



## Therapeutic Effectiveness of *Kaalani Ennai* for the Management of *Kaalani* (Corn Foot) – A Case Series

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### KEYWORDS

Kaalani, Kaalani ennai, Corn foot, Callosity.

### ABSTRACT:

The siddha system of medicine is broadly classified into 32 internal medicines & 32 external medicines, of which the external medicines play a significant role in the treatment & management of various skin diseases. A corn is a horny thickening that is surrounded by a cone-like structure, with the base at the surface and the tip pointing within. It is more concerning to the patient and thicker than a callosity. The centre of the corn produces a searing sensation when pressure is applied directly. When pressure is concentrated at one spot in corn, the central core functions as a thorn. The main objective of the study was determining the effectiveness of Kaalani ennai (External medicine) in the treatment of Kaalani (Corn foot). The entire study was conducted in OPD of Department of Pura Maruthuvam, Ayothidass Pandithar hospital, National Institute of Siddha, Chennai, Tamilnadu, India. Institutional Ethical Clearance was obtained for this study on (12/07/2023;NIS/24/2023/MP/57) the clinical trial was done in 10 patients and diagnosed as Kaalani (corn foot) within the age limit of 20-70 years of both sex. The trial medicine Kaalani ennai (External medicine) was applied daily over the corn and covered with bandage for 48 days. The clinical improvement was documented in case report forms by using Visual analogue scale and EQ-5D Scale. Based on the reduction of clinical symptoms, Visual analogue scale and EQ-5D scale, the trial drug is therapeutically effective in the treatment of Kaalani.

### 1.Introduction:

The Siddha system of medicine offers preventive, curative, and rejuvenate healthcare by following the principles of *Pancha Boodham*. This traditional medical practice, emphasizes a variety of external therapies, particularly the administration of treatments through non-oral routes. These therapies primarily aim to maintain a healthy balance among the three physiological factors or humors—*Vatham*, *Pitham*, and *Kabam*—as well as the seven body tissue types (*Udal Thathukkal*): *Saaram*, *Senneer*, *Oon*, *Kozhuppu*, *Enbu*, *Moolai*, and *Sukkilam* or *Suronitham*.

Long-term, intermittent pressure and friction on the sole likely to result in corn. It is a natural kind of hyperkeratosis that shields the delicate skin and underlying structures from pressure and abrasion. It is painful hyperkeratosis that develops on the soles and across the toes and has a conical shape. Pain results from pressure on nerve endings caused by corn hyperkeratosis that is forced into the skin. Clinically, a corn is a polished, flesh-coloured, spherical papule<sup>1</sup>.

In *Siddha maruthuvam sirappu* literature, corn is caused by increased friction of the foot without the usage of foot wear, piercing the foot by thorns, and walking through the coarse stones<sup>2</sup>.



According to the *Sambasivam Pillai* dictionary, *Kaalani* is the corn or callosity of the sole and toes<sup>3</sup>.

In *Agathiyar Rana Vaithiyam*, *Kaalani* is caused by walking on bare foot on hard surfaces and stones, and untreated thorn pricks can cause uneven skin surface clustering<sup>4</sup>.

This *Kaalani Ennai* preparation was mentioned for the treatment of *kaalani* (corn foot). This *Kaalani Ennai* contains *Gowri padanam* (arsenic penta sulfide), castor oil and cow's butter. This formulation is indicated for the treatment of *kaalani* (corn foot) that have been mentioned in ancient siddha literature, *Agathiyar aayul vedham* 1200.

## 2. Materials & Methods:

### 2.1. Ingredients Of The Trial Drug:

Purified *Gowri paadanam*

Castor oil

Cow's Butter

### 2.2. Purification Of Gowri Padanam

*Gowri padanam* is soaked in *Indigofera tinctoria* (*Avuri*) and *Momordica charantia* (*Paagal*) leaf juices, each for 3 days<sup>5</sup>.

### 2.3. Preparation:

*Gowri padanam* is made into powder and ground with castor oil, followed by cow's butter<sup>6</sup>.

