Original Article

Evaluation of dynamic corneal response parameters and the biomechanical E-staging after Intacs® SK implantation in keratoconus

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Purpose: This retrospective longitudinal study evaluated the biomechanical E-staging in KC corneas before and after intracorneal ring segment (ICRS) implantation (Intacs® SK, Addition Technology, Illinois, United States). **Methods:** Biomechanical E-staging for ectatic corneal diseases was applied retrospectively on 49 KC corneas of 41 patients who underwent ICRS implantation. The main outcome parameters included the Corvis Biomechanical Factor (CBiF, the linearized Corvis Biomechanical Index and the biomechanical parameters included), the resulting biomechanical E-staging, the stress-strain index, thinnest corneal thickness (TCT), maximal anterior keratometry (Kmax), and the anterior radius of curvature (ARC). They were evaluated at 1.9 ± 1.1 months preoperatively and postoperatively after 2.8 ± 0.7, 5.8 ± 1.0, and 10.6 ± 2.3 months. **Results:** The CBiF decreased (4.9 ± 0.5 | 4.7 ± 0.5, P = 0.0013), and the E-staging increased significantly (2.8 ± 0.8 | 3.1 ± 0.9, P = 0.0012, paired t-test) from preoperatively to the first postoperative follow-up. The difference remained significant after 6 months; however, there was no more difference after 11 months. TCT was stable, whereas Kmax and ARC significantly decreased after ICRS implantation (TCT: 464 ± 49, 470 ± 51, 467 ± 38, 461 ± 48; Kmax: 56.3 ± 4.5, 54.7 ± 4.5, 54.2 ± 4.8, 54.1 ± 4.3; ARC: 51.5 ± 3.4, 48.3 ± 3.8, 48.6 ± 3.0, 48.6 ± 3.2 preoperatively and 3, 6, and 11 months postoperatively, respectively). Besides Kmax and ARC, Ambrósio's relational thickness to the horizontal profile (ARTh) was the only parameter that was significantly lower than preoperatively at any follow-up ($P \leq 0.0024$, Wilcoxon matched-pairs test). **Conclusion:** Intacs® SK implantation results in an increasing biomechanical E-staging in the first postoperative months with stabilization near preoperative values after 1 year. Significantly lower ARTh values at any follow-up document the ICRS effect and contribute to a slightly higher postoperative biomechanical E-staging value.

Key words: Biomechanical E-staging, biomechanics, CBI, CBiF, Corvis, intracorneal ring segments, keratoconus

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The implantation of intracorneal ring segments (ICRSs) was initially developed to correct mild myopia[1] but has nowadays found its main role in the treatment of corneal ectasias such as post-laser *in situ* keratomileusis keratectasia[2] or keratoconus (KC).[3,4] Although early KC stages may achieve a good distance visual acuity with glasses, intermediate and advanced KC eyes typically require rigid oxygen-permeable contact lenses to achieve a full visual rehabilitation because of the advanced corneal thinning and irregular astigmatism formation.[5] ICRS implantation is a therapeutic option that enables ophthalmologists to delay or even avoid a corneal transplantation in KC patients who are unable to handle or tolerate contact lenses.[6]

ICRS implantation includes an intrastromal tunnel creation, which used to be performed with a microkeratome and is nowadays more commonly performed with the femtosecond laser, reducing tunnel complications,[7] and subsequent implantation of the ring segments into the stroma of the human cornea.[3,8–10] Regarding tomography, there is consensus in the existing literature that ICRS implantation causes flattening of the cornea, thereby reducing myopic refraction and finally improving the uncorrected and corrected distance visual acuity of KC patients.[3,11–13] The mechanism of action of ICRS has been described via an arc-shortening effect within the cornea due to the added implant volume in the cornea.[14] An additional "artificial-limbus effect" caused by continuous ICRS has also been reported.[14]

Biomechanically, KC has a decreased resistance to deformation when compared to healthy corneas.[15] The Corvis ST® (CST, Oculus, Wetzlar, Germany) measures the corneal deformation after applying a standardized air puff.[16,17] CST measurements indicated that the highest radius of curvature during the corneal deformation phase decreased significantly after KeraRing or MyoRing implantation in KC.[10] Another recent study investigated several CST parameters (integrated radius, deformation amplitude ratio, stiffness parameter A1,

