FORMULARIO DE PREGUNTAS Y RESPUESTAS N°01 DE LAS OBSERVACIONES FORMULADAS AL ESTUDIO, DOCUMENTOS PREVIOS Y ANÁLISIS DEL SECTOR PARA ADELANTAR PROCESO DE SELECCIÓN DE MÍNIMA CUANTÍA N° MC-218-2024-HOMIL, CUYO OBJETO ES "SUMINISTRO DE INSUMOS Y/O DISPOSITIVOS MÉDICO-QUIRÚRGICOS (LENTES INTRAOCULARES FAQUICOS) REQUERIDOS PARA LA REALIZACIÓN DEL PROGRAMA QUIRÚRGICO DE OFTALMOLOGIA EN SALAS DE CIRUGÍA DEL HOSPITAL MILITAR CENTRAL".

EL SEÑOR SUBDIRECTOR ADMINISTRATIVO DEL HOSPITAL MILITAR CENTRAL EN CALIDAD DE ORDENADOR DE GASTO y,

El comité técnico estructurador, proceden a emitir respuesta oportuna a la observación realizada por el oferente dentro del proceso de selección de la referencia de la siguiente manera:

OBSERVACION FORMULADA POR LA FIRMA BIOTECH

OBSERVACION No.01

LENTE INTRAOCULAR FAQUICO DE IMPLANTE RETRO-IRIDIANO PRELENTICULAR ESFERICO

Fabricado en colámero un tipo de colágeno derivado del porcino e hidroxietilmetacrilato un material hidrófilo, flexible y biocompatible asociado a un cromóforo que absorbe la luz uv, está diseñado como un lente fáquico refractivo con una zona óptica cóncava convexa con disposición en domo en su cara anterior para minimizar el contacto con el cristalino, cuenta con hápticas de forma rectangular en forma de plato mono pieza, diseñado para implantarse en la cámara posterior apoyando sus hápticas sobre el sulcus cilia

Con el fin de asegurar la pluralidad de los oferentes se solicita excluir el material colamero

Asunto: Observaciones **MC-218-2024**

Revisando el pliego publicado por parte de ustedes y estudio previo folio 4 apartado 10: Especificaciones técnicas, donde se establece la siguiente descripción de los lentes:

LENTE INTRAOCULAR FAQUICO DE IMPLANTE RETRO-IRIDIANO PRELENTICULAR TORICO

fabricado en colámero un tipo de colágeno derivado del porcino e hidroxietilmetacrilato un material hidrófilo, flexible y biocompatible asociado a un cromóforo que absorbe la luz uv, está diseñado como un lente fáquico refractivo con una zona óptica cóncava convexa con disposición en domo en su cara anterior para minimizar el contacto con el cristalino, cuenta con hápticas de forma rectangular en forma de plato mono pieza, diseñado para implantarse en la cámara posterior apoyando sus hápticas sobre el sulcus ciliar

porcino, Teniendo en cuenta que la ausencia del 0,2% de colágeno porcino no afecta el desempeño del producto. Se adjunta el cuadro comparativo de los materiales del lente ICL que es el que tiene el material solicitado en el pliego y el material del lente Eyecryl Phakic, marca Biotech.

El material de Eyecryl Phakic es: Acrílico Hidrófilo (sin fuente animal) Composición: 74% 2 hidroxietilmetacrilato y metilmetacrilato, 26% de agua
El material de Staar, ICL, es: el colágeno porcino 0,2% (contiene proteína de colágeno de origen animal) Composición-60% poli-hidroxietilmetacrilato - HEMA, agua (36%), benzofenona (3,8%). Staar llama el Colámero (colágeno-copolímero). Staar afirma que es collamar donde en realidad la porción de colágeno porcino es solo del 0,2%.

