"LUCIAN BLAGA" UNIVERSITY – SIBIU

CONTRIBUTIONS TO THE EXTENSION OF INDICATIONS OF THE TORIC INTRAOCULAR LENSES IMPLANTATION

PHD STUDENT: GENOVEVA OLARU

PHD SCIENTIFIC SUPERVISOR: PROF. DR. ADRIANA STĂNILĂ

KEYWORDS:

- CORNEAL ASTIGMATISM
- CATARACT
- TORIC ARTIFICIAL LENS

SUMMARY

I. Introduction……..4

II. The theoretically part……..5

1. Ocular anatomy and physiology terms...……..……..5

1.1. Introduction…….……5

1.2. The cornea.....6

1.2.1. The anatomy and physiology of the cornea.....6

1.2.2. Corneal biomechanics……..……7

1.2.3. Light transmision through the cornea.....7

1.2.4. The optical characteristics of the cornea.....7

1.3. The crystalline.....8

1.3.1. The anatomy of the crystalline.....8

1.3.2. The biochemical composition of the crystalline.....9

1.3.3. The role of the crystalline.....9

2. The astigmatism.....9

2.1. Definition.....9

2.2. History.....10

2.3. Physiopathology.....10

2.4. The age related changes in astigmatism.....11

2.5. The astigmatism in the ethnics groups.....11

2.6. The astigmatism classification.....12

2.7. Clinical signs and symptoms.....14
2.8. The diagnostic tests of the astigmatism.....14
3. The therapeuticaly options in correction of the corneal astigmatism.....18
3.1. The eyeglasses and the contact lenses.....18
3.2. The surgical correction of the astigmatism.....19
3.2.1. The incisional procedures.....19
3.2.2. The excimer laser procedures.....24
3.2.3. The artificial toric lenses implantation.....27
4. The therapeuticaly options in patients with cataract and astigmatism.....28
4.1. The corneal incisions.....28
4.2. The artificial toric lenses.....29
5. Conclusions.....33
III. The practically part.....34
A. The purpose of the paper.....34
B. The hypothesis.....34
C. The analysis of entire lot taken in the study.....34
1. Material and method.....34
1.1. The demographic dates.....34
1.2. The preoperative evaluation of the patients.....35
1.3. Biometric measurements.....37
1.4. The surgical technique.....51
2. Results, the statistically processing of the dates and discussions.....66
2.1. The postoperative visual acuity.....66
2.2. The postoperative refractive status and correlations with the refractive target.....73
2.3. The spectacle independence.....82
2.4. The postoperative obtained astigmatism.....83
2.5. The rotational stability of the artificial toric lens.....91
D. The particular cases analysis.....93
1. Material and method.....93
1.1. The demographic dates.....93
1.2. The preoperative evaluation of the patients.....93
1.3. Biometric measurements.....95
1.4. The surgical technique and intraoperative incidents.....99
2. Results and discussions.....102
2.1. The postoperative visual acuity.....102

2.2. The postoperative refractive status and correlations with the refractive target.....103
2.3. The spectacle independence.....104
2.4. The postoperative obtained astigmatism.....105
2.5. The rotational stability of the artificial toric lens.....106
2.6. Discussions.....106
IV. Conclusions.....108
V. Bibliography.....109
VI. Annex-printed papers……..…….115

ABSTRACT

During the last years, cataract surgery has taken a refractive tendency, especially since the appearance of artificial crystalline lenses, which give multifocality, asphericity, and toricity. This trend has given birth to the term of „refractive cataract surgery".

The refractive cataract surgery may be defined as the surgery of cataract with a double purpose: to improve vision and the reduce spectacle dependence for distance vision, near vision or both. In this context, in these patients, the management of astigmatism is very important.

In order to fulfill every patient's needs, various brands have put on the market a whole range of devices and have developed a multitude of techniques, such as the toric artificial crystalline lenses, which improve cataract patient's vision and the pre-existing corneal astigmatism.

