UNIWERSYTET MEDYCZNY
IM. PIASTÓW ŚLĄSKICH WE WROCŁAWIU

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Ocena porównawcza kwalifikacji i wyników pooperacyjnych u pacjentów z wszczepioną soczewką niedyfrakcyjną o wydłużonej ogniskowej z innymi soczewkami wewnątrzgałkowymi

Praca doktorska

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Pracę dedykuję lek. Halinie Piotrowskiej.

Spis treści

I. Wykaz zastosowanych skrótów

skrót	pełna nazwa w języku angielskim	pełna nazwa w języku polskim
AF	fluorescein angiography	angiografia fluoresceinowa
AMD	age-related macular degeneration	zwyrodnienie plamki związane z wiekiem
BCDVA	best corrected distance visual acuity	najlepiej skorygowana ostrość widzenia do dali
BCIVA	best corrected intermediate visual acuity	najlepiej skorygowana ostrość widzenia do odległości pośredniej
BCNVA	best corrected near visual acuity	najlepiej skorygowana ostrość widzenia do bliży
EDOF	extended depth of focus	wydłużona głębia ogniskowania
MRSE	manifest refraction spherical equivalent	ekwiwalent sferyczny wykazanej refrakcji
NFZ	-	Narodowy Fundusz Zdrowia
OCT	optical coherence tomography	koherentna tomografia optyczna
RK	radial keratotomy	keratotomia radialna
UBM	ultrasound biomicroscopy	ultrabiomikroskopia
UCDVA	uncorrected distance visual acuity	nieskorygowana ostrość widzenia do dali
UCIVA	uncorrected intermediate visual acuity	nieskorygowana ostrość widzenia do odległości pośredniej
UCNVA	uncorrected near visual acuity	nieskorygowana ostrość widzenia do bliży
WHO	World Health Organization	Światowa Organizacja Zdrowia

II. Wykaz publikacji stanowiących pracę doktorską

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III. Streszczenie

Wstęp: Zaćma jest chorobą polegająca na zmętnieniu soczewki. Wraz z jaskrą i zwyrodnieniem plamki związanym z wiekiem są głównymi przyczynami ślepoty na świecie. Od wielu lat rośnie w Polsce liczba wykonywanych zabiegów fakoemulsyfikacji zaćmy. Jedynie w trakcie pandemii SARS-CoV-2 zanotowano spadek liczby operacji o ok. 30 % ze względu na panujące obostrzenia i obawy pacjentów przed zakażeniem SARS-CoV-2. Zabieg usunięcia zaćmy wskazany jest u pacjentów, u których pogorszenie widzenia wpływa negatywnie na wykonywanie czynności życiowych lub zawodowych, a korekcja okularowa lub za pomocą soczewek kontaktowych nie poprawia znacząco ostrości widzenia.

Cele: Ocena porównawcza kwalifikacji, ostrości widzenia, niezależności od korekcji okularowej oraz występowania zjawisk fotooptycznych u pacjentów z wszczepioną soczewką niedyfrakcyjną o wydłużonej ogniskowej (EDOF) i u pacjentów z wszczepionymi innymi soczewkami wewnątrzgałkowymi.

Materiał i metody: Jednoośrodkowe, prospektywne badanie porównawcze zostało przeprowadzone w Oddziale Okulistycznym w WS – SPZOZ w Zgorzelcu. Do badania włączono pacjentów z zaćmą obustronną, którzy chcieli ograniczyć swoją zależność od okularów. Grupa badawcza, w której wszczepiano soczewki niedyfrakcyjne EDOF, składała się z 70 oczu u 35 pacjentów. Grupy kontrolne składały się z: 52 oczu u 26 pacjentów, u których wszczepiano soczewki wieloogniskowe, oraz 52 oczu u 26 pacjentów, u których wszczepiano soczewki jednoogniskowe. Badania kontrolne odbyły się 2 tygodnie, 2 miesiące oraz 6 miesięcy po zabiegu usunięcia zaćmy. W trakcie wizyt kontrolnych oceniano: nieskorygowaną i skorygowaną ostrość wzroku z 4 m, 80 cm, 40 cm; wadę refrakcji wyrażoną jako ekwiwalent sferyczny wykazanej refrakcji (MRSE); wrażliwość na kontrast; ciśnienie wewnątrzgałkowe. Pacjenci wypełniali również ankietę dotyczącą niezależności od korekcji okularowej, występowania zjawisk fotoptycznych oraz oceniali stopień satysfakcji z zabiegu.

Wyniki: 6 miesięcy po zabiegu porównano jednooczną i obuoczną ostrość wzroku oraz MRSE pomiędzy trzema grupami. Wszystkie główne analizy, z wyjątkiem porównania poziomu nieskorygowanej ostrości wzroku do dali (zarówno jedno-, jak

i obuocznej), wykazywały istotność statystyczną. Po 6 miesiącach od operacji częściej obserwowano halo i glare u pacjentów z soczewką wieloogniskową niż u pacjentów z soczewką EDOF i jednoogniskową (65 % oczu z soczewką wieloogniskową vs. 6 % oczu z soczewką EDOF i 0 % oczu z soczewką jednoogniskową). Korekcji okularowej wymagało 35 % pacjentów z soczewką niedyfrakcyjną EDOF, 96 % pacjentów z soczewką jednoogniskową i 0 % pacjentów z soczewką wieloogniskową.

Wnioski: Do wszczepienia soczewek niedyfrakcyjnych EDOF kwalifikuje się większość pacjentów zgłaszających się w celu usunięcia zaćmy. Profil pacjentów kwalifikujących się do wszczepienia soczewek niedyfrakcyjnych EDOF jest więc podobny do profilu pacjentów kwalifikujących się do wszczepienia soczewek jednoogniskowych. Ostrość widzenia do dali, odległości pośredniej oraz bliży poprawia się u pacjentów po wszczepieniu soczewki wewnątrzgałkowej niedyfrakcyjnej EDOF. Najlepszą ostrość widzenia do bliży zapewniają jednak soczewki wieloogniskowe. Wszczepienie soczewki EDOF zwiększa znacznie niezależność od korekcji okularowej w stosunku do wszczepienia soczewek jednoogniskowych, ale największy stopień niezależności od korekcji okularowej zapewniają soczewki wieloogniskowe. Zjawiska fotooptyczne po wszczepieniu soczewek niedyfrakcyjnych EDOF występują nieznacznie częściej niż w przypadku wszczepienia soczewek jednoogniskowych, ale zdecydowanie rzadziej niż w przypadku zastosowania soczewek wieloogniskowych.

IV. Abstract

Background: Cataracts are a disease involving clouding of the lens. Together with glaucoma and age-related macular degeneration, they are the leading causes of blindness worldwide. The number of cataract phacoemulsification procedures performed in Poland has been increasing for many years. Only during the SARS-CoV-2 pandemic was there a decrease of about 30% in the number of operations due to the prevailing restrictions and patients' fear of SARS-CoV-2 infection. Cataract surgery is indicated for patients whose deterioration of vision affects the performance of activities of daily living or work, and correction with glasses or contact lenses does not significantly improve visual acuity.

Aims: To evaluate the comparative qualification, visual acuity, independence from spectacle correction and incidence of photic phenomena in patients with an implanted non-diffractive extended depth of focus (EDOF) lens with other intraocular lenses.

Material and methods: This single-center, prospective, comparative study was conducted at the Ophthalmology Department of the Hospital in Zgorzelec. Patients with bilateral cataracts who wanted to reduce their dependence on glasses were included in the study. The study group in which the non-diffractive EDOF lens was implanted consisted of 70 eyes in 35 patients. The control groups consisted of: 52 eyes in 26 patients implanted with a multifocal lens and 52 eyes in 26 patients implanted with a monofocal lens. The follow-up examinations took place 2 weeks, 2 months and 6 months after cataract surgery. During the control, the following were evaluated: uncorrected and corrected visual acuity at 4 m, 80 cm, 40 cm, refractive error expressed as manifest refraction spherical equivalent (MRSE), contrast sensitivity, intraocular pressure. Patients also completed a questionnaire on independence from ocular correction, the occurrence of photic phenomena, and rated satisfaction.

Results: Six months after cataract surgery, monocular and binocular visual acuity and MRSE were compared between the three groups. All main analyses, except for the comparison of the level of uncorrected distance visual acuity (both monocular and binocular), were significant. At 6 months after cataract surgery, halo and glare were observed more frequently in patients with a multifocal lens than in patients with EDOF and monofocal lenses (65% of eyes with a multifocal lens vs. 6% of eyes with an EDOF lens and 0% of eyes with a monofocal lens). Spectacle correction was

required by 35% of patients with a non-diffractive EDOF lens, 96% of patients with a monofocal lens and 0% of patients with a multifocal lens.

Conclusions: Most patients presenting for cataract surgery are eligible for non-diffractive EDOF lens implantation. The profile of patients qualifying for non-diffractive EDOF lenses is therefore similar to that of patients qualifying for monofocal lenses. Visual acuity for distance, intermediate distance and near vision improves in patients after non-diffractive EDOF intraocular lens implantation. However, the best near visual acuity is provided by multifocal lenses. Implantation of an EDOF lens significantly increases independence from spectacle correction compared to monofocal lenses, but the greatest degree of independence is provided by multifocal lenses. Photic phenomena after implantation of non-diffractive EDOF lenses occur slightly more often than with monofocal lenses, but far less often than with multifocal lenses.

V. Wstęp

1. Zaćma

Soczewka jest jedną ze struktur układu refrakcyjnego oka. Jej moc łamiąca wynosi ok. 19 D. Soczewka ma dwubiegunowy kształt i leży za tęczówką, a przed komorą ciała szklistego. Składa się z torebki, nabłonka, kory oraz jądra soczewki. Otoczona jest licznymi włókienkami, które łączą torebkę soczewki z wyrostkami ciała rzęskowego. Opisane włókienka uczestniczą w procesie akomodacji. Z wiekiem soczewka traci zdolność do zmiany swojego kształtu i akomodacji.

Zaćma jest chorobą polegająca na zmętnieniu soczewki, która z wiekiem zmienia swoją gęstość, przejrzystość oraz kolor. Wymienione zmiany zachodzą również pod wpływem niektórych leków, promieniowania, substancji toksycznych czy urazu (1).

1.1 Epidemiologia

Zaćma jest obecnie najczęstszą przyczyną utraty wzroku na świecie. Według szacunkowych danych Światowej Organizacji Zdrowia (WHO) 285 milionów osób na świecie cierpi na zaburzenia widzenia, a 39 milionów – to osoby niewidome. Zaćma wraz z jaskrą i zwyrodnieniem plamki związanym z wiekiem (AMD) stanowią główne przyczyny ślepoty na świecie, przy czym ta pierwsza odpowiada za 51 % przypadków utraty wzroku. Zdecydowana większość (do 90 %) osób chorych na zaćmę to mieszkańcy krajów rozwijających się. Ponadto zaćma jest jedną z najczęstszych patologii prowadzących do pogorszenia ostrości wzroku (33 %), plasując się na drugim miejscu po wadach refrakcji (1,2).

Od wielu lat rośnie w Polsce liczba wykonywanych zabiegów fakoemulsyfikacji zaćmy. Jedynie w trakcie pandemii SARS-CoV-2 zanotowano spadek liczby operacji o ok. 30 %, do czego przyczyniły się panujące obostrzenia i obawy pacjentów przed zakażeniem SARS-CoV-2 w trakcie hospitalizacji (3). W 2018 roku wykonano ponad 313 tysięcy zabiegów usunięcia zaćmy, a w 2019 roku – 355 tysięcy (4). W 2020 roku przeprowadzono tylko ok. 233 tysięcy zabiegów. Spadek liczby wykonywanych zabiegów, jak wspomniano wcześniej, wiązał się z pandemią. Natomiast w 2021 roku liczba zabiegów usunięcia zaćmy zaczęła ponownie wzrastać w stosunku do

poprzedniego roku i wyniosła ok. 270 tysięcy. Powyższe dane pochodzą z rejestrów publicznych (5).

Wiek stanowi główny czynnik ryzyka rozwoju zaćmy. Wraz z wiekiem rośnie prawdopodobieństwo wystąpienia choroby. Palenie tytoniu koreluje z większym ryzykiem wystąpienia zaćmy zarówno jądrowej, jak i podtorebkowej tylnej. Udowodniono również, że choroby metaboliczne (w tym cukrzyca) oraz ekspozycja na światło ultrafioletowe należą do czynników ryzyka rozwoju zaćmy. Do pozostałych czynników ryzyka zaliczamy: nadciśnienie tętnicze, kortykosteroidoterapię, uwarunkowania genetyczne, urazy oka oraz wysoką krótkowzroczność (1).

1.2 Kwalifikacja do zabiegu usunięcia zaćmy

Zabieg usunięcia zaćmy jest wskazany u pacjentów, u których pogorszenie widzenia wpływa negatywnie na wykonywanie czynności życiowych lub zawodowych, a korekcja (okularowa lub za pomocą soczewek kontaktowych) nie poprawia znacząco ostrości widzenia.

Wizyta kwalifikacyjna powinna odbywać się w ośrodku, w którym ma być wykonany zabieg. Wpisanie na listę oczekujących na usunięcie zaćmy uzależnione jest od spełnienia odpowiednich kryteriów. Należy zawsze rozważyć, czy spodziewane korzyści z operacji i poprawa widzenia przewyższają ryzyko związane z zabiegiem.

Głównym kryterium branym pod uwagę przy kwalifikacji do usunięcia zaćmy jest występowanie zmętnienia soczewki w badaniu w lampie szczelinowej. Wymienione badanie należy przeprowadzić po wcześniejszym badaniu ostrości wzroku (do dali i do bliży) oraz po rozszerzeniu źrenic mydriatykami. Trzeba również uwzględnić subiektywne odczucia pacjenta co do pogorszenia ostrości widzenia (6–8).

Według najnowszych wytycznych opracowanych przez Stowarzyszenie Chirurgów Okulistów Polskich kwalifikacja do zabiegu usunięcia zaćmy w ramach NFZ wymaga obuocznej ostrości widzenia do dali z najlepszą korekcją nie większą niż 0,6 lub nie lepszą niż 0,3, gdy nie uwzględniamy ostrości widzenia w drugim oku. W przypadku pilnych wskazań (ze względu na dynamikę procesu chorobowego lub gorsze rokowanie) można odstąpić od wymienionych kryteriów. Indywidualnego podejścia wymagają również: różnowzroczność pooperacyjna powyżej 3,0 D; jaskra zamkniętego kąta lub z wąskim kątem przesączania z zagrożeniem ostrego

zamknięcia kąta; zaćma u kierowców zawodowych, u których pogorszenie widzenia w przebiegu zaćmy bezpośrednio wpływa na wykonywanie zawodu (6).

U pacjentów z astygmatyzmem regularnym należy rozważyć wszczepienie soczewki torycznej, a w przypadku astygmatyzmu rogówkowego – zastosowanie nacięć relaksacyjnych rogówki lub operację „on-axis".

Badanie okulistyczne przed zabiegiem usunięcia zaćmy powinno obejmować:

– autokeratorefraktometrię,

– badanie ostrości widzenia (do dali i do bliży, bez korekcji i z korekcją),

– pomiar ciśnienia wewnątrzgałkowego,

– badanie biomikroskopem przedniego odcinka oka,

– badanie dna oka i zmętnienia soczewki (po rozszerzeniu źrenic),

– wykonanie biometrii.

W niektórych przypadkach wskazane są następujące badania dodatkowe:

– topografia rogówki,

– perymetria statyczna i/lub kinetyczna,

– OCT przedniego i tylnego odcinka oka,

– ultrabiomikroskopia (UBM),

– angiografia fluoresceinowa (AF),

– badania elektrofizjologiczne (5).

VI. Materiał i metody

Niniejszy rozdział przedstawia zarys metodologii wykonanych badań. Szczegółowy opis metodologii znajduje się w pierwszej publikacji wchodzącej w skład pracy doktorskiej.

1. Plan badania

Jednoośrodkowe, prospektywne badanie porównawcze zostało przeprowadzone w Oddziale Okulistycznym Wielospecjalistycznego Szpitala – Samodzielnego Publicznego Zespołu Opieki Zdrowotnej w Zgorzelcu. W trakcie pracy przestrzegano założeń Deklaracji Helsińskiej. Projekt badania został zatwierdzony przez Komisję Bioetyczną przy Uniwersytecie Medycznym we Wrocławiu. Od wszystkich pacjentów uzyskano pisemną zgodę na udział w badaniu.