Eyecryl Phakic Vs Evo Visian ICL

FEATURES	EYECRYL™ PHAKIC IOL	Evo Visian ICL™
Material	Hydrophilic Acrylic (No Animal source) Composition- 74% 2 Hydroxyethylmethacrylate and Methylmethacrylate, 26% water	Porcine Collamer (contains collagen protein from animal source) Composition-60% poly-hydroxyethylmethacrylate – HEMA, water (36%), benzophenone (3.8%), and 0.2% porcine collagen, and called it the Collamer (collagen-copolymer)
Vault	Comparable	Comparable
Post-operative visual outcomes	Comparable	Comparable
Flexibility	Lens doesn't try to open upside down in the eye, Less chances of optic getting scar if touched with forceps/sharp instruments, Handling is easy	Extremely Flexible
Rotational stability	Good rotational stability if sizing is proper	Good rotational stability if sizing is proper
Injection system	Easy loading	Complicated loading
Incision Size	2.8 mm	3.2 mm
ASPHERIC	Yes (S.A. = 0)	V4C version-No, Evo range-Yes
Online stock availability	Yes	No
Online order placing	Yes	No
Diopter range	Available up to -23.00D (can customized more than this)	Available up to -18.00 D

El colamero hace a la lente Staar más flexible que la Eyecryl phakic, dentro del ojo esa mayor rigidez del Eyecryl phakic es una ventaja porque permite mayor estabilidad de la lente y disminuye los riesgos de generar catarata o aumentar la presión intraocular.

La eficacia del producto puede ser revisada en los siguientes estudios:

Comparison of Dynamic Vault Changes Following Implantation of Two Different Models of Phakic Intraocular Lenses

Sheetal Brar, MS; Sanjali Tadas Wadhokar, MS; Supriya Samak Sriganesh, MS; Sri Ganesh, MS, DNB

ABSTRACT

PURPOSE: To compare the dynamic vault range (the difference in the central vault height from scotopic to photopic light condition) after implantation of the ICL/TICL (STAAR Surgical) and Eyecryl phakic/Eyecryl phakic toric intraocular lens (IOL) (Biotech Healthcare).

METHODS: This retrospective study included patients with myopia or myopic astigmatism eligible for phakic IOL implantation with either the ICL/TICL or Eyecryl phakic/Eyecryl phakic toric IOL. Vault changes in varying light conditions (scotopic, mesopic, and photopic) were assessed using an anterior segment optical coherence tomography-based tomographer and dynamic vault range (DVR) was compared between the two groups.

RESULTS: A total of 60 eyes from 36 patients (30 eyes in each group) with a mean age of 28.63 ± 6.36 years were included. The mean postoperative follow-up at the time of assessment was 9.4 ± 5.3 and 8.9 ± 5.28 months ($P = .75$) in the ICL and Eyecryl groups, respectively. The mean values of scotopic, mesopic, and photopic vault were 490.56 ± 238.64, 453.56 ± 224.30, and 373.96 ± 200.24 µm in the ICL group and 515.46 ± 174.34, 490.26 ± 184.04, 450.43 ± 173.92 µm in the Eyecryl group ($P = .32, .24$, and $.05$, respectively). The DVR was 116.6 ± 59.29 µm in the ICL group versus 65.03 ± 31.78 µm in the Eyecryl group ($P < .001$).

CONCLUSIONS: The Eyecryl phakic IOL showed significantly fewer light-induced changes in the central vault height (DVR) compared to the ICL, which may be attributed to the difference in the material of the two phakic IOL models. This may be clinically significant in eyes with low postoperative vaults with respect to their follow-up and risk assessment of cataractogenesis in the long term.

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El montaje del eyecryl phakic es mucho más sencillo así como su implantación.

