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Research Article

Sam's Technique of Cone-shaped Orbital Implant

Sameera Irfan*

Department of Oculoplastics, Envision Squint and Oculoplastics Centre, Lahore, Pakistan

***Corresponding Author:** Sameera Irfan, Department of Oculoplastics, Envision Squint and Oculoplastics Centre, Lahore, Pakistan.

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Abstract

Purpose: To study the effectiveness of a Cone-shaped orbital implant either as a primary or a secondary procedure.

Primary Surgical Outcome: To achieve satisfactory cosmetic appearance with a reasonable symmetry between the two eyes, good implant motility, and prosthesis worn comfortably.

Methods: A prospective, interventional study of 261 consecutive cases who had orbital implant surgery at a tertiary care centre, from Jan 2009 to Jan 2021. There were 146 males and 115 females between the age 17-62 years (median age 23 years). 218 cases had an enucleation with a primary orbital implant. 43 cases had a secondary implant for an empty socket (26 cases), exposed, or posteriorly migrated implant (17 cases) that was removed and replaced by a secondary orbital implant.

The indications, surgical technique, post-operative complications, and longterm aesthetic outcome are discussed in detail. The limitations and risks of the procedure were fully explained to the patients. Patients and their attendants were counselled regarding the fitting of final prosthesis, its care and the need for regular follow-up visits. All cases were followed up for a minimum period of 12 months while 50% cases visited had an average follow-up of 7 ± 3 years.

Results: The most serious complication was post-operative infection; despite a meticulous surgical technique, it occurred in 14 cases (6.42%) in the primary implant group and 6 cases (13.95%) of the secondary group. It was managed conservatively in all cases. However, recurrent purulent discharge, wound dehiscence, and implant exposure necessitated the removal of implant in 2 primary cases (0.91%). Conjunctival scarring due to previous surgeries resulted in 3 mm wound dehiscence and implant exposure in 3 cases (6.97%) of the secondary group. A mucus membrane graft was needed to cover the defect. A lid tightening procedure was needed in 12 cases (27.90%) in the secondary implant group who had worn prosthesis in an empty socket prior to the secondary implant surgery. Good implant motility was noted in all primary cases due to the fully-integrated nature of the implant. It was good in only 11 cases (25.59%) where all rectus muscles were attached to the implant and fair in 14 cases (44.18%) where a few muscles could be salvaged. Motility was absent in 13 secondary cases (30.23%) where no muscles could be found. All primary cases had a good cosmesis and 100 % patient satisfaction.

Conclusion: The technique described here is simple, with a short learning curve. It is an inexpensive option amongst a vast array of costly fully-integrated orbital implants that are commercially available. It offers good cosmetic results with minimal post-operative complications.

Keywords: Enucleation; Evisceration; Orbital Implant; Post-enucleation Socket Syndrome; Implant Wrappings; Integrated Orbital Implant

Introduction

Eyes are a major feature on a person's face. Trauma to an eye, whether accidental or following repeat surgical procedures, and chronic ocular infection (panophthalmitis) can result in a painful blind eye that gradually shrinks in size (becomes phthisical) as compared to the good eye. On the other hand, uncontrolled glaucoma (especially neovascular) or an intraocular tumor results in a gradual enlargement of the eyeball, along with visual loss. Both shrunken or an enlarged eyeball not only appears cosmetically disfiguring on the face but results in a chronically irritable eye due to band keratopathy or recurrent corneal erosions. The facial disfigurement and the loss of an eye causes a lot of emotional trauma to the patients, a lowered self-esteem, and can adversely affect their lives, as explained by Wang KJ., *et al*. (2020) [1]. In this regard, an oculoplastic surgeon and a prosthetist/ocularist (a paramedical technician who fabricates and fits the custom-made prosthesis) work as a team to provide the best possible functional and cosmetic result to restore not only the facial appearance but also a patient's confidence.

There are two kinds of surgical procedures to remove a blind, disfiguring, and painful eye. S. Irfan (2017) [2] explained the indications and surgical technique in detail. In an evisceration, only the intra-ocular contents are removed via a limbal incision, retaining an empty, clean scleral envelope, with its attached rectus muscles and the optic nerve. The other procedure is an enucleation in which the whole eyeball along with a small stump of the severed optic nerve is removed, leaving the rectus muscles along with the covering tenon sheath inside the orbital cavity. The indications for both procedures are almost similar, and the decision regarding which procedure to be performed depends upon the expertise of a surgeon.

