SWISS MADE

SAV-IOL TORIC CALCULATOR

Intraocular Lenses with
Extended Depth of Focus

User Guide

EN

SWISS ADVANCED VISION
INTRAOCULAR LENS

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SAV-IOL Toric Calculator

The SAV-IOL Toric Calculator (the Calculator) is resource for the treating physician to aid in intraocular lens (IOL) cylinder power calculation for cataract patients with corneal astigmatism. Patient keratometry and biometric data and planned surgery information that is part of a pre-operative work up prior to toric IOL (TIOL) implantation are required by the user of the SAV-IOL Toric Calculator. The Calculator will suggest several SAV-IOL TIOLs from which the surgeon may choose to treat a patient's refractive cylinder resulting from corneal astigmatism. To minimize postoperative astigmatism, the Calculator will also provide suggested intra-operative axial placement of the IOL that is to minimize postoperative astigmatism.

This second version of the SAV-IOL Toric Calculator offers a feature that takes into consideration induced astigmatism caused by the posterior surface of the cornea. It allows the user to apply the Abulafia - Koch Regression formula [1], which is based on clinical data and utilizes standard keratometry measurements of the cornea's front surface. This formula estimates the additional astigmatic effect of the posterior cornea, resulting in an overall net astigmatism value for the cornea. When applied to a clinical patient group, the Abulafia - Koch Regression has demonstrated improved predictability for the refractive outcomes of Toric Intraocular Lens (TIOL) procedures. It's important to note that this regression formula was developed based on eyes within the normal range of eye biometry and without a history of corneal refractive surgery. The results obtained from the regression may not be applicable to individual eyes with corneal abnormalities, such as Keratoconus, post Penetrating Keratoplasty, or post-refractive surgery. Only anterior corneal curvatures values are appropriate for use of the Abulafia Koch Regression.

Various diagnostic tools used in anterior segment imaging and biometry, such as Scheimpflug devices and optical coherence tomography (OCT) imagers, have the capability to measure curvature values for both the front and back surfaces of the cornea. By inputting these total corneal power values, the calculator will yield astigmatism results that accurately reflect the total cornea. **It's important to note that if the user decides to enter total corneal (frontside and backside) power values, the Abulafia - Koch Regression should be deactivated (uncheck the box).**

This second version of the SAV-IOL Toric Calculator will estimate the Effective Lens Position (ELP) of the TIOL and adjust the cylinder power on the corneal plane by using Spherical Equivalent (SE) power, biometry and keratometry values and the SRKT formula [2].

The SAV-IOL Toric Calculator is openly accessible on the SAV-IOL website (https://sav-iol.com/toric-calculator/) for all Users and compatible with internet web browsers including Internet Explorer, Google Chrome, Firefox, Safari and Microsoft Edge.

1. Terms and Conditions

To access the Calculator, the user must read the Terms and Conditions of use for SAV-IOL Toric Calculator.

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After reading the Terms and Conditions, the User must check the *"I accept the Terms and Conditions"* checkbox to indicate acceptance and then click on *"Continue"*. If wanted, the user has the possibility to print the Terms and Conditions of use for SAV-IOL Toric Calculator by clicking on the *"Print"* button.

2. Configuration

After accepting the Terms and Conditions, the data input page of the SAV-IOL Toric Calculator is shown.

2.1 Global Informations

The user **must** fill the following required fields:

Field	Description
Surgeon's name	Any identification of surgeon
Date	Any date (of surgery, of calculation or of the day)
Patient ID	Any identification of patient
Age	Age of the patient

Those fields will appear in the printed results page.

2.2 Calculation Options

The user can customize the Calculator for her/him preferred calculation method of use. Following parameters can be chosen:

Field	Description
K index	The default value for the K index is the standard value of 1.3375. A drop-down list proposes other values to the user.
Include PCA (A-K)	The user can choose with the radio buttons to include the Posterior Corneal Astigmatism (PCA) or not. YES – PCA is included This calculation method, based on the Abulafia-Koch (AK) regression, uses standard keratometry measurements (anterior K values) and estimates total cornea astigmatism. This method improves the prediction of the postoperative result of astigmatism by considering theoretically the effect of the PCA [1]. By default, the PCA is selected for the calculation.

	The final print out will indicate if the AK regression has been chosen for the calculation. NO – PCA is NOT included This calculation method uses standard keratometry measurements (anterior K values) and estimates total cornea astigmatism (also called "Standard K" method). This method should be used if the user wants to use values from the "Total K (TK)" method. If user uses TK values with the PCA included, a refractive error would occur as the posterior corneal astigmatism would be included twice in the calculation.

