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Microstructure and mechanical properties of synthetic brow-suspension materials

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ABSTRACT

Levator palpebrae superioris (LPS) is a muscle responsible for lifting the upper eyelid and its malfunction leads to a condition called “ptosis”, resulting in disfigurement and visual impairment. Severe ptosis is generally treated with “brow-suspension” surgery, whereby the eyelid is cross-connected to the mobile tissues above the eyebrow using a cord-like material, either natural (e.g. fascia lata harvested from the patient) or a synthetic cord. Synthetic brow-suspension materials are widely used, due to not requiring the harvesting of fascia lata that can be associated with pain and donor-site complications.

The mechanical properties of some commonly-used synthetic brow-suspension materials were investigated — namely, monofilament polypropylene (Prolene®), sheathed braided polyamide (Supramid Extra® II), silicone frontalis suspension rod (Visitec® Seiff frontalis suspension set), woven polyester (Mersilene® mesh), and expanded polytetrafluoroethylene (Ptose-Up). Each material underwent a single tensile loading to the failure of the material, at three different displacement rates (1, 750 and 1500 mm/min).

All the materials exhibited elastic–plastic tensile stress–strain behaviour with considerable differences in elastic modulus, ultimate tensile strength, elastic limit and work of fracture. The results suggest that, as compared to other materials, the silicone brow-suspension rod (Visitec® SFSS) might be the most suitable, providing relatively long-lasting stability and desirable performance. These findings, together with other factors such as commercial availability, cost and clinical outcomes, will provide clinicians with a more rational basis for selection of brow-suspension materials.

1. Introduction

Ptosis is a condition characterised by drooping of one or both upper eyelids, resulting in visual impairment and disfigurement; as ptosis can be congenital or acquired, it impairs the quality of life of many people from infancy to the aged. Ptosis arises from many causes, such as eyelid tumours, injury to the oculomotor nerve, or maldevelopment of the levator palpebrae superioris muscle (LPS) that is responsible for lifting the upper eyelid. Amongst the various methods for treatment of ptosis, “brow-suspension” surgery is usually performed where there is poor or absent LPS function: during the surgery, the upper eyelid is internally attached to the frontalis muscle using brow-suspension materials to aid the poorly-functioning LPS [1–3].

Fascia lata is commonly used as a brow-suspension material due to its high efficacy and low rate of complications (such as granuloma formation, infection or long-term extrusion) as compared with other suspensory materials [4–7]. However, harvesting the fascia lata requires an extra incision on the patient's leg, that may result in early postoperative leg pain or impaired gait, and carries a risk of persistent scarring [8]; the extra surgery also increases the operative time and the risk of infection, and harvesting sufficient fascia lata may be problematic in small children [4,6]. These limitations with the biological fascia lata have led to the use of alternative, synthetic filamentous materials — such as silicone rod [9–12], polyester mesh [13–16], expanded polytetrafluoroethylene (ePTFE) strip [17–19], monofilament polypropylene [20,21] and braided polyamide [22–24]. These synthetic materials, being readily available and easy to handle, are used widely in a brow-suspension surgery — either as a permanent solution, or as a temporary suspensory material in very small children.

When implanted, any brow suspension material will be subjected to a rapid tensile stretch during blinking and therefore the mechanical characteristics of such materials are important, as described in the examples below:

- Stress–strain relationship: the stress or strain induced by a blinking action must lie within the elastic region of stress–strain curves for

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the material so that the material can return to its original configuration after the stretch during blinking.
- Tensile strength and work of fracture, the latter is related to the "toughness" of the material: this property provides an indication of how much strength/load the material can endure before its fracture — which might be practically useful during knot-tying.
- Elastic modulus or rigidity: to comprehend the degree of pliability of the material for its handling and control during the surgical procedure and knot security.

Many papers have reported the mechanical properties of surgical suture materials such as Gore-Tex®, Prolene®, Mersilene® and monofilament nylon (Ethicon®) [25–32], as they are widely used in several branches of surgery — such as tendon repairs and cardiovascular, gynaecological or orthopaedic surgeries. To date, however, there have been no reported comparisons of the mechanical properties of commonly-used brow-suspension materials. Furthermore, most reported tensile tests for suture materials have been performed at a strain rate ranging from 3 to 50 mm/min; considering that the peak speed during blinking can reach 15 000 mm/min [33], the reported values of tensile strength and elastic modulus might not represent the actual ones in this particular usage.

The surgeon's choice of brow-suspension material is based upon various considerations, such as the patient's age and overall health condition, the intended duration for the implant, the professional experience during previous ophthalmic procedures, and some knowledge of the biological and physical properties of the material. The material selection is a key factor in achieving a stable and long-lasting lift of the dysfunctional upper eyelid and, in order to assist surgeons in their choice of material, the mechanical properties of suspensory materials are investigated in this study.

