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RECONSTRUCTION OF MANDIBULAR DEFECTS USING INDIVIDUAL VASCULARIZED AUTOGRAFTS COMBINED WITH MACROPOROUS TITANIUM FIBER MATERIAL

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ABSTRACT — The choice of donor material poses a problem for surgeons handling reconstruction of large combined bone defects or limited maxillofacial bone defects. Restoration methods, applicable in reconstructive microsurgery are based on materials of non-biological origin and musculoskeletal autogenous transplants which have complications and may inhibit the processes of osseointegration. Our study aimed to improve the efficiency of surgical treatment and rehabilitation of patients with mandibular defects using vascularized autograft in combination with macroporous titanium fiber material. The reconstruction of the defective mandible caused by chronic osteomyelitis, trauma, benign tumors was performed in 107 patients either by means of conventional methods (titanium plates, free and vascularized bone autografts), or by a novel engineered bone substitute. Our novel vascularized bone autotransplant combines a macroporous fiber titanium material and spiral bone autochips. For its fabrication we applied digital 3D technologies and methods of rapid prototyping, whereas its vascularization was harvested in iliac crest. Unlike the standard methods of reconstruction, the use of the engineered vascularized implant showed a significant reduction in stages, volume and invasiveness of surgical procedures and an improvement of esthetic and functional outcomes in patients with mandibular defects.

KEYWORDS — bone tissue engineering, 3D modeling, rapid prototyping, porous titanium fiber mesh (TFM), bone autotransplant.

INTRODUCTION

The conditions following cancer treatment, such as severe maxillofacial traumas, post-traumatic deformities of the facial skeleton with a bone defect are common in maxillofacial surgery [1, 7, 15].

Accelerating mobility and speed of modern society, the spread of weapons and military conflicts, there is a growing incidence of post-traumatic deformities of various origin affecting bones. The corresponding surgical reconstruction requires a more sofisticated and comprehensive approach [2, 5, 10, 13, 16].

As reported by various authors, the number of patients with maxillofacial traumas ranges from 11 to 25% (Bernadsky Yu. I., 2016; Kulakov A. A., 2017; Drobyshev A. Yu., 2017; Bayrikov I. M., 2018), whereas some other researchers, both national and interantional ones, claim the rate to be at 30–38% (Balin V. N., 2015; Wong K. H., 2016; Guerrissi J. O., 2018).

The rate of post-traumatic complications varies, according to the references, from 7 to 36% (Zuev V. P., 2015; Erokhina I. L., 2016; Eshiev A. M., 2018; Andra A., et al., 2018). Specialized hospitals sometimes fail to offer timely and high-quality care, which leads to repeated surgical interventions and the emerging mandibular defects of disturbed continuity [9, 14].

At the current stage, reconstructive maxillofacial surgery progress utilizes widely reconstructive surgery methods capable of improving defects while relying on materials of non-biological origin (titanium, teflon, polyethylene, etc.) or on multicomponent musculoskeletal autografts involving microvascular technology. These methods have advantages and disadvantages and universally applicable to the fullest extent, which inevitably leads to traumatization of both the donor and the recipient areas [3, 4, 6, 8, 11, 12].

Furthermore, despite numerous fundamental studies, a number of issues still require more detailed consideration, namely, the change patterns involving the status of bone and soft tissue structures after resection of various jaw parts, depending on the causes behind it, and the timing of the removal.

MATERIALS AND METHODS

In our work, we rely on a combined method, which implies using vascularized autografts and a

unique macroporous titanium fiber material. The reliability of the study can be confirmed a sufficient number of clinical observations (107) and numerous X-ray data, processing of the outcomes obtained through advanced statistical analysis methods. The hypotheses were tested relying on the methods of parametric statistics. The description of the quantitative parameters was performed using the mean and the error of the mean. The observations frequency was expressed as a percentage. The level of statistical significance through the study was set at 0.05. The obtained data of aesthetic indicators, both prior to, and after the surgery were processed statistically using the MS Excel 2010 software package.

Through our project, we used a combined treatment method to replace mandibular defects based on using vascularized autografts and a macroporous titanium fiber material.

The surgical treatment planning, the pre-surgery preparation, the surgical stages of the treatment were carried out following the clinical recommendations offered by the Chief Freelance Maxillofacial Surgeon of the Russian Ministry of Health *Protocol for treating patients with facial skeleton bones defects*.

Written voluntary informed consent (approved by the Samara State Medical University Ethics Committee of 22/11/2015, Protocol #147) was obtained from each of the patients treated for mandibular defects, the signed papers allowing clinical trials, taking photos and videos, as well as using the outcomes in research work.

We had 107 patients under our observation, all of them divided into 2 groups. Group I (76 persons), standard and widely used methods were employed to reconstruct mandibular defects — titanium reconstructive plates in 32 people; free bone autografts — in 22 people, and vascularized bone autografts used in other 22 people.

The study group included patients of Group II, who were treated using vascularized bone autografts in combination with a through-porous non-woven titanium material. The group in question included a total of 31 patients. Vascularized autografts were used to treat the patients of the study group. Their maturation was carried out in the anterior abdominal wall subject to the method developed at the Maxillofacial Surgery and Dentistry Department of the Samara State Medical University.

The patients were selected from those seeking medical assistance in the Maxillofacial Surgery and Dentistry Clinic of the Samara State Medical University (Samara, Russia) and in the Department of Maxillofacial Surgery of the Research Institute — Regional Clinical Hospital # 1 (Krasnodar, Russia).

The patients' general and local status regarding the issue of the potential reconstruction of mandibular defects was evaluated following the traditional plan. First of all, the clinical section of the examination was carried out, which included an interview survey; the patient's general status evaluation; an examination; evaluation with extra diagnostic methods (ultrasound, CT, MRI), and evaluation involving rapid prototyping methods (Fig. 1, 2).

