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Efficacy of lacrimal plug for dry eyes after refractive surgery

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- Clinical Study -

[Abstract] Objective This study is to evaluate the clinical efficacy of dissolvable VisiPlug lacrimal plug on dry eyes after refractive surgery. **Methods** Forty-six eyes of 23 patients with mild to moderate dry eyes were managed with VisiPlug lacrimal plug after refractive surgery. Questionnaires on dry eye symptom and comfort degree to lacrimal plug, Schirmer I test (SIt), fluorescent staining and tear film break-up time (BUT) were taken from cases before refractive surgery and plug insertion, and at 2w and 3m after refractive surgery. **Results** The eye symptom worsened in all cases with obvious decreasing SIt and BUT right after the refractive surgery but relieved significantly with increasing SIt and BUT and decreasing frequency of artificial tears application after the application of VisiPlug. Three months after the insertion, no fluorescent staining of corneal epithelium were found in all cases. Except one case of plug dislocation in one eye 1d after the insertion, no other complications were observed. **Conclusions** VisiPlug lacrimal plug are found to be effective and safe in treatment of dry eyes after refractive surgery. The application can help to increase tear production, improve tear-film stability, alleviate dry eye symptom, and replace treatment with artificial tears. (China J Ophthalmol and Otorhinolaryngol, 2011, 11:22-25)

[Keywords] lacrimal apparatus; embolization, therapeutic; keratectomy, subepithelial, laser assisted; Keratomileusis, laser in situ; dry eye

Since the first excimer photorefractive keratectomy (PRK) introduced by Stephen and Trokel of Columbia University of USA in 1983, the excimer laser corneal refractive surgery has undergone continuous development and optimization processes from LASIK (laser in situ keratomileusis), LASEK (laser sub-epithelial keratomileusis), Epi-LASIK (epipolis laser in situ keratomileusis) to FemtoLasik.

Despite the unceasing advancement of surgical technology of equipment contributing to the obvious reduction of incidences of surgically related severe complications in recent years, the refractive surgery inevitably causes damage to corneal nerves, degrading the corneal sensation and lessening tear secretion. The induced postoperative dry eye syndrome has become one of major complaints [1-3]. Severe dry eye might cause irritation, vision

fluctuation, degrading visual acuity, refractive regression, etc.

We selected 23 patient suffering mild to moderate postoperative LASIK dry eye symptom to apply with dissolvable VisiPlug lacrimal plug and conduct clinical efficacy observation. The results were satisfactory and the details are reported below.

1 Material and Methods:

1.1 Material 23 cases (46 eyes) from myopic patients were selected and treated with LASIK by our division since March through July of 2009, amongst 9 cases (18 eyes) were males, 14 cases (28 eyes) were female, age in 19~36, average age 29. All cases had preoperative SE -2.5 ~ -9.5 D. All patients had no lacrimal sickness and history of lacrimal duct embolism treatment.

The selection criteria are: (1) with preoperative moderate dry eye syndrome; (2) with Schirmer I test (SIt) values within 5 ~ 10 mm; (3) Break-Up Time (BUT) in 5 ~ 10 s range; (4) negative corneal fluorescence staining; (5) with history of taking artificial tears and still in inefficacy. All patients signed the hospital's **Ethics Committee Approval** and **Informed Consent** and voluntarily accepted VisiPlug lacrimal plug after the refractive surgery.

1.2 Methods All patients were applied routinely with 4 ~ 6 times/d artificial tears after refractive surgery. LASIK patients were applied with lacrimal duct embolism within 1w after the removal of bandage lens. Xero-dacryological evaluation were conducted before refractive surgery and VisiPlug insertion, and at 2w and 3m after VisiPlug operations, including procedures of : (1) using slit lamp microscope to exam ocular surface and observe corneal epithelium with fluorescein; (2) after fluorescent staining, measuring BUT between the last scardamyxis and the first dark spot appearing on the cornea; (3) taking SIt values by using a folded head-end 5 mm TearFlo sterile strip (Rose Stone, India) with 35 mm scale and placing it at 1/3 exterior of lower eyelid to take wetted length for 5 min with the patient's eye closed; (4) conducting questionnaire of eye syndromes (dryness, foreign body, inflammation, decayed light hypersensitivity, asthenopia, vision fluctuation).

