2016 Chronic Wound Healing Case Series: Statistical Results:

A Case Series study with an ingestible, calibrated formulation of PLANT-BASED LIPIDs (the adjuvant) at a University Wound Healing & Hyperbaric Center has been completed. The study's duration was 16 weeks. Patients were seen weekly and treated with a <u>high level of standard treatment plus the ingestible PEO adjuvant</u>. **Patients ingested the adjuvant until complete healing, or results after a maximum of 16 weeks — the study's duration**.

Patients completing the study consisted of: 6 (venous leg ulcer patients) VLUs / 3 PUs / 3 Traumas (including hematoma) / 1 Surgical / 1 Burn. All patients had standard treatment plus the ingestible PEO adjuvant.

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* 8 of the 14 patients experienced complete healing.

* Skin graft patients were included.

The outpatient clinic treats various wounds including: pressure ulcers, venous leg ulcers, diabetic foot ulcers, trauma, surgical, soft tissue radiation wounds, burns, etc. Both wound surface area and wound volume quickly and significantly improved. **With all 14 patients taken as a group for statistical analysis, <u>both wound surface area and wound volume statistically improved</u> (decreased) with the PEO adjuvant. The magnitude of the effect was significant, and the percentage of the population it worked in was also significant**.

Of particular note is that the PEO adjuvant was <u>equally effective in healing both small and large wounds</u>. Diabetic patients also improved. (*See* Appendix):

* **8 / 14 patients experienced 100% healing.**
* **<u>Surface area</u> decreased by at least 33% in 13 / 14 patients.**
* **<u>Surface area</u> decreased by at least 70% in 10 / 14 patients.**
* **Volume decreased by at least 33% in 13 / 14 patients.**
* **Volume decreased by at least 70% in 12 / 14 patients.**
* **<u>Diabetic patients</u> experienced 63% decreased wound surface area and 77% decreased wound volume.**

The "small wound" group consisted of 9 patients, and the "large wound" group consisted of 5 patients. A "**large wound**" was defined as a wound with a **surface area ≥ 14 cm²**. Wound surface areas and wound volumes were measured at commencement of the addition of the PEO adjuvant, and final results were either at the end of the 16-week study or when the wound healed.

Alex Kiss, Ph.D. (biostatistics) performed the 3rd-party statistical analysis of data. Paired t-tests were run for each group. Because of the relatively small number of patients in each group, for confirmation, the Wilcoxon signed rank test was also performed. By both statistical measures, **with all 14 patients taken as a group for statistical analysis**, both wound surface areas and volumes statistically improved with the PEO adjuvant. **When subsets of small wounds and large wounds (surface area ≥ 14 cm²) were statistically analyzed with both statistical measures, the adjuvant was also shown to be <u>equally effective in the healing of both small and large wounds</u>**. Dr. Kiss' analyses follow:

Across all 14 patients, surface area showed an average drop of 7.9 units (standard deviation = 11.1) from initial to final measurement (a MAXIMUM of 16-weeks of ingestible PEO Adjuvant). A paired t-test was run to compare this change and it was found to be statistically significant (p=0.02).

APPENDIX — detailed statistical analysis
(Alex Kiss, Ph.D. (biostatistics))

Woundsastart = wound surface area initial
Woundsafinal = wound surface area final
Woundvolstart = wound volume initial
Woundvolstart = wound volume final

Overall data

Variable	N	Mean	Std Dev	Minimum	Maximum
Woundsastart	14	11.003	12.839	0.450	36.850
Woundsafinal	14	3.139	7.884	0.000	29.970
Woundvolstart	14	4.094	4.868	0.045	16.200
Woundvolfinal	14	0.983	1.919	0.000	5.994

Paired t-tests were run to compare change start with final

Surface area: mean change in surface area was a drop of 7.9 units (sd = 11.1)

Analysis Variable: sachange

N	Mean	Std Dev	Minimum	Maximum
14	-7.864	11.057	-36.850	-0.450

A paired t-test was run. It showed that the decrease in surface area **was statistically significant (p=0.02).**

Analysis Variable: sachange

t Value	Pr > |t|
-2.66	0.0196

Small wound group

group=S					
Variable	N	Mean	Std Dev	Minimum	Maximum
Woundsastart	9	2.80	2.55	0.45	7.50
Woundsafinal	9	1.19	1.75	0.00	4.32
Woundvolstart	9	3.57	5.93	0.05	16.20
Woundvolfinal	9	0.79	1.56	0.00	4.32

<u>Surface area</u>: mean change in surface area was a drop of 1.6 units (sd = 1.03)

group=S

Analysis Variable: sachange

N	Mean	Std Dev	Minimum	Maximum
9	-1.607	1.029	-3.900	-0.450

A paired t-test was run. It showed that the **decrease was statistically significant (p=0.002)**.

group=S

Analysis Variable: sachange

t Value	Pr > |t|
-4.69	0.0016

group=S

Analysis Variable: volchange

N	Mean	Std Dev	Minimum	Maximum
9	-2.776	4.397	-11.880	-0.045

A paired t-test was run. It showed that the decrease in volume was close, but *not* statistically significant (p=0.09).

