# Machine learning-based analysis of adverse events in reported posterior chamber IOL implantation procedures
# Final Reports

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**Abstract**

Posterior chamber IOL implantation is the latest technology for correcting refractive error, with STAAR's Visian ICL product virtually monopolizing the market. While it has many outstanding benefits, it also carries some risks. The Manufacturer and User Facility Device Experience (MAUDE) dataset provides a wealth of valuable medical data, including patient information, device information, manufacturer information, and free text records. To gain insight into these risks, I examined relevant reports in the MAUDE dataset from 2014 to 2023, covering all Visian ICL-related reports, and identified a range of adverse events associated with posterior chamber IOL implantation, including device problems, elevated intraocular pressure (IOP), visual disturbances, refractive problems, decentration/incorrect size/lens rotation, glaucoma, pigmentation, pain, infections, cataracts, swelling/edema, pupil ovalization, eye injuries, loss of corneal endothelial cells, loss of vision, and discomfort. I also examined the trends in these adverse events over time and the associations with the lens model. This study reveals the importance of the surgeon's surgical skills and the selection of the suitable lens model and size, emphasizes the need for regular return visits to follow the patient's post-operative condition, and sheds light on future directions for product optimization and updating.

# 1 Introduction and Background

Phakic intraocular lens (pIOLs) implantation is an emerging method of corneal refractive error correction. Compared to corneal refractive surgery (e.g., LASIK), it improves visual outcomes while preserving lens function, and is often used to correct high myopia and hyperopia, but it has potential risks. (Chang & Pineda 2010) The incisional surgery required for implantation can lead to complications including angle closure glaucoma, pupillary block, bleeding or even perforation from periocular anesthetic injections, endothelial, iris, and crystalline lens damage due to human error, irreversible damage to the phakic IOL, damage to the corneal endothelium, acute glaucoma, and elevated intraocular pressure (IOP), Urrets-Zavalia syndrome, chronic glaucoma and uveitis, pigment dispersion syndrome, pupil ovalization, iris stromal atrophy, endophthalmitis, cataracts, corneal dystrophy, endothelial cell loss, suspensory ligament injury, dislocated IOL, ciliary body inflammation, alteration of the blood/aqueous barrier, persistent aqueous flare, cystoid macular edema, macular edema, Loss of Visual Acuity glare, surgically guided astigmatism, early post-operative hyphema, ischemic optic neuropathy,

diplopia. (Lovisolo & Reinstein 2005) (Kohnen et al. 2010) (Chen & Sun 2018) The occurrence of these adverse events poses a threat to patient safety and satisfaction, so it is critical to understand them.

To delve deeper into this issue, the report used machine learning techniques to analyze the MAUDE (Manufacturer and User Facility Equipment Experience) dataset. This dataset contains all reported incidents where a medical device may have presented or caused a serious injury. Only 2 types of pIOLs have been approved by the FDA as learned through the FDA's Device Finder (Devices@FDA):

1. Visian ICL: The Visian ICL (Implantable Collamer Lens) marketed by Staar Surgical. This lens was approved by the FDA in 2005 to help treat myopia from -3.00 to -20.00 diopter. It is placed on the natural lens behind the iris and is undetectable to the naked eye. ('Phakic Intraocular Lens Implantation for the Correction of Myopia: A Report by the American Academy of Ophthalmology' 2009)

2. Verisyse: The Visian lens sits below the iris, while the Verisyse lens (Johnson & Johnson Vision) sits above the iris. This lens was approved by the FDA in 2004 for the correction of moderate to severe myopia from -5.00 diopters to -20.00 diopters.

There are 3 types of pIOLs implantation: anterior chamber angle support, iris fixation, and posterior chamber implantation. Currently, anterior chamber angle-supported pIOL is no longer used in refractive surgery, and iris-fixed pIOLs is also gradually decreasing in use due to damage such as corneal endothelial cell detachment. Posterior chamber implantable IOLs are becoming increasingly popular. (Sucu, Agca & Tulu 2021) And the fact that Visian ICLs are constantly being updated, almost all of the data in the FDA database is currently on Visian ICLs. pIOLs in this report only refer to Visian ICLs, which are posterior chamber implantable lenses. Additionally, the toric phakic intraocular lens (pIOL) and the regular phakic intraocular lens (pIOLs) are two different intraocular lenses that are used to correct different types of refractive errors. The regular phakic intraocular lens corrects mild astigmatism but is not intended to be the primary purpose. Toric phakic intraocular lens is a phakic intraocular lens specifically designed to correct astigmatism and has the ability to correct moderate to severe astigmatism in addition to myopia or hyperopia. (Mohankumar & Mohan 2024) Toric lenses have their own unique design and shape compared to regular lenses and have been developed in almost a decade less time than regular lenses. In addition, besides the material and manufacturing process problems of the

device, complications of pIOL implantation are related to the accuracy of the preoperative examination, the doctor's judgment of the patient's data (e.g., choosing the size of the lens), Patient's own underlying disease, the anesthesia method, or the surgeon's play during the surgery (Lovisolo & Reinstein 2005; Kohnen et al. 2010; 'Phakic Intraocular Lens Implantation for the Correction of Myopia: a Report by the American Academy of Ophthalmology ' 2009).

