

OPEN NON RANDOMIZED TRIAL OF PRO-OXY IN THE TREATMENT OF ACNE VULGARIS

There were 50 patients including one patient with one follow-up only that was included in the analysis.. The mean age of the population was  $20 \pm 2.15$  years, majority of who females, single / not married and college students. The mean age of acne onset was  $16 \pm 3.84$  years with mean duration of the condition of  $3.56 \pm 2.56$  years. The details of the patients' characteristics are shown in Table 1.

Table 1. Characteristics of Patients in the Study

Characteristics	mean	SD
Age (years)	20	2.15
Age of Onset of Acne (years)	16	3.84
Duration of Acne (years)	3.56	2.56
	No.	%
Gender		
Male	16	32.0
Females	34	68.0
Total	50	100
Civil Status		
Single	49	98.0
Married	1	2.0
Total	50	100
Highest Educational Attainment		
High School	3	6.0
College	46	92.0
Not Indicated	1	2.0
Total	50	100
Occupation		
Nurse	1	2.0
Student	45	90.0
Elevator Operator	2	4.0
Hospital Aide	1	2.0
Janitor	1	2.0
Total	50	100

The assessments of Non-Inflamed Open Comedone Lesions are shown in Table 2.1. There was significant increase in the lesions at the forehead on the 4<sup>th</sup> and 8<sup>th</sup> week. However, on the 12<sup>th</sup> week there were significant decrease observed. There were also significant decrease in the number of lesions on the chin and nose areas on the 12<sup>th</sup> week observation. The overall evaluation of the lesions regardless of the area showed increase on the 4<sup>th</sup> and 8<sup>th</sup> week but not statistically significant. On the 12<sup>th</sup> week however, significant drop was observed.

Table 2.1. Assessment of Non-Inflamed Lesion Counts by Observation Periods  
Open Comedones

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	mean	SD	Mean	SD	mean	SD
Forehead						
Pre-treatment	1.28	2.37	1.31	2.39	1.31	2.39
Follow-up	4.12	10.19	2.65	3.07	0.29	0.79
Difference	2.84	10.60	1.35	3.85	1.02	2.46
p-value	0.035 * ↑		0.022 * ↑		0.007 **	
Right Cheek						
Pre-treatment	2.12	3.73	2.04	3.73	2.16	3.76
Follow-up	3.24	5.40	2.35	3.34	1.43	3.57
Difference	1.12	6.96	0.31	5.04	0.74	3.75
p-value	0.395 ns		0.405 ns		0.147 ns	
Left Cheek						
Pre-treatment	2.36	5.18	2.39	5.23	2.41	5.22
Follow-up	2.04	4.01	1.31	2.62	0.90	3.10
Difference	0.32	6.64	1.08	5.93	1.51	5.33
p-value	0.978 ns		0.402 ns		0.078 ns	
Chin						
Pre-treatment	1.24	2.72	1.27	2.75	1.27	2.75
Follow-up	0.66	1.49	0.86	2.58	0.24	0.99
Difference	0.58	3.04	0.41	3.71	1.02	2.94
p-value	0.241 ns		0.354 ns		0.018 *	
Nose						
Pre-treatment	0.44	1.43	0.45	1.44	0.45	1.44
Follow-up	0.36	1.12	0.12	0.33	0.04	0.20
Difference	0.08	1.79	0.33	1.51	0.41	1.47
p-value	0.858 ns		0.127 ns		0.026 *	
All Lesions						
Pre-treatment	7.44	9.56	7.45	9.66	7.59	9.60
Follow-up	10.42	14.06	7.29	7.01	2.90	7.27
Difference	2.98	17.89	0.16	12.61	4.69	8.69
p-value	0.162 ns		0.484 ns		0.000 ***	

The Non-Inflamed Closed Comedone Lesion counts generally decreased in all areas and all observation periods. However, statistical significant was observed in all areas on week 8 except in Chin and Nose. On week 12, statistical significant was observed on Forehead, Right Cheek areas and in the assessment of the lesions regardless of the area. as shown in Table 2.2.

