ACRIVA BB T UDM 611 TORIC INTRAOCULAR LENS ROTATIONAL STABILITY POST-MARKETING SURVEY

1. **Purpose:** To evaluate the rotational stability and refractive and visual outcome of toric IOL implantation Acriva BB T UDM 611 for correction of pre-existing corneal astigmatism following cataract surgery.

2. Preface and background:

With the age, a normal crystalline lens opacifies (cataract) disabling the eye in generating a clear image and reproducing contrast. The only therapeutic solution to this problem is surgical replacement of the crystalline lens with an intraocular lens (cataract surgery). An increasingly important goal of modern cataract and implant surgery is to obtain the most desirable outcome for the patients, thus contributing to spectacle-free vision and highest quality of life.

The ideal state of the human phakic eye without any refractive error is known as emmetropia; rays of light perfectly focusing from an infinite distant object onto the fovea without accommodation.

Refractive power of the eye is determined by three main parameters: power(s) of the cornea, power of the crystalline lens and axial length of the eye. Deficiencies in one or more of these parameters lead to various types of refractive errors known as myopia, hyperopia and astigmatism[1].

Astigmatism is a common refractive condition of the eye caused by a difference in degree of refraction in different meridians. Regular astigmatism is typically characterized by an aspheric cornea with different refractive powers in orthogonal meridians.

The cataract surgery is becoming a refractive surgery where astigmatism control is essential. Advancements in intraocular lens technology now provide for a reliable and effective option for patients with astigmatism. Prior toric IOLs were introduced, cataract patients could only benefit from surgical correction of myopia or hyperopia. Patients with astigmatism had to either have standard treatments as corneal refractive surgery (LASIK: Laser assisted in situ Keratomileusis, PRK: photorefractive keratotomy, PLRI: peripheral limbal relaxing incisions or PCRI: peripheral corneal relaxing incisions) after lens implant surgery or continue to depend on spectacles or contact lenses.

With toric IOLs inserted after cataract removal, astigmatic imperfections of the eye's shape are compensated, resulting in clearer vision without the need for multiple procedures, as is common in other astigmatism surgeries. The recovery time is shorter and more comfortable for the patient.

3. General Description

The investigational devices of this post marketing survey share a common platform, i.e a single-piece, foldable, monofocal, toric, aspheric, IOL made from acrylate. It is used in cataract patients and is implanted into the capsular bag of the human eye, using cartridge injector system.

VSY
BIOTECHNOLOGY

1.1. Lens Material

The lens material used in both IOLs is a biocompatible, hydratable copolymer consisting of 2-Hydroxyethyl methacrylate and Ethoxyethyl methacrylate (p-co-HEMA/EOEMA) with UV absorber (4-Methacryloxy-2-hydroxybenzophenone). The lens material features a water content of 25% at 35°C and a hydrophobic surface: contact angle approx 70°.

The acrylate material used for the IOLs features excellent biocompatibility, and it is non-toxic towards the intraocular tissues. It has already been used in clinical application in many other lens types since decades.

1.2. Lens Design

The total length of the IOLs is 11.0 mm.

The optic diameter is 6.0 mm.

1.3. Picture of IOL

The haptic features a special “4-haptic design” for excellent rotational stability and centration over time.

The IOLs are designed to be implanted through a micro incision down to 1.8 mm (true MICS). This technique offers the following advantages:

- minimized risk of surgery induced astigmatism,
- rapid wound healing and accelerated post-operative regeneration,
- low risk of endothelial cell loss,
- reduced risk of inflammation.

2. Materials and Methods:

2.1. Post marketing survey after implantation of Toric Iols: Acriva BB T UDM 611 Protocol: Post Marketing Toric IOL Survey

2.1.1. Main objective:

For refraction stability evaluation, D30 follow-up values will be considered. as reference values. Stability of refraction and especially of cylinder will be assessed. Objective and subjective refraction will be evaluated.