On scale 0 ~ 4 (0: None, increasing with severity) on syndromes and evaluation on comfort level with VisiPlug (Very comfortable, good, fair, discomfort), which was taken scores subjectively from patient to patient.

Lacrimal Plug: The set of dissolvable VisiPlug (Lacrimedics, USA) was supplied by Beijing Medical Instruments. The lacrimal plugs (or punctal plug) came with two sizes in diameter, 0.4 mm and 0.5 mm.

Under slit lamp microscope, applied teardrop topical anesthesia with oxybuprocaine

hydrochloride, instructed the patient to stare straight, applied tender pressure to the lower eyelid to expose teardrop location, selected a correct size of Lacrimal plug and placed the plug with a pair of tweezers to the exposed teardrop location, followed by releasing the pair of tweezers and by using a swab to pull the lower eyelid skin to straighten the lacrimal canaliculus vertically and horizontally. Finally, the remaining plug was pushed into the lacrimal canaliculus by using the tip of the pair of tweezers. The patient then was instructed to blink to squeeze the plug further toward the lacrimal sac. As the operation was finished, checked the plug to ensure no exposure, followed by applying antibiotic eye drops.

1.3 Statistical Method The data analysis conducted was using SPSS 12.0.

"t-test" was adopted for the total average score of questionnaires, SIt and BUT over preoperative and postoperative periods. $P<0.05$ was used as the criterion for statistical significance.

2. Results

2.1 Overview Refractive surgeries were conducted successfully on all patients, with no postoperative complications. Nine cases (18 eyes) operated by LASEK, with bandage lens removed 5 ~ 7 d after the surgery, showed no epithelial tissue damage. The rest 14 cases (28 eyes) were operated by LASIK.

2.2 Survey on Lacrimal Plug Efficacy Posterior refractive surgery, the total score of 6 cases increased from preoperative 7.6 ± 3.2 to postoperative 13.6 ± 4.0, amongst, 6 cases of those of LASIK increased from preoperative 7.2 ± 2.8 to postoperative 13.7 ± 4.2.

After the lacrimal plug treatment, patients' dry eye symptom had obvious improvement, 6 cases had total score decreased from preoperative 13.6 ± 4.0 to postoperative 2w's 4.5 ± 2.3 and 3m's 3.8 ± 3.0, respectively. Compared with that of prior application of lacrimal plug, the deviation ($t = 27.403$, $P < 0.01$; $t = 17.863$, $P < 0.01$) had statistical significance. The comparison of the total score of 2w and 3m of after the application of lacrimal plug showed no statistical significance ($t = 1.515$, $P = 0.137$).

Three months after lacrimal plug, dry eye discomfort of 16 cases (32 eyes) was eliminated and applications of artificial tears reduced from preoperative 4~6 times/d to postoperative 1~2 times/d. Posterior discomfort of lacrimal plug of 6 cases (11 eyes) was totally eliminated, requiring no more application of artificial tears. That of one case (2 eyes) had no significant improvement, requiring applications of artificial tears 4 times/d to alleviate the syndrome.

Assessment of level of comfort postoperative lacrimal plug: two cases (4 eyes) scored well, 8 cases (15 eyes) scored good, and 13 cases (26 eyes) scored fair.

2.3 Corneal fluorescent staining 23 cases, priori refractive surgery, had corneal transparence and negative fluorescence staining. After the surgery, one case (2 eyes) had slight fluorescence staining spots on corneal epithelium. 2w after application of plug, one case, 2 eyes, still had the same symptom and 3m recheck still showed negative corneal fluorescence staining.

