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ORIGINAL PAPER

One Year Follow-Up After Veriflex Phakic Intraocular Lenses Implantation for Correction of Myopia

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ABSTRACT

Objectives: The aim of this study was to evaluate visual and refractive outcomes after Veriflex phakic intraocular lenses (pIOL) implantation in moderately myopic eyes as well as postoperative complications. **Methods:** This prospective clinical study included 40 eyes of 26 patients which underwent implantation of Veriflex for correction of myopia from -6.00 to -14.50 diopters (D) in the Eye Clinic Svjetlost Sarajevo, from January 2011 to January 2014. Uncorrected distance visual acuity (UDVA), manifest residual spherical equivalent (MRSE), intraocular pressure (IOP), endothelial cell (EC) density were evaluated at one, three, six and 12 months. Other complications in postoperative period were evaluated. For statistical analysis SPSS for Windows and Microsoft Excel were used. **Results:** Out of 26 patients 14 had binocular and 12 monocular procedure, with mean age of 29.8±6.5 years. After 12 months mean UDVA was 0.73±0.20. Mean MRSE was -0.39±0.31D and 90% of eyes had MRSE within ±1D. EC loss was 7.18±4.33%. There was no significant change of IOP by the end of 12 months follow up period. The only intraoperative complication was hyphema and occurred in one eye. Few postoperative complications were: subclinical inflammation in three eyes (7,5%), pigment dispersion in four eyes (10%), ovalisation of papilla in 2 eyes (5%) and decentration of pIOL in 2 eyes (5%). **Conclusion:** Implantation of iris-claw phakic lenses Veriflex for treating moderately high myopia is a procedure with good visual and refractive results and few postoperative complications.

Key words: iris claw intraocular lens, myopia, refractive surgery.

1. INTRODUCTION

The main objective of refractive surgery is improving the patient's quality of life by decreasing their dependence of spectacles and contact lenses. This is why any complication after refractive surgery has a dramatic impact on the patient's quality of life. Over the last 2 decades, excimer laser keratorefractive procedures have become the standard of care for correction of wide range of refractive errors with generally excellent outcomes (1).

For patients not suitable for corneal surgery, implantation of phakic intraocular lens (pIOL) can be a good alternative (2).

Currently, there are two types of pIOL: anterior chamber pIOL and posterior chamber pIOL. The iris fixated lenses are anterior chamber pIOL and can be rigid, made of polymethyl methacrylate (PMMA) or foldable version where optic is made of polysulfone and two opposed PMMA haptics that enable fixation on the mid-peripheral iris (3). This foldable phakic IOL has the advantage over PMMA Artisan lens because it can be inserted/removed through a small corneal incision without sutures (4).

Phakic IOLs have a number of advantages such as preserving corneal tissue and decreasing the risk of ectasia, maintaining the corneal shape without inducing high order aberrations and the possibility of removal (5). The other advantages are the facts that iris-claw pIOLs can be centered over the pupil, which is important in eyes with a decentred pupil, than preservation of the tear film and the accommodation (6).

The main disadvantages of the iris claw pIOL are the difficulty of implantation, the potential damage to the iris and endothelium. Postoperative complications are endophthamitis, IOP elevation, subclinical inflammation, cor-

neal decompensation, dislocation of pIOL, cataract formation, retinal detachment, pupil ovalisation and pigment dispersion (7-10).

Many studies showed safety, efficacy and high predictability of pIOLs implantation (11-13).

2. MATERIAL AND METHODS

This prospective clinical study included 40 eyes from 26 patients who underwent implantation of Veriflex for correction of myopia from -6.00 to -14.50D in Eye Clinic Svjetlost Sarajevo from January 2011 to January 2014.

Each patient included in this study had stable myopia for two years and contraindication for corneal refractive surgery. Anterior chamber depth (ACD) was ≥ 3.0mm, EC count was ≥ 2300 cells/mm2, mesopic pupil diameter ≤ 6.5mm, astigmatism ≤ 2.0D.

Exclusion criteria were: patients younger than 21 years of age, active pathology of the eye, cataract, glaucoma, chronic or recurrent uveitis, prior operative procedure, macular and retinal pathology, autoimmune systemic diseases, diabetes, and pregnancy.

