

Integrated Hydroxyapatite Implant and Non-integrated Implants in Enucleated Asian Patients

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Abstract

Introduction: This study compares the outcome and complications of integrated hydroxyapatite implant and non-integrated orbital implants following enucleation in Asian patients. **Materials and Methods:** This is a retrospective study of enucleated patients with coralline hydroxyapatite implants versus non-integrated implants (acrylic, glass and silicone) at the Singapore National Eye Centre from January 1991 to December 2000. The outcomes measured were implant migration, extrusion, socket infection, conjunctival dehiscence and implant exposure. Statistical analysis was done using the 2-sample *t*-test. **Results:** Twenty-one patients had the hydroxyapatite implant and 38 non-integrated implants (27 acrylic, 9 glass and 2 silicone). The mean duration of follow-up was 2.7 years and 4 years for the hydroxyapatite implant and non-integrated implants respectively. Three patients with pre-existing severe socket contracture before enucleation surgeries were excluded from the study. Four cases of implant migration, 4 cases of implant extrusion and 3 cases of socket infection were encountered; all were sockets fitted with non-integrated implants. There was a higher rate of conjunctival dehiscence for sockets with hydroxyapatite implants (6 out of 21) compared to sockets with non-integrated implants (3 out of 35). This was statistically significant ($P = 0.048$). **Conclusions:** Implant complications of migration, extrusion and socket infection were found in non-integrated implants and none in coralline hydroxyapatite implants, which had a significantly higher rate of conjunctival dehiscence. Most of these were easily managed with only a small number progressing to implant exposure.

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Introduction

Much has been published on the complications of integrated and non-integrated implants.¹⁻³ Most studies on integrated implants pertain to experience with the hydroxyapatite implant, with the coralline (such as the Bio-Eye) {Integrated Orbital Implants, Inc., San Diego, California, USA} type dominating its cancellous bone counterpart (the Molteno M-sphere) {IOP, Inc., Costa Mesa, California, USA}. In recent years, the synthetic hydroxyapatite (FCI)⁴ synthetic hydroxyapatite {FCI, Issy-Les-Moulneaux, France} and porous polyethylene (Medpor) {Porex Surgicals, Georgia, USA} implants have also been introduced.⁵ As is the case with most other centres around

the world, the coralline hydroxyapatite implant remains a very popular choice among oculoplastic surgeons performing enucleation in Singapore.

The non-integrated implants have been known to have a higher rate of complications, such as implant migration and extrusion.^{2,6} Non-integrated implants include the acrylic, glass and silicone spheres. A significant advantage over the hydroxyapatite implant is that they are far more affordable. With the current dismal economical climate pervasive in many parts of the developing world, it is unavoidable that some patients will choose the non-integrated implant due to cost constraints. It is, therefore, expected that these implants will continue to be used. The potential complications of

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non-integrated implants and techniques that may contribute towards reducing the complications of these implants must be emphasised. In addition, the patient at high risk of implant-related complications with these implants must also be identified.

As the Food and Drug Administration (FDA) in the United States only approved the hydroxyapatite implant for general use in 1989, statements that more time was needed before the long-term complications became more fully understood² frequently accompanied early reports of its complications. In recent years, there have been several reports on hydroxyapatite implants pertaining to the complications of conjunctival erosion, thinning, dehiscence and implant exposure. The majority requires no more than just conservative treatment, with only some needing patch graft procedures⁶⁻⁸ and the occasional explantation. This study aims to find out if the rates of these complications are different, or if they are more severe, in the Asian population.

The specific aims of this retrospective comparative study of coralline hydroxyapatite implant and non-integrated implants were to determine the complication rates of implant migration, extrusion and socket infection in the Asian socket, to identify risk factors for developing these complications, and to study the frequency and severity of the problems of conjunctival dehiscence and implant exposure in Asian patients who have had hydroxyapatite implantation.

Materials and Methods

This study evaluates the long-term efficacy and complications of the integrated hydroxyapatite implant versus the non-integrated implants, all of which were spherical, in sockets that were enucleated with implantation at the Singapore National Eye Centre from January 1991 to December 2000. Seven surgeons, 4 of whom were from the Oculoplastics Service and 3 from the Paediatric Ophthalmology Service, performed most of the surgeries. Three other surgeons performed the procedure on 1 to 2 patients only.

