Complications of intrastromal Corneal Ring Segments Implantation with Femtosecond laser for Channel Creation

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INTRODUCTION

The implantation of intracorneal ring segments is a minimal invasive surgical procedure for keratoconic[1] or post-LASIK ectatic[2] corneas. Before the introduction of femtosecond laser technology, tunnel creation was accomplished manually using mechanical devices[3-12]. This step of the procedure related with a number of possible complications such as epithelial defects, anterior or posterior corneal perforations, infectious keratitis, asymmetric segment placement, corneal stromal edema around the incision, extension of the incision towards the central visual axis or the limbus and persistent incisional gapping[3-7]. Recently, tunnel creation is performed using the femtosecond laser, which can deliver energy accurately to a precise depth in a programmed way. Studies indicate that Intacs implantation using a femtosecond laser is a safe and effective procedure for treating keratoconic corneas[13-21]. The femtosecond laser minimizes procedure time and decrease the risk of inflammation or infection.

The IntraLase Femtosecond Laser (Advanced Medical Optics, Santa Ana, California, USA) has many advantages over the mechanical technique, particularly owing to its safety and minimally invasive method. The femtosecond laser minimizes procedure time, and causes less discomfort, epithelial defects, and risk of inflammation or infection. 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[18,20]. Notably, there is a significantly decreased chance of the intraoperative incidences of anterior or posterior perforation[3].

There are several different types of intracorneal rings, with varying curvature, width and zone of implantation. The Keraring (Mediphacos, Belo Horizonte, Brazil) is a newly developed implantable intrastromal corneal ring segment made of PMMA and is characterized by a triangular cross section that induces a prismatic effect on the cornea. The Keraring's apical diameter is 5 mm and the flat basis width is 0.6 mm with variable thickness (0.15 to 0.30 mm thickness with 0.5 mm steps) and arc lengths (90°, 160° and 210°).

According to our knowledge, this study is the first large clinical trial for the complications of this type of intracorneal ring segment using the femtosecond laser for tunnel creation in keratoconic patients.

There was a study in which we investigated Intraoperative and postoperative complications and solutions of intrastromal corneal ring segments implantation in keratoconic eyes using a femtosecond laser for channel creation between the years 2004-2007 in our hospital.

Eight hundred fifty keratoconic eyes underwent intrastromal corneal ring segment implantation (Keraring, Mediphacos, Belo Horizonte, Brazil), using a Femtosecond laser (IntraLase, Advanced Medical Optics, Santa Ana, California, USA) for tunnel creation. All procedures were performed by the same surgeon (EC) at Dunya Eye Hospital, Istanbul, Turkey. Prior to their participation in the study, all patients were informed about the possible complications and gave informed consent in adherence to institutional guidelines and the tenets of the Declaration of Helsinki.

Mean patients' age was 28.32 ± 7.28 (range, 18 to 44 years), and all of them completed at least one year of follow-up. All patients had clear central corneas and contact lens intolerance. Corneal thickness was at least 350 µm at the tunnel location. Patients were excluded if any of the following criteria applied after the preoperative examination: history of herpes, keratitis, corneal dystrophies, diagnosed autoimmune disease, systemic connective tissue disease, acute or grade IV keratoconus, and endothelial cell count of less than 1000 cells/mm^2.

A complete ophthalmologic examination was performed preoperatively, including uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, biomicroscopy, corneal topography [Orbscan IIz (Bausch & Lomb, Rochester, NY), WaveLight Allegretto Topolyzer (WaveLight Laser Technologie, Erlangen, Germany)] and endothelial cell density measurement with specular microscopy (Konan Specular Microscope SP 9000 Noncon Robo Pachy Konan Medical Inc. Hyogo, Japan).

The surgical procedure was performed under sterile conditions and topical anesthetic drops. The Purkinje reflex was chosen as the central point and marked under the WaveLight Allegretto Biomicroscope. A 5-mm marker was used to locate the exact ring channel. Corneal thickness was measured intraoperatively using ultrasonic pachymetry (Sonogage, Cleveland, Ohio, USA) along the ring location markings. Tunnel depth was set at 80% of the thinnest corneal thickness on the tunnel location.

Arc length and thickness were chosen according to the manufacturer's nomogram. A 60 kHz femtosecond laser was used to create the ring channels. The channel's inner diameter was set to 4.4 mm, and the outer diameter was 5.6 mm. The entry cut thickness was 1 µm, and the ring energy used for channel creation was 1.30 µj. The entry cut energy was 1.30 µj and channel creation timing with the femtosecond laser was 15 seconds. The intracorneal ring segments were implanted immediately after channel creation, before the bubbles disappeared, as they revealed the exact tunnel location. To avoid any injury to the incision area, the segment was directly implanted with the special Keraring forceps.

