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Original Article

A titanium implant for Chiari malformation Type 1 surgery

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ABSTRACT

Background: Concepts of Chiari malformation Type 1 (CM1) surgery in the present time significantly different. The most common complications are pseudomeningocele (12%) and postoperative CSF leak (5%). The development of pseudomeningocele may be associated with inappropriate restoration of bone and muscles relations.

Methods: The pilot study involved 11 patients aged 24–64 years with a diagnosis of CM1 who had indications for surgical treatment. Special titanium implant enabling fixation of the occipital and cervical muscles at the projections of their normal attachments was developed, it was placed to occipital bone on the final stages of surgical intervention. Surgical technique promoted tightened wound closure neutralizing formation of "dead space" at the place of occipital craniectomy and between muscle layers. The implant was produced by direct metal laser sintering method for each patient individually.

Results: There were no complications during the hospitalization and follow-up period. Postoperative MRI demonstrated adequate formation of the cisterna magna and the absence of pseudomeningocele. During follow-up period there were no signs of pseudomeningocele, CSF leak, surgical scar complications, implant-associated infections, and other complications.

Conclusion: In the study group, no pseudomeningocele cases as long as any other complications associated with surgery had been revealed. The efficacy of the proposed surgical technique using the developed implant should be evaluated in clinical trials with larger patient samples. To simplify preoperative planning and manufacturing of the implant for each patient individually, a set of implants with different specified sizes was developed.

Keywords: Acquired meningocele, Chiari malformation Type 1, Three-dimensional printing, Titanium implants

INTRODUCTION

Chiari malformation Type 1 (CM1) is herniation of the stretched cerebellar tonsils into the spinal canal through the foramen magnum, which was first described by Hans Chiari in 1891[5] and has had more than a century of history. In the population, the rate of this condition is 0.5–3.5% and is revealed in postmortem anatomical studies in 0.62%.[3] In Russia, the prevalence of CM1 ranges from 33 to 82/100,000 population.[19] Despite the consensus among specialists regarding the indications for surgical treatment of CM1, surgical concepts vary significantly. The main debatable aspects include the extent of bone resection, need

and extent of dural incision, dissection of the arachnoid membrane, need for interventions on the cerebellar tonsils, need for revision of the fourth ventricle, choice of material for duraplasty, need, and extent of grafting for resected bone structures. As can be seen from the above procedures, the amount of surgery can vary significantly. However, even close adherence to all main surgical guidelines does not always avoid postoperative complications. The most common complications are pseudomeningocele (12%) and postoperative CSF leak (5%);[3] however, the occurrence of these conditions in the literature varies significantly,[1,6,7,12,17,19] not reaching 1% in some series.[27] The development of pseudomeningocele (retrooccipital intramuscular and interfascial CSF cysts) may be due to the fact that, despite layer-by-layer suturing of the deep neck muscles, they are not fixed to the occipital bone, as it anatomically occurs before surgery because these complications are observed even in the case of a water-tight duraplasty and application of adhesive compositions.[17]

Aim

The aim of this pilot study was to assess rate of pseudomeningocele after CM1 surgery in adults using a specially developed titanium implant.

MATERIALS AND METHODS

Study group description

The pilot prospective, single-center, and non-randomized cohort study involved 11 patients aged 24–64 years with a diagnosis of CM1 who had indications for surgical treatment (posterior fossa correction). The study was approved by the local ethics committee of the institution. All patients provided signed informed consent. Criteria for inclusion in the study were as follows:

1. Age of 18–80 years, regardless of gender
2. Indications for surgical treatment of CM1
3. Surgical treatment involving posterior fossa decompression, dural opening, subarachnoid revision, and formation of the cisterna magna using a dural graft
4. Signed informed consent to participate in the pilot study.

Exclusion criteria included:

1. Previous surgery for CM1
2. Refusal to provide information about the state of health and postoperative follow-up MRI scans.

The duration of postoperative follow-up <6 months was the criterion for early withdrawal of the patient from the study.

