OPTOM 472 Vision Science 3

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includes contributions from a number of associate investigators and graduate students

Clinical Research and Evidence Based Practice

Dept of Optometry and Vision Science
The University of Auckland.

Relevant Background Information

My Background
- all set for private practice *but*
- a diversion to MSc(Optom) and PhD degrees
- maintenance of clinical skills with locums & part-time practice
- continuation into academic optometry

Clinical Residencies in
- **Low Vision** with Ian Bailey (now UCBerkeley)
- **Colour Vision** with Barry Cole (UoM)

Research
- **Visual ergonomics** (applied research),
- **Visual Psychophysics** (theoretical research)
  - Visual acuity and contour interaction (crowding)
  - Defocus and the perception of blur,
  - Multifocal VECP (electrophysiology)
- **Clinical research**
  - Low Vision (CCTV reading, Refractive error meast of LV patients)
  - Spectacle lens wearer trials
  - Vision components of other research topics
  - Optics and Clinical Optometry projects

Overview and Aims of this Lecture

1. To set the context of clinical research in the foundation of **Evidence Based Practice**.

2. To provide examples of **evidence from clinical research**:

   a) that has been **widely adopted** in current clinical practice (modern visual acuity charts)

   b) that has essentially **been overlooked** in clinical practice (cataract grading scales)

3. To look at some of the **clinical research projects** that have been conducted here **at Auckland that are contributing to the evidence base for practice**

Evidence Based Practice

- See Word document and Lecture resources on Evidence based practice

- See File
  472 Lec RJJ - 2 Evidence Based Practice in Optometry.pdf

Examples of Practice Based on Evidence

- See Word document and Lecture resources on Evidence based practice that has been **widely adopted** in current clinical practice (modern visual acuity charts)

- See File

  472 Lec RJJ - 3 Example - Visual Acuity Chart adoption.pdf

Examples of Practice Based on Evidence

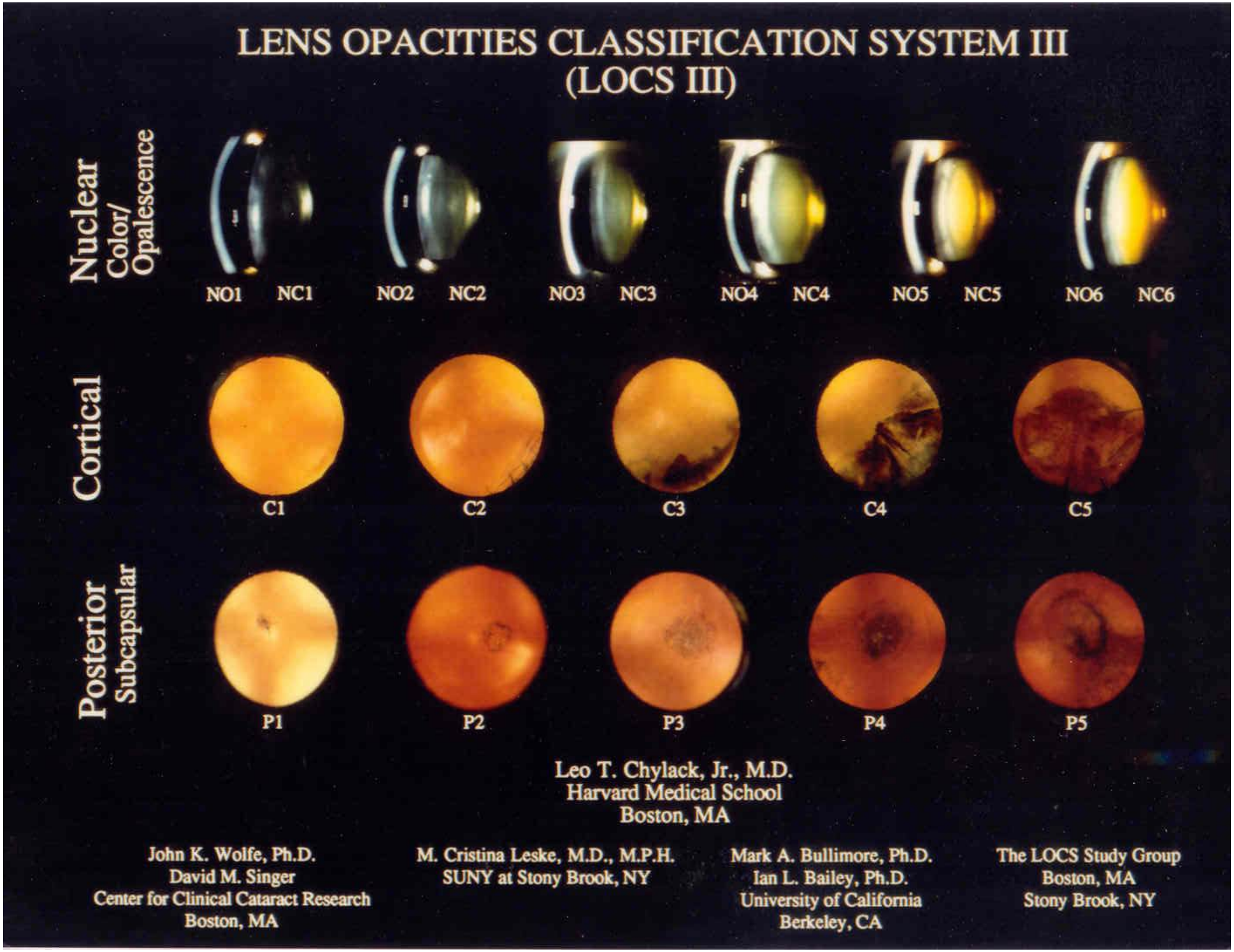
- See Word document and Lecture resources on Evidence based practice that has essentially been **overlooked** in clinical practice (cataract grading scales)

- See File

  472 Lec RJJ - 4 Example - Scaling - LOCSIII Cataract Grading

- A colour version of the LOCS III grading scheme is on the next slide

LOCS III Cataract grading system



Research to provide evidence for Practice

- Development of Grading Scales for management of prosthetic eye wearers.

- See file on CECIL

472 Lec RJJ - 5 Example - PhD res -Grading scales for conj inflam w Prosthesis wearer.pdf

Research to provide evidence for Practice

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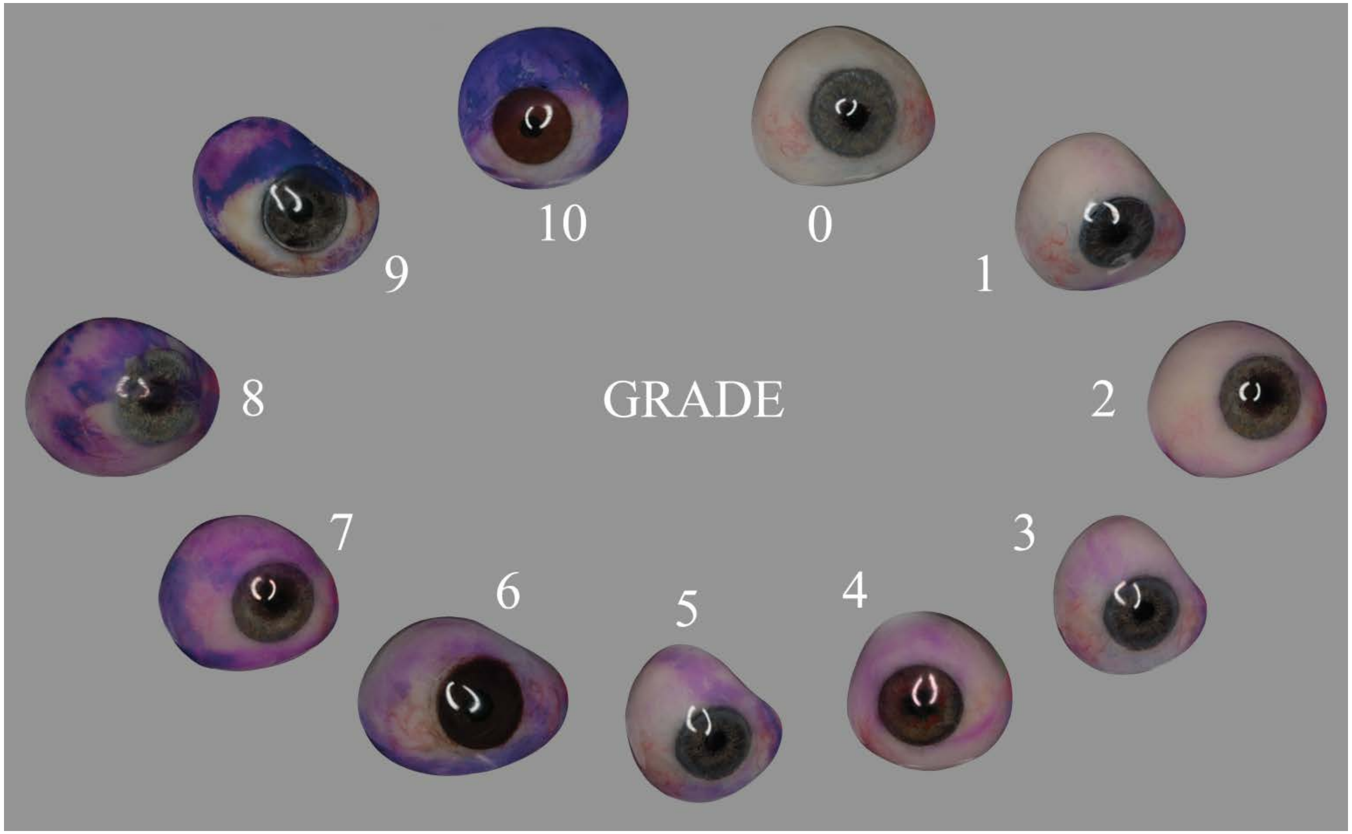

Research to provide evidence for Practice

- Detailed examination of the van Herick grading system for anterior chamber angles. A Part V student research Project.
- See files

  472 Lec RJJ - 6 Example - Part V res - Critical examination of Van Herick technique.pdf
- *and view the manuscript via the Philson Library course website …*

  or look for the paper using citation:

  Leung M, Kang SSO, Turwhenua J, Jacobs RJ. Effects of illumination and observation angle on the van Herick procedure. Clinical and Experimental Optometry 2012; 95(1): 72-77.