Table 2.2. Assessment of Non-Inflamed Lesion Counts by Observation Periods  
Closed Comedones

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	mean	SD	Mean	SD	Mean	SD
Forehead						
Pre-treatment	9.38	12.59	9.55	12.66	9.57	12.65
Follow-up	6.98	9.57	5.41	5.85	2.88	4.17
Difference	2.40	14.54	4.14	13.04	6.69	12.66
p-value	0.119 ns		0.050 *		0.000 ***	
Right Cheek						
Pre-treatment	1.98	4.13	2.02	4.17	1.96	4.17
Follow-up	0.82	2.27	0.51	1.37	0.08	0.34
Difference	1.16	4.85	1.51	4.01	1.88	4.22
p-value	0.121 ns		0.012 *		0.002 **	
Left Cheek						
Pre-treatment	0.94	3.15	0.96	3.18	0.96	3.18
Follow-up	0.62	1.62	0.08	0.45	0.41	1.72
Difference	0.32	3.70	0.88	3.23	0.55	3.40
p-value	0.962 ns		0.041 *		0.423 ns	
Chin						
Pre-treatment	0.36	1.54	0.37	1.55	0.37	1.55
Follow-up	0.64	3.03	0.41	1.47	0.55	2.25
Difference	0.28	3.11	0.04	2.21	0.18	2.57
p-value	0.598 ns		0.809 ns		0.932 ns	
Nose						
Pre-treatment	0.96	2.18	0.98	2.19	0.98	2.19
Follow-up	0.66	1.45	0.73	1.90	0.37	1.04
Difference	0.30	2.42	0.25	2.98	0.61	2.33
p-value	0.377 ns		0.471 ns		0.067 ns	
All Lesions						
Pre-treatment	13.62	15.03	13.88	15.08	13.84	15.11
Follow-up	9.72	10.35	7.14	6.45	4.22	6.06
Difference	3.90	18.04	6.74	16.24	9.61	15.05
p-value	0.157 ns		0.010 **		0.000 ***	

The assessments of Non-Inflamed Lesions regardless of whether open or closed comedones are shown in Table 2.3. Generally lesions in all sites decreased but statistical significance was observed on the 12<sup>th</sup> week except on the Chin area.

Table 2.3. Assessment of Total Non-Inflamed Lesion Counts by Observation Periods

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	mean	SD	Mean	SD	mean	SD
Forehead						
Pre-treatment	10.66	12.53	10.86	12.58	10.88	12.56
Follow-up	11.10	17.34	8.06	7.06	3.16	4.23
Difference	0.44	21.42	2.80	13.45	7.71	12.86
p-value	0.487 ns		0.244 ns		0.000 ***	
Right Cheek						
Pre-treatment	4.10	6.01	4.06	6.07	4.12	6.07
Follow-up	4.06	6.32	2.86	3.82	1.51	3.62
Difference	0.04	8.69	1.20	6.56	2.61	4.71
p-value	0.925 ns		0.491 ns		0.000 ***	
Left Cheek						
Pre-treatment	3.30	6.43	3.35	6.49	3.37	6.48
Follow-up	2.66	4.27	1.39	2.78	1.31	3.44
Difference	0.64	7.85	1.96	7.29	2.06	6.01
p-value	0.926 ns		0.130 ns		0.030 *	
Chin						
Pre-treatment	1.60	3.74	1.63	3.77	1.63	3.77
Follow-up	1.30	3.74	1.27	3.77	0.80	2.40
Difference	0.30	5.20	0.37	5.47	0.84	4.26
p-value	0.537 ns		0.453 ns		0.149 ns	
Nose						
Pre-treatment	1.40	2.57	1.43	2.59	1.43	2.59
Follow-up	1.02	1.90	0.86	1.90	0.41	1.08
Difference	0.38	2.93	0.57	3.31	1.02	2.74
p-value	0.345 ns		0.250 ns		0.012 *	
All Lesions						
Pre-treatment	21.06	19.08	21.33	19.18	21.43	19.10
Follow-up	20.14	22.33	14.43	10.97	7.18	9.78
Difference	0.92	30.69	6.90	23.14	14.25	18.25
p-value	0.594 ns		0.065 ns		0.000 ***	

A highly significant decrease in papules was observed in all sites and observation periods as shown in Table 3.1.

