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Original Article

Visual and Refractive Outcome after 12 Years of Treatment of Type 1 Prethreshold Retinopathy of Prematurity

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Abstract

Aim: In this study, the best corrected visual acuity (BCVA) and refraction in preterm-born infants in South-Eastern Bulgaria after 12 years of treatment for type 1 prethreshold retinopathy of prematurity were presented, and the outcomes of laser treatment and cryotherapy were compared.

Materials and methods: Since 2010, we have treated 319 eyes of 164 prematurely born children for type 1 prethreshold retinopathy of prematurity and were prospectively followed up. The mean (range) gestational age was 28.6 weeks of gestation (23–33) and the mean (range) birth weight was 1143 g (570–1990). Cryotherapy was applied on 76 eyes (23.2%), laser was used in 215 eyes (65.5%), anti-VEGF – in 10 eyes (3%) and surgery – in 18 eyes (5.5%). Twelve children (24 eyes, 7.3%) were lost to the follow-up. BCVA was tested in 114 eyes and refraction in 190 eyes. Because of the small number of eyes treated surgically or with anti-VEGF (18 and 10, respectively), these children's eyes were excluded from the statistical analysis.

Results: Fifty eyes showed BCVA between 0.6 and 1.0; 25 eyes – between 0.2 and 0.5; 5 eyes – between 0.04 and 0.1; 5 eyes between light perception –0.03 and 4 eyes were totally blind. Laser-treated eyes showed statistically significantly higher BCVA compared to the cryotherapy treated eyes (Fisher's exact test, p=0.012). Myopia (any myopic refraction) was found in 50 eyes; hyperopia (>+2 D) – in 20 eyes; astigmatism (difference between the two principal meridians >0.75 D) – in 70 eyes, and emmetropia – in 30 eyes. Although in the laser-treated group more eyes showed emmetropic and hyperopic refraction compared to cryo treated group (25 eyes vs. 7 eyes – emmetropia and 15 eyes vs. 5 eyes – hyperopia, respectively), the difference did not reach statistical significance (Fisher's exact test, p=0.106).

Conclusion: Timely treatment of type 1 prethreshold retinopathy of prematurity leads to very good anatomical and functional results. Laser treatment leads to significantly higher BCVA, compared to cryotherapy. Emmetropia and hyperopia are more commonly seen in laser-treated eyes.

Keywords

outcome, refractive, ROP, treatment, visual

INTRODUCTION

Retinopathy of prematurity (ROP) is still among leading causes for preventable but irreversible blindness in children all over the world. The development and improvement of obstetrics and gynecology, neonatology, and perinatal medicine significantly increases the survival rate of prematurely born children. This in turn shifts the focus on these patients from mere survival at any cost to quality of life. Visual system, just like the whole organism of the preterm born babies, is still immature and they show higher incidence of ophthalmological complications like ROP, decreased visual acuity, refractive errors, strabismus, nystagmus, amblyopia, visual field defects, etc. compared to their full-term peers.[1,2] Timely screening and treatment of patients at risk decrease unfavorable anatomical outcome in ROP.[3,4] However, significant refractive errors (more commonly astigmatism and myopia) are frequently associated findings in ROP patients, especially in treated ones.[5-11] Early studies on ROP focused mainly on anatomical success, meaning presence of no retinal detachment, no retinal folds, macular/disc dragging[12], but with newcoming treatment modalities, quality of life emerges as a leading goal in these children. Visual impairment in early childhood is a heavy psychological and economic burden for the kid, his/her family and society in general. Good visual acuity, timely ocular alignment (when necessary), wider visual field and stereopsis guarantee better socialization and realization of these patients. There are numerous data in literature about visual acuity[13-24] and stereopsis[25] in preterm-born children.

AIM

To present the best corrected visual acuity (BCVA) and refraction in preterm-born children 12 years after treatment of type 1 prethreshold ROP in a single center in Bulgaria and compare the laser and cryo-treated patients.