2.4 Sit and BUT Postoperative SIt values were 9.5 ± 2.5 mm and 10.6 ± 3.1 mm for 2w and 3m, respectively, obviously better than preoperative values of 6.9 ± 1.6 mm ($t = -10.626$, $P < 0.01$; $t = -7.483$, $P < 0.01$). The comparison of SIt values of 2w's and 3m's posterior application of lacrimal plug showed no statistical significance ($t = -0.257$, $P = 0.798$). The comparison of BUT values of 2w's and 3m's postoperative application of lacrimal plug had obvious increased from preoperative 6.7 ± 1.3s to 8.7 a-1.8s and 9.0 ± 1.8s, respectively, obviously better than the preoperative values ($t = -10.208$, $P < 0.01$; $t = -10.877$, $P < 0.01$). Postoperative 2w's and 3m's values showed no statistical significance ($t = -1.401$, $P = 0.168$).

2.5 Complications All patients had no epiphora and conjunctival hyperemia after VisiPlug operation. 6 eyes having mild postoperative foreign object discomfort, after normal blinking for 10 min, the symptom went away. One eye had loosing plug 1d after operation.

3 Discussion

As the refractive surgery gaining popularity, postoperative dry eye syndromes draw more attention. Refractive surgery might cause damage to corneal nerves, degradation of corneal sensation, postoperative reflex scardamyxis and reduction of tear secretion, corneal deformity, increasing abnormality and decreasing tear film stability, which can induce various dry eye (xerophthalmia) syndromes [4-12]. The damage to corneal nerves by LASIK flap procedure is more obvious, the microkeratome suction causes high incidences of postoperative dry eye syndromes. EBM studies also suggested that all refractive surgeries needing to take effective measures to intervene possible or severe postoperative dry eye syndromes [13-14]. Therefore, postoperative emphasis on dry eye syndromes after refractive surgery must be given sufficient attention.

Conditions of preoperative ocular surface plays a critical factor in postoperative dry eye syndromes [1,4, 8]. In case with preoperative dry eye problem, the patient will have higher probability of severe postoperative dry eye occurrence. This study conducted assessment on refractive surgeries for selected myopic patients with minor and moderate dry eye syndromes, patients continuously to have dry eye syndromes after applying artificial tears, and patients who have to have refractive surgery, postoperatively followed by VisiPlug treatment.

VisiPlug is made of polydioxanone suture (PDS) with 0.4 ~ 0.5 mm in diameter, easy to implant. When implanted under body temperature for a while, the plug will shrink in length and expand in width. It is dissolved after 180d. In case any discomfort or epiphora, the plug can be removed by syringing of the lacrimal passage.

During this study, it was noticed that patients felt worsening postoperative dry eye syndromes with dropping SIt and BUT. 6 cases applied with VisiPlug had apparent mitigation of dry eye symptom. Most patients had discomfort improved and applications of artificial tears reduced or stopped. One case (2 eyes) with sever preoperative dry eye symptom, requiring deeper ablation, had slower recovery and deduction in tear production. Postoperative application of VisiPlug did not show any improvement. 3m follow-up exam still indicated reliance on using artificial tears. Postoperative SIt and BUT are correlated with improvement and results after applying VisiPlug are obvious. Portion of patients had SIt and BUT returned to normal and all symptoms eliminated. As the corneal nerves recovering, corneal sensation and tear production were returning to normal.

Patients suffering preoperative dry eye, if taking proper postoperative measures, will have corneal epithelium intact or healed properly. In this study, except one case (2 eyes) had corneal epithelium impairment 2w after surgery, the rest cases all showed negative corneal fluorescence staining during follow-up check. During follow-up exam, no patients implanted with VisiPlug showed complications of epiphora, foreign object, puncta lacrimalis, dacryocystitis, etc. Only one case had object dropping out from inner canthus 1d after surgery, followed by reoccurrence of dry eye symptom. The specific was unknown, may be related to a loosing plug caused by improper implantation. Almost 50 % of patients accepted VisiPlug lacrimal plug well, which suggests VisiPlug being safe and comfortable for dry eye patients.

The past studies [9-12, 15-16] suggested, 3 ~ 6 months after the refractive surgery, most patients had dry eye syndromes eliminated or alleviated to minor suffering as corneal nerves recovers, ocular surface improves and tear secretion returns to normal. While VisiPlug dissolved around 180d after implantation, which differs from other plugs staying inside lacrimal passage for long time and causing complications such as epiphora and local infection, etc. It has more advantages than draw backs, suitable for postoperative treatment of dry eye syndromes after refractive surgery. It does not require surgical removal after implantation and it is safe and efficacious.

