Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 13 (4), 2022; 1048-1053

A comparative clinical study of *Shatavari Ghrita aschyotana* and Carboxy methyl cellulose 0.5% eye drop in the management of dry eyes with special reference to smartphone users

Research Article

Rasika R Bansod[1*], Anil Deshmukh[2], Rohan Bargal[3], Rekha Jori[3]

1. P.G. Scholar, 2. Professor and HOD, 3. Assistant Professor, Department of Shalakyatantra, SST's Ayurved Mahavidyalaya, Sangamner. MH. India.

Abstract

Advanced technologies like computers, Internet surfing, Smartphone use, T.V., use of Air conditioners, more polluted dusty hot environment etc. has completely changed the World. Due to this long-term exposure to visual display terminal a new group of eye and vision problems has emerged with dry eyes. Dry Eye disease is an inflammation of cornea and conjunctiva due to inadequate secretion of tears. No specific remedial measures have been mentioned for Dry Eye Disease in modern medicine. Considering all the lacunas of established treatment and increased prevalence rate of disease due to changing lifestyle it is necessary to look for alternative therapy which is safe, cheap, easily available, and more effective. Aim: To evaluate and compare the effect of *Shatavari Ghrita Aschyotana* and Carboxymethylcellulose 0.5%eye drop in patients suffering from *Shushkakshipaka* (Dry eye syndrome). Material and methods: A total 70 patients of the age group 20-30 years presenting with signs and symptoms of *Shushkakshipaka* w.s.r. to dry eye disease were selected randomly from OPD of the department of *Shalakyatantra*. The 35 patients of trial group were treated with *Shatavari Ghrita Aschyotana* and 35 patients of control group were subjected to Carboxymethylcellulose 0.5% eye drop. Results: *Shatavari Ghrita Aschyotana* is more effective as compared to Carboxymethylcellulose 0.5% eye drop.

Key Words: *Shushkakshipaka,* Dry eye syndrome, *Shatavari Ghrita Aschyotana,* Carboxymethylcellulose 0.5% eye drop.

Introduction

Smartphones are increasingly in the high use amongst the youngsters. 90% of youngsters who spend hours or more in front of smartphone per day associated with a measurable adverse effect of the eyes. Smartphones enable diverse events including browsing the web, watching videos, group chatting, and social networking as compared to the previous generations, therefore time spent viewing at the display screens has increased to more than 3.5 hours/day as compared to 3.25 Hours/Day in 2013. As per the studies in 2019 the average time spent using smartphone was 3.5 hours/day in India. (1)

Recent studies have reported that there is strong association between ocular health and the smartphone use. It is related to the DED (Dry Eye Disease) affecting the tear film and the ocular surface. Eyes need to stay moist to stay healthy. Normally people blink every 10 second or so, when your eyes blink it releases tear film, it soothes and coats your eyes. Excessive exposure to smartphones, we tend to blink half times as normal which leads to rapid evaporation of the tear film, triggering off vicious cycle of dry eye disease. Decreased blink rate of the eyes causes evaporation of tear film causing the loss of lipid layer in the tear film causing low tear break up time. The lipid layer of the tear film functions to prevent evaporation of tear from the surface of the eyes. With a deficiency in the lipid component, tear evaporates quickly resulting in increased exposure of the ocular surface to the damage and desiccation. Upon longstanding dry eye disease, patients are predisposed to the complications like breakdown of the corneal epithelium, which is the outermost layer of the cornea with subsequent scarring & infections. (2)

Surveys conducted earlier have shown that there will be 15.6% smartphone users and annual rate of growth of smartphone users in India would be around 129%, even more than that of China (109%). The concern grows as the average age of a child getting a smartphone is 10.3 years. Use of these smartphones and/or other video display terminals (laptops, desktops, tablets, television) for long hours has been associated with a decreased maximum blink interval, hence development of dry eye symptoms. In addition, many people report ocular fatigue after prolonged work with Smartphone use. (3)

*** Corresponding Author:**
Rasika R Bansod
PG scholar,
Department of Shalakyatantra,
SST's Ayurved Mahavidyalaya,
Sangamner, India.
Email Id: drrasikabansod@gmail.com