2. Pacjenci i metody

Do badania włączono pacjentów w wieku ≥35 i ≤75 lat z zaćmą obustronną, którzy chcieli ograniczyć swoją zależność od korekcji okularowej, i u których planowano zabieg fakoemulsyfikacji. Pacjenci pozostawali w obserwacji przez 6 miesięcy. Grupa badawcza, w której wszczepiano soczewki niedyfrakcyjne EDOF, składała się z 70 oczu u 35 pacjentów. Grupy kontrolne składały się z: 52 oczu u 26 pacjentów, u których wszczepiano soczewki wieloogniskowe, oraz 52 oczu u 26 pacjentów, u których wszczepiano soczewki jednoogniskowe.

Pooperacyjne wizyty kontrolne przeprowadzono po 2 tygodniach, 2 miesiącach (6–8 tygodniach) i 6 miesiącach od zabiegu. Badania kontrolne obejmowały: badanie w lampie szczelinowej przedniego i tylnego odcinka oka, badanie ciśnienia wewnątrzgałkowego, badanie wady refrakcji wyrażonej jako ekwiwalent sferyczny wykazanej refrakcji (MRSE). W trakcie wizyt kontrolnych wykonywano również badanie jednoocznej ostrości wzroku w skali logMAR: nieskorygowanej ostrości widzenia do dali (UCDVA) z 4 m, najlepiej skorygowanej ostrości widzenia do dali (BCDVA), nieskorygowanej ostrości widzenia do odległości pośredniej (UCIVA) z 80 cm, najlepiej skorygowanej ostrości widzenia do odległości pośredniej (BCIVA), nieskorygowanej ostrości widzenia do bliży (UCNVA) z 40 cm, najlepiej skorygowanej ostrości widzenia do bliży (BCNVA). Przeprowadzano także badanie jednoocznej

wrażliwości na kontrast (test Pelli-Robson, tablice GIMA). Każdy pacjent wypełniał ankietę dotyczącą niezależności od korekcji okularowej i występowania zjawisk fotooptycznych oraz oceniał stopień satysfakcji z zabiegu.

Po sześciu miesiącach od operacji drugiego oka oceniano obuoczną nieskorygowaną ostrość wzroku: UCDVA, UCIVA, UCNVA.

3. Analiza statystyczna

Analizy wykonano przy pomocy oprogramowania statystycznego R, wersja 4.1.3. Zmienne ilościowe porównywano między grupami testem Kruskala-Wallisa lub ANOVĄ, a pomiędzy pomiarami – testem Wilcoxona. Wybrano testy nieparametryczne, ponieważ zmienne dotyczące pomiarów istotnie odbiegały od rozkładu normalnego (sprawdzano to testem Shapiro-Wilka). Różnicę między medianami wraz z 95% przedziałem ufności podawano przy porównaniach dwóch pomiarów. Zależności między zmiennymi jakościowymi analizowano przy pomocy testu chi-kwadrat lub dokładnego testu Fishera. W analizie przyjęto poziom istotności równy $\alpha = 0.05$.

VII. Cele pracy doktorskiej

Soczewka niedyfrakcyjna o wydłużonej ogniskowej (EDOF) jest stosunkowo nową soczewką na polskim rynku. Dotychczas opublikowano na świecie niewiele badań poświęconych wynikom pooperacyjnym po wszczepieniu soczewki niedyfrakcyjnej EDOF, a przeprowadzone badania dotyczą głównie pacjentów bez obciążeń okulistycznych.

W niniejszej pracy przedstawiono wyniki pooperacyjne po wszczepieniu soczewki niedyfrakcyjnej EDOF u pacjentów zarówno bez dodatkowych obciążeń, jak i z różnymi chorobami okulistycznymi, a także po uprzednio przebytych zabiegach z zakresu chirurgii refrakcyjnej.

Liczba pacjentów z zaćmą i po zabiegach chirurgii refrakcyjnej stale się zwiększa, co stanowi niejednokrotnie wyzwanie dla chirurgów okulistów. Dzięki dostępowi do coraz nowszych soczewek wewnątrzgałkowych możliwy jest indywidualny dobór soczewki do pacjenta.

W związku z powyższym, w pracy doktorskiej przyjęto następujące cele:

1. Wskazanie grupy pacjentów kwalifikujących się do wszczepienia soczewki wewnątrzgałkowej niedyfrakcyjnej EDOF.
2. Ocena ostrości widzenia do dali, odległości pośredniej oraz bliży po zabiegu usunięcia zaćmy z wszczepieniem soczewki niedyfrakcyjnej EDOF w porównaniu do wszczepienia soczewek jedno- i wieloogniskowych.
3. Ocena uniezależnienia od korekcji okularowej u pacjentów po zabiegu usunięcia zaćmy z wszczepieniem soczewki niedyfrakcyjnej EDOF w porównaniu do wszczepienia soczewek jedno- i wieloogniskowych.
4. Odpowiedź na pytanie: Czy po zabiegu z wszczepieniem soczewki niedyfrakcyjnej EDOF występują działania niepożądane typowe dla soczewek wieloogniskowych?

VIII. Publikacje wchodzące w skład cyklu doktorskiego

Journal of
Clinical Medicine

MDPI

Article

Evaluation of Visual and Patient—Reported Outcomes, Spectacle Dependence after Bilateral Implantation with a Non-Diffractive Extended Depth of Focus Intraocular Lens Compared to Other Intraocular Lenses

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Abstract: Purpose: To evaluate postoperative outcomes, spectacle dependance and the occurrence of the photic phenomena in patients after cataract surgery following the implantation of a non-diffractive extended depth of focus (EDOF) intraocular lens was compared to monofocal and multifocal lenses. **Methods:** We enrolled patients with bilateral cataracts who wanted to reduce their dependence on glasses in the study. They were followed for 6 months. The study group in which the EDOF lens was implanted consisted of 70 eyes in 35 patients. The control groups consisted of: 52 eyes in 26 patients in whom a multifocal was implanted and 52 eyes in 26 patients with implanted monofocal lens. After a total of 2 weeks, 2 months and 6 months post-surgery the following were evaluated: uncorrected and corrected visual acuity at 4 m, 80 cm, 40 cm, manifest refraction expressed as mean refractive spherical equivalent (MRSE), contrast sensitivity, intraocular pressure. A questionnaire on independence from ocular correction, the occurrence of photic phenomena, and patient satisfaction was also completed. **Results**: Monocular and binocular visual acuity and MRSE 6 months after the procedure were compared between three groups. All of the main analyses, except for comparisons of uncorrected distance visual acuity (both monocular and binocular) level, were significant. Contrast sensitivity was lower among patients with multifocal lens than among patients with EDOF lens. Halo and glare after 6 months were seen more often among patients with multifocal lens than among patients with the other lens (65% of eyes with multifocal lens vs. 6% of eyes with EDOF lens and 0% of eyes with monofocal lens). Glasses were needed by 35% of patients with EDOF lens, and by 96% of patients with monofocal lens and in none of the patients with multifocal lens. **Conclusions**: Most patients qualify for the implantation of a non-diffractive EDOF lens. Post-operative visual acuity improves at any distance. The best monocular visual acuity for intermediate distances is provided by an EDOF lens, and for near distance by a multifocal lens. The EDOF lens definitely increases independence from spectacle correction compared to monofocal lenses; however, the greatest degree of independence from spectacles is provided by multifocal lenses. The incidence of photic phenomena is slightly higher than that of a monofocal lens, and much lower for a multifocal lens.

Keywords: cataract surgery; EDOF; intraocular lens; presbyopia; multifocal lens; photic phenomena

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1. Introduction

Cataract surgery is one of the most frequently performed procedures around the world. Intraocular lenses (IOLs) have developed significantly in recent years. IOLs are used in cataract surgery to replace a cloudy lens and in refractive lens exchange (RLE). The most common implanted lenses are monofocal lenses, which provide good acuity to one type of vision correction, mainly for a far distance. In addition to monofocal lenses, premium lenses, which have a more advanced structure and different optical properties are available. These lenses correct presbyopia, i.e., insufficient accommodation that occurs

physiologically after the age of 40. Premium lenses include multifocal intraocular lenses (MIOLs), extended depth of focus lenses (EDOF) and accommodative lenses. These lenses improve visual acuity after cataract surgery and allow for full or partial independence from spectacle correction. Both the extension of life expectancy, lifestyle changes and greater professional activity of the elderly contribute to the willingness to become independent from eyeglass correction not only in the distance, but also in the near and intermediate distance [1].

MIOLs allow for the greatest degree of independence from eyeglass correction, but they have a lower contrast sensitivity and a higher rate of photic phenomena, such as halo and glare. The eligibility criteria for implantation in this group of lenses are the most stringent, and the eyes should be free of any pathology so that patients can achieve the best possible postoperative results [2].

EDOF lenses can be positioned between monofocal and multifocal lenses. They provide good uncorrected distance and intermediate visual acuity; however, visual acuity without near correction may be insufficient. They work by creating a single, elongated focus to increase the depth of field. The elongated focus is designed to eliminate the close-up and distance overlap that occurs with multifocal lenses, thus eliminating the halo effect. In addition, EDOF lenses provide a continuous focus range, without the power distribution being unevenly divided, and thus avoiding secondary out-of-focus images [3,4]. Compared to multifocal lenses, they do not lower contrast sensitivity and cause less dysphotopsia [5].

There are different methods of creating these lenses. One of them is the use of spherical aberration, however, it differs from patient to patient in the population and is influenced by pupil width [6,7]. Another way is to use diffraction optics to obtain the EDOF effect. However, this can lead to the development of a dysfunction similar to those seen after multifocal lens implantation, and uncorrected near vision acuity may not be satisfactory [8]. Another method may be the use of a circular mask, as with the IC-8 lens, a small-aperture EDOF lens. However, this can reduce the amount of light entering through the diaphragm and is typically used in the non-dominant eye [9].

An increasing number of patients presenting for cataract surgery want to be independent from eyeglass correction, and at the same time are afraid of the photic phenomena after the procedure. There has been a growing number of patients after refractive surgery in the past who would like to regain independence from eyeglass correction and do not qualify for multifocal lens implantation. The same applies to patients with ocular diseases who would like to choose premium lenses. For these patients, EDOF lenses provide a chance to improve uncorrected acuity at all distances. Due to the fact that the EDOF Vivity lens (Alcon Laboratories, Inc., Fort Worth, TX, USA) has a unique, non-diffractive optical part; it allows patients to see well from near to distance. It is based on the non-diffractive X-wave technology, which modifies the wave front and creates one elongated focus without splitting the light. Thanks to these properties, the lens reduces the risk of dysphotopsia and does not worsen the contrast sensitivity. In the construction of the lens, two zones can be distinguished: the transition zone 1 is responsible for stretching the wave front and creating a continuous elongated focus, while the transition zone 2 is responsible for shifting the wave front from hyperopia to short-sighted in order to use all the light energy. It has 1.5 D defocusing and negative asphericity of the anterior surface (−0.2 µm) [10–12]. Moreover, the extended depth of focus, such as that seen in the Vivity lens, can "forgive" the imperfection of IOL power selection caused by the difficulty in calculating IOL power (especially in patients who have undergone refractive surgery in the past) [10].

To date, few articles have been published on postoperative outcomes in patients with non-diffractive EDOF lens implantation, including one in patients with ocular pathologies. This paper additionally includes patients with a history of refractive surgery, who will be increasingly more numerous in the future and would like to choose a premium lens. To the best of our knowledge, there are currently no publications on the comparison of the Vivity lens with monofocal and multifocal lenses. This work may provide some insight into lens selection, especially for patients with ocular pathologies and after refractive

surgery who are ineligible for MIOLs or are worried about their side effects. The aim of the article is to evaluate the postoperative results, spectacle dependence, the occurrence of the photic phenomena in patients after cataract surgery using a non-diffractive EDOF–Vivity intraocular lens compared to multifocal and monofocal intraocular lenses.

2. Patients and Methods

2.1. Study Design

This single-center, prospective, comparative study was conducted at the Ophthalmology Department of the Hospital in Zgorzelec in line with the Helsinki Declaration and approved by the Bioethics Committee at the Medical University of Wroclaw. Written consent was obtained from all patients.

2.2. Study Population

The study group in which the Vivity lens was implanted (DFT015 or the toric version of the lens-called the EDOF group) consisted of 70 eyes in 35 patients. The control groups consisted of 52 eyes in 26 patients in whom a Panoptix multifocal lens (TNTFOO or the toric version of the lens-called the MULTI group) was implanted and 52 eyes in 26 patients with implanted monofocal lens (SA60WF or the toric version SN6AT3-7-called the MONO group). All lenses implanted in the patients involved in our study are single-piece, aspheric, are constructed of the same material-hydrophobic, and are based on the same platform-Acrysof (Alcon Laboratories, Inc., Fort Worth, TX, USA) [10,11,13–15]. The EDOF and multifocal lens were donated by the Alcon Company for the purpose of this study.

The study included patients aged 35–75 diagnosed with bilateral cataracts in whom the removal of the cataract was planned by phacoemulsification.

Exclusion criteria included: patients under the age of 35, over the age of 75, pregnant, after a corneal transplant, with a history of past eye injuries, diseases of the anterior and posterior segment of the eye that may have significantly reduced the quality of vision after surgery, such as: advanced glaucomatous neuropathy, advanced diabetic retinopathy, amblyopia, corneal scarring and dystrophy, exudative age-related macular degeneration (AMD), post-posterior vitrectomy condition or elective surgery, and clinically significant severe dry eye syndrome. Patients after cerebral events that could have affected visual acuity were also excluded from the study.

2.3. Preoperative Assessment

The pre-operative examination consisted of: anterior and posterior segment examination in a slit lamp, intraocular pressure examination, refraction examination (NIDEK ARK-510A-Nidek Co. Ltd., Gammagori, Aichi, Japan), monocular visual acuity examination in logarithm of the minimum angle of resolution (logMAR) scale: uncorrected distance visual acuity (UCDVA) at 4 m, best corrected distance visual acuity (BCDVA), uncorrected intermediate visual acuity (UCIVA) at 80 cm, best corrected intermediate visual acuity (BCIVA), uncorrected near visual acuity (UCNVA) with 40 cm, best corrected near visual acuity (BCNVA), monocular contrast sensitivity at 40 cm (Pelli-Robson test, GIMA charts, Gessate, Italy), biometry using an Argos SS-OCT optical biometer (Movu, Inc., Kamaki, Japan) and IOL Master 500 (Carl Zeiss Meditec AG, Jena, Germany), Oculazer ™ WaveLight® II corneal tomography and topography (Alcon Laboratories, Inc., Fort Worth, TX, USA), posterior segment optical coherence tomography (OCT) (OCT III, Carl Zeiss Meditec AG, Jena, Germany). A standardized ETDRS chart at 4 m, 80 cm, and 40 cm was used to measure visual acuity (VA).

In the study, the refractive result was written as a spherical equivalent, defined as the sum of the spherical power and half of the cylindrical power [16]. The results obtained were classified as myopia, emmetropia or hyperopia. For myopia there was a spherical equivalent less than −0.5 D, for emmetropia-a spherical equivalent in the range of −0.5 and +0.5 D, and in the case of hyperopia, a spherical equivalent greater than +0.5 D. This division was adopted in accordance with other large cross-sectional and dynamic studies [16–18].

2.4. Postoperative Assessment

Controls were performed 2 weeks, 2 months (6–8 weeks) and 6 months after cataract surgery. Controls included: anterior and posterior segment examination in a slit lamp, an intraocular pressure test, manifest refraction expressed as mean refractive spherical equivalent (MRSE), monocular visual acuity test in the logMAR scale: UCDVA, BCDVA, UCIVA, BCIVA, UCNVA, BCNVA, monocular contrast sensitivity and the postoperative questionnaire.

Six months after the second eye surgery, binocular visual acuity was assessed: UCDVA, UCIVA, UCNVA.

Measurements were performed under photopic conditions (250–300 lumens/mm^2) in all cases. The preoperative and postoperative examinations were carried out by the same person.

