Hill-RBF Calculator Instructions for Use

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Preface

Thank you for choosing the Hill-RBF Calculator for IOL power selection prior to cataract surgery. Provided you carefully follow these instructions for use, the use of the calculator should be reliable and trouble-free.

WARNING!
Please read the instruction manual carefully before using this calculator. It contains important safety information for both the patient and the surgeon.

Introduction

The Hill-RBF Calculator is an advanced, self-validating method for IOL power selection employing pattern recognition and a sophisticated form of data interpolation. It has been optimized for use with biometry data from the Haag-Streit LENSTAR LS 900 optical biometer in combination with the Alcon SN60WF biconvex IOL for powers from +6.00 D to +30.00 D and IOL powers up to +35.00 D based on a similar biconvex IOL design. For IOL powers from +5.00 D to -5.00 D, it performs best with this combination of biometry device and the Alcon MA60MA extended range IOL.

The Hill-RBF on-line calculator may also be used with data from other optical biometers, which provide clinically equivalent biometry data as compared to the LENSTAR LS 900. It may also be used with other biconvex IOL models in the power range of +6.00 D to +35.00 D and other meniscus design IOL models in the power range of +5.00 D to -5.00 D.

Intended purpose

Intended use

The Hill-RBF Calculator is designed to assist the user in selecting the appropriate IOL power for cataract surgery when optical biometry is used to calculate the power of a biconvex intraocular lens (IOL) from +6.00 D to +35.00 D IOL power and for a meniscus design IOL from +5.00 D to -5.00 D IOL power.

Indication

Replacement of the natural crystalline lens; e.g.: aphakia or cataract.

Contraindications

Since this is a software product, there are no contraindications.

Patient population

All patients who are eligible for implantation of biconvex or meniscus design IOL.

Intended users

This software product is intended to be used by ophthalmic surgeons.

Clinical benefit

The Hill-RBF Calculator employs the Hill-RBF algorithm for the selection of appropriate power for biconvex intraocular lenses. The correct lens selection is essential for optimal post-operative visual acuity after IOL implantation.

Reporting

Adverse events that suggest that an erroneous IOL power calculation may have caused an adverse event **must** be reported to your Haag-Streit representative and to the local competent authority.

Safety

WARNING!
These signs must be strictly adhered to, to ensure safe operation of the instrument and to avoid endangering users and patients.

Patient population

The Hill-RBF Calculator is an advanced, self-validating method for IOL power selection employing pattern recognition and a sophisticated form of data interpolation. This method of IOL power selection performs well for short, normal and long eyes. Based in artificial intelligence, this methodology is data driven and free of calculation bias. This approach also employs multiple validating boundary models, indicating to the user when it is performing within a defined area of accuracy.

IOL models and biometry devices supported

The Hill-RBF Calculator is meant to serve as an adjunct tool to assist physicians in selecting the appropriate IOL power for a particular patient. It is intended to be used in conjunction with a comprehensive ophthalmic examination and the appropriate diagnostic tests and measurements necessary for cataract surgery candidates. It was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF for IOL powers ranging from +6.00 D to +30.00 D and IOL powers from +30.50 D to +35.00 D based on a similar biconvex IOL design. Because patients requiring IOL powers in excess of +30.00 D are relatively uncommon, there may be more out-of-bounds indications for this expanded power range. For IOL powers from +5.00 D to -5.00 D, the prototype IOL is the extended range Alcon MA60MA. The Hill-RBF method performs best when using the Haag-Streit Lenstar LS900 biometer and these two IOL models. The Hill-RBF method may also be used with other biconvex and meniscus design IOL models within the power range of +35.00 to -5.00 D. The switch in lens-design from a biconvex to meniscus design is at + 5.00 D. Calculations from +5.00 D to -5.00 D are based on a meniscus lens design, calculations from +6.00D to +35.00D are based on a biconvex lens design.

WARNING!
Using other data sources or IOL models other than the SN60WF and MA60MA, may reduce the overall performance of the calculator. The Hill-RBF Calculator can only be used with biconvex IOL designs for IOL powers from +6.00 D to +35.00 D and meniscus IOL designs for IOL powers from +5.00 D to -5.00 D. For example, anterior chamber IOLs are often based on a convex-plano design and are therefore not suitable to be used in combination with the current release of the Hill-RBF Calculator.

Disclaimer

The results obtained by the Hill-RBF Calculator are not intended to serve as medical or surgical instruction or be definitive; nor can it be guaranteed that the results will be accurate for every case. Physicians who use the calculator must arrive at their own independent determinations regarding the proper treatment of their patients and are solely responsible for the final post-operative refractive outcome. By using the Hill-RBF Calculator, the user agrees to waive all claims against and hold Warren E. Hill and Haag-Streit AG harmless from any claims arising out of your use of this tool.