The mean (M) age of patients was 40.7 ± 14.9 years; the distribution by gender was as follows: three (27.3%) males and 8 (72.7%) females. Before surgery, all patients underwent clinical and instrumental examination including MRI (Toshiba Vantage Titan 1.5 T.) and CT scan (Toshiba Aquilion 64) of the brain. In the presence of a syringomyelia cyst, additional MRI examination of the cervical spine was performed. Surgery was performed using a microsurgical technique with a Carl Zeiss Opmi Vario 33 microscope. On the 1st postoperative day, all patients underwent an MRI scan of the brain; if a syringomyelia cyst was present, and MRI of the cervical spine was also performed. CT scan of the brain was performed on the 7th day after surgery. In the postoperative period, all patients were followed up in the neurosurgical department. The patients were discharged from the hospital after removal of skin sutures and the formation of an adequate postoperative skin scar.

Clinical outcomes after surgery were evaluated using the Chicago Chiari Outcome Scale (CCOS). The patients were examined during follow-up visits at 1, 3, 6, 12, 18, and 24 months after surgery, with MRI of the brain being performed at 6, 12, and 24 months.

The study also included a simulation analysis group ($n = 188$), these patients did not participate directly in the study. The results of their tomographic examinations were used as the basis for mathematical modeling and analysis of the skull anatomical structures in relation to the designed implants.

Surgical technique

Surgery is performed under general anesthesia; the patient is placed in a concord position, with the neck flexed and the head immobilized in a Mayfield bow. At the first stage, an autologous fat graft, approximately 4–6 cm^3 in volume, is harvested from the upper outer quadrant of the left gluteal region. The main stages of surgery in the posterior cranial fossa include: A midline incision in the cervical-occipital region, from the inion to C2 level; exposure of the occipital bone and C1 lamina; resection of a occipital bone portion at the square of 2 × 3 – 3 × 3 cm depending on the posterior fossa configuration and patient's age; C1 laminectomy; dissection and partial resection of the atlanto-occipital membrane; and Y-shaped dural opening, with the base toward the transverse sinus [Figure 1a]. Opening of the arachnoid membrane; partial coagulation of the cerebellar tonsils at low bipolar current if the tonsils descend below the C1 lamina; revision of the entrance to the fourth ventricle through the Magendie's foramen. A tight dura mater closure with a dura substitute synthetic grafts and application of an additional sealant (autologous fat graft) over the duraplasty area using fibrin-thrombin glue. Placement of a specially designed titanium plate [Figure 1b] to fix the occipital and neck muscles. Dural tenting to the titanium plate with nonabsorbable suture, followed by tight layered suture of the muscles with simultaneous fixation to the titanium implant [Figure 1c]. Tight layered suture of soft tissues and skin.

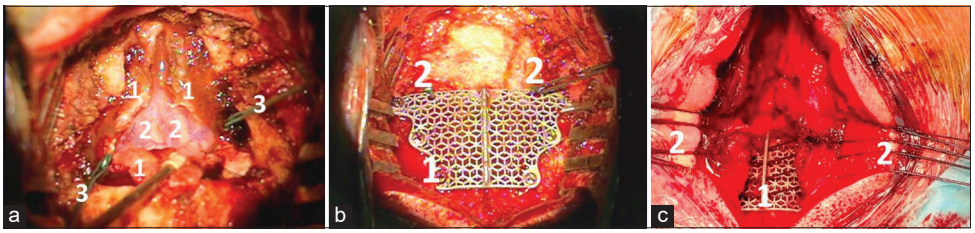

Figure 1: (a) Surgical approach to the posterior fossa. 1 – Dura mater (resected in a Y-like way), 2 – cerebellar tonsils under the arachnoid, 3 – stitches for dural tenting (b) Implant fixation and dural tenting. 1 – Titanium implant, 2 – Stitches for dural tenting (c) Closure of the posterior fossa. 1 – Titanium implant, 2 – muscle stitches.

