Chapter 19
Intracorneal Ring Segments and Keratoconus

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19.1 Introduction

Intracorneal ring segments (ICRS) are small devices made of synthetic material which are implanted within the corneal stroma in order to induce a change in the geometry and the refractive power of the tissue (Fig. 19.1). Blevatskaya in 1966, was whom first introduced the idea of implanting a corneal ring in order to change the refractive power of the eye [1]. Such a ring was composed of a 360° device which led to a several complications mainly due to the metabolic alterations in the corneal stroma which

Fig. 19.1 Intracorneal ring segments

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was the reason to abandoned the 360° ring designs; afterwards, a new approach with the segments types that we know nowadays begins to be studied. During the decades of the 1970 and 1980, ring segments designs were widely investigated in order to provide the efficacy necessary to treat refractive errors. In the decade of the 1990, specifically in 1996, Intacs Technology, received the CE certificated and later in 1999, the FDA approval for the use of intracorneal ring segment (ICRS) implantation in the correction of myopic refractive errors [2]. Although several theoretical models as well as clinical research demonstrate the efficacy and predictability of this novel technology in the correction of low to moderate myopia, ICRS was rise above by the upcoming corneal excimer laser surgery due to the excellent refractive results of the latest technology [2]. In despite of the aforementioned, in the year 2000, Prof. Joseph Colin proposed to take advantage of the corneal modelling abilities of ICRS and use it for the treatment of keratoconus [3]. Afterwards, several investigators have reported good results when treating keratoconus patients using intracorneal ring segments, as well as delaying and also avoiding more complex surgeries as keratoplasty procedures.

Corneal ectatic disorders are a group of diseases characterize for progressive alterations in the morphology of the corneal tissue that negatively impact in the visual function and the optical quality of the patients [4]. Keratoconus is by far the more frequent pathology among this group of entities; its main features are corneal thinning, gradual corneal protrusion, and progressive irregular astigmatism [5]. The incidence in the general population is relatively low and variable, between 4/1000 and 6/1000 nine with other authors reporting that the current incidence is 1/2000 per year [6]. In addition, the incidence may vary according to the geographic region; though there are also studies supporting the fact that the prevalence is higher in zones with higher UV exposure or with a combination of genetic and environmental factors [7]. Regarding the therapeutic approaches, several treatment has been proposed in order to treat this disease, such as, contact lens wearing, thermokeratoplasty procedures, corneal collagen cross linking, intracorneal ring segment (ICRS) implantation and lamellar and penetrating keratoplasty [8–11].

The purpose of the present chapter is to update the main features of intracorneal ring segment implantation in the treatment of patients suffering from keratoconus.

19.2 Intracorneal Ring Segments Designs

Currently we have several models of ICRS that are commercially available; the ones that are widely spread used in the clinical practice are the hexagonal cross section segments represented by the Intacs (Addition technologies) (Fig. 19.2) and the triangular cross section represented by the Kerarings (Mediphacos) (Fig. 19.3). The main characteristics of these two types of ring segments are summarize in Table 19.1. Moreover, there is a variation of the Intacs, known as the Intacs SK, that because of the smaller diameter and different design have a more flattening capabilities and are reserved for those keratoconic cases that present high myopic refractive errors. The only true ring with a total 360° diameter that is currently available on the market is

