

PHARMACEUTICAL MANUFACTURING AND STANDARDISATION OF HERBAL COSMETICS W.S.R. PRALEPA (CREAMS)

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ABSTRACT

Context: The skin constitutes a major part of the body and serves as a dividing line between the individual and his environment. The skin is a metabolically active organ with vital functions including the protection and homeostasis of the body. The colour of the human skin is derived from a variety of chemical and physical properties associated with the skin structure. All individuals' except albinos have some melanin pigment in their skin. Melanin contributes colour quality to the skin and protects the organism from the ultra-violet rays. Complexion refers to the natural colour, texture, and appearance of the skin, especially that of the face. Von Luschnan's chromatic scale is a method of classifying skin colour which consists of 36 opaque glass tiles which were compared to the subject's skin. In the *Ayurvedic* classics, *Bahi Parimarjana* means, the medicine intended for external use only. For that purpose, in *Ayurveda* different forms of external applications are described for the convenience of treatment of different diseases. They are *Lepa*, *Udvardhana*, *Upanaha*, *Abhyanga*, *Malhara* etc. Without defining creams under *Panchvidha kashaya kalpana*, we can correlate Cream preparation with *Lepa* or *Malhar kalpana*. Creams are those emulsions which are either oil in-water or water-in-oil type. *Kumkumadi tailam* was mostly given in *Kshudra rog chikitsa* of texts. Its usual *rogadhikar* being *Vyanaga*, *Nilika*, *Vaivarnya*, *Palita*, *Vali*, *Tilakalaka*, *Pidika*, *Mukha kasharya*, *Dushchaya* etc. It is an effective *tailam* and now being utilized by cosmetic companies. **Aims:** In the present study, we are comparing the effect of three *varnya* creams and *kumkumadi tailam* on improving complexion grades as per Von Luschan's Chromatic scale of skin colours and also studying the other factors which affects the clinical treatment.

Key-words: Skin, *Varnya*, *Lepa*, Creams, *Kumkumadi Tailam*, Von Luschan's Chromatic Scale

INTRODUCTION

The need of cosmetic and perfumery for man can be dictated because of his following urges -Urge of need of using, Urge of beautification, Urge of artistic sensitivity, Urge of

healthy ways, Urge of romantic lives, and Urge of piousness. *Meghdootam* (Uttarmegha -12) commentator *Mallinath* gave five types of *Prasadhana* or *Bhushan* –

◆ *Kacha dharya* - Hair decoration

◆ *Deha dharya* - Body decoration

◆ Parideha	- Garment decoration
◆ Vilepana	- Cosmetics
◆ Deshik	- Place wise decoration

In western world, cosmetic has its origin in Roman slaves whose function was to bathe men and women in perfume. Later its growth and development is seen in all parts of world. Today, mineral, earthy formulas that are environmentally safe are dominating the cosmetic industry. India's cosmetics and toiletries industry is tipped to grow 27 percent over 2006-2011, according to Euromonitor, due to the country's strong economic performance and youthful demographic structure.

CONCEPTUAL STUDY

Skin is described extensively in ancient literature. It is related to *Doshas*, *Dhatus*, *Updhatu*, *Mala*, and *Strotas*. *Varnotpatti* (Pigmentation) in skin occurs in two steps:-

1. *Sahaja Varnotpatti*
2. *Jatottar Varnotpatti*

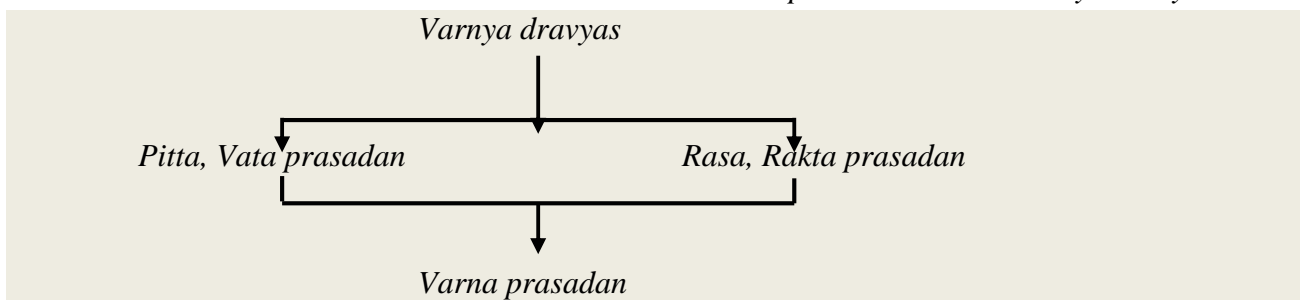
Skin is the seat of *bhrajaka pitta* which imparts the characteristic complexion to skin and also performs *deepan* and *pachan* of substance used for *Abhyanga*, *lepa*, *parishek* etc. According to Modern science, Melanin contributes colour quality to the skin and protects the organism from the ultra-violet rays. Various colour grading scales are also given like Fitzpatrick scale and Von Luchnan scale.

