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In-vitro assessment of a novel intraocular lens made of crosslinked polyisobutylene

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ABSTRACT

Purpose: To describe and analyse the particularities of the material and the optical quality of the first intraocular lens (IOL) (Eyedeal® lens) made of crosslinked polyisobutylene (xPIB).
Methods: We assessed the material quality using an accelerated ageing process (to provoke glistenings) and compared values with a control, AcrySof® lens. Using the sessile drop method, the contact angle of the new IOL was measured. Images of the lens surface were recorded by scanning electron microscopy (SEM). Optical quality was assessed by measuring the labeled power and modulation transfer function (MTF) using standard metrology equipment (OptiSpheric IOL PRO2).
Results: The Eyedeal® lens had an average glistening density result of 7.46 ± 3.78 MV/mm^2 compared to the control AcrySof® whose glistenings number was 142.42 ± 72.47 MV/mm^2. The contact angle was 97.2° whereas the angle of AcrySof material is between $73.3 \pm 2.4°$ and $84.4 \pm 0.1°$. Using SEM, Eyedeal® lenses were examined and all appeared to be comparable to modern IOLs made of acrylic materials. The power and MTF values were normal and conformed to ISO standards.
Conclusions: In the laboratory, the new Eyedeal® lens showed equivalence to current hydrophobic- or hydrophilic-acrylic lens models. It showed superiority in its glistening density result compared to the control lens.

1. Introduction

Since the first lens crystalline replacement on November 29, 1949, performed by Sir Harold Ridley, (Apple, 2000, 2006) there have been many significant advances made to intraocular lenses (IOLs). Ridley's IOL, made by Rayner, was composed of rigid plastic - namely, polymethyl methacrylate (PMMA). Other materials have been used in IOLs later, such as silicone, hydrogel, and acrylate (Apple, 2000, 2006; Pérez-Vives, 2018). Acrylate-based IOL materials are currently dominating the market as they offer several advantages over previous materials, such as flexibility that allows micro incisions or good optical and chemical properties that have remained stable for years in patient's eyes.

Based on these findings, a material was recently used/introduced in IOL research for the first time that seems to be up to all these challenges: a crosslinked polyisobutylene (xPIB) derivative (Pinchuck, 2022). The origins of polyisobutylene (PIB) research go back to the American researcher Dr. Joseph P. Kennedy at Akron University (Kennedy et al., 1990). Later, the group around Dr. Leonard Pinchuck at Corvita Corporation developed mechanisms to generate/establish xPIB-based materials for implantable applications. (Pinchuk, 1998, 2000) good optical and chemical properties that have remained stable for years.

Recently, a monofocal IOL made of xPIB was developed by Xi'an Eyedeal Medical Technology Co., Ltd. under the name Eyedeal® Lens (Pinchuk, 2022). The Eyedeal® lens is a single-piece, aspheric, monofocal IOL (Fig. 1).

Abbreviations: IOL, Intraocular lens; xPIB, Corsslinked Polyisobutylene; MV, Microvacuole; SD, Standard Deviation; SEM, Scanning Electron Microscopy; MTF, Modulation Transfer Function.

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1.1. Properties of the IOL material

As with established IOLs, this new IOL has UV protection built into the material, which is a frequently used and well-proven UV-absorber, UV-13, a benzotriazole derivative. The absorber is crosslinked into the polyisobutylene matrix and this creates a UV wavelength cut-off at 400 nm.

To make sure to have a flexible polymer with low glass-transition temperature (T_g), high Abbe number and refractive index (n_D) the material parameters have to be chosen carefully for the material challenges for IOL polymers.

As shown in Table 1, the new Eyedeal® lens material is compared with the conventional Alcon AcrySof® material (Alcon, Fort Worth, Texas, USA). The IOL made of AcrySof® material is widely available – has FDA approval, CE mark and approvals from other regulatory authorities around the world.

In comparison to the AcrySof® material the Eyedeal® lens material does not contain ester groups: i.e. there are no labile linkages on the side chains, which are more polar than the backbone. The absence of polar groups in the material shows an n_D of 1.52 in comparison to 1.55 for AcrySof® material. The difference in n_D is small as quaternary carbon atoms (21.4% for Eyedeal® material; one of the highest percentages of any organic polymer) seem to increase the n_D and the Abbe number (Pinchuck, 2022).

1.2. Peculiarities of the Eyedeal® lens material

The Eyedeal® lens material is a polymer based on crosslinked polyisobutylene (xPIB) (**A**), wich is made of crosslinkable PIB (**B**) (Fig. 2a.)).

During the last step of the synthesis of xPIB (**A**), a thermal [4 + 4] cycloaddition, heat is the only additional reactant of the highly atom economic reaction (Trost, 1991), no further chemicals which might cause impurities in the final polymer **A** are used for the reaction (Fig. 2b.)).

The final polymer **A** has an aliphatic backbone and is 3-D crosslinked via an aromatic/non-aromatic bridge/structure, i.e. it is a carbohydride which contains only carbon and hydrogen atoms in its structure $[C_{36}H_{52}]_n$. **A** is an inert product which does not contain oxygen atoms and (thus) cleavable groups that can dissociate over time and which do not cause adverse reactions in adjacent tissue or detrimentally affect the clarity of the optic by crazing, hazing or glistening. Another advantage of the PIB structure are the alternating quaternary carbon atoms (due to the two methyl groups) and the secondary carbon atoms at the backbone of the polymer which avoid oxidations to double bonds. It is known that conjugated double bonds on the backbone of polymers can lead to degradation (Pinchuck, 2022).

