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An open-labeled randomized non-comparative clinical trial on the efficacy of fairfoot ointment in Vipadika

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Abstract

In Ayurveda, cracked or fissured feet are often associated with an imbalance in the Vata dosha. An excess of Vata in the body can lead to various skin issues, including dry and cracked skin, not only on the feet but on other parts of the body. Fairfoot ointment, a proprietary product, is an antifungal and antiseptic combination of Jathyadi Grutham, Jeevanthyadi Yamakam and Karanja Thailam, intended for external application of cracked feet and other skin conditions like chapped lips, anal fissures etc. An open-labeled randomized non-comparative clinical trial study was conducted on 30 patients presenting with cracked feet, fissures, dry scaly skin, pain, and itching to prove the efficacy in Vipadika. The associated symptoms of pigmentation and skin elasticity were also evaluated as part of this trial. A visual analog scale (VAS) was used to quantify pain. On a Likert scale of 1 to 5, dryness, wrinkles, scaling, itching, and skin laxity were scored. At each point of examination, the amount of cracking and pigmentation were counted. The study involved four evaluations of the participants. Following pairwise analysis using the SPSS 16.0 program, data were examined using Repeated Measure ANOVA. The results of the study showed a considerable reduction in the symptoms of dryness, cracking, pain, and itching. Additionally, there was a statistically significant decline in the symptoms of skin laxity, wrinkles, sealing, and pigmentation. No adverse events were observed during the course of the experiment, suggesting that the medication is safe. Clinical findings indicate that Fairfoot ointment could be used for the improvement and treatment of patients with Vipadika.

Keywords: Cracked feet; Pigmentation; Antifungal; VAS; ANOVA; Vipadika.

1. Introduction

As the biggest organ in the body, the skin is crucial in defending the body against infections. Depending on its location, skin has different morphologies and functions [1]. Despite being extremely thick, the skin on the foot's plantar surface is particularly viscoelastic. When bearing weight, it experiences high amounts of frictional, compressive, and shear stress, all of which it can withstand [2].

Cracked foot is a much prevalent skin condition, where the skin of the heels becomes dry and hard followed by the formation of cracks in the foot. This is because of to the pressure exerted on the foot due to walking and standing [3]. Cracked feet are commonly associated with Vata imbalance in Ayurveda. According to Ayurveda, cracked feet are classified as a sickness under Kshudra Kushtha, which refers to minor skin ailments [4]. Vata governs movement in the body and is responsible for dryness. When Vata is aggravated, it can lead to dry and cracked skin, including on the feet. Factors such as cold weather, excessive walking or standing, dehydration, improper diet, and stress can aggravate Vata dosha [5]. Foot fissures or cracks are frequently linked to an imbalance in the Vata dosha. An excess of Vata in the body

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can cause dry and cracked skin, not only on the feet but also on other parts of the body [6]. Rehydrating the stratum corneum is the treatment for this condition. Alpha-hydroxy acids or urea-containing emollients are especially efficient at lessening dryness. For cracked feet, moisturizing lotions or ointments with glycerin, mineral oil, or petroleum jelly can also be utilized [7].

The Ayurvedic advice for treating Padadari involves treating the affected area with fomentations and ointments as well as performing a siravedha (puncture) of the foot veins. Additionally, according to Ayurveda, the affected area should be plastered with an ointment made of Gairika (red ochre), powdered Sarja Rasa (resin derived from Shorea robusta), clarified butter, Madhucchishta (wax), Vasa (lard), and Majja (marrow) [8]. Numerous herbs are said to have outstanding Vranaropak (wound healing power) in ancient Ayurvedic writings. Goghrit, Jatyadi Taila, Ral (Shuddha), and Tila Taila may assist to maintain moisturized, supple skin, which aids in the proper healing of cracks and the reduction of symptoms [9]. Jathyadi Grutham and Jeevanthyadi Yamakam are traditional Ayurvedic formulations known for their effectiveness in promoting wound healing and reducing inflammation [10,11]. Karanja Thailam, derived from the Karanja tree, is also used in Ayurveda for its antimicrobial and wound-healing properties [12]. The product Fairfoot ointment, combining Jathyadi Grutham, Jeevanthyadi Yamakam, and Karanja Thailam, is formulated to address this imbalance in the Vata dosha. These ingredients are known for their Vatahara (balancing Vata) properties, along with anti-inflammatory, wound-healing, antimicrobial, and antiseptic properties. By combining these ingredients, Fairfoot ointment aims to moisturize, soothe, and heal cracked feet, thereby addressing not only the cosmetic concerns but also relieving associated symptoms such as pain, itching, scaling, wrinkling, and pigmentation of the skin.

2. Materials and Methods

An open-labeled randomized non-comparative clinical trial (Figure 1: IEC/doc/35/17 dated 21-04-2017) was conducted to prove the efficacy of Fairfoot Ointment in Cracked Feet vis-à-vis Vipadika conducted on 30 patients presenting with cracked feet, fissures, dry scaly skin, pain, and itching. The patients were instructed to apply the medicine 2-3 times a day, after thorough cleaning of the affected pat and proper wiping. All participants were given Gandarvahastadi Kwatha twice daily internally to ensure loss to follow up. Associated symptoms such as skin laxity and pigmentation were evaluated as part of this investigation. A Visual Analog Scale was used to evaluate pain (VAS) [13]. Skin conditions such as dryness, wrinkles, scaling, itching, and laxity were rated on a five-point Likert scale [14]. At every assessment point, the coloration and number of cracks were measured. Throughout the trial, participants were evaluated four times: once at the start (BT), once a week after medication application (AT1), twice following application (AT2), and once a week after terminating medication application (AF) [15].

Table 1 Visual Analog Scale

Subjective parameters	**Scale**
Cracks on feet	Counting
Pain	Visual analogue scale (VAS)
Dryness, Wrinkles, Scaling, Itching, Skin Laxity	Likert scale of 1 to 5

At the end of the trial, all 30 participants completed the trial with no loss to follow-up. Data was analyzed using Repeated Measure ANOVA followed by pairwise analysis using SPSS 16.0 software [16]. The statistical probability of 5% was set for the test to be deemed significant.

3. Results and Discussion

Fairfoot is a combination of the following formulations.