El lente Eyecryl Phakic está siendo implantado en más de 20 países del mundo con excelentes resultados. Cuenta en Colombia con registro sanitario desde hace cinco años. Se han implantado en el país más de 1000 unidades las cuales han demostrado su efectividad y cuenta con estudios a más de cinco años de implantación. Contamos con 170 médicos en Colombia usuarios del producto.

access to innovation

En Colombia se realizó el siguiente estudio en el 2021 y actualmente se está complementando con información actualizada a la fecha

Early results with the EyeCryl Phakic Toric intraocular lens implantation in keratoconus patients

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Abstract

Objective: Refractive management in keratoconus is challenging. Although some kinds of phakic intraocular lenses have been studied in keratoconus so far, no study evaluated the results of EyeCryl Phakic Toric intraocular lenses in this kind of patients.
Materials and Methods: This is a retrospective chart review study, including all keratoconus patients implanted with an EyeCryl Phakic Toric intraocular lens in at least one of their eyes by an experienced cornea surgeon in Colombia. Follow-up to 6 months after surgery was also included.
Results: A total of 20 eyes of 14 patients were included, with an average age of 29.3 ± 4.2 years. Spherical equivalent improved from a pre-surgical value of -10.31 D to +0.09 D at 6 months. 65% of the patients improved at least one line in the best-corrected distance visual acuity. At 6 months, 70% of the patients were within ± 0.50 D of spherical equivalent emmetropia. No complications occurred in any of the patients.
Conclusion: EyeCryl Phakic intraocular lenses are an excellent option in keratoconus patients with high refractive error.
Keywords: intraocular lens, keratoconus, refractive disorder, ophthalmology
Abbreviations: KC = Keratoconus, P-IOL = phakic intraocular lenses, ICL = Implantable Collamer Lens, WTW = White to White, SD = standard deviation, ANOVA = an analysis of variance, UDVA = monocular uncorrected distance visual acuity, CDVA = corrected distance visual acuity

x 297 mm

the Visian Toric Implantable Collamer Lens: Results of a 2-Year Prospective Comparative Study

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Abstract

PURPOSE: To compare the 2-year visual and refractive outcomes with the Eyecryl Phakic Toric IOL (EP TIOL) (Biotech Vision Care Pvt Ltd) and Visian Toric ICL (TICL) (STAAR Surgical) for correction of high myopic astigmatism .

METHODS : This prospective, interventional, non-randomized comparison study included eligible patients who underwent toric phakic IOL surgery in one or both eyes with either the EP TIOL or TICL for myopic astigmatism. Two years postoperatively, both lenses were compared for their safety, efficacy, stability, and patient satisfaction. Vector analysis of astigmatism was performed using the Alpins method with the ASSORT software (ASSORT Party Ltd).

RESULTS: A total of 50 eyes were included , of which 25 eyes received EP TIOL implantation and the remaining 25 received TICL implantation. Preoperative mean ± standard deviation of spherical equivalent (SE) and cylinder was -10.15 ± 4 .04 and -2.08 ± 0 .86 diopters (D) in the EP TIOL group and -10.21 ± 3.97 and -2.17 ± 0 .9 5 Din the TICL group , respectively . At 2 years of follow-up, there was no significant difference between the mean uncorrected distance visual acuity, corrected distance visual acuity, spherical equivalent , and residual astigmatism between the two groups ($P > .05$ for all parameters). Ninety-two percent of eyes in the EP TIOL group and 88% of eyes in the TICL group were within ±0 .50 D of refractive astigmatism. Vector analysis of astigmatism showed a comparable Correction Index of 0.98 in the EP TIOL group and 0.94 in the TICL group, signifying a mild undercorrection of 2% and 6% , respectively. Two eyes in the TICL group underwent exchange for high vault and one eye required realignment due to significant postoperative rotation.