2. Material and methods

2.1. Accelerated ageing/glistening formation

We compared the new lens with the Alcon AcrySof® IOL. The AcrySof® lenses were all manufactured in 2018 and all had a labeled expiry date of 2023-09-30. Glistening induction, as well as image acquisition and analysis were performed according to a well-established protocol for accelerated IOL aging which has been described in several previous publications from our laboratory (Łabuz et al., 2018a; Yildirim et al., 2020; Weindler et al., 2019) and one that is originally based on the methodology described by Thomes & Callaghan (Thomes and Callaghan, 2013).

Five IOLs of each of the two models were transferred to glass vials containing 20 ml of 0.9% Sodium Chloride solution (B. Braun, Melsungen, Germany). These vials were maintained in a water bath at 45 °C ± 1 °C for 24 h. The temperature was reduced to 37 °C ± 1 °C for 2.5 h -before placing each IOL on a heated microscope stage at 37 °C, and an optical microscope, EMZ-8TR Trinocular Zoom Stereo Microscope (Meiji Techno, Saitama, Japan) fitted with an Infinity-2CB digital camera (Lumera, Nepean, Canada) was used to obtain photographic images of each lens. A 14-fold magnification was selected to center the IOL on a grid, before a photograph of the central IOL optic was taken in 90-fold magnification. The ImageJ (1.49v) software was used to obtain the glistening number using the same parameters as described previously in detail (Łabuz et al., 2018a; Yildirim et al., 2020). The number of glistenings was given in mean microvacuoles per square millimeter (±SD) and compared to the modified clinical (Miyata) glistening grading system, with grade 0 (<50 MVs/mm^2), grade 1 (50–100 MVs/mm^2), grade 2 (100–200 MVs/mm^2) and grade 3 (>200 MVs/mm^2) (Miyata et al., 1997).

2.2. Contact angle measurement

Contact angle was measured three times on a contact angle goniometer (Dataphysics OCA35, Filderstadt Germany) using the sessile drop configuration. A droplet of 15–25 μl was deposited using an automated Hamilton syringe. For measurement of the advancing contact angle the droplet was inflated at a rate of 1 μl/s during the measurement. Contact angle was fitted considering the curvature of the lens. The receding contact angle could not be measured because of pinning, therefore the drop lost contact to the needle during aspiration (1 μl/s). From this instant an upper limit of 30° for the receding contact angle can be estimated.

2.3. Scanning electron microscopy (SEM) analysis

The SEM imaging was performed on additional four samples of the Eyedeal® IOL. Four images of each lens of randomly-chosen sample areas of 1. The optic, 2. The Haptic, 3. The optic edge and 4. The Haptic-optic junction.

The lenses were removed from their packaging and immediately placed on an SEM holder. The IOLs' surfaces were evaluated with a Hitachi SU8000 microscope (Japan). SEM was performed in a low kV at 700V acceleration voltage, and the focus was set at approx. 14 mm in order to use the signal of a lower detector (Everhardt-Thornley Detector). The IOLs were examined on both anterior and posterior surfaces with x30 to ×300 magnification.

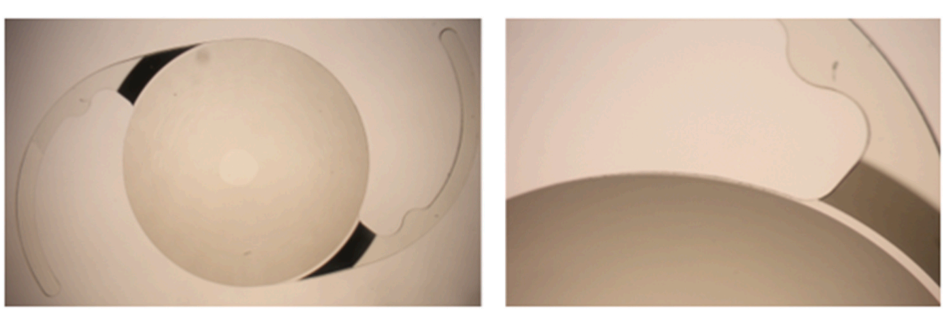
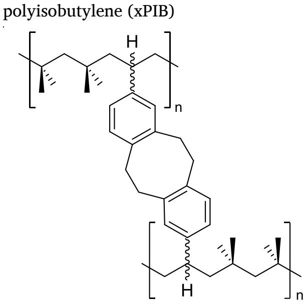
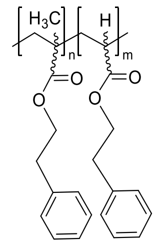


Fig. 1. Photograph of the Eyedeal® lens. (The black stripes are artifacts that occurred when taking photos.)

Table 1
Chemical and physical properties and parameters of Eyedeal® and AcrySof® material.

Properties/parameter	Eyedeal®	AcrySof®
Chemical composition	crosslinked polyisobutylene (xPIB)	crosslinked phenylethylmethacrylate (PEMA) and phenylethylacrylate (PEA)
Structure[a]		
Heteroatoms	none	oxygen
Polarity	unpolar no polar groups	unpolar contains polar groups
n_D	1.52	1.55
Abbe number	50	37
T_g	−62.3 °C	14–16 °C
Water content	0.05%	0.1–0.5%

[a] We do not have a clearly clarified stereochemistry for these structures, so we had to resort to the wavy lines to accurately represent the structure.

