THE HYDROXYAPATITE ORBITAL IMPLANT: A PROSPECTIVE STUDY

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SUMMARY

The hydroxyapatite orbital implant was first released for use as an orbital implant in humans in August 1989. It has been shown to be well tolerated, providing good motility of the artificial eye with a low complication rate when used as a primary implant.[1] This prospective study evaluated the hydroxyapatite orbital implant used as both a primary and a secondary implant. Sixty patients were implanted between October 1992 and November 1994, 28 being implanted as a primary procedure at the time of enucleation or evisceration, and 32 as a secondary procedure. Seven patients underwent second-stage drilling and pegging of the implant. The mean follow-up time was 13 months (range 2–26 months). A standardised operative and post-operative protocol was followed. The patients were evaluated post-operatively for the amount of enophthalmos, degree of upper lid sulcus deformity, motility of the prosthesis, location of the implant in the socket, socket status and the presence or absence of discharge, position of the drill hole and coverage of the implant. Complications and their management were documented. Both patient and surgeon made a subjective assessment of cosmesis and the patient's satisfaction with the overall result was noted. The results of this study show the hydroxyapatite orbital implant to provide excellent motility of the artificial eye and good cosmesis with a low rate of complications when used both as a primary and as a secondary implant.

Since the first glass sphere was implanted in 1885[2] many different types of orbital implant have been used in an attempt to provide the anophthalmic patient with as natural an appearance as possible and to minimise the problems of a resultant post-enucleation socket syndrome. The ideal orbital implant should be easy to insert, comfortable and cause the minimum of complications. It should provide good cosmesis with the resultant motility of the artificial eye matching that of the fellow eye in all directions of gaze. Orbital implants can be classified as integrated or non-integrated, and may be buried or partially exposed. Exposed implants were used in the early 1940s and allowed coupling of the prosthesis to the implant to give good motility. Unfortunately they were associated with an unacceptable rate of chronic infection and extrusion. Integrated orbital implants have also had a tendency to extrude, occasionally many years after implantation.[3,4]

The hydroxyapatite orbital implant is a buried integrated implant which is composed of calcium phosphate derived from the exoskeleton of marine coral (Fig. 1). Its microstructure is a system of

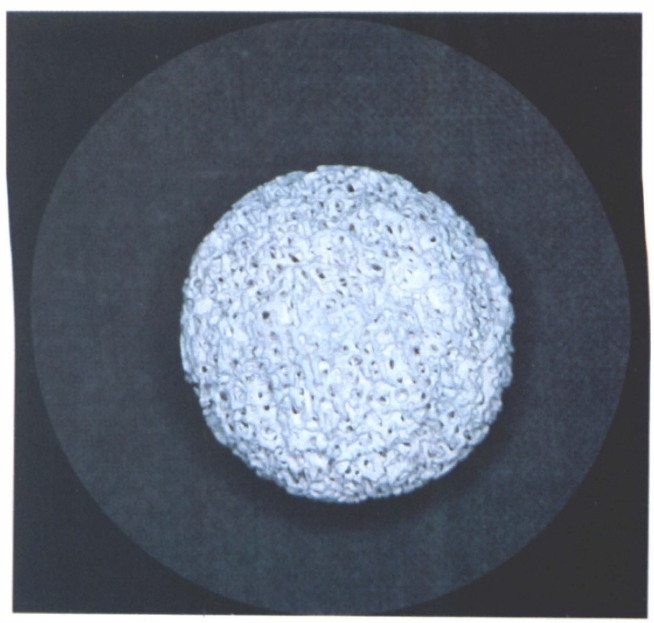

Fig. 1. *The hydroxyapatite orbital implant.*

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Table I. Assessment of results

1. Volume replacement
2. Motility
3. Location of implant in socket
4. Status of socket
5. Socket discharge
6. Coverage of the implant
7. Prosthesis fitting problems
8. Position of the drill hole
9. Complications
10. Additional surgery
11. Cosmetic result
12. Patient satisfaction

interconnecting pores approximately 500 μm in diameter and resembling that of human cancellous bone.[5] It is inert, biocompatible, non-toxic, non-allergenic[6] and has been used in bone augmentation surgery.[7] It becomes integrated with orbital tissues by fibrovascular tissue ingrowth into the pores.[6]

Good motility is achieved by attaching the extraocular muscles to the implant. The motility can later be improved by directly coupling the prosthesis to the implant by means of a motility peg. This allows fine saccadic movements to be directly transmitted to the artificial eye with no lag. The peg is inserted into a hole which has been drilled into the implant once the implant has become fully vascularised. The hole becomes lined by conjunctival epithelium, so that the implant itself is not exposed and the peg can be tolerated as a foreign body. The peg also supports the weight of the artificial eye, reducing the likelihood of lower lid laxity and providing extra stability.