2.1.2. Further Objectives:

- Visual acuity recovery (far uncorrected and best corrected visual acuity
- Predictability of cylinder correction: difference between expected cylinder and achieved cylinder at D90 min.
- Surgical Induced Astigmatism
- Evaluation of IOL position
- Evaluation of patient satisfaction and visual symptoms (glare, halos, blurring, other)

2.1.3. Implantation of 15 eyes minimum

2.1.4. Inclusion criteria:

- Patient age 55-85 years
- Healthy eyes with cataract
- Stable corneal condition within the last 12 months
- Stable refraction within the last 12 months (equal or less than 0.5D of variation)
- Regular corneal astigmatism with only slight irregularities (confirmed by topography measurement) comprised between 1D and 12D
- Assured follow-up examination
- Uncomplicated cataract surgery and implantation into capsular bag by injector

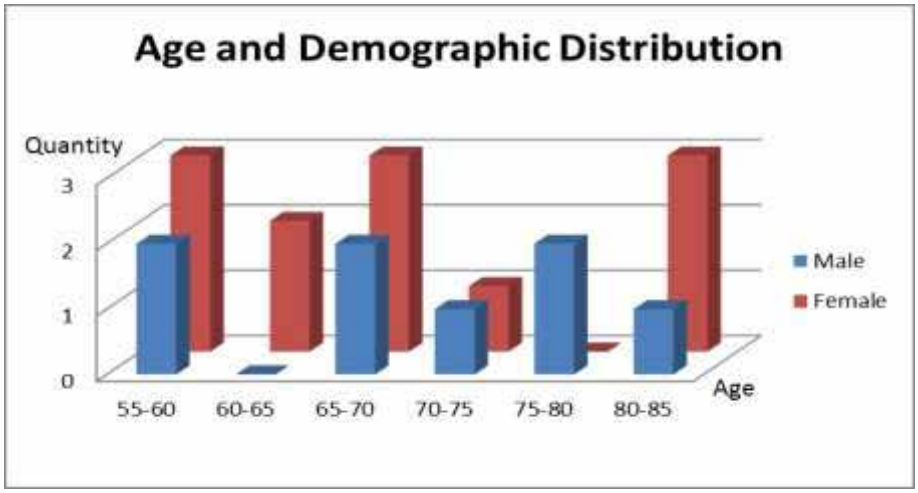
2.1.5. Exclusion criteria

- Any kind of macular degeneration and impairment of retina (clinical diagnosis)
- Adult persons under legal protection or unable to give an informed consent
- Persons who forfeited their freedom by administrative or legal order
- Pseudophakia in target eye
- Cornea guttata; keratoplasty
- Glaucoma
- Irregular astigmatism, especially keratoconus
- Amotio operation; anamnesis with vitreous surgery
- Amblyopia
- Pseudoexfoliation syndrome; uveitis
- Monophtalmia
- Diabetes
- Pathologic myosis
- Intraocular tumours; endotamponade
- Physiologic intraocular processes or other pre-existing processes that permanently limit the best corrected visual acuity to ≤ 0.1
- Intraoperative complications; damaged capsular bag; intraocular haemorrhage, zonular weakness or floppy capsule

2.1.6. Number of patients: 20 patients, 26 eyes

Demography: 8 male, 12 female patients

Age: Between 55 - 83 years



Graph – 4.1.

2.1.7. Name of Doctors / Centers

Undisclosed

2.1.8. Post-op follow-up of minimum 3 months

- Starting date: 24.05.2013
- Ending date: 03.04.2014
- Minimum follow up: 73 days
- Maximum follow up: 108 days

3. Results: (ANNEX I, ANNEX II, ANNEX III)

Proof of rotational stability:

3.1. Measurement of the visual, subjective, non-corrected acuity in the middle of an optotype, first measurement between 1st and 6th week en second measurement between 3th and 6th month after implantation

