## Ophthalmology

A topic of current interest in ophthalmology is whether or not spherical refraction is different between the

**Table 8.3** Spherical refraction in the right and left eye

| (*i*) Person | ($x_i$) Spherical refraction OD (right eye) (diopters) | ($y_i$) Spherical refraction OS (left eye) (diopters) | ($d_i = x_i - y_i$) Difference (OD – OS) | (*i*) Person | ($x_i$) Spherical refraction OD | ($y_i$) Spherical refraction OS | ($d_i = x_i - y_i$) Difference (OD – OS) |
|---|---|---|---|---|---|---|---|
| 1 | +1.75 | +2.00 | –0.25 | 9 | 0 | 0.50 | –0.50 |
| 2 | –4.00 | –4.00 | 0 | 10 | –1.00 | –1.25 | +0.25 |
| 3 | –1.25 | –1.00 | –0.25 | 11 | +0.50 | –1.75 | +2.25 |
| 4 | +1.00 | +1.00 | 0 | 12 | –8.50 | –5.00 | –3.50 |
| 5 | –1.00 | –1.00 | 0 | 13 | +0.50 | +0.50 | 0 |
| 6 | –0.75 | +0.25 | –1.00 | 14 | –5.25 | –4.75 | –0.50 |
| 7 | –2.25 | –2.25 | 0 | 15 | –2.25 | –2.50 | +0.25 |
| 8 | +0.25 | +0.25 | 0 | 16 | –6.50 | –6.25 | –0.25 |
| | | | | 17 | +1.75 | +1.75 | 0 |

left and right eyes. For this purpose refraction is measured in both eyes of 17 people. The data are given in Table 8.3.

8.13 Is a one-sample or two- sample test needed here?

8.14 Is a one-sided or two-sided test needed here?

8.15 Which of the following test procedures is appropriate to use on these data? (More than one may be necessary.)

a. Paired t test
b. Two-sample t test for independent samples with equal variances
c. Two-sample t test for independent samples with unequal variances
d. One-sample t test

8.16 Carry out the hypothesis test(s) in Problem 8.15 and report a p-value.

8.17 Estimate a 90% CI for the mean difference in spherical refraction between the two eyes.

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## Cardiovascular Disease

A study was performed in 1976 to relate the use of oral contraceptives to the levels of various lipid fractions in a group of 163 nonpregnant, premenopausal women ages 21–39. The mean serum cholesterol among 66 current users of oral contraceptives was 201 ± 37 (mg/dL) (mean ± sd), whereas for 97 nonusers it was 193 ± 37 (mg/dL).

8.18 Test for significant differences in mean cholesterol levels between the two groups.

8.19 Report a p-value based on your hypothesis test in Problem 8.18.

8.20 Derive a 95% CI for the true mean difference in cholesterol levels between the groups.

8.21 Suppose the two-tailed p-value in Problem 8.19 = .03 and the two-sided 95% CI in Problem 8.20 = (–0.6, 7.3). Do these two results contradict each other? Why or why not? (Note: These values are not necessarily the actual results in Problems 8.19 and 8.20.)

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**Pulmonary Disease**

Forced expiratory volume (FEV) is a standard measure of pulmonary function representing the volume of air expelled in 1 second. Suppose we enroll 10 nonsmoking males age 35–39, heights 68–72 inches in a longitudinal study and measure their FEV (L) initially (year 0) and 2 years later (year 2). The data in Table 8.5 are obtained.

**Table 8.5** Pulmonary function in nonsmokers at two points in time

| Person | FEV year 0 (*L*) | FEV year 2 (*L*) | Person | FEV year 0 (*L*) | FEV year 2 (*L*) |
|---|---|---|---|---|---|
| 1 | 3.22 | 2.95 | 6 | 3.25 | 3.20 |
| 2 | 4.06 | 3.75 | 7 | 4.20 | 3.90 |
| 3 | 3.85 | 4.00 | 8 | 3.05 | 2.76 |
| 4 | 3.50 | 3.42 | 9 | 2.86 | 2.75 |
| 5 | 2.80 | 2.77 | 10 | 3.50 | 3.32 |
| | | | Mean | 3.43 | 3.28 |
| | | | sd | 0.485 | 0.480 |

8.30 What are the appropriate null and alternative hypotheses in this case to test if mean pulmonary function has decreased over 2 years?

