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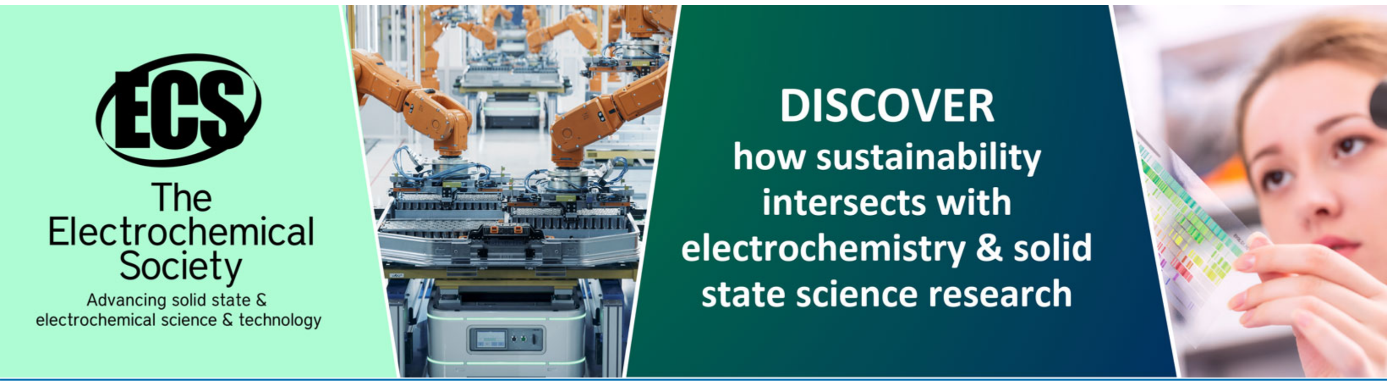

Construction aspects of intraocular artificial lenses

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Abstract. A cataract is a disease of the 21st century. In highly developed countries, the opacification of the intraocular lens is removed and replaced with an implant. This article discusses the essential aspects related to the construction of implants that imitate the natural lens of the eyeball. The research was carried out owing to X-ray microtomography. Observer design differences in the two lenses' structures contribute to the implant's quality in question. The study aimed to check and compare two types of implants in terms of the design and manufacturing quality of the given lenses. The common element of the implants in question was their material and manufacturer. Lenses of the same material were used to maintain the same optics. The results gave a comparison in terms of the quality of the product in terms of the creation and modelling of the lenses than the properties of the material itself from which they were made.

1. Cataract epidemiology

A cataract is a disease of the 21st century. Cataracts are clouding of the intraocular lens that develops, causing blurred vision. The lens is behind the pupil; this usually transparent structure allows the light to reach the retina [1–3]. After reaching the retina, this light is converted into nerve signals which are then sent to the brain for visual interpretation. If a cataract develops in this lens, some of that light may not reach the retina, and vision will become less clear. These cloudy patches usually take a long time to develop, which means that visual impairment develops gradually. Cataracts eventually worsen until it interferes with daily life, affecting the ability to read or drive, for example. Surgery is required to remove and replace the damaged lens.

In highly developed countries, the opacification of the intraocular lens is removed and replaced with an implant. The expectations related to this implant are very high. A number of life aspects of a patient with an implanted implant depend on the quality of workmanship, the type of material used, and the design of the lens implant. The comfort of life and the quality of the received image significantly depend both on the design of the lens implant, the material from which it is made, but also on the implementation process itself in the patient's eyeball. This article discusses the important aspects related to the construction of implants that imitate the natural lens of the eyeball. Artificial eye lenses are made of acrylic. Acrylic is biocompatible with the human body and can withstand high pressures when used correctly [4,5]. Acrylic does not chip like glass, whereas scratches and damage are milder, which is why it is an ideal polymer for producing cataract lenses. Most implants are made of the same or a similar material. It perfectly transmits visible light and dispenses ultraviolet light, which is harmful to human eyes in large doses. Although the lenses are made of similar materials, the manufacturing process is different [6,7]. Cheaper lenses are made up of several parts. The optical body is made of acrylic material, but the mounting brackets are made of another material. The aim of the research was to compare two implants in terms of design and quality of the tested lenses [8]. The common element of the tested lenses was the material from which they were made. The only difference was the manufacturing technology, mainly the method of making the hooks that fix the implant in the patient's eyeball. The tests were performed with the use of X-ray microtomography. Design differences in the construction of the tested lenses were observed, which significantly affect the usability of a given implant. Thus, the research was carried out to determine the functional values and quality of workmanship and modeling of the lenses.