CONCLUSIONS: At least for the first 2 years postoperatively, both toric phakic IOLs were safe and effective in managing high myopic astigmatism with comparable visual results and patient satisfaction.

access to innovation

A clinical trial on phakic intraocular lens for the treatment of refractive amblyopia in children and adolescents

Arvind Kumar Morya, Kirandeep Kaur[1], Bharat Gurnani[2], Siddharam S Janti[3], Ankur Kumar Shrivastava[4], Antarvedi Tejaswini[5], Aprajita Sinha[5], Dharavath Venkatesh[6]

Purpose: To analyze the demographics and clinical outcomes of posterior chamber phakic intraocular (IOL) implantation for refractive amblyopia in children and adolescents. **Methods:** A prospective interventional study was performed on children and adolescents with amblyopia at a tertiary eye care center from January 2021 to August 2022. Twenty-three eyes of 21 anisomyopic and isomyopic amblyopia patients operated for posterior chamber phakic IOL (Eyecryl phakic IOL) as a treatment for amblyopia were included in the study. Patient demographics, pre- and postoperative visual acuity, cycloplegic refraction, anterior and posterior segment examination, intraocular pressure, pachymetry, contrast sensitivity, endothelial count, and patient satisfaction scores were evaluated. Patients were followed up at day 1, 6 weeks, 3 months, and 1 year after surgery, and visual outcomes and complications were documented. **Results:** The mean age of patients was 14.16 ± 3.49 years (range: 10-19 years). The mean intraocular lens power was − 12.20 diopter spherical (DS) in 23 eyes and − 2.25 diopter cylindrical (DC) in four patients. The mean unaided distant visual acuity (UDVA) and best-corrected visual acuity (BCVA) were 1.39 ± 0.25 and 0.40 ± 0.21 preoperatively on the log of minimum angle of resolution (logMAR) chart. Postoperatively, the visual acuity improved by 2.6 lines in 3 months period and maintained till 1 year. Postsurgery, contrast sensitivity in the amblyopic eyes significantly improved, and the average endothelial loss recorded was 5.78% at 1 year, which was statistically insignificant. Patient satisfaction score was statistically significant, with 4.736/5 recorded on the Likert scale. **Conclusion:** Posterior chamber phakic IOL is a safe, effective, and alternative method for treating amblyopia patients who are noncompliant with glasses, contact lenses, and keratorefractive procedures.

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Key words: Amblyopia, anisometropia, anisomyopic, isomyopic, phakic IOL

Quedamos atentos a cualquier información adicional requerida.

Cordialmente

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The Outcomes of Posterior-Chamber Phakic Intraocular Leos Implantation in Patients with High Myopia

Yüksek Miyopisi Olan Hastalarda Arka Kamara Fakik Goz i9i Lens implantasyonun Gorsel Sonu9lan

G Fikret UCA R', G ervet CETI KAYA'

•Kon yagoz Eyc Hosp ita l C linic of Ophthalmology, Konya , TURK EY

ABST R.ACT Obj ekti'e: To cvaluatc thc outcomcs of postcrior-chamber phakic intraocular lcns (pIOL) implantation in patients wilh high myopia . **'Ia tari al a nd Meth ods:** Scventy-six cycs of 38 patients who had high myopia and undcrgonc Eyccrylphakic IOL implantation wcrc cnrollcd in thc study. Eighlcen ofthcm (47%) wcrc malcs and 20 (53%) wcrc fcmalcs. Thcir mcan agc was 28.97 ± 4. 1 O (22 - 36) ycars. Uncorrected visual acu ity (UCVA), bcst corrcctcd visual acuity (BCVA), autor cfractivc and lcral omctric mcasurcmcnts wcrc cvaluatcd prc and postopcrativc by . **Res ults:** Thc mcan 1st wcck, 1stmonlh a nd 6th month postopcrativc sphc rica l, astigmatic and sphcrical equivalcn! (E) valuc wcrc sig nificanl.ly lowcr than tho sc of prcoperativc valucs , and thc mcan I s i wcc k, 1 s tmonth and 6th month pos topcrativc UC VA and BCVA valucs wcrc signilicantly highcr than lhosc prcopcrativc valucs (p <0 .05) . Thc mcan 1s t wcck, ls tmon th and 6" month postopcrativc antc rior chambcr dcpth (ACD) valucs wcrc signific ant ly lowcr lhan prcopcrativc valucs (p>0.05). Thcrc were no significan! diffcrcnccs bctwccn prcopcrativc and postopcrativc central comsal thickncss (CCT), cndothclial cell dcnsi ty (EC D) and intraocular prcssu rc (IO P} mcasurcm cnts (P>-0.05) . Thc postopcrativc fir.st-wcak mcan sphcrical valuc was 0. 11 ±0 .44 D, and it was s tablc until I thc s ixth month. Postopcrative 6th month mcan cndothclial cell loss was 3% in comparl on with prcopcrativc valucs . Thc diffcrcncc was not sign ificant (p>-0.05). Additionally .no ab normal l morphologic changes in cndothclial cell !ayc r wcrc obscrvcd in spcc ular microscopy. **cnclusion:** Eyccrylphakic IO L implantation is a safe. cffcctivc . prcdictablc . and stab lc treatmcnt mcthod for high -myopi a patients in thc short -tcrm. Long-tcrm rcsults of p!OL implantation should be invcstigatcd in fmhcr studies.