According to Ali Kord., *et al*. (2014) [3], evisceration becomes necessary in a painful, blind eye with active, uncontrolled infection like endophthalmitis or panophthalmitis as it does not disturb the integrity of the optic nerve. On the other hand, enucleation, in which the optic nerve is severed, can potentiate the spread of infection along the cut meninges in such cases. However, sutures that are necessary to hold an implant can cut through the inflamed scleral envelope, so a primary evisceration is followed by a secondary implant later once the infection has died down. Evisceration may also be preferred in patients who cannot tolerate general anaesthesia or who have bleeding disorders as the annulus of Zinn is not disturbed which reduces the chances of intra-operative and postoperative bleeding. It is generally believed that evisceration results in a better implant motility and cosmesis than an enucleation, as the patient's original scleral envelope and the surrounding rectus muscles are not disturbed. But complications, like extrusion and postoperative infection were reported to be higher following an evisceration by Tawfiq., *et al*. (2007) [4] and by Alwitry A., *et al*. (2007) [5]. This was attributed to continuous contraction of the scleral shell with the passage of time and tenon/conjunctival scarring due to previous surgeries.

According to Chiu SJ., *et al*. (2021) [6], enucleation is reserved for suspected intra-ocular malignancy and when insufficient sclera is not available (phthisical eye) to adequately cover the implant and for full of orbital volume restoration. The modern surgical technique of enucleation and orbital implant restores both the motility of an artificial eye and its cosmetic appearance at par with evisceration. Rasmussen ML (2010) [7] reported invasive ocular malignancies and their consequences as the most common indication of enucleation in tertiary centres. Evisceration should not be performed in such cases to prevent metastasis and to get adequate tumour tissue for histological diagnosis.

An eyeball is a slightly elongated sphere with an approximate diameter of 24 mm. Following enucleation, the empty orbital cavity has a volume deficit of about 7 millilitres, and it assumes a sunken appearance. Christoph Hintschich (2014) [8], has described the resultant four deformities, as the Post-enucleation socket syndrome. This comprises of enophthalmos (appearance of a hollowed orbit), ptotic upper eyelid, with a deep upper lid sulcus, and lower lid laxity. This volume deficit must be replaced by an artificial eye that should correct all four features of the post-enucleation socket syndrome and restore a perfect cosmetic appearance.

The constructed artificial eye, following an enucleation or evisceration, has two components: an orbital implant and an ocular prosthesis. The orbital implant is placed in an empty socket by an oculoplastic surgeon and it should ideally restore 70% volume of the orbital cavity. Once the surgical wound has healed in about six weeks, the patient is referred to a professional prosthetist for the fitting of a custom-made prosthesis that is inserted inside the conjunctival fornices, overlying the implant. The weight of the

prosthesis is supported by the underlying implant and it restores the remaining 30% volume of the orbital cavity. Insufficient volume replacement by a smaller sized implant or wearing a glass prosthesis alone without an underlying implant would not correct all features of the post-enucleation socket syndrome, as explained by Rokohl AC (2019) [9].

With time, the weight of a larger prosthesis may result in progressive sagging of the lower eyelid and the prosthesis will fall out of the eye when patient stoops or bends the head. A prosthesis without an orbital implant will also lack any motility which is provided by the rectus muscles attached to the implant and makes the overlying prosthesis move in coordination with the healthy eye.

Prostheses made up of precious stones, bronze, copper, and gold were common amongst the ancient Egyptians. In the 19th century, glass eyes remained popular until the Second World War, after which the supply of glass became difficult as Germany was the main supplier. Consequently, methyl methacrylate, from which dentures were made by the dentists, began to be used for manufacturing both the orbital implants as well as the prosthesis. The prosthesis is painted with iris colour and conjunctival vessel markings, resembling a patient's other healthy eye. Common materials used to fabricate an ocular prosthesis presently are glass and methyl methacrylate; PMMA prostheses are heavier than cryolite glass, while glass prosthesis causes mechanical irritation due to hydrolytic surface changes and ocular discharge, according to Rokohl AC.., *et al*. (2018) [10].

The orbital implants vary according to their make, design, and cost. They can be simple spheres made up of PMMA, acrylic or porous polyethylene, coralline Hydroxyapatite, nonporous alloplastic, dermis fat grafts, bioceramic, synthetic Hydroxyapatite, and mammalian bone. The decision as to which product should be used is determined by factors such as the experience of a surgeon, patient's preference, the cost, and availability of the implant rather than the clinical superiority of one implant over the other.

A standard sphere, made of PMMA or acrylic, can be placed into the orbital cavity, without attaching rectus muscles to it. Therefore it acts as a non-integrated orbital implant which corrects the volume loss but has limited movement. A non-integrated implant is prone to migrate posteriorly or sink downwards into the orbital cavity with time. However, this reduces the total operating time, the overall cost of the procedure, and avoids creating a second surgical site for harvesting autogenous wraps.

