Japanese National Questionnaire Survey in 2018 on Complications Related to Cranial Implants in Neurosurgery

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Abstract

Cranial implants are commonly used throughout the world, yet the data on complications remain partly clarified. The aim of this study was to gather real data in 2018 on complications related to cranial implants in neurosurgery. The survey population consisted of 1103 institutes supplying neurosurgical treatment. The survey consisted of two-stage questionnaire. First the incidence of complications was investigated, then the secondary questionnaire was e-mailed to the respondents about the detailed of the complications. As the result, the annual incidence of complications related to cranial implants was 0.558% in Japan. Titanium plate and mesh were used predominantly in craniotomy and cranioplasty, respectively. The second survey collected data on 449 cases with complications (infection: 63%, implant exposure: 46%, multiple answer). Postoperative infection was associated with male sex, brain tumor, short interval between surgery and complication, usage of ceramics, hydroxyapatite, resin, and artificial dura, hyponutrition, multiple surgeries, dirty wound, and sinusitis as patient factors, and CSF leakage, ruptured sutures, and sinus maltreatment as surgery factors. Meanwhile, long hospital stay was associated with age, male sex, mRS 3–5 before complication, short interval between initial surgery and complication, large craniotomy, long operative time, usage of ceramics and artificial dura, multiple surgeries and dirty wound as patient factors, ruptured suture as a surgical factor, and bacterial infection, especially MRSA infection, as the complication and treatment consisting of removal as complication factors. In conclusion, this is the first Japanese national survey on complications related to cranial implants in neurosurgery. It is important to recall that complications may arise years after surgery and to be aware of the risk factors associated with complications.

Key words: artificial bone, cranioplasty, infection, re-operation, titanium plate

Introduction

Craniotomy and cranioplasty are standard procedures in neurosurgery, and various cranial implants are widely used for these procedures throughout the world. The titanium plate and screw system was invented and first used for neurosurgery in 1991; since then, various other fixation systems, artificial bones and artifacts have been developed and are now commonly used. In most cases, the clinical course after surgery is uneventful; in some cases, however, various complications related to cranial implants, including infections and skin troubles, can arise.2 Some cases require multiple surgeries or tissue reconstruction with vascularized tissue transplantation,3,4 severely burdening patients and their medical teams.

This study reports the results of our national questionnaire survey on complications related to cranial implants in neurosurgery, including the overall complication rate and risk factors for infection and long hospital stay.
Methods

The survey consisted of a two-stage questionnaire on complications related to cranial implants in neurosurgery. The first-stage survey population consisted of 1103 institutes offering neurosurgical treatment. The first stage of the survey was mailed to all of these institutes in October 2018; the second stage was emailed to all institutes that had responded to the first stage with a due date in February 2019. This study was approved by the Institutional Review Board (IRB)/Ethics Committee of Okayama University Hospital, Japan (IRB No. 1808-043). Opt-out informed consent was obtained from patients.

Questionnaire

The questionnaire was in Japanese and consisted of multiple-choice (multiple answers allowed) or written response questions. The first stage collected institutional information on craniotomy and cranio-plasty, namely, the number of annual craniotomies; the cranial implants used in craniotomy (titanium plate, titanium mesh, absorbable plate, and others); the cranial implants used in cranioplasty (titanium mesh, ceramics, hydroxyapatite, ultra-high-molecular-weight polyethylene, and others); and the number of cases with complications related to cranial implants.

The second stage collected detailed information on each case in which complications had occurred. Data collected included age at the initial surgery and at complication, neurological ability before complication (modified Rankin scale [mRS]), sex, reason for initial surgery (trauma, aneurysm, tumor, pediatric disease, and others), operative time of initial surgery (hours), craniotomy site (fronto-temporal, bifrontal, parietal, occipital, posterior fossa, and others), craniotomy area (cm²), implants used in craniotomy (titanium plate, titanium mesh, absorbable plate, and others) and in cranioplasty (titanium mesh, ceramics, hydroxyapatite, ultra-high-molecular-weight polyethylene, and others); other materials used (artificial dura, dural prosthetics, burr hole cap, bone cement, and others); institute performing the initial surgery (own and other); complications (infection, implant exposure, implant migration, skin depression, and others); infecting organism, cause of complication (Part A, patient factors: sinusitis, cancer, diabetes mellitus, previous irradiation, multiple surgeries, malcirculation, hyponutrition, thin skin, advanced age, dirty wound, others; Part B, surgical factors: ruptured sutures, skin ischemia, cerebrospinal fluid (CSF) leakage, sinus meltreatment, uncovered implant, implant malfixation, others; Part C, device factors: malsterilization, implant breakage, and others); outcome severity/response level (no treatment, non-surgical treatment, re-operation, aftereffect, and death), treatment method in surgery (system removal, suturing, implant covering, tissue transplantation, and others), involvement of plastic surgeons (plastic surgeons only, combination of plastic surgeons and neurosurgeons, and neurosurgeons only), and length of hospital stay.