Patients with >6 months of follow-up were identified from a search of the operation code for the enucleation procedure.

Six patients from an earlier study were included in our total study population of 58 patients.⁹ However, the study design was different and the authors looked at the hydroxyapatite implant alone in both enucleation and evisceration surgery, both as primary or secondary implants.

The case records were retrieved and information obtained from the consultation notes and intraoperative reports. Where information was incomplete and documentation inadequate, 2 patients were recalled and examined by the investigators.

The patients' age, sex and race, as well as indications and dates of enucleation, secondary implantation in certain cases, and the date of prosthesis fitting, were recorded.

The type and size of implant, usage of wrapping materials, socket complications and implant complications were studied. The latter included migration, extrusion, conjunctival dehiscence and implant exposure. The socket complications studied included orbital infection. For patients who had complications, their subsequent management and outcome were studied.

The preoperative consultation included obtaining informed consent and screening for metastatic disease in patients with intra-ocular tumours. The patient was anaesthetised and the standard enucleation procedures were performed.

A 360-degree peritomy was performed around the corneoscleral limbus. Tenon's fascia was carefully dissected and the recti muscles isolated. Locking double-armed 6.0 Vicryl (polyglactin) {Johnson and Johnson, Belgium} sutures were passed through and the muscles transected at their insertion. This was followed by isolation and transection of the oblique muscle. Optic nerve transection was performed with a pair of enucleation scissors. Haemostasis was achieved by a combination of sustained pressure with a gauze pack for several minutes, cautery and cotton pledgets soaked with 0.25% phenylephrine hydrochloride in some cases. Absorbable vicryl sutures were used for attachment of muscles, closure of Tenon's and conjunctiva.

Each surgeon chose the size of the implants; generally, 20-mm spheres were used in adults and children >36 months old, and 18-mm sphere was used in younger children.

Where donor sclera was used as a wrapping material, they were screened for infectious disease, cancer and other conditions using a standard protocol for tissue donation. The sclera was also pretreated with antibiotics and 10% iodine. They were wrapped around the implants and sutured with 5.0 Vicryl (polyglactin) {Johnson and Johnson, Belgium}. For those wrapped around the integrated hydroxyapatite implants, 4 rectangular scleral windows measuring approximately 6 x 5 mm were made to allow for fibrovascular ingrowth at these areas. They were aligned with the 4 recti and each muscle was secured to the anterior lip of the window using the preplaced double-armed 6.0 Vicryl suture.

In sockets where the implant was not wrapped, the muscles were imbricated anterior to the implant. Tenon's capsule was closed with interrupted 5.0 or 6.0 sutures and the conjunctiva closed with 6.0 Vicryl sutures. A conformer was placed to maintain the fornices and pressure dressing was applied to the socket for 48 hours. The patients were referred for prosthesis fitting approximately 6 weeks

after the implant.

When sockets were not implanted at the time of enucleation, secondary implantation was performed to localise the extra-ocular muscles, pass double-armed 6.0 Vicryl sutures and treat them in the same manner as sockets in primary implantation: each muscle was secured to the anterior lip of the scleral window where wrapped hydroxyapatite implants were used and imbricated anterior to the unwrapped non-integrated implants.

Statistical analysis was performed using the 2-sample *t*-test.

Results

A total of 68 eyes in 67 patients were enucleated at our centre. One patient had bilateral enucleation. Fifty-three sockets had implants placed at the time of enucleation and 7 sockets had secondary implantation at a later date. The 8 sockets that did not receive any implant were excluded from this study. A single case of implantation with the Medpor implant was excluded from the study, as it was the purpose of our study to only compare the hydroxyapatite implant with the non-integrated implants.

Implanted sockets that had enucleation performed elsewhere were excluded.

With the above inclusion and exclusion criteria, 58 patients and 59 sockets were included in the study; 1 patient had bilateral enucleation. There were 43 males and 15 females; their mean age was 26 years (range, 1 to 87 years).

The racial distribution matched the demographic profile of multi-racial Singapore: 72.4% Chinese ($n = 42$), 17.2% Malays ($n = 10$), 5.2% Indians ($n = 3$) and 5.2% other races ($n = 3$).