MATERIALS AND METHODS

Three hundred and nineteen eyes of 164 preterm-born children were treated for type 1 prethreshold ROP according to Bulgarian national strategy for screening and treatment of the disease[4] and were prospectively followed up for 12 years in a single center. There were 88 (53.6%) boys and 76 (46.4%) girls **(Fig. 1)**. The gestational age of our cohort was 28.6 weeks of gestation on average (range 23–33), and birth weight was 1143 g (range 570–1190 g). Seventy-six eyes (23.2%) were treated by cryotherapy, and 215 eyes (65.5%) were treated by laser, 10 eyes (3%) – with intravitreal anti-VEGF, and 18 eyes (5.5%) underwent vitreo-retinal surgery in advanced cases (ROP stages IV – A, B, and/or V outside Republic of Bulgaria) **(Fig. 2)**. Ten children (20 eyes, 6.1%) were lost to follow-up. For the purpose of the current investigation, BCVA and cycloplegic refraction were checked between September 1st and October 1st, 2022. BCVA was available for 114 eyes. It was tested using Snellen visual acuity chart in all verbal children, presented in decimal scale and then converted to logarithm of minimal angle of resolution (logMAR). Each eye was examined separately. Cycloplegic refraction was available for 190 eyes. It was checked by using 1% cyclopentolate eye drops three

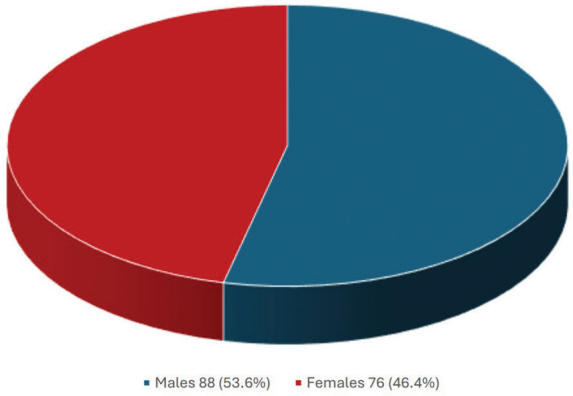

Figure 1. Distribution of the patients by sex.

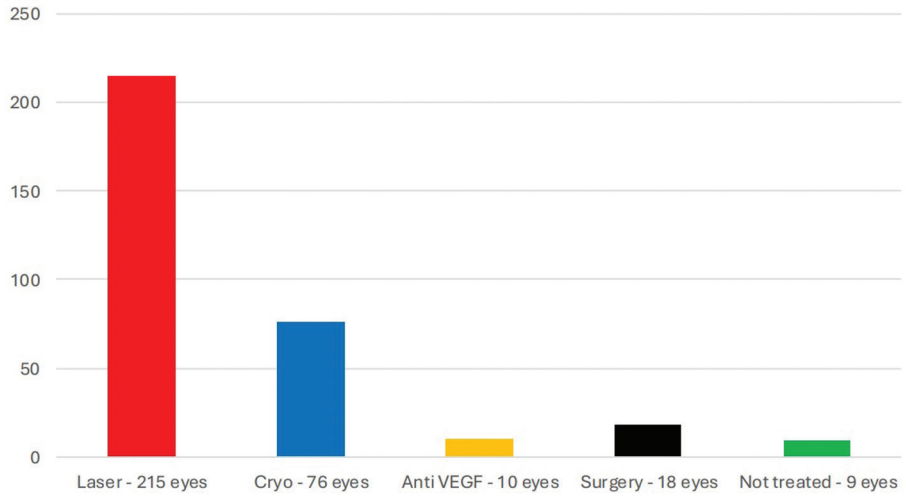

Figure 2. Treatment applied to all 164 patients (presented as number of eyes treated).

times with interval of 15 minutes. Thirty minutes after last administration, the degree of cycloplegia was assessed according to pupillary size and light reflex. It was considered sufficient if pupils were larger than 6 mm and there was absence of pupillary light reflex.[6] If light reflex was present, another drop of cyclopentolate was administrated and the degree of cycloplegia was reassessed. Refraction was then tested with autorefractor (Topcon Autorefractometer RM 8800, TOPCON, Japan), or with streak retinoscope in younger and uncooperative children. Because a very small number of eyes underwent surgical and with anti-VEGF treatment (18 and 10, respectively), these patients were excluded from the statistical analysis. Refraction and visual acuity between the cryo and laser-treated groups were assessed by Fisher's exact test.