2. X-ray microtomography

X-ray microtomography has roots in computed tomography (CAT or CT), which has been used in medical imaging for 40 years. Computed tomography is an extension of conventional projection radiography, a technique that can quickly (with a sufficiently strong source) generate a two-dimensional image of an object's internal structure [9,10]. Broken bones or tooth decay can be easily identified in such shots due to the differences in X-ray absorption between the bone and the surrounding tissue [11–13].

Computed tomography addresses these problems by combining the information from a series of two-dimensional X-ray absorption images captured as the object rotates about one axis. It should be noted that rotation is relative. Medical scanners keep the object stationary while the X-ray source and detector rotate around it. Using the mathematical principles of tomography, this series of images is reconstructed to produce a three-dimensional image digital, in which each voxel (volume element or 3D pixel) represents X-ray absorption at that point [14–16]. Due to the relationship between X-ray absorption and material density, the internal 3D structure can be inferred from the images, and the interior features can be uniquely positioned. The resulting 3D images are typically displayed as 2D "slices" series [17,18].

X-ray microtomography consists of X-ray tubes, a system of detectors, a rotating table and manipulators. The heart of an X-ray microtomography is the X-ray tube that emits radiation [19–21]. Sensors convert X-rays into a signal that is then analyzed by a computer. The manipulator enables the sample to be moved in three mutually perpendicular XY planes.

3. Construction of the IOL

The lenses are made of soft acrylic material. The subjects were performed for the AcrySof (R) IQ ASPHERIC Natural IOL and AcrySof (R) SOFT ACRYLIC MULTIPIECE STERILE PCL (IOL/PC) implants (fig. 1, fig. 2). The contact lenses analyzed were Alcon silicone hydrogel lenses: Air OPTIX plus [22,23].

AcrySof (R) IQ, filtering UV and blue light, one-piece intraocular lens (1OL) is an optical implant that replaces the human crystalline lens for optical correction in adult cataract patients. The AcrySof (R) IQ lens with Alcon's patented blue light-filtering chromophore filters light like a human crystalline lens in the blue-light wavelength range of 400 - 475 nm. In addition to standard UV light filtering, the AcrySof (R) IQ lens reduces blue light transmittance from 62% at 400 nm to 23% at 475 nm. The lens consists of a soft acrylic material with a high refractive index. After implantation, the lens gently unfolds into the full-size lens body. The lens has two-convex optics with additional elements [24,25]. The posterior surface of the AcrySof (R) IQ IOL Model SN60WF is designed with negative spherical aberration to compensate for the positive spherical aberration of the mean cornea. The optical diameter of the lens is 6 mm, the overall height is 13 mm, and the focusing power is 12.5D [26,27].

AcrySof (R) SOFT ACRYLIC MULTIPIECE STERILE PCL (IOL/PC) UV absorbing, multi-part, the foldable acrylic lens is an optical implant replacing the human crystalline lens for vision correction in adult patients after cataract surgery. The optics consist of soft acrylic material with a high refractive index. After implantation, the lens gently unfolds into a full-size body [28]. The lens is biconvex, asymmetrical in the front part with additional elements. The optical diameter is 6 mm, the overall height is 13 mm, and the focusing power is 29D.

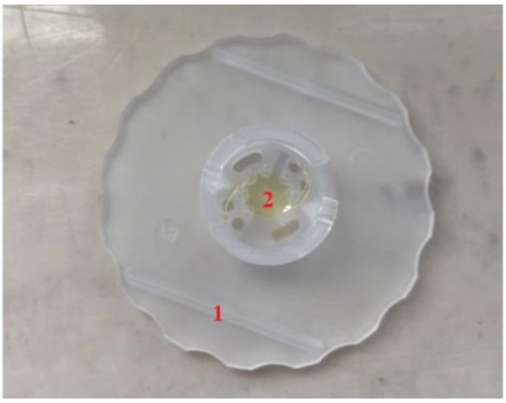

Figure 1. Measuring lens: AcrySof (R) IQ ASPHERIC Natural IOL. 1 – transport container, 2 – lens [29]