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stress-strain-index, and highest concavity radius) 3 months after Intacs® SK (Addition Technology, Illinois, United States) ICRS implantation and concluded that this type of ICRS implantation did not affect corneal CST biomechanical measurements in early follow-up examinations.[18]

The Corvis Biomechanical Factor (CBiF) is the linearized term of the non-linear Corvis Biomechanical Index (CBI) and serves as a basis for the biomechanical E-staging for KC and other ectatic corneal diseases.[19,20] Five stages E0–E4 resulted out of the division of the CBiF value range in analogy to the ABC tomographic parameters of Belin's ABCD KC staging system.[21] The CBiF and thus also the biomechanical E-staging are no standalone parameters but are based on a combination of the following dynamic corneal response (DCR) parameters: 1) Ambrósio relational thickness to the horizontal profile (ARTh), 2) stiffness parameter A1 (SP-A1), 3) integrated radius (IR), 4) deformation amplitude ratio 2 mm (DA ratio: 2 mm), and 5) the velocity of the corneal apex at inward applanation (A1 velocity).

The purpose of this study was to evaluate the biomechanical E-staging and the DCR parameters included therein at different follow-up times after ICRS implantation of Intacs® SK in KC corneas to assess whether biomechanical E-staging composed of DCR parameters or single DCR parameters are influenced by ICRS implantation.

Methods

This retrospective longitudinal study was based on KC patients who underwent Intacs® SK ICRS implantation. The study is part of a clinical observational trial (trial number: NCT03923101, U.S. National Institutes of Health; https://ClinicalTrials.gov) that was approved by the regulatory body, the local ethics committee of Saarland (Ethikkommission bei der Ärztekammer des Saarlandes, reference number: 121/20) and adheres to the tenets of the Declaration of Helsinki.[22] Each patient provided written consent for data analysis.

Adult patients (≥18 years old) with KC who did not tolerate contact lenses and were thus treated with Intacs® SK ICRS implantation (made of polymethylmethacrylate) from January 2017 to December 2021 were assessed for inclusion. Patients required a thinnest corneal thickness (TCT) of more than 450 µm in the 6-mm zone, a maximal anterior keratometry (Kmax) of less than 65 D,[4] and the ICRS configuration was based on the patient's preoperative corneal tomography and the manufacturer's nomogram. The implantation was performed under topical anesthesia with oxybuprocaine eyedrops (Conjuncain® EDO®, Bausch and Lomb, New York, USA) by the same experienced surgeon (LD) in all patients included in this study. First, the tunnel creation and a small incision to insert the ICRS were performed using the femtosecond laser (IntraLase FS laser, Johnson and Johnson, California, United States). Second, the Intacs® SK ICRSs were inserted manually under sterile conditions. Postoperatively, the patients received a 17-mm bandage contact lens, artificial tears, and topical antibiotic eyedrops (Floxal® EDO®, Bausch and Lomb, New York, USA) for the first week. They also received non-preservative dexamethasone eyedrops (Dexa Sine®, Novartis, Basel, Switzerland) five times daily tapering off weekly by one while continuing topical treatment with artificial tears.

Patients were included if a Pentacam (Oculus, Wetzlar, Germany) and a CST examination with a quality score of "OK" were available preoperatively and postoperatively. Patients were excluded (1) if they underwent Intacs® SK ICRS implantation because of other diagnoses than KC or (2) if they had previous eye surgery. None of the patients underwent prior or simultaneous corneal crosslinking.

Preoperative and postoperative Pentacam and CST examinations were exported. Main outcome parameters included the Pentacam-derived TCT, the Kmax, the anterior radius of curvature (ARC, the "A" parameter of the ABCD KC classification), the Belin-Ambrósio Deviation Index (BAD-D), the CST-derived CBiF, the dynamic corneal response (DCR) parameters included therein, the resulting biomechanical E-staging, and the stress-strain index.

The values of the main outcome measure parameters were checked for normal distribution by using the Shapiro-Wilk test assuming normal distribution with $P > 0.05$. Preoperative and postoperative findings were subsequently compared using the two-tailed paired *t*-test (if normally distributed) or the Wilcoxon matched-pairs test (if not normally distributed) assuming significant differences with $P < 0.05$. Calculations were done using GraphPad Prism software (version 5.0, GraphPad Software, San Diego, California, USA).