The implant is wrapped in a donor scleral shell. Its vascularised buried state is a deterrent to migration and extrusion of the implant and confers a low rate of infection.[1] Shields *et al.*[1] have shown in a study of 250 cases that the hydroxyapatite orbital implant gives good cosmetic results and motility and is well tolerated when used as primary implant at the time of evisceration or enucleation. The majority of their patients had undergone an enucleation for intraocular malignancy. In contrast in our study, over 50% of the patients had undergone hydroxyapatite orbital implantation as a secondary procedure to replace an existing extruding or migrated implant, or to improve cosmesis and prosthetic motility in an anophthalmic patient with no orbital implant. The objective of our study was to assess prospectively the results of the hydroxyapatite orbital implant used both as a primary and as a secondary implant.

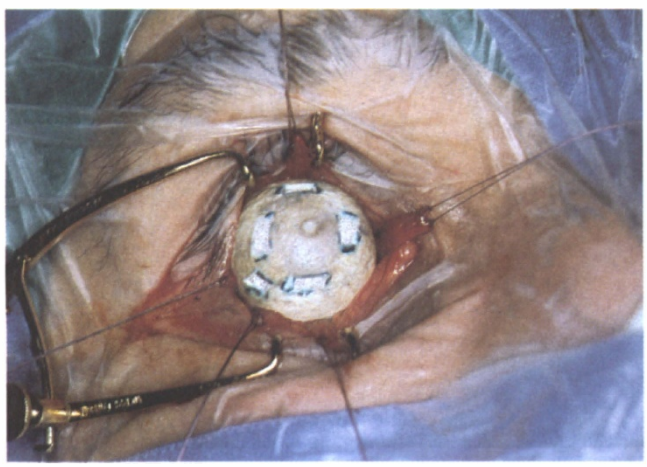


Fig. 2. *The hydroxyapatite orbital implant wrapped in sclera, with windows cut for the attachment of the rectus muscles and the inferior oblique muscle.*

PATIENTS AND METHODS

Sixty patients were followed who had undergone implantation with an hydroxyapatite orbital implant by the oculoplastic/orbital service at Manchester Royal Eye Hospital between October 1992 and November 1994. Twenty-seven of these were referred for an enucleation and implant and one for evisceration and implant. Thirty-two anophthalmic patients were referred for a secondary implant. Of these, 24 had undergone previous enucleation without an implant and 8 already had an existing implant *in situ*.

The surgery was performed with the patient under general anaesthesia by both the consultant (B.L.) and a number of surgeons in training. Cefuroxime 750 mg was given intravenously during the procedure (or erythromycin if the patient was allergic to penicillin) followed by cephradine (or erythromycin) 500 mg q.d.s. orally for 1 week post-operatively. The doses were adjusted for children according to their body weight. Ketoralac 10 mg was also given intravenously at the time of surgery followed by indomethacin 25 mg t.i.d. for 2 weeks post-operatively unless its use was contraindicated. A pressure dressing was applied at the end of surgery and left *in situ* for 1 week. Topical antibiotics were then used for 5 weeks. The patients were reviewed at 1 week, 3 weeks and 6 weeks post-operatively. At the 3 week appointment, the ocularist fitted a surgical

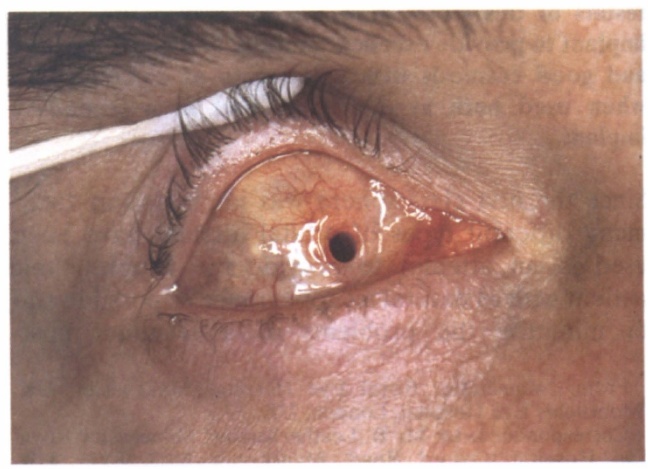


Fig. 3. *The socket of a patient who has a hydroxyapatite orbital implant, showing the position of the drill hole.*

Table II. Indications for enucleation or evisceration

	Primary implant group (n = 28)	Secondary implant group (n = 32)
Painful blind eye	21 (75%)	12 (37.5%)
Previous trauma	8	5
Retinal detachment	4	2
Iatrogenic	4	0
Congenital cataract	0	1
Congenital glaucoma	2	2
Corneal myxoma	1	0
Congenital toxoplasmosis	1	0
Coats' disease	1	0
Central retinal vein occlusion	0	1
Endophthalmitis	0	1
Choroidal melanoma	3 (11%)	0
Penetrating injury	3 (11%)	13 (41%)
Congenital microphthalmia	1 (3%)	1 (3%)
Retinoblastoma	0	4 (12.5%)
Choroidal sarcoma	0	1 (3%)
Unknown	0	1 (3%)

conformer. After 6 weeks, arrangements were made for a custom-made artificial eye to be fitted if the socket was sufficiently quiet. If any residual oedema was present or if a conjunctival gape had not yet healed, this was delayed for a further 4 weeks. The patients were then reviewed at intervals by the surgeon and ocularist. If the patients wished to undergo the second stage drilling procedure this was undertaken no sooner than 6 months following primary implantation and 12 months following secondary implantation. Bone or MRI scans were not routinely performed prior to the drilling procedure.

