

**CLZ-003 OPTIMIZED CLENZIDERM M.D.
MILD TO MODERATE FACIAL ACNE VULGARIS**

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**12 WEEK FINAL ANALYSIS
January 2012**

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Barbara Coffey, Project Coordinator**



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MAIN INCLUSION CRITERIA

- Male or Female subjects between the ages of 12 through 25 years of age (inclusive);
- Mild to moderate facial acne (excluding the nose), with normal skin: 17 to 40 inflammatory (papules, pustules, and nodules), 10 to 100 non-inflammatory (open and closed comedones), up to 2 nodulo-cystic lesions may be present;
- A Physician's Global Assessment of mild to moderate (2 – 3)

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DEMOGRAPHICS

N	22*
Gender Male (%)	68%
Gender Female (%)	32%
Age (Mean)	15.6
White/Caucasian (%)	81%
Black/African American (%)	5%
American Indian/Alaska Native (%)	5%
Caucasian & Asian (%)	9%

* All 22 subjects enrolled completed study

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STUDY TREATMENT REGIMEN

Optimized CLENZIderm M.D.™ System	
AM	PM (evening prior to bedtime)
<ul style="list-style-type: none">• Daily Care Foaming Cleanser (2% salicylic acid)	<ul style="list-style-type: none">• Daily Care Foaming Cleanser (2% salicylic acid)• Pore Therapy (2% salicylic acid)• Therapeutic Lotion (5% BPO)

CLENZIderm M.D.™ Therapeutic Moisturizer was provided if needed for dryness or other tolerability symptoms. Nu-Derm® Healthy Skin Protection SPF 35 sunscreen was provided to use if exposed to sun.

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EFFICACY

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- **Non-Inflammatory Lesions = Open and Closed Comedones**
- **Inflammatory Lesions = Papules, Pustules and Nodules**
- **Total Lesions = Non-Inflammatory and Inflammatory Lesions**

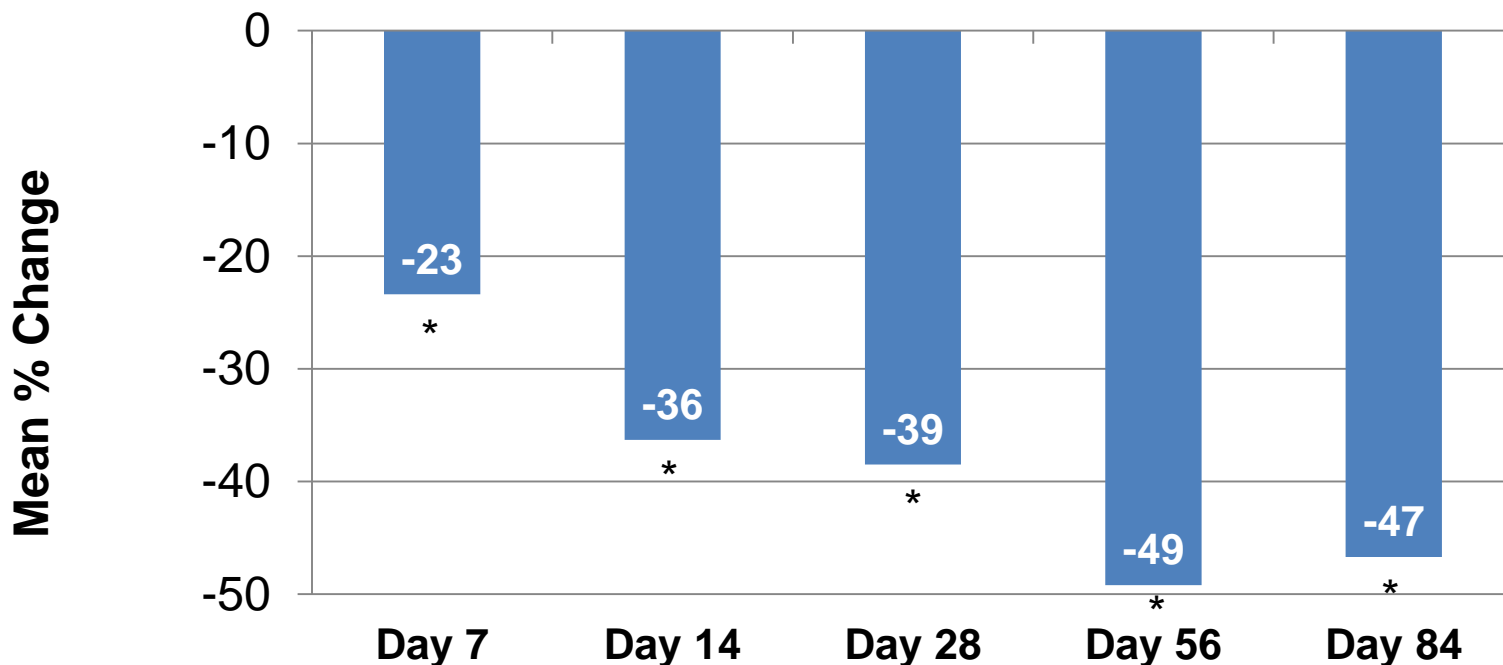
Lesion Definitions

- **Open Comedone** – Non-inflamed partially plugged hair follicle with dilated/open orifice with a black surface
- **Closed Comedone** – Non-inflamed partially plugged hair follicle with a closed orifice, white in color
- **Papule** – A solid, elevated inflammatory lesion less than 0.5 cm
- **Pustule** – An elevated inflammatory lesion less than 0.5 cm, contains pus
- **Nodule/Cyst** – Palpable solid inflammatory lesion, greater than 0.5 cm, has depth, not necessarily elevated

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LESION COUNTS – INFLAMMATORY LESIONS % CHANGE FROM BASELINE



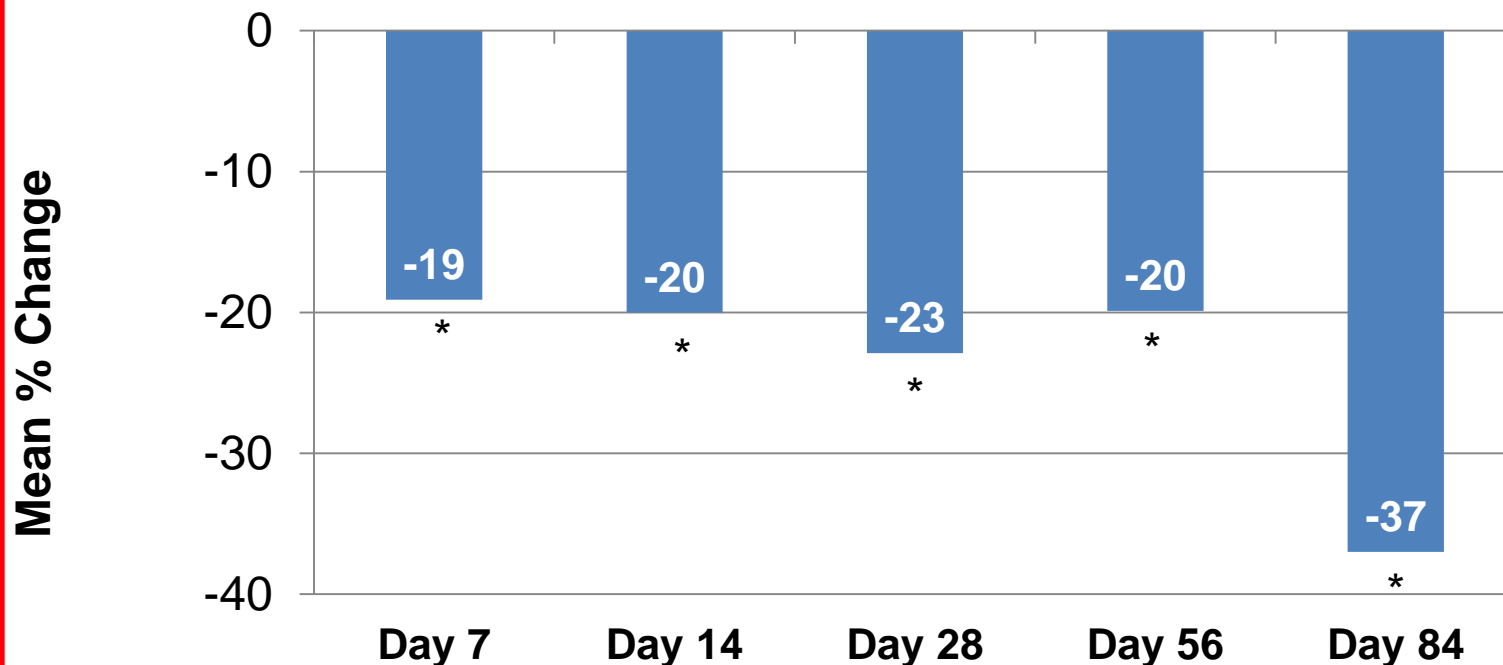
Statistically significant reduction lesions all visits

* $p \leq 0.01$ vs. Baseline

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LESION COUNTS – NON-INFLAMMATORY LESIONS % CHANGE FROM BASELINE



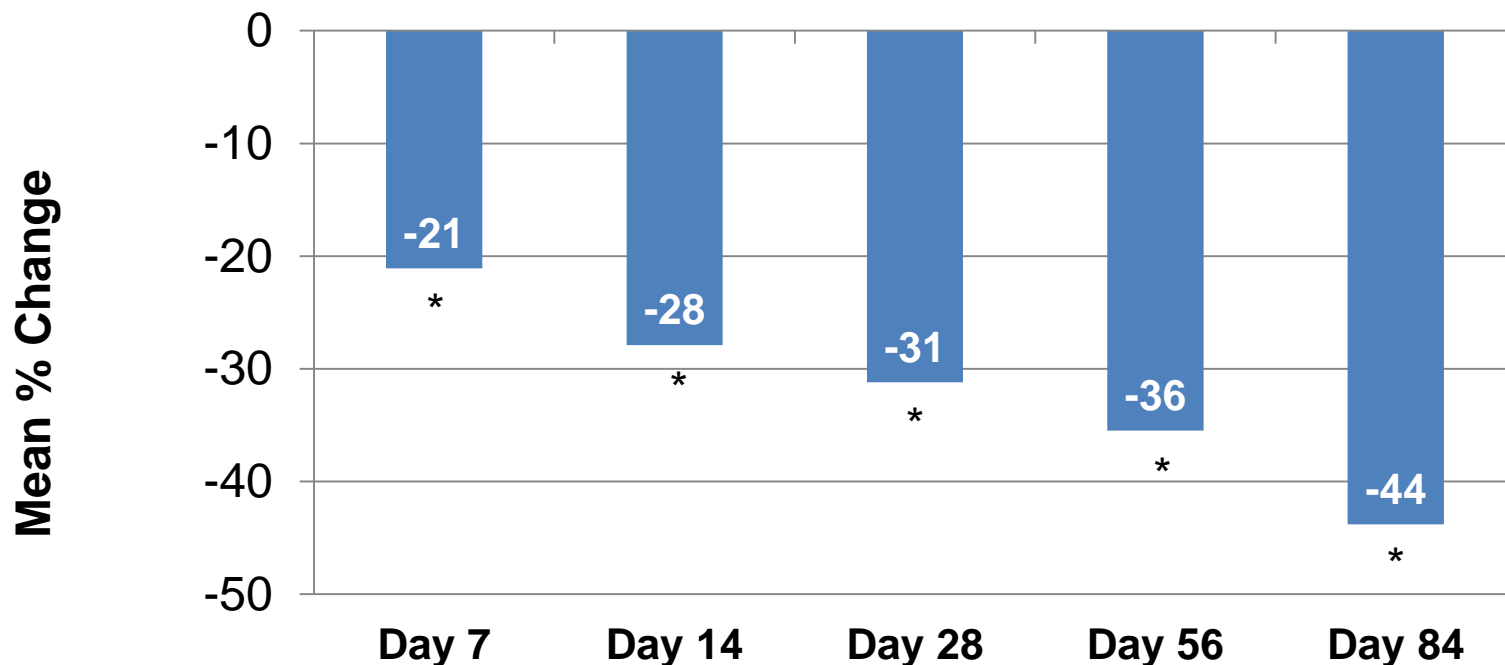
Statistically significant reduction lesions all visits

