Changes in Corneal Biomechanical Properties after Artiflex® and Visian® ICLV4c Implantation Using Scheimpflug-Based Noncontact Tonometer: A Comparative Analysis

Alterações nas Propriedades Biomecânicas da Córnea Após Implante de Artiflex® e Visian® ICLV4c Usando Tonómetro de Não Contato Baseado em Scheimpflug: Uma Análise Comparativa

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ABSTRACT

INTRODUCTION: Our purpose was to compare changes in biomechanical properties after Artiflex® and Visian® ICLV4c implantation.

METHODS: A prospective, nonrandomized, comparative, interventional case series study with corneal biomechanical evaluation by an ultra-high-speed Scheimpflug imaging during non-contact tonometry (Corvis ST, OCULUS®).

RESULTS: The study included 38 eyes: 23 Artiflex-treated eyes and 15 implantable collamer lens (ICL)-treated eyes. The average age at surgery and the mean follow-up time were similar between groups (p=0.170 and p=0.252, respectively). Artiflex- and ICL-treated eyes showed a significantly stiffer behaviour in 12/28 and 4/28 of first and in 5/11 and 1/11 of second generation biomechanical corneal parameters compared to preoperative values, respectively. Both groups showed a softer behaviour in the same only 2/28 of first generation parameters. Comparing Artiflex- and ICL-treated eyes, the "PachySlope" was the only postoperative parameter that differed between groups, but the difference already exists in preoperative evaluation. All biomechanical parameters had a similar or less proportion of eyes within ectasia susceptibility interval at postoperative in both Artiflex- and ICL-treated eyes. There was a significant increase of intraocular pressure (evaluated by different methods, all with p<0.05) in Artiflex-treated eyes after surgery, compared to preoperative values.

CONCLUSION: Overall it seems that there is an increase in corneal resistance after both phakic intraocular lens implantation (supported by less proportion of eyes within ectasia susceptibility interval at postoperative) or in aqueous humour resistance. The effect seems to be higher in Artiflex-treated eyes because of more postoperative biomechanical parameters changed and higher IOP (evaluated by different methods) than ICL-treated eyes, when comparing the pre and postoperative period. These findings support the safety of these surgical options for the correc-

tion of the refractive error of eyes with contraindications to laser ablation from a biomechanical viewpoint.

KEYWORDS: Biomechanical Phenomena; Cornea; Lens Implantation, Intraocular; Phakic Intraocular Lenses; Refractive Surgical Procedures.

RESUMO

INTRODUÇÃO: O nosso objetivo foi comparar as alterações nas propriedades biomecânicas após a implantação de Artiflex® e Visian® ICLV4c.

MÉTODOS: Estudo prospetivo, não randomizado, comparativo, de série de casos com avaliação biomecânica da córnea por sistema de Scheimpflug durante tonometria de não contato (Corvis ST, OCULUS®).

RESULTADOS: O estudo incluiu 38 olhos: 23 olhos tratados com Artiflex e 15 olhos tratados com lente implantável de collamer (ICL). A média de idade na cirurgia e o tempo médio de acompanhamento foram semelhantes entre os grupos (p=0,170 e p=0,252, respetivamente). Olhos tratados com Artiflex e ICL mostraram um comportamento significativamente mais rígido em 12/28 e 4/28 parâmetros biomecânicos de primeira e em 5/11 e 1/11 parâmetros biomecânicos de segunda geração em comparação com os valores pré-operatórios, respetivamente. Ambos os grupos mostraram um comportamento menos rígido em apenas 2/28 dos parâmetros de primeiro geração e de forma semelhante. Comparando os olhos tratados com Artiflex e ICL, o "PachySlope" foi o único parâmetro pós-operatório que diferiu entre os grupos, mas a diferença já existia na avaliação pré-operatória. Todos os parâmetros biomecânicos tiveram uma proporção semelhante ou menor de olhos dentro do intervalo de suscetibilidade à ectasia no pós-operatório, tanto nos olhos tratados com Artiflex como com ICL. Houve aumento significativo da pressão intraocular (avaliada por diferentes métodos, todos com p<0,05) nos olhos tratados com Artiflex após a cirurgia, em comparação aos valores pré-operatórios.

CONCLUSÃO: Em geral, houve um aumento na resistência da córnea após o implante de lentes intraoculares fáquicas (suportado por menor proporção de olhos dentro do intervalo de suscetibilidade à ectasia no pós-operatório) ou na resistência do humor aquoso. O efeito parece ser maior em olhos tratados com Artiflex por ter mais parâmetros biomecânicos alterados no pós-operatório e PIO mais elevada (avaliada por métodos diferentes) do que olhos tratados com ICL, quando comparamos o período pré e pós-operatório. Esses achados apoiam a segurança dessas opções cirúrgicas para a correção do erro refrativo dos olhos com contraindicação à ablação com laser do ponto de vista biomecânico.

PALAVRAS-CHAVE: Córnea; Fenómenos Biomecânicos; Implante de Lente Intraocular; Lentes Intraoculares Fáquicas; Procedimentos Cirúrgicos Refrativos.