Data analyses

Excel sheets were used to summarize the data. Continuous data are shown as mean ± standard deviation. Categorical data are shown as frequency and percentage. Statistical analyses were performed using JMP 13 software (SAS Institute Inc.). The univariate associations between each potential risk factor and the occurrence of infection and hospital stay longer than 30 days were assessed using Pearson’s chi-square test or Fisher’s exact test, as appropriate. In these assessments, the following rules were applied to identify the risk factors. Diseases were classified into vascular, tumor, traumatic brain injury (TBI) and others (epilepsy, pediatric disease, microvascular decompression, abscess, etc.). Craniotomy site was classified into fronto-temporal, bifrontal, occipital or posterior fossa, and Others (frontal, temporal, etc.). The cutoff points for each continuous variable (age at initial surgery, interval between initial surgery and complication, area of craniotomy, and duration of operation) were determined according to a previous study on analyzing risk factors. Then, we constructed multivariable logistic regression models to estimate the odds ratios (OR) and 95% confidence intervals (CI) of the variables for the development of infection and hospital stay longer than 30 days. We selected clinically relevant variables consistent with the previous reports (age, sex, ADL, types of disease, interval, area of craniotomy, duration of operation, location of craniotomy, devices, and artifacts). Results are presented as OR with 95% CIs. Significance was set at p <0.05.

Results

A flow diagram shows how the cases with complication were included in this study by the two-stage questionnaire survey (Fig. 1).

The first survey

Incidence of complications related to cranial implants

Out of the 1103 institutes to which we sent our first survey, 337 institutes responded (30.6%). Among
Survey on Complications Related to Cranial Implant

A flow diagram to show cases included in this study

The first survey was mailed to 1,103 institutes

337 institutes responded
183 reported one or more complications

Annual surgeries: 29,832
Cases with complication: 832/5 years
Annual incidence: 0.558%

The second survey e-mailed on 832 cases

Detailed data on 449 cases were obtained
Data were statistically analyzed

Fig. 1 A flow diagram to show cases with complication included in this study.

The responding institutes, 154 reported “no complication related to cranial implants” (45.7%) and 183 reported “or more complications” (54.3%). The total number of annual craniotomies at the responding institutes was 29832. The number of cases with complications related to cranial implants occurring within 5 years was 832. The calculated annual incidence of complications related to cranial implants was 0.558% per year.

Cranial implants used in Japan

For craniotomy, 92.6% of institutes used titanium plate (312/337), 35.9% used titanium mesh (121/337), and 18.4% used absorbable plate (62/337). For cranioplasty, 46.9% of institutes used titanium mesh (158/337), 36.2% used hydroxyapatite (122/337), 33.8% used ceramics (114/337), 25.8% used ultra-high-molecular-weight polyethylene (87/337), 3.3% used resin (11/337), and 2.7% used bone cement (9/337).

The second survey

Out of the 832 cases with complications reported by 183 institutes, details on 449 cases (54.0%) at 68 institutes (37.2%) were obtained in the second survey. These data are shown in Table 1. Age at initial surgery and age at complication were 52.1 ± 0.9 (0–86) and 57.3 ± 0.9 (0–86) years, respectively. The interval between initial surgery and complication was 63.7 ± 4.8 (0–576) months. Neurological ability before complication (mRS) was distributed as follows: mRS0: 123 cases (27.4%), mRS1: 103 cases (22.9%), mRS2: 45 cases (10.0%), mRS3: 52 cases (11.6%), mRS4: 69 cases (15.4%), mRS5: 49 cases (10.9%), and unknown/no response: 8 cases. The distribution of male/female sex was 195/252 (unknown/no response: 2). The reasons for the initial surgery were as follows: tumor: 157, aneurysm: 119, trauma: 84, intracerebral hemorrhage: 20, cerebral infarct: 18, moyamoya disease: 13, epilepsy: 9, pediatric neurosurgery: 7, arteriovenous malformation (AVM): 7, others: 12, and unknown/no response: 3. The operative time of initial surgery was 5.6 ± 0.2 (1–17) hours. Distribution of craniotomy sites was as follows: fronto-temporal: 227, bifrontal: 74, parietal: 44, frontal-parietal (+temporal): 36, posterior fossa: 27, occipital: 10, frontal: 9, temporal: 6, others: 14, and unknown/no response: 2. The craniotomy area was 83.3 ± 3.1 (4–900) cm². The implants used in craniotomy were as follows: titanium plate: 314, titanium mesh: 43, absorbable plate: 27, titanium clamp: 8, others: 3, and unknown/no response: 84. The implants used in cranioplasty were as follows: resin: 42, titanium mesh: 40, ceramics: 23, hydroxyapatite: 16, ultra-high-molecular-weight polyethylene: 8, wire: 5, others: 8 (cranioplasty: 139). Other materials used in combination were as follows: artificial dura: 98, bone cement: 23, burr hole cap: 12, shunt/Ommaya reservoir system: 7, dural prosthetics: 5, others: 2. In 392 cases, the initial surgery had been performed at the same institute where the complication was treated; in 54 cases, the initial surgery had been performed at another institute (unknown/no response: 3).