**Dosage:** Sufficient quantity

## 3. Standard Operative Procedure

### 3.1. Pre-Treatment Procedure:

## 7. Observation:

Table 1: Gender distribution among study population

S:NO	GENDER	NUMBER OF CASE	DISTRIBUTION
1	MALE	4	40%
2	FEMALE	6	60%

The site was cleaned with *Padikara neer* and allowed to dry.

### 3.2. Main Procedure:

The trial medicine was applied over the corn (daily).

### 3.3. Post Treatment Procedure:

The site was covered with a bandage.

**Duration:** 48 days

### 4. Inclusion Criteria:

- Age: 20-70 years
- Sex: Both male and female
- Presence of corn, callosity, Pain
- Willing to give blood samples for investigation.
- Willing to take photograph.
- Willing to participate in trial and signing consent by fulfilling the condition of Proforma.

### 5. Exclusion Criteria:

- History of uncontrolled Diabetes
- History of Rheumatoid arthritis
- History of Peripheral neuropathy
- History of foot ulceration
- History of taking oral steroid
- History of Hansen's disease

### 6. Assessment:

Patients were assessed based on clinical signs and symptoms of corns, including painful, polished, and circumscribed papules on the soles or toes. A thorough evaluation ensured the accurate identification of eligible cases. Those meeting the criteria were enrolled in the study.



