Integration of Bacterin Osteosponge Disc in Craniotomy Defects

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Abstract
Trephination has long been part of the neurosurgery repertoire of operative techniques to gain access to the brain for management of chronic subdural hematomas and tumor biopsy as well as part of a preceding step for craniotomy in tumor removal. Burrholes are the name given to these skull defects created and left behind from the act of trephination and for a certain period of time these defects were usually left unfilled. It was later found that these patients were cosmetically dissatisfied with the resultant depressions overlying the scalp; therefore, various methods of filling in these burrholes were developed. The purpose of our study is to determine if indeed the Bacterin Osteosponge is able to promote bony regeneration and to what degree. Full bony integration of the Bacterin Osteosponge disc will eventually undergo remodeling and therefore become seamless with the skull. Ultimately the patient may not even notice where the burrhole was placed, providing greater patient satisfaction. This is a retrospective study involving 68 patients for a total of 149 total burrholes with implants placed initially in 2010 to as late as 2014. Follow-up computed tomography (CT) scans varied from 1 day to 46 months. A scale was developed to quantify the extent of bony integration. Grade 1 is less than 25% bone filling of the burrhole, grade 2 is between 25-49%, grade 3 is 50-74%, grade 4 is 75-99%, and grade 5 is 100%. Of the 68 patients in our study, two patients for a total of four burrholes achieved grade 1 regeneration at 49 days post operative, one patient with one burrhole achieved grade 2 regeneration at 1 year 8 months 1 week and 5 days, two patients for a total of three burrholes achieved grade 3 regeneration (one at 1 year 8 months 1 week and 5 days while the other patient was 3 years 9 months 2 weeks and 4 days), one patient had two burrholes with one burrhole achieving grade 4 regeneration, and the other burrhole achieved grade 5 regeneration at 3 years 6 months and 8 days. The earliest timeframe for bony regeneration seen was 49 days postoperatively; the latest bony regeneration seen was at 3 years 9 months 2 weeks and 4 days.

Keywords: Integration; Bacterin osteosponge disc; Craniotomy defects; Burrholes; Trephination; Neurosurgery repertoire; Subdural hematomas; Tumor biopsy

Introduction
Trephination is the act of creating a circular defect in the skull down to the dura mater. Trephination has long been part of the neurosurgery repertoire of operative techniques to gain access to the brain for management of chronic subdural hematomas and tumor biopsy as well as part of a preceding step for craniotomy in tumor removal, in the management of acute subdural hematomas, as well as aneurysm surgery [1]. Burrholes are the name given to these skull defects created and left behind from the act of trephination and for a certain period of time these defects were usually left unfilled. It was later found that these patients were cosmetically dissatisfied with the resultant depressions overlying the scalp; therefore, various methods of filling in these burrholes were developed. The options to cover or fill in the burrholes include silastic burrhole implants [2], titanium burr hole covers, polyethylene covers, and polylactide burrhole implants [3].

Complications from the aforementioned options include infection, allergic reaction, and screw fractures or loosening leading to failure of the burrhole cover. The Bacteria Osteosponge is an implant made from human demineralized cancellous bone that is both osteoconductive and osteoinductive. The osteosponge performs as a scaffold for cellular in growth and exposes bone-growth-inducing proteins to the healing environment. One of the distinctive characteristics of this implant is its malleability. This property allows the implant to conform into irregularly shaped bony environments helping it to fill in defects. The osteoconductive and osteoinductive assets theoretically allow the implant to fuse with the skull allowing it to become one with...
the bony skull ultimately resulting in a smooth interface and a
cosmetically satisfying, more comfortable patient.

**Purpose**

The purpose of our study is to determine if indeed the
Bacterin Osteosponge is able to promote bony regeneration and
to what degree. Full bony integration of the Bacterin Osteosponge
disc will eventually undergo remodeling and therefore become
seamless with the skull. Ultimately the patient may not even
notice where the burrhole was placed, providing greater patient
satisfaction.

**Patients and Methods**

This is a retrospective study involving 68 patients for a total
of 149 total burrholes with implants placed initially in 2010 to as
late as 2014. Follow-up computed tomography (CT) scans varied
from 1 day to 46 months. Follow-up CT scans were done as part
of the standard post-operative work-up or as indicated in such
situations for as altered mental status or head trauma suggesting
intracranial pathology. The patients who were involved included
those who needed burrholes either for chronic subdural
hematomas, stereotactic brain biopsy, ventriculoperitoneal
shunts, external ventricular drains, craniotomies for brain
tumors, acute subdural hematomas, and brain edema.

The average age of the patients was 64 years with the
youngest being 20 years and oldest being 96 years of age. The
diameter of the burrhole was measured on CT scan images. A
scale was developed to quantify the extent of bony integration.
Grade 1 is less than 25% bone filling of the burrhole; grade 2
is between 25-49%, grade 3 is 50-74%, grade 4 is 75-99%, and
grade 5 is 100%. Raw data may be seen on Appendix 1.