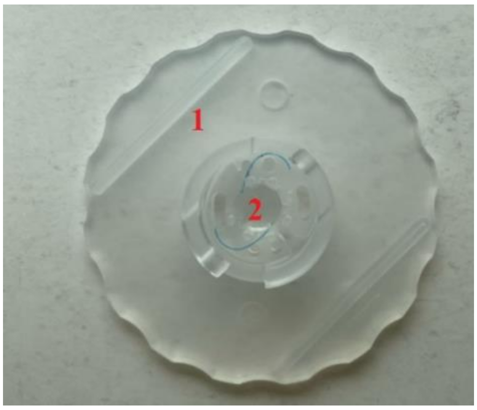

Figure 2. Measuring lens: AcrySof (R) SOFT ACRYLIC MULTIPIECE STERILE PCL (IOL/PC). 1 – transport container, 2 – lens [29]

4. Lenses Research

The tested samples were scanned using the Skyscan1174 device. The camera pixel size was 23.22 μm. The distance between the object and the source amounted to 181.60 mm. The voltage was 50kV, and the current was 800 μA up. The revolution step was 7º. Scanning took place without a filter and lasted 30 min. 24 s. The 3D model of tested lenses was processed in the Nrecon program.

Fig. 3 shows two samples of tested lenses – I and II. Their edges and mounting fixtures stand out. The sample is made uniformly. Its arms and body are made of one material. Sample II is a combination lens. This means that its fixtures were probably not attached until the lens was made.

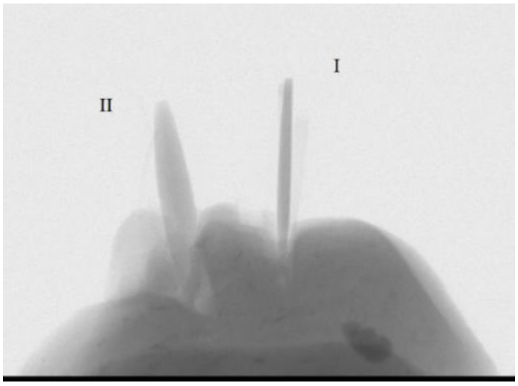

Figure 3. Tested lenses, I – Sample No. I, II – sample No. II.

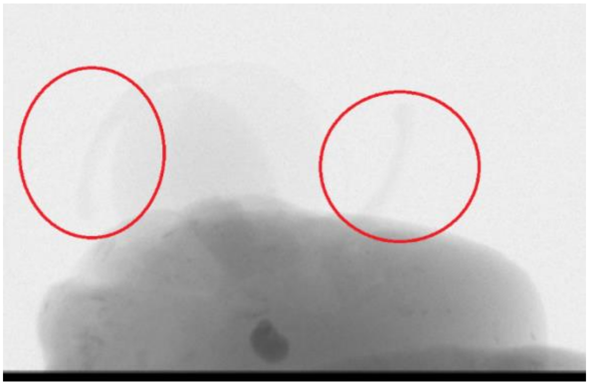

Figure 4. Photo of the samples: The mounting brackets are already visible.

Fig. 4 shows the size of the lenses and fixtures. Lens No. I has thicker handles, more stable with a homogeneous design. They are more visible in the photos. Lens II, on the other hand, is the more visible part of its body. Its fixtures are less visible and thinner, which can suggest that the structure of the fixtures is less stable, and they are more prone to mechanical damage (fig. 5).

The next step was to reconstruct the flat images into a three-dimensional image of the lensless image. The reconstruction was done with CT vox: version 3.3.0.r1403 64bit. and DataViewer: version 1.5.6.2 64bit.

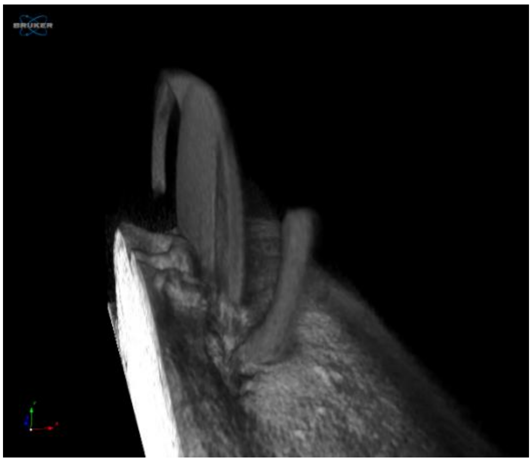

Figure 5. View of the I lens from CT vox

Figure 6. Photo with visible artefact on the lens

The artefact seen in fig. 6 may depict the irregularity of the lens itself. Light may be unfocused in this area, causing image distortion and aberrations after implantation. This artefact may also be caused by the fact that the tests were conducted on the samples for disposal and may show various types of deformations and porosities that are not present in the lenses ready for implantation because of their imperfection.

