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Keratoscopy Assisted Implantation of Intrastromal Corneal Ring Segment (ICRS) in Keratoconus, Limited Case Series

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Abstract

Purpose: To evaluate the potential use of manual keratoscope for proper centration of implanted intrastromal corneal ring segment (ICRS) in keratoconus.

Methods: Forty participants were randomly divided into two subgroups according to the use of manual keraoscope intraoperatively (MKI), femtolaser assisted (Visumax) implantation of Keraring 160° arc length intrastromal corneal ring segment (ICRS) was performed. A preoperative ocular evaluation was performed as well as postoperatively regarding uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), K1, K2, K max, corneal volume, Anterior chamber depth (ACD), and corneal elevations 6 months after the procedure.

Results: Corrected distance visual acuity (CDVA) shows a significant difference between the two groups (P<0.05). Moreover, statistically significant differences were found regarding K1, K2, K max, and corneal elevation front (P<0.01). However, spherical error, cylindrical error, spherical equivalent, corneal volume, Anterior chamber depth, and elevation back did not show statistical differences.

Conclusions: These preliminary findings may suggest that intraoperative application of hand-held manual keratoscope may play a role in proper positioning of corneal ring segments, further refinement of such intraoperative tools is needed to maximize corneal regularization.

Keywords: Manual Keratoscope; Femtolaser; ICRS; Keratoconus

Abbreviations: ICRS: Intrastromal Corneal Ring Segment; MKI: Manual Keraoscope Intraoperatively; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; ACD: Anterior Chamber Depth; SE: Spherical Equivalent; ORA: Optiwave Refractive Analysis

Introduction

Intrastromal corneal ring segments (ICRS) are a surgical tool for the treatment of corneal ectasia [1-3]. The implantation of ICRS results in redistribution of the peripheral corneal lamellae, producing flattening of the central cornea and decreasing lower and higher-order aberrations [4]. Changes in ICRS thickness and size, a combination of techniques, and the addition of femtosecond lasers to dissect more predictable channels represent an improvement toward more predictable results [5]. A widely used implant is the Kerating (Mediphacos, Belo Horizonte, Brazil) ICRS, which is made of polymethyl methacrylate (PMMA) and has a triangular cross-section. It is inserted with the apex facing the anterior corneal surface and the base facing the posterior corneal surface. 150 to 350 μm thickness; and 90° to 355° of arc. According to the Kerating nomogram proposed by the manufacturer, when placing the ICRS, it is advised to put it in the area divided by the steepest meridian so that its tips lie equidistant from the line representing the steepest meridian, in other words making the ring straddles the cone [6-7]. Nevertheless, the final positioning procedure relies on the surgeon experience and preferences with no intraoperative clues for proper placement in effective position. This case series aimed to study the potential use of hand-held keratoscope for proper centration of implanted intrastromal corneal ring segments (ICRS) in keratoconus.

Patients and Methods

This randomized prospective interventional trial was conducted at Tiba Ophthalmic center, Menoufia governorate, Egypt. during the period from June 2018 to June 2020 on patients with keratoconus grade 2-3 defined by Amsler-Krumeich classification [8] with type 1 cone asymmetry, i.e., 100% of the steep area (red) is located on one side of the reference or type 2 cone asymmetry, i.e., The distribution of the steep area is approximately 20% / 80% (Figure 1). Before the commencement of this study, all procedures were reviewed and approved by the Ethical Committee of the Menoufia University Hospital and followed the tenets of the Declaration of Helsinki. Written informed consent was obtained from each patient after full discussion of the procedure involved, duration of treatment, possible intraoperative maneuvers, and potential postoperative complications.

The enrolled eyes were suffering confirmed clinical and topographic keratoconus, mean central keratometric (K) reading less than 60 diopters (D), clear cornea, with a minimal corneal thickness of 450 µm at the intended track site. Exclusion from the study entailed opacified corneas, a corneal thickness of less than 450 µm at the track site and associated ocular pathologies such as cataract; glaucoma; retinal disorders and uveitis. A detailed history carried out preoperatively to exclude any systemic diseases that might compromise the procedure. All Subjects underwent a full ophthalmological examination including determination of uncorrected and corrected distance visual acuities measured by decimal notation, manifest and cycloplegic refraction, and a slit lamp and fundus examination to exclude any pathology that might be a contraindication for surgery. Corneal tomography was routinely performed preoperatively using high-resolution rotating Scheimpflug camera system Pentacam® HR (oculus GmbH, Wetzlar, Germany).

