·Clinical Research·

Comparative study of modified and conventional secondary hydroxyapatite orbital implantations

Yong Zhao[1], Mao-Nian Zhang[1], Yun-Xian Gao[2], Xiao-Wei Gao[3], Bing Ren[3]

[1]Department of Ophthalmology, Chinese PLA General Hospital, Beijing 100853, China

[2]Department of Ophthalmology, the Affiliated Hospital of Xinjiang Medical University of TCM, Urumuchi 830000, Xinjiang Uygur Autonomous Region, China

[3]Department of Ophthalmology, Chinese PLA 474th Hospital, Urumuchi 830013, Xinjiang Uygur Autonomous Region, China

Correspondence to: Yun-Xian Gao. Department of Ophthalmology, the Affiliated Hospital of Xinjiang Medical University of TCM, No.116 Huanghe Road Shayibake District, Urumuqi 830000, Xinjiang Uygur Autonomous Region, China. yunxiangao@yeah.net

Abstract

• **AIM: To compare the clinical effects of the modified and conventional secondary hydroxyapatite orbital implantations.**

• **METHODS: A total of 40 patients who had received eye enucleation were equally randomized into the modified and conventional groups. Twenty patients were treated by conventional method. The four rectus muscles were separated, and then an orbital implant wrapped with xenogenous sclera was implanted. Twenty patients were treated by modified method. An implant unwrapped with xenogenous sclera was directly implanted into the muscle pyramid. The operating time, costs, clinical effects, and complications of the two groups were compared.**

• **RESULTS: The average operating time of the modified group was 20.5±5.6min, whereas that of the conventional group was 56.8±14.6min （P<0.01). The average cost of the modified group was 7 800±340RMB （1 274±55.6USD), whereas that of the conventional group was 9 800 ± 660RMB (1 601±107.8USD) （P<0.01). The two groups did not show significant difference in orbital implant mobility or postoperative complications.**

• **CONCLUSION: The modified secondary hydroxyapatite orbital implantation has advantages in operating time, surgery cost, and complication reducing. It is worthy for wide clinical application and further study.**

• **KEYWORDS:** hydroxyapatite; orbital implantation; orbit

INTRODUCTION

Changes in the shape and size of the conjunctival sac tend to occur after eye enucleation due to lack of an intraorbital implant. These changes may include lower lid chalasis and ectropion, lower fornix shallowness, upper conjunctival sac regression, deepened sag of the upper fornix, concentric contraction or even closure of the conjunctival sac caused by a reduced size or extensive scarring of the conjunctivas. They bring serious spiritual burdens to patients and greatly influence their physical and mental health. Secondary hydroxyapatite orbital implantation is an important treatment method to improve patients' facial appearance after eye enucleation [1]. Hydroxyapatite orbital implants have the virtues of non-toxicity, non-sensibilization, good histocompatibility, less post-operative complications, and satisfactory clinical effects[2,3].

However, secondary hydroxyapatite orbital implantation is hard to operate in technique. In a conventional procedure, the four rectus muscles have to be separated, and then an orbital implant wrapped with xenogenous sclera is implanted. However, since complete muscle separation is difficult to achieve due to a complicated anatomic structure of the muscles, in most cases who need secondary orbital implantation, only the fascia tissues which are partially connected to these muscles are used for contact with the wrapped implant instead. This condition consequently influences the activity of the orbital mount. Furthermore, this procedure requires long operating time and high surgery costs and the risk of post-implantation complications such as infections and mount exposure is high. Primary and secondary orbital implantations after eye enucleation or evisceration for patients with severe endophthalmitis show no significant difference in the occurrence of post-implantation complications[4]. A little autogenous sclera used for anterior topping of an orbital implant in orbital implantation can bring about a better effect [5]. Primary implantation of orbital implants unwrapped with autogenous sclera after eye enucleation has a higher rate of orbital implant exposure than after eye evisceration [6]. For patients receiving secondary orbital implantation, things get worse.

Since most patients cannot provide autogenous sclera, xenogenous sclera has to be used instead. Meanwhile, xenogenous sclera in itself is limited in source and may lead to graft rejection. These factors inevitably increase the risk of the occurrence of orbital implant exposure.

Based on the aforementioned, in the current study, the conventional secondary orbital implantation was modified, in which an implant unwrapped with xenogenous sclera was directly implanted into the muscle pyramid. The operating time, cost, curative effect, and complications were observed and then compared with the conventional procedure to explore the feasibility and superiority of the modified method.

SUBJECTS AND METHODS

Subjects A total of 40 patients (40 eyes) who received treatment between September 2009 and March 2011 were enrolled. They were randomized into the modified and conventional groups. Each patient of the treatment plan generated by the random allocation sequence generation, and placed in order, sealed, opaque envelope. Qualified patients agreed to enter the test, the envelope can be opened, patients in order to receive appropriate operation. The modified group was comprised of 15 males and 5 females with an average age of 30.6 years (ranging from 16 to 44 years) and an average post-enucleation time span of 8.15 years. The conventional group included 14 males and 6 females with an average age of 29.8 years (ranging from 14 to 40 years) and an average post-enucleation time span of 7.88 years. No significant differences between the gender ratios, ages, and post-enucleation time spans of the two groups were observed. The patients were subjected to eye enucleation for reasons such as eyeball rupture, ocular tumor, panophthalmitis, atrophy of eyeball, corneal perforation caused by severe keratitis, and so on. The size of a needed orbital implant for each patient was determined based on computerized tomography (CT) of the affected orbit and B ultrasonic measurement of the healthy axial length. Intraoperative steel ball measurement was performed when necessary.