The second type of implants are PMMA or acrylic semi-spheres with holes into which the rectus muscles are secured with sutures. They behave as "semi-integrated implants" and are placed in the orbital cavity unwrapped. They offer some motility as well as volume replacement.

In the last 3 decades, the fully-integrated implants have been popularised amongst oculoplastic surgeons because of their better cosmetic results and implant motility. They comprise of a circular or a cone-shaped implant, made up of different natural or synthetic materials, which may be porous or non-porous. The pores allow fibrovascular tissue to grow inside the implant and form a permanent integration with the orbital tissues, thus functioning as fully integrated implants. Theoretically, their integrated nature reduces the risk of implant migration or extrusion and improves implant motility. Schellini S., *et al*. (2016) [11] compared integrated orbital implants with non-integrated orbital implants for treating anophthalmic sockets in a Cochrane review. They reported uncertainties about the real roles of integrated (hydroxyapatite (HA), porous polyethylene (PP), versus nonintegrated (polymethylmethacrylate (PMMA)/acrylic and silicone) orbital implants in treating anophthalmic socket treatment.

In another meta-analysis by Schellini S., *et al*. (2016) [12], the porous polyethylene (Medpore) implant was shown to have enhanced motility and reduced exposure rates than the bioceramic implants made of aluminum oxide. Rectus muscles were sutured to pre-placed holes in the implant, without a wrap, and they could be linked to the prosthesis via a coupling device. This was achieved by drilling a hole in the anterior surface of implant, the peg and implant were linked with a ball-socket joint that enhances the motility of prosthesis. However, the high cost of commercially available integrated implants and their ready availability remains an important cause for concern for both the patients and the surgeon.

The rectus muscles can easily be sutured to the wrapping material which improves implant motility and reduced the chances of implant extrusion. The advantages and disadvantages of different

wrapping materials have been explained by Quaranta-Leoni FM (2008) [13]. Previously, the human-donor sclera was popularly used. In the recent years, its use has declined due to the potential risk of transmitting viral infections like hepatitis B or C, human immunodeficiency virus (HIV), and Creutzfeldt-Jakob disease (due to prions). Even tissues / organs from seronegative donors may transmit HIV. Other safer and better implant wrappings are autogenous fascia lata, temporalis fascia, rectus abdominus sheath, and posterior auricular muscle complex grafts. In order to retrieve these tissues, a second operative site needs to be explored which prolongs the operative time, and a potentially increased risk of complications.

In this study, we used a self improvised, fully-integrated orbital implant following enucleation that was extremely cost-effective. Prolene mesh (non-absorbable material) was wrapped around a circular PMMA sphere to make a cone-shaped orbital implant that would achieve a perfect fit into the orbital cavity. We aimed to find out the tissue reactivity, the efficacy, and long-term cosmetic results following this technique. The indications, surgical technique, and post-operative complications are discussed in detail.

Materials and Methods

A prospective interventional study was conducted at a tertiary care centre from Jan 2010 to Jan 2020. A total of 269 consecutive cases were recruited initially. There were 147 males and 122 females between the age 17-62 years (median age 23 years). Out of these, 226 cases had an enucleation and a primary of orbital implant while 43 cases had a secondary orbital implant following removal of an extruded implant in 16 cases (37.21%), an empty socket following enucleation performed elsewhere in 10 cases (23.25%), while 16 cases (37.21%) had a posteriorly migrated, or tilted primary implant that was removed and replaced by secondary orbital implant.

The 226 primary cases underwent an enucleation and an orbital implant by a single surgeon (SI). The indications for enucleation were a grossly disorganised eye following an old perforating injury, gross phthisis bulbi (shrunken eyeballs) and painful blind eyes due to neovascular glaucoma or chronic uveitis. All indications are demonstrated in table 1. Cases who had a primary evisceration, orbital deformities following road traffic accidents, and irradiated shrunken sockets were excluded from the study.

Characteristics		Number	Percentage
Gender	Female	115	44%
	Male	146	56%
Age	17-62 years	median 23 years	
Group	Primary Implant	218 cases	83.5%
	Secondary Implant	43 cases	16.5%
Indications: Enucleation and Primary Implant	Phithisis bulbi	77 cases	35.33%
	Painful blind eye (glaucoma, uveitis)	69 cases	31.65%
	Ocular trauma	67 cases	30.73%
	Malignant Melanoma	5 cases	2.29%
		Total 218 Primary cases	
Secondary Implant	Tilted/migrated implant	17 cases	39.54%
	Empty socket	10 cases	23.25%
	Implant extrusion	16 cases	37.21%
		Total Secondary Implant 43 cases	

Table 1: Demographics of total 261 consecutive cases.