Dry eye Disease is increasing in recent times. Advances in the diagnostic technology have added into the prevalence rate as well. Prevalence of dry eye is estimated to be 14-33% worldwide. i.e., 1 out of every 7 patients could have this condition. Even though no authentic prevalence survey has been carried out in India, it is estimated that 45% of patients older than 40 years may have this problem i.e., one out of every 5 above 30 years attending OP could have this condition. (4)

Regarding the treatment options, tear substitutes and tear stimulants are the main stay of the medical management. But these tear lubricants are failed to reproduce the tears because the natural tears are the complex mixture of lipids, mucin and water. These drugs can give lubrication to the ocular surface but will not correct the underlying tissue damage & pathophysiology. The main culprit is the preservatives containing in these drops mainly benzalkonium chloride which induce corneal toxicity & desquamation, many of the patient's developed allergy to this chemical and ultimately it worsens the dry eye problems i.e., patients cannot tolerate these preservatives containing eye drops for long term basis. New concept of preservative free eye drops came into existence to overcome these problems, but unfortunately these are very difficult to manufacture, frequent contamination on storage and microbial keratitis in many patients are reported due to use of this drops. The main problem is the expense of these medicines and one should remember that these medicines are prescribed as lifelong therapy and many of the patients are not able to afford these drops due to high cost of these drugs or compliance also remains the question. (5)

Ayurveda system of medicine considers this problem a systemic & medically manageable/curable one. So, the systemic treatment modalities like *Snehapaan* orally, *Nasya karma*, *Basti chikitsa* and *Rasayana* orally as well as topical ocular therapeutic procedures (*kriyakalpa*) like *Seka/Parisheka* (closed eye irrigation), *Ashchyotana* (eye drops), *Tarpana*, *Snehana Putpaka* and *Snehana Anjana* (lubricating collyrium) are encouraged in the literature. (6)

Ayurvedic line of treatment gave equally good relief in subjective and objective parameters as well as it was cost effective and preservative free. The artificial tear substitutes and lubricants have short duration of action and develop sensitivity due to toxicity of preservatives in the medicine. The use of preservative free drug is very costly and many time patients ignore the prescribed treatment. Considering all the lacunae of established treatment and increased prevalence rate of disease due to changing lifestyle it is necessary to look for alternative therapy which is safe, cheap, easily available, and more effective.

Aschyotana is one of the types of *Kriyakalpa in* which *Bindu* of *Ghrita* or *Kwatha* are put into the eyes. Thus, *Shatavari Ghrita Aschyotana* is selected to assess the parameters of dry eyes in terms of clinical features and stability of the treatment.

Purpose of this study is to find out solution for the relief from dry eyes which occurs post smartphone overuse specifically more than for 3.5 hours. *Shatavari Ghrita* has the *Shatavari, Khseera, Goghruta. Shatavari* is having *Madhura Rasa, Guru Snigdha Gunas, Sheeta Virya, Madhura Vipaka, Vatapittahara, Chakshushya, and Rasayana* properties. So, it is *Vatapittashamaka* ana *Kaphakara*, Eye is developed from *Majja Dhatu Ghrita* is *Meda Majja, Shukradhatu vardhak* and it acts as eye tonic. *Goghrita* also contains Vitamin A, D, E, K in rich quantity. Vitamin A & E are well known for their antioxidant property and are helpful in preventing tissue damage and thus lubricates the eye surface and enhances the lipid layer of the tear film.

Aims

- To evaluate the effect of *Shatavari ghrita* in patients suffering from *Shushkakshipaka* (Dry eye syndrome).
- To compare the efficacy of *Shatavari Ghrita Aschyotana* with Carboxymethylcellulose 0.5%eye drop in *Shushkakshipaka*.

Objectives

- To see the adverse effect of *Shatavari Ghrita Ashchyotana* if any.
- To study *Shushkakshipaka* in detail.
- To standardize the *Shatavari ghrita* for its medicinal use.
- To analyse *Shatavari ghrita* for its physical and chemical properties.

Material and methods

A total 70 patients of the age group 20-30 years presenting with signs and symptoms of *Shushkakshipaka* w.s.r. to dry eye disease were selected randomly from OPD of the department of *Shalakyatantra*. The 35 patients of trial group were treated with *Shatavari Ghrita Aschyotana* and 35 patients of control group were subjected to Carboxymethylcellulose 0.5% eye drop.