Fig. 19.2 Intacs ICRS

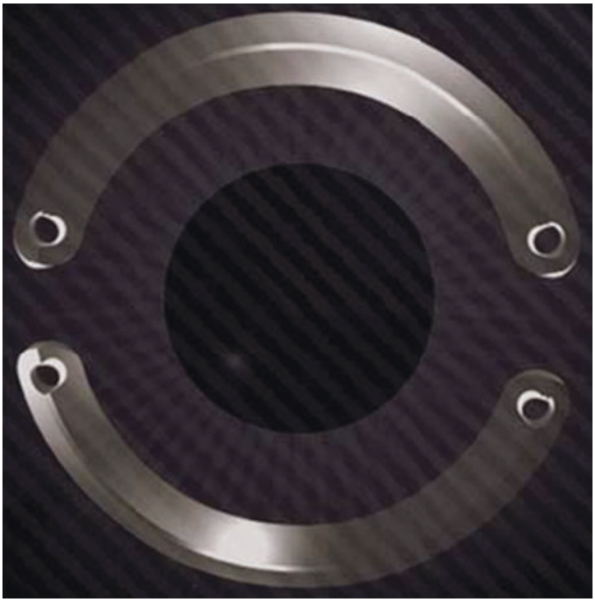


Fig. 19.3 Keraring ICRS

the Myoring from Dioptex (Fig. 19.4). Due to the full ring design, this model of ICRS is special used in those keratoconus that showed a topographic pattern with a center steepening, high keratometries and a high myopic refractive error.

In recent years, Mediphacos developed an interrupted ring of 355°, which is available in a diameter of 5.7 mm and a thickness ranging from 200 to 300 μm. Although there are just few studies published in the literature reporting results with

Table 19.1 Intracorneal ring segment main characteristics

Model	Intacs	Kerarings
Arc length (degrees)	150°	90–210°
Cross section	Hexagonal	Triangular
Thickness (mm)	0.25–0.35	0.15–0.35
Inner diameter (mm)	6.77	6.00
Outer diameter (mm)	8.10	7.00

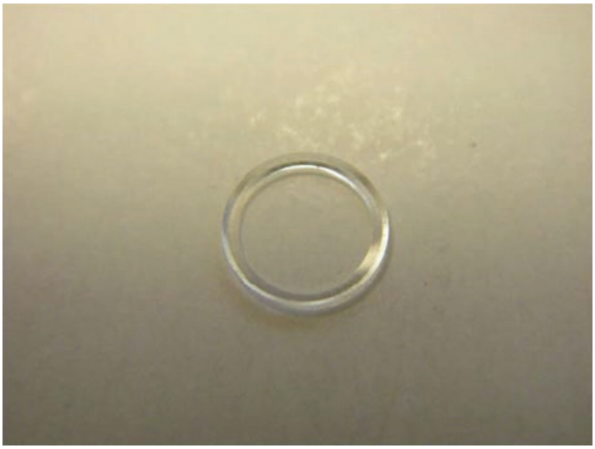


Fig. 19.4 Myoring ICRS

this type of ring, they show an improvement in the visual and refractive status of patients with central keratoconus. On another hand, our investigation team recently developed a new type of ICRS, the V-R technology, which is not yet commercially available and combines an asymmetric design in an almost completely full ring of 350° of arc length (Fig. 19.5). The potential advantages of the latest design is that will achieved both, the reduction of the asymmetry of the cornea that is observed when the segments are implanted and the significant flattening induced when using the full ring devices. Additionally because it is an incomplete ring can be implanted through a single incision in the cornea.

19.3 Mechanism of Action of the ICRS

Intracorneal ring segments acts as spacer elements between the collagen fibres of the corneal tissue [12]. Thus, ICRS induce an arc shortening effect of the geometry that in consequence flattens the central area of the cornea. Some theoretical models based on finite element analysis have proven that the flattening observed after ICRS implantation is directly proportional to the thickness of the segment and inversely proportional to the corneal diameter where is implanted. This means that the thicker and the smallest the diameter, the higher the flattening effect that will be induced by the segment [13]. Nevertheless, these theoretical models apply just to normal

Fig. 19.5 V-R technology ICRS

corneas where there is an orthogonal arrangement of the collagen fibers. As have been demonstrate, in patients with keratoconus this special arrangement of the collagen fibers is lost, which leads to a more unpredictable result when evaluating the effect of corneal implants in this type of patients [14]. Another theory that may explain the mechanism of action of the ICRS is the "Thickness law" proposed by Barraquer which quote that when tissue is added to the periphery of the cornea or tissue is removed from the center a flattening of the cornea will be achieved and vice versa [15]. However, there is not enough scientific data published in the literature that supports the latest theory to explain the flattening effect of ICRS.

