Mandible Exoskeleton - First Results of Development and Implementation

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Abstract

Today, fractures of the lower jaw account for up to 80 % of the total number of injuries to the bones of the facial skeleton. At the moment, compression-distraction osteosynthesis is one of the methods of treatment of fractures and defects of the lower jaw. The considerable duration of treatment remains its main disadvantage. The available compression-distraction osteosynthesis devices do not allow to eliminate the phenomena of masticatory muscle dysfunction. In this context, the aim of the study was to develop and introduce into clinical practice a lower jaw exoskeleton for the treatment and rehabilitation of patients with lower jaw fractures and defects.

During the progress of the project, virtual modeling of the design of the exoskeleton of the lower jaw "EXOCHEL" has been carried out, possibility of representation and fixation of mandible fragments by means of exoskeleton "EXOCHEL" has been evaluated on 10 native anatomical preparations of human mandible, the stability of fixation of the lower jaw by means of an exoskeleton on the stand created for this purpose has been investigated; the possibility of compensation of the load on the masticatory muscles and the temporomandibular joint has been investigated by means of one-side suspension of the load to a special frame fixed on the lower jaw of the subjects with further evaluation of functional activity of the masticatory muscles by gnatodynamometry method, techniques of installation of lower jaw exoskeleton on 3 unidentified corpses of adult men has been developed. The exoskeleton test was conducted for a therapeutic purpose on a mongrel dog (2 years old) with a lower jaw body defect on the right, which arose as a result of injury by a shell from traumatic small arms.

Experimental article (J Int Dent Med Res 2020; 13(2): 400-406)

Keywords: Exoskeleton, model, jaw, experiment, fracture.

Received date: 14 February 2020 **Accept date:** 10 March 2020

Introduction

Fractures of the lower jaw account for up to 80% of the total amount of damage to the bones of the facial skeleton. [1,2]The solution to this problem has not only medical, but also economic and social significance, due to the increase in the length of disability period of such patients, as well as the decline in the quality of life and their social disadaptation[1,2].

At the moment, compression-distraction osteosynthesis is one of the methods of treatment of fractures and defects of the lower jaw[3]. The considerable duration of treatment remains its main disadvantage.[4,5] Therefore, various methods have been proposed to accelerate bone tissue regeneration, including early functional load under conditions of preservation of lower jaw mobility and restoration

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of compressive activity of the masticatory muscles[4,5]. Available devices of compression-distraction osteosynthesis do not allow to eliminate phenomena of dysfunction of the masticatory muscles[6-8]. Thus, the functional load cannot be considered as adequate and complete.[9-12]In order to compensate for the lost functions, increase the strength of human muscles and expand the amplitude of movements, exoskeleton devices were proposed, one of the representatives of which is the exoskeleton of the upper limb "EXAR," developed on the basis of FSBOU "Volgograd State Medical University."[9-12]

It is designed for rehabilitation and habilitation of disabled people with upper flaccid para (mono) paresis[13-16]. In the analysis of the literature, the use of exoskeleton in patients with fractures and defects of the lower jaw has not been found.

Objective: development and introduction of a lower jaw exoskeleton in clinical practice for the treatment and rehabilitation of patients with lower jaw fractures and defects.

Materials and methods

For virtual modeling of the design of the exoskeleton of the lower jaw "EXOCHEL," of fractures of the lower jaw with the installation of the apparatus, as well as in the development of the device for mutual spatial orientation and control of the depth of immersion of osteofixators, the software package "CINEMA 4D" for PC was used. (Fig. 1).

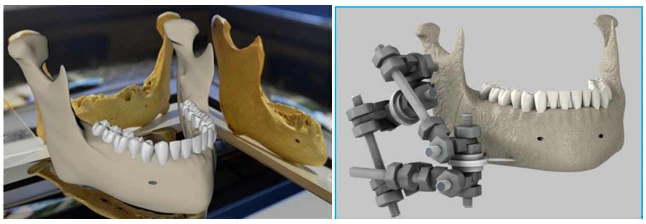


Figure 1. Modeling in CINEMA 4D.

a **b** **c**

Figure 2. Details of the exoskeleton of the lower jaw "EXOCHEL."

Parts of compression-distraction Ilizarov apparatus (Fig. 2a) and osteofixators (pins with external thread) (Fig. 2b). Details are certified. The anatomically dependent elements of the apparatus were reproduced on a 3D printer (Fig. 2c).

In order to assess the possibility of repositioning and fixing fragments of the lower jaw by means of exoskeleton "EXOCHEL," single oblique fractures of the lower jaw were modeled on 10 native anatomical preparations of the lower jaw of human by means of drill with diamond disk (Fig. 3).

