Use of a vertebra digital model for an implant design

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\textit{Abstract.} In this paper, we consider some possible design options for the reconstruction of an injured vertebra based on the local information on its surface before the injury. We used the methods of guaranteed identification for the reconstruction of the vertebra surface. Using the vertebra surface model, we have developed designs of anatomically shaped vertebra implants. In this case, the vertebral implant has a foramen vertebrale. Therefore, we have designed a split-type implant. To ensure the stiffness of the implant assembly, we have considered two fastening options for implant structural components: the dovetail groove mounting and fastening with asymmetric surfaces. Taking into account the existing best practices in medicine and in order to fasten implant structural components, we have selected options for connecting the components by means of asymmetric surfaces and with fasteners. In our opinion, the considered fastening options for vertebral implant components can be used in the replacement of other bones. When designing an atomically shaped vertebral implant, we selected a structure that weighed as close to a natural vertebra as possible. We also designed the structure to maximize its load-carrying capacity. We suggest to produce implants from blocks of allogenic osteoplastic material. This will enable implant components to be set properly and not to be rejected by the immune system.

1. Introduction

According to the data of WHO, the annual growth rate of serious orthopaedic injuries worldwide is estimated at 1.7\% [1]. Spinal injuries almost always lead to very serious consequences (80-95\% of cases result in disability) [2-4]. Such injuries are treated by surgical intervention [5, 6]. In case of a complicated spinal injury after preliminary decompression of the nervous structures, reconstruction of the damaged segment of spine is carried out. A comparative analysis of the effectiveness of treatment results for people with spinal injuries showed that implants are a promising and rather effective way of reconstructing injured vertebrae. Approximately 65-70\% of spinal neurosurgeries involve implantation.

The choice of implant design and material depends on many factors that may be incompatible.

The implant material should have the following properties [7]:

- biocompatibility with the surrounding anatomical structures;
- environmental compatibility and hypoallergenicity;
- porous structure;
- density should correspond to the density of healthy bone tissue;
- strength properties should match the density of healthy bone tissue;
- elasticity, plasticity, viscosity, thermal conductivity, electrical conductivity and magnetic permeability should correspond to the density of healthy bone tissue.

Ideally, a vertebral implant should be made of the patient’s bone material, which is impossible in case of considerable bone loss. For this reason, the optimal implant material is bone tissue (xenomaterial) of farm animals. Physical and technical properties of implant material largely determine its design.

As an anatomical object, a vertebra may have one or three holes (sacrum has 8 holes). The spinal cord goes through the largest of them, the vertebrae foramen. The spinal blood vessels go through the other two holes in the transverse foramen. Spinal cord injury is unacceptable when installing the implant. For this reason, the implant construction should be split-type. In this case, the structural elements should allow the spinal cord to be located without injury. At the same time, the assembled vertebral implant structure should meet the above requirements.

The article is devoted to the review of the designs of split-type vertebral implants with the analysis of structural and technological solutions.

2. Research objective of vertebral surface reconstruction

When a vertebra is destroyed as a result of an accident, there is no information about its original surface. Photos of vertebra splinters may be available. In this case, the reconstruction of the pre-destruction surface of the vertebra can be carried out using the surfaces of its splinters. This means that the available deterministic information about the surface of the destroyed vertebra is local.

The surface shapes of vertebrae of different parts of the spine are quite diverse. The variability of the sizes and proportions of vertebral surface depends on many factors (ethnicity, gender, age, health, environment, diet, etc.) [8, 9]. The literature provides no information about the average anatomical parameters of vertebrae. For this reason, a statistical description of a vertebra is impossible.

To describe the shape of a vertebra, we used the methods of guaranteed identification [10], which implies:

- lack of statistical information on the shape of the injured vertebra;
- available permissible variations of the anatomical parameters of a vertebra.

With regard to the reconstruction of vertebral surface this means the following: the variability of the possible vertebral surfaces is unknown, but limited a priori.

When constructing a parametric 3D model of a vertebra, the solution of the problem of reconstructing its pre-destruction surface reduces to finding an information set. The latter consists of all parameter values of the parametric model that are compatible with the restrictions imposed on the model. This means that the solution of the surface reconstruction problem is a set in the model parameter space.

We evaluated the point estimate of the reconstructed surface by solving a minimax problem.

