Bogotá, D.C., agosto de 2024

FORMULARIO No. 1 DE OBSERVACIONES Y RESPUESTA AL ESTUDIOS PREVIO PARA ADELANTAR EL PROCESO DE SELECCIÓN ABREVIADA DE MENOR CUANTÍA N° SA-059-2024 CUYO OBJETO ES "SUMINISTRO DE INSUMOS Y/O DISPOSITIVOS MÉDICO-QUIRÚRGICOS 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,

Los comités estructuradores, proceden a emitir respuestas oportunas a las observaciones realizadas por los oferentes dentro del proceso de la referencia de la siguiente manera:

OBSERVACIONES FORMULADAS POR LA FIRMA BIOTECH HEALTH CARE COLOMBIA S.A.S

OBSERVACIÓN No. 1

Revisando el pliego publicado por parte de ustedes y estudio previo folio 8 apartado 4: 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

RESPUESTA OBSERVACIÓN No. 1

Teniente en cuenta la observación presentada, el comité técnico estructurador se permite indicar que una vez realizado el análisis de las especificaciones técnicas se evidencia que en aras de garantizar los principios de la contratación pública estos son pluralidad de oferentes, selección objetiva, responsabilidad e igualdad de oferentes, se acepta la observación y se excluye el material colamero porcino.

OBSERVACIÓN No. 2

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 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.

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.

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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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

Kepa Balparda*, Claudia Marcela Vanegas-Ramírez, Tatiana Herrera-Chalarca***, Laura Andrea Silva-Quintero******
***Department of Research and Surgery, Black Mammoth Surgical, Medellin, Colombia**
****Department of Ophthalmology, Universidad Pontificia Bolivariana, Medellín, Colombia**
*****Department of Clinical Research, Black Mammoth Surgical, Medellín, Colombia**
******School of Medicine, Universidad CES, Medellín, Colombia**

Correspondence to: Kepa Balparda, MD, PhD,
Director of Research and Surgery, Black Mammoth Surgical, Medellin, Colombia,
Carrera 43 # 29 - 35, Office 712, Medellín, Colombia,
Phone: (+57) 3145 024 586, E-mail: kb@kepabalparda.com

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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

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

Sheetal Brar, MS, Megha Gautam, MS, Smith Snehal Sute, MS, Savio Pereira, MS, and Sri Ganesh, MS, DNB

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Abstract

PURP OS E: 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 .

METH ODS : This prospective, interventional, non-randomized compar ison study included eligible patients who underwent toric phakic IOL surgery in one or both eyes with either the EP TIOL or TICL for myopic astigmat is m. Two years postoperat ively, both lenses were compared far their safety, efficacy, stab ility, and patient satisfaction. Vector analysis of astigma tism was performed using the Alpins method with the ASSORT sof t ware (ASSORT Party Ltd).

RESU LTS: A total of 50 eyes were included , of which 25 eyes received EP TIOL implantation and the remaining 25 received TICL impl antat ion. Preoperative mean ± standard deviation of spherica l equiva lent (SE) and cylinder was -10.15 ± 4 .04 and -2.08 ± o .86 diopters (D) in the EP TIOL group and -10.21 ± 3.97 and -2.17 ± 0 .9 5 Din the TICL g roup , respectively . At 2 years of follow-up, there was no sign ificant differ ence between the mean unco rrected distance visua l acuity, corrected distance visual acuity, spherical equivalent , and residua l as tigmatism 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 g roup were within ±0 .50 D of refractive astigmatism. Vector analysis of as tigma tism showed a comparable Correction Index of 0.98 in the EP TIOL group and 0.94 in the TICL g roup, 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.

CONCLUS IONS: At least for the first 2 years postoperative ly, both toric phakic IOLs were safe and effective in managing high myopic astigmatism with comparab le visua l res ults and patient satis faction.

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 cvaluate the outcomes of posterior-chamber phakic intraocular lens (pIOL) implantation in patients with high myopia. **'la teri al a nd Meth ods.** Seventy-six eyes of 38 patients who had high myopia and undergone Eyecrylphakic IOL implantation were enrolled in the study. Eighteen ofthem (47%) were males and 20 (53%) were females. Their mean age was 28.97 ± 4. 1 O (22 - 36) years. Uncorrected visual acu ity (UCVA), best corrected visual acuity (BCVA) autor cfractive and kera lometric measurements were evaluated pre and postoperative ly. **Res ults.** The mean 1st week 1stmonth a nd 6th month postoperative sphe rica l, astigmatic and spherical equivalent' (E) value were sig nificant ly lower than the se of preoperative values and the mean 1 s t wee k, 1 s tmonth and 6th month pos topcrative UC VA and BCVA values were significantly higher than those preoperative values (p < 0 .05). The mean 1s t week 1s tmon th and 6" month postoperative ante rior chamber depth (ACD) values were signific ant ly lower than preopcrative values (p< 0.05). There were no significant' differences between preoperative and postoperative central corneal thickness (CCT) endothelial cell dens ity (EC D) and intraocular pressu re (IO P) measurem ents (P>-0.05) . The postoperative fir st week mean sphe rica l valu e was 0 .11 ± 0 .44 D, and it was s table until 1 the s ixth month. Postoperative 6th month mean endothelial cell loss was 3% in comparison with preopcrative values . The difference was not sign ificant (p>0.05). Additionally no ab normal morphologic changes in endothelial cell 'aye r were observed in spec ular microscopy. **onclusion:** Eyecrylphakic IO L implantation is a safe, effective , predictable , and stab le treatment method for high -myopi a patients in the short -term. Long-term results of pIOL implantation should be investigated in further studies.

