Beth Israel Deaconess Medical Center

A teaching hospital of Harvard Medical School

An Open Label, Three Arm Study of the Safety and Clinical Efficacy of Topical Wound Care vs. Oral Levofloxacin vs. Combined Therapy for Mild Diabetic Foot Infections

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Overview

- Mild DFU's
- Randomized, 3 arm study
  - Levofloxacin + Saline
  - OIS-1080
  - OIS-1080 + Levofloxacin
- Clinical and Micro Cure
- Observed at 3, 10, and 21 days

Topical Treatment for DFU's

- Martinez-DeJesus, et al; Efficacy and safety of neutral pH superoxidised solution in severe diabetic foot infections; Int. Wound J; 4(4):353-362, 2007.
  - Not randomized, and no control, but showed reduction in cellulitis, odor, edema, and improved granulation tissue.

- Hadi, et al; Treating infected diabetic wounds with superoxidized water as anti-septic agent : a preliminary experience; J Coll Physicians Surg Pak. 2007 Dec;17(12):740-3
  - Randomized to saline vs. topical treatment. Demonstrated a statistical improvement with superoxidized saline.

Study Design

Mild DFI (IDSA / UTC 1B)

↓

Screening / Debridement / Culture - Photo

↓

Randomization

↓

OIS-1080 | Levo + Saline | OIS-1080 + Levo

				CE	ME	S
Visit	2	Day 3 ± 1	Δ Treatment		x	x
	3 *	Day 10 ± 1	EOT	x	x	x
	4	Day 21-28	TOC	x		x

* Primary Objective

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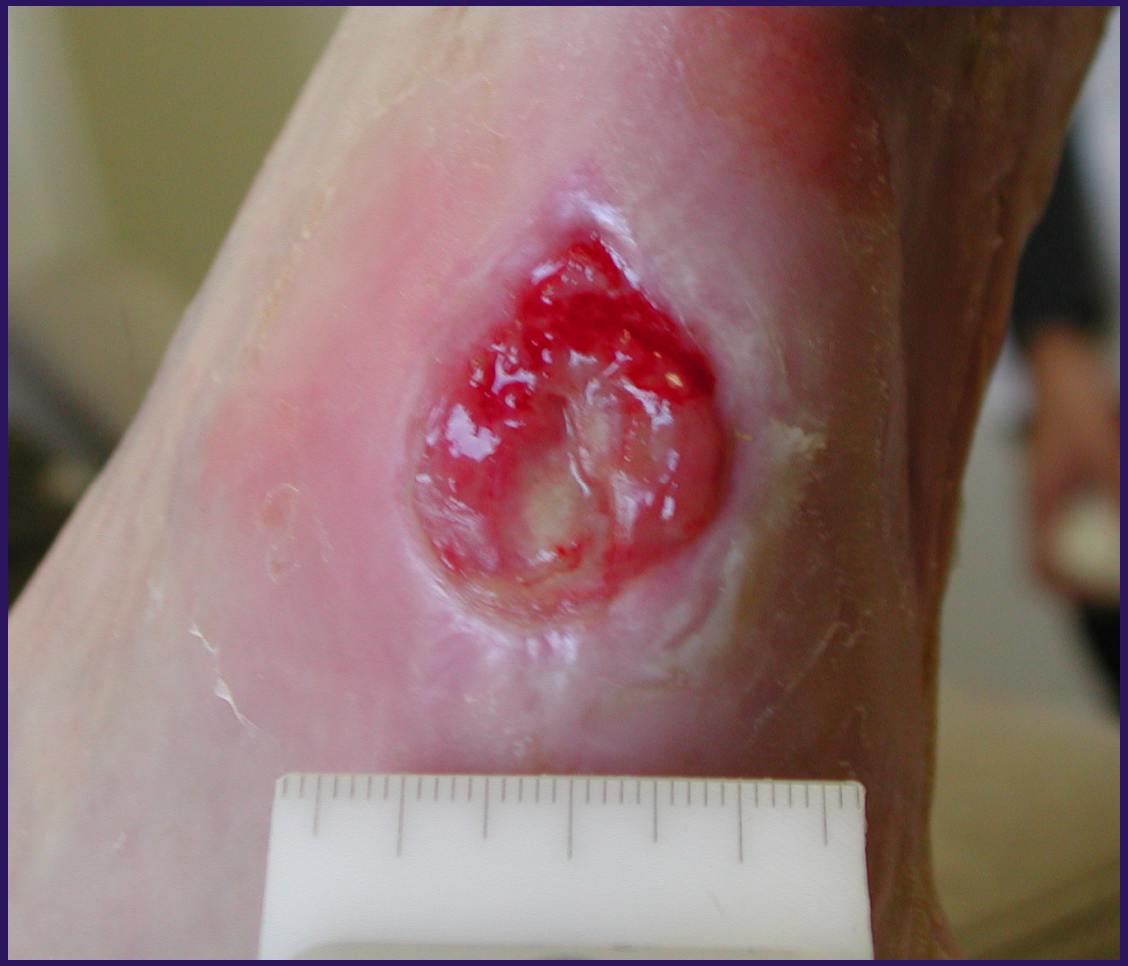
Mild Diabetic Foot Infection