19.4 Surgical Techniques

In order to implant the intracorneal ring segments into the deep of the stroma we need to performed channels in the corneal tissue where the rings will be inserted. These channels or tunnels can be created manually or assisted by the femtosecond laser. In the following lines we will explain both procedures.

In the mechanical or manual technique, the surgeon must mark the center of the pupil in order to use it as a reference point during the procedure. Then a calibrated diamond knife is used to create an incision at a depth of 70% of the corneal pachymetry. A suction ring is placed around the corneal limbus in order to fixate the eye during the dissection of the corneal stroma. Then, two semicircular dissectors are placed through the incision and advance in the deep stroma in a clockwise and counter clockwise movement aiming to perform a tunnel within the corneal lamellas (Fig. 19.6). Once the channel is created, the ICRS is inserted.

Fig. 19.6 Manual stromal dissectors for ICRS implantation

The other technique to create the tunnels is using the femtosecond laser assisted technique. In this case, a disposable suction ring of the femtosecond laser system is placed and centred. Afterwards, the cornea is flattened with a disposable aplannation cone which allows a precise focus of the laser beam thus creating a dissection on the desire depth. Then the tunnel is created at approximately 70% or 80% of the corneal pachymetry without direct manipulation of the eye. Finally, ICRS are inserted in the created tunnels.

Independently of the procedure used in order to perform the stromal tunnels in some exceptional cases and just if the surgeons considered that is necessary a 10-0 nylon suture can be placed to close the incision site.

Finally, in order to insert the full ring design ICRS, the Myoring, into the deep of the stroma a pocket must be created within the corneal lamellas. This pocket can be performed using a system device design for this purpose by the manufacturer known as the PocketMaker microkeratome [16]. The other approach to create this space in the middle in the corneal stroma is by using the femtosecond laser assisted technique with an entrance to the pocket of aprox. 5 mm [17].

19.5 Nomograms for Implantation

In order to choose the arc length, number, thickness and position of the segments in the cornea, we need to use the implantation nomograms. Even when several authors have reported good results when implanting ICRS in keratoconic eyes, the main limitations that nomograms have is that most of them are based in anecdotic clinical data or variables that are very subjective in patients with keratoconus, such as, spherocilyndrical refraction and topographic pattern of the cone. For instance, in an investigation conducted by our research group it was found that based on the topographic pattern of the keratoconus the best choice was to implant one segment in those cases of inferior steepening and two segments in central cones [18].

Other works published in the literature support that the best location to implant the segments is by placing the corneal incision in the temporal site of the cornea [19–23].

There are other works that have reported good results when implanting the ICRS guided by the comatic axis [24]. Recently, our research team published a scientific work in which we concluded that the best outcomes for implanting ICRS were observed in those cases where the refractive and topographic cylinder did not differ in more than 15° [25].

As we can see, there are different approaches regarding the guidelines to be used when implanting ICRS. Nevertheless, today the most widespread nomograms that are used in the clinical practice are those developed by the main manufacturers of ICRS.

Our research team is currently working with artificial intelligence (AI) software approach in order to optimize and refined the results of ICRS implantation [26]. Specifically, together with the CSO manufacturer an informatic software was developed based on a neural network which analyzed clinical data in order to provide a simulation of the best combination of ICRS that will induce the best optical function to a specific cornea. The main advantage of this approach is that a system based on AI is able to train itself by the inclusion of continuous input (cases implanted) that is upload on its system. This way, in the mean that we simulate more cases, the better the optical quality that can be predicted by the system thus providing better results after ICRS implantation. Figure 19.7 shows a screen display of a simulation provided by the neural network.

