Complications of Intra Corneal Ring Segment Implantation with Femtosecond Laser Channel Creation in patients with Keratoconus (Explanations and Solutions)

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ABSTRACT: The present study analyzes the complications of intracorneal ring segment implantation using a femtosecond laser for channel creation in patients with keratoconus. This technique, as in all surgical procedures, a risk of complications is always present and must be addressed appropriately to ensure that optimal results are achieved with the least possible incidence of adverse effects. We fully discussed possible intra- and post-operative complications of this surgery and how to manage them. Complications such as endotelial perforation, incorrect entry of the cannell, galvanometer lag error, abnormality-shaped channel creation, vacuum loss, segment migration, decenteration, axis incision, corneal melting, neovascularization and infection are described and discussed.

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INTRODUCTION

Patients with moderate to advanced forms of keratoconus will often require surgical intervention to improve visual acuity. While corneal transplantation can be an effective form of treatment for keratoconus, the surgical procedure involved in surgeries like penetrating and deep lamellar keratoplasty is notably invasive and the risk of complications is considerable1-4. The therapeutic treatment of patients with keratoconus and post-LASIK ectasia can be achieved effectively using the minimally invasive surgical procedure of intrastromal corneal ring segment (ICRS) implantation, which has been reported to provide excellent visual outcomes with a lower rate of complications5-8. However, as in all surgical procedures, a risk of complications is always present and must be addressed appropriately to ensure that optimal results are achieved with the least possible incidence of adverse effects.

MANUAL VERSUS FEMTOSECOND-ASSISTED CHANNEL CREATION

Prior to the advent of femtosecond laser technology, channel creation required for ICRS implantation was only achievable manually using mechanical devices. Studies have shown that manual channel creation for ICRS implantation has been associated with various potential complications, including infectious keratitis, epithelial defects, anterior or posterior corneal perforations, corneal stromal edema around the incision, extension of the incision towards the central visual axis or the limbus, and asymmetric segment placement9-11.

In our experience, since the introduction of femtosecond laser technology, the procedure for channel creation for ICRS implantation has improved, and the risk of complications has been significantly reduced. These improvements in the surgical procedure can be at least partially attributed to the ability of the femtosecond laser to deliver energy with precision12. In addition, femtosecond laser technology allows for the customization of channel creation as the channel depth can be programmed according to the needs of the individual cornea. The IntraLase femtosecond laser (Advanced Medical Optics, Santa Ana, California, USA) can be used to separate the cornea by producing 1-2 μm circular air bubbles, while with the mechanical method the cornea is dissected through the collagen fibers without cutting the fibers. It uses a flat cone which planalates the cornea causing a fixed depth of
channel from the surface towards the bottom. This means that at the thinner corneal areas the channel is formed at a deeper point. Femtosecond laser technology has been reported extensively as a safe and effective device for the treatment of keratoconic eyes using ICRS implantation. In our experience, the femtosecond laser has improved the channel creation procedure for ICRS implantation because it minimizes procedure time and reduces the risk of inflammation and infection.

PREVALENCE OF COMPLICATIONS: CLINICAL STUDIES

We conducted a large clinical study investigating the incidence of complications during ICRS implantation with femtosecond-assisted channel creation. The study included 850 eyes of 531 patients with mild to moderate keratoconus. All eyes underwent ICRS implantation with the Keraring (Mediphacos, Belo Horizonte, Brazil). Channels for ring segment insertion were created using the IntraLase femtosecond laser. All patients gave informed consent prior to the surgery, in adherence to institutional guidelines and the tenets of the Declaration of Helsinki.

