Int. J. Oral Maxillofac. Surg. 2016; xxx: xxx–xxx
http://dx.doi.org/10.1016/j.ijom.2016.06.008, available online at http://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical Paper
Trauma

A prospective randomized study comparing fibrin sealant versus suture for conjunctival wound closure in orbital wall fracture surgery

H.-J. You, S.-T. Son, D.-Y. Kim, S.-K. Han
Department of Plastic Surgery, Korea University College of Medicine, Seoul, Republic of Korea

H.-J. You, S.-T. Son, D.-Y. Kim, S.-K. Han: A prospective randomized study comparing fibrin sealant versus suture for conjunctival wound closure in orbital wall fracture surgery. Int. J. Oral Maxillofac. Surg. 2016; xxx: xxx–xxx. © 2016 Published by Elsevier Ltd on behalf of International Association of Oral and Maxillofacial Surgeons.

Abstract. The purpose of this randomized prospective study was to compare the clinical outcomes of orbital wall fracture surgery involving transconjunctival wound closure with fibrin sealant to the outcomes achieved with a conventional suture method. All surgeries were performed using the same technique, except that the conjunctival closure was achieved using either a buried 6–0 Vicryl suture ($n = 10$) or fibrin sealant ($n = 10$). The time to conjunctival closure and time required for complete wound healing were investigated. Postoperative discomfort in the two groups was compared at day 1, day 3, week 1, and week 4. Postoperative subconjunctival haemorrhage and peri-orbital ecchymosis were observed. The mean conjunctival closure time was significantly shorter in the fibrin group than in the suture group. All conjunctival wounds healed by the end of the first week. On postoperative days 1 and 3, the discomfort scores were significantly lower in the fibrin group. Subconjunctival haemorrhage and peri-orbital ecchymosis were less frequent in the fibrin group. Fibrin sealant proved to be as effective as sutures for conjunctival wound closure. Fibrin sealant allows a more comfortable early postoperative course and may be an excellent alternative for conjunctival wound closure in orbital wall fracture surgery.

Key words: conjunctival wound closure; fibrin sealant; fibrin glue; orbital wall fracture surgery.

Accepted for publication 9 June 2016

Orbital wall fractures are a common result of orbital trauma. The transconjunctival approach to orbital wall fracture repair has been used widely by many plastic surgeons and is associated with a lower risk of postoperative complications, including lid malposition. This technique allows rapid access to the inferior orbital rim and floor, provides adequate exposure for fracture visualization, and produces no visible scars.[1,2]

Usually, a 6–0 polyglactin suture is used to close the transconjunctival incision during orbital wall fracture surgery; however, such sutures can cause irritation and discomfort in the early postoperative period.

0901-5027/000001+06

Please cite this article in press as: You HJ, et al. A prospective randomized study comparing fibrin sealant versus suture for conjunctival wound closure in orbital wall fracture surgery, *Int J Oral Maxillofac Surg* (2016), http://dx.doi.org/10.1016/j.ijom.2016.06.008

In addition, other suture-related complications may occur, such as a prolonged inflammatory reaction at the suture site, suture granuloma, and conjunctivitis.[3] It is believed that such problems could be minimized with the use of fibrin sealant as an alternative transconjunctival closure method.

Recently, wound closure with fibrin-based tissue adhesives has gained increased acceptance in other types of ocular surgery, including conjunctival closures in pterygium and strabismus surgery. Fibrin sealant (also called fibrin glue) is a biological glue composed of fibrinogen and thrombin. The adhesive properties of fibrin glue have proven useful for preventing excessive bleeding and enhancing tissue adhesion.[3] Many previous studies have identified a high biocompatibility and shortened operative time with fibrin sealant, but fewer reports have objectively compared fibrin sealant and sutures for conjunctival wound closure, especially during orbital wall fracture surgeries.[3–8] The purpose of this study was to compare the efficacy and tolerance of fibrin sealant and sutures for closure of the transconjunctival incision in orbital wall fracture surgery.

Materials and methods

A prospective randomized study involving 20 patients with orbital wall fractures was conducted from December 30, 2013 to February 25, 2015. This study was approved by the necessary institutional review board. Written informed consent was obtained from all participants.

Patients

The selected subjects were aged 19 years or older, had been diagnosed with orbital wall fractures, and were scheduled to undergo orbital fracture surgery via transconjunctival incision. However, those who required combined transcaruncular or lateral canthotomy approaches were excluded. Other exclusion criteria were pregnancy or lactation, an inability to understand the given explanation of the procedures prior to providing consent, and current treatment with corticosteroids, immunosuppressive agents, or anti-platelet agents.