To summarize the above, early scheduled preventive intervention for postoperative refractive surgery patients, the procedure can deliver better postoperative recovery and vision improvement. Patients with minor dry eye symptom, after the application of VisiPlug, can have obvious relief, increasing tear production and tear film stability, reducing or even

replacing the application of artificial tears. However, further assessment over more samples and longer period of follow-up examination for clinical efficacy of VisiPlug is still required.

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Q & A

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1. Which of the following does not belong to retinal vasoproliferative tumor?

A. Mostly found in lower half of peripheral of retina, especially retina at inferior temporal;

B. Pathologically mixed abnormal proliferation of imbalanced vessel tissues and glial cell;

C. Often found in middle-aged and elderly patients;

D. Often secondary vasoproliferation.

2. Different clinical manifestations between retinal cone cell under-nutrition and Stargardt are:

A. Anomalopia often found before impaired vision acuity;

B. Fundus appearing as buphthalmia;

C. Genetic heterogeneity or manifold of heredity;

D. Usually separated from nyctalopia.

3. Showing serous retinal detachment but no inflammatory reactions are:

A. Vogt-Koyanagi-Harada syndrome;

B. Choroidaltumor, especially, metastatic tumor;

C. Sympathetic Ophthalmia;

D. Disseminated intravascular coagulation (DIC).

4. Which of the following description about Oguchi isease (Cogche's disease) are incorrect?

A. Genetic nyctalopia;

B. Different retina colors under light and dark adaptations;

C. Normal light adaptation electroretinography, dark adaptation electroretinography with a, b waves attenuation or invisibility;

D. Autosomal recessive inheritance with normal field of vision and chromatic sensation.

5. Which one of the following does not belong to Stickler syndrome?

A. High myopia since childhood with RD;

B. Systemic anomaly including flat face, cleft, and bone dysplasia;

C. Ocular anomalies including vitreous optical cavity with cord, myopia and retinal lattice degeneration;

D. Belonging to autosomal dominant inheritance, seldom also having glaucoma and cataract.

6. Which of the following related to juvenile xanthogranuloma are incorrect?

A. Belonging to non-neoplastic histiocytosis with poor prognosis;

B. Manifesting as idiopathic anterior chamber hemorrhage, increased anterior chamber cells

and intraocular pressure, etc;

C. Xanthomas ;

D. Cases of acute attack requiring treatment with cortical hormone.

7. Which of the following related to syphilis are incorrect?

A. Congenital syphilis on minor manifesting as erythra, hepatosplenomegaly, fundus oculi and Choroidal inflammation;

B. Congenital syphilis with good reaction to Corticosteroids;

C. Inflammatory response induced by acquired syphilis at anterior or posterior segment as posterior vitreous inflammation manifestation, papillitis, etc.

D. Hormone therapy efficacious for acquired syphilis effect.

8. Which of the following about ocular toxocariasis are incorrect?

A. Often coming with systemic ocular toxocariasis manifestation, such as fever, irritability, pale complexion, etc.

B. Deterministic diagnosis by clinical examination, history, and ELISA (Enzyme Linked Immunosorbent Assay);

C. Human as intermediate host whose stool sample test for ova and parasite pathol ogically meaningless;

D. Ocular toxocariasis treatment with anti-worm medicine taken by per os or periocular injection potentially severity additive.

9. Which of the following does not belong to morning glory syndrome symptom?

A. Mostly unilateral and poor vision since childhood;

B. Retina tissue with different degree of pigmentation encircling optic disc;

C. Choanoid around the center of optic disk with fundus covered with cotton velvet-like material and white color in center;

D. Over 10 or 20 vessels in various diameters radiant straightly outward through choanoid peripheral, showing leakage on fluorescence imaging.

10. Which of the following related to Fuchs' heterochromic uveitis are incorrect?

A. Mostly common complications including cataract and glaucoma;

B. Mostly moderate monocular morbidity;

C. Possibly with vitreous opacity;

D. Often seeing tiny KP over cornea and posteriori synechia.

(Answers are given in this issue)

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