ERCHONIA LUNULA™

Toenail Onychomycosis Clinical Study Results

ERCHONIA CORPORATION

September 12, 2014

Study results based on the protocol: An Evaluation of the Effect of the Erchonia LUNULA™ on Treating Toenail Onychomycosis Clinical Study Protocol

Version 7.0; December 27, 2012

OrganiCare

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STUDY INFORMATION

SPONSOR
Erchonia Corporation
2021 Commerce Drive
McKinney, TX 75069
Contact: Mr. Steven Shanks, President
Telephone: 214-544-2227
Fax: 214-544-2228
e-mail: sshanks@erchonia.com

MONITOR
Erchonia Corporation
2021 Commerce Drive
McKinney, TX 75069
Contact: Mr. Joseph Zapolsky
Telephone: 214-544-2227
Fax: 214-544-2228
e-mail: jzapolsky@erchonia.com

CLINICAL CONSULTANT
Regulatory Insight, Inc.
Nashville Office
1503 Red Oak Drive
Brentwood, TN 37027
Contact: Elvira Walls, Clinical Consultant
Telephone: 615-712-9743
Fax: 615-712-9852
e-mail: Elvira@reginsight.com

REGULATORY CONSULTANT
Regulatory Insight, Inc.
Denver Office
33 Golden Eagle Lane
Littleton, CO 80127
Contact: Kevin Walls, Principal Consultant
Telephone: 720-962-5412
Fax: 720-962-5413
e-mail: kevin@reginsight.com

PRINCIPAL INVESTIGATOR/TEST SITE
Mr. Robert Sullivan
BSc. (Hons) Podiatry, MSc. Pod Surgery, PgC.Acup, .FIChPA. M.Inst.Ch.P.
Clinical Director
Midleton Foot Clinic
22 New Cork Road,
Midleton,
Co. Cork, Ireland
Telephone: 021-4621044
e-mail: midletonfootclinic@gmail.com

ETHICS COMMITTEE
Institute of Chiropodists and Podiatrists (Ireland) Ethics Board
Approval #: LLNS/RS0312

PURPOSE OF STUDY
The purpose of this clinical study was to demonstrate the efficacy of the Erchonia LUNULA™, manufactured by Erchonia Corporation, for the treatment of onychomycosis of the toenail, when applying the LUNULA™ to the toenail for 12 minutes one time per week for 4 consecutive weeks, for a total of 4 treatment administrations.

STUDY DESIGN
This clinical study was a single site, single group (active procedure only) non-randomized non-blinded design.

The rationale for this study design can be found in the accompanying clinical study protocol document.

STUDY DEVICE

The Erchonia LUNULA™ Laser is a dual-diode laser of 635 nm and 405 nm wavelength. The light emitting diodes are manufactured by DLC and classified by the Center for Devices and Radiological Health (CDRH) as Class II laser diodes. The LUNULA™ is a portable floor device with an AC power adapter.

The LUNULA™ Laser has the following specifications:

Power	16.0-18.5mW for the 635nm diode 21.5-24.0mW for the 405nm diode
Wavelength	635nm & 405nm
Waveform	Constant Wave (CW)
Energy Source	Dual diode collected then line dispersed (coherent)
Power Supply	100-240 VAC 50/60 Hz
Energy Delivery	Portable floor device
Treatment Time	12 minutes

The Erchonia LUNULA™ Laser is shown in Figure 1 below:

Figure 1: The Erchonia LUNULA™ Laser

The Erchonia LUNULA™ is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there was no possible instance of residual effect, a pair of specialty glasses was provided for use during in-office procedure applications with the Erchonia LUNULA™ laser device. These safety glasses are Kentek Corporation Filter #6101 light blue glasses with approximate VLT 63% that sufficiently and effectively block the laser light spectrum of the LUNULA™ laser device as follows: 405nm (OD 1.22) & 635nm (OD 2.07).

STUDY SUBJECT POPULATION

RECRUITMENT AND COMPENSATION

All qualifying study subjects were recruited from among the investigator's normal pool of patients who voluntarily came to his office seeking treatment for toenail onychomycosis.

Qualifying subjects were neither charged nor compensated for participating in the clinical study, including the cost of the laser procedures.

SAMPLE

- One hundred and nine (109) subjects were enrolled in the study.
- Of the 109 subjects, all had a great toenail with qualifying onychomycosis enrolled and 30 subjects had multiple toenails with qualifying onychomycosis enrolled, resulting in a total of 139 toenails enrolled in the study, as follows:
  - ✓ 109 great toenails
  - ✓ 28 second (2nd) digit toenails
  - ✓ 2 third (3rd) digit toenails

- Eighty-one (81) subjects had only a great toenail enrolled.
- All multiple toenails enrolled from the same subject were on the same foot side.
- All 139 toenails had positive mycology for onychomycosis upon lab testing at enrollment.
- All 139 toenails completed the 4 week treatment administration protocol and were successfully followed through to the final week 48 study assessment visit without deviation.
- All 139 toenails received the active treatment with the Erchonia LUNULA™ study device.

ELIGIBILITY CRITERIA

All subjects and toenails that qualified as eligible for participation in this clinical study satisfied each of the following inclusion criteria and none of the following exclusion criteria.

Inclusion Criteria

- Onychomycosis present in at least one great toenail, identified as current bacterial/fungal infection classified by the investigator as onychomycosis, with the nail presenting positive on visual inspection for somewhat thickened nail plate with a cloudy appearance and some discoloration (white to yellow to brown).
- Subject is willing and able to refrain from employing other (non-study) treatments (traditional or alternative) for his or her toenail onychomycosis throughout study participation.
- Subject is willing and able to refrain from the use of nail cosmetics such as clear and/or colored nail lacquers throughout study participation.
- Male or female.
- 18 years of age or older.

Exclusion Criteria

- Spikes of disease extending to nail matrix in the affected great toenail(s).

- Infection involving lunula of the affected toenail(s), e.g., genetic nail disorders, primentary disorders.
- Affected great toenail(s) has less than 2mm clear (unaffected) nail plate length beyond the proximal fold.
- Presence of dermatophytoma (defined as thick masses of fungal hyphae and necrotic keratin between the nail plate and nail bed) on the affected great toenail(s).
- Chronic plantar (moccasin) tinea pedis.
- History of current or past psoriasis of the skin and/or nails.
- Concurrent lichen planus.
- Onychogryphosis.
- Any of the following conditions of the affected great toenail(s) is present:
  - proximal subungual onychomycosis
  - white superficial onychomycosis
  - dermatophytoma or "yellow spike/streak"
  - exclusively lateral disease
- Confounding problems/abnormalities of the great toenail(s).
- Any abnormality of the affected great toenail(s) that could prevent a normal appearing nail if clearing of infection is achieved.
- Inability for the affected great toenail(s) to become normal in the opinion of the investigator.
- History of multiple repeated failures with previous therapies for onychomycosis.
- Trauma to the affected great toenail(s).
- Use of oral antifungal agents in the past 6 months.
- Use of topical antifungal agents in the past 1 month.
- Prior surgical treatment of the affected great toe(s).
- Subject is unwilling or unable to refrain from employing other (non-study) treatments (traditional and alternative) for his or her toenail onychomycosis throughout study participation.
- Subject is unwilling or unable to refrain from the use of nail cosmetics such as clear and/or colored nail lacquers until the end of study participation.
- Cancer and/or treatment of any type of cancer within the last six months.
- Peripheral vascular disease or peripheral circulatory impairment.
- History of uncontrolled diabetes mellitus.
- Known immunodeficiency.
- Known sensitivity, or contraindication, to light therapy.
- Pregnant, breast feeding, or planning pregnancy prior to the end of study participation.
- Serious mental health illness such as dementia or schizophrenia; psychiatric hospitalization in the past two years.
- Developmental disability or cognitive impairment that would preclude adequate comprehension of the informed consent form and/or ability to follow study subject requirements and/or record the necessary study measurements.
- Involvement in litigation and/or receiving disability benefits related in any way to the parameters of the study.
- Participation in a clinical study or other type of research in the past 30 days.

STUDY PROCEDURE ADMINISTRATION

PROCEDURE ADMINISTRATION PROTOCOL

Each study toenail received four (4) total procedure administrations with the Erchonia LUNULA™ laser across a consecutive three-week period: one procedure administration per week, each procedure administration seven days apart. Exposure time to the Erchonia LUNULA™ Laser was 12 minutes directed at the treated toenail(s), at a distance of about 4 inches away from the toenail(s). Each procedure administration took place at the investigator's test site.

STUDY OUTCOME EVALUATION

STUDY OUTCOME MEASURES

The following study measures were recorded for each study toenail at each evaluation point:

- ✓ High-resolution digital photographs
- ✓ Measurement of millimeter (mm) of clear (uninfected) nail bed
- ✓ Calculation of per cent (%) of toenail onychomycosis disease involvement

Measurement of mm of clear nail and calculation of % onychomycosis disease involvement were objectively and independently determined using topographical software (digital photo-planimetry software ([DPPS], PictZar® Digital Planimetry) and triangulation methodology translated to a clear linear measurement. Additional detailed information on this process is contained in the accompanying clinical study protocol document.