Results

This study included 49 corneas of 41 patients older than 18 years of age who underwent Intacs® SK ICRS implantation because of KC. The mean age of the patients was 31 ± 10 years; 32 patients were males, and nine patients were females. Preoperative measurements were available at 1.9 ± 1.1 months preoperatively for 49 corneas of 41 patients. Postoperative measurements were available at 2.8 ± 0.7 months (35 corneas of 28 patients), 5.8 ± 1.0 months (33 corneas of 29 patients), and 10.6 ± 2.3 months (29 corneas of 24 patients).

The analysis of tomographic parameters revealed that Kmax and ARC were significantly lower postoperatively at any follow-up ($P \leq 0.0023$, paired *t*-test, Table 1).

The TCT was measured slightly higher than preoperatively at any follow-up without reaching statistical significance. The Belin-Ambrósio deviation index (BAD-D) was significantly higher at 3 ($P = 0.001$) and 6 months ($P = 0.0056$, Table 1) postoperatively and comparable to preoperatively after eleven months ($P = 0.5874$, Table 1). The CBiF decreased significantly from pre- to postoperatively at 3 ($P = 0.0013$) and 6 months ($P = 0.0036$, Fig. 1, Table 1) and remained slightly lower after 11 months ($P = 0.0935$).

The biomechanical E-staging that results out of the CBiF increased accordingly at 3 ($P = 0.0012$) and 6 months postoperatively ($P = 0.0035$) and remained slightly higher than preoperatively after 11 months ($P = 0.0935$, Fig. 1, Table 1).

Considering the DCR parameters, the integrated radius was measured significantly higher at 3 ($P = 0.0009$, Table 1) and 6 months postoperatively ($P = 0.0011$, Table 1). SP-A1 increased slightly at 3 and 11 months after Intacs® SK ICRS implantation and was slightly lower than preoperatively at 6 months postoperatively.

The only CST-based parameter that showed significantly differing values at each follow-up compared to preoperative

Table 1: Main outcome measures at different follow-up examinations after Intacs® SK intracorneal ring segment implantation in keratoconus

A	Preoperatively	Follow-up at 3 months	*P*
n corneas (patients)	35 (28)	35 (28)	
Kmax	56.3±4.5	54.7±4.5	**0.0023^{T*}**
ARC	51.5±3.4	48.3±3.8	**<0.0001^{T*}**
TCT	464±49	470±51	0.1302^{W}
BAD-D	8.7±2.3	10.0±3.7	**0.001^{W*}**
ARTh	197.8±78	155.3±80	**0.0002^{W*}**
SP-A1	63.1±17	64.7±21	0.8763^{W}
IR	11.1±2.0	12.2±2.8	**0.0009^{T*}**
DA ratio 2 mm	5.5±0.9	5.9±1.3	0.069^{T}
A1 velocity	0.169±0.03	0.171±0.04	0.6569^{T}
SSI	0.885±0.2	0.869±0.2	0.8506^{W}
CBiF	4.9±0.46	4.7±0.5	**0.0013^{W*}**
E-Staging	2.8±0.8	3.1±0.9	**0.0012^{W*}**
B	**Preoperatively**	**Follow-up at 6 months**	***P***
n corneas (patients)	33 (29)	33 (29)	
Kmax	56.7±4.4	54.2±4.8	**0.0003^{W*}**
ARC	51.4±3.1	48.6±3.0	**<0.0001^{T*}**
TCT	462±42	467±38	0.1317^{T}
BAD-D	8.7±2.5	9.6±3.3	**0.0056^{W*}**
ARTh	202.0±85	157.9±91	**<0.0001^{W*}**
SP-A1	63.2±14	62.8±18	0.9156^{T}
IR	10.8±2.2	11.9±2.9	**0.0011^{T*}**
DA ratio 2 mm	5.3±0.9	5.6±0.9	**0.0378^{T*}**
A1 velocity	0.163±0.03	0.166±0.02	0.4937T
SSI	0.924±0.3	0.930±0.3	0.8863^{W}
CBiF	4.9±0.4	4.7±0.5	**0.0036^{T*}**
E-Staging	2.7±0.8	3.1±0.8	**0.0035^{T*}**
C	**Preoperatively**	**Follow-up at 11 months**	***P***
n corneas (patients)	29 (24)	29 (24)	
Kmax	56.5±4.6	54.1±4.3	**0.0004^{T*}**
ARC	51.8±3.1	48.6±3.2	**<0.0001^{T*}**
TCT	453±49	461±48	0.0528^{W}
BAD-D	8.8±2.3	8.9±2.8	0.5874^{T}
ARTh	194.3±81	165.4±89	**0.0024^{W*}**
SP-A1	63.0±18	65.0±16	0.4550^{T}
IR	10.9±2.2	11.4±2.5	0.1749^{T}
DA ratio 2 mm	5.4±1.0	5.6±1.2	0.2509^{T}
A1 velocity	0.165±0.03	0.169±0.03	0.3487^{T}
SSI	0.918±0.2	0.922±0.2	0.9138^{T}
CBiF	4.9±0.5	4.8±0.5	0.0935^{T}
E-Staging	2.8±0.9	2.9±0.9	0.0933^{T}