8.31 In words, what is the meaning of a type I and a type II error here?

8.32 Carry out the test in Problem 8.30. What are your conclusions?

Another aspect of the preceding study involves looking at the effect of smoking on baseline pulmonary function and on change in pulmonary function over time. We must be careful, since FEV depends on many factors, particularly age and height. Suppose we have a comparable group of 15 men in the same age and height group as in Table 8.5 who are smokers, and we measure their FEV at year 0 and year 2. The data are given in Table 8.6.

**Table 8.6** Pulmonary function in smokers at two points in time

| Person | FEV year 0 (*L*) | FEV year 2 (*L*) | Person | FEV year 0 (*L*) | FEV year 2 (*L*) |
|---|---|---|---|---|---|
| 1 | 2.85 | 2.88 | 9 | 2.76 | 3.02 |
| 2 | 3.32 | 3.40 | 10 | 3.00 | 3.08 |
| 3 | 3.01 | 3.02 | 11 | 3.26 | 3.00 |
| 4 | 2.95 | 2.84 | 12 | 2.84 | 3.40 |
| 5 | 2.78 | 2.75 | 13 | 2.50 | 2.59 |
| 6 | 2.86 | 3.20 | 14 | 3.59 | 3.29 |
| 7 | 2.78 | 2.96 | 15 | 3.30 | 3.32 |
| 8 | 2.90 | 2.74 | | | |
| | | | Mean | 2.98 | 3.03 |
| | | | sd | 0.279 | 0.250 |

8.33 What are the appropriate null and alternative hypotheses to compare the FEV of smokers and nonsmokers at baseline?

8.34 Carry out the procedure(s) necessary to conduct the test in Problem 8.33.

8.35 Suggest a procedure for testing whether or not the change in pulmonary function over 2 years is the same in the two groups.

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**Hypertension**

The effect of sodium restriction on blood pressure remains a controversial subject. To test this hypothesis a group of 83 individuals participated in a study of restricted sodium intake ( $\leq$ 75 mEq/24 hrs) for a period of 12 weeks. The effect on diastolic blood pressure (DBP) is reported in Table 8.8.

**Table 8.8** Effect of sodium restriction on diastolic blood pressure

| | Baseline period | | | Diet period | | | Change from control (diet-baseline) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | sd | *n* | Mean | sd | *n* | Mean | sd | *n* |
| Age < 40 | 69.7 | 8.5 | 61 | 69.1 | 8.5 | 61 | –0.7 | 6.2 | 61 |
| Age ≥ 40 | 77.0 | 8.0 | 22 | 71.9 | 7.5 | 22 | –5.0 | 4.7 | 22 |
| Total | | | | | | | –1.8 | 6.1 | 83 |

8.42 What is the appropriate procedure to test for whether sodium restriction has had an impact on mean DBP?

8.43 Implement the procedure in Problem 8.42 for people age < 40 using the critical-value method.

One of the interesting findings is the difference in response to dietary therapy between people in the two age groups.

8.44 Test the hypothesis that the response to sodium restriction is different in the two groups and report a pvalue.

8.45 Obtain a 95% CI for the response to dietary therapy in each age group separately.

8.46 Obtain a 95% CI for the difference in response between the 2 age groups.

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**Cardiovascular Disease, Pediatrics**

A family-based behavior-change program was used to modify cardiovascular risk factors among teenage children of patients with ischemic heart disease. The mean baseline level and change in HDL-cholesterol level after a 6-month period in the program is given in Table 8.15.

**Table 8.15** Mean baseline level and change in HDL-cholesterol level (mmol/L) among teenage children over a 6-month period

| | Mean | sd | *n* |
|---|---|---|---|
| Baseline | 1.20 | 0.32 | 44 |
| 6–months | 1.12 | 0.35 | 44 |
| Difference (6 months-baseline) | –0.08 | 0.23 | 44 |

8.66 What test procedure can be used to test if there has been a change in mean HDL-cholesterol levels among teenage children who undergo such a program?