STUDY OUTCOME ASSESSMENT TIME POINTS

There were 5 study outcome assessment time points in this study:

- ✓ Pre-Treatment Administration (Baseline)
- ✓ End of Procedure Administration Phase
- ✓ Week 12 Post-Procedure Administration End (Interim Evaluation)
- ✓ Week 36 Post-Procedure Administration End (Study Endpoint)
- ✓ Week 48 Post-Procedure Administration End (Follow-Up Evaluation)

POTENTIAL CONFOUNDING STUDY FACTORS

There were no potential confounding factors identified throughout study duration, as follows:

- ➢ Abstinence from Non-Study Treatments for Onychomycosis: As a study qualification criteria subjects agreed to not partake in any non-study treatment(s) for toenail onychomycosis (including oral medications and nail lacquer, non-alternative therapies such as acupuncture and home remedies) during study participation. Subjects recorded a daily diary during study participation recording compliance/non-compliance with the criteria. All subjects reported compliance with this study abstinence requirement throughout study participation.

- Abstinence from Use of Nail Cosmetics: As a study qualification criteria subjects agreed to not partake in the use of any toenail cosmetics on the study toenail throughout the course of study participation. Subjects recorded a daily diary during study participation recording compliance/non-compliance with the criteria. All subjects reported compliance with this study abstinence requirement throughout study participation.

- Concomitant Medication Use: As a study qualification criteria, subjects agreed to maintain their pre-study concomitant medication and therapy use. Medications routinely taken, and therapies routinely engaged in, were recorded at baseline, and subjects were required to record any deviations from this baseline reporting in their daily diary. No subject reported any deviation in concomitant medication/therapy use notable enough to impact study outcome measures.

RESULTS SUMMARY AND CONCLUSION

BACKGROUND: The purpose of this clinical study was to demonstrate the efficacy of the Erchonia LUNULA™, manufactured by Erchonia Corporation, for the treatment of onychomycosis of the toenail, when applying the LUNULA™ to the toenail for 12 minutes one time per week for 4 consecutive weeks, for a total of 4 treatment administrations.

STUDY DESIGN: This clinical study was a single site, single group (active procedure only) non-randomized non-blinded design.

STUDY MEASURES: Millimeter (mm) of clear (uninfected) nail bed and per cent (%) of toenail onychomycosis disease involvement were objectively and independently determined using topographical software digital photo-planimetry software and triangulation methodology translated to a clear linear measurement at baseline; at the end of the procedure administration phase, and at 12 weeks, 36 weeks and 48 weeks post procedure administration end.

STUDY PROCEDURE: Study toenails received 4 procedure administrations with the Erchonia LUNULA™ across a consecutive 3-week period: each procedure administration 7 days apart. Exposure time to the laser was 12 minutes directed at and about 4 inches above the toenail.

SUBJECTS AND SAMPLE: One hundred and nine (109) subjects completed the study. Subjects were 18 years or older with current bacterial/fungal infection classified by the investigator and confirmed through lab testing as positive for onychomycosis.

- Forty-six (46) male subjects (42%) and 63 (58%) female subjects were enrolled in the study.
- Subject age averaged 41.75 years.
- All subjects were Caucasian.

A total of 139 toenails were treated in this study: 109 great toenails; 28 2nd digit toenails and 2 3rd digit toenails. All toenails received the active study procedure administrations.

- Seventy two (72) toenails were on the right foot and 67 toenails were on the left foot.
- The average duration of toenail onychomycosis at study entry was 25.97 months.
- The average percentage of toenail onychomycosis disease involvement at baseline was 63.21%.
- The average mm of clear nail from the lunula at baseline was 5.90 mm.

A series of t-tests for independent samples found no statistically significant difference in the baseline measurements of duration of toenail onychomycosis, % toenail onychomycosis disease involvement and mm clear nail between toenails on the right and left feet ($p>0.05$).

STUDY RESULTS

Primary Outcome Measure: Change in mm of Clear Nail from Baseline to Study Endpoint: The primary efficacy outcome measure in this study was pre-determined as the mm of clear nail growth at Week 36 post procedure administration end relative to Baseline (pre-procedure administration). Individual toenail success was defined as 3 mm or more of clear nail growth at 36 weeks relative to baseline. Overall study success was defined as an anticipated 60% of treated toenails meeting the individual toenail success criteria.

Ninety six per cent (96%) of all study treated toenails met the study individual toenail success criteria**,** exceeding the pre-established overall study success goal of 60% by 36%. The magnitude of the mean change in mm of clear nail from baseline to 36 weeks post-procedure evaluation for all treated toenails was an increase of 8.82 mm, 5.82 mm in excess of the pre-established 3 mm increase success criteria. A t-test for paired samples found this mean change of +8.36 mm in clear nail to be statistically significant (t=-23.02; df=138; p<0.0001).

This primary analysis finding was replicated when considering the two study subsamples of great toenails and 2nd digit toenails, separately.

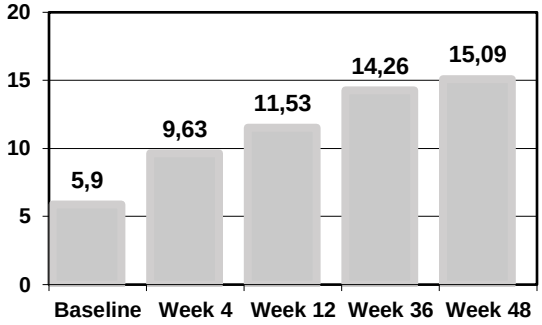
Additional Measures:

Change in mm of Clear Nail Across Study Duration: Table 1 and Chart 1 below show the mean mm of clear nail across the five study evaluation points of baseline; week 4 (end of procedure administration phase); and week 12, week 36 (endpoint) and week 48 (follow-up evaluation) following procedure administration end.

Table 1: Mean mm clear nail across study duration

Evaluation Phase	mm clear nail
Baseline	5.90
Week 4	9.63
Week 12	11.53
Week 36	14.26
Week 48	15.09

Chart 1: Mean mm clear nail across study duration



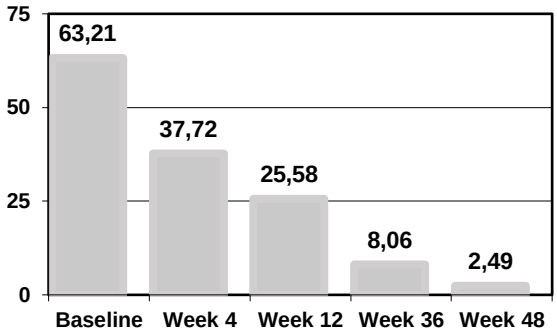
ANOVA analysis found that mean mm clear nail increased significantly across and between all 5 study evaluation points, indicating a progressive and cumulative treatment effect of the laser.

Change in % Onychomycosis Disease Involvement Across Study Duration: Table 2 and Chart 2 below show the mean % of toenail onychomycosis disease involvement across the 5 study evaluation points of baseline; week 4 (end of procedure administration); and week 12, week 36 (endpoint) and week 48 (follow-up evaluation) following procedure administration end.

Table 1: Mean % onychomycosis disease involvement across study duration

Evaluation Phase	% Disease
Baseline	63.21
Week 4	37.72
Week 12	25.58
Week 36	8.06
Week 48	2.49

Chart 1: Mean % onychomycosis disease involvement across study duration



ANOVA analysis found that mean % toenail onychomycosis disease involvement decreased significantly across and between all 5 study evaluation points, indicating a progressive and cumulative treatment effect of the laser.

These additional findings were replicated when considering the two study subsamples of great toenails and 2nd digit toenails, separately.

ADVERSE EVENTS: No adverse event was reported for any subject throughout study duration.

CONCLUSION: The Erchonia LUNULA™ is an effective tool for treating toenail onychomycosis and preventing re-infection, significantly and progressively increasing mm of clear nail and decreasing % onychomycosis disease involvement over a 48 week period following completion of the 3-week procedure administration phase.

SAMPLE DEMOGRAPHICS

The following sample demographics were recorded at Baseline (Pre-Procedure) evaluation:

- Gender
- Age
- Ethnicity

GENDER

There were 46 male subjects and 63 female subjects enrolled in this study.

Fifty three (53) of the 139 enrolled toenails (38%) belonged to male subjects; and 86 of the 139 enrolled toenails (62%) belonged to female subjects, divided amongst great toenails, 2nd digit toenails and 3rd digit toenails, as shown in Table 1 below.

Table 1: Subject Gender by Toenail Type

Toenail Type	Male Subjects	Female Subjects
Great toenails (n=109)	46	63
2nd digit toenails (n=28)	7	21
3rd digit toenails (n=2)	-	2
All toenails (n=139)	53	86

AGE (YEARS)

The average age of subjects at the time of study enrollment was 42.38 years and ranged from 19 to 69 years. Table 2 below shows subject age at the time of study enrollment by gender.

