A new method using xenogeneicacellular dermal matrix in the reconstruction of lacrimal drainage

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ABSTRACT
Aims To prospectively evaluate the reliability and efficacy of a new treatment for the reconstruction of the lacrimal duct using a new histo-engineered material, xenogeneic (bovine) acellular dermal matrix.

Method Five patients (five eyes) with partial or total absence of the lacrimal duct were included in the study. Four patients (four eyes) suffered from traumatic injuries to the lacrimal duct and one patient (one eye) had congenital absence of the lacrimal drainage system. A pedicle graft of conjunctiva was taken from the fornix area and rolled into a tube structure after being attached to the acellular dermal matrix.

Results The average duration of follow-up for the patients was 7.2 months (ranging from 6 to 12 months). After surgery, the new duct in the nasal cavity could be observed above the middle turbinate by nasal endoscopy. Patency was confirmed by pressing in the area of the lacrimal sac and visualising air bubbles in the nasal cavity. Additionally, the meatus above the middle turbinate of the nasal cavity was stained and visualised after patients underwent Jones dye test 1 (JDT1). Five tear ducts proved to be effective through irrigation testing and epiphora symptoms were alleviated in all cases.

Conclusions The newly reconstructed lacrimal duct, formed by the shift of autogenous conjunctival petal and the attachment of acellular dermal matrix, was successful in all five cases and suggests a new solution for the complex lacrimal duct lesion and congenital anomalies of the lacrimal duct.

INTRODUCTION
Lacrimal duct injury is a common problem in facial trauma, and it is often accompanied by angular deformity, eyelid injury or orbital fracture. The spectrum of severity ranges from simple lacrimal canaliculard laceration to more complex injuries, such as distortion, laceration and displacement in the whole lacrimal drainage duct. Congenital absence of lacrimal puncta in children is a very rare condition. Congenital absence of bilateral whole lacrimal duct (the lack of the puncta, lacrimal canaliculi, lacrimal sac and nasolacrimal duct) is much rarer.1

The formation of a new duct for the treatment of these recalcitrant lacrimal system obstructions is especially challenging worldwide. Many previous studies took advantages of nasal mucoperiosteal flaps, venous vessels and oral mucosa ectcetera to reconstruct new tear conduits. These studies chose Jones tube or extradural tube as the support in the new duct after surgeries.2–4 However, disadvantages relating to internal support were observed. In spite of the high rate of functional success in the early postoperative stage, these methods were noted to be associated with low rate of patient satisfaction and a number of complications. One such complication was prolonged inflammation resulting in ductal atresia and graft rejection necessitating removal. One study showed the use of Medpor glass tubes in rebuilding the lacrimal duct;5 however, this could cause chronic inflammation and tissue growth, leading to tube blockage and many patients in underdeveloped areas could not afford the great expenses of this tube. Therefore, exploring and creating an effective and reliable tear drainage system is an important area of development in the reconstruction of lacrimal drainage systems.6–9

The aim of this study is to explore a new treatment for the reconstruction of the lacrimal duct by using a histo-engineered material, xenogeneic (bovine) acellular dermal matrix, and prospectively evaluating the reliability and efficacy of this approach.

MATERIALS AND METHODS
Patients
A review was conducted for the recruitment of five patients (five eyes) with partial or total absence of the lacrimal duct. These patients were admitted to Sichuan Provincial People’s Hospital during July 2012 and February 2013. Four patients suffered traumatic injuries to the lacrimal duct (four eyes) and one patient had a congenital absence of the lacrimal duct (one eye) (figure 1A–E). There were two male (two eyes) and two female (two eyes) patients with trauma (table 1). The fifth patient was a 9-year-old boy with a congenital abnormality of the tear duct. The four traumatic cases received operations 9 months to 1 year from when the accident occurred. All patients presented with complaints of epiphora.

Methods
All cases underwent a complete eye examination including assessment for any associated ocular injuries. The four cases with traumatic lacrimal duct injury received probing of the lacrimal system; however, the probe could not completely pass through the upper and lower lacrimal canaliculus confirming lacrimal injury. A CT scan was used to show higher tissue density and bony pieces in the lacrimal sac area. Fracture and obstruction of the naso-lacrimal duct were found in these cases. The lacrimal puncta in the 9-year-old boy’s eyes could not be found bilaterally on slit lamp examination (figure 1B–E). The colour Doppler ultrasonography examination for this patient showed no...
obvious lacrimal sac structure in both sides. Absence of lacrimal sac was suspected, and the right eye was chosen for operation at random. Surgical materials included Heal-all Oral Biofilm, xenogeneic (bovine) acellular dermal matrix provided by Yantai Zhenghai Bio-Technology Co., Ltd (size: 2 cm×2.5 cm).

Procedures:
1. A skin incision was placed in the medial canthal region. A subcutaneous tunnel was created between the lacrimal fossa and the lacrimal caruncle (figure 2A).
2. A patch of 2.0 cm×0.8 cm conjunctival petal from the conjunctival fornix area that served as a free graft (figure 2B). The Heal-all Oral Biofilm was immersed in normal saline so that the conjunctival petal could attach to the oral biofilm (figure 2C).
3. The reconstructed complex of biofilm and conjunctival petal was rolled and fixed by suture into a tube-like structure, thus forming a duct with the conjunctival epithelium forming the inner wall and the biofilm the outer wall (figure 2D). The calibre of the complex conduit was approximately 2–3 mm length.
4. A bony window was created to expose the underlying nasal mucosa, which was cut in an ‘H’ shape.
5. The premade lacrimal duct was brought through the tunnel with one end fixed onto the lacrimal caruncle area, and the other end was anastomised with nasal mucosa. The centre area of the duct was fixed to the surrounding orbicular muscles by suture (figure 2E). Thus, a tear drainage conduit leading into the nose was successfully established.