In accordance with [10], we defined an information set as a system of inequalities:

\[ \mathcal{C}(k_0 + 1, k_1) = \left\{ \begin{array}{l} q(k) = P(k)c + \eta(k), \quad k \in [k_0 + 1, k_1] \\
\sum_{k=k_0+1}^{k_1} \|\eta(k) - \eta_0(k)\|^2_{S_0(k)} \leq 1 \end{array} \right. \]  

(1)

where \( k \) is the discrete time (iteration number); \( k \in \mathbb{Z}, [k_0 + 1, k_1] \) are the numbers of iterations for which the parameters were estimated; \( k_1 \geq k_0 + 1 \); \( c \) is the vector to be determined (identifiable vector); \( q(k) \) is the output vector; \( P(k) \) is the input matrix; \( \eta(k) \) is the vector of undefined information (interference vector).

The physical meaning of inequalities (1) is as follows:

- the length of the vertebral body along the longitudinal axis is equal to the average length of the adjacent vertebrae (geometric constraint);
- the maximum sectional area of the foramen vertebrale of the injured vertebra is 10% larger than the average maximum sectional area of the adjacent vertebrae (geometric constraint);
- the weight of the 3D model of the vertebra differs from the weight of the real pre-destruction vertebra in the range of ± 5% (the density of the vertebra model corresponded to the density of the bone material).
We approximated the last constraint by a quadratic function. We used an ellipsoidal set of errors to measure the difference between the 3D model and the real pre-destruction vertebra.

\[ \varepsilon(k_0, k_1) = \varepsilon_{\delta(k_1)}(0, L(k_1)) = \left\{ \varepsilon \mid \|\varepsilon\|^2_{L(k_1)} \leq 1 - \delta(k_1) \right\} \]

where

\[ L(k_1) = L_0 + \sum_{j=k_0+1}^{k_1} P_j(k) S_0 P(k) \]

Here \( S_0 \) is a given positive definite matrix (recurrent parameter). We chose the vertebra model that provided the minimum set of errors, i.e.

\[ \varepsilon(k_0, k_1) \to 0 \]

3. Research method
A calf vertebra was used to construct a vertebral implant (Fig. 1 a, c, e).

We chose two vertebra fragments, which we considered splinters. The surface of a smaller splinter was approximated by polynomials (Fig. 1 b, d, e) point by point, the coordinates were calculated on a GLOBAL Performance coordinate measuring machine (Manufacturer: HEXAGON MANUFACTURING INTELLIGENCE. Contact: 10617 Trenton Ave, St. Louis, MO 63132, USA). As a result of using the method of guaranteed identification [10], we reconstructed the vertebral surfaces by its fragments. Various projections of the resulting 3D model of the vertebra are shown in Fig. 1 b, d, f.

Further, a model of a real vertebra shown in fig. 1 d and in fig. 2 was used to construct the vertebral implant design.

![Figure 1. A calf vertebra: a, c, e – photograph of various types of a real calf vertebra; b, d, f – corresponding types of a 3D model of a calf vertebra.](image)

The vertebra MRI results can be used to assign the dimensions and proportions of the real vertebra to the implant 3D model. This is possible when a physician caring for the patient observes the dynamics of the disease for a long time. When a vertebra is injured as a result of an accident, there is no information about its surface before the destruction. Only the information about the surface of its splinters is available (photos). The surface of the vertebra splinter in Fig. 1 was formed as follows. We generated a random surface, and we detached a fragment from the vertebral body on the said surface.

Fig. 2 shows the surface of the vertebra without its fragment (splinter) reconstructed by the method of guaranteed identification.

Note: the holes in the transverse foramen may be missing in the vertebra model (Fig. 3). We believe that the lack of a vertebral arch (transverse process) is not a significant deviation of the
implant shape from the shape of a real vertebra. On the real vertebra (Fig. 1) one vertebral arch was missing. The absence of the arch is not caused by technological limitations of modern machine equipment.

![Figure 2. The reconstructed pre-destruction surface of vertebra without the vertebral body splinter.](image)

![Figure3. Possible 3D model of a calf vertebra without the vertebral arches.](image)

4. The results of the design of an anatomical vertebral implant

We believe that the deformation resistance (stiffness) of the assembled implant structure is necessary for a successful rehabilitation of the patient after the installation of the implant instead of the destroyed vertebra. The probability of regeneration (union) of the implant’s structural elements in the patient’s soft tissues is high if the implant is made of animal bone tissue and if the assembled implant structure is highly stiff.