Table 2: Subject Age by Gender

Age (years)	Males (n=46)	Females (n=63)	All Subjects (n=109)
Mean	40.30	43.89	42.38
Standard Deviation	11.78	10.74	11.28
Range	19 - 66	22 - 69	19 - 69

A **t-test for two independent samples** revealed no statistically significant difference in subject age between male and female subjects: μa-μb=-3.58; t=-1.65; df=107; p(two-tailed)=0.102 (p>0.05).

ETHNICITY

All (100%) of subjects enrolled in this study were Caucasian.

BASELINE (PRE-PROCEDURE) VARIABLES AND MEASURES

The following sample variables and measures were recorded at Baseline (Pre-Procedure) evaluation:

- Foot/toenail side
- Duration of toenail onychomycosis
- Percent (%) of onychomycosis toenail involvement
- Millimeters (mm) of clear (uninfected) nail

FOOT/TOENAIL SIDE

There were 53 right feet and 56 left feet enrolled in this study, essentially an even division of feet side allocation in this study.

Seventy two (72) of the 139 enrolled toenails (52%) were on the right foot; and 67 of the 139 enrolled toenails (48%) were on the left foot; once again, an approximately even division between feet sides. The breakdown of right and left toenails by great, 2nd digit and 3rd digit toenails is shown in Table 3 below.

Table 3: Foot Side by Toenail Type

Toenail Type	Right Foot	Left Foot
Great toenails (n=109)	53	56
2nd digit toenails (n=28)	17	11
3rd digit toenails (n=2)	2	-
All toenails (n=139)	72	67

DURATION OF TOENAIL ONYCHOMYCOSIS (MONTHS)

The number of months since onset of the onychomycosis in the study treated toenail was recorded at enrollment.

The average duration of toenail onychomycosis of the 139 infected toenails treated in this study across all subjects was 25.99 months and ranged from 4 to 90 months.

Table 4 below shows the mean, standard deviation and range of the number of months since the onset of toenail onychomycosis in the 139 treated toenails by foot side.

Table 4: Duration of Toenail Onychomycosis by Foot Side

# *Months*	Right Foot (n=72)	Left Foot (n=67)	All Toenails (n=139)
Mean	26.43	25.51	25.99
Standard Deviation	18.15	18.86	18.43
Range	5 - 60	4 – 90*	4 – 90*

** True range is 4-60 months, with 2 outliers of 80 months and 90 months.*

A **t-test for two independent samples** revealed no statistically significant difference in duration of toenail onychomycosis between right and left feet toenails:
μa-μb=-0.923; t=+0.29; df=137; p(two-tailed)=0.77 (p>0.05).

PERCENT (%) BASELINE TOENAIL ONYCHOMYCOSIS INVOLVEMENT

The percent (%) of the total toenail that was onychomycosis disease involved was recorded at enrollment (pre-treatment – baseline) for each of the 139 enrolled toenails.

Table 5 below shows the % toenail onychomycosis involvement at pre-treatment (baseline) by foot side (right and left) for all toenails combined and by toenail type (great toenail, 2nd digit toenail and 3rd digit toenail).

Table 5: % Baseline Toenail Onychomycosis Involvement by Foot Side by Toenail Type

All Toenails	**Right (n=72)**	**Left (n=67)**	**All (n=139)**
Mean	63.83	62.76	63.21
Standard Deviation	22.94	25.02	23.88
Great Toenails	**Right (n=53)**	**Left (n=56)**	**All (n=109)**
Mean	62.81	59.45	61.08
Standard Deviation	24.78	24.82	24.75
2nd Digit Toenails	**Right (n=17)**	**Left (n=11)**	**All (n=28)**
Mean	66.76	79.64	71.82
Standard Deviation	17.74	19.17	19.07
3rd Digit Toenails	**Right (n=2)**	**Left (n=0)**	**All (n=2)**
Mean	58.50	-	58.50
Standard Deviation	12.02	-	12.02

T-tests for two independent samples revealed no statistically significant difference at baseline in % of onychomycosis disease involvement between all right and left toenails combined; between the right and left great toenails; or between the right and left 2nd digit toenails. There was insufficient sample for 3rd digit toes for statistical analysis to be performed:

- ✓ All Toenails: μa-μb=0.86; t=+0.21; df=137; p(two-tailed)=0.83 (p>0.05).
- ✓ Great Toenails: μa-μb=3.36; t=+0.71; df=107; p(two-tailed)=0.48 (p>0.05).
- ✓ 2nd Digit Toenails: μa-μb=-12.87; t=-1.82; df=26; p(two-tailed)=0.08 (p>0.05).

CATEGORY OF % BASELINE TOENAIL ONYCHOMYCOSIS INVOLVEMENT

Toenails were further categorized according to the following four categories of % toenail onychomycosis involvement at baseline:

- ✓ 0% - 24%
- ✓ 25% - 49%
- ✓ 50% - 74%
- ✓ 75% - 100%

Table 6 below shows the breakdown of the number and percentage of great toenails and 2nd digit toenails by category of % toenail onychomycosis involvement pre-treatment (at baseline) by foot side (right and left) and for all toenails combined.

Table 6: Category of % Baseline Onychomycosis Involvement by Foot Side by Toenail Type

All Toenails	**# (%) Right Toenails (n=72)**	**# (%) Left Toenails (n=67)**	**# (%) All Toenails (n=139)**
0% - 24%	5 (7%)	6 (9%)	11 (8%)
25% - 49%	16 (22%)	17 (25%)	33 (24%)
50% - 74%	21 (29%)	20 (30%)	41 (29%)
75% - 100%	30 (42%)	24 (36%)	54 (39%)
Great Toenails	**# (%) Right Toenails (n=53)**	**# (%) Left Toenails (n=56)**	**# (%) All Toenails (n=109)**
0% - 24%	5 (9%)	6 (11%)	11 (10%)
25% - 49%	13 (25%)	16 (28.5%)	29 (27%)
50% - 74%	12 (23%)	16 (28.5%)	28 (25%)
75% - 100%	23 (43%)	18 (32%)	41 (38%)
2nd Digit Toenails	**# (%) Right Toenails (n=17)**	**# (%) Left Toenails (n=11)**	**# (%) All Toenails (n=28)**
0% - 24%	-	-	-
25% - 49%	3 (18%)	1 (9%)	4 (14%)
50% - 74%	7 (41%)	4 (36%)	11 (39%)
75% - 100%	7 (41%)	6 (55%)	13 (47%)

Overall, the breakdown of category of % Baseline Onychomycosis Involvement was comparable between right and left toenails.

MILLIMETERS (MM) OF CLEAR (UNINFECTED) TOENAIL

Millimeters (mm) of clear (uninfected) toenail was recorded at enrollment (pre-treatment – baseline) for each of the 139 enrolled toenails.

Table 7 below shows the mm of clear (uninfected) toenail at pre-treatment (baseline) evaluation by foot side (right and left) by toenail type (great toenail, 2nd digit toenail and 3rd digit toenail) and for all toenails combined.

Table 7: mm of Clear (Uninfected) Toenail by Foot Side by Toenail Type

All Toenails	**Right (n=72)**	**Left (n=67)**	**All (n=139)**
Mean	5.50	6.33	5.90
Standard Deviation	4.21	4.95	4.58
Great Toenails	**Right (n=53)**	**Left (n=56)**	**All (n=109)**
Mean	6.53	7.25	6.9
Standard Deviation	4.41	4.86	4.6
2nd Digit Toenails	**Right (n=17)**	**Left (n=11)**	**All (n=28)**
Mean	2.59	1.64	2.15
Standard Deviation	1.42	1.63	1.35
3rd Digit Toenails	**Right (n=2)**	**Left (n=0)**	**All (n=2)**
Mean	3	-	3
Standard Deviation	1.41	-	1.41

T-tests for two independent samples revealed no statistically significant difference at baseline in mm of clear (uninfected) toenail between the right and left toenails overall, between the right and left great toenails or between the right and left 2nd digit toenails. There was insufficient sample for 3rd digit toes for statistical analysis to be performed:

- ✓ All toenails: μa-μb=-0.83; t=-1.07; df=137; p(two-tailed)=0.29 (p>0.05).
- ✓ Great Toenails: μa-μb=-0.72; t=-0.81; df=107; p(two-tailed)=0.42 (p>0.05).
- ✓ 2nd Digit Toenails: μa-μb=0.95; t=+1.64; df=26; p(two-tailed)=0.11 (p>0.05).

STATISTICAL ANALYSIS

PRIMARY EFFICACY OUTCOME ANALYSIS

The aim of this study was to determine if there is a treatment effect of application of the Erchonia LUNULA™ for individuals with onychomycosis of the toenail.

The primary efficacy outcome measure in this study was the mm of clear nail growth at post-procedure Week 36 relative to Baseline (pre-procedure administration).

Study Success Criteria

- ✓ *Individual toenail success criteria* was defined as 3 mm or more of clear nail growth at 36 weeks post-procedure administration end as evaluated relative to baseline (pre-treatment administration).

- ✓ *Overall study success criteria* was defined as an anticipated 60% of treated toenails meeting the individual success criteria.

Evaluation Time Point

The study end evaluation time point at which study success was analyzed was 36 weeks following completion of the fourth and final study procedure administration with the Erchonia LUNULA™.

