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2024
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Kruger, Hester. (2024). A comparison of rebound and applanation tonometry in anaesthetised children with and without Primary Congenital Glaucoma: A cross-sectional comparative study [Master's dissertation, University of the Witwatersrand, Johannesburg]. WireDSpace.

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Title Page

A comparison of rebound and applanation tonometry in anaesthetised children with and without Primary Congenital Glaucoma: A cross-sectional comparative study.

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Declaration

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I Hester Kruger (Student number: 452815) am a student registered for the degree of MMED Ophthalmology in the academic year 2024.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: Kruger Date: 15 January 2024

Contribution statement

Declaration: Student's contribution to article and agreement of co-author(s)

I, Hester Kruger, student number 452815, declare that this Research Report is my own work and that I contributed adequately towards research findings published in the article(s) stated below which are included in my Research Report.

Signature of Student **Date** 15/01/2024

Name of Primary Supervisor: Dr Natasha Naidu

Signature of Primary Supervisor .....**Date** 17/01/2024.....

Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article by the student as part of her Research Report. In cases where the student is not the 1st author of a published article, the primary supervisor must explain (under comments) why the student is entitled to use the paper for her degree purposes.

Article 1: Title: A comparison of rebound and applanation tonometry in anaesthetized children with and without Primary Congenital Glaucoma: A cross sectional comparative study.

Journal name, year, volume and page numbers: N/A

Authors	Name	Signature	Date
1st author	Dr. Hester Kruger		15/01/24
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3rd author	Dr. Natasha Naidu		17/01/2024
4th author	Prof. Ismail Mayet		19/01/24

Comments by primary supervisor:

This article has not been published. It is being submitted in publishable format. The student was actively involved in each stage of the research project. She has drafted the original protocol, performed the data

collection, and has drafted the final document. She displayed an understanding of the topic and basic research methodology.

Acknowledgements

The author would like to acknowledge the Anaesthetic department of the Chris Hani Baragwanath Academic Hospital in Johannesburg, South Africa, for their contribution to the study.

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Author's Guidelines for intended journal: Journal of African Vision and Eye Health

Overview

The author guidelines include information about the types of articles received for publication and preparing a manuscript for submission. Other relevant information about the journal's policies and the reviewing process can be found under the about section. The **compulsory cover letter** forms part of a submission and must be submitted together with all the required **forms.** All forms need to be completed in English.

Original Research Articles

An original article provides an overview of innovative research in a particular field within or related to the focus and scope of the journal, presented according to a clear and well-structured format.

Submission status	open
Word limit	5000-8000 words (excluding the abstract, tables, figures, graphs, and references)
Abstract	maximum: 250 words requires structural headings: Background, Aim, Setting, Methods, Results, Conclusion and Contribution
Main text	requires structural headings, refer to the full structure 'Ethical considerations' is a sub-section in the manuscript and must include: • Name of the ethical review committee • Study approval number • Manner of consent (written, oral) for human participants • Description of measures taken to maintain the confidentiality of data • If the study was not human or animal research or the study was determined to be non-human subjects research or exempt, the authors must provide a statement with those details in this section.
References	60 or less, adhere to the **Vancouver referencing style**
Tables, figures and graphs	7 or less, adhere to the Illustrations requirements found in the AOSIS House style guide
Formatting requirements	apply the guidelines located on the **Formatting requirements page** and the **AOSIS house style guide**
Compulsory supplementary file(s)	the **Authorship, disclosure statements, copyright, and license agreement form**, **Ethical Clearance/Waiver Documentation** and any other relevant form applicable to your submission
Ethical clearance/waiver documentation	evidence of ethical clearance for the study, such as the study approval letter or certificate from the Institutional Review Board (IRB), a waiver from the IRB et cetera

Additional formatting guidelines for the African Vision and Eye Health Journal can be found below.

Language usage

General elements

- **Quotations:** Use single quotation marks for quotations. For quotations within quotations, use double quotation marks. Quotations of more than 30 words are to be indented. Do not use quotation marks for indented quotations unless it is direct speech (e.g. interviewee responses).
- **En dashes and hyphens:** Use an en dash (i.e. extended hyphen that can be found in the Insert box under Symbols in Microsoft Word) in ranges of numbers and dates. Use hyphens only for words that are hyphenated.
- **Dates:** Format dates as '02 October 2006', except at the beginning of sentences where numerals and dates should either be spelt out or the sentence should be rearranged.
- **Percentage:** The per cent symbol (%) is used in conjunction with all numbers (e.g. 12%). Numbers that have been written out will appear with 'percent' (e.g. five percent). 'Percentage' is used in a general sense.
- **Numbers:** Numbers from one to nine must be written out. Numbers from 10 onwards, must be used as numerals, except at the beginning of a sentence.
- **Spacing and punctuation:** There should be one space (and not two) between sentences; one space before unit terms (e.g. 5 kg, 5 cm, 5 mmol, 5 days, 5 °C, etc.), but no space before the percentage symbol (%). Thousands and millions are marked with a space and *not* a comma (e.g. 1000, 1 000 000). Ranges are expressed with an extended hyphen (i.e. en dash), not with a short hyphen (e.g. 1990–2000).
- **Units:** The use of units should conform to the SI convention and be abbreviated accordingly. Metric units and their international symbols are used throughout, as in the decimal point (not the decimal comma), and the 24-hour clock.
- **Foreign language:** Foreign language words should be italicised, unless these words are part of normal usage. Consult the Oxford English Dictionary if in doubt.
- **Acronyms:** If a phrase with an established acronym or abbreviation is used and appears more than five times in your manuscript, please include the acronym or abbreviation in brackets after first mention of the phrase, and then use the acronym or abbreviation only. Please note that you should not define acronyms or abbreviations in any of your headings. If either has been used in your abstract, you need to define them again on their first usage in the main text.

Sensitive and political terms

- **Race and ethnicity**: Try to avoid terms such as 'blacks' and 'whites'; use instead 'black *people'*, 'white *people'*, etc. 'Caucasian', 'Mongoloid', 'Negroid', etc. are generally to be avoided except in human population studies. 'Mixed race' is preferable to 'half-caste' or 'coloured'.
- **Disabilities:** Avoid using 'the disabled', 'the handicapped', and instead use 'people with disabilities not 'the disabled' or 'people with learning difficulties', not 'mentally handicapped'.
- **Disease**
    - Avoid health-determined categorisation.
        - Use 'people with diabetes'; not 'diabetics'.
        - Use 'people with cancer'; not 'cancer sufferers'.

        - Use 'sexually transmitted infection (STI)' and not 'sexually transmitted disease (STD)'.
    - Avoid phrasing that dehumanises a patient. Many authors use case (instance of a disease) when they mean patient (i.e. the person or individual who is ill with the (disease).
- **AIDS**
    - Ensure that 'AIDS' is used for the disease and 'HIV' for the virus, e.g. do not use 'AIDS carrier', 'AIDS positive', 'AIDS virus' or 'catching AIDS or HIV/AIDS' (avoid using the solidus here).
    - 'AIDS sufferer/victim' is inappropriate; use 'people with AIDS'.
    - Refer to 'people who practise high-risk activities' and not '*high-risk groups*'.
    - The expression 'full-blown AIDS' is unnecessary if the correct distinction has been made between HIV and AIDS.
- **Male versus Female**
    - 'Male' and 'female' are *adjectives*, so be careful to use them as such (i.e. a *male* patient and a *female* frog, but a 35-year-old *man*, a French *woman* and a group of 25 *men* and 35 *women*).
- **Sexuality:** Avoid the terms '*homosexual activities*' (if achievable within the manuscript's context, specify which activity is being referred to, especially when dealing with medical research.) Avoid using '*homosexuals*' (specify homosexual men or homosexual women).
- **Gender:** Use gender neutral nouns. Avoid the use of 'man' if not specifically referring to men; for example:
    - for 'man' use 'humans'
    - for 'man-kind' use 'the human race'
    - for 'man-power' use 'workforce'
    - for 'man-made fibre' use 'synthetic fibre'
- **'He/she', 'him/her' and 'his/hers':** For 'he/she', 'him/her' and 'his/hers' rather use 'he or she', 'her or him', 'his or hers' (without a solidus) or change to plural 'they'. Use inclusive pronouns: use 'he or she', or rephrase the sentence (rephrasing to the plural form often works):

✗ … *Any observer* of changes in publishing technology will perceive that *he* has need of…

✓ … ***Observers*** of… will perceive that *they* have…

Beware of referring to people with stereotypical pronouns (e.g. 'the doctor treated *his* patient'; 'the secretary tidied *her* desk').

- **Geography**
    - The terms *Third World*, *poor countries* and *underdeveloped countries* should be avoided.
    - *Developing* or *non-developed country/society* is better, but it is best to specify countries or regions instead.
    - *Western society* and *Western World* should only be used in relation to geography; otherwise, use *developed world/society* or, even better, specify the countries themselves or the region.

Tables, figures and photographs

Tables should in an Excel (.xls) format. Ensure that all personal identifying information is removed from the supplementary files as indicated in the provided instructions. All captions should be provided together on a separate page. Tables and figures should use numerical numbers.

- **Organise your visual presentation**: Once you have read through the analyses and decided how best to present each table or figure, think about how you will arrange them within the manuscript. The analyses should tell a story' that leads the reader through the steps needed to logically answer the question(s) that you as author are posing in the Introduction. The order in which you present the results can be as important in convincing the readers as what you actually are saying in the text.
- **How to refer to tables and figures in the text:** Every figure and table included in the paper *must* be referred to in the body of the text. Use sentences that draw the reader's attention to the relationship or trend you wish to highlight, referring to the appropriate figure or table only in parenthesis e.g.:
    - Germination rates were significantly higher after 24 h in running water than in controls (Figure 4).
    - DNA sequence homologies for the purple gene from the four congeners (Table 1) show high similarity, differing by at most 4 base pairs. (Avoid sentences that give no information other than directing the reader to the figure or table, e.g. Table 1 shows the summary results for male and female heights at Bates College.)
- **Abbreviation of the word 'Figure':** When referring to a figure in the text, the word 'figure' is never abbreviated as 'Fig.'; the same rule applies to the usage of 'table'. Both words are spelled out completely in descriptive legends.
- **How to number tables and figures:** Figures and tables are numbered independently, in the sequence in which you refer to them in the text, starting with Figure 1 and Table 1. If, in revision, you change the presentation sequence of the figures and tables, you must renumber them to reflect the new sequence.
- **The acid test for tables and figures:** Any table or figure you present must be clear, well-labelled, and described by its legend to be understood by your intended audience without reading the results section. That is, it must be able to stand alone and be interpretable. Overly complicated figures or tables may be difficult to understand in or out of context, so strive for simplicity whenever possible.
- **Descriptive legends or captions:** To pass the acid test above, a clear and complete legend (sometimes called a caption) is essential. Like the title of the manuscript itself, each legend should convey as much information as possible about what the table or figure intends to tell the reader:
    - the results that are being shown in the graph(s), including the summary statistics plotted
    - the organism studied in the experiment (if applicable)
    - a context for the results: the treatment applied or the relationship displayed, etc.
    - location (*only* if a field experiment)
    - specific explanatory information needed to interpret the results shown (in tables, this is frequently done as footnotes)
    - culture parameters or conditions if applicable (temperature, media, etc.)