Patient Demographics

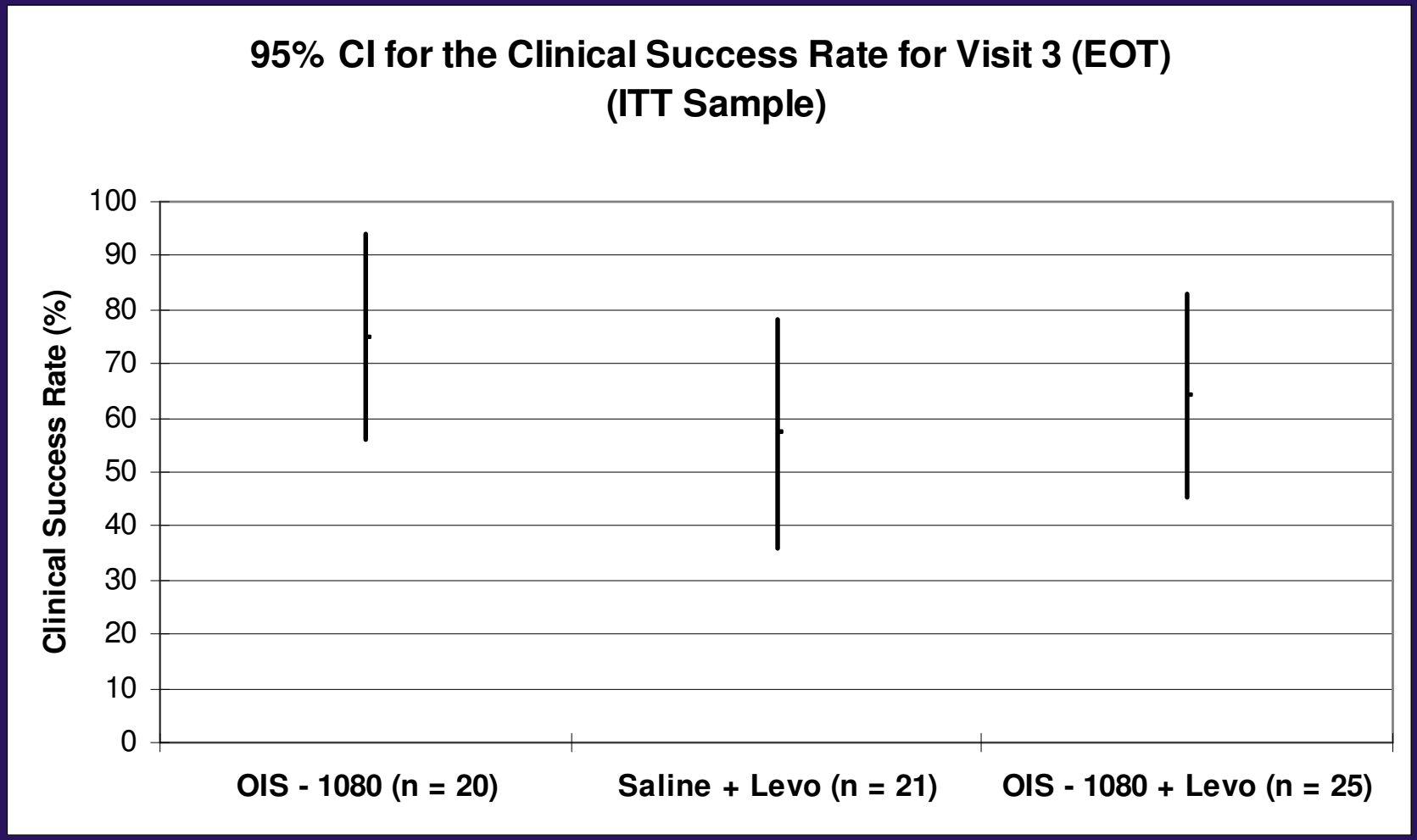
	OIS - 1080 (n = 21)	Saline + Levo (n = 21)	OIS-1080+ Levo (n = 25)
Age (in years)	**55.4 ± 12.81**	**56.5 ± 12.21**	**59.2 ± 12.94**
Gender (% Male)	**76.2%**	**76.2%**	**68.0%**
BMI	**32.56 ± 5.94**	**31.68 ± 5.93**	**30.11 ± 6.39**
Type I Diabetes **Type II Diabetes**	**23.8%** **76.2%**	**28.6%** **71.4%**	**20.0%** **80.0%**