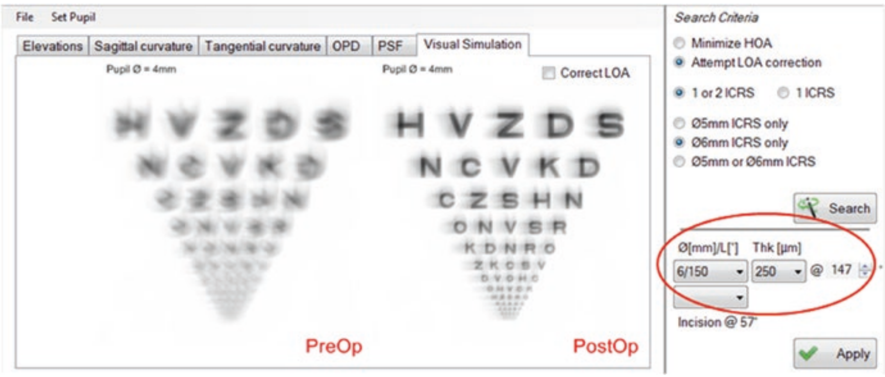


Fig. 19.7 Screen display of the neural network used for ICRS implantation guidance showing a preoperative (preop) and postoperative (postop) visual simulation of a patient. Red circle: segment type and location where the incision should be placed

19.6 ICRS Clinical Outcomes

Since the first report in the year 2000 when Colin and col. published their results after ICRS implantation for the treatment of keratoconus [3] several authors have demonstrate the efficacy of this surgical technique in reducing the spherical equivalent and keratometric readings as well as improving the visual function in patients with keratoconus [27–31]. The majority of those studies report an improvement in the uncorrected and corrected visual acuity, as well in the spherical equivalent and a reduction in the corneal astigmatism. Most of the authors observed a central flattening of the cornea that is consistent with a mean reduction of the keratometric readings that goes between 3 and 5 diopters [27–31]. Additionally, investigations that have assessed the optical quality by analysing the changes in anterior corneal higher order aberrations have found a reduction in these variables after ICRS implantation, specifically an improvement of the asymmetric aberrations (coma and coma-like) which are the ones that more limitations induces in keratoconic patients. These changes observed in the aberrometric coefficient are expected to occur due to the capability of the implants in regularizing the geometry of the corneal tissue [31–33].

As we can see most of the authors who have analysed the results of implanting ICRS in patients suffering of keratoconus agreed in the good outcomes regarding the visual function, refraction and anterior corneal higher order aberration; nevertheless, in a recent multicentric study performed by our research team it was found that the efficacy of ICRS implantation was related to the visual limitation of the patients at the moment of the surgery [31]. In that study we aimed to assess the outcomes of the surgical procedure based on a grading system that takes into account the visual acuity of the patients diagnose of keratoconus [34]. We observed that those patients with good spectacle corrected visual acuity at the moment of the surgery were more prone to lose lines of corrected vision after ICRS implantation; on the other hand, those cases with a severe limitation of the visual function before the procedure were the ones that benefit the most from the surgical procedure [31] (Table 19.2). These findings lead us to the consideration that ICRS implantation in cases with keratoconus and good vision should be undertaken with extreme caution because of the risk of loosing vision in this group of patients.

In relation to long-term results of ICRS implantation for the treatment of keratoconus there have been some controversies regarding the stability of the procedure after long period of time. While some studies reported the long term stability of this technique [22, 33, 35]. There is a clear limitation in most of these investigations as they do not state whether or not the patients that they are evaluating within their

Table 19.2 Percentage of corrected visual acuity after ICRS implantation according to the vision of keratoconic patients

Visual acuity	Gain ≥1 line CDVA	Lost ≥1 line CDVA	Lost ≥2 lines CDVA
CDVA ≥ 0.6 Grade I + II	37%	36%	25%
CDVA ≤ 0.4 grade IV + plus	82%	10%	4%

cohort belong to cases with the progressive or stable form of the disease, or they just analyze patients with stable form of keratoconus. In a recent study carried out by our research group was observed that long term stability of ICRS implantation depends on the progression pattern of keratoconus at the moment of the surgical technique. Thus, in those cases with the stable form of the disease, ICRS implantation remains without significant changes after long period of follow up. Nevertheless, in those cases that shows clinical signs of progression, the benefit achieved immediately after the procedure is expected to be lost after long period of time. From that work, we conclude that stability of the keratoconus should be established before considering ICRS in patients with keratoconus [36].

