3
Distribution of the number of patients by country

of implant destabilization when using standard titanium mesh compared to the application of a personified device (4/13 vs. 1/18, marginal statistical significance). According to the opinion of a number of researchers [21, 25, 27, 32], an optimal serial product for the reconstruction of the anterior regions of the C1– C2 vertebrae does not exist, making the application of patient-specific implants for this purpose particularly demanded.

Implant-template for transarticular arthrodesis of the C1–C2 vertebrae

The original design of an individual implant is presented by a group of Australian authors [14, 17]. The product has the form of a frame fixed by screws to the posterior arch of the atlas, relying on the posterior structures and bearing cylindrical guides for transarticular screws, that is, it is an implantable navigation template (Fig. 5).

For the preliminary formation of transarticular canals, the authors used a separate directing device made of plastic, also manufactured using the 3D printing method. In reports on the use of this design in three patients, there are no indications of any advantages, other than ergonomic ones, in connection with which the value of the described technology compared to the application of non-implantable templates appears doubtful.

Congruent interbody implants

The individualization of interbody cages opens paths to overcoming two problems inherent in serial products. Firstly, imparting to the contact surfaces of the product a shape congruent to the vertebral endplates of the superior and inferior vertebrae increases the contact area and contributes to a uniform load distribution, which reduces the probability of implant “subsidence” in the postoperative period [13, 29, 37]. Secondly, the personified cage possesses a predefined angle between the contact surfaces, making it an effective means of correcting sagittal and frontal balance (Fig. 6).

Smith et al. [12] showed that in 65 patients, the average difference between the planned and obtained segmental correction angle was 1°, while a disruption of sagittal balance after surgery occurred significantly less frequently compared to a group of patients in whom serial implants were used. Ashgar et al. [11] demonstrated a significantly higher rate of restoration of impaired sagittal balance parameters when individual cages were used. Three teams of authors used personified interbody implants for single-stage correction of sagittal and frontal balance in elderly patients with degenerative diseases caused by previously operated lumbar hemivertebrae [28, 37, 40]. Studies that compared the rate of subsidence of serial and personified interbody implants were not found, however, reports of single observations confirm the complete preservation of correction in the long-

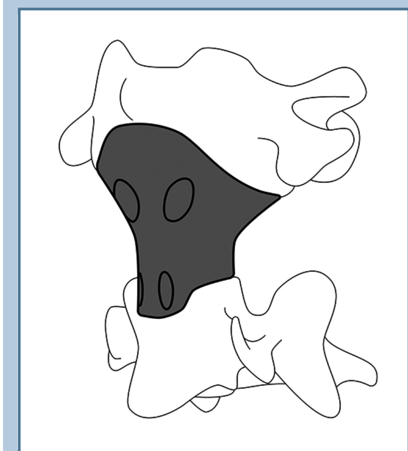

Fig. 4
Anterior upper cervical implant with a supporting surface for the C1 vertebra. Author’s drawing

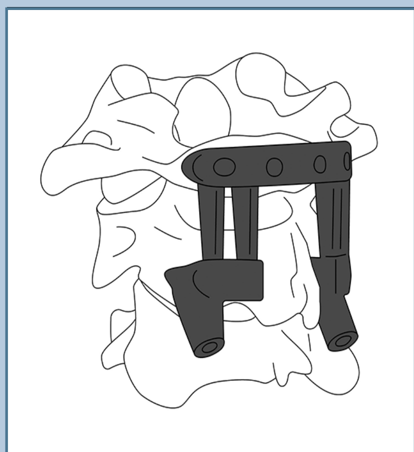

Fig. 5
Implant-template for transarticular arthrodesis of the C1–C2 vertebrae. Author’s drawing

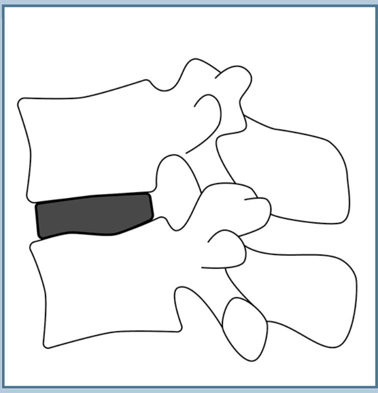

Fig. 6
Congruent interbody implant. Author's drawing

term period [13, 15, 28, 37, 40]. There are data on both the isolated use of individual cages [13, 16, 37] and installation in combination with a transpedicular construct [12, 28, 40]. Fixation of the implants to the bodies of the superior and inferior vertebrae with screws [13, 37] or anterior plates [15, 28, 40] is possible. Practically in all cases, the cages were installed in the lumbar spine, there is only one report on the application of an individual interbody implant at the level of the C6–C7 vertebrae [16]. The experience reflected in the literature on the use of congruent interbody implants is the largest (228 observations out of 340), and for this type, advantages over serial products have been demonstrated.

