Femtosecond Laser Top Hat Penetrating Keratoplasty

Wound Burst Pressures of Incomplete Cuts

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Objective: To investigate the pressure required to rupture femtosecond laser top hat configuration corneal dissections with incomplete dissections.

Methods: Twenty corneoscleral buttons underwent femtosecond laser top hat configuration dissections. Group A had complete dissections; group B, 100-µm gaps in the anterior side cut; group C, 50-µm gaps in the anterior side cut; group D, 100-µm gaps in the lamellar cut; and group E, 50-µm gaps in the lamellar cut. The pressure required to rupture each cornea was measured.

Results: The mean (SD) pressure required to rupture the corneas was 111 (74) mm Hg for group A, 1565 (509) mm Hg for group B, 747 (209) mm Hg for group C, 550 (303) mm Hg for group D, and 392 (166) mm Hg for group E (P = .03 for all compared with group A).

Conclusions: Incomplete femtosecond laser top hat dissections are highly resistant to rupture by direct pressurization. Gaps in the anterior side cuts are stronger than comparably sized gaps in the lamellar cuts.

Clinical Relevance: Undertaking femtosecond laser keratoplasty in a 2-site setting should, theoretically, have a high level of safety. Burst pressures are high enough to resist an inadvertent sudden increase in intraocular pressure providing that incomplete recipient laser dissections are undertaken.

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Penetrating Keratoplasty (PKP) has provided visual rehabilitation for many corneal diseases for more than 100 years. Although it is often said to be one of the most successful transplantations in the body, its limitations include a prolonged visual recovery time; unpredictable, high, and irregular astigmatism; and a permanent reduction in the tensile strength of the eye.

More than 50 years ago, Jose I. Barraquer, MD, described a “keratoplasty in two planes” that had a smaller anterior diameter and a larger posterior diameter, with an intrastromal lamellar dissection connecting the 2 planes. In 2003, Busin1 reintroduced this concept with his description of the top hat configuration for PKP. Its advantages over standard PKP include increased mechanical strength and faster wound healing, allowing complete removal of the sutures by 3 to 6 months postoperatively, with subsequent refractive stability.2,3 It also allows the introduction of a graft with a large posterior diameter and greatly increased endothelial cell numbers while keeping the anterior diameter smaller to maintain a safe distance from the limbus and allow greatly increased wound surface area for healing and resistance to wound rupture.

Using a femtosecond laser to create top hat configuration PKP dissections has recently been reported in laboratory and clinical studies,2,4 with promising early results. In many surgical practices, the femtosecond laser and the PKP operating room are in different sites, sometimes in the same building but sometimes several miles apart. This leads to the logistical difficulties of transferring patients and donor corneas between the 2 sites after femtosecond laser dissections of the recipient and the donor. It also raises concerns about the safety of a patient moving with a full-thickness corneal dissection from one site to another. It is not known how much pressure such a dissection could withstand before rupture of the wound should the patient strain excessively, rub the eye, or sustain an injury between the 2 components of the femtosecond laser PKP procedure. To improve the margin of safety in patients undergoing this procedure in a 2-site surgery setting, surgeons may create incomplete laser dissections in recipient eyes, leaving a “gap” of uncut cornea in either the anterior side cut or the lamellar cut.
In this study, we assessed the amount of pressure required to burst corneas with femtosecond laser top hat PKP dissections in a cadaver eye model. We created complete and incomplete corneal dissections to allow comparison of the strength of these corneas.