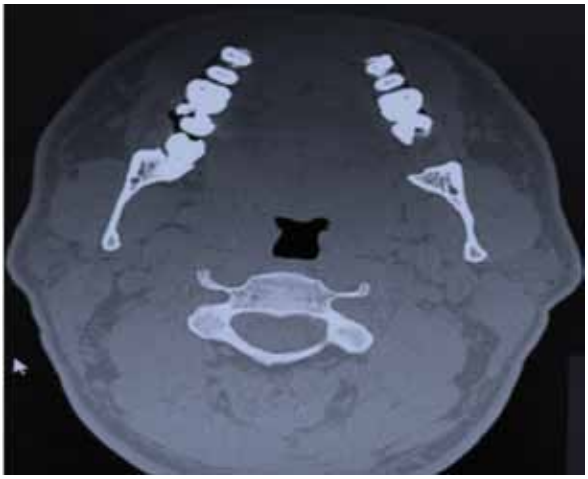


Fig. 1. *Defect of the chin of the lower jaw in 3D format*

The clinical data of 107 patients, revealed that 30% of the cases had deformities that developed after surgical treatment for chronic osteomyelitis of various etiologies; 30% more (30 patients) had lower jaw defects associated with maxillofacial injuries; another 30% of the patients (30 persons) had mandibular defects originating from the removal of benign neoplasms, while 10% (10 patients) featured mandibular issues following complications of reconstructive surgeries (rejection of previously transplanted autografts and titanium plates) and oncological surgeries (Fig. 3).

The through-porous non-woven titanium material is an elastic-porous homogeneous mass fabricated by cold pressing of titanium chips stacked in a certain way. The production of the said chips involved using a titanium rod of various diameters, which depended on the required diameter of the spiral and the distance between the turns.

The desired parameters were set on the computer and within 17±6 minutes the number of spirals were obtained required for producing an implant of any size to be further used for replacing the lower jaw defect. The spirals in their length exceeded the defect length by 10±1 mm. The excess length was needed to bend the spiral ends inside the structure. This helped avoid

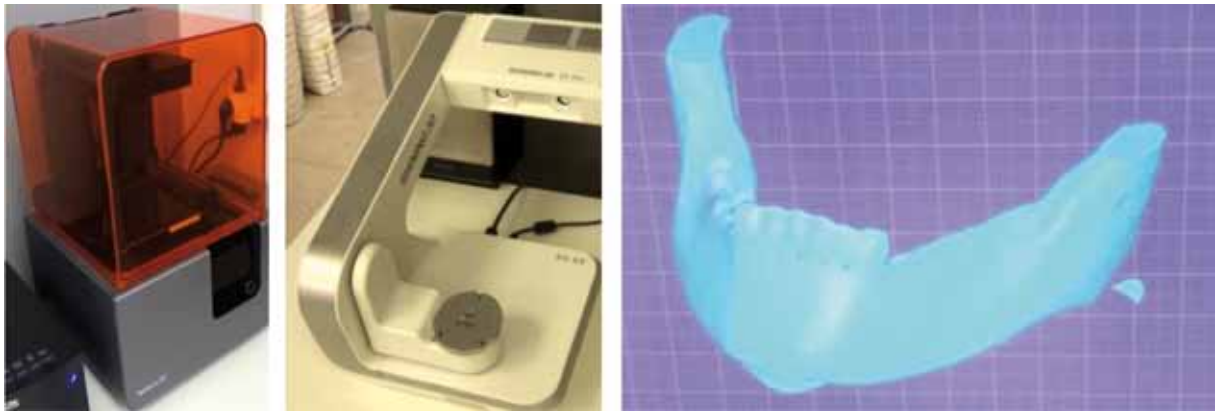


Fig. 2. Device for obtaining stereolithographic lower jaw: a — 3D printer; b — 3D scanner; c — 3D model of the lower jaw

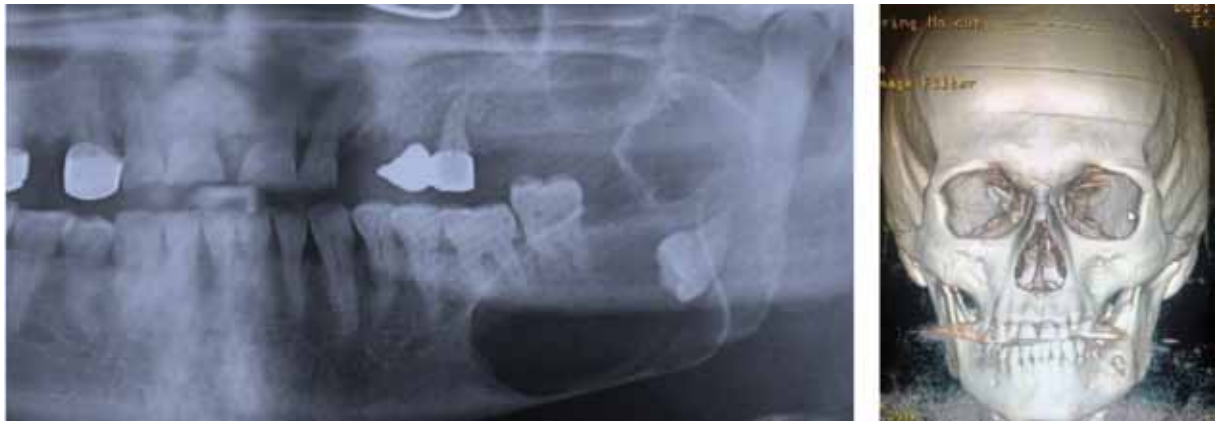


Fig. 3. Orthopantomogram (a) and computed tomogram (b) with the possibility of 3D reconstruction of the lower jaw defect. Patient A., years old. D.S: large follicular cyst of the mandibular body on the left

any sharp edges of the implant and allowed hermetic insulation of the autobone chips through the first stage of developing the bioengineered composition. The technology for obtaining a medical implant is protected by a patent (Patent # 2733687).

To fabricate implants replacing the jaw defect, chips with a thickness of 0.05-0.015 mm were used. The spiral coil diameter was 0.8±0.2 mm, the distance between the coils thus making 0.8±0.2 mm. The chips were made on a numerically controlled machine (Fig. 4).

The engineered bone substitute is a combination of a non-woven titanium material with through porosity fabricated from titanium chips and a spiral-shaped autobone. In order to obtain a spiral-shaped autobone, a spiral-shaped milling cutter was designed and manufactured jointly with the KASKAD Machine-Engineering Plant (Krasnodar, Russia, with a respective patent obtained (Patent # 2733687).

The technology for producing engineered bone substitutes from macroporous titanium fiber material is based on the titanium chips cold pressing method. Jaw implants are supposed to augment bone defects, which means they are to have a respectively designed shape and size. To achieve these, a specially manufactured mold was used. The individual mold was based on a dental flask used to produce plastic prostheses.

In order to obtain an individual mold for a mandibular defect with no disturbed continuity, the neoplasm was removed within healthy tissues using a milling cutter and a drill, on a stereolithographic model. The resulting defect was filled with molten dental wax. Once cooled, the resulting wax model of the potential jaw implant was removed with the mold to be made further (Fig. 7–9).