Populations Examined

It was intended for two analyses to be performed:

- *Intent-to-treat analysis*: including all subjects who had measures recorded at baseline, and
- *Per-protocol analysis*: excluding subjects with major protocol deviations, incompletes, etc.

It was intended that handling of missing data be according to the Last Observation Carried Forward (LOCF) method.

As all 139 toenails enrolled in this clinical study had all study measurements recorded at all evaluation time points through to the final week 48 post-procedure administration end evaluation visit, only the ITT analysis was performed to evaluate study success.

Primary Outcome Measure Analyses

Proportion of Successes

- Ninety-six per cent (96%) (134/139) of all study treated toenails met the study individual success criteria at week 36 post-procedure administration end evaluation**,** exceeding the pre-established overall study success goal of 60% by 36%.

Change Scores: All Toenails

Table 8 below show the mean and standard deviation of mm of clear nail at 36 weeks post-procedure administration end (study endpoint) evaluation relative to baseline (pre-procedure) evaluation, and the change (increase) in mm of clear nail between the two evaluation points for all 139 treated toenails.

Table 8: Clear Nail at Baseline (Pre-Procedure) and 36 Weeks Post-Procedure

n=139	**Pre-Procedure**	**36 Weeks**	**Change**
Mean	5.90	14.26	8.36
Standard Deviation	4.58	4.66	4.08

The mean increase in mm of clear nail from pre-procedure (baseline) administration evaluation to 36 weeks post-procedure administration end evaluation for all treated toenails was 8.82 mm, 5.82 mm in excess of the pre-established 3 mm increase success criteria.

A **t-test for paired samples** revealed the mean change of +8.36 mm in clear nail from pre-procedure administration to 36 weeks post-procedure administration end to be statistically significant: μa-μb=-8.36; t=-23.02; df=138; p(two-tailed)<0.0001

This sizeable and statistically significant increase in mm of clear nail from baseline to study endpoint across all treated toenails - almost 3 times the pre-established goal - indicates that there is a strong treatment effect of the application of the Erchonia LUNULA™ to treating toenail onychomycosis.

Change Scores: Great Toenails

Table 9 below show the mean and standard deviation of mm of clear nail at 36 weeks post-procedure administration end (study endpoint) evaluation relative to baseline (pre-procedure) evaluation, and the change (increase) in mm of clear nail between the two evaluation points for the subset of the 109 treated great toenails.

Table 9: Clear Nail at Pre-Procedure & 36 Weeks Post-Procedure for Great Toenails

n=109	**Pre-Procedure**	**36 Weeks**	**Change**
Mean	6.90	16.11	9.22
Standard Deviation	4.64	3.34	4.02

The mean increase in mm of clear nail from pre-procedure (baseline) administration evaluation to 36 weeks post-procedure administration end evaluation for great toenails was 9.22 mm, 6.22 mm in excess of the pre-established 3 mm increase success criteria.

A **t-test for paired samples** revealed the mean change of +9.22 mm in clear nail from pre-procedure administration to 36 weeks post-procedure administration end for the great toenail subsample to be statistically significant: μa-μb=-9.22; t=-21.94; df=108; p(two-tailed)<0.0001

Change Scores: 2nd Digit Toenails

Table 10 below show the mean and standard deviation of mm of clear nail at 36 weeks post-procedure administration end (study endpoint) evaluation relative to baseline (pre-procedure) evaluation, and the change (increase) in mm of clear nail between the two evaluation points for the subset of the 28 treated 2nd digit toenails.

Table 10: Clear Nail at Pre-Procedure & 36 Weeks Post-Procedure for 2nd Digit Toenails

n=28	**Pre-Procedure**	**36 Weeks**	**Change**
Mean	2.21	7.54	5.32
Standard Deviation	1.55	1.32	1.66

The mean increase in mm of clear nail from pre-procedure (baseline) administration evaluation to 36 weeks post-procedure administration end evaluation for 2nd digit toenails was 5.32 mm, 2.32 mm in excess of the pre-established 3 mm increase success criteria.

A **t-test for paired samples** revealed the mean change of +5.32 mm in clear nail from pre-procedure administration to 36 weeks post-procedure administration end for the 2nd digit toenail subsample to be statistically significant: μa-μb=-5.32; t=-17.00; df=27; p(two-tailed)<0.0001.

SUPPORTIVE MEASURES ANALYSIS

Proportion of Successes at All Evaluation Points Relative to Baseline

A. All Toenails

Table 11 below shows the number and percentage of all of the 139 treated toenails that met the study individual success criteria of 3 mm or more increase in clear nail at each of procedure administration end (after completion of the 4-week procedure administration protocol), week 12, week 36 and week 48 following procedure administration end, respectively, assessed relative to baseline (pre-procedure administration).

Table 11: Individual Success Across Study Duration Relative to Baseline: *All Toenails*

Post-Procedure Week (n=139)	**#**	**%**
Procedure Administration End	105	75.5%
Week 12	120	86%
Week 36	134	96%
Week 48	137	99%

- By the end of the procedure administration period – 4 weeks after baseline – 75.5% of all treated toenails had already met the individual success criteria of 3 or more mm of increase in clear nail, exceeding the pre-established overall success rate at 36 weeks post-procedure administration end of 60% by 15.5%.

- A progressively increasing 86% of all study treated toenails met the study individual success criteria at week 12 post-procedure evaluation relative to baseline, exceeding the pre-established overall success rate at 36 weeks post-procedure administration end of 60% by 26%, while still being 24 weeks shy of study endpoint evaluation.

- By 36 weeks, all but five toenails (96%) had met the study individual success criteria, exceeding the pre-established overall success rate at 36 weeks post-procedure administration end of 60% by 36%. .

- All but two toenails (98%) attained study success by 48 weeks post-procedure administration end relative to baseline evaluation.

- **This progressively increasing and high healing rate culminating in all but 5 of the 139 treated toenails attaining study success at study endpoint evaluation relative to baseline, and all but two treated toenails attaining individual success by study follow-up evaluation at 48 post-procedure administration end demonstrates the efficacy of the Erchonia LUNULA™ in treating toenail onychomycosis that is of lasting duration without evidence of reinfection over a total period of one year**.

B. Great Toenails

Table 12 below shows the number and percentage of the 109 treated great toenails that met the study individual success criteria of 3 mm or more increase in clear nail at each of procedure administration end (after completion of the 4-week procedure administration protocol), week 12, week 36 and week 48 following procedure administration end, respectively, assessed relative to baseline (pre-procedure administration).

Table 12: Individual Success Criteria Across Study Duration Relative to Baseline: *Great Toenails*

Post-Procedure Week (n=109)	**#**	**%**
Procedure Administration End	88	81%
Week 12	98	90%
Week 36	105	96%
Week 48	107	98%

- By procedure administration end relative to baseline - a short 4-week timeframe – 81% of all treated great toenails had already met the individual success criteria of 3 or more mm of increase in clear nail, exceeding the pre-established overall success rate at 36 weeks post-procedure administration end of 60% by 21%.

- A progressively increasing 90% of study treated great toenails met the study individual success criteria at week 12 post-procedure evaluation relative to baseline, exceeding the pre-established overall success rate at 36 weeks post-procedure administration end of 60% by 30%, while still being 24 weeks shy of study endpoint evaluation.

- By 36 weeks post-procedure end, all great toenails (100%) met the study individual success criteria.

- All but two study great toenails (98%) attained study success by 48 weeks post-procedure administration end assessment.

- This progressively increasing and high healing rate for the study subsample of great toenails across study duration supports the efficacy of the Erchonia LUNULA™ in treating toenail onychomycosis that is of lasting duration without evidence of reinfection over a total period of one year.

C. 2nd Digit Toenails

Table 13 below shows the number and percentage of the 28 treated 2nd digit toenails that met the study individual success criteria of 3 mm or more increase in clear nail at each of procedure administration end (after completion of the 4-week procedure administration protocol), week 12, week 36 and week 48 following procedure administration end, respectively, assessed relative to baseline (pre-procedure administration).

Table 13: Individual Success Criteria Across Study Duration Relative to Baseline: *2nd Digit Toenails*

Post-Procedure Week (n=28)	**#**	**%**
Procedure Administration End	15	54%
Week 12	20	71%
Week 36	27	96%
Week 48	28	100%

- By procedure administration end relative to baseline, 54% of all treated 2nd digit toenails had already met the individual success criteria of 3 or more mm of increase in clear nail, just 6% shy of the pre-established overall success rate at 36 weeks post-procedure administration end of 60%.

- A progressively increasing 71% of study treated 2nd digit toenails met the study individual success criteria at week 12 post-procedure evaluation relative to baseline, exceeding the pre-established overall success rate at 36 weeks post-procedure administration end of 60% by 11%, while still being 24 weeks shy of study endpoint evaluation.