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

RESULTS

The overall complication rate was 6,5% (55 cases).

Intraoperative complications

The **intraoperative complications** were summarized in Table 1.

Incomplete tunnel formation occurred in 22 eyes (2.6 %).. In 12 of the cases, the ring was manipulated and implanted successfully, and in 4 cases the ring was moved from the opposite direction and implanted from the canal created by the first ring. In the remaining 6 cases, a mechanical separator was used(Figure 1).

Galvanometer lag error occurred in 5 cases (0.6 %). In all cases the error occurred two seconds before the completion of the incision. In two of the cases, the procedure was restarted and the error occurred again exact at the same time. A 30º knife was used then to complete the cut.

There were 5 (0.6 %) cases of endothelial perforation, which were present intraoperatively as bubbles in the anterior chamber (Figure 2). Unfortunatelly in first two cases we couldn`t recognized. In the first case, when the suture was removed one month postoperatively, the Seidel effect was noticed at the incision. A suture was placed again, and removed one month later. No further complications were observed (Figure 3). In the second case the ring was displaced, moving into the anterior chamber, and was explanted. In the third and fourth cases, the channel was recreated with a targeted depth of 30 µm superficially than the original channel. Edema was prevalent around the segment in one of these cases (Figure 4). In the last case the procedure was postponed for 1 month. Channels were created 90 µm superficially to protect the endothelium.

Incorrect entry of the channel was a complication that occurred in two eyes (0.2 %) while using the 150 µm ring.

Vacuum loss occurred in one eye (0.1%) in 7 th second. Vacuum was created again at the same conjunctival and corneal plan and same corneal marking was used. Channel was completed successfully at the same location and depth.

The overall intraoperative complication rate was 4,1% (35 cases).

Postoperative complications

The postoperative complications observed in this study have been summarized in Table 2.

Segments' migration was observed in 7 cases (0.8%), (Figure 5). A suture was placed at the incision and removed 2 months later, preventing any further migration.

Discomfort was observed in 6 cases (0,7%) who

Corneal melting (Figure 6) was observed in 2(0.2%) eyes. In both cases, the melting had already begun when the patient was seen in the second postoperative month, where the ring had migrated towards the incision site.

There were 4 incidences (0.5 %) of superficial movement of the ring (Figure 7), in 4 eyes of 2 patients. The patients were 16 and 17 years old with very thin corneas, with a minimum thickness of 375-385 µm. The depths of the channels were 300 and 304 µm respectively. After 3 months, in both eyes of each patient, epithelial changes were noted above the ring, and the stroma around the ring was hazy. The 4 rings were removed before melting started. After 1 month, collagen cross-linking was performed in the 4 eyes using pure riboflavin to make the cornea thicker than 400 µm.

There was one (0.1%) case of infection following implantation. A mechanical separator was used to complete the channel, resulting a large epithelial defect. The patient experienced corneal abscess formation at the incision site that was treated with intense antibiotics.

The overall postoperative complication rate was 2,4% (20 cases).

DISCUSSION

Today IntraLase is the most popular femtosecond laser. However it should be used with precaution and certain principles must be adhered to, so that complications can be avoided. These complications have been investigated in this study.

In the first study that ever published about segment implantation (Intacs) with the use of femtosecond laser, Ratkay-Traub et al[13] reported no intraoperative complications and minimal deposits in the tunnels of two eyes (12.5%). Carrasquillo et al[14], also reported no intraoperative complication during of femtosecond laser for tunnel creation. Postopertively, 2 eyes (12.5%) developed corneal neovascularization and one eye (6.25%) had a fungal infection in the setting of soft contact lens wear seven months after surgery. Ertan et al, in three studies of segment implantation with the use of femtosecond laser, had as the most common complications epithelial plugs in 15.2%[15] and 24.6%[16] of eyes while segments' migration occurred in three eyes (4.5%)[17]. Coskunseven et al[18] reported no intraoperative complications and 3 (6%) cases of segment migration in the first postoperative day.

In the only comparative study regarding INTACS inserts using the femtosecond laser or a mechanical spreader of Rabinowitz et al[12] reported three (15%) patients had significant epithelial defects and one patient (5 %) with a gram-positive infection during the postoperative period in the femptosecond group. In the mechanical spreader group one patient (5%) had INTACS extruction due to superficial placement of the segment.

In other studies after segment implantation with the traditional mechanical method Kanellopoulos et al[7] reported six (30%) cases of intracorneal ring segment movement and one (5%) case of corneal melt. As the most common complication, Ruckhofer et al[4] reported corneal perforation in 4 (2.4%) eyes, while Zare et al[11] reported segment movement and exposure in 3 (10%) eyes.