Randomization was carried out preoperatively by simple coin tossing into two groups:

Group A (unaided implantation of ICR), and Group B (Keratoscopy assisted implantation of ICR).

Surgical Procedures

All the surgical procedures were performed by the same surgeon (MS) under topical anaesthesia; Benoxinate hydrochloride 0.4% Sterile Ophthalmic Solution, with sterile conditions. For comparative purposes, the authors did not stick to the proposed nomograms to avoid confounding variables; all cases received single intracorneal ring segment Keraring 160° / 300 µm (Mediphacos, Belo Horizonte, Brazil). The VisuMax® platform (Carl Zeiss Meditec, Oberkochen, Germany) was used to create the tunnel and access incision for ring implantation. The small-sized suction cup is applied to the machine, centration is obtained by asking the patient always to look at the flickering green light and suction is applied when the corneal vertex reflex is aligned. The data used in tunnel creation included inner diameter of 5 mm, an outer diameter of 6.2 mm, inner depth of 380 µm, outer depth of 395 µm, upper width of 0.6 mm, lower width of 1 mm and access incision at the steepest meridian on the topography. After tunnel creation, the access incision is opened with a Sinskey hook.

From this point patients were divided into either; group A where empirical implantation of ICR took place to apparently straddle the cone (Figure 2), or group B where sterile hand-held Maloney manual keratoscope (Jedmed Instrument Co, St Louis, USA) is insinuated between the operating microscope and the patient`s cornea pre-insertion (Figure 3), the reflected mire shows irregularity that corresponds to the cone, insertion of the ICR is carried out. Fine adjustment of the implanted ICR took place under the keratoscope, this was carried out by pushing the ring into the tunnel until the mire is regularized. (Video) At the end of the procedure, a soft contact lens is applied over the cornea. Postoperative treatment included Gatifloxacin 0.3%, prednisolone acetate 1% and lubricant eye drops with strict instructions to avoid eye rubbing. All patients were followed at day one postoperatively to ensure the absence of early postoperative complications and bandage contact lens is removed then, regular follow up of patients is done at first, third and sixth month.

It is worth mentioning that all candidates underwent corneal cross-linking, four weeks after segment implantation, with standard epi- off accelerated protocol (10 minutes). During the 6th month of follow up, comprehensive evaluation was carried out, including manifest refraction, uncorrected distance visual acuities (UDVA) and corrected distance visual acuity (CDVA). Further assessment of the anterior segment was performed with Scheimpflug analysis Pentacam® HR (oculus GmbH, Wetzlar, Germany) which generates images of the anterior segment in 3 dimensions using a noncontact method. The data collected was keratometric readings (K1- K2 - Mean K and K max), maximum elevation in the central 4-mm zone using the 9-mm diameter best fit sphere (BFS) for both front and back corneal surfaces, corneal thickness, corneal volume and anterior chamber depth (ACD). Data were stored in an Excel spreadsheet (Microsoft Corp.). The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 18.0. Qualitative data were represented as frequencies and relative percentages.

Results

This study included 40 eyes of 40 patients (30 males & 10 females). The Demographic data of the studied groups are summarized in (Table 1). All procedures passed uneventfully both intra and postoperatively, with good postoperative segment position. There were statistically significant differences in terms of the sphere, cylinder, and spherical equivalent (SE) at six months compared to the preoperative values. Nevertheless, no significant differences existed between both groups regarding the variables mentioned earlier. Corrected distance visual acuity (CDVA) in decimal notation also improved significantly to 0.41 ± 0.17 in group A and 0.56 ± 0.26 in group B ($P<0.01$) with significant differences between the two groups, as shown in (Table 2). The anterior corneal surface showed marked flattening in the

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form of significant reduction of K1, K2 and K max compared to the preoperative values, and this particularly evident in the keratoscope assisted implantation (Figure 4). Scheimpflug imaging showed a reduction of maximum elevations in the front and back surfaces; this is easily explained by flattening effect exerted on the cornea. However, no significant differences were noted between the two groups regarding corneal volume, ACD or thinnest location (Table 3). summarizes Scheimpflug image analysis of the cornea and anterior chamber. We should report no cases of extruded ring segments at the incision site in both groups nor other complications.