- sample sizes and statistical test summaries, as they apply

Do not simply restate the axis labels with a 'versus' written in between.

Example: Figure 1: Height frequency (%) of White Pines (Pinusstrobus) in the Thorncrag Bird Sanctuary, Lewiston, Maine, before and after the Ice Storm of 1998. Before, n = 137, after, n = 133. Four trees fell during the storm and were excluded from the post-storm survey.

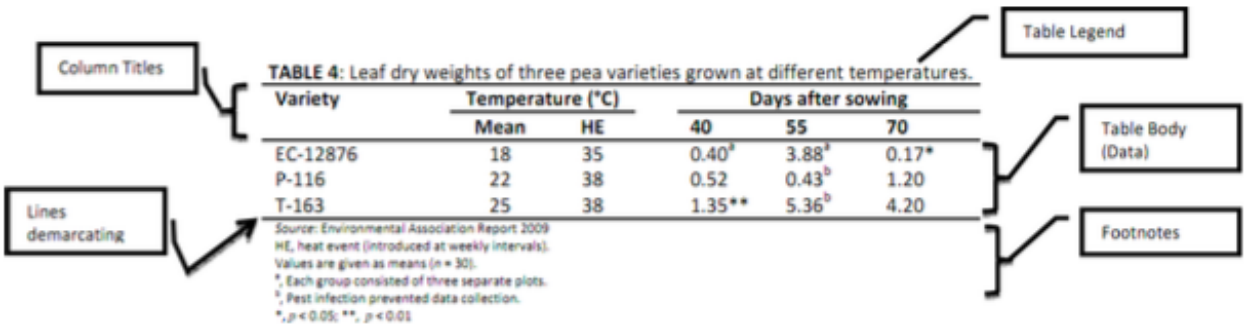


TABLE 4: Leaf dry weights of three pea varieties grown at different temperatures.

Variety	Temperature (°C)		Days after sowing		
	Mean	HE	40	55	70
EC-12876	18	35	0.40[a]	3.88[a]	0.17*
P-116	22	38	0.52	0.43[b]	1.20
T-163	25	38	1.35**	5.36[b]	4.20

Source: Environmental Association Report 2009
HE, heat event (introduced at weekly intervals).
Values are given as means (n = 30).
[a], Each group consisted of three separate plots.
[b], Pest infection prevented data collection.
*, $p < 0.05$; **, $p < 0.01$

Note: Questions frequently arise about how much methodology to include in the legend, and how much results reporting should be done. For laboratory reports, specific results should be reported in the results text with a reference to the applicable table or figure. Other than culture conditions, methods are similarly confined to the Methods section.

Footnotes to tables, figures and photographs

Do not introduce footnotes in the body of the manuscript. Footnotes should be used as follows:

- Copyright and permissions to reproduce should be clearly stated.
- Notes about the table as a whole can be left unlinked (i.e. no linking letters or numbers or symbols) or linked to, for example, a relevant column heading.
- Notes about specific parts of the table should be linked using superscript lower case letters (preferred), superscript numbers or symbols.
- If lower case letters are used, it could be confused with the table data; use symbols or numbers instead.
- Do not make use of superscript numbers in parentheses (brackets).
- If an abbreviation is mentioned for the first time in a table (e.g. 'CE' in Table 1), it must be defined in a footnote to that table, (e.g. HE, Heat event (introduced at weekly intervals).
- Asterisk footnotes are reserved for probability values in tables and usually signify the following values: *, $p \leq 0.05$; **, $p \leq 0.01$; ***, $p \leq 0.001$. The asterisk is often used in mathematics and should therefore be avoided as a footnote symbol.
- Footnote links should be placed after punctuation. The preferred order of footnote symbols in tables (which should be superscripted) is †, ‡, §, ¶ (these are doubled if more footnotes are needed, e.g. ††).
- When superscript numbers or letters are used in text, beware of potential confusion with other superscripts (e.g. 2 for 'squared').
- Footnotes should be in the following order:

- source notes
- other general notes
- notes on specific parts of the table (following the order in the table itself)
- notes on level of probability

Guidance on submitting creatives electronically

Please supply images as the size intended for final publication. Resizing of images is time consuming and can result in loss of quality.

Supply your manuscript creatives in one of the following three preferred formats:

- **TIFF:** This is an image made up of pixels and is the most universal and most widely supported format across Windows and Mac platforms. Most graphics packages can save a file as a TIFF. The higher the resolution (i.e. the number of pixels) the sharper the final image.
  - Colour or greyscale photographic images: 300dpi
  - Line art or combination images: 600/900dpi
  - We would recommend using this format for photographic images.
- **EPS**: An EPS is essentially an envelope for holding text and images. Line art can be produced as an EPS (in Illustrator, for example). There are virtually no limits to scaling line art saved as an EPS. It can also contain TIFF images. However, please ensure that all fonts are embedded (that is, saved as outlines) and that line weights are not defined as hairline.
- **PDF**: This format is, again, like an EPS in that it is an envelope for holding different kinds of images and line art. Great care should be taken to ensure that fonts are embedded and that original images are at the correct size and resolution before being saved as a PDF. It is possible to save or export as TIFF or EPS from most graphics applications, just as it is possible to save direct to a PDF from most graphics packages by using a postscript printer driver. PDF creation packages (e.g. Acrobat Distiller) are also now widely available.

Other file formats

- **JPEG**: A JPEG compressed TIFF is acceptable as long as the degree of compression is moderate. It is better to use a JPEG for online images as a good quality image is achievable even with a high degree of compression.
- **GIF**: A format suitable for images that contain few colours. Again, this should only be used for images intended for the web.
- We cannot guarantee the quality of images supplied in other formats.

Colour:

- *Greyscale, CMYK, RGB.*
- **Greyscale** art should be saved in greyscale mode.
- **C**yan**M**agenta**Y**ellow**B**lack are the base colours used during the printing process.
- Any colour that is to appear in print must be in CMYK mode.
- **R**ed**G**reen**B**lue are the colours used by monitors and default scanner settings. Any colour that is to appear online must be in RGB mode.

Guidelines for Math

- Set display equations in MathType. Each display equation should be in its own MathType object. Each MathType object should contain the entire equation, including final punctuation. The equation number should be set as Microsoft Word regular text, outside the MathType object, separated by either a tab or a space.
- Set in-text (inline) math in Microsoft Word regular text. Exception: If in-text (inline) math has elements that should be stacked or have rules, circumflexes, arrows, or other accents spanning over more than one character, set in MathType as 'Inline Equation.'
- If any characters cannot be found in Word's Symbol palette ('(normal text),' 'Times New Roman,' or 'Symbol'), please set in MathType.
- No display equations are allowed in figure captions, table titles, or table footnotes. If a display equation occurs in a text footnote, it is best to recast it as inline math. There are a few journals with lengthy footnotes with style exceptions to this rule.
- No numbered equations are allowed in table footnotes.
- Display and/or numbered equations ARE allowed in table body, but must be 'inline' when converted to MathML equations.

Fonts: Unicode fonts

Please use standard (UNIcode) fonts such as Palatino, Times New Roman, Helvetica and Symbol. Fonts that have not been embedded will usually be replaced by Courier, resulting in character loss or realignment.

Understanding Unicode

The explanation at Unicode.org is a good place to begin.

'Unicode provides a unique number for every character, no matter what the platform, no matter what the program, no matter what the language.' (Unicode.org, 2011)

Put more simply, no matter what font is used, your computer and other computers will always know exactly what symbol is called for and display the text correctly.

Note: AOSIS Publishing publishes in four different formats, namely, PDF, HTML, XML and ePUB. If your manuscript is not unicode compliant, then it will not be possible to produce all four formats. We will send the back to you to make the fonts Unicode compliant to enable us to produce all four formats.

How to check whether your font-type is unicode compliant

1. Open your manuscript in your text editor.
2. Highlight all the text within your manuscript and change the font to Arial or Times New Roman.
3. Scrutinise your entire manuscript.
    - **Document reads perfectly?** If the words are readable and identifiable, then the font that you are using is unicode compliant.
    - **Document has changed certain or all characters?** Font used is not unicode compliant and needs to be changed prior to submission to this journal.

Which fonts are Unicode compliant?

- To use Unicode, you will need to install (or find already installed) Unicode fonts on your computer. This is neither difficult nor costly.
- For basic information and links to numerous Unicode fonts, see http://www.alanwood.net/unicode/fonts.html
    - Arial Unicode MS
    - Courier New
    - DejaVu Serif
    - Gentium
    - Garamond
    - Minion Pro
    - Myriad Pro
    - Tahoma
    - Times New Roman
    - Verdana

Unicode in Windows

Installing fonts on a Windows computer is fairly simple.

1. Download the font.
2. If it is a compressed file (such as .zip), expand it.
3. Open the fonts folder by clicking on Start, then Settings, then Control Panel, then Fonts.
4. Drag the font file(s) into this folder. It should automatically install.

Using the insert symbol function

- Use the Insert Symbol function (found in the Insert menu). This function allows you to choose characters from a grid displayed in its own window. Double-clicking the desired character inserts it at the cursor in the document.
- Use the symbol insert window to assign keystrokes to the characters you use most often. For example, you might assign the keystroke alt+a to the lower case a with macron, and alt+shif+A to capital A with macron.

Keyboard for Windows

The preferred method for typing in Unicode. Essentially this means telling Windows that you want a different keyboard layout to be available for use. At this step things might vary from computer to computer.

- Click on Start, then Settings, then Control Panel.
- Double click Regional and Language Options. The window that opens should have three tabs: Regional Options, Languages, and Advanced.
- Click on the Keyboards and Languages tab.
- Options include installing additional languages or changing the keyboard. Read the guidelines provided by Windows carefully.
- Select 'Change keyboards' in the same window after installing additional language.
- To make it your default keyboard you must choose it in the drop down list under Default Input Language at the top of this window. Click Add.
- Proceed to select the 'Language Bar' tab at the top and ensure that the box 'Show additional Language bar icons in the taskbar' is ticked.

- Now there should be a little keyboard icon in the task bar at the bottom of your screen (if there wasn't already). (It will be next to the blue square with EN in it, which signifies that the current input language is English. If you use no other languages, this icon might not be there.) When you click on the small keyboard icon, a list of keyboard choices pops up. If you made Alt-Latin the default, it should be in bold type. (However, it may not appear until the next time you restart your computer. Until then it might be a blank line in the list.)