* $p \leq 0.01$ vs. Baseline

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LESION COUNTS – TOTAL LESIONS % CHANGE FROM BASELINE



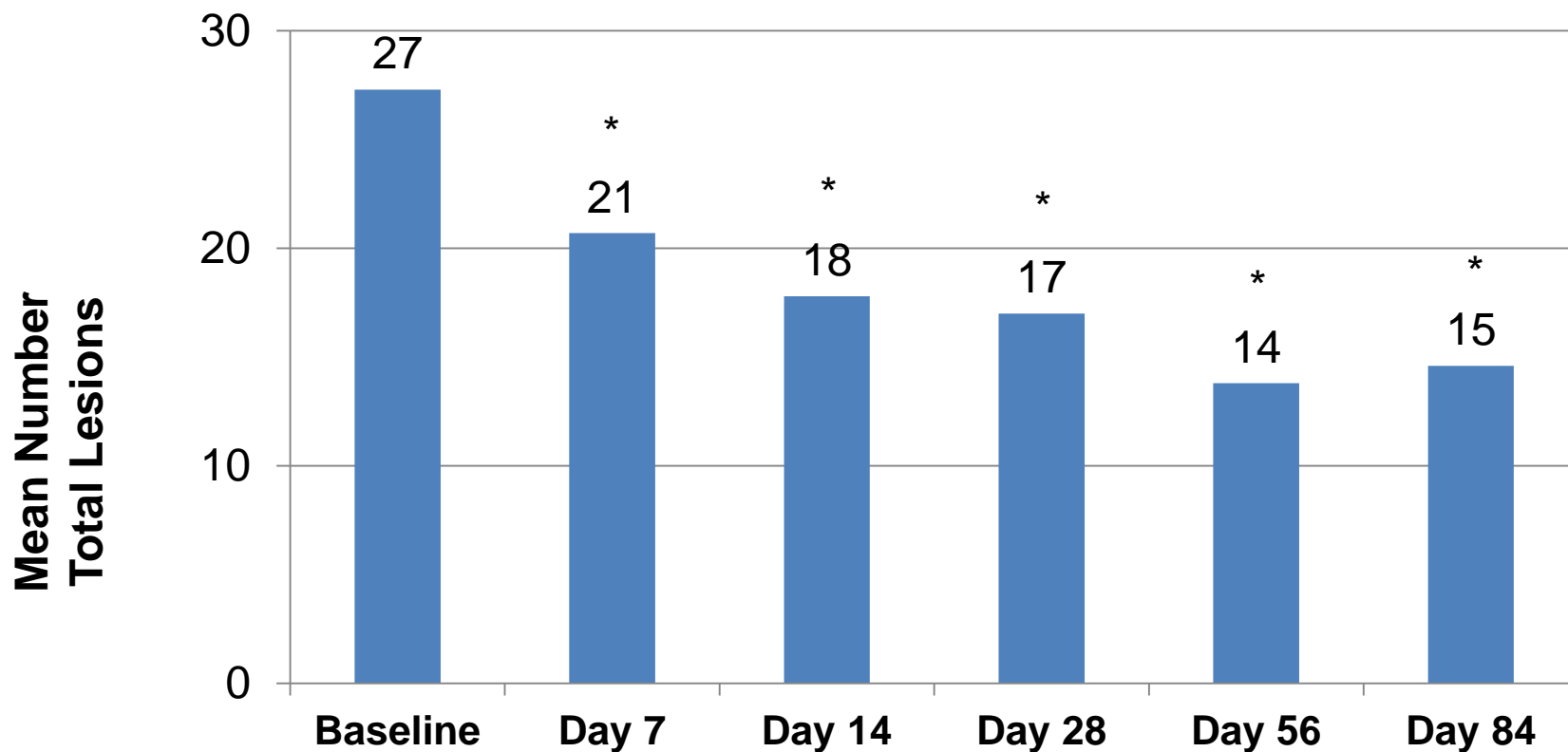
Statistically significant reduction lesions all visits

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TOTAL INFLAMMATORY LESION COUNT

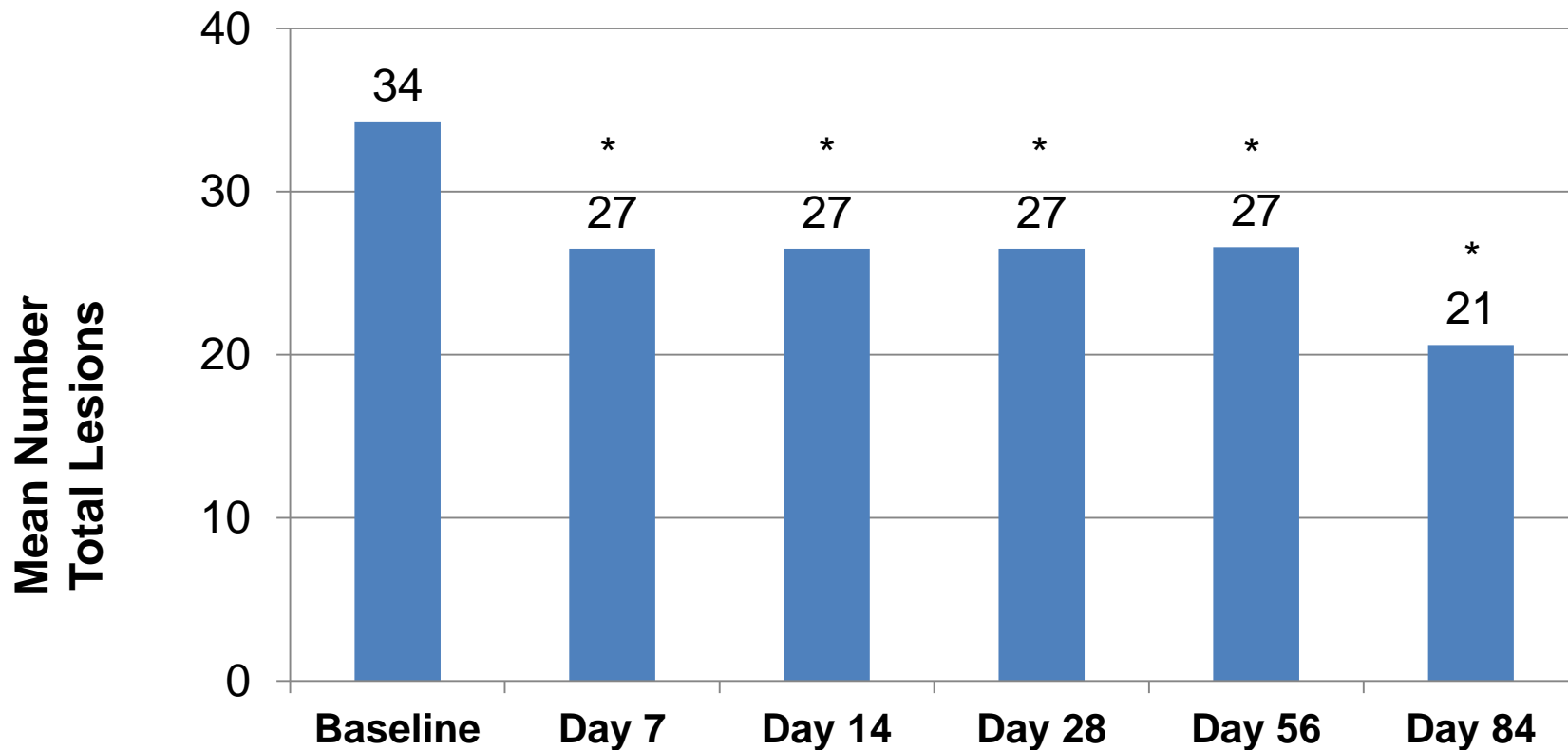


* $p \leq 0.01$ vs. Baseline

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TOTAL NON-INFLAMMATORY LESION COUNT

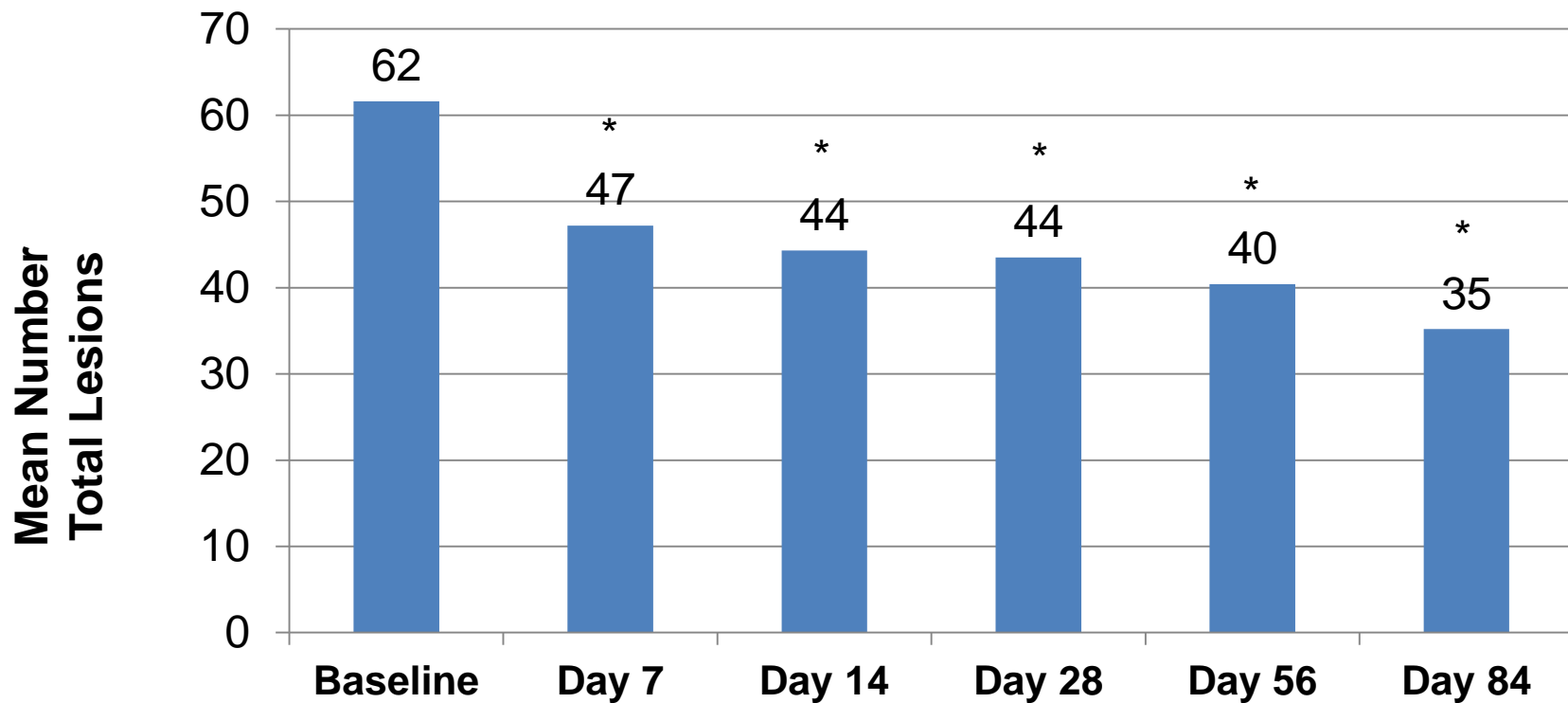


* $p \leq 0.01$ vs. Baseline

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TOTAL LESION COUNT (NON-INFLAMMATORY & INFLAMMATORY COMBINED)