A: 3 months postoperatively, B: 6 months postoperatively, C: 11 months postoperatively. Kmax, maximal anterior keratometry. TCT, Thinnest Corneal Thickness. BAD-D, Belin-Ambrósio Deviation Index. ARTh, Ambrósio Relational Thickness to the horizontal profile. SP-A1, stiffness parameter A1. IR, integrated radius. DA ratio 2 mm, deformation amplitude ratio at 2 mm. A1 velocity, velocity at inward applanation. SSI, stress-strain index. CBiF, Corvis Biomechanical Factor (linearized Corvis Biomechanical Index). E-Staging based on the CBiF. Bold and asterisks, significant difference between preoperative values and values at follow-up examination (calculated by (1) paired two-tailed *t*-test^{T}, if normally distributed or by (2) Wilcoxon matched-pairs test^{W} if not normally distributed – as determined by Shapiro-Wilk test)

values was ARTh - it was significantly lower than preoperatively regardless of the follow-up time [Table 1]. The stress-strain-index did not show a significant change at any postoperative follow-up.

Discussion

This study investigated whether Intacs® SK ICRS implantation affects the CST-based DCR parameters that form the Corvis

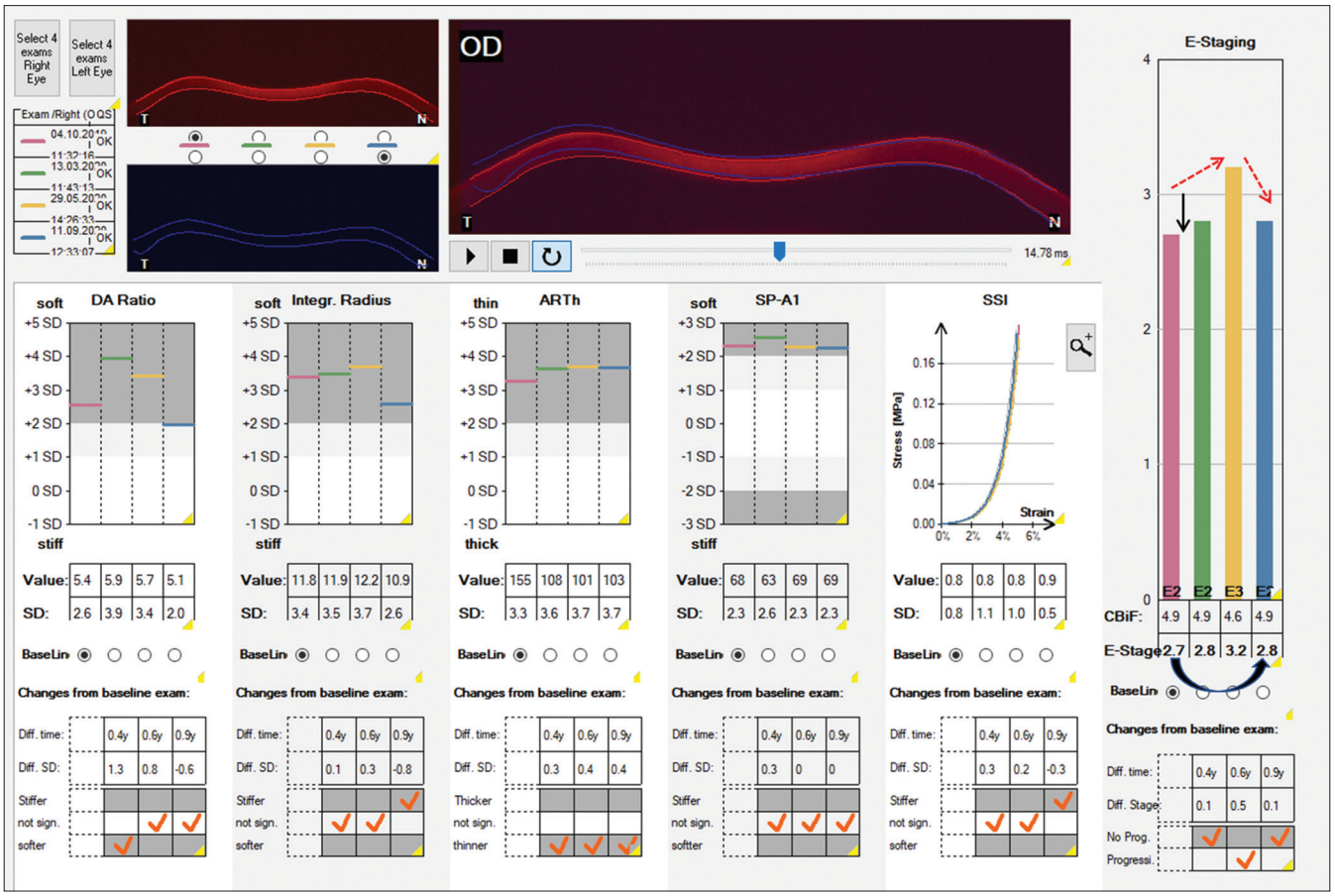

Figure 1: Homburg Biomechanical E-Staging as provided by the Corvis ST® (Oculus, Wetzlar, Germany). Red, baseline examination (October 04, 2019). Intacs® SK intracorneal ring segment (ICRS) implantation was performed on November 28, 2019 (black arrow). Green: first follow-up (March 13, 2020), yellow: second follow-up (May 29, 2020), each with increasing E-stage compared to baseline (red dotted arrows). Blue: third follow-up (September 11, 2020) with a decreasing E-stage comparable to baseline (red dotted arrows). "E-Stage" indicating biomechanical E-stage values for each follow-up with baseline (2.7), increasing values at first (2.8) and second follow-up (3.2) and subsequent stabilization near to baseline value (2.8, black curved arrow). Maximal anterior keratometry readings: 53.8D | 50.9D | 51.8D | 51.9D. Decreased values for Ambrósio Relational Thickness to the horizontal profile after Intacs® SK ICRS implantation (108 | 101 | 103) when compared to baseline (155)