**Results**

Of the 68 patients in our study, two patients for a total of
four burrholes achieved grade 1 regeneration at 49 days post
operative, one patient with one burrhole achieved grade 2
regeneration at 1 year 8 months 1 week and 5 days, two patients
for a total of three burrholes achieved grade 3 regeneration (one
at 1 year 8 months 1 week and 5 days while the other patient
was 3 years 9 months 2 weeks and 4 days), one patient had two
burrholes with one burrhole achieving grade 4 regeneration,
and the other burrhole achieved grade 5 regeneration at 3
years 6 months and 8 days. The earliest timeframe for bony
regeneration seen was 49 days postoperatively, the latest bony
regeneration seen was at 3 years 9 months 2 weeks and 4 days.

**Discussion**

In essence, regeneration was observed in 10 of the 149
burrholes yielding a rate of 6.7% despite the Osteosponge’s
inherent osteoconductive and osteoinductive properties.
There may be a number of reasons for the low rate of osteo-
regeneration. One of the largest reasons may be related to Wolff’s
law. Wolff’s law states that the inner architecture and the shape
of a particular bone is molded by the compressive forces placed
upon it [4]. In other words if there is stress on a certain spot on
the bone, that area will in turn create remodeled bone thereby
reinforcing the area to withstand those compressive forces. The
skull is not a load-bearing bone and therefore may not serve as
an effective conduit for the osteosponge to regenerate bone.

Indeed, a number of our patients were lost to follow up and
therefore did not have imaging beyond the immediate post-
operative period and therefore may not have had a chance for
us to document regeneration. Some of our patients, however,
have had imaging four years post-operatively and still did
not regenerate bone. We must also take into account medical
illnesses that may not promote adequate bone growth such as
osteoporosis, osteopenia, radiation therapy, and smoking status
[5].

Consideration should also be made regarding past medical
history in those patients whose burrhole did regenerate. Data
collection regarding the common past medical problems amongst
the patients’ whose burrholes regenerated bone with Bacterin
Osteosponge discs may help us to decide if regeneration was
due to medical issues promoting bone growth or truly due to the
implants inherent properties. Lifestyle choices such as smoking
may play a role in regeneration of bone within the osteosponge
disc filled burrhole as well. We did not collect such data for our
current study; however, this opens up opportunity to explore
such items.

One benefit of having regeneration of bone within the
burrhole is seamless interface of the burrhole with the
remaining skull. The reason why seamless integration is so
important is due to one basic principle: patient satisfaction.
One common complaint that patients from our institution will
voice postoperatively is the sensation of a bump while they are
brushing or combing their hair if a burrhole cover was used. If
nothing is used in the burrhole, the appearance of a depression
is seen and that tends to also lead to patient dissatisfaction. Data
collection regarding patient satisfaction and scores regarding
cosmetic appearance and daily annoyance was not obtained
during this study; however, this provides opportunity for future
research regarding satisfaction as it pertains to the Bacterin
Osteosponge disc.

Indeed, there have been many efforts to ensure cosmetic
fulfillment while thwarting annoyances for patients whose
skulls have undergone trephination. One group described using
methyl methacrylate material placed in a plastic bag to fill
the void. This method, of course, would not be able to achieve
regeneration of bone; however, filling the void may be enough to
quell any negative disposition related to the burrhole or implant.
Unfortunately, this group did not report patient outcomes in
regards to satisfaction [6]. Another group examined the use of
quick-setting hydroxyapatite cement and absorbable plates
to fill in defects caused by trephination. They examined local
inflammatory reactions and bone growth and concluded that no significant inflammation was evident and also that there was evidence of peripheral bone growth at 6 months. Unfortunately, this study was done with animal models and therefore they did not and could not examine patient satisfaction regarding cosmesis and convenience [7].

Future research on whether patient satisfaction is influenced by having full regeneration of bone inside the skull void may be of benefit as well. If patients are happy with their postoperative appearance or postoperative sensation of the filled burrhole without full integration of the implant or full regeneration of bone within the burrhole, perhaps a less expensive alternative may be used to fill the skull void. Instead of spending thousands of dollars studying which elements and to which combination and ratio is the best for regeneration of bone within a burrhole, perhaps simply filling that skull void is good enough to keep the patient happy so long as there are no issues with infection and inflammatory reaction associated with the implant.

Another interesting research study that could be explored would be the cost to healthcare in using such implants. If indeed full bone regeneration and integration of implant is not needed for patient satisfaction then the least costly implant or method of filling in the skull void may be used, potentially making a significant impact on the cost of neurosurgery and the overall cost of healthcare for the future.

References