A thorough ophthalmic and medical history was taken, followed by a complete ophthalmic examination. All cases with an enlarged or even normal sized globe had a B-scan ultrasound to exclude the presence of an intra-ocular tumour. Pre-operative photographs of the face were taken. Patients and their care-takers were fully explained and counselled the limitations and risks of the whole procedure, post-operative management, the fitting of final prosthesis, long-term care of the prosthesis and the need for regular follow-up visits. Patients who were taking blood thinners were instructed to stop these medications two weeks prior to surgery after consultation with their physician. Diabetic and hypertensive patients were instructed to ensure a strict control of their blood sugar and BP status prior to surgery.

Surgical technique: All patients were given injection Cefuroxime 1 Gm I/V, injection Transamine 1 Gm I/V and injection dexamethasone 500 mg I/V. in the morning prior to surgery. The surgery was performed under general anaesthesia. The upper face was painted with pyodine solution and a drop of pyodine was also instilled into the conjunctival sac for 5 minutes. Under full aseptic conditions, a 4/0 silk suture was passed through the conjunctiva of upper and lower fornices, out through the lid skin, and tagged to the surgical drape with a clamp. This step ensured that the conjunctival fornices were maintained, and the conjunctiva would not be dragged during wound closure at the end of the procedure.

Since most eyes had a scarred conjunctiva due to past trauma, 2 cc of xylocaine with adrenaline was injected with a 27G needle to balloon conjunctiva from the underlying tenon. Then, a 360° peri-limbal peritomy was performed carefully to preserve as much of the conjunctiva and Tenon's capsule as possible. Horizontal cuts at 3 and 9 o'clock were made into the conjunctiva and tenon to expose the underlying sclera.

To perform an enucleation, the four rectii and inferior oblique muscles were exposed, tagged with 5-0 Vicryl sutures and then released by resecting them at their attachments to the globe. A 4/0 silk suture was passed through the medial or the lateral rectus tendon-stump attached to the globe so as to lift the globe upwards by traction on these sutures. Whilst the globe was held upwards, a long, curved scissors was passed underneath the globe to cut the Optic nerve and the globe was delivered. In case of a suspected malignancy, an enucleation was performed with minimum pressure on the globe, the eyeball lifted up with an evisceration spoon and the maximum available length of optic nerve was cut. In suspected choroidal melanoma, patients systolic BP was lowered to 50-60 mm Hg prior to neurectomy to avoid blood borne metastasis.

To stop bleeding from the cut vessels of the annulus of Zinn surrounding the optic nerve, the empty socket was immediately packed with a ribbon gauze (already soaked in a solution of pyodine and adrenaline 1:10,000) inserted into the empty intra-conal space. Pressure by an assistant's hand was kept over the packed socket for 10 minutes to obtain haemostasis. The gauze was gently removed, the Tenon's capsule was held open via artery-forceps by the assistant, and the intra-conal space inspected for any bleeding vessels that needed cauterisation. In order to minimise the risk of implant exposure, the rent in posterior Tenon's capsule, where the optic nerve penetrated, was enlarged further by using a blunt haemostat. This allowed the posterior placement of implant into the intra-conal space.

The cases which already had an enucleation and an empty socket, the conjunctiva and tenon was similarly opened. The posterior tenon capsule was opened, enlarged further, and held taut with haemostats to assess the volume of the cavity, and search for the rectus muscles.

The cases which had an exposed or a posteriorly migrated implant, the implant was removed after incising the conjunctiva and tenon. The rectus muscles found sutured to the implant were salvaged and the implant removed. Any bleeding vessels were cauterised.

In order to obtain an optimum fit of implant inside the orbital cavity, proper sizing of the implant was done by a set of graduated sizing spheres while keeping in mind the thickness of the wrapping. A sterilised PMMA spherical ball, soaked in an antibiotic/pyodine solution (80 mg gentamicin in 100 cc pyodine) was wrapped in a 5 x 5 cm prolene mesh in the shape of a cone, the mesh being held in place around the PMMA ball with 5/0 Ethibond suture tied in a purse-string manner, as demonstrated in figures 1 and 2, 3. The cone-shaped implant was inserted inside the opened posterior tenon capsule and pushed further back within the intra-conal space. In all primary cases and in 13 secondary cases where the rectus muscles could be salvaged, the 4 rectii and the inferior oblique muscle, tagged with 5/0 vicryl sutures, were anchored to the prolene mesh along the anterior surface of implant by mattress sutures. The suture that tagged the muscle to the prolene mesh traversed inwards through the posterior tenon, then through the prolene mesh, then outwards through the posterior tenon, back to the rectus muscle, tied and cut. Once all the four recti and inferior oblique were similarly attached to the implant, the posterior tenon covering the implant was closed, tension-free, with a 5/0 vicryl running suture. Then the anterior tenon was closed with 5/0 vicryl, running suture and lastly, the conjunctiva was closed similarly.

