BIOS506 Project Instructions

1. The project involves an analysis of data from the Prospective Evaluation of Radial Keratotomy (PERK) study, a nine-center clinical trial evaluating a standardized procedure of radial keratotomy, a surgical treatment for myopia (near-sightedness). A description of the study and the variables you are to analyze is provided below. The specific questions you are asked to address with your analyses are given after the study description (See Questions 1-3 below).

2. The reason for the project is for you to think about the material discussed this semester in a more real world situation. The techniques are usually discussed in class in a very focused context. The project provides an example of how you will have to figure out the appropriate analyses for a set of data and how to present the results.

3. The project is due at **12pm on December 12, 2017**, but can be turned in earlier. Please submit a hard copy of your report. Put your names and group number on the title page only. After the class on comparing two binomial proportions, we will have covered everything you need to do the project.

4. You are to turn in a report that you should consider as similar to a journal article. The report should be typewritten, double spaced, with 1 inch margins, font no smaller than Arial 12 pt, and no longer than 8 pages excluding tables and graphs. Put the tables and graphs after the text. Do not merge the tables and graphs into the text. You can include as many tables and graphs as you wish as long as they are properly labeled (include a number and title on the table or graph) and are referred to by this number in the text.

5. The form of report should be as follows:

Title Page. Include a title page for your report. Put your names and group number on this page only.

Introduction. Describe myopia (nearsightedness) and give a brief background for the study. Describe the purpose of the report. This can be done in terms of the primary questions to be explored and presented in the report (See Questions 1-3 below).

Methods. Describe the study design, the inclusion and exclusion criteria, the surgical technique and refraction. For each question to be explored (See Questions 1-3 below), give your analysis strategy; that is, tell which statistical techniques were used (mentioning the parameters that are tested) and which variables from the study they were applied to. It is not necessary to include the mathematical details. Provide the assumptions for the statistical tests. Include a comment about the alpha level or p-value to indicate statistical significance. For confidence intervals, give a one-sentence description. Do not put any data summaries in the Methods section. Save those for the Results section.

Results. Give summary statistics for the patient characteristics (age, gender, etc.) including the numbers of patients (These results could be summarized in a table.). Give the overall results (that is, for all patients) for the outcome measures (see Question 1 below). Give appropriate summary statistics, confidence intervals and graphs. When describing whether any of the patient characteristics has an effect on the outcome measures (See Questions 2 and 3 below), you only need to consider the effect of one patient characteristic at a time (Next semester you will learn about multivariable methods.).

For each analysis, include the appropriate summary statistics in the text or in tables and include graphs that you think are relevant for describing the results. Label the tables and figures (graphs) with a number (Table 1, Table2, etc.; Figure 1, Figure 2, etc) and a title. Include references to the tables and figures in the text. Do not include any tables or figures that you do not reference in the text.

Exactly how the Results section gets packaged (ie, what to put in the text, what to put in tables, what to put in graphs, what to exclude) is something of an art form. See the attached article "*Guidelines for statistical reporting in articles for medical journals*". That article discusses these issues. For example, how to construct a table and what the accompanying text would look like. The presentation should be clear and logical. Within each of the major sections (Methods, Results, etc.) it can be helpful to make subsections with their own subheadings. Material should not be duplicated in the different locations. Statements should be demonstrated with the appropriate descriptive statistics (means/standard deviations or percentages); don't just report a p-value and make a statement without providing the relevant statistical summaries.

The writing should also be clear. Simpler is better. If you have described your statistical methods adequately there is no need to write repeatedly in the text "the p-value was less than .05 and so the null hypothesis can be rejected...". For example, you could write "the mean change in refraction was significantly different for men and women (men: xxx, women: yyy, p = .001)". Be specific - if you are comparing means, say so.

Do not write sentences such as: "Baseline variables are shown in Table 1." Instead, write a descriptive or interpretative comment and refer to Table 1 parenthetically. Such as "Among the 952 patients, 376 (39%) were male and the mean age was 57 years (Table 1). Table 1 should contain the number and percentages of males and females and the summary statistics for age (at least mean and standard deviation).