Criteria for selection of patients

Inclusion Criteria

- Patients between 20-30 years of age.
- Smartphone users complaining of eye strain, dry eyes, foreign body sensation, headache, redness, pricking sensation in the eyes, blurring sensation, painful blinking of the eyes, diplopia with 3 or more features.
- Minimum 3 hours of smartphone use per day and minimum uses for 6 months.

Exclusion criteria

- Patients suffering from infectious conditions of the eyes like conjunctivitis, scleritis, uveitis, glaucoma etc.
- Any fundus pathology like optic atrophy, diabetic retinopathy, hypertensive retinopathy, papilledema etc.
- Patient willing to Participate.

Withdrawal criteria

Patient can be withdrawn from the trial if:

- Occurrence of serious adverse effects and they will be reported
- The protocol has been violated or patient has become uncooperative.

Assessment Criteria (7): Assessment was done based on following signs and symptoms:

Sr no.	Symptoms	Details	Score
1	*Ruksha Vartma Akshi* (Dryness of the eyes)	Absent (No feeling of dryness)	0
		Mild (Occasionally present and very mild feeling of dryness.)	1
		Moderate (Frequently present moderate feeling of dryness)	2
		Severe (feeling of dryness present almost all the time.)	3
2	*Gharsha* (foreign body sensation in the eyes)	Absent (No sensation)	0
		Mild (sensation of foreign body)	1
		Moderate (tolerable sensation)	2
		Severe (intolerable sensation)	3
3	*Toda* (Pricking sensation in the eyes)	Absent (No pricking sensation)	0
		Mild (tolerable, not disturbing daily routine)	1
		Moderate (tolerable and disturbing daily routine)	2
		Severe (intolerable and disturbing daily routine)	3
4	*Daha* (Burning sensation)	Absent (No burning sensation)	0
		Mild (present but not distressing)	1
		Moderate (Distressing but without disturbance of daily life)	2
		Severe (very distressing and interfering with daily life)	3
5	*Raga* (Redness)	Absent (No redness)	0
		Mild (Some vessels are detectible)	1
		Moderate (Individual vessels are detectible)	2
		Severe (Individual vessels are not easily detectible)	3
6	*Krichonmilan* (Painful blinking of the Eyes)	Absent (No difficulty in lid movements)	0
		Mild (Occasional difficult in lid movements)	1
		Moderate (Frequent and moderate difficulty in lid movement)	2
		Severe (feeling of difficulty in lid movements almost all the time)	3

Objective criteria

1	*Vishushkabhava* (i.e., Dryness of eyes) This parameter was decided based on Schirmer's test.	Absent (20 - 35 mm)	0
		Mild (15 - 20 mm)	1
		Moderate (5 - 15 mm)	2
		Severe (< 5 mm)	3
2	Tear Film break up test (Dryness of the eyes)	Absent (> 15sec's)	0
		Mild (≥ 10sec &≤ 15sec's)	1
		Moderate (≥ 5sec & ≤ 10sec's)	2
		Severe (< 5sec's)	3
	Follow ups: - 7th , 15th, 21st , 30th days.		

The graded values were later totally and individually scored and assessed statistically to find out the rate of effect of treatment. The age, gender, occupation, habitat wise distribution of patients with socioeconomic status was also recorded and assessed statistically. The effect of treatment in each group was assessed separately by analysing the pre-treatment and post treatment data, scores and values. The comparison of the effect of therapy of two groups done by statistical analysis.

***Shatavari Ghrita* (8)**

Ingredients of drug and preparation of *Shatavari Ghrita:*

1. *Shatavari Kalka*: 2 *Pala* (80 gm)
2. *Shatavari Kwatha*: 128 *Tola* (1280 ml)
3. *Goghrita*: 1 *Prastha* (640 gm)
4. *Godugdha*: Quantity same as *Kwatha* (1280 ml)

All the above ingredients are taken into utensils along with stirrer and kept on gas stove or burner. The above mixture is heated till "*Snehasiddhi Lakshana*" appears in mixture or 640 ml of *Ghrita* remains in utensil**.**

Table 1: Drug Regimen

Subject	Group A	Group B (9)
Number of patients	35	35
Age group	20-30 years	20-30 years
Drug name	*Shatavari Ghrita Aschyotana*	Carboxymethylcellulose 0.5% eye drop.
Dose of drug	A dose of 2 drops twice a day	A dose of 2 drops twice a day
Route of administration	Local	Local
Duration	30 Days	30 Days
Follow up	0th,7th,14th, 21st,30th	0th,7th,14th, 21st,30th

Data thus collected, summarized, and statistically analyzed as per protocol.