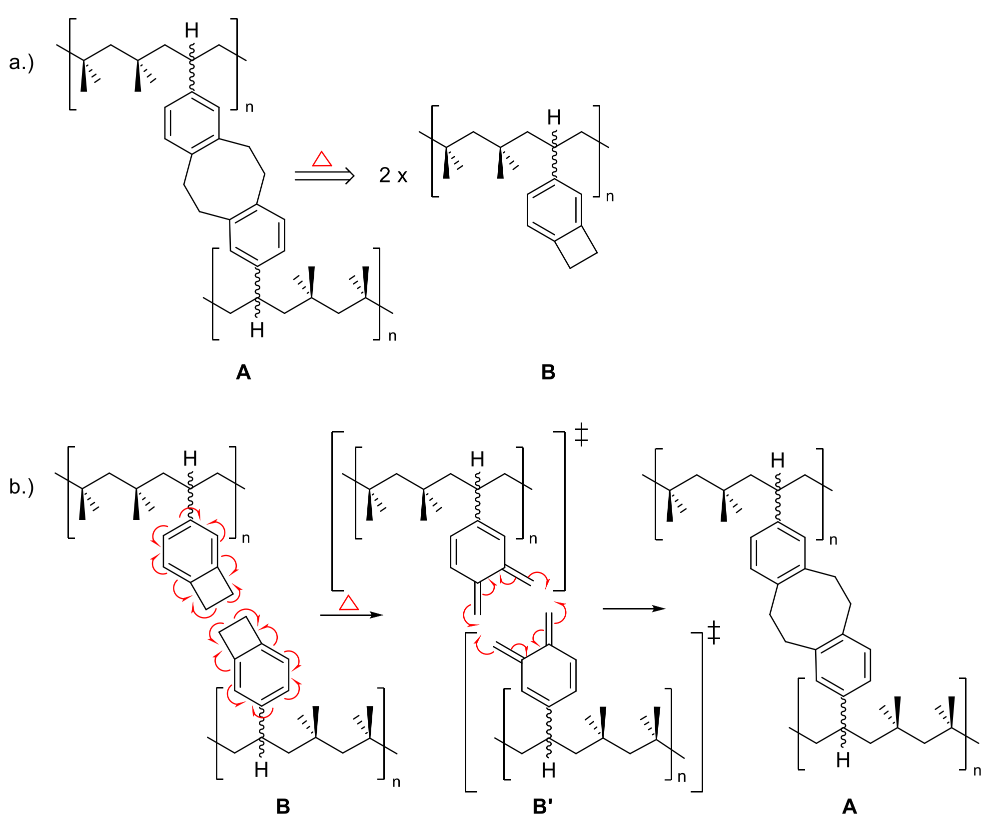


Fig. 2. Synthesis of xPIB. a.) Retrosynthesis of xPIB (**A**) made of crosslinkable PIB (**B**); b.) Mechanism of the thermal [4 + 4] cycloaddition reaction. The red arrows show the electron migration to cleave and build up double- and single-bonds. **B**′ is the unstable transition state of the reaction which converts in the thermodynamic more stable product **A**.

2.4. Optical metrology

The optical quality and manufacturing reliability was assessed by measuring the nominal power and the modulation transfer function (MTF) of five +20D Eyedeal® lens. The MTF is an internationally recognized standard for testing IOLs' optical performance (Łabuz et al., 2018b; Bass et al., 2009; ISO-11979-2. Part 2, 2014; Boreman, 2001; Lee et al., 2020; Thibos et al., 2004).

The laboratory's OptiSpheric IOL PRO2 (Trioptics GmbH, Germany) was used, which has been described in detail in our earlier publications (Son et al., 2020; Łabuz et al., 2018b; Lee et al., 2020). Measurements were carried out in accordance with the ISO 11979 standard (ISO-11979-2. Part 2, 2014). An IOL was placed on a lens holder and submerged in a balanced salt solution with a refractive index of 1.336 at room temperature. First, the nominal power was derived from the effective focal length (EFL) measurements in monochromatic (546 nm) light and using the magnification method. The assessment was performed without a model cornea and through a 3 mm aperture. Given that the nominal power of the Eyedeal® IOLs measured at room temperature changes substantially compared to that under 35°, the correction was applied. A value of 0.47D was used, which was calculated using the refractive index data provided by the manufacturer.

Secondly, the optical performance was objectively assessed through the MTF measured in 546 nm light at 3- and 4.5 mm apertures. An aberration-neutral model cornea was used. The MTF was presented graphically and compared at a single frequency of 100lp/mm, which corresponds to the visual acuity of 20/20. Furthermore, the MTF Strehl Ratio was calculated as the area under the MTF curve normalized by the area under a diffraction-limited MTF calculated up to 100lp/mm.

Measurements were performed with at least two repetitions and averaged. MTF data were analyzed with custom-made software (Matlab, Mathworks, USA).

3. Results

Based on this information, we established an Eyedeal®/AcrySof® comparison study in terms of material properties. The study focused on the hydrophobic material quality (the presence of glistenings and contact angle measurement), the surface finish (examined by Scanning Electron Microscopy (SEM)) and the optical quality (via Modulation Transfer Function (MTF)) of the new lens.

3.1. Hydrophobic material quality

a.) Glistenings

As the new xPIB material is known for a thermal cycloaddition as polymerization, i.e. without any additional reactants in the last step of the synthesis, there are no impurities in the final polymer which might swell differently in an aqueous surrounding or separates into different immiscible domains caused by thermal stress to cause water-filled vacuoles (glistenings) in the polymer (Kato et al., 2001; Thomas and Muniandy, 1987). Furthermore, the xPIB material does not contain polar groups, like esters, which increase the polarity of the polymer and might increase the absorbance of water. Esters have the ability to bond water molecules via hydrogen bondings due to their inherent polarity or can even be cleaved to the corresponding acid and alcohol by hydrolysis (Fig. 3).