In relation to long arc length types of ICRS or completely full ring devices, most of the published data agree that these designs induce a more pronounced corneal flattening than those achieved by the conventional segments. Alio and co workers published in 2011 a pilot study analysing the clinical results of Myoring implantation where it was found that a mean reduction of around 8 diopters in the mean keratometric reading 6 months after Myoring implantation can be achieved [17]. In the same way, Jadidi et al. conducted a study where the authors analysed the 355° arc length ICRS manufactured by Mediphacos and they found that the mean keratometry was reduced in more than 5 diopters 6 month after ICRS impantation [37]. In a recent study conducted by a our research team where results of a 350° asymmetric intracornealring, V-R technology, were analysed, it was found that 1 year after the surgical procedure a mean reduction of more than 7 diopters can be observed in the spherical equivalent of patients with keratoconus [38].

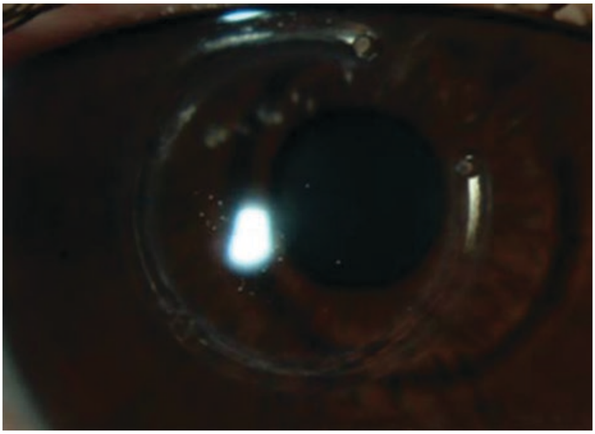
19.7 Complications

Implanting ICRS in keratoconic patients is considered to be a safe surgical procedure mainly due to the advent of the femtosecond technology that provides more precise and predictable size and depth of the stromal tunnels. Even when rare, most of intraoperative complications have been describe when performing the channels with the manual technique.

Complications after ICRS implantation can be divided in: surgical related complications, postoperative complications and optical related complications.

Among the surgical procedure related complications after ICRS implantation, as previously commented, they are often seen when using the manual technique and very rarely with the femtosecond assisted procedure. These complications are usually related to an inadequate depth of the stromal channels, segment decentration or asymmetric position of the segment within the tunnels [39]. The most severe surgical related complication is corneal perforation which usually occurs during the rotational movement with the manual dissector. Complications related to femtosecond laser assisted technique usually are mild, like suction ring lost, subconjuntival hemorrhage and just in less than 0.6% of the cases a corneal perforation may be observed [40].

Fig. 19.8 Segment migration. In the lower part of the image contact between the two segments can be seen



Postoperative complications are not often present and when they are most of it usually does not represent a major risk for the eye of the patient. In any case, one of the most fear complications after this surgical technique is infectious keratitis; although, is have been reported to be less than 0.1% of the cases when dissecting the tunnels using the femtosecond laser assisted technique [41].

Extrusion and migration (Fig. 19.8) of the segment are among other of the complications that might be seen after ICRS implantation. Once again most of the published data agree that this complication is more often observed when using the mechanical technique [39, 41]. When present, extrusion or migration of the segments does not represent a clinically relevant event and may induce just a mild refractive change in the cornea thus the case might be followed just by observation. However, in some cases, severe photic phenomena, recurrent epithelial defect and stromal inflammation that could even lead to more severe complications like infectious keratitis and corneal melting may appear and in these cases segment explantation should be perform [42].

Corneal neovascularisation (Fig. 19.9) is other of the postoperative complications that may appear usually at late stages after ICRS implantation. Although rare when appear is mainly due to dissection of the tunnel to close to the corneal limbus.

A postoperative event that is often observed after ICRS complications are white deposits within the stromal tunnel (Fig. 19.10). Even when its incidence have been reported by some authors to be as high as in 60% of the cases [42]. These channel deposits does not induce any optical or structural alteration and are considered to be completely benign thus any specific treatment should be performed when they are observed [43].