A soft good healthy skin gives glowing appearance and a radiant complexion. The total health of the skin is reported by its texture, colour, tone, luster, complexion etc. According to Ayurveda, there are some factors which influence the healthy skin;

1. *Udana Vayu*
2. *Bhrajaka Pitta*
3. *Rasa Dhatu*
4. *Rakta dhatu*
5. *Ahara vihara*
6. *Ritus*
7. *Prakriti*
8. *Vayas*
9. *Agni*
10. *Ojas*
11. *Manas*

Hence, it may be summoned up that food, nutrition, *Dinacharya*, *Ritucharya*, *Drugs*, *Panchakarma* etc. are very essential in procuring healthy skin, when used externally or internally.

Acharya have given many drugs for increasing complexion. Whatever brings softness, suppleness and beauty to the skin, provides luster and Complexion and bring the discolored skin to the natural colour is termed as *varnya*, *varna prasadan* and *varchasya dravya*.

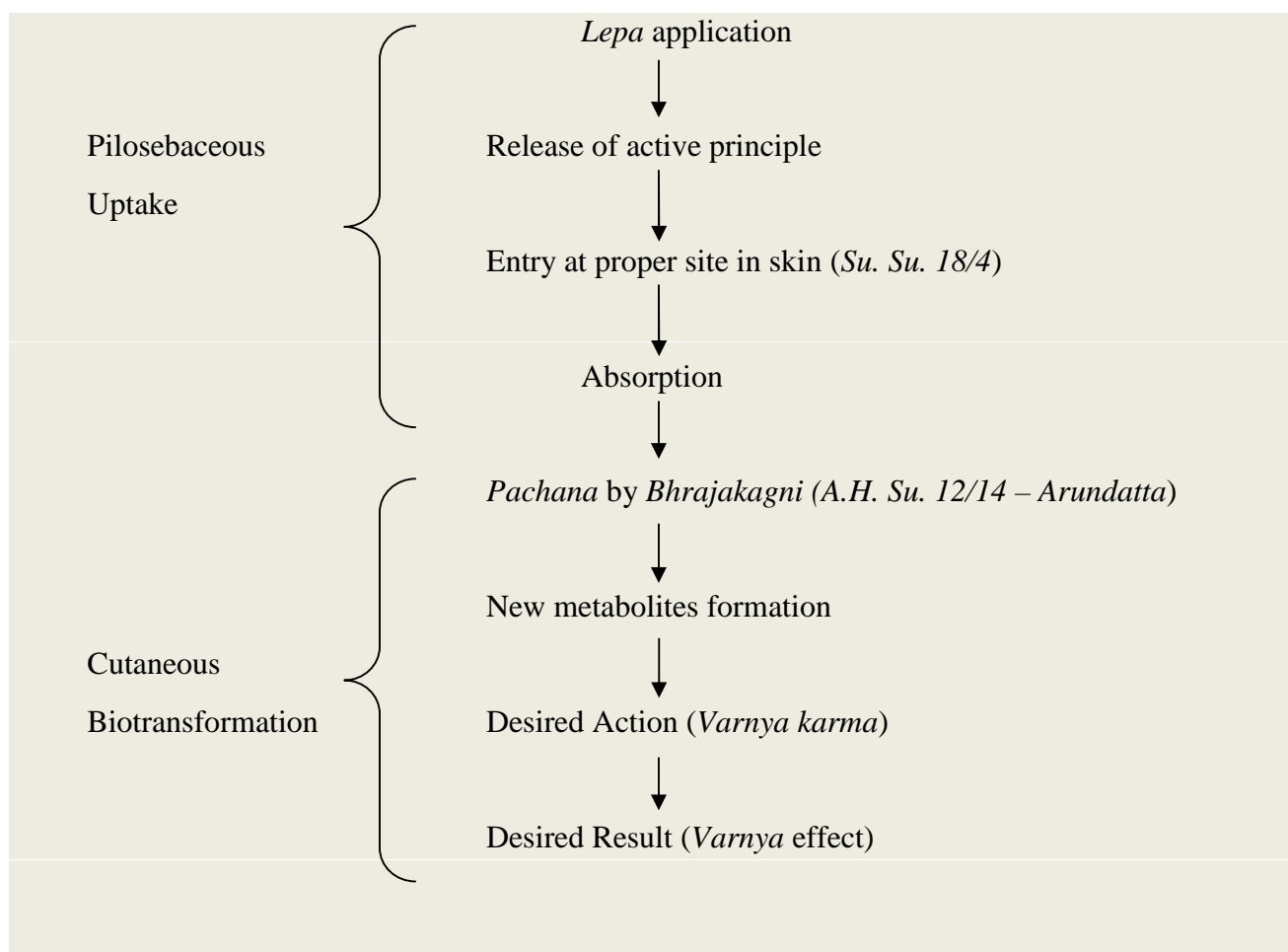


For *Varnya* effect, *Lepan Karma* (in the form cream and oil) is selected here as per the indi-

cation by *Acharya Sushruta*. *Acharya Sharangdhara* gave beautiful description of *lepa*

saying it to be *satmaya* to body right from the birth. *Lepa* should be rubbed in an upward or reverse direction of the hairs over the skin to

make the action of application more quick & effective. The probable mode of action of *Lepa* can be described in two steps as follows:



The *Acharyas* also scientifically describes preparation of *lepa* which were as par with modern cream preparation. Bases used were also herbo-mineral. There were many references in which the final product was in an emulsion form.