In the analysis of the new hydrophobic IOL material, for accelerated ageing or known as microvacuoles/glistenings, (Thomes and Callaghan, 2013; Łabuz et al., 2018a; Yildirim et al., 2020) stereomicroscope images of all IOLs were taken at 37 °C, immediately after incubation of the IOLs in aqueous NaCl-solution at high temperature (45 °C) and the images underwent analysis with ImageJ software for calculation of microvacuoles per square millimeter within the lens (MV/mm^2) (Fig. 4).

Subsequently, values were converted to microvacuoles/mm^2 and the severity of the glistenings was tabulated according to the Miyata Scale[14] (Fig. 5, Table 2).

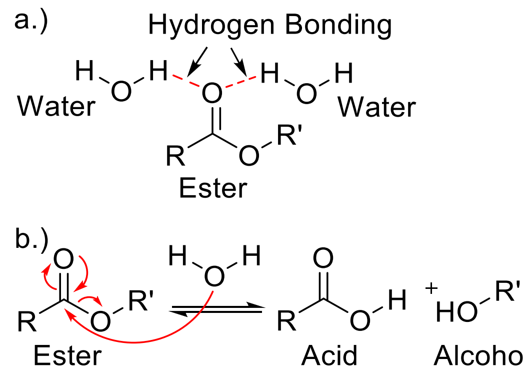


Fig. 3. Esters in the presence of water. a.) The oxygen atom at the carbonyl group binds water via hydrogen bonding; b.) Hydrolysis: Esters dissociate in the presence of water to the corresponding acid and alcohol.

b.) Contact angle measurements

A parameter for surface characterization is the contact angle that is formed between the optic surface, air and water. It describes the physicochemical properties of intraocular lenses. The hydrophobicity has, among other things, an influence on the bacterial colonization and the associated risk of contracting endophthalmitis. Alava et al. (2005) postulate that bacterial colonization decreases with increasing hydrophobicity.

The xPIB material of the Eyedeal® IOL is known to be hydrophobic and the contact angle measurement was performed by a dataphysics goniometer.

The two contact angles “advancing” and “receding” were recorded (Fig. 6). Droplet is inflated and sucked from a needle onto/from the Eyedeal® lens. The circle is fitted to the baseline to evaluate the advancing contact angle.

Averaging between 15 and 25 s leads to an advancing contact angle of 97.2°.

However, here when sucking water back into the needle the droplet pins to the lens, i.e. the receding contact angle is very low, the needle will detach from droplet before the last water is sucked in, so the receding contact angle could not be measured but it is very small.

The Eyedeal® lenses are hydrophobic with a contact angle of almost 100°.

However, the lenses show clear "pinning", i.e. the wetting limit line does not retract when the drop is removed with the cannula.

In comparison, the AcrySof® material shows a contact angle of 73.3 ± 2.4° (Dick et al., 2001) to 84.4 ± 0.1° (Jung et al., 2017).

3.2. Surface finish

Shown by scanning electron microscopy (SEM) the optic center of the Eyedeal® IOLs was smooth and clearly finished in all cases (Fig. 7). The SEM imaging, however, revealed small filament-like residues at the lens periphery and the haptics.

3.3. Optical metrology

a.) Nominal power

Table 3 shows the corrected nominal power measured in the studied IOLs.

b.) MTF measurements

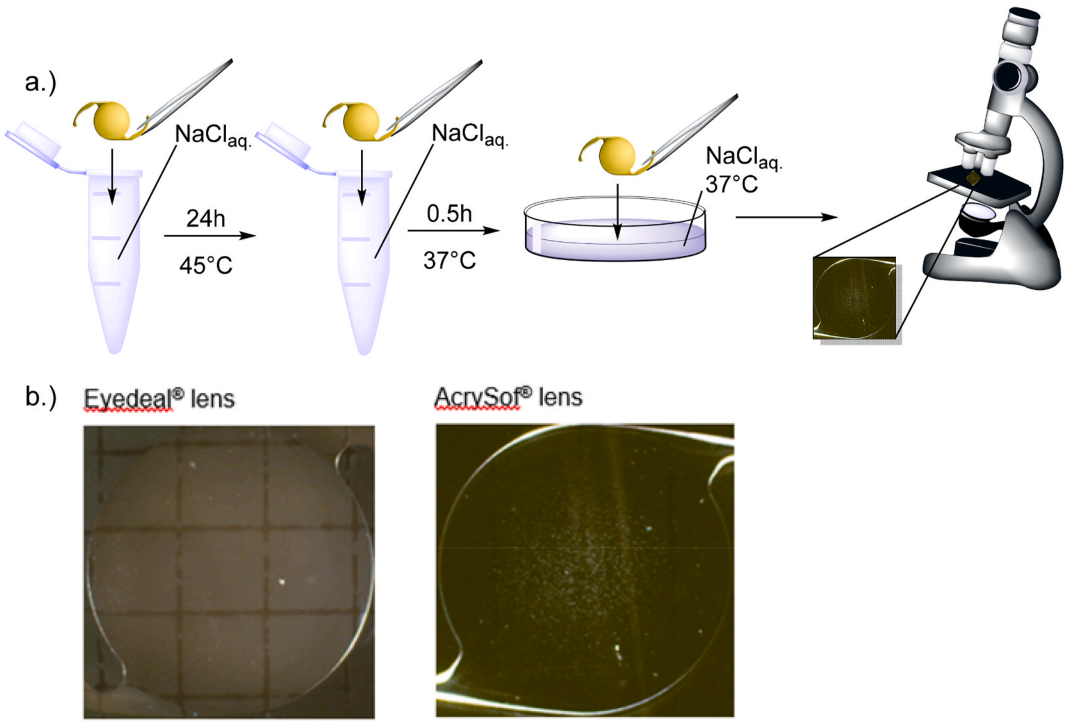


Fig. 4. Gistenings study. a.) Schematic flow of glistenings generation and analysis. b.) Microscopic images of an average Eyedeal® IOL (#3) respectively AcrySof® IOL (#1) after glistening induction with a 14× magnification.