Jathyadi Grutham which is explained in Astanga Hridayam, Uttara sthana, Vrana pratishedham is a combination of skin friendly drugs which is indicated in various kinds of Vrana. Jathyadi Grutham is prepared from Jathi *(Jasminum grandiflorum)*, Nimba *(Azadiracta indica)*, Patola *(Trichosanthes dioica)*, Katuki *(Picrorhiza kurroa)*, Darvi *(Berberis aristata)*, Haridra *(Curcuma longa)*, Sariba *(Hemidesmus indicus)*, Manjista *(Rubia cordifolia)*, Hareetaki *(Terminalia chebula)*, Madhuka *(Madhuca longifolia)*. Madhucchishta and Tuttam are also added as patrapaka.

Jeevanthyadi Yamakam which is explained in Astanga Hridayam, Chikitsa sthanam, Kusta chikitsa is yet another combination of skin friendly drugs Jeevanthi *(Holostemma ada-kodien)*, Manjista *(Rubia cordifolia)*, Darvi *(Berberis*

aristata), Kampillakam *(Mallotus philippensis)*, prepared with a dual combination of fats i.e. Gritham and Tila thaila. Sarjarasa, Madhucchishta and Tuttam are added as patrapaka into it. It is one yoga exclusively mentioned for Vipadika (cracked foot) and also indicated in different types of skin diseases including psoriasis, leprosy etc.

Karanja Thaila (Oil of *Pongamia pinnata*) used in treatment of Alopecia, herpes, boils, eczema and abscesses.

Fairfoot ointment shows a remarkable reduction in cracked foot as well as its associated symptoms. The reduction in mean score during the treatment is depicted in the table below.

3.1 Test for Normality

The data was analysed for Normality using the visual method by computing the Q-Q plot (Figure 2) and by Kolmogorov-Smirnov test and Shapiro-Wilk test. Age was the parameter used for the test. The results are given below (Table 2).

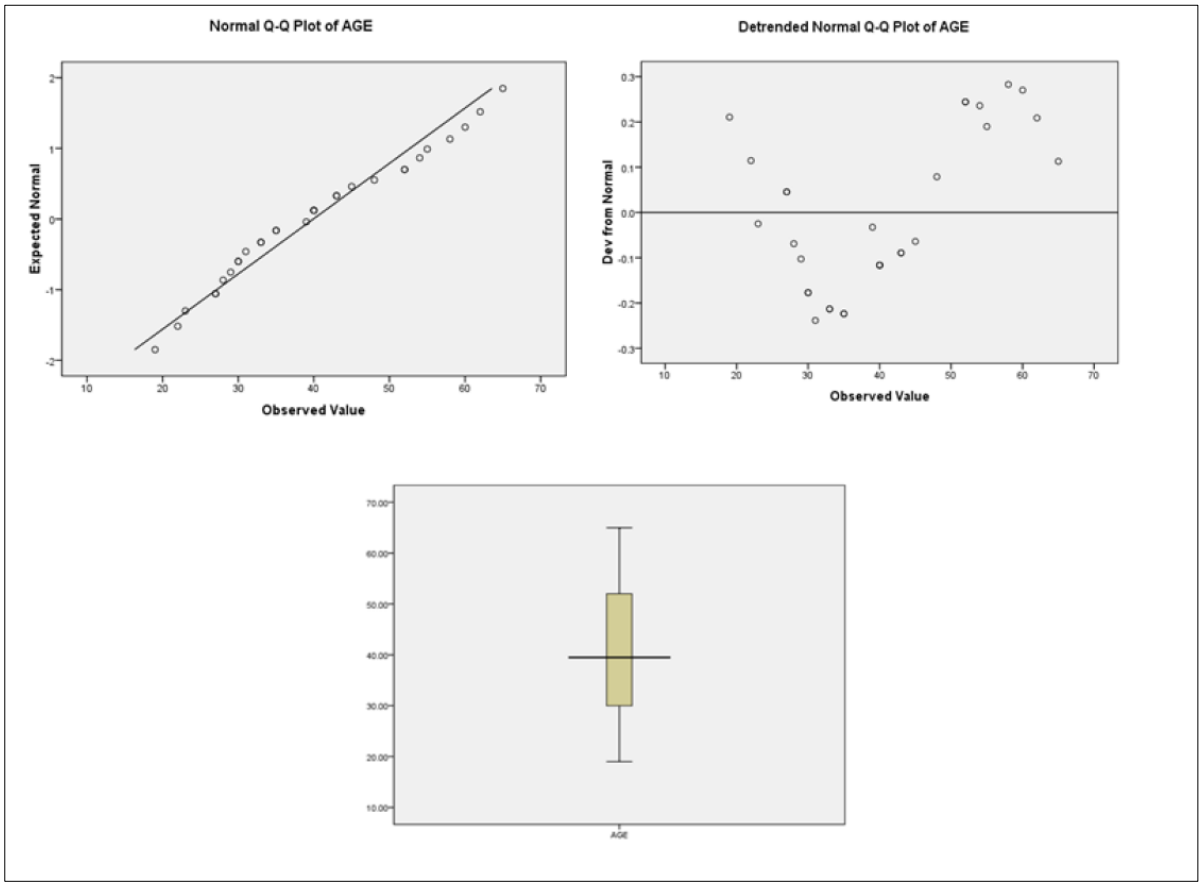

Figure 1 Q-Q plot for Normality

Table 2 Tests of Normality

	Kolmogorov-Smirnov[a]			**Shapiro-Wilk**		
	Statistic	df	Sig.	Statistic	df	Sig.
AGE	0.117	30	0.200*	0.958	30	0.279

a. Lilliefors Significance Correction; *. This is a lower bound of the true significance.

The Q-Q Plot shows a close approximation to the Normal distribution. Statistical tests, Kolmogorov-Smirnov and Shapiro-Wilk tests gave an insignificant value (P>0.05) suggesting that there is no evidence to reject the null hypothesis that the sample does not follow normal distribution. Considering this results, Parametric tests were employed for testing the efficacy of the drug (Table 3).

