INVESTIGATION OF INTRAOCULAR LENSES SURFACE ROUGHNESS BY ATOMIC FORCE MICROSCOPY

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Abstract. *The aim of this study was to evaluate the surface roughness of intraocular lenses (IOLs) generated by the manufacturing process and to determine the roughness parameters of 3D surface using atomic force microscopy (AFM). Intraocular lenses commercially available from a single manufacturer: Pharmacia & Upjohn Co. were investigated. Three intraocular lenses, model 911A CeeOn Edge®, were analyzed on different areas of the posterior optic surface. For imaging surface roughness of intraocular lenses on nanometer scale we employed atomic force microscopy in contact mode with ambient air. Three parameters obtained by atomic force microscopy (Sa, Sq and Sz) were used in evaluation of intraocular lenses surface roughness. The parameters of surface roughness are an auxiliary index of biocompatibility and generates useful information about the material surface quality. The information generated in study may assist researchers in choosing, designing and manufacturing of intraocular lenses with optimal performance characteristics.*

Keywords: *engineering design, intraocular lenses, surface roughness, biocompatibility, atomic force microscopy*

1. INTRODUCTION

Cataract surgery with intraocular lens (IOL) implantation has become the most common medical procedures among persons age 65 and older. The success of this medical procedure is derived from several factors, such as surgical techniques, superior tools, skills and maneuvers, implant designs and preoperative diagnostics.

The foldable IOL, made of a soft polymer (silicone or acrylic) of appropriate power, is folded during insertion (either using a holder/folder, or a proprietary insertion device provided along with the IOL) to allow implantation into the capsular bag within the posterior chamber (in-the-bag implantation) through a small incision. The IOL fixation into the capsular bag is made by the haptics.

The requirements for foldable IOLs with advanced optical and mechanical properties, stability and biocompatibility have rapidly evolved. As high standards have been reached in modern cataract surgery, IOL implantation has become a safe and reliable procedure.

The most frequent postoperative complication after cataract surgery is posterior capsule opacification (PCO - secondary cataract, after cataract) [1]. This phenomenon is attributed to the migration and proliferation of residual lens epithelial cells (LECs) onto the central posterior capsule, leading to progressive loss of visual acuity. A better understanding of PCO mechanisms would have obvious medical and financial immediate benefits [2].

The main strategies to prevent or reduce the incidence of PCO are: new surgical techniques, new biomaterials composition, an IOL advanced manufacturing technology and optimal design, a higher biocompatibility and advanced surface characteristics of IOLs [3, 4, 5].

Careful application and utilisation of these factors by surgeons could lead to a significant reduction of PCO and a long-term biocompatibility of the implant [6, 7].

Although surgical techniques, the biomaterials, manufacturing technology and design of IOLs have been extensively discussed, the surface characteristics of IOLs contribute significantly to an understanding of its clinical performance into the ocular environment, but are difficult to measure, evaluate and quantify [8 – 15].

The IOLs surface characteristics are referred to the physicochemical surface properties and surface topography.

Three-dimensional (3D) characterization of IOLs surface topography is an integral part of IOLs quality control and permits a better understanding of the functional performance of IOLs surfaces and a better control of their manufacturing.

In order to understand phenomena such as contacting surfaces, friction and lubrication surface, topography quantification is important. Unfortunately, the impact of IOL surface topography is not entirely understood.

It has also been shown that the inflammatory cell adhesion to the IOL optical surface is directly proportional to the *Sa* value of the IOLs [16 - 26]. Also, the deteriorative effect of surface roughness on the optical quality of retina image is minimal unless the average roughness is over 50 nm, which extremely exceeds the range of roughness of IOLs used in clinic.

The complexity of IOL surface topography requires 3D surface characterization and measurement techniques at nanometer spatial resolution [27 - 29].

IOLs surfaces have an unique and complex topography, created by different manufacturing processes, and requires 3D surface characterization and measurement techniques at nanometer spatial level.

The results analysis offer a better understanding of IOLs behavior inside the ocular environment and in IOLs quality control.

2. THE SURFACE AMPLITUDE PARAMETERS

Surface topography is the 3D representation of the finer irregularities of the surface texture, usually including those irregularities that result from the inherent action of the manufacturing process.