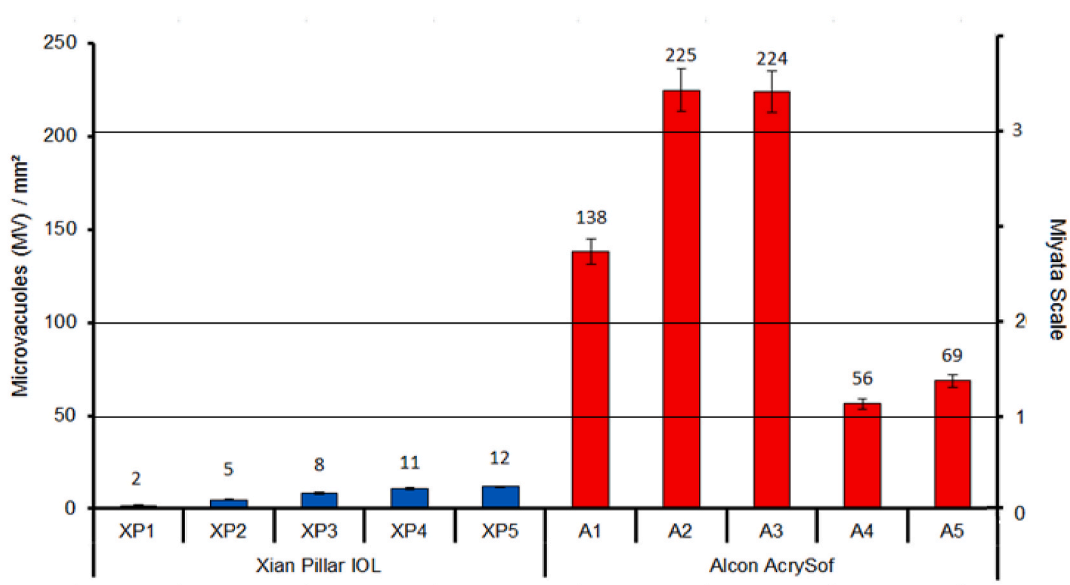


Fig. 5. Results. Glistenings measured in units of microvacuoles/mm^2 for each IOL charted against the Miyata Scale.

Table 2
Average values and standard deviation of the two IOL models.

	Eyedeal®	AcrySof®
Average MV	7	142
SD	±4	±72

Fig. 8 shows the MTF curves of the five IOLs measured at the 3- and 4.5-mm apertures.

Table 4 summarizes the discrete-value MTF and Strehl ratio results of the studied IOL for both apertures.

4. Discussion

A new IOL material must be at least as good as a conventional lens material. The most important requirements for the new hydrophobic lens material would be the material quality in terms of glistenings, its physical-chemical properties in terms of contact angle measurements, the optical properties in terms of power and MTF, the surface quality, the manageability for the surgeon and of course the compatibility in the eye. Since this paper would like to focus on the new material/the new IOL and its properties, only material quality, the surface finish and the optical properties are described here.