Summary of this lecture

Modern practice is increasingly evidence based

The evidence is sometimes widely adopted and changes practice

It can take time to change practice methods even when evidence is compelling

You are developing the critical skills needed for Evidence Based Practice.

The research needed to underpin modern practice can be done by local practitioners

- in private practice
- in academic settings

NZ is in dire need of more home-grown academically inclined optometrists

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"application of knowledge to decision making in optometric practice"

EVIDENCE BASED PRACTICE (EBP):

EBP involves

Acquisition and use of:

Information skills
Critical appraisal skills
Basic statistics knowledge and skills
Interpretation skills +

Clinical application of these skills.

EBP is becoming embedded in Competency Based Occupational Standards

In all health professions including medicine:

e.g. In ***Speech Pathology*** EBP is listed as the first principle of competent practice
"In all work contexts and decision-making, the speech pathologist must consider the recommended evidence base for the speech pathology practice."
Reference: Speech Pathology Australia. Competency Based Standards p.8, 2011.

How are EBP skills acquired?

The BOptom programme is designed to provide you with these skills by way of activities presented across the courses in the whole programme:

You are encouraged to review and be critical of the original sources of knowledge.
Some elements of EBP skills are being emphasised in this OPTOM 472 Vision Science 3 course (e.g. the statistics, the critical appraisal, and interpretation).
Courses with problem based learning require EBP skills
The final year research project is a major application of EBP skills.

Summary of what EBP is for the clinical professions

These summary statements from the University of Minnesota (http://hsl.lib.umn.edu/learn/ebp/) provide an excellent overview:

"Evidence-Based Practice (EBP) is a thoughtful integration of the best available evidence, coupled with clinical expertise. As such it enables health practitioners of all varieties to address healthcare questions with an evaluative and qualitative approach. EBP allows the practitioner to assess current and past research, clinical guidelines, and other information resources in order to identify relevant literature while differentiating between high-quality and low-quality findings.

The practice of Evidence-Based Practice includes five fundamental steps.

Step 1: Formulating a well-built question

Step 2: Identifying articles and other evidence-based resources that answer the question

Step 3: Critically appraising the evidence to assess its validity

Step 4: Applying the evidence

Step 5: Re-evaluating the application of evidence and areas for improvement."

Evidence based practice is important because:

The literature contains an ever increasing amount of information relevant to the practitioner

The number of researchers working and publishing in all areas of clinical practice is high and the knowledge and understanding of clinical areas is always improving.

It is essential that practitioners keep abreast of developments in their field to maintain patient safety.

Continuing Professional Development (CPD) is mandatory and the Optometrists and Dispensing Opticians Board requires evidence that you are undertaking regular CPD for the renewal of your annual practicing certificate.

Some CPD providers use speakers who bring an EBP approach to their presentations.

Evidence based review resources are often available. These resources synthesise and critically appraise the literature that is available in selected areas. They provide practitioners exposure to a greater variety of evidence.

There are still unanswered questions in relation to clinical care.

Resources for Evidence Based Practice are easy to use and you can search for answers to clinical questions.

Research findings are slow to become integrated into clinical practice.

It can take many years for recommendations to be adopted when an EBP is not part of practice.

e.g. visual acuity measurements still use non-logarithmic charts for some practitioners. In March I answered an enquiry from a graphic designer who wanted to produce a 2012 version of the 1950's British Standard chart.

EVIDENCE BASED PRACTICE MODEL from University of Minnesota

TO FIND THE EVIDENCE A CLINICIAN NEEDS TO FOLLOW FIVE STEPS

STEP 1 Formulate the question

In order to search the EBP resources you first need to decide what you are looking for

the **P**atients condition, disorder, disease

How would I describe a group of patients similar to this one patient

the **I**ntervention or Finding you want to know about

Define which intervention you are considering for this group of patients

a **C**omparison intervention or finding (if applicable)

the **O**utcomes you want to know about.

May be as simple as a comparison of cost effectiveness

May be a change in a physical sign, outcome of a diagnostic test, response to therapy

Apply PICO as a systematic way of identifying the important concepts in a case and formulating the search question.

STEP 2 Search the Databases / Resources

Categories of information resources:

General information resources

Provide background information

Useful for conditions that are outside your area of good knowledge

Will give you an overview that will help you formulate more specific questions.

e.g. Wikipedia

Filtered resources

Clinical specialists and subject specialists have posed questions and then undertaken the search to come to conclusions based on the resources they find.

You the searcher can look at the results of other people's searches.

You still need to evaluate the "filtered" results and also whether the actual question that is being answered is close enough to your question to have provided useful answers.

e.g. Cochrane database of systematic reviews,

e.g. PsycBITE – www.psycbite.com a project that rates the methodological quality of research papers dealing with Brain-Impairment treatments - includes the discipline of optometry.

It is possible that one day there will be a similar project dealing with aspects of vision.

Unfiltered resources

You will need to come to these if your question (or a similar one) has not already been the topic of a review.

You are going back to the primary literature yourself

e.g. Medline, PsycINFO, CINAHL, PubMed, Google Scholar, others.

Full text publications available free through the UoA library

STEP 3: Critically appraise the evidence to assess its validity

If the evidence is from a reviewing source that can be trusted (e.g. Cochrane Systematic reviews) then your task is to see whether the review actually answers the question you are asking

If the evidence is from a primary source then you need to check the strength and validity of the evidence yourself. The following can be a guide

Was the question addressed in the publication formulated well?

Were the methods designed to enable the question to be addressed appropriately

e.g. were the participants selected appropriately,

assigned to "treatment groups" appropriately

(e.g. randomly or with a balanced design)

Were the results and the statistical analyses valid

Were the conclusions supported by the results and analyses.

The research design can also guide you in appraising the evidence. A six-level hierarchy of research designs is often presented to assist the critical appraisal process. The best quality design is at the top of the list. Sometimes this list is presented as a pyramid because the best quality design (a systematic review) is also the most rare.

/ \

/ ***Systematic Reviews*** \

/ ***Randomised Controlled trials*** \

/ ***Cohort Studies*** \

/ ***Case-Control Studies*** \

/ *Case Series, Case reports* \

/ *Editorials, Expert Opinion* \

Evidence-based decisions for patient care should be based on the highest level research design available for the question that has been formulated. Case series and case reports is usually the minimum level of evidence required and most clinical questions require higher levels of evidence.

STEP 4: Apply the evidence

Once you are happy that the study is valid and is of sufficiently high quality, you need to decide how to apply the information obtained to the question you formulated in step 1. This may need some clinical experience to understand how well the study applies to your situation. You may be wise to consult colleagues to clarify your thinking.

STEP 5: Re-evaluate the application of evidence and look for areas for improvement

This is where you evaluate how well your decision (based on the evidence collected) applied to your individual patient. This evaluation could involve:

questions about how successful the treatment was if your decision was related to treatment
questions about whether the EBP process you used could be improved
even re-visiting the literature to see if any new information is available after the original search.

Take Home Message:

An optometrist who has Evidence Based Practice skills will be able to evaluate the new literature critically and will be able to apply valid research knowledge to clinical practice earlier.

Other sources of help on this topic

In addition to the modules on EBP at the University of Minnesota http://hsl.lib.umn.edu/learn/ebp/ other sources incluee:

University of Illinois at Chicago
http://gollum.lib.uic.edu/applied_health/node/3
and other modules in the left hand column. (last accessed May 2012)

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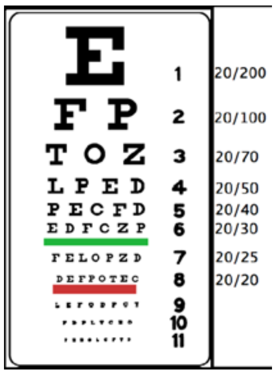
APPLICATION OF EVIDENCE BASED PRACTICE

Example of the development and adoption of Visual Acuity charts based on the "logMAR" principles

1. Review: Development of visual acuity charts.

The introduction to the document:
http://www.isd.mel.nist.gov/US&R_Robot_Standards/Visual_Acuity_Standards_1.pdf
gives a good concise history of how different visual acuity test charts were developed.

1862 Snellen chart used 9 letters; C. D, E, F, L, O, P, T, Z.
Snellen developed his own "font" there letters were on a grid 5x5 square and had very obvious serifs.



As you know the denominator is the distance from which the stroke with of the letter subtends 1' of arc (visual angle).

The progression of sizes is somewhat arbitrary and is not a geometric progression.

Since those times research into "contour interaction" and crowding has shown that the visibility of an object is influenced by neighbouring objects in a way that depends on the proximity of the neighbour.