Following a standard procedure, creamy die stone was made, which was then poured into the flask up to the middle of the side height. The wax composition

Fig. 4. Titanium shavings for the production of non-woven titanium through-porosity fabric

Fig. 5. General view of the manufactured cutter: a — shank; b — working part; c — cutter edge

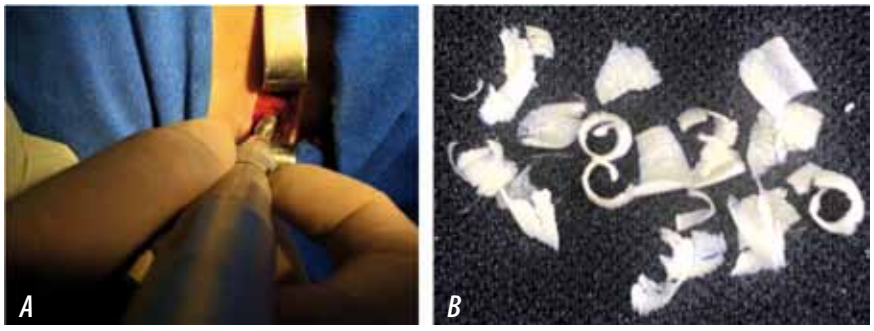


Fig. 6. A — The stage of sampling of bone autochips from the iliac crest; B — View of bone chips following cut with the original cutter

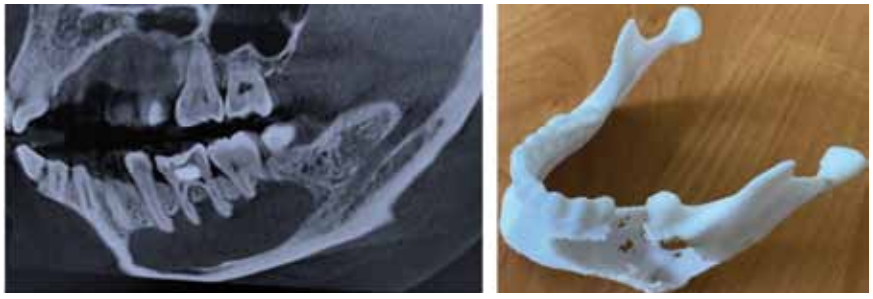


Fig. 7. X-ray and lithographic model of the lower jaw of the affected tumor

Fig. 8. Removal of a neoplasm and formation of a bone cavity on a stereolithographic model

was placed in the die stone in the center to the middle of its depth. Once the die stone was hard, a brush was used to cover its entire surface with a layer of paper glue, and then, once the glue dried, another portion of die stone was prepared, yet in salt water that time. When the die stone was completely dissolved to make a creamy substance, it was poured into the flask up to the upper edge. The flask was then covered with a lid and pressed down. When the die stone was completely solid, the flask was opened in the reverse order. A jet

Fig. 9. Individual wax composition of the jaw implant

of hot water helped melt the wax blank, and a mold for an individual implant was obtained. Knowing the volume of the implant and the porosity to be obtained, we used a special formula to calculate the amount of titanium chips required. In 85% of the implants, the porosity was 75±5% of the total implant volume. After weighing the required amount of chips, we got to laying them in the mold. Bone chips were obtained from the retromolar area or from the ilium. The result was a pyramidal stack of titanium chips with layers of autobone chips. The mold was assembled the right way based on the flask grooves. The cuvette flask placed under a mechanical press to be further squeezed until both halves were completely closed (Fig. 10).

removed part of the lithographic model, the teeth were cut off along with the tumor-altered part of the lower jaw.

The obtained lithographic model was used to bend a titanium reconstructive dynamic plate, in view of an additional section to be used for fixing the plate to the healthy stump of the lower jaw. On the upper part of the plate replacing the lower jaw branch, a titanium condylar process with a joint head was attached using special screws.

Having completely covered the resulting lithographic model with wax, we set to producing a plaster mold following the method described above. A titanium reconstructive plate was placed in the center

Fig. 10. Mold for the stage of cold pressing: a — finished mold; b — the stage of laying the components of the bioengineering composition; c — stage of cold pressing

a *b* *c*

In cases where a bioengineered design was required to replace the half of the lower jaw after its resection, a slightly different technology was employed.

For this purpose, a large flask was made (115 mm long, 35 mm wide and 70 mm high), while its components and the disassembly specifics were similar to the previous one.

A lower jaw lithographic model was made based on the CT data. Subject to the rules of oncology, retreating 2–2.5 cm from the tumor, resection of the affected area on the lower jaw was performed with its continuity disturbed. In the event that the condylar process was affected, resection was performed with the branch and the condylar process removed. On the

of the substitute depth. On all sides, the reconstructive plate was covered with a macroporous titanium fiber material combined with autobone. Given its shape, it matched the resected part of the lower jaw (Fig. 11, 12).

The first (control) group included 76 patients who were operated on following the standard conventional methods. After sequestration and cystectomy, the bone cavities were filled with blood clots or osteoplastic material. 37 patients had lower jaw tumors, of which 7 had true defects not only in the lower jaw yet also in the soft tissues. Patients with soft and bone tissue defects were operated on in two stages. Through the first stage, soft tissues were repleted. Microsurgical

Fig. 11. An intermediate stage in the fabrication of an engineered biomaterial

Fig. 12. Bioengineering design

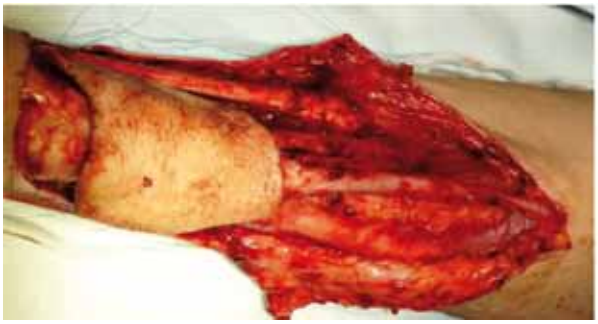
techniques were used in 4 patients, while Filatov-Gillies tubed pedicle was used in the rest of the patients (Fig. 13).

In the second stage, the bone defect, which developed following the surgery, was filled with a split rib autograft or an ilium segment (Fig. 14).

The remaining 30 patients who had bone defects only were operated on using reconstructive titanium plates combined with autobone.

In the main group, in 31 patients with mandibular defects were augmented with the engineered bone autograft fabricated by us.