The Eyedeal® IOL is made of a polymer that is new in intraocular

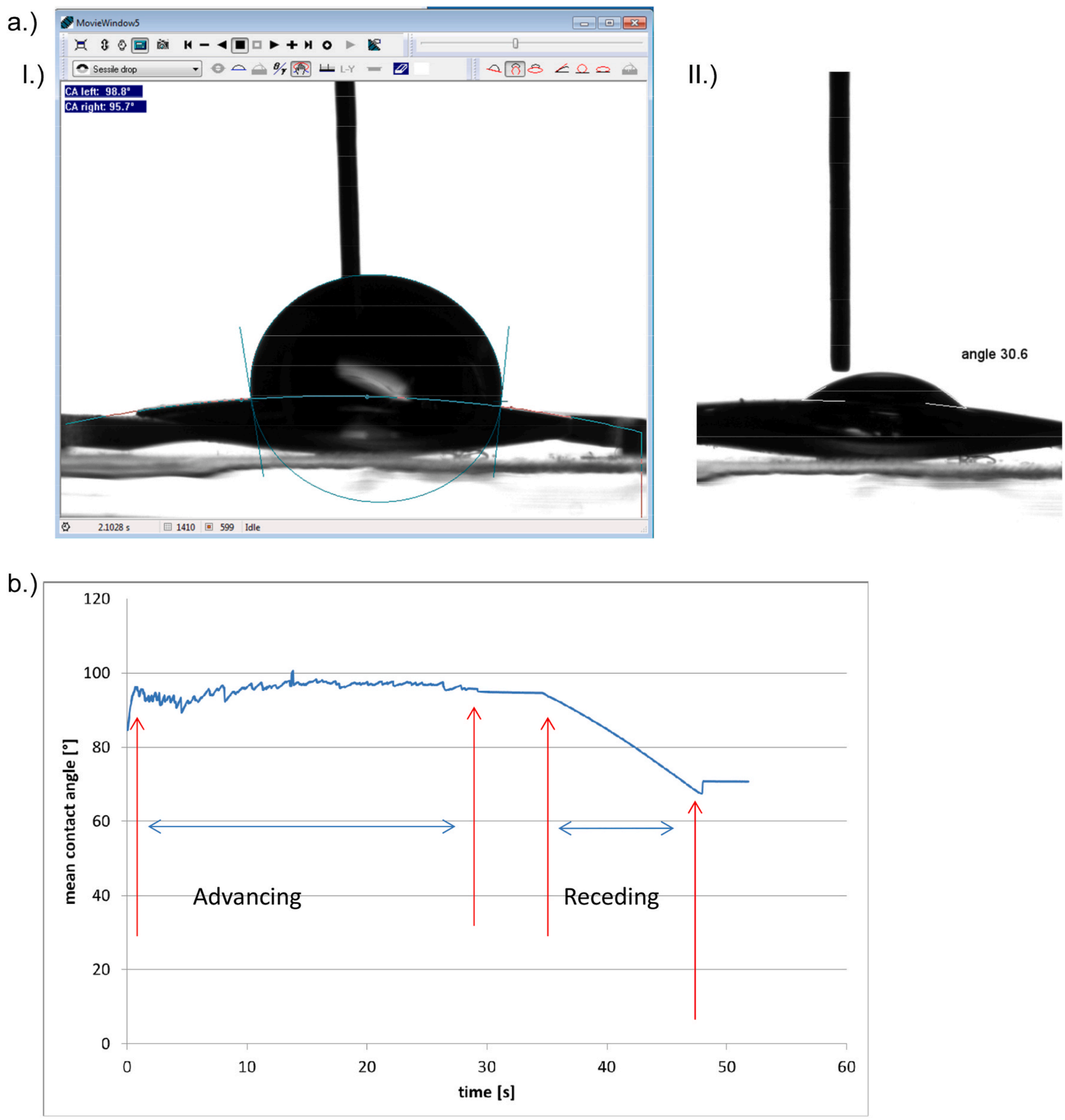


Fig. 6. Contact angle measurement. a.) I.) The advancing contact angle. II.) The receding contact angle. b.) The droplet is placed, inflated (=advancing) and then suck up again (=receding). Here shown in timeseries. Mean = average of left and right side contact angle of the droplet.

lens technology: a crosslinked polyisobutylene (xPIB) which has been used in other medical applications including glaucoma devices (Pinchuk et al., 2016, 2017, 2018) but this is the first time in IOLs (Pinchuck, 2022). It is as far as we know, the first non-acrylate IOL since silicone elastomer was introduced as an IOL material, on a small scale in the 1960s by Edward Epstein and later on a larger, commercially successful scale in the 1980s.

Glistenings are fluid-filled microvacuoles that form within the matrix of the IOL when it is exposed to an aqueous environment (Thomes and Callaghan, 2013). They have mostly been reported in hydrophobic acrylic IOLs (Miyata et al., 2000; Miyata and Yaguchi, 2004; Weindler et al., 2019).

In 2013, Thomes & Callaghan reported on the continuous manufacturing process improvements in the AcrySof® polymer with respect to reducing the incidence of glistening formation in the optic of these lenses by comparing lenses manufactured in 2003 with lenses manufactured in 2012 (Thomes and Callaghan, 2013). Their results showed that AcrySof® IOLs manufactured in 2012 demonstrated a significant reduction in glistening density (87% reduction in mean density) compared with IOLs manufactured in 2003.

What is clear from the present study is that the Eyedeal® is superior in terms of glistenings density when compared with the glistening density results for the AcrySof® lenses. It should also be emphasized that the test conditions represent a kind of worst-case scenario and the clinical situation will never be able to live up to that level. Essentially an average glistenings number of below 10–20 mv/mm^2 is considered zero on the clinical Miyata scale and will not produce significant visible glistenings on slit lamp examination. The Eyedeal® single-piece hydrophobic aspheric IOL accounted for 7 ± 4 MV/mm^2, which was considered “glistening free”. The AcrySof® SN60WF hydrophobic IOL accounted for 142 ± 72 MV/mm^2. In comparison with the competitor model the Eyedeal® lens is superior.

Our study did not attempt to simulate temperature fluctuations in the human eye. Although glistening formation induced in vitro by alterations of temperature can produce morphological aspects that in general appear exaggerated in comparison to the clinical situation (Thomes and Callaghan, 2013; Son et al., 2020), nevertheless in vitro studies are considered appropriate models to predict the clinical outcome (Łabuz