Preoperatively, all patients underwent a complete ophthalmic examination, which included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, biomicroscopy, corneal topography (Orbscan IIz, Bausch & Lomb, Rochester, New York, USA), WaveLight Allegretto Topolyzer (WaveLight Laser Technologie, Erlangen, Germany), and endothelial cell density using specular microscopy (Konan Specular Microscope SP 900 Noncon Robo Pachy, Konan Medical Inc., Hyogo, Japan). All patients had clear central corneas without scars and were contact lens intolerant. At the location of the channel, corneal thickness was at least 350 µm. Patients were excluded from the study if they met any of the following criteria during the preoperative examination: history of herpes, corneal dystrophies, keratitis, acute or grade IV keratoconus, systemic connective tissue disease, diagnosed autoimmune disease, and an endothelial cell count of less than 1000 cells/mm².

The mean age of the patients was 28.32 ± 7.28 (range, 18 to 44 years). In all cases the surgical procedure was performed under sterile conditions and topical anesthetic drops were applied. We chose the Purkinje reflex as the central point, which was marked under the WaveLight Allegretto Biomicroscope, and a 5-mm marker was used to pinpoint the channel. Intraoperatively, ultrasonic pachymetry (Sonogage, Cleveland, Ohio, USA) was used to measure corneal thickness along the ring location markings. The depth of the tunnel was programmed at 80% of the minimum corneal thickness at the channel location.

In each case, the arc length and thickness of the Keraring was chosen in accordance to the manufacturer’s nomogram. A 60kHz IntraLase femtosecond laser was used to create the ring channels in all eyes, with the inner diameter programmed to 4.4 mm and the outer diameter set to 5.6 mm. Entry cut thickness was 1 µm and the energy used for channel creation was set to 1.30 µj. The duration for channel creation with the femtosecond laser was approximately 15 seconds. In each case, as soon as the channel was created, the ICRS was immediately implanted before the bubbles disappeared, as these served as markers of the location of the channel. Special Keraring forceps were used to implant the segment, to avoid adverse effects around the incision area.

Any complications that occurred intraoperatively and postoperatively were recorded. Postoperatively antibiotic steroid eye drops were prescribed, taken 4 times daily for 2 weeks. The patients were instructed to avoid rubbing their eyes and to use preservative-free artificial tears frequently. On the first postoperative day, a slit-lamp biomicroscopic examination was performed, and the healing of the wound and migration of the segment was evaluated in each eye. At the last follow-up examination manifest refraction, UCVA and BSCVA, slit-lamp, and topographic examination were performed.

In total, complications were noted in 49 cases (5.7%), with 35 cases (4.1%) of intraoperative complications and 14 cases (1.6%) of postoperative complications. The rates of the various intraoperative and postoperative complications are detailed in Tables 1 and 2.

Our study shows that there is a possibility for a small rate of complications to occur during the ICRS implantation procedure with femtosecond-assisted channel creation, particularly involving incomplete channel creation and segment migration. However, these rates of complications are significantly lower, and generally less serious than the complications reported with other.

<table>
<thead>
<tr>
<th>Intraoperative complications</th>
<th>%</th>
<th>Eyes</th>
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<tbody>
<tr>
<td>Endothelial perforation</td>
<td>0.6</td>
<td>5</td>
</tr>
<tr>
<td>Vacuum loss</td>
<td>0.1</td>
<td>1</td>
</tr>
<tr>
<td>Galvonometer system malfunction</td>
<td>0.6</td>
<td>5</td>
</tr>
<tr>
<td>Incorrect entry of the channel</td>
<td>0.2</td>
<td>2</td>
</tr>
<tr>
<td>Incomplete channel formation</td>
<td>2.6</td>
<td>22</td>
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<table>
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<tr>
<th>Postoperative complications</th>
<th>%</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Migration</td>
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<td>7</td>
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<tr>
<td>Superficial migration</td>
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<td>4</td>
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<tr>
<td>Corneal Melting</td>
<td>0.2</td>
<td>2</td>
</tr>
<tr>
<td>Mild infection</td>
<td>0.1</td>
<td>1</td>
</tr>
</tbody>
</table>
more invasive surgical procedures for the treatment of keratoconus and post-LASIK ectasia\textsuperscript{1-4,16,17}.