Table 3.1. Assessment of Inflamed Lesion Counts by Observation Periods (Papules)

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	mean	SD	Mean	SD	mean	SD
Forehead						
Pre-treatment	5.42	5.81	5.53	5.82	5.45	5.87
Follow-up	3.16	3.45	2.82	3.15	2.59	2.89
Difference	2.26	4.90	2.71	5.59	2.86	6.68
p-value	0.002 **		0.001 ***		0.011 *	
Right Cheek						
Pre-treatment	6.80	6.00	6.92	6.00	6.69	6.02
Follow-up	3.32	4.51	4.82	6.70	3.51	4.05
Difference	3.48	6.67	2.10	7.87	3.18	6.04
p-value	0.000 ***		0.002 **		0.001 ***	
Left Cheek						
Pre-treatment	7.96	5.69	8.12	5.63	7.98	5.75
Follow-up	4.40	5.65	4.06	5.55	2.90	3.79
Difference	3.56	7.28	4.06	6.14	5.08	5.91
p-value	0.000 ***		0.000 ***		0.001 ***	
Chin						
Pre-treatment	3.86	3.99	3.94	3.99	3.94	3.99
Follow-up	1.58	2.55	1.39	2.19	1.45	2.13
Difference	2.28	3.90	2.55	4.18	2.49	4.13
p-value	0.000 ***		0.000 ***		0.000 ***	
Nose						
Pre-treatment	2.20	4.06	2.24	4.09	2.24	4.09
Follow-up	0.30	0.81	0.37	0.67	0.63	1.55
Difference	1.90	4.25	1.88	4.17	1.61	4.21
p-value	0.002 **		0.002 **		0.008 **	
All Lesions						
Pre-treatment	26.24	14.09	26.76	13.75	26.31	14.23
Follow-up	12.76	11.46	13.47	12.95	11.08	9.70
Difference	13.48	15.08	13.29	14.30	15.22	15.01
p-value	0.000 ***		0.000 ***		0.000 ***	

Generally, a decrease was observed in the pustular lesion counts in all sites, but statistical significance was obtained only on week 8 of Forehead; from week 4 to week 12 of Left Cheek; and week 4 and week 8 of Chin. Assessment of all Pustules Lesions showed significant decrease from week 4 to week 8, Table 3.2.

Table 3.2. Assessment of Inflamed Lesion Counts by Observation Periods (Pustules)

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	mean	SD	Mean	SD	mean	SD
Forehead						
Pre-treatment	0.62	1.67	0.63	1.68	0.63	1.68
Follow-up	0.22	0.58	0.10	0.42	0.51	1.31
Difference	0.40	1.61	0.53	1.57	0.12	1.83
p-value	0.137 ns		0.018 *		0.775 ns	
Right Cheek						
Pre-treatment	0.50	1.31	0.51	1.33	0.49	1.33
Follow-up	0.80	1.85	0.53	1.29	0.16	0.43
Difference	0.30	1.80	0.02	1.39	0.33	1.41
p-value	0.569 ns		0.748 ns		0.144 ns	
Left Cheek						
Pre-treatment	0.66	1.48	0.67	1.49	0.63	1.48
Follow-up	0.24	0.69	0.16	0.62	0.12	0.73
Difference	0.42	1.34	0.51	1.52	0.51	1.92
p-value	0.027 *		0.020 *		0.004 **	
Chin						
Pre-treatment	0.66	1.69	0.67	1.70	0.67	1.70
Follow-up	0.24	0.92	0.41	1.57	0.14	0.46
Difference	0.42	1.42	0.27	2.34	0.53	1.62
p-value	0.041 *		0.376 ns		0.026 *	
Nose						
Pre-treatment	0.34	1.47	0.35	1.48	0.35	1.48
Follow-up	0.22	0.93	0.08	0.34	0.27	0.97
Difference	0.12	0.75	0.27	1.54	0.08	1.41
p-value	0.301 ns		0.250 ns		0.491 ns	
All Lesions						
Pre-treatment	2.78	4.11	2.84	4.13	2.78	4.15
Follow-up	1.72	2.81	1.29	2.37	1.20	2.02
Difference	1.06	3.50	1.55	3.35	1.57	4.30
p-value	0.013 *		0.002 **		0.016 *	

A decrease in Nodule counts were observed in most sites. However statistical significant decrease was observed on week 4 and week 12 of Right Cheek. The assessment of all Nodule lesions regardless of site showed significant decrease on week 12 as shown in Table 3.3.