Of them, 9 persons were diagnosed with odontogenic cysts, another 3 — with the lower jaw osteomyelitis. These patients developed the defects after sur-



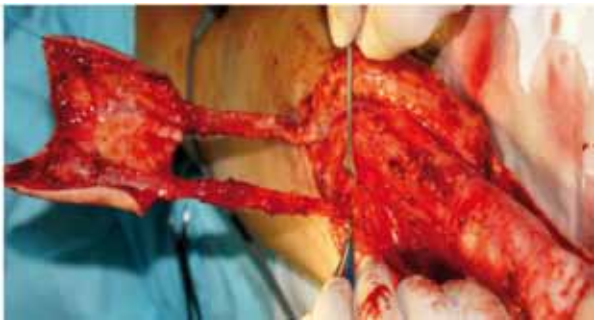
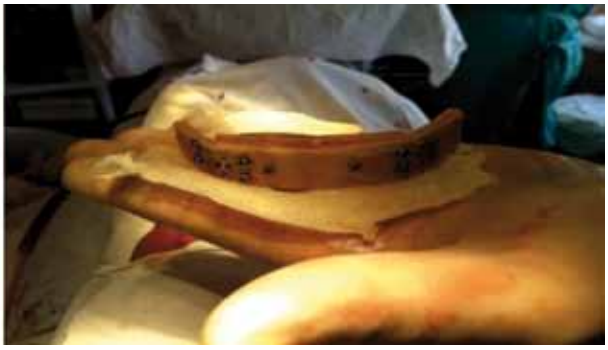


Fig. 13. Transplant-ready radial flap

A



B

Fig. 14. A — the stage of the collection of the parietal bone site; B — formed free bone autograft, ready for transplantation

gical interventions that did not lead to any disturbance in the jaw continuity. Once the major focus removed, the resulting bone cavity was profoundly washed with an antiseptic solution. A visual examination of the resulting bone defect revealed altered bone tissue areas, which were removed with a milling cutter down to healthy tissues. The causative teeth were removed. Following respective indications, the root resection was performed. Any sharp edges and resected roots were smoothed down with a cutter. The resulting bone cavity was filled with a specially prepared bioengineered structure made of the NWTMTP based on the lithographic model produced subject to the specifically designed method.

In 5 patients with true bone and soft tissue defects, a full-layer muscle-skin grafting was used, which contained inside a mature bioengineered structure of the NWTMTP in combination with bone autochips.

Of these patients with true bone and soft tissue defects, 3 had half-resected lower jaw with the condylar process exarticulation.

All other patients of the main group were treated for mandibular defects using an autotransplantant made by our method and harvested in the anterior abdominal wall. No skin was used there.

Harvesting and autotransplantation of engineered vascularized autotransplantant

The stage of the harvesting the autotransplantant in all cases was performed in the anterior abdominal wall. Prior to placing the autotransplantant in the anterior abdominal wall, surgical marking was performed on the abdomen skin; the course of the perforant vessels was outlined with a surgical marker, the entire process controlled by ultrasound (Fig. 15).

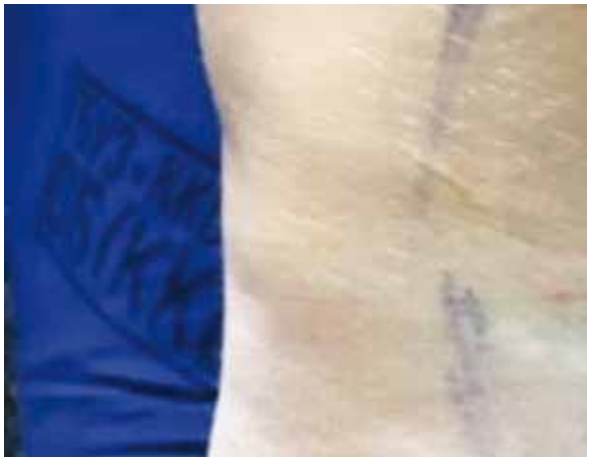


Fig. 15. *Surgical marking of axial vessels on the skin of the abdomen*

The incision line was applied strictly in the iliac crest projection. The crest was detected by palpation. The incision length of the was 9±3 cm. Once the iliac crest was skeletonized, autobone chips or bone fragments were collected (Fig. 16).

For this purpose, a physiodispenser and the specifically designed milling cutter were used to get a spiral-like autobone. Following our method, the titanium and bone chips were stacked in a sterile plaster mold in layers so as to make a pyramid. A dynamic reconstructive perforated plate was placed in the chip thickness, after which a manual press (pre-autoclaved and additionally wrapped with a sterile sheet) was used to compress both halves of the mold until they were completely in contact. Further on, the bioengineered structure was extracted. To ensure its maturation, it was to be placed in the anterior abdominal wall. During that, the perforant vessels markings on the abdomen skin were used as the reference points. The superficial abdominal muscle was dissected horizontally from the existing incision while the dissection went from the anterior vaginal wall of the rectus abdominis muscle up to the volume so as to ensure a smooth passage through it and the desired positioning of the bioengineered structure. The latter was fixed to the surrounding soft tissues with 2–3 sutures of absorbable material (Fig. 17).

X-ray examination was performed on a monthly basis in order to monitor the biocomposition location (Fig. 18).

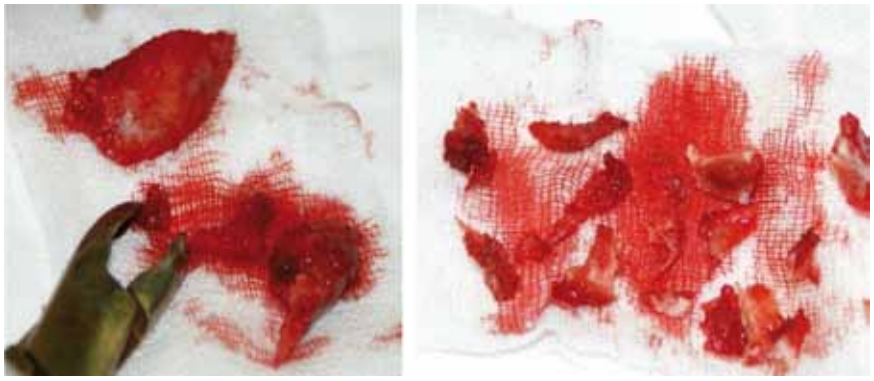
We performed intraoperative ultrasound scanning in order to identify the location of axial blood vessels.