Preoperative examination included: uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) (shown in decimal Snellen values), manifest and cycloplegic refraction using autorefractometar (Rexxam Co., Ltd., Kagava, Japan), IOP (Ato Non-Contact Tonometar, Reichert Inc., Buffalo, NY, USA), biomicroscopic examination (Construction StrumentiOftalmicy–CSO, Florence, Italy), fundus examination, corneal toporgaphy (Wavelight, Allegreto Oculyser, Erlangen, Germany), EC count (Specular CSO, Florence, Italy) and pupil size (Pupilographer, Florence, Italy).

Phakic IOL calculations are based on nomograms or software developed by the manufacturers (AMO) which accounts refractive error, corneal curvature, and anterior chamber depth, with target of emmetropia. When the emmetropic lens were not available (because of 0.50D steps in lenses), slight myopia was preferred.

Corneal incision of 3.2 mm was centered at twelve o'clock . Two vertical paracentesis were performed at two and ten o'clock. After the intracameral injection of myotic and viscoelastic material the pIOL (Veriflex, AMO, Santa Ana, CA, USA) was implanted in anterior chamber. Phacic IOL was fixated with enclavation needle on three and nine o'clock position on iris. After peripheral iridectomy and removal of viscoelastic material, hydration was performed along corneal incisions.

One and seven days after surgery, UDVA, IOP and biomicroscopic examination were recorded. At other testing intervals (one, three, six and twelve months), a complete examination was performed, which included UDVA, CDVA, IOP, MRSE, EC count, biomicroscopy (slit-lamp exam), ophtthalmoscopy.

This investigation was approved by the Ethics Committee at Eye Clinic Svjetlost, Sarajevo. The Tenets of the Helsinki Agreement were followed throughout. All patients signed informed consent for the study.

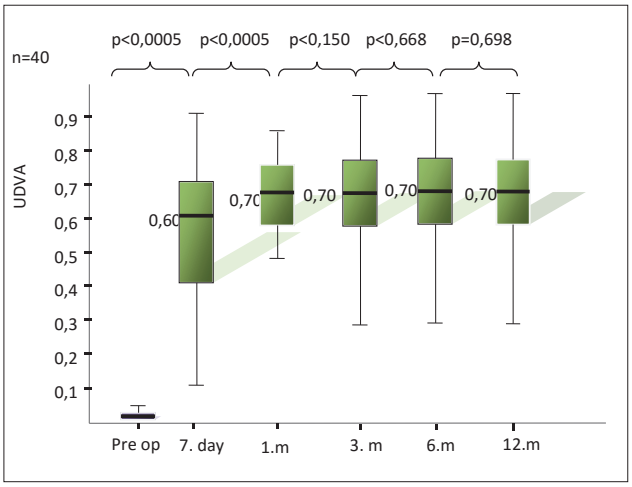
Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 19.0 for Windows (Chicago, IL, USA) and Microsoft Excel version 11.0 (Redmond, WA, USA). The comparisons between the preoperative and postoperative periods was performed with the Wilcoxon signed rank test. Value of $p<0.05$ was considered statistically significant.

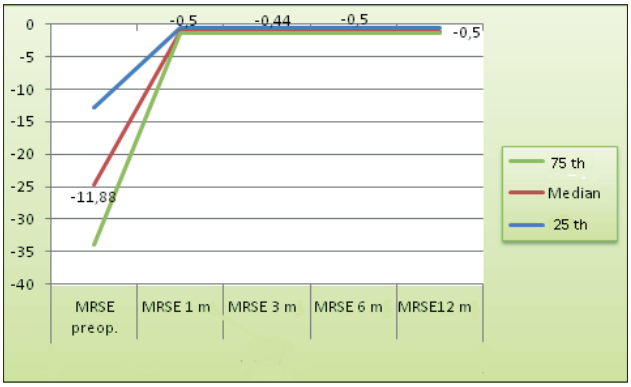
3. RESULTS

Refractive outcomes of 40 eyes from 26 patients, who underwent implantation of Veriflex were observed. Out of these patients 14 of them had binocular and 12 monocular procedure, 53.8% (14/26) were males and 46.2% (12/26) females. Mean age was 29.8±6.50 (21-41) years. Preoperative mean UDVA was 0.02±0.02, and mean CDVA 0.63±0.15. Mean preoperative sphere was -10.64±2.03D (from -14.50 to -6.00D). Mean astigmatism was -1.07 ± 0.65D (from -2.00 to -0.25D). Mean SE preoperatively was -1.88±2.16D. Mean Veriflex lens power was -11.04±2.16D. Mean ACD was 3.70±0.25mm. Preoperative mean of EC was 2605.57±131.75. Intraocular pressure preoperatively was 15.12±2.34mmHg.

