Bovine pericardium (Tutopatch®) wrap for hydroxyapatite implants

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Abstract

Purpose To evaluate bovine pericardium (Tutopatch®) as a wrapping material for hydroxyapatite implants in patients undergoing enucleation for uveal melanoma.

Method Prospective cohort study of patients who had enucleation for uveal melanoma between January 2003 and August 2003 were included in the study. Any patient with less than 3 months follow-up was excluded. Enucleation was performed under general anaesthesia followed by insertion of hydroxyapatite implants wrapped in bovine pericardium (Tutopatch). The recti muscles were sutured directly to the wrap. The tenon's capsule and conjunctiva were closed in two layers. A conformer was inserted at 1 week and artificial eye at 2–3 months. The patients were followed up regularly and were assessed for cosmetic result, exposure of implant, and the need for any further surgical procedures.

Results A total of 19 patients (seven male and 12 female) were included in the study. Median age at diagnosis was 63 years (range 38–80 years). Median follow-up was 26 months (range 22–30 months). No patient developed postoperative complications of wound dehiscence. The overall cosmetic result was excellent in all the patients. The rate of postoperative complications compared favourably with published data using other wrapping materials/implants.

Conclusion Tutopatch® is a safe wrapping material for hydroxyapatite orbital implants in patients undergoing enucleation for uveal melanoma.

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Introduction

Enucleation is the primary treatment for large uveal melanoma and was initially performed without the use of orbital implants. Mules¹ introduced orbital implants more than 100 years ago. With the advent of hydroxyapatite implant in 1989, a new era in the use of orbital implants had begun.

Hydroxyapatite implant have the advantage of getting integrated in the orbital tissues, but the hard rough external surface makes suturing of muscles to the implant difficult. Various wrapping materials like donor human sclera,² polyester heart fibre patches,³ rectus abdominis sheath,⁴ posterior auricular muscle,⁵ vicryl mesh,⁶ and bovine pericardium have been used.⁷

Processed bovine pericardium has the added advantage of being available in a sterilized prewrapped form and autologous tissue does not need to be harvested. Processed bovine pericardium is commercially available as Ocuguard (Ocuguard Supple®, Bio-Vascular Inc., St Paul, Minnesota, USA) and as Tutoplast® (Tutogen Medical GmbH, Germany and Marketed in the UK by Wescott Medical Limited, Durham. UK). Although both products are derived from bovine pericardium, Ocuguard® is processed with glutaraldehyde, ethanol, and propylene oxide, and Tutoplast® is processed by osmosis to destroy the cellular content, oxidative treatment, sodium hydroxide to eliminate prions and to make the collagen more readily resorbable. It is then dehydrated with acetone and sterilized using low-dose gamma radiation. Since Ocuguard® is processed using glutaraldehyde, there is potential risk of wound dehiscence probably due to the decrease in the resorbability of the collagen. We undertook a pilot study to evaluate Tutoplast® as a wrapping material in patients with uveal melanoma needing enucleation.

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Material and methods

Prospective cohort study patients who required enucleation for uveal melanoma (either primary or secondary when there was evidence of growth after another form of treatment) were included. All cases had an insertion of hydroxyapatite implant that was wrapped in processed bovine pericardium (Tutoplast®). All cases with less than 3 months postoperative follow-up were excluded.

Surgical technique

All patients had surgery under general anesthesia as an in-patient. A standard surgical protocol was followed for all cases. Three experienced consultant ocular oncologists performed all the surgeries. After a 360° peritomy at the corneoscleral limbus, the tenon's capsule was dissected to provide access to the extraocular muscles. All four recti muscles were isolated with double ended 6-0 Vicryl sutures before transection at their insertion. The oblique muscles were also identified and transected but were not attached to the implant. Following section of the optic nerve, hemostasis was achieved by combination of digital pressure and insertion of gauze soaked in warm saline into the deep orbit for several minutes.

Either a size 18 or 20 mm hydroxyapatite orbital implant was used after assessing the orbital volume. The bovine pericardium wrap (Tutopatch® manufactured by Tutogen Medical) was rinsed in saline for a minimum of 3 min and then was used to wrap the hydroxyapatite implant. (Figure 1) As the wrap is supplied as a square sheet, the posterior loose ends of the wrap were anchored securely on the implant with a 6-0 Dacron suture joining the loose ends of the wrap. The four recti muscles were sutured directly to the wrap. The posterior tenon's capsule and the conjunctiva were closed in two layers

Figure 1 Coloured photograph of the wrapped implant ready for implantation.