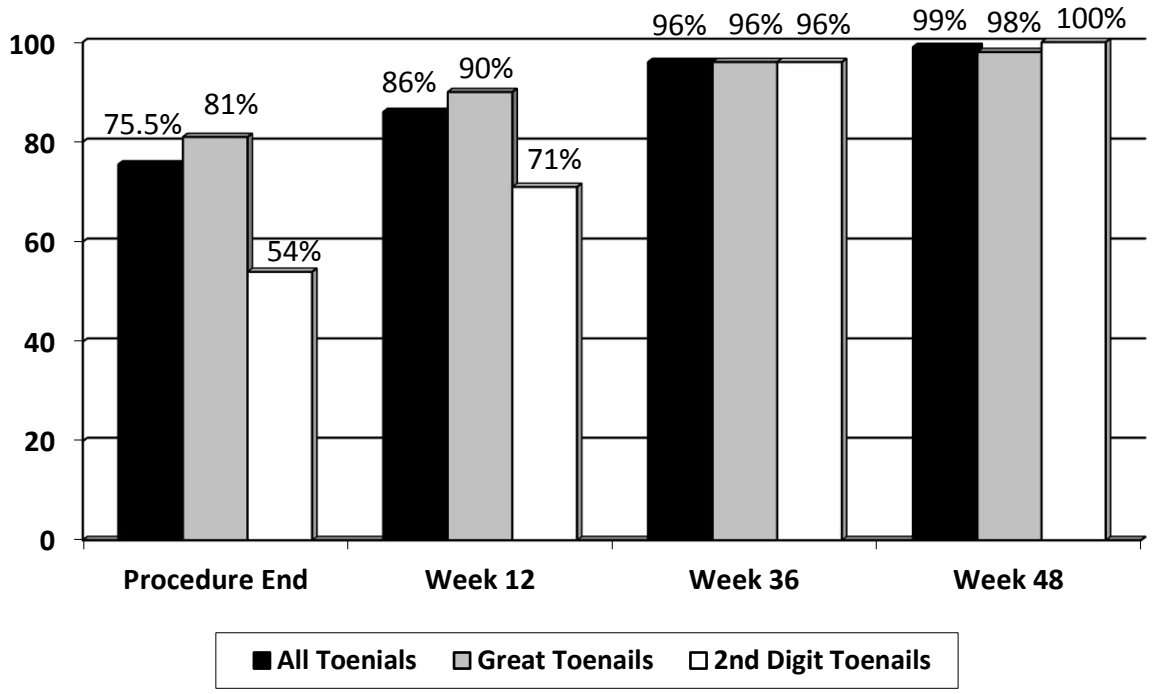
- By 36 weeks post-procedure administration end, all but one 2nd digit toenail (96%) had met the study individual success criteria.

- A 100% study success rate was attained for study 2nd digit toenails by 48 weeks post-procedure administration end assessment.

- Again, this progressively increasing and high healing rate for the study subsample of treated 2nd digit toenails by week 48 post-procedure end evaluation clearly supports the efficacy of the Erchonia LUNULA™ in treating toenail onychomycosis that is of lasting duration without evidence of reinfection over a total period of one year.

Chart 1 below illustrates the proportion of individual successes at each study evaluation point relative to baseline for all 139 study treated toenails, and for the subsamples of the 109 great toenails and the 28 2nd digit toenails, as presented in Tables 11, 12 and 13 above, respectively.

Chart 1: Proportion of individual successes across study duration relative to baseline for all toenails, great toenails and 2nd digit toenails.



mm Clear (Uninfected) Nail Across All Study Evaluation Points

Millimeter (mm) of clear (uninfected) nail was measured for all toenails at the following evaluation points:

- ✓ Baseline (pre-procedure administration)
- ✓ Procedure Administration End
- ✓ 12 Weeks Post-Procedure Administration End (Interim Evaluation)
- ✓ 36 Weeks Post-Procedure Administration End (Study Endpoint)
- ✓ 48 Weeks Post-Procedure Administration End (Follow-Up Evaluation)

A. All Toenails

Table 14 below show the mean and standard deviation of mm of clear nail at each of the 5 evaluation points for all of the 139 treated toenails.

Table 14: mm Clear Nail Across Study Duration: *All Toenails*

n=139	**Baseline**	**Procedure End**	**Week 12**	**Week 36**	**Week 48**
Mean	5.90	9.63	11.53	14.26	15.09
Standard Deviation	4.58	4.74	4.89	4.66	4.60

- It can be seen from Table 14 above that as early as following completion of the 4-week procedure administration phase, the mean increase in clear nail was 3.73 mm – 0.73 mm in excess of the pre-established clinically meaningful increase of 3 mm.

- It is also noted that mean mm clear nail increased progressively and substantially across each successive evaluation point.

- **ANOVA analysis for 5 correlated samples** found the changes in mean mm clear nail across the 5 evaluation points to be statistically significant: F=330.33; p<0.0001

  Subsequent **Tukey HSD Test analysis** found the changes across and between each of the 5 evaluation points to be statistically significant, as follows:

p<0.01	p<0.01	p<0.01	p<0.05
Baseline to Procedure End	Procedure End to Week 12	Week 12 to Week 36	Week 36 to Week 48
Baseline to Week 12	Procedure End to Week 36	Week 12 to Week 48	
Baseline to Week 36	Procedure End to Week 48		
Baseline to Procedure End			

Therefore, across all toenails in this study, there was a progressive and statistically significant increase in mean mm clear nail across the 12 months evaluation phase, supporting the finding of the primary outcome analysis of a strong treatment effect of the application of the Erchonia LUNULA™ to treating toenail onychomycosis.

B. Great Toenails

Table 15 below show the mean and standard deviation of mm of clear nail at each of the 5 evaluation points for the subsample of 109 treated great toenails.

Table 15: mm Clear Nail Across Study Duration: *Great Toenails*

n=109	**Baseline**	**Procedure End**	**Week 12**	**Week 36**	**Week 48**
Mean	6.90	10.84	13.05	16.12	17.10
Standard Deviation	4.64	4.56	4.34	3.34	2.76

- It can be seen from Table 15 above that as early as following completion of the 4-week procedure administration phase, the mean increase in clear nail for great toenails was 3.94 mm – 0.94 mm in excess of the pre-established clinically meaningful increase of 3 mm.

- It is also noted that mean mm clear nail for great toenails increased progressively and substantially across each successive evaluation point.

- **ANOVA analysis for 5 correlated samples** found the changes in mean mm clear nail for great toenails across the 5 evaluation points to be statistically significant: F=301.27; p<0.0001

  Subsequent **Tukey HSD Test analysis** found the changes across and between each of the 5 evaluation points to be statistically significant, as follows:

p<0.01	p<0.01	p<0.01	p<0.05
Baseline to Procedure End	Procedure End to Week 12	Week 12 to Week 36	Week 36 to Week 48
Baseline to Week 12	Procedure End to Week 36	Week 12 to Week 48	
Baseline to Week 36	Procedure End to Week 48		
Baseline to Procedure End			

C. 2nd Digit Toenails

Table 16 below show the mean and standard deviation of mm of clear nail at each of the 5 evaluation points for the subsample of 28 treated 2nd digit toenails.

Table 16: mm Clear Nail Across Study Duration: *2nd Digit Toenails*

n=28	**Baseline**	**Procedure End**	**Week 12**	**Week 36**	**Week 48**
Mean	2.21	5.14	5.96	7.54	7.83
Standard Deviation	1.55	2.07	2.01	1.32	1.28

- It can be seen from Table 15 above that as early as following completion of the 4-week procedure administration phase, the mean increase in clear nail for 2nd digit toenails was 2.93 mm – just 0.07 mm short of the pre-established clinically meaningful increase of 3 mm, which is quite sizeable for 2nd digit toenails.

- It is also noted that mean mm clear nail for 2nd digit toenails increased progressively and substantially across each successive evaluation point.

- **ANOVA analysis for 5 correlated samples** found the changes in mean mm clear nail for 2nd digit toenails across the 5 evaluation points to be statistically significant: F=97.12; p<0.0001

  Subsequent **Tukey HSD Test analysis** found the changes across and between each of the following evaluation points to be statistically significant, as follows:

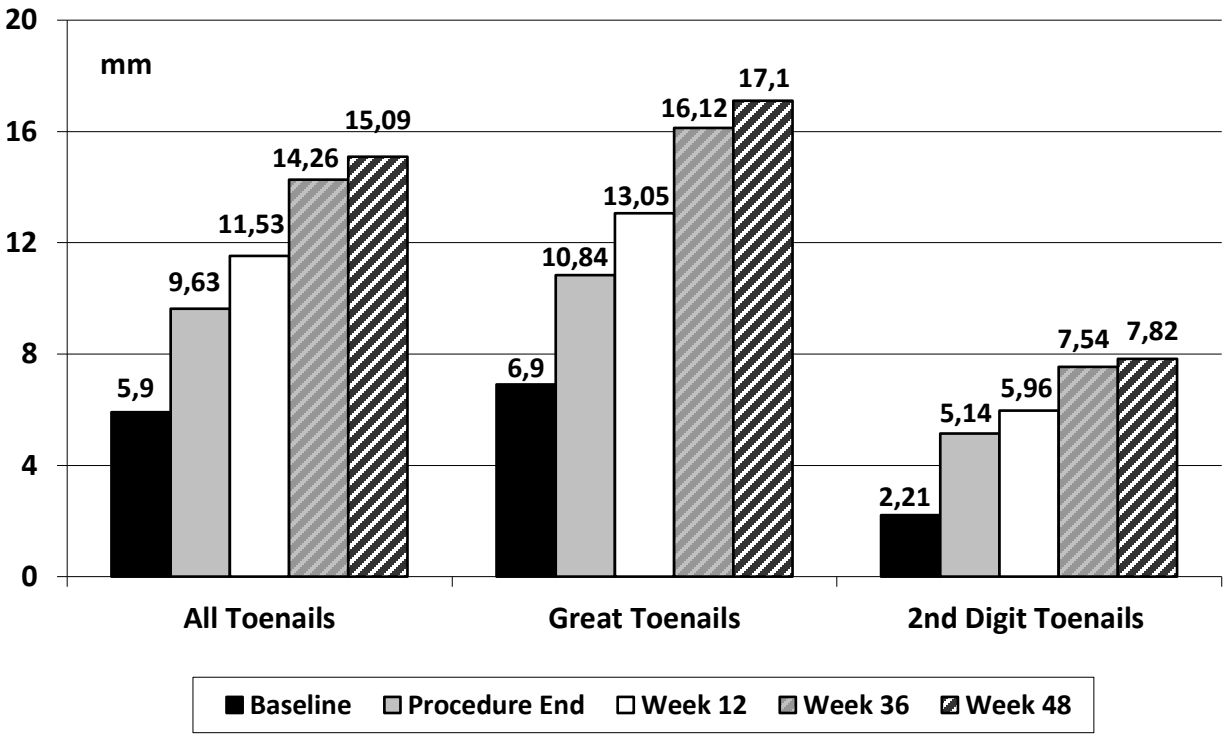
p<0.01	p<0.01	p<0.01
Baseline to Procedure End	Procedure End to Week 36	Week 12 to Week 36
Baseline to Week 12	Procedure End to Week 48	Week 12 to Week 48
Baseline to Week 36		

Baseline to Procedure End

Therefore, the pattern of progressive and statistically significant increase in mean mm clear nail across the 12 months evaluation phase found for all toenails combined is replicated when considering each of the 2 subsamples of great toenails and 2nd digit toenails, separately, providing further support for the primary outcome analysis finding of a strong treatment effect of the application of the Erchonia LUNULA™ to treating toenail onychomycosis.

Chart 2 below illustrates the progression of mm of clear nail across study evaluation points for all 139 study treated toenails, and for the subsamples of the 109 great toenails and the 28 2nd digit toenails, as presented in Tables 14, 15 and 16 above, respectively.

Chart 2: mm of clear nail across study duration for all toenails, great toenails and 2nd digit toenails.



Percent (%) of Onychomycosis Disease Involvement Across All Study Evaluation Points

The percent of the total toenail that was onychomycosis disease involved was measured for all toenails at the following evaluation points:

- ✓ Baseline (pre-procedure administration)
- ✓ Procedure Administration End
- ✓ 12 Weeks Post-Procedure Administration End (Interim Evaluation)
- ✓ 36 Weeks Post-Procedure Administration End (Study Endpoint)
- ✓ 48 Weeks Post-Procedure Administration End (Follow-Up Evaluation)

A. All Toenails

Table 17 below shows the mean and standard deviation of the percent (%) of toenail onychomycosis disease involvement at each of the 5 evaluation points for all of the 139 treated toenails.

Table 17: Toenail Onychomycosis Disease Involvement Across Study Duration: *All Toenails*

n=139	**Baseline**	**Procedure End**	**Week 12**	**Week 36**	**Week 48**
Mean	63.21%	37.72%	25.58%	8.06%	2.49%
Standard Deviation	23.88	23.88	21.76	13.92	9.72

- It can be seen from Table 17 above that mean % toenail onychomycosis disease involvement decreased progressively and substantially across each successive evaluation point to a negligible remaining level.

- **ANOVA analysis for 5 correlated samples** found the changes in mean % toenail onychomycosis disease involvement across the 5 evaluation points to be statistically significant: F=417.68; p<0.0001

  Subsequent **Tukey HSD Test analysis** found the changes across and between each of the 5 evaluation points to be statistically significant, as follows:

p<0.01	p<0.01	p<0.01	p<0.01
Baseline to Procedure End	Procedure End to Week 12	Week 12 to Week 36	Week 36 to Week 48
Baseline to Week 12	Procedure End to Week 36	Week 12 to Week 48	
Baseline to Week 36	Procedure End to Week 48		
Baseline to Procedure End			

Therefore, across all toenails in this study, there was a progressive and statistically significant decrease in mean % toenail onychomycosis disease involvement across the 12 months evaluation phase culminating in a 92% clearance rate for toenail onychomycosis disease involvement in all study treated toenails, supporting the primary outcome analysis finding of a strong treatment effect of the application of the Erchonia LUNULA™ to treating toenail onychomycosis.

B. Great Toenails

Table 18 below shows the mean and standard deviation of the percent (%) of toenail onychomycosis disease involvement at each of the 5 evaluation points for the subsample of 109 treated great toenails.

Table 18: Toenail Onychomycosis Disease Involvement Across Study Duration: *Great Toenails*

n=109	**Baseline**	**Procedure End**	**Week 12**	**Week 36**	**Week 48**
Mean	61.08%	39.07%	26.46%	9.22%	3.02%
Standard Deviation	24.75	23.75	21.55	15.01	10.80

- It can be seen from Table 18 above that mean % toenail onychomycosis disease involvement decreased progressively and substantially across each successive evaluation point.

- **ANOVA analysis for 5 correlated samples** found the changes in mean % toenail onychomycosis disease involvement across the 5 evaluation points for the subsample of 99 great toenails to be statistically significant: F=315.23; p<0.0001

  Subsequent **Tukey HSD Test analysis** found the changes across and between each of the 5 evaluation points to be statistically significant, as follows:

p<0.01	p<0.01	p<0.01	p<0.01
Baseline to Procedure End	Procedure End to Week 12	Week 12 to Week 36	Week 36 to Week 48
Baseline to Week 12	Procedure End to Week 36	Week 12 to Week 48	
Baseline to Week 36	Procedure End to Week 48		
Baseline to Procedure End			

C. 2nd Digit Toenails

Table 19 below shows the mean and standard deviation of the percent (%) of toenail onychomycosis disease involvement at each of the 5 evaluation points for the subsample of 28 2nd digit toenails.

Table 19: Toenail Onychomycosis Disease Involvement Across Study Duration: *2nd Digit Toenails*

n=26	**Baseline**	**Procedure End**	**Week 12**	**Week 36**	**Week 48**
Mean	71.82%	34.54%	23.96%	4.14%	0.61%
Standard Deviation	19.07	23.89	22.52	7.90	3.21

- It can be seen from Table 19 above that mean % toenail onychomycosis disease involvement decreased progressively and substantially across each successive evaluation point.

- **ANOVA analysis for 5 correlated samples** found the changes in mean % toenail onychomycosis disease involvement across the 5 evaluation points for the subsample of 26 2nd digit toenails to be statistically significant: F=111.39; p<0.0001

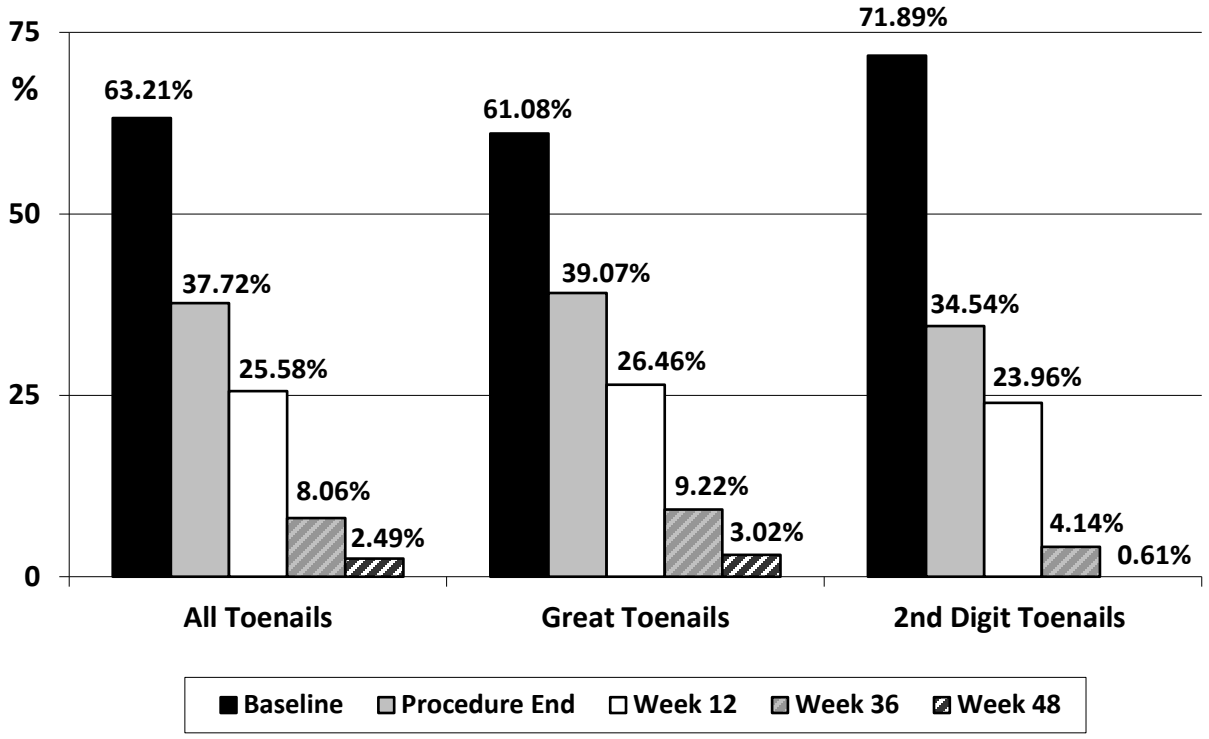
  Subsequent **Tukey HSD Test analysis** found the changes across and between the 5 evaluation points to be statistically significant, as follows:

p<0.01	p<0.01	p<0.01
Baseline to Procedure End	Procedure End to Week 36	Week 12 to Week 36
Baseline to Week 12	Procedure End to Week 48	Week 12 to Week 48
Baseline to Week 36		
Baseline to Procedure End		

Therefore, the pattern of progressive and statistically significant decrease in mean % toenail onychomycosis disease involvement for all toenails combined is replicated when considering each of the 2 subsamples of great toenails and 2nd digit toenails, separately, providing further support for the primary outcome analysis finding of a strong treatment effect of the application of the Erchonia LUNULA™ to treating toenail onychomycosis.

Chart 3 below illustrates the progression of mean % toenail onychomycosis disease involvement across study evaluation points for all 139 study treated toenails, and for the subsamples of the 109 great toenails and the 28 2nd digit toenails, as presented in Tables 17, 18 and 19 above, respectively.

Chart 3: mean % toenail onychomycosis disease involvement across study duration for all toenails, great toenails and 2nd digit toenails.



Incidence of Complete (100%) Nail Clearance Across All Study Evaluation Points

Table 20 below shows the cumulative number and percentage of toenails that attained complete (100%) clearing without evidence of any remaining disease involvement at each of the 4 post-procedure evaluation points, for all 139 toenails combined, and for the subsamples of the 109 great toenails, the 28 2nd digit toenails and the 2 3rd digit toenails, separately,

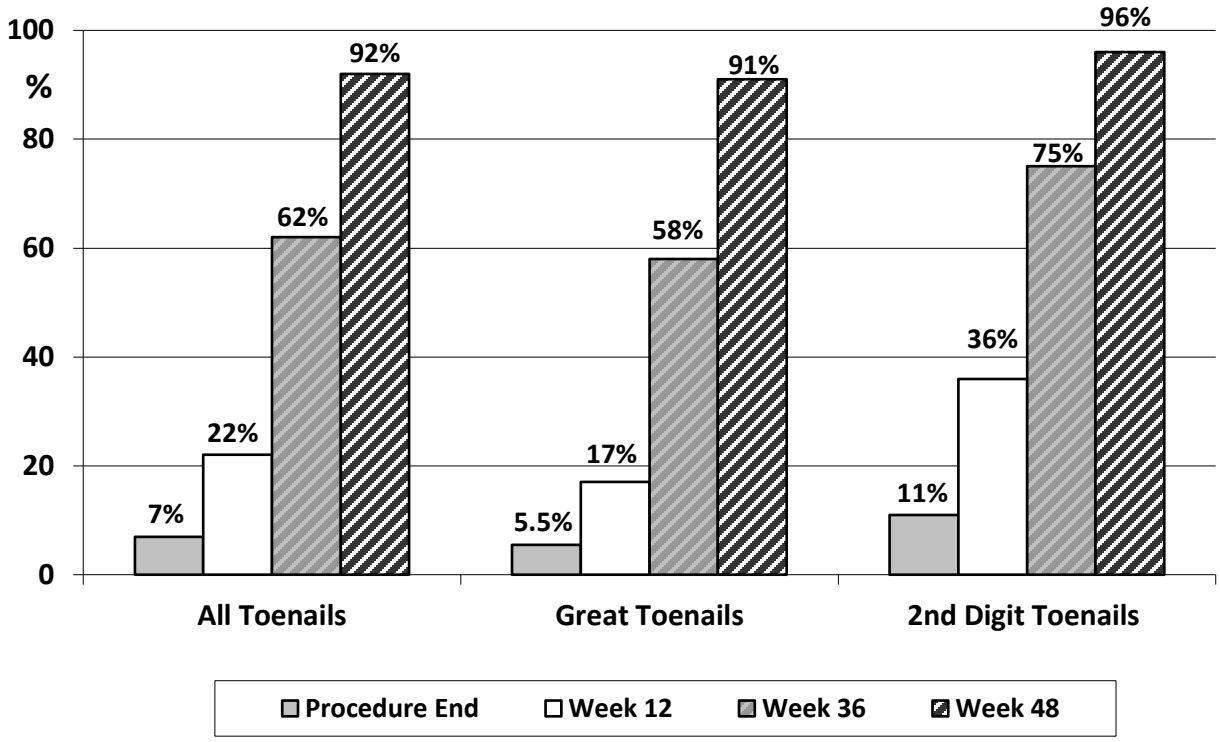
Table 20: Cumulative Complete Toenail Clearance Across Study Duration Relative to Baseline

All Toenails (n=139)	**#**	**%**
Procedure Administration End	10	7%
Week 12	31	22%
Week 36	86	62%
Week 48	128	92%
Great Toenails (n=109)	**#**	**%**
Procedure Administration End	6	5.5%
Week 12	19	17%
Week 36	63	58%

Week 48	99	91%
2nd Digit Toenails (n=28)	**#**	**%**
Procedure Administration End	3	11%
Week 12	10	36%
Week 36	21	75%
Week 48	27	96%
3rd Digit Toenails (n=2)	**#**	**%**
Procedure Administration End	1	50%
Week 12	2	100%
Week 36	2	100%
Week 48	2	100%

Chart 4 below illustrates the cumulative percentage of toenails that attained complete (100%) clearing without evidence of any remaining disease involvement at each of the 4 post-procedure evaluation points for all toenails combined, and for the subsamples of great toenails and 2nd digit toenails, separately, as contained in Table 20 above.

Chart 4: Cumulative % of toenail attaining compete clearing across study duration



Therefore, the cumulative percentage of toenails attaining complete (100%) nail clearance increased progressively and substantially across study duration, culminating in 92% of toenails demonstrating complete nail clearance without evidence of residual disease involvement by study completion at 48 weeks post-procedure administration end. This pattern was comparable for all toenails combined and for the subsamples of great toenails and 2nd digit toenails. This finding lends further support to the primary outcome analysis finding of a strong treatment effect of the application of the Erchonia LUNULA™ to treating toenail onychomycosis without incidence of re-infection after one year.

INDIVIDUAL SUBJECT RESULTS

MILLIMETERS (MM) OF CLEAR (UNINFECTED) TOENAIL

Table 21 below shows individual toenail mm of clear nail results for the 139 enrolled and treated toenails across the 5 evaluation points of baseline (pre-procedure administration); week 4 (end of the procedure administration phase); week 12 post procedure administration end (interim evaluation); week 36 post procedure administration end (study endpoint) and week 48 post procedure administration end (follow-up evaluation) by the variables of gender (male, female); foot side (right or left), toenail type (great, 2nd digit, 3rd digit); and % baseline onychomycosis disease involvement.

Subject ID	Gender M/F	Foot Side R/L	Toenail Type Great/2nd/3rd	% Baseline Disease Involvement	mm Clear Nail: Baseline	mm Clear Nail: Week 4	mm Clear Nail: Week 12	mm Clear Nail: Week 36	mm Clear Nail: Week 48
RS001A	F	Left	Great	88	2	6	9	13	16
RS001B	F	Left	2nd	100	0	3.5	5	8	8
RS002	F	Left	Great	100	0	4.5	7	16	16
RS003A	F	Right	Great	83	3	6	13	18	18
RS003B	F	Right	2nd	75	2	5	4	8	8
RS004	F	Left	Great	65	7	14	20	20	20
RS005	M	Right	Great	38	10	13	13	12	12
RS006	F	Right	Great	76	5	9	17	21	21
RS007	F	Right	Great	100	0	4	10	18	18
RS008	M	Left	Great	40	12	17	20	20	20
RS009A	F	Left	Great	80	3.5	6	13	18	18
RS009B	F	Left	2nd	100	0	6	7	7	7
RS010	F	Right	Great	75	5	10	20	20	20
RS011A	F	Right	Great	80	4	8	7	14	20
RS011B	F	Right	2nd	75	2	4.5	8	8	8
RS012	M	Right	Great	47	10	14.5	16	19	19
RS013	F	Left	Great	80	4	9	9	13	20