Typing with the alternative keyboard is simple. For most letters you will do things as you always have. When you need a special character or a character with a diacritic or accent, you will use key combinations with the Alt key to the right of the space bar (the one on the left side does not work for this in Windows, unfortunately). For example, to type the letter 'a' with a macron you hold down the Alt key and press the letter a, release them both, then type the letter a. For letters with a dot below them, hold down Alt, press the period key, release both, and then type the letter which needs the dot.

Unicode in Macintosh

To enter Unicode text on a Macintosh, you have several options.
Firstly, you may use the **Character Pallette**, which is found in the Input Menu (the flag menu in the upper right, near the clock).

- If the Character Pallette option is not shown, enable it by doing the following:
  - Go to the Apple menu, select System Preferences.
  - In the Preferences window, choose International.
  - Select Input Menu.
  - Check Character Pallette. You can also check Keyboard Viewer, Unicode Hex Input, and US Extended at this time.
  - Check Alt-Latin. If it is not there, see below for information on installing it.
  - Make sure the "Show Input Menu in menu bar" option is checked.
- To use the Character Pallette to enter Unicode characters in a document, just keep it open in the background. When you need a character, you can enter it by double clicking on it in Character Pallette.
- A useful feature of Character Pallette is the ability to designate frequently-used characters as favourites, saving you the trouble of finding the different letters each time you need them.
- For more information on Character Pallette, see Alan Wood's site: http://www.alanwood.net/unicode/utilities_fonts_macosx.html

Secondly, you may use the excellent and extremely simple **Alt-Latin keyboard** or **LatinTL keyboard**, both of which were created specifically for this purpose by Kino.

- To install either keyboard (or both of them), you must first download AltLatin.zip and/or LatinTL_X.dmg.sit from Alt-Latin page).
- If your browser does not automatically expand the .zip or .sit file, tell it to save the file to your desktop (so it will be easy to find), then manually expand it. Usually this can be done simply by double-clicking the file, which will start the appropriate decompression program. LatinTL expands to a disk image, but for the purpose of installation you can treat it just like a folder.
- Follow the instructions in the 'readme' file to install the keyboard(s).

- Make it visible in the Input Menu by following the instructions given above for the Character Pallette.
- Because Alt-Latin and LatinTL work like any other keyboard, you will not have to change keyboards unless you need to type in a different alphabet, such as Arabic.
- Entering letters with diacritics using either keyboard is very simple:
    1. Make sure you are using a Unicode font. It may work with other fonts, but you should use Unicode (OS X comes with Lucida Grande and there are others available).
    2. To enter a vowel with a macron, simply hold down either **option** key and hit the letter 'a' simultaneously. Release them, then type the letter that needs the macron (using the shift key if you need a capital).
    3. For letters with dots below, press option and period, release, then type the letter.
    4. Hamza is shift+option+P, and 'ayn is option+p. (This may not work in Microsoft Word with Alt-Latin – reason unknown. If it does not work, use the LatinTL keyboard instead, or use the Character Pallette for these two characters. These keystrokes do work in TextEdit and other software with Alt-Latin.)
- The PDF file included with Alt-Latin shows maps of the keyboard, in case you need something not mentioned here, or you may use our maps found on http://www.lib.uchicago.edu/e/collections/mideast/encyclopedia/unicode.html.
- The layout of LatinTL is very similar, with only a few differences, and it also includes maps. (See the Alt-Latin page for a description of the differences.)
- **Click** here **for diagrams of the Alt-Latin keyboard** (usable for LatinTL as well, with a few differences) and for downloads.
- The diagrams are for the Windows version, but the layout is almost identical to the Mac version. The main difference is that where the Windows version uses only the Alt key to the right of the space bar, the Mac version uses either of the two Option keys. This makes the Mac version a little more comfortable to use, since you can use either hand. (There is no Windows version of LatinTL.)
- There are downloadable PDF files of the diagrams available on the same page, in case you would like to print them for easier reference while typing.
- Kino's site (linked above) also has numerous other Macintosh keyboard and font resources, such as some keyboards based on non-US layouts (notably a UK variant of Alt-Latin).

Thirdly, you may want to use Knut S. Vikør's **Jaghbub keyboard layouts** (and, perhaps, his Unicode fonts).
His Arabic Macintosh pages have long been one of the web's most useful sources for Mac users who need to type Arabic or transliteration, and he has updated both the pages and the downloadable resources he created.

- The page on transliteration, 'Writing Arabic with Latin letters', explains the issues and provides a downloadable file containing the JaghbUni font package and the American Diacs. keyboard layout.
- The Jaghbub font package page gives more information about the three fonts included, as well as German, French, Italian, Danish, Swedish, Norwegian, US and UK keyboard layouts for typing diacritics in Unicode fonts.
- There are also separate keyboard layouts for typing IPA characters in Unicode fonts for the same national standards (that is, the non-option keys

follow the regular national keyboard standard, but the IPA characters are all placed on option keys under no particular standard).

For any keyboard layout, you can always select **Keyboard Viewer** from the Input Menu to see what different keystrokes will do.

These instructions were taken from:
http://www.lib.uchicago.edu/e/collections/mideast/encyclopedia/unicode.html

Draft Article

A comparison of rebound and applanation tonometry in anaesthetised children with and without Primary Congenital Glaucoma: A cross-sectional comparative study.

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Abstract

Background

Intraocular pressure (IOP) measurement should be accurate in a paediatric population with primary congenital glaucoma.

Aim

To investigate the difference between the change in IOP measurements using rebound tonometry (RBT) and handheld applanation tonometry (Perkins Applanation Tonometer / PAT) in patients with and without primary congenital glaucoma (PCG).

Setting

Soweto, South Africa.

Methods

Demographic data, including age and gender was analysed. IOP measurements were done under anaesthesia, using RBT and PAT at 0, 5 and 10 minutes after induction and prior to intubation. Corneal pachymetry and corneal diameters were measured..

Results

65 children were included, 19 with PCG and 46 without PCG. The mean age (SD) was 3.2 (2.27) and 4.8 (2.42) years respectively. The overall mean difference in IOP between RBT and PAT across both PCG and non-PCG groups was found to be 4.92 mmHg (95% CI 2.80 – 7.03) p <0.001, with RBT having higher readings. This difference was greater in the PCG group, with the IOP difference of 9.05 mmHg (95% CI 2.6 – 15.5) p=0.004. Mean corneal pachymetry (SD) was 585.6 (81.48) µm in the PCG group and 518.31(39.90) µm in the non-PCG group. Univariate analysis showed that IOP was significantly related to corneal pachymetry, with a 11 mmHg increase in IOP for every 100 µm change in corneal thickness for measurements done with RBT (p<0.001), compared to 4mmHg using PAT. (p=0.008). Mean horizontal corneal diameter (SD) was 13.95(1.24) mm in the PCG group, compared to 11.09(0.32) mm in the non PCG group.

Conclusions

IOP measurements done with RBT in children with and without PCG were overestimated compared to PAT. This difference was more pronounced in PCG patients. In addition, IOP was significantly related to corneal thickness.

Keywords: Intraocular Pressure; Applanation tonometry; Rebound Tonometry; Primary Congenital Glaucoma

1. Introduction

PCG is a developmental glaucoma that accounts for most of the primary paediatric glaucoma.[1] The incidence varies with ethnicity, with the highest incidence occurring in Slovakia and Saudi Arabia reported at 1 in 1 250 and 1 500 live births respectively.[2] Prevalence rates are lower for other parts of Europe, North America and Australian populations, ranging from 1:10 000 to 1:38 000.[3–5] Sub-Saharan African studies report PCG to account for up to 4% of all new glaucoma cases.[6] In South Africa, glaucoma contributes to 6.7% of childhood blindness.[7]

Raised intraocular pressure (IOP) is a modifiable risk factor in glaucoma.[1] Handheld applanation tonometers, like the Perkins Applanation Tonometer (PAT) are frequently used in paediatric patients but often require general anaesthesia. Commonly used anaesthetic agents like Sevoflurane and Propofol, have an IOP lowering effect,[8,9] while ketamine raises IOP with doses above 4mg/kg.[10] Additionally manipulation of the airway may further cause fluctuations in IOP.[11]

RBT offers the advantage over applanation tonometry (AT) in that it does not require any topical anaesthesia and needs less patient co-operation making it a good

adjunct to in-office IOP measurement in awake children.[12] It's reliability, however, still needs to be established in the paediatric population.

Some previous studies comparing RBT to AT in paediatric patients with PCG have found that RBT overestimates IOP compared to AT,[13–16] while others[17] found RBT to be comparable. There is, therefore, clinical equipoise regarding whether there is a significant difference between RBT and AT when comparing PCG eyes to non PCG eyes under general anaesthesia without the potential effect of the volatile agents. We also do not know if this difference is more pronounced in PCG patients compared to non-PCG patients.

This study therefore aimed to assess the difference between rebound tonometry and handheld applanation tonometry in paediatric patients with PCG compared to healthy controls when undergoing examination under anaesthesia (EUA). The role of possible predicting factors of IOP in study participants, including corneal pachymetry, corneal diameter and age were also investigated. In addition the role of age and gender on IOP is also assessed.

2. Materials and Methods

This single centre, non-interventional, prospective study included patients diagnosed with PCG undergoing EUA and a control group undergoing routine unilateral ophthalmological procedures under anaesthesia. The study was conducted between

2020 and 2022 at St John Eye Hospital, Soweto, South Africa. The hospital is affiliated with the University of the Witwatersrand. Ethics study approval number M200664.

The study protocol followed the principles of the declaration of Helsinki and received approval from the University of the Witwatersrand Human Research Ethics Committee. Written informed consent was obtained from all parents, and informed medical assent was obtained from patients 7 years and older. Patient confidentiality and anonymity was maintained by assigning each patient to a study number. Data was stored on a password protected electronic database.

Inclusion criteria consisted of patients 10 years and younger. The study group included PCG group patients undergoing routine EUA. The control group included paediatric patients undergoing routine unilateral ophthalmological procedures. These included lens washouts, chalazion and molluscum contagiosum excision and eyelid surgery.

Exclusion criteria included, the presence of any corneal disease not related to PCG and secondary causes of glaucoma.

One eye per study patient was included. Where both eyes qualified as a study eye, a computer-based randomisation sequence was used to determine which eye should be included.

Demographic data obtained included age and gender.

Anaesthesia was standardized and based on the Chris Hani Baragwanath Academic Hospital's anaesthetic department protocol, recommended by Van Der Walt et al.[18] This protocol, consisted of sevoflurane gas induction limited to 6% until placement of an intravenous cannula and given via a mask, followed by a ketamine bolus of 2mg/kg and a titrated ketamine infusion of no more than 4mg/kg. Topical oxybuprocaine 0.4% drops and sodium fluorescein staining was placed on the ocular surface.

IOP measurements were recorded first with rebound (RBT) followed by applanation (PAT) tonometry. The measurements were done as the sevoflurane gas was switched off and repeated 5 and 10 minutes later. All measurements were done prior to intubation.

