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Research Paper

Clinical Trial of Dilatant Mat Over Emulsion Technology for Instant Pain Relief

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ABSTRACT

The present clinical trial discuss the pain relieving effect, the possible mechanism of action and the reason of a topical formulation- Akshun ultra gel that had employed Dilatant Mat over Emulsion technology. The formulation technology enables the volatile counteractive agents to suffer zero loss, permeate deep into the skin and offer instant pain relief. Various kinds of pain such as neck pain, back pain, joint pain, cervical spondylitis and musculoskeletal pain has responded well to the treatment. The thermal image pattern of skin before and after treatment was also used for evaluation of relief, details are presented in the article.

INTRODUCTION

Head ache, pain in the neck & back region, cervical region, joint pain etc., are not just agonizing in nature but also would persist for prolonged period of time due to the cause being systemic.[1] such persistent pain would affect not only the quality of life but also the overall productivity of the sufferer. [2]

More often, the management of such pain requires the intervention of a strong non-steroidal analgesic preparations for a prolonged course of time.[3] Long term usage of such analgesic preparations known to result in various side effects such acute gastritis, hepatic and renal damage.[4] The arthritic pain require lifelong medication, where the rotation both the steroidal and non-steroidal drugs are needed. [5] Topical pain relieving preparations are although available for the treatment, but their use is limited due to their poor effect and or the relief is short-lived.[6] The counter irritant (s) based topical formulations in combination with some analgesic drugs like diclofenac or lignocaine have been made to manage the pain through topical route but such formulations found to have limited

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success in treating pain due to systemic or age or life style associated reasons. [7]

The topical formulation with variety of active agents having diverse effect to reduce the pain instantaneously is yet to be studied.

Rubefacients, coolants, vasodilatants, tinkling sensation causing substances etc., are largely used in topical pain relieving products.[8] But still the combination of all such substances in the same formulation need not ensure each individual ingredient to offer their specific benefit and thereby the 'benefit cascade' all such substance from the product resulting in instant relief.

The formulation technology and choice of the base alone can ensure each and every ingredient in the formulation is preserved independently and are made to exert their specific benefit that finally translate to significant relief of pain.

Akshun ultra gel is a unique formulation where viscoelastic and thermo-physical properties of fluid dynamics has been harmonized. Two dissimilar viscoelastic fluids one being an emulsion and the other being single phase gelling agent has been combined in the form of a mat over emulsion to hold different active agents with varying degrees of volatility within the same formulation, to offer a variety of counterirritant actions and relieve the pain, instantly.

MATERIALS AND METHODS

The clinical trial was conducted as per global guidelines involving human volunteers for drug evaluation. The trial protocol and all other relevant documents needed for trial were approved by Institutional Ethics Committee and the trial was registered in Clinical Trial Registry of India - **CTRI No - CTRI/2025/06/089199.**

The clinical trial was aimed to evaluate the pain relieving efficacy of Akshun ultra gel, a topical preparation in relieving the following types of pain of systemic and or life style led origin such as

Types of pain	Number of patients	
	Male	Female
Neck pain	5	5
Joint pain	3	5
Back pain	2	10
Cervical Spondylitis	7	7
Musculoskeletal pain	3	2
Arthritic pain	-	1

For the present clinical trial, both direct and indirect parameters were measured where the direct parameters include

i) Extent of relief
ii) Time required for perceivable relief
iii) Frequency/ number of application needed
iv) Duration of relief
v) Initial sensory feel
vi) Duration of the sensory feel

The indirect parameter include, the thermal imaging of the skin for Doppler changes before and after the test product application.

The Doppler change on the skin surface is the indicator of increased vasodilation and associated pain relief.

Demographic details of the patients

50 patients suffering from various types of pain were included in the pain

Gender	Age in years			
	18- 25	26 - 40	41 - 55	Above 55
Female	5	10	10	5
Male	3	7	5	5

Patient Enrolment Details

Patient ID	Gender	Start Date	End Date
M001-M009	M	09/07/2025	09/08/2025
M0010 – M0020	M	10/07/2025	10/08/2025
F001-F0011	F	14/07/2025	14/08/2025
F0012-F0015	F	16/07/2025	16/08/2025
F0016-F0026	F	18/07/2025	18/08/2025
F0027-F0029	F	20/07/2025	20/08/2025
F0030	F	23/07/2025	23/08/2025

Duration of the study – 30 days

Inclusion criteria

1) Availability of the patients for the entire study period and their willingness to adhere to the protocol requirements and willing to sing the informed consent form (ICF).
2) Patients in the age group between 18 to 55 years, both male and female.
3) Patients who have no evidence of life-threatening disease within 28 days prior to commencement of the study.
4) Patients suffering from cervical spondylitis, low back pain or pain in the joints of chronic nature.
5) Patients, who are willing to avoid sun bath, swimming in pool, prolonged sun exposure or artificial UV rays during the study.
6) Patients who are willing to not to take any other pain relieving products (topical and oral) including steroids during the study period.