Discussion. Give a summary of the main results to answer the questions asked at the beginning of the study but don't repeat everything you said in the Results section. In general, the Discussion does not introduce new data summaries that were not presented in the Results section. Mention any problems you encountered such as assumptions of the methods used that were not met and how you handled the problems.

7. Do not submit unlabeled SAS output. You can submit portions of SAS output if they are labeled as either tables or figures as described above and they are discussed and referenced in the text of the report. Include SAS output only if it has been labeled and discussed in your report.

8. You do not have to use linear regression to analyze this data. Linear regression is the last topic we will cover in this class. You will have more practice next semester analyzing data with linear regression.

9. One of the patient characteristics, diameter of the central clear zone, has 3 categories. Most of the statistical methods we discuss in this class that deal with categorical variables handle variables with only 2 categories. For the project it will be acceptable to apply these methods to each pair of categories (You will learn methods for handling more than 2 categories in later classes).

PERK Study Description

The Prospective Evaluation of Radial Keratotomy (PERK) study was a nine-center clinical trial funded by the National Eye Institute to evaluate a standardized procedure of radial keratotomy, a surgical treatment for myopia (near-sightedness). The study did not have a control group. The effect of radial keratotomy was assessed by evaluating the change in refraction from before surgery to one year after surgery. For safety reasons, each patient had surgery in one eye and then had to wait one year before the second eye could be operated. For the project, data for only the first operated eye will be analyzed. Patients had to be at least 21 years of age to participate in the study.

Myopia is measured by what is called the refraction, which is a measure of the power of the lens required for the patient to see well. If the refraction is 0, then no lens is required for the patient to see well. By convention, a negative refraction indicates nearsightedness or myopia and a positive refraction indicates farsightedness or hyperopia. The larger the refraction (in absolute value), the more nearsighted or farsighted the eye is. To be eligible for the study, a patient's refraction in each eye had to be in the range -2 to -8 diopters (the units for measuring lens power). The primary assessment of the effect of the surgery was made by comparing the refraction at baseline (before surgery) to the refraction at one year after surgery. The goal of the study was to achieve a refraction of 0 diopters after surgery, although a refraction in the range -1 to +1 was considered a good refractive outcome. A change in refraction of more than one diopter from before to after surgery would be considered a clinically important change. Also, a difference in the mean change in refraction between groups (such as between men and women) of more than 0.5 diopters would suggest a clinically important effect.

The surgical procedure consists of 8 radial incisions placed like the spokes of a wheel in the cornea. The surgeons attempted to control the amount of change in refraction induced by the surgery by varying the diameter of a circular zone in the center of the cornea in which no incisions were made. Eyes with more nearsightedness receive a smaller central clear zone. The diameter of the clear zone was determined from the baseline refraction (-2 to -3.12 = 4.0mm; -3.25to -4.37 = 3.5mm; -4.5 to -8.00 = 3.0 mm) The incisions start at the edge of the central clear zone and extend to the limbus (the white part of the eye). With a smaller clear zone, the incisions would be longer and would hopefully result in a greater change in refraction.

In this project you are to investigate the following questions:

1. What is the overall result of the operation, that is, what refraction was obtained after surgery, what percent of patients achieved a good refractive outcome (-1 to +1 diopters, inclusive), and what change in refraction was induced?

2. Are any of the patient characteristics (age, gender, use of soft contact lens before surgery, intraocular pressure and the diameter of the clear zone) related to the change in refraction?

3. Are any of the patient characteristics related to whether or not the patients obtained a good refractive outcome (-1 to +1 diopters)?

Description of PERK Study Data Files

The file PERK.SAS7BDAT contains a SAS data set with observations for 386 patients enrolled in the study for whom follow-up data were available at one year after surgery. Data for the first eye operated of each patient is included. The data files contain the following variables:

Variable	Description
ID	Patient identification number
AGE	Patient age at the time of surgery (years)
SEX	Patient Sex (1 = Male, 2 = Female)
HXSFTCON	Use of soft contact lens before surgery (1 = No, 2 = Yes)
IOP	Preoperative intraocular pressure (mmHG)
DCZ	Diameter of the central clear zone (3, 3.5, or 4 mm)
BASEREF	Baseline refraction (Diopters)
YR1REF	1 year refraction (Diopters)