This study is focused on five commonly-used synthetic suspensory materials and tensile tests were performed to estimate the stress–strain relationship, ultimate tensile strength, work of fracture and elastic modulus. Three different strain rates, ranging within the capability of the tensile-testing apparatus, were employed to assess the influences of the strain rate on the mentioned mechanical characteristics. In addition, the microstructure of the suspensory materials was examined before and after the mechanical tests.

2. Materials and methods

2.1. Materials

The following commonly-used synthetic brow-suspension materials were purchased and used as received:

4-0 monofilament polypropylene (Prolene®; Ethicon Ltd., UK),
3-0 sheathed braided polyamide (Supramid Extra® II; S. Jackson Inc., USA),
Silicone frontalis suspension rod (Visitec® Seiff frontalis suspension set (Visitec® SFSS); Beaver-Visitec International Ltd., UK),
Woven polyester mesh (Mersilene® mesh; Ethicon Ltd., UK),
Expanded polytetrafluoroethylene (Ptose-Up; FCI Ophthalmics Inc., USA).

2.2. Tensile testing

Uniaxial tensile tests of the unknotted brow-suspension materials were performed using a testing machine (Hounsfield, Redhill, England) controlled by a computer software (QMat 5.44, SDL Atlas, Rock Hill, SC, USA). Different grips were used to securely hold the materials, depending on their shape. For suture-type materials (Prolene®, Supramid Extra® II and Visitec® SFSS), two polished aluminium cylinders of 10 mm diameter were used in series. Each suture material was passed once around the aluminium cylinders and fixed to metal pegs with a slip knot at each end in order to ensure the secure anchorage of the material during the tensile tests; the slip knot being applied in order to minimise the local stress concentration around the knot during the tests. This mounting set-up could not be used for mesh-type materials (Mersilene® mesh and Ptose-Up), while retaining their original cross-sections, since applying slip knots would have caused appreciable deformation of the materials, most likely generating high local stress concentration. Hence, apposing rectangular clamps with rubber contact surfaces were used instead to securely grip the mesh-type specimens, each end of a specimen being mounted by manually tightening the screws. A double-sided adhesive tape was also needed to prevent slippage of the Ptose-Up samples on the rubber surfaces during tests.

Once a specimen was mounted onto the testing apparatus with a nominal gauge length of 50 mm for the suture-type materials and 15 mm for the mesh-type materials, the overhead grip was programmed to move upward at a pre-determined displacement rate until the specimen broke. For each material three different displacement rates were investigated: "slow" (1 mm/min), "intermediate" (750 mm/min) and "fast" (1500 mm/min). Due to its substantial capacity for elongation, the Visitec® SFSS silicone rod was tested using a "slow" displacement rate of 5 mm/min and, because of the limited availability of test material, Ptose-Up was only tested at two rates ("slow" and "fast").

Three samples of each suspensory material were tested at the different displacement rates mentioned above, and the tests were conducted at 18.2 ± 0.2 °C with 34.2 ± 0.5% humidity. For each specimen the applied load (N) and the resulting strain (%) were continuously recorded using a 250 N load cell with 0.1 N accuracy and an external laser extensometer (Hounsfield S500), respectively. Small strips of red reflective tape were applied at the top and the bottom of the grips to allow direct strain measurements by the laser extensometer during tensile testing. The load recorded was converted to engineering stress by dividing the load by the initial specimen dimensions. The elastic limit was determined to be the force at which the linear elastic region of force–strain curve finished and the yield tensile strength (σ_y) was identified with the standard 0.2% offset yield strength; that is, the stress at which the stress–strain curve deviates by a strain of 0.2% from the linear elastic region of the curve, or as the stress at which the stress–strain curve levelled off. The corresponding strain (ε_y) was taken as the yield tensile strain. The failure load (F_{max}) and the ultimate tensile stress (UTS) were determined as the maximum force and the maximum engineering stress reached on the force–strain curve and the stress–strain curve obtained, respectively, and the corresponding strain (%) was taken as the ultimate tensile strain. In addition, the elastic modulus and work of fracture were calculated as the gradient of the stress–strain curve in the initial linear region and the area under the curve up to the fracture point (summing the area of the trapezoids defined by pairs of points), respectively.

When the suture-type materials did not break between the aluminium cylinders the data obtained were ignored. Similarly, when the mesh-type materials broke at the edge of the rectangular grip the data obtained were ignored so that the accurate mechanical properties of the materials could be determined.

2.3. Structural characterisation

The size (such as the diameter of the cross-section for suture-type materials and the thickness for mesh-type materials) of each suspensory material was measured with an optical microscope (Nikon Eclipse Me600) and a digital calliper (Mitutoyo). The measurements were taken at 3 random places along each specimen and three specimens for each material were analysed.

The surface morphology and cross-section of each suspensory material were examined using a scanning electron microscope (SEM, JEOL JSM-6301F). Secondary electron imaging mode was used at an accelerating voltage of 3 kV with the associated software (SemAfore) to collect images. Prior to imaging, all the specimens were sputter coated with