2.5. Subjective Visual Quality Questionnaire

Patients were asked "yes/no" questions regarding independence from glasses, the occurrence of postoperative dysphotopsia such as halo, glare, starburst, was assesed on a scale from 1 to 5 in increments of 1 (1-slight, 5-very high). In addition, patients were asked to rate their satisfaction with the procedure (scale from 1 to 5).

2.6. Surgical Technique

All cataract surgery with implantation of an appropriate intraocular lens was performed by the same surgeon (H.P.). All the procedures were uneventful. They were performed under drip (Alcaine) and intraocular (Mydriane) anesthesia. The lenses were implanted through a 2.2 mm corneal incision into the lens bag. At the end of the procedure, in accordance with European standards, cefuroxime solution was administered into the anterior chamber.

Implant power for the Vivity lens was calculated on an Argos optical biometer using Barret's formula, setting postoperative results to either emmetropia (18 patients, 36 eyes) or minimonovision (17 patients, non-dominant eye set to target ~ −0.75D). Eye dominance was determined by taking the Mile's test. For Panoptix lenses, the Argos biometer and Barret's formula were used, setting postoperative results to emmetropia. Implant power of monofocal lenses was calculated using an IOL Master 500 or Argos biometer, using the SRK/T formula or the Barret formula by setting the target to emmetropia. With axial length <22 mm, the Haigis formula was used. In the case of patients after previous radial keratotomy, measurements were made on an Argos biometer using the Barret true K formula.

2.7. Statistical Analysis

All analyses were performed in statistical environment R, version 4.1.3. Quantitative variables were compared between groups with the Kruskal-Wallis test or with ANOVA analysis and between measurements—with the Friedman's test (for more than two measurements) or Wilcoxon's test for dependent samples (for two measurements). These tests were chosen because all variables' distributions significantly differed from the normal distribution (checked with Shapiro-Wilk's test). Median differences with 95% confidence intervals were given when comparing two measurements. Dependencies for qualitative variables were analyzed with the chi-square test or the Fisher's exact test. Significance level in the analysis equalled $\alpha = 0.05$.

3. Results

Pre- and postoperative data of 174 eyes (87 patients) were included in the analysis. A total of 35 patients (70 eyes) received the Vivity IOL (19 toric and 51 non-toric), 26 patients (52 eyes) underwent the implantation of monofocal (12 toric and 40 non-toric) lens, and 26 patients (52 eyes) the PanOptix lens (10 toric and 42 non-toric).

3.1. Demographics and Preoperative Data

Detailed demographic characteristics, biometry values, mean preoperative refractive errors and visual acuity (VA), contrast sensitivity, and intraocular pressure from the three groups are presented in Table 1.

Table 1. Demographics and preoperative characteristics (refractive and monocular VA (logMAR) data, ocular pathologies) of the three groups.

Variables	EDOF n = 70 Eyes n = 35 Subjects	MONO n = 52 Eyes n = 26 Subjects	MULTI n = 52 n = 26 Subjects	*p*	p^1	p^2	p^3
	Me (Q1; Q3) or M ± SD/n (%)						
Sex (female)	23 (65.7)	15 (57.7)	19 (73.1)	0.506	-	-	-
Age	57.74 ± 9.37	60.69 ± 10.65	59.46 ± 8.41	0.439 [2]	-	-	-
Refractive error							
Myopia	31 (44.3)	27 (51.9)	12 (23.1)	**0.012** [1]	-	-	-
Emmetropia	5 (7.1)	2 (3.8)	9 (17.3)				
Hyperopia	34 (48.6)	23 (44.2)	31 (59.6)				
Axial lenght (mm)							
Short < 22	8 (11.4)	4 (7.7)	1 (1.9)	0.070 [1]	-	-	-
Medium 22–26	57 (81.4)	48 (92.3)	49 (94.2)				
Long > 26	5 (7.1)	0 (0.0)	2 (3.8)				
Toric IOL	19 (27.1)	12 (23.1)	10 (19.2)	0.606	-	-	-
MRSE (D)	0.50 (−2.50; 1.75)	−1.00 (−2.50; 2.31)	1.12 (−0.25; 2.00)	0.329	-	-	-
UCDVA	0.70 (0.30; 1.00)	0.70 (0.40; 0.77)	0.40 (0.29; 0.70)	**0.017**	0.624	**0.015**	**0.010**
BCDVA	0.25 (0.20; 0.30)	0.25 (0.25; 0.32)	0.25 (0.25; 0.25)	**0.004**	**0.005**	0.735	**0.002**
UCIVA	0.75 (0.43; 0.93)	0.60 (0.40; 0.90)	0.70 (0.48; 0.94)	0.236	-	-	-
BCIVA	0.20 (0.10; 0.40)	0.30 (0.10; 0.40)	0.20 (0.10; 0.30)	0.229	-	-	-
UCNVA	0.80 (0.70; 1.15)	0.70 (0.50; 0.86)	0.80 (0.60; 1.02)	0.054	-	-	-
BCNVA	0.30 (0.10; 0.50)	0.40 (0.20; 0.40)	0.20 (0.18; 0.32)	**0.014**	0.131	0.297	**0.001**
Contrast sensivity	1.80 (1.70; 1.90)	1.70 (1.58; 1.80)	1.80 (1.70; 1.83)	0.051	-	-	-
IOP (mmHg)	17.30 (16.25; 17.30)	17.30 (14.60; 17.30)	17.30 (14.60; 17.30)	0.270	-	-	-
ACD (mm)	3.15 (2.94; 3.52)	3.03 (2.80; 3.23)	3.17 (2.89; 3.36)	**0.012**	**0.003**	0.193	0.113
IOL power (D)	22.25 (19.50; 24.00)	23.00 (21.12; 23.62)	23.00 (21.00; 24.50)	0.553	-	-	-
Ocular pathology							
Glaucoma	4 (11.4)	8 (30.8)	2 (7.7)	0.0681	-	-	-
AMD	4 (11.4)	4 (15.4)	1 (3.8)	0.3751	-	-	-
Retinopathy	4 (11.4)	4 (15.4)	0 (0.0)	0.1171	-	-	-
Refractive surgery	4 (11.4)	0 (0.0)	0 (0.0)	0.0371	-	-	-

Table 1. *Cont.*

Variables	EDOF n = 70 Eyes n = 35 Subjects	MONO n = 52 Eyes n = 26 Subjects	MULTI n = 52 n = 26 Subjects	*p*	p[1]	p[2]	p[3]
	Me (Q1; Q3) or M ± SD/n (%)						
PEX	2 (5.7)	2 (7.7)	4 (15.4)	0.5261	-	-	-
Drug-induced cataract	8 (22.9)	4 (15.4)	0 (0.0)	0.0251	-	-	-

Qualitative variables were described as n (%) and quantitative variables—as median with quartile 1 and 3 or mean with standard deviations. Dependencies between groups and qualitative variables were made using chi-square test or Fisher's exact test [1]. Comparisons of quantitative variables' level were made with Kruskal-Wallis test or with ANOVA [2] analysis. *p*—*p* value for main analyses; *p* value for post-hoc analyses: p[1]—EDOF vs. MONO p[2]—EDOF vs. MULTI, p[3]—MONO vs. MULTI. Abbreviations: mm—milimiters, IOL—intraocular lens, AMD—age-related macular degeneration, PEX—pseudoexfoliation syndrome, MRSE—mean refraction spherical equivalent, D-diopters, mmHg—millimetres of mercury, UCDVA—uncorrected distance visual acuity at 4 m, BCDVA—best corrected distance visual acuity, UCIVA—uncorrected intermediate visual acuity at 80 cm, BCIVA—best corrected intermediate visual acuity, UCNVA—uncorrected near visual acuity at 40 cm, BCNVA—best corrected near visual acuity.

Among the MULTI group there was a smaller proportion of eyes with myopia than in the other groups (23% vs. 44% for EDOF and 52% for MONO) and a higher proportion of eyes with emmetropia (17% vs. 7% for EDOF and 4% for MONO) or with hyperopia (60% vs. 49% for EDOF and 44% for MONO), $p = 0.012$. The analysis comparing quantitative variables was significant for: UCDVA ($p = 0.017$), BCDVA ($p = 0.004$), BCNVA ($p = 0.014$) and ACD ($p = 0.012$). Post-hoc analyses showed that patients from the MULTI group had a lower level of UCDVA variable than EDOF and MONO groups and lower level of BCNVA than the MONO group. Patients from the MONO group were characterized by a higher level of BCDVA than two remaining groups and by a lower level of ACD than patients from EDOF group ($p < 0.050$ for all post-hoc analyses), Table 1.

3.2. Refractive and Visual Outcomes

Monocular and binocular visual acuity and MRSE 6 months after the procedure were compared between EDOF, MONO and MULTI groups. All main analyses, except for comparisons of UCDVA (both monocular and binocular) level, were significant ($p < 0.050$). Post-hoc analyses showed that the level of: MRSE, BCDVA and BCIVA was higher among MULTI group than among EDOF group ($p < 0.010$ for all post-hoc analyses). Contrast sensitivity was lower among MULTI group than among EDOF group. The level of UCIVA (both monocular and binocular visual acuity) was higher in the MONO group than in the EDOF and MULTI groups ($p < 0.001$ for all post-hoc analyses) and higher in the MULTI group than in the EDOF group ($p < 0.050$ for both post-hoc analyses). The level of UCNVA (both monocular and binocular visual acuity) was higher in the MONO group than in the EDOF and MULTI groups ($p < 0.001$ for all post-hoc analyses) and higher in the EDOF group than in the MULTI group ($p < 0.001$ for both post-hoc analyses). The level of BCNVA was higher among MULTI group than among MONO group ($p = 0.007$), Table 2.

Table 2. Comparison of postoperative data (6 months after cataract surgery) between three groups.

Variables	EDOF	MONO	MULTI	*p*	p[1]	p[2]	p[3]
	Me (Min–Max)						
MRSE (D)	−0.25 (−1.25; 0.50)	0.00 (−1.00; 0.75)	0.25 (−0.50; 0.75)	**<0.001**	0.053	**<0.001**	0.221
Monocular visual acuity (logMAR)							
UCDVA	0.00 (−0.20; 0.20)	0.00 (−0.10; 0.40)	0.00 (−0.15; 0.20)	0.433	-	-	-

Table 2. *Cont.*

Variables	EDOF	MONO	MULTI	*p*	p[1]	p[2]	p[3]
	Me (Min–Max)						
BCDVA	0.00 (−0.20; 0.00)	0.00 (−0.20; 0.00)	0.00 (−0.15; 0.00)	**0.008**	0.335	**0.009**	0.233
UCIVA	0.00 (−0.10; 0.30)	0.30 (−0.10; 0.60)	0.10 (−0.20; 0.30)	**<0.001**	**<0.001**	**0.004**	**<0.001**
BCIVA	0.00 (−0.10; 0.10)	0.00 (−0.20; 0.20)	0.00 (−0.20; 0.20)	**0.008**	0.590	**0.004**	0.331
UCNVA	0.40 (0.00; 0.60)	0.50 (0.10; 0.90)	0.10 (0.00; 0.20)	**<0.001**	**<0.001**	**<0.001**	**<0.001**
BCNVA	0.00 (−0.10; 0.20)	0.00 (−0.10; 0.10)	0.00 (0.00; 0.30)	**0.008**	0.301	0.229	**0.007**
Binocular visual acuity (logMAR)							
UCDVA	0.00 (−0.15; 0.10)	0.00 (−0.10; 0.14)	0.00 (−0.15; 0.10)	0.767	-	-	-
UCIVA	0.00 (−0.10; 0.10)	0.20 (−0.20; 0.40)	0.00 (−0.10; 0.14)	**<0.001**	**<0.001**	**0.015**	**<0.001**
UCNVA	0.26 (0.00; 0.46)	0.40 (0.04; 0.70)	0.00 (0.00; 0.10)	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Contrast sensitivity	2.00 (1.80; 2.00)	2.00 (1.80; 2.00)	1.90 (1.80; 2.00)	**<0.001**	0.907	**<0.001**	0.063

Variables were described as median with range of scores (min–max). Comparisons of quantitative variables' level were made with Kruskal-Wallis test. *p*—*p* value for main analyses; *p* value for post-hoc analyses: p[1]—EDOF vs. MONO, p[2]—EDOF vs. MULTI, p[3]—MONO vs. MULTI.

When the EDOF group is divided into two subgroups: (1) patients with target set to emmetropia, (2) patients with minimonovision (non-dominant eye set to target ca. −0.75 D) the results of binocular uncorrected visual acuity 6 months after surgery are as follows, Table 3.

Table 3. Comparison of uncorrected binocular acuity at all distances between four groups (EDOF group divided into 2 subgroups: emmetropia i minimonovision).

Variables	Emmetropia	Minimonovision	MONO	MULTI	*p* for Main Analyses
	Me (Q1; Q3)				
UCDVA	0.00 (−0.09; 0.00)	0.00 (−0.10; 0.00)	0.00 (−0.06; 0.00)	0.00 (−0.09; 0.00)	0.904
UCIVA	0.00 (0.00; 0.03)	0.00 (−0.06; 0.00)	0.20 (0.10; 0.24)	0.00 (0.00; 0.06)	**<0.001**
UCNVA	0.30 (0.22; 0.36)	0.20 (0.10; 0.30)	0.40 (0.30; 0.50)	0.00 (0.00; 0.03)	**<0.001**
***p* value for post-hoc analyses**					
				UCIVA	UCNVA
Emmetropia vs. minimonovision				**0.040**	0.062
Emmetropia vs. MONO				**<0.001**	**0.001**
Emmetropia vs. MULTI				0.172	**<0.001**
Minimonovision vs. MONO				**<0.001**	**<0.001**
Minimonovision vs. MULTI				**<0.001**	**<0.001**
MONO vs. MULTI				**<0.001**	**<0.001**

Variables were described as median with quartile 1 and 3. Comparisons of quantitative variables' level were made with Kruskal-Wallis test.

Refractive and Visual Outcomes in Baseline and after 6 Months in Each Group

In the EDOF group at the baseline the level of: UCDVA (MD 95% CI = 0.70 (0.63; 0.82); $p < 0.001$), BCDVA (MD 95% CI = 0.25 (0.30; 0.35); $p < 0.001$), UCIVA (MD 95% CI = 0.75 (0.64; 0.80); $p < 0.001$), BCIVA (MD 95% CI = 0.20 (0.25; 0.35); $p < 0.001$), UCNVA (MD 95% CI = 0.40 (0.45; 0.60); $p < 0.001$), BCNVA (MD 95% CI = 0.30 (0.25; 0.40); $p < 0.001$) and IOP (MD 95% CI = 2.85 (1.90; 3.00); $p < 0.001$) was higher than after 6 months. The level of contrast was lower at the baseline than after 6 months (MD 95% CI = −0.20 (−0.35; −0.20); $p < 0.001$).

In the MONO group almost all comparisons between baseline and after 6 months were significant (except of the MRSE level). At the baseline the level of: UCDVA (MD 95% CI = 0.70 (0.55; 0.75); $p < 0.001$), BCDVA (MD 95% CI = 0.25 (0.30; 0.38); $p < 0.001$), UCIVA (MD 95% CI = 0.30 (0.30; 0.50); $p < 0.001$), BCIVA (MD 95% CI = 0.30 (0.24; 0.33); $p < 0.001$), UCNVA (MD 95% CI = 0.20 (0.13; 0.33); $p < 0.001$), BCNVA (MD 95% CI = 0.40 (0.30; 0.40); $p < 0.001$) and IOP (MD 95% CI = 2.80 (0.85; 2.45); $p < 0.001$) was higher than after 6 months. The level of contrast sensivity was lower at the baseline than after 6 months (MD 95% CI = −0.30 (−0.35; −0.25); $p < 0.001$).