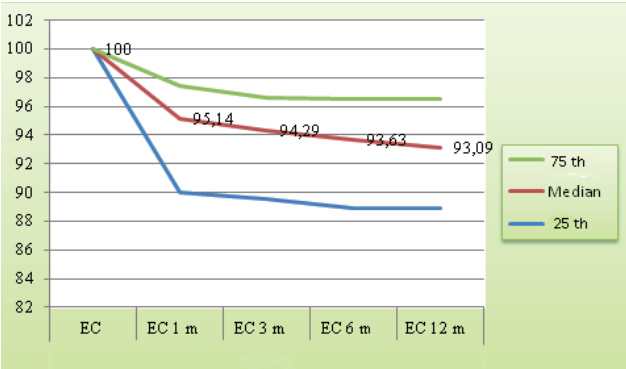
After 12 months, mean UDVA was 0.73±0.20. Statistically significant progression of UDVA between measurement intervals in first month was found ($p<0.05$), after which there was no statistically significant change (Graph 1). After 12 months UDVA was ≥0.5 in 87.5% of eyes, and UDVA was ≥0.8 in 57.5% of eyes. Mean MRSE was -0.39±0.31D after one year. The MRSE values were dropping significantly one month after the treatment to -0.46D (ranging -1.13 to -0.50D) compared to -11.88D preoperatively ($p<0.005$), and stayed stable without statistically significant changes over the



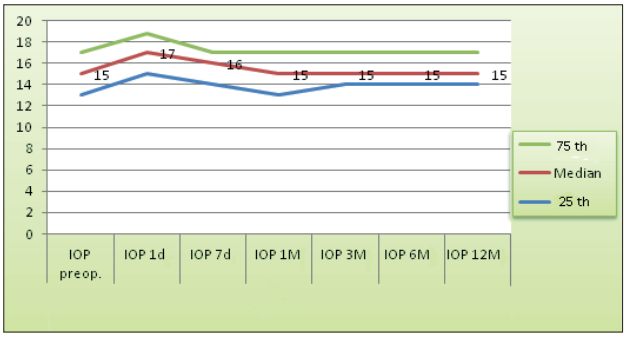
Graph 1. UDVA values in follow up period (UDVA- Uncorrected distance visual acuity, Pre op – Preoperative, m- months, n – number)



Graph 2. MRSE values in follow up period (MRSE (D)- manifest residual sphere equivalent, pre.op- preoperative)



Graph 3. EC loss in follow up period (EC - endothelial cells, m- months)



Graph 4. IOP (mmHg) in follow up period (IOP- Intraocular preassure, M- months)

follow up period (Graph 2). After 12 months, 90% of eyes had MRSE within ±1.0D.

One eye (2.5%) lost one Snellen line and fifteen eyes (37.5%) gained one line, six eyes (15%) gained two lines and four eyes (10%) gained three lines.

After one year, EC loss was 7.18±4.33%. ($p<0.005$) (Graph 3). The loss of endothelial cells was the biggest in first postoperative month (6,10±4,21%)

Hyphema occurred as the only intraoperative complication in one eye. Postoperative complications were IOP elevation in 2 eyes (5%), subclinical inflammation in three eyes (7.5%), pigment dispersion in four eyes (10%), pupil ovalisation in two eyes (5%) and decentration of pIOL in two eyes (5%).

4. DISCUSSION

Phakic IOLs are an effective treatment for the correction of moderately high myopia and have significant advantages such as immediate diopter correction, stability, relative simplicity and reversibility (11).