**METHODS**

Twenty human corneoscleral buttons not suitable for transplantation (Eye Bank of Canada, Ontario Division, Toronto) were used in this study. All the buttons were from adult donors aged 18 to 75 years, and all were used within 10 days of the time of death. The buttons were removed from a corneal storage medium (Optisol; Bausch & Lomb Surgical, Irvine, California) and were mounted on an artificial anterior chamber (Automated Corneal Shaper; Chiron Inc, Irvine) (out of production), ensuring that a tight seal was obtained. The chamber was attached via a 3-way connector to a digital manometer (Universal Biometer DPM-III; Bio-Tek Instruments, Winooski, Vermont) and an isotonic sodium chloride infusion. The chamber was pressurized to approximately 20 mm Hg by elevating the isotonic sodium chloride solution on a drip stand to 27.2 cm above the anterior chamber. The mounted cornea was transferred under the femtosecond laser (IntraLase FS 60 KHz; IntraLase Corp, Irvine), and each cornea underwent applanation with a new corneal applanation cone until the fluid meniscus was at least 9 mm in diameter (outside the indicator seen through the laser eyepieces and on the viewing screen).

In group A, 4 corneas underwent complete top hat configuration dissections with standardized laser settings. Groups B through E each included 4 corneas that underwent identical dissections except that an incomplete cut was programmed in. This left uncut gaps of 100 and 50 µm at the posterior aspect of the anterior side cut (groups B and C, respectively) and of 100 and 50 µm at the outer aspect of the lamellar cut (groups D and E, respectively) (Figure 1). For groups D and E, the anterior depth of the posterior side cut was extended more anteriorly, in accordance with the laser manufacturer’s recommendations.

The laser settings for each study group are as follows. For the lamellar cut, all groups had the same depth (300 µm), inner diameter (7.4 mm), energy use (2.6 mJ), tangential spot separation (5 µm), radial spot separation (5 µm), and spiral start (out). The only difference among groups was in outer diameter (groups A-C, 9.1 mm; group D, 8.8 mm; and group E, 8.9 mm). For the anterior side cut, all groups had the same diameter (7.5 mm), angle (90°), energy use (2.6 mJ), spot separation (µm), layer separation (4 µm), and depth in glass (50 µm). The only difference among groups was in posterior depth (group A, 330 µm; group B, 200 µm; group C, 250 µm; and groups D and E, 330 µm). For the posterior side cut, all groups had the same diameter (9.0 mm), angle (90°), posterior depth (1200 µm), energy use (2.6 mJ), spot separation (3 µm), and layer separation (3 µm). The only difference among groups was in anterior depth (groups A-C, 270 µm; and groups D and E, 240 µm).

After laser dissection, each anterior chamber was disconnected from the isotonic sodium chloride infusion, and an isotonic sodium chloride–filled 20-mL syringe was immediately connected to the anterior chamber via the 3-way tap. The cornea was gradually pressurized by manually pushing in the syringe plunger until rupture of the dissection. The maximal pressure measured by the digital manometer before rupture was recorded as the burst pressure for each cornea.

Statistical analysis was performed using a software program (SPSS version 13.0; SPSS Inc, Chicago, Illinois). The Mann-Whitney test was used to compare burst pressures in the study groups. P < .05 was considered statistically significant.

**RESULTS**

The pressure required to rupture each cornea is detailed in the Table and represented graphically in Figure 2. The pressure required to rupture incomplete dissections was significantly greater than for complete dissections (P < .001). Corneas with anterior side cut gaps required higher pressures to rupture than did those with lamellar gaps (P=.003). Corneas with 100-µm gaps tended to have higher burst pressures than did those with 50-µm gaps, but this difference was not significant (P=.16).

**COMMENT**

The femtosecond laser is well established as an excellent device for corneal flap formation in laser in situ keratomileusis surgery. It has been shown to effectively and accurately create smooth lamellar dissections in the anterior cornea and anterior side cuts at variable angles, with minimal collateral tissue damage or inflammation. Adaptations to the femtosecond laser have recently become available (IntraLase Enabled Keratoplasty; IntraLase Corp), enabling it to create ring-shaped lamellar cuts.

*Figure 1. Schematic diagram of the laser dissections undertaken in the 5 study groups: complete dissection (A), a 100-µm gap in the anterior side cut (B), a 50-µm gap in the anterior side cut (C), a 100-µm gap in the lamellar cut (D), and a 50-µm gap in the lamellar cut (E).*
at variable depths and penetrating posterior side cuts at variable angles. This greatly increases the range of possible corneal dissection patterns and allows its use for PKP, particularly with specially shaped transplantations, such as top hat transplantations.

