Use of Osteoplug™ polycaprolactone implants as novel burr-hole covers

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ABSTRACT

Introduction: The aim of this study was to evaluate the outcome of Osteoplug™, a novel biodegradable polymer burr-hole cover implant, used in patients with burr holes done for drainage of chronic subdural haematoma.

Methods: 12 patients with chronic subdural haematoma had Osteoplug™ implants inserted into their burr holes after evacuation of the haematoma. Osteoplug™ is a biodegradable polycaprolactone implant with a mushroom-button shape, designed specifically to fit into a 14-mm diameter burr hole. It has an upper rim of 16-mm diameter and a body diameter of 14 mm, with a honeycomb-like architecture of 400–600 µm pore size. The Osteoplug™ snaps onto the 14-mm diameter burr hole snugly after the evacuation of the liquefied haematoma is done. All 12 patients were followed up for a period ranging from ten months to two years (mean 16 months) postoperatively. They were evaluated for their clinical, radiological and cosmetic outcomes.

Results: Osteoplug™ provided good cosmesis by preventing unsightly depressions over the skull postoperatively in all the 12 patients. Postoperative computed tomography, done at one year, showed signs of good osteointegration into the surrounding calvarial bone, with multifoci mineralisation throughout the scaffold in one patient. There was no case of infection or any adverse systemic reaction noted. Patient satisfaction was high.

Conclusion: The Osteoplug™ polycaprolactone burr-hole covers are suitable, biodegradable implants with good medium-term results. They provide an ideal scaffold for osteogenesis and excellent cosmesis. There were no adverse events in all 12 patients, with a mean follow-up of 16 months.

Keywords: biodegradable polymer, burr-hole covers, osteoconduction, osteogenesis, Osteoplug™, polycaprolactone implants

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INTRODUCTION

Burr holes are commonly utilised in neurosurgery. However, it has been found that the residual depression on the scalp over the usually uncovered burr hole is often unacceptable to the patient from a cosmetic perspective (Fig. 1). To overcome this problem, many materials from bone grafts to synthetic materials, such as titanium, ceramics and hydroxyapatite polymers, have been used to cover burr holes in an attempt to obtain an ideal cosmetic result.[1-3] Our group at the Department of Surgery, National University Hospital, Singapore, together with the Department of Biomedical Engineering at the National University of Singapore, has recently developed a unique bioresorbable polycaprolactone (PCL) polymer scaffold designed to snap-fit into the burr-hole skull defect.[4] This has been patented and also received US Food and Drug Administration (FDA) approval for human clinical use. The advantage of a PCL polymer scaffold is that it allows natural osteogenesis to occur into the burr-hole defect. This new bone integrates, and eventually blends with the patient's native bone perfectly, with excellent cosmetic results. Radiologically, it becomes difficult to discern the presence of a previous burr-hole surgery, and the site can look totally normal. There is subsequently no presence of any foreign material left *in situ* in the long term. This study evaluates the medium-term outcome using our novel biodegradable PCL burr-hole plugs in patients with chronic subdural haematoma.

METHODS

The PCL scaffold is characterised by a slow-degrading synthetic polymer framework and provides a biomimetic milieu for the initial blood-clot phase of wound healing. The entrapped blood clot acts as a cell delivery vehicle. The completely interconnected architecture of the PCL scaffold allows for rapid and homogeneous vascularisation.[4] The design not only assists in early and proper integration of the implant into the native host bone, but also allows for adequate delivery of nutrients to the invading precursor cells. The implants had a mushroom- button design with an

Fig. 1 Photograph shows a patient's unsightly defect over a previous burr-hole site.