Biomechanical Index (CBiF) and thus the biomechanical E-staging at different follow-up times.

Prior to the introduction of the CST, an assessment of corneal biomechanics was enabled by the ocular response analyzer (ORA, Reichert Instruments, Depew, New York, United States). Some studies investigated the biomechanical effects of ICRS implantation with this device. One study examined KC corneas 6 months after Intacs® SK ICRS implantation and reported that the corneal curvature decreased significantly without altering the biomechanical parameters corneal hysteresis or corneal resistance factor as measured by the ORA.[23] Corneal hysteresis reflects mostly corneal viscosity, and the corneal resistance factor depends on the elastic properties of the cornea; both parameters are reported to be significantly reduced in advanced KC corneas.[24] Other studies found a significantly lower corneal resistance factor within the first 1–6 months after ICRS implantation[3,24] that increased at later follow-up examinations.[8]

Hence, the ORA detected a biomechanical KC progression or worsening within the first postoperative months after ICRS implantation in these studies. In our study, the biomechanical KC severity as measured by the CST ("E-staging") also increased significantly at 3 and 6 months after Intacs® SK ICRS implantation, although there was a clear tomographic stabilization with flattening of the cornea as shown by Kmax and ARC [Table 1]. It has been hypothesized that this biomechanical KC progression results out of a weakening of the stromal collagen lamellae caused by the tunnel creation when using the femtosecond laser.[3,8] The consequence would be that a more central ICRS implantation would lead to a greater biomechanical weakening due to a dissection of (para-)central collagen lamellae,[3] whereas a more peripheral implantation would have less effect on corneal biomechanics. In addition, it could be assumed that biomechanical stabilization would occur during the course of histopathological changes, including stromal remodeling and fibrosis formation within the corneal stroma around the ICRS.[8,25]