Exclusion criteria

1) Patients require definite systemic therapy
2) Patients who are allergic counter irritant based preparations
3) Patients who cannot comply with the protocol

Details of the test drug - Akshun ultra gel

The test drug is white coloured creamy gel for topical application. The formulation is composed of
Gaultheria fragrantissima -20%
Mentha piperata -5%
Cinnamomum camphora -2%
Trachyspermum ammi -1%
Eucalyptus globulus – 1%

Usage instruction

Akshun ultra gel was provided to the patients with clear instruction to apply the gel over the painful region and then gently massage to absorb the gel into the skin.
Twice or thrice daily application of the gel was instructed to the volunteer, however, the choice was decided based on the anatomical region of pain.

Evaluation Score

Extent of relief – This was measured using a 5 point scale where 0 score was given for no and the score 5 was given for complete relief. Using the score obtained, the extent of relief was calculated.

i) Time required for perceivable relief was measured by recording how much time was taken by each volunteer to experience the relief on a time scale of 15 minutes to 1 hour. The scoring was used to understand both product efficacy and the type of pain and treatment requirements of different types of pain.
ii) Frequency/ number of application needed by the subjects vis-à-vis type of pain was recorded for each subject and also the weight difference of the test drug provided to each subject was measured. Based on the findings,

at what frequency the product was needed to get a relief was calculated.

iii) Duration of relief – How long each patient could experience relief vis-à-vis the medical condition was recorded

iv) Initial sensory feel – the list of different counter irritant effects such as vasodilation, burning sensation, cool feel were recorded for each subject.

v) Duration of the sensory feel – was measured based on how long the sensory feel lasted post product usage, this was done to understand both safety of the product and non-hypoallerginic nature of the product.

Recording on the extent of pain relief- on 0 - 5 scale
0 to 1 – No relief
2 to 3 – Moderate relief
4 to 5 – Complete relief

B) Indirect measurement

The indirect measurement of pain relief was made using thermal imaging and photography of colour Doppler change on the skin before and after application of the gel. The Doppler change in the skin was measured and correlated for the increased vasodilation and associated pain relief. The initial and final Doppler change as measured by the blood flow where increase would indicate intense orange- red colour change while no increase would show no such change.

Results

Extent of relief in male patient vis-à-vis days

The 5 patients who suffered from neck pain reported complete relief by day 15 whereas only 3 of the 7 patients with cervical spondylitis reported moderate relief on day 15, however on day 30, 6 of 7 reported complete relief. Those who suffer from back pain and musculoskeletal pain reported only mild relief on day 30.

The statistical analysis by paired t test revealed the treatment response to be statistically significant with p value is .00109, $p < 0.05$ on day 30. Table - 1

Types of pain	**Number**	**Extent of relief in a scale 0 to 5 on day 15 & day 30**	
		Day 15- relief score/no of patients in parenthesis	**Day 30-relief score/no of patients in parenthesis**
Neck pain	**5**	**5 (5)**	**5 (5)**
Joint pain	**3**	**5 (3)**	**5 (3)**
Back pain	**2**	**5 (2)**	**5 (2)**
Cervical Spondylitis	**7**	**3 (7)**	**5 (6)**
Musculoskeletal pain	**3**	**2 (3)**	**2 (3)**
Arthritic pain	**-**	**-**	**-**

Extent of relief in female patient vis-à-vis days

The 20 female patients (5 each neck and joint pain and 10 with back pain) reported complete relief by day 15. The patients with musculoskeletal pain and cervical spondylitis pain reported significant relief by day 30 of treatment. The statistical analysis by paired t test revealed the treatment response to be statistically significant with p value is .00109, $p < 0.05$ on day 30. Table - 2

Types of pain	Number	Extent of relief in a scale 0 to 5, on day 15 & day 30	
		Day 15- relief score/no of patients in parenthesis	Day 30-relief score/no of patients in parenthesis
Neck pain	**5**	**5 (5)**	**5 (5)**
Joint pain	**5**	**5 (5)**	**5 (5)**
Back pain	**10**	**5 (5)**	**5 (8)**
Cervical Spondylitis	**7**	**3 (7)**	**4 (7)**
Musculoskeletal pain	**2**	**4 (2)**	**5 (2)**
Arthritic pain	**1**	**4 (1)**	**4 (1)**

Time of perceivable relief

Both male and female patients with neck pain, joint pain, back pain reported perceivable relief in pain within 10 minutes of the usage whereas 15 minutes was required to perceive relief in the case of cervical spondylitis and musculoskeletal pain. Table -3

Types of pain	Number	Time of perceivable relief/ minutes				
		5	10	15	30	60
Neck pain	**10**	**-**	**+/10**	**+/10**	**+/10**	**+/10**
Joint pain	**8**	**-**	**+/8**	**+/8**	**+/8**	**+/8**
Back pain	**12**	**-**	**+/12**	**+/12**	**+/12**	**+/12**
Cervical Spondylitis	**14**	**-**	**-**	**+/10**	**+/12**	**+/14**
Musculoskeletal pain	**5**	**-**	**-**	**+/5**	**+/5**	**+/5**
Arthritic pain	**1**	**-**	**-**	**-**	**+/1**	**+/1**

+ = Perceivable relief ; - = No perceivable relief

Duration of relief after single application

Total relief from pain was reported by patients with different types of pain for minimum of 1 hour. Post 1 hour most people could not even recall pain until a question was posed.