INTRODUCTION

Refractive surgery was once almost synonymous with LASER. Nevertheless, phakic intraocular lens (pIOLs) has been a widely accepted alternative to surface ablation, such as for patients with higher refractive errors and any condition that could worsen after laser ablation (dry eye or form fruste keratoconus).[1] pIOLs have several other advantages over LASER ablation techniques including no risk of developing keratectasia,[1,2] fast visual recovery and rehabilitation, excellent refractive accuracy and stability, preservation of physiological accommodation, and reversibility.[3-6]

Comparing Artiflex® (Ophtec, Groningen, Netherlands) and Visian® ICLV4c (Staar Surgical AG, Nidau, Switzerland) implantation, two pIOLs options often used,[7] both showed similar refractive stability, predictability, safety, efficacy, quality of vision, and high patient satisfaction in our previous study.[8] To the best authors' knowledge, the comparative effect on biomechanical parameters after these two procedures options has not so far been investigated. This is also clinically meaningful because the postoperative biomechanical characteristics may impact the refractive outcomes[9,10] and in the measurement of the intraocular pressure,[11] not forgetting the inclusion of some patients with suspicious corneas for these procedures.

This study aimed to compare the effect on biomechanical

properties after Artiflex® and Visian® ICLV4c implantation using a Scheimpflug-based noncontact tonometer, in a sample of normal patients and patients with suspicious corneas.

MATERIAL AND METHODS

STUDY DESIGN

A prospective, nonrandomized, comparative, interventional case series was performed, and it included a group of patients scheduled for refractive surgery at the ophthalmology department at the Centro Hospitalar Universitário do Porto (CHUP) for myopic and/or astigmatic correction between December 2020 and July 2021, that underwent Artiflex® and Vision® ICLV4c implantation for having contraindications to laser ablation. All patients underwent a complete eye examination, tomographic and biomechanical assessment of the cornea before surgery and after 1-3 months after the procedure. This study was conducted following the norms of the Declaration of Helsinki (1964) and its latest amendment (Brazil, 2013). The authors ensured that all patients' anonymity was carefully protected. Approval was obtained from the "Departamento de Ensino, Formação e Investigação" (DEFI).

PARTICIPANTS

The eyes included respected the pIOL implantation criteria followed in our department: age between 21 and 45 years old; refractive stability for more than 1 year; pupillary diameter inferior to 6 mm; corrected anterior chamber depth (from endothelium) superior to 3 mm (Artiflex) and 2.8 mm (ICL); central endothelial cell density superior to 2500/mm^2; absence of corneal ectasia, previous refractive surgery, history of glaucoma, uveitis, significant retinal pathology or detachment, and chronic systemic disease. The exclusion criteria for both groups were: follow-up less than 1 month.

PARAMETERS

The following variables were analysed:

- Demographic characteristics of the study population (gender, age at surgery, type of surgery, type of intraocular lens) (Table 1);
- Clinical features before and after the procedure [best-corrected distance visual acuity (CDVA), uncorrected distance visual acuity (UDVA), sphere and cylinder refraction, cylinder axis, spherical equivalent (SE), IOP, objective scattered index (OSI), endothelial cell density (ECD), and time of follow-up] (Table 2);
- Cornea biomechanical parameters [dynamic corneal response first and second-generation parameters] (Table 3).
- Cornea tomographic parameters [the final "D" of Belin/Ambrósio Enhanced Ectasia Display (BAD-D), average pachymetry progression index (RPIavg), maximum ambrosia relational thickness (ARTmax), maximum keratometry (Kmax), index of vertical asymmetry (IVA), index of surface variance (ISV), index of height decentration (IHD), and index of height asymmetry (IHA)] (Table 4).
- Ectasia risk assessment: preoperative and postoperative proportion of eyes within ectasia susceptibility interval and within the ectasia high-risk interval using 6 Corvis first generation parameters and 5 Corvis second generation parameters, which have known cut-offs (see Table 5).

Demographic and clinical data were collected from the patients' clinical records. For numerical analysis, the decimal visual acuity was converted to the logarithm of the minimum angle of resolution (logMAR) values. The IOP was assessed with Goldmann applanation tonometer (gIOP); noncontact tonometer (ncIOP) and biomechanical corrected (bcIOP) by the Corvis ST®; Ehlers (eIOP), Shah (sIOP), Dresden (dIOP) and Spoerl (spIOP) correction by the Pentacam® corrected system. Tomographic data was assessed with a Scheimpflug camera (Pentacam, OCULUS®). The corneal biomechanical assessment was made through ultra-high-speed Scheimpflug imaging during noncontact tonometry (Corvis ST, OCULUS®). The dynamic corneal response first and second-generation parameters included were detailed in our previous study.[8]

SURGICAL TECHNIQUE

All surgical procedures were performed at our center, under general anesthesia. Preoperatively, miosis was achieved through instillation of pilocarpine 2% for Artiflex and mydriasis through instillation of tropicamide 1% for Visian ICLV4c implantation. After administration of a topical anesthetic, limbal reference marks were placed at 0° and 180° (3- and 9-o'clock positions) with a needle in slit lamp in case of toric pIOL implantation. Intraoperatively, the limbal reference marks were used to mark the alignment axis, with a Mendez degree gauge.