Key words: High myopia phakic IO L: sphcrica l e quivalcnt: CVA

O ZE T Anza :Ytk sck miyo pisi olan hastalarda arka kamara Fakik In - tracktilcr lcn s (pIOL) im plantasyonunn gorscl so nuc;lan m dcgcrlcndirmck **Gere c; ve Yii ntemler:** Ytksck miyopi si olan ve Eyc cryl **Fakik IOL** imp lantasyonu uygula nan 38 has tanm 76 gozli t; ahatma kapsamma almdl. Hastalann 18 ' i (% 47) crkck 20's i isc (%53) kadmdl. Ortalama- yaslan 28.97 ± 4.10 (22 - 36) idi. Dtinclhilmcmis gtirnc kc ski nlig i. dti- nclthnis gorme kcski nligi , oto refrak tif ve kc ratomctrik o k;tinkcr amcl iya t onccsi ve sonr as md a dcgcr lcn dirildi . **Bul gul ar:** Ortalama amaliyat sonrasl 1h a fla, 1. ay ve 6.ay sfcrik, astigmatik ve sfcrik cS- dcgcr (E) amcliyat onccsi dcgcrc gorc anlamh olarak daha dtistiktti e amaliya t sonras, dtinclhilmcmis ve dtinclti lmis gorme kcskinligi, amel iyat onccs inc gorc anlamh olarak daha ytksckti (P<0.05). Ortalama amc liyat so nrasl 1. ha fla, 1. ay ve 6.ay on kamara dcrinligi , amc liya t onccsi dcgcrc gorc anlamh olarak daha dtistiktti (P<0.05). Amcliyat oncesi ve amcliyat son rasl komca kalmhg 1, endotel hticrc sayls I ve gozic;i basmcl dagcrlcrinde anlamh bir dcgi si klik gozlcnmcdi (p>0.05). Amcliyat so nras, 1.1-lafla onalama sfcrik dcgcr0 .11 ± 0 . 44 D idi ve bu dcgcr 6.Aya kadar s tabil scy rcsti. Posto pcratif 6.aydaki cndotcl hticre ka ybl % 3 ' tti, prcopcratif dcgcrc gorc anlamh bir dtistis dcgildi (p>0.05).Aynca ,, s pcktifc r mikr oskopidc cndotcl hticrc tabaka s mda ano rmal mo rfoloj ik dcgisiklikler gozlcnmcdi. **So nu :** Eyccryl **Fakik IOL implant** asyonu, ytksck miyopisi olan hastalarda k1sa donemdc gtvenli ,cfkm ve on gortilcbilir bir tcdavi sag la maktad ir. Uzun donem sonuc;lan ic;in ilcr c;alnmalann yapl lmasl gc rckir.

Anah ta r Kelimeler: Yiiksck miyop i: fakik IO L; sfcnk cadcgcr: dtinclt lmcmis gorme ke sk inligi

RESPUESTA OBSERVACIÓN No.01

SE ACEPTA LA OBSERVACION Y SE EXCLUYE EL MATERIAL COLAMERO PORCINO.

Elaboró:

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