During measurements, children were placed in the supine position, with the head turned to the opposite side of the study eye for both tonometers. RBT using the Icare® TA01i (Icare, Tiolat Oy Helsinki, Finland) was performed prior to measuring

IOP with PAT (Perkins, Clement-Clarke, Haag-Streit, Harlow, United Kingdom) at each specified time interval. The average of two measurements using RBT and one measurement from PAT was captured. A single study investigator (HK) performed all measurements.

Corneal pachymetry was measured using the Ocuscan® RxP (Alcon Laboratories, California, U.S.A) pachymeter. Horizontal and vertical corneal diameters were measured using a calliper, under view of a microscope.

A sample size of 82 patients was calculated using Satterthwaite's t-test with 80% power to detect a difference of at least 2mmHg between the means of the differences between AT and RBT in the PCG and non-PCG groups. Unequal variances were assumed. We added a margin for error and got a final sample size of 90 patients, with 45 patients in each group. Due to the rarity of PCG patients attending the hospital, the required number of PCG patients was not reached. However, upon interim analysis the results were found to be significant, and the decision was made to stop recruitment.

Data was collected and stored on an electronic database, using Research Electronic Data Capture (REDCap®).[19,20] Results were analysed using STATA. (Version16.1).

Categorical data was presented as a number or mean ± standard deviation (SD)

A paired t test was used to assess the differences between RBT and PAT at the specified time intervals. A two-sample t test was used to derive the differences between the two instruments in the PCG and non PCG group.

Evaluation of the concordance between RBT and PAT in the PCG and non PCG group was done using Lin's concordance correlation coefficient. To analyse possible predictive factors between groups, univariate and multivariate linear mixed effects models were used.

3. Results

3.1. Demographics

A total of 65 eyes of 65 children were included in the study, 19 with PCG and 46 patients without PCG. One patient developed bronchospasm during measurements, accounting for the missing data point at 10 minutes. See figure 1. Thirty nine patients were male (58.2%) and 26 (41.8%) were female. In the PCG group, 13 patients (68%) were male.The mean age (SD) in years in the PCG group and the non-PCG group was 3.12 (2.27) and 4.85 (2.42) respectively. See table 1.

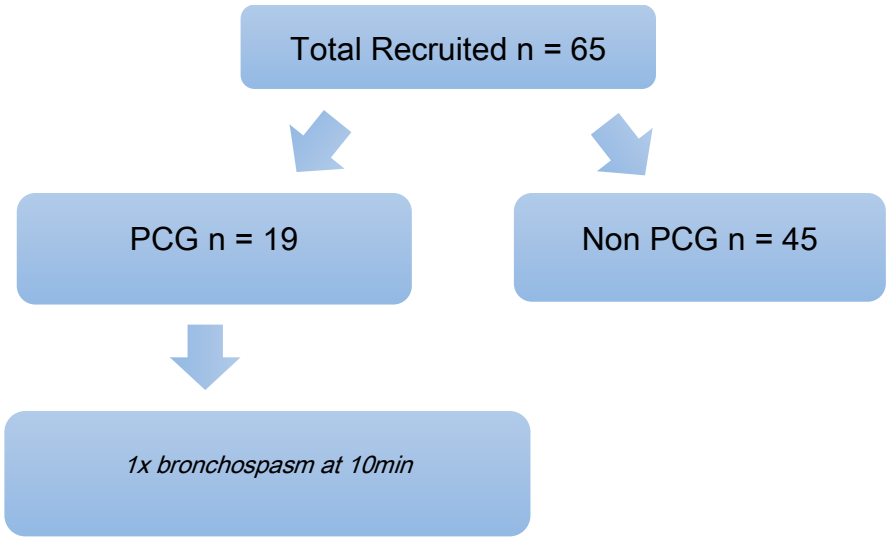
Table 1: Patient demographics

Demographics

	Patients enrolled (n)	**Male**	**Female**	**Mean age ± SD (years)**
PCG	19	13	6	3.12 ± 2.27

Non PCG	46	26	20	4.85 ± 2.42
TOTAL	65	39	26	3.83 ± 2.49

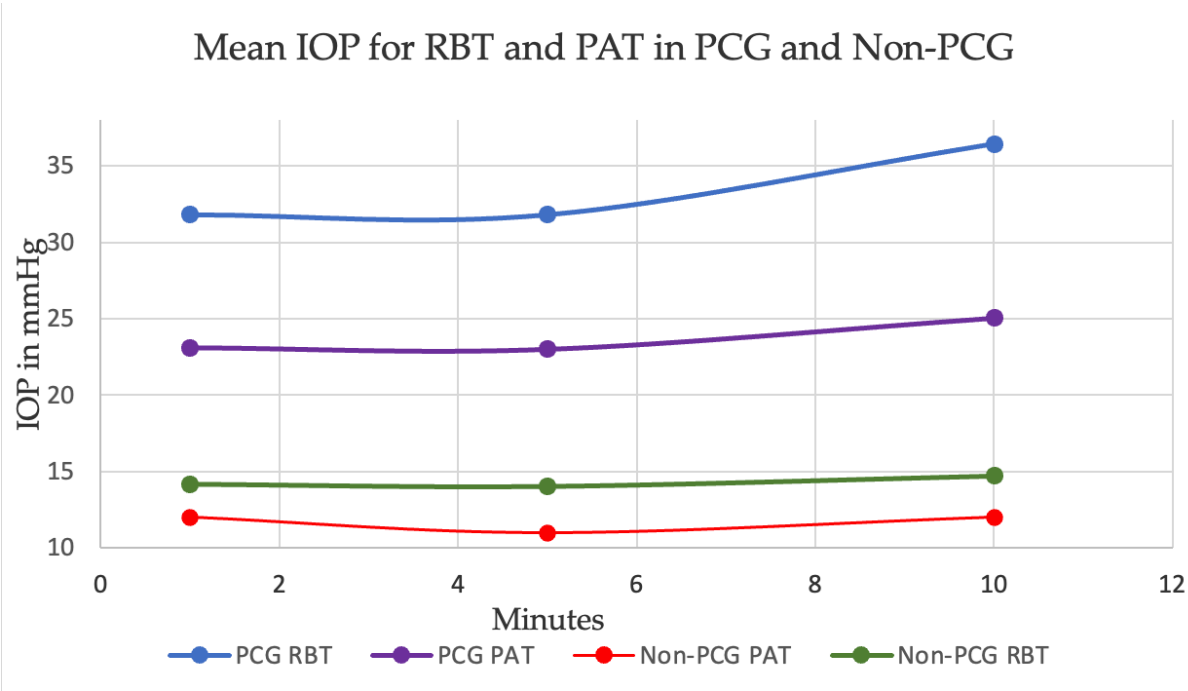
Figure 1: Outline of patient recruitment.



3.2. Mean IOP

The overall mean(SD) IOP obtained was higher with RBT, measuring 20.92(13.79) mmHg, compared to PAT measuring 16.00(8.40) mmHg. In the PCG group, the mean IOP measured with RBT and PAT at 10 min was 36 (17.07) mmHg and 25.06(10.29) mmHg respectively. In the non-PCG group, IOP was 14.71(4.20) mmHg and 12.38(3.47) mmHg using RBT and PAT at 10 min, respectively. See figure 2.

Figure 2: Mean IOP for RBT and PAT for PCG and non PCG patients at 0, 5 and 10 minutes after sevoflurane gas was switched off.



3.3. Mean IOP difference between RBT and PAT

Analysis of the overall IOP differences between RBT and PAT, regardless of patient group, were statistically significant at each time interval. RBT measured IOP higher compared to PAT by 4.37 mmHg (95% CI2.52 – 6.21) ($p< 0.001$), 4.52 mmHg (95%CI 2.91 – 6.13) ($p< 0.001$), and 4.71 mmHg (95% CI 2.80– 7.03) ($p< 0.001$), at 0, 5 and 10 minutes respectively. See table 2.

Table 2: Overall difference between RBT and PAT

Overall difference between RBT and PAT

Time Interval	Number of patients (n)	Mean IOP difference (mmHg)	95% Confidence Interval	p value
0 min	65	4.37	2.52 – 6.21	p<0.001
5 min	65	4.52	2.91 – 6.13	p<0.001
10min	64	4.71	2.80– 7.03	p<0.001

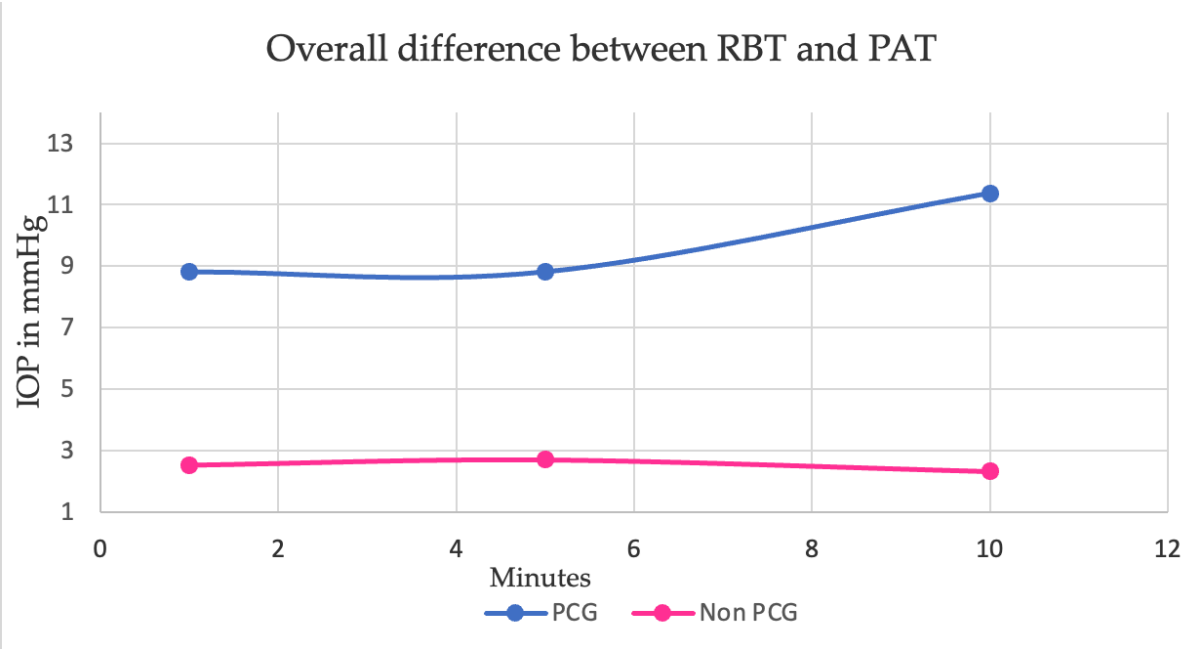
3.4. Mean IOP difference between RBT and PAT between groups

Between the PCG and non PCG groups, RBT overestimated IOP significantly at all time intervals. The mean IOP difference for both groups measured 6.17 mmHg (95% CI 0.19 – 12.14) (p = 0.02), 6.10 mmHg (95% CI 1.36 – 10.84) (p = 0.007) and 9.05 mmHg (95% CI 2.60 – 15.5) (p = 0.004) at 0, 5 and 10 minutes respectively.