Table 3 Descriptive Statistics

		AGE	SEX	EDU	ECO	MARITAL	Religion	Occupation
N	Valid	30	30	30	29	30	30	30
	Missing	0	0	0	1	0	0	0
Mean		39.93	1.73	1.37	1.83	0.87	1.63	2.23
Std. Deviation		12.779	0.450	1.129	0.384	0.346	0.490	1.251
Minimum		19	1	0	1	0	1	1
Maximum		65	2	3	2	1	2	4

3.2 Effect of therapy on Cracking

The symptom cracking was assessed four times during the trial. Being dependent observations, the data was analysed using Repeated Measure ANOVA using SPSS 16.0 Software. The reduction in mean score during the treatment is depicted in the table below (Table 4).

Table 4 Effect of therapy on Cracking

CRACK No	Mean	Std. Deviation	N
CRACK1	2.70	0.750	30
CRACK2	1.57	1.073	30
CRACK3	1.03	0.850	30
CRACK4	0.40	0.724	30

Table 5 Mauchly's Test of Sphericity [b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
CRACK	0.776	7.028	5	0.219	0.880	0.976	0.333

The change in the symptom Cracking during various assessments were tested using Mauchly's test of sphericity. The table above (Table 5) shows the results of the test. The test was found to be statistically insignificant (P>0.05) suggesting that the treatment effect in the various groups were comparable. So Multiple comparisons were used for comparing the effect of treatment. The results are shown in the table below (Table 6). Figure 3 shows effect of therapy on cracking.

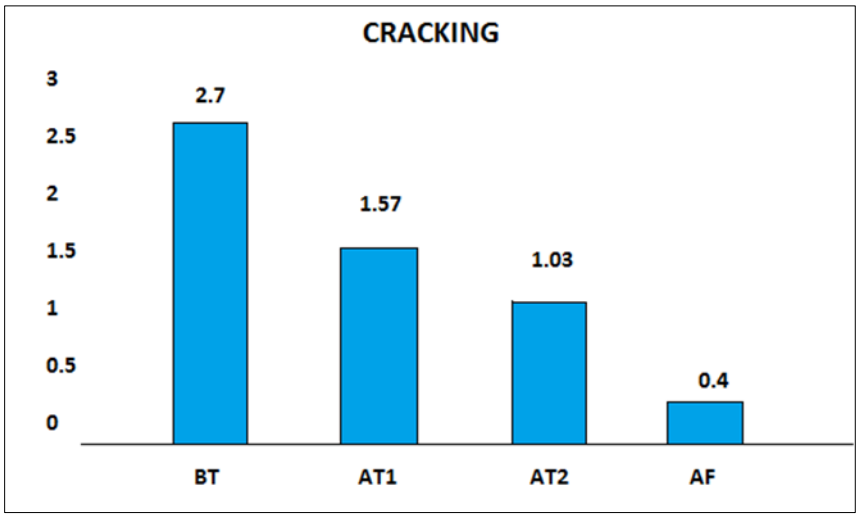

Figure 2 Effect of therapy on Cracking

Table 6 Pairwise Comparisons

Measure:MEASURE_1						
(I) CRACK	(J) CRACK	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
					Lower Bound	Upper Bound
1	2	1.133*	0.164	0.000	0.668	1.598
	3	1.667*	0.154	0.000	1.230	2.103
	4	2.300*	0.160	0.000	1.847	2.753
2	1	-1.133*	0.164	0.000	-1.598	-0.668
	3	0.533*	0.124	0.001	0.181	0.886
	4	1.167*	0.152	0.000	0.736	1.598
3	1	-1.667*	0.154	0.000	-2.103	-1.230
	2	-0.533*	0.124	0.001	-0.886	-0.181
	4	0.633*	0.112	0.000	0.315	0.951
4	1	-2.300*	0.160	0.000	-2.753	-1.847
	2	-1.167*	0.152	0.000	-1.598	-0.736
	3	-0.633*	0.112	0.000	-0.951	-0.315

Multiple comparisons of treatments at BT, AT1, AT2 and AF showed significant change throughout ($P<0.001$) indicating that the medicine brought out favorable significant changes throughout the treatment period.

3.3 Effect of therapy on Dryness

The symptom dryness was assessed four times during the study. The following table (Table 7) displays the mean values of reduction following each assessment of dryness, which was assessed on a five-point Likert scale. Results showed highly significant change in Dryness score.

Table 7 Effect of therapy on Dryness

DRY No	Mean	Std. Deviation	N
DRY1	2.50	0.820	30
DRY2	1.53	0.937	30
DRY3	0.83	0.913	30
DRY4	0.40	0.563	30

The symptom dryness was assessed four times during the study. The efficacy of the treatment on the symptom dryness was assessed using Repeated Measure ANOVA. The results are shown in the table below (Table 8).

Table 8 Mauchly's Test of Sphericity[b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
DRY	0.707	9.607	5	0.087	0.835	0.921	0.333

On analyzing the symptom Dryness using RM ANOVA, the test was found to be statistically insignificant (P>0.05) showing that the treatment effects are comparable between the groups. Further the data was subjected for Multiple comparisons with Bonferoni corrections. The results are shown in the table below (Table 9).

Table 9 Pairwise Comparisons

Measure:MEASURE_1						
(I) DRY	(J) DRY	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	0.967*	0.140	0.000	0.571	1.362
	3	1.667*	0.154	0.000	1.230	2.103
	4	2.100*	0.130	0.000	1.732	2.468
2	1	-0.967*	0.140	0.000	-1.362	-0.571
	3	0.700*	0.098	0.000	0.423	0.977
	4	1.133*	0.142	0.000	0.732	1.535
3	1	-1.667*	0.154	0.000	-2.103	-1.230
	2	-0.700*	0.098	0.000	-0.977	-0.423
	4	0.433*	0.133	0.017	0.057	0.810
4	1	-2.100*	0.130	0.000	-2.468	-1.732
	2	-1.133*	0.142	0.000	-1.535	-0.732
	3	-0.433*	0.133	0.017	-0.810	-0.057

Pair wise analysis showed highly significant change in the Dryness score at 0.1% level (P<0.001) in comparisons BT vs AT1 and AT1 vs AT2. The comparison AT2 vs AF showed a significance at 5% level only (P<0.05). Figure 4 shows effect of therapy on dryness.