Table 2: Statistical evaluation of Subjective parameters before treatment and after treatment (Trial group)

Symptoms	Sum of Positive Rank	Sum of Negative rank	W Value	Rs Value	P Value	Sig.
Ruksha Vartma Akshi	0	-630.0	-630.0	0.7530	<0.0001	Yes
Gharsha	0	-630.0	-630.0	0.3368	<0.0001	Yes
Toda	0	-630.0	-630.0	0.6144	<0.0001	Yes
Daha	0	-630.0	-630.0	0.8284	<0.0001	Yes
Raga	0	-465.0	-465.0	0.7510	<0.0001	Yes
Krichhonmilan	0	-253.0	-253.0	-	<0.0001	Yes

- As for all the above factors sum of positive ranks is 0 (zero) which indicates, there wasn't any single case in which severity of the symptoms was increased.
- Since the **P value is < 0.05**, the level of significance for factors *Ruksha Vartma-Akshi, Gharsha, Toda, Daha, Raga, Krichhonmilan*
- There is strong evidence to reject the **null** hypothesis for above stated factors.
- So, the effect of therapy is statistically **significant** on above stated factors.

Table 3: Statistical evaluation of Objective parameters before treatment and after treatment (Trial group)

Criteria	Mean of diff.	BT Mean	AT Mean	S.D. of diff.	t value	P value	Significance
Vishushkabhava	-1.800	2.45	0.65	0.6774	15.72	<0.0001	Yes
Tear film break up test	-2.029	2.45	0.42	0.2956	40.60	<0.0001	Yes

- Since the **P value is < 0.05**, the level of significance for *Vishushkabhava*, Tear film break up test
- There is strong evidence to reject the null hypothesis for factors stated above.
- So, the effect of therapy is statistically **significant** on *Vishushkabhava*, Tear film break up test.

Table 4: Statistical evaluation of Subjective parameters before treatment and after treatment (Control group)

Symptoms	Sum of Positive Rank	Sum of Negative rank	W Value	Rs Value	P Value	Sig.
Ruksha Vartma Akshi	0	-630.0	-630.0	0.6995	<0.0001	Yes
Gharsha	0	-435.0	-435.0	0.4904	<0.0001	Yes
Toda	0	-465.0	-465.0	0.3936	<0.0001	Yes
Daha	8.500	-342.5	-342.5	0.0670	<0.0001	Yes
Raga	0	-55.00	-55.00	0.5528	<0.0001	Yes
Krichhonmilan	0	-36.00	-36.00	0.6146	<0.0001	Yes

- As for all the above factors sum of positive ranks is 0 (zero) which indicates, there wasn't any case in which severity of the symptoms was increased, except factor *Daha*.
- Since the **P value is < 0.05**, the level of significance for factors R*uksha Vartma-Akshi, Gharsha, Toda, Raga, Krichhonmilan* are considered.
- There is strong evidence to reject the **null** hypothesis for above stated factors.
- So, the effect of therapy is statistically **significant** on above stated factors.

Table 5: Statistical evaluation of Objective parameters before treatment and after treatment (Control group)

Criteria	Mean of diff.	BT Mean	AT Mean	S.D. of diff.	t value	P value	Significance
Vishushkabhava	-1.400	2.42	1.02	0.7356	11.26	<0.0001	Yes
Tear film break up test	-0.657	2.34	1.11	3.351	1.160	0.2541	Yes

- Since the **P value is < 0.05**, the level of significance for *Vishushkabhava*, Tear film break up test
- There is strong evidence to reject the null hypothesis for Sr. Uric acid.
- So, the effect of therapy is statistically **significant** on above factors.
- The test used is **Mann Whitney U test** for two independent samples.