The types of complications were as follows: infection: 281, implant exposure: 205, skin depression: 7, implant migration: 6, others: 10. The infecting organisms were as follows: methicillin-sensitive Staphylococcus aureus (MSSA): 66, methicillin-resistant Staphylococcus aureus (MRSA): 64, Enterobacter: 14, methicillin-sensitive Staphylococcus epidermidis: 12, Streptococcus: 10, Corynebacterium: 9, Pseudomonas aeruginosa: 9, Propionibacterium: 7, others: 40, culture negative: 36, and unknown/no response: 12. The number of cases with concomitant infection was 15. The causes of complication were separately considered as Part A: patient factors, Part B: surgical factors, and Part C: device factors. The patient factors (Part A) were as follows: thin skin: 148, multiple surgeries: 132, advanced age: 57, previous irradiation: 55, cancer: 34, hyponutrition: 32, diabetes mellitus: 29, dirty wound: 27, malnutrition: 23, others: 85, unknown/no response: 80. The surgical factors (Part B) were as follows: uncovered implant: 147, ruptured suture: 31, CSF leakage: 23, sinus malformation: 17, skin ischemia: 12, implant malfixation: 9, others: 9, and unknown/no response: 221. Almost no respondents identified any device factors (Part C) (3/449 responses); the device factors that were reported were as follows: malsterilization: 2, implant breakage: 1. The outcome severity/response levels were as follows: re-operation: 439 (dead: 3,
Table 1  Data of patients with complications related to cranial implants

| Factor                                    | Evaluation       |
|-------------------------------------------|------------------|
| **Age at the initial surgery (y)**        | 52.1 ± 0.9 (0–86)|
| **Age at complication (y)**               | 57.3 ± 0.9 (0–86)|
| **Duration (months)**                     | 63.7 ± 4.8 (0–576)|
| **mRS**                                   | The number of cases % |
| 0                                         | 123 27.4          |
| 1                                         | 103 22.9          |
| 2                                         | 45   10.0         |
| 3                                         | 52   11.6         |
| 4                                         | 69   15.4         |
| 5                                         | 49   10.9         |
| **Male/Female**                           | 195/252          |
| **Disease for the initial surgery**       | The number of cases % |
| Tumor                                     | 157 35.0         |
| Aneurysm                                  | 119 26.5         |
| Trauma                                    | 84   18.7        |
| Intracerebral hemorrhage                  | 20   4.5          |
| Cerebral infarct                          | 18   4.0          |
| Moyamoya disease                          | 13   2.9          |
| Epilepsy                                  | 9    2.0          |
| Pediatric                                 | 7    1.6          |
| AVM                                       | 7    1.6          |
| Others                                    | 12   2.7          |
| **Operative time (hours)**                | 5.6 ± 0.2 (1–17) |
| **Area of craniotomy (cm²)**              | 83.3 ± 3.1 (4–900) |
| **Craniotomy site**                       | The number of cases % |
| Fronto-temporal                           | 227 50.6         |
| Bifrontal                                 | 74   16.5         |
| Parietal                                  | 44   9.8          |
| Frontal+parietal (+T)                     | 36   8.0          |
| Posterior fossa                           | 27   6.0          |
| Occipital                                 | 10   2.2          |
| Frontal                                   | 9    2.0          |
| Temporal                                  | 6    1.3          |
| Others                                    | 14   3.1          |
| **Implants used in craniotomy**           | The number of cases |
| Titanium plate                            | 314              |
| Titanium mesh                             | 43               |
| Absorbable plate                          | 27               |
| Titanium clamp                            | 8                |
| **Implants used in cranioplasty**         | The number of cases |
| Resin                                     | 42               |
| Titanium mesh                             | 40               |
| Ceramics                                  | 23               |
| Hydroxyapatite                            | 16               |
| Polyethylene                              | 8                |
| Others                                    | 13               |
| **Materials used in combination**         | The number of cases % |
| Artificial dura                           | 98               |
| Bone cement                               | 23               |
| Burr hole cap                             | 12               |
| Shunt/reservoir system                    | 7                |
| Dural prosthetics                         | 5                |
| Others                                    | 2                |
| **Institute of surgery performed**        | The number of cases % |
| Own                                       | 392 87.3         |
| Other                                     | 54   12.0         |
| **Kind of complications**                 | The number of cases |
| Infection                                 | 281              |
| Implant exposure                          | 205              |
| Skin depression                           | 7                |
| Implant migration                         | 6                |
| Others                                    | 10               |
| **Infecting organisms**                   | The number of cases |
| MSSA                                      | 66               |
| MRSA                                      | 64               |
| Enterobacter                              | 14               |
| MSSE                                      | 12               |
| Streptococcus                             | 10               |
| Corynebacterium                           | 9                |
| *Pseudomonas aeruginosa*                  | 9                |
| Others                                    | 40               |
| **Cause of complications**                | The number of cases % |
| Part A: patient factor                    | The number of cases |
| Thin skin                                 | 148              |
| Multiple surgeries                        | 132              |
| Aged                                      | 57               |
Table 1 (Continued)

| Factor                        | Evaluation |
|-------------------------------|------------|
| Previous irradiation         | 55         |
| Cancer                        | 34         |
| Hyponutrition                 | 32         |
| Diabetes mellitus             | 29         |
| Dirty wound                   | 27         |
| Malcirculation                | 25         |
| Others                        | 85         |