All analyses were significant in the case of the MULTI group. At the baseline the level of: MRSE (MD 95% CI = 0.87 (0.00; 1.37); $p = 0.043$), UCDVA (MD 95% CI = 0.40 (0.40; 0.57); $p < 0.001$), BCDVA (MD 95% CI = 0.25 (0.25; 0.28); $p < 0.001$), UCIVA (MD 95% CI = 0.60 (0.60; 0.80); $p < 0.001$), BCIVA (MD 95% CI = 0.20 (0.15; 0.25); $p < 0.001$), UCNVA (MD 95% CI = 0.70 (0.65; 0.80); $p < 0.001$), BCNVA (MD 95% CI = 0.20 (0.20; 0.25); $p < 0.001$) and IOP (MD 95% CI = 2.90 (1.55; 2.50); $p < 0.001$) was higher than after 6 months. The level of contrast sensivity was again lower at the baseline than after 6 months (MD 95% CI = −0.10 (−0.20; −0.15); $p < 0.001$)

3.3. Evaluation of Dysphotopsia

Halo and glare after 6 months were experienced more often among subjects form the MULTI group than among subjects from the two other groups (65% of eyes in MULTI group vs. 6% of eyes in the EDOF group and 0% of eyes in the MONO group; $p < 0.001$ for halo and 10% of eyes in the MULTI group vs. 3% of eyes in the EDOF group and 0% of eyes in the MONO group; $p = 0.045$). No other significant difference was detected between groups and between the occurrence of photic phenomena 6 months after the procedure, Table 4.

Table 4. Comparison of occurrence of photic phenomena 6 months after the procedure between three groups.

Variables	EDOF n = 70 Eyes	MONO n = 52 Eyes	MULTI n = 52 Eyes	*p*
	n (%)			
Halo	4 (5.7)	0 (0.0)	34 (65.4)	**<0.001** [2]
Halo level				
1	1 (25.0)	-	13 (38.2)	0.563
2	3 (75.0)	-	12 (35.3)	
3	0 (0.0)	-	8 (23.5)	
4	0 (0.0)	-	1 (2.9)	
5	0 (0.0)	-	0 (0.0)	
Glare	2 (2.9)	0 (0.0)	5 (9.6)	**0.045**
Glare level				
1	0 (0.0)	-	4 (80.0)	0.143
2	1 (50.0)	-	1 (20.0)	
3	1 (50.0)	-	0 (0.0)	
4	0 (0.0)	-	0 (0.0)	
5	0 (0.0)	-	0 (0.0)	
Starburst	4 (5.7)	2 (3.8)	8 (15.4)	0.097
Starburst level				
1	1 (25.0)	0 (0.0)	2 (25.0)	0.899
2	3 (75.0)	2 (100.0)	4 (50.0)	
3	0 (0.0)	0 (0.0)	2 (25.0)	
4	0 (0.0)	0 (0.0)	0 (0.0)	
5	0 (0.0)	0 (0.0)	0 (0.0)	

Variables were described as n (%). Dependencies between groups and qualitative variables were made using chi-square test [2] or Fisher's exact test.

3.4. Spectacle Dependence and Patient Satisfaction

Glasses were needed by 35% of subjects from the EDOF group, by 96% of subjects from the MONO group and by no one from the MULTI group (this was a statistically significant dependency—$p < 0.001$). Every patient from every group was satisfied (both for the right and left the eye). Most of subjects from each group rated their satisfaction (both for right and left eye) with a number 5 (97% for right eye and 86% for left eye in the EDOF group; 92% for right eye and 81% for left eye in the MONO group; 77% for right eye and 85% for left eye in the MULTI group; $p = 0.552$ for the dependency between groups and level of satisfaction for right eye and $p > 0.999$ for the dependency between groups and level of satisfaction for left eye). Among the MULTI group, there was a greater proportion of subjects that rated their satisfaction for the right eye with the number 4 than in two other groups (23% vs. 3% in EDOF and 8% in MONO; $p = 0.038$), Table 5.

Table 5. Number of patients needing glasses and satisfaction rating broken down by groups.

Variable	EDOF n = 35 Subjects	MONO n = 26 Subjects	MULTI n = 26 Subjects	*p*
	n (%)			
Glasses	14 (35.0)	25 (96.2)	0 (0.0)	**<0.001** [2]
Satisfaction (right eye)	35 (100.0)	26 (100.0)	26 (100.0)	-
Satisfaction (left eye)	35 (100.0)	26 (100.0)	26 (100.0)	-
Level of satisfaction (right eye)				
1	0 (0.0)	0 (0.0)	0 (0.0)	**0.038**
2	0 (0.0)	0 (0.0)	0 (0.0)	
3	0 (0.0)	0 (0.0)	0 (0.0)	
4	1 (2.9)	2 (7.7)	6 (23.1)	
5	34 (97.1)	24 (92.3)	20 (76.9)	
Level of satisfaction (left eye)				
1	0 (0.0)	0 (0.0)	0 (0.0)	0.932
2	0 (0.0)	0 (0.0)	0 (0.0)	
3	0 (0.0)	0 (0.0)	0 (0.0)	
4	5 (14.3)	5 (19.2)	4 (15.4)	
5	30 (85.7)	21 (80.8)	22 (84.6)	

Dependencies were calculated using chi-square test [2] or Fisher's exact test.

4. Discussion

4.1. Qualification

Due to the non-diffractive structure of the lens and one elongated focus, the EDOF lens can be implanted in patients who do not qualify for multifocal lens implantation or are afraid of either the photic phenomena or reduced contrast sensitivity. In the case of multifocal lenses, the eligibility criteria are the strictest, and patients should be free of ocular diseases in order to achieve the best possible vision after surgery. As can be seen in Table 1, the patients who were qualified for cataract surgery with a non-diffractive EDOF lens had eyes with various ocular pathologies or past refractive surgeries, which did not impair the prognosis for improved vision after surgery, and thus patient satisfaction after surgery was high. The profile of patients in this case is similar to that of patients qualified for surgery with monofocal lens implantation.

4.2. Postoperative Results

The non-diffractive EDOF lens provides good acuity of distance vision, intermediate distance and functional near vision, confirmed by previous studies [19]. In our study, patients who had the Vivity lens implanted achieved a significant improvement in VA at all distances. The UCDVA at 4 m monocular is similar between the EDOF, the MONO

group and the MULTI group. In the case of the monocular UCIVA at 80 cm, VA is better for patients in the EDOF group than for the MONO and MULTI groups (UCIVA EDOF = 0.0, MULTI = 0.1, MONO = 0.3, respectively). In the case of monocular UCNVA, patients in the EDOF group achieved a worse VA than patients in the MULTI group and better than in the MONO group, as confirmed by other published studies comparing EDOF lenses with multifocal and monofocal lenses [15,19–21]. The worse monocular UCIVA at 80 cm for the MULTI group compared to the EDOF group may be due to the fact that the PanOptix lens has a focus to intermediate distance at 60 cm [15].

To the best of our knowledge, no study has been published, comparing at the same time the Vivity lens with monofocal and multifocal to date. In a large randomized study, Bal C. et al. compared postoperative outcomes in patients implanted with a Vivity lens compared to an aspheric monofocal lens. They described better intermediate and near distance vision after implantation of the Vivity lens and a similar visual impairment profile compared to the aspheric monofocal IOL [20].

In the study by Kohnen T. et al. the postoperative outcomes after bilateral Vivity lens implantation with target refraction set to emmetropia were assessed (32 eyes—16 patients). Patients achieved: binocular uncorrected VA for distance, intermediate distance and near distance, respectively, 0.01 ± 0.05 logMAR at 4 m, 0.05 ± 0.05 logMAR at 80 cm, 0.07 ± 0.06 logMAR at 66 cm and 0.25 ± 0.11 logMAR at 40 cm [22]. The results obtained in our study, for EDOF lens implantation with target refraction set to emmetropia were very similar (Me [Q1; Q3]): binocular UDCVA at 4 m 0.00 (−0.09; 0.00) logMAR, binocular UCIVA at 80 cm 0.00 (0.00; 0.03) logMAR, and binocular UCNVA at 40 cm 0.30 (0.22; 0.36) logMAR, respectively.

Arrigo A. et al. describes the authors' own experiences in healthy eyes (108 eyes—54 patients) after EDOF Vivity lens implantation. Very good results of distance vision and intermediate distance were described; in the case of near vision, the need for an addition of at least +1.0 D was indicated. Monocular UCDVA was 0.1 ± 0.04 logMAR, monocular BCDVA was 0.0 ± 0.03 logMAR, respectively [23]. Patients in our study with an implanted Vivity lens also needed a near vision supplement of about 1D or more and median monocular UCDVA was 0.0 logMAR, median monocular BCDVA was 0.0 logMAR.

The use of the minimonovision system in the case of the Vivity lens improves the VA for near vision and increases the degree of independence from ocular correction. In the paper by Newsom T. et al. describing the results of binocular Vivity lens implantation with target of slight myopia −0.75 D, 29 of 33 eyes achieved UCNVA binocular 0.2 logMAR or better [24]. Very similar results were obtained in our patients wih minimovision, whose median binocular UCNVA was 0.2 logMAR.

Rementería-Capelo LA et al. describes the postoperative results after binocular Vivity lens implantation in patients with ocular pathology. A monocular UCDVA was achieved in the test group of 0.03 ± 0.8 logMAR, compared to the control group with an implanted Vivity lens without eye pathology −0.1 ± 0.07. The statistical difference between binocular UCDVA in both groups was not described, as was the case of defocus curves and contrast sensitivity [25]. The result of this study is similar to ours, which evaluated the visual acuity of both healthy patients and those with ocular pathology (median of monocular and binocular UCDVA was 0.0 logMAR). These results, although described on small groups and with a wide range of ocular disorders, give evidence that ocular disorders do not disqualify from Vivity lens implantation. Postoperative results in these patients are very good.

4.3. Spectacle Dependance

Therefore, EDOF lenses can be positioned between monofocal and multifocal lenses, they provide good uncorrected visual acuity for distance and intermediate, but uncorrected visual acuity for nearsightedness may be insufficient. In our study, glasses were needed by 35% of subjects from the EDOF group, by 96% of subjects from the MONO group and by no one from the MULTI group (this was a statistically significant dependency—$p < 0.001$). In a study by Rementería-Capelo LA et al., 40% of patients in both study groups (with and

without ocular pathology) reported never using close-up glasses [25]. Similar results were described by Kohnen et al. (38%) [22]. The higher degree of independence from spectacle correction among our patients with EDOF lens implantation may be due to the different profile of qualified patients for the procedure. In addition, our EDOF group was not a homogeneous group and some patients had the target set to emmetropia and some had the minimovision system applied. This was due to patient preference and their desire to improve their near vision. In addition, each patient prefers a different reading distance, which also contributes to the different results.

As you know, the use of a minimovision system in the cases of the Vivity lens improves near vision acuity and increases the degree of independence from spectacle correction. Newsom T. et described a high level of satisfaction and a greater degree of independence from ocular correction with the monovision system than without monovision with implantation of the same lens [24].

4.4. Occurance of Photic Phenomena

In our study, a small number of patients after EDOF implantation reported photic phenomena (14% patients). Patients who reported the occurrence of dysphotopsia described these side effects as minor, not disrupting normal functioning, similar to the previous reports [20,22,23]. Compared to patients in the MONO group, the incidence of dysphotopsia is slightly more frequent, but it is definitely seen less than in patients in the MULTI group. The study by Rementería-Capelo LA et al. described that patients reported a higher prevalence of halos and glare than other reports on Vivity IOL, especially in the study group, with ocular pathologies: 60% halo, 54% glare, compared to the control group, where the incidence of halo was 28% and 48% [25]. Kohnen et al. found that 25% reported halo and 25% glare [22]. Arrigo et al. reported that 30% and 33% of patients reported halo and glare [23]. The differences between the studies may be due to differences in the questionnaires used in the study and the "inquiry," an active question about the presence of dysphotopsia, and this has been shown to increase reporting rates [26].

A paper by Newsom T. et described that the use of a monovision system when implanting a Vivity lens compared to target refraction set to emmetropia does not increase the frequency of photic phenomena [24].

4.5. Contrast Sensivity

Although this was not the main aim in the study also described was the contrast sensivity. Some patients, due to the fear of decreased of contrast sensivity after surgery, choose not to implant multifocal lenses and select EDOF lenses. According to the manufacturer, the Vivity lens has a safety profile similar to that of monofocal lenses [11,19]. In our study, contrast sensitivity in patients implanted with the Vivity lens did not differ significantly from patients implanted with a monofocal lens and was better than that of patients implanted with a multifocal lens. It is difficult to relate the results of this study to others, since contrast sensitivity was tested only with nearsighted charts and only under photopic conditions.

In our study, we encountered a few limitations. First, it was conducted at a single center, so the number of patients in the study was limited. Secondly, each study group included both healthy patients and patients with eye pathology and after refractive surgery. Studies focusing on specific ocular pathologies or on patients after specific refractive procedures, with larger numbers of patients, would be necessary to best determine which type of IOL would provide the greatest benefit for a given group of patients. In addition, comparing data from our study with other published studies is problematic due to different inclusion/exclusion criteria, study conditions and procedures.

5. Conclusions

The majority of patients presenting for cataract surgery who whished to increase independence from spectacle correction are eligible for the implantation of a non-diffractive

EDOF lens. Postoperative visual acuity improves at any distance. In the case of the monocular uncorrected intermediate visual acuity at 80 cm, it is better for patients with EDOF lens than with monocofal or multifocal lens. In the case of monocular uncorrected near visual acuity at 40 cm, patients with EDOF lens achieved worse visual acuity than patients with multifocal lens and better than with monofocal lens. The EDOF lens definitely increases independence from spectacle correction compared to monofocal lenses (65% vs 4%); however, the greatest degree of independence from spectacles is provided by multifocal lenses (100%). Only 14% patients after EDOF implantation reported photic phenomena. Compared to patients with monofocal lens, the incidence of dysphotopsia is slightly more frequent, but definitely it is seen less than in patients with multifocal lens.

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Case Report

Cataract Surgery after Radial Keratotomy with Non-Diffractive Extended Depth of Focus Lens Implantation

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Abstract: Radial keratotomy was a popular surgical procedure used to treat myopia. Patients who underwent radial keratotomy several years ago, are currently reporting to the ophthalmologist due to worsening of vision associated with age-related cataracts. In this case report we present a case of a 60-year-old woman who underwent radial keratotomy with 16 incisions in the right eye and 12 incisions in the left eye. The patient reported to an ophthalmologist due to a deterioration of vision caused by a cataract. We described, in detail, the difficulties encountered during the diagnostic procedures, differences in the calculation of intraocular lens, and intraoperative difficulties as compared to patients who had not undergone radial keratotomy. We also present the obtained postoperative results.

Keywords: radial keratotomy; cataract; EDOF; phacoemulsifacation; cataract surgery

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1. Introduction

In the 1980s and 1990s, radial keratotomy (RK) was a popular surgical procedure used to treat myopia. The aim of RK is to flatten the central curvature of the cornea. This effect is achieved by making radial incisions in the cornea (usually 8–16), the depth of which reach 90% of the corneal thickness. In this manner, the procedure changes the curvature of the anterior and posterior surfaces of the cornea [1]. However, more and more patients, who had undergone RK in the past, report to the ophthalmologist due to worsening of vision caused by age-related cataracts.

Patients who underwent RK are a unique group of patients. They pose a special challenge for cataract surgeons at every stage of treatment, starting from the selection of the proper type of intraocular lens (IOL), calculation of IOL power, choosing the best place for the corneal incision, and ending with months of postoperative follow-up during which refraction may change constantly [2]. The expectations of patients, who want to reduce spectacle dependence after cataract surgery, are an additional challenge which may not always be met.

2. Case Report

A 60-year-old patient was admitted to the Department of Ophthalmology of the Voivodeship Hospital in Zgorzelec due to a deterioration of vision in both eyes seen over several months. In 1989 she underwent bilateral myopic RK (no documentation was available). She reported that before the procedure she had used corrective glasses with a power of −4,5 Dsph. After RK she did not require any spectacle correction for the next 15 years. In 2004, the patient started wearing progressive glasses again. On the day of admission, before cataract surgery, her refraction was: OD (right eye) +4.25/−0.75 ax 159, OS (left eye) +3.5/−0.5 ax 5; and visual acuity OD UCDVA (uncorrected distance visual acuity) at 4 m 1.0 logMAR, BCDVA (best corrected distance visual acuity) 0.2 logMAR

(+4.0 Dsph), UCIVA (uncorrected intermediate visual acuity) at 80 cm 1.1 logMAR, BCIVA (best corrected intermediate visual acuity) 0.1 logMAR, UCNVA (uncorrected near visual acuity) at 40 cm 1.1 logMAR, BCNVA (best corrected near visual acuity) 0.3 logMAR; OS: UCDVA 1.0 logMAR, BCDVA 0.2 (+3.25 Dsph), UCIVA 1.1 logMAR, BCIVA 0.1 logMAR, UCNVA 1.0 logMAR, BCNVA 0.2 logMAR. The ophthalmological examination revealed incisions made during RK in the anterior segment—in OD 16 and OS 12 (Figure 1) Anterior and posterior segments of the eye were normal. The patient was informed in detail about the difficulties in calculating IOL power after the RK procedure and that corneal regeneration after cataract surgery takes more time. The possibility of postoperative refractive error was explained to the patient. The patient was qualified for cataract surgery, after conducting comprehensive ophthalmological examinations such as: biometry on the Argos SS-OCT biometer (Movu, Inc., Komaki, Japan) and IOL Master 500 (Carl Zeiss Meditec AG, Jena, Germany) (Figure 2), corneal tomography on scanning system Oculazer™ WaveLight® II (Alcon Laboratories, Inc., Fort Worth, TX, USA) (Figure 3), optical coherence tomography (OCT) (OCT III, Carl Zeiss Meditec AG, Jena, Germany) of the anterior and posterior segment. Implantation of a non-diffractive lens with an extended depth of focus (EDOF), Acrysof IQ Vivity (Alcon Laboratories, Inc., Fort Worth, TX, USA) was chosen.