UDVA showed significant improvement over preoperative values in first postoperative week and remained stable throughout the whole follow-up period. Preoperative UDVA was 0.03±0.20 and increased to 0.73±0.20 at the last postoperative visit. Mean postoperative UDVA values from 1 to 12 months did not show statistically significant differences $p>0.05$. Therefore, stable UDVA was achieved in the early postoperative period after implantation of Veriflex.

After 12 months UDVA was ≥ 0.5 in 87.5% of the eyes and UDVA was≥ 0.8 in 57.5% of the eyes. Coullet reports UDVA ≥ 0.5 in 77.4% of the operated eyes after 1 year follow up, (14) Budo 76.8% (15) and Girek Ciacura 80% (16). Dick reports UDVA ≥0.5 in 97.2% but after the follow up of two years (17). Results of other authors are very similar to results of our study.

Mean SE decreased from -11.15±2.16D preoperatively to MRSE -0.39±0.31D postoperatively . These results are similar or better than those reported in previous studies. Coulett reports MRSE -0.58 ± 0.55D after one year (14), Dick reports -0,15 D after 24 months follow up period (17).

In our study after 12 months 90% of eyes had MRSE within ±1D, compared to Dick, who reported 94.3% of eyes within ± 1D after 2 years (17).

Coullet reported loss of 2 lines in 9.7% eyes, gain of 1 line in 22.6%, and gain of 2 of or more lines in 25.8% (14). Compared to our results 2.5% of eyes lost one Snellen line and 37.5% gained one line, 25% gained two or more lines.

Bourne reports physiological EC loss of 0.6%, (18), however surgical trauma can lead to increased loss of EC. Foldable lenses with their ability to open inside of the eye as well as potential moving inside of the eye postoperative can cause lowering of endothelial tolerance. Also chronic subclinical inflammation is, according to literature, higher after Veriflex implantation and can be toxic for endothelium and cause EC loss.

EC loss after 12 months period was 7.18±4.33%. The most prominent EC loss was in first postoperative month 6.10±4.33% and improved for 1,0% in period of 12 months. This is in accordance with results of Coulett who reports 9.0% EC loss, (14) but differs from other authors, Dick showed 1,1% (17), Hashemi 3,04% EC loss at the end of follow up period (19).

Yag-laser preoperative iridotomy or intraoperative iridectomy was performed in order to prevent acute papillary blockage and IOP elevation (20). Differences in preoperative IOP compared to first postoperative day IOP measurements were statistically significant $p=0.011$. (Graph 4) In later follow up period there was no statistically significant difference among intervals in IOP values ($p>0.05$). In many studies there are reports of IOP postoperatively (21, 22) This is explained with viscoelastic remains in CA during the surgery, therefore it is recommended to adequately wash out the viscoelastic during the surgery.

It is also possible that IOP elevation can be a result of as a reaction to corticosteroid local therapy postoperatively (corticosteroid responder). In accordance to this theory is the fact that two patients had to stay on anti-glaucoma therapy 7 days after the end of corticosteroid therapy. IOP elevation was observed in 7.5% eyes (1 patient binocular and one monocular). In all cases the regulation of IOP was possible with local anti-glaucoma therapy. Also, in all cases the therapy was excluded after 5 weeks.

However, some studies describe complications with these lenses (11). Hyphema as intraoperative complication occurred in one patients, which was absorbed in first postoperative week. Silicon material of Veriflex optics can cause inflammation. In this study there was small number of eyes (7,5%) with subclinical inflammation, which can be explained with use of antibiotic and steroid eye drops postoperatively from the first postoperative day during one month of follow up. In all reported cases subclinical inflammation went away after higher dose of corticosteroid local therapy in first postoperative month. Zuberbühler reports 5.8% eyes with subclinical inflammation after Veriflex implantation (23).

Pigment dispersion occurred in four eyes (10%) and without

affect on final visual acuity. Dick reported pigment dispersion in 4.8% eyes (17). Pupil ovalisation occurred in 2 eyes (5%) and was followed with pupil decantation in 2 eyes (5%). In both cases there were no optical phenomena.

CONCLUSION

We concluded that the implantation of phakic IOLs Veriflex for the correction of myopia may be a relatively safe and effective procedure with good visual and refractive results over a one-year period. However, long-term follow-up may be necessary to confirm the long-term safety of these phakic IOLs.

• Conflict of interest: none declared

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