To overcome these challenges, the report specifically focuses on the analysis of free text reports in the dataset, which is mostly originated from physicians and contains a large number of records for devices (lenses, lens injectors), patient's status, patient's complaints and treatments in surgery, and contains a lot of professional vocabulary of the healthcare industry. The keywords in the free text are extracted through natural language processing techniques, on the basis of which a classification model is trained to achieve the purpose of categorizing the occurrence of adverse events.

For these concerns, my study aims to provide an in-depth analysis of surgeries involving pIOLs implantation based on the MAUDE dataset. My objectives are as follows:

1. Analyse the trend of adverse events reported during the years 2014-2023.

2. Analyse the trend of these symptoms by identifying and extracting the keywords of complications mentioned in the free text.

3. Analyse in depth the factors behind the special distribution of adverse events.

# 2 Methods

## 2.1 Data collection

The Manufacturer and User Facility Device Experience (MAUDE) database is a searchable database of medical device reports (MDRs) of adverse events involving medical devices over the last ten years, regulated by the FDA Center for Devices & Radiological Health. (Luschi, Nesi & Iadanza 2023)

I extracted data related to phakic intraocular lens from it and merged some patient and device related data to form the original dataset. This dataset contains all reports related to phakic intraocular lens submitted to the FDA during the period 2014-2023, as well as the corresponding patient questions, device questions, and free-text-form descriptions of the

report. The process of extracting the data was divided into 4 steps and Figure 1 shows the flowchart of the whole process. This part is done in the python programming language.

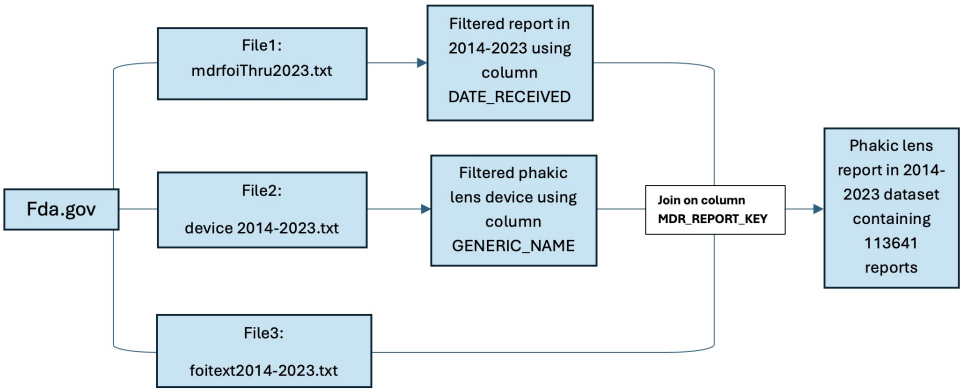


Figure 1. Data collection and filtration process

First, we start with the master file(mdrfoiThru2013ṫxt) and filter out the data from 2014 to 2023.

Then, we merge the device data from 2012 to 2023 through MDR_REP -ORT_KEY, and filter the data that contains both "phakic" and "lens" in GENERIC_ NAME or BRAND_NAME through MDR_REPRT_KEY, and merge the problem code information of the patient and the problem code information of the device as well as the problem code information of the device through MDR_REPRT_KEY. and "lens" in GENERIC_NAME or BRAND_NAME.

Finally, the patient's free text information (foitext.txt) from 2014 to 2023 was merged into the dataset by MDR_REPORT_KEY. The dataset ultimately contained 117,180 obs.

## 2.2 Data clean

### 2.2.1 Variable Selection

Since in this study we focused on the complication information contained in the free text in the adverse events, the selected variables were: MDR_REPORT_KEY, DATE_RECEIVED, BRAND_NAME, GENERIC _NAME, MANUFACTURER_D_NAME, MODEL_NUMBER, ADVERSE _EVENT_FLAG, FOI_TEXT.

As mentioned earlier the FDA has approved 2 pIOLs, a posterior implantable pIOL from STAAR, the Visian ICL, and an anterior implantable pIOL from Johnson & Johnson, the Verisyse, and the Visian ICL is the more popular. After looking at the manufacturer names in the dataset, it was found that out of over 110,000 reports, only a few dozen

cases were from the Johnson & Johnson group and occurred in the early years, and there were over 280 cases with no manufacturer information, which is unrepresentative of the huge dataset, so this study chose to focus on the Visian ICL from STAAR, and removed the dataset other than the STAAR 's dataset.

Although the patient problem codes have simply recorded each reported patient problem, such as ambiguity, infection, etc., the vast majority of the information in the free text was filled out by the physicians, with detailed descriptions of problems with the equipment, what happened during the procedure, and the course of events, containing a great deal of information about the symptoms in greater detail, and thus this section was the main focus of this study. Table 1 shows a sample of the dataset.