3.5 ± 0.5 months later, the next stage was launched. Isolating the bioengineered structure from the surrounding tissues without a vascular pedicle presented no serious issue. The end sections of the dynamic plate with holes for the intraosseous screws were separated with gauze swabs. The sprouted part of the non-woven titanium material had to be isolated with a sharp tool (Fig. 19).

Following the generally accepted method, the tumor-affected area of the jaw was skeletonized, which was resected retreating 2 cm from the tumor into the healthy jaw. 10 patients had the lower resection jaw with their condylar processes exarticulation. In 13 patients, the joint was preserved (Fig. 20).

Prior to installing the bioengineered structure, the remaining part of the jaw was placed in the central occlusion position while controlled by the splint (Fig. 21).

A reconstructive dynamic titanium plate, along with the bioengineered structure, was attached to the jaw stump with 3-4 standard bicortical intraosseous Stryker system screws (Fig. 22).



A B

Fig. 16. A — Bone fragments from the iliac crest; B — Bone chips taken from the iliac crest

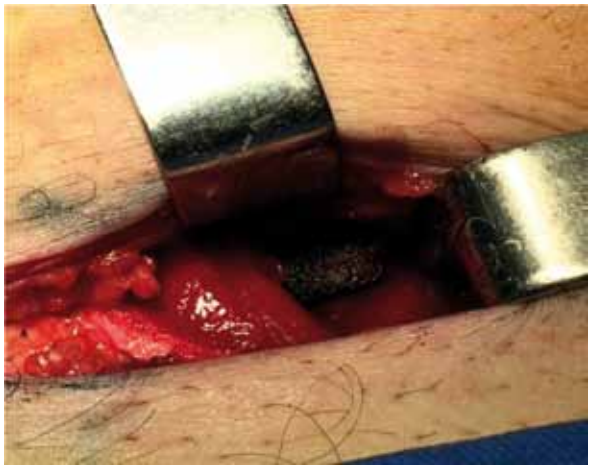


Fig. 17. The engineered biomaterial is fixed in the thickness of the rectus abdominis muscle (the wound is ready for suturing)

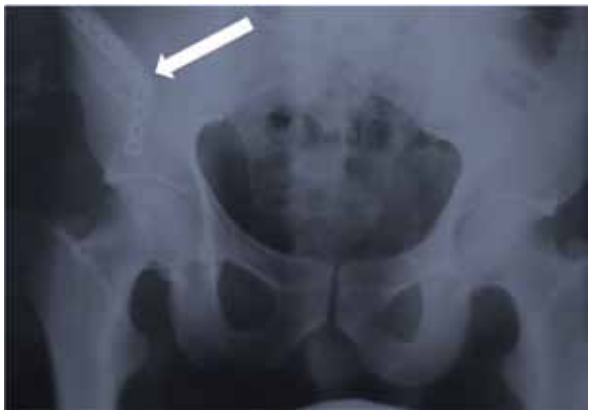


Fig. 18. X-ray of the pelvic bones. The arrow indicates a bioengineering structure

In 5 patients with soft tissue and jaw defects, the bioengineered structure – taken as a single conglomerate – was transferred to the affected area together with the surrounding skin and soft tissues (Fig. 23).

When working on a plastic surgery for a soft tissue defect, a reasonable idea is to have two teams of surgeons, for one of them to be responsible for preparing the recipient zone, the other team modeling the grafting. For all cases within our study, a team of duly certified microsurgeons were involved. In each clinical case, a mandatory ultrasound Doppler examination of the perforant and axial vessels was done (Fig. 24).

While controlling the bite, a dynamic reconstructive titanium plate was attached to the exposed lower jaw stumps, which was ran, as reinforcement, into the bioengineered structure depth (Fig. 25).

After that, microsurgeons used microscopes to stitch the facial vessels with vessels feeding the complex soft-tissue grafting with the bioengineered structure inside, applying traditional vascular sutures. The facial soft tissues and the transplanted grafting were stitched in layers (Fig. 26).

15 patients of the main group had their bone defects replaced with a bioengineered structure simultaneously with the lower jaw resection. All patients were treated for ameloblastomas, often recurrent tumors of the lower jaw. During that, no true soft tissue defects were observed. Before the lower jaw resection, individual molds were made based on our method, which were sterilized and delivered to the operating room.

During the surgery, bone chips were taken from the ilium using the specially designed cutter as mentioned earlier (Fig. 27).

As we started manufacturing a bioengineered structure, layers of titanium and bone chips were placed in layers into the earlier prepared mold, to make a pyramid and compressed. In the center of that the reconstructive plate was to be found (Fig. 28).

The resulting bioengineered structure was placed in the lower jaw defect area that developed following the tumor resection, to be fixed afterwards, and then the structure was covered with surrounding soft