RESULTS

Fifty out of 114 tested eyes demonstrated Snellen BCVA (in decimals) between 0.6 and 1.0 (logMAR 0.2–0); 25 eyes – between 0.5 and 0.2 (logMAR 0.7–0.3); 5 eyes – between 0.1 and 0.04 (logMAR 1.3–1.0); 5 eyes – between 0.03 and LP (logMAR <1.3) and 4 eyes were totally blind **(Fig. 3A)**. Laser treatment led to significantly higher BCVA in comparison to cryo therapy (Fisher's exact test, p=0.012) **(Fig. 3B)**. Fifty eyes out of 190 examined were myopic (any myopic refraction); 20 were hypermetropic (>+2 D); 70 – astigmatic (difference between the two principal meridians >0.75 D) and 30 eyes – emmetropic **(Fig. 4A)**. Although that larger number of laser-treated eyes showed emmetropic and hyperopic refraction compared to cryo-treated

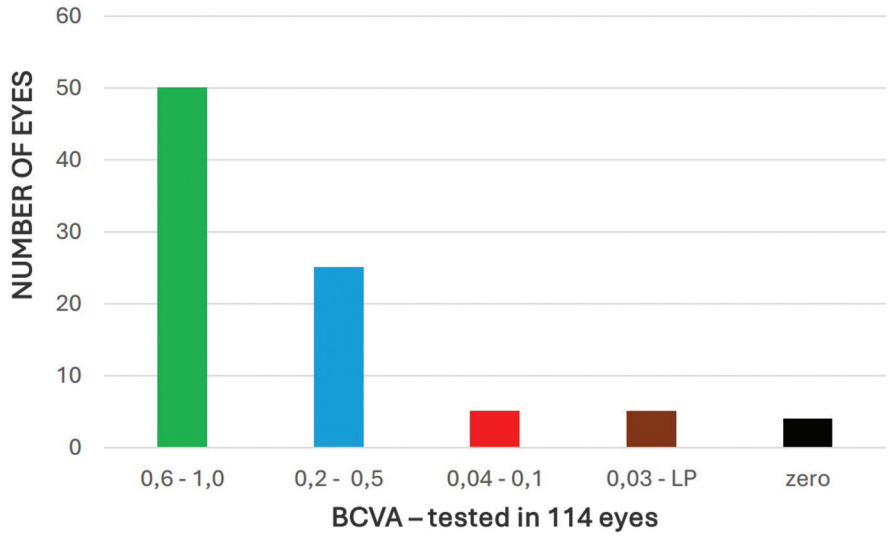

Figure 3A. Best corrected visual acuity, presented as Snellen VA – decimals.

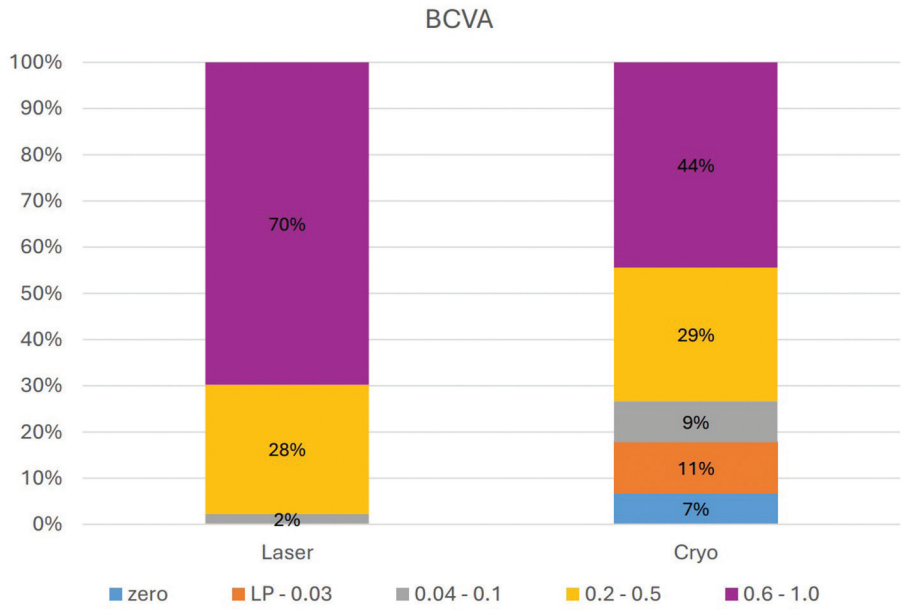

Figure 3B. Best Corrected Visual Acuity (BCVA): LASER vs CRYO. The laser-treated eyes show significantly higher BCVA compared to the cryo-treated eyes presented as Snellen VA – decimals (Fisher's exact test, p=0.012).