Table 2: Age distribution among study population

S:NO:	AGE	NUMBER OF CASES	DISTRIBUTION
1	20-35	5	50%
2	36-50	3	30%
3	51-70	2	20%

Table 3: Occupational status distribution among study population

S:NO:	OCCUPATION	NO OF CASES	DISTRIBUTION
1	IT	3	30%
2	HOUSE WIFE	4	40%
3	RETIRED	1	10%
4	SECURITY	2	20%

Table 4: Dietary habits distribution among study population

S:NO:	DIET	NO OF CASES	DISTRIBUTION
1	VEGETARIAN	2	20%
2	NON-VEGETARIAN	8	80%

Table 5: Duration of corn distribution among study population

S:NO:	DURATION OF CORN	NO OF CASES	DISTRIBUTION
1	UPTO 1 YEAR	4	40%
2	1-2 YEAR	3	30%
3	2-3 YEAR	3	30%

Table 6: Site of corn distribution among study population

S:NO:	SITE OF CORN	NO OF CASES	DISTRIBUTION
1	RIGHT SOLE	6	60%
2	LEFT SOLE	1	10%
3	BOTH SOLE	3	30%

Table 7: Number of corn distribution among study population

S:NO:	NUMBER OF CORN	NO OF CASES	DISTRIBUTION
1	SINGLE	4	40%



2	MULTIPLE	6	60%
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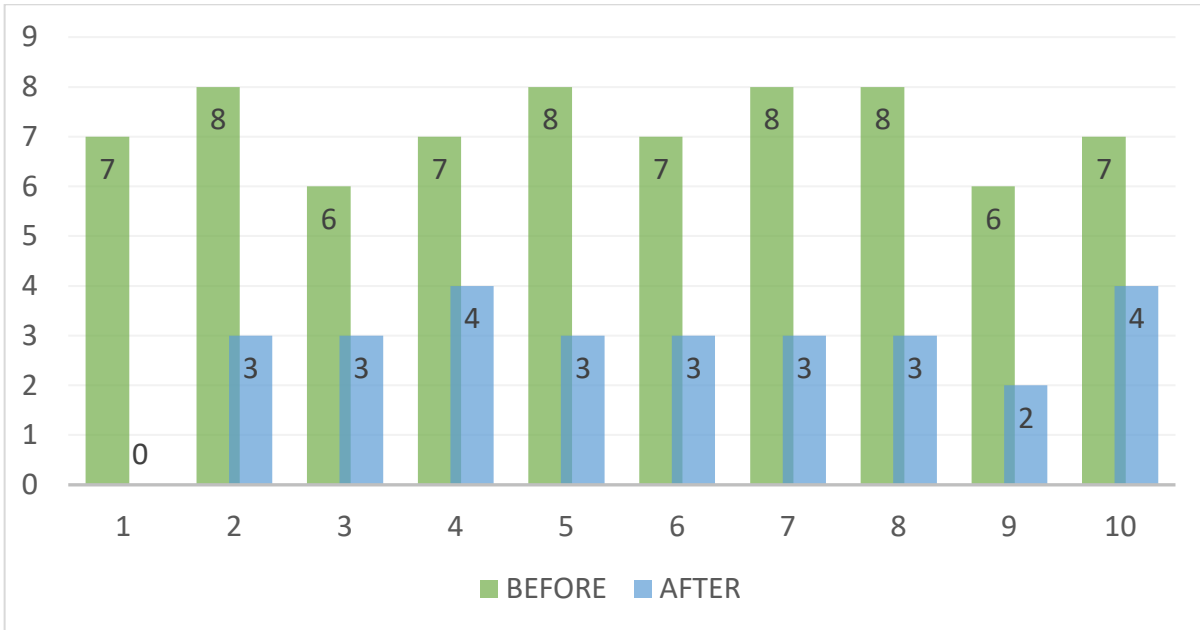


Figure 1: Visual analogue scale- Before Treatment

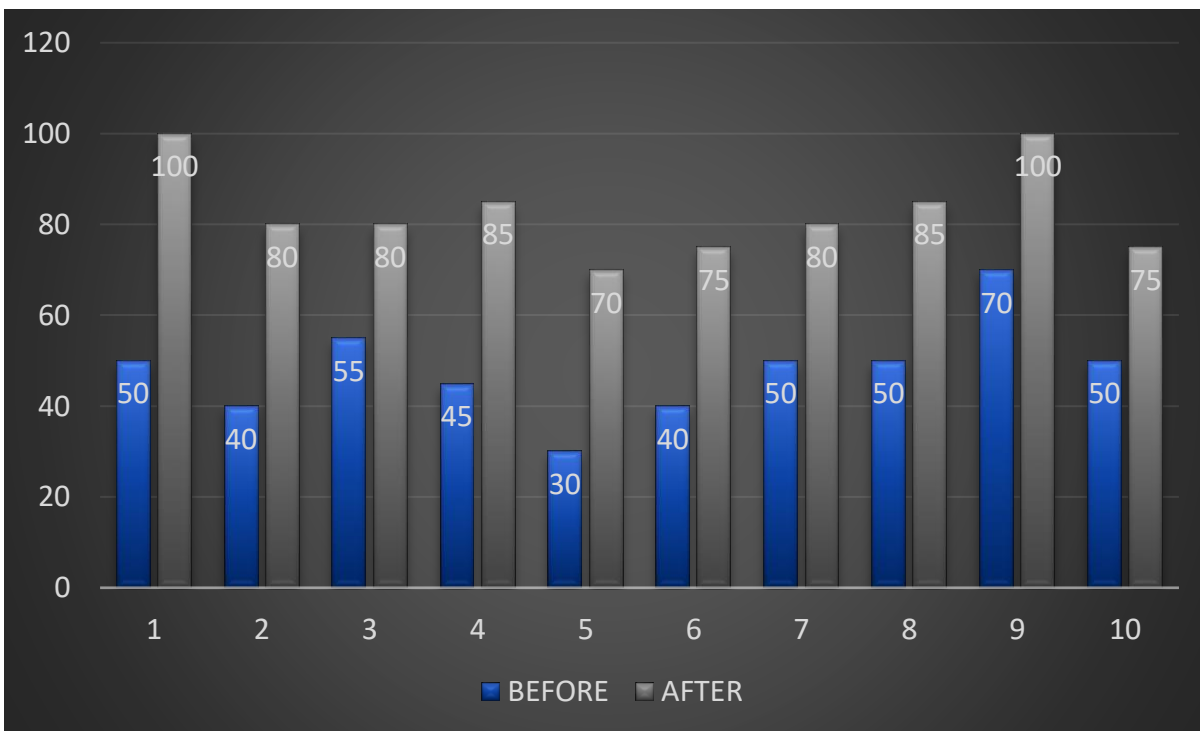


Figure 2: EQ-5D Scale- Before Treatment and After Treatment



**8.Result:**

S:NO:	BEFORE TREATMENT	AFTER TREATMENT
<b>Patient 1</b>		
<b>Patient 2</b>		
<b>Patient 3</b>		
<b>Patient 4</b>		