Part B: surgical factor

| The number of cases         |            |
|-------------------------------|------------|
| Uncovered implant            | 147        |
| Ruptured suture              | 31         |
| CSF leakage                   | 23         |
| Sinus maltreatment            | 17         |
| Skin ischemia                 | 12         |
| Implant malfixation           | 9          |
| Others                        | 12         |

Incident level

| The number of cases | %   |
|---------------------|-----|
| Re-operation        | 439 | 97.8|
| Medication          | 7   | 1.6 |

Treatment methods

| The number of cases | %   |
|---------------------|-----|
| Removal with suture | 352 | 78.4|
| Transplantation      | 32  | 7.1 |
| Removal with coverage| 18  | 4.0 |
| Others               | 40  | 8.9 |

Involvement of plastic surgeons

| The number of cases |       |
|---------------------|-------|
| Neurosurgeons only  | 339   | 75.5 |
| N+P                 | 94    | 20.9 |
| Plastic surgeons only| 14   | 3.1  |

Length of hospital stay (days)

| 36.9 ± 3.0 (0–910) |

AFV: arteriovenous malformation, MRSA: methicillin-resistant Staphylococcus aureus, mRS: modified Rankin scale, MSSA: methicillin-sensitive Staphylococcus aureus, MSSE: methicillin-sensitive Staphylococcus epidermidis. Frontal+parietal(+T): frontal+parietal with/without temporal, N+P: neurosurgeon+plastic surgeon.

Risk factors for infection

The results of the univariate analyses of factors related to infection in comparison with other complications are summarized in Table 2. The univariate analyses revealed that male sex, tumor as initial disease, interval shorter than 1 month between initial surgery and complication, usage of ceramics, usage of hydroxyapatite, usage of resin, usage of artificial dura, hyponutrition, multiple surgeries, dirty wound, sinusitis, CSF leakage, ruptured suture, and sinus maltreatment were significantly associated with infection. In contrast, vascular disease, bifrontal craniotomy, usage of titanium mesh, usage of burr-hole cap, and thin skin were negatively associated with infection. The results of the multivariate analyses of factors related to infection as a complication are summarized in Table 3. The multivariate analyses revealed that male sex, tumor as initial disease, interval shorter than 1 month between initial surgery and complication, usage of resin, and usage of artificial dura were significantly associated with infection.

Risk factors for hospital stay longer than 30 days

The results of the univariate analyses of factors related to hospital stay longer than 30 days are summarized in Table 4. The univariate analyses revealed that age at initial disease, male sex, mRS, interval shorter than 1 month between initial surgery and complication, craniotomy area more than 100 cm², operative time over 10 hours, usage of ceramics, usage of artificial dura, multiple surgeries, dirty wound, ruptured suture, infection, presence of bacteria, presence of MRSA, and removal as treatment were associated with hospital stay longer than 30 days. The results of the multivariate analyses of factors related to hospital stay longer than 30 days are summarized in Table 5. The multivariate analyses revealed that age at initial disease, male sex, mRS, interval shorter than 1 month between initial surgery and complication, craniotomy area more than 100 cm², operative time over 10 hours, usage of titanium plate, usage of ceramics, and usage of artificial dura were associated with hospital stay longer than 30 days.

Discussion

Key findings

This is the first study revealing the current rates of and factors associated with complications related to cranial implants in neurosurgery in Japan. This
### Table 2  Univariate analysis for factors associated with infection