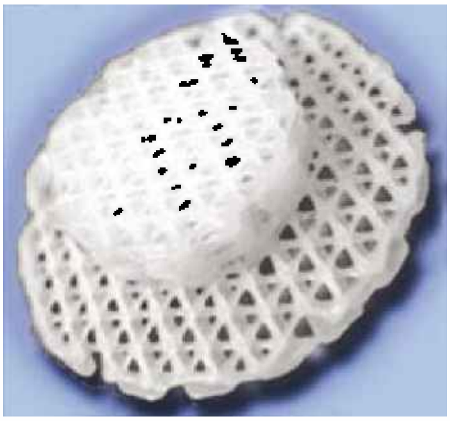

Fig. 2 Photograph shows an Osteoplug™, which is a bioresorbable polycaprolactone implant used to cover burr-hole skull defects.

Fig. 3 Intraoperative photograph shows an Osteoplug™ inserted into the burr hole and sealed with 0.5 ml of fibrin glue.

Fig. 4 Photograph shows a patient with a good cosmetic result after the Osteoplug™ burr-hole cover was used.

upper rim of 16-mm diameter and a central cylinder with a 14-mm body diameter. The honeycomb-like architecture of 400–600 µm pore size provides a porosity of 60%–70%. It is designed to be placed snugly with a snap-fit, without plates and screws. The larger cap ensures that the plug is not pushed too deeply into the cranium (Fig. 2).

12 patients with burr-hole evacuation of chronic subdural haematoma and Osteoplug™ implants, done at National University Hospital, Singapore, from August 2006 to December 2007, were included in our retrospective review. All procedures were performed under general anaesthesia. Patients were cleaned and draped in a standard manner, with a longitudinal incision made over the scalp and the pericranium lifted off with a sharp periosteal elevator. All patients then underwent a routine 14-mm burr-hole placement to evacuate the liquefied haematoma. Either one or two burr holes were created, depending on the location and extent of the bleed. After the evacuation of the haematoma, an Osteoplug™ was inserted into each burr hole and sealed with 0.5 ml of fibrin glue (Tisseel, Baxter Hyland Immuno, Vienna, Austria) (Fig. 3). The patients were evaluated periodically in the outpatient clinic at approximately three- to six-monthly intervals. Assessments made included local or systemic reactions to the implant, clinical palpation to determine the firmness over the site of the implant and patient satisfaction with the cosmetic outcome. Postoperative computed tomography (CT) was performed in all patients at intervals ranging from immediate postoperation to one year later.

RESULTS

There were 11 male and one female patients, with ages ranging from 46 to 87 (mean 74) years. The follow-up period ranged from ten months to two years (mean 16 months). All 12 patients had an uneventful postoperative recovery. None of the implants needed to be removed due to infection or otherwise. There were no local or systemic inflammatory reactions and no detectable swelling over the implants. All 12 patients had no infections, and were pleased with the cosmetic outcome (Fig. 4). All the patients had postoperative CT of the brain done. However, these were usually done less than three months postoperatively and at this stage, they did not show any radiological

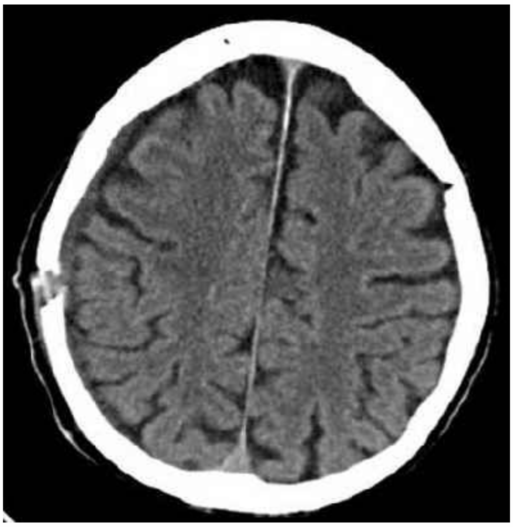

Fig. 5 Axial CT image of the brain at one month postoperation shows the burr hole clearly.

