Integrated Hydroxyapatite Implant and Non-integrated Implants in Enucleated Asian Patients
CT Chuah,1 FRCS, M Med (Ophth), SP Chee,2 FRCS, M Med, FRC (Ophth), KS Fong,1 FRCS, M Med (Ophth), YM Por,1 MRCS, MRC (Ophth), CT Choo,3 FRCS, FRC (Ophth), FAMS, C Luu,4 PhD, LL Seah,1 FRCS, FRC (Ophth), FAMS

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.

Key words: Conjunctiva dehiscence, Exposure, Implant, Socket infection

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 (FCL)4 synthetic hydroxyapatite {FCI, Issy-Les-Moulineaux, 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.6-8 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

1 Oculoplastics Service
2 Oculoplastics Service and Ocular Immunology Service
3 Aesthetic Eyelastics Service
Singapore National Eye Center
4 Singapore Eye Research Institute
Address for Reprints: Dr Chin Tek Chuah, Singapore National Eye Center, 11 Third Hospital Avenue, Singapore 168751.
Email: chuahct@singnet.com.sg

Ann Acad Med Singapore 2003;33:477-83

Key words: Conjunctiva dehiscence, Exposure, Implant, Socket infection
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. 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 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. 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 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. 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 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. 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.
Comparison of Hydroxyapatite and Non-integrated Implants—CT Chuah et al

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.

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 cephazolin 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 1985 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 al. 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. Suter et al. 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 Choo 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>
<thead>
<tr>
<th>Table 2. Implant Complications and Their Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implant migration</strong></td>
</tr>
<tr>
<td>Age (y)/Race/Sex</td>
</tr>
<tr>
<td>37/Chinese/M</td>
</tr>
<tr>
<td>3/Malay/M</td>
</tr>
<tr>
<td>2/Chinese/M</td>
</tr>
<tr>
<td>31/Chinese/M</td>
</tr>
<tr>
<td><strong>Implant extrusion</strong></td>
</tr>
<tr>
<td>Age (y)/Race/Sex</td>
</tr>
<tr>
<td>23/Chinese/M (Pre-existing socket contracture)</td>
</tr>
<tr>
<td>20/Chinese/M (Pre-existing socket contracture)</td>
</tr>
<tr>
<td>2½/Chinese/M</td>
</tr>
<tr>
<td>20/Chinese/M (Had socket infection post-op)</td>
</tr>
</tbody>
</table>
Comparison of Hydroxyapatite and Non-integrated Implants—CT Chuah et al

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. Allen\textsuperscript{15} 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.\textsuperscript{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...

Table 2. Contd.

<table>
<thead>
<tr>
<th>Age (y)/Race/Sex</th>
<th>Indication</th>
<th>Implant type and size</th>
<th>Implant wrap</th>
<th>Time of event</th>
<th>Management and outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>72/Chinese/M</td>
<td>Cosmesis Previous trauma</td>
<td>HA #20</td>
<td>Donor sclera</td>
<td>4 weeks post-op</td>
<td>Spontaneous healing</td>
</tr>
<tr>
<td>29/Chinese/M</td>
<td>Cosmesis Previous trauma</td>
<td>HA #20</td>
<td>Donor sclera</td>
<td>12 months post-op</td>
<td>Spontaneous healing</td>
</tr>
<tr>
<td>39/Chinese/M</td>
<td>Cosmesis (congenital)</td>
<td>HA #22</td>
<td>Donor sclera</td>
<td>4 years post-op</td>
<td>Spontaneous healing</td>
</tr>
<tr>
<td>35/Nepalese/F</td>
<td>Painful blind eye</td>
<td>HA #20</td>
<td>Donor sclera</td>
<td>Stitch granuloma 2 yrs 8 months post-op</td>
<td>Granuloma resolved after stitch removed; spontaneous conjunctival healing thereafter</td>
</tr>
<tr>
<td>40/Indian/M</td>
<td>Cosmesis (traumatic endophthalmitis with subsequent phthisis)</td>
<td>HA #18</td>
<td>Donor sclera</td>
<td>12 days post-op; progressed to implant exposure 3 weeks post-operatively</td>
<td>Autogenous fascia lata patch graft</td>
</tr>
<tr>
<td>21/Chinese/F</td>
<td>Cosmesis (congenital glaucoma with 2 failed filtration surgeries)</td>
<td>HA #22</td>
<td>Donor sclera</td>
<td>25 days post-op; progressed to implant exposure 8 months later</td>
<td>Buccal mucosal membrane patch graft</td>
</tr>
<tr>
<td>25/Chinese/M</td>
<td>Cosmesis (congenital glaucoma with multiple surgeries done)</td>
<td>Acrylic #12</td>
<td>Donor sclera</td>
<td>Implant exposure noted 18 days postoperatively</td>
<td>Scleral patch graft performed 4 months postoperatively; failed; eventually had dermis fat graft</td>
</tr>
<tr>
<td>58/Chinese/F</td>
<td>Severe panophthalmitis Secondary implantation</td>
<td>Acrylic</td>
<td>Donor sclera</td>
<td>1 month post secondary implantation</td>
<td>Conformer removed with spontaneous conjunctival healing</td>
</tr>
<tr>
<td>39/Chinese/M</td>
<td>Malignant melanoma of the choroid</td>
<td>Acrylic #18</td>
<td>Donor sclera</td>
<td>2 months post-op; progressed to frank implant exposure</td>
<td>Fascia lata patch graft</td>
</tr>
<tr>
<td>47/Chinese/M</td>
<td>Cosmesis (previous trauma from fish hook)</td>
<td>Acrylic</td>
<td>Donor sclera</td>
<td>Socket infection 3 months post-op; treated with antibiotics; resulted in socket contracture; frank implant exposure noted 9 months post enucleation</td>
<td>Implant removed Secondary hydroxyapatite implant subsequently</td>
</tr>
</tbody>
</table>

July 2004, Vol. 33 No. 4
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. 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.

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.

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. Insertion was hampered by the rough surface of the hydroxyapatite implant and Goldberg et al. have implicated this as a cause of conjunctival dehiscence. Nunery et al. 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 al. 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.

Acknowledgements

The authors acknowledge the assistance of the Department of Pathology, Singapore General Hospital, especially Dr Elizabeth Cheah; the kind advice and input from Professor Jack Rootman and Dr Wong Tien Yin; and the encouragement from Dr Ang Chong Lye, Medical Director, Singapore National Eye Centre (SNEC) and Associate Professor Donald Tan, Director, Singapore Eye Research Institute. We also thank the Clinical Audit Department and Medical Records Department, SNEC, for technical support.

REFERENCES