**Table 8: Statistical analysis of results of Visual analogue scale (Before and after treatment)**

Visual analogue scale	Before	After
Mean	7.2	2.8
Standard Deviation	0.79	1.14
Standard Error of the Mean (SEM)	0.25	0.36
T Value	11.0	
P Value	$1.61 \times 10^{-6}$	

The study demonstrated a significant reduction in pain intensity, as assessed by the Visual Analogue Scale (VAS), following the intervention. The mean VAS score decreased from  $7.2 \pm 0.79$  before the intervention to  $2.8 \pm 1.14$  after the intervention, indicating substantial improvement. The Standard Error of the Mean (SEM) was 0.25 before and 0.36 after, reflecting a consistent precision in the measurements. Statistical analysis revealed a highly significant T value of 11.0, with a corresponding P value of  $1.61 \times 10^{-6}$ , confirming that the reduction in pain was not due to chance and highlighting the effectiveness of the treatment.

**Table 9: Statistical analysis of results of EQ-5D Scale (Before and after treatment)**

EQ-5D Scale	Before	After
Mean	48.00	83.00
Standard Deviation (S.D.)	10.59	10.06
Standard Error of the Mean (S.E.M.)	3.35	3.18
T-Value	14.16	
P-Value	0.00000019	

The statistical analysis of the EQ-5D scale values revealed significant improvements after the intervention. The mean EQ-5D score increased from  $48.0 \pm 10.59$  (standard deviation) before the intervention to  $83.0 \pm 10.06$  after. The Standard Error of the Mean (SEM) was 3.35 before and 3.18 after, reflecting reliable data precision. A paired t-test analysis produced a highly significant T value of -14.16, with a P value of  $1.86 \times 10^{-7}$ , indicating a substantial and statistically significant improvement in EQ-5D scores post-intervention.

### 9. Discussion:

In this study, the therapeutic effectiveness of Siddha topical medicine *Kaalani ennai* was determined for pain of *Kaalani* (corn foot) through visual analogue scale, and improvement in the quality of life of patients was evaluated through the EQ-5D Scale.

The clinical trial was carried out according to the established protocol, following the endorsement of the Institutional Ethical Committee (IEC) and registration with the Clinical Trial Registry - India. A total of 10 patients were diagnosed with *Kaalani* and were enrolled in the study on screening 20 patients, who reported to the Outpatient Department (OPD) of the Department of Pura Maruthuvam, Ayothidoss Pandithar Hospital, National Institute of Siddha. Prior to their inclusion in the trial, the patients provided informed consent.

In this study, all the 10 patients were treated with *Kaalani ennai* bandaging daily up to 48 days. Clinical prognosis and outcome assessments were noted in all patients on 0th day, 8th day, 15th day, 22nd day, 29th day, 36th day, 43rd day and 49th day of treatment.

After completion of trial, the patients were advised to visit the out-patient ward of Department of Pura Maruthuvam for follow-up and to document any recurrences.

The gender distribution among the study population shows a higher proportion of female participants (60%) compared to males (40%), which may be attributed to factors such as improper footwear usage among females. This suggests that footwear habits could play a significant role in the prevalence of the condition being studied.



The age distribution indicates that 50% of cases in the 20-35 age group are likely due to wearing hard shoes and heels, which may contribute to foot-related issues. In the 36-50 age group, accounting for 30% of cases, not wearing appropriate footwear appears to be a key factor. For the 51-70 age group, 20% of cases could be attributed to a combination of aging-related factors and reduced awareness of proper foot care. Addressing footwear-related issues across these age groups can help reduce the prevalence of foot-related conditions.