The indications for enucleation included intraocular malignancy ($n = 21$), blind and cosmetically unacceptable (to the patient) eye ($n = 14$), painful blind eye ($n = 20$), trauma ($n = 3$); (this group referred to cases where severe trauma resulted in totally disorganised eyes with no visual potential and enucleation surgery was offered to reduce the risk of sympathetic ophthalmia) and others (a case of panophthalmitis). The indications and the types of implants used are shown in Table 1.

Table 1. Indications for Enucleation and Their Breakdown by Implant Type

Indications	Non-integrated implants	Integrated implants
Intraocular malignancy	19	2
Painful blind eye	8	6
Cosmetically unacceptable blind eye	9	11
Trauma	1	2
Others	1	0

Implant types were decided by the surgeons, in close consultation with patients. Patients' choices were not randomised and may have been influenced by surgeon preference over the study period.

Twenty-one sockets received the hydroxyapatite implant and 38 sockets received non-integrated implants (27 acrylic, 9 glass and 2 silicone). The mean duration of follow-up was 3.2 years for the entire study population (range, 0.25 to 11.5 years); it was 2.7 years and 4 years for hydroxyapatite implants and the non-integrated implants, respectively.

All hydroxyapatite implants were wrapped: 20 with donor sclera and 1 with Mersilene mesh. For non-integrated implants, 21 were wrapped with donor sclera, 2 with fascia lata and the rest were not wrapped.

There was 1 case of intraoperative complication: a lost superior rectus muscle. Subsequently, except for limited elevation, there were no other problems.

There were 4 cases of socket infection in our series.

One patient had enucleation for retinoblastoma without primary implantation and developed mucopurulent discharge 1 week later. Topical cephalosporin was prescribed with resolution of the orbital infection. The patient had a hydroxyapatite implant many months later after the socket was cleared of the tumour. It is therefore correct to infer that the clinical course of this case of socket infection had no relationship with the type of implant that was used.

The remaining cases were sockets with non-integrated acrylic implants. One child (enucleation for retinoblastoma) was treated effectively with topical Neosporin. Another patient progressed to implant extrusion and a diabetic patient was left with large implant exposure. Subsequently, the latter had an implant exchange (hydroxyapatite placed).

There were 4 cases of implant migration in sockets implanted with non-integrated acrylic implants; 2 were sockets enucleated for retinoblastoma, 1 was enucleated for cosmesis in a patient with previous trauma and 1 had primary enucleation in a severely traumatised eye with extensive loss of uveal tissue.

One case was wrapped with donor sclera and the rest were not wrapped; the extraocular muscles were imbricated over the implants.

There were 4 cases of implant extrusion in non-integrated implants: 2 with wrapped glass implants in sockets with pre-existing socket contracture and the other 2 with acrylic implants (one was wrapped in donor sclera and the other was unwrapped).

There were 10 cases of conjunctival dehiscence; 5 cases either progressed to or were associated with frank implant exposure, and had surgery to address this problem. Conjunctival dehiscence occurred when the conjunctiva

falls apart at the suture closure line, thereby exposing the underlying tissues.

Six cases happened with hydroxyapatite implants and the rest were with acrylic implants. In the latter group, 1 case was a socket with pre-existing severe socket contracture and another was complicated by socket infection. When cases with pre-existing socket contracture were excluded from the statistical analysis (as they are known to predispose to implant exposure, extrusion and conjunctival dehiscence), hydroxyapatite implants were statistically at higher risk of causing conjunctival dehiscence ($P = 0.048$; 2-sample test of proportion). However, most of these cases did not require further surgery. The complications and their management are summarised in Table 2.

Discussion

The coralline hydroxyapatite implant was pioneered by Perry in 1985¹⁰ and it was approved by the FDA in the US in 1989. Though Schmidt had introduced bone-derived hydroxyapatite in 1899, it was not used as widely as its coralline counterpart. Other hydroxyapatites that are not as commonly used as the coralline variety include synthetic hydroxyapatite and Chinese hydroxyapatite. Through the years, the coralline hydroxyapatite implant has gained popularity and is now the treatment of choice in many centres worldwide.

The advantages of the coralline hydroxyapatite implant

include lower rates of extrusion, migration and resistance to infection. In one of the largest series to date, Shields et al⁶ did not report any case of implant migration and extrusion, but there was 1 case of presumed orbital infection and he also observed problems of conjunctival erosion. There have been many reports on conjunctival dehiscence and implant exposure.^{7,11-13} Suter et al¹⁴ discussed the complication of exposure in bone-derived hydroxyapatite implant, where there is a strong tendency towards self-healing as opposed to coralline hydroxyapatite in other studies.

