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Research Article

Changing the geometry of polymer spherical orbital implants

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ABSTRACT

BACKGROUND: Over the past decades, various polymer implants have been actively used in the rehabilitation of patients with anophthalmos to form a volumetric support stump and improve the results of cosmetic prosthetics.

AIM: To assess clinical symptoms and features of the X-ray picture in patients with anophthalmos after implantation of polymeric spherical endoprostheses with a modified geometry.

MATERIALS AND METHODS: The study is based on the analysis of 30 patients with anophthalmos after enucleations (23) and eviscerations (7) performed using various methods of procedure and insertion into tissues of an implant made of domestic polytetrafluoroethylene. All patients underwent a multispiral computed tomography (MSCT) of the eye sockets according to the same algorithm.

RESULTS: On the basis of the performed studies, the fact of making a change in the geometry of the implanted spherical implants was revealed, while the parameters of the modified part of the spheres were different and ranged from 14 to 18 mm of final diameters with the initial diameters of the spheres ranging from 18 to 20 mm. A decrease in the volume of spheres with modified geometry from 0.114 to 0.651 cm^3 was revealed with initial diameters ranging from 18 to 20 mm.

CONCLUSIONS: Changes in the geometry of the orbital spheres do not improve the results of cosmetic prosthetics in patients, increase the percentage of implant exposure at different times after surgery, and increase the manifestations of anophthalmic syndrome.

Keywords: anophthalmic syndrome; orbital polymer implants; post-nucleation stump.

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Научная статья

Изменение геометрии полимерных сферичных орбитальных имплантатов

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АННОТАЦИЯ

Актуальность. За последние десятилетия в реабилитации пациентов с анофтальмом активно используются различные полимерные имплантаты для формирования объёмной опорной культи и улучшения результатов косметического протезирования.

Цель — оценить клиническую симптоматику и особенности рентгенологической картины у пациентов с анофтальмом после имплантации полимерных сферичных эндопротезов с изменённой геометрией.

Материалы и методы. Исследование базируется на анализе 30 пациентов с анофтальмом после проведённых энуклеаций (23) и эвисцераций (7) в различных методиках выполнения и введения в ткани имплантата, выполненного из отечественного политетрафторэтилена. Все пациенты прошли мультиспиральное компьютерное томографическое исследование глазниц по единому алгоритму.

Результаты. На основании выполненных исследований выявлен факт внесения изменения в геометрию имплантированных сферичных имплантатов, при этом параметры изменённой части сфер были различны и составили от 14 до 18 мм конечных диаметров при исходных диаметрах сфер от 18 до 20 мм. Выявлено уменьшение объёма сфер с изменённой геометрией от 0,114 до 0,651 см^3 при исходных диаметрах от 18 до 20 мм.

Заключение. Внесение изменений в геометрию орбитальных сферичных имплантатов не приводит к повышению результатов косметического протезирования у пациентов, увеличивает процент обнажения имплантатов на разных сроках после операции и вызывает проявления анофтальмического синдрома.

Ключевые слова: анофтальмический синдром; орбитальные полимерные имплантаты; постэнуклеационная культя.

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BACKGROUND

Over the past decades, microsurgery has seen significant advances in the development and creation of unique surgical technologies. This was greatly facilitated by the creation of new polymer materials as implants to replace the functions of lost organs and missing volumes [1].

In parallel with the creation of new materials, methods for assessing the biological safety of new and known polymers and implants based on them, and the influence of model environments (simulating various conditions of the human body) on the stability of the initial structure of implanted materials are being successfully developed [2].

When developing polymer products, the basic and specific conditions for the presence of an implant in living tissues are taken into account — the movement of tissues surrounding the implant, the possibility of infection, modeling the conditions of inflammation in the body where the polymer material is located, etc. [3–5].

From the middle of the twentieth century orbital implants are being successfully developed and introduced into clinical practice to form a supporting stump during globe removal [6–12].

Currently, several types of polymer spherical endoprosthetic implants are certified and implemented in Russia. According to the Russian literature data, orbital spherical implants based on polytetrafluoroethylene (PTFE) material have shown good engraftment and stability within orbital tissues [13].