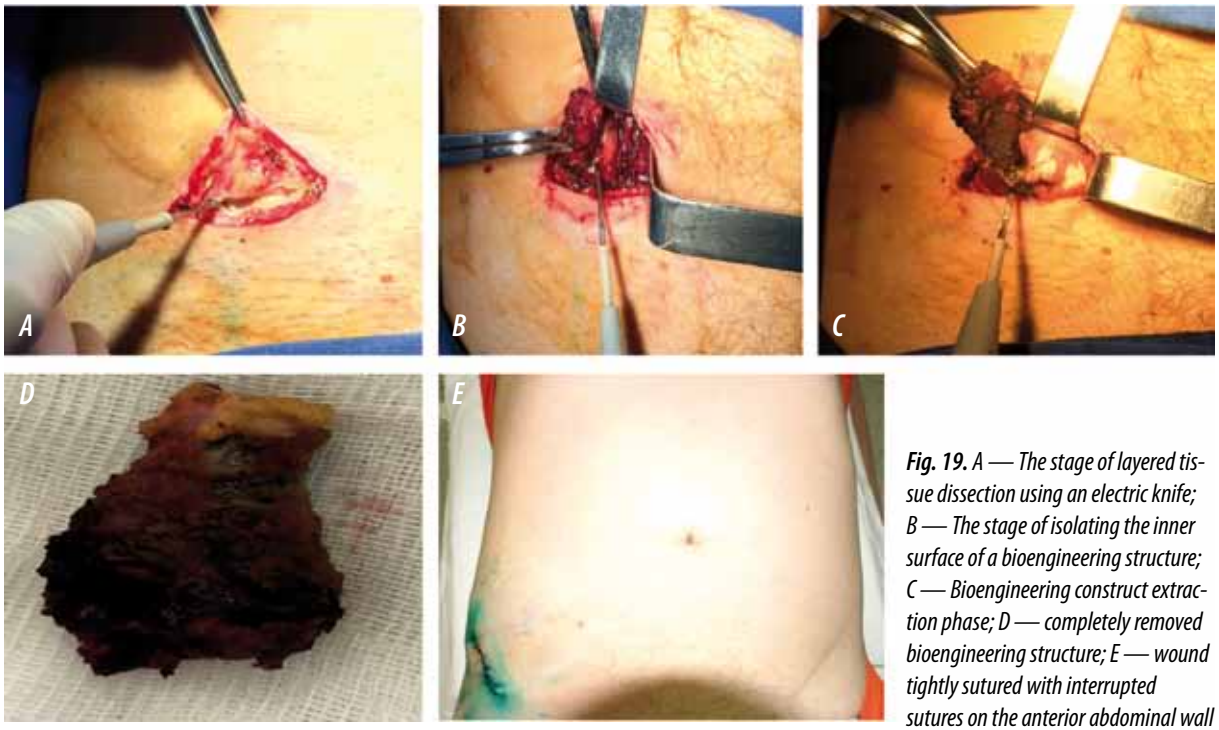


Fig. 19. *A — The stage of layered tissue dissection using an electric knife; B — The stage of isolating the inner surface of a bioengineering structure; C — Bioengineering construct extraction phase; D — completely removed bioengineering structure; E — wound tightly sutured with interrupted sutures on the anterior abdominal wall*

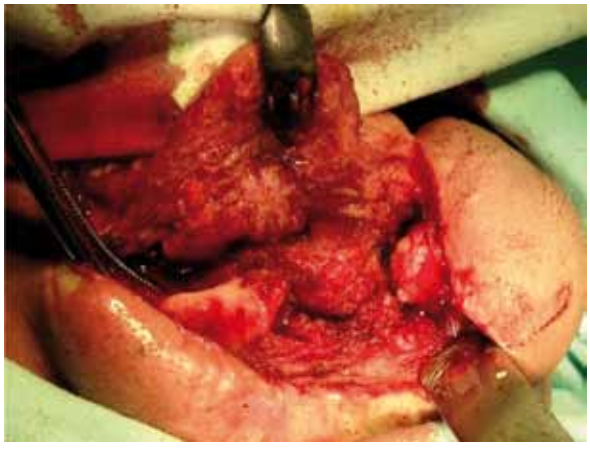


Fig. 20. *Patient K., 34 years old. D.S. Ameloblastoma of the lower jaw on the left. Resection of the affected area of the lower jaw performed*

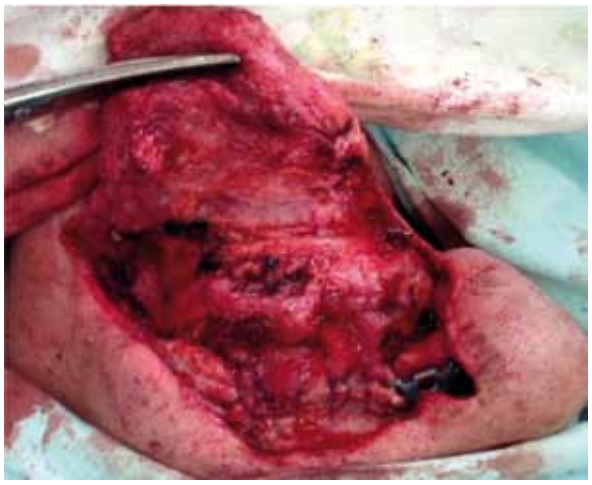


Fig. 22. *The graft is fixed in the wound; the wound is ready for suturing*

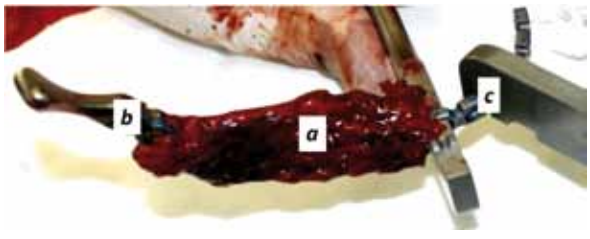


Fig. 21. *The stage of adjusting the bioengineering structure: a — matured bioengineering structure; b — titanium head of the condylar process; c — keys for bending*

tissues. The wound on the side of the mouth and skin was sutured tightly. Drainage was ensured with rubber drains (Fig. 29).

RESULTS AND DISCUSSION

The data from evidence-based medicine research projects revealed a 47% reduction in absolute risk with a confidence interval of 3–59%. The number of patients who need to be treated with our method (number needed to treat / NNT) was 2 (CI — 2–3).