You can see that in the Snellen chart the larger letters have smaller spacing to letters above and below. For a valid measure of visual acuity contour interaction needs to be controlled for.

Research in the 1950's showed that the visibility of characters on the chart was not uniform

1959 Louise Sloan (an ophthalmologist working in low vision) defined a variation in the "font" used for visual acuity chart optotypes – still on a 5x5 grid but without serifs. She selected 10 letters for use on her charts and proposed that all 10 letters should be presented with standard spacing on each row (or across two rows).

1976 Ian Bailey and Jan Lovie proposed a more manageable chart using non serif letters on a 5x4 grid. They chose the 10 letters from the 1953 British Standard for letter charts. They laid out the chart with controlled spacing between letters and between lines, and chose a logarithmic progression of sizes with an increment of 0.1 log minutes of arc between lines.

1979 ETDRS charts developed using the layout principles of the Bailey-Lovie chart but with Sloan letters. These charts used in research with scoring procedures that include letter by letter counting. Allow even minor changes in vision to be detected free of chart artefacts

1984 The GOLD standard design for VA charts was set when the International Council of Ophthalmology (ICO) prescribed the design requirements for modern visual acuity test charts
http://www.icoph.org/dynamic/attachments/resources/icovisualacuity1984.pdf

TODAY "logMAR" principles are widely adopted worldwide.

SUMMARY: Two reasons why the Snellen Chart and charts based on early standards such as the 1953 British standard are out-dated.

Reason 1

The spacing of letters on your chart design is quite wide when the letters are small (they are well spaced and as a consequence are easier to read). The letters are very crowded when the letters are large (this makes them harder to identify). This chart design provides a vastly different task to people with different levels of vision. The task is very much easier for people with good vision and much more difficult for people with poorer vision.

Reason 2

A person with good vision will be presented with many more letters than someone with poorer defocused vision.

This makes the statistical analysis of data gathered from this chart virtually impossible to undertake.

A person with poor vision gets only 2 or three chances to get the letters right, whereas a person with better vision gets many more chances. In any comparison of levels of vision, the number of letters presented must be taken into account and this is difficult when the number is variable.

For these two reasons it is recommended that any new chart that you design conforms to the principles in the 1984 ICO document.

In brief any new acuity chart design should have:

The same number of letters/symbols in each line

The same relative spacing (in terms of letter size on a row) between letters and between rows

A geometric progression of letter sizes

A size range that covers the range of visual performance expected from the target population.

As most young people can see very well, the minimum size of letter should be 3m when viewing is from 6m (or 1.5m when viewing is from 3m. Letter detail will subtend 30 seconds of arc at the eye (0.5 minutes of arc or 1/120 of a degree).

The largest size should be set by the poorest level of vision expected in the target population.

The letters used in the chart should be approximately equally legible. (There is debate in the literature about which letter set this is).

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<u>APPLICATION OF EVIDENCE BASED PRACTICE</u>

Example of Clinical Grading Scales / Grading Systems

1. Clinical data comes in different formats according to the measurement scale:

- Keeping track of what is happening in your practice
  e.g. how many low vision patients had each type of pathology
  THE TYPES OF PATHOLOGY SEEN ARE ON A **NOMINAL** SCALE
  THE FREQUENCIES OF EACH TYPE - ON AN **EQUAL INTERVAL** SCALE
  to analyse these kinds of data you need <u>non parametric</u> tests

- Grading the severity of a condition
  e.g. how severe is a colour vision defect on a scale Mild, Moderate, Strong, Severe.
  THIS SEVERITY DATA IS ON AN **ORDINAL** SCALE
  to analyse this kind of data you need <u>non parametric</u> tests

- Making quantitative measurements using a scale
  e.g. tear breakup time (measured in seconds)
  THIS IS DATA ON A **RATIO** SCALE
  to analyse this kind of data you can use <u>parametric</u> tests or the numbers can be manipulated so that non parametric statistics can be used. Non parametric tests are appropriate when the data is not normally distributed

<u>Reference</u> Engel T Psychophysics II Scaling Methods, *in* Kling JW and Riggs LA (ends) Woodworth and Schlosberg's Experimental Psychology. London, Methuen, 1971 Chap 3 pp 48-49

<u>REVIEW OF SCALES FOR DATA COLLECTION</u>

NOMINAL (or name) scale *(p48 Woodworth & Schlosberg)*

Data is presented with <u>names</u> on the X axis and another measure on the Y axis
e.g. number of myopes, emmetropes, & hyperopes in your practice

The X axis would have these three names on The Y axis would perhaps have the number of cases in each named category or the % of total cases in each named class.

You could transform this X axis scale by substituting
other equivalent names
e.g. shortsighted, "normal", longsighted
other symbols which maintained the differences between the three groups
e.g. A, B, C
e.g. Group 1, Group 2, or Group 3,
e.g 1, 2, 3.
BUT this last set of labels or names (1,2,3) must not be interpreted as being numbers in the usual sense of the word.. they are just symbols (or names) for the 3 groups.

ORDINAL (or order) SCALES *(p48 W & S)*

These arrange things in order of magnitude:

e.g. top place (1st) in the lab test
second place in the test
third place etc

NB this scale says nothing about the actual marks each person got.

This scale allows you to make comparisons of the following type:

greater than; … less than
better than; … worse than
harder than; … easier than
more comfortable: less comfortable than.

The scale used to present data obtained on an ordinal scale could be a rank order:

1, 2, 3, 4, 5, 6, etc using numbers
First, second, third, fourth, fifth etc using words.

Any transformation which preserves the order can be done
so we could use the numbers

3, 19, 49, 101, 110, 121, 122 As LABELS to represent the same order.

NB the order is preserved and
the ordinal scale says <u>nothing</u> about the magnitude differences between items on the scale.

In the grading of nuclear cataract for example

Grade 1 is less dense than grade 2 which is less dense than grade 3 etc.

Ordinal scales can be coarse

e.g Grades 0 to Grade 4 could include all severities of nuclear cataract

OR ordinal scales could be fine.

e.g. Grades 0 to 10 could encompass the severities of nuclear cataract

BUT no matter how fine, ordinal scales do <u>not</u> allow you to calculate amount of change.

INTERVAL SCALES (Equal interval scales)

These scales go one step further than ordinal scales as they allow <u>differences to be calculated</u> between items on the scale.

e.g. Temperatures 10 deg Celsius, 20 deg C, and 30 deg C are all 10 deg apart

But 20° C is not twice as hot as 10° C - even though it is warmer.
This is because 0° Celsius is not a true zero.. it is just the freezing point of water.
We would need to use the Kelvin scale to get a true zero and to get ratios to work (see next section).

Cataract could be graded on an equal interval scale if for example multiple photographic reference points that were equally spaced perceptually were to be added to the scale. This would allow graders to assign cataract severity on a continuous scale – and for change to be measured.

RATIO SCALES <u>(an interval scale with a true zero as a constant unit)</u>

e.g. IOP 6mm, 12mm, 18mm are all 6mm apart in pressure.

and as the zero is a true pressure, then 12 mm is twice the pressure of 6mm

CONSIDERATIONS INVOLVED IN SELECTING AN ORDINAL SCALE

Ordinal scales often used in clinical research

e.g. grading cleanliness of a contact lens
grading how comfortable a lens is
grading density of cataract
grading Anterior Chamber angle (usually 1 through 4)

Let us look more closely at grading cataract now

Why grade cataract? what is the purpose of grading:

to indicate severity
to be able to tell if there has been a change (deterioration) at a later date from ageing
or to be able to tell if there is an improvement perhaps because of a drug treatment.

(The grading of cataracts is a good example as there have been standardised scales established to grade selected features of cataracts as we will see later).

For the grading of nuclear cataracts FOUR standard photographs have been commonly used to provide four reference levels of severity.
Sometimes the four photos exist only as memories in the clinicians head.

The clinician observes the patient's crystalline lens with a standardised arrangement of the slit lamp biomicroscope. If the degree of nuclear opacification appears to be equal to or greater than that shown in the Grade 2 photograph BUT less than that shown in the Grade 3 photograph .. then Grade 2 is assigned.

Sometimes this is graded as 2+ to indicate the grade is less than 3 and more than or equal to 2.

It is a fact that subjective impressions are not always consistent.
For all systems used to grade a continuous variable there is a statistical probability that a second observation will result in a grade which is different from the first when in fact there has been no real difference in the conditions being compared.

Similarly there will be times when the assigned grades remain the same even though there has been a change in the condition being evaluated.

The clinician has to develop **confidence limits** to be applied when determining whether there is a difference between two readings.

In research, confidence limits are often set at 95% so that there is only a 5% chance that you will say the readings are the different when they are actually the same.
i.e. there is a low chance that you will say they are different when they are really not different.

THESE confidence limits depend on the clinician's ability to be consistent in the assignment of grades.
If the clinician is very consistent in assigning grades, then the range of grades between the upper and lower confidence limits for change will be small.

In describing consistency of grading, reference is often made to **CONCORDANCE** or **FREQUENCY OF PERFECT AGREEMENT** (or the KAPPA statistic).

Agreement (as to the assigned grade) could be between repeated measurements made by the one observer OR
Agreement could be between a single measurement made by each of two different observers.

A high level of agreement between two measurements has become seen to be important.
In studies comparing systems of grading cataract severity, a good system has been said to be one that allows HIGH CONCORDANCE.

It is seen as good when two people grading the same eye of the same patient agree. You might even agree with this statement.