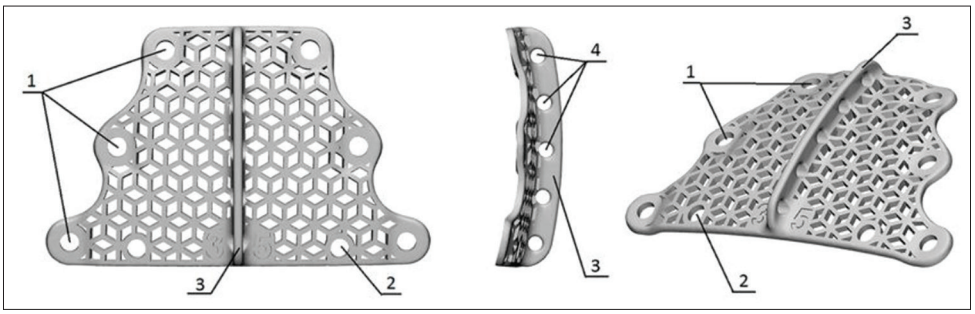

Figure 2: Titanium implant for Chiari 1 posterior fossa reconstruction. 1 – Hole for screw fixation to the occipital bone, 2 – Dural tenting hole, 3 – Fixation ridge, 4 – Aperture for muscle fixation.

Titanium implant

To achieve our objectives, we developed a titanium implant [Figure 2] enabling fixation of the occipital and cervical muscles at the projections of their normal attachments and, if necessary, stretching of the dura mater in the caudal direction. The implant was produced by direct metal laser sintering three-dimensional (3D) printing for each patient individually, based on the anatomical structure of the posterior cranial fossa in the projection of occipital bone resection. The implant had a trapezoidal shape curved in two planes (sagittal and axial), with a lightweight (mesh) structure, which ensured its tight adherence and firm fixation to the bone with screws through mounting holes [1 in Figure 2]. The vertical midline ridge [3 in Figure 2] with holes 4 in the [Figure 2] on the outer side of the plate provided tight fixation of the muscles, which were separated during surgery, to each other and to the occipital bone at their anatomical attachment points. A rough external surface of the implant promoted good adhesion of the fixed muscles and the formation of a reliable scar. In addition, the plate had additional holes 2 in [Figure 3] for pulling the dura mater to it.

Surgical features associated with application of the implant

The surgical technique involving application of the titanium implant was modified: the dura mater is sewn with non-absorbable sutures, and ligatures of the sutures [3 in Figure 1a] are inserted into the holes [2 in Figure 2] to fix the dura mater. The autologous fat graft is placed on the duraplasty area and fixed by fibrin-thrombin glue. The titanium plate is overlaid on the formed occipital bone defect so that about 1/3 of the upper part of the defect is covered with the implant [Figure 4]. Then, the implant is tightly fixed to the occipital bone with screws [Figure 1a] through the mounting holes [1 in Figure 2]. Next, the ligatures are tied, and the dura mater is tented to the inside of the implant [Figure 1b]. Then, the occipital and cervical muscles separated during surgery are sutured together through the openings [4 in Figure 2] located in the vertical ridge [3 in Figure 2] on the outer side of the implant [Figure 1c]. Knots are tied after placing all sutures. As the knots are tightened, the occipital and cervical muscles are tightly fixed together and to the titanium implant.

Assessment of implant variants

In the study, implants were prepared for each patient individually. The following implant parameters were variable: bending in the axial and sagittal plane; the distance between holes for fixation to the occipital bone. Parameters such as the mesh pattern and roughness and the vertical ridge for suturing the occipital and cervical muscles remained unchanged. Therefore, depending on the contour of the patient's occipital bone, only the implant curvature and the distance between mounting holes were changed. The geometry of implants is presented in [Table 1].

Assessment of the occipital bone structure variability (simulation analysis group)

In the study, we also assessed the variability of the occipital bone structure in the area of its resection using 3D skull models of patients who underwent previous surgery for CM1 at the neurosurgical clinic in 2005–2016 without using the titanium implant. For this, 188 preoperative CT scans of the skull of patients with this pathology were analyzed. Available images were exported in the form of a series of digital DICOM data to a program for generating a 3D model; then, the radii of the axial and sagittal curvature of the occipital bone were measured. Next, a 3D model of the skull was generated based on control postoperative radiographic scans, and the size of an occipital craniectomy defect was measured.