An Emulsion can be defined as a thermodynamically unstable mixture of two essentially immiscible liquids. Creams are those emulsions which are either oil in-water or water-in-oil type. Vanishing cream, Cold cream and all purpose cream are all types of skin creams. Herbal cosmetic creams are gaining much popularity these days but there is certain limitation to it:-

1. Lack of product uniformity, quality control, formulation stability and preservation.

2. Natural extracts are not as consistent as modern constituents.

So it is strongly felt that the acclaimed use of herbal ingredient in cosmetics should be based on rational, controlled experiments, and tests should also be conducted so as to examine the presence of medicinal effects.

Use of *Kumkumadi tailam* for *varnya* effect is very old. This preparation is given with much importance in many texts. There are as many as 9 types of *Kumkumadi tailam* with little or more difference in ingredients. *Kumkumadi tailam* of *Chakra dutta Kshudra rog chikitsa* 63-65 was selected. The type of *Kumkumadi tailam* selected in the study has got following advantages:-

1. It has only 5 *kalka dravya*, *til tailam* and *aja kshira*, which are easily available, non controversial, effective and has been mentioned in almost all type of *Kumkumadi tailam*.
2. It is only *kalka sadhita tailam* and there is no requirement of *kwatha* formation. *Aja kshira* is used as *drava dravya*.
3. It has easy and short method of preparation.

4. *Kesar* is taken 1/16 of *tailam* hence making it cost effective.

DRUG REVIEW

In the present study 3 preparations viz, *Kumkumadi tailam*, *Varnya cream1* (Cold cream made of *Kumkumadi tailam*), *Varnya cream 2* (Vanishing cream), and *Varnya cream 3*(All purpose cream) were prepared. The constituent drugs of these preparations are tabulated here:

TableNo.1: Main ingredients of formulations

S.No.	Drug	Botanical Name	Part Used	Name of the formulation		
				<i>Kumkumadi tailam</i> and <i>Varnya cream 1</i>	<i>Varnya cream 2</i>	<i>Varnya cream 3</i>
1.	<i>Kumkuma</i>	<i>Crocus sativus</i>	Stigma	✓		
2.	<i>Laksha</i>	<i>Tachardia lacca</i>	Resin	✓		
3.	<i>Raktachandan</i>	<i>Pterocarpus santalinus</i>	Heartwood	✓		
4.	<i>Majishtha</i>	<i>Rubia cordifolia</i>	Root	✓	✓	
5.	<i>Yashtimadhu</i>	<i>Glycyrrhiza glabra</i>	Root	✓		
6.	<i>Tila</i>	<i>Sesamum indicum</i>	Seed oil	✓		
7.	<i>Aja dugdha</i>	Goat milk	Milk	✓		
8.	<i>Padamaka</i>	<i>Prunus cerasoides</i>	Heartwood		✓	
9.	<i>Lodhra</i>	<i>Symplocos racemosa</i>	Bark		✓	
10.	<i>Shwetachandan</i>	<i>Santalum album</i>	Heartwood		✓	
11.	<i>Kamala</i>	<i>Nelumbo nucifera</i>	Flower		✓	
12.	<i>Priyangu</i>	<i>Callicarpa macrophylla</i>	Fruit		✓	
13.	<i>Pattanga</i>	<i>Caesalpinia sappan</i>	Heartwood		✓	
14.	<i>Shati</i>	<i>Hedychium spicatum</i>	Rhizome		✓	
15.	<i>Palash</i>	<i>Butea monosperma</i>	Seed		✓	
16.	<i>Haldi</i>	<i>Curcuma longa</i>	Rhizome			✓
17.	<i>Methi</i>	<i>Trigonella foenum gracum</i>	Seed			✓
18.	<i>Daruhaldi</i>	<i>Berberis aristata</i>	Wood			✓
19.	<i>Jatiphala</i>	<i>Myristica fragrance</i>	Seed			✓
20.	<i>Madyantika</i>	<i>Lawsonia inermis</i>	Leaves			✓
21.	<i>Nagrang</i>	<i>Citrus aurantium</i>	Peel			✓

The drugs of *Kumkumadi tailam* are *Pittashamaka*, *Guru snigdha*, *Madhuratikata rasa* and almost pacifying *virya* and *vipaka*, thus making this combination ideal one.

The drugs selected for Vanishing cream have mostly *Laghu or Ruksha guna*, *Madhura Tikta Kashaya Katu rasa*, *Sheeta virya*, *Katu vipaka* and *Kaphapitta shamakata*. All are having *varnya karma* in there action.

The drugs selected for all purpose cream has *Laghu Ruksha guna*, *Tikta Katu rasa*, *Ushna virya*, *Katu vipaka*, *Tridosha shamakata*. These drugs are having cleansing action along with *varnya* effect. Hence they were selected to see the effect of cleansing specific drugs on *varnya* effect.

PHARMACEUTICAL STUDY

In the pharmaceutical study *Kumkumadi tailam* and *Varnya* creams are prepared three times each to standardise the SOP.

In *Kumkumadi tailam*, there was loss of 7.8% in sample 1, 6.25 % in sample 2 and 6.25 % in sample 3. The losses are may be due to instrumentation loss, handling loss and *kalka* loss.

Varnya cream 1 was made in Cold cream form and *Kumkumadi tailam* made before was the main ingredients. Modern chemical used were minimal. Emulsion was made with proper agitation by blender for aesthetic purpose perfume was also added. There was loss of 12.5% in sample 1, 11.65% in sample 2 and 9.8 % in sample 3. Losses are may be due to instrumentation loss, handling loss and evaporation loss.

Varnya cream 2 was made in Vanishing cream form. *Kwath* was made of main ingredients. Modern chemical used were minimal. Emulsion was made with proper agitation by blender for aesthetic purpose perfume was also added. There was loss of 10.5% in sample 1, 11.77% in sample 2 and 9.66 % in sample 3. Losses are may be due to instrumentation loss, handling loss and evaporation loss.

Varnya cream 3 was made as all purpose cream. *Kwath* was made of main ingredients. Modern chemical used were minimal. Emulsion was made with proper agitation by blender for aesthetic purpose perfume was also added. There was loss of 14.59% in sample 1, 12.24% in sample 2 and 11.85 % in sample 3. Losses are may be due to instrumentation loss, handling loss and evaporation loss.

ANALYTICAL STUDY

In order to produce quality herbal formulations, it is essential that standardization and validation of herbal materials and process is done and documented. A standard is the numerical value which quantifies the parameters and thus quality and purity of a material.

1. Analysis of Raw material (These tests were done to identify the genuine sample)

i. For *Kesar* following tests were done

- Colour of Stigma : Orange Red
- Test for moistness : Negative
- H₂SO₄ test : Positive
- Organic dye test : Positive

ii. For Sesame oil following test were done

- Boudouine test : Positive

2. Analysis of the finished product

Table No.2: The Comparative Organoleptic parameters of all three samples of *Kumkumadi tailam*

S.No.	Parameters	Sample 1	Sample 2	Sample3
1	Colour	Reddish	Reddish	Reddish
2	Odour	Specific	Specific	Specific
3	Taste	Astringent	Astringent	Astringent
4	Consistency	Oily	Oily	Oily