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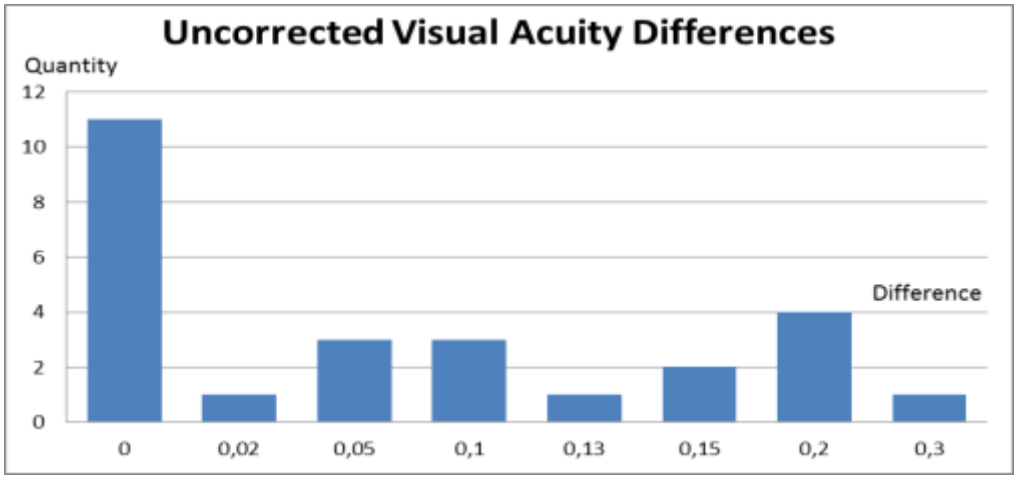
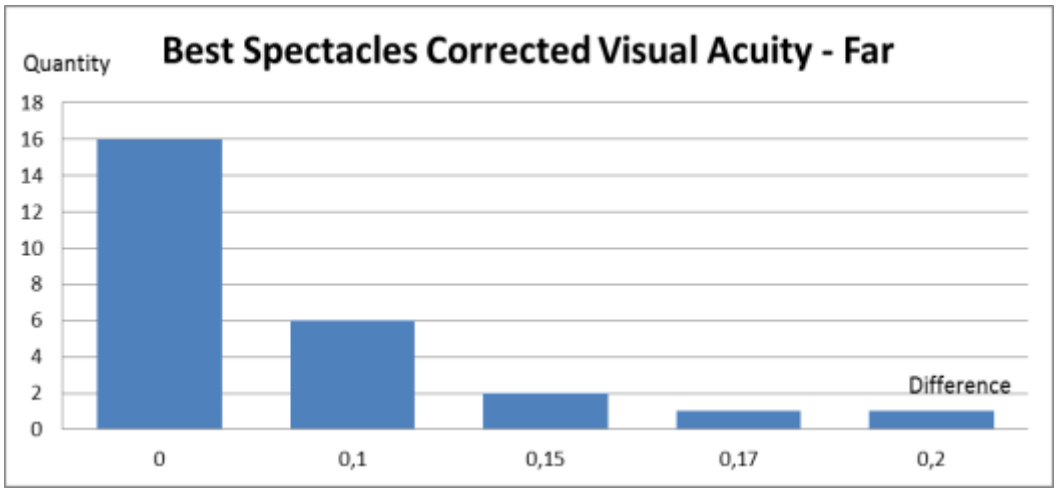
- Acceptable Criteria: residual astigmatism of max 0.5D to 0.75D
- Compared to target refraction

- Results for uncorrected visual acuity differences have been recorded as:
  100% of all eyes have residual astigmatism ≤ 0.3,
  96% of all eyes ≤ 0.2,
  81% of all eyes ≤ 0.15,
  73% of all eyes ≤ 0.13,
  69% of all eyes ≤ 0.1,
  57% of all eyes ≤ 0.05,
  46% of all eyes ≤ 0.02.