3.5. Mean IOP difference between RBT and PAT in PCG vs non PCG

The mean IOP difference in the PCG group was larger, measuring 8.81 (95% CI 4.15 – 13.47), 8.81 (95% CI 4.15 -13.47) and 11.38 mmHg (95% CI 2.80 – 7.03) at 0, 5 and 10 minutes respectively. See figure 3.

Figure 3: Overall difference between RBT and PAT in PCG vs non PCG at 0, 5 and 10 minutes after Sevoflurane gas was switched off.



Our data showed that the IOP difference between RBT and PAT was more disconcordant in the PCG group, and that these differences were larger with time, with a difference of 8.71 mmHg (95% LOA 15.49 – 32.91) p< 0.001, 8.81 mmHg (95% LOA 10.13 – 27.76) and 11.38 mmHg (95% LOA 13.71 – 36.56) at 0 , 5 and 10 minutes respectively.

Mean horizontal corneal diameter (SD) was 13.95(1.24) mm in the PCG group, compared to 11.09(0.32) mm in the non PCG group.

Mean central corneal thickness (CCT) (SD) was 585.6(81.48) µm in the PCG group and 518.31(39.9) µm in the non-PCG group. Corneal pachymetry significantly influenced IOP measurements during univariate and multivariate analysis. Our data showed that for every 100 µm increase in corneal pachymetry, IOP will increase by

11 mmHg (p<0.001) for measurements done with RBT, compared to 4 mmHg (p=0.002) for measurements done with PAT during univariate analysis. Multivariate analysis showed that pachymetry and age had a significant effect on measurements done with RBT, but not with measurements done with PAT. Gender did not influence IOP measurements. See table 3.

Table 3: Multivariate analysis for pachymetry, age and gender using PAT and RBT

Multivariate Linear Mixed Effects Models analysis for pachymetry, age and gender

Group	Parameter	Coefficient	Standard Deviation	P Value
PAT	Pachymetry	0.01	-0.01 – 0.03	0.293
	Age	-0.04	-0.008 – 0.09	0.1
	Gender	0.48	-2.38 -3.35	0.74
RBT	Pachymetry	0.05	0.01 – 0.09	<0.01
	Age	-0.09	-0.007 -0.16	0.03
	Gender	-1.78	-6.31 -2.75	0.44

4. Discussion

The aim of this study was to compare the IOP difference between RBT and PAT amongst two groups, with and without PCG. Our findings showed that RBT significantly overestimated IOP in both PCG and non PCG children. This IOP difference between RBT and PAT was more pronounced in the PCG group when

compared to the non-PCG group. To our knowledge, this is the first study to report such a large difference between RBT and PAT in PCG children.

Previous literature has reported RBT to overestimate IOP in children with[13–16] and without glaucoma.[12,21] Our data correlates with these findings, regardless of the clinical group. The reason for the discrepancy between RBT and PAT is not clear. Corneal thickness[16] and corneal biomechanics[22] have been reported to influence IOP measurements, however, the difference between the mechanism of the two tonometers should also be kept in mind. While PAT is based on the Imbert-Fick principle[1], determining the force needed to flatten an area of central cornea, RBT calculates IOP from the rate of deceleration of a probe after it hits the cornea.[12]

In our analysis, the difference in IOP between RBT and AT was most pronounced in the PCG group. Strzalkowska et al[13], reported a mean IOP difference between RBT and PAT of 6.0±6.1mmHg in their study investigating the optimal timing of measuring IOP in children with and without PCG undergoing anaesthesia.

In a larger study consisting of 194 eyes of 105 children with glaucoma, Angmo et al[23] showed a mean difference between PAT and RBT of 2.34mmHg in the subgroup of patients with corneal scarring.

Martinez de la Casa et al[16] found the mean IOP difference between RBT and PAT to be 3.1 mmHg± 4.0 mmHg, $p<0.001$) in awake children with a mean age of. 8.8 years ±2.9. This is in comparison to our study, where the children were younger and asleep with a mean age of 3.83 years ± 2.49.

Other authors[14,17,24] have reported differences in IOP between RBT and PAT of less than 1mmHg. In a Spanish study, Perez-Garcia et al[24] found a mean difference in IOP of 0.98 mmHg (p = 0.47) when comparing RBT and AT in PCG patients. Esmael et al[14] also found that RBT was more likely to overestimate IOP when IOP is greater than 15mmHg, the difference between devices being 0.59 mmHg± 2.60. Although the trend towards RBT overestimating IOP is similar, our study showed markedly higher IOP differences between devices. This can perhaps relate to the advanced cases of PCG that present to our centre, along with our anaesthetic protocol that controls for confounding factors influencing IOP, such as anaesthetic drugs. In addition, our results showed an increase in IOP difference with time possibly due the effect of sevoflurane wearing off, along with the change in corneal biomechanics in buphthalmic eyes.

Corneal thickness in our study population showed that PCG patients had thicker corneas compared to the control group. This can be explained by PCG patients presenting with corneal oedema. In addition, corneal pachymetry in the non PCG group was thinner than average. Taking into account that our patient population was all from African descent, our findings correlate with previous studies[25,26] that found thinner corneal thickness measurements in African patients, compared to Caucasian patients. Corneal diameter was found to be larger in patients with PCG.

During our analysis, corneal pachymetry was found to be a significant predictor of IOP on univariate analysis. Our results revealed that for every 100 μm increase in

corneal pachymetry, IOP will increase by 11 mmHg ($p<0.001$) for RBT compared to PAT of 4 mmHg ($p=0.002$).

The literature is divided on the role of CCT and IOP. Morales-Fernandez et al[22] did not find an association between IOP and CCT in their study which compared corneal biomechanical properties in patients with and without PCG during their multivariate analysis. This was attributed to corneal hysteresis and corneal resistance factor being more sensitive predictors of IOP compared to pachymetry alone. However, Perez-Garcia et al[24] found a significant correlation between IOP and corneal pachymetry, using linear regression in healthy children. This finding was not observed in children with PCG. This can be explained by the differences in corneal changes that take place due to PCG, including corneal oedema, Haab's striae, multiple prior surgeries and topical medications used. In addition, our analysis revealed that age and gender had no influence on IOP.

Appraisal:

Limitations of the study included the limited number of PCG patients at the centre. The initial calculated sample size of 45 patients was not obtained for the PCG, due to the nature of the prevalence of the condition.

Despite this, statistical significance was still reached due to the marked difference in IOP recorded between tonometers.

Although a single operator performed all measurements, the operator was not masked to the device nor the underlying condition of the study participant. This

would not affect the reading with reference to RBT, but the operator can influence the reading of the PAT.

5. Conclusion

IOP measurements done with rebound tonometry in children with and without PCG were overestimated compared to handheld PAT. This difference was more pronounced in PCG patients compared to non-PCG patients. In addition, IOP was significantly related to corneal thickness. Based upon this study's results, we need to be mindful that when accepting IOP measurements IOP with RBT in children with PCG, PAT is more likely to give an accurate IOP. Larger studies will be helpful to establish a constant between RBT and PAT.

6. Additional statements

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (protocol code M200664, date of approval 2020/06/26).

Informed Consent Statement: Written informed consent was obtained from all parents. Informed written medical assent was obtained from participants 7 years and older.

Data Availability Statement: Data is kept on a password protected data base (REDCap®) and access to the data base can be obtained from hettie.kruger@gmail.com.

Acknowledgments: We would like to acknowledge the Anaesthetic department of the Chris Hani Baragwanath Academic Hospital in Johannesburg, South Africa, for their contribution to the study.

Conflicts of Interest: The authors declare no conflict of interest.

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Annexures

Annexure A: Approved protocol

A comparison of rebound and applanation tonometry in anaesthetised children with and without Primary Congenital Glaucoma: A cross sectional comparative study

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Plagiarism declaration for written work

I Hester Kruger as a postgraduate student registered for a MMed at the University of the Witwatersrand declare the following:

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- I am aware plagiarism is wrong.
- I confirm that this written work is my own work except where I have stated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or if I have failed to acknowledge the ideas or writing of others.

Signature: H Kruger

Date: 18 April 2020

It is estimated that 14 million children in the world are blind. [1] In developing countries, 1.5 per 1000 children are blind.[2,3] Primary congenital glaucoma (PCG) contributes to 5% of visual impairment and blindness in children.[1]

PCG is a developmental glaucoma that accounts for the majority of primary paediatric glaucomas. It usually occurs before three years of age due to an obstruction that prevents the drainage of the aqueous humour. This is caused by the abnormal development of the trabecular meshwork and anterior chamber angle.[2]

The incidence of PCG varies with ethnicity. The highest incidence occurs in Slovakia and Saudi Arabia, reported at 1 in 1 250 and 1 500 live births respectively. This is possibly to due to a high rate of consanguinity. [5] In Great Britain the incidence of PCG is reported at 1 in 18 500.[3] Sub-Saharan African studies reported PCG to account for up to 4% of all new glaucoma cases.[4]

Limited epidemiological data exists on the prevalence of PCG in Sub-Saharan Africa. [6] Two separate African studies reported on the causes of visual impairment in children attending schools for the blind. An Ethiopian study found the prevalence of glaucoma amongst scholars to be 1.7%. [5] In a South African study, the prevalence amongst a group a of scholars was found to be 6.7%. [6]

Clinical features of PCG include epiphora, buphthalmos, (corneal enlargement) corneal oedema, Haab's Striae (rupture of Descemet's membrane) and raised intraocular pressure (IOP).[5]
Complications of untreated PCG include irreversible blindness, chronic ocular pain, opacification of the cornea and a deformed globe.[5] Additionally, visually impaired children, in developing countries, are known to experience increased morbidity and mortality compared to their visually abled counterparts.[6]

The measurement of IOP is necessary in both the diagnosis and monitoring of PCG. To monitor IOP in PCG patients is essential as progression can occur at any time during follow up and even years after stability in IOP has been achieved.[5]

IOP is measured with a tonometer. Properties of an ideal tonometer include that it must be accurate, repeatable, reproducible and minimally influenced by corneal properties.[7]

Four tonometry modalities exist:[8]

- Applanation Tonometry
- Rebound Tonometry
- Indentation Tonometry
- Dynamic Contour Tonometry

Modalities available in our facility at St John Eye Hospital in Johannesburg include applanation tonometry (AT) and rebound tonometry (RBT).

Applanation Tonometry

Applanation Tonometry (AT) works on the principle that the force required for a probe to flatten a central area of cornea is equal to the IOP.[7]

The gold standard for measuring IOP is considered to be the Goldmann Applanation Tonometry (GAT). It is a stationary slit lamp mounted apparatus, utilizing a cone shaped tonometer prism to gently come into contact with the cornea. This method requires topical anaesthesia and fluorescein sodium staining of the cornea. A single measurement is done by the operator, who visualises and aligns two fluoresced semicircles. A high level of co-operation is expected from the patient undergoing GAT, such as resisting to blink and move away from the slit lamp during the procedure. This makes GAT in young paediatric patients difficult and sometimes impossible.