RS014A	M	Left	Great	43	12	17	21	21	21
RS014B	M	Left	2nd	89	1	7	9	9	9
Subject ID	**Gender M/F**	**Foot Side R/L**	**Toenail Type Great/2nd/3rd**	**% Baseline Disease Involvement**	**mm Clear Nail: Baseline**	**mm Clear Nail: Week 4**	**mm Clear Nail: Week 12**	**mm Clear Nail: Week 36**	**mm Clear Nail: Week 48**
RS015	F	Right	Great	87	2	7.5	9	15	15
RS016	F	Left	Great	56	7	8	9	12	16
RS017	M	Left	Great	44	10	11	12	7	16
RS018	M	Right	Great	61	7	13	16	18	18
RS019A	F	Right	Great	67	6	13	14	18	18
RS019B	F	Right	2nd	67	3	9	9	9	9
RS020	M	Left	Great	19	18	21	22	22	22
RS021A	F	Right	Great	47	10	15	16	19	19
RS021B	F	Right	2nd	75	2	8	8	8	8
RS022	M	Right	Great	94	1	5	8	9	9
RS023	F	Left	Great	100	0	2	2	6	16
RS024	F	Right	Great	30	14	20	20	20	20
RS025A	F	Left	Great	44	9	15	13	15	16
RS025B	F	Left	2nd	67	3	7	7	9	9
RS026	M	Right	Great	72	5	10	10	15	22
RS027A	F	Left	Great	40	12	17	18	20	20
RS027B	F	Left	2nd	75	2	4	3	8	8
RS028	F	Left	Great	83	3	6	5	15	18
RS029	F	Right	Great	27	11	14	15	15	15
RS030	F	Right	Great	70	6	12	13	20	20
RS031	M	Right	Great	50	9	8	11	15	18
RS032	F	Right	Great	50	8	12	14	16	16
RS033A	F	Right	Great	22	14	16	18	18	18

RS033B	F	Right	2nd	43	4	6	7	7	7
RS034	M	Right	Great	100	0	6	8	16	18
RS035A	F	Left	Great	31	11	15	15	16	16
Subject ID	**Gender M/F**	**Foot Side R/L**	**Toenail Type Great/2nd/3rd**	**% Baseline Disease Involvement**	**mm Clear Nail: Baseline**	**mm Clear Nail: Week 4**	**mm Clear Nail: Week 12**	**mm Clear Nail: Week 36**	**mm Clear Nail: Week 48**
RS035B	F	Left	2nd	67	3	6	6	9	9
RS036	F	Left	Great	80	3	6	6	6	6
RS037A	M	Right	Great	75	4	2	6	23	16
RS037B	M	Right	2nd	63	3	2	5	8	8
RS038A	F	Right	Great	71	5	11	12	17	17
RS038B	F	Right	2nd	75	2	7	5	8	8
RS039	M	Left	Great	81	3	7	10	12.5	16
RS040A	F	Right	Great	95	1	7	14	17	19
RS040B	F	Right	2nd	44	4	5	5	6	7
RS041A	F	Left	Great	100	0	5	13	15	16
RS041B	F	Left	2nd	100	0	1	6	6	7
RS042A	F	Right	Great	78	4	5	5	6	11
RS042B	F	Right	2nd	33	6	8	8	9	9
RS043	M	Left	Great	20	16	18	19	20	20
RS044	M	Left	Great	36	14	18	19	22	22
RS045	F	Left	Great	76	4	6	9	17	17
RS046	M	Left	Great	100	0	4	6	12	18
RS047A	F	Left	Great	44	9	14	15	16	16
RS047B	F	Left	2nd	44	5	8	9	9	9
RS048	F	Left	Great	71	5	9	12	16	17
RS049	M	Left	Great	69	5	11	12	16	16
RS050	M	Left	Great	21	15	17	17	19	19

RS051	M	Left	Great	61	7	11	12	16	18
RS052	F	Left	Great	60	8	14	16	20	20
RS053	F	Left	Great	24	13	16	17	17	17
RS054	M	Right	Great	44	9	13	15	16	16

Subject ID	Gender M/F	Foot Side R/L	Toenail Type Great/2nd/3rd	% Baseline Disease Involvement	mm Clear Nail: Baseline	mm Clear Nail: Week 4	mm Clear Nail: Week 12	mm Clear Nail: Week 36	mm Clear Nail: Week 48
RS055	M	Left	Great	47	8	10	11	13	13
RS056A	M	Right	Great	76	4	10	14	17	17
RS056B	M	Right	2nd	88	1	4	8	8	8
RS057	F	Left	Great	53	9	10	12	16	19
RS058	F	Left	Great	25	15	17	18	18	18
RS059	F	Right	Great	47	9	13	15	17	17
RS060A	F	Right	Great	78	4	8	10	18	18
RS060B	F	Right	2nd	56	4	8	9	9	9
RS061	M	Left	Great	44	9	12	14	16	16
RS062A	F	Right	Great	71	5	7	12	17	17
RS062B	F	Right	2nd	71	2	3	3	6	7
RS063	F	Right	Great	71	4	7	9	13	14
RS064	M	Right	Great	26	14	19	19	19	19
RS065	M	Right	Great	78	4	10	15	17	18
RS066	M	Right	Great	93	1	3	4	14	15
RS067	F	Right	Great	60	6	12	13	15	15
RS068A	F	Right	Great	94	1	5	10	16	16
RS068B	F	Right	2nd	63	3	5	6	8	8
RS068C	F	Right	3rd	67	2	5	6	6	6
RS069	M	Right	Great	84	3	10	19	19	19
RS070	F	Left	Great	65	7	12	20	20	20

RS071	M	Left	Great	22	14	18	18	18	18
RS072	M	Left	Great	53	7	10	10	12	15
RS073	F	Left	Great	60	6	9	11	15	15
RS074	F	Right	Great	76	4	9	12	17	17
RS075	F	Left	Great	81	3	8	12	16	16
Subject ID	**Gender M/F**	**Foot Side R/L**	**Toenail Type Great/2nd/3rd**	**% Baseline Disease Involvement**	**mm Clear Nail: Baseline**	**mm Clear Nail: Week 4**	**mm Clear Nail: Week 12**	**mm Clear Nail: Week 36**	**mm Clear Nail: Week 48**
RS076	F	Right	Great	33	10	13	15	15	15
RS077	F	Left	Great	80	4	10	17	20	20
RS078	F	Right	Great	47	7	11	14	15	15
RS079	M	Right	Great	87	2	8	11	15	15
RS080	F	Left	Great	100	0	6	12	14	16
RS081	F	Left	Great	100	0	4	9	17	19
RS082A	M	Left	Great	33	5.5	15	15	18	18
RS082B	M	Left	2nd	67	2	3	3	5	6
RS083	F	Right	Great	19	13	15	10	16	16
RS084	F	Left	Great	67	6	10	10	10	10
RS085	M	Right	Great	87	2	5	6	12	15
RS086	M	Right	Great	60	8	16	17	19	20
RS088	M	Left	Great	39	11	14	16	18	18
RS089A	F	Right	Great	19	13	16	16	16	16
RS089B	F	Right	2nd	50	3	6	6	6	6
RS089C	F	Right	3rd	50	4	8	8	8	8
RS090	F	Left	Great	65	6	10	12	16	17
RS091	M	Right	Great	32	15	15	15	15	11
RS092	M	Left	Great	73	4	9	10	13	15
RS093	M	Right	Great	19	13	16	16	16	16

RS094	M	Left	Great	40	12	16	16	18	20
RS095	M	Left	Great	63	6	11	15	16	16
RS096	M	Left	Great	16	16	18	19	19	19
RS097	F	Right	Great	40	12	16	18	20	20
RS098	M	Right	Great	22	14	18	18	18	18
RS099	F	Left	Great	67	5	10	15	15	15
Subject ID	**Gender M/F**	**Foot Side R/L**	**Toenail Type Great/2nd/3rd**	**% Baseline Disease Involvement**	**mm Clear Nail: Baseline**	**mm Clear Nail: Week 4**	**mm Clear Nail: Week 12**	**mm Clear Nail: Week 36**	**mm Clear Nail: Week 48**
RS100A	M	Right	Great	35	13	13	13	17	20
RS100B	M	Right	2nd	67	2	4	4	6	6
RS101A	M	Right	Great	85	3	6	8	16	20
RS101B	M	Right	2nd	90	1	3	5	9	10
RS102A	F	Right	Great	100	0	4	4	9	10
RS102B	F	Right	2nd	100	0	4	4	5	5
RS103A	F	Left	Great	75	4	7	8	13	16
RS103B	F	Left	2nd	100	0	3	3	7	10
RS104	F	Right	Great	81	3	3	10	14	16
RS105	M	Right	Great	70	6	9	12	16	20
RS106	F	Left	Great	100	0	6	8	16	18
RS107	F	Left	Great	59	7	14	16	17	17
RS108	M	Left	Great	30	14	17	19	20	20
RS109A	M	Left	Great	37	12	15	17	19	19
RS109B	M	Left	2nd	67	2	4	5	6	6
RS110	F	Left	Great	79	3	8	9	12	14