Table 6: Comparative statistical evaluation of Trial group and Control group

Symptoms	Sum of Rank in Trial G	Sum of rank in Control G	U Value	P Value	Sig.
Ruksha Vartma-Akshi	915	1570	285	<0.0001	Yes
Gharsha	957.5	1528	327.5	0.0002	Yes
Toda	1078	1407	448	0.0339	Yes
Daha	1094	1392	463.5	0.0491	Yes
Raga	1225	1260	595	>0.9999	No
Krichhonmilan	1068	1418	437.5	0.0009	Yes

- Since the **P value is < 0.05**, the level of significance for factors *Ruksha Vartma-Akshi, Gharsha, Toda, Daha, Krichhonmilan*
- There is strong evidence to reject the **null hypothesis** for above stated factors.
- Since the **P value is > 0.05**, the level of significance for factor raga
- There is strong evidence to accept the **null hypothesis** for raga factor.
- The test used is **Student Unpaired t test** for two independent samples.

Table 7: Comparative efficacy of therapy on Objective parameters in Trial and Control group

Criteria	Mean(B) Control Group	Mean(A) Trial Group	BT Mean	AT Mean	Diff. between Mean(B-A) ± SEM	t value	P value	Sig.
Vishushkabhava	1.029	0.6571	2.435	0.835	0.3714±0.1324	2.806	0.0065	Yes
Tear film break up test	1.686	0.4286	2.395	0.765	1.257±0.5984	2.101	0.0394	Yes

- Since the **P value is < 0.05**, the level of significance for above stated factors, there is strong evidence to reject the **Null** hypothesis.
- So, there is **significant difference** in Trial group and Control group on an average if factors *Vishushkabhava*, Tear film break up test are considered.

Results

- There is **statistically significant effect** of *Shatavari Ghrita aschyotana* in the management of dry eyes with special reference to smartphone users."
- There is **statistically significant effect** of Carboxy Methyl Cellulose 0.5% eye drop in the management of dry eyes with special reference to smartphone users."
- There is **statistically significant difference** in between Trial group and Control group on an average if factors R*uksha Vartma-Akshi, Gharsha, Toda, Daha, Krichhonmilan, Vishushkabhava,* Tear film break up test are considered except factor *raga*.
- While, comparing Trial vs Control group, **Trial group is statistically significant than Control group.**

Discussion on Observation

Age

The observation shows 22.85% patients in Control group & 37.14% in Trial group were from 20-24 years age group. While, 77.15% patients from Control group & 62.86% patients were between the age group of 25-30 years. In both the groups maximum patients participated belonged to 25 to 30 years age group.

Gender

The patients participated in this study were selected irrespective of their sex. But the data collected showed that in Control group 80% were male & 20% were female patients. Also, in Trial group there were 62.86% male & 37.14% were female patients. So, we can assume that dry eyes (*Shushkakshipaka*) are more prevalent in male smartphone user patients.

Occupation

For this clinical trial patients having various occupations got enrolled. In both the groups maximum patients (Control – 42.85% & Trial – 37.14%) were students, followed by businessman (Control – 22.85% & Trial – 31.42%). In both these categories use of smartphone is excessive as students may get extra time & businessman have to handle more smartphone related work leading to dry eyes.

Socio-economic status

Maximum patients in both the groups belonged to middle income group (Control – 71.42% & Trial – 65.71%), followed by lower income group (Control – 14.28% & Trial – 28.57%) & upper income group (Control – 14.28% & Trial – 05.71%). So, we can assume that dry eye disease (*Shushkakshipaka*) is more prevalent in middle income group. But it may be due to locality in which this hospital is located. To confirm this another separate study may be required.

Addiction

Control group – 27.57% patients were not having any type of addiction. 25.71% patients were habitual of alcohol with smoking, followed by 22.85% patients with alcohol & tea. While, 14.28% patients were addicted to alcohol, smoking & tea. Remaining 8.57% patients had tea addiction. Trial group – 42.85%

patients were not having any type of addiction. 22.85% patients had addiction of alcohol and tea, 17.14% had addiction of alcohol with smoking.