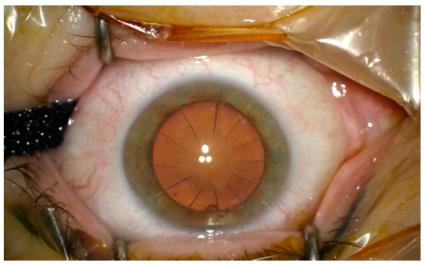

Figure 1. The picture shows 12 incisions after radial keratotomy in the left eye.

Name:
ID:
Date of birth:
Age of patient:
Examination date:
Surgeon: **Surgeon**
Lens: Alcon DFT015 Vivity

Target ref.: -0.4 D
n: 1.3375

The measurements should be checked for plausibility, as there may be pathological changes!

OD right		**OS** left
AL: 26.59 mm (SNR = 314.2)		AL: 26.29 mm (SNR = 232.1)
K1: 33.38 D / 10.11 mm @ 146°		K1: 34.83 D / 9.69 mm @ 39°
K2: 34.54 D / 9.77 mm @ 56°		K2: 35.41 D / 9.53 mm @ 129°
R / SE: 9.94 mm / 33.96 D		R / SE: 9.61 mm / 35.12 D
Cyl.: -1.16 D @ 146°		Cyl.: -0.58 D @ 39°
ACD: 3.41 mm		ACD: 3.49 mm
Status: Phakic		Status: Phakic

SRK®/T		**Holladay 1**		**SRK®/T**		**Holladay 1**	
A const:	119.20	SF:	1.61	A const:	119.20	SF:	1.61
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
24.5	-1.41	24.5	-1.46	24.5	-1.76	24.0	-1.39
24.0	-1.01	24.0	-1.06	24.0	-1.36	23.5	-1.00
23.5	-0.61	23.5	-0.66	23.5	-0.96	23.0	-0.61
23.0	**-0.21**	**23.0**	**-0.27**	**23.0**	**-0.57**	**22.5**	**-0.22**
22.5	0.18	22.5	0.11	22.5	-0.18	22.0	0.16
22.0	0.56	22.0	0.50	22.0	0.20	21.5	0.53
21.5	0.94	21.5	0.88	21.5	0.58	21.0	0.90
Emme. IOL: 22.73		Emme. IOL: 22.65		Emme. IOL: 22.27		Emme. IOL: 22.21	
HofferQ		**Haigis**		**HofferQ**		**Haigis**	
pACD const:	5.39	A0 const:	1.177	pACD const:	5.39	A0 const:	1.177
		A1 const:	0.400			A1 const:	0.400
		A2 const:	0.100			A2 const:	0.100
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
26.5	-1.5	26.0	-1.45	26.0	-1.7	25.5	-1.53
26.0	-1.1	25.5	-1.05	25.5	-1.3	25.0	-1.14
25.5	-0.8	25.0	-0.66	25.0	-0.9	24.5	-0.75
25.0	**-0.4**	**24.5**	**-0.28**	**24.5**	**-0.6**	**24.0**	**-0.37**
24.5	0.0	24.0	0.10	24.0	-0.2	23.5	0.00
24.0	0.3	23.5	0.48	23.5	0.1	23.0	0.38
23.5	0.7	23.0	0.85	23.0	0.5	22.5	0.74
Emme. IOL: 24.46		Emme. IOL: 24.13		Emme. IOL: 23.71		Emme. IOL: 23.51	

(* = value has been edited, ! = borderline value)

Figure 2. Result of intraocular lens power calculation using the IOL Master 500.

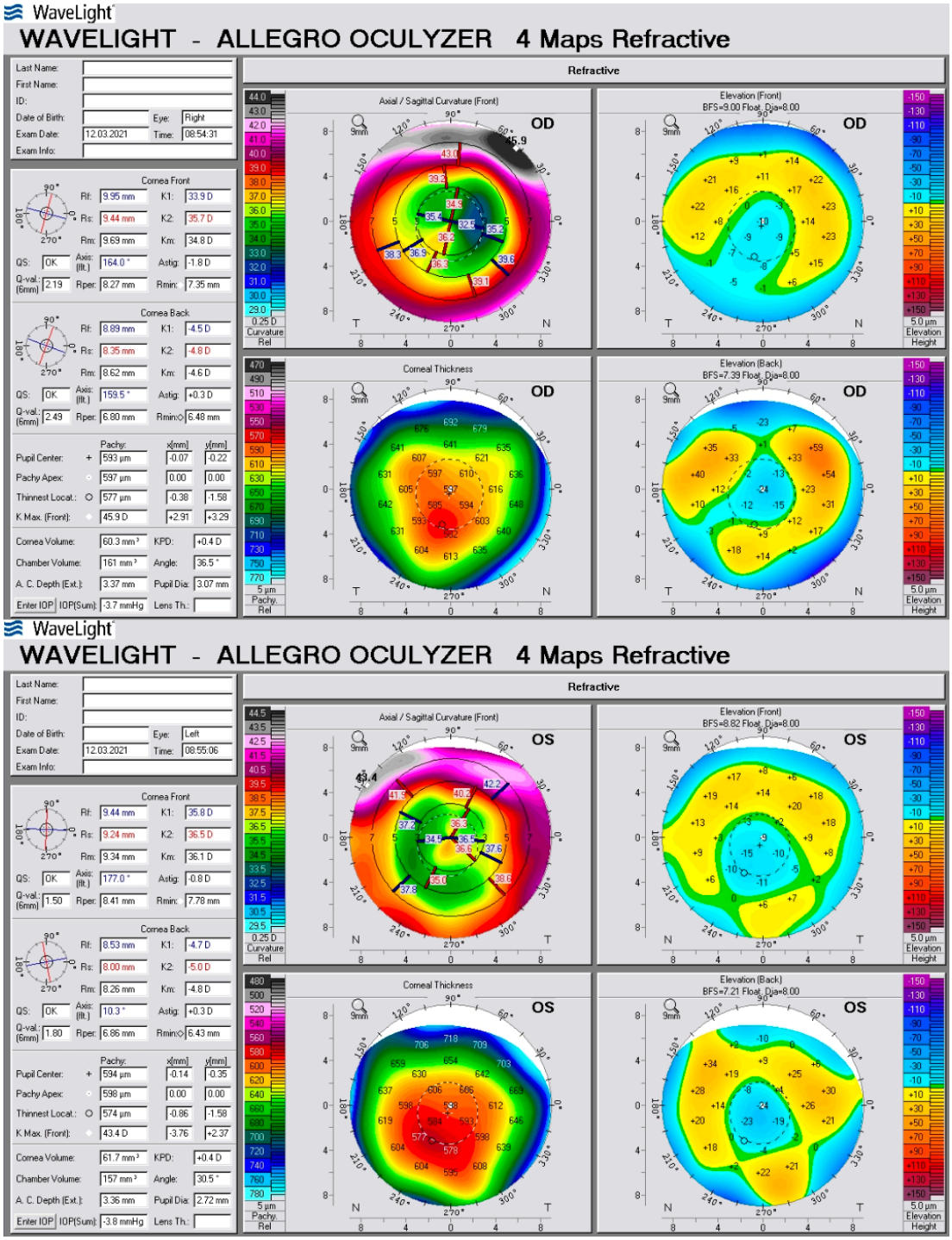

Figure 3. Corneal tomography shows irregular astigmatism in both eyes.

Only the OS corneal curvature was measured using the Argos optical biometer. We were unsuccessful in measuring the curvature in OD. Both eyes were examined without any problems on the IOL Master 500 biometer. To calculate the implant power on the Argos optical biometer, we used results of K1 and K2 from IOL Master (Figure 4). Considering the presence of the irregular and asymmetrical astigmatism of low value, seen in the topography, the implantation of a toric lens was rejected.

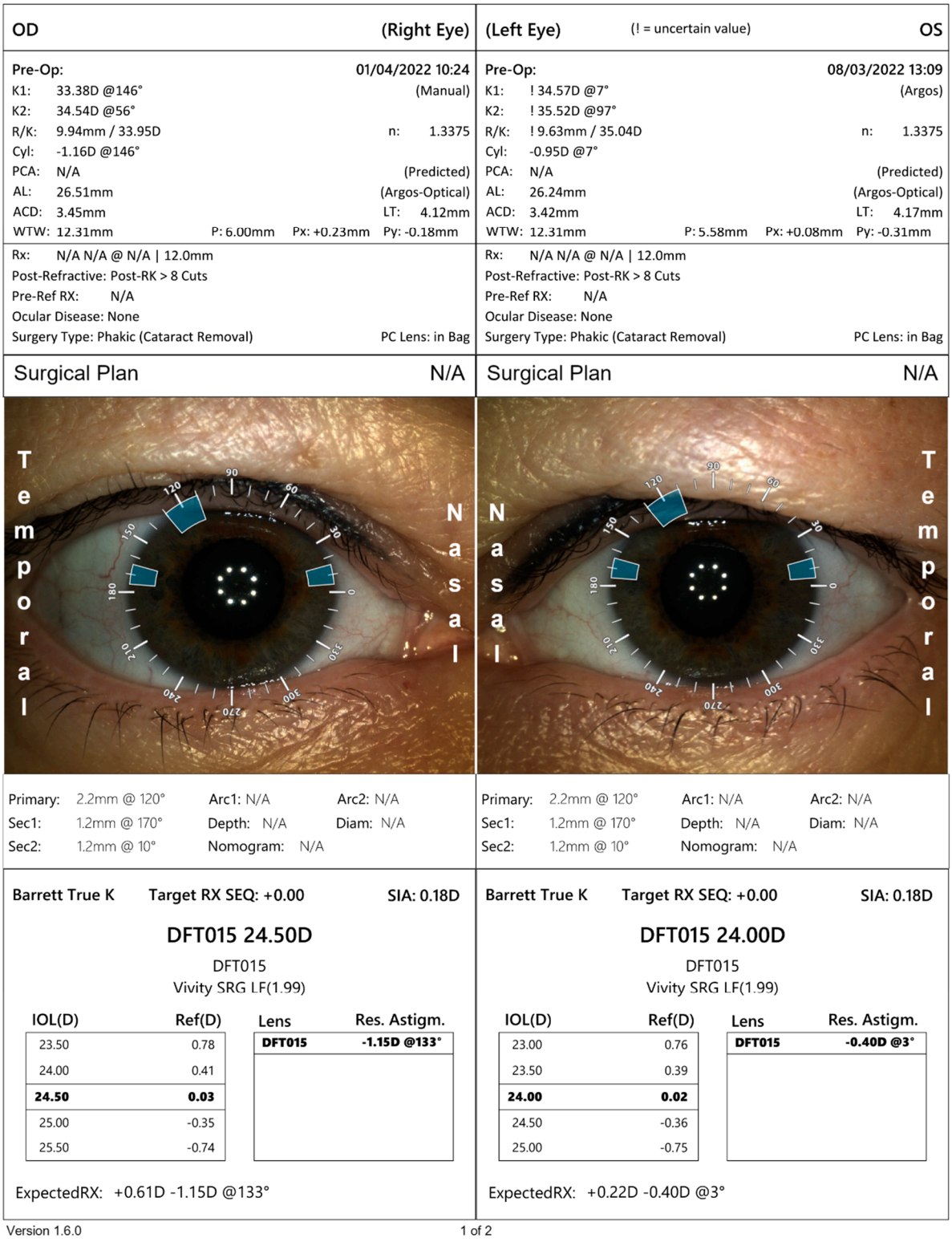

Figure 4. Result of intraocular lens power calculation using the Argos biometer.

The results of IOL power, calculated using the Barret's True K formula was obtained with the use of an online calculator: the IOL Calculator for Eyes with Prior RK, which was developed by the American Society of Cataract and Refractive Surgery (ASCRS) (Figure 5). The Argos optical biometer was used. Both measurements were similar. Due to the lack of documentation from the RK surgery and a low amount of data which could be entered into

the calculator, we chose the IOL power by averaging the measurement from IOL Master, the Argos optical biometer and the ASCRS calculator.

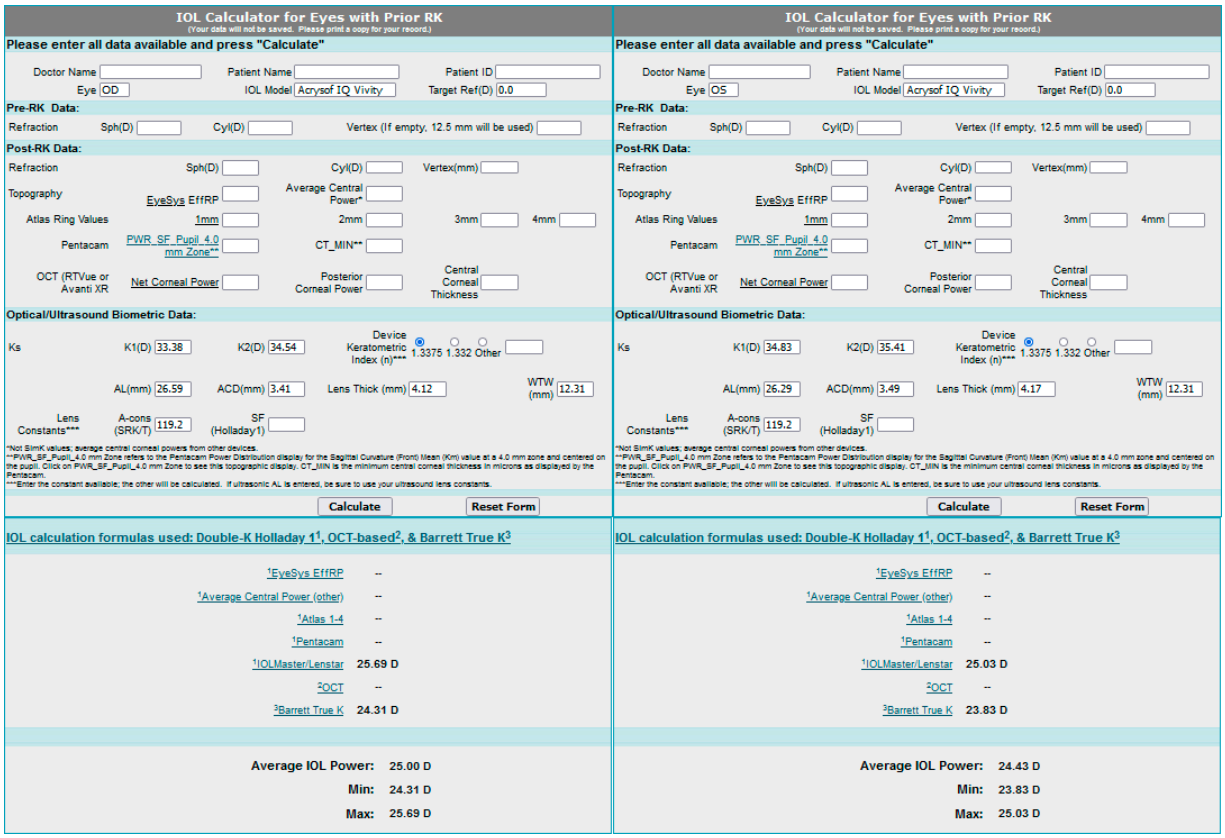

Figure 5. Result of intraocular lens power calculation using ASCRS calculator for the right and the left eye.