The patients attended for a review by the same examiner (J.L.A.) between October 1994 and January 1995. The parameters assessed are shown in Table I. The degree of volume replacement provided by the implant was assessed both by the difference in Hertel exophthalmometry readings between the natural eye and the artificial eye, and by a qualitative assessment of the degree of upper lid sulcus deformity, grading this as absent, mild, moderate or severe. The motility of the artificial eye was assessed qualitatively for both saccadic and smooth pursuit movements in a vertical and horizontal plane. The patients were asked to express their satisfaction with the results of the surgery with regard to cosmesis and artificial eye motility.

The patients' hospital records and histopathological reports were reviewed to determine the indication for enucleation/evisceration.

SURGICAL TECHNIQUE

The surgical technique used is similar to that described by Perry.[5] The size of the porous hydroxyapatite implant to be used is determined by placing a standard acrylic sphere into the orbit with the posterior Tenon's fascia opened exposing intraconal fat. Allowance is made for the increase in actual diameter of the implant caused by wrapping it with donor sclera.

The donor sclera is pre-treated with antibiotic solution (gentamicin). The implant is then wrapped in the scleral shell, which is sutured around it with 5-0 Vicryl sutures. The sclera is trimmed to fit well and five rectangular windows (5 × 7 mm) are marked in pen and then cut out where the rectus muscles and inferior oblique muscle are to be attached (Fig. 2). The implant is inserted into the muscle cone and the muscles are attached to the anterior lips of the scleral windows using 5-0 Vicryl sutures. In secondary implantation, where an implant is present, this is removed. The recti are identified pre-operatively. Meticulous dissection of the extraocular muscles would increase the risk of post-operative haematoma and oedema, so the tissue that is thought to contain the recti is attached to the implant. Where no implant is present the extraocular muscles cannot usually be identified and the Tenon's fascia in the approximate positions of the recti is attached to the implant instead. Anterior Tenon's fascia is closed over the implant with interrupted 5-0 Vicryl sutures, and the conjunctiva is closed with interrupted 7.0 Vicryl sutures. Antibiotic ointment is inserted into the socket and a heavy pressure dressing is applied.

When the implant is vascularised, it can be drilled and made into a direct motility implant. Technetium-99 bone scan studies have shown a 20 mm sphere to be vascularised at approximately 6 months, but in

Table III. Indications for secondary implantation (n = 32)

Post-enucleation socket syndrome	30 (94%)
No implant	24
Implant	6
Extrusion of previous implant	2 (6%)

Table IV. Size of implant

Implant size (mm)	Primary group (n = 28)	Secondary group (n = 32)
16	5 (18%)	4 (13%)
18	21 (75%)	26 (81%)
20	2 (7%)	2 (6%)

Table V. Amount of relative enophthalmos of artificial eye

Difference (mm)	Primary implant group (n = 28)	Secondary implant group (n = 32)
0	3 (11%)	5 (15%)
1	7 (25%)	9 (28%)
2	7 (25%)	6 (19%)
3	6 (21%)	7 (22%)
4	4 (14%)	3 (10%)
5	1 (3%)	2 (6%)

some cases it takes as long as 10 months.[6] Drilling is therefore delayed until approximately 6 months in primary cases and 12 months in secondary cases and is performed under retro-implant local anaesthesia. The ocularist makes a template of the patient's prosthesis with a hole in the region of the pupil. With the template in position in the socket, the surface of the conjunctiva is marked through this hole to indicate the position for drilling. This area is drilled with a hand-held drill whilst the implant is stabilised with forceps. A hole 3 mm in diameter and 10 mm in depth is drilled perpendicular to the plane of the orbit (Fig. 3). A temporary flat-headed peg is inserted which is replaced 3–4 weeks later by a permanent round-headed peg.

RESULTS

There were 33 male and 27 female patients studied. The mean age was 36 years (range 2.5–72 years). The mean follow-up time was 13 months (range 2–26 months). The indications for enucleation or evisceration are shown in Table II. (One patient in the primary implant group underwent evisceration following an expulsive haemorrhage during a penetrating keratoplasty.) The indications for secondary implantation are shown in Table III. Ninety-four per cent of patients underwent secondary implantation for poor cosmesis secondary to a post-enucleation socket syndrome. Of these, 24 patients had no implant at the time of the secondary surgery, while 6 already had an existing implant which was removed and exchanged for a hydroxyapatite implant. Two patients (6%) underwent secondary implantation because their previous implant was extruding. In these cases the implants were magnetic Roper-Hall implants.

The sizes of implants used are shown in Table IV.