| Factors                              | Complications           | Univariate                          |
|--------------------------------------|-------------------------|-------------------------------------|
|                                      | Infection | Other | Odds ratio of infection | p value |
|                                      | n = 168    | n = 281 |                             |         |
| **Patients’ characteristics**        |            |       |                          |         |
| Age at the initial surgery ≤10 years (%) | 5 (3.0)    | 12 (4.3) | 1.45 (0.50–4.20) | 0.49     |
| Age at the initial surgery ≥70 years (%) | 31 (18.5)  | 48 (17.1) | 0.91 (0.55–1.50) | 0.71     |
| Male sex (%)                         | 51 (30.4)  | 146 (52.3) | 2.51 (1.68–3.77) | <0.001   |
| mRS 3–5 (%)                          | 58 (34.7)  | 111 (40.4) | 1.27 (0.85–1.90) | 0.24     |
| **Disease**                          |            |       |                          |         |
| Vascular (%)                         | 85 (51.2)  | 95 (33.8) | 0.49 (0.33–0.72) | <0.001   |
| TBI (%)                              | 25 (15.1)  | 62 (22.1) | 1.60 (0.96–2.66) | 0.071    |
| Tumor (%)                            | 43 (25.9)  | 113 (40.2) | 1.92 (1.26–2.93) | 0.0022   |
| Others (%)                           | 13 (7.8)   | 11 (3.9)  | 0.48 (0.21–1.10) | 0.076    |
| **Operation**                        |            |       |                          |         |
| Interval ≤1 month (%)                | 8 (4.8)    | 77 (27.4) | 7.50 (3.52–15.99) | <0.001   |
| Area of craniotomy ≥100 cm² (%)      | 41 (25.6)  | 93 (34.1) | 1.50 (0.97–2.32) | 0.067    |
| Operative time ≥10 hours (%)         | 14 (11.4)  | 31 (13.4) | 1.21 (0.62–2.37) | 0.58     |
| **Location**                         |            |       |                          |         |
| Fronto-temporal (%)                  | 89 (53.0)  | 173 (61.8) | 1.43 (0.97–2.11) | 0.067    |
| Bifrontal (%)                        | 46 (27.4)  | 35 (12.5) | 0.38 (0.23–0.62) | <0.001   |
| Occipital or posterior fossa (%)     | 13 (7.7)   | 28 (10.0) | 1.32 (0.67–2.63) | 0.42     |
| Others (%)                           | 20 (11.9)  | 44 (15.7) | 1.38 (0.78–2.43) | 0.26     |
| **Devices**                          |            |       |                          |         |
| **Craniotomy**                       |            |       |                          |         |
| Titanium plate (%)                   | 131 (78.0) | 197 (70.6) | 0.68 (0.43–1.06) | 0.088    |
| Absorbable plate (%)                 | 10 (6.0)   | 17 (6.1)  | 1.03 (0.46–2.29) | 0.95     |
| **Cranioplasty**                     |            |       |                          |         |
| Titanium mesh (%)*                   | 41 (24.4)  | 44 (15.8) | 0.58 (0.36–0.93) | 0.024    |
| Ceramics (%)                         | 4 (2.4)    | 22 (7.9)  | 3.51 (1.19–10.37) | 0.016    |
| Hydroxyapatite (%)                   | 2 (1.2)    | 16 (5.7)  | 5.05 (1.15–22.24) | 0.018    |
| Polyethylene (%)                     | 2 (1.2)    | 6 (2.2)   | 1.82 (0.36–9.14) | 0.72     |
| Resin (%)                            | 6 (3.6)    | 38 (13.6) | 4.26 (1.76–10.30) | <0.001   |
| **Artifacts**                        |            |       |                          |         |
| Artificial dura (%)                  | 18 (10.7)  | 80 (28.5) | 3.31 (1.91–5.77) | <0.001   |
| Burr-hole cap (%)                    | 9 (5.4)    | 3 (1.1)   | 0.19 (0.05–0.71) | 0.012    |
| Cement paste (%)                     | 9 (5.4)    | 17 (6.0)  | 1.14 (0.50–2.61) | 0.76     |
| **Factors associated with patients** |            |       |                          |         |
| Aged (%)                             | 25 (14.9)  | 35 (12.5) | 0.81 (0.47–1.41) | 0.46     |
| Cancer (%)                           | 11 (6.5)   | 25 (8.9)  | 1.39 (0.67–2.91) | 0.38     |
| DM (%)                               | 8 (4.8)    | 21 (7.5)  | 1.62 (0.70–3.73) | 0.26     |
| Thin skin (%)                        | 89 (53.0)  | 61 (21.7) | 0.25 (0.16–0.37) | <0.001   |
| Hyponutrition (%)                    | 5 (3.0)    | 27 (9.6)  | 3.47 (1.31–9.18) | 0.0082   |
| Malcirculation (%)                   | 13 (7.7)   | 12 (4.3)  | 0.53 (0.24–1.19) | 0.12     |
| Multiple surgeries (%)               | 35 (20.8)  | 94 (33.5) | 1.91 (1.22–2.99) | 0.0042   |
Survey on Complications Related to Cranial Implant

The national questionnaire survey has revealed a record high number of cases with complications. The calculated annual incidence of complications related to cranial implants is 0.558% per year. For craniotomy and cranioplasty, titanium plate and mesh were mainly used, respectively. Among 832 cases with complications reported by 183 institutes that responded to the primary survey, detailed data on 449 cases (54.0%) at 68 institutes (37.2%) were obtained in the second survey. Our questionnaire results shed light on various complications and have allowed us to identify risk factors for infection, including male sex, tumor as the initial disease, and usage of resin, ceramics, hydroxyapatite, and artificial dura. Hyponutrition, multiple surgeries, dirty wound, and sinusitis were patient-derived risk factors. CSF leakage, ruptured suture, and sinus maltreatment were surgery-derived risk factors. The multivariate analyses showed that male sex, tumor as initial disease, interval shorter than 1 month between initial surgery and complication, craniotomy area more than 100 cm², operative time over 10 hours, and usage of titanium plate, ceramics, and artificial dura were risk factors for hospital stay longer than 30 days.

Incidence and characteristics of complications related to cranial implants

The incidence of complications related to cranial implants has been explored in several studies. Several large neurosurgical centers in the United States have jointly released a report on complications related to craniotomy, in which, over 11 years from 1997 to 2007, surgery was required for postoperative infection in 0.5% of cases (82/16540 cranial surgeries). In that study, brain tumor was the most frequent causative disease and MSSA was the most common offending organism. That study and ours have a great deal in common in terms of the incidence, causative disease, and offending organism. That study and ours have a great deal in common in terms of the incidence, causative disease, and offending organism.