Fig. 7 shows an image of lens No. II. One can clearly see that it is much thicker than lens No. I.

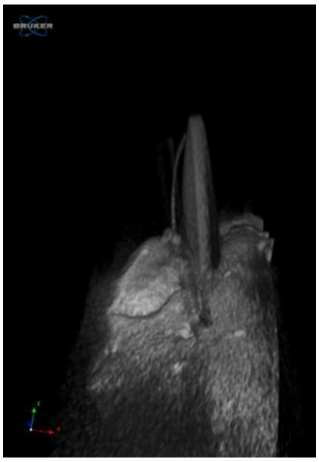

Figure 7. Lens II, visibly thicker than lens I

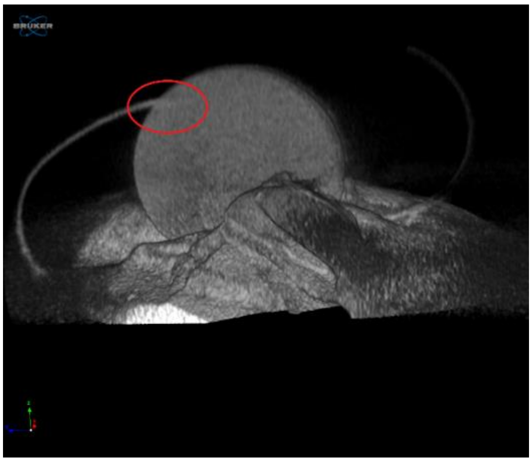

Figure 8. Lens II with visible joint

Fig. 8 presents the linking component. It can be seen that the lens design is not uniform, which makes it susceptible to mechanical damage during surgery and can also cause postoperative complications if it breaks down after implantation.

Fig. 9 shows the thickness of lens II. The thickness of the lens II depends on its focusing power. It can be seen that the lens is thicker than the I lens.

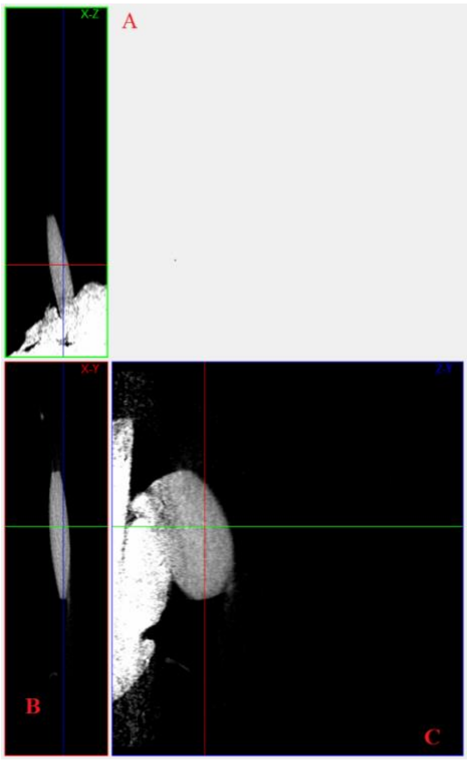

Figure 9. Photos from DataViewer, A – general view, B – lens thickness, C – cross view

The last element of the work was the measurements of cataract implants using the CT Analyzer software, version 1.18.8.0. The I lens was 6.17 mm in optical height, and the II lens was 6.26 mm (fig. 10). The differences could be due to the accuracy of the cursor reaching the limits of the lenses. On the other hand, the most interesting measurement was the thickness. The lenses differed in thickness, as it can be seen from earlier scans. Implant I is 0.42 mm and implant II – 0.95 mm. The manufacturer does not specify the exact thickness of the lenses, only the focusing power. Implant II is 2.2 times thicker and more convex, confirming the focusing power of both lenses (implant I 12.5D and implant II 29.0D).