2.3 Pre-Operative Information

The user **must** choose and fill the following required fields:

Field	Description
Eye Selection	Radio button to select the eye to be operated. The temporal (T) and nasal (N) sides of patient is indicated. This selection will display in all images and print out for the calculation results. Left eye (OS) – Examination view  Right eye (OD) – Examination view 
Lens Model	SAV-IOL Toric lens model can be chosen with this drop-down list: • Lucidis 108MT • Lucidis 124MT • Eden 108MT • Eden 124MT • Other A-cst Other A-cst is proposed to use the incision location optimization feature of the SAV-IOL Toric Calculator with any lens model.

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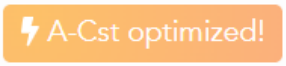
A-constant (A-cst)	A-constant is used in SRK/T formula [2]. The constant is a theoretical value that relates the lens power to axial length (AL) and keratometry. The value of the A-constant will be automatically loaded depending on the Toric lens model chosen. User can change this value to optimize the calculation. If the value is changed, an indication of the change "optimized" will appear next to the field. 
Spherical Equivalent Power (SE)	The SE in [D] for the patient can be chosen with this drop-down list. SE is calculated with the method chosen by the user for the particular eye for which the cylinder calculation is being performed.

2.4 Biometry

The user must fill the following required fields:

Field	Description
Axial Length (AL)	Distance in [mm] between the corneal epithelium and the fovea. User must enter value between 12.00 to 32.00 [mm]
Anterior Chamber Depth (ACD)	Distance in [mm] between the corneal epithelium and the anterior capsule of the lens. User must enter value between 1.00 to 6.00 [mm]

Both parameters are used to estimate the Effective Lens Position (ELP) of the IOL and will adjust the TIOL cylinder power on the corneal plane.

The following field is optional:

Field	Description
White-to-white (WTW)	Horizontal distance between the borders of the corneal limbus. User can enter value between 8.00 to 14.00 [mm]

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2.5 Keratometry

The user must enter the following required information:

Field	Description
K notation	These radio buttons are used to select the K notation preference to be used for the current calculation. Input data can be given in diopters [D] or millimeters [mm].
Flat K1	User must enter the patient's anterior corneal curvature value on the flat axis as measured by standard keratometry in either radius [mm] or diopters [D]. The entered value must be within a range of 6.14 to 11.25 [mm] or 30.00 to 55.00 [D]. User must enter the angle of the anterior cornea flat axis as measured by keratometry in the range of 0° to 180°.
Steep K2	User must enter the patient's anterior corneal curvature value on the steep axis as measured by standard keratometry in either radius [mm] or diopters [D]. The entered value must be within a range of 6.14 to 11.25 [mm] or 30.00 to 55.00 [D]. A value that is 90° from the flat axis will automatically be generated.
Surgically Induced Astigmatism (SIA)	User must enter a value in a range from 0.00 to 2.00 [D] for the expected change in corneal astigmatism due to the surgical incision. User must enter the angle of the incision (incision location) planned for the surgery in the range of 0° to 180°.

All numeric entries that are decimal values may be entered using either a dot (.) or a comma (,) to serve as the decimal point. For example, 40.08 may be entered or as 40,08 and will be recognized by the calculator as the same value.

Pre-operative astigmatism (Pre-op Ast.) will be calculated based on K1 and K2 values.

3. Results

Once all required fields have been filled by the user, this latter can press on "CALCULATE" to display the results of calculation and a visual aid.

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By clicking on the “CLEAR” button all input data of the user will be erased and the table of results will disappear.

3.1 Graphical representation

Once the entire dataset has been input, the user is prompted to press the "CALCULATE" button. This action triggers an update in the graphical representation of the eye, illustrating the computed values, and presenting the steep and flat axes of the cornea, along with the incision and TIOL placement (lens alignment).

3.2 Results and Selection

The calculator will calculate and display the value of the net corneal astigmatism (combination of pre-operative astigmatism and surgically induced astigmatism).

The calculator will display up to three lens options depending on the user’s data. The TIOL options will be listed in a table from the undercorrected residual astigmatism to overcorrected residual astigmatism. The lens selection shown as the central option in the center will be the TIOL with cylinder power that will minimize the residual astigmatism. In the extreme cases (low net corneal astigmatism or high net corneal astigmatism) only two options are displayed.

To help the user, three types of indications are proposed on the right-hand side of the results table.