* $p \leq 0.01$ vs. Baseline

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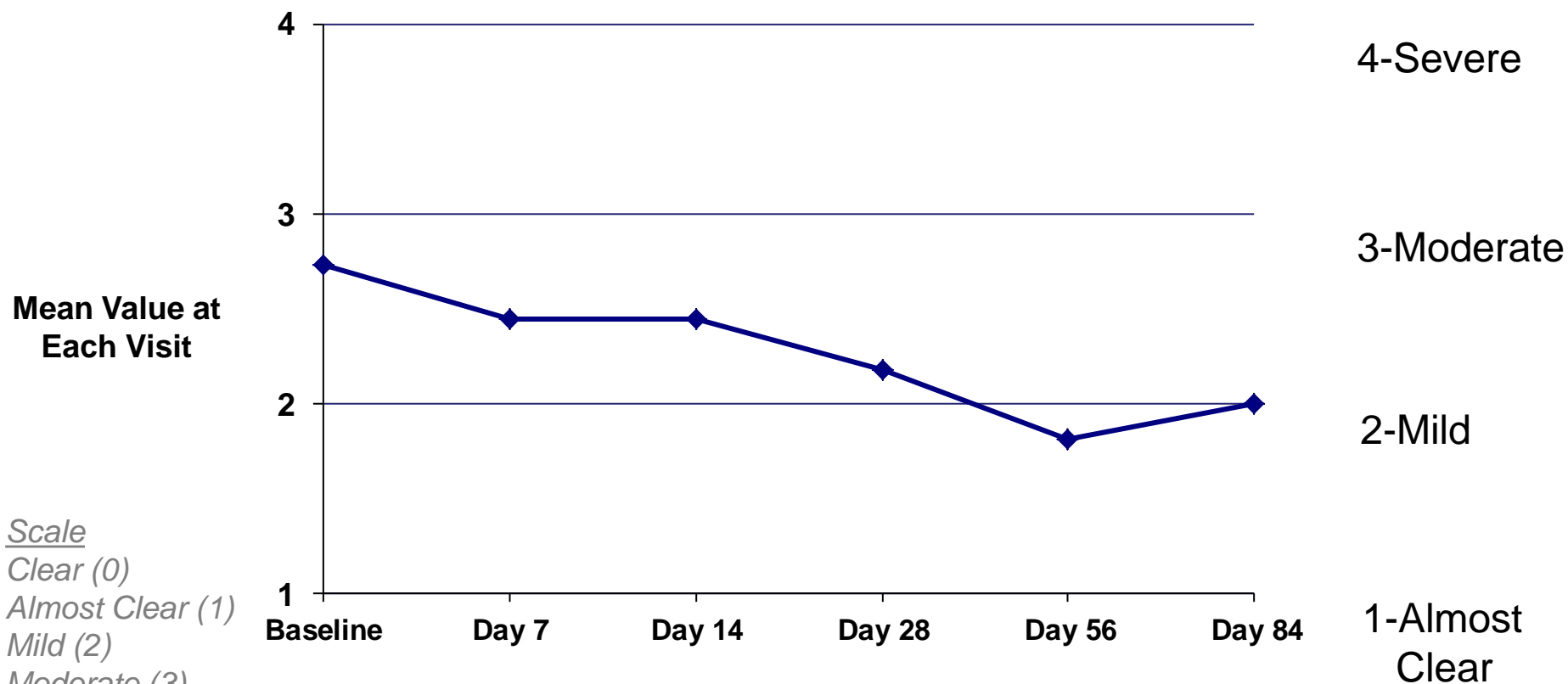
PHYSICIAN GLOBAL ASSESSMENT SCALE

0 - Clear	Normal, clear skin with no evidence of acne vulgaris
1 - Almost Clear	Skin is almost clear: rare non-inflammatory lesions present, with rare non-inflamed papules (papules must be resolving and may be hyperpigmented, though not pink)
2 - Mild	Some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only; no nodulo-cystic lesions)
3 - Moderate	Non-inflammatory lesions predominate, with multiple inflammatory lesions evident: several to many comedones and papules/pustules, up to two nodulo-cystic lesions may be present
4 - Severe	Inflammatory lesions are more apparent: many comedones and papules/pustules; there may or may not be a few nodulo-cystic lesions
5 - Very Severe	Highly inflammatory lesions predominate: variable number of comedones, many papules/pustules nodulo-cystic lesions

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PHYSICIAN GLOBAL ASSESSMENT



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TOLERABILITY

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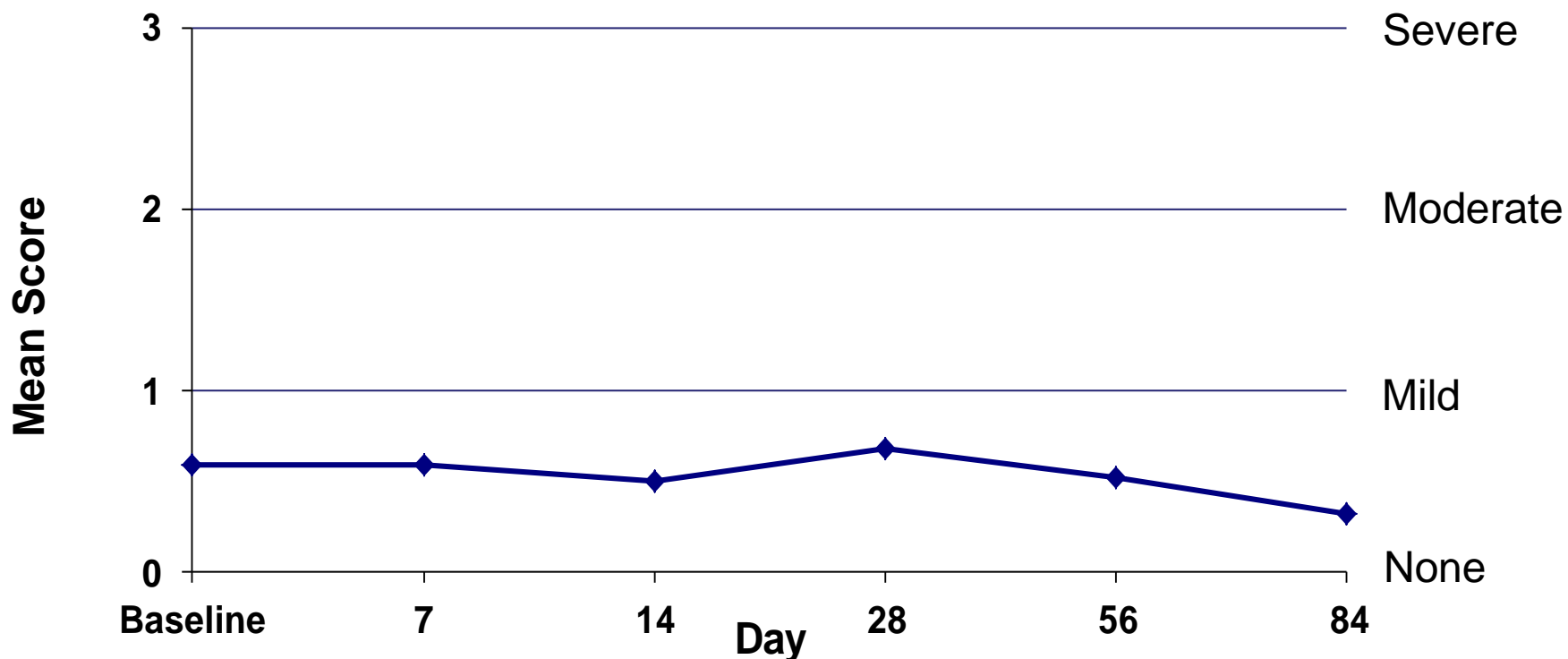
TOLERABILITY - ERYTHEMA

0	None – no erythema present (may be minor discoloration)
1	Mild – light pink, noticeable
2	Moderate – pink-red, easily noticeable
3	Severe – deep or bright red, may be warm to the touch

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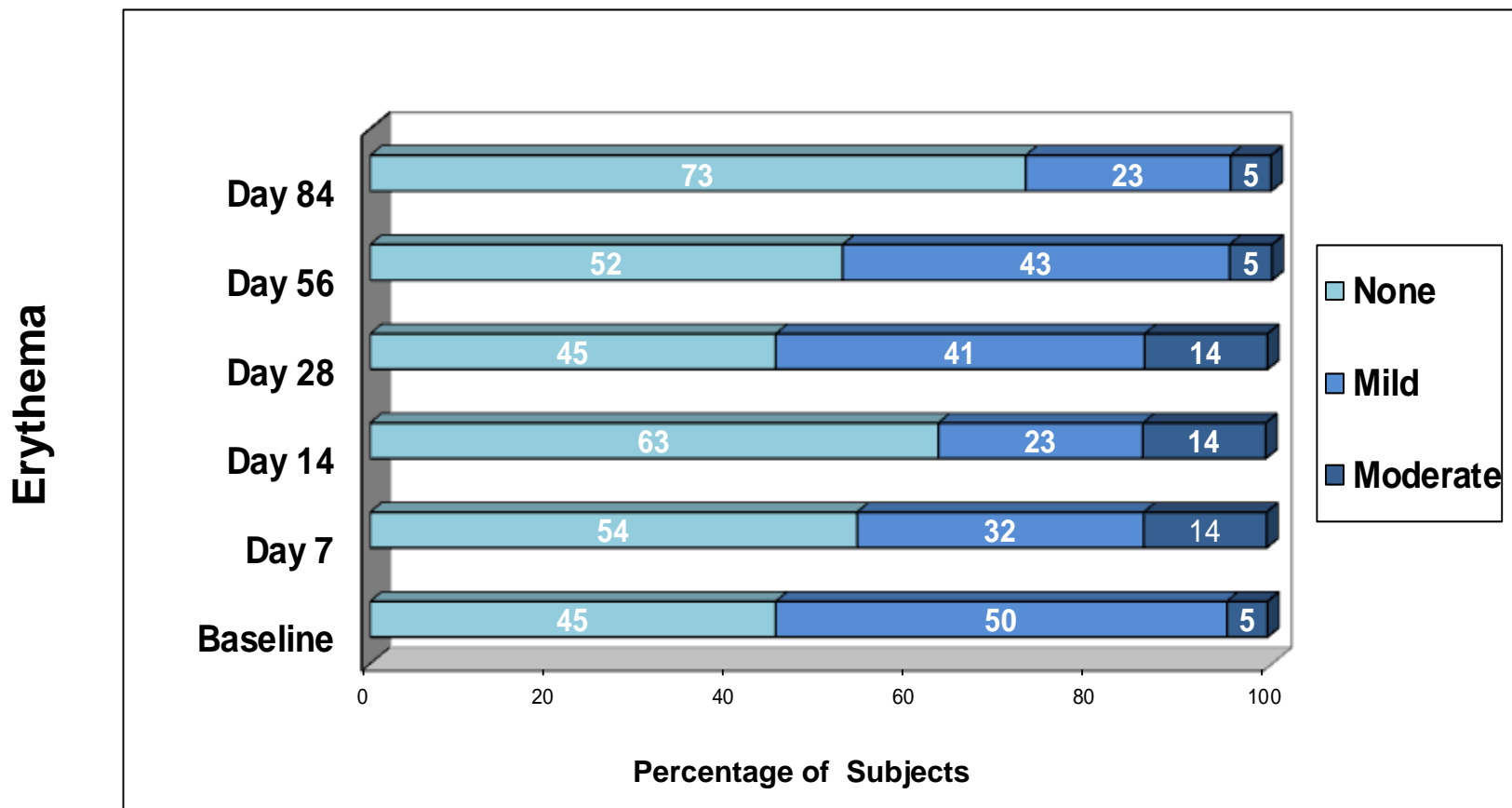
TOLERABILITY - ERYTHEMA



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TOLERABILITY ASSESSMENTS BY VISIT