Baseline Study Ulcer Assessment

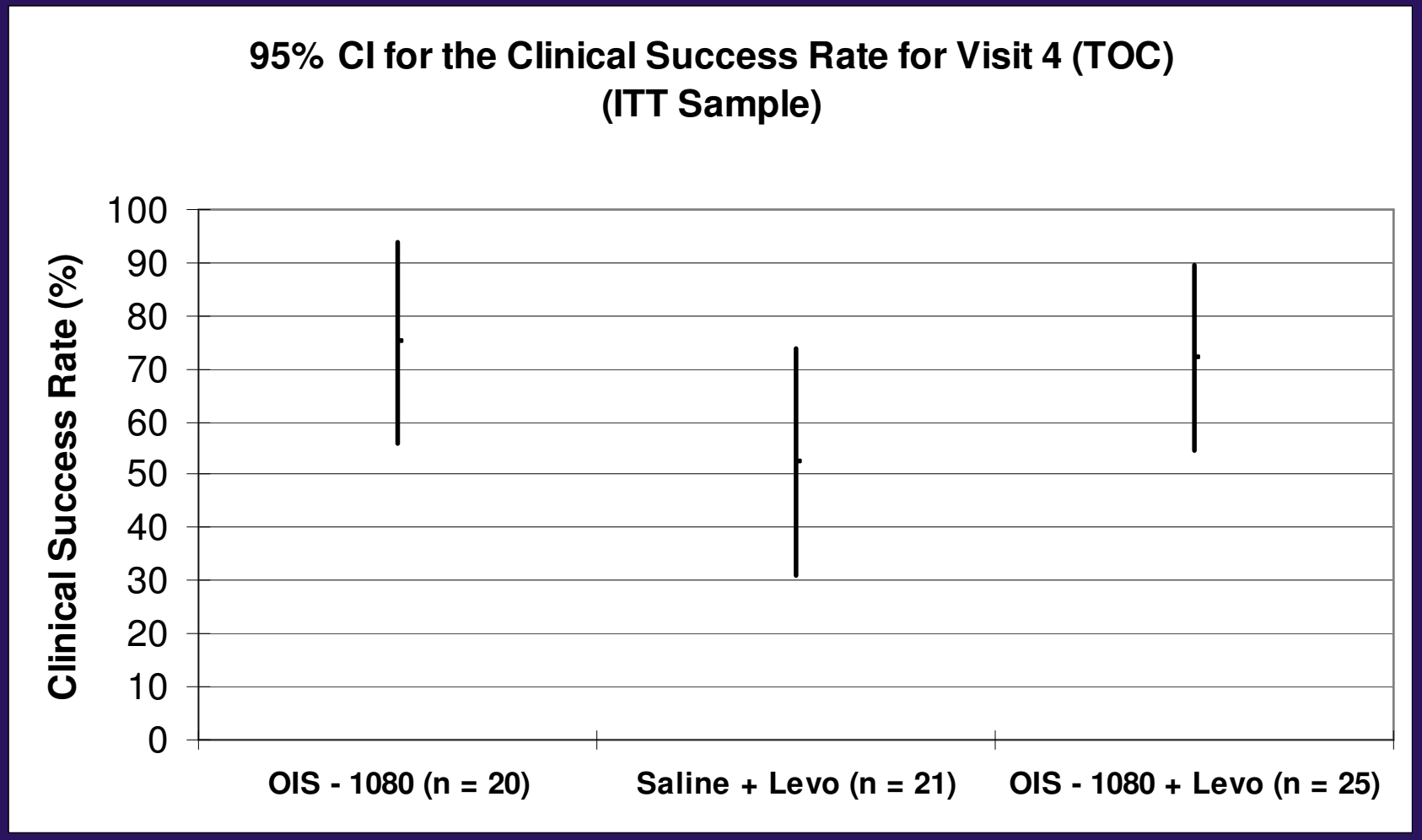
	OIS – 1080 n = 21	Saline + Levo n = 21	OIS – 1080 + Levo n = 25
Length of time of study ulcer present (weeks)	15.80 ± 19.05	13.60 ± 15.55	15.10 ± 23.78
Wound Area (cm^2) Min Max	2.26 ± 2.45 0.27 8.72	1.55 ± 1.25 0.47 4.63	2.18 ± 1.87 0.31 7.45