Table 1. Sample of dataset

| | MDR_REPORT_KEY | DATE_RECEIVED.x | BRAND_NAME | GENERIC_NAME | MANUFACTURER_D_NAME | MODEL_NUMBER | ADVERSE_EVENT_FLAG | FOI_TEXT |
|---|---|---|---|---|---|---|---|---|
| 1 | 5835230 | 2016/07/29 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | VICMO13.7 | Y | THIS PRODUCT IS MANUFACTURED IN THE U.S. BUT N... |
| 2 | 5835230 | 2016/07/29 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | VICMO13.7 | Y | THE REPORTER INDICATED THE SURGEON INSERTED A... |
| 3 | 5835230 | 2016/07/29 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | VICMO13.7 | Y | ADDITIONAL INFORMATION: DEVICE EVALUATION – T... |
| 4 | 5167031 | 2015/10/21 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | TICM120V4 | Y | THIS PRODUCT IS MANUFACTURED IN THE U.S. BUT N... |
| 5 | 5167031 | 2015/10/21 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | TICM120V4 | Y | THE REPORTER INDICATED THE SURGEON IMPLANTED ... |
| 6 | 5167031 | 2015/10/21 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | TICM120V4 | Y | (B)(4). ADDITIONAL DATA: DEVICE EVALUATION: PRO... |
| 7 | 5638613 | 2016/05/06 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | VICMO13.2 | Y | THIS PRODUCT IS MANUFACTURED IN THE U.S. BUT N... |
| 8 | 5638613 | 2016/05/06 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | VICMO13.2 | Y | THE REPORTER INDICATED THE SURGEON IMPLANTED ... |
| 9 | 5638613 | 2016/05/06 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | VICMO13.2 | Y | DEVICE EVALUATION: PRODUCT EVALUATION FOUND ... |
| 10 | 5648789 | 2016/05/11 | ICL (IMPLANTABLE COLLAMER LENS) | PHAKIC INTRAOCULAR LENS | STAAR SURGICAL COMPANY | VICMO13.2 | N | THIS PRODUCT IS MANUFACTURED IN THE U.S. BUT N... |

Showing 1 to 10 of 117,180 entries, 8 total columns

### 2.2.2 Correction values

After checking the GENERIC_NAME, it was found that there are various names, but most of them contain spelling mistakes and input formatting errors, after correcting all of them, two types of GENERIC_NAME were obtained: "Phakic intraocular lens" and " Phakic toric intraocular lens".

Based on the Model Numbers mentioned in the product information documents published by STAAR Surgical (edfu.staar.com/edfu), the values in the Model Numbers were cleaned and corrected, and the Model Numbers now include "VTICMO", "VICMO ", "VTICM5", "VICM5", "VICM6","VTICH", "VICH","TICM","MICL" and "Unknown". It is important to mention here that numbers such as 12.7 13.2 in the model numbers represent different lens diameters (mm), which usually depend on the patient's optical diameter (mm) (Premarket Approval (PMA) 2024), and therefore this part is not taken into account when considering differences between models.

### 2.2.3 Data preprocessing

The original data went through some data preprocessing process on R version 4.3.1 with the following steps:

1. Convert text to lowercase for uniform processing.

2. Remove the meaningless parts of the free text, such as all non-alphabetic and numeric characters, stop words, punctuation, by calling functions in the stringr and tidytext package.

3. Remove prepositions, pronouns from free text.

4. Collect the vocabulary of complications that may be caused by implantation of Visian ICL by consulting a large number of references, and collect as many keywords as possible that may be involved in the related symptoms, and customize these keywords into seventeen major categories. The categorization table can be seen in Table 2.

5. By writing a function to segment the text into n lengths of consecutive word combinations. Here the choice was made to categorize the text into 1-4 word lengths, for example independent words, phrases consisting of 2 words, phrases consisting of 3 words, and phrases consisting of 4 words. This is because the shortest keyword length is 1 and the longest keyword length is 4 in the keyword categorization table related to identifying adverse events. Such as "Blur", "pupil block"," Unreactive fixed pupil", "Loss of endothelial cell". This will minimize the loss of valuable information.

6. According to Table 2, the segmented phrases will be categorized by text analysis techniques, and only one categorization will be retained for each report with repeated occurrences and will not be double counted. For example, if both "IOP Elevation" and "Increased IOP" appear in the same row of records, then "Intraocular pressure (IOP) Elevation" will be categorized in the column of classification. pressure (IOP) Elevation" will only appear once in the category column, because both keywords are in that category. This avoids double counting the number of categories and affecting the actual distribution.

7. Finally, the report that did not recognize any classification in the category was removed, which means that nothing of interest to us was mentioned in the free text of that report.