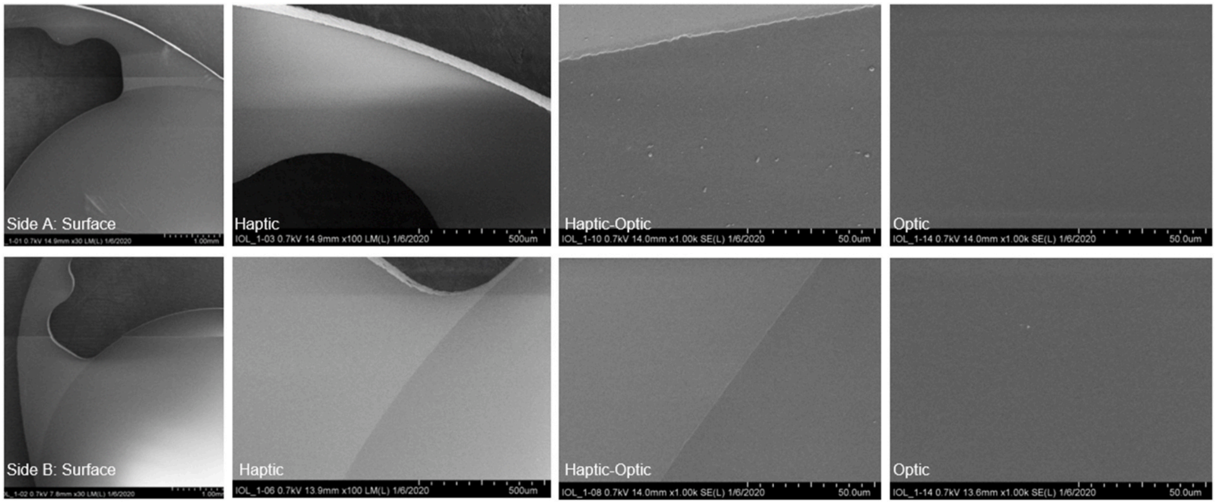


Fig. 7. SEM images of the Eyedeal® IOL.

Table 3
The refractive power of the studied Eyedeal® lenses. L = lens, D = diopters, SD = standard deviation.

Power [D]	L1	L2	L3	L4	L5	Average
Mean	20.055	20.019	19.987	20.01	20.000	20.004
SD	0.001	0.012	0.002	0.004	0.001	0.03

et al., 2018b). It is uncertain that glistenings produced with in vitro methods arise due to the same mechanism or are of the same kind as glistenings in lenses in clinical observation. The rate of the temperature fluctuation seems to have a significant effect on the extent of glistening formation. Although in vitro analysis might provide an assessment of the tendency of a material to form glistenings, the correlation between in vitro test results and in vivo observations remains requires further investigation.

The contact angle is a parameter for surface characterization. It describes the physicochemical properties i.e. the hydrophobicity of the IOL. With a contact angle of 97.2° the Eyedeal® lenses show an increased hydrophobicity compared to AcrySof® material which shows a contact angle of 73.3 ± 2.4° (Dick et al., 2001) to 84.4 ± 0.1° (Jung et al., 2017). As the Eyedeal® lens material does not have any oxygen atoms in its structure, unlike the AcrySof® material, i.e. it is very unpolar, the water molecules cannot be attracted by partial electric charges (Tetz and Jorgensen, 2015) or even hydrogen bonds. Due to the higher hydrophobicity of the Eyedeal® lens material the lens might have the lower risk of bacterial colonization according to Alava et al. (2005).

Using SEM, the Eyedeal® lenses were examined in the optic and haptic area; all appeared to be comparable to modern IOLs made of acrylic materials. The observed residues of filament-like structure resemble in their appearance polymer fibers, which may form during a melt or solution spinning of a thermoplastic polymer.

The manufacturer contends that xPIB's relatively high refractive index (1.512 at 35 °C) and high Abbe number (50), are considered suitable for IOL optic design. The elastomer it has a low Young's

Table 4
Modulation transfer function (MTF) values of the analyzed lenses measured at 100 lp/mm and the Strehl ratio.

	L1	L2	L3	L4	L5	Average
	Pupil = 3 mm					
Strehl ratio	0.97	0.97	0.97	0.95	0.93	0.96 ± 0.02
MTF@100 lp/mm	0.63	0.63	0.63	0.60	0.57	0.61 ± 0.03
	Pupil = 4.5 mm					
Strehl ratio	0.88	0.88	0.90	0.90	0.83	0.88 ± 0.03
MTF@100 lp/mm	0.60	0.60	0.63	0.65	0.52	0.60 ± 0.05

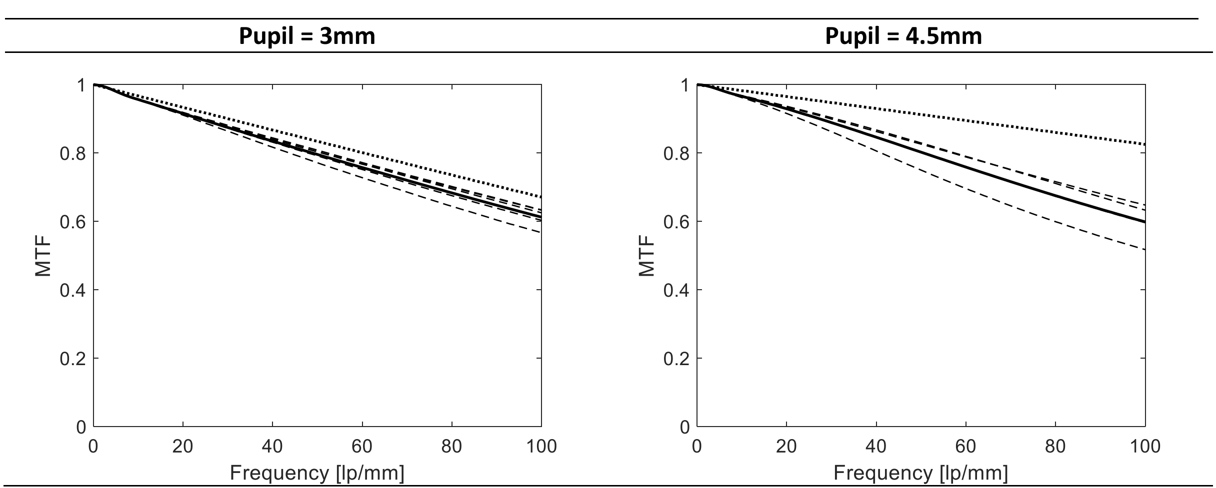


Fig. 8. The modulation transfer function (MTF) of the Eyedeal® IOLs measured at a 3- and 4.5-mm pupil. The dashed line shows the results of individual IOLs; the solid line is the average value; the dotted line is the diffraction-limited curve.