Mean ± Standard Deviation

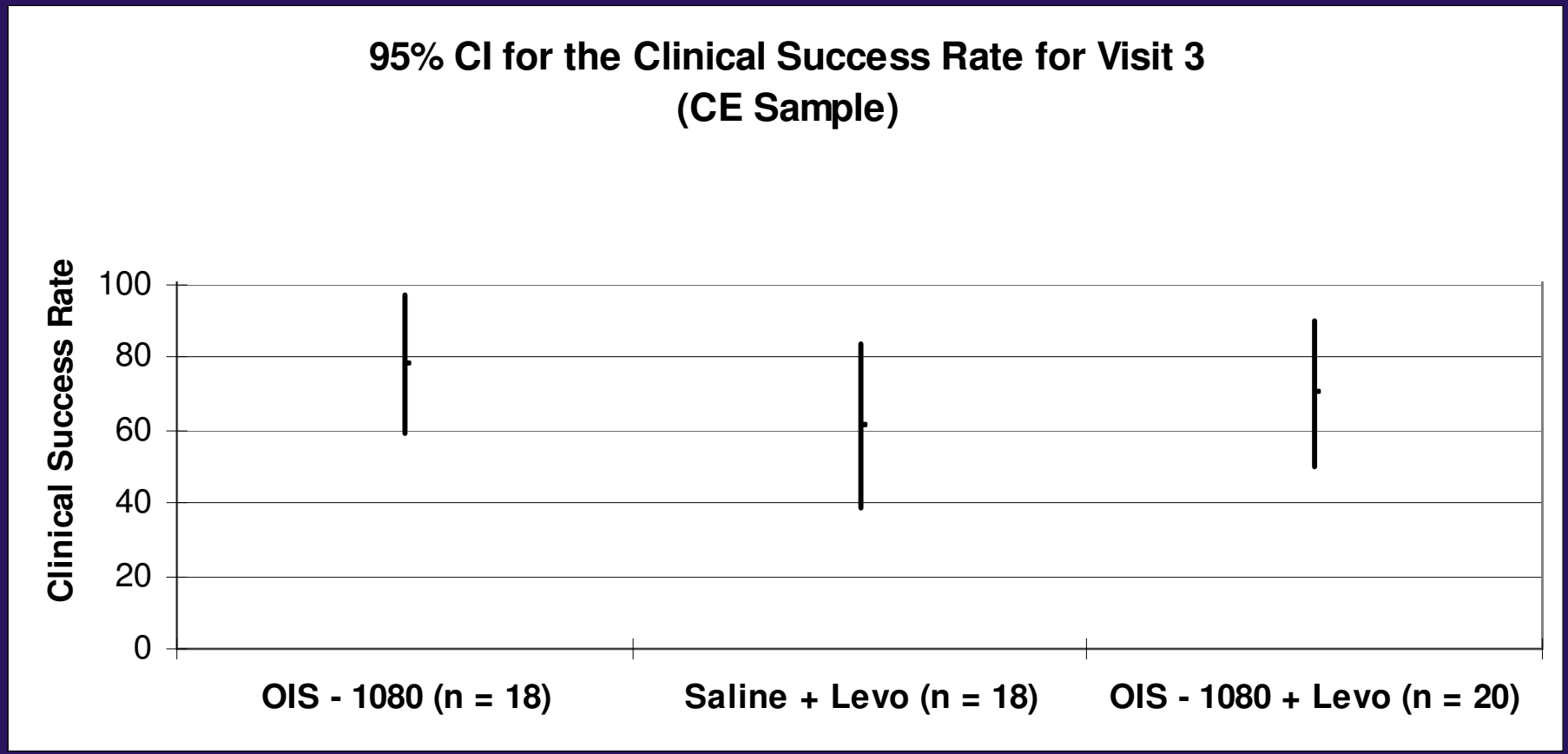
Clinical Success Rate for Visit 3 (ITT Sample)