group=S

Analysis Variable: volchange

t Value	Pr > |t|
-1.89	0.0948

Large wound group

group=L

Variable	N	Mean	Std Dev	Minimum	Maximum
Woundsastart	5	25.77	9.94	14.00	36.85
Woundsafinal	5	6.64	13.12	0.00	29.97
Woundvolstart	5	5.04	2.22	1.96	7.37
Woundvolfinal	5	1.33	2.62	0.00	5.99

<u>Surface area</u>: mean change in surface area was a drop of 19.1 units (sd = 12.2)

group=L

Analysis Variable: sachange

N	Mean	Std Dev	Minimum	Maximum
5	-19.126	12.188	-36.850	-5.230

A paired t-test was run. It showed that the **decrease was statistically significant (p=0.02).**

group=L

Analysis Variable: sachange

t Value	Pr > |t|
-3.51	0.0247

<u>Volume</u>: mean change in volume was a drop of 3.7 units (sd = 2.5)

group=L

Analysis Variable: volchange

N	Mean	Std Dev	Minimum	Maximum
5	-3.713	2.472	-7.370	-1.046

A paired t-test was run. It showed that the **decrease was statistically significant (p=0.03**).

group=L

Analysis Variable: volchange

t Value	Pr > |t|
-3.36	0.0283

Ingestible PEO adjuvant equally effective in healing both small and large wounds

Percentage decrease in surface area was compared between small and large wound groups using a t-test. The result showed no statistical difference (p=0.94) in percent change between the two groups, i.e., the large group didn't have a larger percentage decrease than the small group (**the mean percent change was 77% for L compared with 78% for Small**).

The TTEST Procedure

Variable: Maximum_of_16_weeks___decrease_i

group	N	Mean	Std Dev	Std Err	Minimum	Maximum
L	9	0.7695	0.2960	0.0987	0.3333	1.0000
S	5	0.7833	0.3688	0.1649	0.1486	1.0000
Diff (1-2)		-0.0138	0.3221	0.1797		

group	Method	Mean	95% CL Mean		Std Dev	95% CL Std Dev	
L		0.7695	0.5419	0.9970	0.2960	0.2000	0.5671
S		0.7833	0.3254	1.2412	0.3688	0.2209	1.0597
Diff (1-2)	Pooled	-0.0138	-0.4053	0.3777	0.3221	0.2310	0.5317
Diff (1-2)	Satterthwaite	-0.0138	-0.4692	0.4416			

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	12	-0.08	0.9400

Percentage decrease in volume was compared between small and large wound groups using a t-test. The result showed no statistical difference (p=0.71) in percent change between the two groups, ie, the large group didn't have a larger percentage decrease than the small group (the **mean percent change was 80% for L compared with 86% for Small**).

The TTEST Procedure

Variable: Maximum_of_16_weeks___decrease_0

group	N	Mean	Std Dev	Std Err	Minimum	Maximum
L	5	0.7988	0.3696	0.1653	0.1486	1.0000
S	9	0.8575	0.2201	0.0734	0.3438	1.0000
Diff (1-2)		-0.0587	0.2790	0.1556		

group	Method	Mean	95% CL Mean		Std Dev	95% CL Std Dev	
L		0.7988	0.3399	1.2577	0.3696	0.2214	1.0620
S		0.8575	0.6883	1.0267	0.2201	0.1487	0.4217
Diff (1-2)	Pooled	-0.0587	-0.3977	0.2803	0.2790	0.2001	0.4605
Diff (1-2)	Satterthwaite	-0.0587	-0.5085	0.3911			

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	12	-0.38	0.7126

Analysis of diabetic patients

Even with the small sample size of 5 diabetic patients, the diabetic healing as measured by decreased wound surface area was significant.

Surface area: mean change in surface area was a drop of 1.9 units (sd = 1.3)

dgroup=diab

Analysis Variable: sachange

N	Mean	Std Dev	Minimum	Maximum
5	-1.922	1.289	-3.900	-0.450

A paired t-test was run. It showed that the decrease was statistically significant (p=0.03).

dgroup=diab

Analysis Variable: sachange

t Value	Pr > |t|
-3.33	0.0290

The adjuvant worked to decrease wound surface area just as well in diabetic patients as in the non-diabetic patient group.

Percentage decrease in surface area was compared between diabetics and non-diabetics using a t-test. The result showed no statistical difference (p=0.24) in percent change between the two groups, i.e. the diabetic group didn't have a larger percentage decrease than the non-diabetic group (the mean percent change was 64% for diabetic compared to 85% for non-diabetic).

The TTEST Procedure

Variable: Maximum_of_16_weeks___decrease_i

dgroup	N	Mean	Std Dev	Std Err	Minimum	Maximum
Non-diab	9	0.8494	0.2847	0.0949	0.1486	1.0000
diab	5	0.6394	0.3374	0.1509	0.3333	1.0000
Diff (1-2)		0.2100	0.3033	0.1692		

dgroup	Method	Mean	95% CL Mean		Std Dev	95% CL Std Dev	
Non-diab		0.8494	0.6306	1.0683	0.2847	0.1923	0.5455
diab		0.6394	0.2205	1.0584	0.3374	0.2022	0.9696
Diff (1-2)	**Pooled**	0.2100	-0.1586	0.5786	0.3033	0.2175	0.5007
Diff (1-2)	**Satterthwaite**	0.2100	-0.2089	0.6289			

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	12	1.24	0.2382