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Integration of Bacterin Osteosponge Disc in Craniotomy Defects

Thuy M Nguyen* and Tejpaul Pannu

Department of Neurosurgery, Michigan State University-College of Osteopathic Medicine, USA

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***Corresponding author:** Thuy M Nguyen, Department of Neurosurgery, Beaumont Health System, Dearborn, MI, Michigan State University-College of Osteopathic Medicine, USA, Tel: 417-894-5402; Email: mthuynguyen@gmail.com

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 hydroxyapaptite 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.

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