RESULTS
The average duration of follow-up for the five patients was 7.2 months (ranging from 6 to 12 months). Epiphora symptoms disappeared after surgery (table 1). The opening side of the newly reconstructed lacrimal duct could be seen in the lacrimal caruncle after surgery (figure 2A). The Heal-all Oral Biofilm was immersed in normal saline so that the conjunctival petal could attach to the oral biofilm (figure 2C).

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age</th>
<th>Preoperation</th>
<th>Postoperation</th>
<th>Angular deformity</th>
<th>JDT1 test</th>
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<td>1</td>
<td>Female</td>
<td>19</td>
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<td>Disappeared</td>
<td>Improved</td>
<td>(+)</td>
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<td>Epiphora and angular deformity and fracture</td>
<td>Improved</td>
<td>Improved</td>
<td>(+)</td>
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<tr>
<td>3</td>
<td>Female</td>
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<td>Epiphora and angular deformity and fracture</td>
<td>Improved</td>
<td>Improved</td>
<td>(+)</td>
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<tr>
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<td>Male</td>
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<td>Epiphora</td>
<td>Disappeared</td>
<td>–</td>
<td>(–)</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>9</td>
<td>Epiphora</td>
<td>Disappeared</td>
<td>–</td>
<td>(–)</td>
</tr>
</tbody>
</table>

–, no angular deformity; +, positive result of the patients examined by JDT1 test; JDT, Jones dye test.

Figure 1 A nine-year old boy with congenital absence of total lacrimal drainage. This patient has a normalexternal appearance (A) with absence of bilateral upper and lower lacrimal puncta (B–E).
This study reports a new approach in the reconstruction of the lacrimal duct. This fistula was lined entirely with normal mucosal epithelium and was followed up for half a year. The inner wall of the new duct was patent and epithelialised. At the first step, and when the mucosal duct reconstruction was finished it will degenerate automatically in the surrounding tissues. This study reports a new approach in the reconstruction of the lacrimal duct that addresses the issue of support for the new conduit as well as the histological structure of the inner wall on the lacrimal drainage system. We used an outer support to envelop the reconstructed lacrimal duct, xenogeneic (bovine) decellularised dermal matrix, which had a good cellular framework, certain elasticity and supportive features. Thus, the new conduit could maintain a stable position and patency for long-term tear drainage. We chose the conjunctival petal to set up an alternate draining route for tear passage. For the complex lacrimal duct lesion and congenital anomalies of the new duct.

Creating decellularised whole organ allograft created a new field of study and a promising future technology. Decellularised tissues have been reported to regenerate a variety of tissues, such as skin, trachea, cardiac valve, heart, lung, liver, kidney, vascular, muscle; the inner wall covered by mucosal tissue that has secretory and anti-infection qualities; (5) no immunogenicity and can exist in the body for a long time without ocular irritation.

**DISCUSSION**

In the present study, we chose a new surgical method in lacrimal duct reconstruction, which is the conjunctiva that consists of thin and frail, making it in itself liable to external compression and adhesion and closure with the contraction of the orbicularis muscle; (4) the inner wall covered by mucosal tissue that has secretory and anti-infection qualities; (5) no immunogenicity and can exist in the body for a long time without ocular irritation.

Recently, major achievements in creating decellularised whole organ allograft have been reported worldwide.10 So far, there is no report about the application of decellularised dermal matrix in lacrimal duct reconstruction. As a bridge between the conjunctival sac and nasal cavity, the drainage system should meet the following requirements: (1) the tear passage should maintain unobstructed drainage; (2) no chronic proliferation of granulation tissue that could obstruct the duct or meatus; (3) the inner wall of lacrimal duct will not adhere and collapse; (4) the inner wall covered by mucosal tissue that has secretory and anti-infection qualities; (5) no immunogenicity and can exist in the body for a long time without ocular irritation.

The oral biofilm is capable of degenerating and regenerating simultaneously. Thus, it will induce the pipe shape from the surrounding tissues in the first step, and when the mucosal duct reconstruction is finished it will degenerate automatically in the second step. After the autologous tissue takes shape, the scar proliferation and occlusion will not occur to the anastomosis of both ends of newly built lacrimal duct, and the newly formed lacrimal duct will not adhere and collapse.

In conclusion, this surgical method suggests a new solution for the complex lacrimal duct lesion and congenital anomalies of the lacrimal duct using acellular dermal matrix.
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Contributors  LC, ZW, CQ and RC: contact and interact with patients. BG: wrote the manuscript. JJ: corrected the manuscript.

Competing interests  None

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Figure 3  Photograph of the opening end of the newly-built lacrimal ducts. The intra-operative picture shows the opening of newly-rebuilt lacrimal duct in the lacrimal caruncle (A). The amplification figure of the newly-rebuilt lacrimal duct in the lacrimal caruncle (B). The appearance of the tear conduit on the lacrimal caruncle 5 days after surgery. The arrow refers to the opening point with suture and swollen conjunctiva (C). The appearance of the lacrimal caruncle 1 year later after surgery. The arrow refers to the area, where it is difficult for us to find the opening point (D). The opening point of the new duct was observed above the middle turbinate under nasal endoscopy. When we pressed the lacrimal sac area, we could see the air bubbles flow out from the new duct via nasal endoscope (the green arrow, E). The arrow refers to the staining on the tear duct opening nasally visualized by nasal endoscopy after the JDT1 test (F).
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