Patients were enrolled and randomized into one of two treatment groups: in the fibrin group, conjunctival closure was achieved using a fibrin sealant kit (Beriplast P Combi-Set; CSL Behring, Marburg, Germany); in the suture group, closure was achieved using a buried 6–0 polyglactin suture (Vicryl; Ethicon US LLC, Cincinnati, OH, USA). Randomization schedules were stratified using a permuted-block method with a block size of 4–6, and a statistical analysis system and treatment allocation ratio of 1:1.

Surgical techniques

Surgery was performed within 1–20 days after the injury (average 9.4 ± 5.7 days). All subjects underwent surgery while under general anaesthesia. After the forced duction test, corneal protectors were inserted. Two pairs of 6–0 Prolene traction sutures were placed on the upper and lower ciliary margins. The lower eyelid was everted and then the position of the lower tarsal plate through the conjunctiva was noted. Three pairs of 6–0 Prolene sutures were placed just superior and inferior to the designed incision line, which was located 2–3 mm beneath the inferior border of the tarsal plate. The conjunctiva was infiltrated with 2% lidocaine containing epinephrine 1:100,000. A number 15 blade was used to incise the conjunctiva. A conjunctival/lower lid retractor flap was elevated using a Bovie cautery. A pre-septal dissection was performed carefully. The dissection plane was located between the orbicularis oculi muscle and the orbital septum towards the inferior orbital rim. Soft tissue overlying the inferior orbital rim was incised using the Bovie cautery while protecting the globe and intra-orbital contents with a malleable retractor. The periosteum was incised on the arcus marginalis, and sub-periosteal dissection was performed with a Freer elevator; the fractured orbital floor was subsequently exposed. After repositioning the displaced peri-orbital tissue, a titanium-reinforced porous polyethylene implant (SynPOR; Synthes, West Chester, PA, USA) was trimmed adequately, bent to shape, and placed over the fracture site. The forced duction test was repeated to ensure complete release of the peri-orbital tissues, as well as unrestricted superior and inferior movement of the globe. The position of the implant was re-checked to confirm that no migration had occurred during the forced duction testing. The periosteum was suspended or sutured to the inferior orbital rim with an interrupted 5–0 polyglactin (Vicryl) suture. At the end of the surgery, all traction sutures were removed, and conjunctiva closure was achieved in each group as described previously.

In the fibrin group, 3–5 drops of fibrin sealant were instilled on both edges of the conjunctiva, and moderate pressure was applied using a pair of forceps to achieve firm adhesion (Fig. 1). In the suture group, the conjunctiva was closed with 4–6 stitches of buried 6–0 polyglactin suture (Vicryl). A foam dressing was applied to the infraorbital area for compression in both groups. Postoperatively, antibiotic eye drops and ointment were applied four times daily in both groups until complete wound healing was achieved.

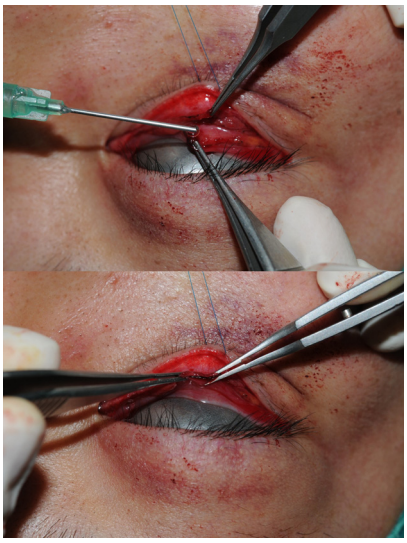

Fig. 1. Top: application of fibrin sealant to the transconjunctival incision. Bottom: sutureless closure of the conjunctiva.

Evaluation

The wounds were evaluated daily until complete wound healing was achieved. The wound evaluation was performed in a single-blind fashion. The patients were not aware of the method of treatment, although this factor was known to the wound evaluators.

The primary efficacy criteria were the mean conjunctival closure time and the mean time required for complete healing. Complete healing was defined as a completely epithelialized state with no discharge. Patient discomfort was assessed using a visual analogue scale (VAS; range 0–10, with a score of 0 indicating 'no discomfort at all' and a score of 10 indicating 'the worst discomfort') on days 1, 3, 7, and 28 and compared between the fibrin and suture groups. Postoperative subconjunctival haemorrhage and peri-orbital ecchymosis were also observed on days 1, 3, 7, and 28 in both groups. Furthermore, safety was monitored at the indicated time points by evaluating adverse events.

Please cite this article in press as: You HJ, et al. A prospective randomized study comparing fibrin sealant versus suture for conjunctival wound closure in orbital wall fracture surgery, *Int J Oral Maxillofac Surg* (2016), http://dx.doi.org/10.1016/j.ijom.2016.06.008