Regarding the Artiflex implantation, a 3.2-mm superior corneoscleral incision was used. Two paracenteses were placed at 2 and 10 o'clock in Artiflex Myopia or adjusted according to the axis to be implanted in the Artiflex Toric. A cohesive viscoelastic substance was inserted through the paracentesis to maintain sufficient anterior chamber depth, protect the endothelium, and facilitate adjusting the PIOL within the eye during fixation. The pIOL was introduced through the 3.2-mm incision with a lens implant spatula and, after subtle rotation of the pIOL, it was fixated, on the horizontal axis in Artiflex Myopia or on the predetermined axis in Artiflex Toric, with the use of a disposable enclavation needle (Ophtec). An iridectomy was performed at 12 o'clock to avoid pupillary block glaucoma. Concerning Visian ICLV4c implantation, the IOL was inserted through a 3.2 mm clear temporal corneal incision and was placed in the posterior chamber, on the horizontal axis. For both procedures, the remaining ophthalmic viscoelastic substance was completely washed out of the anterior chamber with a balanced salt solution, and the incisions were hydrated and not sutured.

After surgery, all patients received topical ofloxacin 3

mg/mL 5 times a day for 2 weeks, prednisolone acetate 10 mg/mL 5 times a day for 3 weeks, and flurbiprofen sodium 0.3 mg/mL 5 times a day for 4 weeks. Oral prednisolone was also used on all patients, on a tapered schedule.

STATISTICAL ANALYSIS

Statistical analysis was performed using the SPSS program (SPSS Statistics, version 22.0 for Windows, SPSS Inc., IBM, Somers, NY). The normality of the variables was evaluated by the Shapiro-Wilk test. For pre and post-treatment analysis, the Wilcoxon test and paired sample T-test were used. The comparison between independent continuous variables was performed using the Mann-Whitney test and T-Student test. The Fisher exact test was used for nominal scaled data. Pearson and Spearman's bivariate correlation test were used to study linear correlations. For interpretation, a correlation coefficient was considered "very weak" if between 0 and ±0.19, "weak" if between ±0.20 and ±0.39, "moderate" if between ±0.40 and ±0.59, "strong" if between ±0.60 and ±0.79, and "very strong" if between ±0.80 and ±1.0. *P* values less than 0.05 were considered statistically significant.

RESULTS

DEMOGRAPHIC DATA

Twenty one patients (38 eyes) were included, 38% male and 62% female, aged 22 to 40 years, with a mean age of 30.75±5.22 years.

Artiflex® was implanted in 23 eyes (13 patients), 39% (9/23) with the Artiflex yopia, and 61% (14/23) with the Artiflex Toric. The mean age at surgery was 32.30±4.72 years and the mean follow-up was 1.30±0.71 months.

Visian® ICLV4c was implanted in 15 eyes (8 patients), 67% (10/15) with the spherical model, and 33% (5/15) with the toric model. The average age at surgery was 28.19±5.29 years, statistically different to Artiflex-treated eyes and the mean follow-up was 1.57±0.70 months, similarly to Artiflex-treated eyes (p=0.170 and p=0.252, respectively). (Table 1)

Table 1. Demographic data

	Artiflex	Visian ICL V4c	*p*-value
N (Eyes/patients)	23/13	15/8	NA
Gender			
Female	8/13	5/8	0.664
Male	5/13	3/8	
Age at surgery, y (mean±SD)	32.30±4.72	28.19±5.29	0.170
Time of follow-up, m (mean±SD)	1.30±0.71	1.57±0.70	0.252
Type of IOL			
Myopia/Spherical	9/23	10/15	0.184
Toric	14/23	5/15	

Bold text represents a statistically significant *p*-value.

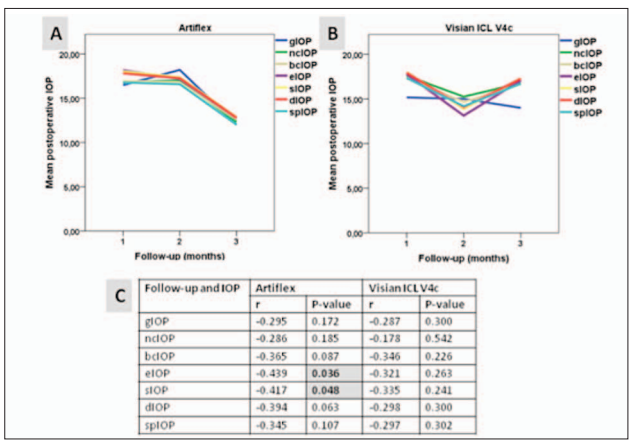
ICL, implantable collamer lens; N, number; NA, not applicable; m, months; SD, standard deviation; y, years.

CLINICAL OUTCOMES

Comparing to preoperative values, Artiflex- and ICL-treated eyes had a significant improvement of the sphere (both with p<0.001) and cylinder refraction (p<0.001 and p=0.003, respectively) and SE (both with p<0.001). Additionally, CDVA improved from 0.07±0.09 logMAR to -0.02±0.06 logMAR (p=0.001) in ICL-treated eyes, not seen in Artiflex-treated eyes, and there was a significant worsening of ECD (p<0.001) and IOP (evaluated by different methods, all with p<0.05) in Artiflex-treated eyes, not present in ICL-treated eyes (Table 2).

Comparing directly Artiflex- and ICL-treated groups, all mean postoperative clinical measurements were similar and cylinder refraction was the only parameter different in preoperative evaluation (Table 3).