Data-set to illustrate the above concepts - from Bailey et al in 1991

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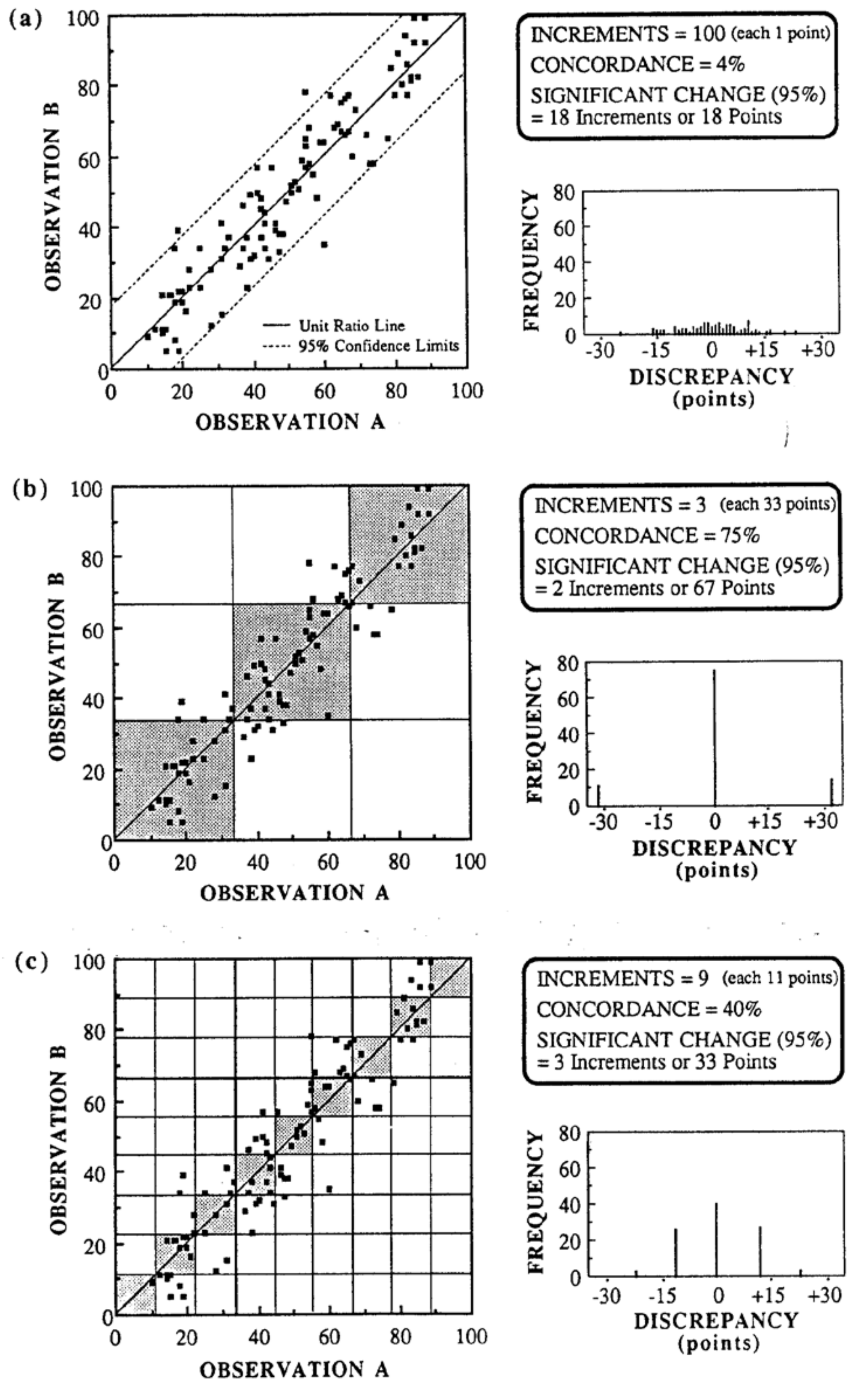


Fig. 1. (**a**) Scatter plot of 100 pairs of independent observations with scores assigned on a 100-point scale. The solid line at 45° is the locus for perfect agreement, and the parallel dotted lines are the 95% confidence limits assuming that the variance of discrepancies is uniform across the scale. The histogram to the right shows the distribution of the discrepancies (Discrepancy = Observation B − Observation A). (**b**) The effects of superimposition of a coarse three-step grading system on the original data set. Points that lie within the shaded areas would be assigned the same grade by both observation A and observation B. The histogram to the right shows the distribution of the discrepancies for this coarser scale. (**c**) The effects of superimposition of an intermediate nine-step grading system on the original data set. Points that lie within the shaded area would be assigned the same grade by both observation A and observation B. The histogram to the right shows the distribution of the discrepancies for this intermediate scale.

Figure 1 from: Bailey IL, Bullimore MA, Raasch TW, Taylor HR. Clinical grading and the effects of scaling. Investigative Ophthalmology and Visual Science 1991; 32: (2) 422-432.

We will look at a data set now that demonstrates some of these concepts:

These data (shown in fig 1 from Bailey et al 1991) have been generated by a Monte Carlo method (random number type method) but we can think of them as the results of grading cataract if we want to continue to think clinically.

A large number (thousands) of patients were rated using a scale of 1 to 100.
From all these patients, 100 patients were selected. These 100 were chosen so that their cataract densities ranged from 10 to 90. These 100 patients are the data set to be considered.

These patients were rated for cataract a second time using the same 1 - 100 scale.

The results are plotted as points with the X axis being the first grade (observation A) and the Y axis being the repeated measurement (observation B).

There is perfect agreement between the two measurements when the point falls on the straight diagonal line. (i.e. observation B = observation A)

> The box on the side of the figure 1a that has the distribution of Discrepancies shows that there were in fact 4 readings that were exactly the same.
>
> Look at the number at 0 on the X axis of the frequency / discrepancy graph and trace across to the number on the Y axis.

As you can see there were quite a few times when the repeat grades were <u>close</u> to the 1st ones.
either just a bit higher (above the line on the main plot or to the right on the discrepancy plot)
or
just a bit lower (below the line on the main plot or to the left on the discrepancy plot).

The standard deviation of the discrepancy distribution is +/- 8.7 points.

If we want to know how different a second reading would have to be from the first so that we are 95% certain that it was different to the first, we would use the standard deviation of this distribution of "discrepancies" or "differences b/w readings".

To obtain any 95% confidence intervals we need to multiply a SD by 1.96.
i.e. we would need to get a grade almost 2 SD's (actually 1.96) larger or 2 SD's smaller than the first reading to be 95% sure that the reading was not just different by chance.
i.e. 95% confidence interval = + / - 1.96 SD's

Now 1.96 x 8.7 is 17.1.

As we only have increments of size 1 (we don't have 0.1 on our scale), we would need a change of 18 units in our cataract grade to be sure of a change.

This change is required on <u>either</u> side of an original grading i.e. +/-18 for us to be 95% confident the second reading was different from the first.

Now LET US SEE WHAT WOULD HAVE HAPPENED IF WE ONLY HAD THREE GRADES TO ASSESS CATARACT DENSITY.

We can take the same data and rather than re-doing the grading we can divide the 100 step grading scale into just 3

0-33, 34-67, 68-100
Gr I Gr II Gr III

Now we can look at the concordance (agreement) we would achieve:
i.e. the Frequency of Perfect agreement.

This is shown by the shaded cells on the main graph on the left (earlier this was the points on the 45˚ line).
Now we find that, instead of only 4 points being in agreement, 75% of the time the grade is identical on the second observation.

BUT we need also to look at the data where there is <u>not</u> perfect agreement.

<u>First where the second rating was higher</u>

there are about 6 instances where when grade 1 was assigned on the 1st occasion, grade 2 was assigned on the second. [these are the points above the left-most shaded box in graph (b)]

There are about 8 instances where Gr 2 was assigned 1st and Gr 3 was the 2nd assigned grade
So the discrepancy of +1 interval occurred about 14 times in all
your lecturer will point these out

There were no instances where the second grade was higher by 2 steps (the top box on the left)

This is shown on the discrepancy graph by the bar over at +1

<u>Next where the second rating was lower</u>

There are about 11 points in total (6 in box where obs A = II and 5 in the box where observation A = III)

There were also no instances where the 2nd grade was lower by 2 steps (the bottom box on the right)

This is shown on the discrepancy graph by the bar over at -1

<u>**To apply 95% confidence limits to the measurement of change**</u> we go to the discrepancy graph (which you will remember in this case describes the discrepancies found due to chance only..) and find the number of scale increments which encompass 95% or more of the discrepancy distribution.

We then choose this number of scale interval as the number which must be exceeded for us to be 95% sure that the difference we find is not due to 5% chance.

An increment of 1 scale interval can be easily seen to cover <u>less</u> than 95% of the points so this cannot be the 95% confidence interval. Therefore we need to examine data for 2 scale intervals.

An increment of 2 scale intervals actually covers 100% of the points. As this is the next interval which covers 95% of the points or more it (2 scale intervals) must therefore be taken as the 95% confidence interval.

So when this coarse scale interval is used we need a change of 2 scale intervals to reliably detect change.

This could only happen if
    a grade I cataract became a grade III cataract
OR
    a Grade III cataract cleared to become a Grade I cataract.

WHAT IF WE WANTED TO MEASURE HOW MUCH A CLINICAL CONDITION (e.g cataract) HAD CHANGED?

We cannot use an Ordinal scale.

We need to use an Interval scale.