Indication	Description
✔ Recommended	The option with the smallest residual astigmatism will always be recommended for the user.
Flipped	This indication appears with options that will flip the residual astigmatism of the patient.
Standard IOL	With low net corneal astigmatism, the residual astigmatism with a standard option (without cylindrical power) is also shown.

3.3 Incision Location Optimization

Once the user has selected an IOL, he/she has the possibility to use the incision location optimization tool by clicking on the switch button on the right-hand side of the ribbon. Once clicked, the ribbon unfolds, and the optimization tool is ready-to-use.

The incision location optimization tool is composed of 5 elements:

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Element	Description
SIA and IOL Selected	This element displays a summary of the surgically induced astigmatism amplitude and the IOL selected previously by the user. The denomination meaning for IOL selected field is: • Standard IOL = standard IOL without cylindrical power • TIOL100 = TIOL with a cylindrical power of 1.00 [D] • TIOL150 = TIOL with a cylindrical power of 1.50 [D] • TIOL225 = TIOL with a cylindrical power of 2.25 [D] • TIOL300 = TIOL with a cylindrical power of 3.00 [D] • TIOL375 = TIOL with a cylindrical power of 3.75 [D] • TIOL450 = TIOL with a cylindrical power of 4.50 [D]
Optimization Parameter	The field “SIA Amplitude” is automatically filled with the previous value of surgically induced astigmatism amplitude. The user has the possibility to change this value to observe the influence of the SIA amplitude on the optimization by using the slider below the SIA amplitude field. If the previous value of SIA amplitude is 0, the user is invited to change the value for the optimization. By changing the SIA amplitude value, the Graph, Optimized Results and Graphical Representation are updated according to user input for optimization.
Graph	Based on the “Optimization Parameter” value, The graph shows the residual astigmatism value for each incision degree from 0° to 180°. When the residual astigmatism amplitude is a positive value, the residual astigmatism is undercorrected. When the residual astigmatism amplitude is a negative value, the residual astigmatism is overcorrected. The minimal value(s) is/are indicated on the graph with an orange dot(s).
Optimized Results	Results of the Incision Location Optimization are presented.

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	If more than one minimal value for the optimized incision location is proposed, the user has the possibility to choose between the different points in the list of the field "Optimized incision location". If more than one minimal value for the "Optimized incision location" is proposed, by convention the value closer to the temporal (T) side of patient is chosen in the range of 0° to 180°. For right eye if the minimal value for the "Optimized incision location" is between 0° to 45°, it is proposed to the user to make the incision at +180° to be on the temporal side (T). For left eye if the minimal value for the "Optimized incision location" is between 135° to 180°, it is proposed to the user to make the incision at +180° to be on the temporal side (T). Depending on the value chosen for the "Optimized incision location", the residual astigmatism after optimization value is updated accordingly (amplitude and orientation).
Graphical Representation	The same graphical representation of the eye as in the initial configuration is shown. The optimized incision location is also shown.

If the Incision Location Optimization has be chosen, the value of the optimized surgically induced orientation will appear in the results printout.

3.4 Print

3.4.1 Print without Incision Location Optimization

By clicking on the "PRINT" button, a pop-up message will appear to confirm the parameters used for the calculation.

Here an example of pop-up message:

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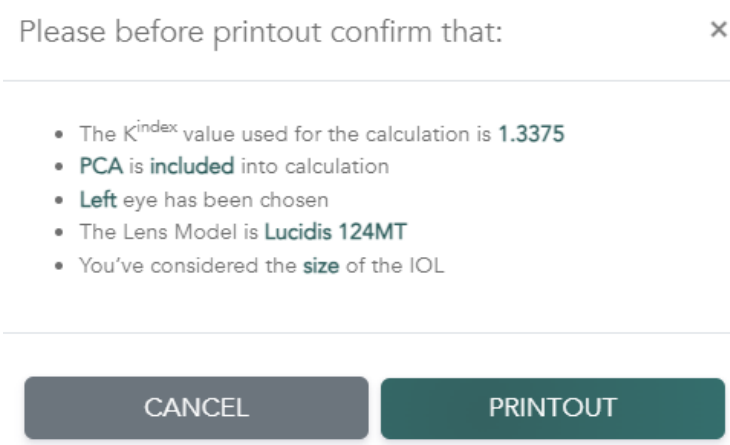

The user must check that all parameters are conform. By clicking on "PRINTOUT", the user will generate a PDF document that summarizes the calculation.