The potential advantages of using a femtosecond laser for top hat PKPs include precise placement and matching of dissections, which allows the donor tissue to fit exactly into the recipient eye in a jigsaw puzzle–like manner. This facilitates anterior and posterior alignment of the tissue. Using the laser to make suture alignment marks on the donor and recipient corneas also allows the surgeon to place sutures more accurately, minimizing tissue distortion or rotational misalignment. The laser also may increase the ease and speed of donor and recipient preparation compared with the manual technique and provides a wide range of possible shapes and sizes of wound configurations, which can be personalized to suit individual patients.

A disadvantage of femtosecond laser PKPs is that in many practices the femtosecond laser is not in the same operating room used for the transplantation part of the procedure. We were concerned about the safety of transporting patients with femtosecond laser top hat dissections from the laser surgery center to the PKP operating room, several miles away. To minimize the risk of wound rupture, the patients’ operated-on eyes are securely covered with a pad and a rigid shield; patients are instructed to avoid any eye rubbing or straining while en route. We also choose to leave small uncut gaps in the femtosecond laser dissections. There are 3 potential sites for the gap in top hat dissections: the posterior aspect of the anterior side cut, the outer aspect of the lamellar cut, and the posterior aspect of the posterior side cut. Attempting to leave a gap at the opposite end of each of these cuts would lead to difficulty in finding the plane of the cut in the cornea. In our early cases, we made the gap in the posterior side cut; however, we found that these dissections required a blade or corneal scissors to remove the recipient button, negating some of the benefits of the femtosecond laser dissection. We subsequently made the gap in the anterior side cut but found that identifying the plane of the subjacent lamellar cut was sometimes difficult, and a sharp blade was often required to cut through the undissected stromal lamellae. Therefore, prefer to leave the gap in the lamellar cut, which can generally be simply opened using a blunt spatula and allows the posterior side cut to be easily identified.

Top hat–shaped PKPs have been shown to resist rupture better than standard PKPs in laboratory studies.² ³ The larger-diameter posterior flange may create a valve-like effect, helping to seal the wound when intraocular pressure is elevated. However, the mechanical stability of the laser-dissected corneas before removal of the button from the “recipient” eye, with complete or incomplete dissections, has not been previously described.

We found that the pressure required to rupture top hat laser dissections is as low as 2 mm Hg in group A (complete dissections). The chance of spontaneous rupture before corneal transplantation would, therefore, be unacceptable if these dissections were undertaken in patient eyes. Mean burst pressures were significantly higher in all the other groups, and the lowest pressure resulting in graft rupture was 250 mm Hg in group E, which had 50-µm gaps in the lamellar cut. Dissections with 100-µm gaps did not require significantly more pressure for rupture than those with 50-µm gaps. However, dissections with gaps in the anterior side cut required more pressure for rupture than did those with gaps in the lamellar cut. This is likely explained by the need to rupture through stromal lamellae with anterior side cut gaps, whereas lamellar gaps

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (Complete Cut)</th>
<th>Group B (Anterior 100-µm Gap)</th>
<th>Group C (Anterior 50-µm Gap)</th>
<th>Group D (Lamellar 100-µm Gap)</th>
<th>Group E (Lamellar 50-µm Gap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>110.8 (73.7)</td>
<td>1564.5 (508.8)</td>
<td>746.8 (208.5)</td>
<td>550.3 (303.3)</td>
<td>392.3 (166.4)</td>
</tr>
<tr>
<td>Median</td>
<td>142.0</td>
<td>1664.5</td>
<td>735.0</td>
<td>459.5</td>
<td>349.5</td>
</tr>
</tbody>
</table>

Table. Burst Pressure for Each Cornea

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*P<.05 compared with the complete cut group (Mann-Whitney test).
can be more easily ruptured, largely by splitting along stromal lamellae.