In 2003 Ratkay-Traub \textit{et al} reported the first ever published study of ICRS implantation using the femtosecond laser for channel creation\textsuperscript{12}. In this study no intraoperative complications were noted, while postoperative complications were limited to only a 12.5\% incidence of minimal deposits. Similarly there were no intraoperative complications identified in a study by Carrasquillo \textit{et al}, while postoperatively 12.5\% of eyes developed corneal neovascularization and 6.25\% developed a fungal infection after wearing soft contact lenses for seven months after surgery\textsuperscript{13}.

In studies observing complications following the manual creation of channels for ICRS implantation, ring segment migration, corneal melting and corneal perforation have been reported to occur most frequently\textsuperscript{9-11}. In a comparison of mechanical versus femtosecond laser-assisted channel creation for ICRS implantation, Rabinowitz \textit{et al} reported the incidence of ICRS extrusion due to superficial ring placement in the mechanical group, and the occurrence of epithelial defects and gram-positive infection in the femtosecond group\textsuperscript{18}.

There appears to be conflict among literature regarding the most frequently occurring complications in ICRS implantation. These discrepancies can be attributable to the varying number of studied eyes, the method of channel creation used (manual versus femtosecond laser technology), and the varying characteristics of the ring segments used in the studies.

MANAGING THE COMPLICATIONS

Endothelial Perforation

Perforation of the endothelium can occur as a result of inaccurate preoperative pachymetry, or if the tunnel is created with too great a depth (Figure 1). Using femtosecond laser technology for channel creation provides adequate accuracy, but each cone has a standard deviation of between 10 and 15 \( \mu \)m. Achieving an accurate preoperative pachymetry in a 5-mm optical zone at the implantation site will help to reduce the incidence of epithelial perforation during channel creation. The point of the thinnest pachymetry at the channel location can be used as a reference point, and the incision depth should be 80\% of this (Figure 2). The solution to endothelial perforation is to stop channel creation as soon as it is identified before the incision. The surgery can be resumed a month later, where a new channel can be create at about 90 \( \mu \)m superficially, so that the endothelium is protected\textsuperscript{10} (Figure 3).

Incomplete Channel Creation

Incomplete channels can occur when using the femtosecond laser. Although there is no solid explanation for the creation of incomplete channels, since it is possible to implant the ring segment after forwarding a...
segment from the opposite side, it means some bridges are formed within the channel probably owing to insufficient energy (Figure 4). This can be eliminated by increasing the energy level or decreasing spot separation. Incomplete channels can be dealt with by using a mechanical spreader to complete the channel.

Incorrect entry of the Channel

Incorrect entry of the channel and proceeding another depth channel can occur while using the 150 µm ring. From our experience we believe that the incorrect entry of the channel is a consequence of not using a channel starter in the femtosecond laser procedure. A second channel can be created at another corneal depth, using the bubbles created from the first channel creation as guidance.

Galvanometer lag error

Galvanometer lag error is a technical complication experienced with the femtosecond laser device. The error can be located in the memory system of the femtosecond laser, which malfunctions when it attempts to recall the operation center if the center is changed. This can result in the creation of a channel next to the previous one. Femtosecond laser systems like the IntraLase do not incorporate a separate incision cut program, and so when the procedure is restarted, it starts with channel creation. The incidence of galvanometer lag error during channel creation can be reduced by maintaining the vacuum. If the error does occur, the channel creation procedure should be postponed, and the second attempt should be carried out using the same cone, using a depth of 30 µm superficially. If the error occurs during the creation of the incision cut, the incision should be continued with a blade. Using a blade, a second channel can be made above or below the original site, and should be made immediately, using the bubbles to locate the channel.