Table VI. Qualitative assessment of upper eyelid sulcus deformity

Sulcus deformity	Primary implant group (n = 28)	Secondary implant group (n = 32)
Absent	10 (36%)	14 (44%)
Mild	6 (21%)	6 (19%)
Moderate	8 (29%)	7 (22%)
Severe	4 (14%)	5 (15%)

The 18 mm size was most frequently selected for both the primary and secondary implant groups. Table V shows the differences in Hertel exophthalmometry measurements between the artificial eye and the fellow eye. The range was 0–5 mm and the mean 2 mm. There was little difference between the primary and secondary groups. Thirty-nine per cent of the primary group and 38% of the secondary implant groups were left with 3 mm or greater relative enophthalmos.

The assessment of the degree of upper eyelid sulcus deformity is shown in Table VI. There was little difference between primary and secondary groups: 43% of the primary group and 37% of the secondary group had moderate or severe sulcus deformity.

The results of a subjective assessment of the degree of motility of the prosthesis are shown for both smooth pursuit and saccades (Table VII), in patients who had and had not yet had a peg inserted. In the unpegged group, the degree of motility was superior for the primary group for both smooth pursuit and saccades: 40% of unpegged primary patients had good motility for smooth pursuit compared with 25% of patients in the unpegged secondary group, and 48% of the unpegged primary group had good motility for saccades compared with 25% of the unpegged secondary patients. There were less noticeable differences in the few patients in the pegged group: only 1 (33%) of the 3 pegged primary patients had good prosthetic motility for smooth pursuit and 2 (67%) had good motility for saccades, while of the 4 secondary implant patients who had been pegged 2 (50%) had good smooth pursuit and 3 (75%) had good saccadic motility. (All the pegged group of primary patients, however, did feel that the

Table VII. Surgeon's assessment of implant motility

	Primary implant group		Secondary implant group	
Motility	Pegged (n = 3)	Unpegged (n = 25)	Pegged (n = 4)	Unpegged (n = 28)
Smooth pursuit				
Poor	0	2 (8%)	1 (25%)	8 (29%)
Fair	2 (67%)	13 (52%)	1 (25%)	13 (46%)
Good	1 (33%)	10 (40%)	2 (50%)	7 (25%)
Saccades				
Poor	1 (33%)	0	0	5 (18%)
Fair	0	13 (52%)	1 (25%)	16 (57%)
Good	2 (67%)	12 (48%)	3 (75%)	7 (25%)

Table VIII. Post-operative complications

Complications	Primary implant group (n = 28)	Secondary implant group (n = 32)
None	24 (85%)	26 (82%)
Implant exposure	3 (11%)	1 (3%)
Conjunctival cyst	0	1 (3%)
Eccentric implant	0	3 (9%)
Orbital cellulitis	1 (4%)	0
Socket injection	0	1 (3%)

motility of their implant had been significantly improved by drilling, as did 3 of 4 of the pegged secondary group.) In 2 of the primary implant group, drilling was felt to be unnecessary as the motility was excellent without it.

In the primary group all implants were centrally placed in socket. Three (9%) of the secondary group had displaced implants. All the primary implant group had a healthy socket. Four (11%) of the secondary group had an inflamed socket. Seventy-five per cent of the primary group and 66% of the secondary group said that they experienced regular discharge from the socket.

Four (14%) primary implant patients and 1 (3%) of the secondary group had conjunctival breakdown and exposure of the implant at the time of review. Chronic exposure was not causing any problems in these patients. There were no cases of extrusion or migration of the implant. Three (11%) of the primary group had prosthetic fitting problems, as did 5 (16%) of the secondary group. The problems were attributable to lower lid laxity unable to support the weight of the prosthesis prior to drilling, slippage of the prosthesis on the implant, and the drill hole becoming blocked so that the peg could not be fitted. One patient had a very prominent natural eye requiring a large implant for symmetry. This caused instability of the prosthesis so that he was unable to wear the prosthesis until it had been pegged.

Three of the primary implant group had undergone drilling at the time of review, as had 4 of the secondary group. One patient out of both primary and secondary groups had an eccentric drill hole. However, both these patients still had good movements. The drill hole of a patient in the secondary group became filled with granulation tissue shortly after drilling and required re-drilling; this was successfully achieved.

There were no operative complications. Table VIII lists the post-operative complications. Two patients in the primary group had exposure of the implant which required mucous membrane grafts and 1 required both mucous membrane and scleral patch grafts. In the secondary group, 1 patient needed both mucous membrane and scleral patch grafts to close an area of exposed implant.

There was only 1 case of orbital cellulitis in the primary implant group, which resolved successfully with intravenous antibiotics. A superficial socket infection attributed to *Haemophilus influenzae* resolved with topical antibiotics. Three (9%) patients in the secondary group had implants which were not centrally placed. In 1 this resulted in a secondary ectropion which required repositioning of the implant with fornix-deepening sutures. Two of these patients were left with poor motility of the prosthesis. One patient in the secondary implant group developed a conjunctival cyst which required surgical excision.