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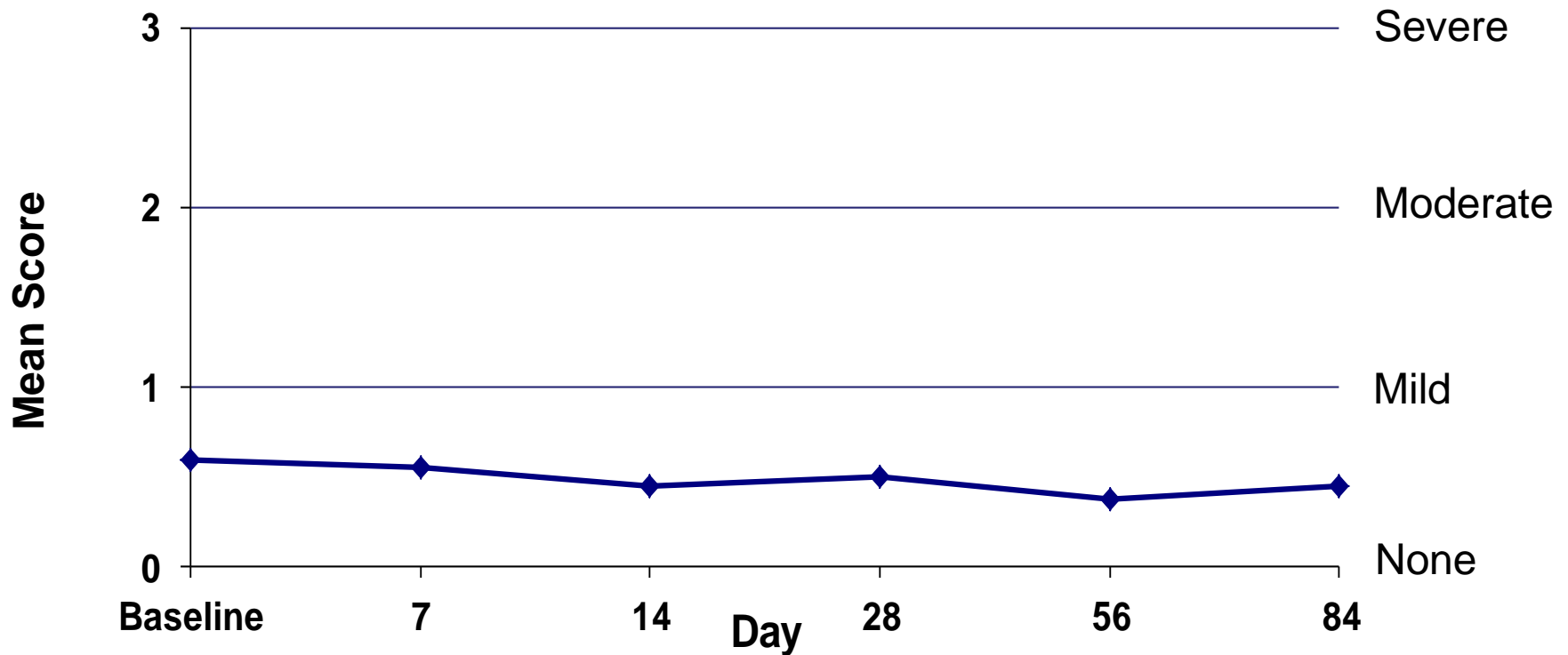
TOLERABILITY - DRYNESS

0	None – no dryness present
1	Mild – slight but definite roughness
2	Moderate – moderate roughness
3	Severe – marked roughness

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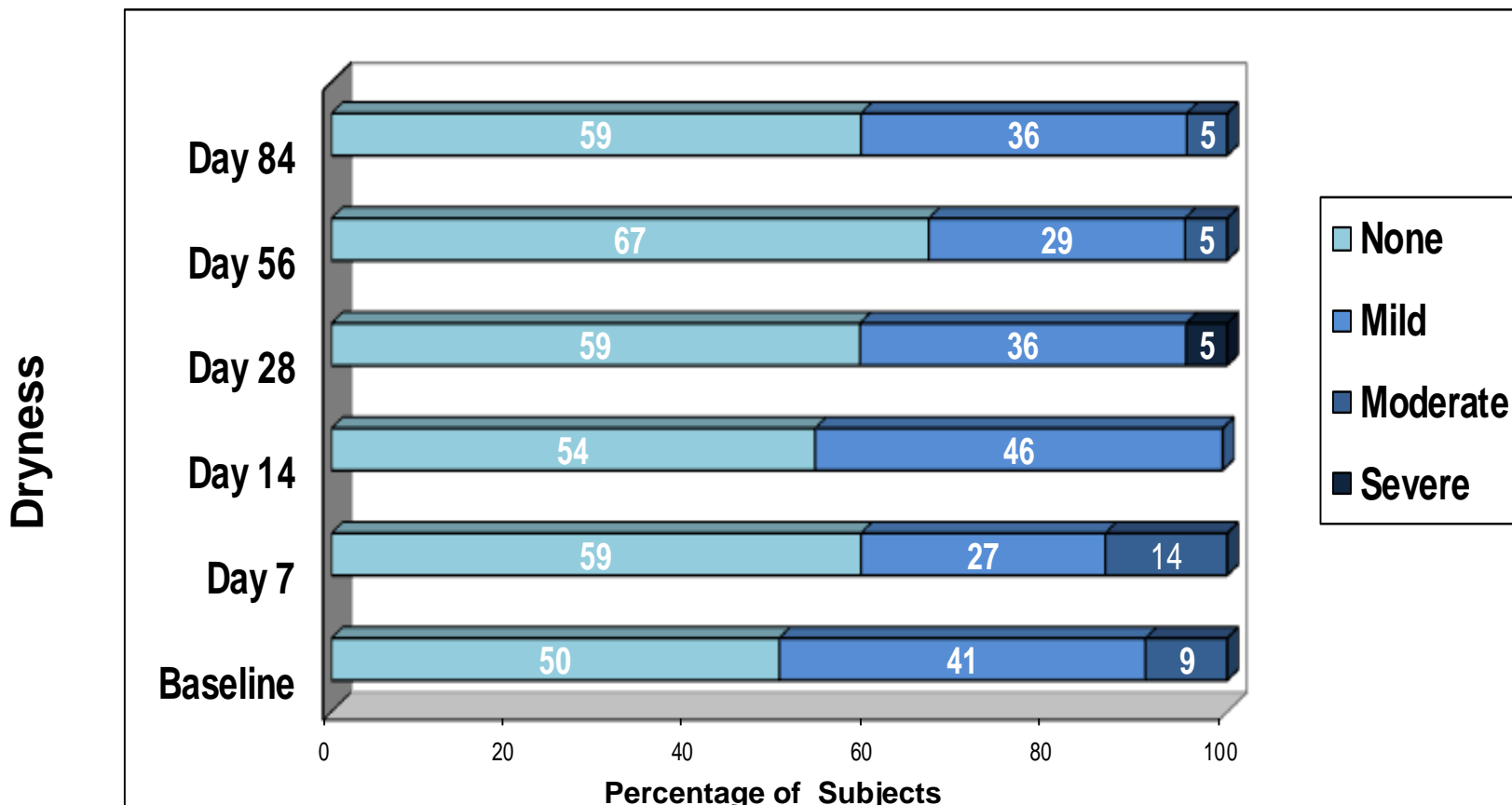
TOLERABILITY - DRYNESS



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TOLERABILITY ASSESSMENTS BY VISIT



(Day 28 1 Subject Severe Dryness)

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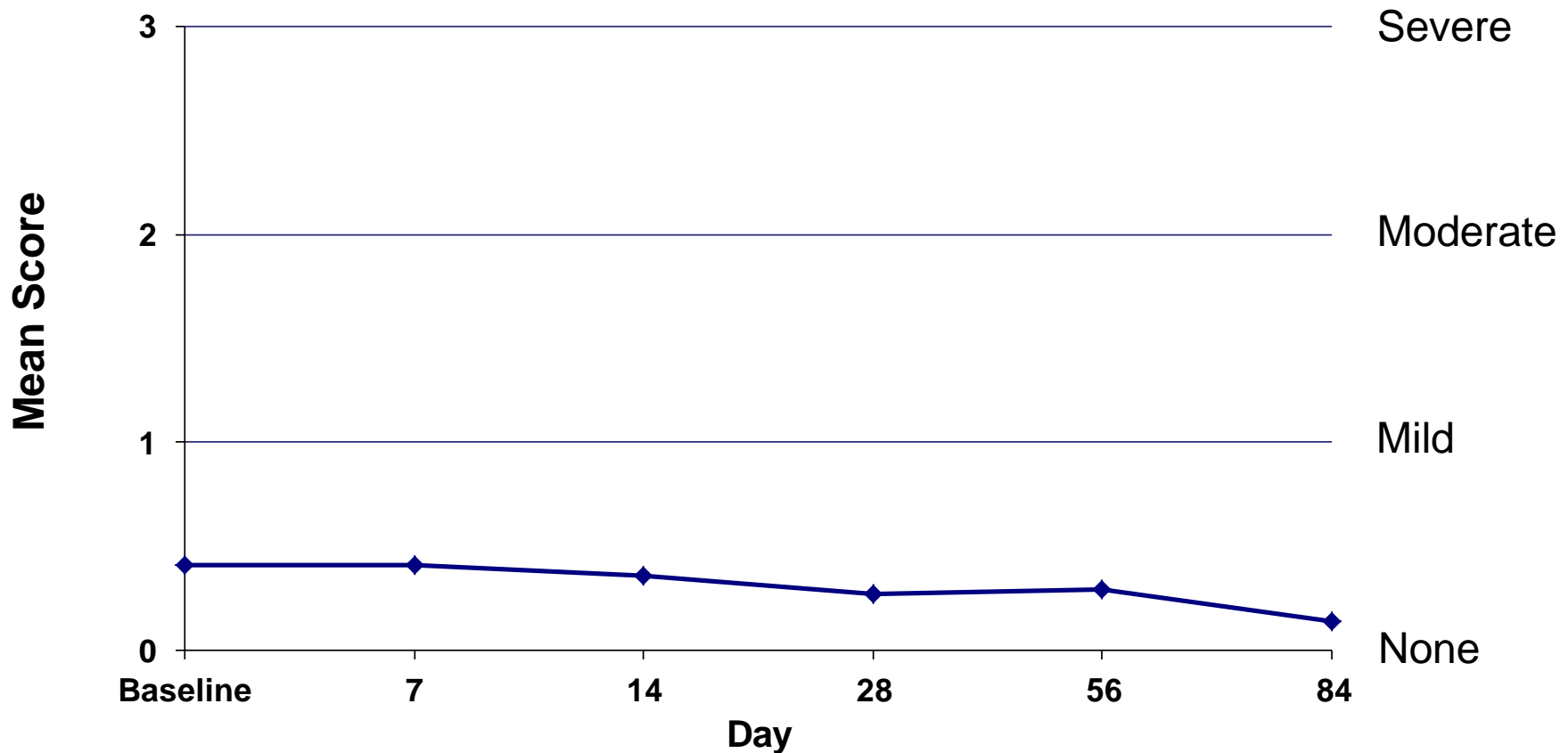
TOLERABILITY - PEELING

0	None – no peeling present
1	Mild – slight peeling
2	Moderate – definitely noticeable peeling
3	Severe – extensive peeling