Table 1 Table showing the age, sex, and follow-up of the patients

Patient no.	Age (years)	Sex	Follow-up (months)
1	46	F	30
2	38	F	29
3	80	F	28
4	80	M	28
5	63	M	28
6	43	F	28
7	40	F	27
8	52	F	27
9	66	M	26
10	53	F	26
11	63	M	26
12	76	M	24
13	68	F	23
14	70	F	24
15	37	M	26
16	66	F	26
17	51	F	23
18	78	F	24
19	70	M	22

with interrupted 6-0 Vicryl sutures. Marcaine 0.5% was injected into the subtenon's space for postoperative analgesia and a pressure bandage was used overnight. The patient was discharged next day after ensuring the wound was secure with a 3-week course of topical steroids and antibiotics to help decrease postoperative inflammation and prevent infection, respectively. The patient was reviewed at 1 week and a conformer was inserted at that time. A temporary artificial eye was inserted approximately 6 weeks postoperatively and replaced with permanent artificial eye after 3 months. After this, the patient was reviewed every 3–6 months when the wound was examined to assess cosmetic appearance, ocular motility, wound dehiscence, and implant exposure (Table 1).

Results

In total, 19 consecutive cases (seven male and 12 female) that were operated between January and August 2003 were included in the study. The median age at diagnosis was 63 years (range 37–80 years). The median postoperative follow-up was 26 months (range 22–30 months).

One patient had undergone two sessions of transpupillary thermotherapy 6 years previously and had documented growth. Two further patients had undergone ruthenium plaque brachytherapy, which was followed by growth of the tumour needing enucleation. All the patients were happy with the cosmetic appearance and ocular motility.

No patient had any intraoperative complications. One patient had some lower lid laxity but as the cosmetic result was good she decided not to have anything done. Another developed a conjunctival granuloma which was excised. There was no wound dehiscence, exposure, or extrusion of the implant. The overall cosmetic result was excellent in all the patients (100%).

Discussion

The characteristics of a good wrapping material are that it is safe and easy to use. Autologous materials have the advantage of reduced risk of transmission of viral infections but they need additional surgery on the patient to harvest these tissues that can leave scars that the patients may not be happy with⁸ and also cause complications like vascular compromise to the ear during harvesting of posterior auricular membrane.⁵

Wound dehiscence is one of the potential complications in the use of orbital implants. Dehiscence rates of 0–40% have been reported with various wrapping materials in numerous studies. The incidence of dehiscence is attributed to both the surgical technique and the wrapping material, probably due to the postoperative inflammation.⁹ Sclera, which has been the most commonly used wrapping material, has a wound dehiscence rate of 1–33%.^{10,11} Dehiscence rates of 5–23% with the use of bovine pericardium wraps (Ocuguard[®]) have also been reported.^{7,9,12} There are no published studies on the use of Tutopatch[®] as a wrapping material, but lack of our complications in our pilot study compares favourably to published studies with the other wrapping materials. We accept that it is a small pilot study and we do not have a long follow-up but most of the complications reported in previous studies commonly happen within the first few months of surgery. A low complication rate in this pilot study could be attributed to the fact that all cases were performed by experienced Consultant Ophthalmologists who undertook meticulous wound closure, which is known to be an important factor in preventing dehiscence.⁸

Although we are not aware of any disease transmission from sclera, segments of human immunodeficiency virus genome have been identified by polymerase chain reaction in preserved human sclera.¹³ This has raised concerns regarding the possibility of transmission of infections with the use of sclera. Treatment of bovine pericardium with sodium hydroxide eliminates the prions by hydrolysis, eliminates viruses by destroying nucleic acids and makes the collagen easily resorbable facilitating biointegration of the hydroxyapatite implants. As prion infections have a latency of 30–40 years and there is no useful test to screen for prion infection, it is probably safer to use alternative

materials.¹⁴ However, Tutoplast[®] manufactured by the same company is used for duraplasty with no evidence of transmission of infections.¹⁵