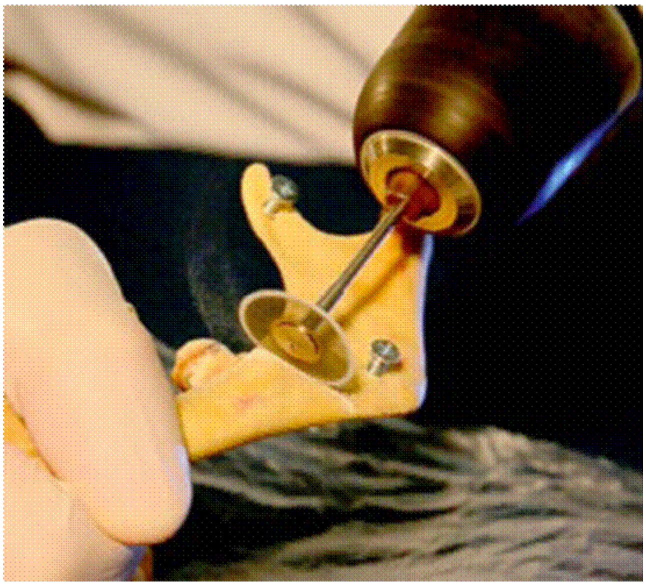


Figure 3. Modeling of lower jaw defect.

Figure 4. Carrying out tests of the load on the structure of the "EXOCHEL" apparatus.

In order to study the stability of lower jaw fixation with the help of an exoskeleton, a special stand was created to simulate the load to which the lower jaw with the exoskeleton was fixed. Sequentially suspending weights of 2 kg, 5 kg, 7 kg, 10 kg and 12 kg (Fig. 4) to the complex "exoskeleton - lower jaw," the value of divergence of fragments of lower jaw was estimated.

a b c

Figure 5. Stages of study of compensation of load on chewing muscles in volunteers.

The study of the possibility of compensating for the load on the masticatory muscles and the temporomandibular joint was carried out with the participation of 70 volunteers of both sexes (37 females (54%) and 33 males (46%)) between the ages of 19 and 23. The main criterion of non-inclusion was the presence of acute, or exacerbation of chronic, pathology, gross defects and deformations of tissues and organs of the maxillofacial region. Simulation of the load on the masticatory muscles was carried out using a modified device to obtain diagnostic models of the lower jaws with a weight of 0.5 kg suspended from one of the edges (Fig. 5a).

Functional activity of masticatory muscles was evaluated by gnatodynamometry before and after testing (Fig. 5b). By simple randomization, all volunteers were divided into 2 groups of 35. For the participants of the first group, load was simulated by carrying a load device for 20 minutes. The second group of test subjects used elastic rubber traction drawn from the apparatus to the helmet, oriented parallel to the total traction vector of the masseter, temporalis and medial pterygoid muscles themselves (Fig. 5c).

The development of the technique of installation of the lower jaw exoskeleton was carried out on 3 unidentified corpses of adult men (age 65, 72 and 84 years).

The exoskeleton test was conducted for a therapeutic purpose on a mongrel dog (2 years old) with a defect in the body of mandible on the right side, caused by a traumatic bullet injury.

Clinical introduction of the lower jaw exoskeleton "EXOCHEL" was carried out on two patients of the department of maxillofacial surgery of GBUZ "Volgograd regional clinical hospital No. 1" with the diagnosis "Traumatic osteomyelitis of the lower jaw body on the right" and "False joint in the area of the lower jaw body on the right." The protocol of the research was submitted to the approval of the Regional ethical committee of the Volgograd medical scientific center, protocol No. 2070 - 2018 of 19.10.2018. For clinical trial the informed consent of patients had been received.
EXCEL is used for statistical analysis of data.

Results

Having analyzed the data on the peculiarities of the design and mechanism of action of the exoskeleton of the upper limb "EXAR," as well as the devices of transosseous compression-distraction Ilizarov apparatus for osteosynthesis, the exoskeleton of the lower jaw "EXOCHEL" has been developed and patented (patent for the invention № 2655086 of 23.05.2018). Its structure is shown in Fig. 6.