Astigmatism is a type of refractive error of the eye characterized by blurred vision due to the imposibility of ocular optics to focus a punctiform object into a clear image on the retina. There is a number of options for the patients that want astigmatism correction, from eyeglasses to the latest laser technology. Chosing the right treatment will depend on many factors, including lifestyle, medical history and the degree of refractive error.

Cataract is an opacity of the crystalline lens, congenital or gained, causing impairment of vision. Approximately 15-29% of the cataract patients have an corneal astigmatism bigger that 1.00 D that impede obtaining a maximal visual acuity without glasses. The management of astigmatism consists of correcting it as much as possible or eliminating it.

Arcuate keratotomy, the limbal relaxing incision, toric artificial crystalline lenses, excimer laser treatment and various types of incisions have been described in the literature, for the after-cataract surgery management of astigmatism.

Toric artificial lenses are considered one of the ideal solutions for the patients with cataract and astigmatism. The first toric artificial lens was used by Shimitzu, in 1994. The first

posterior chamber toric lens that was extensively available was produced by Staar Surgical and was implanted in 1999. It was introduced in North America by Gimbel and Ziemba.

In the present, there are numerous toric artificial lenses available, such as those from Acri.Tec, Alcon, Abbott Medical Optics, Oculentis, Rayner, Staar and others. Some of them are also available on toric multifocal platform.

Acrysof toric artificial lense has a SN60AT single-piece design. It is a hydrophobic acrylic lens with an incorporated yellow cromophore and 6 mm optic. It may be implanted through a 2.2 mm incision. The IQ toric version is aspheric and was launched in Aprilie 2009. The lens has the axis marked with 3 reference dots on each side of the optic periphery that indicate the most convex axis.

This paper aims to analyze the result obtained following toric IOLs implantation in patients with cataract and pre-existent corneal astigmatism. It also tries to widen the area of indications for this type of implant, thus establishing both its benefits and its limits.

This is a prospective clinical study on a consecutive group of patients with cataract and corneal astigmatism in which the broadening of Acrysof Toric IOL implantation indication for the cases with secondary corneal astigmatism was followed.

A lot of 164 patients, 210 eyes respectively, with cataract and corneal astigmatism, was taken into study; all of them undergone cataract surgery and had Acrysof Toric IOL implanted at the Ophthalmology Ward of "Constantin Papilian" Military Emergency Hospital from Cluj Napoca, between September 2007 and August 2011.

The lot comprised of 61 men and 103 women aged 14-86 years old. Pre-operative measured visual acuity was under 0.1 in 112 eyes, 0.2 – 0.7 in 92 eyes and over 0.8 in 6 eyes. Pre-existing corneal astigmatism was 0.75 D – 9.1 D.

In all the cases, keratometry was performed by autorefractometer; in patients with high values of corneal astigmatism and in those with irregular astigmatism, corneal topography was performed using the Oculyzer topography device, which is based on Pentacam technology.

Depending on the density of cataract, we used ultrasound biometry or optical biometry using interferometry, being known that optical biometry can not be done in cases of mature cataracts or in posterior subcapsular cataracts. For ultrasound biometry, we used Ultrascan device, and for optical biometry – Biograph device. Ocular and orbital ultrasonography was performed in all the patients.

The aimed refractive target was emetropy (-0.25 - +0.75) in 143 eyes, myopia (>-0.5) in 62 eyes and hypermetropia (+2 - +3) in 5 eyes. The surgically-induced astigmatism (SIA) was 0.25 D in 182 eyes (86.66%) and 0.50 D in 28 eyes (13.33%).

The resulted biometrical data were uploaded to an online calculator that can be found at *www.acrysoftoriccalculator.com.*

The dioptric value of the implanted IOLs was between +6D and +30D, reaching all the available values in case of Acrysof Toric, and all the available models, from SN60T3 to SN60T9. Untill October 2009, we had implanted the SN60T5 model even in patients with a higher than 2 D astigmatism, as models SN60T6 - SN60T9 had not been available in our country.

