

Outcome of porous implants: Incidence of complications, management, and morbidity

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Objective : To determine the incidence of complications and the outcome associated with the use of three kinds of ocular porous implants.

Material and Method : Retrospective review of 133 consecutive case series. All patients undergoing orbital implantation either primary or secondary implantation of 49 coral hydroxyapatite, 43 human bone hydroxyapatite and 39 bovine bone hydroxyapatite from September 1995 to September 2007 were included. Charts were reviewed for preoperative diagnoses, type and size of implant, use of a wrapping material, and complications. Patients were followed for signs of inflammation, infection, extrusion, or other complications.

Results : There are more exposures of human bone hydroxyapatite (8.16%) and bovine bone hydroxyapatite (7.69%) than coralline hydroxyapatite implants (2.22%). Spontaneous healing of exposures occurred in 25% (2 of 8) of cases. Covering exposures with patch grafts underneath vascularized conjunctival flaps was the most successful method of surgical repair in 2 cases (25%). Chronic infection of the 2 exposed human bone hydroxyapatite leading to the removal of the 2 implants (1.5%) . Conjunctival granulomas and late exposure developed in 2 and 3 patients after peg coupling respectively. There were no cases of implant migration or prolonged inflammation related to the covering material.

Conclusion : Careful selection of surgical technique, implant type and size may help reduce the risk of severe complications.

Keywords : Orbital implantation, coral hydroxyapatite, human bone hydroxyapatite, bovine bone hydroxyapatite, extrusion of hydroxyapatite, exposure of hydroxyapatite, patch grafts, peg coupling

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The removal of globe creates anatomic and physiological alteration of the orbital tissue and orbital bones. A volume deficit occurs when an eye is enucleated. Deep upper lid sulcus, ptosis, lower lid laxity, and enophthalmus of the artificial eye together constitute the post-enucleation socket syndrome, which creates an asymmetry of the face. The orbital implant will restore the orbital volume by placing it in the orbital cavity allows correcting volume deficit, so the implant with attached extraocular muscles, together with an artificial eye, creates an illusion of real eye. Therefore, a much better symmetry, better movement of the artificial eye, and less severe form of

postenucleation syndrome were observed in patients who underwent orbital endoimplantation after eyeball removal. For the last 100 years, various materials have been used for these purposes. In recent decades, most orbital implants have been made from silicone or plastic. Historically, the use of non-porous synthetic ocular implants has led to complications such as exposure, extrusion, migration, infection, poor motility, and poor cosmesis. Since 1985, natural porous hydroxyapatite (HA) has been used as an orbital implant material because it has unique properties. Hydroxyapatite was first used as an orbital implant in 1983. In August 1989, the FDA released the first HA orbital implant. There are several benefits to wrapping the implant. These include: increased motility, ease of insertion, ease of muscle attachment, and decreased risk of exposure. The use of an unwrapped implant allows the rough surface of the

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Human bone hydroxyapatite



Coral hydroxyapatite



Bovine bone hydroxyapatite

hydroxyapatite material to snag on orbital tissues during insertion, and may also cause abrasion of the overlying tissues during movement, thereby increasing the risk of exposure. Orbital implant migration occurred in a significant greater proportion of patients who received a non-porous implant (15.5%) than those who received a porous implant (0.7%)⁽¹⁾. Implant exposure occurred at a low rate that was not significantly different in the two subgroups (2.1% in porous and 1.5% in non-porous)⁽¹⁾. With the increasing use of hydroxyapatite orbital implants, the complication of exposure has become apparent to oculoplastic surgeons. Many kinds of patch grafts, such as amniotic membrane⁽²⁾, sclera, dermis, and hard palate mucosa, autogenous retro-auricular myoperiosteal graft⁽³⁾ have been used to cover exposed hydroxyapatite implants with inconsistent results.

Objective

To determine the safety and efficacy, the incidence of complications and the outcome associated with the use of hydroxyapatite as an orbital implant material with the use of donor human sclera to cover different kinds of porous implants. To identify what factors may predispose patients to exposure of porous anophthalmic implants and to determine the outcome of exposed porous implants including infection and migration with the use of different porous orbital implants after enucleation, evisceration and secondary implantation surgery.

Material and Method

Retrospective review of one hundred and thirty-three consecutive patients underwent implantation of three kinds of porous hydroxyapatite wrapping with donor sclera. The consecutive case series of patients undergoing enucleation, evisceration, or secondary orbital implantation from September 1995 to September 2007 were included. Charts were reviewed for pre-operative diagnoses, type and size of implant, use of a wrapping material, and complications. Forty-five patients received coral hydroxyapatite, 49 patients received human bone hydroxyapatite, and 39 received bovine bone hydroxyapatite. Mean implant diameter was 19.03 mm. Mean follow-up was 44.1 months (range, 2 to 85 months). Patients were followed 1 week, 1 month, and several months after surgery for signs of inflammation, infection, exposure, extrusion, or other complication. The peg-coupling were done in 10 patients who received coral hydroxyapatite and one bovine bone hydroxyapatite who showed well vascularization by bone scan.