The fornix maintaining silk sutures were removed and a conformer was placed over the conjunctiva; antibiotic ointment was squirted through the hole of the conformer to cover the

Figure 1: Post-enucleation Socket Syndrome, showing four features: enophthalmos, deep upper eyelid sulcus, ptosis upper lid, lower lid laxity.

Figure 2: Diagram demonstrating: a: eyeball supported by rectus muscles. b: Following enucleation, prosthesis supported only by the lower eyelid, which sags down by its weight, with ptosis of upper lid and enophthalmos. c: demonstrates that the presence of orbital implant bears the weight of the prosthesis and prevents lower eyelid from sagging down.

Figure 3: a: Demonstrating prolene mesh 6x6 cm, and PMMA ball implant (hollowed from within). b: The ball implant rolled into praline mesh in the form of a cone and held inside it with 5/0 ethibond suture.

conjunctiva. Both eyelids were sutured together with a 4/0 silk suture, to hold the conformer in place and to control post-operative conjunctival and socket oedema. To control pain post-operatively, 3cc of 0.75% Bupivacaine was injected inside the muscle cone. A firm pressure dressing was applied and maintained for 3-4 days, antibiotics, transamine (to control bleeding post-operatively), and pain medication were given I/V for 48 hrs. after which the patients were discharged from the hospital on oral antibiotics and painkillers for 1 week.

On the 5th post-op day, pressure dressing was removed, the silk suture closing the eyelids temporarily was also removed and the socket was washed with a diluted pyodine solution without disturbing the conformer. The patients were instructed to keep the socket clean and to instil antibiotic eyedrops 4 times daily through the hole of the conformer. The conjunctival surfers were removed on the 7th post-operative day.

All cases were followed-up weekly for the next 6 weeks. At each follow-up visit, the socket was examined after removing the conformer and irrigated with a diluted pyodine solution.

The conformer was thoroughly cleaned with soap and water and re-inserted into the socket.

After which they were sent to the prosthetic lab for sizing and fitting of the final prosthesis (artificial eye). After the final fitting of the prosthesis, patients were assessed regarding pain or discomfort after wearing the prosthesis, stretching of the eyelids or the conjunctival lining, level of comfort while opening and closing of eyelids, ptosis upper lid or lid lag. Patients were instructed to take the prosthesis out of the socket at bed-time and wear it in the morning after cleaning it, and instilling a lubricant ointment into the socket, daily.

To assess the outcome of surgery, post-operative photographs were taken at the 12 month follow-up. At that visit, they were evaluated regarding the degree of volume replacement, upper lid sulcus deformity (graded as absent, mild, moderate, severe), enophthalmos (measured by a ruler placed at the lateral canthal angle), motility of the implant and prosthesis (graded as poor, fair, good). Any post-operative complications involving the eyelid or the socket like lagophthalmos, lower lid laxity, shrunken fornices were noted and the need for further surgery evaluated. Patient satisfaction regarding cosmesis and comfort were graded as poor, fair or good.They were instructed regarding the need for regular follow-up visits, initially 3 monthly for a year, and then annually for as long as possible.

Results

A total of 261 consecutive cases were included in the study out of the initial 269 cases as they completed the 12 month post-operative follow-up. The final assessment and the results were noted for these 261 cases. 8 cases from the primary implant group did not attend that visit and were dropped out of the study. 50% of our cases came for follow-ups for an average period of 7 ± 3 years.

The demographics of the 261 cases are shown in table 1. Out of these, 218 cases had an enucleation and a primary of orbital implant while 43 cases had an evisceration initially, followed by a secondary orbital implant. There were 146 males and 115 females between the age 17-62 years (median age 23 years). The indications for enucleation are shown in table 1. For both primary and secondary groups, the size of implant most frequently selected was medium (18 mm).

The various parameters assessed as the final surgical outcome are shown in table 2. The degree of relative enophthalmos between the prosthetic eye and the fellow eye was measured by a ruler placed at the lateral canthal angle. Amongst the primary orbital implant cases, no relative enophthalmos could be detected in 172 cases (79.89%) and was only 1 mm in 46 cases (21.11%). Out of the secondary implant group, there was no enophthalmos in 11 cases (25.60%), 1 mm in 27 cases (62.80%), and 2 mm in 5 cases (11.60%). There was no residual upper eyelid sulcus deformity in 192 cases (88.07%) and was of a mild degree (1 mm) in 26 cases (11.93%) of primary implant group; it was absent in 13 cases (30.23%) of the secondary implant group and was mild (1-2 mm) in 30 cases (69.77%).