The graphical representation of the variation of IOP (measured by different methods) over follow-up in the Artiflex- and ICL-tread eyes can be seen in Figs. 1A and 1B, respectively. In Artiflex-treated eyes, the linear correlation study showed moderate negative correlations between duration of follow-up and the following IOP measurements: eIOP (r=-0.439, p=0.036) and sIOP (r=-0.417, p=0.048) (Fig. 1C).



Follow-up and IOP	Artiflex		Visian ICL V4c	
	r	P-value	r	P-value
gIOP	-0.295	0.172	-0.287	0.300
ncIOP	-0.286	0.185	-0.178	0.542
bcIOP	-0.365	0.087	-0.346	0.226
eIOP	-0.439	0.036	-0.321	0.263
sIOP	-0.417	0.048	-0.335	0.241
dIOP	-0.394	0.063	-0.298	0.300
spIOP	-0.345	0.107	-0.297	0.302

Figure 1. **The variation of intraocular pressure (IOP) measured by different methods over follow-up.** A) The graphical representation in Artiflex-treat eyes. B) The graphical representation in ICL-treated eyes. c) Correlations between duration of follow-up and the IOP evaluated by different methods, in Artiflex- and ICL-treated eyes. Boxes highlighted in gray correspond to a significant *p*-value.

bcIOP, intraocular pressure biomechanically corrected by the Corvis ST; dIOP, intraocular pressure by Dresden correction; eIOP, intraocular pressure by Ehlers correction; gIOP, intraocular pressure by Goldmann applanation tonometer; ICL, implantable collamer lens; IOP, intraocular pressure; ncIOP intraocular pressure by Corvis ST noncontact tonometer; sIOP, intraocular pressure by Shah correction; spIOP, intraocular pressure by Spoerl correction.

Fig. 2 (A-C) represents the mean pre and postoperative CDVA, SE, and ECD by groups.

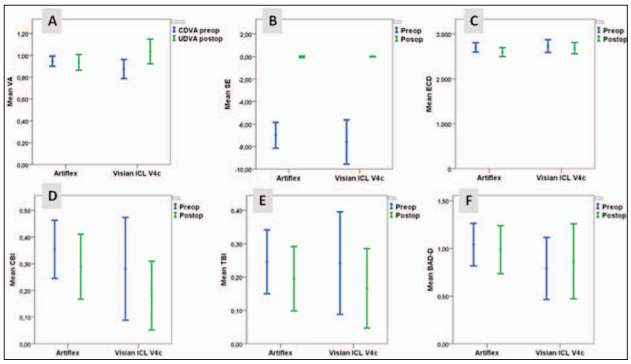


Figure 2. **The means postoperative of main clinical, corneal biomechanical, and tomographic parameters by groups.** A) CDVA. B) SE. C) ECD. D) CBI. E) TBI. F) BAD-D.

BAD-D, the final "D" of Belin/Ambrósio Enhanced Ectasia Display; bcIOP, intraocular pressure biomechanically corrected by the Corvis ST; CBI, corvis biomechanical index; CDVA, corrected distance visual acuity; ECD, endothelial cell density; ICL, implantable collamer lens; SE spherical equivalent; TBI, tomographic biomechanical index.

treated eyes showed a significantly softer behaviour in 2 of 28 and a stiffer behaviour in 4 of 28 parameters. When comparing directly Artiflex- and ICL-treated groups, all mean postoperative measurements were similar, and "A1 Deformation Amplitude" was the only parameter different in preoperative evaluation (Table 3).

Regarding second generation corneal biomechanical parameters and compared to preoperative values, Artiflex-treated eyes showed a significantly stiffer behaviour in 5 of 11 parameters and ICL-treated eyes in only 1. No parameter show significantly softer behaviour for both groups. When comparing directly Artiflex- and ICL-treated groups, the "PachySlope" was the only postoperative parameter that differed between groups, but the difference already exists in preoperative evaluation. Additionally, groups differed in 3 of 11 parameters in preoperative.

The linear correlation study, between the duration of follow-up and the first and second generation corneal biomechanically parameters, did not show significant correla-

Table 2. Clinical outcomes.