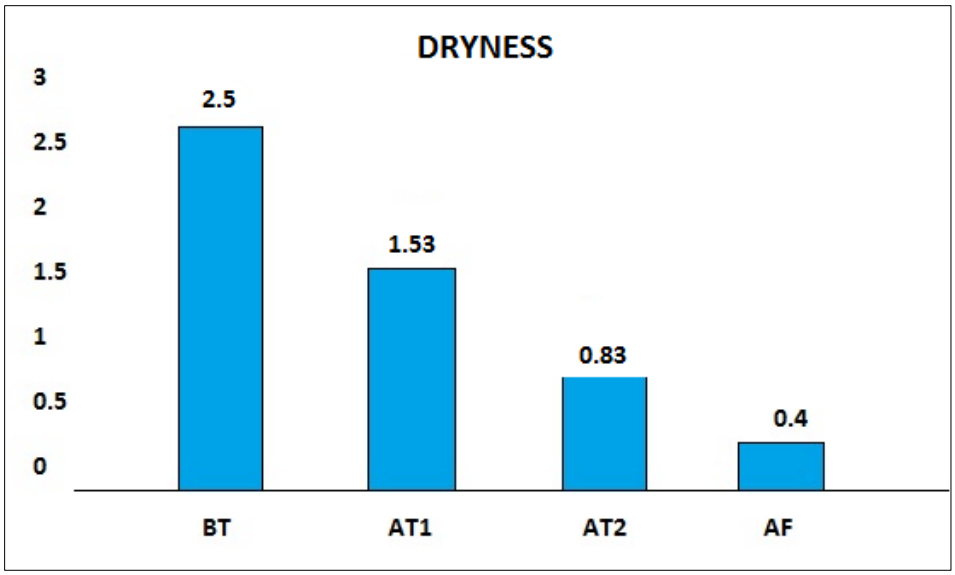

Figure 3 Effect of therapy on Dryness

3.4 Effect of therapy on Pain

Pain was measured using a Visual Analog Scale (VAS). The change in the symptom of Pain score during the treatment is shown in the table below (Table 10).

Table 10 Effect of therapy on Pain

PAIN No	Mean	Std. Deviation	N
PAIN1	2.37	0.809	30
PAIN2	1.20	0.887	30
PAIN3	0.57	0.679	30
PAIN4	0.17	0.379	30

The change in the symptom of Pain during various assessments were tested using Mauchly's test of sphericity. The table below (Table 11) shows the results of the test. The test was found to be statistically insignificant (P>0.05) suggesting that the treatment effect in the various groups were comparable.

Table 11 Mauchly's Test of Sphericity[b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
PAIN	0.799	6.216	5	0.286	0.875	0.970	0.333

Multiple comparisons were performed on the data to assess the real efficacy of the treatment with Bonferroni corrections. The results are shown in the table below (Table 12).

Table 12 Pairwise Comparisons

Measure:MEASURE_1						
(I) PAIN	(J) PAIN	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	1.167*	0.128	0.000	0.805	1.528
	3	1.800*	0.147	0.000	1.384	2.216
	4	2.200*	0.155	0.000	1.762	2.638
2	1	-1.167*	0.128	0.000	-1.528	-0.805
	3	0.633*	0.131	0.000	0.262	1.005
	4	1.033*	0.162	0.000	0.573	1.493
3	1	-1.800*	0.147	0.000	-2.216	-1.384
	2	-0.633*	0.131	0.000	-1.005	-0.262
	4	0.400*	0.123	0.018	0.051	0.749
4	1	-2.200*	0.155	0.000	-2.638	-1.762
	2	-1.033*	0.162	0.000	-1.493	-0.573
	3	-0.400*	0.123	0.018	-0.749	-0.051

Pair wise analysis showed highly significant change in Pain score at 0.1% level (P<0.001) in comparisons BT vs AT1 and AT1 vs AT2. The comparison AT2 vs AF showed a significance at 5% level only (P<0.05). Figure 5 shows effect of therapy on pain.

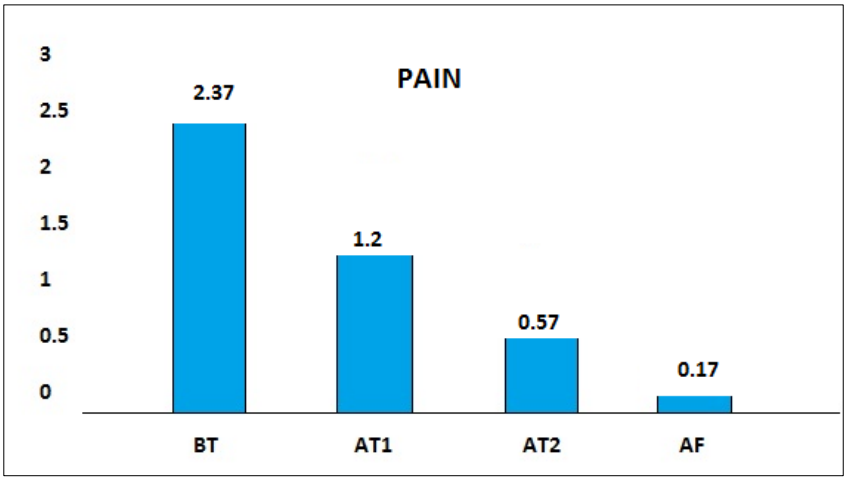

Figure 5 Effect of therapy on Pain

3.5 Effect on therapy on Itching

Itching was graded on a five point Likert Scale subjectively. The reduction in the symptoms of itching during the various assessments is as given in the table below (Table 13).

Table 13 Effect on therapy on Itching

ITCH No.	Mean	Std. Deviation	N
ITCH 1	2.40	1.037	30
ITCH 2	1.40	0.855	30
ITCH 3	1.00	0.947	30
ITCH 4	0.23	0.430	30

The change in the symptom of Itching during various assessments were tested using Mauchly's test of sphericity. The table below (Table 14) shows the results of the test. The test was found to be statistically insignificant (P>0.05) suggesting that the treatment effect in the various groups were comparable.

Table 14 Mauchly's Test of Sphericity[b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
ITCH	0.787	6.647	5	0.249	0.869	0.962	0.333

Multiple comparisons were performed on the data to assess the real efficacy of the treatment with Bonferroni corrections. The results are shown in the table below (Table 15).