Interestingly, reports on the advantages and disadvantages of coralline hydroxyapatite over glass, acrylic and silicone implants, where fibrovascular ingrowth into the sphere does not take place are extremely scarce in the Asian population. In a related paper, Fong and Choo⁹ reported on our initial experience with hydroxyapatite implants in evisceration and enucleation, either as the primary implant or as an implant exchange procedure for problems such as impending extrusion and the post-enucleation socket syndrome. In this paper, sockets that were enucleated elsewhere were excluded; only implantations carried out in our centre following enucleation were studied so that the surgical techniques were more or less standardised and the risk factors (if any) for complications were well documented.

As the cost of hydroxyapatite implant is much higher than an acrylic sphere, it is important to note that

Table 2. Implant Complications and Their Management

Implant migration					
Age (y)/Race/Sex	Indication	Implant type and size #	Implant wrap	Management and outcome	
37/Chinese/M	Cosmesis (previous trauma)	Acrylic #18	Donor sclera	Offered implant exchange but refused	
3/Malay/M	Retinoblastoma	Acrylic #18	Non	Implant exchanged. Hydroxyapatite	
2/Chinese/M	Retinoblastoma	Acrylic #18	Non	Implant exchanged. Hydroxyapatite size 20	
31/Chinese/M	Severe trauma	Acrylic #16	Non	Implant exchanged. Hydroxyapatite size 20	
Implant extrusion					
Age (y)/Race/Sex	Indication	Implant type and size	Implant wrap	Time of extrusion	Management and outcome
23/Chinese/M (Pre-existing socket contracture)	Cosmesis Previous multiple retinal surgery	Glass #16	Donor sclera	12 days post-op	Secondary implantation of hydroxyapatite implant
20/Chinese/M (Pre-existing socket contracture)	Cosmesis Previous severe ocular trauma	Glass #16	Donor sclera	4 month post-op	Offered 2 stage reconstruction viz re-implantation followed by mucous membrane graft. Refused surgery
2½/Chinese/M	Retinoblastoma	Acrylic #16	Non	6 weeks post-op	Secondary implantation followed 1 month later by socket reconstruction with mucous membrane graft
20/Chinese/M (Had socket infection post-op)	Painful blind eye	Acrylic #16	Donor sclera	4 weeks post-op	Refused further surgery

Table 2. Contd.

Conjunctival dehiscence with/without implant exposure					
Age (y)/Race/Sex	Indication	Implant type and size	Implant wrap	Time of event	Management and outcome
72/Chinese/M	Cosmesis Previous trauma	HA #20	Donor sclera	4 weeks post-op	Spontaneous healing
29/Chinese/M	Cosmesis Previous trauma	HA #20	Donor sclera	12 months post-op	Spontaneous healing
39/Chinese/M	Cosmesis (congenital)	HA #22	Donor sclera	4 years post-op	Spontaneous healing
35/Nepalese/F	Painful blind eye	HA #20	Donor sclera	Stitch granuloma 2 yrs 8 months post-op	Granuloma resolved after stitch removed; spontaneous conjunctival healing thereafter
40/Indian/M	Cosmesis (traumatic endophthalmitis with subsequent pthisis)	HA #18	Donor sclera	12 days post-op; Progressed to implant exposure 3 weeks post-operatively	Autogenous fascia lata patch graft
21/Chinese/F	Cosmesis (congenital glaucoma with 2 failed filtration surgeries)	HA #22	Donor sclera	25 days post-op; Progressed to implant exposure 8 months later	Buccal mucosal membrane patch graft
25/Chinese/M (Severe socket contracture, small implant used)	Cosmesis (congenital glaucoma with multiple surgeries done)	Acrylic #12	Donor sclera	Implant exposure noted 18 days postoperatively	Scleral patch graft performed 4 months postoperatively; failed; eventually had dermis fat graft
58/Chinese/F	Severe panophthalmitis Secondary implantation	Acrylic	Donor sclera	1 month post secondary implantation	Conformer removed with spontaneous conjunctival healing
39/Chinese/M	Malignant melanoma of the choroid	Acrylic #18	Donor sclera	2 months post-op; progressed to frank implant exposure	Fascia lata patch graft
47/Chinese/M (Diabetic)	Cosmesis (previous trauma from fish hook)	Acrylic Size not recorded	Donor sclera	Socket infection 3 months post-op; treated with antibiotics; resulted in socket contracture; frank implant exposure noted 9 months post enucleation	Implant removed Secondary hydroxyapatite implant subsequently

there is a lower rate of migration, extrusion and infection in the long run.