After using the online calculator, the estimated postoperative astigmatism was 0.00 D – 4.51 D. In most of the cases (83.80%), the estimated postoperative astigmatism was under 0.5 D, but there are still 6.19% of cases with estimated astigmatism higher than 2 D. This situation is due to both cases with higher than 4 D astigmatism and cases with 2 D – 4 D astigmatism in which T5 model was implanted.

Regarding the *surgical procedure*, implantation of a toric artificial lens requires only a slight variation from the standard cataract extraction and implantation procedure. After the surgeon applies a standard phaco technique - clear corneal incision, the surgeon has to complete two important surgical steps: marking of the eye and aligning the IOL with the predetermined axis.

Marking of the eye is essential as IOL positioning depends on it for a maximal efficacy. In study cases, pre-operative marking was done using a counterweight marker, under the biomicroscope, with previously dilated pupil, marking the horizontal axis. Intraoperative marking was performed using a Cionni marker – in the first cases before implantation, then the marking was done at the beginning of the surgery, marking the most refringent axis to which the IOL would be positioned, taking into consideration the previously marked horizontal axis.

The primary corneal incision was 2.2 mm in 129 eyes, 2.4 mm in 53 eyes, 2.75 mm in 16 eyes and 3 mm in 12 eyes. In 3 eyes, counterincisions were done. The incision axis was at 110 degrees in 205 eyes, 90 degrees in 4 eyes and 180 degrees in 1 eye.

The capsulorrhexis was performed using Utrata forceps, lifting the capsular flap and, through a rotation clockwise, a 5.5 mm opening was made.

The phacoemulsification technique used in most of the cases was „stop&chop”; in hard cataract cases, the „divide&conquer” technique was used, and in „clear lens exchange”, the crystalline lens content was eliminated by bimanual irigation/aspiration.

The intraocular lenses were implanted using the Monarch I and II, and Royale I and II injectors, with C and D cartridges. After the implantation of the IOL in the crystalline bag, an gross alignment was made, namely rotating the IOL to app. 10-20 degrees anticlockwise from the final position. By bimanual technique, the vascoelastic substance was removed from the front part of-

, but especially from behind the crystalline, to avoid the post-operative axis dislocation of the toric artificial lense. This maneuvre allows creating a IOL-bag adherence, thus consolidating the IOL's position at the preset axis, as IOL stability is mandatory for its eficacy. The fine alignment consists of positioning the toric artificial lense at the pre-calculated most refringent axis. Using a cannula with saline solutine, the IOL will be rotated until the 3 reference dots at the basis of the haptics that mark the axis of the toric component of the crystalline are aligned with the marked axis.

The intraoperative incidents that occurred in the study group were few and related especially to the traumatic cataract cases in which some degrees of crystalline subluxation or zonula instability were present.

The postoperative complications in the study group were:

- Posterior capsula opacification – in 3 cases, including one with posterior polar cataract where the opacity had not been completely removed during surgery
- Rhegmatogenous retinal detachment – in 2 cases: 1 year postoperatively in one case, and 3 months postoperatively in the other; both cases have undergone surgery and regained about 70% of their vision
- Repositioning of IOL – in 2 cases, 6 weeks postoperatively
- Re-changing of IOL – in 1 case, 1 week postoperatively, due to a 3D refractive error.

Evalution of patients was done postoperatively at 1 day, 2 months, 6 months and 1 year.

The folow-up parameters were:

- Visual acuity
- Postoperative refractive status
- Spectacle independence
- Gained postoperative astigmatism
- IOL rotatory stability.

An 100% of visual acuity improvement was observed, with an ascending trend from the fistr postoperative day to 2 months postoperatively. Most of this is due to the transitory corneal oedema that occurs in cases of advanced cataract. The data that were retrieved at 2 months remained unchanged at 6 months, respectively 1 year postoperatively.