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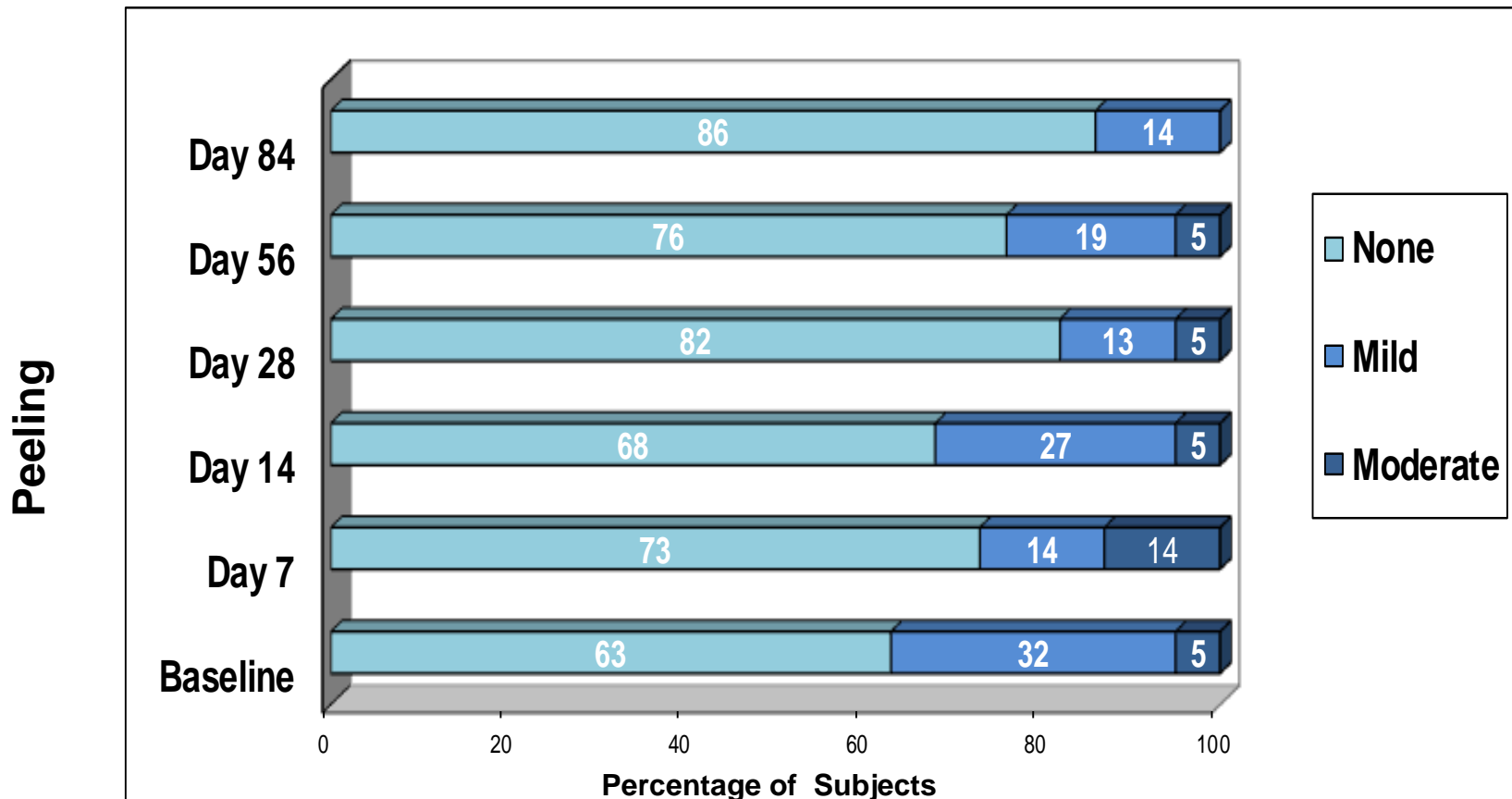
TOLERABILITY - PEELING



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TOLERABILITY ASSESSMENTS BY VISIT



(Day 28 1 Subject Severe Dryness)

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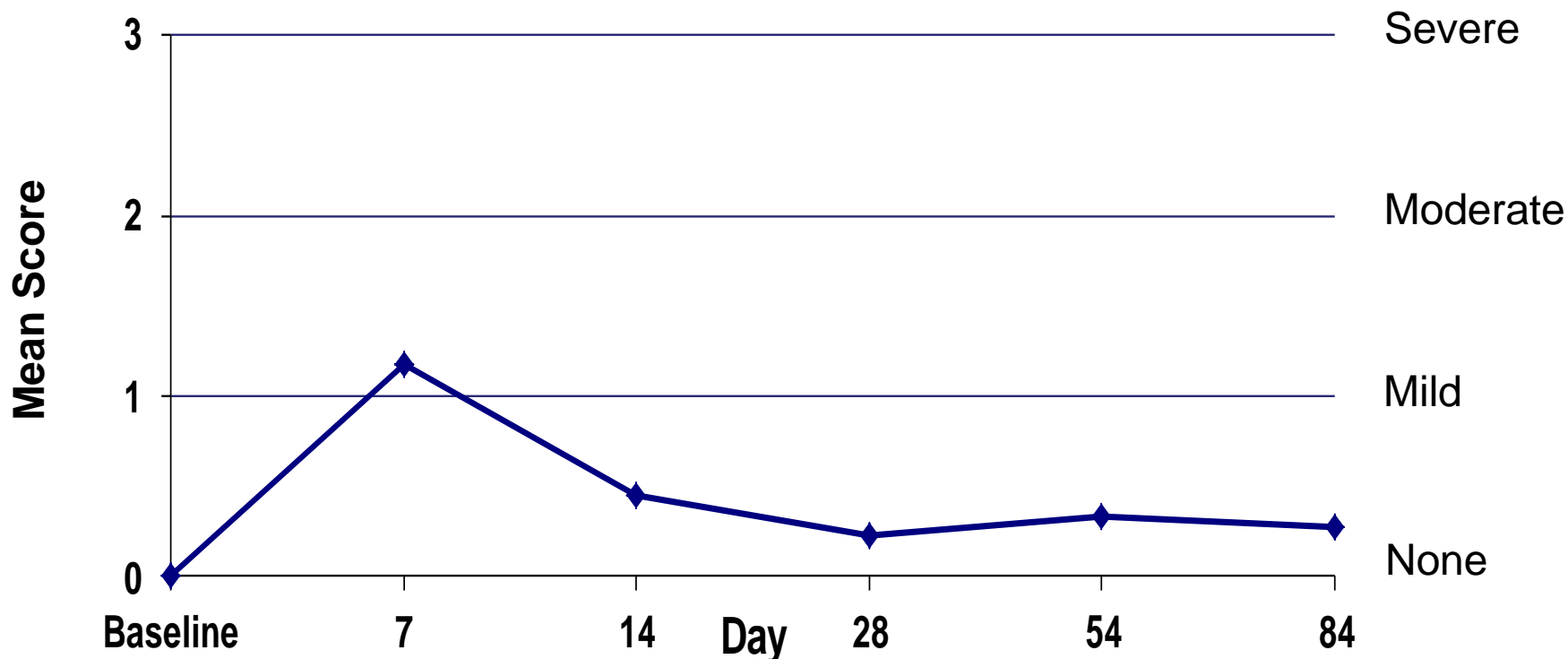
TOLERABILITY – STINGING/BURNING

0	None – no stinging/burning
1	Mild – light warm, tingling sensation, not really bothersome
2	Moderate – definite warmth, tingling/stinging sensation that is somewhat bothersome
3	Severe – hot tingling/stinging sensation which is disturbing normal activity

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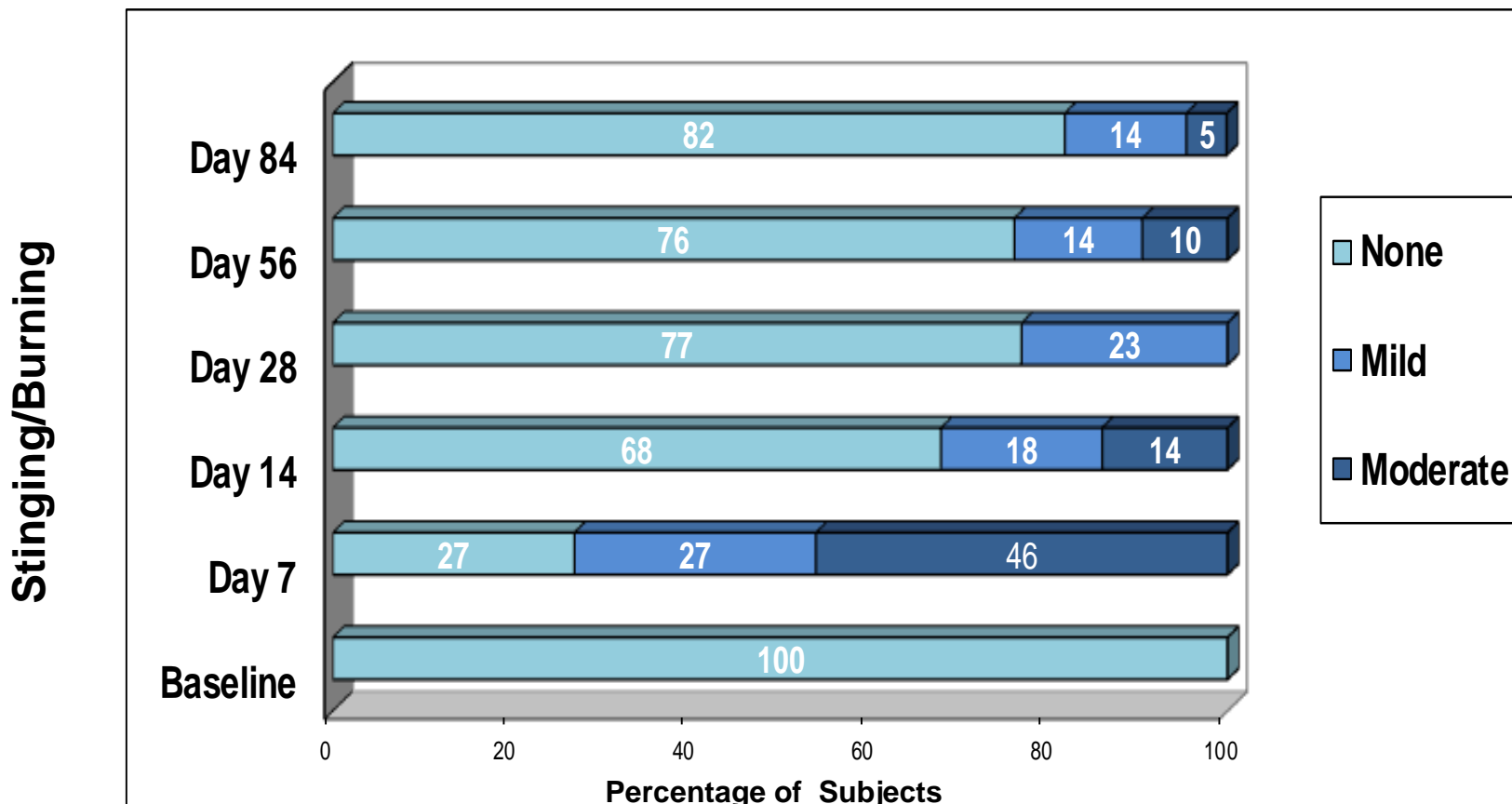
TOLERABILITY – STINGING/BURNING



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TOLERABILITY ASSESSMENTS BY VISIT