In September 2021 cataract surgery of OD, was performed. Implantation of IOL Acrysof IQ Vivity with a power of 24.0 D was used. Two weeks after the surgery, during a follow up visit, we obtained the following refractions: OD: +1.75/−1.75 axis 144, UCDVA 0.2 log mar, BCDVA 0.0 logMAR (+1.25/−1.0 ax 145), UCIVA 0.4 logMAR, BCIVA 0.14 logMAR, UCNVA 0.6 logMAR, BCNVA 0.1 logMAR (Table 1). After one month, during the control visit, the refraction was OD: +0.25/−1.25 ax 142, and the patient gained visual acuity: UCDVA 0.1 logMAR, BCDVA 0.0 logMAR (−0.75 ax 145)), UCIVA 0.3 logMAR, BCIVA 0.1 logMAR, UCNVA 0.6 logMAR, BCNVA 0.1 logMAR. In November 2021 cataract surgery of OS was performed using implantation of IOL Acrysof IQ Vivity with a power of 23,5D. Both procedures were performed by the same surgeon who used an Infinity phacoemulsifier from Alcon. No complications were seen after both surgeries. Two weeks after the second procedure we received the following refraction: OS −0.0/−0.5 ax 73, and the patient's visual acuity was OS UCDVA 0.0 logMAR, BCDVA −0.1 log MAR (−0.25 Dsph), UCIVA 0.5 logMAR, BCIVA 0.1 log MAR, UCNVA 0.5 logMAR BCNVA 0.1 logMAR. Another control visit was conducted 6 weeks after the surgery of the second eye. Refraction and visual acuity are displayed in Table 1.

Table 1. Refraction and visual acuity (logMAR) before and after (2 weeks and 6 weeks) cataract surgery.

	Refraction	UCDVA	BCDVA	UCIVA	BCIVA	UCNVA	BCNVA
Preoperative data							
OD	+4.25/−0.75 ax 159	1.0	0.2	1.1	0.1	1.1	0.3
OS	+3.5/−0.5 ax 5	1.0	0.2	1.1	0.1	1.0	0.2
2 weeks after cataract surgery							
OD	+1.75/−1.75 ax 144	0.2	0.0	0.4	0.14	0.6	0.1
OS	−0.0/−0.5 ax 73	0.0	−0.1	0.5	0.1	0.5	0.1
6 weeks after cataract surgery							
OD	0.0/−1.25 ax 165	0.1	0.0	0.3	0.1	0.6	0.1
OS	−0.25/−0.25 ax 59	0.0	−0.1	0.0	0.0	0.4	0.0

Abbreviatons: OD—right eye, OS—left eye, UCDVA—uncorrected distance visual acuity at 4 m, BCDVA -best corrected distance visual acuity, UCIVA—uncorrected intermediate visual acuity at 80 cm, BCIVA—best corrected intermediate visual acuity, UCNVA—uncorrected near visual acuity at 40 cm, BCNVA—best corrected near visual acuity.

After both procedures the patient did not report any dysphotopsias and was pleased with the effects of the operation. Currently the patient does not require spectacles for distance or intermediate distance. She only uses power lenses for small print or in poor quality light.

The last control visit was conducted 6 months after the last surgery in order to evaluate the possible refractive changes connected to past RK. Table 2 presents the results of the control visit.

Table 2. Refraction and visual acuity (logMAR) 6 month after cataract surgery.

	Monocular		Binocular
	OD	OS	OU
Refraction	0.0/−1.25 ax 165	−0.5/−0.25 ax 59	
UCDVA	0.1	0.0	0.0
BCDVA	0.0 (0.0/−0.75 ax 165)	−0.1 (−0.25 Dsph)	−0.1
UCIVA	0.3	0.0	0.0
BCIVA	0.1 (0.5/−0.75 ax 165)	0.0	0.0
UCNVA	0.6	0.4	0.3
BCNVA	0.1 (1.0/−0.75 ax165)	0.0 (0.75 Dsph)	0.0

Abbreviatons: Dsph—Diopter sphera, OD—right eye, OS—left eye, OU—both eyes, UCDVA—uncorrected distance visual acuity at 4m, BCDVA—best corrected distance visual acuity, UCIVA—uncorrected intermediate visual acuity at 80 cm, BCIVA—best corrected intermediate visual acuity, UCNVA—uncorrected near visual acuity at 40 cm, BCNVA—best corrected near visual acuity.

3. Discussion

The procedure of cataract surgery in patients who underwent RK is challenging for cataract surgeons due to difficulties in preoperative measurements of IOL as well as high expectations of patients regarding good vision after surgery. Earlier studies [3,4] showed that the refraction results after cataract surgery are difficult to predict in this group of patients.

3.1. Choice of the IOL

Our patient wanted to be independent of spectacles, however she was afraid of intensified visual disturbances such as halo and glare. After the RK procedure she reported dysphotopsia under meso and scotopic conditions—glare and halo. Difficulties in determining the curvature of the cornea and performing the calculation of the appropriate IOL power were caused by corneal irregularities after RK. It was difficult to predict the residual refractive error after the planned cataract surgery. In the case of multifocal lenses, which

minimize the need to wear glasses, it is crucial to carefully select IOL power and to correct astigmatism, in order to achieve good visual acuity. Moreover, multifocal lenses may exert side effects like halo and glare, which may be enhanced by corneal aberrations in post-RK patients. The patient was advised not to choose multifocal lenses due to these reasons. Instead, the patient was offered an EDOF lens, Vivity.

The IOL provides an extended range of vision from a distance with excellent intermediate and functional near vision. It is based on non-diffractive X-wave technology, which modifies the wave front and produces one elongated focus without splitting light. Thanks to these properties, the lens reduces the risk of dysphotopsia. It does not lessen the contrast sensitivity and is less sensitive to decentration than multifocal lenses. This lens is built from Acrysof, a hydrophobic material, and contains UV and blue light filters. It has −1.5 D defocus and negative asphericity of the anterior surface (−0.2 µm) which is particularly important in patients with positive corneal aberrations. The difference between the results of the autorefractometer and the actual postoperative refractive error is typical for Vivity lenses. Hence, it is recommended to calculate the refraction manually with maximum plus technique [5]. The EDOF lenses appear to be an opportunity for post-RK patients who want some independence from spectacles. The extended depth of focus, such as that seen in the Acrysof IQ Vivity non-diffractive lens, can "forgive" the imperfection of IOL power selection caused by the difficulty in calculating IOL power in post-RK patients. Thanks to the elongated focal point and the resulting broadened defocus curve, patients can achieve acceptable UCVA (uncorrected visual aquity) levels over a larger residual refractive error width. This is a very important consideration in patients after RK surgery due to postoperative residual refractive error fluctuations.

3.2. Choice of IOL Power Calculation

Corneal incisions performed during RK procedures may contribute to greater measurement errors when standard methods are employed, especially regarding parameters necessary for the correct selection of the IOL (thickness and breaking power of the central part of the cornea). False measurement results of refractive power of the cornea come from the differences between the central flattened area of cornea after RK (3 mm) and the area which is measured by keratometer (up to 4 mm) [3]. Measurement errors may lead to incorrect calculations of effective lens position (ELP) and IOL power which may, in turn, result in postoperative hyperopia [6]. Newer third and fourth generation calculating formulas enable better ELP estimation [7,8]. Turnbull et al. recommend the use of the following formulas in order to calculate the IOL power—depending on available data before and after RK,

- in the case of available medical history before and after a RK procedure:

Barrett True K [History]

Barrett True K [Partial History]

- in the case of the missing information in medical history before and after RK procedure:

Barrett True K [No History]

Standard Haigis formula.

In the study conducted by this group of authors, the method of True K and the standard Haigis formula were able to give much better results during the postoperative period than the DK-Holladay-IOLM, Potvin-Hill or Haigis methods (with shift of −0.5D) [9].

Thanks to the IOL ASCRS calculator, which is available online, one can calculate the lens power after RK and LASIK/PRK procedures (also after both hyperopia correction and myopia correction). They are easy to use and widely available. The introduction of data into the online calculator is used to calculate the IOL power by using seven different calculating formulas. The best solution seems to be the use of the averaged result from all available formulas [10].

It should be kept in mind that the RK procedure not only changes the corneal curvature but may also create alternating flat and convex zones on the corneal surface. This makes it

difficult to determine the flat and steep meridian of the cornea [11]. Results of following keratometries (no matter what kind of apparatus had been used) are not repetitive and may differ from each other. This may affect the result of IOL power calculation and may result in refractive errors.

3.3. Incision Type

Cataract phacoemulsification increases the risk of RK incisions dehiscence or rupture [12,13]. Cases of ruptures or dehiscence of scars seen during surgical procedures such as retinal detachment surgery, phacoemulsification of cataracts or corneal transplant have been described in literature [14]. Even many years after RK surgery, the cornea does not return to its original integrity, and the scar tissue may contain corneal epithelial cells [15]. That is why it is crucial to properly plan the location of the cuts and maintain special caution during cataract phacoemulsification.

In this case the main incisions were made more circumferentially than in standard cataract surgery in order to minimize above the risks. Lateral incisions were made between two neighbouring scars after RK (Figure 6).

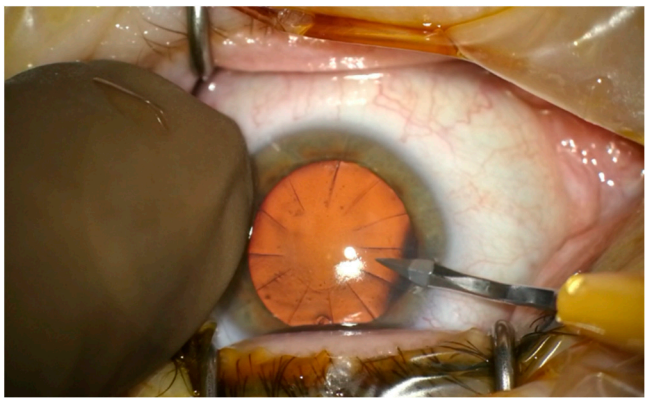

Figure 6. Location of lateral cuts between 2 neighboring incisions after radial keratotomy.

Meduri et al. showed that it was valid to place an incision within the cornea only in cases when there was enough room to cut between adjacent RK scars without disturbing their continuity. Disturbing the continuity of the RK scars may lead to scar dehiscence and leakage of aqueous humor. In the case when the location of an incision after RK start to open or leak, it should be sealed with a 10-0 nylon suture and the sutures should not be removed for 2 weeks [16]. The cataract removal procedure should be as short as possible due to reduced corneal stability after RK. The operator should restrict the movements of the phacoemulsifier head within the anterior chamber in order to prevent postoperative astigmatism [10].

3.4. Refractive Outcomes of Phacoemulsification in Post-RK Eyes

There are only a few publications on EDOF lens implantation in patients after radial keratotomy. This is primarily due to surgeons' fear of implanting optically advanced intraocular lenses in patients who present corneal 'multifocality'.

A study by Bartman et al. described the postoperative outcomes of 12 patients with a history of radial keratotomy (24 eyes) after implantation of an EDOF, Tecnis Symfony lens. They described an improvement in UCVA from 20/73 (Snellen equivalent) to 20/33 after 6 months and an average manifest SE that improved from +1.68D (preoperative) to −0.18 D (6 months after surgery). A high degree of patient satisfaction after the surgery was obtained [2].

Agarwal et al. described 2 cases of unilateral implantation of the IC-8 IOL in patients after bilateral radial keratotomy and 1 case after bilateral radial keratotomy and astigmatic keratotomy (AK) achieving good UCDVA, UCIVA and UCNVA in most cases [17].

4. Conclusions

Cataract surgery in patients who underwent RK is challenging for cataract surgeons due to difficulties encountered while choosing IOL power, planning the location of corneal incisions and a prolonged corneal regeneration after the procedure. It is hard to meet patients' expectations when it comes to achieving spectacle independence after the procedure. The non-diffractive EDOF lenses give a chance to achieve satisfactory postoperative effects, while avoiding the typical side effects seen after multifocal lenses.

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ARTYKUŁ PRZEGLĄDOWY REVIEW ARTICLE
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Patient with cataract – observations after 2 years of the pandemic and future prospects

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HIGHLIGHTS

The pandemic has contributed to a decrease in cataract procedures performed, and some patients are now presenting at a more advanced stage of the disease, which is associated with higher intraoperative risks and longer recovery after surgery.

ABSTRACT

Cataract is a disease in which the natural lens becomes completely or partially cloudy. During the pandemic, there was a significant decrease in the number of cataract surgeries performed compared to previous years, due to fear of the disease and the safety of the procedures performed. Cataract surgery should be performed in patients whose visual acuity deterioration has an impact on the performance of life or work activities. Due to the pandemic, some patients report to a more advanced stage of cataract, which leads to a reduction in their quality of life. Such surgery can be associated with a higher risk of surgical complications and longer recovery time. The development of new intraocular lens technologies, increased life expectancy, as well as changing lifestyles and increased activity of the elderly contribute to the increasing choice of premium intraocular lenses by patients. These lenses enable patients to achieve satisfactory uncorrected visual acuity not only for distance, but also for near and intermediate distances.

Key words: cataract, pandemic, intraocular lenses, EDOF, multifocal lenses

INTRODUCTION

Cataract is a disease involving complete or partial opacity of the natural lens of the eye. It is the most common reversible cause of blindness in the world. According to the estimates, in Poland there are 800,000 people with cataract. During the pandemic period, we observed a significant decrease in the number of cataract surgeries in comparison to previous years. In 2020, the number of procedures dropped by nearly 30% compared to 2019.

This decrease was observed mostly among patients above 70 years, but it also affected other age groups. People were afraid of contracting COVID-19 and that cataract procedures were not safe. Postponing surgery is not only associated with decreased patient comfort, but it also leads to further disease progression, which may result in more difficult surgery and longer recovery time [1].

In addition, intumescent cataract can lead to secondary glaucoma and uveitis. Poor insight into deeper structures of the eye due to severe lens opacity can delay diagnosis and treatment of other ocular diseases such as age-related macular degeneration (AMD), glaucoma, or diabetic retinopathy.

Cataract surgery should be performed in patients whose decreased visual acuity affects their daily or occupational activities despite wearing glasses or contact lenses. The Polish Society of Ophthalmology (PTO) and the Association of Polish Ophthalmic Surgeons (SCOP) have developed the following criteria for qualifying patients for cataract surgery:

- best-corrected binocular near visual acuity of less than or equal to 0.6
- best-corrected monocular near visual acuity of 0.3 or less.

The above criteria do not have to be met in case of urgent indications, such as rapid disease process or worse postoperative visual acuity due to prolonged surgery waiting, or if the cataract significantly impairs patient's daily functioning or occupational performance [2].

In the case of preoperative regular astigmatism above 2D, patients can undergo toric lens implantation as part of the Polish National Health Fund reimbursement [3].

During the pandemic, cataract removal procedures did not differ from the ones performed before. However, to increase patient's safety, special procedures related to the use of personal protective equipment and disinfectants were implemented, increased distance between patients was provided, and efforts were made to schedule patients for specific times. Due to appropriate sanitary regime cataract removal procedures were safe during the pandemic [1].

The pandemic period has meant that some patients now present at a more advanced stage of cataract and the procedure carries a higher risk of intraoperative complications. In addition, the pandemic period may have slightly increased the waiting time for cataract surgery, but thanks to the procedures being performed mainly on a same-day basis and the removal of limits on cataract procedures funded by the Polish National Health Fund from 1 April 2019, waiting time has been significantly reduced. The last few months have seen a renewed increase in the number of cataract removal procedures performed compared to the first months of the pandemic.

MODERN TECHNOLOGIES IN CATARACT SURGERY

Intraocular lenses (IOLs) have undergone significant development in recent years. IOLs are used in cataract surgery to replace the cloudy lens and in refractive lens exchange (RLE). Under the Polish National Health Fund, the patient has the option of cataract surgery with the implantation of a monofocal lens, which gives good visual acuity to one distance, mainly distant VA. Apart from the above, there are lenses of more advanced construction and different optical properties, called premium lenses.