In a study on 5361 prospectively evaluated neurosurgical procedures, the rate of subsequently culture-proven infection was 0.61%, although two-thirds of these procedures were spinal procedures. In a single-institute retrospective investigation of the removal of titanium plates after craniotomy, over 3 years from 2014 to 2016, 1.6% (5/319) of patients who had undergone craniotomy later underwent removal of the plates because of pain and
protrusion, although this might be a relatively high incidence.\(^7\)

Studies specifically addressing complications after cranioplasty offer additional detailed information. The incidence of complications related to titanium mesh was reported at the relatively high rate of 29% among 127 cranioplasties in Western Australia.\(^8\)

Infection was the most frequent complication type with an incidence of 18%. Large titanium mesh was a significant risk factor for infection. Similar data have been reported in a study in England\(^9\) in which the rates of complication and titanium plate removal were 26.4% and 10.3%, respectively. In 69% of cases with system removal, removal was indicated due to infection. The risk factors associated with complications were trauma as the initial disease and large skull defect (larger than 100 cm\(^2\)).

In another study, 155 non-titanium cranioplasties performed between 2005 and 2016 at a single institute in Japan were retrospectively reviewed.\(^10\) The overall complication rate was 12.3%. Infection was the most frequent complication, occurring at a rate

### Table 3 Multivariate analysis for factors associated with infection

| Variables          | Multivariate |          | p value |
|--------------------|--------------|----------|---------|
|                    | Odds ratio   | 95% CI   |         |
| **Patients’ characteristics** |              |          |         |
| Age at the initial surgery ≥70 years | 1.77         | 0.86–3.62 | 0.12    |
| Male sex           | 2.5          | 1.38–4.52 | 0.0024  |
| mRS 3–5            | 1.16         | 0.64–2.13 | 0.62    |
| **Disease**        |              |          |         |
| Vascular           | 2.3          | 0.61–8.67 | 0.22    |
| TBI                | 2.14         | 0.51–8.96 | 0.3     |
| Tumor              | 3.99         | 1.10–14.52| 0.036   |
| Others             | Ref          | Ref      | NA      |
| **Operation**      |              |          |         |
| Interval ≤1month   | 15.2         | 5.27–43.8 | <0.001  |
| Area of craniotomy ≥100 cm\(^2\) | 0.89         | 0.45–1.77 | 0.74    |
| Operative time ≥10 hours | 1.78         | 0.77–4.12 | 0.18    |
| **Location**       |              |          |         |
| Fronto-temporal    | 1.13         | 0.44–2.90 | 0.79    |
| Bifrontal          | 0.53         | 0.20–1.44 | 0.22    |
| Occipital or posterior fossa | 1.37         | 0.43–4.32 | 0.59    |
| Others             | Ref          | Ref      | NA      |
| **Devices**        |              |          |         |
| **Craniotomy**     |              |          |         |
| Titanium plate     | 0.77         | 0.34–1.77 | 0.54    |
| **Cranioplasty**   |              |          |         |
| Titanium mesh*     | 0.6          | 0.29–1.25 | 0.18    |
| Ceramics           | 6.8          | 1.32–35.05 | 0.022 | |
| Hydroxyapatite     | 4.1          | 0.47–36.09 | 0.2     |
| Resin              | 6.9          | 1.45–32.84 | 0.015  |
| **Artifacts**      |              |          |         |
| Artificial dura    | 2.28         | 1.10–4.75 | 0.027   |
| Burr-hole cap      | 0.019        | 0.0014–0.25 | 0.0027 |

*Titanium mesh was used both in Craniotomy and Cranioplasty. It is placed in Cranioplasty for certain reasons of data collection. mRS: modified Rankin scale, TBI: traumatic brain injury.
## Table 4  Univariate analysis factors associated with hospital stay longer than 30 days