The distribution of cases across different occupations highlights distinct factors contributing to foot-related issues. The highest percentage, 40%, is observed among housewives, likely due to prolonged exposure to improper footwear. In the IT sector, 30% of cases are attributed to uncomfortable footwear, commonly associated with prolonged sitting or long hours in unsuitable shoes. Security personnel, contributing 20% of cases, experience friction due to prolonged standing and physical activity, which exacerbates foot conditions. Retired individuals account for only 10%, suggesting reduced physical activity and the potential for improved awareness or reduced exposure to foot-related risks. Addressing footwear-related concerns across these occupations can help mitigate these issues.

According to the duration of corn instances, 40% of cases happen in the first year, indicating early development and a quicker beginning. Perhaps as a result of extended exposure to relevant factors, 30% of patients show a moderate development in the 1-2 year range. Likewise, chronic or persistent foot-related problems are highlighted in 30% of instances that last two to three years. The length of time that corn-related conditions last can be decreased by taking care of these early indicators and avoiding long-term problems.

The distribution of corn cases reveals that 60% are located on the right sole, indicating a higher prevalence on one side, possibly due to dominant foot usage or shoe fit. The 10% on the left sole suggests a lesser involvement, which may be due to uneven pressure distribution. The 30% of cases affecting both soles highlights more widespread issues, possibly related to prolonged standing or improper footwear. Addressing

footwear and pressure distribution can help reduce the site-specific prevalence of corns.

The distribution of corn cases shows that 40% involve single corns, which may result from localized pressure or minor footwear issues. The 60% of cases with multiple corns suggests prolonged or cumulative factors such as repetitive pressure, improper footwear, or standing for extended periods. This pattern highlights the importance of addressing both localized and broader contributing factors, such as footwear and activity habits, to reduce the occurrence of multiple corns. Preventive measures and proper footwear choices are key to managing and reducing the number of corns.

The data from the Visual Analogue Scale (VAS) highlights a significant reduction in pain levels following the intervention. The mean VAS score decreased from  $7.2 \pm 0.79$  before the intervention to  $2.8 \pm 1.14$  after, indicating a substantial improvement in patient-reported pain levels. The Standard Error of the Mean (SEM) values, 0.25 before and 0.36 after, reflect consistent precision in measurements across the samples. The decrease in mean values suggests a marked therapeutic effect, which is further supported by the low variability in the data, as indicated by the standard deviation.

Statistical analysis revealed a highly significant T value of 11.0, with a corresponding P value of  $1.61 \times 10^{-6}$ , confirming that the observed reduction in pain is statistically significant and unlikely due to random chance. These results emphasize the efficacy of the intervention in managing pain, as evidenced by the substantial reduction in VAS scores. The findings underscore the potential of this approach to improve clinical outcomes for individuals experiencing pain, reinforcing its value in therapeutic applications.

The EQ-5D scale data demonstrates a significant improvement in the quality of life among participants following the intervention. The mean EQ-5D score increased from  $48.0 \pm 10.59$  before the intervention to  $83.0 \pm 10.06$  after, indicating a substantial positive impact. The consistent Standard Deviation (SD) and Standard Error of the Mean (SEM) values before (10.59 and 3.35, respectively) and after (10.06 and 3.18) reflect reliable and precise measurements, reinforcing the



validity of the observed changes. The marked increase in mean scores suggests that the intervention was effective in enhancing participants' perceived health and well-being.

Statistical analysis revealed a highly significant T value of -14.16, with a corresponding P value of  $1.86 \times 10^{-7}$ , indicating that the improvement in EQ-5D scores is unlikely to have occurred by chance. This highlights the robustness of the intervention in achieving meaningful clinical outcomes. The results underscore the potential of this approach to significantly improve quality of life, supporting its application in similar contexts. Further research could explore long-term impacts and examine whether the benefits are sustained over time.

## 10. Conclusion:

The study demonstrated the effectiveness of *Kaalani Ennai*, a Siddha external medicine, in treating *Kaalani* (corn foot). Regular application of the medicine over 48 days led to significant pain reduction and improvement in patients' quality of life, as evidenced by VAS and EQ-5D scales. Complete resolution of corns was observed in 40% of patients, with partial improvement in the remaining cases. The treatment was well-tolerated, indicating its potential as a safe and effective option for managing corn foot. These findings highlight the relevance of Siddha medicine in addressing common dermatological conditions.

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