The discrepancy between the complication rates reported in the literature, are mainly due to variations in the number of studied eyes (in the current study we included 850 eyes) and difference in segments' characteristics (Intacs or Kerrarings). The only study regarding Kerrarings implantation using femtosecond laser for channel creation, was from our department reported no intraoperative complication in 150 eyes. In the current study, we had 33 (4%) and 14 (1.6%) complicated cases during or immediately after the procedure respectively.

Incomplete tunnel creation and segments' migration were the most common intra- and postoperatively complication respectively.

Incomplete tunnel formation occurred in 22 (2.7%) eyes and In 12 of the cases, the ring was manipulated and implanted successfully, and in 4 cases the ring was moved from the opposite direction and implanted from the canal created by the first ring. In the remaining 6 cases, a mechanical separator was used.

Although there is no solid explanation for the creation of incomplete channels, since it is possible to implant the ring after forwarding a ring from the opposite site, it means some bridges are formed within the channel probably owing to insufficient energy. This can be eliminated by increasing the energy level. The IntraLase machine can have energy level fluctuations, and this can be solved by increasing the energy level or decreasing spot separation.

Galvanometer lag error occurred in 5 (0.6%) eyes .It is a technical problem of the device. The error is located at the memory system of the femptosecond which is unable to recall the operation center if this center is changed. In that case, a second channel has to create next to the previous one. Additionally the system does not have a separate incision cut program, therefore when the procedure is restarted, it begins with channel creation. To avoid the galvo error during channel creation, it is important to maintain the vacuum. If the galvo error does occur, the surgery should be postponed, and the second surgery should be performed with the same cone, (using a depth of 30 µm superficially). In case that galvo error is experienced during incision creation, the incision should be continued with a blade, even if there is only 1 second remaining. With the blade, another channel can be created above or below of the original plane immediately, before the bubbles disappear so that it is easier to locate the channel.

Endothelial perforation occurred in our study in four eyes (0.5%). It can be caused by incorrect preoperative pachymetry or deeper tunnels' creation of the tunnel. Femtosecond channel creation is very predictable but each cone has a 10-15 µm standard deviation. To avoid the incidence of endothelial perforation, it is important to achieve correct and accurate pachymetry in a 5-mm optical zone at the implantation site. which can be achieved with the combined use of the Pentacam, Visante OCT (Carl Zeiss Meditec) and ultrasonic pachymetry The reference point should be the point of thinnest pachymetry at the tunnel locations. The depth of the incision should be 80 % of the thinnest corneal pachymetry (Figure 8). Endothelial perforation can be prevented by stopping channel creation as soon as the complication is recognized before the incision. Femptosecond channel creation is circular, rather than raster, starting from the central and continuing towards the periphery,if perforation is going to happen it will be during the first few seconds therefore the surgeon must observe the bubbles very carefully.

If bubbles are noted, and endothelial perforation appears to be the case, surgery should be postponed for at least one month. Then a new channel should be created 90 µm superficially to protect the endothelium[7].

Vacuum loss occurred in one (0.1%) eye during channel creation,. 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 plan, following 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 quickly, before the bubbles disappear, as the bubbles can make it easier to locate the channel. It is recommended that a diamond knife is used, with a size smaller than that of the created incision depth.

The incorrect entry of the channel and proceeding another depth channel that occurred in 2(0.2 %) eyes in this study may have been caused by the technique used, as a canal separator and sutures were not used, and epithelization was completed on the first postoperative day. Unlike the mechanic technique, using the femtosecond laser does not provide any channel starter. If we implant the 150 ring directly without using any starter we can easily form a second channel because the channel width is only 2-3 microns. so the channel should be relocated quickly, using the bubbles before they disappear.

The most common postoperative complications was segments' migration. Segments migration was observed in 7 cases (0.8%). Although it is not possible to compare migration occurrence during IntraLase channel creation with the mechanical method in this study, it is possible to consider previously published studies. In a 150-eye keraring implantation study group[17], three eyes (6 %) showed segment migration to the incision site on the first postoperative day. In this previous study, to avoid melting, the migrated segment was repositioned away from the incision site and the patients were advised not to rub the eye and to keep a bandage contact lens and patch on the eye for 24 hours. There was no serious second migration, hence no need to reposition any segment again. There were no occurrences of intra- or late post-operative complications in this series of patients.

Although rubbing the eye might play a key role in causing migration, there are other influential factors, because migration occurred in some cases despite placing a contact lens in each eye after repositioning and despite advising patients against eye-rubbing. Contributing factors to migration include oval-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 develop an empty space around itself of about 500 µm. The incision site should be at least another 500 µm away from this space in order to heal properly, otherwise healing problems may develop. (Figure 9)

Migration can be easily recognized by the surgeon on the first postoperative day. If the migration is 0.5-0.7 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 been 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 in the first 24 hours. If migration reoccurs, a suture should be placed and remain for at least 2 months (Figures 10 and 11).