	Mean±SD				*P*-value			
	Artiflex		Visian ICL V4c		Artiflex: PRE VS POST	ICL: PRE VS POST	PRE: Artiflex VS ICL	POST: Artiflex VS ICL
	PRE	POST	PRE	POST				
CDVA, logMAR	0.03±0.06	0.01±0.06	0.07±0.09	-0.02±0.06	0.306	**0.001**	0.143	0.169
UDVA, logMAR	-	0.03±0.08	-	-0.01±0.10	NA	NA	NA	0.173
SPH, D	-6.17±2.58	0.00±0.23	-7.18±2.87	0.03±0.13	**<0.001**	**<0.001**	0.266	0.608
CYL, D	-1.65±1.27	-0.03±0.16	-0.87±0.77	-0.05±0.19	**<0.001**	**0.003**	**0.039**	0.906
AXIS, º	53.91±70.65	3.91±18.77	78.33±73.91	8.67±33.57	**0.003**	**0.003**	0.313	0.906
SE, D	-7.00±2.66	-0.02±0.18	-7.62±3.04	0.01±0.03	**<0.001**	**<0.001**	0.513	0.609
OSI	3.11±4.55	2.17±1.90	2.12±0.21	1.46±0.96	0.496	0.102	0.675	0.309
ECD, cell/mm²	2703.70±239.22	2599.83±230.20	2718.27±223.42	2686.54±207.40	**<0.001**	0.306	0.852	0.269
gIOP, mmHg	14.30±2.43	16.26±3.67	13.62±1.50	15.00±2.00	**0.013**	0.085	0.372	0.233
ncIOP, mmHg	13.87±1.89	16.28±4.30	14.37±1.51	16.46±3.78	**0.004**	0.065	0.398	0.897
bcIOP, mmHg	14.29±1.79	16.33±3.89	14.27±1.52	16.11±3.78	**0.002**	0.060	0.971	0.914
eIOP, mmHg	14.50±2.45	17.24±4.54	14.28±2.72	15.68±5.00	**0.015**	0.157	0.158	0.219
sIOP, mmHg	15.27±2.11	17.21±4.35	14.56±2.14	16.14±4.56	**0.007**	0.162	0.318	0.448
dIOP, mmHg	15.00±1.99	17.04±4.28	14.54±1.90	16.18±4.37	**0.004**	0.177	0.486	0.610
spIOP, mmHg	13.83±1.83	16.10±4.25	14.05±1.49	15.89±3.97	**0.002**	0.124	0.690	0.865

Bold text represents a statistically significant p-value.
Green box represents a statistically significant improvement compared to baseline.
Orange box represents a statistically significant worsening compared to baseline.

Abbreviations: AXIS, cylinder axis; bcIOP, intraocular pressure biomechanically corrected by the Corvis ST; CDVA, corrected distance visual acuity; CYL, cylinder refraction; D, dioptre; dIOP, intraocular pressure by Dresden correction; ECD endothelial cell density; eIOP, intraocular pressure by Ehlers correction; gIOP, intraocular pressure by Goldmann applanation tonometer; ICL, implantable collamer lens; NA, not applicable; ncIOP intraocular pressure by Corvis ST noncontact tonometer; OSI, objective scattered index; PRE, preoperative; POST, postoperative; SD, standard deviation; SE, spherical equivalent; sIOP, intraocular pressure by Shah correction; SPH, sphere refraction; spIOP, intraocular pressure by Spoerl correction; UDVA, uncorrected distance visual acuity.

CORNEA BIOMECHANICAL OUTCOMES

Concerning first generation corneal biomechanical parameters and comparing to preoperative values, Artiflex-treated eyes showed a significantly softer behaviour in 2 of 28 and a stiffer behaviour in 12 of 28 parameters. ICL-tions for Artiflex- and ICL-treated eyes. Fig. 2 (D-E) represents the mean postoperative CBI and TBI by subgroups.

CORNEA TOMOGRAPHIC OUTCOMES

For Artiflex-treated eyes, the mean RPIavg improved

Table 3. Biomechanical outcomes.