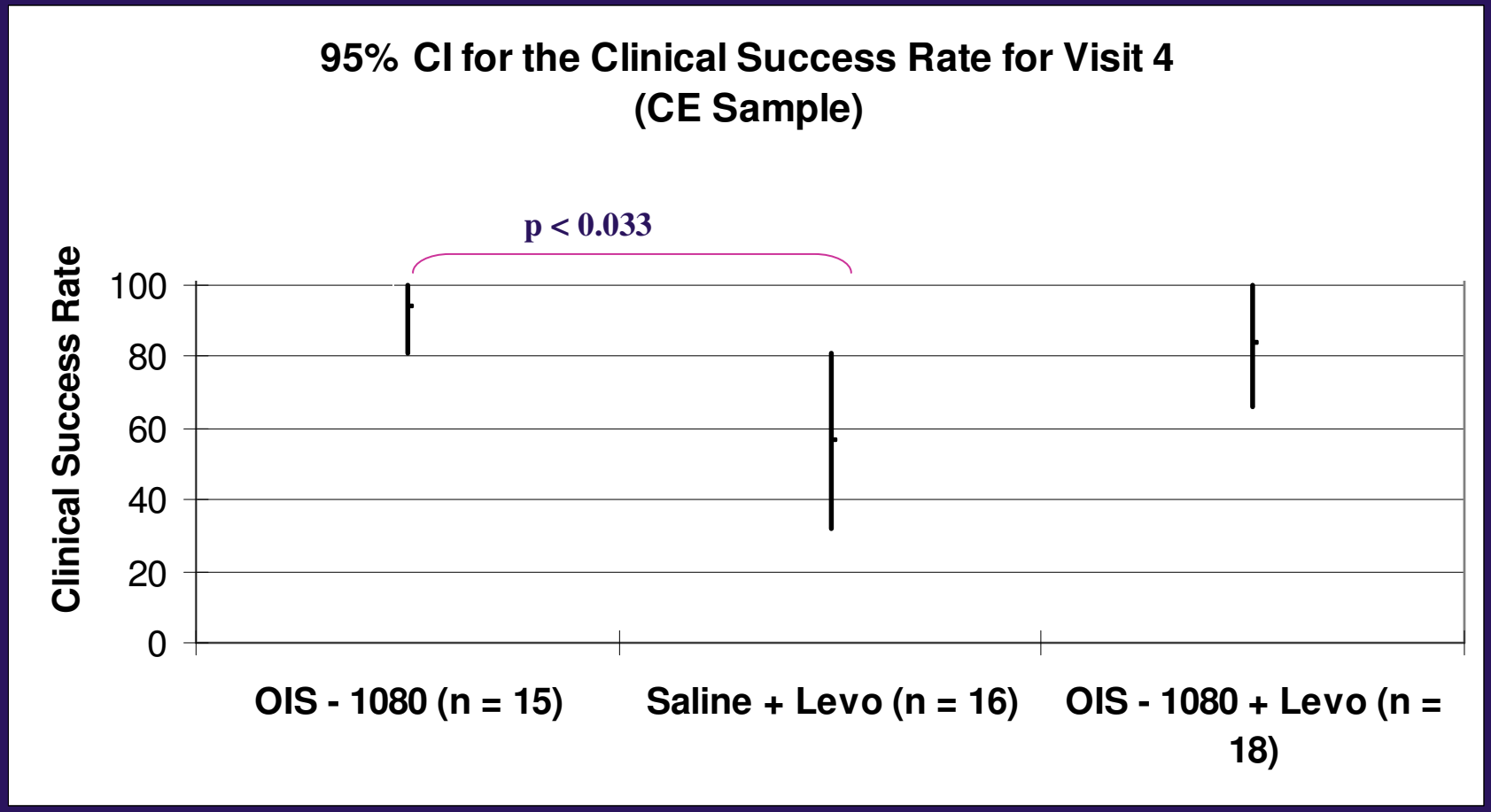
Clinical Success Rate for Visit 4 (ITT Sample)