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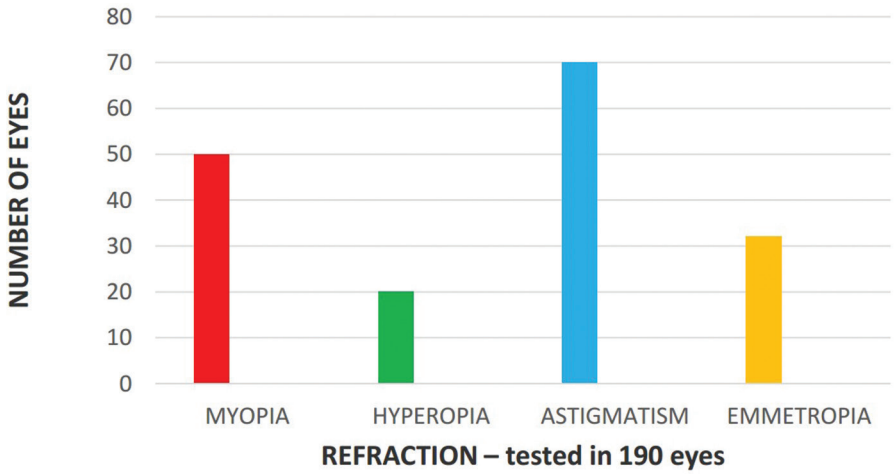

Figure 4A. Refractive errors in the tested group.

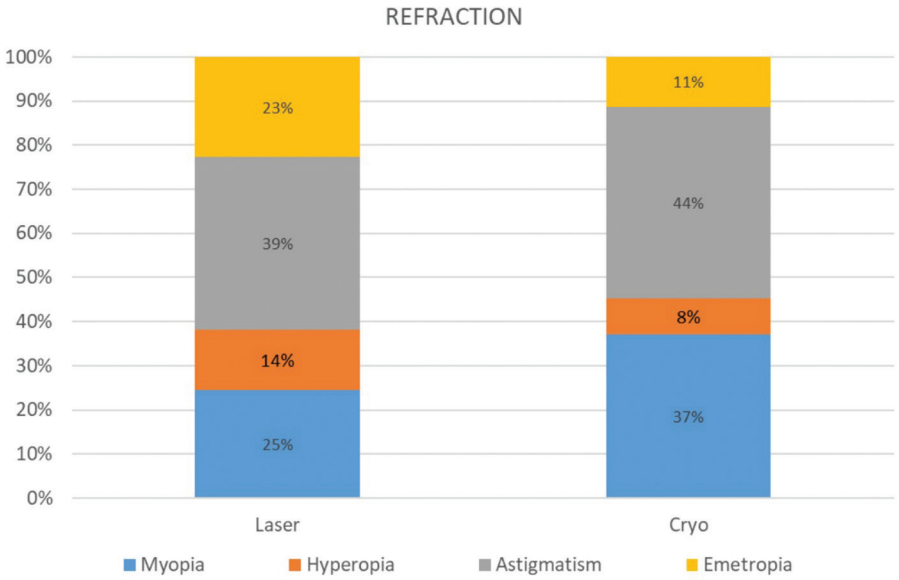

Figure 4B. Refraction: LASER vs CRYO. More eyes in the laser-treated group show emmetropia and hyperopia compared to the cryo-treated group, but the difference was not statistically significant (Fisher's exact test, p=0.106).

eyes (25 vs. 7 emmetropia and 15 vs. 5 hyperopia, respectively), the difference was not statistically significant (Fisher's exact test, p=0.106) **(Fig. 4B)**.

DISCUSSION

Since CRYO-ROP study, treatment results were evaluated by favorable structural outcome: lack of retinal detachment, retinal folds, macular and/or disc dragging.[12] Later on, ET-ROP study proved that earlier treated eyes with type 1 prethreshold ROP showed significantly better visual outcomes compared to threshold ROP reached ones, but still the majority of them were with subnormal vision.[4,14] The BEAT-ROP study showed even better structural and visual outcomes in eyes, treated with intravitreal bevacizumab, especially in zone I active disease.[26,27] The RAINBOW study comparing two different dosses of ranibizumab (0.2 mg and 0.1 mg) intravitreally versus laser showed a very positive result in anti-VEGF groups in terms of disease regression, but less so in terms of reactivations.[28] The FIREFLEYE study recently showed that intravitreal aflibercept had no advantages, or disadvantages compared with laser photocoagulation concerning primary retinal outcome[29] and is safe after 2 years of follow-up.[30] However, studies on medium and long-term functional outcomes concerning visual acuity and refractive status are scarce in literature.