A summary of the further surgical procedures undertaken is shown in Table IX. Two patients in the secondary implant group required lid surgery, for ptosis or lid retraction that had been present prior to the hydroxyapatite implant surgery. Lid surgery was undertaken in 1 patient in the primary group who had volume deficiency, lower lid laxity and upper lid retraction. This patient required a proplast subperiosteal implant, lateral tarsal strip and upper lid retractor recession to correct this. The lower lid laxity had also been present pre-operatively and he had undergone unsuccessful upper lid surgery 20 years previously. Three (11%) of the primary group had volume deficiency requiring a subperiosteal implant, as did 1 (3%) of the secondary group.

Table X shows the subjective assessment of the cosmetic result made by the surgeon and patient. In both primary and secondary groups, a higher percentage of patients considered their cosmetic

Table X. Assessment of cosmetic result

Results	Primary implant group (n = 28)	Secondary implant group (n = 32)
Assessment by surgeon		
Poor	1 (4%)	6 (19%)
Fair	12 (43%)	11 (34%)
Good	15 (53%)	15 (47%)
Assessment by patient		
Poor	2 (7%)	6 (19%)
Fair	4 (14%)	8 (25%)
Good	22 (79%)	18 (56%)

Table IX. Additional surgical procedures undertaken

Procedure	Primary implant group (n = 28)	Secondary implant group (n = 32)
Subperiosteal implant	3 (11%)	1 (3%)
Patch grafting	3 (11%)	1 (3%)
Ptosis surgery	0	2 (6%)
Lower lid lateral tarsal strip	1 (4%)	0
Upper lid levator recession	1 (4%)	0
Excision of socket cyst	0	1 (3%)
Implant repositioning	0	2 (6%)

result to be better than did the surgeon. Seventy-nine per cent of patients in the primary group and 56% of patients in the secondary group considered themselves to have a good cosmetic result. Ninety-three per cent of the primary group said they were very pleased with the results, and 87% of the secondary group were very pleased and felt there had been improvement as a result of the surgery. Only 2 (8%) of the primary and 4 (12%) of the secondary group patients were disappointed in their post-operative results.

DISCUSSION

The hydroxyapatite orbital implant was developed to improve cosmesis and prosthetic motility in anophthalmic patients and to reduce the unacceptable complication rate associated with other orbital implants. It offers a number of advantages: it can be directly coupled to the artificial eye allowing excellent motility and stability along with a reduction in weight transferred to the lower lid. The fibrovascular ingrowth discourages migration and extrusion, and its vascularised, buried nature confers a low rate of infection.

Previous studies by Shields *et al.* and Dutton have shown the hydroxyapatite orbital implant to be well tolerated with good motility as a primary implant in adults[1,11,13,14] and also in children.[8] Our study confirms the good results when it is used as a primary implant (Fig. 5), and demonstrates that it can also be used successfully as a secondary implant in patients who have a post-enucleation socket syndrome (Fig. 6). It may also be used as an exchange implant in patients who have poor cosmesis and motility with their present implant, or whose existing implant has extruded or migrated into an abnormal position in the socket.