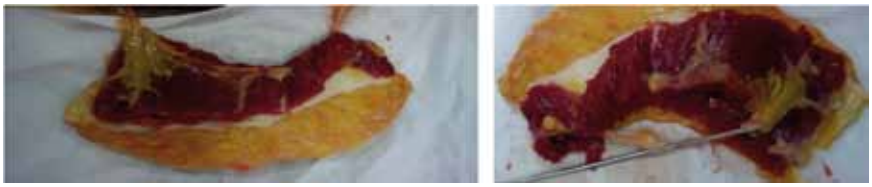


Fig. 23. General view of an autograft with a bioengineering structure inside

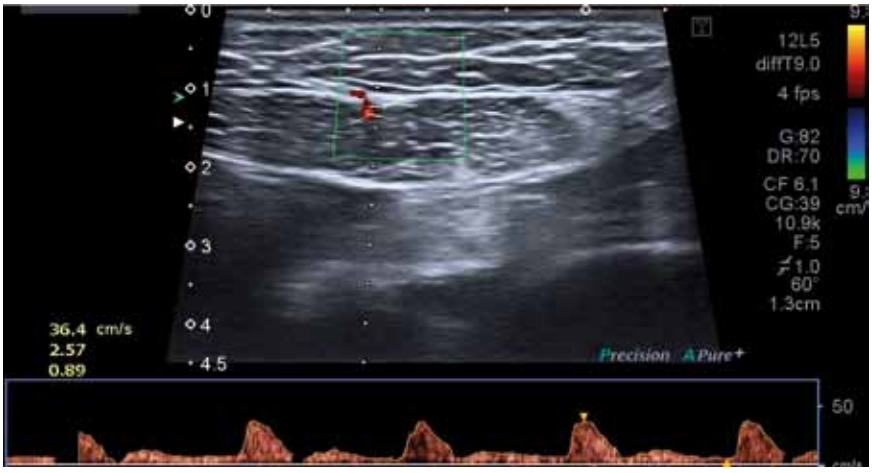


Fig. 24. Ultrasound examination of intraoperatively perforated vessels

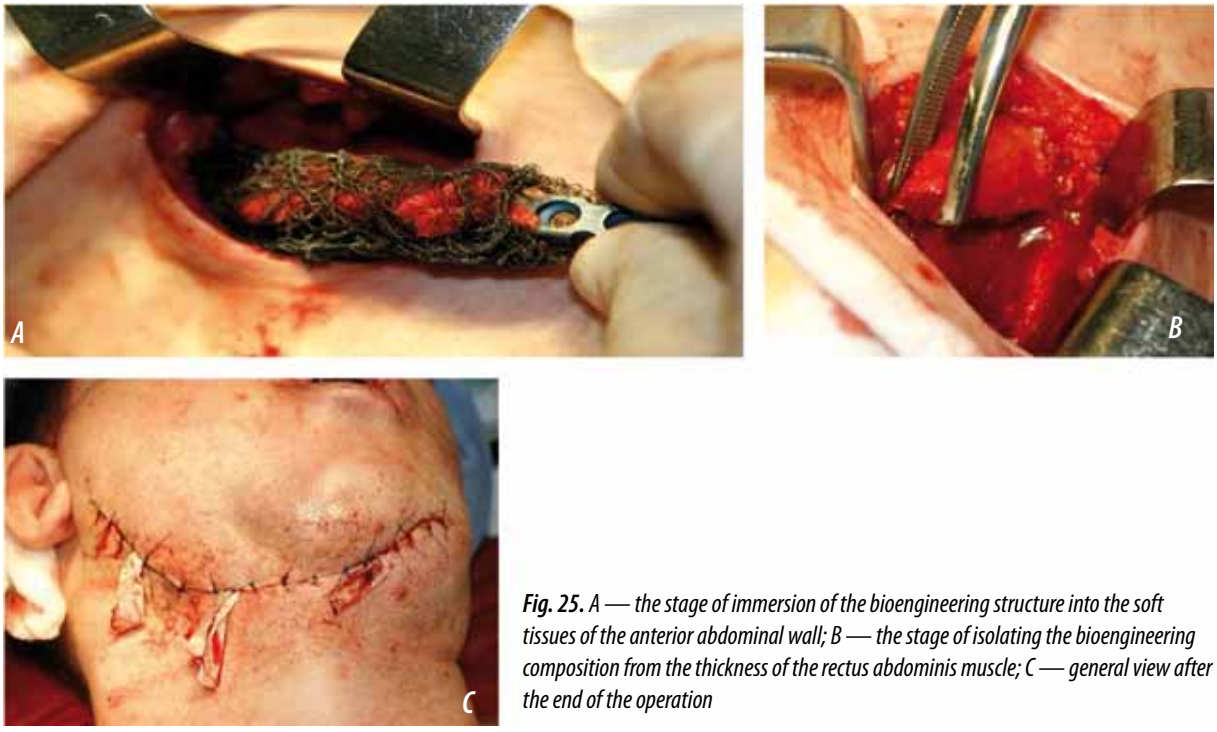


Fig. 25. A — the stage of immersion of the bioengineering structure into the soft tissues of the anterior abdominal wall; B — the stage of isolating the bioengineering composition from the thickness of the rectus abdominis muscle; C — general view after the end of the operation

The relative risk reduction was at 94% with a CI of 59–116%, which stands for a very high clinically significant effect. The odds ratio was 0.03 with a CI of 0.01–0.26, whereas the risk of adverse outcomes proved very low (χ^2 — 18.83; p = 0.0001).

These results here reveal a fairly high rate of insufficient aesthetic effectiveness in the control group if compared to the group treated using the specially developed method — 24 VS. 3%, respectively (χ^2 — 4.99; p = 0.026). The relative risk reduction was 84% with a

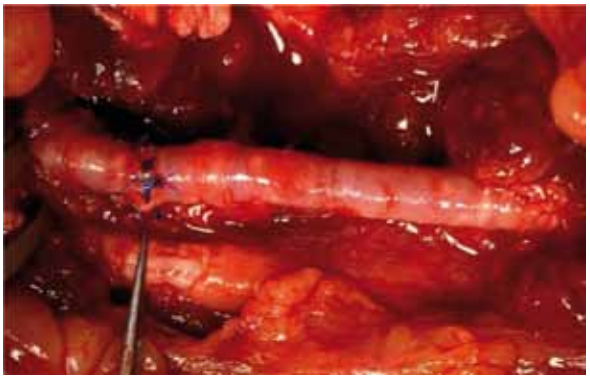


Fig. 26. General view of sutured vessels (magnification ×6)

confidence interval ranging from 2 to 133%. The absolute risk reduction was 21% with a CI of 5 to 32%. The number of patients who need to be treated in order to prevent one adverse outcome (poor aesthetic effect) is 5 with a CI of 3 to 19. The odds ratio of 0.11 with a CI of 0.02–0.85 means that, when using the newly developed method, the risk of an unfavorable outcome was 5 times as low compared to the generally accepted one ($p = 0.026$), this implying that the effectiveness of the proposed technology in terms of ensuring aesthetic effect is to be viewed significant both statistically and clinically.

An unfavorable outcome (poor functional result) was observed in many fewer cases — 3% and 42%,

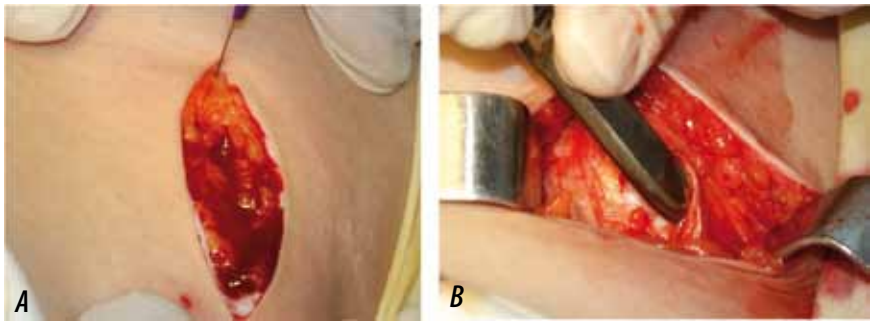


Fig. 27. A — Skin incision with an electric knife; B — Skeleton stage of the iliac crest