In mechanical engineering, the dovetail groove mount [11] is used to fasten the blades of a gas turbine engine to a turbine disk. This fastening design is characterized with high stiffness. The dovetail groove mount is also widely used in traumatology [12, 13].

We considered the constructions of a vertebral implant, where the dovetail groove mount was used to connect the constituent structures. We analysed a flat dovetail groove and a dovetail groove on cylindrical surfaces. The dovetail groove mounts that we use have the following design features (Fig. 3):

- The inner dovetail (bed frame) and the outer dovetail (sleds) are made on either flat or cylindrical surfaces.
- The sleds have a split design; consequently, the joint surface of the split parts eliminated reciprocal transverse displacements.
- The joint surfaces of a mortise on the inner dovetail and of a spike on the outer dovetail are sloped 2–3 over the length of the mortise.

Fig. 4 shows two structural components of the dovetail groove, which are connected to each other by means of the mortise and the spike with a trapezoidal cross-section. In addition to the above, the mortise and spike surfaces consist of fragments of flat surfaces. The implant structure given in Fig. 4 has a one-piece design. We believe that the internal cavity of the vertebral model may correspond to the substantia spongiosa of the corpus vertebrae. The absence of this cavity would increase the weight.
of the implant compared with that of its natural vertebral analogue. Additionally, the absence of the cavity would increase the stiffness of the implant compared with that of its natural vertebral analogue.

**Figure 4.** The vertebral implant with the elements connected by means of dovetail groove mounting: a - the dovetail spike (assembled and disassembled); b - the spike installed into the dovetail groove; c - the vertebral implant model without substantia spongiosa (disassembled); d - the vertebral implant model (assembled).

The increased weight and stiffness of the implant will inevitably result in degradation of adjacent anatomical structures. To give the implant physical and technical properties that are the most similar to those of natural vertebrae, we developed a hollow model of the vertebral implant. In this case, elements of the implant model were connected with the help of the dovetail groove formed from fragments of cylindrical surfaces. In this fastening design, the joined surfaces constitute a large area, giving the implant a greater ability to resist deformation. The tilted side edges of the mortise and the spike of the dovetail groove give additional stiffness to the assembled implant structure. This model of the vertebral implant is shown in Fig. 5.

To give the greatest stiffness to the implant assembly at the adjoining surfaces of the structural elements corresponding to the processus spinosus and the right neural spine, we grooved a trigonous mortise and a spike (Fig. 5 e, f).

Medical experience in the installation of vertebral implants shows that the vertebrae adjacent to the injured (or damaged) vertebra can be slid apart for a maximum of 10 mm. This fact indicates limited applicability of the vertebral implant structures shown in Figs 4-5. However, we think that the considered structures can be used to treat other compound fractures. The suggested implant design method can be used to treat different fracture types, for example, fractures of the collum ossis femoris.

To expand the opportunities to use the implant shown in Figs. 4 and 5, we suggest making two mortises for the dovetail groove on the implant body. The angle between the mortises should be determined by the implant installation operation plan. Figure 6 shows two mortises for trapezoidal spikes on a cylindrical surface that corresponds to the corpus vertebrae. The angle between the elements of the two grooves at the point of their intersection on the cylindrical surface is 90°. The mortise and spike surfaces are formed by freeform complex surfaces. Figure 6e shows the vertebral implant model, in which the elements are fixed by means of two dovetail mortises. The angle between
the mortises is 130°. This type of implant does not require any significant movement of the adjacent vertebrae during its installation. However, installation of the implant structural components corresponding to the processus spinosus and the two neural spines requires considerable space. This may lead to traumatizing the adjacent anatomical structures. Moreover, an implant of the design shown in Fig. 6e is difficult to manufacture, it has a large and complex joining surface that in our view can lead to a longer rehabilitation period after the surgery.

Figure 5. The vertebral implant with the elements connected by means of dovetail groove mounting: a - the dovetail spike (assembled and disassembled); b - the spike installed into the mdovetail groove; c - the vertebral implant model without substantia spongiosa (disassembled); d - the vertebral implant model (assembled); e - part of the implant model, which corresponds to the processus spinosus and the right neural spine; f - part of the implant model, which corresponds to the left neural spine; g - assembled corpus vertebrae model and the part of the implant model, which corresponds to the processus spinosus and the right neural spine; h - assembled implant components forming the foramen vertebrale.