Biomechanical parameters	Mean±SD				*P*-value			
	Artiflex (n=23)		Visian ICL V4c (n=15)		PRE VS POST		Artiflex vs ICL	
	PRE	POST	PRE	POST	Artiflex	ICL	PRE	POST
ncIOP (mmHg)	13.87±1.89	16.28±4.30	14.37±1.51	16.46±3.78	**0.004**	0.065	0.398	0.897
cCCT (µm)	522.30±26.76	531.78±30.96	546.60±36.11	554.21±33.90	**0.020**	0.144	**0.023**	**0.047**
1st generation parameters								
DefoA.Max (mm)	1.12±0.11	1.02±0.14	1.09±0.05	1.02±0.13	**<0.001**	0.124	0.575	0.918
A1 Time (ms)	7.63±0.21	7.94±0.51	7.65±0.18	7.96±0.47	**0.002**	**0.027**	0.702	0.898
A1 Velocity (m/s)	0.15±0.02	0.14±0.02	0.15±0.01	0.14±0.02	**<0.001**	**0.012**	0.796	0.803
A2 Time (ms)	22.30±0.46	21.91±0.61	22.13±0.22	21.90±0.56	**0.005**	0.154	0.143	0.958
A2 Velocity (m/s)	-0.28±0.03	-0.25±0.04	-0.27±0.02	-0.25±0.03	**0.004**	**0.047**	0.407	0.674
HC Time (ms)	17.26±0.49	16.80±0.60	17.32±0.44	16.73±0.66	**0.002**	**0.023**	0.703	0.736
Peak Dist. (mm)	5.12±0.28	4.88±0.40	5.02±0.17	4.86±0.42	**0.005**	0.118	0.226	0.889
Radius (mm)	5.99±0.46	6.17±0.77	6.31±0.62	6.28±0.88	0.144	0.709	0.070	0.708
A1 DefoA. (mm)	0.13±0.01	0.13±0.01	0.14±0.01	0.14±0.01	0.909	0.576	**0.044**	0.377
HC DefoA. (mm)	1.12±0.11	1.02±0.14	1.09±0.05	1.02±0.13	**<0.001**	0.124	0.575	0.918
A2 DefoA. (mm)	0.33±0.05	0.31±0.04	0.34±0.05	0.32±0.05	**0.046**	0.397	0.608	0.429
A1 DL (mm)	2.21±0.12	2.21±0.10	2.24±0.14	2.23±0.14	0.923	0.202	0.380	0.582
HC DL (mm)	6.61±0.45	6.17±0.62	6.47±0.38	6.26±0.75	**0.003**	0.177	0.347	0.688
A2 DL (mm)	2.73±0.82	2.68±0.62	2.56±0.39	2.47±0.50	0.766	0.139	0.399	0.304
A1 DA (mm)	0.09±0.01	0.09±0.00	0.09±0.01	0.09±0.01	0.395	0.368	0.119	0.674
HC DA(mm)	0.97±0.10	0.88±0.14	0.93±0.05	0.88±0.14	**0.003**	0.153	0.184	0.995
A2 DA(mm)	0.10±0.01	0.10±0.01	0.10±0.01	0.10±0.01	0.711	**0.041**	0.156	0.435
DA Max (mm)	0.98±0.10	0.88±0.14	0.95±0.05	0.91±0.16	**0.001**	0.551	0.408	0.632
DA Max (ms)	16.62±0.70	16.74±0.63	16.75±0.67	16.62±0.94	0.484	0.470	0.575	0.635
WEM.Max (mm)	0.24±0.05	0.22±0.04	0.24±0.05	0.23±0.05	**0.068**	0.433	0.813	0.632
WEM.Max (ms)	21.76±0.56	21.56±0.67	21.73±0.50	21.55±0.78	0.149	0.124	0.843	0.966
A1 DArea (mm2)	0.16±0.02	0.16±0.02	0.17±0.02	0.16±0.02	0.641	0.186	0.323	0.907
HC DArea (mm2)	3.48±0.54	3.06±0.69	3.30±0.33	3.09±0.68	**0.003**	0.222	0.265	0.902
A2 DArea (mm2)	0.21±0.04	0.21±0.03	0.22±0.03	0.21±0.04	0.857	0.276	0.503	0.976
A1 dArcL (mm)	-0.02±0.00	-0.02±0.00	-0.02±0.00	-0.02±0.00	0.589	0.151	0.226	0.711
HC dArcL (mm)	-0.11±0.02	-0.11±0.02	-0.13±0.02	-0.12±0.03	0.401	0.082	0.053	0.285
A2 dArcL (mm)	-0.02±0.00	-0.02±0.00	-0.02±0.00	-0.02±0.00	0.523	**0.016**	0.131	0.640
dArcLMax (mm)	-0.13±0.03	-0.12±0.03	-0.15±0.03	-0.15±0.04	0.119	0.754	0.084	0.062
2nd generation parameters								
MIR (mm^-1)	0.20±0.02	0.20±0.01	0.19±0.02	0.20±0.04	0.100	0.484	**0.029**	0.567
DARM (2 mm)	4.43±0.33	4.29±0.44	4.24±0.42	4.06±0.35	0.104	0.156	0.134	0.104
PqS (µm)	35.30±6.51	32.65±7.40	40.42±4.96	39.82±5.04	**0.008**	0.867	**0.014**	**0.003**
DARM (1 mm)	1.56±0.03	1.55±0.04	1.54±0.04	1.53±0.04	0.855	0.397	0.344	0.186
ARTh	621.43±126.18	666.89±151.10	612.97±145.23	646.70±127.66	0.050	0.279	0.850	0.679
bcIOP	14.30±1.79	16.33±3.89	14.27±1.52	16.11±3.78	**0.002**	0.060	**0.006**	0.914
IR (mm^-1)	10.07±0.92	9.24±1.17	9.15±1.02	8.71±0.93	**0.001**	0.121	0.953	0.15
SP-A1	95.67±16.91	108.37±21.98	99.89±12.59	114.07±18.08	**0.004**	**0.049**	0.414	0.420
CBI	0.35±0.25	0.29±0.28	0.30±0.33	0.18±0.22	0.053	0.114	0.552	0.231
TBI	0.26±0.22	0.19±0.20	0.19±0.21	0.17±0.18	0.187	0.074	0.364	0.695
SSI	0.84±0.13	0.90±0.13	0.88±0.08	0.88±0.11	**0.016**	0.799	0.263	0.566

Bold text represents a statistically significant *p*-value.
Green box represents a statistically significant improvement compared to baseline.
Orange box represents a statistically significant worsening compared to baseline.

Abbreviations: ARTh, Ambrosio Relational Thickness (horizontal 8 mm); bcIOP, Biomechanically corrected intraocular pressure; CBI, corvis biomechanical index; cCCT, corvis-derived central corneal thickness; DA, Deflection Amplitude; DArea, Deflection Area; dArcL, delta arc length of corneal surface; DARM, DA Ratio Max; DefoA, Deformation Amplitude; DL, Deflection Length; IR, integrated radius; MIR, Max InverseRadius; PqS, PachySlope; SD, standard deviation; SP-A1, stiffness parameter at applanation 1; SSI, stress strain index; TBI, tomographic biomechanical index; WEM, Whole Eye Movement.

Table 4. Tomographic outcomes.