Table 3.3. Assessment of Inflamed Lesion Counts by Observation Periods (Nodules)

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	mean	SD	mean	SD	mean	SD
Forehead						
Pre-treatment	0.06	0.31	0.06	0.32	0.06	0.32
Follow-up	0.04	0.20	0.02	0.14	0.00	0.00
Difference	0.02	0.38	0.04	0.29	0.06	0.32
p-value	0.705 ns		0.317 ns		0.180 ns	
Right Cheek						
Pre-treatment	0.26	0.97	0.27	0.97	0.27	0.97
Follow-up	0.00	0.00	0.02	0.14	0.00	0.00
Difference	0.26	0.97	0.25	0.99	0.27	0.97
p-value	0.024 *		0.054 ns		0.024 *	
Left Cheek						
Pre-treatment	0.20	1.03	0.20	1.04	0.20	1.04
Follow-up	0.00	0.00	0.08	0.45	0.00	0.00
Difference	0.20	1.03	0.12	1.15	0.20	1.04
p-value	0.109 ns		0.588 ns		0.715 ns	
Chin						
Pre-treatment	0.10	0.42	0.10	0.42	0.10	0.42
Follow-up	0.08	0.40	0.02	0.14	0.02	0.14
Difference	0.02	0.59	0.08	0.45	0.08	0.34
p-value	0.888 ns		0.194 ns		0.102 ns	
Nose						
Pre-treatment	0.22	1.28	0.22	1.30	0.22	0.30
Follow-up	0.10	0.58	0.27	1.72	0.00	0.00
Difference	0.12	1.42	0.04	2.06	0.22	1.30
p-value	0.680 ns		0.854 ns		0.102 ns	
All Lesions						
Pre-treatment	0.84	2.30	0.86	2.32	0.86	2.32
Follow-up	0.22	0.71	0.41	2.04	0.02	0.14
Difference	0.62	2.45	0.45	2.94	0.84	2.30
p-value	0.107 ns		0.062 ns		0.003 **	

All Inflamed Lesions regardless of type as shown in Table 3.4 decreased significantly in all sites.

Table 3.4. Assessment of All Inflamed Lesion Counts by Observation Periods

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	Mean	SD	mean	SD	mean	SD
Forehead						
Pre-treatment	6.10	6.20	6.22	6.20	6.14	6.26
Follow-up	3.42	3.66	2.94	3.19	3.10	3.48
Difference	2.68	5.09	3.29	5.86	3.04	7.28
p-value	0.000 ***		0.000 ***		0.018 *	
Right Cheek						
Pre-treatment	7.56	6.41	7.69	6.41	7.45	6.43
Follow-up	4.12	5.61	5.37	7.41	3.67	4.11
Difference	3.44	7.13	2.33	8.08	3.78	6.55
p-value	0.000 ***		0.005 **		0.000 ***	
Left Cheek						
Pre-treatment	8.82	6.19	9.00	6.12	8.82	6.26
Follow-up	4.64	5.69	4.31	5.89	3.02	4.05
Difference	4.18	7.21	4.69	5.76	5.80	6.43
p-value	0.000 ***		0.000 ***		0.000 ***	
Chin						
Pre-treatment	4.62	4.60	4.71	4.60	4.71	4.60
Follow-up	1.90	3.29	1.82	3.09	1.61	2.21
Difference	2.72	4.28	2.90	5.11	3.10	4.59
p-value	0.000 ***		0.000 ***		0.000 ***	
Nose						
Pre-treatment	2.76	5.02	2.82	5.06	2.82	5.06
Follow-up	0.62	1.28	0.71	1.84	0.90	2.31
Difference	2.14	4.72	2.10	4.13	1.92	5.13
p-value	0.002 **		0.001 ***		0.004 **	
All Lesions						
Pre-treatment	29.86	15.72	30.45	15.32	29.94	15.87
Follow-up	14.70	13.28	15.16	14.41	12.31	10.63
Difference	15.16	15.04	15.29	13.95	17.63	17.08
p-value	0.000 ***		0.000 ***		0.000 ***	

The overall assessments of lesions regardless of whether Inflamed or Non-Inflamed are presented in Table 4. Highly significant decrease in the lesion counts were observed in all sites and all observation periods.