The 1 year postoperatively results show a visual acuity of over 0.8 in 83.25% of eyes, comparatively to the FDA study that reported a visual acuity of 20/25 without correction in 66% patients with unilateral toric IOL, and 97% of bilateral toric IOL patients. The study data are superposable with the values that were reported by other authors.

As regarding the aimed preoperative refractive target, it was aquired in 66.70% eyes. The refraction was +75/-0.25 D in 50% eyes; >-0.5 D in 33.83% eyes; >+0.75 D in 16.17% eyes,

compared to the prospective observational Spanish study, in which the aquired refraction was +/-1D in 80% cases and +/-0.5 D in 93.9% cases.

Spectacle independence was aquired in 115 eyes (58%), the rest of the patients needing eyeglasses. Of the spectacle dependent patients, 64 have myopy and 19 have hypermetropy.
The Canadian multicentric study that was done in 2008 on 222 eyes (117 patients) shows a percent of 80% patients that did not need distance spectacles anymore.

In our study, we obtained an astigmatism decrease in 71.42% eyes. The correlation between the estimated and aquired values was 68.94% eyes. 24.21% are values of 1 D, the rest (6.85%) are >1.5 D. The results are very good and are comparable to those reported from the Spanish prospective observational study on 30 eyes, in which the mean refractive cilinder decreased from 2.34 D +/- -1.28 to -0.72 D +/- -0.43 D.

The rotational stability of Acrysof Toric IOL was assessed on a 50 eyes sample, 2 months postoperatively. These eyes were dilated, re-marked under the biomicroscope, then brought to OR, where the most refringent axis at which the IOL had been positioned was marked. It was assessed if the lense was axis-aligned or not. Of the sample, in 2 cases the rotation of the IOL with approximately 30 degrees was observed. In these cases, surgical re-intervention was decided and the IOL was re-positioned, with a good evolution at follow-up. In 3 cases, the rotation was of maximum 10 degrees, and in the rest of the cases the IOL had a good axis-alignment, with at most 5 degrees rotation.
Data provided by this study show an excellent rotational stability of the Acrysof Toric IOL, with a lower than 5 degree rotation in 90% of the followed eyes. The data are comparable to those described in the literature by various authors, in various study groups – such as in Dr. Chang's study, which reports 85% IOLs with under 5 degree rotation from the preset axis. For every degree of IOL rotation, 3.3% of lens cylinder power is lost.

Of the whole study group, 15 patients (10 men and 5 women, aged 25 – 85), respectively 15 eyes, carry particular conditions that represent an absolute or relative contraindication for the implantation of this type of crystalline. In these, cataract surgery was also performed and Acrysof Toric IOL was implanted.

The particularities of these cases are as follows:

- 5 cases of traumatic cataract with zonula instability, crystalline subluxation, with or without vitreous herniation into the anterior chamber, one of the cases having adherent corneal scar and post-traumatic iris coloboma
- 5 cases of corneal dystrophy that have led to secondary corneal astigmatism and decreased visibility during surgical intervention
- 3 cases of corneal scars after pterigyum surgery

- 1 case of keratoconus stoped from evolution
- 1 case of post-keratoconus corneal transplant

The last two cases led to significant secondary corneal astigmatism.

The same protocol was used as that described above for the cases with cataract and regular corneal astigmatism.

The keratometry that was performed with the auto-refractometer showed very variable values; that is why the cornea was topographed and the topographic keratometric values were taken into consideration for the biometrical lense calculation, as well as for implant positioning. The pre-existent corneal astigmatism was between 1.25 D and 9.10 D. The dioptric value of the implanted IOLs was between +9 D and +30 D. The aimed refractive target was emetropy in 13 eyes and myopia in 2 eyes.

Surgically-induced astigmatism (SIA) was 0.25 D in 10 eyes and 0.50 D in 5 eyes. According to the calculations realized by the online soft, the estimated postoperative astigmatism was 0.00 D and 4.51 D.