Statistical analysis

The data were analyzed using the Statistica 10.0 software package. In the pilot study group, descriptive statistics for scale variables were analyzed (data are presented as M and standard deviation (SD), median, minimum and maximum values, quartiles Q1 and Q3): radii of the axial and sagittal curvature, surgery duration, intraoperative blood loss, and hospital stay duration. Clinical outcomes (CCOS) and the presence of pseudomeningocele and other postoperative complications were analyzed during follow-up visits.

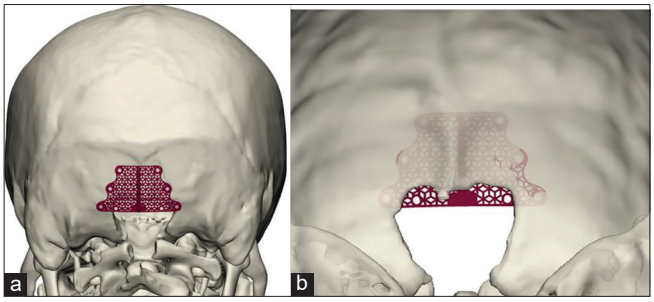

Figure 3: Three-dimensional model of the scull with a titanium implant, based on a postoperative CT scan. (a) Posterior view, (b) frontal view.

RESULTS

The follow-up period ranged from 30 to 9 months; the M surgery duration was 175.5 (12.5) min; intraoperative blood loss was 215.5 (197.4) ml; and hospital stay duration was 13.4 (3.5) days. There were no complications during the hospitalization period. Postoperative CT revealed tight fixation of the titanium implant to the occipital bone in all patients. Postoperative MRI demonstrated adequate formation of the cisterna magna and the absence of pseudomeningocele. After discharge from the hospital, patients underwent follow-up examinations at 1, 3, 6, 12, 18, and 24 months after surgery; MRI of the brain was performed at 6, 12, and 24 months. There were no signs of pseudomeningocele, CSF leak, surgical scar complications, implant-associated infections, and other complications. The number of postoperative visits of each patient is shown in [Table 2]. Clinical outcomes in patients at the latest follow-up visit were scored 13–16 (CCOS); the median score in the group was 15. Improvement in the clinical picture occurred in ten patients; one patient had no clinical changes. There were no deteriorations in the condition.

An analysis of simulated implants (n = 11) revealed that variable components of the implant geometry were the sagittal curvature (radius = 50 and 70 mm) and the implant width (35–25–15 mm and 40–30–20 mm between the centers of mounting holes). Assessing the variability of the occipital bone curvature in the posterior fossa craniectomy area in patients from simulation analysis group (n = 188) found that the axial radius of the occipital curvature varied from 74 to 190 mm, with a M of 115.5 (22) mm, a median of 115 mm, Q1 of 110 mm, and Q3 of 130 mm. The sagittal radius of the occipital curvature varied from 35 to 121 mm, with a M of 63.9 (15.6) mm, a median of 61.5 mm, Q1 of 51 mm, and Q3 of 73 mm.

The obtained data were used to design a set of 32 implants covering all possible combinations of these parameters. Next, the stage of fixation was emulated: each of the produced titanium implant variants was matched to each virtual skull model (n = 188) in a 3D modeling environment using a