The stiffness parameter A1 (SP-A1) can be used as a CST-based measure for corneal stiffness: If it was approximately comparable to preoperatively at 3 ($P = 0.8763$) and 6 ($P = 0.9156$, Table 1) months after ICRS implantation, it increased slightly, although not significantly ($P = 0.4550$): from 63.0 preoperatively to 65.0 11 months postoperatively in our study [Table 1]. Another recent study also investigated CST-based DCR parameters,

including the thickness-independent stress-strain-index in KC patients after ICRS implantation at 3 months postoperatively, and did not find any significant changes when comparing the measuring results to preoperatively.[18] In addition, in our study, the stress-strain index did not undergo any significant changes at different follow-up examinations.

However, there was one CST-based parameter that was significantly lower throughout all postoperative follow-up examinations in our study when compared to preoperatively: Ambrósio's relational thickness to the horizontal profile (ARTh, Table 1), which is a thickness-dependent parameter; lower values indicate a centrally thinner cornea with a fast thickness increase toward the periphery of the cornea.[16]

As there was no significant change of the thinnest corneal pachymetry postoperatively in our study [Table 1] or in another study after Intacs® SK ICRS implantation,[9] this ARTh decrease and thus the faster thickness increase of the cornea in the periphery is probably attributable to the ICRS themselves implanted within the 6-mm zone. As a result of the corneal thickening in the ICRS implantation zone, the central cornea appears to be comparably thinner, although the thinnest pachymetry itself would actually not have changed. To a certain extent, this result could be expected as the ICRS implantation might not influence the thinnest nor the central corneal pachymetry but rather that of the implantation zone.

As in other studies, a stabilization with constant TCT and significantly decreased Kmax and ARC values was measured tomographically already from the first follow-up examinations.[3,8,9,11] The clinician might prefer ARC values to the single point parameter Kmax because they are measured over a 3.0-mm zone centered at the thinnest corneal point.[26] In contrast, the initially significantly higher BAD-D indices after 3 and 6 months indicated a tomographic progression [Table 1]. However, as the BAD-D also includes pachymetric progression data (from the central to the peripheral cornea[27]), the increase of BAD-D together with the decrease of ARTh can be explained by the midperipheral thickness changes caused by the Intacs® SK ICRS implantation within the 6-mm zone.

There arises a limitation for the application of the biomechanical E-staging from these results and conclusions: It cannot be assumed that the implantation-related and thickness-dependent change of ARTh will regress over time as the cornea will retain a thickness increase in the midperiphery because of ICRS implantation. As ARTh contributes to the CBiF and the final biomechanical E-staging value, a tendentially higher biomechanical E-staging has to be expected after ICRS implantation.

Other limitations of this study are (1) the moderate sample size of patients who underwent Intacs® SK ICRS implantation, (2) the dropout rate at the different postoperative follow-up examinations, and (3) the inclusion of both eyes per patient in eight cases.

Conclusion

In summary, there is a tomographical stabilization with stable TCT and significantly decreasing Kmax and ARC values after Intacs® SK ICRS implantation from the first postoperative follow-up examinations. Biomechanically, there appears to be a "weakening" of the cornea within the first postoperative months, which may be attributable to the impact of surgery upon the stromal collagen lamellae. There is an increase of the biomechanical E-staging in the first postoperative months. Approximately 1 year after ICRS implantation, the biomechanical E-staging stabilizes near to its preoperative level, and ARTh shows the only significant change in biomechanical parameters, which is most likely because of a corneal thickening in the midperipheral implantation zone. Finally, this study revealed that there are changes after Intacs® SK ICRS implantation that are detected by the CST and that should be clearly differentiated from a further progression in the longitudinal evaluation of KC corneas after ICRS implantation.

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Ethical approval

This study was approved by the local ethics committee (Ethikkommission bei der Ärztekammer des Saarlandes, reference number 121/20).

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