Premium IOLs correct presbyopia, or insufficient accommodation, which occurs physiologically after about 40 years of age. Premium lenses include multifocal intraocular lenses (MIOLs), extended depth of focus (EDOF) and accommodative lenses. They increase patients' comfort after own lens removal and allow for full or partial independence from spectacle correction, but the associated costs are to be borne by the patient. Both the increase in the life expectancy as well as lifestyle changes and increased

professional activity of elderly people contribute to the desire to become independent from spectacle correction, not only for distance but also for near and intermediate distances [4].

MULTIFOCAL LENSES

Multifocal lenses, particularly trifocal ones, were developed to provide better uncorrected distant, intermediate and near vision and have now virtually replaced bifocal lenses. Their principle of operation is based on the division of light energy into three foci. We can distinguish between diffractive, refractive and hybrid MIOLs. However, trifocal lens technology has its disadvantages. First, intermediate visual acuity is not as good as distant and near [5–7].

Second, due to the diffractive design of the lens, there is a reduction in contrast sensitivity [8, 9]. Third, diffractive optics and the presence of rings in the optical system of the lens result in photopic dysphotopsias such as halo and glare. Although trifocal lenses currently provide the greatest independence from spectacle correction, some patients may be dissatisfied due to the aforementioned side effects [10].

DIFFRACTIVE MULTIFOCAL LENSES

Multifocal diffraction lenses work by interference of light. They are equipped with concentric diffraction rings on their surface that get closer together as they move away from the center. Their number and placement are responsible for the number of additional foci in the optical system and where they will form.

In general, these lenses provide good far and near vision, but in some cases intermediate distance vision is unsatisfactory. Their performance is not as dependent on pupil the width as that of refractive MIOLs and they are less sensitive to decentration. However, they decrease contrast sensitivity compared to monofocal lenses [11, 12]. This group include the following lenses: PanOptix (by Alcon), AT LISA tri (by Carl Zeiss), RayOne Trifocal (by Rayner), Sulcoflex (by Rayner).

PanOptix (Alcon)

PanOptix is a single-piece, diffractive, aspheric, non-apodized, hydrophobic lens built on the Acrysof IQ platform. It has a biconvex optical surface, UV and blue light filtering (fig. 1).

The lens is based on a quad-focal design and uses ENLIGHTEN optical technology to redistribute light from a focal point located at 120 cm to a point in the far field to enhance visual acuity to the far field. In addition, this technology provides high (88%) light energy utilization and low pupil width dependence in all lighting conditions [13, 14].

FIGURE 1

Acrysof IQ PanOptix – a diffractive multifocal lens with ENLIGHTEN optical technology (courtesy of Alcon Poland).

The lens has near addition of +3.25 D (40 cm) and intermediate addition of +2.17 D (60 cm).

RayOne Trifocal (Rayner)

A trifocal, preloaded, diffractive lens with near addition of +3.5 D (37.5 cm) and intermediate addition of +1.75 D (75 cm). Constructed of Rayacryl hydrophilic acrylic material. The overall diameter of the lens is 12.5 mm, the optical part covers 6 mm. It has a 4.5-mm diffraction zone with 16 diffraction rings (steps). The > 4.5 mm zone operates on the principle of monofocal optics. The lens is biconvex with aberration-neutral technology (fig. 2) [15].

Sulcoflex Trifocal (Rayner)

This is a unique diffractive trifocal lens docked into the ciliary sulcus. It has near addition of +3.5 D (37.5 cm) and intermediate addition of +1.75 D (75 cm). It is constructed of Rayacryl acrylic hydrophilic material. The overall diameter of the lens is 14 mm with an optical diameter of 6.5 mm. Its anterior surface is convex, while the posterior one is concave. The lens is aberration-neutral.

It can be implanted during the so-called DUET procedure, i.e., when a monofocal lens is implanted into the capsular bag with simultaneous implantation of a Sulcoflex trifocal lens in the ciliary sulcus (fig. 3). It can also be implanted in the presbyopia correction surgery or after previous cataract surgery with implantation of a monofocal lens. It can also be used to correct ametropia after surgery. Notably, Sulcoflex lens surgery is reversible [16].

MULTIFOCAL REFRACTIVE LENSES

Multifocal refractive lenses have zones of different refractive index based on Snellen's law. The effectiveness of refractive lenses depends on their centration and the pupil width. In addition, they can cause positive dyspho-

FIGURE 2

RayOne Trifocal (courtesy of Rayner Poland).

topsias, such as halo and glare, and reduce contrast sensitivity [11, 12]. This group includes the following lenses: Mplus (Oculentis), Mplus X (Oculentis), Precizon (Ophtec BV).

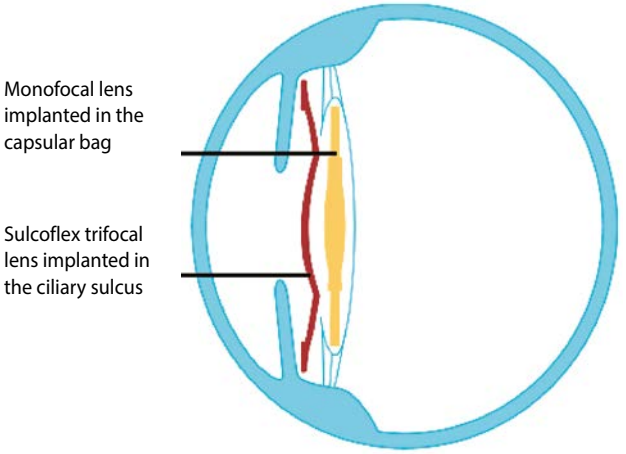
HYBRID MULTIFOCAL LENSES

Some MIOLs are hybrid lenses as they include both refractive and diffractive elements. This is intended to provide a smooth transition between successive foci. Lenses in this group include TECNIS Synergy (from Johnson & Johnson).

The optical system of MIOLs can be rotationally symmetric (all diffractive and most refractive models) or rotationally asymmetric (some refractive models). Aspheric designs also exist to reduce spherical aberrations and increase contrast sensitivity [11, 12, 17, 18]. Most multifocal lenses also come in a toric version to correct astigmatism.

FIGURE 3

Schemat umiejscowienia soczewki trójogniskowej Sulcoflex (za zgodą Rayner Polska).



EXTENDED DEPTH-OF-FOCUS (EDOF) LENSES

EDOF lenses fill the gap between monofocal and multifocal lenses as they provide very good distant and intermediate vision, but inadequate quality of near vision. They create a single elongated focal point to enhance depth of focus, which is intended to eliminate the overlapping of near and distant images caused by multifocal lenses, thus eliminating the halo effect.

In addition, EDOF lenses provide a continuous range of focus without asymmetric IOL power distribution, which helps avoid the presence of secondary out-of-focus images [19, 20]. Moreover, compared to multifocal lenses, they improve contrast sensitivity and are associated with a lower risk of positive dysphotopsias. The American Academy of Ophthalmology has developed criteria for classifying intraocular implants as EDOF.

There are many different EDOF lens technologies. Kohnen proposed to divide them into four categories: small aperture IOLs, bioanalogic IOLs, and lenses with diffractive and non-diffractive optics [21]. Many lenses classified as EDOF are actually hybrid lenses, because they combine EDOF with multifocality. For the purposes of this article, we have not included the difference between "pure" EDOF and hybrid IOL. The following lenses fall into this group: Vivity (Alcon), TECNIS Symfony (Johnson & Johnson), AT LARA (Carl Zeiss), Mini WELL Ready (SIFI Medtech), IC-8 (AcuFocus), WIOL -CF (Medicem), and TECNIS Synergy (Johnson & Johnson).

VIVITY (ALCON)

Vivity (Alcon) is a single-piece, non-diffractive, aspheric lens with an extended depth of focus. It is based on non-diffractive wavefront-shaping X-WAVE™ technology, which creates a single extended focus without splitting light (fig. 4). With these properties, the lens reduces the risk of dysphotopsia and does not compromise contrast sensitivity. Moreover, it is less sensitive to decentering than multifocal lenses. It is constructed of Acrysof's hydrophobic material, has UV and blue light filtering, as well as a defocus of 1.5 D and negative anterior surface asphericity (-0.2 µm) [22].

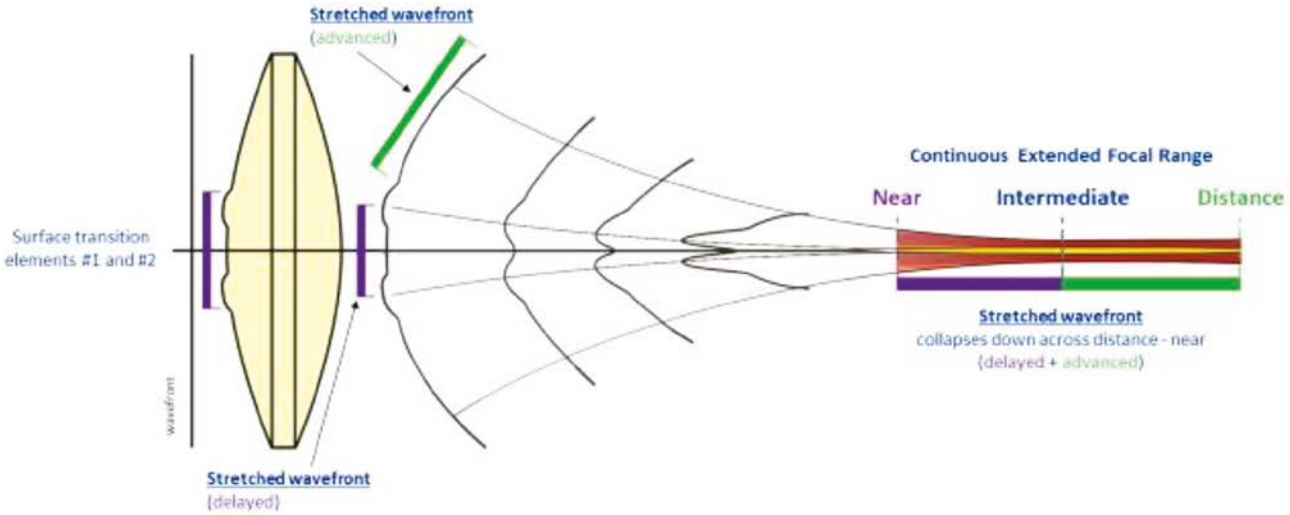
RayOne EMV is a new lens on the market that is neither EDOF nor multifocal IOL. It provides an extended depth of vision and can be classified as an enhanced monofocal lens.

RAYONE EMV (RAYNER)

Developed in collaboration with Professor Graham Barrett, it is a preloaded monofocal+/non-diffractive EDOF

FIGURE 4

EDOF Vivity non-diffractive lens based on X-WAVE technology with 2 visible zones - transition zone 1 responsible for stretching the wavefront and creating a continuous elongated focus, transition zone 2 responsible for shifting the wavefront from hyperopic to myopic to utilize all the light energy (courtesy of Alcon Poland).



hydrophilic lens that provides an extended range of vision by exploiting positive spherical aberration. The overall lens diameter is 12.5 mm and the optical diameter is 6.0 mm. The lens has an aspheric front and biconvex shape. It amplifies/compensates for the corneal natural positive spherical aberration, resulting in an increased range of visual acuity.
As it meets ISO standards for monofocal intraocular lenses, it is less dependent on variable pupil width, decentration and tilt. RayOne EMV can be used for bilateral emmetropia and is also optimized for use in a monovision system. For emmetropia, it allows for better intermediate vision than standard monovision lenses, providing approximately 1.25 D of extended visual range.
When used in a monovision system, the non-dominant eye can be set to minimovision (-0.25 to -0.75 D), micromovision (-0.75 to -1.50 D), or monovision (-1.50+ D) to provide patients with 1.50-2.00 D, 2.00-2.75 D, and 2.75+ D of extended visual acuity, respectively [23].

QUALIFYING PATIENTS FOR PREMIUM LENSES

When qualifying patients for a premium lens, one of the most important steps is the interview, which should address the patient's occupation and the distance of vision they use most often. A patient's unrealistic expectations for postoperative vision should be a reason for disqualifying them from surgery with implantation of a certain type of lens.

Patients should be informed about the IOLs available on the market and possible side effects associated with their implantation. An important part of the interview should also include a question about driving in poor light or at night, as this is one of the arguments for choosing a lens other than MIOLs. We should also take into consideration the personality of the patient requesting the procedure and their desire to become independent from spectacle correction.
With multifocal lenses, which divide the incoming light into several foci, the brain perceives several images simultaneously. Processing these images requires central neural regulation of visual stimuli, and this process is called neuroadaptation and can take several months [24]. At the same time, these lenses provide the greatest degree of independence from spectacle correction. It has been found that individuals with certain personality types (neurotic personality), who are overly structured and controlling of themselves and their environment, are more likely to experience dysphotopsias such as halo and glare [25].
Failure of neuroadaptation after MIOLs implantation can lead to patient dissatisfaction and frustration. The most reported symptoms by patients that are indications for MIOLs explantation are blurred vision, glare, and halo [26, 27]. However, patient's dissatisfaction with ametropia is far more common than the need for IOL replacement [28]. Postoperative ametropia mainly de-

pends on the accuracy of preoperative biometry and the effective lens position (ELP) [29].

The most common reasons for disqualification from multifocal lens implantation are concomitant ophthalmologic diseases and abnormalities involving the ocular optic system: retinal diseases such as AMD, diabetic retinopathy, optic nerve diseases, PEX, large κ and α angle, corneal diseases (dystrophies, ectasias, irregular astigmatism and higher order aberrations (HOAs), high refractive errors, dry eye syndrome, as well as visual impairment) [30].

Contraindications to implanting EDOF lenses are similar to those for implanting MIOLs; however, these lenses are less sensitive to the pupil width, decentration, residual postoperative refractive error, and tolerate greater κ and α angles. They represent a compromise between good intermediate and distant vision, with often inadequate near vision without spectacle correction, and a lower incidence of optical phenomena. It is possible to improve near vision with EDOF lenses by using a minimovision system. These lenses are often recommended for patients who do not need precise near vision, work primarily at intermediate distances, drive in mesopic and scotopic conditions, want to become independent of spectacle correction, or had undergone refractive surgery.

Moreover, after cataract surgery with premium IOL implantation we should always consider the prognosis for vision improvement and the cost of the procedure to the patient. Premium lenses require particularly accurate preoperative measurements to best calculate IOL power in order to achieve postoperative emmetropia. With multifocal and EDOF lenses, it is very important to correct corneal astigmatism considering the influence of posterior corneal astigmatism. In MIOLs, postoperative astigmatism should be less than 0.5 D to maintain the best possible visual acuity. EDOF lenses are less demanding in this regard, but the best possible correction of astigmatism should be sought.

CONCLUSIONS

During the Covid-19 pandemic, some patients presented to ophthalmologists with a more advanced stage of cataract which is associated with a higher-risk procedure. In addition, the pandemic may have slightly increased cataract surgery waiting time. On the other hand, procedures were performed mainly in ambulatory settings and there were no longer any limits on cataract surgery reimbursement by the Polish National Health Fund, waiting time has dramatically decreased. In recent years, there has been a significant development of IOLs. Due to the prolongation of life expectancy as well as lifestyle changes and increased professional activity of elderly people, patients more often strive to become independent from spectacle correction not only for distant, but also for near and intermediate vision.

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Marta Misiuk-Hojło: 50%; Anna Dołowiec-Kwapisz: 50%.

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None.

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Ethics:
The content presented in the article complies with the principles of the Helsinki Declaration, EU directives and harmonized requirements for biomedical journals.

IX. Omówienie publikacji wchodzących w skład pracy doktorskiej

Publikacja nr 1

W ostatnich latach obserwuje się znaczny rozwój technologii soczewek wewnątrzgałkowych. We wstępie opisano zwięźle różnice między najczęściej wszczepianymi soczewkami jednoogniskowymi, a soczewkami zaliczanymi do grupy premium – soczewkami EDOF oraz wieloogniskowymi. Przedstawiono również budowę oraz działanie soczewki niedyfrakcyjnej EDOF.

W kolejnych akapitach szczegółowo opisano metodologię badania. Cele niniejszego artykułu pokrywają się z celami pracy doktorskiej. W publikacji przedstawiono porównanie wyników pooperacyjnych w trzech grupach pacjentów, tj. w grupie badanej – z wszczepioną soczewką niedyfrakcyjną EDOF oraz w dwóch grupach kontrolnych – z wszczepionymi soczewkami jedno- i wieloogniskowymi. Ponadto porównano takie parametry jak ostrość wzroku, MRSE, IOP oraz czułość kontrastową przed zabiegiem i 6 miesięcy po zabiegu.