Table 15 Pairwise Comparisons

Measure:MEASURE_1						
(I) ITCH	(J) ITCH	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	1.000*	0.166	0.000	0.530	1.470
	3	1.400*	0.156	0.000	0.958	1.842
	4	2.167*	0.192	0.000	1.622	2.711
2	1	-1.000*	0.166	0.000	-1.470	-0.530
	3	0.400*	0.123	0.018	0.051	0.749
	4	1.167*	0.145	0.000	0.757	1.576
3	1	-1.400*	0.156	0.000	-1.842	-0.958
	2	-0.400*	0.123	0.018	-0.749	-0.051
	4	0.767*	0.164	0.000	0.303	1.231
4	1	-2.167*	0.192	0.000	-2.711	-1.622
	2	-1.167*	0.145	0.000	-1.576	-0.757
	3	-0.767*	0.164	0.000	-1.231	-0.303

Pair wise analysis showed highly significant change in Pain score at 0.1% level (P<0.001) in comparisons BT vs AT1 and AT2 vs AF. The comparison AT1 vs AT2 showed a significance at 5% level only (P<0.05). Figure 6 shows effect of therapy on itching.

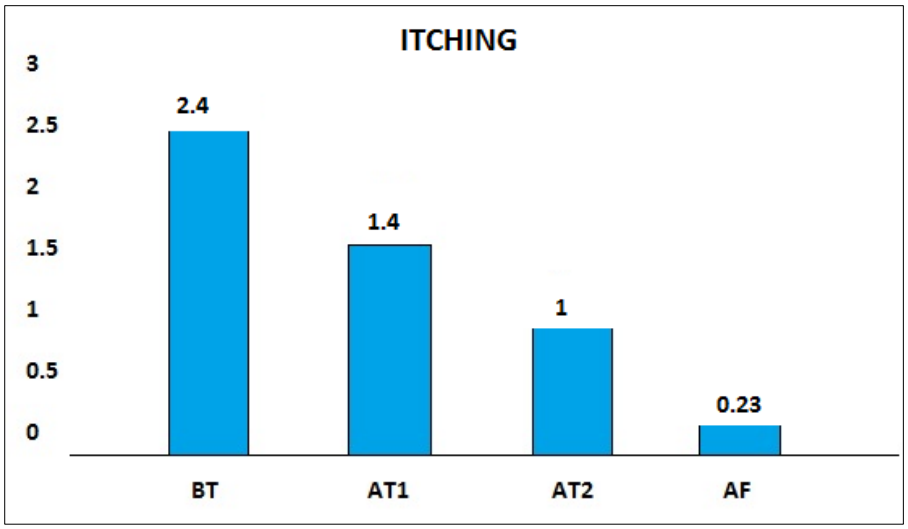

Figure 7 Effect of therapy on Itching

3.6 Effect of therapy on Number of Cracks

Number of cracks was assessed at each point of assessment. The reduction in the number of crack during various assessments is as given below (Table 16).

Table 16 Effect of therapy on Number of Cracks

CRACK No	Mean	Std. Deviation	N
CRACK_NO_1	2.0667	0.82768	30
CRACK_NO_2	1.4667	0.89955	30
CRACK_NO_3	0.9333	0.78492	30
CRACK_NO_4	0.4667	0.73030	30

The change in the number of cracks during various assessments were tested using Mauchly's test of sphericity. The table below (Table 17) shows the results of the test. The test was found to be statistically significant (P<0.05), so Hyunh-Feldt corrected significance was considered and the P value was fixed as 0.860 (P>0.05) making the treatment effect in the various groups were comparable.

Table 17 Mauchly's Test of Sphericity[b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
CRACK_NO	0.650	11.944	5	0.036	0.786	0.860	0.333

Pair wise analysis showed highly significant change in Pain score at 0.1% level (P<0.001) in all comparisons viz., BT vs AT1, AT1 vs AT2 and AT2 vs AF.

Further the data was subjected for Multiple comparisons with Bonferoni corrections. The results are shown in the table below (Table 18). Figure 7 shows effect of therapy on number of cracks.

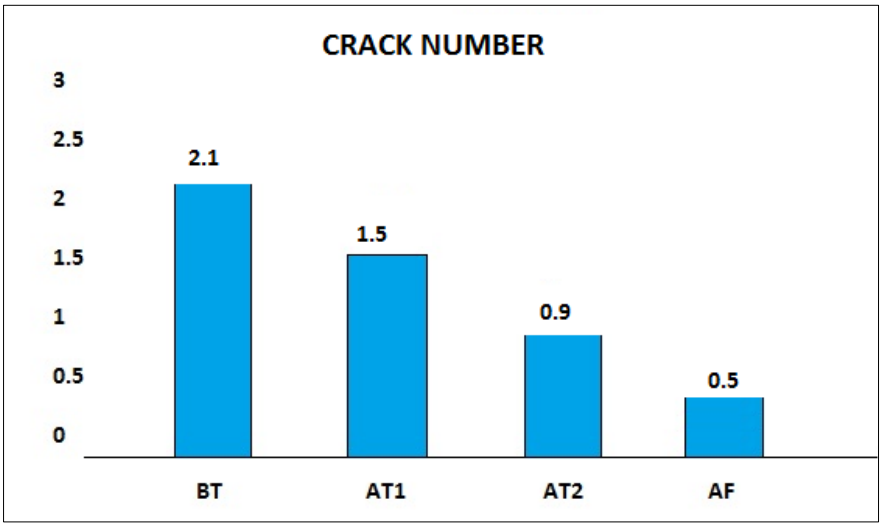

Figure 8 Effect of therapy on Number of Cracks

Table 18 Pairwise Comparisons

Measure:MEASURE_1						
(I) CRACK_NO	(J) CRACK_NO	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	1	0.600*	0.141	0.001	0.202	0.998
	2	1.133*	0.164	0.000	0.668	1.598
	3	1.600*	0.156	0.000	1.158	2.042
2	1	-0.600*	0.141	0.001	-0.998	-0.202
	3	0.533*	0.124	0.001	0.181	0.886
	4	1.000*	0.127	0.000	0.641	1.359
3	1	-1.133*	0.164	0.000	-1.598	0-.668
	2	-0.533*	0.124	0.001	-0.886	-0.181
	4	0.467*	0.093	0.000	0.204	0.729
4	1	-1.600*	0.156	0.000	-2.042	-1.158
	2	-1.000*	0.127	0.000	-1.359	-0.641
	3	-0.467*	0.093	0.000	-0.729	-0.204

3.7 Effect of therapy on Scaling

Scaling was graded and was assessed at each point of assessment. The reduction in scaling during various assessments is as given in the table below (Table 19).