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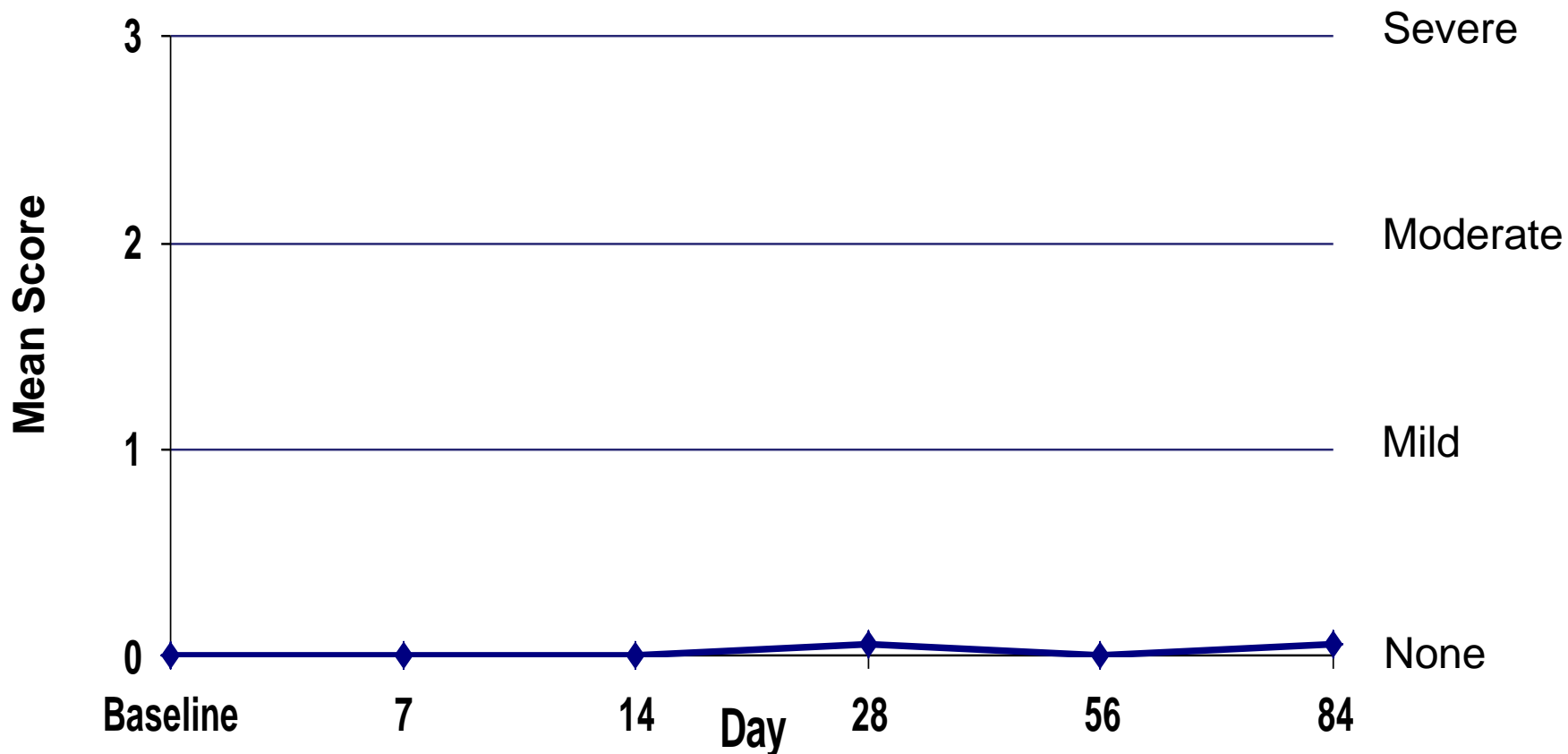
TOLERABILITY – ITCHING

0	None – no itching
1	Mild – occasional, slight itching
2	Moderate – constant or intermittent itching that is somewhat bothersome
3	Severe – bothersome itching which is disturbing normal activity

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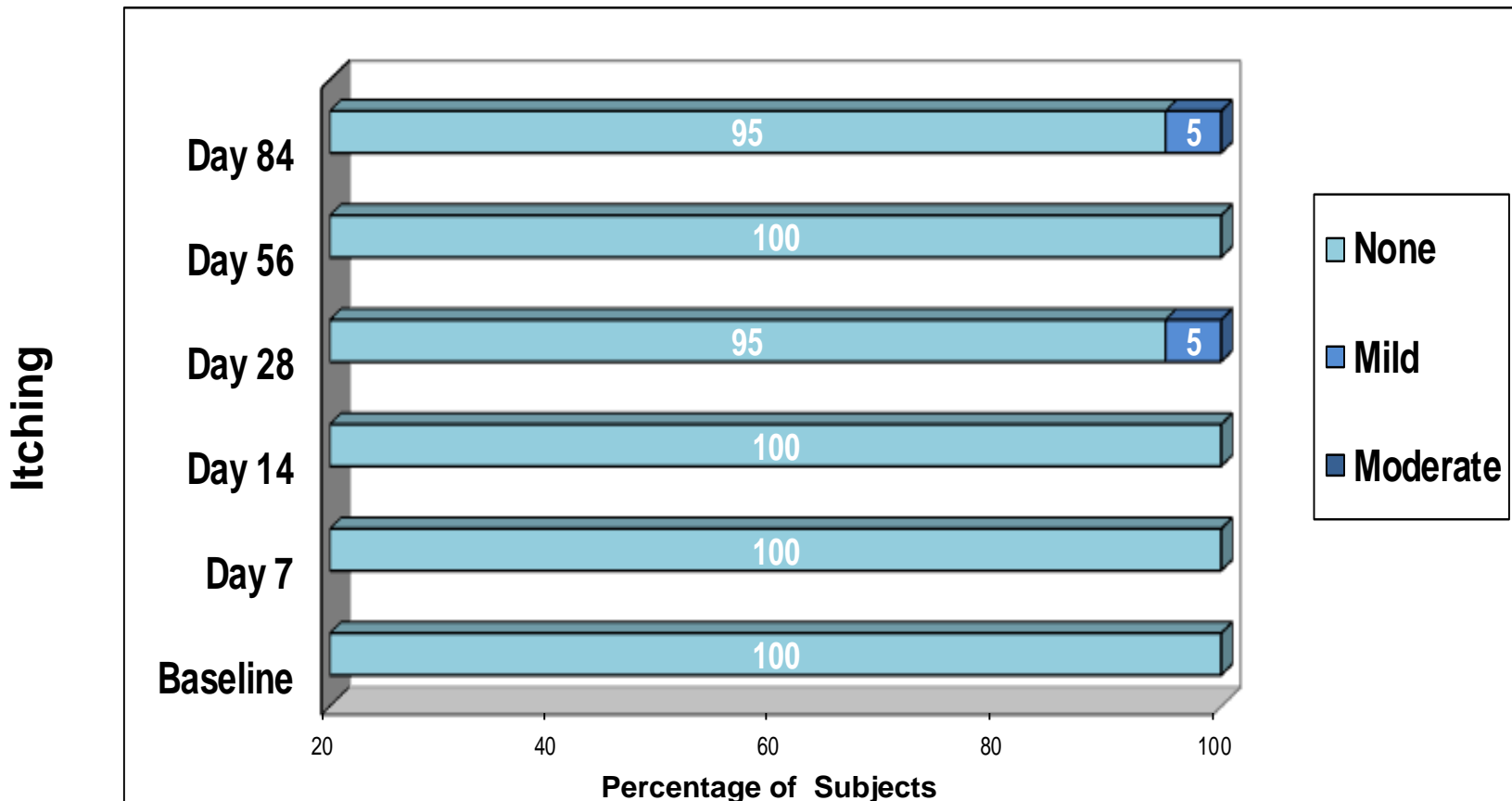
TOLERABILITY – ITCHING



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TOLERABILITY ASSESSMENTS BY VISIT



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SUBJECT QUESTIONNAIRES

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TREATMENT RELATED ADVERSE EVENTS

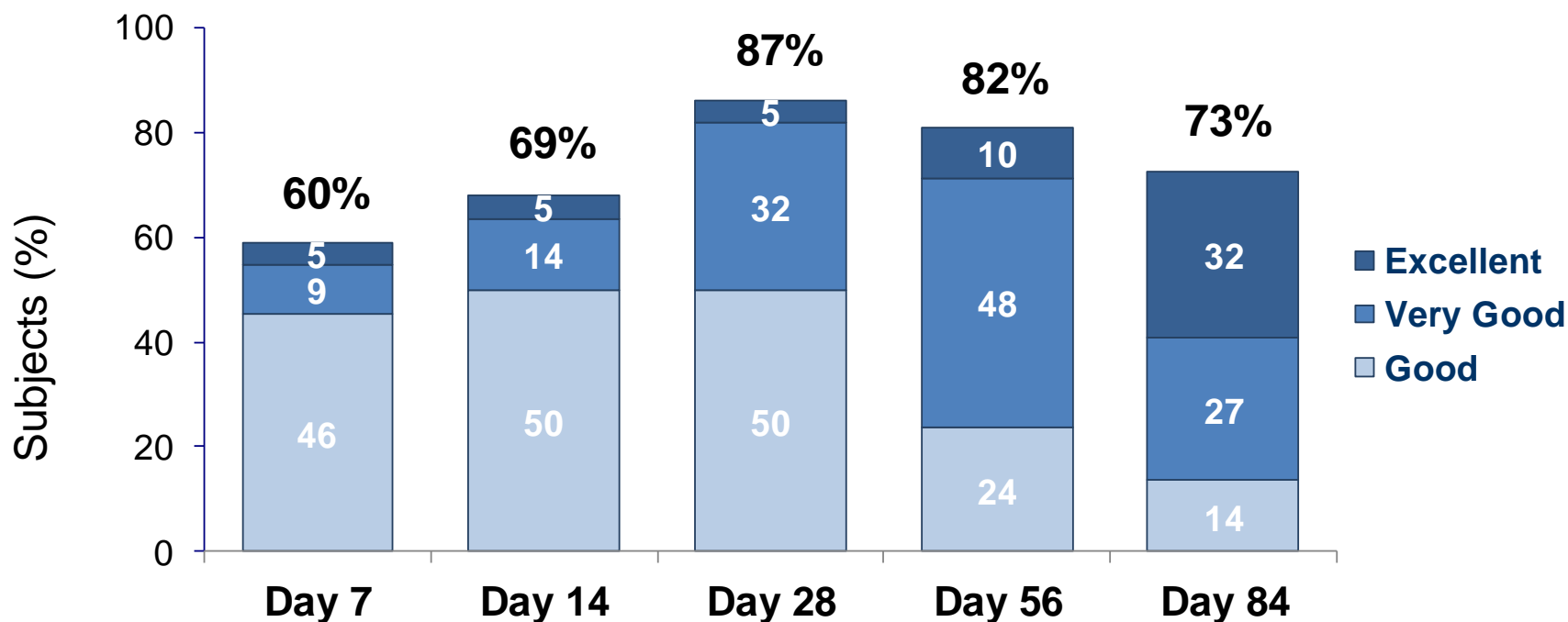
ADVERSE EVENT DESCRIPTION	AE INTENSITY	TOTAL # SUBJECTS
Facial Dryness and Peeling*	Severe	1

* Rated by Investigator, no treatment required by subject

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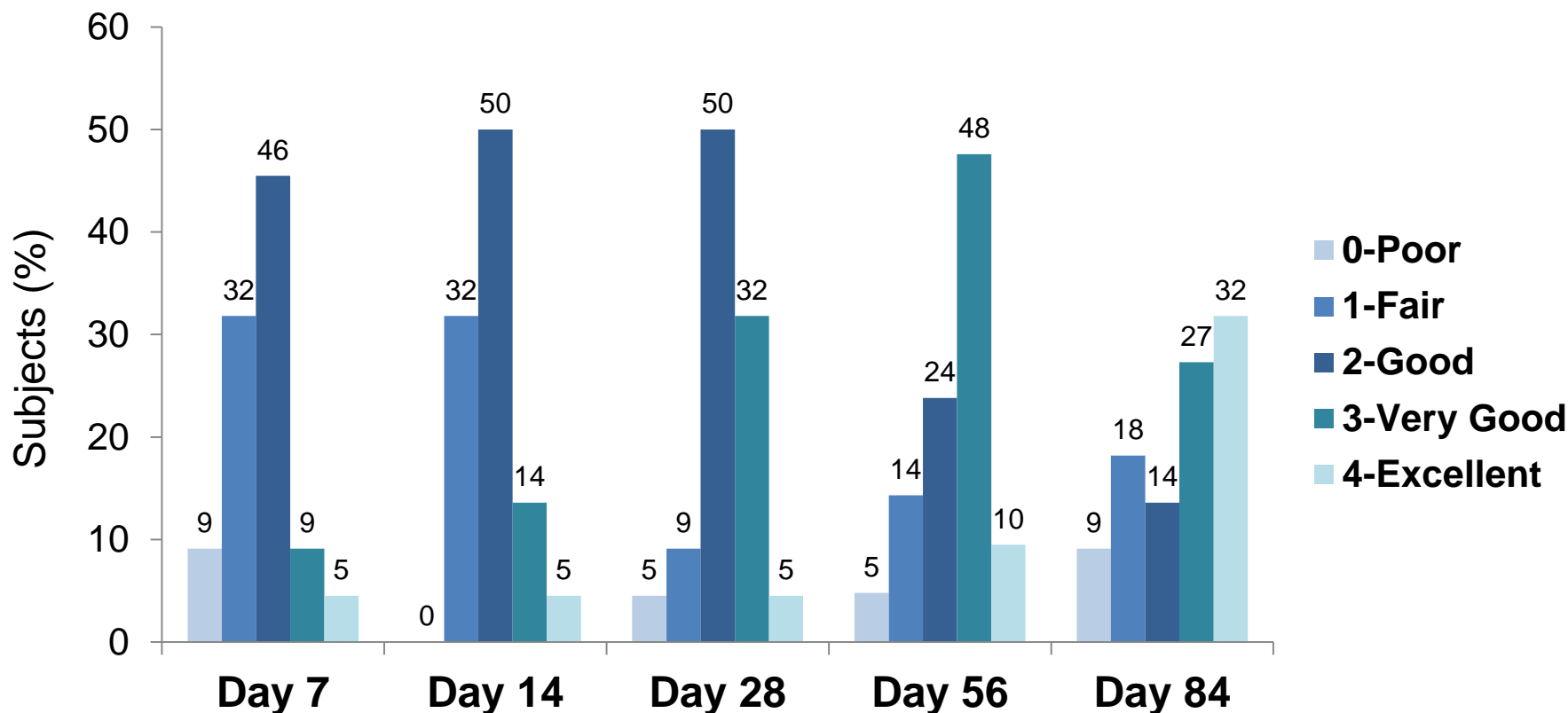
SUBJECT SELF-ASSESSED ACNE IMPROVEMENT (Good, Very Good & Excellent)