**Table2. Keywords used to identify the classification of adverse events**

| Category | Keywords | Category | Keywords |
|---|---|---|---|
| Device problems | OPTIC BROKEN\|OPTIC TORN\|HAPTIC TORN\|BROKE INJECTION\|DIOPTER TORE BROKE\|BREAK INJECTION\|WAS TORN\|LENS TEAR\|LENS STUCK\|DUE TO DEVICE | Inflammation | INFECTION、INFECTED、INFLAMMATION、ENDOPHTHALMITIS、TOXIC ANTERIOR SEGMENT SYNDROME、TASS、UVEITIS、UGH、UVEITIS GLAUCOMA HYPHEMA、HYPOPYON、ULCER、KERATITIS、CONJUNCTIVITIS、CYST、CILIARY BODY INFLAMMATION、UGH SYNDROME |
| Decentration/Incorrect size /Phakic Intraocular Lens Rotation | LENS ROTATION\|LENS DECENTRATION\|INCORRECT SIZE\|DISLOCATED\|DISLOCATION\|LUXATION\|DIMENSIONAL SPECIFICATION CLAIM\|REPOSITIONED | Edema | SWELLING、EDEMA、OEDEMA、SWOLLEN、CYST |
| pigment dispersion/lens deposits | PIGMENT DISPERSION/PIGMENT DEPOSITION/IRIS PIGMENT\|DEPOSIT | Eye injury | CORNEAL DECOMPENSATION\|CORNEAL DAMAGE\|CAPSULAR BAG TEAR\|IRIS DAMAGE\|ENDOTHELIAL DAMAGE\|ENDOTHELIAL CELL INJURY\|CORNEAL ABRASION\|SUSPENSORY LIGAMENT INJURY\|VITREOUS HUMOR\|OPTICAL NERVE DAMAGE |
| Discomfort | FATIGUE\|IRRITATION\|SENSITIVITY\|VITREOUS FLOATERS\|DISCOMFORT\|ITCH\|PRURITUS\|FOREIGN BODY\|HEADACHE\|DIZZINESS\|DRY EYE\|EXCESSIVE TEAR | Refractive problems | UNREACTIVE FIXED PUPIL\|FIXED IRIS\|REFRACTIVE SURPRISE |
| Visual disturbances | BLUR\|VISUAL IMPAIRMENT\|VISUAL DISTURBANCE\|FOGGY VISION\|DYSPHOTOPSIAS\|REDUCED VISION\|GLARE\|HALO\|FLARE\|DAZZLING\|HAZING\|LIGHTPOINT\|DIPLOPIA\|DOUBLE VISION | Cataract | CATARACT |
| Glaucoma | PUPILLARY BLOCK GLAUCOMA\|MALIGNANT GLAUCOMA\|ACUTE GLAUCOMA\|SECONDARY GLAUCOMA\|ANGLE CLOSURE GLAUCOMA\|ANGLE CLOSURE\|PUPIL BLOCK\|IRIS ATROPHY | Loss of Vision | BLIND、LOSS EYESIGHT、LOSS OF VISION |
| Pain | HURT\|PAINFUL\|ACHE\|SUFFERING\|PAIN | Bleeding | BLEED、HYPHEMA、BLOOD、RED EYE |
| Pupil Ovalisation/Iris Retraction | PUPIL OVALISATION\|IRIS ATROPHY | Loss of Corneal Endothelial Cells | ENDOTHELIAL CELL LOSS\|LOSS OF ENDOTHELIAL CELL |
| Intraocular Pressure(IOP) Elevation | IOP ELEVATION\|ELEVATED IOP\|INCREASED IOP\|INTRAOCULAR PRESSURE ELEVATION\|ELEVATED INTRAOCULAR PRESSURE\|EXCESSIVE VAULT\| INCREASED EYE PRESSURE\|EYE PRESSURE ELEVATION\|ELEVATED EYE PRESSURE | Other | Any of the above keywords never appear |

## 2.3 Keyword recognition and extraction

To extract the undesirable events in free text, I have chosen to use the N-grams technique in NLP algorithms. N-grams are very commonly used technique in text analysis for generating all possible combinations of consecutive n-words in textual data and are widely used in text mining and natural language processing tasks. (Dey 2023) By decomposing the text into N-grams, complex sentence structures are turned into smaller and more manageable structures, contextual information is obtained by considering the words before and after, which makes the information more accurate and also improves the accuracy of sentiment analysis. (Daniel & Martin 2024) In addition, to identify and categorize the extracted words and phrases, I chose the keyword matching method. (Nasar, Jaffry & Malik 2019) by creating a customized list of keywords and matching these keywords with information from patient reports to identify the adverse event categories of these words and phrases. The keyword taxonomy used to identify and categorize this information is presented in Table 2, where the keywords include terms related to the implantation of lenses with pIOLs and complications associated with their implantation procedures, which belong to are taken from a number of published studies. (Lovisolo & Reinstein 2005; Kohnen et al. 2010; Chen & Sun 2018)

By generating combinations of 1-4 consecutive words from words in free text based on context through the N-grams method, the keywords of symptoms related to pIOLs were extensively extracted to avoid critical information being overlooked, and then these keywords matched to the adverse event categories were matched to patient reports through the keyword matching method. Through the combined use of these two methods, the key information in the free text and the patient experience

were deeply mined, and the categories of adverse events that appeared in the patient reports as well as their frequencies were determined, as seen in Table 3. It can be seen that the categories of adverse events with relatively high frequencies are device problems, elevated IOP problems, visual impairment problems, and refractive problems. The less frequent ones such as loss of corneal endothelial cells, loss of vision, bleeding, and eye injuries are also of great concern because these symptoms, when they occur, will cause immediate harm or even irreversible damage to the patients and have a significant impact on their lives.

**Table 3. Adverse event categories and frequency**

| category | frequency | percentage |
|---|---|---|
| DeviceProb | 7933 | 18.32 |
| Intraocular Pressure(IOP) Elevation | 7711 | 17.81 |
| Visual disturbances | 6406 | 14.80 |
| RefractiveProb | 4688 | 10.83 |
| Decentration/Incorrect size/Phakic Intraocular Lens Rotation | 4422 | 10.21 |
| Glaucoma | 2920 | 6.74 |
| Pain | 1702 | 3.93 |
| Pigment Dispersion/lens Deposits | 1670 | 3.86 |
| Discomfort | 1345 | 3.11 |
| Inflammation | 1345 | 3.11 |
| Cataract | 1146 | 2.65 |
| Edema | 1057 | 2.44 |
| Pupil Ovalisation | 417 | 0.96 |
| Eye Injury | 259 | 0.60 |
| Bleeding | 130 | 0.30 |
| Loss of Vision | 80 | 0.18 |
| Loss of Corneal Endothelial Cells | 76 | 0.18 |

# 3 Results

## 3.1 Annual trends

It was mentioned earlier that pIOLs are an emerging field and have not been in actual clinical development for very long, which can be seen more clearly in Figure 2, which shows the frequency and trend of all reports associated with pIOLs and those labeled as adverse events by the FDA during the period 2014-2023. Although the FDA approved Visian ICL in 2005, it has only been documented in MAUDE since 2014. There

was a significant increase in frequency in 2017 and 2019, the remaining years had small fluctuations in frequency, but generally showed a steady upward trend.