Vicryl mesh has also been used by many people with different levels of access. Jordan *et al*⁶ reported an exposure rate of 2.1% within the first 2–3 months of surgery. Other authors have reported a high exposure rate in cases where vicryl mesh was used.⁸ In a comparison between sclera and vicryl mesh, there was an exposure rate of 9.4% in (3/32) cases.¹⁶ The advantages of using vicryl mesh is the easy availability, it does not require donor tissue, is readily available, and no risk of the transmission of diseases, but it has a learning curve since the polyglactin 910 mesh-wrapped implant has different handling properties than a sclera-wrapped implant.⁶

Our pilot study suggests that the use of bovine pericardium (Tutopatch[®]) is a safe alternative to the other wrapping materials. Use of Tutopatch[®] decreases surgical time, as the autologous tissue does not need to be harvested. Most importantly, bovine pericardium wrap compared favourably with other wrap materials and has a low rate of complications in the setting of primary enucleation of uveal melanoma.

References

- 1 Mules PH. Eviceration of the globe with artificial vitreous: 1884–1894. *Adv Ophthalmic Plast Reconstr Surg* 1990; **8**: 69–72.
- 2 Shields JA, Shields CL, De Potter P. Hydroxyapatite orbital implant after enucleation—experience with 200 cases. *Mayo Clin Proc* 1993; **68**: 1191–1195.
- 3 Chen X, Gao D, Yin S. Application of polyester fiber heart patches to secondary intraorbital implantation of hydroxyapatite spheres. *Zhonghua Zheng Xing Wai Ke Za Zhi* 2000; **16**: 270–272.
- 4 Kao SC, Chen S. The use of rectus abdominis sheath for wrapping of the hydroxyapatite orbital implants. *Ophthalm Surg Laser* 1999; **30**: 69–71.
- 5 Naugle Jr TC, Lee AM, Haik BG, Callahan MA. Wrapping hydroxyapatite orbital implants with posterior auricular muscle complex grafts. *Am J Ophthalmol* 1999; **128**: 495–501.
- 6 Jordan DR, Klapper SR, Gilberg SM. The use of vicryl mesh in 200 porous orbital implants: a technique with few exposures. *Ophthalm Plast Reconstr Surg* 2003; **19**: 53–61.
- 7 Gayre GS, Debacker C, Lipham W. Bovine pericardium as a wrapping for orbital implants. *Ophthalm Plast Reconstr Surg* 2001; **17**: 381–387.
- 8 Custer PL. Enucleation: past, present, and future. *Ophthalm Plast Reconstr Surg* 2000; **16**: 316–321.
- 9 Char DH. Early wound dehiscence with use of hydroxyapatite orbital implant covered with calf pericardium. *Br J Ophthalmol* 2001; **85**: 627–628.
- 10 Shields CL, Shields JA, De Potter P. Hydroxyapatite orbital implant after enucleation. Experience with initial 100 consecutive cases. *Arch Ophthalmol* 1992; **110**: 333–338.

- 11 Inkster CF, Ng SG, Leatherbarrow B. Primary banked scleral patch graft in the prevention of exposure of hydroxyapatite orbital implants. *Ophthalmology* 2002; **109**: 389–392.
- 12 Arat YO, Shetlar DJ, Boniuk M. Bovine pericardium *vs* homologous sclera as a wrapping for hydroxyapatite orbital implants. *Ophthalmic Plastic Reconstr Surg* 2003; **19**(3): 189–193.
- 13 Seiff SR, Chang Jr JS, Hurt MH, Khayam-Bashi H. Polymerase chain reaction identification of human immunodeficiency virus-1 in preserved human sclera. *Am J Ophthalmol* 1994; **118**: 528–529.
- 14 Nunery WR. Risk of prion transmission with the use of xenografts and allografts in surgery. *Ophthalmic Plastic Reconstr Surg* 2001; **17**: 389–394.
- 15 Filippi R, Schwarz M, Voth D, Reisch R, Grunert P, Perneczky A. Bovine pericardium for duraplasty: clinical results in 32 patients. *Neurosurg Rev* 2001; **24**: 103–107.
- 16 Oestreicher JH, Liu E, Berkowitz M. Complications of hydroxyapatite orbital implants: a review of 100 consecutive cases and a comparison of Dexon mesh (polyglycolic acid) with scleral wrapping. *Ophthalmology* 1997; **104**: 324–329.