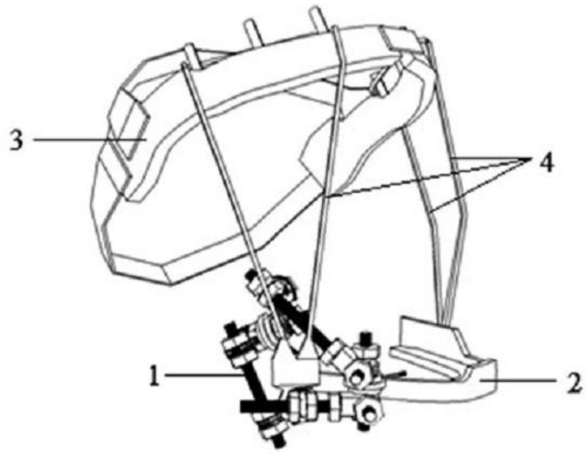


Figure 6. Exoskeleton of lower jaw "EXOCHEL"
1-shows a device of closed extracurricular osteosynthesis of the lower one;
2-inferior arc;
3-device for fixation relative to the arch of the brain part of the head;
4-are elastic members.

The exoskeleton of the lower jaw "EXOCHEL" is fully suited to the technical and clinical anatomical requirements developed by us. Computer simulation and reproduction on cadaver material of fractures and defects of the lower jaw showed that the exoskeleton of the lower jaw is able to provide a closed, anatomically accurate reposition of the lower jaw, eliminating displacement of fragments in sagittal, frontal and horizontal planes, to perform compression and distraction of jaw fragments (Fig. 7) and maintain the mobility of the lower jaw in the temporomandibular joint (Fig. 8).

Figure 7. Elimination of lower jaw defect using EXOCHEL exoskeleton.

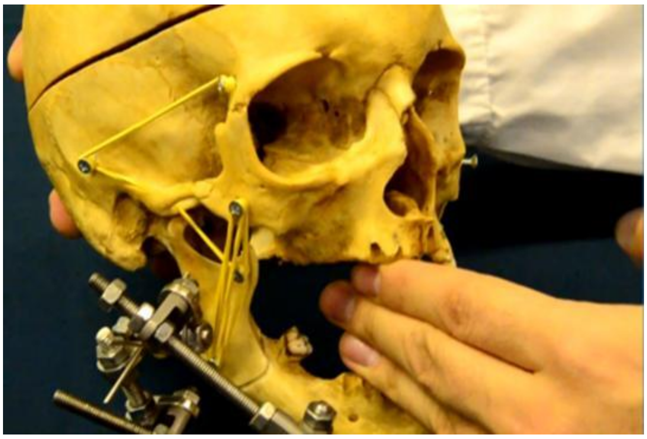


Figure 8. Volume of lower jaw movements.

At the next stage, experiments with load on the exoskeleton-lower jaw system revealed the absence of significant displacement of lower jaw fragments at a load of 2 kg. (0.0 cm), 5 kg (0, 01 ± 0.01 cm) and 7 kg (0, 07 ± 0.02 cm), at a load of 10 kg - the displacement was 0, 17 ± 0.02 cm, 12 kg - 0, 3 ± 0.03 cm, but when the load was eliminated the fragments returned to the initial position (Fig. 9).

a **b**

Figure 9. State of bone fragments at load of 12 kg (a), after load removal (b).

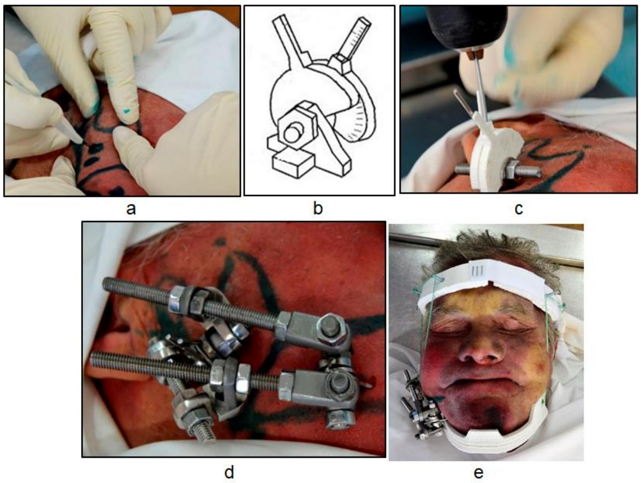


Figure 10. Stages of installation of lower jaw exoskeleton.

The first group				The second group			
Initial Indicators		After Load Simulation		Initial Indicators		At compensation simulated loadings	
Values (V), H	Frequency (p)	Values (V), H	Frequency (p)	Values (V), H	Frequency (p)	Values (V), H	Frequency (p)
390	1	260	5	390	2	370	2
420	2	290	1	440	10	410	10
440	6	350	2	480	12	450	12
480	11	390	6	540	8	510	8
500	4	420	2	550	2	520	2
510	6	430	14	650	1	610	1
540	2	450	4				
550	2	540	1				
650	1						
n=35		n=35		n=35		n=35	
M=486,86		M=395,14		M=486		M=456,59	
m=7,88		m=11,35		m=8,96		m=8,65	

Table 1. Indicators of gnatodynamometry of the subjects based on the results of the study.