Interval scales for cataract or other clinical conditions can be created when
(i) multiple photographic reference points that are equally spaced perceptually are added to the scale.
(ii) graders are instructed to assign grades using a continuous scale e.g. if the grade looks like it is halfway between 5 and 6 but a little closer to 5, then a grade of 5.4 is assigned.

SUMMARY:

A coarse grading scale increases concordance (agreement between observations) but decreases sensitivity to change.

Take Home Messages:
an ordinal scale with finer intervals enables smaller changes to be proven significant.
an interval scale with fine intervals enables the degree of change to be measured.

AND

If you are using a fine scale, you need **not** to be worried when repeat assessments do not agree (even when it is you making the measurements on different occasions).

EXAMPLE of an Interval Scale for Cataract Assessment:

Classification of Cataract: an example of Clinical Grading System using an INTERVAL scale

The Lens Opacity Classification System III (Leo Chylack Jr et al)

1. Introduction / History

In research and clinical studies up until 1976 cataract was usually described only by traditional clinical terms including:

- the anatomical location of the opacities, (cortical, nuclear, posterior subcapsular etc)
- etiology (presumed cause) of the cataract (traumatic, steroid induced, radiation, age related etc)

Sometimes a grade from 1 to IV was added to indicate severity together with perhaps drawings to indicate extent etc.

In 1976 the National Eye Institute in the US funded the Cooperative Cataract Research Group (CCRG). This group looked at ways of classifying and grading cataract so that potential treatments of cataract (drugs, diet supplements etc.) could be evaluated, and so that lens appearance could be correlated with lens structure on an anatomical and biochemical level etc.

They developed a means of classifying whole lenses removed from the eye with the intracapsular technique. When the intracapsular technique fell into disuse the group looked at several of the *in vivo* methods of grading cataract by subjective appearance in comparison to sets of standard photographs.

2. Clinical Grading Scales

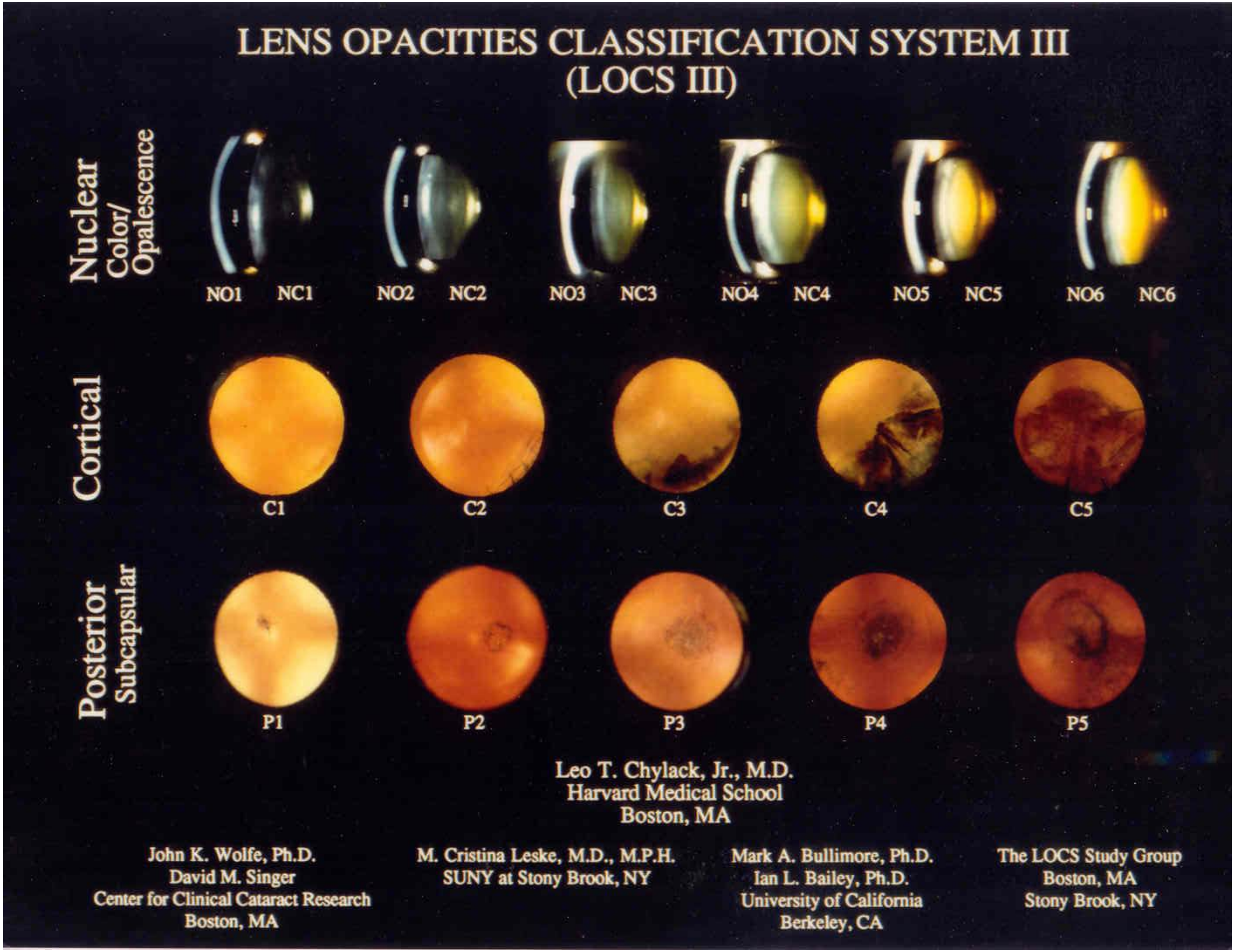
The initial Lens Opacity Classification System (LOCS) was a coarse scale and was thought to be good as practitioners using the scale were able to obtain good agreement between each other when they used the scale (good Concordance)

However the original LOCS did not have good ability to discriminate change.

The third version of the Lens Opacity Classification System (LOCSIII) has a finer scale and is what is used today in many places including the Univ of Auckland Optometry Clinic.

3. Exercise

Discuss how the LOCSIII grading scale for cataract balances the need for ability to discriminate fine changes in cataract with the need for practitioners to feel that the scale is easy to use and is reliable.


LENS OPACITIES CLASSIFICATION SYSTEM III
(LOCS III)
Nuclear
Color/
Opalescence
NO1 NC1
NO2 NC2
NO3 NC3
NO4 NC4
NO5 NC5
NO6 NC6
Cortical
C1
C2
C3
C4
C5
Posterior
Subcapsular
P1
P2
P3
P4
P5
Leo T. Chylack, Jr., M.D.
Harvard Medical School
Boston, MA
John K. Wolfe, Ph.D.
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The LOCS Study Group
Boston, MA
Stony Brook, NY

************NOT INCLUDED IN THE HARD COPY LECTURE HANDOUT*************

References

Leske MC. Chylack LT Jr. Wu SY. Schoenfeld E. He Q. Friend J. Wolfe J. Incidence and progression of nuclear opacities in the Longitudinal Study of Cataract. Ophthalmology. 103(5):705-12, 1996 May.
Abstract
PURPOSE: To estimate incidence and progression rates of nuclear opacities in the Longitudinal Study of Cataract, an epidemiologic study of the natural history of all types of lens opacities. METHODS: The Lens Opacities Classification System III was used to assess longitudinal changes between baseline and follow-up lens photographs for the 764 Longitudinal Study of Cataract participants. Baseline data, collected until December 1988 as part of a case-control study, included color slit, retroillumination, and Scheimpflug photographs. The same data were collected by the longitudinal Study of Cataract at four subsequent visits at yearly intervals. RESULTS: Among patients free of nuclear opacities at baseline, the incidence of new opacities was 6% after 2 years and 8% after 5 years of follow-up. The progression of pre-existing nuclear opacities was much higher. After 2 years, nuclear opacities had progressed in more than one third of the patients with pre-existing opacities; after 5 years, almost half had progressed. Older age was significantly related to higher incidence of new nuclear opacities, but not to progression of pre-existing opacities. Patients with other opacity types had higher nuclear incidence and progression rates. CONCLUSIONS: In this clinic-based, older-patient population, new nuclear opacities developed in less than one tenth of the patients after 5 years of follow-up. In contrast, almost one half of the patients with pre-existing opacities had worsened after 5 years. These estimated rates can be used to plan intervention or other studies of nuclear changes in similar populations.

Chylack LT Jr. Wolfe JK. Friend J. Tung W. Singer DM. Brown NP. Hurst MA. Kopcke W. Schalch W.
Validation of methods for the assessment of cataract progression in the Roche European-American Anticataract Trial (REACT) [see comments]. Ophthalmic Epidemiology. 2(2):59-75, 1995 Jun.
Abstract
The Roche European-American Anticataract Trial (REACT) will assess the effect of antioxidants on progression of cataract in humans. This report evaluates the methods used in REACT. Seventy three subjects (139 eyes) with cortical (C), posterior subcapsular (P), nuclear (N) or mixed cataract were seen twice within two weeks for eye examinations, assessments of visual function, lens photographs and CCD images. The degree of cataract and nuclear color (NC) were assessed with subjective (LOCS III) and objective (computerized, CASE 2000 CCD) methods. Repeat visit values were used to calculate intraclass correlation coefficients (r1) and 95% tolerance limits (TL). A clinically significant change (CSC) was defined as one step in LOCS III. The relative power of each method to detect cataract change and sample sizes needed to achieve statistically significant results were calculated. The r1 values for visual function tests ranged from 0.76 to 0.88; if these tests of visual function were used to detect a clinically significant change in cataract severity, sample sizes of 840 to 2707 per group would be needed. The r1 values for LOCS III were 0.88 to 0.97, and sample sizes ranged from 50 to 135 per group. The r1 values for the CCD were 0.93 to 0.98, and sample sizes ranged from 1 to 42 with poorer values relating to measurement of P. We conclude that the methods used in REACT are reproducible. The analytical algorithms in the image analysis programs did not permit differentiation between C and P opacification; therefore, P cataract is best measured with LOCS III. REACT sample sizes are adequate to detect a difference of 0.2 LOCS III units/year between the mean rates of cataract progression in two groups.
Registry Numbers 0 (Vitamins).