A number of methods are used to visualize orbital structures, the most informative of which is multislice computed tomography (MSCT). Using MSCT of the orbits, it is possible to fully characterize all orbital structures, including installed implants [14, 15].

The purpose of the work was to study the characteristics of clinical manifestations and the diagnostic images of the orbital tissues after implantation of a PTFE polymer liner with intraoperative changes within the construction of the product.

MATERIALS AND METHODS

We examined 30 patients (12 men and 18 women) with anophthalmos (operations were performed by various surgeons in several medical institutions) with implantation of the liners (orbital spheres). The implant material was porous PTFE produced in Russia. The period after surgery was from 6 months up to 7.5 years with routine consultations and requests to replace a cosmetic prosthesis. 22 patients complained of discharge from the conjunctival cavity. The nature of the discharge ranges from mucous to purulent.

Patients underwent MSCT using the unified "Orbit" algorithm (scanning parameters), followed by the construction of multiplanar reconstructions and analysis of the obtained images, according to the developed algorithm [16].

RESULTS

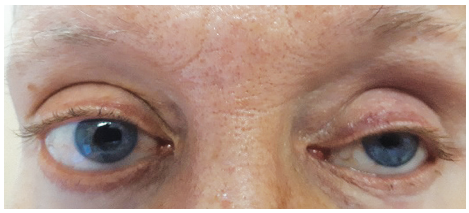
As a result of our research, we found out that 28 patients complained about the retraction of the prosthesis (Fig. 1), 2 patients — about the "protrusion of the globe prosthesis" (Fig. 2), 25 — about constant discharge from the conjunctival cavity, 7 people — about unpleasant feelings within the anophthalmic orbit while eye movement, 6 — to a frequent requests for a new prosthesis.

From the medical documentation available from patients, we established that anophthalmos was a consequence of various interventions: enucleation (23), evisceration in various techniques (7).

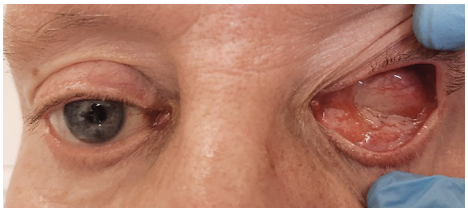
During a general ophthalmological examination at a slit lamp, we identified the following features: stretching of the skin of the upper and lower eyelids (23), ptosis of the upper eyelid of varying severity (23), limited mobility of the musculoskeletal stump in the main gaze positions (20). Palpation of the anophthalmic orbit in 4 patients revealed mild pain in the soft tissues of the orbit; in 8 people, with slight pressure on the tissue, the external prosthesis easily slipped out of the conjunctival cavity. After removing the external cosmetic prosthesis, we found that 20 patients had external prostheses made of plastic, and 10 — out of glass. The nature of the surface of cosmetic prostheses in all examined patients was approximately the same — without cracks, chips, roughness or obvious surface defects. All patients regularly received prosthetics at the Laboratory of Complex Ocular Prosthetics (St. Petersburg) within the recommended time frame. When examining the conjunctival cavity, we found that the anterior surface of the supporting stump in 22 patients was of irregular shape: with truncation of the upper internal quadrant — in 6 patients, the upper external quadrant — in 4, the lower internal — in 9, and the lower external — in 3 patients.

The presence of suture material was detected in 5 operated patients (Fig. 3, 4); in 3 patients there were repeated attempts to apply sutures to close the conjunctival defect. In 21 examined patients, the surface of the stump was covered with conjunctiva, and in 9 its defects were detected (Fig. 5). In 6 patients, granulation changes and fibrous deformations of the mucous membrane of the stump and fornix were noted in the fornix (Fig. 6).