We have designed the vertebral implant structure (Fig. 7) best suited for the installation instead of the injured (damaged) vertebra. The suggested implant may be installed with a minimum risk to the medulla spinalis. We think that the implant installation should be carried out as follows [13-15]:
- The medulla spinalis should be placed into the foramen vertebrale formed by two structural components with neural spines (see Fig. 7).
- Then, the central part of the implant that corresponds to the corpus vertebrae should be mounted.
- The assembled structure should then be fixed by a fastening element, which may be removed after completion of the patient’s rehabilitation (after the implant elements have coalesced).
Figure 6. The vertebral implant, in which elements are connected by means of two dovetail grooves: a - two trapezoidal mortises on the cylindrical surface and two trapezoidal spikes (one spike is installed in the mortise, the other is prepared for its installation in the mortise); b - the concealed ridges and sides in the cylinder shown in Fig. 6a; c - cross-sectional view of the cylinder shown in Figure 6a; d - the two types of trapezoidal spike. e - the implant 3d model with two disassembled mortises.

Our opinion is that this implant design is more technologically advanced than the formerly considered structures and has a higher shear stiffness due to the complex asymmetric joining surfaces of the implant components [16]. The implant design shown in Fig. 7 is protected by the patent [17]. One of the design disadvantages is the absence of a cavity inside the implant, which increases its weight compared to that of a natural vertebra. The fastening element hole displacement in relation to the implant axis corresponding to the corpus vertebrae results in maximum stiffness of the assembled structure. In addition, a through-hole in the structure reduces the load-carrying capacity (compression stiffness) of the implant.

We shall note that all the components of the above vertebral implant structures can be produced on modern CNC machines. CNC machining of implant components enables us to control the roughness of the machined surface according to the CNC machining strategy and operation conditions. Particular roughness of implant surfaces will facilitate the regeneration of both bone tissue and adjacent anatomical structures [18]. We suggest to use various methods of development [19-28] and control [26-34] of micro and nanostructures to form the required roughness.

Besides, we believe that the number and the shape of the components of the implant structure should take into account the nature of the vertebral injury (disease), as well as the surgical intervention plan. Modern CAM-systems allow to perform almost any dissection of the vertebral model. Each implant model should be optimized so that the implant structure had the stiffness of a real vertebra. In this case, the implant will have the required bearing capacity and will not destroy the adjacent anatomical structures.

The approach to implant structure design and the fastening of implant components may also be used to design implants for the replacement of other human skeletal bones, for example, the collum ossis femoris. These investigations will be the subject of our future publications.
5. Conclusion
The existing tools of CAD-systems allow to develop a vertebra model with the required accuracy, which allows to design a split-type anatomically shaped vertebral implant. The shape of each component of the implant structure should take into account the nature of the vertebral injury (disease), as well as the surgical intervention plan. The connection of structural components with asymmetric surfaces ensures maximum stiffness of the joint components.

The application of the method of guaranteed identification when reconstructing the surface of an injured vertebra allows to obtain a model of a vertebra with the following characteristics:
1. The maximum cross-sectional area of the foramen vertebrale is enlarged by the required amount.
2. The enlargement of the maximum cross-sectional area of the foramen vertebrale does not reduce the ability of the model to resist the external force impact (stiffness);
3. The enlargement of the maximum cross-sectional area of the foramen vertebrale excludes the possibility that the adjacent vertebrae touch each other when moving.

The vertebral implant thus developed has the following advantages:
1. The anatomical shape of the implant allows for mutual movement of the implant and the adjacent vertebrae, which correspond to the movements of a healthy spine;
2. The choice of xenomaterial as the implant material allows to avoid the implant rejection by the patient’s immune system;
3. The split-type nature of the implant and the enlarged cross-sectional area of the implant foramen vertebrale reduce the invasiveness of the operation in comparison with the existing methods of spinal surgeries.

The implant structures reviewed have several disadvantages:
1. They do not have the weight of natural vertebrae.
2. They do not have the stiffness of natural vertebrae.
3. They cannot adapt their shape and weight according to the changes in hormonal levels caused by age-related changes of the patient;
4. The implant structures reviewed are not tied to a specific surgical intervention plan.

We will continue to work to eliminate these disadvantages and will present the results in our further publications.

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