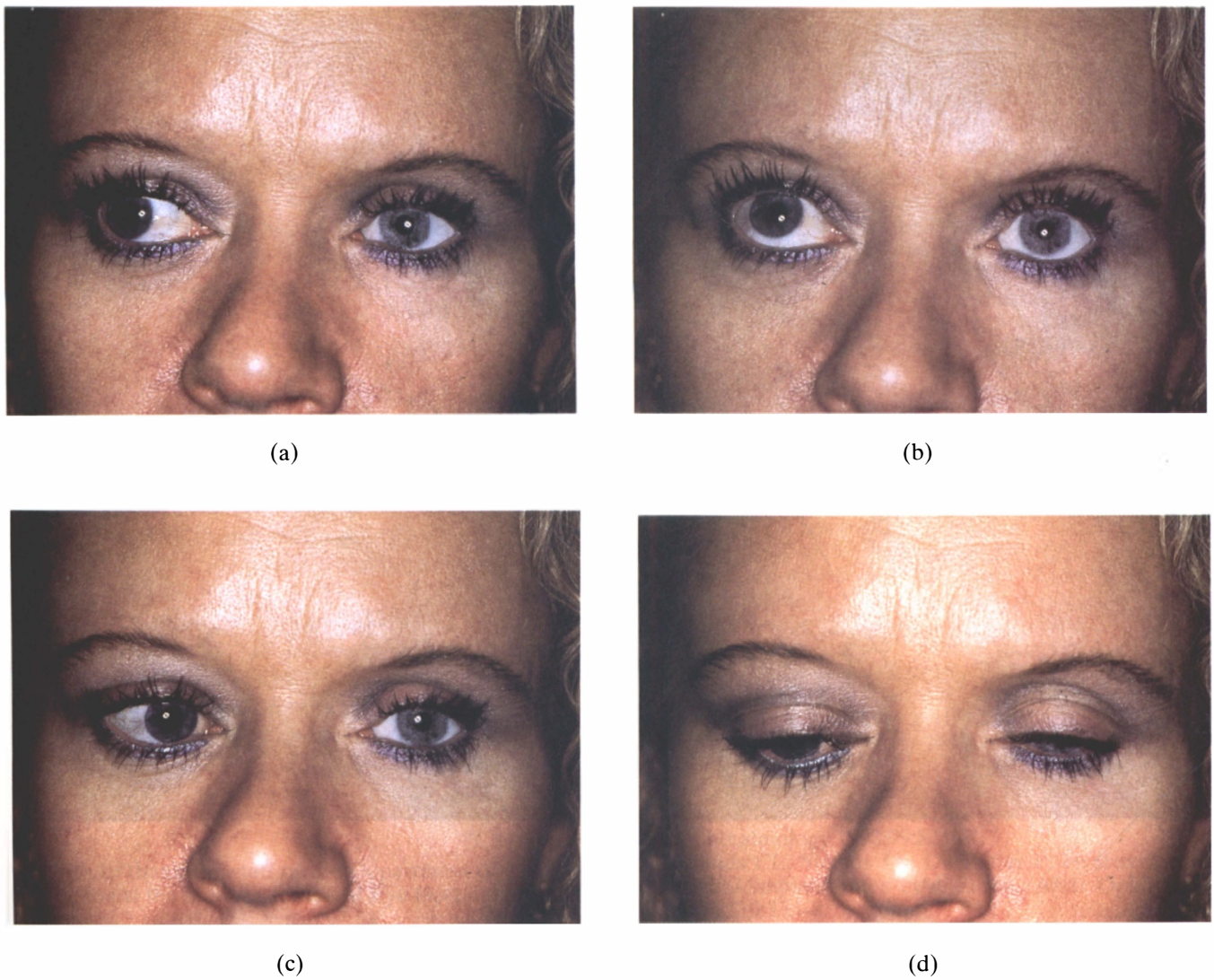
Good motility can be achieved in some patients without drilling. The primary group achieved superior motility for both smooth pursuit and saccades. The coupling of the artificial eye to the implant achieved by the motility peg allowed the fine, darting 'conversational' movements of the eye to be mimicked, and the range of movement of the artificial eye to be improved (Fig. 4). Most patients felt that pegging had improved the movement in their prosthesis. There were similar complication rates between primary and secondary groups (15% of the primary group and 18% of the secondary group experiencing complications). Exposure of the implant requiring active management occurred in 11% of the primary and 6% of the secondary groups. Early areas of exposure caused by conjunctival dehiscence in the first few weeks often heal spontaneously or after resuturing of the conjunctiva.[9] Exposure occurring at a few months or later may be caused by a poorly fitting artificial eye causing pressure necrosis, inadequate closure of Tenon's fascia, or a lack of vascularisation of the implant.[10] Steps should be taken at the time of implantation to minimise the incidence of implant exposure, by choosing the appropriate size of implant for the socket, by obtaining good coverage of the implant with healthy tissue under minimal tension, and by avoiding excess pressure on the tissues by the artificial eye.[9] Management of exposure can best be done by debulking of the anterior surface of the implant along with free autogenous tissue grafts (scleral patch and buccal mucous membrane grafts or hard palate mucosal graft). Chronic exposure of small areas of the implant when vascularised, however, seems to be well tolerated[7] (Fig. 7). There were no cases of extrusion in this study. There was no migration of the implants, but 3 of the secondary implants were eccentrically placed at the time of surgery. There was a very low rate of infection. Only 1 case of orbital cellulitis and 1 of socket infection occurred, both of which resolved with the appropriate antibiotic treatment. Most patients in both groups experienced some mild discharge from the socket, but few found this troublesome.

The number of additional surgical procedures required was not significantly higher in the secondary implant group. It is important to advise patients preoperatively that further surgery, such as lid surgery or subperiosteal implantation, may be required to correct the features of a post-enucleation socket syndrome.

A high proportion of patients in all groups assessed their cosmetic result to be good, but the percentage was slightly higher for the primary group. Most importantly, patient satisfaction was very high in both groups. Eighty-one per cent of patients in the secondary group considered their comfort and cosmesis to have been improved by the hydroxyapatite implant. Most patients reviewed were emphatic that their surgery had been thoroughly worthwhile.

It remains our policy to use donor sclera to wrap the implant. In addition, a scleral patch graft from the same donor is now routinely placed subconjunctivally. The sclera acts as a guard against implant exposure and results so far have shown a significant reduction in incidence of exposure. It becomes gradually epithelialised if the conjunctival wound dehisces post-operatively (Fig. 8). In the light of recent concerns about possible slow virus transmission by donor sclera, all patients are counselled about this potential risk pre-operatively. Autogenous fascia lata can be used as an alternative if the patient objects to the use of donor sclera. There have been no recorded cases of disease transmission by donor sclera.