When analyzing diagnostic images after performing MSCT in all examined patients according to the previously described algorithm [16], we identified a change in the size and geometry of the orbital spheres in the form of a "cut" part (Fig. 8). The parameters of the modified part,

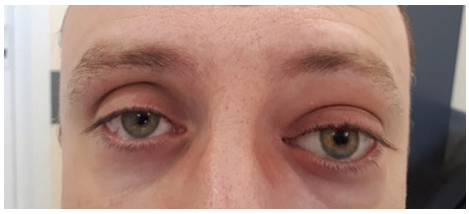


a



b

Fig. 1. Patient, 61 y. o., 4 years after surgery: *a* — left-side anophthalmos, retraction of the cosmetic prosthesis, deepening of the upper orbito-palpebral sulcus, ptosis; *b* — without the prosthesis, discharge in the cavity, flattened anterior surface of the stump, deep upper fornix. State after surgery with the introduction of an implant with modified geometry
Рис. 1. Пациент, 61 год, 4 года после операции: *a* — анофтальмический синдром слева, западение косметического протеза, углубление верхней орбито-пальпебральной борозды, птоз верхнего века; *b* — без протеза, отделяемое в полости, уплощённая передняя поверхность культи, глубокий верхний свод. Состояние после операции с введением имплантата с изменённой геометрией



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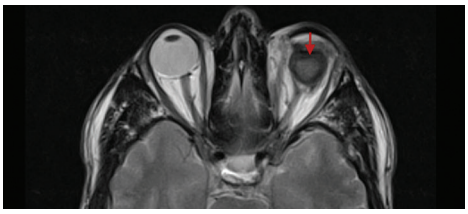


b

Fig. 2. Patient, 34 y. o. 3 years after surgery: *a* — exophthalmos of the left prosthesis, deformation and stretching of the eyelids, of the conjunctival cavity; *b* — MRI-exam. The arrow shows the front surface of the implant with modified geometry
Рис. 2. Пациент, 34 года. 3 года после операции: *a* — выстояние наружного протеза левого глаза, деформация и растяжение век, растяжение конъюнктивальной полости; *b* — МРТ-исследование. Стрелкой показана передняя поверхность имплантата с измененной геометрией

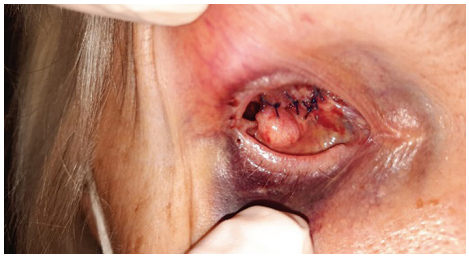


Fig. 3. Patient, 45 y. o. Knots of non-absorbable material on the front surface of the stump
Рис. 3. Пациент, 45 лет. Узлы нерассасывающегося шовного материала на передней поверхности опорной культи

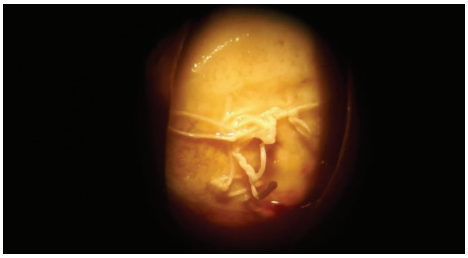


Fig. 4. Suture material on the stump, implant exposure (photo slit lamp)
Рис. 4. Шовный материал на передней поверхности культи. Обнажение имплантата (фото-щелевая лампа)

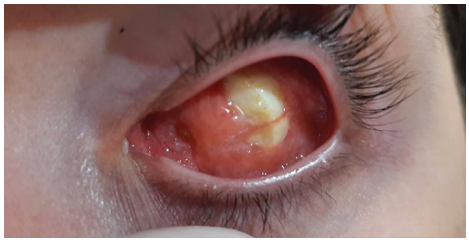


Fig. 5. Patient, 28 y. o. 2 years after surgery. Defect of the epithelium above the surface of the implant with modified geometry, chronic conjunctivitis
Рис. 5. Пациент, 28 лет. 2 года после операции. Дефект эпителия над поверхностью имплантата с изменённой геометрией, хронический конъюнктивит