Data safety

The use of this Calculator may involve the entry of certain confidential patient data, which may be deemed “protected health information” (“PHI”) under the Health Insurance Portability and Accountability Act of 1996 and Standards for Privacy of Individually Identifiable Health Information, 45 CFR Parts 160 & 164 (“HIPAA”) as amended, or supplemented by additional legislation or regulations from time to time. All information during transfer of the data from the original computer and the server is encrypted. The data provided is stored for the purpose of improving the performance of the Calculator and for ongoing research. All PHI data is encrypted using technology customary to the industry. Haag-Streit, as the provider of the Hill-RBF Calculator service, uses reasonable efforts to avoid unauthorized disclosure of data.

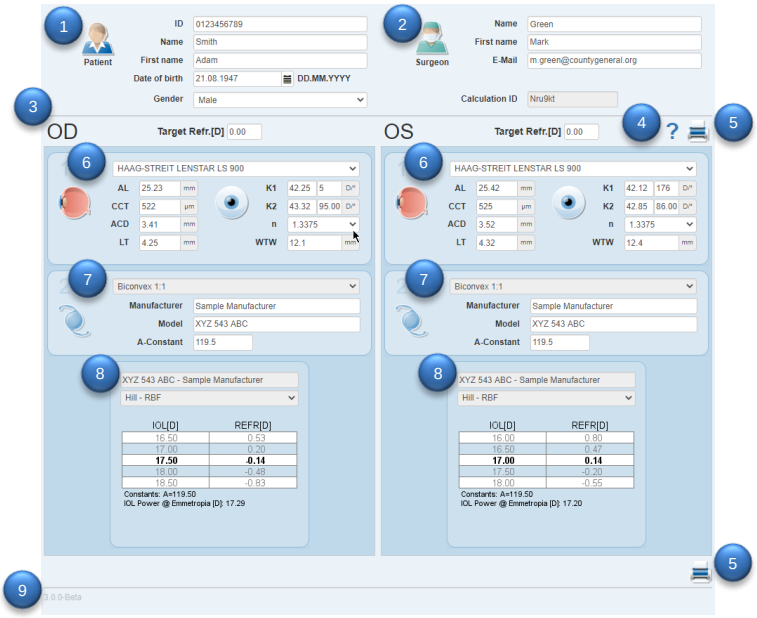
Supported web browsers

The Hill-RBF Calculator was tested on the following web browsers:

Edge (Microsoft) V. 44.18362.449.0
Firefox (Mozilla) V. 76.0.1 (Macintosh) V. 79.0 (Windows)
Chrome (Google) V. 81.0.4044.138 (Macintosh) V 84.0.4147.105 (Windows)
Safari (Apple) V. 13.1

Introduction

User interface



1 Patient data entry fields.

Mandatory fields are the patient identification number (ID), the family name (Name) and the birthdate in the required format.

2 Surgeon data entry fields.

3 Select the target refraction for the right (OD) and the left (OS) eye.

In the current release of the Hill-RBF Calculator, target refraction values from +1.00 D to -2.50 D are mostly supported, depending on the pre-operative measurements.

4 Clicking on the „?“ opens the on-line help file.

5 Clicking on the printer icon generates a PDF file of the current calculation.

> ⚠ The printout is displayed in a separate tab of the browser. Therefore pop-ups have to be enabled in the browser settings to allow the display of the PDF report.

6 Input fields for biometry data Mandatory fields are the device name selection, axial length (AL), anterior chamber depth (ACD), flat - (K1) and steep keratometry value (K2) and their corresponding meridians in degrees. The WTW, LT, CCT and patient gender are optional. This additional information, however, will enhance the calculation accuracy.

7 Input field for the IOL data. The Hill-RBF Calculator was developed based on optical biometry data using the LENSTAR LS900 and surgical outcome data following the implantation a biconvex aspheric IOL (Alcon SN60WF) for IOL powers of +6.00D to +35.00D and a meniscus aspheric IOL (Alcon MA60MA) for IOL powers of +5.00 D to -5.00 D. The calculator performs best when theses particular IOLs are used. The calculator may also be used with other IOL models from any manufacturer with equivalent lens design at a certain IOL powers.

8 The result field displays the proposed power of the IOL and the anticipated spherical equivalent for the refractive outcome.

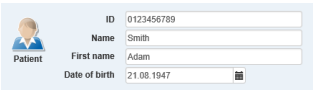
9 Version number of the Hill-RBF Calculator currently in use.

Operation

This chapter describes the use of the Hill-RBF Calculator step by step.