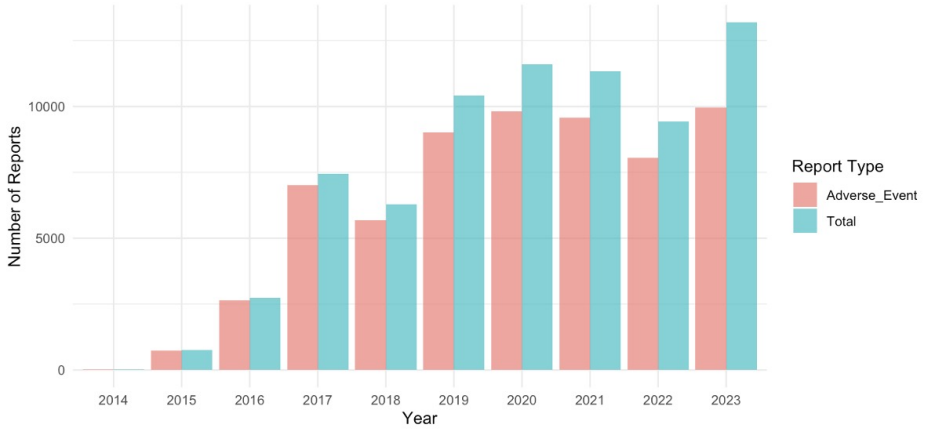


Figure 2. Total reports and Adverse event reports by Year

As can be seen by plotting the number of reports identified as adverse events by the FDA as a percentage of the total number of reports (Figure 3), the percentage of reports labeled as adverse events by the FDA as a percentage of the overall number of reports has been decreasing over the years, which indicates that the technology is moving in a better direction and that many experts in the field are doing excellent work in reducing the incidence of adverse events in this procedure.

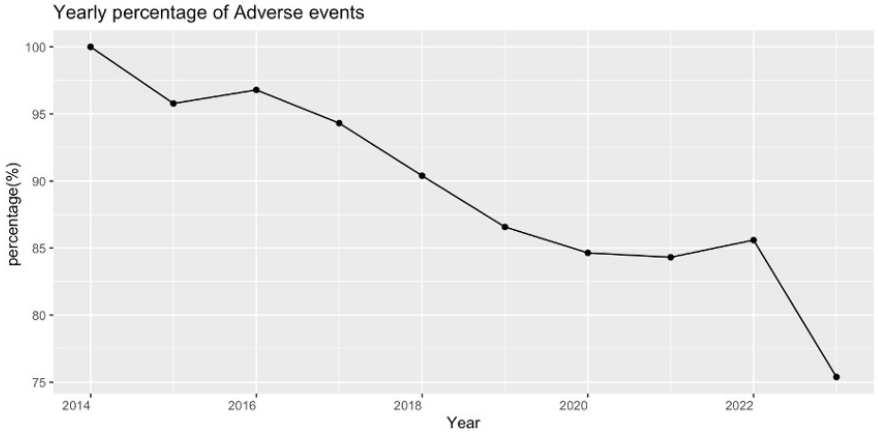


Figure 3. Line graph of percentage of adverse events to total reports per year

According to the keyword categorization of the top 17 most frequently occurring adverse events in pIOLs surgery summarized using N-grams and keyword extraction (Table 3),"Device problems" was the most frequent adverse event in the dataset, with 7,933 reports, approximately 18.32%, mentioning keywords from this classification. Other common adverse events included "elevated intraocular pressure" (ap-

proximately 17.82%), "visual impairment" (approximately 14.8%), and "refractive problems" (approximately 10.83%), "lens rotation (approximately 10.21%)," and "glaucoma" (approximately 6.74%), which accounted for nearly 80% of the adverse events.

## 3.2 Trends in identified adverse events

To further describe the characteristics of the distribution of adverse events for each year of the decade, I normalized the data, which is to calculate the number of each type of adverse event as a percentage of the total number of events for each year, as shown in Figure 4. Because of the large number of categories, I ranked the adverse events according to their frequency of occurrence and divided them into two groups, one representing the first 8 adverse events, and the other representing the remaining 9 adverse events.