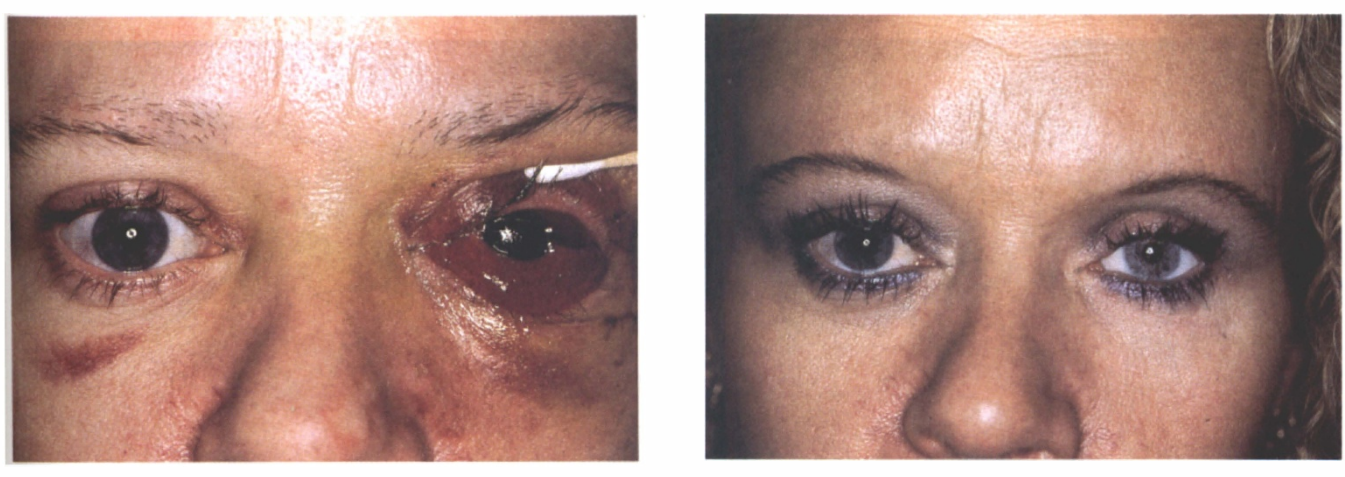
Our study has shown the hydroxyapatite orbital



(a) (b)

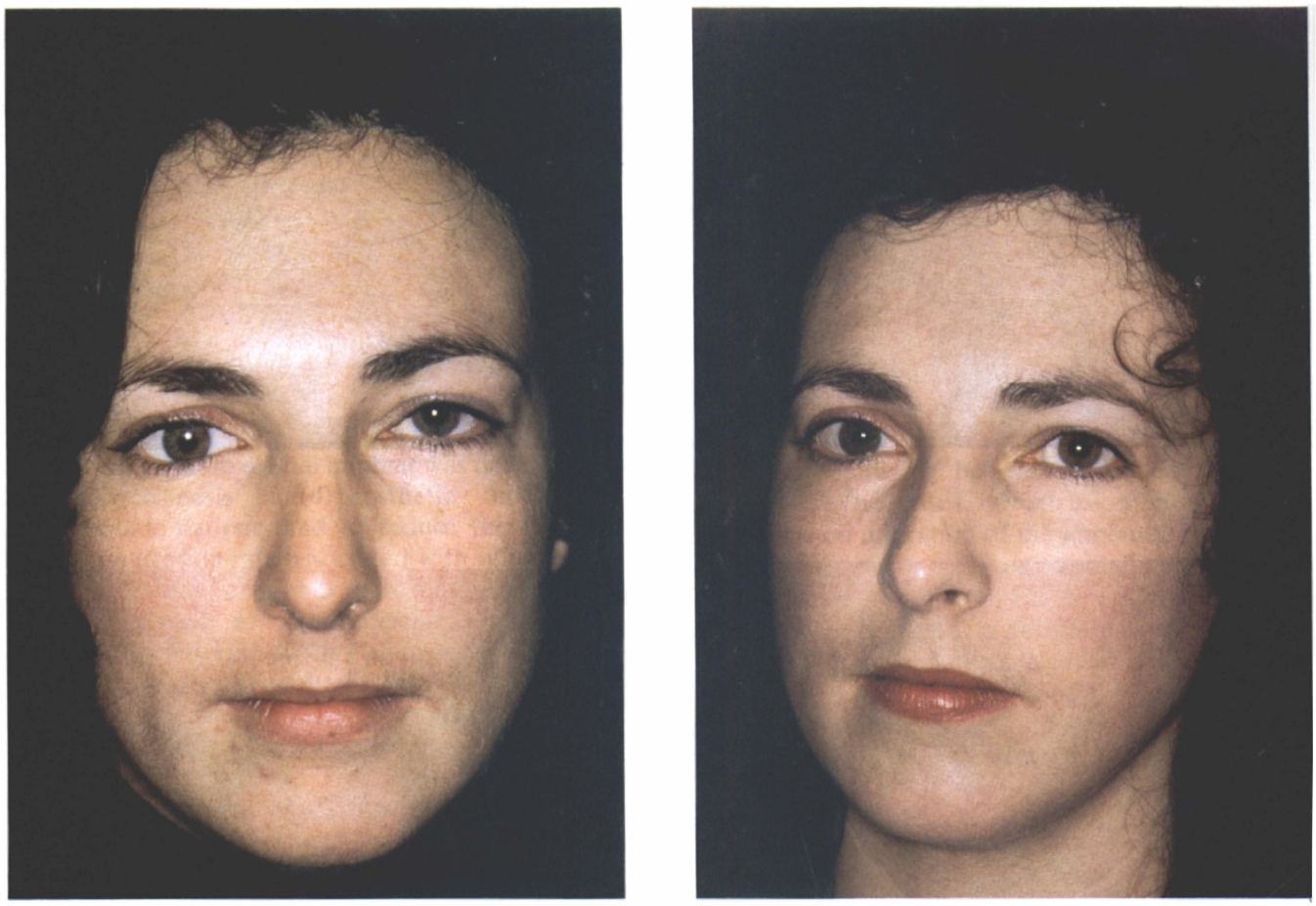
(c) (d)