Having investigated possibilities of compensation of load on masticatory muscles (Table 1), the initial gnatodynamometry values have been determined, which in the first group were 486, 86 ± 7.88 H, in the second group - 480, 0 ± 8.96 H (p = 0.942758), and were not different from the average values according to the literature. The gnatodynamometry values in the first group after the load simulation have decreased to 395, 14 ± 11.35 H (p = 0). The participants of the second group under conditions of compensation of load on mastication muscles under gnatodynamometry showed values of 456, 29 ± 8.65 H, which were close to initial values (p = 0.019887), and which were considerably higher than those in the second group (p = 0.000060) (Fig. 10, table 1).

The method we developed to install the lower jaw exoskeleton was as follows: through two skin punctures up to 0.5 cm long in the projection of one of the lower jaw fragments, taking into account the fracture line and conventional safety zones (Fig. 11a) with the

help of the developed and patented device for mutual spatial orientation and control of immersion depth (patent for invention № 2646568 dated 05.03.2018) (Fig. 11b) and the drill, two osteofixators were introduced into the bone parallel to the bone surface and the skin with a predetermined convergence angle (30 ° - 60 °) and on the entire thickness of the bone (Fig. 11v). Ends of osteofixators are cut to the required length. Similarly, two more osteofixers were inserted into another fragment of the lower jaw.
A pre-assembled device for closed non-focal osteosynthesis was attached to each pair of osteofixers (Fig. 11 g). After that device for fixation of exoskeleton relative to calvaria of the cranium and inferior arch oriented along lower edge of lower jaw were supplied and applied. Elements of lower jaw exoskeleton were connected to each other by means of detachable joints and elastic elements (Fig. 11d).

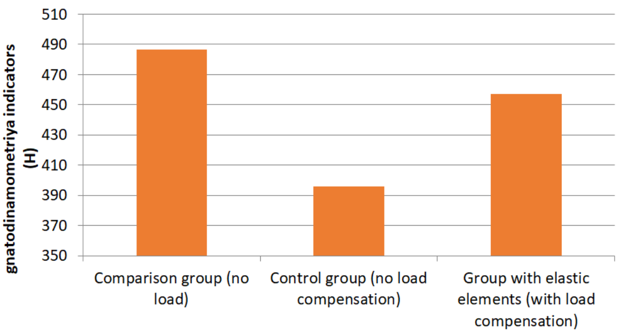


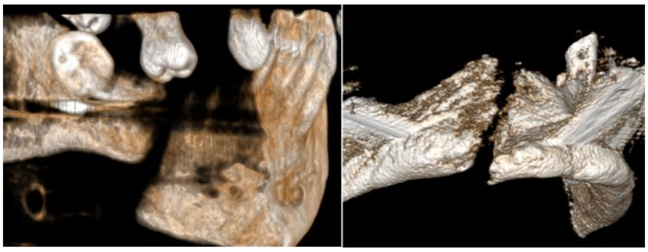
Figure 11. Results of a gnatodinamometriya.

Test of exoskeleton on a dog.

During the external examination of the dog, the deformation was determined of the facial part of the head due to the displacement of the lower jaw to the right (Fig. 12a). In palpation, there was a disruption in the continuity of the lower jaw along its lower edge, as well as pathological mobility of fragments of the lower jaw on the right. During the examination of the oral cavity, a malocclusion was detected due to displacement of the jaw fragments to the affected side, as well as a defect of the body and alveolar part of the lower jaw with teeth up to 2.0 cm long located on it. The wound of soft tissues in the projection of the defect was healed by secondary tension. In the operating room of the veterinary clinic "Help to a Friend," an exoskeleton of the lower jaw was installed under intravenous anesthesia (Fig. 12b). During postoperative case follow-up on 1, 7, 14, 21, 28, 35 days after operation, there was a clear tendency to reduce the size of the defect due to newly formed bone tissue on average 1-2 mm weekly. At the end, complete restoration of the defect and complete rehabilitation of the affected animal were observed.

a b

Figure 12. Type of dog before operation (a), 2nd day after operation (b).



a **b**

Figure 13. Computer tomogram before operation (a), 21 days after (b).