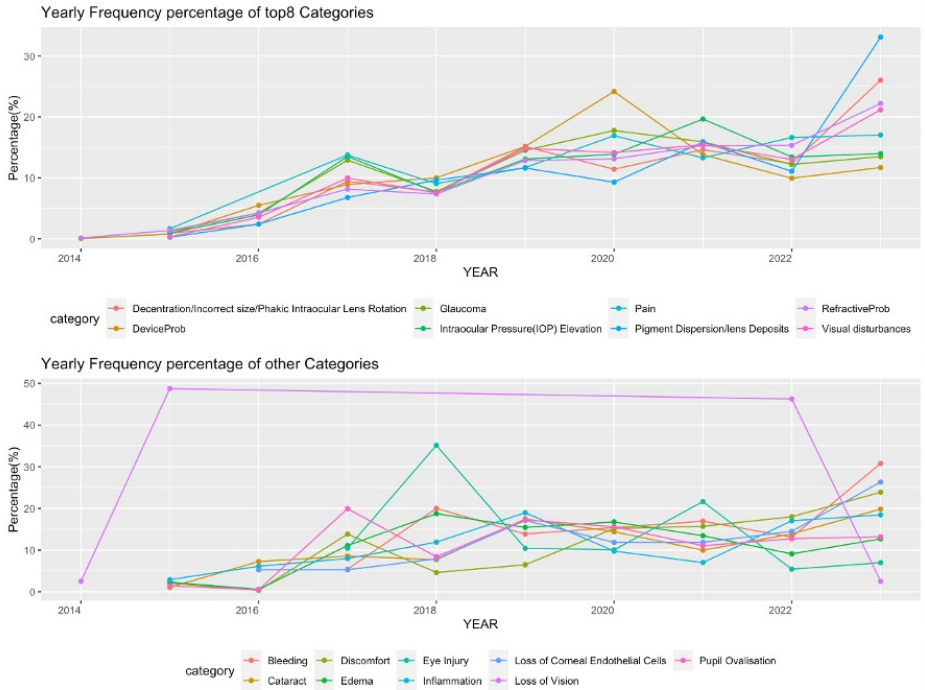


Figure 4. Line graph of percentage of top 8 adverse events and bottom 9 adverse events per year

From the graph we can observe the trend of adverse events over time. In the top 8 adverse events graph, "pain", "IOP elevation" and "glaucoma" reached a small peak in 2017, followed by a peak in 2020 for "device problems", which significantly outweighed the other adverse events, but declined significantly in the last few years, and finally peaked in 2023 for "pigment dispersion/lens deposits", "decentration/incorrect size/phakic intraocular lens rotation", refractive problems, and visual disturbances problems. On the other hand, the first thing that will be

noticed in the graph of the last 9 adverse events is that almost 50% of the "loss of vision" occur in 2015 and more than 45% of the "loss of vision" occur in 2022. Since blindness issues are very serious medical errors, the frequency of these types of adverse events will be tightly controlled provided they pass FDA authorization, so the percentage of concentrated occurrences of this event will be extremely high given the small overall number. Then there is a significant increase in Eye injury peaking in 2017 to 2018, followed by a yearly decrease, with Bleeding and Loss of Corneal Endothelial Cells and Discomfort having a significant increase in 2022 to 2023, and Cataracts, Edema, Inflammation, and Pupil ovalisation as prevalent problems .

Most of the keywords for device problems are related to broken and torn lenses, which typically occur during the surgical procedure prior to implantation in the eye. There are usually 2 techniques for implantation of posterior chamber IOL lenses: the injection technique and the forceps technique. The injection technique requires the use of customised forceps to carefully grasp the lens for examination under a microscope and also to avoid lens contact with the plunger of the syringe during injection. (Lovisolo & Reinstein 2005) Both of these processes have the potential to cause the lens to break. The forceps technique is technically more demanding and carries a higher risk of intraocular trauma, as it requires a larger incision and must be performed very smoothly and gently, otherwise there is also a risk of broken lenses. (Lovisolo & Reinstein 2005)

There is a correlation between pigment dispersion/lens deposites and lens rotation/decentration or Incorrect lens size.(Kohnen et al. 2010) Incorrect lens size is not a complication, but precise selection of lens size is critical because it determines the vault, the distance between the anterior surface of the crystalline lens and the IOL, and inappropriate size may increase adverse events such as pupillary obstruction, hyperpigmentation, glaucoma, and endothelial cell detachment.(ICL Sizing 2024) This space arching over the crystalline lens allows atrial water to flow through the lens to minimize the occurrence of adverse events such as cataracts. (Implantable Collamer Lens 2024) The standard method for lens sizing is to use STAAR's online calculator and ordering system, degree calculations for ICL are also performed using this calculator, and some doctors choose to to use ultrasound biomicroscopy for sulcus-to-sulcus measurement.(Phakic IOL Surgery 2023) This method measures the rise of the anterior capsule, which is a factor in lens size.(Packer 2018) There have been a number of studies that have shown a weak correlation between the WTW (white-to-white) measurements required by STAAR's online calculation and ordering system and the actual hypothesized position

of the lens placement.(Reinstein et al. 2009) This may be one of the reasons for these adverse events, it also can cause refractive problems such as overcorrection or undercorrection. Therefore, the use of multiple measurements is more helpful in accurately selecting lens sizes, thereby reducing the likelihood of adverse events. Pigment dispersion/lens deposites or decentration can also cause visual disturbances problems such as glare and blurred vision. (Kohnen et al. 2010) This may be the reason why all three have had relatively similar trends over the years.

It is important to note that for all types of pIOLs, there is no established direct relationship between pIOLs and retinal detachment (Kohnen et al. 2010) because the probability of retinal detachment is inherently higher in the population of patients suffering from high myopia. (Lovisolo & Reinstein 2005) Therefore retinal detachment was not considered among the types of adverse events of concern in this study.

