Aphakic IOL for Children: Multi-Center Prospective Study

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Financial disclosure

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No financial interest related to product

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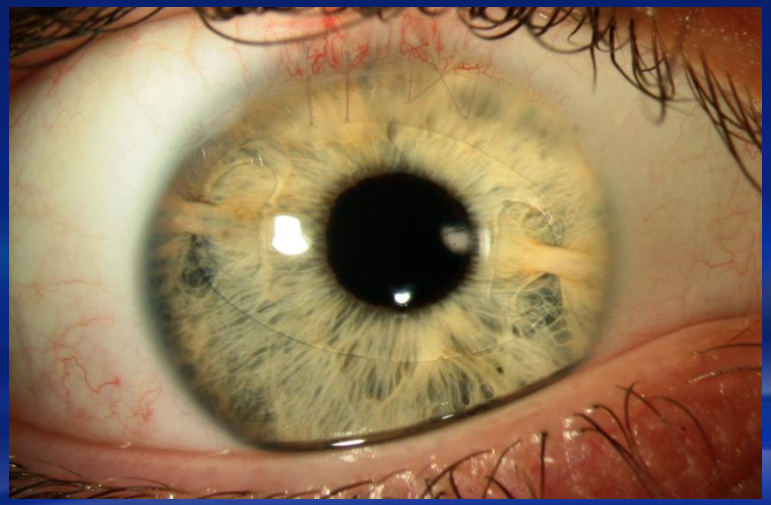
Purpose

- To report outcome of the ARTISAN® aphakia lens for aphakia in children
  - Surgical intervention and other postoperative complications
  - Visual acuity



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Study design

- Prospective, open-label, non-randomized, multicenter study under *FDA approved IDE* (Investigational device exemption)
- ClinicalTrials.gov Identifier: NCT01547442
- Targeted criteria:
  - Sample size: 300 subjects* (390 accounting for lost to follow-up)
  - Investigational sites: 20
  - Follow-up: minimum 5 years

* Fellow eye surgery is allowed after 1 week of the first eye, however, data from the second eye did not contribute to the cohort population or the primary analysis

Study design

- Inclusion criteria:
  - Age *2 to 21 years*
  - Visually significant cataract, need IOL replacement surgery or have compromised capsular bag prohibiting implantation of a standard posterior chamber IOL
  - Informed consent / assent
- Exclusion criteria:
  - Age: <2 years, patients that are not able to meet the extensive postoperative evaluation , when the patient has no useful vision or vision potential in the fellow eye , mentally retarded patients, history of corneal disease that may affect vision, abnormality of the iris (e.g. aniridia) , ACD<3.2 mm, uncontrolled glaucoma , high preoperative intraocular pressure(>25 mmHg) , chronic or recurrent uveitis or history of the same , preexisting macular pathology , patients with a RD or a family history of RD Retinal or optic nerve disease that may limit the visual potential of the eye, diabetes mellitus , pregnant, lactating, or plans to become pregnant during the course of the study

Study design

- Endpoints:
  - Effectiveness: 85% of subjects with potential for increase in VA preoperatively should see improvement in BCDVA at 12 months postoperatively
  - Safety: No more than 5% of subjects should experience reduction in VA
  - Additional safety endpoint: incidence of adverse events

PARAMETER	Preop	Visit 1 1 day	Visit 2 1 wk	Visit 3 1 mo	Visit 4 3 mos	Visit 5 6 mos	Visit 6 1 yr	Visit 7 2 yrs	Visit 8 3 yrs	Visit 9 4 yrs	Visit 10 5 yrs
Informed Consent/Assent	x										
Type of Cataract / Etiology	x										
UCDVA			x	x	x	x	x	x	x	x	x
BCDVA	x		x	x	x	x	x	x	x	x	x
Manifest Refraction	x					x	x	x	x	x	x
IOP	x	x	x	x	x	x	x	x	x	x	x
Medications	x	x	x	x	x	x	x	x	x	x	x
Corneal Status	x	x	x	x	x	x	x	x	x	x	x
Corneal Edema	x	x	x	x	x	x	x	x	x	x	x
Pachymetry	x					x	x	x	x	x	x
Corneal Curvature, Axial Length, Corneal Diameter, Anterior Chamber Depth, Pupil Size and Shape	x										
Endothelial Cell Count (if possible)	x					x	x	x	x	x	x
Anterior Chamber Status	x	x	x	x	x	x	x	x	x	x	x
Fundus Condition	x					x	x	x	x	x	x
Other Complications/ Pathologies	x	x	x	x	x	x	x	x	x	x	x
Report Surgical Reintervention(s)		x	x	x	x	x	x	x	x	x	x
Evaluation of Lens and Enclavation		x	x	x	x	x	x	x	x	x	x
Report Adverse Event(s)		x	x	x	x	x	x	x	x	x	x