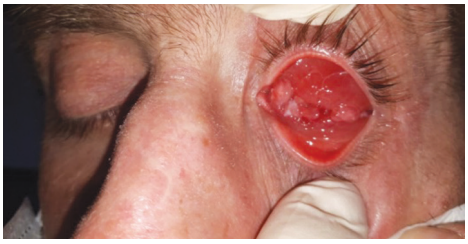


Fig. 6. Patient K., 42 y. o. 3 years after surgery. Granulation in the conjunctivas cavity of the anophthalmic orbit
Рис. 6. Пациент, 42 года. 3 года после операции. Грануляции в конъюнктивальной полости анофтальмической орбиты

as well as the dimensions of the implants themselves, were different (Tables 1–3). The initial parameters (diameters) of the orbital spheres were 18, 19 and 20 mm. During a computed tomography study, we analyzed the dimensions of the implanted materials, determining the volume of the liners through the radius and height of the cut part using the formula: $V = 1/3\pi h^2(3r - h)$, where π is a constant equal to 3.14; r is the radius of the ball; h is the height of the spherical segment of the implant.

Table 1. Parameters of the investigated implants (at basic values of the diameter 20 mm and volume of the sphere $V = 4.186$)
Таблица 1. Параметры исследованных имплантатов (при базовых значениях диаметра, 2r, 20 мм и объёме сферы $V = 4{,}186$)

No. patient	Height to the cutaway part (h)	Volume of the remain implant, cm^3	The difference of the volumes
1	15	3.535	0.651
2	15	3.535	0.651
3	16	3.754	0.432
4	16	3.754	0.432
5	16	3.754	0.432
6	16	3.754	0.432
7	16	3.754	0.432
8	16	3.754	0.432
9	16	3.754	0.432
10	16	3.754	0.432
11	16	3.754	0.432
12	17	3.935	0.251
13	17	3.935	0.251
14	17	3.935	0.251
15	18	4.072	0.114

Table 2. Parameters of the investigated implants (at basic values of the diameter 19 mm and volume of the sphere $V = 3.583$)
Таблица 2. Параметры исследованных имплантатов (при базовых значениях диаметра, 2r, 19 мм и объёме сферы $V = 3{,}583$)

No. patient	Height to the cutaway part (h)	Volume of the remain implant, cm^3	The difference of the volumes
1	15	3.181	0.402
2	15	3.181	0.402
3	15	3.181	0.402
4	15	3.181	0.402
5	15	3.181	0.402
6	15	3.181	0.402
7	15	3.181	0.402
8	16	3.351	0.232
9	16	3.351	0.232
10	16	3.351	0.232
11	16	3.351	0.232

Table 3. Parameters of the investigated implants (at basic values of the diameter 18 mm and volume of the sphere $V = 3.047$)
Таблица 3. Параметры исследованных имплантатов (при базовых значениях диаметра, 2r, 18 мм и объёме сферы $V = 3{,}047$)

No. patient	Height to the cutaway part (h)	Volume of the remain implant, cm^3	The difference of the volumes
1	14	2.669	0.378
2	14	2.669	0.378
3	15	2.828	0.219
4	15	2.828	0.219

Analyzing the data obtained, we found that the dimensions of the modified geometry of the implanted orbital liners differed, the volume loss with an initial diameter of 20 mm averaged 0.4038 cm^3, with a diameter of 19 mm — 0.340 cm^3, with a diameter of 18 mm — 0.298 cm^3 (Fig. 7–11).

Thus, as a result of changes in geometry, orbital implants, in our opinion, will not fully perform one of their functions — restoration of the volume of the supporting stump. Clinically, this is expressed in the displacement of the anterior surface of the formed stump deeper into the orbit; with further rehabilitation in such patients, the ocular prosthetist will be forced to make a more convex (due to thickness) form of the external prosthesis, which will lead to the installation of a heavier prosthesis into the cavity, which will affect its mobility.

In the soft tissues around the changed implanted spheres, we identified compactions, without signs of calcification and destruction of the orbital walls (Fig. 7, 8). In addition, in one patient, not only a change in the geometry of the sphere in the form of a cut-off part was noted (Fig. 10, *a*), but also the presence of many fragments of polymer material with identical radiographic density. These implant fragments were located behind the posterior pole of the polymer liner within the soft tissues till the apex of the orbit (Fig. 10, *b*).