Symptom wise percentage relief

Symptoms	Control group %	Trial group %
Ruksha Vartma-Akshi	57.45	83.16
Gharsha	57.92	87.80
Toda	62.71	78.18
Daha	64.23	87.62
Raga	41.17	72.38
Krichhonmilan	45.09	100
***Vishushkbhava* (Schirmers test)**	57.85	73.46
Tear film break up test	51.28	82.85

In the present study the patients treated with *Shatavari Ghrita ashchyotana* and Carboxy Methyl Cellulose 0.5% eye drop shown significant effect in the management of dry eyes with special reference to smartphone users.But, *Shatavari Ghrita ashchyotana* is better in treating above symptoms than Carboxy Methyl Cellulose 0.5% eye drop.

Overall relief in symptoms of Dry eyes (*Shushkakshipaka*) –

- In Control Group is – 54.71%.
- In Trial Group is – 83.18%.

No side effects observed during treatment or at the end of treatment.

Probable mode of action

- Primary samprapti *ghataka* of *Shushkakshipaka* are vitiated *Vata, Pitta dosha* & *Rakta dhatu*.
- Main ingredient of *Shatavari Ghrita* is *Shatavari* & *go-ghrita*. *Ghruta* is said to be one of the best *Yogavahi*, *Vata-Pittashamaka*, and *Rasayana*. Due to its properties *ghruta* can penetrate into *Sukshma srotasa*. Thus, it can cross the barriers of absorptions in the eyeball & provides nourishment & strength.
- The ingredients of *Shatavari, Ghruta* have *Madhura rasa, Guru, Snigdha gunas, Sheeta virya, Madhura vipaka, Vata-Pittahara, Chakshushya*, and *Rasayana* properties. As per *Bhavaprakasha Shatavari* is *Chakshushya*.
- *Shatavari ghrut*a due to its *Vata-Pittahara, Snigdha, Chakshushya guna* helps in reducing the vitiation of *Vata* & *Pitta dosha* leading to *samprapti vighatana* & reduction in the symptoms. Also, *Ghruta* contains Vitamin A keeps the epithelial tissue of the body intact, keeps the outer layer of the eyeball moist.

Conclusion

After conducting clinical study, assessment of parameters & data analysis, it can be concluded that:

- *Shatavari Ghrita aschyotana* is effective in the management of dry eyes with special reference to smartphone users (Trial group).
- Carboxy Methyl Cellulose 0.5% eye drop is effective in the management of dry eyes with special reference to smartphone users (Control group).
- While, comparing Trial vs Control group, **Trial group is more significant than Control group.**

Limitations of the study

Although clinical trial shows promising results, but study was carried out on small population & with limited time frame. So, for generalisation and more confirmation of results we need much larger sample size, patients from different localities & increased time period.

References

1. Arpita, D'Souza M., Dhar T., Savita & Alex S, Severity of Mobile Phone and Internet Use Among B.Sc. Nursing Students. Nitte University Journal of Health Science. December,2013; 3(4); 359-363.
2. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye Workshop. *Ocul Surf.* 2007; 5:75–92.
3. Arpita, D'Souza M., Dhar T., Savita & Alex S, Severity of Mobile Phone and Internet Use Among B.Sc. Nursing Students. Nitte University Journal of Health Science. December,2013; 3(4); 359-363.
4. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop. *Ocul Surf.* 2007; 5:75–92.
5. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye Workshop. *Ocul Surf.* 2007; 5:75–92.
6. Pravin M Bhat, Study on the role and efficacy of *Triphala Ghrita Aschyotan* in *Vataj Abhishyanda* w.r.t Allergic Conjunctivitis. International Journal of *Ayurvedic* Medicine, 2016;7(2);123-129
7. *Vaidya yadunandana Upadhyaya*, Editor. *Ashtanghridaya* of *vaghbat*, *sutrasthan*; *ayushkamiyaadhyay*: Ch.1, Ver.5, Reprint ed. Varanasi: Chaukhamba Sanskrit santhan,2000; p.3.
8. Mishra B S, editor, *Bhavaprakasha* with *Vidyothini* Hindi Commentary, 11th edi. Varanasi *Choukhamba* Sanskrit Bhawan; 2010. p.no.186-187.
9. Management and therapy of dry eye disease: report of the Management and Therapy Subcommittee of the International Dry Eye Workshop (2007) *Ocul Surf.* 2007;5(2):163–178.

*****