Table No.3: The comparative values of Physico chemical parameters of all three samples of *Kumkumadi tailam*

S. No.	Parameters	Sample 1	Sample 2	Sample3	Average
1	Specific gravity	0.9190	0.9188	0.9184	0.9187
2	Refractive index	1.4659	1.4659	1.4651	1.4656
3	Butyrorefractometer	59	59.5	58	58.9
4	Acid value	2.71	3.24	3.51	3.15

5	Saponification value	227.53	238.11	237.15	234.26
6	Ester value	224.82	234.87	233.64	231.11
7	Iodine value	26.19	20.95	21.45	22.86
8	Peroxide value	10.29	10.07	10.46	10.27

HPTLC REPORT

Sample: Methanolic extract of 3 samples of *Kumkumadi tailam*

Mobile phase: Petroleum Ether: Diethyl Ether (70:30)

Detection: Vanillin Sulphuric acid.

Measurement wavelength: 254

Table No. 4: Rf values of the three samples of all three samples of *Kumkumadi tailam*

Values	Sample 1	Sample 2	Sample3
1 peak	0.06	0.06	0.06
2 peak	0.17	0.17	0.14
3 peak	0.36	0.36	0.31
4 peak	0.39	0.46	-
5 peak	0.49	0.52	-
6 peak	0.64	0.63	-

ii. Test results of *Varnya cream 1*, *Varnya cream 2* and *Varnya cream 3*

Table No. 5: The Comparative Organoleptic parameters of three samples of creams

S.No.	Parameters	<i>Varnya cream 1</i>	<i>Varnya cream 2</i>	<i>Varnya cream 3</i>
1	Colour	Light pink	Light brown	Dark brown
2	Odour	Jasmine	Jasmine	Jasmine
3	Taste	Bitter	Bitter	Bitter
4	Consistency	semisolid	semisolid	semisolid

Table No.6: The comparative values of Physico chemical parameters of all three samples of creams

S.No.	Parameters	<i>Varnya cream 1</i>	<i>Varnya cream 2</i>	<i>Varnya cream 3</i>
1	pH	7.5	7.7	7.7
2	Total fatty matter	75.26%	24.81%	50.78%
3	Loss on drying	4.12%	48.65%	22.50%
4	Rancidity test	Negative	Negative	Negative

CLINICAL STUDY

Volunteers were divided in four groups of 15 patients each. Those of group 1 were given *Kumkumadi tailam*, group 2 was given *Varnya cream 1*, group 3 was given *Varnya cream 2* and group 4 was given *Varnya cream 3*. They were given 25 ml *Kumkumadi tail* and 50 gms of Cream for 1 month trial. The volunteers were asked to apply the oil and cream after

washing their face with clean water and mild cleanser at night. They were directed to massage it on face until it is absorbed with upward and outwards strokes.

GENERAL OBSERVATIONS

Age - Maximum numbers i.e. 76.66% of the patients were between age group of 23-29 years followed by 11.66 % of patients who belongs to age group of 30-36 years indicating that younger generation is more conscious about beauty and personality. Younger age is

the perfect age when people communicate more in the society for carrier as well as social purpose; data support the same.

Sex - In the study females about 60 % are found more than males about 40% suggestive of more consciousness about beauty in females

Marital status - In present study it was found that 55% patients were unmarried. Etiological factors like sun exposure, acne vulgaris, lichen planus etc. are seen more in unmarried persons. Hence the present study supports the reason.

Socio economic status - 91.66% of persons were belonging to middle class and 5 % belonged to lower class which shows that people of upper class usually have good skin owing to their comforts. But this data is only representative of socio-economic status of the individuals attending the hospital where study has been carried out.

Occupation - In present study specifically students were registered more by 91.66%. Students are getting more and more aware of their looks these days hence all readily got registered in the study.

Diet - Most of the individuals i.e. 86.66% were Vegetarian because more hindu population was registered.

Koshtha - Maximum individuals registered i.e. 53.33% were of *madhyam koshtha* as at young age *koshtha* is usually *madhyam*.

Agni Bala - In 46.67% individuals the status of the Agni was found *Sama* which indicates that in this disease *Jatharagni* is least involved.

Sharirika Prakriti - 41.66% individuals had *Kaphapitta prakruti* followed by 36.66% individuals of *Vatapitta prakruti* and 21.66% individuals of *Vata kapha prakruti*. *Pitta Prakriti* is always related with the complexion changes, this result proves that.