Fig. 4. *A patient demonstrating good motility of the artificial eye following primary implantation and second stage drilling: (a) lateral gaze, (b) upgaze, (c) lateral gaze, (d) downgaze.*



(a) (b)

Fig. 5. *Pre-operative (a) and post-operative (b) appearances of a patient who had a primary hydroxyapatite orbital implant.*



(a) (b)

Fig. 6. *Pre-operative (a) and post-operative (b) appearances of a patient who had a secondary hydroxyapatite orbital implant.*

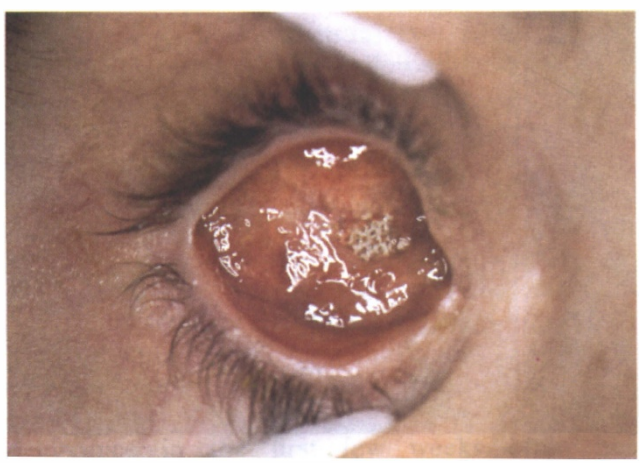


Fig. 7. *A socket showing chronic exposure of a hydroxyapatite orbital implant.*

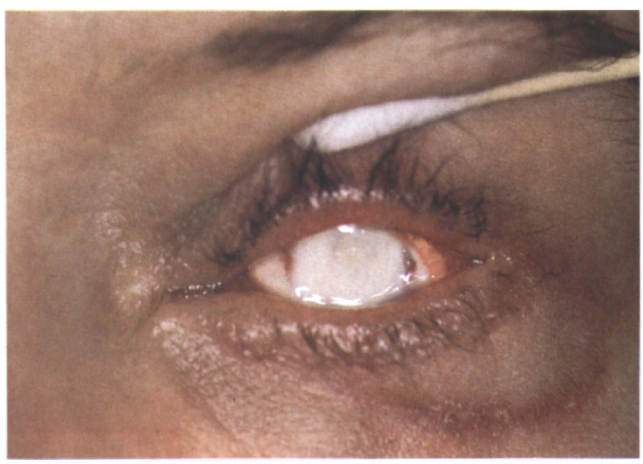


Fig. 8. *A patient with post-operative conjunctival wound dehiscence.*

implant to give good cosmesis and motility with a low rate of serious complication, both as a primary and as a secondary implant following a wide range of indications for enucleation or evisceration. Its use can be justified to improve cosmesis, motility and comfort in a patient unhappy with their existing anophthalmic state. Drilling of the implant is not always necessary but when undertaken provides extra stability and support for the prosthesis, and allows fine movement mimicking that of the natural eye. We have had no problems drilling the implants and do not consider the expense of bone or MRI scans to be necessary if sufficient time is permitted to elapse after implantation.[12] We wait a minimum of 6 months in all primary implant cases and a minimum of 12 months in secondary implant cases irrespective of the size of implant used.

The exclusion criteria for the use of this implant we have applied in our series have been nystagmus, severe orbital and adnexal trauma, and poorly controlled diabetes mellitus. The major disadvantage of the hydroxyapatite implant is its expense, and for this reason its use has been confined to patients under the age of 75 years.

It should be emphasised that excellent results from the use of the hydroxyapatite implant can only be achieved by the appropriate post-operative care provided by a suitably trained and experienced ocularist.

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Key words: Anophthalmic, Enucleation, Hydroxyapatite, Orbital implant, Socket.

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