Results

Complications included postoperative chemosis in 9/133 cases (6.77%). There are more exposures of human bone hydroxyapatite 4/49(8.16%) and bovine bone hydroxyapatite 3/39(7.69%) than coralline hydroxyapatite implants 1/55 (2.22%). Primary and secondary implantation was equal in number of the exposures. Spontaneous healing of exposures occurred in 2/4 cases (25%) and exposure requiring surgical repair 2/8 cases (25%). Covering exposures with patch grafts underneath vascularized conjunctival flaps was the most successful method of surgical repair. Chronic infection of the 2 exposed human bone hydroxyapatite leading to the removal of the 2/133 implants (1.5%). Motility peg placement was performed successfully in 11 patients (10 coral and 1 bovine bone hydroxyapatite), complication after peg coupling including 3 cases of conjunctival granulomas and 4 cases of late exposure around the hole. There were no cases of implant migration or prolonged inflammation related to the covering material. Conditions leading to the removal of 2 of the 133 (1.5%) implants were primary exposure following with chronic infection. Two patients (1.5%) required postoperative tarsorrhaphies to control chemosis. Magnetic resonance imaging was obtained in 15 patients approximately one year after surgery (3, 1 and 10 cases of human bone, bovine bone and coral hydroxyapatite respectively). Human bone HA showed signs of incomplete fibrovascular in-growth in all 3 case while bovine bone HA and coral HA showed complete fibrovascular in-growth.



Exposed hydroxyapatite

Discussion

The frequency of complications depends on type of applied orbital implant⁽⁴⁾. Careful choice of implant type may help reduce the risk of implant exposure. Bovine bone and coral hydroxyapatite appear to be a safe and effective orbital implant material. They appear to be bio-compatible, non-allergenic and allows for fibrovascular integration and motility peg placement⁽⁷⁾. Human bone hydroxyapatite is also safe and effective but seems to have slowed fibrovascular ingrowth which leading to chronic infection and removal of the implants in 2 exposed cases. Spontaneous healing of exposures occurred in small lesion while exposed HA larger than 3mm. were successfully corrected with patch grafts underneath vascularized conjunctival flaps. The factors may predispose patients to exposure of porous anophthalmic implants are orbital content of the patients and surgical techniques of implantation. Less orbital tissue may predispose to early exposure. Shallow implantation either primary or secondary and evisceration without posterior sclerotomy may also the predisposing cause of the exposure. Injudicious antibiotic use and smaller implants do not decrease the risk of implant extrusion⁽⁹⁾. The most common complications among the peg coupling cases were granulation tissue, discharge, overgrowth of conjunctiva, and peg falling out. The prevalence of the last three complications was statistically lower in titanium peg compared with polycarbonate⁽⁸⁾. The authors believe that more care was needed when performing motility coupling post placement. In addition, longer postoperative follow-up is needed after insertion of a motility coupling⁽⁵⁾. Implant complications of migration, extrusion and socket infection were not found in coralline hydroxyapatite implants. Most of these were easily managed with only a small number progressing to implant exposure⁽⁶⁾. The theoretical risk of sympathetic ophthalmia does not appear to be a concern to most surgeons⁽⁹⁾ as well as in the present study. Infection in hydroxyapatite orbital implants is an uncommon but severe complication. The patients will have a history of chronic socket discharge, orbital discomfort, conjunctival breakdown and implant exposure. Repeated attempts at covering the exposed implant failed. The causative agents of the infection were reported in the other study as *Aspergillus fumigatus*⁽¹⁰⁾, *Staphylococcus aureus* and *Streptococcus anginosus* infection⁽¹¹⁾. Although enucleation and evisceration produce aesthetically similar outcome, eviscerated eyes have better implant

motility. Both enucleation and evisceration may result in enophthalmos sulcus contour defects and incomplete transfer of implant motility to the prosthesis⁽¹²⁾.

Conclusion

There were no complications of implant extrusion, exposure, infection, or migration. Donor sclera covering of different kinds of porous implants appears to be a successful surgical technique associated with few serious complications. The potential benefits of this technique must be balanced by the increased cost of the wrapping material and the rare but potential risk of transmitting infectious disease.

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อุบัติการณ์ของภาวะแทรกซ้อนและวิธีการแก้ไขในการใช้วัสดุหนุนเบ้าตาชนิดมีรู

เจลา พงศ์ประยูร

วัตถุประสงค์ : เพื่อศึกษาผลและภาวะแทรกซ้อนจากการใช้ ocular porous implants สามชนิด

วัสดุและวิธีการ : ศึกษาย้อนหลังดูผลการรักษาผู้ป่วย 133 ราย ที่ได้รับการผ่าตัดแบบ primary หรือ secondary implantation โดยใส่ coral hydroxyapatite 49 ราย, human bone hydroxyapatite 43 ราย และ bovine bone hydroxyapatite 39 ราย ตั้งแต่ กันยายน พ.ศ. 2538 ถึง กันยายน พ.ศ. 2550 ดูประวัติการวินิจฉัยโรค ชนิดการผ่าตัด ชนิดและ ขนาดของ implants ผลการผ่าตัดและโรคแทรกซ้อน

ผลการศึกษา : human bone hydroxyapatite และ bovine bone hydroxyapatite มี exposure rate 8.16% และ 7.69% มากกว่า coralline hydroxyapatite ซึ่งมี exposure rate 2.22%. การ expose ขนาดเล็กหายเอง 2 ราย (25%) ต้องทำ patch grafts จาก conjunctival flaps 2 ราย (25%) ในผู้ป่วยที่ใช้ human bone hydroxyapatite และมี exposure เกิด chronic infection จนต้องเอา implants ออก 2 ราย (1.5%) ผู้ป่วยที่เจาะรูใส่ peg เกิด conjunctival granulomas และ late exposure 2 และ 3 ราย ไม่พบ implant migration หรือ prolonged inflammation

สรุป : การเลือกวิธีการผ่าตัด วัสดุและขนาด ของ implant จะช่วยลดอัตราและความรุนแรงของภาวะแทรกซ้อน