Manas prakruti - More individuals i.e. 61.66% were registered of *Rajsika prakriti* followed by 20% patients of *Sattva rajsika prakruti*. This may be because at young age people are of more *Rajsika prakruti*.

Type of skin - 10 Patients of group 1 was having dry to normal skin. in group 2, 7 patients were having normal to oily skin followed by 4 patients of dry to normal skin, group 3 had 8 patients of dry to normal skin and group 4 had 5-5 patients each of dry and dry to normal skin. In total maximum patients registered are of dry to normal skin i.e. 45 % which may be due to the weather condition of Jaipur.

Cleanser used - Maximum patients 70% were using soap for cleansing skin, which may be the reason of dry skin conditions.

**EFFECT OF THE THERAPY AS NOTED BY VON LUCHNAN SCALE
INCIDENCE OF VONLUCHNAN SCALE**

Table No. 7 Effect of therapy in 60 patients as per Von luchnan scale

S.No.	Scale no.	Group I		Group II		Group III		Group IV		Overall effect		
		Regd.	Relid.	Regd.	Relid.	Regd.	Relid.	Regd.	Relid.	Regd.	Relid.	%
1.	I (15-20)	05	01	05	02	05	03	05	01	20	07	35%
2.	II (21-26)	05	04	05	03	05	01	05	01	20	09	45%
3.	III (27-30)	05	03	05	03	05	02	05	05	20	13	65%
	Total	15	08	15	08	15	06	15	07	60	29	48.33%
	Percentage	53.33%		53.33%		40.00%		46.66%		48.33%		

Here we registered equal number of patient's i.e.5 in all scaling grades in all groups. This is

to see the effect on all grades equally. Results showed that group 1 and group 2 got maxi-

maximum relief by 53.33%, followed by 46.66% in group 4 and 40% in group 3. Scaling wise maximum relief was seen in III (27-30) with

65% followed by 45% in scale II (21-26) and then 35% in scale I (15-20).

Table No. 8 Comparative effect on Complexion

Groups	N	Mean		Dif.	% of Change	SD	SE	t	p
		BT	AT						
Group I	15	23.40	22.87	0.53	2.28	0.52	0.13	4.00	<0.01
Group II	15	24.13	23.53	0.60	2.49	0.63	0.16	3.67	<0.01
Group III	15	23.27	22.87	0.40	1.72	0.51	0.13	3.06	<0.01
Group IV	15	24.07	23.60	0.47	1.94	0.52	0.13	3.50	<0.01

OVER ALL EFFECT OF THE THERAPY

The overall effect of therapy can be summed up as:-

1. *Kumkumadi tailam* was the best therapy amongst all for *varnya* effect with maximum relief of 53.33% and showing significant results with p value (<0.01).
2. Cold cream made of *Kumkumadi tailam* is equally good with relief percentage of 53.33% and showing significant results with p value (<0.01).
3. All purpose cream having drugs with cleansing action along with *varnya karma* also worked well on *varnya* effect with relief percentage of 46.66% and p value (<0.01).
4. Vanishing cream made of *varnya* drugs gives 40% relief and p value (<0.01) shows significant results.
5. *Tailam* therapy is better than cream therapy. Cold cream works better than all purpose cream, which in turn works better than vanishing cream. This may be because trial was conducted during winters and vanishing cream may not have worked well at that time.
6. Maximum relief was seen in more dark people with scale 27-30, which was 65%. This was followed by less dark people of scale 21-26 with 45% relief, and fairer people of scale 15-20 with 35% relief. This shows that *Varnya* therapy works better with dark complexion. This may be be-

cause colour changes occurring on dark skin are more apparent than on fairer skin.

CONCLUSION

To conclude the present work the final results found are -

- ◆ Cream had its roots in the past.
- ◆ *Kumkumadi tailam* and *Varnya* creams can be formulated as per parameters laid down by CCRAS.
- ◆ *Kumkumadi tailam* and all *Varnya* creams have effect on *Varnya* of individuals.
- ◆ *Tailam* therapy works better than Cream therapy. Cold cream works better than All purpose cream, which in turn works better than Vanishing cream.
- ◆ Dark complexioned people gets more benefit than fair complexioned.

Though understanding of any concept and observing the facts comprise the main part of any presentation, the critical analysis and interpretation of the data available with the textual references is also important. So the data available can be reutilized for further studies, and to arrive at some definite conclusions. It is hoped that data collected in this study will be helpful in the understanding this topic further.

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