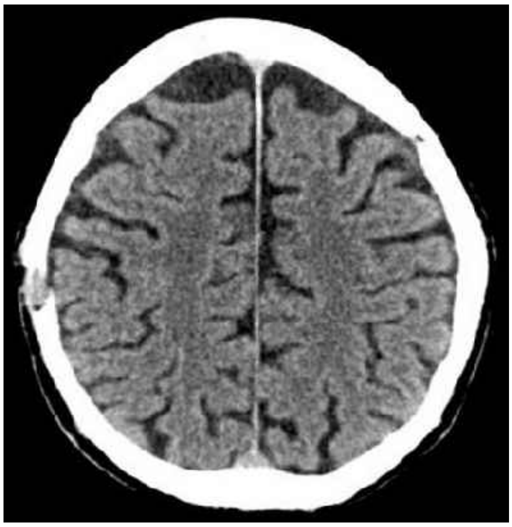

Fig. 6 Axial CT image of the brain at four months postoperation shows early osteogenesis of the burr hole.

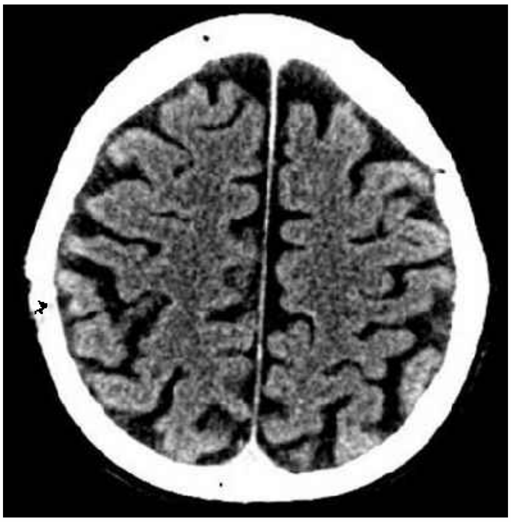

Fig. 7 Axial CT image of the brain at one year postoperation shows that the burr hole defect has been covered with native bone.

osteointegration yet. One patient had a postoperative CT done at one year which demonstrated signs of good integration into the surrounding calvarial bone, with multifoci mineralisation throughout the scaffold. Examples of the follow-up CT showing osteogenesis in the PCL implant at the burr hole are shown (Figs. 5–7).

DISCUSSION

The ideal graft material should not only provide a physical shape of the defect, but also resemble the properties of the bone. Easy handling is also an important surgical factor. PCL is an important biomaterial and has been used in the manufacture of sutures, prosthetics and drug delivery systems. It provides a cell scaffold for integration. The biomechanical strength of the implant after three months *in vivo* demonstrated stiffness of 60% of normal bone.[5] PCL does not interfere with imaging techniques as well. The slow-degrading PCL framework allows neovascularisation to seed for wound healing.[6] At three months, our PCL implants demonstrated multiple foci of mineralisation. At two years, this process provided a stable integration of graft material into the bony tissue.

The implantation of allografts, autografts, metals and ceramics have their own disadvantages and complications. Burr-hole covers made of polyethelyne,[1] hydroxyapatite[2] as well as titanium[3] miniplates have been used, with good initial outcome. However, these materials do not have the ideal properties of biodegradability as well as osteoconduction. Medium-term outcomes following two years of implantation of these materials have also not been reported. Our current study, with a medium-term follow-up, further reinforces our earlier pilot study that PCL implants are well tolerated, and have excellent biocompatibility and good cosmetic results.[4] It allows rapid and homogenous vascularisation, and assists in proper integration with the native host bone.

The Osteoplug™ PCL burr-hole covers are suitable, biodegradable implants with good long-term results, including providing a scaffold for osteogenesis and cosmesis. There were no reports of adverse events up to two years post-implantation. This is a novel and unique biological solution to a common neurosurgical problem. It is different from other existing commercial burr-hole cover products in the market which use synthetic non-biological material.

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