Parameters assessed	Primary Implant = 218 cases	Secondary Implant = 43 cases
Relative enophthalmos	0 = 172 cases (79.89%) 1mm = 46 cases (21.11%)	0 mm = 11cases = 25.60% 1 mm = 27cases = 62.80% 2 mm = 5 cases = 11.60%
Lid sulcus deformity	0 mm = 192 cases = 88.07% 1 mm = 26 cases = 11.93%	0 mm = 13 cases = 30.23% 1-2mm = 30 cases = 69.77%
Implant migration	nil	3 cases = 6.97 %
Implant extrusion	nil	nil
implant tilting	nil	2 cases = 4.65%
Post-op Infection	14 cases = 6.42%	6 cases = 13.95%
Mucoid Discharge	26 cases = 11.92%	15 cases = 34.88%
Implant Motility	Good = all cases 100%	Good = 11 cases = 25.59% Fair = 19 cases = 44.18% absent = 13 cases = 30.23%
Lagophthalmos	Nil	Nil
Lid retraction	Nil	Nil
Ptosis	Nil	Nil
Entropion	Nil	Nil
Lower lid laxity = ectropion	Nil	12 cases = 27.90%
Post-op discomfort, pain	14 cases = 6.42%	6 cases = 13.95%
Cosmetic result	Good = 199 cases = 91.28% Fair = 19 cases = 8.71%	Good = 11 cases = 25.58% Fair = 32 cases = 74.41%
Implant exposure,	2 cases = 0.91%	3 cases = 6.97 %
Removal of implant	2 cases = 0.91%	nil
Secondary surgical procedure	primary implant removal, followed by secondary implant = 2 cases (0.91%)	Mucus membrane graft for wound dehiscence = 3 cases = 6.97% Lateral Tarsal strip = 12 cases = 27.90%

Table 2: Final Surgical Outcome in 261 cases at 12 months post-operative follow-up.

Post-operative infection occurred in 14 primary cases (6.42%) and in 6 secondary cases (13.95%) at 4 - 6 weeks post-operatively. It was accompanied by mild to moderate orbital pain in all these cases. It was found to be due to poor hygiene and improper cleaning of the socket. Patients and attendants were instructed regarding meticulous cleaning of the socket by irrigating with a solution of distilled water and pyodine instilled with a syringe through the conformer hole. On every follow-up visit, the socket was examined after removing the conformer and irrigated with diluted pyodine solution. The conformer was thoroughly cleaned with soap and water and re-inserted into the socket. Broad spectrum antibiotic (Fortum 500 mg) was injected into the orbital cavity for 3 consecutive days and instilling hourly antibiotic eye drops.

3 patients were found to have a purulent discharge on naso-lacrimal sac compression. They were advised regular sac compression, maintaining lid and socket hygiene and had a DCR subsequently. In only 2 cases of the primary implant group, infection could not be controlled conservatively resulting in recurrent purulent discharge, conjunctival and tenon dehiscence with implant exposure. Therefore, the implant along with the prolene mesh wrapping had to be removed by incising the conjunctiva and tenon. Pus was noted in the meshes of the wrap and was sent for microbial culture. The cavity was left open for frequent instillation of topical antibiotics and cleaning. This was followed by a secondary orbital implant a month later in only 2 cases (0.91%) of the primary group only.

Excessive mucoid discharge was noted in 26 cases (11.92%) of the primary group and 15 cases (34.88%) of the secondary group. In all of them, this was found to be due to continuous wearing of the prosthesis day and night for weeks.

There was no case of implant migration or extrusion in the primary group. Tilting of implant was seen in 2 cases (4.65%) and slight upward migration in 3 cases (6.97%) of the secondary implant group after 18 months post-operatively. These were the cases in which no rectus muscles could be isolated. There were 3 cases (6.97%) of conjunctival dehiscence and implant exposure of 3 mm due to shortened conjunctival fornices because of previous surgeries. The conjunctival defect was covered by a mucous membrane graft.

The degree of implant motility within the socket was found to be good in all cases (100%) in the primary implant group versus only 11 cases (25.59%) of the secondary implant group, fair in 19 (44.18%) cases in which a few rectus muscles could be salvaged and attached to the implant. The implant restored volume but offered no motility in 13 cases (30.23%) where no muscles could be isolated. No lagophthalmos, lid retraction, ptosis or entropion was noted in any case of the primary implant group patients and they all had a normal eyelid closure. However, 12 cases (27.90%) in the secondary implant group had a lax lower lid resulting in its ectropion due to wearing of prosthesis alone in an empty socket for years previously. They all needed a secondary lower lid tightening by a lateral tarsal strip procedure about 1 month post-operatively as it was allowing the glass conformer to fall out of the eye when patients stooped down.