The surgical technique consisted of the same steps as for the normal cases. The corneal incision was made in all the cases at 110 degrees, except for the keratoconus case, in which it was made at 90 degrees in order to further reduce the pre-existent astigmatism. The size of the incision was 2.2 mm in 7 cases, 2.4 mm in 3 cases, 2.57 mm in 3 cases, and 3 mm in 2 cases.

Difficulties were encountered in cases of corneal involvement that led to hypotransparency and, thus, decreased visibility – it was necessary to colour the anterior capsula in order to perform capsulorrhexis. In the case of corneal transplant, besides the partial clarity of the central cornea, the pupil did not dilate and had irido-crystalline synechiae. It was needed to dilate the pupil mechanically with irian retractors for performing the phacoemulsification. In 4 of the traumatic cataract cases, the crystalline bag was stabilised with a tension ring. In 2 cases, at the zonula dehiscence site there was vitreous herniation into pupilar area, necessitating anterior vitrectomy. In one case with traumatic cataract, corneal leucoma and iris coloboma, pupil reconstruction was done.

In these presented particular cases, the results of the toric artificial lens implantation were very good:

- Visual acuity of over 0.2 in 86.66% eyes
- Neutralization of astigmatism in 78.58% eyes. In 21.42% eyes, the results were not accordant; 2 eyes have a restant astigmatism of 2 D and 3.5 D, respectively, and 1 eye (the keratoconus eye) has an astigmatism decrease more significant then the estimated one (9.1->4.51->0.75 D).

- Rotational stability in 93.33% eyes. In a single case of traumatic cataract with a 60-80 degree temporary zonulolysis, a crystalline rotation of approximately 30 degree was noticed. In this case, surgical reintervention was done about 2 months postoperatively and the IOL was repositioned to the corresponding axis.
- The refractive target was achieved in 11 eyes (78.57% eyes). In 3 cases, a refraction of over 1.5 D was achieved; this sitution was met in corneal dystrophy cases and this error is possible to be due to the variable keratometric values, which influece crystalline calculus and also it axis alignment.
- Optic correction was needed in 5 eyes: 2 eyes with myopy target, and 3 eyes with restant hypermetrophy.

The published data are a few, only isolated cases, without larger group studies.

Dr. Davidorf J. presented, at the 2009 Annual ASCRS Meeting in San Francisco, Acrysof Toric crystalline implantation in a patients with astigmatism secondary to perforant keratoplasty. Patient's visual accuity had improved, and corneal astigmatism decreased from 5.75 D to 1 D, with stable results 1 month postoperatively.

Dr. Nuijts R considers that, in cases with keratoconus stopped from evolution, implantation of a toric artificial crystalline is a solution leading to a reduction in astigmatism of 75-80 %.

Dr. Kanellopoulos J presents a case of corneal dystrophy in which he implanted a Acrysof toric IOL with very good results (AV=20/25).

Regarding the traumatic cataract, online there are a lot of videos done by various surgeons, showing the benefits of this type o crystalline.

Conclusions

As shown in the current study, the Acrysof Toric artificial lens brings remarcable improvement regarding viasual acuity, spectacle independence, and decrease or elimination of astigmatism. Being made on the same platform as Acrysof Single Piece, it is easy to implant and offers important bag stability, due to its highly biocompatible and adhesive properties. The implantation technique for this type of lens necessitates a minumum learning curve. The result are spectacular and the patients are very pleased.

As concerning toric artificial lens implantation in cases with secondary irregular corneal astigmatism, during current study we achieved a visual acuity enhancement, a decrease in astigmatism, and a decrease in spectacle dependence. In most of the cataract cases with affected zonula, IOL's stability was proven as it remained in the preset position.

Less satisfactory results were obtained in the few cases of corneal dystrophy, where refractive errors were present. These cases remain a difficult problem to solve.

Toric artificial lens is a very effective method of correcting astigmatism in cataract patients, and can be used succesfully in cases with irregular astigmatism (keratoconus stopped from evolution, corneal scars) and also in traumatic cataract with zonula involvement.