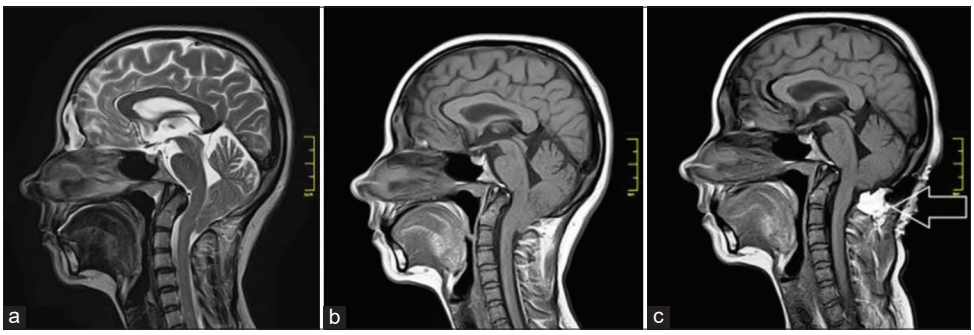

Figure 4: Preoperative (a and b) and postoperative (c) MRI scans. Fat graft is denoted by the arrow.

Table 1: Variation in implant specifications in the study group.

	Axial curvature radius, mm	Sagittal curvature radius, mm	Screw hole distance, mm
Implant 1	115	75	35–25–15
Implant 2	115	75	40–30–20
Implant 3	115	75	35–25–15
Implant 4	115	50	35–25–15
Implant 5	115	75	40–30–20
Implant 6	115	50	40–30–20
Implant 7	115	75	35–25–15
Implant 8	115	75	35–25–15
Implant 9	115	75	40–30–20
Implant 10	115	75	35–25–15
Implant 11	115	75	40–30–20

Table 2: Cumulative patients visit schedule.

	1 mo	3 mo	6 mo	12 mo	18 mo	24 mo
Patient 1	+	+	+	+	+	+
Patient 2	+	+	+	+	+	+
Patient 3	+	+	+	+	+	+
Patient 4	+	+	+	+	+	
Patient 5	+	+	+	+	+	
Patient 6	+	+	+	+	+	
Patient 7	+	+	+	+	+	
Patient 8	+	+	+	+		
Patient 9	+	+	+	+		
Patient 10	+	+	+	+		
Patient 11	+	+	+	+		

simulation analysis group database. It was found that the set of typical sizes may be reduced to four variants because at least one of the implants presented in [Table 3] matched to each skull model.

Clinical case

A 33-year-old female diagnosed with CM1 was hospitalized in April 2019 with complaints of headaches intensifying during the Valsalva test, cough headaches, and occipital and cervical pain. Preoperative MRI data are presented in Figure 3. The patient underwent surgery according to the described technique; the duration of surgery was 150 min; and blood loss was 100 ml. The patient underwent MRI of the brain [Figure 3c] on the 1st postoperative day and CT scan of the skull on the 7th postoperative day; Figure 4 shows a 3D reconstruction of the skull with a fixed titanium implant partially covering a formed bone defect. One month after surgery, the patient noted a decrease in the intensity of headaches and regression of cough headache. Occipital headache regressed after 3 months; complete regression of complaints presented before surgery occurred after 6 months. The outcome was scored 16 (CCOS). There were no surgical complications; no pseudomeningocele and an adequate surgical scar [Figure 5] were revealed in a MRI scan at 12 months after the surgery.

DISCUSSION

As described above, to date, there are many surgical approaches in the treatment of patients with CM1. At the final surgical stages, a number of authors have suggested using titanium mini-plates for prevention of cerebellar prolapse,[6,10,11,24] which was first described by Williams in 1978,[25] or for additional caudal fixation (dural tenting) of the dura mater to achieve a larger volume of a formed cisterna magna.[4] Some authors have used autologous bone flaps[22] or titanium meshes to prevent compression of a large occipital cyst by edematous muscles[27] and by postoperative scars.[13,15,18,20]

An important aspect of any surgery is to restore the normal anatomy in the approach area as much as possible. Usually, on closing a wound at the final stages of surgery for CM1, the occipital muscles are sutured together, but not attached to the occipital bone. In this case, a small "dead space" is formed in the occipital bone resection area, which may become a cavity for accumulation of exudate or cerebrospinal fluid and subsequently progress in pseudomeningocele that accounts for about 12%,[3] on average, and reaches, in some series, 40% of complications after cranial and spinal interventions.[9,14,16,21,23,26] In some cases, this condition may occur asymptomatically, causing complaints of a cosmetic defect when it occupies significant space. In clinically significant situations, pseudomeningocele causes local pain,[21] symptoms of hypertensive or hypotensive headaches or, gradually progressing, and occupying more space, may lead to cerebrospinal fluid leak, which increases the risk of infection by 10.2 times.[2] In some cases, correction of pseudomeningocele is a difficult task involving a series of interventions.[8]

To prevent the development of pseudomeningocele, we has developed a titanium implant that has special elements for

Table 3: Implant standard size types.