We present long-term results of visual and refractive outcome (12 years of follow-up) in children with type 1 prethreshold ROP. On the Snellen visual acuity chart, 50 of the 114 examined eyes had a BCVA greater than 0.5 (logMAR 0.3 or better). Cycloplegic refraction was checked

in 190 eyes with autorefractor or streak retinoscope in uncooperative patients. Majority of our patients (70 eyes) showed astigmatic refraction and 50 eyes showed myopic refraction. It is noteworthy that 30 eyes were emmetropic. It is the CRYO-ROP study that provided the first data on relation between visual acuity and structural retinal residua after treatment of threshold ROP.[13] The study protocol used ETDRS visual acuity chart and found that visual deficits are more commonly seen in eyes with marked retinal residua. The severity of ROP though did not predict the visual acuity of an individual eye, because within the single retinal structural residua category, VA can vary between total blindness (no light perception) and normal.

Comparing VA of 6-year-old children treated earlier and when the threshold ROP was reached, ET-ROP study showed significant benefit from early treatment for type 1 but not for type 2 ROP.[14] This was a major advance in the battle for quality of life in ROP suffering children. This study changed the treatment criteria in the entire world.[4] Introducing the terms 'type 1' and 'type 2' ROP was the cornerstone of ET-ROP conclusions because 52% of type 2 ROP eyes showed spontaneous regression.

In a study of fifty-seven children (114 eyes) in Saudi Arabia, Al-Otaibi et al. found that 70% of treated eyes with 'normal retina' (no macular dragging, retinal detachment, pale optic disc or end stage ROP) showed "favorable VA outcome".[16] Using Snellen visual acuity chart, the authors suggested "favorable VA" ≥20/160 in cooperative children and presence of central steady maintain fixation in uncooperative children. Myopia was the most often seen refractive error in this study group (74 eyes). We should emphasize here that patients from this cohort were treated with diode laser, but the treatment criteria were the threshold ROP.

Ziylan et al. compared 107 eyes of 56 ROP treated children with 202 eyes of 101 control preterm children with spontaneous regression of ROP and found that the treated group showed significantly higher incidence in terms of unfavorable visual outcome (defined as Snellen visual acuity more than 2/10), myopia (≥−0.5) and astigmatism (≥1.5).[17] All 107 eyes were treated with diode laser photocoagulation and the authors suggested that ablative therapy could contribute to development of myopia later in life.

Rodriguez et al. found that thirty-nine out of 46 eyes in 23 infants treated with intravitreal bevacizumab for type 1 prethreshold ROP showed normal visual acuity (defined as 0.3 logMAR or better).[19] The authors also tried to find correlation between the functional outcomes and fluoresceine angiography (FA) findings in these children. Visual acuity in this group was examined by HOTV chart, Lea chart, or Snellen visual acuity chart and converted to logMAR. The authors found that a high percent of patients had abnormal vascular patterns on FA, but neither these findings nor baseline ROP were predictive of VA.

Laser photocoagulation is so far the gold standard of treatment in ROP, but there are publications suggesting that intravitreal anti-VEGF agents can decrease the incidence of refractive errors compared to ablative treatment. Simons et al. compared the development of refractive errors in extremely preterm infants with type 1 prethreshold ROP treated with intravitreal bevacizumab and laser.[20] They found that incidence of myopia and its progression during the first 3.5 years of age is higher in the laser-treated group than in the anti-VEGF-treated group. Using Teller acuity cards, authors found that final VA in both groups was similar (0.47 logMAR, equal to 20/60).

Comparing BCVA, spherical equivalent and central, parafoveal and perifoveal retinal thickness in children treated with ant-VEGF, laser and spontaneously regressed, Kizilay et al.[21] also found no significant difference in BCVA of the two treated cohorts, but children with spontaneous regression showed significantly better results. In a study of Riera et al.[22] on functional results in children treated with intravitreal bevacizumab, myopia was reported to be only 20%, compared to 77% hyperopia and only 3% emmetropia. The authors found BCVA >0.5 in 85% of the patients.

Using the Swedish national ROP register, Larsson et al.[23] reported quite a high number of eye problems in children treated for ROP. They found BCVA >0.5 in only 14% of the study group, refractive errors in 52%, strabismus in 38% and "significant eye problems" in 65%. The authors emphasized on the fact that the main risk factor for visual impairment in their group was the necessity of retreatment. So, except that preterm-born children require long-term follow-up, they also need timely, accurate, and precise first treatment.