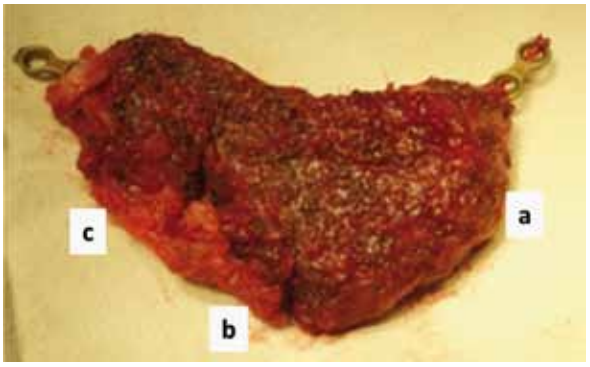


Fig. 28. Bioengineered composition ready for transplantation into the area of the lower jaw after removal of the ameloblastoma: a — the body of the lower jaw; b — the angle of the lower jaw; c — the branch of the lower jaw

respectively. The absolute risk reduction was 39% with a confidence interval of 22–50%. The number of patients to be treated with the proposed intervention was 3 (CI — 2–5). The relative risk reduction was 92% with a CI of 53–120%. Values exceeding 50% correspond to a clinically significant effect. The odds ratio was 0.05 with a CI of 0.01–0.36, i.e., the risk of an adverse outcome in terms of failure to arrive at a positive functional effect while employing the proposed method was very low.

The method was also associated with a high statistically and clinically significant positive result in terms of assessing the intervention effectiveness subject to factor like the patient's psychoemotional satisfaction following the surgical and orthopedic rehabilita-

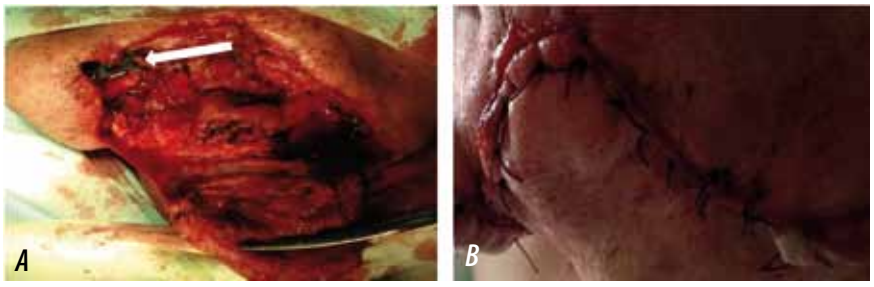


Fig. 29. A — Surgical wound after resection of a part of the lower jaw body on the right and replaced with a bioengineering composition; B — View of a sutured and drained wound

Table 1. *Key indicators of the intervention effect following the treatment of defects based on the specially developed method (Group I), compared to the defect reconstruction based on conventional methods (Group II)*

Comparison groups	Indicators							
	Event Rate in Treated Group %	Event Rate in Control Group %	Relative Risk Reduction % 95% CI	Absolute Risk Reduction % 95% CI	NNT 95% CI	Odds Ratio 95% CI	x2	P
Poor aesthetic effect								
Groups I and II	3	24	84 2-133	21 5-32	5 3-19	0.11 0.020.85	4.9 9	P = 0.026
Poor functional effect								
Groups I and II	3	42	92 53-120	39 22-50	3 2-5	0.05 0.01 0.36	13. 84	P =0.00 01
Poor psychoemotional status following the final stage of the surgical and orthopedic rehabilitation								
Groups I and II	3	50	94 59 -116	47 3 - 59	2 2 - 3	0.03 0.01 0.26	18. 83	P = 0.00 01

tion stage. Unsatisfactory psychoemotional status after surgical and orthopedic rehabilitation based on the proposed method, if matched against the conventional treatment, was much lower — 3% and 50%, respectively.

The absolute risk reduction was 47% with a confidence interval of 3–59%, whereas the number of patients in need of treatment (NNT) was 2 (CI 2–3). The relative risk reduction was 94% at a CI of 59–116%, which stands proof to a very high clinically significant effect. The odds ratio was 0.03 at a CI of 0.01-0.26, while the risk of adverse outcome proved very low (χ^2 — 18.83; = 0.0001).

In view of the above, the key indicators used to evaluate the intervention effectiveness in patients operated on using the proposed method, if compared to conventional methods, reveal a high clinical statistical significance of the obtained outcomes as well as point at the feasibility of employing the proposed treatment methods in practical healthcare.

The obtained outcomes allow recommending these technologies to be scaled up thus embracing a wider clinical practice.

CONCLUSIONS

1. Improved treatment effectiveness for patients with mandibular defects, which was due to employing a vascularized individual bioengineered composition based on non-woven titanium material with through porosity. The risk of an unfavorable treatment outcome while using the proposed method was 5 times as low compared to the generally accepted ones.

2. Analysis of the treatment results in patients with lower jaw defects, based on the data reported by specialized maxillofacial hospitals of the Samara and the Krasnodar Regions of Russia revealed the following: 32% of patients were not satisfied with the treatment outcomes, of which aesthetic dissatisfaction accounted for 18%, whereas another 14% of patients were not satisfied with the orthopedic structures.

3. The study helped obtain experimental proof, protect by a patent, manufacture and implement into clinical practice a special cutter to be used for spiral-shaped bone sampling (Patent # 2733687).

4. A 3D prototyping-based method of sampling and shaping a vascularized autograft combined with a non-woven titanium material with through-porosity has been offered its theoretical explanation as well as implemented in clinical practice. If using the proposed method, the risk of adverse outcomes with no positive functional result achieved remains very low, the odds ratio being at 0.05 with a CI of 0.01–0.36.

5. A new method of mandibular defects individual replacement has been improved relying on digital technologies, as well as the method has been protected by a patent and introduced into clinical practice. In case of using the proposed method, the rate of the patient's unsatisfactory psychoemotional status following the surgical and orthopedic rehabilitation stage was much lower, if compared to the conventional treatment — 3% and 50%, respectively.

6. The specifically designed individual vascularized autografts, while combined with a non-woven titanium material with through porosity allowed increasing the aesthetic and the functional outcomes as well as bring up the rate of the psychoemotional satisfaction following the treatment. Insufficient functional results were observed in 3% of the cases; the absolute risk reduction reached 47% with a confidence interval of 3–59%. The number of patients that needed

treatment (CNNT) was 2 (CI 2–3). The relative risk reduction was 94% with a CI of 59–116%, which corresponds to a very high clinically significant effect. The odds ratio was 0.03 with a CI of 0.01–0.26, while the risk of arriving at an adverse outcome proved very low (χ^2 — 18.83; p = 0.0001).

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