Modulus and a high elongation at break (about 250–300%), as a result it is expected that an IOL made of xPIB can go through smaller incision sizes in the surgical operation (Pinchuck, 2022). This has yet to be established in clinical experience.

The manufacturer argues that an ideal IOL material would not contain cleavable groups (hydrolysable or oxidizable groups) such as esters, ethers, urethanes, carbonates, carbamates, amines, urea, tertiary halogens, etc., anywhere in the polymer including its side- and end-groups. The IOL polymer chemistry must be such that slow nucleophilic substitution reactions must not occur in the device in the eye over time, where these slow dissociations of "good leaving groups" result in the concomitant formation of acid groups or hydroxyl groups. Cleavage of these groups on the backbone can lead to biodegradation, crazing, glare, whitening and molecular release. Cleavage of these groups on side branches can also lead to molecular release and the production of hydroxyl or acid moieties both on the backbone as well as on the leaving group, which can draw in water and cause glistening or whitening. Besides potentially damaging the IOL, the molecules released in the confines of the eye can manifest clinically as inflammation, irritation, corneal endothelial cell loss, retinal changes and fibrosis of the lens capsule. The manufacturer states that crosslinked polyisobutylene (xPIB) does not have these cleavable groups.

The first commercial use of polyisobutylene-based polymers in human medicine was with the triblock copolymer from this family, it has a center block of polyisobutylene and the outer glassy-segments that are polystyrene. The triblock polymer is called "poly(styrene-*block*-isobutylene-*block*-styrene)" or "SIBS" and is the drug-carrier in Boston Scientific Corporation's (Natick, MA) TAXUS® paclitaxel-eluting coronary stent (Pinchuk et al., 2021; Strickler et al., 2010; Boden et al., 2009; Kamath et al., 2006). This material was selected by Boston Scientific over many other well-known candidate materials for this coronary application due to its superb biocompatibility, biostability and lack of inflammatory reaction. TAXUS® was cleared for use in the body by the FDA in 2004, and since 2001 it has been used in human medicine outside the U.S.A. Stainless steel stents coated with SIBS have been used in millions of patients for approximately ten years without any reported adverse events relating to biodegradation or inflammation of the coating material. SIBS has also been used as a glaucoma shunt in the eye, the "MIDI Arrow" currently undergoing clinical trials by InnFocus, Inc. (affiliate of Innovia LLC in Miami, FL) (Pinchuk et al., 2016, 2017, 2018). The proximal end of the MIDI Arrow protrudes into the anterior chamber and is visible under slit lamp examination. Observations of the "MIDI Arrow for over one year in human eyes do not demonstrate inflammation, encapsulation, calcification or glistening. Other investigations are expected to confirm the biocompatibility of polyisobutylene-based polymers in other applications of the human anatomy.

Light scattering can be caused by particles within the IOL material. In hydrophobic lenses small liquid filled vacuoles (i.e., glistenings) are known to cause light scattering. In a study from 2017 glistenings were induced in seven AcrySof® IOLs (Alcon Inc, Texas, USA) and the effect of glistenings on straylight levels was found to be proportional with their total number and surface portion (Łabuz et al., 2017). Recently, we have assessed MTF and straylight levels in hydrophilic acrylic monofocal IOLs with centrally localized calcification showing that the reduction in the IOL's optical quality strongly depends on density and size of calcium deposits (Łabuz et al., 2018c).

The power measurement results (Table 3) indicate that all studied lenses were correctly labeled for their nominal power as the reported and labeled values were virtually identical. In addition, the optical metrology demonstrated that the Eyedeal®'s optical design provides an excellent Strehl ratio and MTF levels for both apertures, which at 3 mm was nearly diffraction-limited. Although at 4.5 mm the Strehl ratio was slightly decreased, it remained at a high level of 0.88, on average. According to the ISO standard, a monofocal IOL should have a 100lp/mm MTF value equal to or greater than 0.43 at the 3-mm pupil. Table 3 shows that the Eyedeal®'s MTF (@ 100 lp/mm) ranges from 0.57 to 0.63, confirming that its optical performance complies with the manufacturing standards.

5. Summary and conclusions

The results confirm that the Xi'an Pillar Eyedeal® IOL made of hydrophobic crosslinked polyisobutylene (xPIB) is superior in terms glistenings formation compared to lenses made of the standard AcrySof® SN60WF material. An average result of around 7 ± 4 MV/mm^2 of the Eyedeal® IOL was much better than Alcon AcrySof® whose number was around 142 ± 72 mv/mm^2. The Eyedeal® lens has a contact angle of almost 100°. The SEM imaging confirmed that the Eyedeal® IOL features good surface finishing. The new Eyedeal® IOL has a nominal power conformed to ISO standards. It has excellent MTF performance for both apertures that correspond to a photopic and mesopic pupil size.

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CRediT authorship contribution statement

Sonja K. Schickhardt: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Grzegorz Łabuz:** Writing – original draft, Data curation, Conceptualization. **Donald J. Munro:** Supervision. **Ingo Lieberwirth:** Conceptualization. **Lu Zhang:** Conceptualization. **Hui Fang:** Conceptualization. **Gerd U. Auffarth:** Supervision, Conceptualization.

Declaration of competing interest

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Data availability

Data will be made available on request.

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