Lenses have different structures, shapes and uses. When analyzing both Alcon lenses, the differences in the structure and shape of the lenses are observed. The connection elements are also visible. The fixtures of the lenses are made of a different material than the optical surface. Thus, it may be expected that these fixtures are more prone to deformation. Implant No. II is thicker, which proves its focusing power. A broader and more convex lens is better captured by microtomography. Implant no. I is made of a homogeneous material; no connection elements were observed there. The microtomography better mapped the lens. Fasteners are more stable and more visible. The specific arcs characteristic of this type of lens have also been mapped. The CT image shows that the fixation element is thicker than the lens itself, which may result in better mounting of the lens in the eye. This artefact can be observed on an ophthalmic implant. It was created as a result of image reconstruction by a computer program. Artefacts can be avoided, but scan time is increased. Longer time means more photos, which translates into more accurate representation.

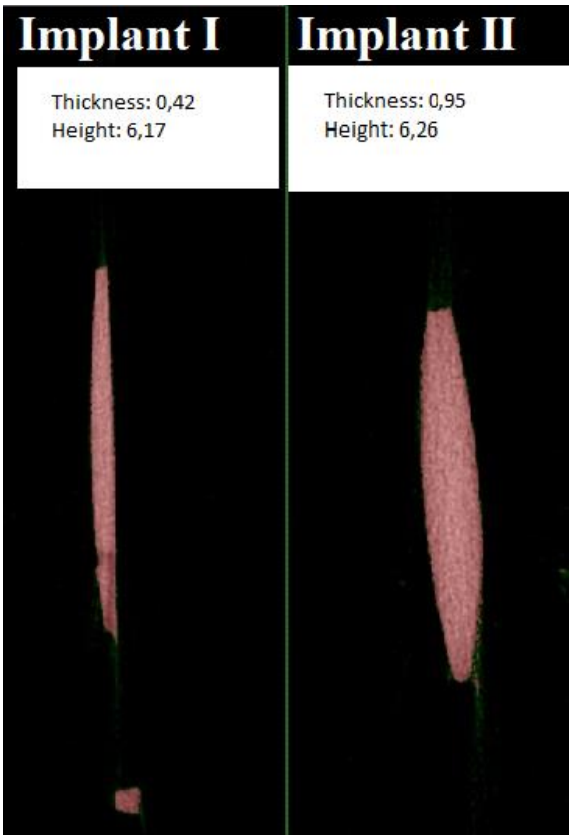

Figure 10. Comparison of the size, thickness and curvature of intraocular lens implants

5. Conclusions

The following conclusions can be drawn by analyzing all parameters of intraocular lenses. Additionally, an element connecting the body with the fixtures was observed.

Cataract implants differ in thickness due to their focusing power. The very height of the lenses is the same. Both lenses are also made of acrylic material with a high light factor. The manufacturer does not provide precise information on the exact composition of the lens [30–32].

In recent years, X-ray microtomography research has been combined with other technologies, e.g., before destructive testing, to obtain models that will be used for measurements in reverse engineering. Analysis of research results shows that the multi-method approach enhances research opportunities. Unfortunately, currently none of the techniques for testing materials is without limitations. In the case of X-ray microtomography, the limitations include the reduction of the ability to penetrate the X-ray into the material under test as its density increases.

In summary, two different ophthalmic implants were analyzed in the research. Even though IOL implants were made of similar acrylic material, their design was different. The most significant difference can be seen in the fasteners. The AcrySof (R) SOFT ACRYLIC MULTIPIECE STERILE PCL lens consists of elements joined together. Owing to the microtomography, the connection element can be seen. The AcrySof (R) IQ ASPHERIC Natural IOL lens is constructed of a single material. It has no connecting elements. As it can be expected, the homogeneous surface makes the lens more resistant to mechanical damage [33–35].

The details of joining two different materials are usually more susceptible to damage. It is an interference with the optical structure of the lens itself. The connection element can cause various unforeseen aberrations. Combining two different materials is a deliberate procedure. By choosing a cheaper part, the producer can lower the production cost. The AcrySof (R) IQ ASPHERIC Natural IOL lens is not without its drawbacks. As a rule, these lenses have a Halo effect due to the additional coatings that protect the retina from UV radiation. Unfortunately, when examining the structures themselves, without focusing on optical phenomena, the AcrySof (R) IQ ASPHERIC Natural IOL lens has an advantage in care and attention to artistry. When choosing an implant, attention must be paid to economy and specification of each lens.

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