Tomographic parameters	Mean±SD				*P*-value			
	Artiflex (n=23)		Visian ICL V4c (n=15)		PRE VS POST		Artiflex vs ICL	
	PRE	POST	PRE	POST	Artiflex	ICL	PRE	POST
BAD-D	1.04±0.52	0.99±0.58	0.79±0.59	0.87±0.71	0.219	0.390	0.173	0.569
RPIavg	1.02±0.12	0.98±0.12	1.01±0.15	1.00±0.16	**0.009**	0.639	0.975	0.663
ARTmax	409.43±60.08	413.39±76.15	452.87±110.07	455.73±128.87	0.702	0.826	0.124	0.210
Kmax	45.23±1.60	45.18±1.47	45.09±1.43	45.14±1.45	0.503	0.515	0.780	0.931
ISV	19.17±5.49	18.65±4.50	17.33±4.51	17.73±3.86	0.166	0.276	0.300	0.516
IVA	0.10±0.05	0.11±0.05	0.12±0.05	0.12±0.04	**<0.001**	**0.001**	0.162	0.408
IHA	13.18±43.91	4.50±4.18	5.37±3.33	5.66±3.39	0.681	0.396	0.235	0.224
IHD	0.01±0.02	0.01±0.00	0.01±0.00	0.01±0.00	0.345	0.277	0.359	0.151

Bold text represents a statistically significant p-value.
Green box represents a statistically significant improvement compared to baseline.
Orange box represents a statistically significant worsening compared to baseline.

Abbreviations: ARTmax, maximum ambrosia relational thickness; BAD-D, the final "D" of Belin/Ambrósio Enhanced Ectasia Display; ICL, implantable collamer lens; IHA, index of height asymmetry; IHD, index of height decentration; ISV, index of surface variance; IVA, index of vertical asymmetry; Kmax, maximum keratometry; PRE, preoperative; POST, postoperative; RPIavg, average pachymetry progression index (RPIavg); SD, standard deviation.

(*p*=0.009) compared to the preoperative value. The mean IVA worsening (*p*<0.001) in this group of patients, but improved in ICL-treated eyes (*p*=0.001). The other tomographic parameters maintained stability after procedures (Table 4). There were no differences in preoperative and postoperative tomographic parameters when comparing Artiflex- and ICL-treated eyes (Table 4). Fig. 2F represents the mean postoperative BAD-D by subgroups.

ECTASIA RISK ASSESSMENT

All biomechanical parameters had a similar or less proportion of eyes within ectasia susceptibility interval at postoperative in both Artiflex- and ICL-treated eyes. Regarding ectasia high-risk cut-off, for Artiflex-treated eyes, the proportion of eyes within the ectasia high-risk interval at postoperative was higher than preoperative in 3/11 parameters, similar in 5/17 and less in 3/11. For ICL-treated,

Table 5. Ectasia risk assessment.

	Ectasia Susceptibility Cut-off	% within interval PRE		% within interval POST		Ectasia High-risk cut-off	% within interval PRE		% within interval POST	
		Artiflex	ICL	Artiflex	ICL		Artiflex	ICL	Artiflex	ICL
Corvis 1st generation parameters										
A1 Time (ms)	<7.46	21.7	13.3	**8.7**	**6.7**	<7	0	0	**0**	**0**
A1 Velocity (m/s)	>0.14	82.6	100	**43.5**	**46.7**	>0.19	0	0	**0**	**0**
A2 Velocity (m/s)	>-0.52	100	100	**100**	**93.3**	>-0.37	100	100	**100**	**93.3**
Radius (mm)	<7.52	100	93.3	**95.7**	**80.0**	<6.9	95.7	86.7	**78.3**	**73.3**
A1 Deflection Length (mm)	>1.78	100	100	**100**	**93.3**	>2	91.3	93.3	**100**	**93.3**
A2 Deflection Length (mm)	>1.48	100	100	**100**	**93.3**	>1.8	95.7	100	**95.7**	**86.7**
Corvis 2nd generation parameters										
DA Ratio Max (2 mm)	>4.80	17.4	6.7	**13**	**6.7**	>4.86	4.3	6.7	**13**	**6.7**
DA Ratio Max (1 mm)	>1.10	100	100	**100**	**93.3**	>1.63	0	0	**4.3**	**0**
Stiffness parameter in A1	<93.74	43.5	26.7	**26.1**	**13.3**	<80.8	21.7	13.3	**13**	**0**
Corvis biomechanical index	>0.07	87	66.7	**65.2**	**66.7**	>0.5	30.4	33.3	**21.7**	**6.7**
Tomographic biomechanical index	>0.29	43.5	33.3	**30.4**	**26.7**	>0.79	0	0	**0**	**0**

Yellow box represents a stable value.
Green box represents an improvement compared to baseline.
Orange box represents a worsening compared to baseline.

Abbreviations: ICL, implantable collamer lens; PRE, preoperative; POST, postoperative.

it was higher than preoperative in none parameter; similar in 6/11 and less in 5/11. The "A2 Velocity" and "A1 Deflection Amplitude" were the biomechanical parameters with higher representation of eyes within the ectasia high-risk interval for Artiflex and ICL-treated eyes.

DISCUSSION

The current study investigated the biomechanical behaviour and intraocular pressure differences after Artiflex® and Vision® ICLV4c implantation in cases with contraindications to laser ablation.

Regarding biomechanical behaviour, both two types of pIOLs implantation showed differences in biomechanical behaviour after the procedure. Comparing to the preoperative and accounting both first and second generation parameters, Artiflex-treated eyes showed a stiffer behaviour in 17/39 parameters and ICL-treated eyes in 5/39. Both techniques showed a softer behaviour in the same only two parameters: A2 velocity and HC Time. Comparing directly the 2 techniques, postoperative results were similar, except in "Pachyslope" that had already been in preoperative.