Table 19 Effect of therapy on Scaling

SCALING No	Mean	Std. Deviation	N
SCALING_1	1.7	0.65126	30
SCALING_2	0.9	0.84486	30
SCALING_3	0.53	0.62881	30
SCALING_4	0.1667	0.37905	30

The change in Scaling during various assessments were tested using Mauchly's test of sphericity. The table below (Table 20) shows the results of the test. The test was found to be statistically insignificant (P>0.05) suggesting that the change in scaling due to the treatment was comparable between the groups.

Table 20 Mauchly's Test of Sphericity[b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
SCALING	0.688	10.353	5	0.066	0.805	0.883	.333

Further the data was subjected for Multiple comparisons with Bonferoni corrections. The results are shown in the table below (Table 21).

Table 21 Pairwise Comparisons

Measure:MEASURE_1						
(I) SCALING	(J) SCALING	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	0.800*	0.111	0.000	0.485	1.115
	3	1.167*	0.108	0.000	0.861	1.473
	4	1.533*	0.115	0.000	1.208	1.858
2	1	-0.800*	0.111	0.000	-1.115	-0.485
	3	0.367*	0.112	0.017	0.049	0.685
	4	0.733*	0.151	0.000	0.305	1.161
3	1	-1.167*	0.108	0.000	-1.473	-0.861
	2	-0.367*	0.112	0.017	-0.685	-0.049
	4	0.367*	0.102	0.007	0.079	0.654
4	1	-1.533*	0.115	0.000	-1.858	-1.208
	2	-0.733*	0.151	0.000	-1.161	-0.305
	3	-0.367*	0.102	0.007	-0.654	-0.079

Pair wise analysis showed highly significant change in Pain score at 0.1% level (P<0.001) in comparison BT vs AT1, 5% level of significance was shown by the comparison AT1 vs AT2 and the comparison AT2 vs AF showed a significance at 1% level (P<0.01). Figure 8 shows effect of therapy on scaling.

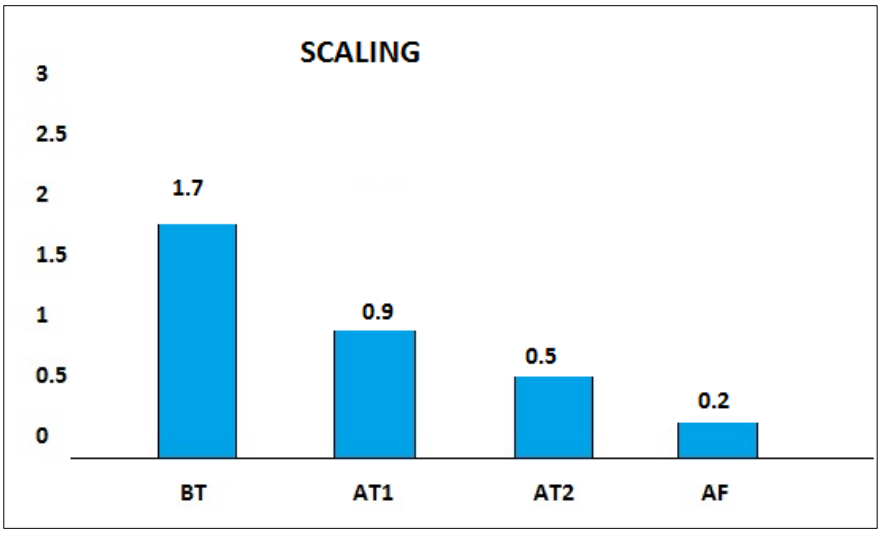

Figure 9 Effect of therapy on Scaling

3.8 Effect of therapy on Wrinkling

Wrinkling was assessed at each point of assessment on a five point Likert scale. The reduction in wrinkles during various assessments is as given in the table below (Table 22).

Table 22 Effect of therapy on Wrinkling

WRINKL No	Mean	Std. Deviation	N
WRINKL_1	1.67	0.80230	30
WRINKL_2	1.2	0.84690	30
WRINKL_3	0.6667	0.71116	30
WRINKL_4	0.2667	0.52083	30

The change in the symptom wrinkling during various assessments were tested using Mauchly's test of sphericity. The table below (Table 23) shows the results of the test. The test was found to be statistically significant (P<0.05). Hence Huynh-Feldt corrected P value was considered and the treatment effects were made comparable using Multiple comparisons.

Table 23 Mauchly's Test of Sphericityb

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
WRINKLE	0.603	14.023	5	0.016	0.735	0.798	0.333

Pair wise comparisons of the data were performed on the data applying Bonferoni corrections and the results are tabulated below (Table 24).

Table 24 Pairwise Comparisons

Measure:MEASURE_1						
(I) WRINKLE	**(J) WRINKLE**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[a]**	**95% Confidence Interval for Difference[a]**	
					Lower Bound	Upper Bound
1	2	0.467*	0.104	0.001	0.171	0.762
	3	1.000*	0.096	0.000	0.728	1.272
	4	1.400*	0.132	0.000	1.026	1.774
2	1	-0.467*	0.104	0.001	-0.762	-0.171
	3	0.533*	0.115	0.000	0.208	0.858
	4	0.933*	0.159	0.000	0.484	1.382
3	1	-1.000*	0.096	0.000	-1.272	-0.728
	2	-0.533*	0.115	0.000	-0.858	-0.208
	4	0.400*	0.103	0.003	0.109	0.691
4	1	-1.400*	0.132	0.000	-1.774	-1.026
	2	-0.933*	0.159	0.000	-1.382	-0.484
	3	-0.400*	0.103	0.003	-0.691	-0.109

Pair wise comparisons showed that the comparison BT vs AT1 showed significant reduction in symptoms at 1% level (P<0.01). The comparison AT1 vs AT2 was significant at 0.1 % level (P<0.001) and the comparison AT2 vs AF showed significance at 1% level (P<0.01). Figure 9 shows effect of therapy on wrinkling.