Considering a surface topography $z(x_i, y_j)$ defined in a rectangular coordinating system *OXYZ*, with *M* and *N* being the measurement points on *OX* and *OY* axes respectively ($i = 1,\dots, M$ and $j = 1, \dots, N$). If l_x and l_y are the lengths on *OX* axis and *OY* axis of the measured surface *A*, than it could be expressed as:

$$A = l_x \cdot l_y;\ l_x = (M-1)\cdot\Delta x,\quad l_y = (N-1)\cdot\Delta y \qquad (1)$$

The S amplitude parameters are defined as [30]:

a) The arithmetic mean deviation of the surface (*Sa*) is the arithmetic mean of the absolute values of the surface departures from the mean plane and is given by:

$$Sa = \frac{1}{MN}\sum_{j=1}^{N}\sum_{i=1}^{M}\left|z(x_i, y_j) - \bar{z}\right| \qquad (2)$$

with $\bar{z}$ representing the mean height:

$$\bar{z} = \frac{1}{MN}\sum_{j=1}^{N}\sum_{i=1}^{M} z(x_i, y_j) \qquad (3)$$

b) The root mean square deviation of the surface (*Sq* or *RMS*) is defined as:

$$Sq = \sqrt{\frac{1}{MN}\sum_{j=1}^{N}\sum_{i=1}^{M}\left|z(x_i, y_j) - \bar{z}\right|^2} \qquad (4)$$

c) The ten point average of the absolute heights (*Sz*) of the five highest peaks (z_{pi}) and five deepest valleys (z_{vi}) is given by:

$$Sz = \frac{1}{5}\left[\sum_{i=1}^{5}\left|z_{pi} - \bar{z}\right| + \sum_{i=1}^{5}\left|z_{vi} - \bar{z}\right|\right] \qquad (5)$$

3. EXPERIMENTAL PROCEDURE

Three intraocular lenses, model 911A CeeOn Edge® (Pharmacia & Upjohn Co.) with +20.0 diopters (D), were analyzed on different areas of the posterior optic surface.

Specifications of the CeeOn Edge® 911A include a three-piece lens, the silicone material, equi-biconvex, foldable, with a refractive index of 1.46 and an optic size of 6 mm featuring no optic rim along a full optic zone. The overall length of the IOL is 12 mm with a square edge design featuring a haptic angulation of 6 degrees. The haptic material is polyvinylidene fluoride and uses a Cap C design.

Topographic analysis of the IOL’s surface optic was performed with an atomic force microscope (Alpha 300A, WITec, Ulm, Germany) which was operated in contact mode with ambient air at room temperature (21 - 24 °C) and approximately 50 % relative humidity.

A silicon nitride square pyramidal tip attached to a ‘D’-type, ‘V’-shaped cantilever with a tip curvature of 15 nm and a nominal spring constant of 0.2 N/m was used for measurements.

Before AFM imaging, every IOL was received as sterile implantation samples from the manufacturer and was removed with an atraumatic forceps and then was placed onto a sample holder.

The measurements of each sample were made over on 4 different reference areas of 4 μm x 4 μm with a 256 pixel x 256 pixel image definition at a scan rate of 1 Hz, to verify the reproducibility of the observed features.

For analyze of AFM images and evaluation of surface roughness parameters WITec Project software (WITec GmbH, Ulm, Germany) was used [30].

Three quantitative parameters were used to characterize the morphology and roughness of the posterior optic surface: the arithmetic mean deviation of the surface (*Sa*), the root mean square deviation of the surface (*Sq*) and the ten point average of the absolute heights (*Sz*).

Statistical analysis was used to statistically compare the differences among IOLs. Differences with a *P* value of 0.05 or less were considered statistically significant.

4. RESULTS

AFM images revealed that the posterior optic surfaces of all the IOL samples were relatively smooth with numerous protruding microgranular features. Optic edges, haptic-optic junctions and the haptic ends was found to be smooth and regularly shaped.

The surface roughness parameters of IOLs are shown as mean ± standard deviation (SD) in Table 1.

Table 1. Surface roughness parameters of IOLs shown as mean ± standard deviation (SD)

Sa [nm]	*Sq* [nm]	*Sz* [nm]
3.36 ± 0.48	3.85 ± 0.65	22.64 ± 0.24

5. DISCUSSION

The most important factors in IOLs interactions into the ocular environment are the properties of the biomaterials, the surface topography and the contacting conditions [31 – 40].

3D topographical characterization of IOLs surfaces allows for easy and intuitive interpretations with a proper set of parameters and plays an important role in monitoring and improving IOLs manufacturing processes.

The surface roughness of each investigated IOL is according required clinically levels of stability, optical performance and biocompatibility.

6. CONCLUSIONS

Atomic force microscopy, due to its high resolution, is an accurate tool in the non-destructively investigation and analysis of surface topography of the IOLs at a nanometer level [41].

IOLs surface topography permits to choose IOLs more appropriate for different surgical situations and individual patient characteristics and to minimize the potential for PCO [42 - 45].

The study results allow us to have useful information about the IOLs behavior inside the ocular environment.

This investigation of the AFM measurement system is in good agreement with experimental observations from the literature and thus leads to the belief that the results obtained with this measuring instrument are reliable in the case of IOLs surfaces.

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