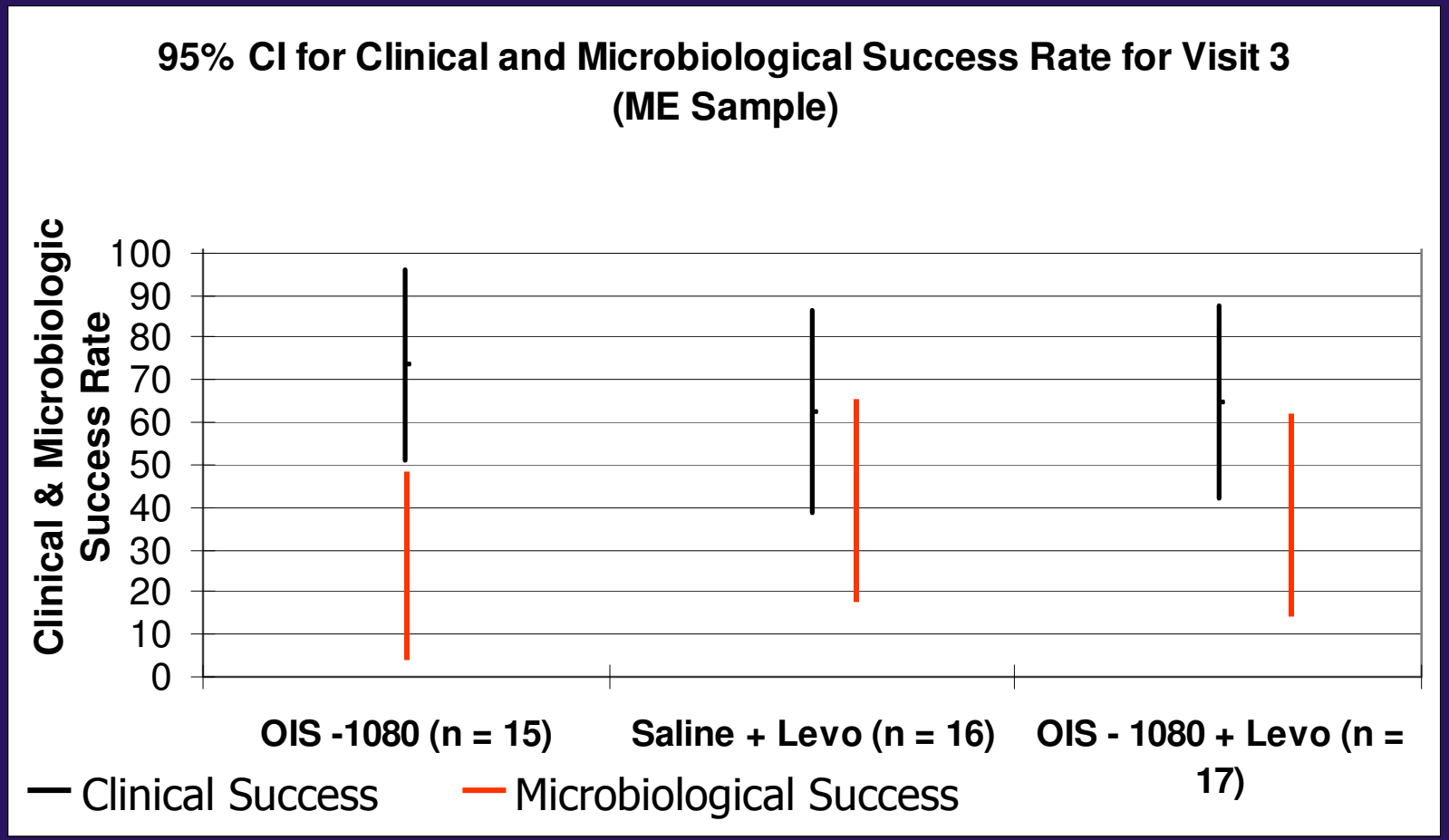
Clinical Success Rate for Visit 3 (Clinically Evaluable Sample)