Unilateral distraction spacers

These implants are very close to congruent interbody cages, however, due to the specific area of application, it is appropriate to consider them as a separate type. Li et al. [39] presented an original method of surgical treatment of congenital scoliosis caused by cervical hemivertebrae using patient-specific implants. The approach involves refusal of hemivertebra resection which is associated with the risk of damaging the vertebral artery, and performing distraction on the corresponding level of the concave side with the installation of personified spacers between the articular facets and the bodies of the superior and inferior vertebrae (Fig. 7).

For additional fixation, a transpedicular construct and an anterior plate were used. A series encompassing 22 observations, the authors indicate such advantages over hemivertebra resection as lesser blood loss and duration of intervention. It is noteworthy that it was precisely the application of patient-specific implants that made an effective distraction treatment of congenital cervical scoliosis possible.

Congruent body-replacing implants

This type of products is intended for the reconstruction of vertebral bodies at one or several adjacent levels (Fig. 8).

Such necessity arose during radical oncological operations [19, 20, 24, 26, 29, 31, 34–36], as well as in the surgical treatment of cervical spondylogenic myelopathy [6] and revision for the destabilization of previously installed serial products [7, 41, 44]. In one case, an individual body-replacing implant was used for a fracture of the C7 vertebra with spinal cord compression [45]. To the advantages of the personified product, in addition to congruent contact surfaces, belongs the possibility of commutating with a posterior construct. For this purpose, the implants were equipped with staples for wire fixation [24, 31], holes for the insertion of serial transpedicular screws [7, 19, 35]. hinged elements with clamps

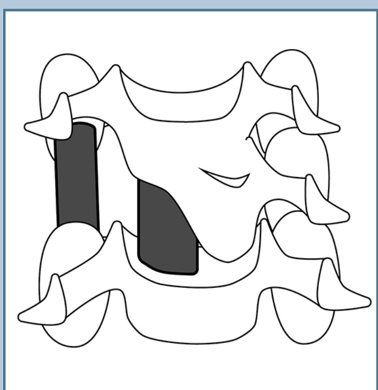

Fig. 7
Unilateral distraction spacers. Author's drawing

for connection with the rods of the posterior instrumentation system [20]. A number of teams used the products with canals for screw fixation to the bodies of the superior and inferior vertebrae [26, 29, 34, 41, 44, 45]. Chung et al. [7] used an implant composed of two (right and left) components to facilitate its installation through a posterior approach, however precise alignment of the product pieces was not achieved by the researchers. Individual body-replacing implants were most frequently applied in the thoracic spine [19, 20, 24, 31, 35, 36], as well as in the subaxial cervical [6, 24, 26, 29, 31, 34, 41, 44, 45] and lumbar [7, 20, 26, 35] spine. The most extensive defect of anterior structures – 6 levels (C3–T1) – was successfully reconstructed by Yang et al. [34]. For the 53 described cases of using personified body-replacing products, there is only one report of implant "subsidence" requiring revision surgery [20]. Despite the lack of comparative studies, the advantages of reconstructing anterior structures with patient-specific implants, provided by congruent supporting platforms and the possibility of commutating with a posterior construct, raise no doubts.

Individual anterior plates

These implants were used for the stabilization of the cervical spine. Shkarubo

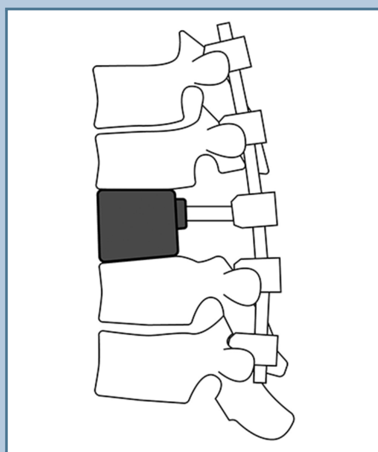

Fig. 8
Congruent body-replacing implant. Author's drawing

et al. [30] in four patients during transoral odontoidectomy simultaneously performed fixation with a personified plate, which was attached with screws to the body of the C2 vertebra and the lateral masses of the C1 vertebra, without the installation of a posterior system. For more extensive resection involving the articular surfaces of the atlas and the body of the C3 vertebra, combined with a posterior construct, the same team used an analogous product with an additional supporting element located between the articular surfaces of the atlas and the body of the C3 vertebra. Jackson et al. [38] applied an individual plate for fixation *in situ* during decompression for cervical discogenic myelopathy caused by Klippel-Feil syndrome associated with pronounced scoliotic deformity (Fig. 9).

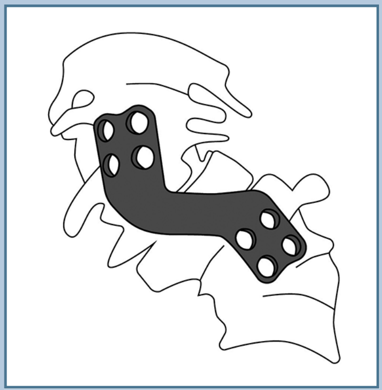

Fig. 9
Individual anterior plate. Author's drawing

Thus, the personification of anterior plates allows performing fixation under conditions where the use of serial products is impossible.