The above complaints, the diversity of the identified clinical picture and radiological findings in the examined patients during MSCT examination of the orbits allowed us to offer patients an individually developed treatment plan. The basis of this plan was intervention in the scope of reconstructive surgery with the replacement of an

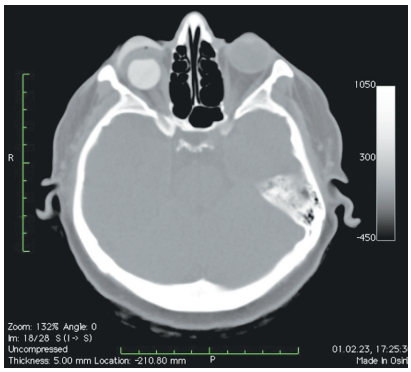


Fig. 7. Patient, 32 y. o. 3 years after surgery with implantation of an endoprosthesis with modified geometry. MSCT of the socket

Рис. 7. Пациентка, 32 года. 3 года после операции с имплантацией эндопротеза с изменённой геометрией. МСКТ-исследование глазниц

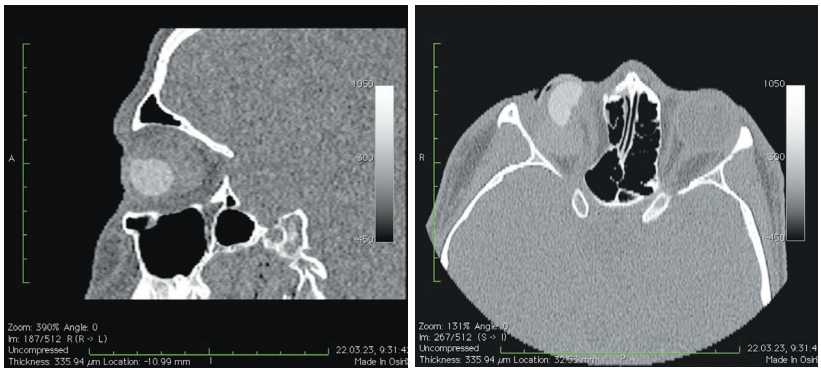


Fig. 8. Patient, 21 y. o. 2,5 years after surgery with implantation of an endoprosthesis with modified geometry. MSCT of the socket

Рис. 8. Пациент, 21 год. 2,5 года после операции с имплантацией эндопротеза с изменённой геометрией. МСКТ-исследование

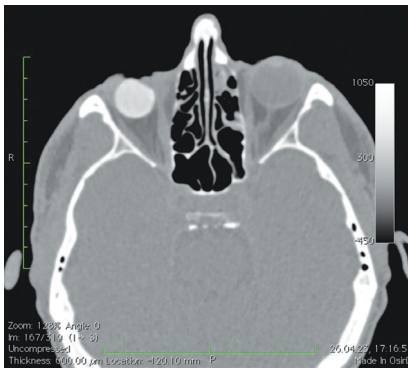
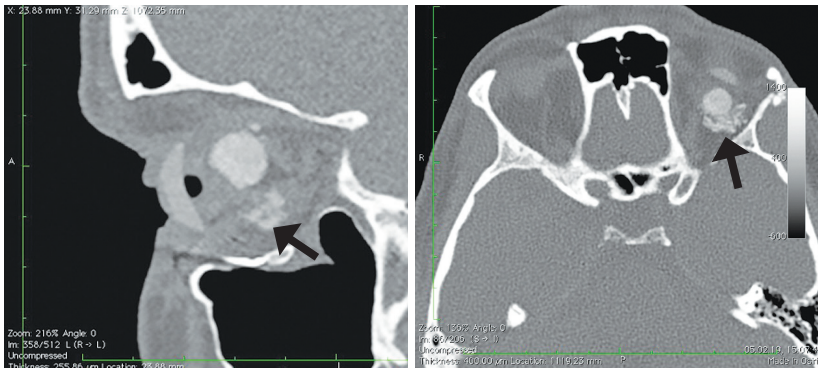