In a cross-sectional observational study, using age specific Children's Visual Function Questionnaire (CVFC), Kesarwani et al. found that ROP significantly decreased the quality of life of patients and their families, and this effect worsened with the severity of ROP.[18]

Strengths and limitations

An advantage of our study is its prospective character. All patients reported in this study are still followed up since their neonatal period. They have an annual comprehensive ophthalmological examination performed by the same ophthalmologist in the same way. As a drawback, we consider the descriptive character of the study, presenting the BCVA and cycloplegic refraction at only one time point, and the relatively small group of patients. We had only 10 eyes treated with different anti-VEGF agents. This did not allow us to form anti-VEGF-treated group and compare these children with enough credibility with the laser- and cryo-treated ones.

CONCLUSION

The results from our study confirm the high percentage of refractive errors in ROP treated children with prevalence of astigmatism and myopia. Preterm birth as well as treat-

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ment modalities for ROP available so far break early the physiological process of emmetropization of the growing child's eye. Treating preterm-born children with type 1 prethreshold ROP provides better structural and functional outcome. Laser-treated eyes in our cohort showed significantly higher BCVA than the cryo-treated ones, but the refractive errors in these patients were common with prevalence of astigmatism, followed by myopia. Although emmetropia and hyperopia showed higher incidence in laser-treated group, the difference was not statistically significant. We strongly recommend that all preterm born children should be carefully followed up at shorter intervals. Comparative studies between differently treated, spontaneously regressed and full-term born children would be of greater value in order to find reliable predictive factors for the development of refractive errors as well as other ocular complications earlier in preterm-born children.

Acknowledgements

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Conflict of Interests

Authors have no conflict of interests to declare. No funding source was used for the current study.

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Визуальные и рефракционные результаты после 12 лет лечения предпороговой ретинопатии недоношенных 1-го типа

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Резюме

Цель: В этом исследовании были представлены наилучшая корригированная острота зрения (BCVA) и рефракция у недоношенных детей в Юго-Восточной Болгарии после 12 лет лечения предпороговой ретинопатии недоношенных типа 1, а также сравнивались результаты лазерного лечения и криотерапии.

Материалы и методы: С 2010 года мы пролечили 319 глаз 164 недоношенных детей от предпороговой ретинопатии недоношенных типа 1 и велось проспективное наблюдение. Средний (диапазон) гестационный возраст составил 28.6 недель беременности (23–33), а средний (диапазон) вес при рождении составил 1143 g (570–1990). Криотерапия была применена на 76 глазах (23.2%), лазер использовался на 215 глазах (65.5%), анти-VEGF – на 10 глазах (3%) и хирургическое вмешательство – на 18 глазах (5.5%). Двенадцать детей (24 глаза, 7.3%) были потеряны для последующего наблюдения. BCVA была проверена на 114 глазах и рефракция на 190 глазах. Из-за небольшого количества глаз, пролеченных хирургическим путём или с использованием анти-VEGF (18 и 10 соответственно), глаза этих детей были исключены из статистического анализа.

Результаты: Пятьдесят глаз показали BCVA от 0.6 до 1.0; 25 глаз – от 0.2 до 0.5; 5 глаз – от 0.04 до 0.1; 5 глаз между световосприятием -0.03 и 4 глаза были полностью слепыми. Глаза, обработанные лазером, показали статистически значимо более высокую BCVA по сравнению с глазами, обработанными криотерапией (точный тест Fisher, $p = 0.012$). Миопия (любая миопическая рефракция) была обнаружена у 50 глаз; гиперметропия (>+2 D) – у 20 глаз; астигматизм (разница между двумя главными меридианами >0.75 D) – у 70 глаз, а эмметропия – у 30 глаз. Хотя в группе, прошедшей лазерное лечение, больше глаз показали эмметропическую и гиперметропическую рефракцию по сравнению с группой, прошедшей криотерапию (25 глаз против 7 глаз – эмметропия и 15 глаз против 5 глаз – гиперметропия соответственно), разница не достигла статистической значимости (точный тест Fisher, $p = 0.106$).

Заключение: Своевременное лечение предпороговой ретинопатии недоношенных 1-го типа приводит к очень хорошим анатомическим и функциональным результатам. Лазерное лечение приводит к значительно более высокой BCVA по сравнению с криотерапией. Эмметропия и гиперметропия чаще наблюдаются в глазах, прошедших лазерное лечение.

Ключевые слова

результат, рефракционный, ROP, лечение, визуальный