This increasing significance of strength/resistance may be due to the corneal or aqueous humour behaviour modifications. On the one hand, the main incision size was 3.2 mm in both procedures. The tissue healing can towards fibrosis enough to strengthen the biomechanical behaviour. The more parameters changed in Artiflex-treated eyes than ICL, when comparing the pre and postoperative period, can be due to the additional two paracenteses needed by Artiflex against the one needed with Visian ICL V4c, or due to the different location of the incision, since it is known that temporal incisions are less inducing of astigmatism than superior ones.[12,13] Although it should not be so significant, because the differences between the two procedures were not present when comparing them directly. On the other hand, aqueous humour behaviour modification seems to be the more probable explanation. In both groups, pIOL was a new structure inserted in the eye, being a new level of resistance in the aqueous humour dynamic. During air puffing, the aqueous humour also should have more resistance in presence of AC pIOL than PC pIOL as in our results. In AC pIOL, the level of resistance is more anterior (with less energy dissipated until reaching the new structure) and central (the aqueous humour only can escape at the AC peripherical). In PC pIOL, the level of resistance is more posterior (with more energy already dissipated until reaching the new structure) and aqueous humour can move more centrally (trough the pupil, which is the main direction of energy after air puff).

These changes in biomechanical behaviour were accompanied by few changes in postoperative tomographic changes: RPIavg and IVA. This is much supportive of the second hypothesis (aqueous humour behaviour modifications), because with corneal modifications due to tissue healing, more structural and tomographic changes would be expected. There were no differences in tomographic parameters comparing directly two procedures too. In the ectasia risk assessment, the proportional of eyes within the interval of susceptibility improved or maintained stable for all biomechanical parameters for both procedures, which means and reinforce again that these procedures are safe surgical approach from a biomechanical viewpoint. When analysing the proportional of eyes within the interval of ectasia high-risk, overall there was also stability on biomechanical parameters.

Although Ali *et al*[14] reported that there was no significant change in corneal biomechanical parameters after ICL implantation in normal and keratoconic eyes, the corneal incision size performed was 3.0 mm and the analysis included only 2 parameters (the corneal hysteresis and corneal resistance factor) of Ocular Response Analyzer (ORA) (Reichert Ophthalmic Instruments®, Buffalo, NY). Instead of using the reflection of the infrared beam to monitor the deformation of the cornea like ORA, Corvis ST uses an ultra-high-speed Scheimpflug camera that takes 140 horizontal 8 mm frames throughout 33 ms. This approach allows a more detailed evaluation of the deformation process and it is known the less value of ORA in assessing biomechanical changes after ablative and incisional corneal surgeries and the need to complement studies with Corvis ST. Li *et al*[15] also report no significant change in the corneal biomechanical parameters after ICL, despite having using Corvis ST, but the sample included only keratoconus eyes, compare only 8 parameters and a 2.8 mm corneal incisional was performed, lower than us. Indeed, the parameters used in this last study also not changed in our study, except SP-A1. The group with more favourable changes at postoperative in our study also was Artiflex-tread eyes, and few changes were noted in ICL-treated eyes. There were no studies with the biomechanical assessment with Artiflex implantation to compare.

Concerning the analysis of postoperative IOP measured by different methods, mean values were similar between Artiflex- and ICL-treated eyes. Comparing to preoperative values, there was a significant increase of IOP (evaluated by different methods) in Artiflex-treated eyes, probably associated with increased corneal or aqueous humour resistance after surgery, which is also more evident in eyes with this type of pIOL. Corticoids did not seem to explain all this tendency because the weaning scheme was the same for ICL-treated eyes and there were only two significant negative correlations found between IOP and duration of follow-up.

One of the strengths of this study is the use of Corvis ST, as explained above.

Another strong point was the broadening of therapeutic options based on our outcomes. The apparent stiffer behaviour after these procedures sustains the application in refractive rehabilitation in stable corneal ectatic pathology, but further studies are needed.

However, this study has some limitations. A short duration of follow-up was included, but we must keep in mind that these procedures did not use sutures and postoperative medication lasts about 1 month, being expected reliable results after 1 month, as we included in our sample. Assessments before 1 month may be influenced by inflam-

matory responses.[14] Although it was a small sample size, the groups were similar regarding demographic and preoperative clinical, tomographic and biomechanical parameters. We think that the absence of a control group is the major limitation. However, we add an "ectasia risk assessment" with normative references to compare better.

In conclusion, this is a pioneer study as it is the first to document the corneal biomechanical changes after Artiflex implantation and the first to compare Artiflex with ICL from this view. These findings may support the safety of these surgical options for the correction of the refractive error of eyes with contraindications to laser ablation from a biomechanical viewpoint. Further research will be needed with a large cohort of patients and a longer follow-up to validate these preliminary findings.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO:

Am and CC: Responsible for gathering the data, presenting the results, and creating the manuscript.

ACA, SM and MCP: Dupervised this project and contributed with their expertise to its conclusion; and all authors read and approved the final manuscript.

All the authors had full access to all the data and take full responsibility for the integrity of the data and the accuracy of the data analysis; all were responsible for conceiving this research.

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