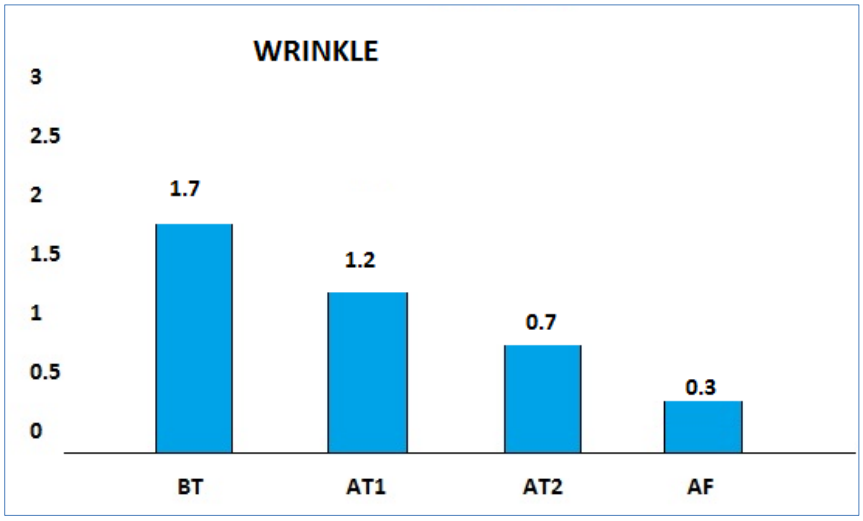

Figure 10 Effect of therapy on Wrinkling

3.9 Effect of therapy on Laxity of Skin

Laxity of Skin was graded on a five point Likert scale. The change in the score of laxity after each assessment is tabulated below (Table 25).

Table 25 Effect of therapy on Laxity of Skin

LAX SKN No	Mean	Std. Deviation	N
LAX_SKN_1	1.9667	0.66868	30
LAX_SKN_2	1.2000	0.80516	30
LAX_SKN_3	0.8333	0.69893	30
LAX_SKN_4	0.1333	0.34575	30

The change in the symptom laxity of skin during various assessments were tested using Mauchly's test of sphericity. The table below (Table 26) shows the results of the test. The test was found to be statistically insignificant (P>0.05). Hence we consider that the treatment effects were comparable.

Table 26 Mauchly's Test of Sphericity[b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
LAX_SKIN	0.734	8.577	5	0.127	0.854	0.944	0.333

Pair wise comparisons of the data were performed on the data applying Bonferoni corrections and the results are tabulated below (Table 27).

Multiple comparisons of the assessments shows highly significant difference in the comparisons BT vs AT1 and AT2 vs AF. The comparison AT1 vs AT2 shows only minimal significance of P < 0.05. Figure 10 shows effect of laxity on skin.

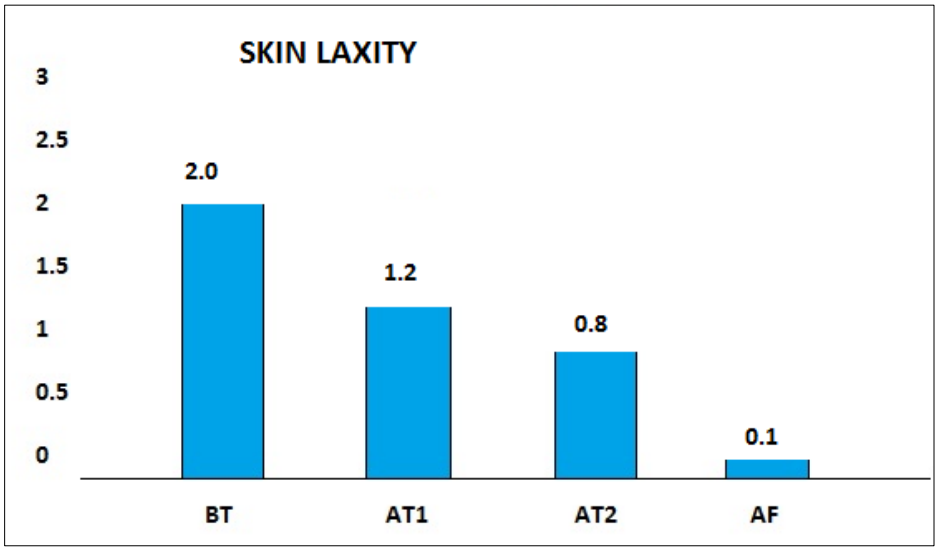

Figure 11 Effect of therapy on Laxity of Skin

Table 27 Pairwise Comparisons

Measure:MEASURE_1						
(I) LAX_SKIN	(J) LAX_SKIN	Mean Difference (I-J)	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a]	
					Lower Bound	Upper Bound
1	2	0.767*	0.149	0.000	0.344	1.189
	3	1.133*	0.150	0.000	0.710	1.557
	4	1.833*	0.128	0.000	1.472	2.195
2	1	-0.767*	0.149	0.000	-1.189	-0.344
	3	0.367*	0.112	0.017	0.049	0.685
	4	1.067*	0.151	0.000	0.639	1.495
3	1	-1.133*	0.150	0.000	-1.557	-0.710
	2	-0.367*	0.112	0.017	-0.685	-0.049
	4	0.700*	0.119	0.000	0.363	1.037
4	1	-1.833*	0.128	0.000	-2.195	-1.472
	2	-1.067*	0.151	0.000	-1.495	-0.639
	3	-0.700*	0.119	0.000	-1.037	-0.363

3.10 Effect of therapy on Pigmentation

Pigmentation was graded on each assessment and the change in the score of pigmentation after each assessment is tabulated below (Table 28).

Table 28 Effect of therapy on Pigmentation

PIGMNTN No	**Mean**	**Std. Deviation**	**N**
PIGMNTN_1	1.4333	0.50401	30
PIGMNTN_2	1.0333	0.61495	30
PIGMNTN_3	0.6333	0.66868	30
PIGMNTN_4	0.1333	0.34575	30

The change in the symptom pigmentation of skin during various assessments were tested using Mauchly's test of sphericity. The table below (Table 29) shows the results of the test. The test was found to be statistically insignificant (P>0.05). Hence we consider that the treatment effects were comparable.