The Perkins Applanation Tonometer (PAT) is a handheld applanation tonometer that is based on the same principals as GAT. The mobility of this device is advantageous in paediatric patients, as it allows the clinician to be mobile and can be used in the

supine position. Although the PAT has become a widely used modality for IOP monitoring in children, it can be perceived as an intimidating instrument causing the child to cry, squeeze their eyes closed and move away from the examiner.[9,10]

Rebound tonometry

Rebound tonometry (RBT) is based on the principle of a probe propelled forward to rebound off the cornea. Once the probe rebounds off the cornea, the IOP is calculated from the deceleration rate of the probe. No corneal anaesthesia is required. The instrument is a hand-held device.[9]

The Icare® TA01i is a rebound tonometer that is a well-tolerated, requires an upright position, needs less patient co-operation and does not require topical anaesthesia.[10] To overcome the problem of using the Icare®TA01 whilst a patient is supine and anaesthetised, the IOP measurements can be done with the child's face turned to the side.[11]

The ICare®Pro is a modified ICare®TA01i tonometer with an inclination sensor, which allows IOP to be measured whilst the patient is in the supine position.[12]

Home-based rebound tonometers, for example, the ICareONE®, is intended for use outside of the clinic. The design of this device is easy to use for patients who require IOP monitoring at home.[13]

When comparing AT to RBT, literature indicates that RBT mostly overestimates IOP.

A North American study by Flemmons *et al* reported a mean difference of 2.3 +/- SD 3.7 mm Hg, p=0.0001 when comparing PAT to the ICare® tonometer in paediatric patients with glaucoma and suspected glaucoma. They reported 32% of ICare® measurements to be more than 3mmHg compared to GAT.[14]

Dahlman-Noor *et al* found poor agreement between the two devices, with the RBT significantly overestimating IOP in awake children with glaucoma. A mean difference in IOP between the devices were found to be 3.3 +/- SD 5.3 mmHg, p<0.001. There was increased disagreement between devices in eyes with thicker corneas.[15]

Studies done to compare PAT to RBT reported that RBT overestimates IOP in PCG. Martinez-de-la-Casa *et al* found that 76% of RBT readings were higher compared to PAT by a significant amount in their study done on 47 eyes of young paediatric glaucoma patients. Measurements were done in a random order. The mean difference in IOP between the two devices was 3.1±4.0mm Hg. In patients with thicker corneas, the RBT overestimation was higher.[16]

A larger Egyptian study by Esmael *et al.* on 223 normal and glaucomatous paediatric eyes compared PAT to ICare®. Between these two devices, the mean IOP difference was found to be 0.59 ± 2.59mmHg P = 0.001. In the glaucomatous group the mean difference was 0.79 ± 2.83 mmHg P = 0.032. They found good correlation between PAT and ICare® and that the ICare® overestimated IOP by 0.59mmHg in cases where the IOP was less than 15 mmHg. 31.8% of patients had an IOP greater than 15mmHg, with a mean difference between devices of 0.04 ± 3.28 mmHg p = 0.914.[20]
A summary of the studies is provided in the following table below.

Repeatable measurements imply that the intra-observer variability should remain constant with measurements done in succession. Although applanation tonometry is considered the gold standard for measuring IOP, due to the corneal biomechanics it's repeatability was found to be inferior to rebound tonometry.[17]

When assessing the repeatability of a rebound tonometer after 8 consecutive IOP measurements on 20 eyes of normal children, a mean difference between the first and last measurement of 0.42 mmHg was found not to be significant.[18]

A larger study by Sahin *et al* found that RBT has good repeatability and reproducibility in their study of 304 normal paediatric eyes. Their intra-observer

correlation coefficients between 2 examiners ranged between 0.964 and 0.974. Intra-subject variation coefficients ranged between 8.4% to 11.4%.[19]

A summary of the studies is provided in the table below.

Studies comparing rebound tonometry (RBT) to applanation tonometry (AT)				
Study	**Year**	**Population**	**n**	**Conclusion**
Flemmons *et al*(14) (USA)	2011	Paediatric patients with glaucoma and suspected glaucoma No age specified	71	RBT overestimated GAT in one-third of children.
Dahlmann-Noor *et al* (15) (UK)	2013	Paediatric patients with glaucoma 4.9-19 years	102	RBT overestimated IOP.
Martinez-de-la-Casa et al(16) (Spain)	2009	Paediatric Patients with glaucoma 3 -13 years	68	RBT overestimated IOP.
Esmael *et al*.[20] (Egypt)	2018	Paediatric patients with and without and glaucoma 4 months – 16 years	223	Good correlation between RBT and PAT.
Studies reporting on repeatability of RBT				
Study	**Year**	**Population**	**n**	**Conclusion**
Dosunmu *et al*(18) (USA)	2014	Paediatric patients with glaucoma 8-17 years	20	RBT is repeatable.
Sahin *et al*(19) (Turkey)	2016	Paediatric patients without ocular conditions 7-15 years	304	RBT is repeatable and reproducible.

The feasibility of awake IOP measurements in young paediatric patients is limited. General Anaesthetic is therefore used during routine examination of young children with PCG. IOP is influenced by different anaesthetic agents. Induction agents, for example, sevoflurane and propofol are associated with a decrease in IOP.[10] Ketamine used at dosages below 4mg/kg does not significantly influence IOP.[21] Currently, ketamine is the anaesthetic agent of choice during examination under anaesthesia (EUA) for PCG.[22]

PCG requires tertiary level care. St John Eye Hospital in Johannesburg, Gauteng, South Africa admits an average of 12 new cases of PCG per year and offers management to an average of 96 PCG patients annually. IOP measurements need to be accurate as their management is based on this parameter.
Difficulties in measurement of IOP in a clinic setting necessitates routine EUA. This adds constrain to a busy theatre as well as cause distress to the child and family to undergo EUA. Compared to PAT, the ICare® tonometer is quick, easy to use, less intimidating and requires no topical anaesthesia or sedation. By analysing data from our South African PCG population we aim to answer the question "How does rebound tonometry correlate to applanation tonometry in anaesthetised children with and without PCG?". The results of this research will provide insight into establishing guidelines for IOP measurement in PCG specific to our patient population and has the potential to reduce time constraints in our theatre.

Aim

This study aims to determine the agreeability of rebound tonometry compared to applanation tonometry when used in anaesthetised children with and without PCG.

Study Objectives

Primary Objectives

- To compare the difference in IOP measured with rebound and applanation tonometry in children with and without Primary Congenital Glaucoma undergoing routine anaesthesia at St John's Eye Hospital in Johannesburg, South Africa.
    - *Null Hypothesis*: There is no IOP difference when measuring the intraocular pressure in children with and without PCG using rebound and applanation tonometry

      H_0: $\mu_{\Delta PCG} = \mu_{\Delta non\text{-}PCG}$
- To compare the level of agreement and correlation between rebound and applanation tonometry in measuring IOP between the PCG and non-PCG patients

  Null Hypothesis: There is no correlation between the ICare® and PAT in measuring IOP

  H_0: r=0

Secondary Objectives

- To assess whether age, corneal thickness and corneal diameter are significant predictors of intraocular pressure using applanation tonometry.
- H_0: $ß_1=0$
- To assess whether age, corneal thickness, corneal diameter and the presence of corneal scarring are significant predictors of the intraocular pressure difference between rebound and applanation tonometry.
- H_0:$ß_1=0$

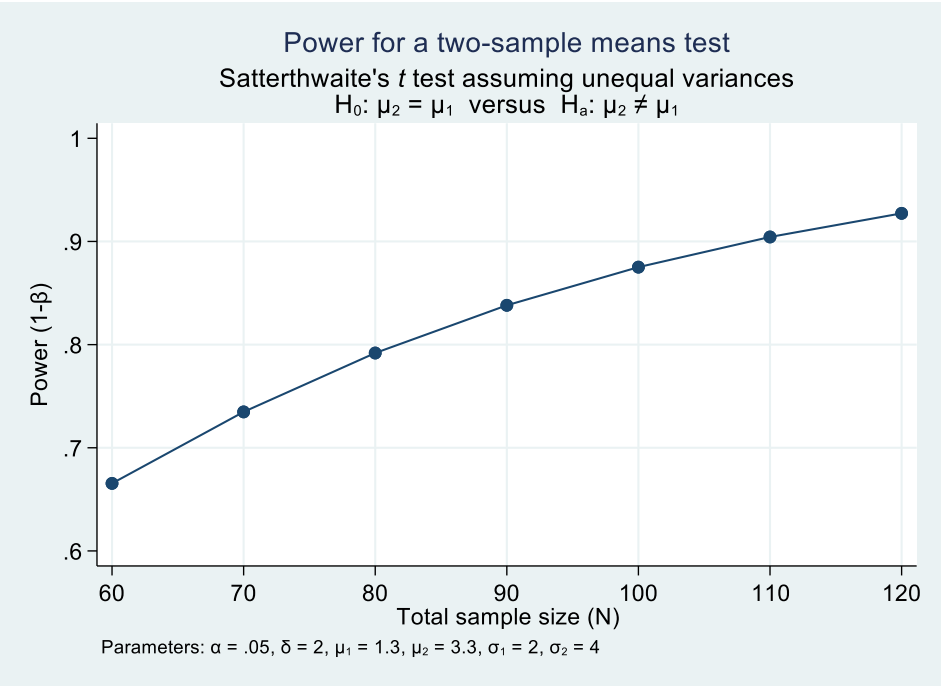
Methods and Materials

Study Design

- A cross-sectional study of the intraocular pressure measurements using rebound and applanation tonometry in paediatric patients with and without Primary Congenital Glaucoma, undergoing routine anaesthesia.

Sample size

A sample size of 82 patients was calculated using Satterthwaite's t-test with 80% power to detect a difference of at least 2mmHg between the means of the differences between applanation and rebound tonometry in the PCG and non-PCG groups. Unequal variances were assumed. We added a small margin for error and got a final sample size of 90 patients (45 in each group).



Inclusion Criteria

- Paediatric patients 10 years and younger undergoing routine anaesthesia at St John Eye Hospital
- Investigation group: children with primary congenital glaucoma undergoing routine examination under anaesthesia
- Control group: children undergoing routine extraocular procedures under anaesthesia; or normal contralateral eyes in those undergoing intraocular procedures.
- Patients whose parents give consent to participation in the study.