The current study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Chinese PLA General Hospital. A written informed consent was obtained from each participant.

Methods

Implanted materials Three specifications of coral hydroxyapatite orbital implants (18mm, 20mm, and 22mm; IOI, USA) were used.

Preoperative preparation Compound tobramycin eye drops were administered for the affected eye 4-6 times per day from 3d before operation. Meanwhile, routine and preoperative examinations were performed.

Surgical procedures Surgical procedures were performed as follows:

1) The conventional group. A balanced mixture of 2% lidocaine and 0.75% bupivacaine (5mL) was used for retrobulbar, orbicularis oculi, and subconjunctival anesthesia. A drainage bag was adhered. The eyelids were dragged open using a retractor. An incision was made about 2mm slightly above the centre of the bulbar conjunctiva and the fascial layer was then incised. Tissues beneath the fascia were separated and organized scar bands were removed. Blunt dissection was performed on, and the contraction points of the superior, inferior, medial, and external rectus muscles were sought and sutured, and then the muscle pyramid was expanded. The hydroxyapatite orbital implant was wrapped with xenogenous sclera which was windowed at four quadrants. A square hole was made at the central site of the inner sterile package plastic membrane of the hydroxyapatite, the four angles were cut radioactively and the implant was then put in. Afterwards, the implant was implanted into the separated pyramid. The plastic membrane was extracted completely and the integrity of the square hole was examined. The depth of the implant was adjusted, the Tenon's capsule was sufficiently separated until into a tension-free state, and then the rectus suture silks and the scleral windows were correspondingly sutured for fixation. The fascia layer was sutured interruptedly, whereas the bulbar conjunctiva was sutured continuously. Tobramycin and dexamethasone ointment were applied into the capsule and a temporary ocular prosthesis was used for support. Mattress suture of the upper and lower eyelids was performed when necessary (*i.e.* according to the palpebral fissure size). Finally, pressure dressing was done. Patients were given antibiotics and hormones by intravenous drip for 3-5d after operation, and thin type ocular prostheses were applied for 2 months.

2) The modified group. The modified group received disinfection and anesthesia using the same method as was done for the conventional group. The bulbar conjunctiva was cut open about 2mm slightly above the centre of the bulbar conjunctiva and the fascial layer was then opened. Tissues beneath the fascia were separated and organized scar bands were removed. Blunt dissection was directly performed until to the muscle pyramid. The pyramid was dilated with steel balls and the size of a needed orbital implant was estimated. The implant was not wrapped with xenogenous sclera. Rather, it was directly placed into the sterile package plastic membrane and then implanted into the separated pyramid, adjust to the appropriate depth and take out the plastic membrane. The fascia layer was sutured interruptedly, whereas the bulbar conjunctiva was sutured continuously. The rest part of the procedure as well as post-operative treatment was the same as was performed for the conventional group.

Position and activity of the orbital implant The position of the orbital implant, *i.e.*, whether the implant occupied the central position, was first observed, and then its activity was evaluated: a mark was made at the centre of the "pupil"; activity with left-right mobility ≥20mm and up and down mobility ≥10mm was recognized as excellent, activity with left-right mobility between 10mm and 20mm and up and down mobility between 5mm and 10mm was good, and activity with left-right mobility ≤10mm and up and down value ≤5mm was poor.

Complications The observed complications included conjunctival wound dehiscence or stenosis, orbital implant exposure and displacement, and post-operative secondary infections. All patients were followed up for at least 12 months after implantation.

Statistical Analysis Data were analyzed using the SPSS13.0 software. Chi-square tests were performed for enumeration data and rank sum tests were performed for ranked data. $P<0.05$ was considered statistically significant.

RESULTS

The operating time spans of the modified group ranged from 18min to 24min with an average of 20.5 ± 5.6min, whereas those of the conventional group ranged from 50min to 76min with an average of 56.8 ± 14.6min ($P<0.01$). The treatment costs of the modified group varied from 7 445RMB (1 216USD) to 8 228RMB (1 344USD) with an average of $7\,800\pm340$RMB ($1\,274\pm55.6$USD), whereas those of the conventional group varied from 9 536RMB (1 558USD) to 10 528RMB (1 720USD) with an average of $9\,800\pm660$RMB ($1\,601\pm107.8$USD) ($P<0.01$).