The study of the possibilities of exoskeleton of the lower jaw "EXOCHEL" in patients of the Department of maxillofacial surgery of GBUZ "VOB No. 1" revealed, that mandibular defect in conditions of minimal additional surgical trauma, closed, anatomically accurate reposition and stable, stable fixation of mandibular fragments, compression for a period of 7 days and subsequent distraction of fragments at a rate of 1 mm per day, maintaining the mobility of the mandible, compensating for the load on the masticatory muscles and TMJ, early functional load has been corrected in the period of 28-33 days (Fig. 13). There were no complications detected during the operation, in the early postoperative period, or at the rehabilitation stage. Wearing the apparatus was painless, did not cause discomfort to patients. The main advantage of the apparatus was considered by patients to be the ease of construction, the ability to chew during meals and to carry out oral hygiene fully, as well as the absence of difficulty in talking, which they were deprived of when wearing previously bent wire tires with intermaxillary traction. (Fig. 14).

Figure 14. Patients with "ExoChel" apparatus installed.

The originality of the development lies in the combination of the advantages of both exoskeletons and compression-distraction devices by G.A. Ilizarov, widely used in clinical practice. Namely:

- closed reposition and external fixation of bone fragments;
- ability to stimulate osteogenesis by compression and distraction;
- maintaining the mobility of the bone in the joints for the implementation of functional load;
- replacement of lost functions, increase of strength of human muscles and expansion of amplitude of movements close to indicators of healthy person.

Thus, computer simulations and experiments on cadaveric material have proved that the device design of the lower jaw exoskeleton for closed non-focal osteosynthesis "EXOCHEL" is able to provide anatomically accurate reposition, eliminating any displacement of the lower jaw fragments in all planes, rigid and stable fixation of the lower jaw fragments in the specified position and compression and distraction between them. The device does not restrict the mobility of the lower jaw, which is important when creating a functional load on the bone.

In our opinion, only maintaining the mobility of the lower jaw is not enough to create an adequate functional load on the bone. This wa1s justified by a persistent decrease in motor activity of the masticatory muscles and micro- and macrostructural changes in the temporomandibular joints observed in patients with fractures and defects of the lower jaw. In order to correct these damages, we proposed to include in the design of the exoskeleton of the lower jaw EXOCHEL elastic traction oriented parallel to the total vector of traction of masticatory muscles, which, as revealed during the tests, allows to compensate for the load on muscles and TMJ by 94%.

The presence of an innovative apparatus, an exoskeleton of the lower jaw, required the development and new technique of its installation. Based on the results of working on cadaveric material, the proposed method of operation according to surgical criteria is minimally invasive, due to small operational access, reduced risk of additional injury of masticatory muscles, periosteum, roots of teeth and branches of facial and trigeminal nerve, preservation of blood supply sources of bone tissue. The use of a device for mutual spatial orientation and control of the depth of immersion of an osteofixator facilitates the operation, significantly reducing its time. Small-sized postoperative wounds should not result in the formation of rough and noticeable scarring on the skin of the face and neck after healing.

The positive results of the trial of the developed exoskeleton in dogs to eliminate the defect of the lower jaw justify the possibility of its introduction into clinical practice.

And the data available at this stage on the introduction of the exoskeleton of the lower jaw EXOCHEL in patients with fractures and defects of the lower jaw of traumatic origin prove the possibility of its use in clinical practice.

Conclusions

Thus, this article describes in detail the device of the lower jaw exoskeleton as an original design that meets all technical and clinical and anatomical requirements. The developed exoskeleton is able to carry out closed and anatomically accurate reposition of the lower jaw, eliminating displacement of its fragments in all planes, compression and distraction between fragments of the lower jaw with preservation of mobility of the lower jaw in the TMJ. The rigidity and stability of fixation of the lower jaw fragments in the specified position by means of the lower jaw exoskeleton has been proved; the ability to compensate for the load on the masticatory muscles, increasing their compressive activity, and the temporomandibular joint by 94% justifies the need to include elastic traction in the structure of the lower jaw exoskeleton. A mini-invasive technique of installing a lower jaw exoskeleton using a developed and patented device for mutual spatial orientation and control of depth of immersion with an osteofixator has been developed and worked out, which greatly facilitates manipulation and thereby reduces the operation time. Testing the exoskeleton in dogs with a lower jaw defect proved that they could be completely eliminated by using the lower jaw exoskeleton. The obtained positive results of the introduction of the developed exoskeleton in patients with lower jaw defects caused by fracture complications justify the possibility of successful use of the EXOCHEL apparatus in clinical practice.

Acknowledgements

The authors thank the local authorities (Volgograde State Medical University) for their support and contributes in this study.

Declaration of Interest

The authors report no conflicts of interest pertaining to any of the products or companies discussed in this article.

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