Abnormally-shaped Channel Creation

During applanation, the corneal surface becomes completely flat while performing the side cut. Once the applanation cone is removed, the cornea returns to its original curved appearance. This means that, particularly in eyes with high astigmatism, the steep meridian will be short while the flat meridian is long, which can cause the formation of oval-shaped channels (Figure 5). It is not possible to completely avoid the incidence of oval-shaped tunnel creation in femtosecond lasers that use flat cones. On the other hand, other femtosecond systems that use curved cones will not cause this complication. However, until further investigations are made, we do not know how the oval channel influences the efficacy of the implanted ICRS, and so it should not be considered a complication. But until studies are able to determine the consequences (if any) of abnormally-shaped channels, the surgeon should approach the oval channel with some caution and attempt to avoid it whenever possible.

Similarly, surgeons may experience the creation of wide channels (Figure 6). The targeted channel depth is calculated from the epithelial surface towards the endothelium because of the usage of a flat cone. This can cause the channel to be closer to the endothelium in areas where the cornea is thinner. Collagen fibers are tighter superficially but much looser deeper. Therefore the bubbles have more space to spread around deeper towards the endothelium, resulting in wider channels. Again, this issue requires closer investigation to determine the effects of wide channels.

**Figure 4.** Incomplete channel formation with bridges.

**Figure 5.** Oval-shape channels – In eyes with high astigmatism, the steep meridian is shorter while the flat meridian is longer, which can cause the formation of oval-shaped channels.

**Figure 6.** Wide channel creation.
Vacuum Loss

Vacuum loss may occur during channel creation, or while making an incision. The risk is increased in keratoconus patients because of high astigmatism. If vacuum loss occurs during channel creation, and there is only meniscus and central applanation is adequate for channel creation, there is no need to terminate the procedure. It is possible to create the vacuum again at the same conjunctival and corneal plane, using the same marking to create the channel at the same location and depth. But if there is uncertainty about the location and depth of the channel, the surgery should be postponed. If vacuum loss occurs during incision, and there is only meniscus and central applanation is adequate for channel creation, the procedure can be continued safely. If there is complete vacuum loss, the procedure should be continued with a blade, with which it is possible to create another channel above or below the original channel. This should be done immediately, before the bubbles disappear, as they can make a good reference point. In our experience, a knife with a diamond blade is ideal, with a size smaller than that of the created incision depth.

Segment Migration

The displacement of implanted ring segments can occur in the channel or superficially. To avoid corneal melting, the migrated segment should be repositioned, and in extreme cases, the segment should be explanted. Although rubbing the eye might play a key role in causing migration, there are other influential factors that must be considered. Contributing factors to migration can include abnormally shaped channels, certain types of astigmatism and the incision site. Furthermore, the movement of the ring within the channel with eye and eye-lid movement can play a significant role in migration, particularly if the movement is towards the incision site, which can disturb the healing of the incision wound, leading to epithelial ingrowth. The ring can thus develop an empty space around itself. The incision site should be kept at a distance from this space in order to heal properly, otherwise healing problems may develop (Figure 7).

Migration can be easily recognized by the surgeon on the first postoperative day. If the migration is between 0.5 and 0.7 mm from the incision site, the patient should receive follow-ups more frequently until re-epithelization is complete at the incision site and it is made certain that the migration has fully stopped. If the migration is less than 0.5 mm from the incision site, the ring should be repositioned, and a contact lens and patch placed on the eye. The patient should be advised not to squeeze or rub the eye for at least 24 hours. If migration reoccurs, a suture should be placed (Figure 8) and left in position for at least 2 months (Figure 9).

The incidence of superficial movement of the ring may be caused as a result of the creation of extremely...
superficial channels, and can also be influenced by the factor of age and corneal thinning. When considering the solution to this complication, the three variables of depth (related to corneal thickness), ring width and the present progression of keratoconus are very important. It is therefore advisable to create the channels at about 70-80% at the incision site. In our study, the channels were created at 80% of the thinnest part of the corneal thickness at the tunnel location. Although it is difficult to know the minimum depth for ring implantation, ICRS like the Keraring are provided with a safety limits reference table that recommends ring sizes for different corneal pachymetries. In the case of superficial movement, the ring should be explanted, as it can form melting and a permanent scar on the cornea (Figure 10).