None of the cases needed ptosis surgery, volume enhancement or removal of the implant because of its migration. The cases who had a mild to moderate enophthalmos and upper lid sulcus deformity were satisfied with their appearance and declined further surgery. Overall patient satisfaction was 100% in the primary group and 90% in the secondary group. The final assessment of cosmetic appearance by the surgeon was considered as good in 199 cases (91.28%) and fair in 19 cases (8.71%) of the primary group. In the secondary group, a good cosmetic appearance was declared in 11 cases (25.58%) and was fair in the remaining 32 cases (74.41%).

Discussion

Following enucleation, orbital haemorrhage is a main concern as blood is an excellent culture medium for bacteria. A perfect homeostasis intra-operatively was ensured in all our cases and the implant was placed in a blood-free intra-conal space. This step was particularly important to prevent bacteria colonising the blood-soaked prolene-mesh where antibiotics given in the intra-operative or the post-operative period may not reach, resulting in post-operative socket infection. Bleeding in the early post-op period, due to reopening of vessels of the annulus of Zinn, was avoided by keeping the patient hospitalised and in bed for 48 hrs post-operatively, administering anti-emetics I/V, Transamine I/V and a pressure dressing for 72 hours. Patients were instructed to avoid bending or weight bearing for 3-4 weeks and eating a light, soft diet for 1 week.

Postoperative infection is a major complication that must be avoided. It promotes wound dehiscence, implant exposure, extrusion, or a chronically irritable socket, which may necessitate the removal of an implant if not managed properly. Despite meticulous instructions to the patients and their care-takers regarding socket cleaning, wound infection occurred in 14 cases (6.42%) in the primary orbital implant group and 6 cases (13.95%) in the secondary implant group, more than a month post-operatively. This was managed conservatively in all except 2 cases (0.91%), in which persistent infection led to wound dehiscence, implant exposure, and peri-orbital pain that necessitated the removal of implant. Interestingly, when implant was being removed, the prolene mesh was found to be densely adherent to tenon at places while at others places, an incomplete fibrous capsule had formed. This indicated that prolene mesh incited a fibrous tissue reaction and formation of a pseudo-capsule which was strongly adherent to tenon and recti, thus becoming fully integrated with the orbital tissues. Therefore, these 5 layers of tissue surrounding the implant prevented its exposure or extrusion (i.e. the pseudo-capsule, the posterior tenon, rectii, anterior tenon and the conjunctiva). In the secondary group, 3 cases developed implant exposure due to conjunctival scarring. So out of 261 cases, 5 cases developed implant exposure (1.91%) during the maximal follow-up of 7 ± 3 years.

In the scientific literature, the exposure rates for porous implants seem to be higher than for nonporous implants due to chronic mechanical irritation of the tenon and conjunctiva by their rough surface if they are placed without a wrap. Lin C-W., *et al*. (2016) [14], reported the exposure rates over a period of 21 years to be 24.7% for Coralline implant, 23.5% for bioceramic implant, and the highest for Medpor i.e. 76.5% even though these implants were wrapped in vicryl mesh (undyed polyglactin, absorbable material). The mesh gradually absorbed after 1-2 months resulting in mechanical irritation of overlying conjunctiva, its dehiscence and high implant exposure.

Tabatabaee Z..., *et al*. (2011) [15] compared the exposure rate of wrapped hydroxyapatite (in Merselene mesh) versus unwrapped porous polyethylene orbital implants in enucleated patients. The rate of exposure was significantly higher [odds ratio (OR) = 7.97, $p < 0.001$] in patients with porous polyethylene (unwrapped integrated implant) (34.0%) than in those with wrapped hydroxyapatite implant (6.1%). Therefore, implant wrapping offers protection against long-term implant exposure or extrusion.

Lin C-W., *et al*. (2016) [14] also suggested that the movement of prosthesis and the continuous erosion of the underlying conjunctiva and Tenon capsule plays important roles in implant exposure. Though peg insertion enhances the motility of prosthesis, but it also increases the exposure rate by the continuous friction at the interface. This was also documented by Jordan DR., *et al*. (2004) [16] in their study of 158 cases of Coralline hydroxyapatite orbital implant (bio-eye). Ye J., *et al*. (2015) [17] that the sutured the rectus muscles end-to-end over the hydroxyapatite spherical implant. This created a joint-like structure over its rough surface, thereby protecting the Tenon's capsule and conjunctiva and reducing the risk of implant exposure to 8.11%.