Here is the list of all elements that will appear onto the printout:

- All Global informations:
  - Surgeon's name
  - Date
  - Patient name or ID
  - Age of patient
- Visual support scheme with steep and flat axis, lens alignment recommendation, incision location and left or right eye.
- Medical chart
  - Eye Selection
  - Lens Model
  - A-Cst value
  - SE Power of IOL
  - Cylinder Power of IOL
  - Lens alignment value
  - Incision location value
  - Indication about inclusion of PCA
- Keratometry and biometry
  - K index value used for the calculation
  - Flat K1 amplitude and orientation values
  - Steep K2 amplitude and orientation values
  - Axial length value
  - ACD value
- Calculation summary
  - Pre-operative astigmatism amplitude and orientation (convention steep orientation chosen)

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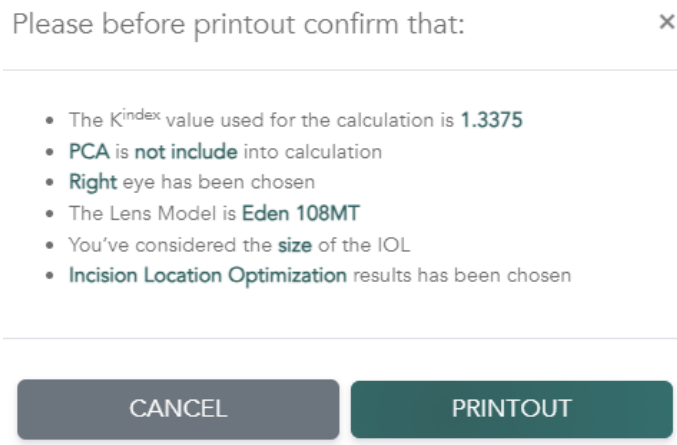
- Initial surgically induced astigmatism amplitude and orientation value
- Net corneal astigmatism amplitude and orientation values
- IOL cylinder power selected
- Predicted residual astigmatism amplitude and orientation values

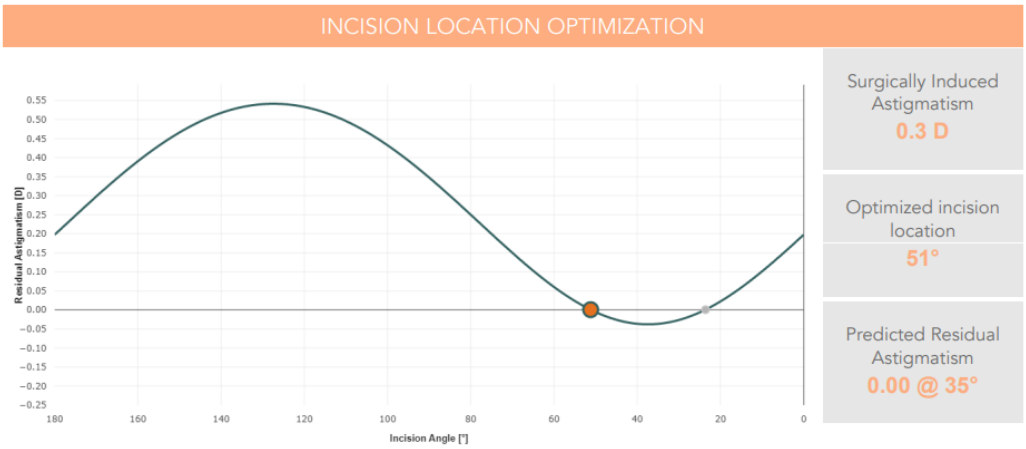
3.4.2 Print with Incision Location Optimization

If the user choses to use the Incision Location Optimization option and wants to print the results with the optimization, he/she can click on “PRINT optimized”.

By clicking on the “PRINT optimized” button, a pop-up message will appear to confirm the parameters used for the calculation. Here an example of pop-up message with incision location optimization option:



The user must check that all parameters are conform. By clicking on “PRINTOUT”, the user will generate a PDF document that summarizes the calculation. All elements listed in chapter 3.4.1 are also included in the optimized results printout. Moreover, the graph of the incision location optimization and results are added to the printout. Here an example of the elements added:



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4. References

[1] Abulafia A et al, "New regression formula for toric intraocular lens calculations," J Cataract Refract Surg 2016; 42(5):663-671

[2] John A. Retzlaff et al, "Development of the SRK/T intraocular lens implant power calculation formula", J Cataract Refract Surg 1990; DOI: 10.1016/s0886-3350(13)80705-5