Exclusion Criteria

- Patients above the age of 10
- Non PCG Corneal disease
- CHED (Congenital Hereditary Endothelial Dystrophy)
- Secondary causes of glaucoma

Collection of data

- Data will be collected prospectively and stored on Research Electronic Data Capture (REDCap®) database. (See Appendix A)
- Parental consent will be obtained
- Medical assent will be obtained from patients above the age of 7 years

- Patients attending routine theatre procedures at the St Johns Hospital will be asked to join the study. These procedures include
    1. Routine examination under anaesthesia for primary congenital glaucoma (PCG)
    2. Routine surgical extraocular procedures and normal contralateral eyes of routine intraocular procedures.
- Standardization of anaesthesia will be done according to the Department of Anaesthesia at Chris Hani Baragwanath's examination under anaesthesia protocol, based on the guidelines designed by University of Cape Town.(22) (Appendix B)
- One drop of local anaesthetic 0,4% oxybuprocaine, will be placed in the eye prior to measurement.
- A single operator will perform the measurements.
- The intraocular pressure will be measured with the Icare® TA01i tonometer and the Perkins applanation tonometer. Three readings with each tonometer will be done on one eye. Measurements will be recorded at baseline, defined as immediately after the aneasthetic induction agent has been administered and the patient is adequately anesthetized, and at 5 and 10 minutes after induction prior to a laryngeal mask or endotracheal tube is placed.
- IOP Measurements will be done whilst the patient is in supine position, with the head turned to the side when using the ICare® and Perkins applanation tonometer. For pressure measurements on the right eye, the patient's head will be turned to the left, and for IOP measurement on the left eye the patient's head will be turned to the right.
- IOP measurement will be done on the centre of the cornea
- Measurement of corneal pachymetry with the Alcon Ocuscan® RxP pachymeter will take place after the IOP measurements.
- Corneal diameter in horizontal and vertical dimensions will be measured using a caliper marked in millimeters.
- Each patient will be assigned a unique reference number and data entries will be encoded. Patient identifiers will be stored separately to their data.
- A password protected REDCap® database will be used to store data.
- The duration of the study is outlined in the gantt chart below:

Duration of study

	Nov 19-Jan 20	Feb 20	March 20	April 20	May 20 – July 20	Aug 20 – May 21	Jun 21 – Jul 21	Aug 21	Sept 21	Oct 21
Literature review and preparation										
Protocol submission supervisor										
Corrections										
Protocol submission										
Assessor group meeting										
Ethics application										
Data collection										
Data analysis										
Report submission supervisor										
Corrections										
Submission of report										

Statistical analysis

- Simple descriptive statistics (mean±SD, median IQR) will be used to describe the demographic data.
- Data will be checked visually for normality of distribution.
- The primary outcome will be analysed using the two-sample t-test if it has a normal distribution or the Wilcoxon ranksum test if the distribution is skewed. Pearson's or Spearman's correlation coeffecients will be used to assess the relationship between the 2 methods of measurement.
- Levels of agreement will be plotted using the Bland Altman plot
- Univariate and multivariate linear regression models will be developed using the following prespecified predictor variables
    - Age
    - Gender
    - Corneal Pachymetry
    - Corneal diameter
    - Exposed (PCG) group: Current treatment and Previous surgery
    - Comparisons (Non PCG) group: Reason for presenting to theatre; either strabismus surgery or unilateral lens washout, using the contralateral eye for our study

Ethics Approval

- Ethical approval will be applied for at the Human Research Ethics Committee
- Patient names and hospital numbers will not be included in the research report thus ensuring patient confidentiality
- The information will be captured on a REDcap® database which will be password protected and only accessible by the investigators
- Patients and parents of patients will have informed consent and medical assent in their home language.
- Each patient will be assigned a unique reference number. Their names will not be linked to their records, only their unique reference number.
- The diagnosis of the patient will be recorded, in order to assign them to the case or control group.

Funding

In the study group, data will be collected on patients going for routine examination under anaesthesia for their primary congenital glaucoma.
In the control group, patients already undergoing anaesthesia will have their intraocular pressure measured.
This study will therefore not incur any additional cost.
In the event that additional costs arise, it will be covered by Dr Hester Kruger.

Presentation Plans

- Present at departmental meeting
- Present at the Ophthalmic Society of Southern Africa (OSSA) annual congress
- Publish in a scientific journal.

Authorship

- First Author – Dr H Kruger
- Co-authors – Dr N Naidu, Prof I Mayet, Dr N Ally

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Protocol Appendices

Appendix A: REDCap® Data collection sheet

Demographics

Record ID	_____
Demographics	
Date Of Birth	_____
Gender	◯ Male ◯ Female

Clinical Data

Record ID

_____

Clinical Data

PCG or Non-PCG?

- ◯ PCG
- ◯ Non-PCG

Non PCG Reason for theatre

- ◯ Strabismus surgery
- ◯ Lens Washout
- ◯ Other

Non PCG Reason for theatre - Description

_____

PCG Medication

- ◯ Prostaglandin Analouge
- ◯ Beta Blocker
- ◯ Alpha Agonist
- ◯ Carbonic Anhydrase Inhibitor
- ◯ Sympathomimetic
- ◯ Other
- ◯ None

PCG Medication Other Description

_____

PCG Previous Surgery

- ◯ None
- ◯ Laser - SLT
- ◯ MIGS
- ◯ Tube
- ◯ Valve
- ◯ Trabeculotomy
- ◯ Trabeculectomy
- ◯ Other

PCG Previous Surgery Other Description

_____

Right or Left Eye?

◯ Right
◯ Left

Corneal Pachymetry

Corneal Diameter Horizontal

Corneal Diameter Vertical

IOP Icare 0

IOP PAT 0

IOP Icare 5

IOP PAT 5

IOP ICare 10

IOP PAT 10

Appendix B: Anaesthetic protocol for measuring intraocular pressure

Based on the Chris Hani Baragwanath Academic Hospital, Department of Anaesthetics EUA protocol.

- No Premedication
- Gas Induction with Sevoflurane, increased gradually and limited to 6% until placement of intravenous (IV) cannula
- Secure IVI cannula
- Maintenance of anaesthesia with IV Ketamine 2mg/kg bolus
- Stop Sevoflurane, start timer
- Maintain ketamine infusion at 4mg/kg for 15 minutes
- Should additional sedation be required, a further ketamine bolus of 1mg/kg may be administered
- One drop of Local Anaesthetic, 4% oxybuprocaine, placed in the eye prior to Measurement.

Appendix C: Turnitin® Report of Protocol

452815:H_Kruger_Protocol_draft_19_April_2020.docx

ORIGINALITY REPORT

12%	5%	7%	7%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to Glasgow Caledonian University Student Paper	1%
2	Submitted to The University of Manchester Student Paper	1%
3	Amanne Esmael, Yomna M Ismail, Abdelrahman M Elhusseiny, Alaa E Fayed, Hala M Elhilali. "Agreement profiles for rebound and applanation tonometry in normal and glaucomatous children", European Journal of Ophthalmology, 2018 Publication	1%
4	Submitted to Aston University Student Paper	1%
5	Submitted to University of Liverpool Student Paper	<1%
6	on-demand.gputechconf.com Internet Source	<1%
7	Gandhi, Nandini G., Sarah K. Jones, and Sharon F. Freedman. "Icare ONE Home	<1%

Informed Assent Form for children above the age of 7 years who will undergo anaesthesia at St Johns Eye Hospital and who we are inviting to participate in a research study on intraocular pressure measurement.

This Informed Assent Form has two parts:

- Information Sheet (gives you information about the study)
- Participant Assent sheet (this is where you sign if you agree to participate)

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

Introduction

My name is Hester Kruger and I will be conducting a study to research and test different ways to measure eye pressure to see which method works best for children with glaucoma (High eye pressure). We want to know which machine measures eye pressure accurately in order to help us to give the correct medicines for our patients and to prevent them from going blind. We think that this research will help us with that.

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian, and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/ guardian also have to agree. But if you do not wish to take part in the research you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at any time and I will take time to explain.

Purpose: Why are we doing this research?

We want to find out which tool for measuring children's eye pressure is the most accurate. We want to know this because we think this will help us choose the correct medicine for them in order to prevent them from going blind.

Choice of participants: Why are you asking me?

We are testing which eye pressure measuring tools work the best on children who are your age – all children below 10 years. We are measuring eye pressure, using two different tools, on children who have normal eyes and those that have high eye pressures since birth (congenital glaucoma).

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes. This is still your clinic; everything stays the same as before. Even if you say "yes" now, you can change your mind later and it is still okay.

Procedures: What is going to happen to me?

We are going to research which way of measuring eye pressure is the most accurate for children. We will measure eye pressure using two different measuring tools while you are sleeping in theatre. By doing research like this, we can see which machine works best and we hope this will help us to take better care of children with high eye pressure.

If you decide that you want to do this, there will be three things that happen while you are asleep in theatre.

1. We will measure your eye pressure using a tool called an Icare ® tonometer.
2. We will measure your eye pressure again using a different machine called a Perkins tonometer
3. We will measure the thickness of the front of your eye using a pachymeter.

All this will happen while you are sleeping. You will not feel any pain at all. You will not have to come back to theatre again afterwards.

You can ask me to stop and explain again at any time and I will explain more about the process.

Risks: Is this bad or dangerous for me?

To measure eye pressure is safe. You will not feel any pain. There are few risks when we measure eye pressure. You might get a small scratch on your eye, which will heal within a few hours. You might feel drowsy and want to cry when waking up.

Discomforts: Will it hurt?

Measuring eye pressure does not hurt. You will be asleep when we measure your eye pressure and will not notice us measuring your eye.

Benefits: Is there anything good that happens to me?

Nothing will happen to you when we measure your eye pressure while you are sleeping.

Reimbursements: Do I get anything for being in the research?

You will not receive anything to participate in the research.

Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research study and we won't share information about you to anyone who does not work in the research study.

Information about you that will be collected from the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number instead of your name. Only the researchers will know what your number is and we will not share that information.

Sharing the Findings: Will you tell me the results?

When we are done measuring your eye pressure in theatre, we will sit down with you and your parent(s)/ guardian(s) and we will tell you what your eye pressures were. After we collect all the children's eye pressures, we will tell more people about the results and which pressure measuring tool we found to be most accurate. We will do this by writing reports and going to meetings with people who are interested in the research that we do.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. No one will be mad or disappointed with you if you say no. it is your choice. You can say "yes" now and change your mind later and it will still be ok.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. You can also ask other doctors in the clinic questions. I have written a telephone number and address where you can reach us or come and see us. If you want to talk to someone else that you know like your teacher or auntie, that's okay too.

If you need to contact me or my supervisors later, you can use the following contact details;

Dr H Kruger, principal investigator, 0722047950, or by e-mail at 452815@students.wits.ac.za

Dr N Naidu, supervisor, on telephone no. 011 933 8774, or by email at natasha.naidu@wits.ac.za

Dr N Ally, supervisor, on telephone no. 011 933 8774, or by email at, naseerally@gmail.com

Prof I Mayet, supervisor, on telephone no. 011 933 8774, or by email at

eyemay.im@gmail.com

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.

Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone no.: 011 717 2700, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

If you choose to be part of this research, I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: PARTICIPANT ASSENT SHEET FOR MINORS* ABOVE 7 YEARS

Study Title: A comparison of the Icare ®Tonometer and the Perkins Applanation Tonometer in anaesthetized children with and without Primary Congenital Glaucoma: A cross-sectional comparative study

I have been given a Participant Information Sheet for Minors, which explains what this study is about; The study was explained to me and I understand what will happen if I take part;

I was given time to ask any questions I wanted to and was happy with the answers I was given; I understand that I will not benefit from the study, should I agree to take part. I also understand that I will not be paid to take part in the study; taking part will not cost me anything either; I have been given a range of contact details, repeated below, should I require further information at a later stage, or have any cause for concern over anything which is done to me during the study; and I understand that even if I agree to take part in the study, I can change my mind later and stop being a part of the study; My parent(s) or guardian(s) know that I have been invited to take part in the study. They agree that I may do so, but the decision to take part is also mine.

Contact details:

Dr H Kruger, Principal Investigator, 0722047950, or by e-mail at 452815@students.wits.ac.za/ Dr N Naidu, Supervisor, on telephone no. 011 933 8774 or by email at natasha.naidu@wits.ac.za/ Dr N Ally, Supervisor, on telephone no.011 933 8774 or email at naseerally@gmail.com/ Prof I Mayet, Supervisor, on telephone no. 011 933 8774 or email at eyemay.im@gmail.com

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.

Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone no.: 011 717 2700, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of Participant: _____
Date: _____
Place: _____
Signature or mark: _____
Name of Parent or Guardian: _____
Date: _____
Place: _____
Signature or mark _____
Witnessed by:
Name of Witness: _____
Signature: _____
Date: _____

* Defined as being persons under the age of 18

Informed Parental Consent Form for children below the age of 10 years who will undergo anaesthesia at St Johns Eye Hospital and who we are inviting to participate in a research study on intraocular pressure measurement.

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you agree that your child may participate)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

I am Hester Kruger; I work at St Johns Eye Hospital as a registrar in Ophthalmology. I am doing research which might help our hospital do more to help children with glaucoma. In our research we will examine children under anaesthesia. We Will measure their eye pressure with two different machines while they are under anaesthesia in theatre. Whenever researchers study children, we talk to the parents and ask them for their permission. After you have heard more about the study, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

In our clinic we see many children with glaucoma. Glaucoma in children is a serious condition which can lead to blindness if not treated accurately. In order for us to know if we are treating our glaucoma patients correctly, we need to correctly measure their eye pressure. We use two different machines at our hospital to measure eye pressure with. We want to know which one is the most accurate so we can be sure that our patients receive the best care.

Type of Research Intervention

This research study will be aimed at all children undergoing anaesthesia at the St Johns eye Hospital. It will be a descriptive study on the eye pressures of these children using two different machines to measure their eye pressure. We will then have a better idea of which machine measures eye pressure the most accurately in children.

Selection of Participants

We have chosen your child to participate in this study because he/she will undergo anaesthesia in theatre. We want to measure the eye pressure of all children who undergoes anaesthesia at St Johns Eye Hospital. We will measure eye pressure using two different machines. The measurement will not hurt and will not affect your child's vision.

Voluntary Participation

Participation in this study is voluntary. You can choose to say no to participate in this study. It will not influence the treatment or care given at the hospital if you or your child decide not to participate. Your child also will be asked if they want to participate in the study. You do not have to decide today. You can think about it and tell me what you have decided later.

Procedure

During the study, while your child is under anaesthesia (asleep) for their procedure, we will instil a drop of local anaesthetic in the eye (pain medication) to make sure that your child does not feel any pain. Then we will measure the eye pressure of each eye using two different machines. The machines rarely cause any harm or affect vision after the procedure. We will also measure the thickness of the front part

of the eye with an ultrasound probe. The thickness measurement rarely causes harm and does not affect vision after the procedure. Your child will not be feeling any pain during the procedure. The measurements will be done by a qualified specialised eye doctor.

After measuring the thickness of the front part of the eye and measuring the eye pressure using two different machines, we will document our findings on an electronic database. Other information that we will include is your child's date of birth, ethnicity, diagnosis and current medication, current and past surgical procedures.

Duration

We will be doing eye pressure measurements while your child is in theatre and asleep. The measurements should not take more than 5 minutes for both eyes. After the anaesthesia and procedure, we will not require any further follow up appointment for our study.

We will be doing measurements on children attending theatre at St Johns Eye Hospital from June 2020 to May 2021.

Risks and Discomforts

Measuring eye pressure and corneal thickness during anaesthesia is a quick procedure, that we do daily on adults who are awake. It will not elicit any pain in your child.

After waking up from the anaesthetic, your child may be drowsy, confused, irritable and crying. This will be temporary.

We will not be using your child's name in the study.

Potential risks during the study:

The procedures we follow to do measurements on your child's eye are routine procedures and carries little risk for harm.

Some of the effects of the local anaesthetic (numbing) drops we put in your child's eye may cause

- Mild irritation and discomfort. Your child won't notice this as he/she will be asleep

- Mild superficial scratch to the top layer of the eye, (epithelial abrasion) which will heal by itself and does not affect your child's vision. This does not happen often.

The devices we use to do measurements on your child's eye is considered safe. The devices we use will briefly and delicately touch your child's eye while he/she is asleep. In some cases, this can lead to a small scratch on the front part of the eye (epithelial abrasion) and will heal within a few hours. This will not affect your child's vision or appearance as this scratch is not visible to the naked eye.

The anaesthetic agents used during the procedure has some side effects. These side effects include drowsiness, coughing, crying and increased saliva. Some children may be allergic to the medication. This is very rare and in this case your child should be well taken care of.

Benefits

There will be no immediate and direct benefit to your child. Your child's participation is likely to help us to learn more about glaucoma and how to help other children with the same condition.

Reimbursements

There will be no reimbursements provided for you or your child during this study.

Confidentiality:

During this study, we will not use your child's name. We will capture his/her date of birth, ethnicity, current medications, measurements of eye pressure and the thickness of the front part of the eye. The information about your child will be allocated to a number instead of his/her name. No-one but the researchers will know what his/her number is. It will not be shared with anyone outside the research project.

Sharing of Research Findings

At the end of the study, we will be sharing what we have learnt from the information we have collected. We will do this by meeting with other doctors at our hospital meeting. We will also be sharing the information in my research paper as part of my

master's degree. We will also share the information at congresses for eye doctors and might publish the results in a paper for interested doctors to learn from our research.

Right to refuse or withdraw

You may choose not to have your child participate in this study. Your child does not have to take part in this research if he/she does not want to. Choosing to participate or not will not affect either you or your child's care at the St John's Eye Hospital. Your child may stop participating in the study at any time that your or he/she wish to.

Who to Contact?

If you have any questions you may ask them now or later or even after the study has started. If you want to ask any questions later, you may contact myself:

Dr H Kruger, Principal Investigator, 0722047950, or by e-mail at 452815@students.wits.ac.za
Dr N Naidu, Supervisor, on telephone no. 011 933 8774 or by email, natasha.naidu@wits.ac.za Dr N Ally, Supervisor, on telephone no.011 933 8774 or by email naseerally@gmail.com, Prof I Mayet, Supervisor, on telephone no. 011 933 8774, or by email mailto:eyemay.im@gmail.com.
Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone no.: 011 717 2700, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Part II: Parental Consent

A comparison of the Icare ®Tonometer and the Perkins Applanation Tonometer in anaesthetized children with and without Primary Congenital Glaucoma: A cross-sectional comparative study

1. I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
2. I was given time to read it, or had it read to me, in the language I best understand;
3. I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
4. I believe I fully understand why the study is being conducted and what the intended outcomes will be;
5. I understand that there will be no immediate benefit to my child, should I agree that he or she participates, nor will I or my child receive any payment; conversely, participation will not cost me or my child anything but my time;
6. I understand that, even if I initially consent for my child to take part in the study, I may subsequently withdraw him or her at any time and would not be required to give any reasons; if that happened, any data collected about my child for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained
7. I have been given a range of contact details, listed below. If I or my child require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.

Contact details:
Dr H Kruger, Principal Investigator, 0722047950, or by e-mail at 452815@students.wits.ac.za/ Dr N Naidu, Supervisor, on telephone no. 011 933 8774 or by email at natasha.naidu@wits.ac.za/ Dr N Ally, Supervisor, on telephone no.011 933 8774 or email at naseerally@gmail.com/ Prof I Mayet, Supervisor, on telephone no. 011 933 8774 or email at eyemay.im@gmail.com

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone no.: 011 717 2700, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of Participant: _____
Date: _____
Place: _____
Signature or mark _____

Witnessed by:
Name of Witness: _____
Signature: _____
Date: _____

Annexure B

Ethics Clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr H Kruger

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200664

NAME: (Principal Investigator)	Dr H Kruger
DEPARTMENT:	School of Clinical Medicine Department of Neurosciences Division of Ophthalmology Medical School University
PROJECT TITLE:	A comparison of rebound and applanation tonometry in anaesthetised children with and without primary congenital glaucoma: a cross sectional comparative study
DATE CONSIDERED:	2020/06/26
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Drs N Naidu & N Ally; Professor I Mayet
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/08/06

This clearance certificate is valid for 5 years from the date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

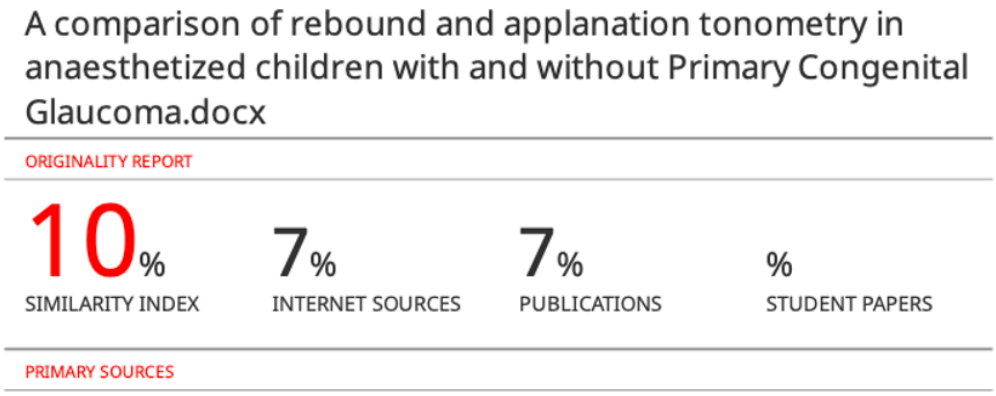
To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore reports and re-certification will be due early in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

2020/08/06
Date

Annexure C

Turn-it-in Report of the final document



A comparison of rebound and applanation tonometry in anaesthetized children with and without Primary Congenital Glaucoma.docx

ORIGINALITY REPORT

10%	7%	7%	%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES