Conference paper

Reconstruction of Postoperative Calvarial and Skull Base byTiNi-based Implants in Cancer Patients

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Abstract

At the Cancer Research Institute together with the Research Institute of Medical Materials and Tomsk State University, various types of implants from titanium nickelid (TiNi) were developed for the reconstruction of skull bone defects. Between 2000 and 2015, a total of 43 patients with malignant and benign calvarial and skull base tumors were treated. All patients underwent surgery alone or in combination with other treatment modalities. Fifty surgeries with primary reconstruction of calvarial and skull base defects using individually fabricated TiNi implants were performed. Our techniques for the reconstruction of postoperative skull bone defects appeared to be highly effective: restoration of supporting structures was achieved in 100% of cases, stability in 96% of patients, integrity and barrier function in 90% of cases. The TiNi implants have high mechanical strength and biocompatibility. No cases of fragmentation and rejection of the implants were registered.

1 Introduction

Skullbase tumors can be primary (arising in skull bones) and secondary (resulting from bone destruction and infiltration, and extending into the cranial cavity from the holes and channels. The extension into the intracranial space causes the occurrence of neurological symptoms leading to a worse quality of life and ultimately to the death of the patient.

2 Experimental

The aim of the study was to improve the methods of reconstruction of postoperative calvarial and skull base defects resulted from tumor resection using the TiNi implants. From 2000 to 2015, 43 patients with malignant and benign skull

tumorsextending into the intracranial cavity, with the age ranging from 10 to 66 years (median age 42 years) were treatedat the Department of Head and Neck Tumors of Tomsk Cancer Research Institute. All patients underwent surgery alone or in combination with other treatment modalities. Malignant tumors spreading to the cranial bones and cavity were present in 27 patients. Squamous cell carcinoma was the most common histological type. Sarcoma, adenocarcinoma, adenoid cystic carcinoma occurred more rarely. The primary tumor most frequently involved the cranial bones. Infi ative meningothelial or fi oblastic meningioma was the most common histological type.Considering the anatomical features of calvarial and skull base structures, various TiNi implants for the adequate reconstruction of skull bone defectswere developed at the Cancer Research Institute together with the Research Institute of Medical Materials. All patients with primary and recurrent cancer received combined modality treatment including preoperative external beam radiotherapy and surgery with reconstruction of calvarial and skull base defects using the TiNi implants. Surgery was performed 3–5 days after completion of radiotherapy.For patients with benign tumors involving bones of the skull, surgery with reconstruction of skull bone defects was the only treatment modality. Fifty surgeries with skull defect reconstruction using individually fabricated TiNi implants were performed. Repeated surgeries were performed in 6 patients because of continuing tumor growth. The main requirement for an effective reconstruction was the preoperative shaping of the implant to fi the bony defect precisely. Creating the 3D model of bone structures extracted from CT image data allowed not only the implant design, but also provided good visualization of the defect for preoperative surgical evaluation and planning. After the tumor removal and hemostasis, the implant was installed in the postoperative cavity and was stabilized with screws to the remaining bone walls. In order to avoid damage to the dura mater, the Tacho Comb plate was placed between the dura mater and the implant. To restore the lost bone structures, mesh TiNi implants (mesh thickness: 120-240 mcm, thread size: 60 mcm) were also used. The TiNi thread consisted of a composite material comprising a core from the nanostructured monolithic TiNi and a porous surface layer (5-7 microns) of titanium oxide. In cases with the closure of large defects, the TiNi mesh was fi ed to the edges of the recipient area using non-absorbable monofilament sutures. In cases with extensive bone defects, when a shape-forming frame was removed, a soft TiNi mesh needed a support when positioning.The TiNi tapes curved in the longitudinal direction from the curvature of the substituted area were used as frame-forming stiffeners. Stiffeners were placed across the defect, above the TiNi mesh, and fixed to the mesh with interrupted sutures (Fig. 1) [1-3].

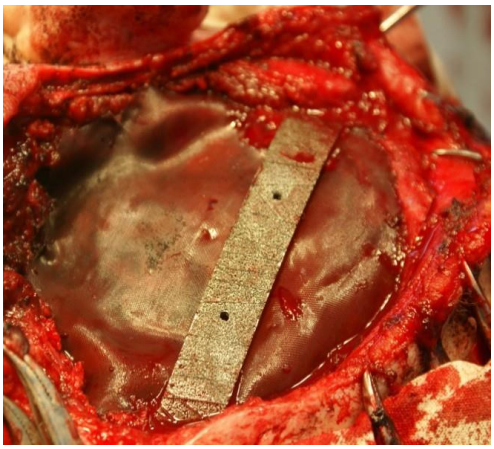

Figure 1 – The TiNi mesh and fixing with interrupted sutures

To accelerate the integration of stiffeners with body tissues, the monolithic stiffener should be covered with a permeable porous TiNi layer. In the postoperative period, the porous structure is saturated with body fluids, transforming later into the connective tissue. Thus, the ingrowth of the internal surface of the stiffener intothe TiNi mesh and of the external surface into soft tissues takes place [1, 4].