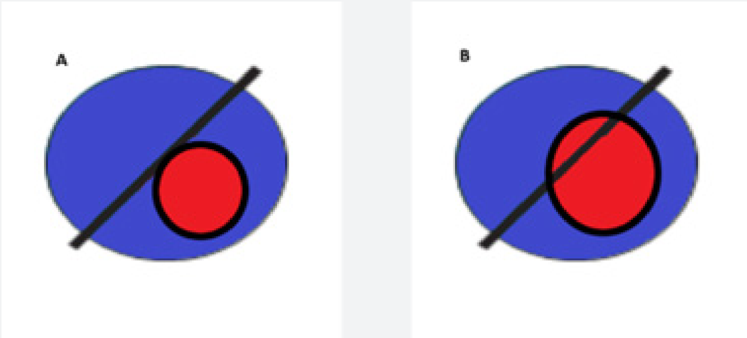

Figure 1: Type 1 cone asymmetry (A) i.e., 100% of the steep area (red) is located on one side of the reference, type 2 (B) cone asymmetry, i.e., The distribution of the steep area is approximately 20% / 80%.

Table 1: Comparison between the two studied groups according to Demographic Data.

	Group A (n = 20)		Group B (n = 20)		p
	No.	%	No.	%	
Sex					
Male	16	80	14	70	0.465
Female	4	20	6	30	
Age (years)					
Min. – Max.	17.0 – 35.0		16.0 – 40.0		0.443
Mean ± SD.	26.75 ± 4.97		28.25 ± 7.08		

p: p Value for comparing between the studied groups

*: Statistically significant at p ≤ 0.05

Group A: Blind implantation of ICRS without keratoscope

Group B: Keratoscope assisted ICRS implantation

Table 2: Refractive and visual outcomes between the two studied groups, preoperatively and 6 months after the procedure.

	Sphere	Group A (n= 20)	Group B (n= 20)	P
Refraction Sphere	Pre-Operative			
	Min. – Max.	-9.75 – -5.50	-8.75 – -3.0	0.463
	Median (IQR)	-3.0 (-6.00–-1.00)	-2.25(-4.0–-1.50)	
	Post-Operative			
	Min. – Max.	-6.0 – -4.12	-7.0 – -3.0	0.818
	Median (IQR)	-1.25(-3.88–0.0)	-1.0 (-3.50– -0.25)	
	Z(p1)	2.483*(0.013*)	0.831(0.406)	
Refraction Cylinder	Pre-Operative			
	Min. – Max.	-9.25 – -2.75	-9.0 – -1.0	0.678
	Median (IQR)	-5.13 (-6.13 – -4.50)	-6.0 (-6.63 – -4.25)	
	Post-Operative			

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	Min. – Max.	-7.0 – -0.75	-7.0 – -2.75	0.478
	Median (IQR)	-4.0 (-4.50 – -2.25)	-3.0 (-4.75 – -1.25)	
	Z(p1)	3.472*(0.001*)	3.073*(0.002*)	
CDVA	Pre-Operative			
	Min. – Max.	0.10 – 0.70	0.01 – 0.70	0.149
	Mean ± SD.	0.28 ± 0.17	0.36 ± 0.21	
	Median (IQR)	0.30 (0.10 – 0.35)	0.40 (0.20 – 0.50)	
	Post-Operative			
	Min. – Max.	0.20 – 0.80	0.10 – 1.0	0.049*
	Median (IQR)	0.40 (0.30 – 0.50)	0.55 (0.35 – 0.80)	
	$Z(p_1)$	3.601*(<0.001*)	3.611*(<0.001*)	

Z: Wilcoxon signed ranks test

p: p Value for comparing between the studied groups

p_1: p Value for comparing between pre- and post-operative

*: Statistically significant at p ≤ 0.05

Group A: Blind implantation of ICRS without keratoscope

Group B: Keratoscope assisted ICRS implantation

Table 3: Scheimpflug image analysis of the cornea and anterior chamber for the two studied groups, preoperatively and 6 months after the procedure.

