An Evaluation of the Use of a Novel Microbicidal Liquid Polymer for the Reduction of Pin-tract Infection in Research Participants Receiving External Fixation Following Deformity Correction and Traumatic Provisional Fixation

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Final Report for DuraDerm Data Analysis

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Here are the results of the analysis of your DuraDerm data. You are interested in determining whether patients undergoing orthopedic reconstructive or repair surgery for deformity correction or trauma who have an external fixation held in place by metal pins experience lower infection rates when DuraDerm in applied to the pin site than patients who receive no DuraDerm (Control). The data set consists of twelve patients who each had, on average, ten pins holding the external fixation in place. Six of the patients were randomly selected to receive a DuraDerm application while the other six patients received no DuraDerm. Both groups of patients received standard pin track care. You would like to answer this question from both the patient-level perspective and the pin-level perspective. A level of significance of $\alpha = 0.05$ was used throughout. SAS version 9.4 (SAS Institute, Inc., Cary, NC) was used for all analyses. Descriptive statistics for the patient demographics are provided in the appendix.

1 Patient-level Results

For the patient-level portion the response variable is whether the patient developed an infection (i.e. had at least one infected pin). The results are given below in Table 1. The top number in each cell is the number of patients in the given category, and the bottom number is the row percentage. For example, two of the patients in the Control group experienced an infection. This accounts for 33.33% of the patients in the Control group.

A chi-square test is usually appropriate for this type of data, however the chi-square test assumes the expected frequency in each cell in at least 5. This does not hold true for this data set, so Fisher's exact test was run instead. Fisher's exact test has no such expected frequency assumption. The two variables were Group (DuraDerm or Control) and Infection (Yes or No). Based on a p-value of 0.45, there is not sufficient evidence to suggest there is a significant association between Group and Infection.

Table 1: Patient infection outcomes

	Infection		
Group	Yes	No	Total
DuraDerm	0	6	6
	0%	100%	
Control	2	4	6
	33%	67%	
Total	2	10	12

Table 2: Pin infection outcomes

	Infection		
Group	Yes	No	Total
DuraDerm	0	60	60
	0%	100%	
Control	14	46	60
	23%	77%	
Total	14	106	120

Note that an *a priori* power analysis indicated that the minimum sample size required to achieve 80% power was 33 patients per group. Due to a lack of 66 available patients, this portion of the analysis is severely under-powered. However, from a descriptive standpoint the results were in line with the values that went into the power analysis. So if the observed trend continued with the appropriate sample size, it would become statistically significant.

2 Pin-level Results

These studies are reported in the literature at both at the patient-level and the pin-level. After consultation with your surgeon it was determined that there is consensus in the orthopedic surgical community that the pins can be treated as independent. Therefore, for the pin-level portion of the analysis the response variable is whether the individual pin site became infected. The results are given above in Table 2.

For this portion of the analysis the chi-square test is appropriate because all of the expected counts are at least five. Do not confuse expected counts with observed counts. The observed count of infections for the DuraDerm group is zero, however the expected count is the column total multiplied by the row total and divided by the total sample size. So for this cell the expected count would be $(14 * 60/120) = 7$.

The same two variables were used (Group and Infection), except now they refer to the individual pins instead of the patients. Based on a p-value of <0.0001, there is strong evidence to suggest there is a significant association between Group and Infection.

One way to quantify this association is in terms of a risk ratio, which is a ratio of the risks of infection for the two groups. The estimated risk ratio for this data set is 0.03. This means that a pin that receives DuraDerm is 0.03 times as likely to become infected as a pin that does not receive DuraDerm. Another way of saying this is the risk of a pin becoming infected is 97% lower for the DuraDerm group compared to the Control group. A 95% confidence interval for the true risk ratio is (0.002, 0.57). So while the observed risk ratio was 0.03, it could feasibly be as high as 0.57.

Let me know if you have any questions about anything contained in this report or related to this research in general. I have enjoyed collaborating with you on this project and hope you consider Wright State University's Statistical Consulting Center for future research.

Sincerely,
Mike Bottomley

3 Appendix

Table 3: Descriptive Statistics for Age

N	*Mean*	*Std Dev*	*Minimum*	*Maximum*
12	52.92	12.90	32	74

Table 4: Descriptive Statistics for Age by Treatment Group

Group	*N*	*Mean*	*Std Dev*	*Minimum*	*Maximum*
Control	6	51.83	11.75	38	67
DuraDerm	6	54.00	15.01	32	74

Table 5: Descriptive Statistics for Age by Infection Status

Infection	*N*	*Mean*	*Std Dev*	*Minimum*	*Maximum*
No	10	52.10	13.71	32	74
Yes	2	57.00	9.90	50	64

Table 6: Frequencies for Gender

Gender	*Frequency*	*Percent*
Female	5	42%
Male	7	58%

Table 7: Frequencies for Gender by Treatment Group

	Group		
Gender	Control	DuraDerm	Total
Female	3	2	5
	60%	40%	
Male	3	4	7
	43%	57%	
Total	6	6	12

Table 8: Frequencies for Gender by Infection Status

	Infection		
Gender	No	Yes	Total
Female	4	1	5
	80%	20%	
Male	6	1	7
	86%	14%	
Total	10	2	12