## 3.3 Relationship between lens model and adverse events

In Figure 4, besides the outliers for loss of vision, it can be noted that in 2015, many new adverse events also appeared, such as "Glaucoma", "Pain", "Intraocular pressure elevation", "Edema", "Cataract" and etc. To further explore the correlating factors behind several key time points of adverse events, I first looked at the frequency of model number used for each year (Figure 5). I found that only one model, VTICMO, was used in reports related to pIOLs in 2014, and starting in 2015, the VICMO model, the TICM model, and the VTICH model were added. VICMO (Visian ICL with KS-AquaPORT™) is an implantable intraocular lens developed by STAAR Surgical for the correction of myopia, which was formally introduced in 2012 with the integration of the revolutionary KS-AquaPORT™ technology. (Packer 2016) The KS-AquaPORT™ technology is a small, central hole design that is designed to improve the aqueous flow and reduce the risk of postoperative elevated intraocular pressure. The MICL (Implantable Collamer Lens for Myopia) was an early lens introduced by STAAR Surgical for the correction of myopia. It is primarily used for the correction of moderate to high myopia and does not correct astigmatism. (Packer 2018) It also uses the traditional collamer material, but it does not have a central pore design, while the TICM (Toric Implantable Collamer Lens Model) is an early design specifically designed to correct both astigmatism and myopia at the same time, and like the MICL, it uses the traditional collamer material and does not have a central pore design. (Tereza Řeháková et al. 2018) The VTICH (Visian Toric Implantable Collamer Lens High Myopia), on the other

hand, is a lens designed to correct both high myopia and astigmatism, and the fact that cases of exceptionally high myopia are rare in reality is one of the reasons why there have been so few reports on this lens. The first addition of these emerging technologies and new models may have been a contributing factor to the surge in blindness and the occurrence of other adverse events in 2015.

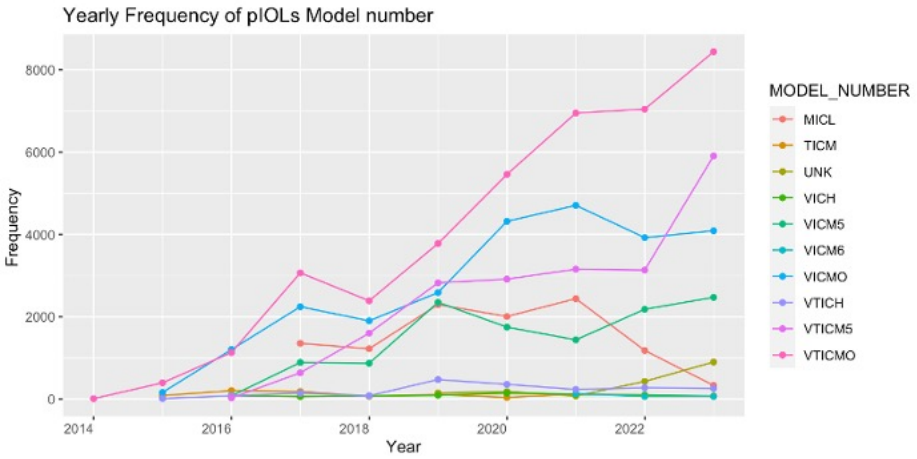


Figure 5. Line graph of the frequency of model numbers in the annual report

It is worth to note that the new model MICL added in 2017 are steadily increasing until 2021, but after 2021 and into 2023 have faded out of sight, while VTICMO, VICM5 and VTICM5 have increased significantly in that time frame. VTICMO (Visian Toric ICL with KS-AquaPORT™) and VICMO belong to the same family EVO Visian ICL of lenses with different features, it is a lens that corrects both astigmatism and myopia, making up for the inability of VICMO to correct astigmatism, they have the same collamer material and KS-AquaPORT™ technology in the central hole design. STAAR optimized the optical design of the VTICMO in 2014 and upgraded the collamer material in 2016, with the subsequent introduction of the VICM5 (Visian ICL Model 5) and VTICM5 (Visian Toric ICL Model 5), both of them are from the EVO+ Visian ICL series (Chen & Chen 2021). These improvements give EVO+ Visian ICL better visual quality than EVO Visian ICL, and better biocompatibility and oxygen permeability than lenses made with the traditional collamer material. (Thompson, Cummings & Wang 2024) While the upgraded offer better visual quality and more advanced materials, they also increase the cost of implantation, and they are currently positioned more towards the more premium market, so the EVO Visian ICL are still the more popular and cost-effective choice for the same type of vision correction procedure. Compared to the MICL, the KS-AquaPORT™ technology in the EVO+ Visian ICL improves the flow of aqueous humor

and reduces the risk of postoperative IOP elevation.(Thompson, Cummings & Wang 2024) Persistently elevated IOP can lead to serious consequences of blindness if not intervened in time. And VTICMO and VTICM5 allow patients to correct astigmatism along with myopia, and its implantation usually does not require a circumferential iris incision like MICL implantation, which simplifies the complexity of the procedure and reduces the risk of many postoperative complications. This is a major reason why MICLs are fading from the market.

I then extracted all reports classified as "Loss of Vision" and identified their corresponding lens models and normalized the data, which is to calculate the number of occurrences of each model as a percentage of the total number of models, as shown in Figure 6.