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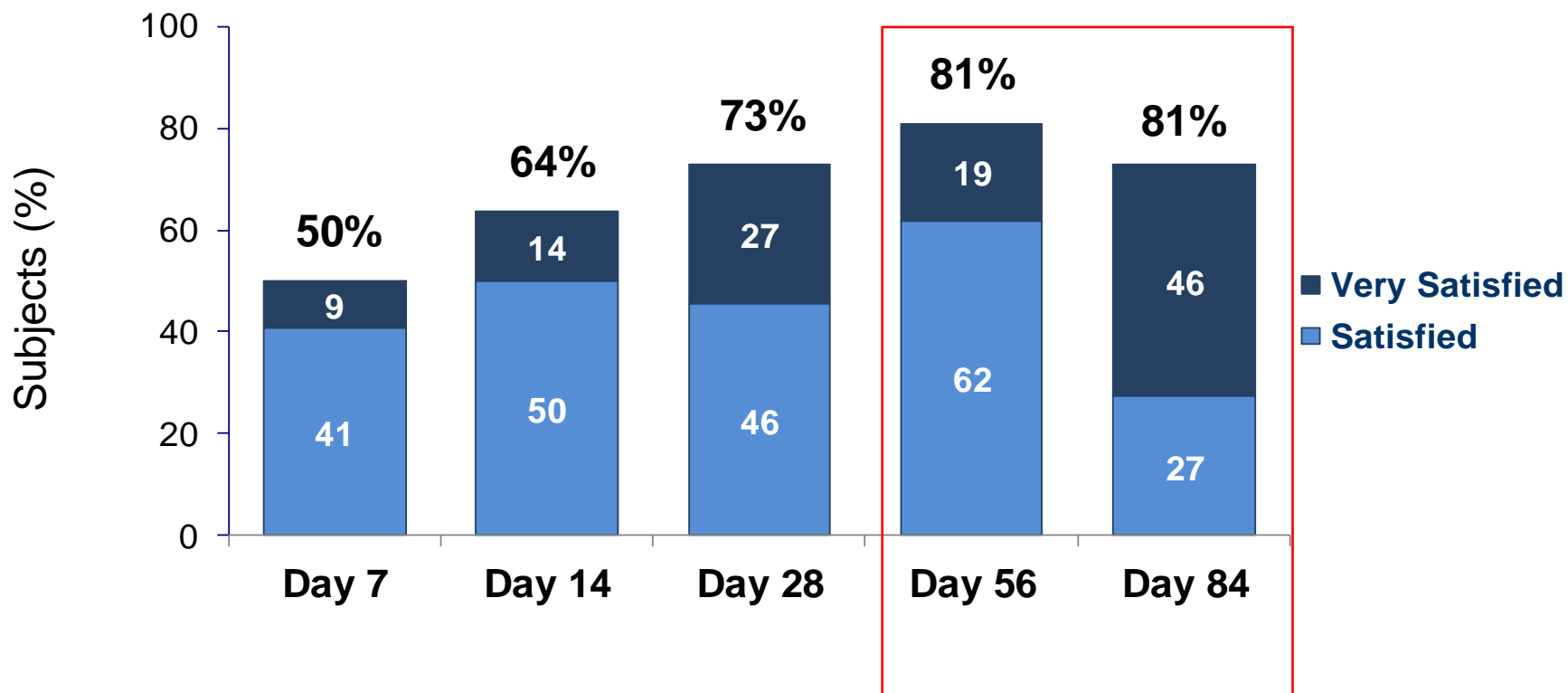
SUBJECT SELF-ASSESSED ACNE IMPROVEMENT



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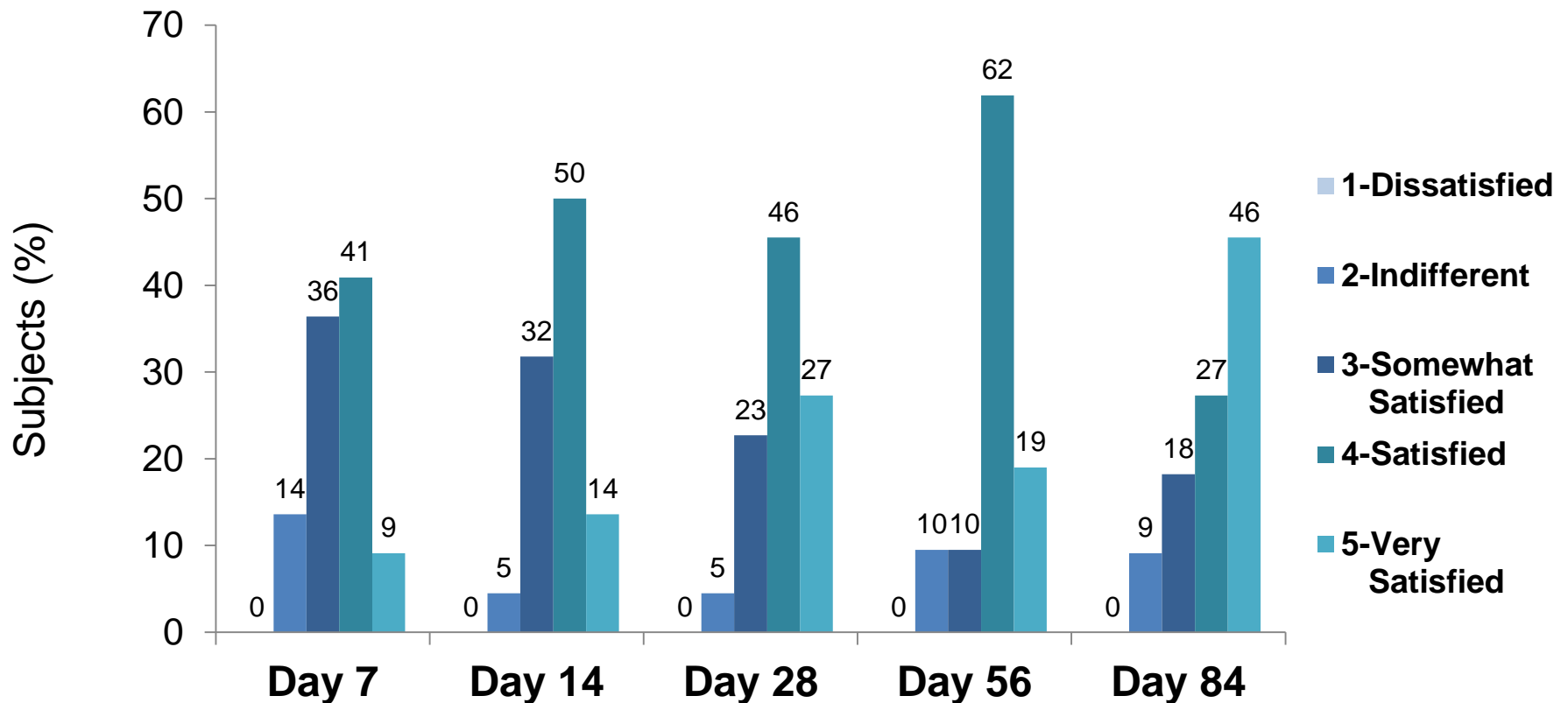
SUBJECT SELF-ASSESSED SATISFACTION OF ACNE IMPROVEMENT (Satisfied + Very Satisfied)



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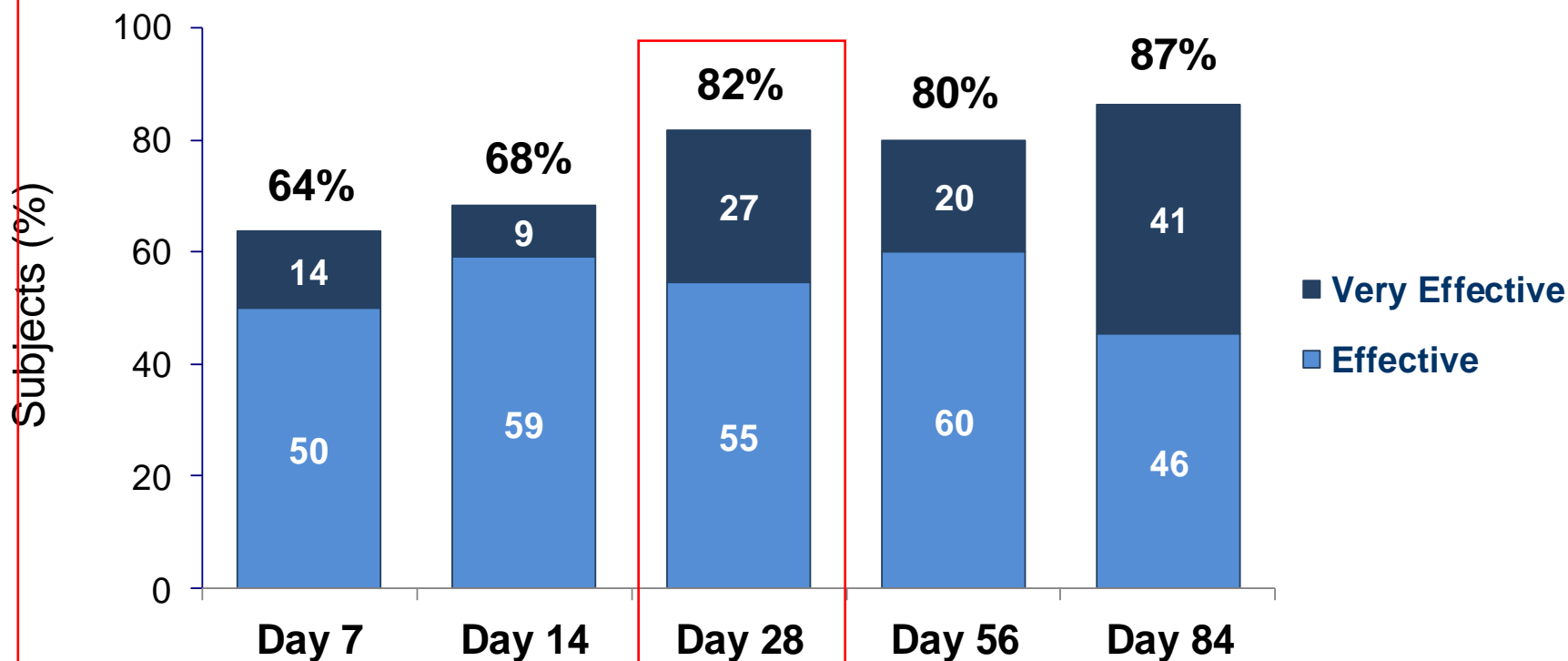
SUBJECT SELF-ASSESSED SATISFACTION OF ACNE IMPROVEMENT