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Results

- Enrollment ongoing
- Enrolled: n = 43 subjects*
  - Secondary IOL implantation: 40
  - Primary IOL implantation: 3
- Age at implantation: 9.9 ±4.4 (3-18) years
- Follow-up:

	1 day	1 week	1 month	3 months	6 months	1 year
n	43	40	37	33	23	8

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*72 eyes

Surgical intervention

3/43 (7%)* subjects

- Revision of the peripheral iridectomy for raised IOP (2 weeks after implantation). Hit with a basketball 6-months later. Operated for dialysis and RD. Last follow-up: retina attached.
- Pupillary block glaucoma requiring 4 re-operations before stabilization (first reoperation - 12 days after implantation)
- Re-enclavation after post-operative trauma (12 weeks after implantation)

**4/72 (5.6%) eyes. One patient in second operated eye required wound leak repair 2 days after surgery.*

Other postoperative complications

	N (%)	Comments
Corneal edema	9/43 (21) Severe 1 Moderate 6 Mild 2	one day (7), One week (1) 1 month (1)
Hyphema	5/43 (11.6)	One day (3) One week (1) One-month (1)
Anterior chamber cells persisted at/after 1 month postoperative visit	6/37 (16.2)	One month (4) 3 months (1) 6-months (1)
Anterior chamber flare persisted at /after 1 month postoperative visit	10/37 (27)	1 month (7) 3 months (3)
Hypopigmentation near haptics	5/33 (15.1)	3 months (3) 6 months (1) 1 year (1)
Mild precipitates on IOL	10/40 (25)	One week (1) 1-months (6) 3-months (1) 1 year (2)

Best corrected distant visual acuity

- One year postoperative (n=8):
  - 20/90 before implantation versus 20/40 after implantation (pair T test, *P=0.11*)
- Last follow-up* (n=37):
  - 20/88 before implantation versus 20/66 after implantation (pair T test, *P=0.17*)

**minimum 1-month follow-up*

Summary

- Implantation of the ARTISAN aphakic IOL in children under an FDA IDE reveals acceptable safety and visual outcomes.
- Adverse events have occurred but without permanent visual consequences.
- Enrollment and monitoring is ongoing.

Acknowledgment

Participating clinical centers (chronological number of subjects enrolled by primary investigator)

- M. Edward Wilson, MD, Storm Eye Institute, Charleston, SC (n = 14)
- David Plager, MD, Riley Hospital for Children, Indianapolis, IN (n = 10)
- Lawrence Tychsen, MD, St. Louis Children's Hospital, St. Louis, MO (n = 9)
- Erin Stahl, MD, Children's Mercy Hospitals and Clinics, Kansas City, MO (n = 6)
- Erick Bothun, MD, Minnesota Lions Children's Eye Clinic, Minneapolis, MN (n = 2)
- Deborah VanderVeen, MD, Boston Children's Hospital, Boston, MA (n = 1)
- Gerald Zaidman, MD, Westchester Medical Center, Valhalla, NY (n = 1)

Other IRB approved clinical centers*:

- Alan Crandall, MD, John Moran Eye Center, Salt Lake City, UT
- Richard Golden, MD, Nationwide Children's Hospital, Columbus, OH
- Kartik Kumar, MD, Robert Cizik Eye Clinic, Houston, TX
- Kanwal (Ken) Nischal, MD, UPMC Eye Center, Pittsburgh, PA
- Kenneth Rosenthal, MD, Rosenthal Eye and Facial Plastic Surgery, Great Neck, NY
- Serena Wang, MD, UT Southwestern Medical Center, Dallas, TX

* Recently approved

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