8.67 Implement the test procedure mentioned in Problem 8.66 and report a p-value (two-sided) as precisely as possible using the appropriate tables.

8.68 Provide a 95% CI for the true mean change over 6 months among teenage children exposed to the program.

8.69 Suppose the results in Problem 8.67 are statistically significant (they may or may not be). Does this necessarily mean that the education program per se is the reason why the HDL-cholesterol levels have changed? If not, is there some way to change the design to allow us to be more confident about the specific effects of the education program?

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**Cardiovascular Disease**
In a 1985 study of the effectiveness of streptokinase in the treatment of patients who have been hospitalized after myocardial infarction, 9 of 199 males receiving streptokinase and 13 of 97 males in the control group died within 12 months.

10.1 Use the normal-theory method to test for significant differences in 12-month mortality between the two groups.

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**Cardiovascular Disease**
A 1979 study investigated the relationship between cigarette smoking and subsequent mortality in men with a prior history of coronary disease. It was found that 264 out of 1731 nonsmokers and 208 out of 1058 smokers had died in the 5-year period after the study began.

10.12 Assuming that the age distributions of the two groups are comparable, compare the mortality rates in the two groups.

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**Obstetrics**
Suppose there are 500 pairs of pregnant women who participate in a prematurity study and are paired in such a way that the body weights of the 2 women in a pair are within 5 lb of each other. One of the 2 women is given a placebo and the other drug A to see if drug A has an effect in preventing prematurity. Suppose that in 30 pairs of women, both women in a pair have a premature child; in 420 pairs of women, both women have a normal child; in 35 pairs of women, the woman taking drug A has a normal child and the woman taking the placebo has a premature child; in 15 pairs of women, the woman taking drug A has a premature child and the woman taking the placebo has a normal child.

10.13 Assess the statistical significance of these results.

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**Cancer**
Suppose we wish to compare the following two treatments for breast cancer: simple mastectomy (S) and radical mastectomy (R). Matched pairs of women who are within the same decade of age and with the same clinical condition are formed. They receive the two treatments, and their subsequent 5-year survival is monitored. The results are given in Table 10.1. We wish to test for significant differences between the treatments.

**Table 10.1** Comparison of simple and radical mastectomy in treating breast cancer

| Pair | Treatment S woman | Treatment R woman | Pair | Treatment S woman | Treatment R woman |
|---|---|---|---|---|---|
| 1 | L[a] | L | 11 | D | D |
| 2 | L | D | 12 | L | D |
| 3 | L | L | 13 | L | L |
| 4 | L | L | 14 | L | L |
| 5 | L | L | 15 | L | D |
| 6 | D[b] | L | 16 | L | L |
| 7 | L | L | 17 | L | D |
| 8 | L | D | 18 | L | D |
| 9 | L | D | 19 | L | L |
| 10 | L | L | 20 | L | D |

[a] L lived at least 5 years.
[b] D died within 5 years.

10.14 What test should be used to analyze these data? State the hypotheses being tested.

10.15 Conduct the test mentioned in Problem 10.14.

NOTE: Look in the NOTES for information about the EXACT method.

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**Mental Health**

A clinical trial is set up to assess the effects of lithium in treating manic-depressive patients. New patients in an outpatient service are matched according to age, sex, and clinical condition, with one patient receiving lithium and the other a placebo. Suppose the outcome variable is whether or not the patient has any manic-depressive episodes in the next 3 months. The results are as follows: In 20 cases both the lithium and placebo members of the pair have manic-depressive episodes; in 10 cases only the placebo member has an episode (the lithium member does not); in 2 cases only the lithium member has an episode (the placebo member does not); in 36 cases neither member has an episode.

10.20 State an appropriate hypothesis to test whether lithium has any effect in treating manic-depressive patients.

10.21 Test the hypothesis mentioned in Problem 10.20.

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