Chylack LT Jr. Wolfe JK. Friend J. Khu PM. Singer DM. McCarthy D. del Carmen J. Rosner B. Center for Clinical Cataract Research, Brigham and Women's Hospital, Boston, Massachusetts.
Quantitating cataract and nuclear brunescence, the Harvard and LOCS systems.
Optometry & Vision Science. 70(11):886-95, 1993 Nov.

Abstract

Subjective and objective systems are used to quantify cataract at The Center for Clinical Cataract Research. We have described each system and its use, presented data on reproducibility and validity, and for objective systems, demonstrated the correlation to the subjective grade of the cataract as defined by the Lens Opacities Classification Systems, Versions II and III (LOCS II and III). The subjective systems are used to classify nuclear color, nuclear opalescence, cortical cataract, and posterior subcapsular cataract. Reported kappa scores for LOCS II range from 0.85 to 1.0. Intraclass correlation coefficients for LOCS III (r1) range from 0.67 to 0.94. The computerized objective system are: (1) fast spectral scanning colorimetry (FSSC) for assessment of nuclear color (r1 = 0.96 to 0.98); (2) nuclear mean density (NMD) for assessment of nuclear opalescence (r1 = 0.97); and (3) percent area opacity (anterior = a; posterior = p) (OPAC-a and OPAC-p) for assessment of cortical and posterior subcapsular cataract (r1 = 0.92 to 0.96).

Karbassi M. Magnante PC. Wolfe JK. Chylack LT Jr.
Center for Ophthalmic Research, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts.
Objective line spread function measurements, Snellen acuity, and LOCS II classification in patients with cataract.
Optometry & Vision Science. 70(11):956-62, 1993 Nov.

Abstract

We tested an instrument to measure the line spread function (LSF) of the eye in order to assess objectively retinal image degradation due to cataract. Optical aberrations from 62 eyes with early to moderate cataract were assessed by measuring the extent of blurring of a best-focused fine line image (LSF) projected onto a subject's retina. The instrument consisted of a slitlamp equipped with a Hruby lens to project the line and a computer-coupled CCD camera to record and measure the blurred image. We hypothesized that the width of the blurred line image (called WSCAT) due to light scattering in the cataractous lens would be affected most by nuclear and subcapsular cataracts. The WSCAT results were compared to the data from two other tests: (1) Snellen acuity and (2) LOCS II cataract classification. Grouping eyes by Snellen acuity we found that WSCAT from the group with 6/4.5 (20/15) or 6/6 (20/20) acuity was distinguishable from the group with 6/9 (20/30) or worse acuity (95% confidence interval). Data also were analyzed using a regression model which corrects for the intraclass correlation between the two eyes of an individual. Results show a significant association between WSCAT and minimum angular resolution (MAR) derived from Snellen visual acuity (regression coefficient of 5.45, p = 0.008). WSCAT also is correlated with both LOCS II nuclear opalescence (NO) and posterior subcapsular (P) categories with regression coefficients of 3.03 (p = 0.004) and 2.07 (p = 0.054), respectively. Results from measurement of LSF indicate the potential for this instrument to assess retinal image degradation associated with nuclear and posterior subcapsular cataract objectively.

Karbassi M. Khu PM. Singer DM. Chylack LT Jr.
Institution
Center for Ophthalmic Research, Brigham and Women's Hospital, Boston, Massachusetts.
Evaluation of lens opacities classification system III applied at the slitlamp.
Optometry & Vision Science. 70(11):923-8, 1993 Nov.
Abstract
The Lens Opacities Classification Systems (LOCS III) was developed and standardized using photograding. The purpose of this study was to assess the validity of LOCS III at the slitlamp and to compare slitlamp with photograding. To do so, two independent observers graded cataract at the slitlamp and in photographs from two sets of patients; the first set consisted of 205 eyes (193 acceptable photographs) and the second set of 51 eyes (51 photographs). The 95% tolerance limits (TL) for grading at the slitlamp ranged from 0.9 to 1.8 for the first set and 0.6 to 1.2 for the second (intraclass correlation coefficients 0.79 to 0.91 vs. 0.70 to 0.97, respectively). Specifically, there was a significant decrease in 95% TL for cortical and nuclear color. For the first set of photograding, the 95% TL were 0.3 to 0.6 between the two observers and 0.6 to 0.8 for the same observer at two different sessions. Similar results were found for photograding the second set. The 95% TL for comparing slitlamp and photograding were generally > 1.0. The results suggest that (1) LOCS III at the slitlamp has 95% TL only slightly worse than those for LOCS III photogradings; (2) LOCS III slitlamp grading for cortical and nuclear color improves with practice; and (3) the slitlamp and photographic gradings cannot be used interchangeably.

Chylack LT Jr. Wolfe JK. Singer DM. Leske MC. Bullimore MA. Bailey IL. Friend J. McCarthy D. Wu SY.
Center for Clinical Cataract Research, Brigham and Women's Hospital, Boston, Mass. 02115.
The Lens Opacities Classification System III. The Longitudinal Study of Cataract Study Group.
Archives of Ophthalmology. 111(6):831-6, 1993 Jun.
Abstract
OBJECTIVE--To develop the Lens Opacities Classification System III (LOCS III) to overcome the limitations inherent in lens classification using LOCS II. These limitations include unequal intervals between standards, only one standard for color grading, use of integer grading, and wide 95% tolerance limits. DESIGN AND RESULTS--The LOCS III contains an expanded set of standards that were selected from the Longitudinal Study of Cataract slide library at the Center for Clinical Cataract Research, Boston, Mass. It consists of six slit-lamp images for grading nuclear color (NC) and nuclear opalescence (NO), five retroillumination images for grading cortical cataract (C), and five retroillumination images for grading posterior subcapsular (P) cataract. Cataract severity is graded on a decimal scale, and the standards have regularly spaced intervals on a decimal scale. The 95% tolerance limits are reduced from 2.0 for each class with LOCS II to 0.7 for nuclear opalescence, 0.7 for nuclear color, 0.5 for cortical cataract, and 1.0 for posterior subcapsular cataract with the LOCS III, with excellent interobserver agreement. CONCLUSION--The LOCS III is an improved LOCS system for grading slit-lamp and retroillumination images of age-related cataract.

Wolfe JK. Chylack LT Jr.
Brigham and Women's Hospital, Massachusetts Eye and Ear Infirmary, Department of Ophthalmology, Harvard Medical School, Boston.
Objective measurement of cortical and subcapsular opacification in retroillumination photographs.
Ophthalmic Research. 22 Suppl 1:62-7, 1990.
Abstract
An image analysis system has been developed for the objective analysis of cortical opacification. Lens photographs are obtained using a Neitz CTR retroillumination camera. The images are digitized using an IBM-PC-based imaging system. We have developed a program, called OPAC, through which the computer analyzes the image using a circular grid consisting of 93 sectors. The program outputs the percent of lens area which is opaque. Ninety-eight photographs, previously

classified by the Lens Opacities Classification System (LOCS II), were analyzed using OPAC as well as a manual, square-grid counting system (GRID). The results show a linear correlation between OPAC and GRID with a correlation coefficient of 0.94. The results obtained with OPAC are also linearly correlated with the LOCS II classifications.

Chylack LT Jr. Leske MC. McCarthy D. Khu P. Kashiwagi T. Sperduto R.
Center for Clinical Cataract Research, Harvard Medical School, Boston, MA 02114.
Lens opacities classification system II (LOCS II) [see comments].
Archives of Ophthalmology. 107(7):991-7, 1989 Jul.

Abstract

The Lens Opacities Classification System, version II (LOCS II), uses a set of colored slit-lamp and retroillumination transparencies to grade different degrees of nuclear, cortical, and subcapsular cataract. The system uses four nuclear standards for grading nuclear opalescence and color, five cortical standards, and four subcapsular standards. The LOCS II can be used to grade patients' cataracts at the slit lamp or to grade slit-lamp and retroillumination photographs; it is easy to learn and can be applied consistently by different observers. We obtained very good interobserver reproducibility of the clinical gradings at the slit lamp, excellent intraobserver reproducibility, very good to excellent interobserver reproducibility of photographic gradings, and good agreement between clinical and photographic gradings. The LOCS II is potentially useful for both cross-sectional and longitudinal studies of cataract.

Getty DJ. Pickett RM. Chylack LT Jr. McCarthy DF. Huggins AW. BBN System and Technologies Corporation, Cambridge, MA 02138.
An enriched set of features of nuclear cataract identified by multidimensional scaling.
Current Eye Research. 8(1):1-8, 1989 Jan.