Implant type	Type 1	Type 2	Type 3	Type 4
Specifications				
Axial radius, mm	115	115	115	115
Sagittal radius, mm	50	50	75	75
Screw hole distance, mm	35–25–15	40–30–20	35–25–15	40–30–20

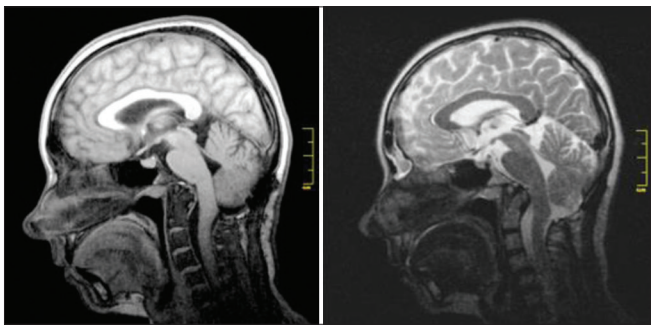

Figure 5: MRI scans 12 mouths after the surgery.

suturing the occipital and deep cervical muscles to their anatomical attachment sites in the area below the inion, and in addition enables dural tenting, and prevents cisterna magna compression by postoperative muscle scars. Placement of the implant was preceded by a water-tight duraplasty using synthetic grafts as well as by overlaying the dura mater with an autologous fat flap fixed by fibrin-thrombin glue.

The fat flap served as a hydrophobic seal in the formed bone defect area, which eliminated the cavity at the site of a removed occipital bone fragment. Tight suturing of the muscles to the titanium implant fixed to the occipital bone enabled restoration of the original anatomical relationships in the surgical site, namely, fixation of the muscles to the occipital bone. This manipulation also reduced the volume of intermuscular and muscular-fascial recesses. In this pilot study, no pseudomeningocele and other postoperative complications were observed.

In the pilot study group, implants were made for each patient individually, based on the anatomical structure of the occipital bone and the area of planned craniectomy. For extensive application of the proposed implants, it is advisable to develop a model set of typical sizes for intraoperative selection of the most suitable implant. The data collected out of 3D skull models from 188 patients operated previously on for CM1 were used to develop a set of implants with specified sizes [Table 3] with allowance for the spread in indicators and SDs.

Backward control was performed at the final stage of approval of the proposed sizes: the most appropriate implant was selected from the developed set of implants (with specified sizes and geometry) for each skull type from the simulation analysis group (n = 188) in the environment for 3D modeling.

Virtual imitation of implant fixation was performed in the occipital craniectomy area according to the described technique. On the basis of virtual modeling of surgery and selection of the most appropriate implant, it was found that at least one implant out of four from the developed set matched to each 3D model of the patient's skull.

Identical simulation was also performed in the pilot study group, and the same results as described above had been received: at least one implant from the set matched to each 3D model of the skull. It is worth noting that 3D models of 11 patients were not taken into account upon developing the set of implants with typical sizes.

CONCLUSION

There were no pseudomeningocele cases in the pilot study group among patients operated on for CM1 using the developed titanium implant. There were also no other complications associated with surgery and the implant.

The efficacy of the proposed surgical technique using the developed implant should be evaluated in clinical trials with larger patient samples.

To simplify preoperative planning and manufacturing of the implant for each patient individually, a set of implants with different specified sizes was developed, which enabled an intraoperative choice of the optimal configuration for the patient.

Declaration of patient consent

Patient's consent not required as patients identity is not disclosed or compromised.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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