Key words: High myopia ; phakic IO L; spherica l e quivalent; CVA

Ö ZE T Ama : Yük sek miyo pisi olan hastalarda arka kamara Fakik In traokülcr len s (pIOL) im plantasyonun gorscl so nuçlan m degerlendirmek.**Gere c; ve Yö ntemler:** Yüksek miyopi si olan ve Eyc cryl Fakik IOL imp lantasyonu uygula nan 38 has tanm 76 gozü t.alısma kapsamına alındı. Hastalann 18 ' s (% 47) erkek 20 s i isc (%53) kadındı. Ortalama- yaslın 28.97 ± 4 10 (22 - 36) idi. Düzeltilmemis görme ke skinliği i. düzeltilmis görme keski nliği , oto rcfrak tif ve ke ratometrik o lçümler amcl iya t öncesi ve sonr as md a değer len dirildi . **Bul gul ar:** Onalama ameliyat sonrasl 1h a fta, 1. ay ve 6 ay sfcrik astigmatik ve sfcrik CSdeğer (.E) anıcliyat öncesi değerc göre anlamlı olarak daha düsüktü e ameliya t sonras, düzclalmcmis ve düzclti lmis görme keskinliği. ameliyat öncesi nc göre anlamlı olarak daha yüksekti (P<0.05). Onalama ame liyat so nrasl 1 ha fta, 1. ay ve 6 ay on kamara derinliği . ame liya t öncesi değerc göre anlamlı olarak daha düsükti e ameliya t sonras, düzclalmcmis ve düzclti lmis görme keskinliği. ameliyat öncesi nc göre anlamlı olarak daha yüksekti (P<0.05). Onalama ame liyat so nrasl 1 ha fta, 1. ay ve 6 ay on kamara derinliği . ame liya t öncesi değerc göre anlamlı olarak daha düsükti e ameliya t sonras, düzclalmcmis ve düzclti lmis görme keskinliği. Ameliyat öncesi ve ameliyat son rasl konuca kadınbg 1, endotel hücre sayı s l ve gözic;t basıncl değerlcrinde anlamlı bir değişiklik gozlenmedi (p>0.05). Ameliyat so nras, 1.1-lıafta onalama sfcrik değer0 .11 ± 0 .44 D idi ve bu değer 6.Aya kadar s tabil sey rcui. Posto pcratif 6 aydaki endotel hücre ka yb l %3 .3 tü. preopcratif değerc göre anlamlı bir düsüs değildi (p>0.05) Aynca , s pekülc r mikr oskopide endotel hücre tabaka sında ano rmal mo rfoloj ik değişikliklcr gozlenmedi. **So nu :** Eyecryl Fakik IOL implant asyonu, yüksek miyopisi olan hastalarda k l sa donemde güvenli ,etkin ve on gorülebilir bir tedavi sag la maktad ır. Uzun dönem sonuçlan için ilcr çalısmalann yapılması gc rekir.

Anah ta r Kelimeler: Yüksek miyop i fakik IO L; sferik eşdeğer; düzeltilmemis görme ke skinligi

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

Arvind Kumar Morya, Kirandeep Kaur, Bharat Gurnani, Siddharam S Janti, Ankur Kumar Shrivastava, Antarvedi Tejaswini, Aprajita Sinha, Dharavath Venkatesh

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.

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

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RESPUESTA OBSERVACIÓN No. 2

Teniente en cuenta la observación presentada, el comité técnico estructurador se permite indicar que una vez realizado el análisis de las especificaciones técnicas se evidencia que en aras de garantizar los principios de la contratación pública estos son pluralidad de oferentes, selección objetiva, responsabilidad e igualdad de oferentes, se acepta la observación y se excluye el material colamero porcino.

Elaboró:

CR (RA) DR. Luis Alberto Ruiz Robles
Comité Técnico Estructurador
Servicio De Oftalmología