In cases of craniofacial tumor resection, the reconstruction of postoperative skull base defect was performedusing the modified method. This method included the use of the prefabricated custom made porous TiNi implant, which was placed on the edges of the defect from the side of the cranial cavity. The defect of the floor of the anterior cranial fossa was covered with periosteal-pericranial flap on the supratrochlear and supraorbital arteries, over which the implant was, installed (Fig.2).

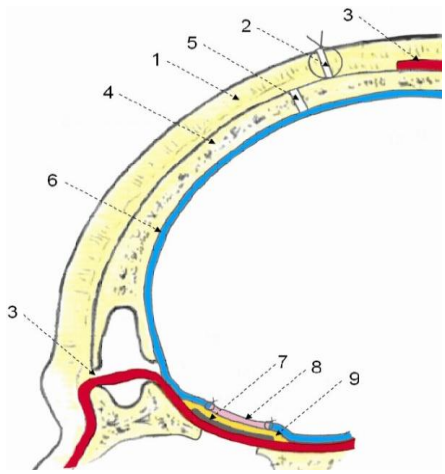

Fig. 2. The reconstruction method of extensive defects of the floor of the anterior cranial fossa 1 –skin-aponeurotic layer of the scalp; 2 - skin incision; 3- pericranial periosteal flap; 4 - frontal bone; 5 - upper edge of bone flap; 6 - dura mater; 7 - plate from the porous TiNi; 8 –dural defect reconstruction with fascia lata free flap or periosteal-pericranial flap; 9 - sealing of the dura mater with Tachocomb

3 Results and discussion

The follow up time ranged from 1 month to 6 years for patients with calvarial and skull base cancer, and from 3 month to 11 years for patients with benign skull tumors. Most patients had no purulent -inflammatory complications in the postoperative period, and had stable fixation of the implant. A slight shift of the implant was observed in 2 patients, requiring no repeated surgery for correcting the implant positioning. Complications related to the exposure and reconstruction of the dura mater at the time of surgery were noted in 4 patients, and were resolved with conservative treatment. Neurological examination of patients in the postoperative period showed no progressive neurological deficit. In cases with tumor spread into the orbital walls without invasion of the eyeball, tumor removal helped to return the eyeball to its normal position in the orbit. The fundus examination before and after surgery showed no abnormalities. The analysis of cerebrospinal fluid on days 7-9 showed cerebrospinal fluid pressure, cellular and protein composition were in the normal limits. Endoscopic examination (via postoperative cavity) revealed that the implant surface was covered with fibrin and granulation tissue on day 10 after surgery. On day 30, the implant surface was completely covered with granulation tissue. Complete epithelialization of the implant surface was noted 40-50 days after surgery. There was no evidence of inflammation in the implantation area. No complications related to the implantation of custom-made TiNi implants were observed. The overall 1-, 3- and 5-year survival rates in patients with malignant tumors were 59.4±10.1%, 37.8±10.7%, and 23.6±10.5%, respectively. The low rate of the 1-year disease-free survival was related to the fact that most patients had stage IV cancer at the time of surgery [2, 5, 6].

Despite a wide range of biomaterials for restoring bone defects of the skull, significant limitations persist. The ideal substitute for undertaking cranioplasty must be biocompatible, strong, and lightweight; it must be inexpensive and easily secured, and must have long-term stability [4, 5]. Future investigations are required to improve the physical and biological properties, particularly with respect to surface interactions.The advantages of reconstruction with TiNi implants include high biochemical and biomechanical compatibility based on super-elasticity and shape memory effect. The porous nature allows ingrowth of soft and bone tissues into the implant providingrepair of the barrier between the cavity of the skull and extracranial space [1]. A computer-generated model allows the fabrication of a custom implant that very accurately represents the anatomic defect. Prefabricated custom made TiNi implants simplify the restoration of complex cranial defects, reduce the surgical time necessary for implant placement and decrease the risk of inflammation in the

implantation area. The use of the TiNi implants enables radiographic examination and postoperative radiation therapy to be safely performed [6].The novel techniques for reconstruction of postoperative defects in patients with calvarial and skull base cancer have allowed surgeons to expand the indications for radical surgery. We recommend to reconstruct postoperative skull base defects in the anterior and middle cranial fossae using the porous and combination of porous and mesh implants from TiNi. Reconstruction of the cranium is necessary to perform using three-layered TiNi implant materials (porous, mesh and stiffeners).

4 Summary

The devised techniques for reconstruction of postoperative calvarias and skull base defects proved to be highly effective: recovery of supporting structures was achieved in 100% of cases, stability in 96% of cases, and integrity and barrier function in 90% of cases. The TiNi implants have high mechanical strength and biocompatibility. No cases of fragmentation and implant rejection were observed.

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