Table 4. Assessment of All Lesions Counts by Observation Periods

Lesion / Site	Observation Periods					
	Week 4 (n=50)		Week 8 (n=49)		Week 12 (n=49)	
	Mean	SD	mean	SD	Mean	SD
Forehead						
Pre-treatment	16.76	13.94	17.08	13.90	17.02	13.96
Follow-up	14.52	17.77	11.00	8.11	6.27	5.35
Difference	2.24	22.61	6.08	15.35	10.76	15.66
p-value	0.035 *		0.016 ns		0.000 ***	
Right Cheek						
Pre-treatment	11.66	8.10	11.76	8.16	11.57	8.16
Follow-up	8.18	8.11	8.22	7.86	5.18	5.38
Difference	3.48	11.11	3.53	8.57	6.39	8.09
p-value	0.017 *		0.002 **		0.000 ***	
Left Cheek						
Pre-treatment	12.12	9.21	12.35	9.16	12.18	9.30
Follow-up	7.30	7.27	5.69	5.99	4.33	5.19
Difference	4.82	11.43	6.65	10.07	7.86	9.49
p-value	0.001 ***		0.000 ***		0.000 ***	
Chin						
Pre-treatment	6.22	5.44	6.35	5.42	6.35	5.42
Follow-up	3.20	5.10	3.08	5.00	2.41	3.18
Difference	3.02	7.11	3.27	6.95	3.94	6.00
p-value	0.002 **		0.000 ***		0.000 ***	
Nose						
Pre-treatment	4.16	5.22	4.24	5.24	4.24	5.24
Follow-up	1.62	2.35	1.53	2.67	1.31	2.52
Difference	2.54	4.80	2.71	3.88	2.94	4.81
p-value	0.001 ***		0.000 ***		0.000 ***	
All Lesions						
Pre-treatment	50.92	22.99	51.78	22.41	51.37	23.01
Follow-up	34.84	26.53	29.59	18.62	19.49	14.57
Difference	16.08	35.19	22.18	24.57	31.88	23.74
p-value	0.000 ***		0.000 ***		0.000 ***	

There was significant improvement in the Investigator's Global Assessment (IGA) of effects of the treatment in all observation periods. A significant decrease in severity of the conditions was presented in Table 5. On the 12<sup>th</sup> week none of the patients showed severe lesions. Only 1 had moderate condition while the rest have mild to clear lesions.

Table 5. Investigator's Global Assessment of Treatment

Investigator's Global Assessment	Observation Periods			
	Pre-Treatment		Follow-Up	
	No.	%	No.	%
4 weeks				
Clear	0	-	0	-
Almost Clear	1	2.0	8	16.0
Mild	29	58.0	34	68.0
Moderate	15	30.0	7	14.0
Severe	5	10.0	1	2.0
Total	50	100	50	100
p-value	0.000 ***			
8 weeks				
Clear	0	-	0	-
Almost Clear	0	-	6	12.2
Mild	29	59.2	39	79.6
Moderate	15	30.6	2	4.1
Severe	5	10.2	2	4.1
Total	49	100	49	100
p-value	0.000 ***			
12 weeks				
Clear	0	-	3	6.1
Almost Clear	1	2.0	6	12.2
Mild	28	57.1	39	79.6
Moderate	15	30.6	1	2.0
Severe	5	10.2	0	-
Total	49	100	49	100
p-value	0.000 ***			

More than half of the patients were very satisfied with the treatment at the end of the study. The rest were satisfied as shown in the table below, Table 6.

Table 6. Patients Satisfactory Assessment of the Treatment

Assessment	No.	%
4 weeks		
Very Dissatisfied	0	-
Dissatisfied	0	-
Somewhat Satisfied	3	6.0
Satisfied	28	56.0
Very Satisfied	19	38.0
Total	50	100
8 weeks		
Very Dissatisfied	0	-
Dissatisfied	0	-
Somewhat Satisfied	1	2.0
Satisfied	27	55.1
Very Satisfied	21	42.9
Total	49	100
12 weeks		
Very Dissatisfied	0	-
Dissatisfied	0	-
Somewhat Satisfied	0	-
Satisfied	22	44.9
Very Satisfied	27	55.1
Total	49	100

#### Data Management and Statistical Analysis

Data were electronically encoded using Dbase 3 Program. To assure accuracy of encoding, data encoded were checked manually 3 times against the Clinical Research Form (CRF). Statistical analyses were performed after editing had been done.

Only patients with at least 1 follow-up observation were included in the analysis. Continuous data were described as mean±sd and categorical data as frequency and percent distribution. To determine significant change in lesion counts and IGA, Wilcoxon Matched Pairs Signed Ranks Test was applied to the data. A  $p \leq 0.050$  was considered significant.