Decentration

Decentration is a complication that has been reported to occur in studies of intrastromal corneal ring segment implantation. The center can be located via the limbus center, the pupil center or the Purkinje reflex, depending on the surgeon’s personal preference (Figure 11). The cone of the IntraLase femtosecond laser has a flat surface, and following applanation it is difficult to accurately locate the center as the position of the cornea and pupil appears to change. For this reason, it is important to mark the center before applanation, whether this is at the limbus or pupil center, or the Purkinje reflex. However, the low light conditions of femtosecond lasers like the IntraLase can make it difficult to see the marking accurately, and channel creation might be decentracted. In this situation it is important to stop channel creation as soon as the decentration is recognized. The surgery can be postponed, and resumed one month later. Using the same cone can also minimize the risk of decentration. Aiming for a depth of 30 µm more than the previous depth, depending on the previous channel depth, can also contribute to preventing decentration. It is important not to be too superficial, because the limit of the minimum channel depth is unknown, and the superficial implantation of rings may result in explantation. In addition to this, there may be neighboring channels that can cause enlargement of the original channel.

Axis Incision

Positional malrotation can lead to a displaced axis incision, when the patient lies down or the surgeon causes rotation during applanation. To prevent this, the cornea should be marked, while the patient is standing up, at the 3 and 9 o’clock positions, and the incision site should also be marked (Figure 12). After applanation the eye may be rotated manually towards the incision axis or the axis can be changed digitally using the femtosecond laser software, if this is available.
Corneal Melting

Corneal melting is a complication that we have noted to occur particularly in cases with superficial displacement of the ring, patients with very thin corneas or in cases with incorrect corneal pachymetry. In all cases of severe corneal melting, it is important that the ring is explanted immediately to prevent corneal scarring.

Neovascularization

Although neovascularization did not occur in our study, it is a complication that has been observed with intrastromal corneal ring segment implantation. The explantation of the ring that have induced deep corneal neovascularization is very important because there is a high risk of melting and extrusion of the segments (Figures 13-14).

Infection

As ICRS implantation can lead to ring segment migration to the incision site, unhealed incision sites can cause corneal vascularization and melting. Eventually, ring extrusion can lead to the prevalence of moderate to severe infection (Figure 15). In our study, in 850 cases there was only one case (0.1%) of mild infection that was treated with intense antibiotics.

CONCLUSION

From our experience, the implantation of intrastromal corneal ring segments is a minimally invasive surgical option for the treatment of keratoconus and post-LASIK ectasia that entails a comparatively low rate of complications. The introduction of femtosecond laser technology has enabled us to create reproducible channels with great accuracy, a quick duration, and minimal complications. Uniform dissection with the femtosecond laser is less than 400 µm and centralization is accurate. Studies have also shown better symmetry and aseptic technique with the femtosecond laser, as well as low vacuum and easy customization of the size of the tunnel. Notably, there is a significantly decreased chance of intraoperative incidences of anterior or posterior perforation.

Each complication has an appropriate solution, and it is important to be familiar with each technological device, and to become accustomed to it, so that it is used with every necessary precaution and the cornea is respected. If these precautionary measures are taken, the femtosecond laser is an efficient and safe method for ICRS channel creation, and has been particularly compatible with the Keraring intrastromal corneal ring segment in our experience. Significantly, most intraoperative and postoperative complications from ICRS implantation are largely dependent upon the implantation technique, and are substantially more prevalent in
manual tunnel creation, when compared to femtosecond laser tunnel creation\(^3\). The possibility of making channel width alterations enables the surgeon to perform customized channel creation, which vastly increases efficacy. But it is important to take the necessary preventative and responsive measures to ensure that adverse effects from channel creation and ICRS implantation are kept to a bare minimum. However, as with all surgical procedures, the patient must always be well-informed about the possibility of complications beforehand.

**REFERENCES**