Bridge-like anterior implants

An original solution to the problem of progressing kyphotic deformity caused by multilevel osteolysis of vertebral bodies in neurofibromatosis and Gorham's disease was proposed by Willemsen et al. [9, 46]. After posterior stabilization (revision in all three cases), the load-bearing capacity of the anterior structures was restored by an individual implant, representing a column with contact platforms, fixed with screws to the bodies of the superior and inferior unaffected vertebrae (Fig. 10).

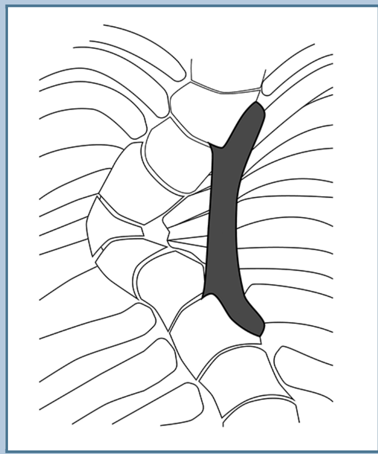

Fig. 10
Anterior bridge-like implant. Author's drawing

With the most extended zone of osteolysis (C7–T10), the authors successfully stabilized practically the entire thoracic spine using a double approach. In the case of non-tumor extended destruction, the bridge-like implant is undoubtedly an excellent alternative to multilevel corpectomy and bone grafting.

"Monolithic" implants

A common technical solution unites two observations distinct from one another, in which completely different tasks faced the operator. Thayaparan et al. [43] encountered the necessity to perform revision stabilization of the lumbosacral junction, wherein the installation of screws in the S1 vertebra was impossible, and the anterior approach was contraindicated. The authors made a decision to create a lower support base consisting of one sacral (S2 level) and two iliac screws from each side. For the commutation of the construct, patient-specific implants were used, representing a rod of a preset configuration with "branches" for each of the iliac screws. Li et al. [42] faced the failure of integuments in the area of a parallel connector linking the iliac hook and the distal component of the distraction system "rib-pelvis" in a patient with meningomyelocele related kyphosis. The exposed connector was removed, and the iliac support and the distal component of the construct were replaced by a "monolithic" (without connecting node) low-profile individual product (Fig. 11).

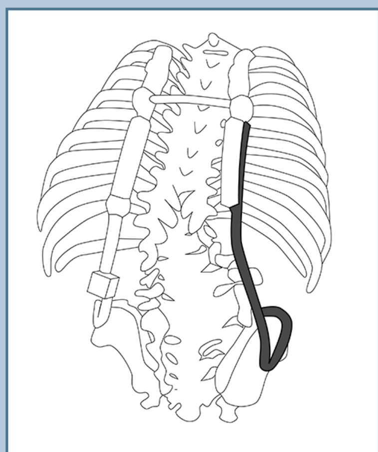

Fig. 11
«Monolithic» implant. Author's drawing

If in the first case the task could, in principle, be solved by means of a bulky and inconvenient construct of serial elements, then given the failure of integuments in the connector area, it is difficult to imagine another as simple and elegant solution.

The analysis of published data allows highlighting the following advantages of patient-specific implants. In certain typical situations, the use of personified products provides better results compared to serial devices (reconstructive implants for the upper cervical region, congruent interbody and body-replacing implants). When solving some rare tasks, for which serial products are unsuitable, the application of individual devices is optimal (bridge-like implants, anterior plates). It should be noted that drawing a clear boundary between these variants is not always possible. An additional positive feature of personified products conditioned by the manufacturing technology (3D printing) is the ability to impart to them a microporous structure that favors osseointegration [22, 24, 27, 33].

On the other hand, surgical intervention using an individual implant involves a lengthy and labor-intensive stage of preoperative planning, requiring the participation of qualified personnel [8, 13, 14, 16, 19, 42]. However, as Mobbs et al. showed [45], with streamlined logistics, a product can be designed, manufactured, and sterilized in less than 48 hours. The second significant limitation is the necessity to strictly follow the previously outlined operation plan, which places extremely high demands. Hu et al. [24] in two cases were forced to refuse the use of a personified product due to a mismatch in the dimensions of the implant and the bone bed, and Girolami et al. [20] directly recommend having an alternative operation plan using serial products. Many teams manufactured several implants of different sizes: from two to three [6, 8, 9, 13, 15, 16, 21–23, 29, 31, 32, 34, 37, 41, 44, 45] to five [39] and even 32 variants [27]. Only in four cases are data provided on which variant of the product was used (smaller [37], matching exactly [9, 37], and larger [9, 29]). Of note, the less frequently used PEEK material, unlike the titanium alloy, can be modified by a surgical instrument during the operation [35].

Thus, the use of patient-specific implants can serve as an important addition to the surgeon's arsenal in the case of a rare problem, and for some typical tasks it represents the optimal solution.

Limitations of the study are associated with the search in a small number of electronic databases, consideration of sources only in English and Russian languages, and the exclusion of articles with inaccessible full text. Some publications could not have been found using the keywords employed.

Conclusion

Patient-specific implants are used when existing serial products do not match the assigned tasks or the anatomical features of the patient. The pathology in the majority of cases is represented by degenerative and oncological diseases in individuals of the older age group. Authors from the United States of America, China, and Australia possess the largest number of observations and publications.

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