W dyskusji przedstawiono porównanie wyników pooperacyjnych z grupy pacjentów z wszczepioną soczewką niedyfrakcyjną EDOF z wynikami z innych opublikowanych badań. Dotychczas opublikowano niewiele prac na ten temat, dotyczyły one głównie pacjentów bez obciążeń okulistycznych. Tylko jedno z opublikowanych badań zawierało grupę pacjentów z chorobami okulistycznymi. Natomiast żadna z prac nie opisuje wyników pooperacyjnych u pacjentów po zabiegach chirurgii refrakcyjnej.

Publikacja nr 2

W artykule przedstawiono przypadek 60-letniej pacjentki po zabiegu keratotomii radialnej (RK), która zgłosiła się do okulisty z powodu pogorszenia widzenia związanego z obecnością zaćmy. Opisano szczegółowo przeprowadzoną diagnostykę przedoperacyjną, odmienności w kalkulacji wszczepu wewnątrzgałkowego i trudności śródoperacyjne w stosunku do pacjentów, którzy nie przeszli RK oraz uzyskane wyniki pooperacyjne.

Pacjenci po RK to unikalna grupa pacjentów, która stanowi wyjątkowe wyzwanie dla chirurgów zaćmy na każdym etapie zabiegu, począwszy od wyboru soczewki wewnątrzgałkowej i jej mocy, poprzez umiejscowienie cięć rogówkowych, skończywszy na wielomiesięcznej obserwacji pooperacyjnej, w trakcie której refrakcja może ulegać ciągłej zmianie. Wysokie oczekiwania pacjentów po zabiegach chirurgii refrakcyjnej, którzy chcą niezależności od okularów po operacji zaćmy, są dodatkowym wyzwaniem i nie zawsze mogą zostać spełnione.

Jest to bardzo aktualny temat, gdyż stale wzrasta liczba pacjentów z zaćmą, którzy w przeszłości przebyli zabiegi z zakresu chirurgii refrakcyjnej.

Opisany sposób kalkulacji mocy wszczepu wewnątrzgałkowego w niniejszej publikacji został użyty do liczenia mocy wszczepu u pacjentów po zabiegach RK w publikacji nr 1.

Publikacja nr 3

Ostatni z artykułów wchodzących do cyklu publikacji to artykuł przeglądowy. W pracy opisano wpływ pandemii na ilość wykonywanych zabiegów usunięcia zaćmy oraz konsekwencje jakie niesie ze sobą odroczenie zabiegu.

Ponadto przedstawiono charakterystykę soczewek premium, które są coraz częściej wybierane przez pacjentów. Są to soczewki o bardziej zaawansowanej budowie i odmiennych właściwościach optycznych od soczewek jednoogniskowych. Korygują prezbiopię, która pojawia się fizjologicznie ok. 40. r.ż. Opisano również proces kwalifikacji do wszczepienia soczewek z grupy premium.

X. Wnioski

1. Do wszczepienia soczewek niedyfrakcyjnych EDOF kwalifikuje się większość pacjentów zgłaszających się w celu usunięcia zaćmy. Profil pacjentów kwalifikujących się do zabiegu z wszczepieniem soczewek niedyfrakcyjnych EDOF jest podobny do profilu pacjentów zakwalifikowanych do wszczepienia soczewek jednoogniskowych, a szerszy niż w przypadku soczewek wieloogniskowych.

2. Ostrość widzenia do dali, odległości pośredniej oraz bliży poprawia się u pacjentów po wszczepieniu soczewki wewnątrzgałkowej niedyfrakcyjnej EDOF. Najlepszą ostrość widzenia do bliży zapewniają jednak soczewki wieloogniskowe, natomiast soczewki EDOF umożliwiają lepsze widzenie bez korekcji do bliży niż soczewki jednoogniskowe.

3. Większość pacjentów po wszczepieniu soczewek wewnątrzgałkowych niedyfrakcyjnych EDOF nie potrzebuje korekcji okularowej do dali, odległości pośredniej, a część – również do bliży. Wszczepienie soczewki EDOF zwiększa więc znacznie niezależność od korekcji okularowej w stosunku do wszczepienia soczewek jednoogniskowych, chociaż największy stopień niezależności od korekcji okularowej zapewniają soczewki wieloogniskowe.

4. Zjawiska fotooptyczne po wszczepieniu soczewek niedyfrakcyjnych EDOF występują nieznacznie częściej niż w przypadku wszczepienia soczewek jednoogniskowych, ale zdecydowanie rzadziej niż w przypadku zastosowania soczewek wieloogniskowych.

XI. Piśmiennictwo

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XII. Załączniki:

1. Zgoda Komisji Bioetycznej

KOMISJA BIOETYCZNA
przy
Uniwersytecie Medycznym
we Wrocławiu
ul. Pasteura 1; 50-367 WROCŁAW

OPINIA KOMISJI BIOETYCZNEJ Nr KB – 759/2021

Komisja Bioetyczna przy Uniwersytecie Medycznym we Wrocławiu, powołana zarządzeniem Rektora Uniwersytetu Medycznego we Wrocławiu nr 278/XVI R/2020 z dnia 21 grudnia 2020 r. oraz działająca w trybie przewidzianym rozporządzeniem Ministra Zdrowia i Opieki Społecznej z dnia 11 maja 1999 r. (Dz.U. nr 47, poz. 480) na podstawie ustawy o zawodzie lekarza z dnia 5 grudnia 1996 r. (Dz.U. nr 514 z 2020 r.) w składzie:

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dr hab. Jacek Zieliński (filozofia)

pod przewodnictwem
prof. dr hab. Jerzego Rudnickiego (chirurgia, proktologia)

Przestrzegając w działalności zasad Good Clinical Practice oraz zasad Deklaracji Helsińskiej, po zapoznaniu się z wnioskiem zgłoszonym przez **lek. Annę Dołowiec-Kwapisz,** doktoranta Uniwersytetu Medycznego we Wrocławiu do projektu badawczego pt.:

„Analiza wybranych parametrów u pacjentów po zabiegu usunięcia zaćmy z wszczepieniem soczewki wewnątrzgałkowej niedyfrakcyjnej o wydłużonej ogniskowej"

w tajnym głosowaniu postanowiła wyrazić zgodę na przeprowadzenie badania w Oddziale Okulistycznym Wielospecjalistycznego Szpitala- Samodzielnego Publicznego Zespołu Opieki Zdrowotnej w Zgorzelcu **pod warunkiem zachowania anonimowości uzyskanych danych**. Badanie będzie prowadzone pod nadzorem prof. dr hab. Marty Misiuk- Hojło.

Pouczenie: W ciągu 14 dni od otrzymania decyzji wnioskodawcy przysługuje prawo odwołania do Komisji Odwoławczej za pośrednictwem Komisji Bioetycznej UM we Wrocławiu.

Opinia powyższa dotyczy projektu badawczego będącego podstawą rozprawy doktorskiej.

Przewodniczący Komisji Bioetycznej
przy Uniwersytecie Medycznym

prof. dr hab. Jerzy Rudnicki

Wrocław, dnia 17 września 2021 r.

KOMISJA BIOETYCZNA
przy
Uniwersytecie Medycznym
we Wrocławiu
ul. Pasteura 1; 50-367 WROCŁAW

OPINIA KOMISJI BIOETYCZNEJ Nr KB – 833/2021

Komisja Bioetyczna przy Uniwersytecie Medycznym we Wrocławiu, powołana zarządzeniem Rektora Uniwersytetu Medycznego we Wrocławiu nr 278/XVI R/2020 z dnia 21 grudnia 2020 r. oraz działająca w trybie przewidzianym rozporządzeniem Ministra Zdrowia i Opieki Społecznej z dnia 11 maja 1999 r. (Dz.U. nr 47, poz. 480) na podstawie ustawy o zawodzie lekarza z dnia 5 grudnia 1996 r. (Dz.U. nr 514 z 2020 r.) w składzie:

dr Joanna Birecka (psychiatria)

dr Beata Freier (onkologia)

dr hab. Tomasz Fuchs (ginekologia, położnictwo)

prof. dr hab. Dariusz Janczak (chirurgia naczyniowa, transplantologia)

dr hab. Krzysztof Kaliszewski (chirurgia endokrynologiczna)

dr prawa Andrzej Malicki (prawo)

dr hab. Marcin Mączyński, prof. UMW (farmacja)

Urszula Olechowska (pielęgniarstwo)

prof. dr hab. Leszek Szenborn (pediatria, choroby zakaźne)

prof. dr hab. Andrzej Szuba (choroby wewnętrzne, angiologia

ks. prof. Andrzej Tomko (duchowny)

prof. dr hab. Mieszko Więckiewicz (stomatologia)

dr hab. Andrzej Wojnar, prof. nadzw. (histopatologia, dermatologia) przedstawiciel Dolnośląskiej Izby Lekarskiej)

dr hab. Jacek Zieliński (filozofia)

pod przewodnictwem
prof. dr hab. Jerzego Rudnickiego (chirurgia, proktologia)

Przestrzegając w działalności zasad Good Clinical Practice oraz zasad Deklaracji Helsińskiej, po zapoznaniu się z wnioskiem zgłoszonym przez **lek. Annę Dołowiec-Kwapisz,** doktoranta Uniwersytetu Medycznego we Wrocławiu, w tajnym głosowaniu postanowiła wyrazić zgodę na zmianę tytułu badania z:

„Analiza wybranych parametrów u pacjentów po zabiegu usunięcia zaćmy z wszczepieniem soczewki wewnątrzgałkowej niedyfrakcyjnej o wydłużonej ogniskowej"
na:
„Ocena porównawcza kwalifikacji i wyników pooperacyjnych u pacjentów z wszczepioną soczewką niedyfrakcyjną o wydłużonej ogniskowej z innymi soczewkami wewnątrzgałkowymi"

pod **warunkiem zachowania anonimowości uzyskanych danych**.
Badanie będzie prowadzone pod nadzorem prof. dr hab. Marty Misiuk- Hojło.

Projekt uzyskał zgodę Komisji Bioetycznej nr 759/2021.

Pouczenie: W ciągu 14 dni od otrzymania decyzji wnioskodawcy przysługuje prawo odwołania do Komisji Odwoławczej za pośrednictwem Komisji Bioetycznej UM we Wrocławiu.

Opinia powyższa dotyczy projektu badawczego będącego podstawą rozprawy doktorskiej.

Przewodniczący Komisji Bioetycznej
przy Uniwersytecie Medycznym

prof. dr hab. Jerzy Rudnicki

Wrocław, dnia 14 października 2021 r.

2. Oświadczenia współautorów

lek. Anna Dołowiec-Kwapisz

Oddział Okulistyczny

WS-SPZOZ w Zgorzelcu

Zgorzelec, 10.09.2022

OŚWIADCZENIE

Oświadczam, że w pracy: Dołowiec-Kwapisz, A.; Piotrowska, H.; Misiuk-Hojło, M. Evaluation of Visual and Patient—Reported Outcomes, Spectacle Dependence after Bilateral Implantation with a Non-Diffractive Extended Depth of Focus Intraocular Lens Compared to Other Intraocular Lenses. J. Clin. Med. 2022, 11, 5246. https://doi.org/10.3390/jcm11175246, mój udział polegał na konceptualizacji, zaplanowaniu metodologii badania, zbieraniu danych, przeprowadzaniu badania, przygotowaniu pierwotnej wersji manuskryptu, nadzorowaniu procesów recenzji i nanoszeniu odpowiednich poprawęk.

Oświadczam, że w pracy: Dołowiec-Kwapisz, A.; Misiuk-Hojło, M.; Piotrowska, H. Cataract Surgery after Radial Keratotomy with Non-Diffractive Extended Depth of Focus Lens Implantation. Medicina 2022, 58, 689. https://doi.org/10.3390/medicina58050689, mój udział polegał na konceptualizacji, zbieraniu danych, przeprowadzaniu badania, przygotowaniu pierwotnej wersji manuskryptu, nadzorowaniu procesów recenzji i nanoszeniu odpowiednich poprawek.

Oświadczam, że w pracy: Misiuk-Hojło , M.; Dołowiec-Kwapisz., A. Patient With Cataract – Observations After 2 Years of the Pandemic and Future Prospects. OphthaTherapy. Therapies in Ophthalmology 2022, 9 (2), 134-41. https://doi.org/10.24292/01.OT.110522, mój udział polegał na przygotowaniu manuskryptu, przeglądaniu piśmiennictwa, nadzorowaniu procesów recenzji i nanoszeniu odpowiednich poprawek.

Anna Dołowiec-Kwapisz

Anna Dołowiec-Kwapisz
lekarz
2968712

prof. dr hab. Marta Misiuk-Hojło

Katedra i Klinika Okulistyki

Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu

Wrocław, 10.09.2022

OŚWIADCZENIE

Oświadczam, że w pracy: Dołowiec-Kwapisz, A.; Piotrowska, H.; Misiuk-Hojło, M. Evaluation of Visual and Patient—Reported Outcomes, Spectacle Dependence after Bilateral Implantation with a Non-Diffractive Extended Depth of Focus Intraocular Lens Compared to Other Intraocular Lenses. J. Clin. Med. 2022, 11, 5246. https://doi.org/10.3390/jcm11175246, mój udział polegał na zaplanowaniu metodologii badania, opracowaniu wersji ostatecznej artykułu i nadzorze merytorycznym pracy.

Oświadczam, że w pracy: Dołowiec-Kwapisz, A.; Misiuk-Hojło, M.; Piotrowska, H. Cataract Surgery after Radial Keratotomy with Non-Diffractive Extended Depth of Focus Lens Implantation. Medicina 2022, 58, 689. https://doi.org/10.3390/medicina58050689, mój udział polegał na opracowaniu ostatecznej wersji artykułu i nadzorze merytorycznym pracy.

Oświadczam, że w pracy: Misiuk-Hojło , M.; Dołowiec-Kwapisz , A. Patient With Cataract – Observations After 2 Years of the Pandemic and Future Prospects. Ophthatherapy 2022, 9, 134-141. https://doi.org/10.24292/01. OT.110522, mój udział polegał na opracowaniu ostatecznej wersji artykułu, przeglądzie przygotowanego artykułu pod kątem istotnej zawartości intelektualnej.

Jednocześnie wyrażam zgodę na włączenie przez lek. Annę Dołowiec-Kwapisz w/w publikacji w postępowaniu o nadanie stopnia doktora w dziedzinie nauk medycznych i nauk o zdrowiu w dyscyplinie nauki medyczne.

Uniwersytet Medyczny we Wrocławiu
KATEDRA I KLINIKA OKULISTYKI
kierownik
prof. dr hab. Marta Misiuk-Hojło

lek. Halina Piotrowska

Oddział Okulistyczny

WS-SPZOZ w Zgorzelcu

Zgorzelec, 10.09.2022

OŚWIADCZENIE

Oświadczam, że w pracy: Dołowiec-Kwapisz, A.; Piotrowska, H.; Misiuk-Hojło, M. Evaluation of Visual and Patient—Reported Outcomes, Spectacle Dependence after Bilateral Implantation with a Non-Diffractive Extended Depth of Focus Intraocular Lens Compared to Other Intraocular Lenses. J. Clin. Med. 2022, 11, 5246. https://doi.org/10.3390/jcm11175246, mój udział polegał na przeprowadzaniu badania okulistycznego, zaplanowaniu metodologii badania oraz opracowaniu ostatecznej wersji artykułu.

Oświadczam, że w pracy: Dołowiec-Kwapisz, A.; Misiuk-Hojło, M.; Piotrowska, H. Cataract Surgery after Radial Keratotomy with Non-Diffractive Extended Depth of Focus Lens Implantation. Medicina 2022, 58, 689. https://doi.org/10.3390/medicina58050689, mój udział polegał na przeprowadzaniu badania okulistycznego i zbieraniu danych oraz opracowaniu ostatecznej wersji artykułu.

Jednocześnie wyrażam zgodę na włączenie przez lek. Annę Dołowiec-Kwapisz w/w publikacji w postępowaniu o nadanie stopnia doktora w dziedzinie nauk medycznych i nauk o zdrowiu w dyscyplinie nauki medyczne.

Halina Piotrowska
specjalista chorób oczu
LG 7479490