Abstract

Development of an improved system for visual classification of cataracts requires a three-step procedure: first, to identify the full range of visible features of cataracts; second, to develop and test scales for the visual assessment of each feature; and third, to establish the epidemiological or clinical validity of each scale for cataract classification. This paper focuses on the first step, applying a powerful psychometric technique for identifying the visible features of nuclear cataracts. New visual features of nuclear cataract were identified using the psychometric procedure of multidimensional scaling (MDS). Each of 5 observers independently examined pairings of slitlamp photographs of 24 cases of pure nuclear cataract, making two different ratings of dissimilarity of each of the 276 possible pairs. The two dissimilarity ratings were, first, of nuclear color and, second, of nuclear structure. MDS analysis of the dissimilarity ratings of nuclear color revealed two major visual features underlying the judgments: one a combination of hue and saturation, and the other brightness. Analysis of the ratings of nuclear structure identified a total of nine features: one distinguishing between immature and mature cataracts, four describing features of the immature cataracts (aspect ratio, background haze, clarity of the embryonal nucleus, and clarity of the outer nuclear shell), and four describing features of the mature cataracts (opalescence, aspect ratio, color of the nucleus, and symmetry). We conclude that there are many more systematic distinctions to be made in the appearance of nuclear cataracts than are now recognized in clinical practice.

Chylack LT Jr. Leske MC. Khu P. McCarthy D. Wu SY.
Center for Clinical Cataract Research, Brigham and Women's Hospital.
Strategies for measuring the rate of age-related cataract formation in vivo.
Lens & Eye Toxicity Research. 6(4):515-22, 1989.
Abstract
The Lens Opacities Classification System (LOCS II) has been tested as a method for detecting and grading longitudinal changes in cataract severity. The LOCS I and II systems have already been tested and validated for cross-sectional classification of human cataracts in vivo. 130 eyes (of 68 patients) were photographed at baseline and follow-up visits with Neitz CTR and Zeiss slit photography. The mean length of follow-up was 14.7 +/- 4.4 months. The severity of nuclear opalescence (NO), cortical (C) and posterior subcapsular cataract (P) was graded in a masked fashion using the LOCS II standards. Side-by-side comparisons of baseline and follow-up photos were also done in a masked fashion to detect more subtle changes than might be evident in the LOCS II gradings. The annual percent progression in cataracts graded by LOCS II standards are: (NO): 12.4%, (C): 17.9%, and (P): 6.5%. The LOCS II standards are offered as a promising subjective method for longitudinal grading of human cataractous change in vivo.

Chylack LT Jr. Rosner B. White O. Tung WH. Sher LD.
Center for Clinical Cataract Research, Harvard Medical School, Boston, MA.
Standardization and analysis of digitized photographic data in the longitudinal documentation of cataractous growth.
Current Eye Research. 7(3):223-35, 1988 Mar.
Abstract
Age-related cataract formation in man can be documented with slit and retroillumination photographs. With digitization and image analysis of such photographs a cataract may be characterized by a frequency distribution of picture elements over a 255 step gray scale spectrum. Transition from a clear to a cataractous lens may be manifested as a change from a unimodal, Gaussian to a multimodal, non Gaussian frequency distribution respectively. How should one compare and contrast these two distributions, so to accurately describe the extent and significance of a change in lens opacification? The in vitro system of cold cataract formation in the rabbit lens was used as a model of the much slower process of age-related cataract formation in man. As in the human lens undergoing progressive opacification, the frequency distribution (number of pixels vs. intensity of gray) for a digitized image of a clear lens at 26 degrees C is unimodal and Gaussian; that of a fully developed cold cataract at 10 degrees C is multimodal and non-gaussian. In spite of the increasing multimodality of the frequency distribution as the temperature dropped and the cataract grew in density and size, the mean gray density proved to be a valid and useful measure to characterize the distribution and to compare different unaligned images. The Wilcoxon Rank Sum Test proved to be useless in comparing the frequency distributions from cataract images because it proved to be too sensitive to subtle changes in the degree of opacification. Anomalous behavior of the opacification process--i.e. clarification as well as opacification of the lens during cold cataract formation caused all pairs to appear statistically significantly different when in appearance there was no difference. The mean of the frequency distribution is less sensitive to this anomalous behavior and is useful as a comparative index. The method of calculating the threshold of significant change in the mean density of a cataract image is presented.

Chylack LT Jr. Leske MC. Sperduto R. Khu P. McCarthy D.
Brigham and Women's Hospital, Boston, MA.
Lens Opacities Classification System.
Archives of Ophthalmology. 106(3):330-4, 1988 Mar.
Abstract
The Lens Opacities Classification System (LOCS) is a simple system for classifying age-related human lens opacities at the slit lamp or in retroilluminated and slit-lamp photographs. The system employs a set of standard Neitz CTR retroilluminated black-and-white photographs for classification of cortical and posterior subcapsular cataracts and a single color slit-lamp photograph for classification of nuclear color and opalescence. We present a detailed description of the system.

Leske MC. Chylack LT Jr. Sperduto R. Khu P. Wu SY. McCarthy D.
Department of Community and Preventive Medicine, State University of New York at Stony Brook 11794-8036.
Title
Evaluation of a Lens Opacities Classification System.
Archives of Ophthalmology. 106(3):327-9, 1988 Mar.
Abstract
A simple system, based on standard photographs, has been developed to classify lens opacities. The system allows the definition of cataract cases and noncases according to the location of lens opacification (nuclear, cortical, posterior subcapsular) and its extent (early or more advanced). Evaluation of the system has shown good to excellent reproducibility for clinical and photographic classifications. Comparisons of clinical and photograph-derived gradings has shown generally good agreement in classifying the presence and type of cataract; this agreement is highest for nuclear cataract. Photographic gradings of posterior subcapsular and, to a lesser degree, cortical opacities tend to underestimate the extent of opacification found by clinical gradings. The Lens Opacities Case-Control Study system is simple, reproducible, and easy to implement; it is offered for use in case-control and other cross-sectional studies of cataract with compatible classification goals.

Chylack LT Jr. Rosner B. Cheng HM. McCarthy D. Pennett M. Brigham & Women's Hospital, Boston, MA.
Sources of variance in the objective documentation of human cataractous change with Topcon SL-45 and Neitz-CTR retroillumination photography and computerized image analysis.
Current Eye Research. 6(12):1381-90, 1987 Dec.
Abstract
In the application of Topcon SL-45 Scheimpflug slit and Neitz CTR retroillumination photography to in vivo documentation of cataractous change, several sources of variance affect the results of each technique. We have measured the between-person, between-photographer, between-focal plane (Neitz), between-photo session, replicate photograph (Topcon), between-image analyst and replicate image analysis variances encountered in in-vivo documentation of human cataracts with the Topcon SL-45 and Neitz-CTR cameras and our system of computerized image analysis.

Leske MC. Chylack LT Jr. Sperduto R. Pennett M. McCarthy D.
State University of New York at Stony Brook.
Progress toward developing a cataract classification system.
Developments in Ophthalmology. 15:9-15, 1987.
Abstract
A cataract classification system is being developed based on a set of standard photographs. The system uses an ordinal scale ranging from 0 (no opacities) to 2 (definite opacities) to classify cataractous changes in the nuclear, cortical, and posterior subcapsular lens zones. The reproducibility of slitlamp-derived and photo-derived classifications using the system was evaluated. The reproducibility between 2 observers for slitlamp-derived classifications was very

high (n = 60). The reproducibility within and among 4 photography readers was also good for photo-derived classifications (n = 100). Discrepancies were found between ratings derived from slitlamp examinations and from photographs; such discrepancies were most frequent for gradings of cortical opacities.

Chylack LT Jr. Rosner B. Garner W. Giblin F. Waldron W. Wolfe J. Leske MC. White O.
Validity and reproducibility of the Cooperative Cataract Research Group
(CCRG) cataract classification system.
Experimental Eye Research. 40(1):135-47, 1985 Jan.

Abstract

The validity and reproducibility with which six classifiers [one experienced (L.T.C.), and five novices (W.G., F.G., W.W., J.W. and O.W.)] used the CCRG cataract classification system was assessed. The validity of index classifications was assessed by computing sensitivities and pairwise interclass correlations between experienced and novice classifiers using the former's classification as the standard. The number of unordered combinations of terms in the CCRG's classification was reduced by combining cortical terms according to the CCRG's accepted system of staged simplification. The number of combinations of terms at each stage is as follows: Stage I (greater than 1000); II (127); III (63); IV (15); V (7); VI and VII (3) and VIII (2). Excellent agreement was obtained between the experienced and novice classifiers for Stages VII and VIII of the classification, good agreement for Stages V and VI and poor agreement for Stages IV, III and II (sensitivities of 97, 96, 72, 59, 40, 24 and 20% respectively). Good agreement was also achieved for the classifications of single lenticular regions, except for subcapsular regions. The intra- and interobserver reproducibility was assessed by computing the Kappa statistic to (1) compare classifications between novice observers and (2) compare repeat classifications made by the same observer by viewing the same cataract once on each of three different days. The novice classifiers had excellent intraobserver reproducibility for Stages VII and VIII (Kappas of 0.87 and 0.97 respectively), good reproducibility for Stages IV, V and VI (Kappas of 0.53, 0.62 and 0.62, respectively) and marginal reproducibility for stages II and III (Kappas of 0.39 and 0.40, respectively). The intraobserver reproducibility of the experienced classifier was superior to the others for virtually all characteristics with excellent reproducibility for Stages IV, V, VI, VII and VIII with Kappas of 0.79, 0.90, 1.0, 1.0 and 1.0, respectively and good reproducibility for Stages II and III (Kappas of 0.55 and 0.64, respectively). These results indicate that the simplified CCRG cataract classification system (Stages IV-VIII) passes the minimum standards for reproducibility. The performance of the experienced classifier far exceeds the minimum standards and indicates the feasibility of improving classifier performance with training and practice.