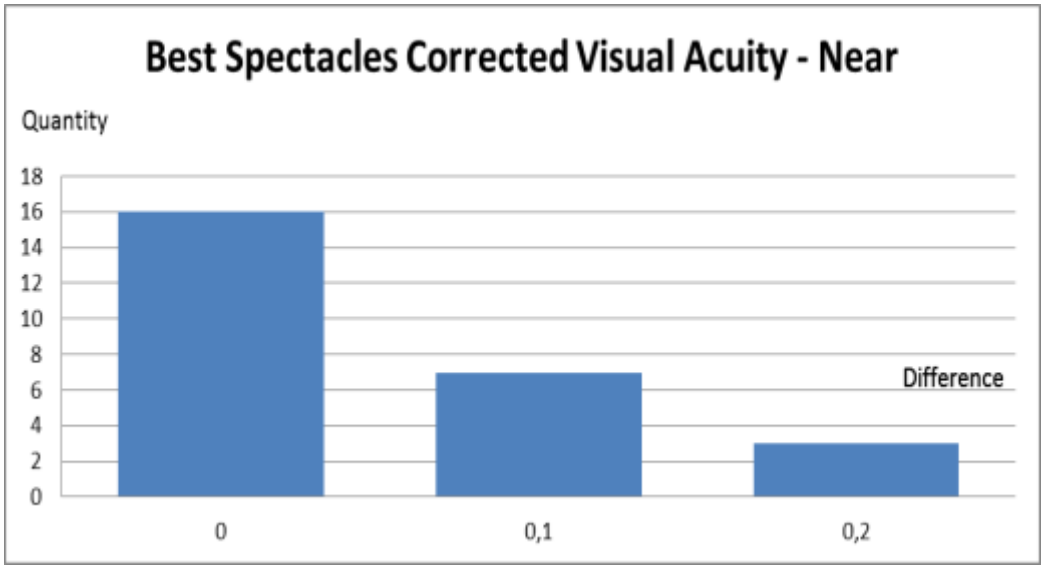
Graph 5.1.

- Results for corrected visual acuity differences for far vision have been recorded as:
  100% of all eyes have residual astigmatism ≤ 0.2,
  96% of all eyes ≤ 0.17,
  92% of all eyes ≤ 0.15,
  84% of all eyes ≤ 0.1.



Graph 5.2.

· Results for corrected visual acuity differences for near vision have been recorded as:
100% of all eyes have residual astigmatism ≤ 0.2,
88% of all eyes ≤ 0.1.

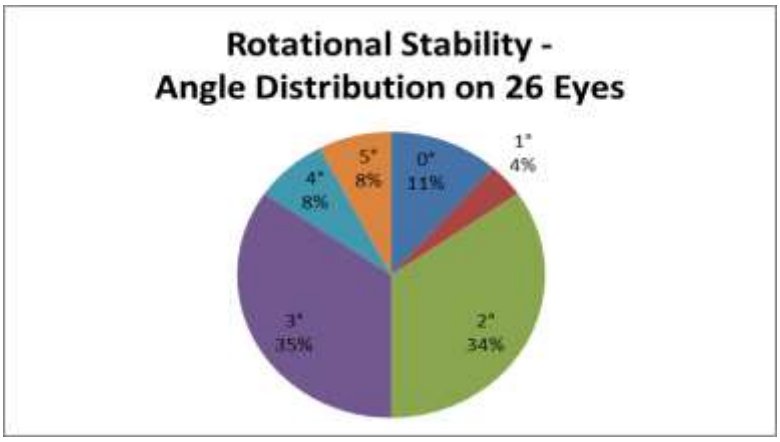


Graph 5.3.

3.2. Measurement of the rotation of the axis of the IOL at 3 months post-op

· Acceptable Criteria: less than 5° in all directions inclusion of the excel table or a graph to show comparison between intended an final.

- Results have been recorded as:
100% of all eyes have ≤ 5°,
92% of all eyes ≤ 4°,
84% of all eyes ≤ 3°,
50% of all eyes ≤ 2°,
15% of all eyes ≤ 1°.



3.3. Measurement of objective astigmatism at central corneal plane of min 4mm diameter by the means of aberrometry :

- Acceptable criteria : astigmatism of 1.0D compared to target
- Refraction

(not necessary if point a. is followed)

4. Conclusion

Implantation of Acriva BB T UDM 611 model IOL from VSY Biotechnology can effectively correct corneal astigmatism thereby enhancing the postoperative refractive outcome and leading high patient satisfaction.

Implantation of Acriva BB T UDM 611 model IOL from VSY Biotechnology complies with specific requirement of:

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[C − 2013/22031]
14 JANVIER 2013. — Arrêté royal modifiant les articles 35 et 35bis de l'annexe de l'arrêté royal du 14 septembre 1984 établissant la nomenclature des prestations de santé en matière d'assurance obligatoire soins de santé et indemnités