Discomfort was observed in 6 eyes .These eyes had incomplete channels which were completed by mechanical method and had some epithelial defects.

Corneal melting was observed in 2(0.2%) eyes. In both cases, in the second postoperative month, the melting had already begun when the patient was seen, where the ring had migrated towards the incision site. Although postoperative follow-up showed adequate epithelization, epithelial ingrowth and melting followed. Significantly, in both cases the patients did not experience any discomfort although the rings were already out of the channel and the melting process had begun. In both cases the rings had to be explanted because of high risk of infection and we used intense antibiotics regimens.

The incidences of superficial movement of the ring in this study may have been caused as a result of the creation of extremely superficial channels, and might also have been 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 common practice to create the channels about 70-80 % at the incision site. In this 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, the Keraring is provided with a safety limits reference table that recommends ring sizes for different corneal pachymetries. In the cases where superficial movement was observed, it was noted that the thickness of the cornea at the tunnel location was 380 µm, and the depth was 304 µm. The ring should be extruded if it has a superficial movement, as it can form a permanent scar on the cornea. . In case of corneal melting, ring has to be explanted.

Although vascularization did not occur in this study, it is a complication that has been observed with intrastromal corneal ring segments[8,9].

The requirement of explantation is very important because there is a high risk of infection.

As these were cases with unhealed incision sites, where melting had started and rings extruded, there is a significant likelihood of the prevalence of moderate to severe infection. However, in this study there were no such incidences.

Using applanating flat cone in intralase has some disadvantages such as decentration, oval shaped tunnel and wider channels.

There were no incidences of decentration in our study, as the center was always marked at the Purkinje reflex before applanation Decantration is a complication that has been reported in previous studies of intrastromal corneal ring segment implantation[10]. The center can be located via the the limbus center, the pupil center or the Purkinje reflex, depending on the surgeon's individual perspective. The cone of the IntraLase femtosecond laser has a flat surface, and following cone applanation it is difficult to accurately locate the center as the position of the cornea and pupil appears to change[21]. 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 (Figure 12). However, the low light conditions of the IntraLase can make it difficult to see the marking accurately, and channel creation might be decentrated. 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; each cone has a standard deviation of 10-15 µm. Aiming for a depth of 30 µm less 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. Positional rotation can lead to incorrect 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 3 and 9 o'clock, and the incision site should also be marked. After applanation the eye may be rotated manually towards the incision axis or the axis can be changed digitally using the IntraLase (Figure 13).

During IntraLase 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, resulting in an oval-shaped tunnel.. However, until further investigations are made, we do not know how the oval channel influences the efficacy of the ICRS, and so it should not be considered a complication. But further investigation may reveal problems caused by the oval-shaped tunnel during ICRS implantation, so the surgeon should consider the oval channel inclination and attempt to rectify it using extra manipulation.

It uses a flat cone which applanates the cornea causing a fixed depth of channel from the surface towards the bottomThe 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 as you go deeper. Therefore the bubbles have more space to spread around deeper towards the endothelium, resulting in wider channels.

In conclusion, we describe several complications of intrastromal corneal ring segments (Kerrarings) implantation with Femtosecond laser for channel creation. Each complication has its own solution, and it is important to be familiar with every 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 IntraLase is the most efficient and safe method for ICRS channel creation, and is particularly compatible with the Keraring intrastromal corneal ring segment. 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 formation, which vastly increases efficacy. However, as with all surgical procedures, the patient must always be well-informed about the possibility of complications beforehand.

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FIGURES

Figure 1: Incomplete tunnel formation: bridges around the segment. In these eyes tunnels were completed with a mechanical separator.

Figure 2: Endothelial perforation of segment presented as bubbles in the anterior chamber.

Figure 3: Siedel Effect

Figure 4: Endothelial perforation, edema around the segment

Figure 5: Segment migration at the incision site.

Figure 6: Corneal melting above the ring segment due to superficial implatation.

Figure 7: Superfificially movement of the segment:

Figure 8: Correct pachmetry

Figure 9: The segment develops empty space around itself

Figure 10:Suture

Figure 11: After remove the suture

Figure 12: Correct centralization

Figure 13: Marking

Table 1: Summary of Intraoperative Complications.

Type of complications	Eyes	%
Incomplete tunnel formation	22	2,6
Galvo error during incision	5	0,6
Endothelial perforation	5	0,6
Incorrect entry of the channel	2	0,2
Vacumm Loss	1	0,1
Total	35	4,1

Table 2: Summary of Postoperative Complications

Type of complications	**Eyes**	**%**
Segments' migration	7	0,8
Discomfort	6	0,7
Superficial Movement	4	0,5
Corneal Melting	2	0,2
Mild infection	1	0,1
Total	24	2,4