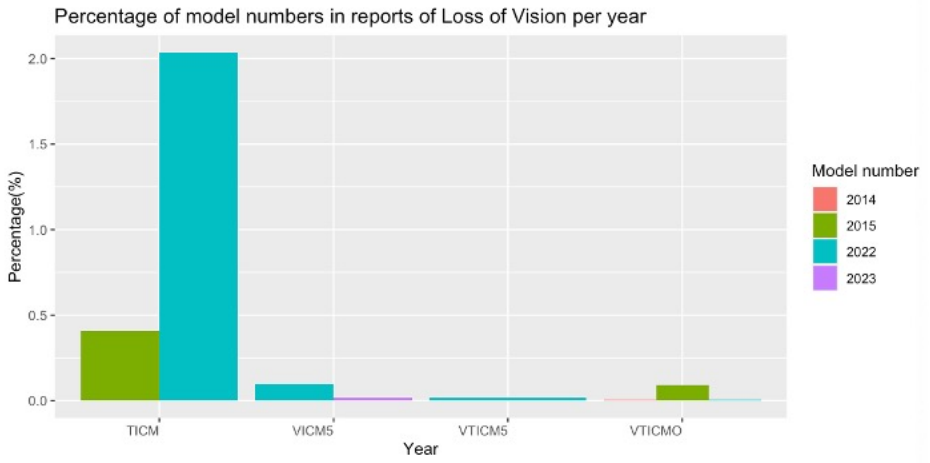


Figure 6. Histogram of percentage of model number for annual reports of Loss of Vision

As can be seen in Figure 6, the TICM model accounted for the majority of all reports containing blindness in 2015 leaving a small portion from the VTICMO model. The TICM (Toric Implantable Collamer Lens Model) model was developed early on as a solution to the inability of the ICL lens to correct astigmatism, and it was a predecessor of the VTICM model product, which was phased out in 2018 with the advent of KS-AquaPORT™ technology. (Class III Product-Collamer Implantable Contact Lenses) Early causes of blindness were influenced by a wide range of factors, and in addition to the lack of timely intervention for elevated IOP, issues such as physician proficiency with the emerging technology and the quality of production in the early stages of device adoption may have contributed to adverse events. (Thompson, Cummings & Wang 2024) This also suggests that the early VTICMO model, the TICM model, and their implantation techniques still need to be improved. In addition, the TICM model accounted for the vast majority of reports containing blindness in 2022, and the disproportionately high proportion of blindness problems highlights the shortcomings of the TICM model even more against the

backdrop of the predominance of VTICMO, VTICM5, and VICMO, and the paucity of overall TICM reports.

# 4 Conclusion

This is a study based on R programming language to extract valuable information from complex text in healthcare industry by applying natural language processing techniques. In this study, based on the complex MAUDE dataset, the cleaning and preprocessing steps of the complex dataset were done using the R programming language, and the dominance of STAAR's Visian ICL product in this type of surgery was found. Then, by using N-grams and keyword extraction techniques, 17 categories of adverse events associated with Visian ICL implantation were identified and extracted as shown in Table 3. Of these, equipment problems and high intraocular pressure (IOP) problems were the most frequently reported problems. This indicates the impact of equipment problems on the surgical procedure and the impact of high IOP problems on the patient's postoperative experience. These findings are a reflection of the need to improve the design of lenses and the proficiency of surgeons in this surgical technique, and timely postoperative visits to patients to keep an eye on their IOP parameters are also an important part of the process. Also Vision disturbances, refractive problem and decentration/Incorrect size/lens rotation were high frequency problems. This reveals that the current standard system for measuring lens size and lens power still needs to be improved, and that the use of multiple measurements is a conservative and effective approach.

When analysing the occurrence of adverse events over the decade and the models used in the reports, it was found that there was a sudden increase in the frequency of adverse events in 2017, which may be related to the upgrading of the lens models, the inclusion of new lens models and the short period of time when the new technology was being used in the clinic on a large scale. Based on the situation of the models used in adverse event reports, the trend of different models with the year was analysed by collecting the development process and characteristics of each model. EVO Visian ICL, as the predecessor of the newly released EVO+, is still the most used model at present, and the newest generation of the product, EVO+, with its more advanced materials and better optical technology, has reached the use of the EVO+ in a short period of time. This study also delved into the outliers of "Loss of Vision", a serious adverse event, in 2015 and 2022, and found that the TICM model may have a strong correlation with this condition, and the VTICM5 and VICM5 models in the newest generation of EVO+ Visian ICLs may

have a strong correlation with this condition. VTICM5 and VICM5 also showed a very small number of blindness events in 2022. This informs future iterations of the product.

# 5 Discussion

In this study, 17 adverse events associated with posterior chamber implantable IOL surgeries, particularly Visian ICLs from STAAR Surgical Company, were identified and extracted using natural language processing techniques based on reports associated with these surgeries in the MAUDE dataset. Annual analyses of these adverse events and corresponding lens models were also performed, revealing temporal trends and potential associations between them. Noteworthy were the most frequently cited device problems and elevated IOP in the report, as well as the relationship between the concentration of blindness and model number in 2017 and 2022. These findings highlight the importance of the surgeon's surgical skills and the selection of the appropriate lens model, emphasize the need for regular return visits to follow the patient's postoperative changes in parameters such as IOP, and provide insight into future directions for product optimization and updating.

By completing these analyses, I can perceive that there seems to be a potential link between different adverse events and complications. In the future, I will try to extend this study in terms of the causal relationship between these adverse events and complications, and analyse whether there is a temporal pattern in the occurrence of adverse events, for example, whether it is affected by seasonal factors, by introducing a time-series model, in order to achieve the purpose of predicting the frequency and range of adverse events in the next 1-3 years.

# A Appendices

The datasets used can be downloaded from: https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files

The codes are available in this Github repository: https://github.com/ManqiZhang0513/Data-science-research-part-A.git

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