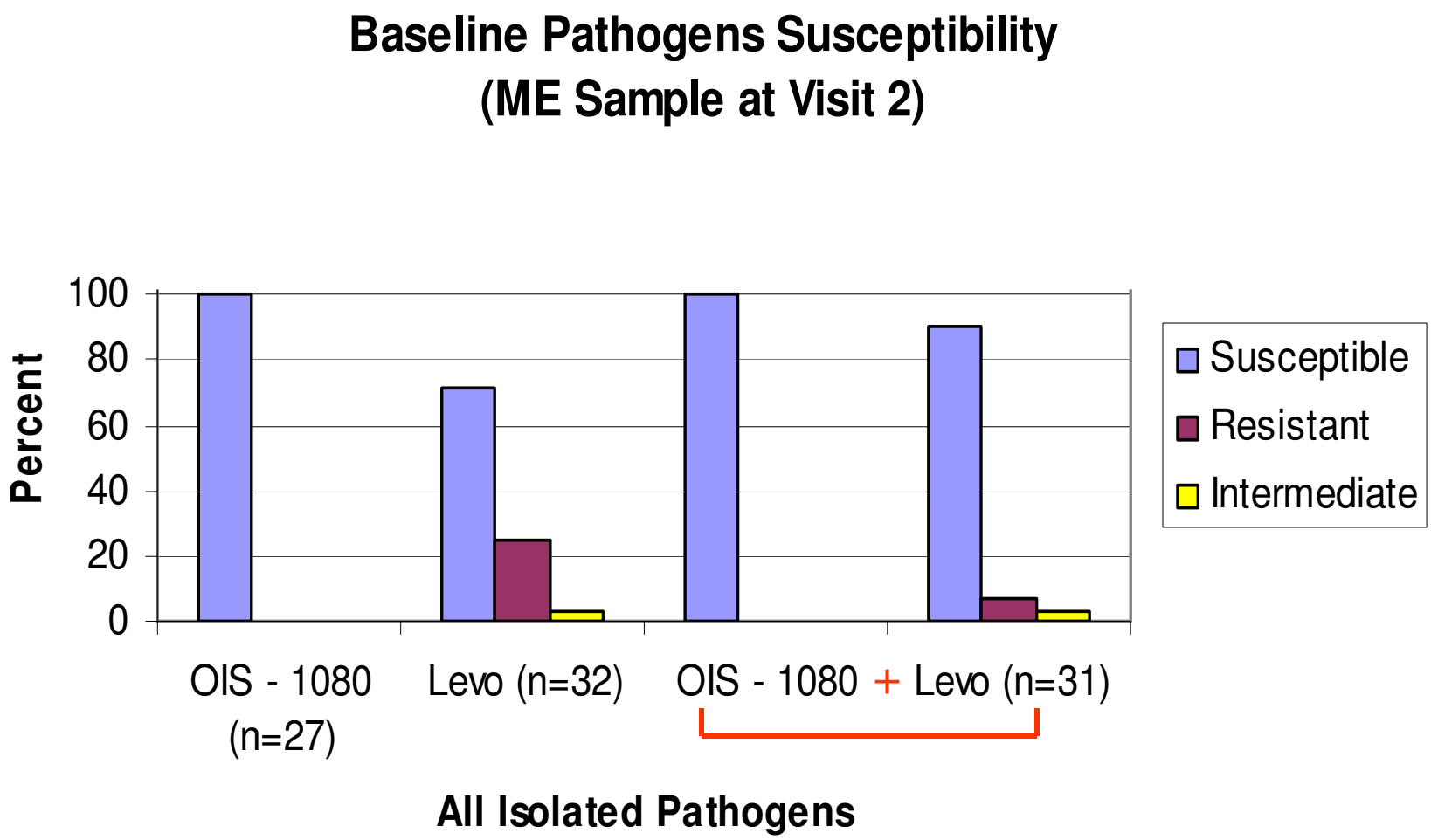
Clinical Success Rate for Visit 4 (Clinically Evaluable Sample)