		Group A (n = 20)	Group B (n = 20)	p
K1	Pre-Operative			
	Min. – Max.	43.90 – 55.0	43.50 – 54.20	0.746
	Mean ± SD.	47.97 ± 2.93	48.29 ± 3.16	
	Post-Operative			
	Min. – Max.	41.40 – 49.10	34.60 – 46.50	0.004*
	Mean ± SD.	44.57 ± 2.22	42.08 ± 2.91	
	t1(p1)	6.997*(<0.001*)	10.613*(<0.001*)	
K2	Pre-Operative			
	Min. – Max.	50.10 – 57.0	42.90 – 58.30	0.219
	Mean ± SD.	52.81 ± 2.21	51.54 ± 3.92	
	Post-Operative			
	Min. – Max.	42.80 – 53.30	37.90 – 52.80	0.006*
	Mean ± SD.	48.20 ± 2.56	45.36 ± 3.51	
	t1(p1)	6.254*(<0.001*)	5.887*(<0.001*)	
K Max	Pre-Operative			
	Min. – Max.	51.40 – 63.0	49.70 – 60.0	0.26
	Mean ± SD.	58.15 ± 3.22	57.03 ± 2.97	
	Post-Operative			
	Min. – Max.	47.50 – 57.0	48.0 – 55.70	0.005*
	Mean ± SD.	53.67 ± 2.92	51.15 ± 2.35	
	t1(p1)	10.082*(<0.001*)	6.841*(<0.001*)	

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Max Elevation (Front)	Pre-Operative			
	Min. – Max.	13.0 – 40.0	11.0 – 55.0	0.068
	Median (IQR)	20.0 (14.50 – 27.50)	28.0 (20.50 – 36.0)	
	Post-Operative			
	Min. – Max.	13.0 – 33.0	15.0 – 45.0	0.001*
	Median (IQR)	15.0 (13.50 – 21.50)	28.50 (18.0 – 37.0)	
	Z(p1)	3.329*(0.001*)	1.197(0.231)	
Max Elevation (Back)	Pre-Operative			
	Min. – Max.	8.0 – 53.0	5.0 – 80.0	0.289
	Median (IQR)	34.50 (17.50 – 45.0)	20.0 (18.0 – 34.)	
	Post-Operative			
	Min. – Max.	8.0 – 40.0	5.0 – 76.0	0.728
	Median (IQR)	26.0 (16.0 – 35.0)	23.0 (16.50 – 32.50)	
	Z(p1)	3.074*(0.002*)	1.400(0.162)	
ACD	Pre-Operative			0.058
	Min. – Max.	2.70 – 4.20	3.14 – 4.21	
	Mean ± SD.	3.33 ± 0.42	3.58 ± 0.37	
	Post-Operative			
	Min. – Max.	2.77 – 3.96	2.89 – 4.19	0.384
	Mean ± SD.	3.23 ± 0.33	3.32 ± 0.33	
	$t_1(p_1)$	2.869*(0.010*)	4.687*(<0.001*)	