| Factors                              | Hospital stay longer than 30 days | Univariate   |
|--------------------------------------|----------------------------------|--------------|
|                                      | No (n=287)                        | Yes (n=154)  |
|                                      | Odds ratio                        | p value      |
| **Patients’ characteristics**        |                                  |              |
| Age at the initial surgery ≤10 years (%) | 11 (3.8)                        | 6 (3.9)      | 1.02 (0.37–2.81) | 1 |
| Age at the initial surgery ≥70 years (%) | 41 (14.3)                      | 37 (24.0)    | 1.90 (1.16–3.12) | 0.011 |
| Male sex (%)                         | 107 (37.5)                       | 85 (55.2)    | 2.05 (1.38–3.05) | <0.001 |
| mRS 3–5 (%)                          | 83 (29.3)                        | 81 (53.6)    | 2.79 (1.85–4.20) | <0.001 |
| **Disease**                          |                                  |              |
| Vascular (%)                         | 122 (42.5)                       | 56 (36.8)    | 0.79 (0.53–1.18) | 0.25 |
| TBI (%)                              | 49 (17.1)                        | 35 (23.0)    | 1.45 (0.89–2.36) | 0.13 |
| Tumor (%)                            | 100 (34.8)                       | 53 (34.9)    | 1.00 (0.66–1.51) | 1 |
| Others (%)                           | 16 (5.6)                         | 8 (5.3)      | 0.94 (0.39–2.25) | 0.89 |
| **Operation**                        |                                  |              |
| Interval ≤1 month (%)                | 39 (13.6)                        | 45 (29.2)    | 2.61 (1.61–4.24) | <0.001 |
| Area of craniotomy ≥100 cm² (%)      | 67 (24.3)                        | 66 (44.0)    | 2.45 (1.60–3.74) | <0.001 |
| Operative time ≥10 hours (%)         | 21 (9.9)                         | 23 (17.0)    | 1.88 (0.99–3.55) | 0.0496 |
| **Location**                         |                                  |              |
| Fronto-temporal (%)                  | 158 (55.1)                       | 100 (65.4)   | 1.54 (1.03–2.31) | 0.037 |
| Bifrontal (%)                        | 58 (20.2)                        | 22 (14.4)    | 0.66 (0.39–1.13) | 0.13 |
| Occipital or posterior fossa (%)     | 33 (11.5)                        | 7 (4.6)      | 0.37 (0.16–0.86) | 0.016 |
| Others (%)                           | 38 (13.2)                        | 24 (15.7)    | 1.22 (0.70–2.12) | 0.48 |
| **Devices**                          |                                  |              |
| **Craniotomy**                       |                                  |              |
| Titanium plate (%)                   | 216 (75.3)                       | 108 (71.1)   | 0.81 (0.52–1.25) | 0.34 |
| Absorbable plate (%)                 | 18 (6.3)                         | 8 (5.3)      | 0.83 (0.35–1.96) | 0.67 |
| **Cranioplasty**                     |                                  |              |
| Titanium mesh (%)*                   | 61 (21.3)                        | 22 (14.5)    | 0.63 (0.37–1.07) | 0.084 |
| Ceramics (%)                         | 12 (4.2)                         | 14 (9.2)     | 2.32 (1.05–5.16) | 0.034 |
| Hydroxyapatite (%)                   | 12 (4.2)                         | 6 (3.9)      | 0.94 (0.35–2.56) | 0.91 |
| Polyethylene (%)                     | 5 (1.7)                          | 2 (1.3)      | 0.75 (0.4–3.92)  | 1 |
| Resin (%)                            | 27 (9.4)                         | 17 (11.2)    | 1.21 (0.64–2.30) | 0.56 |
| **Artifacts**                        |                                  |              |
| Artificial dura (%)                  | 41 (14.3)                        | 56 (36.4)    | 3.43 (2.15–5.46) | <0.001 |
| Burr-hole cap (%)                    | 7 (2.4)                          | 4 (2.6)      | 1.07 (0.31–3.70) | 0.92 |
| Cement paste (%)                     | 15 (5.2)                         | 11 (7.1)     | 1.39 (0.62–3.12) | 0.42 |
| **Factors associated with patients (%)** |                                  |              |
| Aged (%)                             | 38 (13.2)                        | 21 (13.6)    | 1.03 (0.58–1.83) | 0.91 |
| Cancer (%)                           | 20 (7.0)                         | 16 (10.4)    | 1.55 (0.78–3.08) | 0.21 |
| DM (%)                               | 18 (6.3)                         | 11 (7.1)     | 1.15 (0.53–2.50) | 0.73 |
| Thin skin (%)                        | 105 (36.6)                       | 41 (26.6)    | 0.63 (0.41–0.97) | 0.034 |

(Continued)
of 8.4%, followed by postoperative epidural hemorrhage at 2.6% and ruptured suture at 1.3%. In that study, long operative time (over 98 minutes) was a significant risk factor for infection.

Several studies have reported on complication rates in pediatric cranioplasty. A multicenter retrospective study reported an infection rate of 10.5% in 359 pediatric patients.\textsuperscript{11} In a study on pediatric cranial reconstruction for craniosynostosis with resorbable plate system, the incidence of unplanned re-operation was 5.4%.\textsuperscript{12} The relatively low incidences of complications in this study might be explained by the usage of a resorbable plate system and a procedure that does not involve dura opening.

**Risk factors for infection after neurosurgical procedure**

In our study, cases with complications were analyzed and risk factors for infection were explored. Male sex, brain tumor as the initial disease, cranio-plasty with resin, combined usage of several artifacts (artificial dura, burr hole cap, and bone cement), CSF leakage, ruptured suture, sinus maltreatment, hyponutrition, multiple surgeries, dirty wound, and

### Table 4 (Continued)

| Factors                                      | Hospital stay longer than 30 days | Univariate |
|----------------------------------------------|-----------------------------------|------------|
|                                              | No | Yes | Odds ratio | p value |
|                                              | n=287 | n=154 |            |
| Hyponutrition (%)                            | 15 (5.2) | 15 (9.7) | 1.96 (0.93–4.12) | 0.073 |
| Malcirculation (%)                           | 15 (5.2) | 10 (6.5) | 1.26 (0.55–2.87) | 0.58 |
| Multiple surgeries (%)                       | 68 (23.7) | 59 (38.3) | 2.00 (1.31–3.06) | 0.0012 |
| Dirty wound (%)                              | 12 (4.2) | 14 (9.1) | 2.29 (1.03–5.09) | 0.037 |
| Previous irradiation (%)                     | 36 (12.5) | 21 (13.6) | 1.10 (0.62–1.96) | 0.74 |
| Sinusitis (%)                                | 11 (3.8) | 10 (6.5) | 1.74 (0.72–4.20) | 0.21 |