Table 29 Mauchly's Test of Sphericity[b]

Measure:MEASURE_1							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[a]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
PIGMENTATION	0.862	4.131	5	0.531	0.903	1.000	0.333

Pair wise comparison of each assessment was performed with Bonferoni corrections and the results are tabulated below (Table 30).

Table 30 Pairwise Comparisons

Measure:MEASURE_1						
(I) PIGMENTATION	**(J) PIGMENTATION**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[a]**	**95% Confidence Interval for Difference[a]**	
					Lower Bound	Upper Bound
1	2	0.400*	0.103	0.003	0.109	0.691
	3	0.800*	0.111	0.000	0.485	1.115
	4	1.300*	0.085	0.000	1.059	1.541
2	1	-0.400*	0.103	0.003	0-.691	-0.109
	3	0.400*	0.091	0.001	0.142	0.658
	4	0.900*	0.100	0.000	0.617	1.183
3	1	-0.800*	0.111	0.000	-1.115	-0.485
	2	-0.400*	0.091	0.001	-0.658	-0.142
	4	0.500*	0.104	0.000	0.204	0.796
4	1	-1.300*	0.085	0.000	-1.541	-1.059
	2	-0.900*	0.100	0.000	-1.183	-0.617
	3	-0.500*	0.104	0.000	-0.796	-0.204

Pair wise comparison shows significant changes in the symptom at 1% level of significance (P<0.01) in comparisons BT vs AT1 and AT1 vs AT2. In the comparison between AT2 vs AF significance was obtained at 5% level (P<0.05). Figure 11 shows effect of therapy on pigmentation.

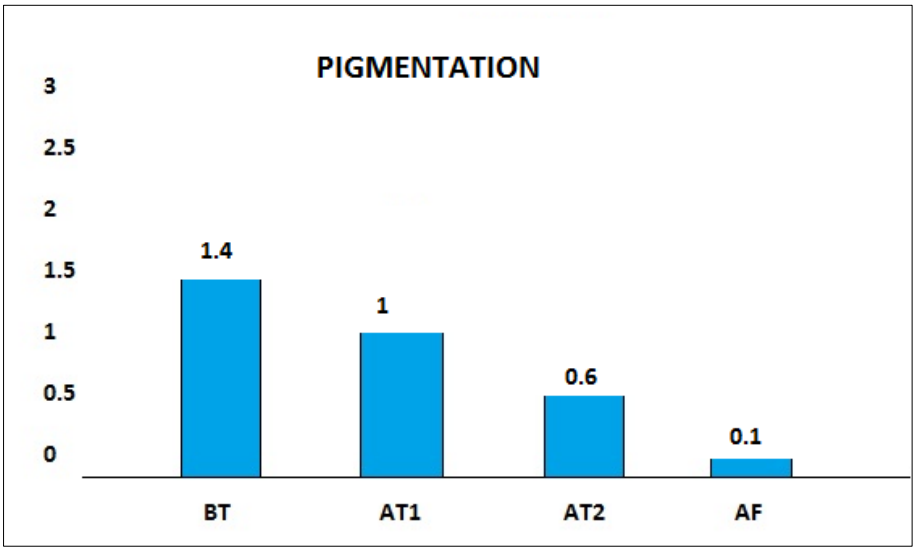

Figure 12 Effect of therapy on Pigmentation

The results of the study shows that the data was normally distributed and the effect of therapy shows significant reduction in the symptoms assessed during the study viz, dryness, cracking, pain and itching. The associated symptoms of Number of cracks, scaling, Wrinkling, laxity of skin and pigmentation also showed statistically significant reduction

The combined effects of the ingredients in the three different formulations of Fair Foot Ointment account for its effectiveness. The Vrana ropana property of Jatyadhi gritha makes the healing of cracks faster. Jeevantyadhi Yamaka which is a combination of Gritha and Taila helps in reduction of Pitta and Vata respectively and prevents further cracks in future. Additionally, because of its Snigdha guna and vatahara properties, it lessens the effects of vata, such as scaling, wrinkles, and suppleness of skin. Karanja taila is well-known for the advantages it offers the skin, including the capacity to heal wounds, its anti-inflammatory qualities, and its capability to alleviate skin conditions.

Each drug's mechanism of action was examined in further detail. Foot crack inflammation is lessened by the ushna virya of Jathi, Darvi, Manjista, Hareetaki, Haridra, and Kampillaka as well as the anti-inflammatory qualities of Darvi and Haridra. The antibacterial property of Nimba, Darvi, Haridra, Kampillaka prevents infection and aggravation of cracks and wounds. The itching caused by fissures is lessened by the kandugna properties of Darvi, Sariba, Haridra, and Kaphahara properties of Katuki, Manjista, Tutta, kampillaka, and Sarjarasa. The Vatapittahara property of Jeevanthi and Madhuka, along with the sheetha virya of Nimba, Madhuka, Jeevanthi, and Sarja, aid in lessening the burning sensation brought on by cracks.The varnya property of Manjista, Sarja and Hareetaki helps in a localised depigmentation action which in turn clears the pigmentation associated with cracks and scaling. The leghaneeya action of tuttha present in both Jeevandyadhi yamaka and Jatyadhi taila helps in vrana shodhana. Its krimigna action of tuttha keeps microbes at bay. The kaphahara and pittahara property of tuttha helps in relieving itching and burning sensation associated with cracks.

3.11 Loss to follow up

No participants failed to complete the trial. All thirty participants completed the study. Any of the participant showing remnants of any complaints were managed under the OPD of Dept. of Agadatantra, VPSV Ayurveda College Kottakkal.

3.12 Adverse events

No participants showed any adverse events during the study period. The study period was uneventful with 100% compliance.

4. Conclusion

The results of the study showed a notable decrease in symptoms like itching, dryness, cracking, and pain. Moreover, there was a statistically significant decrease in indicators of pigmentation, sealing, wrinkles, and skin laxity. The drug was potentially safe with no reported adverse events throughout the trial period indicating that the medicine is safe. Clinical findings indicate that Fair foot ointment could be used for the treatment of patients with Vipadika.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

Ethical Approval was obtained from institutional review board with reference number IEC/doc/CI/35/17; dated on 21/04/2017.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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