There were no cases of implant migration with the hydroxyapatite implant, but there were 4 such cases with the acrylic implant. Allen¹⁵ reported that imbrication of the recti over non-integrated implants can result in implant migration. In our study, 3 of the 4 acrylic implants were not wrapped and the recti were imbricated over the implants. The cases were successfully managed by switching to hydroxyapatite implants, except for 1 patient who refused further intervention.

As implant imbrication is a risk factor for implant migration, all non-integrated implants were subsequently wrapped with donor sclera and none migrated.

There were no cases of implant extrusion with the hydroxyapatite implant and that is attributed to fibrovascular coupling between the host tissue and the hydroxyapatite implant. This phenomenon could also explain the absence of implant migration.¹⁶

The timing of extrusion is also of great importance as early implant extrusion can be attributed to surgical technique; in 1 case, the patient extruded 14 days postoperatively. However, it can be argued that pre-existing socket contracture may have also contributed to this complication.

It is likely that extrusion is due to several factors such as pre-existing socket contracture, socket infection and lack of fibrovascular coupling between the host tissue and the

acrylic implant.

The cases of implant extrusion occurred exclusively within the first 5 years of the study. As the risk factors for implant extrusion, such as pre-existing infection, haemorrhage and poor surgical technique became apparent, no implant extrusions were seen in the next 5 years of our study.

Most reports on the complications of hydroxyapatite implants have described conjunctival dehiscence and implant exposure.^{4,6-8,11-13} Donor sclera from the Florida Eye Bank was used to wrap the implant in our patients. Hence, the implanted spheres did not differ very much in size from those in Caucasian eyes. While awaiting conclusive evidence on anatomical and volumetric differences between the Caucasian and Asian orbits, it is possible that same-sized implants fare differently in Asian sockets from their Caucasian counterparts, especially when it is well-known that implant over-sizing is a risk factor for conjunctival dehiscence and implant exposure.

A distinction must be made between conjunctival dehiscence and erosion as both describe different outcomes. Conjunctival dehiscence (i.e., conjunctiva coming apart at the suture closure line) has also been referred to as “conjunctival exposure”, as it may lead to frank implant exposure.¹⁷

In our study, the rate of conjunctival dehiscence was 28.6% and the implant exposure rate was 9.5%. This compares favourably with the exposure rates of hydroxyapatite implants in other series which ranged from 2.5% to 21.6%, presumably in Caucasian populations.^{7,11,12,18,19}

While poor surgical technique is a cause of conjunctival dehiscence, it is believed that spicules of the hydroxyapatite implant irritated the overlying tissues and, in certain instances, inhibited epithelialisation.⁷ Insertion was hampered by the rough surface of the hydroxyapatite implant and Goldberg et al⁷ have implicated this as a cause of conjunctival dehiscence. Nunery et al¹⁸ have suggested that these problems can be negated by deep implantation of the spheres and wrapping the implants. Though not necessarily specific to hydroxyapatite implants and the problem of conjunctival dehiscence, the measures suggested by Christmas et al²⁰ may also help. They include choosing an appropriately sized implant, wrapping the implant with donor sclera, meticulous closing of the anterior Tenon capsule over the implant, securing the conjunctiva over the implant without tension, and using a posterior vault on the prosthesis to minimise wear and tear.

In our series, conjunctival dehiscence was mostly managed conservatively. While 2 cases required patch graft surgery, none were explanted.

Conclusion

In our series of predominantly Asian patients, the implant complications of migration, extrusion and socket infection occurred only in non-integrated implants compared to coralline hydroxyapatite implant. However, sockets implanted with hydroxyapatite had a significantly higher rate of conjunctival dehiscence and most respond to conservative management. Implant exposure rates were not higher than that seen in Caucasian patients. These long-term advantages make the costly coralline hydroxyapatite implants a more attractive treatment modality.

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