Chylack LT Jr. Ransil BJ. White O.
Classification of human senile cataractous change by the American Cooperative Cataract Research Group (CCRG) method: III. The association of nuclear color (sclerosis) with extent of cataract formation, age, and visual acuity.
Investigative Ophthalmology & Visual Science. 25(2):174-80, 1984 Feb.

Abstract

Nineteen hundred and seventy-six immature human cataracts extracted intracapsularly were classified according to the Cooperative Cataract Research Group (CCRG) method of cataract classification. Data on cataract location and extent, nuclear color, preoperative visual acuity, age, and sex were organized and stored in the PROPHET system. The data were examined for relationships between nuclear color (sclerosis) and the age of the cataractous lens, the extent of opacification in seven anatomical regions including the degree of nuclear opacification and the preoperative visual acuity. Nuclear color correlates with age in a curvilinear manner. Nuclear yellowing increases gradually with increasing nuclear opacification, but the color change is so slight as to be useless for the purposes of inferring the intensity of nuclear opacification from the color of the nucleus. There is no association between the extent of anterior cortical, equatorial cortical, posterior cortical, subcapsular or supranuclear opacification, and nuclear color. Nuclear color impairs vision only for the range dark yellow through black. These data justify the recommendation that nuclear color be abandoned as the single index of the severity of any type of senile cataractous change.

Chylack LT Jr. White O. Tung WH.
Classification of human senile cataractous change by the American Cooperative Cataract Research Group (CCRG) method: II. Staged simplification of cataract classification.
Investigative Ophthalmology & Visual Science. 25(2):166-73, 1984 Feb.
Abstract
One thousand nine hundred and seventy-six cataracts extracted intracapsularly were classified according to the system adopted by the Cooperative Cataract Research Group (CCRG) Consortium. A nine-stage protocol for simplifying the classification data is presented. The method of simplifying the basic CCRG classification emphasizes anatomic similarities among lenses. Simplification is indicated when small numbers of cataracts in any class provide insufficient statistical power to allow detection of scientifically or clinically important differences in rates between comparison groups, if such differences exist; however, simplification unavoidably obscures the anatomic, biochemical, and biophysical features of individual cataracts. Age-specific characteristics of this population of 1976 cataracts are used to demonstrate the effects of the simplification process. The preponderance of mixed cataracts and the relative scarcity of pure cataracts are documented, and the implications of these numbers for cataract research are presented.

Chylack LT Jr. Lee MR. Tung WH. Cheng HM.
Classification of human senile cataractous changes by the American Cooperative Cataract Research Group (CCRG) method. I. Instrumentation and technique.
Investigative Ophthalmology & Visual Science. 24(4):424-31, 1983 Apr.
Abstract
The American Cooperative Cataract Research Group (CCRG) has adopted a system of classifying human cataractous changes that is based on separate and independent photographic documentation of opacification and nuclear color. This system has been extremely useful to the laboratory scientist who wishes to know the significance of associations between laboratory data and the extent or type of cataractous change. It has been applied to the analysis of nearly 2500 cataracts since 1976. This study presents the details of the instrumentation and technique of this new system and the results of classifying 2231 intracapsularly-extracted cataracts.

Bettelheim FA. Siew EL. Chylack LT Jr.
Studies on human cataracts. III. Structural elements in nuclear cataracts and their contribution to the turbidity. Investigative Ophthalmology & Visual Science. 20(3):348-54, 1981 Mar.
Abstract
Gross correlation coefficient between light-scattering intensity and the optical parameters obtained for 48 sections of eight lenses with nuclear cataracts were evaluated. On the basis of these and other data in the literature, the structural elements, within the lens fiber are identified. These give rise to the optical parameters. It is proposed that three processes contribute to nuclear cataractogenesis: (1) syneretic process, (2) increase in the concentration but not in the size of protein aggregates, and (3) association (entanglement) between aggregates and optically anisotropic cytoskeleton or membrane components that leads to a decrease in structural bi-refringence.

Siew EL. Bettelheim FA. Chylack LT Jr. Tung WH.
Studies on human cataracts. II. Correlation between the clinical description and the light-scattering parameters of human cataracts.
Investigative Ophthalmology & Visual Science. 20(3):334-47, 1981 Mar.

Abstract

Eight lenses with nuclear cataracts have been classified. The light-scattering properties of the eight lenses were obtained with thin sections cut perpendicularly to the posterior-anterior axis. Analysis of the light scattering envelop in the I and I+ models yielded eight structural parameters that describe the density and orientation fluctuations. The variation of these parameters within each less corresponded well to the clinical description obtained from the stereoscopic photos.

Chylack LT Jr.
Classification of human cataracts.
Archives of Ophthalmology. 96(5):888-92, 1978 May.

Abstract

A stereoscopic system of lens photography was developed and was applied in the classification of different forms of cataract. Lenses, after surgical extraction, can be classified by a technician, independent of ophthalmological collaboration. This system meets the needs of the laboratory scientist and has been adopted by the Cooperative Cataract Research Group.

Chylack LT Jr. Kinoshita JH.
The Cooperative Cataract Research Group [editorial].
Investigative Ophthalmology & Visual Science. 17(12):1131-4, 1978 Dec.

DEPARTMENT OF OPTOMETRY AND VISION SCIENCE
OPTOM 472 Vision Science 3

"application of knowledge to decision making in optometric practice"

RESEARCH TO PROVIDE EVIDENCE FOR PRACTICE

Example of the Creation of Clinical Grading Scales for use with prosthetic eye wearers

1. The Problem:

Creating the evidence base to underpin examination techniques that have arisen only from "Clinical Experience".

Realising that the evidence found may
- support current practice
- develop current practice
- change current practice to some extent.

2. The Approach:

Development of measuring techniques for clinical parameters that are currently assessed only by "professional judgment".

3. Example: Development of a scale for measuring the socket response to the presence of a prosthesis

See File: Pine et al Measuring tools for artificial eye research proof.pdf
In Press with Clinical and Experimental Optometry

Take Home Message:
A practitioner who has Evidence Based Practice skills will be able to add to the new literature.

Aim: To generate useful clinical grading scales – using a critical understanding of the mathematics of scales.

PROCESS

Assembling clinical photographs of a large number of prosthetic eye wearers

Summer Student project
- Background work on creating scales
  - Print all the photos
  - Assemble and examine them
  - Work out what aspects are important in grading
    - Conjunctival inflammation
  - Ask practitioners what information they use with real patients
  - Ask practitioners what information could be used from just photographs
- Use the information provided to create some possible scales
  - Redness
  - Roughness
  - Amount and characteristics of mucous / discharge present
- Select the least severe on each of the three parameters
- Select the most severe on each parameter
- Find a photograph that represents perceptually the middle severity between least and most
- Find photographs that divide the scale into halves again using appearance
- Continue until you have a scale that is likely to be of clinical use
  - Two interval (3 photo)
  - Four interval (5 photo)
  - Eight interval (9 photo)
  - Other
- Test the scale that is constructed
  - Ask people to create an equal perceptual interval scale in their head between most and least severe
  - Ask people to put photos onto a ruler at a position that reflects how severe the attribute being assessed is (between least and most severe).
  - Re- select photos so that the scale is most closely uniform to the most people

- Use of the final scales by different people to assess how repeatable the judgments are
  - Then work out from the variability of measurements the amount of change that is clinically important

end

DEPARTMENT OF OPTOMETRY AND VISION SCIENCE
OPTOM 472 Vision Science 3

"application of knowledge to decision making in optometric practice"

APPLICATION OF EVIDENCE BASED PRACTICE

Example of the critical evaluation of the van Herick technique for assessing the open-ness of anterior chamber angles.

1. The Problem:

The van Herick technique has been in use for several decades.

The methods of taking measurements have bee subject to "interpretation" over years of clinical practice.

A critical reading of the original research papers describing the technique show that the original methods are NOT the same as those being taught and used today.

Realising that the evidence found may
support original practice
support the methods that have developed through clinical useage
result in a need to change current practice or current teaching.

2. The Approach:

Determine which parts of the method are "theoretically" likely to be most critical to accuracy of results.
Run a series of experiments where the effects of varying parts of the method systematically is investigated
Undertake theoretical modelling to examine whether the results found are supportable by a relatively simple optical model
Publish the results

See
2012 LEUNG M, KANG S, TURUWHENUA J, JACOBS RJ. Effects of illumination and observation angle on the van Herick procedure. Clinical and Experimental Optometry 95(1): 72-77. doi: 10.1111/j.1444-0938.2011.00646.x (first published online 13 Oct 2011).
Available electronically from the Philson library - e-journals

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Take Home Message:
A practitioner who has Evidence Based Practice skills will be able to contribute a critical analysis of methods that have been well established.

Approach

Consider parameters likely to influence measurements
- How close to the limbus
- Magnification
- Beam width
- Where the beam is focused (anterior cornea thru anterior iris)
- Whether a standard set-up would provide a constant angle of illumination on the cornea
- How variable is the inclination of the cornea at the limbus
  - If it is variable, then this will affect the angle of illumination onto the cornea.
- Angle of illumination onto the cornea
- Angle of observation of the result
- The judgment of the person undertaking the measurements

Consider how to control all the variables that are of less interest
- Note if the variables cannot be controlled they need to be randomised

Then systematically vary the parameters to be investigated

Report of the work of the Part V students undertook in 2010 and which has appeared electronically in 2011 and in print in 2012.