Z: Wilcoxon signed ranks test

t: Student t-test t_1: Paired t-test

p: p Value for comparing between the studied groups

p_1: p Value for comparing between pre- and post-operative

*: Statistically significant at p ≤ 0.05

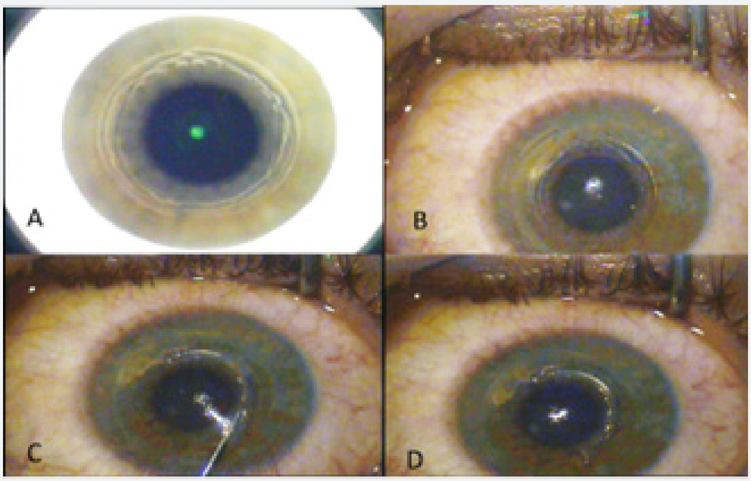

Figure 2: Empirical implantation of ICRS. Tunnel creation with femtolaser (A), preimplantation image (B), empirical positioning of the ICRS into the tunnel to straddle the cone (C), the ICRS in its final position (D).

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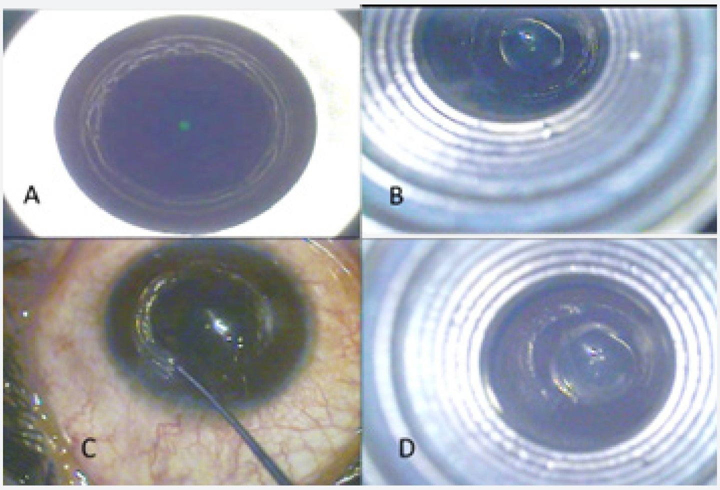

Figure 3: Keratoscope assisted implantation of ICRS. Tunnel creation with femtolaser (A), preimplantation image with hand held Maloney keratoscope showing the distorted mire image at the cone (B), positioning of the ICRS into the tunnel to straddle the cone (C), the ICRS in its final position aiming to regularize the mire image(D).

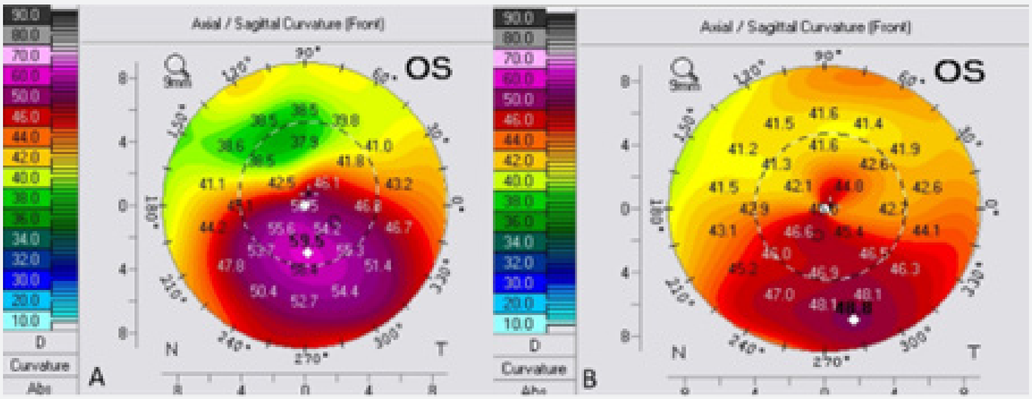

Figure 4: Sagittal curvature map preoperatively (A) and 6 months postoperatively (B); in keratoscope assisted implantation.

Discussion

Intrastromal corneal ring segments showed a dramatic change in the last decades either in the designs, nomograms, or the methods of implantation. Nevertheless, no consensus yet developed for proper and accurate intraoperative placement. To our knowledge, this is the first case series to handle the intraoperative manipulation of ICRS with the assistance of manual keratoscope, in comparison with the traditional method. The different proposed nomograms offer guidelines for surgeons to select parameters necessary for the implantation process. These parameters for ICRS procedures include the number of segment rings, their arc length and thickness as well as the location of insertion. One of the significant pitfalls of nomograms is their empirical character, being built on unpublished clinical data, and their non-correspondence to an accurate mathematical model on the ICRS effect on the ectatic cornea [9]. Spherocylindrical refraction and topographic profile are subjective rather than objective variables in most nomograms [10].

In a case report by Izquierdo L et al. [11] they presented the adaptation of the existing technique of intrastromal corneal ring (ICRS) implantation enabling repositioning of the ring position postoperatively to manage a refractive failure in two patients with keratoconus, refractive failure after ICRS implantation is a significant issue which results mainly from improper positioning of ring segments intraoperatively. Monteiro T et al. [12] found other causes of refractive failure after ICRS implantation that required exchange/adjustment surgery with a new intrastromal corneal ring segment (ICRS) combination after unsuccessful visual and/or refractive outcomes after primary ICRS surgery, and those factors included segment type, arc length and thickness. Kucumen RB et al. [13] evaluated femtosecond laser-created tunnels intraoperatively by anterior segment optical coherence tomography (AS-OCT) during intrastromal corneal ring segment implantation, the qualitative and quantitative evaluation of the

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intrastromal tunnel by AS-OCT before implantation of the ring segments is a practical intraoperative approach that may offer a safer surgery. However, the fine position of the implanted segment on the horizontal level in relation to the cone, cannot be assessed by AS- OCT.

There was no published data regarding proper segment positioning after track creation with femtosecond laser; we believe that intraoperative segment centration is the single most important determining factor to reach the required visual and refractive outcome. Generally, the standard empirical implantation technique is typically done with a preoperative lamp marking and an intraoperative Mendez ring, in order to compensate for the risk of significant cyclotorsion, that could occur with the patient assuming a supine position. In our control group (Group A), we did not rely on these visual estimation markings, which could be considered as a limitation of our study. Nevertheless, this limitation emphasizes the potential advantage of MKI (Group B), as it can inherently control cyclotorsion and reduce the need for preoperative axis marking, by projecting the mire directly onto the supine patient's cornea and enabling real-time visualization of the cone location and axis. In this pilot study, the results showed a better flattening effect on the anterior corneal surface when manual keratoscope was used to guide the implanted segment to its final position.; this could be explained by the direct help of the reflected first Purkinje-Sanson image. Astonishingly, all the measured refractive parameters did not show significant differences between both groups. However, better CDVA was obtained in the MKI group. We hypothesize that this could be attributed to the enhanced corneal-surface regularization process obtained with the use of MKI, potentially reducing higher-order aberrations. However, in order to further confirm this hypothesis, more evidence is needed regarding the correction of high order aberrations such as Coma, which were not directly quantified in this study.

Different intraoperative utilities are recently added to the refractive armamentarium, such intraoperative aberrometer (Optiwave Refractive Analysis [ORA]) and digital eye-tracking (VERION) which are used in mild astigmatic correction. Those technologies may have a promising role in the adjustment of implanted rings to reach the maximum outcome. However, these techniques are not widely spread nor adjusted to deal with keratoconus assessment, so a relatively more straightforward way is to use the reflected mire on the anterior corneal surface as a reference. Limitations of this study include small sample size and the lack of cyclotorsion compensation in the control group. Another limitation, is that we did not study the effect of keratoscope guided implantation on patient satisfaction, nor on higher order aberrations. Additionally, the use of corneal cross-linking on all the patients four weeks after the implantation could have induced a variable degree of flattening to the corneal surface, which might have affected the final results. Further large-scale studies are needed to cover those areas.

Declarations

Ethics approval and consent to participate: All procedures were reviewed and approved by the Ethical Committee of the Menoufia University Hospital and followed the tenets of the Declaration of Helsinki. Written informed consent was obtained from each patient after full discussion of the procedure involved, duration of treatment, possible intraoperative maneuvers, and potential postoperative complications.

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