Another complication that can be present after ICRS implantation and that is very severe is corneal melting. Even when the incidence is very low, around 0.2% according some authors [39], when present explantation of the ICRS should be perform.

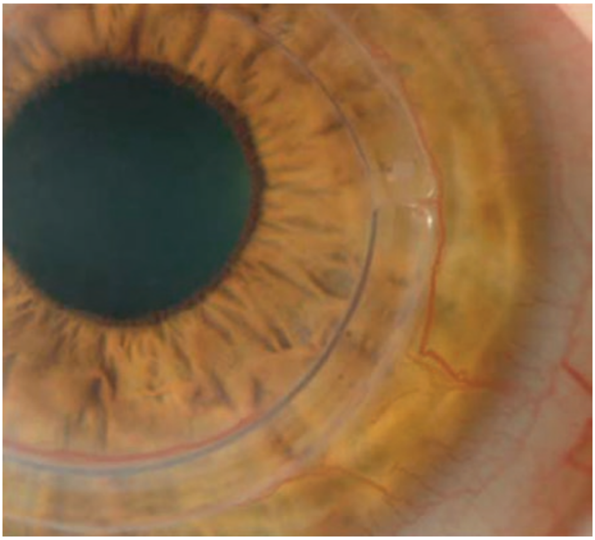


Fig. 19.9 Corneal neovascularization through the stromal channel

Fig. 19.10 Corneal deposit within the segment tunnel

In relation to optical complications after the procedure, photic phenomena as halos and glare might be present usually when the dissection of the tunnel has been decenter or when severe migration of the segment occurs during the postoperative period. Losing corrected visual acuity can be other complication observed in patients with keratoconus and good visual function. Our research team conducted a clinical investigation were it was demonstrate that those patients with more than 0.9 of corrected visual acuity in the decimal scale have around 50% of risk of losing lines of vision after ICRS implantation [31].

Finally, with the advent of new long arc length design an increasing number of complications related to corneal melting and extrusion of the segment have been reported which makes necessary to conduct long term studies analysing a higher number of patients implanted with segments of more than 340° of arc length [37].

In this point it is worth to mention that one of the main advantages that ICRS implantation has is it reversibility. Even when some of the above mentioned complications might appear, some studies have shown that segment explantation can be safely performed with visual, refractive and topographic variables coming to preoperative levels [44].

19.8 Futures Perspective

Nowadays, there is enough scientific based evidence demonstrating the efficacy of ICRS for the treatment of keratoconus. We can have access today to technology and materials that allow us to develop new designs that combines the main features and advantages of different type of rings, as is the case of the currently available long arch length ring type designs, in order to provide a better results to our keratoconic patients. Additionally, there is every time more publications that show the benefit effect of combining different treatment approaches as ICRS together with corneal collagen cross-linking. Moreover, with the advent of artificial intelligence systems and neural network software as well as technology of enormous amount of data analysis we will be able to refine our nomograms of implantation and the predictability of the outcomes based on the analysis of the clinical results from previous success cases implanted with ICRS.

19.9 Summary

In conclusion we can say that ICRS is an effective procedure in the treatment of keratoconus patients. This surgical procedure induces a change in the morphology of the corneal stroma leading to an improvement in the visual function and the quality of life leading in many times to avoid more complex procedures as keratoplasty in patients with keratoconus. Currently, there are many research teams working in improvement of the implantation nomograms; new approaches as using artificial intelligence or big data analysis to increase the predictability of the outcomes after ICRS implantation is nowadays in practice. Although there are some reports analysing the long term stability of the procedure most of the published data agree that ICRS is a stable technique after long period of follow up specifically in those patients with stable keratoconus. ICRS implantation are considered to be a safe and reversible technique and the few complications that are reported is usually when using the manual technique in order to performed the stromal channels. Finally our increased in knowledge and understanding of ICRS together with new designs and better nomograms of implantation will certainly improve the outcomes of implanting ICRS in patients with keratoconus.

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