In our cases, conjunctival wound dehiscence was avoided, firstly, by placing silk sutures to maintain conjunctival fornices and avoiding conjunctiva being dragged during wound closure. Secondly, the dissection of conjunctiva from the underlying tenon was performed carefully, particularly in scarred eyes (due to perforating eye injuries). Thirdly, placement of a proper sized implant ensured closure of tenon and conjunctiva separately in two layers in a tension-free manner. Lastly, if tension on the suture line was felt while placing the conformer, a horizontal nick was given in the conjunctiva deep in the upper and lower fornices and both eyelids were sutured over the conformer with a 4/0 silk suture passed through the grey line of the eyelids.

We had strictly instructed all our cases to remove the prosthesis at night for the rest of their lives. This enables the conjunctival micro-abrasions incurred during the day by the mechanical irritation of the prosthesis to heal overnight. Moreover, they were instructed to instil lubricant eye ointment into the socket before wearing the prosthesis in the morning. 26 cases (11.92%) of the primary group and 15 cases (34.88%) of the secondary group complained of excessive mucoid discharge which was found to be due to continuous wearing of the prosthesis day and night for weeks. This has also been reported by Ruiters S., *et al*. (2020) [18] and was found to be related to continuous mechanical irritation of conjunctival lining by the prosthesis.

Placing a proper sized implant is important not only for the final cosmetic result but for a tension-free closure of the tenon and conjunctiva, preventing wound dehiscence and implant exposure. Excessively large implants compromise the fornices and possibly

limit motility by not leaving enough space for the ocularist to fashion an artificial eye (presthesis). This is only possible if 3 to 5 mm of antero-posterior space is available for the prosthesis to fit in close proximity to the implant.

We had to remove 11 implants performed elsewhere from the secondary group. They were PMMA or acrylic semi-spheres with holes into which the rectus muscles were secured with sutures (the semi-integrated implants). They were found to be either tilted or migrated posteriorly due to stretching or shearing of rectus muscles fibres due to constant movement within the holes of the implants. Implant migration or tilting did not occur in any of our primary cases because of its lesser weight, perfect fit into the orbital cavity (cone shaped), fibrovascular ingrowth into the prolene mesh, the formation of a pseudo-capsule, and the inferior support rendered by the inferior oblique muscle. The implant tilted in only 2 (4.65%) out of 43 secondary cases in which the rectus muscles could not be isolated to be attached to the implant.

The integrated nature of our implant resulted in improved implant motility in all our primary cases. The motility was certainly better in those secondary cases in whom the rectii could be found and attached to the implant. Therefore muscle support is crucial not only for the movement of the artificial eye but in keeping the implant centred and supported inside the orbital cavity.

Eyelid deformities like ptosis, markedly deep upper lid sulcus, lid retraction or entropion can occur due to posterior migration of an implant. They were not seen in any case in the primary implant group and they all had a normal eyelid closure. This was due to the proper sizing of implant, maintaining conjunctival fornices during wound closure which left sufficient room for the fitting of prosthesis, and full integration of implant with the orbital tissues. However, 12 cases in the secondary implant group had a lax lower lid resulting in its ectropion due to wearing of prosthesis alone for years prior to surgery. They all needed a secondary lower lid tightening by a lateral tarsal strip procedure about 1 month postoperatively to prevent the glass conformer from falling out of the eye when the patients stooped. In none of the cases, any volume enhancement was performed; the cases who had a mild enophthalmos (1 -2 mm) and a mildly deep upper lid sulcus were satisfied with their appearance and declined further surgery.

In 2 cases of the primary implant group, a missed nasolacrimal duct obstruction was the underlying cause of wound infection. Therefore a pre-operative assessment of the lacrimal drainage system is mandatory.

The strengths of this study are its prospective nature with 261 consecutive cases included. The minimal follow-up was of one year and maximal of 6 ± 4 years which was completed by 50% of the cases.

The possible drawbacks in the study are a lack of masked evaluation of the final surgical outcomes. The initial case selection, surgery and the final post-operative assessment were performed by a single surgeon, with the possibility of a bias.

Conclusion

The technique described here to improvise a Cone-shaped orbital implant for restoring orbital volume following enucleation is simple, easy to master, and with a short learning curve. It is an inexpensive option amongst a vast array of commercial fully integrated orbital implants that are costly and not readily available. Prolene mesh eliminates the risk of transmission of infection that occurs with autogenous wraps. Our technique offers good cosmetic results with minimal post-operative complications. All such patients must be strictly instructed to remove the prosthesis at sleep time and instil lubricant ointment into the socket prior to wearing it during the day. This practice not only minimises conjunctival irritation and mucoid discharge but prevents implant exposure longterm.

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