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Mechanical properties of collagen membranes modified with pores – are they still sufficient for orbital floor reconstruction?

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Abstract

Adequate mechanical strength is essential for materials used to reconstruct the orbital floor, and collagen membranes have recently been suggested for the repair of isolated fractures of the orbital floor. However, their mechanical properties after modification with pores for increased drainage of blood into the sinus have not been sufficiently investigated. We have tested the mechanical resistance of polydioxanone foils (PDS) to distortion and compared it with that of 3 resorbable collagen membranes (Smartbrane®, Bio-Gide®, and Creos®) in mint condition and when artificially aged (3 weeks, 6 weeks, and 8 weeks) after modification with pores (diameter 2 mm) in a standard configuration (n = 12 in each group). PDS and Creos® had comparable initial values for mechanical resistance of about 2.3 N/mm^2, and Bio-Gide® and Smartbrane® had about 20% and 80% lower initial mechanical resistance, respectively. All materials tested had lower values after artificial ageing. After eight weeks of ageing, PDS lost about 99% of its initial mechanical resistance, Creos® about 66%, Bio-Gide® about 30%, and Smartbrane® about 95%. After 3 weeks the mechanical resistance in all groups was significantly less than the initial values ($p = 0.05$), but there was no difference between samples aged artificially for 6 compared with 8 weeks. The mechanical resistance of the tested materials was not influenced by the presence of pores in a standard configuration and was in the appropriate range for moderate fractures of the orbital floor. We recommend further clinical investigations of collagen membranes modified with pores.

Keywords: Orbital floor; Collagen membrane; PDS; Orbital floor reconstruction

Introduction

One of the most common reconstructive procedures in oral and maxillofacial traumatology is the reconstruction of fractures of the orbital floor.[1,2] The clinical findings (haematoma, hyposphagma, enophthalmos, paraesthesia of the cheek, diplopia, and dysfunctional eye movements) and the diagnostic procedures (computed tomography and cone-beam computed tomography) are widely accepted.[3,4] However, there is ongoing discussion about the correct material for reconstruction. For isolated fractures of the orbital floor we use resorbable materials, and for large, complex ones we use

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3-dimensional bendable or manufactured materials (such as titanium or silicone).[5–9]

A rare but severe postoperative complication of reconstruction of the orbital floor is retrobulbar haematoma, which may lead to loss of vision if untreated.[10–12] An increased intraorbital volume of blood of about 1 – 2 ml leads to compression of the optical nerve and the central artery of the retina, with resulting hypoxaemia of the tissue, which is usually treated with decompression by lateral canthotomy and removal of the reconstructive material.

Polydioxanone (PDS) foils and titanium implants are widely used for reconstruction and they contain pores. However, because they are commonly used in augmentation as a resorbable barrier to prevent invasion of soft tissue, collagen membranes do not possess pores. The pore pattern of titanium implants and PDS foils prevent retrobulbar haematoma caused by drainage into the maxillary sinus.

In the present study, therefore, we wanted to find out whether the mechanical properties of collagen membranes after modification with pores were adequate materials with which to reconstruct the orbital floor.

Material and methods

The modification of the membranes to create pores was made after the pore pattern of a PDS foil had been transferred on to a membrane with a permanent marker. Subsequently, a 2.0 mm biopsy punch (BP-20F, Kai Medical Europe GmbH, Solingen, Germany) was used to cut out round pores (Fig. 1).

Mechanical resistance of the porcine resorbable and pliable collagen membranes and the PDS foils to distortion testing was tested with a Zwick Z010 TN1 universal testing machine (Zwick GmbH, Ulm, Germany; Fig. 2). The universal testing machine consisted of a square with a height-adjustable horizontal transverse arm. The transverse arm was modified with a high-definition force transducer and a punch (diameter, 5.5 mm (23.758 mm^2)). The height of the punch was adjusted with software (testXpert® II, ZwickRoell GmbH, Ulm, Germany). The first/initial position for changing the membranes was about 200 mm above the membrane. Before we started the test procedure, we calibrated the software for the correct height of the transverse arm, and the force transducer in the initial position was set to zero using the integrated buttons in the software. After the test procedure had been started, the punch was brought down about 2 mm above the membrane. It was subsequently moved forwards 12 mm at a continuous speed of 2 mm/minute, navigated by the software (Fig. 3).

The collagen membranes Creos® (0.2 mm, Nobel Biocare, Cologne, Germany), Smartbrane® (0.1 mm, Regedent, Zurich, Switzerland, available from 1 August 2015), and Bio-Gide® (0.4 mm, Geistlich, Wolhusen, Switzerland) as well as the PDS foil (0.15 mm, Ethicon, Norderstedt, Germany) were tested initially in mint condition and then after artificial ageing with fetal calf serum (GIBCO, FBS South American, Ref. 41F3496K, Catalogue No. 10270-106, Invitrogen, Darmstadt, Germany) in an incubator at 37 °C for 3 weeks, 6 weeks, or 8 weeks (Fig. 4). The specimens of membrane were stored in 6-well plates and incubated with the fetal calf serum. They were then stored for 3 weeks, 6 weeks, or 8 weeks in the incubator. Twelve membranes/foils were tested for each group.

Statistical analysis

WinSTAT add-in software for Microsoft Excel (Version 2012.1, R. Fitch Software, Bad Krotzingen, Germany) was used for the statistical analyses. The normality of the distribution of the data was tested using the Kolmogorov-Smirnov test and this having been established, the significance of differences was assessed using analysis of variance (ANOVA). Probabilities of less than 0.05 were accepted as significant.

Results

The results of the evaluation of the mechanical resistance to distortion of the materials are summarised in Table 1. The PDS foil and Creos® membrane exhibited comparable initial values of about 2.3 N/mm^2. The Bio-Gide® membrane had about 20% lower initial mechanical resistance, and the resistance of the Smartbrane® was about 80% lower. All materials tested had reduced values after artificial ageing. After 8 weeks the PDS foil lost about 99% of its initial value, Creos® lost about 66%, Bio-Gide® lost about 30%, and Smartbrane® lost about 95%. In all groups after 3 weeks there was a significant reduction in the mechanical resistance ($p = 0.05$) from the initial value, but there was no significant difference between samples artificially aged for 6 compared with 8 weeks.

Discussion

This is the first study to our knowledge that has provided data about the mechanical resistance of collagen membranes modified with a pore pattern compared with the mechanical resistance of widely-used PDS foils.[7] The common uses of collagen membranes include augmentation of the sinus floor or jaw with substitute bone materials and autologous bone.[13] The membranes serve a barrier function to prevent soft tissue migrating into the substitute bone. In a recent study, these collagen membranes were tested for their mechanical resistance in fractures of the orbital floor, and the values indicated adequate strength.[14] However, drainage of blood and tissue fluid is important in the prevention of retrobulbar haematomas, which have been described in 1%-4% of patients with facial or cranial trauma, and of 1386 patients, 2 lost their vision.[15]

There are some single case reports and data that indicate that vision is lost by up to 8% of patients.[10–12] Postoperative bleeding and formation of a retrobulbar haematoma with loss of vision are an emergency and require immediate treatment