Patient data entry

As a first step, patient data must be entered. This area allows the user to identify the patient for which the calculation is to be carried out.



The fields for the patient ID number and patient’s name (family name) are mandatory entries. The patient’s first name is an optional entry. The patient’s birthdate must be in the following format: DD.MM.YYY. Clicking on the calendar icon next to the date of birth field opens a calendar tool that allows for the easy section of the correct date of birth.

Surgeon date entry

With the current release, all fields in the surgeon data entry section are optional entries.

Data entered in the surgeon entry section will be visible on the printout and this area allows for easy identification of the surgeon.

In a future release, this data will be used to remind the user to provide stable post-operative refraction data for a respective patient. This information is anonymized and will be used as part of an ongoing process to improve the performance of the Hill-RBF Calculator.

Biometry data entry

Entering biometry data is divided into two steps. First, the user selects the biometry device used to acquire the measurement data. Afterwards, the following biometry values are entered: Axial length (AL), anterior chamber depth (ACD) and keratometry flat (K1) and steep (K2) keratometry values and their corresponding meridians in degrees. All other fields are optional with the current release.

Even though only the above-mentioned fields are necessary to calculate IOL power with the current release of the Hill-RBF Calculator, it is recommended that all data available be entered to allow for improved accuracy of the calculation.

WARNING!

The Hill-RBF Calculator was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF for IOL powers from +6.00 D to +30.00 D IOL powers and up to +35.00 D based on a similar biconvex IOL design. For IOL powers from +5.00 D to -5.00 D, it performs best with the Alcon MA60MA extended range biconvex IOL.

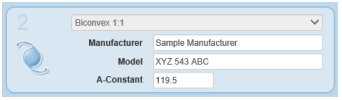
Using other types of biometry, or IOL models, may reduce the overall performance of the calculator. With the current release, the calculator accepts input data from the following optical biometers: HAAG-STREIT LENSTAR LS 900, HAAG-STREIT EYESTAR ES 900, ZEISS IOLMASTER 500, ZEISS IOLMASTER 700, NIDEK AL-SCAN, TOMEY OA 2000, TOPCON Aladdin, OCULUS PENTACAM AXL, ZIEMER GALILEI G6, MOVU/ALCON ARGOS, HEIDELBERG ANTERION.

Selection of the target refraction

Select your desired spherical equivalent target refraction. With the current version of the calculator values from +1.00 D to -2.50 D are accepted.

IOL data entry

Enter the IOL manufacturer's name as well as the specific model name in their respective entry fields. Then add the A-constant for the SRK/T formula that has been optimized for optical biometry in the A-Constant field.



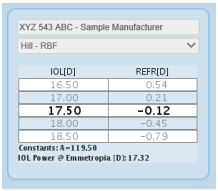
Even though only the A-Constant field is mandatory, entering all data will help to improve the performance of the calculator.

WARNING!

The Hill-RBF Calculator was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF for IOL powers from +6.00 D to +30.00 D IOL powers and up to +35.00 D based on a similar biconvex IOL design. For IOL powers from +5.00 D to -5.00 D, it performs best with the Alcon MA60MA extended range biconvex IOL. The Hill-RBF method performs best with this combination of biometry device and IOLs.

Preforming the IOL calculation

After all mandatory data has been entered, the calculation button at the bottom is enabled.



Clicking on this button will display the IOL calculation result. The Hill-RBF calculator is self-validating, which means that if the pre-operative data is outside one or more internal calculator boundary models, a warning message will be displayed. In this case, it is recommended to validate the calculation with other latest generation IOL calculation formulas, such as the Barrett Universal II formula and/or the Olsen formula.

Printing the calculation result

To print the calculation, click on the printer icon as described in the introduction. A 2nd browser window will open, providing a PDF printout of the results for documentation purposes.

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Disclaimer

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The Hill-RBF Calculator was developed based on LENSTAR LS 900 biometry data in combination with the Alcon SN60WF and the Alcon MA60MA IOL. It performs best with this combination of biometry device and IOL models. It may also be used with other biconvex IOL models in the power range of +6.00 D to +35.00 D and other meniscus IOL models in the power range of +5.00 D to -5.00 D.

WARNING: Using other data sources or IOL models than the original ones the model was derived on, may reduce the overall performance of the calculator. The results obtained by the calculator are not intended to serve as medical or surgical instruction, or be definitive; nor can it be guaranteed that the results will be accurate in every case. Physicians who use the calculator must arrive at their own independent determinations regarding the proper treatment for their patients and are solely responsible for the refractive outcome. By using the Hill-RBF Calculator, the user agrees to waive all claims against and hold Warren E. Hill and Haag-Streit AG harmless from any claims arising out of your use of this tool.

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