Fig. 9. Patient, 57 y. o. 3 years after surgery with implantation of an endoprosthesis with modified geometry. Defect of the anterior surface of the stump, exposure of the orbital implant

Рис. 9. Пациент, 57 лет. 3 года после операции с имплантацией эндопротеза с изменённой геометрией, дефект передней поверхности культи, обнажение края имплантата. МСКТ-исследование



a *b*

Fig. 10. Patient, 42 y. o. The state after surgery using an implant with modified geometry (*a*), and multiple fragments of the same material in the tissues of the orbit (*b*, shown by arrows)

Рис. 10. Пациентка, 42 года. Состояние после операции с использованием имплантата с изменённой геометрией (*a*) и множественными фрагментами из такого же материала в тканях орбиты (*b*, показано стрелками)

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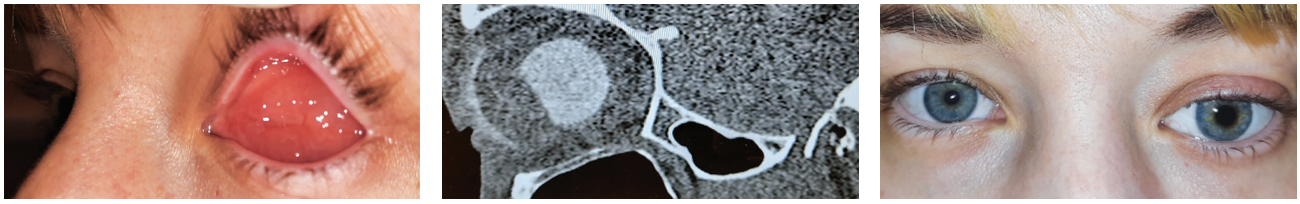

a *b* *c*

Fig. 11. Patient, 33 y. o.: *a* — general view of the conjunctival cavity without prosthesis. Edema of the conjunctiva covering the stump and anophthalmic cavity; *b* — MSCT study. Soft tissue hypertrophy anterior to the implant with modified geometry. Thin-walled prosthesis; *c* — general view with prosthesis. Deformation of eyelids, protrusion of a thin-walled prosthesis due to hypertrophy and edema of soft tissues
Рис. 11. Пациентка, 33 года: *а* — общий вид конъюнктивальной полости без протеза. Отёк конъюнктивальной оболочки культи и анофтальмической полости; *b* — МСКТ-исследование. Гипертрофия мягких тканей кпереди от имплантата с изменённой геометрией. Тонкостенный протез; *c* — общий вид с протезом. Деформация век, выстояние тонкостенного протеза за счёт гипертрофии и отёка мягких тканей

implant with a changed geometry with industrially produced ones, calculated with the parameters of the paired orbit. If a patient subsequently detects a residual volume deficit in the soft tissues of the orbit, further correction of the volume deficit using other surgical techniques was recommended [17].

DISCUSSION OF THE OBTAINED RESULTS

Making design changes intraoperatively and immediately before implantation into the patient's tissue is a practice that was used in ophthalmic surgery during the second half of the twentieth century, when sufficient knowledge was not accumulated about the effects of polymers on body tissues, and the study of toxicity and assessment of the biosafety of implants were approximate. In subsequent years, manufacturers have steadily improved the quality of manufactured polymer implants and used the most advanced methods for assessing the toxicity of made products due to changes in legislation in a number of countries towards stricter requirements for the biosafety of polymer implants [18].

The non-industrial manual (handicraft) method of changing the geometry, in other words, cutting off part of a polymer implant with scissors or a scalpel, in our opinion, has several negative aspects.