Clinical & Micro Response at Visit 3



Pathogens Susceptibility at Visit 2



Treatment Emergent Adverse Events by Relationship to Study Drug

	OIS – 1080 (n = 21)	Saline + Levo (n = 21)	OIS – 1080 + Levo (n = 25)
Emergent Adverse Event	7 (33.3%)	7 (33.3%)	9 (36.0%)
Definitely Not	6 (28.6%)	5 (23.8%)	5 (20.0 %)
Probably Not	1 (4.8%)	2 (9.5%)	1 (4.0%)
Possible			2 (8.0%)
Probable			
Definite			1 (4.0%)

Selected Treatment Emergent Adverse Events by Relationship to Study Drug

- OIS - 1080 + Levo Group
  - Burning sensation: Definite (1)
  - Stomach discomfort: Possible (1)
  - Amnesia: Possible (1)

Conclusions

- The clinical success rate appears to be comparable among the three study arms as shown on the overlapping confidence intervals at Visits 3 and 4

- The micro response did not correlate with the clinical success:
  - "Head of the snake" theory
  - Other mechanism(s) of action of OIS-1080

- 1 out of 45 patients treated with OIS-1080 had a topical related adverse event but no systemic toxicity

Oculus Collaborative Group

Blume P & Palladino M
Jordan D
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Mendicino RW
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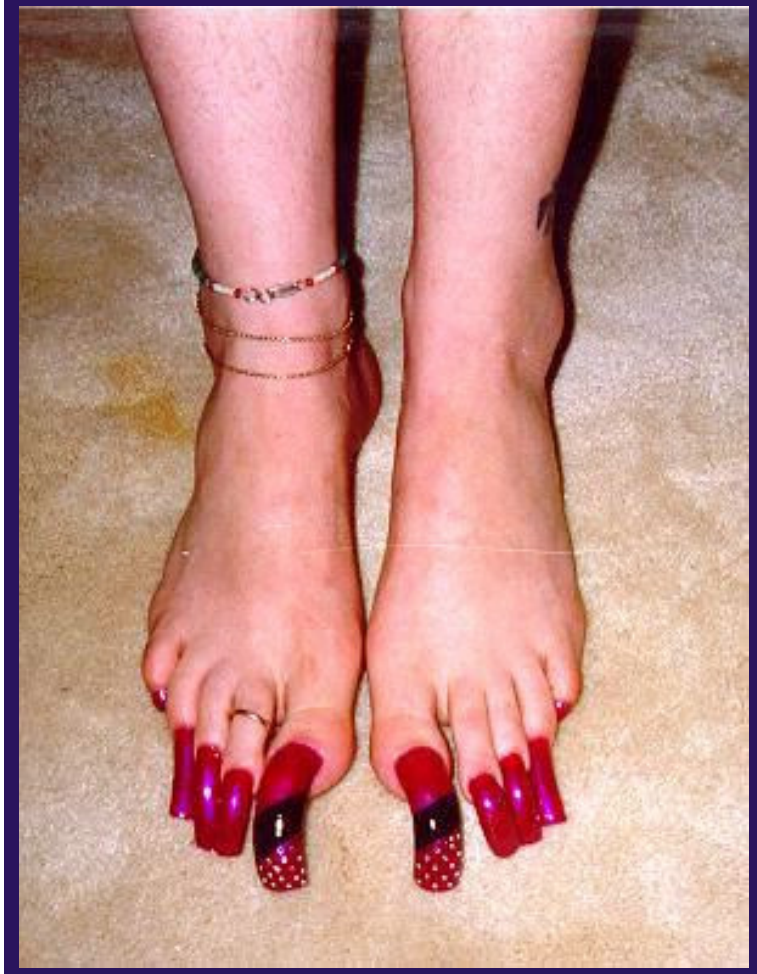

Thank you!

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