**Factors associated with operators**

- Uncovered implant (%)
- CSF leakage (%)
- Skin ischemia (%)
- Implant malfixation (%)
- Ruptured suture (%)
- Sinus maltreatment (%)

**Factors associated with devices**

- Device failure (%)

**Types of complications**

- Exposure (%)
- Infection (%)
- Bacterium positive (%)
- MRSA (%)
- Multi-bacterium (%)

**Treatment**

- Medication alone (%)
- With plastic surgery (%)
- Removal (%)
- Transplantation (%)

\*Titanium mesh was used both in Craniotomy and Cranioplasty. It is placed in Cranioplasty for certain reasons of data collection. CSF: cerebrospinal fluid, DM: diabetes mellitus, mRS: modified Rankin scale, TBI: traumatic brain injury.
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Sinusitis were the relevant risk factors. Cases with these risk factors should be handled with more cautions and steps should be taken to minimize the risks.

In several studies, large skull defect in cranioplasty was the risk factor for infection. In our study, however, an area of craniotomy/cranioplasty over 100 cm\(^2\) was not a significant risk factor. Similarly, long operative time was a significant risk factor in some studies, although it was not significant in ours. The explanation for these discrepancies might lie in the fact that cases with craniotomy and cases with cranioplasty were analyzed together in our study. A retrospective study using data on 258 cranioplasties reported a complication rate of 10.9% (28/258 cases) and found that risk factors for infection were male sex, brain tumor, and surgery at the county hospital. Similarly, in our study, male sex and brain tumor were considered the main risk factors for infection. Very recently, a multicenter retrospective study on autologous cranioplasty revealed that smoking and age less than 45 years were risk factors for complications requiring bone flap removal and that age less than 30 years was a risk factor for bone flap resorption. In our study, we did not assess bone flap resorption because the aim was to assess complications related to cranial implants. As bone flap resorption does sometimes occur, however, its incidence and risk factors should be explored in the future.

### Table 5  Multivariate analysis for factors associated with hospital stay over 30 days

| Variables                          | Odds ratio | 95% CI       | p value |
|------------------------------------|------------|--------------|---------|
| **Patients’ characteristics**      |            |              |         |
| Age at the initial surgery ≥70 years | 2.01       | 1.02–3.99    | 0.044   |
| Male sex                          | 2.91       | 1.64–5.17    | <0.001  |
| mRS 3–5                           | 2.06       | 1.17–3.63    | 0.013   |
| **Disease**                        |            |              |         |
| Vascular                           | 0.99       | 0.29–3.41    | 0.99    |
| TBI                                | 0.49       | 0.13–1.81    | 0.28    |
| Tumor                              | 0.62       | 0.18–2.09    | 0.44    |
| Others                             | Ref        | Ref          | NA      |
| **Operation**                      |            |              |         |
| Interval ≤1 month                  | 3.22       | 1.69–6.12    | <0.001  |
| Area of craniotomy ≥100 cm\(^2\)  | 1.94       | 1.03–3.64    | 0.04    |
| Operative time ≥10 hours           | 7.21       | 3–17.30      | <0.001  |
| **Location**                       |            |              |         |
| Fronto-temporal                    | 0.53       | 0.22–1.26    | 0.15    |
| Bifrontal                          | 0.52       | 0.2–1.39     | 0.19    |
| Occipital or posterior fossa       | 0.13       | 0.035–0.47   | 0.0018  |
| Others                             | Ref        | Ref          | NA      |
| **Devices**                        |            |              |         |
| **Craniotomy**                     |            |              |         |
| Titanium plate                     | 1.26       | 0.64–2.50    | 0.04    |
| **Cranioplasty**                   |            |              |         |
| Titanium mesh*                     | 1.19       | 0.59–2.40    | 0.63    |
| Ceramics                           | 4.05       | 1.32–12.47   | 0.015   |
| **Artifacts**                      |            |              |         |
| Artificial dura                    | 2.8        | 1.47–5.34    | 0.0017  |

*Titanium mesh was used both in Craniotomy and Cranioplasty. It is placed in Cranioplasty for certain reasons of data collection. mRS: modified Rankin scale; TBI: traumatic brain injury.
Study limitations

This was a retrospective questionnaire-based study. The response rate in the primary survey was 30.6% (337/1103 institutes) and that in the second survey was 54.0% of cases with complications (449/832 patients). The response rates may be sufficiently high, yet the results of questionnaire surveys are not guaranteed to accurately represent all cases with complications.

Additionally, we reported the rates of complications related to cranial implants, including both craniotomy and cranioplasty. In our evaluation of the risk factors associated with infection, we only used the data on cases with complications. Our study therefore provides detailed information on cases with complications, but not cases without complications. This situation might limit the usefulness of risk factors for infection and long hospital stay. Although readers should consider these limitations, we believe that our data will be informative to neurosurgeons around the world.

Conclusions

Even after a long and uneventful postoperative period, complications related to cranial implants may arise after craniotomy/cranioplasty. The use of cranial implants is now common practice, but we still need to perform each neurosurgical procedure with care to minimize complications after surgery and keep the risk factors for complications in mind.

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Conflicts of Interest Disclosure

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