Firstly, the mechanical impact is not accompanied by processing of the edges of the cut-off surface of the polymer product, which is technically impossible to perform efficiently during the operation. The left sharp edge of the implant subsequently, when located in the orbital tissues, contributes not only to the contouring of the edge of the implant liner, thinning of the tissues covering it, but also contributes to the formation of a defect in the integumentary soft tissues (Tenon's membrane and conjunctiva) above the "cut" area (Fig. 5). Taking into account the active movement of the formed supporting stump and the close contact with the external cosmetic prosthesis, which must be adjacent with its rear surface to the front surface of the formed supporting stump, using the forces of capillary adhesion, this change in the shape of the front surface of the stump only intensifies. Displacement (rotation) of the "cut surface" of the implant along an unpredictable vector during the wound healing process leads to an uneven profile of the supporting stump, its incomplete adherence to the external prosthesis and the emergence of conditions for the formation of "free spaces" between the stump and the posterior surface of the external prosthesis. Such a space or spaces are quickly filled with thickening tears and create favorable conditions for the development of infectious processes in the conjunctival cavity of the anophthalmic orbit, contribute to chronic inflammation of the eyelids, the appearance and intensification of signs of DASS syndrome — dry anophthalmic socket syndrome [19].

Secondly, the implant itself acquires other biomechanical characteristics after changing the geometry and can shift in the tissues of the orbit during the formation of the capsule under conditions of constant movement of the stump, especially after enucleation (Fig. 10, *b*).

Thirdly, when the geometry of the endoprosthetic implant is changed, its volumetric characteristics are disrupted in the direction of its reduction, as shown in our work (Fig. 1), and taking into account the disappearance of edema in the tissues of the orbit after 4–6 months after the operation, a symptom complex of "orbital volume insufficiency" occurs — the displacement of the stump, deepening of the orbitopalpebral groove of the upper eyelid and prolapse of the upper eyelid, insufficient range of movements of the supporting stump and external prosthesis. In subsequent periods, these processes in the orbital tissues only intensify.

Fourthly, unsaturated bonds appear at the border of the modified implant polymer [20], which, in our opinion, can exhibit their toxic properties, which can be clinically detected in the form of an aseptic inflammatory process with hypertrophy of the soft tissues of the orbit (Figure 11, *a*). An increase in the volume of soft tissues near the musculoskeletal stump (Fig. 11, *b*) directly affects the quality of external ocular prosthetics and the appearance of the patient (Fig. 11, *c*).

Any patient who is about to undergo globe removal surgery would like to receive high mobility in the postoperative period not only of the formed supporting stump, but also the mobility of the cosmetic prosthesis. In this case, the operated patients also pay attention to the characteristics of the upper eyelid, in particular, to the profile of the superior orbital-palpebral groove and the condition of the lower eyelid. With the correct calculation of the parameters of the orbital sphere without changing its geometry and the gentle nature of the surgical intervention, adequate and timely cosmetic individual prosthetics in the postoperative period, the conditions for the occurrence of retraction of the upper eyelid are minimized. All preoperative parameters of the operated globe should be taken into account, the degree of soft tissue subatrophy and the presence of bone deformities of the operated and paired orbit should be identified [15].

In situations where iatrogenic changes occur in the intraoperative geometry of the orbital sphere, the volume of the polymer implant decreases by an arbitrary amount immediately during the implantation process, which is guaranteed to cause retraction of the upper eyelid after the disappearance of edema in the soft tissues of the orbit at the stage of cosmetic prosthetics. Solving the problem of retraction only by selecting and installing a larger external prosthesis will lead to the appearance or intensification of lagophthalmos and additional stress on the lower eyelid in these patients.

CONCLUSIONS

Thus, operations aimed on forming a musculoskeletal stump should be performed using microsurgical techniques under magnification, with the introduction of individually designed orbital spherical implants without any changes to their geometry with reliable tissue coverage to prevent their possible thinning above the surface of the polymer material. If tissue defects are detected above the surface of the implants, microsurgical debridement of the wound with replacement of the implanted material is necessary — in this case, the timing of delayed implantation is decided on an individual basis.

ADDITIONAL INFORMATION

Authors' contribution. Thereby, all authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study. Personal contribution of each author: D.V. Davydov — concept and design of the study, analysis of the data obtained, writing the text, literature review; N.A. Baranova — collection and processing of material, literature review.

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