The two groups did not show significant difference in orbital implant exposure (2 cases in the conventional group versus none in the modified group), conjunctival sac stenosis (3 cases in each group), complications such as implant displacement and secondary infections (none in either group), or activity evaluation (15 excellent cases, 75%) and 4 good cases (20%) in the conventional group versus 16 excellent cases (80%) and 4 good cases (20%) in the modified group ($P=0.68$). However, they did show significant differences in average operating time and surgery costs ($P<0.01$).

DISCUSSION

Secondary hydroxyapatite orbital implantation is an important treatment method for facial esthetic improvements after eye enucleation. However, the conventional surgical method has a complicated procedure; even worse, it is very likely to lead to post-operative complications. Post-operative complications leading to surgery failure can be caused by various reasons. Orbital implant exposure is the most common complication which often occurs within 6 months after operation; once occurring, it will be very hard to treat[7,8]. The premise for the survival of an orbital implant is that there must be sufficient surrounding blood supply to

vascularize the implant as early as possible[9]. The activity of an orbital implant is influenced by factors such as extraocular muscle injury, implant position, titanic miniscrew implantation, and so on[10]. Furthermore, the size and depth of an orbital implant are also factors for post-operative complications.

Eye enucleation can be performed for various reasons as well as with different procedures. It also varies in surgery quality. All these factors entail great difficulty in performing secondary surgery. One of the requirements on the conventional procedure is the separation of the rectus muscles. This process is not only difficult to complete in technique but requires patients' cooperation and long operating time. For patients receiving general anesthesia, separating the muscles will be more difficult. These apparently influence post-operative effect. Furthermore, in the conventional procedure, different kinds of tissues have been used for implant wrapping [11,12]. Bovine cardiac pericardium can lead to an implant exposure incidence of 23%, whereas artificial Dacron patch can lead to an even higher incidence (as high as 46%)[13,14]. Although xenogenous sclera can achieve comparatively good effect, it is limited in source and thus greatly increases patients' costs; meanwhile, it may lead to graft rejection, therefore increasing the risk of orbital implant exposure[15].

Considering these drawbacks of the conventional implantation in technique, modified secondary orbital implantation was adopted in the present study. The modifications include the following aspects.

First, based on the surgical experience of that orbital implants contacted with the partially muscle-connected fascia tissues, instead of the muscles when complete separation of the muscles cannot be achieved, have good activity, we directly implanted the orbital implant into the muscle pyramid rather than separated the muscles in this study. This modified treatment makes patients' cooperation unnecessary and greatly reduces operating time and lessen patients' pains; it does not cause damage to the extraocular muscles and only cause small injury to the surrounding tissues; further, it maximally protects the original blood circulation, thereby benefiting the vascularization of the orbital implant. In this study, the patients were followed up for 12 months to 2 years, and no orbital implant exposure occurred among them. This result proves good safety of the modified technique. The observations demonstrate that as long as an orbital implant is placed at the right place with a right depth within the muscle pyramid, it can have good mobility and a low risk of exposure. The modified procedure does not cause serious damage to the extraocular muscles, which is the premise of good mobility of an orbital implant. In addition, the implant placed at a normal physiological position only causes slight stimulation and compression to the surrounding tissues and has small influence on the tissue blood supply within the

orbit, which further benefits the mobility of the implant.

Second, based on the findings that subconjunctival tissue flaps can be used in repair to orbital implant exposure and that the implantation of orbital implants unwrapped with sclera does not significantly increase the incidence of implant exposure, we did not wrap the implants with xenogenous sclera, which greatly reduced the operating time and patients' costs [16-18]. An orbital implant can integrate with the surrounding tissues around 6 months after implantation[19]. The 12-month follow-up in this study shows that the incidence of implant exposure among the patients did not increase but decreased somewhat. Unwrapping presumably enables the orbital implant to directly contact the intraorbital tissues, thereby benefiting the growth of neovessels into the implant. This presumption is also proved by another correlated study [20]. Additionally, unwrapped implants achieve good effects for patients who need orbital implant replacement[21].

Third, literature has recommended A-scan ultrasonography for measuring the healthy axial length [22]. However, since most patients receive implantation several years after eye enucleation and their affected orbits have seriously depressed, this measurement may lead to large errors. To overcome this drawback, we estimated the size of a needed orbital implant by measuring the healthy axial length using B-scan ultrasonography assisted with CT (or even intraoperative steel ball measurement when necessary). Our method ensured the implant with a right size to the maximum.

To sum up, modified secondary direct implantation of a hydroxyapatite orbital implant unwrapped with xenogenous sclera into the muscle pyramid has advantages of shortened operation time, less serious postoperative reactions and lower surgical costs, compared with the conventional procedure; meanwhile, it does not increase the risk of postoperative complications. However, eye enucleation often leads to postoperative intraorbital telatrophy and conjunctival sac stenosis, which cannot be solved by the current modified procedure. Other unsolvable complications by this method include lower eyelid chalasis and ectropion, lower eyelid entropion, and blepharoptosis. Furthermore, in this study, to avoid the occurrence of implant exposure, the orbital implants were often placed deeply, which led to slightly poor postoperative satiation. Moreover, the modified procedure is also limited by a small number of surgery cases and relatively short observation time.

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