What is a “safe” level of pressure that a recipient cornea needs to be able to withstand while the patient is transferring from one surgical suite to another? Intraocular pressure increases induced by the Valsalva maneuver have been shown to be only 2 to 10 mm Hg in healthy patients.8,9 The magnitude of transient intraocular pressure increases caused by eye rubbing is not well documented, although glaucoma and keratoconus have been attributed to long-term eye rubbing over many years.10 Blunt ocular trauma of adequate severity may rupture even a normal globe, and a femtosecond-lasered cornea would, therefore, be at increased risk.

In a laboratory model, we found that the mean (SD) pressure required to rupture femtosecond laser–dissected standard PKPs after surgical removal of the button and replacement with 16 interrupted 10-0 nylon sutures was 59.0 (6.6) mm Hg. Top hat configuration PKPs with 16 interrupted 10-0 nylon sutures ruptured at a mean (SD) of 102.0 (16.8) mm Hg. In a similar study, Ignacio et al1 found mean (SD) burst pressures of 76.25 (20.98) mm Hg for standard PKPs with a 12-bite 10-0 nylon continuous suture and 86.25 (9.74) mm Hg for top hat PKPs with a 12-bite 10-0 nylon continuous suture. These results suggest that pressures required to burst top hat and especially standard PKPs in patients returning home after completion of transplantations are markedly lower than pressures resisted by all the laser-dissected corneas with gaps in this study.

We should be conservative in drawing conclusions from this study because of the inherent differences between a laboratory-based cadaver cornea model and recipient corneas in the clinical setting. In this study, the cadaver corneas were pressurized gradually while mounted on an artificial anterior chamber. The burst pressures measured were, therefore, a response mostly to static pressurization from the internal aspect of the cornea. These findings, therefore, might not be indicative of the pressures required to rupture a cornea by the dynamic shear forces exerted by repeated eye and eyelid movement, eye rubbing, or a direct external blow, which could cause sudden and substantial shear forces across the femtosecond-lasered dissection, leading to greater wound instability. A top hat configuration wound may be less able to withstand external pressure compared with internal pressure because of the wound architecture with the internal flange, designed to aid closure and healing of the wound in the presence of intraocular pressure. In addition, femtosecond laser dissections in cadaveric corneas preserved in corneal storage medium may not be comparable with those in all patient corneas, which may behave more variably. For example, an edematous cornea with pseudophakic bullous keratopathy might have reduced laser penetration and a less complete femtosecond dissection, perhaps similar to an edematous cadaveric cornea, whereas a clear cornea with keratoconus might have a more complete femtosecond dissection, potentially leading to lower wound burst pressures in vivo. Finally, it is possible that patient eye movement during the femtosecond laser dissection could result in displacement of the laser dissection and unpredictable alterations in the resulting uncut gap, including a full-thickness cut in part of the dissection. This is unlikely because the recipient eye is essentially immobilized by the “patient interface,” consisting of the suction ring, which is applied to the recipient limbus, and the application cone, which is locked into the suction ring during application of the cornea. Once adequate application has been achieved, the surgeon releases the clip on the suction ring, locking the 2 devices together and preventing significant movement of the cornea relative to the laser. It is most likely that vertical movements of the patient would result in movement of the patient’s globe in the orbit rather than the cornea relative to the laser. Significant lateral movement would result in loss of suction, at which stage the entire patient interface becomes detached from the patient and the laser stops. However, because the limbal conjunctiva is not completely fixed to the underlying sclera, it is possible that small lateral movements of the eye could displace the laser dissection. It would, therefore, seem prudent to leave a larger dissection gap, such as 100 rather than 50 µm, to allow for this. We suggest that it is reasonable to use any laser dissection that resists rupture under pressures consistently greater than 200 mm Hg. Although anterior side cut gaps are stronger than lamellar gaps, both are probably more than adequate to withstand potential intraocular pressure spikes caused by straining or moderate external pressure on the eye before corneal transplantation. We find that a 100-µm gap between the lamellar cut and the posterior side cut provides the optimum balance between patient safety and ease of surgical removal of the recipient corneal button.

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