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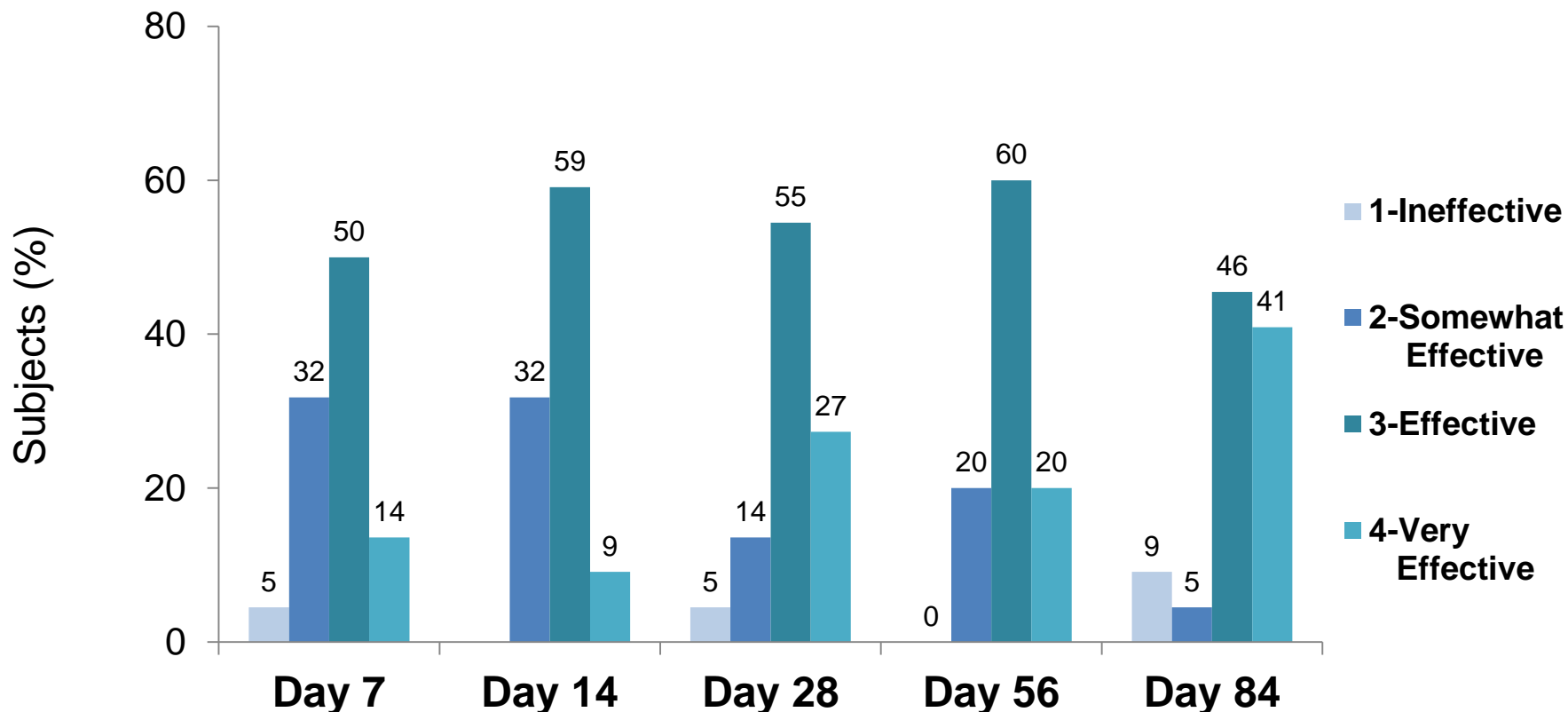
SUBJECT QUESTIONNAIRES EFFECTIVENESS OF TREATMENT PRODUCTS (Very Effective + Effective)



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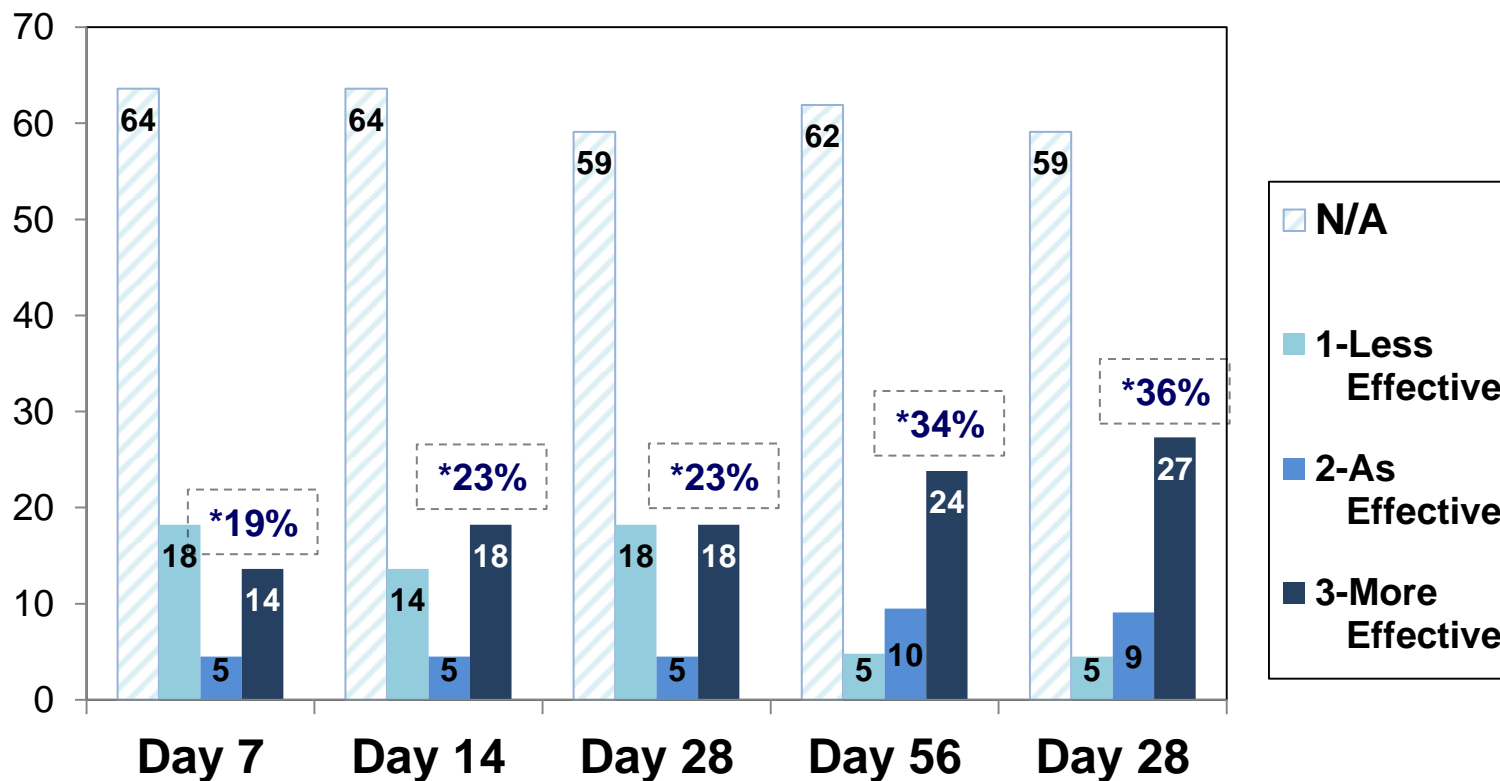
SUBJECT SELF-ASSESSED EFFECTIVENESS OF TREATMENT PRODUCTS



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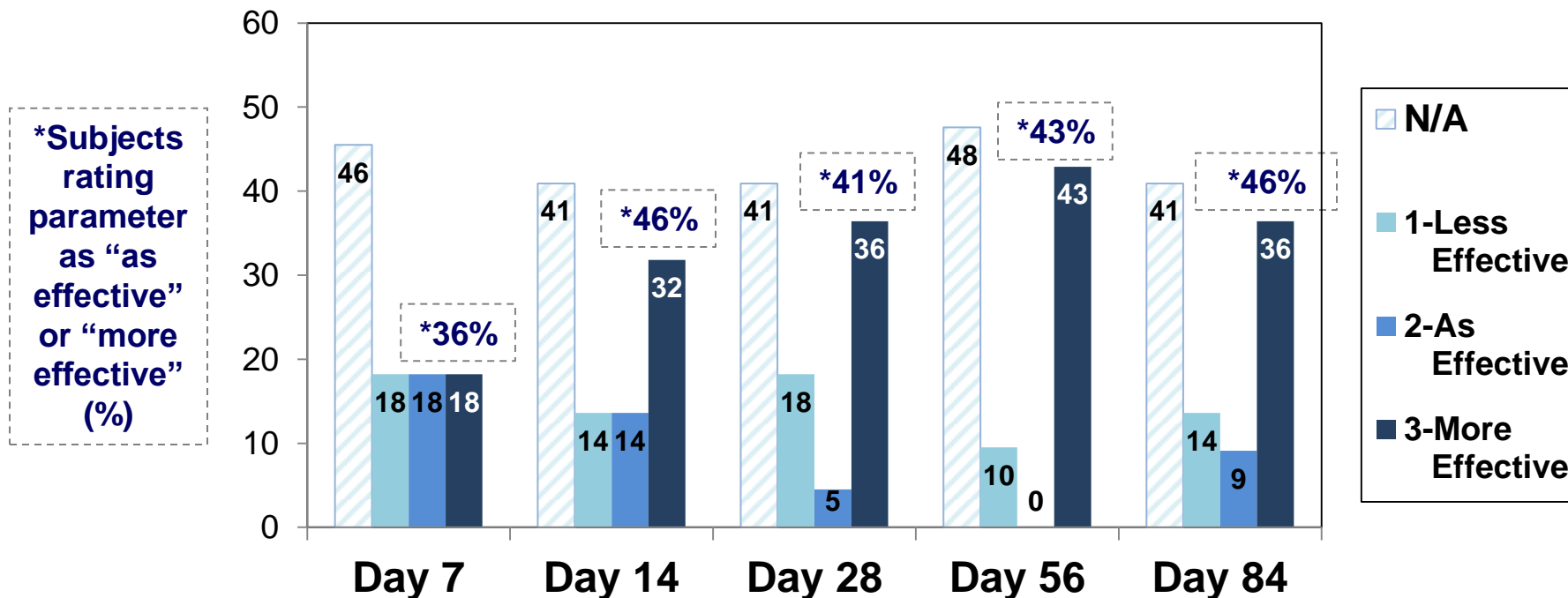
TREATMENT PRODUCT VS. OTHER Rx PRODUCTS USED IN PAST



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TREATMENT PRODUCT VS. OTHER OTC PRODUCTS USED IN PAST



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SUBJECT PHOTOS



BASELINE

DAY 14

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

NSL, 002



BASELINE

DAY 28

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

NSL, 002



BASELINE

DAY 14

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MBH, 004



BASELINE

DAY 28

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MBH, 004



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MBH, 004



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MBH, 004



BASELINE

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD



DAY 84

MBH, 004



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MBM, 006



BASELINE

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD



DAY 84

MBM, 006



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MBM, 006



BASELINE

DAY 7

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DMR, 009



BASELINE

DAY 14

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DMR, 009



BASELINE

DAY 28

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DMR, 009



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DMR, 009



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DMR, 009



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DMR, 009



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MYW, 018



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MYW, 018



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

MYW, 018



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DGV, 022



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DGV, 022



BASELINE

DAY 84

OMP, INC. CLZ003 - SITE #1 LEONARD SWINYER, MD

DGV, 022

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CONCLUSIONS

- Statistically significant reduction in lesions all time points
- Clinically visible signs reduction acne within 2 weeks
- Well tolerated (by week 2 mean erythema, peeling, dryness, stinging/burning, itching was between “none” and “mild”)
- 81% subjects self assessed very satisfied or satisfied with their acne improvement
- 87% subjects self assessed regimen very effective or effective at Day 84 (82% at Day 28)
- 73% subjects self assessed very good or good acne improvement at Day 84 (82% at Day 28)
- Pump delivery problems Therapeutic Lotion and leaking Pore Therapy bottles impacted compliance