The duration of relief between 30 to 60 minutes is statistically insignificant with p value .32222. The result is not significant at $p < .05$ clearly indicating the pain relief offered is stable for 1 hour. Table – 4

Types of pain	Number	Duration of relief in minutes/ patients			
		30	45	60	120
Neck pain	10	+++/10	+++/10	+++/10	+/10
Joint pain	8	+++/8	+++/8	+++/8	+/8
Back pain	12	+++/12	+++/12	+++/12	+/12
Cervical Spondylitis	14	+++/8	+++/10	+++/14	-/14
Musculoskeletal pain	5	+++/5	++/5	+/5	-/5
Arthritic pain	1	++/1	++/1	++/1	-/1

+++ = complete relief; ++ = Moderate relief; + = Mild relief, - = No relief

Frequency of application required

A minimum of 2 applications was required to achieve complete/significant relief. Table 5

Types of pain	Number	Single/ Twice application needed for relief	
		Single	Twice
Neck pain	**10**	7 /10	3/10
Joint pain	**8**	5/8	3/8
Back pain	**12**	2/12	10/12
Cervical Spondylitis	**14**	NA	14/14
Musculoskeletal pain	**5**	1/5	4/5
Arthritic pain	**1**	NA	1/1

Long lasting effect of various sensory feelings

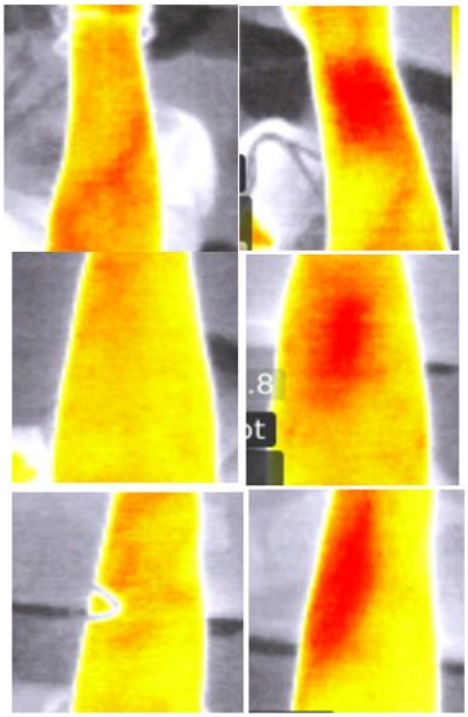
All patients reported the three prominent counter irritant effects such as burning, tingling and cooling sensation within 10 minutes of product usage. Table -6

Sensory feeling	Long lasting effect/ minutes		
	10	30	< 30
Counter irritant sensation	+/50	-	-
Tingling sensation	+/50	-	-
Cooling	+/50	+	-

Indirect measurement – Thermal imaging

Thermal image photography has showed increased sub-epidermal blood flow post treatment. The systemic pain is known to cause muscle contraction and compression of nearby blood vessels, besides vasoconstriction, deep vessel dilation and superficial vessel compression. Skin temperature would reflect blood perfusion due to increased vasodilatation as a result of product application. Such change would provide an indirect understanding about product efficacy and its associated pain relief benefit.

Before **After**



DISCUSSION

The findings of the clinical trial has clearly shown the remarkable pain relief effect of Akshun ultra gel, a topical formulation adopted with mat over emulsion technology for instant, sustained and complete permeation of the actives. The formulation is made with high proportion of methyl salicylate, menthol, camphor, eucalyptus oil and thymol. The mat tightly hold the high volatile, least emulsifier friendly oils within the skeletal armamentarium of emulsion. This technology allows the greater percentage use of counter irritants and in the formulation and also there rapid and sustain permeation. Since all the above ingredients are highly volatile, soon on contact with skin which is slightly at an elevated temperature during pain can evaporate out than get absorbed into the skin and therefore the formulation may unlikely give the expected relief. In order to achieve greater therapeutic value we have adopted mat over emulsion technology in JRK's Akshun ultra gel.

50 patients with near equal balance of both gender were involved in the clinical trial. All the patients (male and female) with neck pain, joint pain and low back pain reported complete relief on day 15 of product usage. Further the statistical analysis by paired t test proved the relief to be statistically signification with p value, $p < 0.05$.

Those who suffered from other types of pain such as musculoskeletal pain, cervical spondylitis and arthritic pain though did not get complete relief but reported noticeable relief by day 30 clearly suggesting that the management of certain pain require also oral medicaments and topical medicaments can only offer transient relief and or may help to reduce the oral drug over load otherwise that may lead to various side effects due to analgesic drugs. The medical conditions that require oral therapy also responded well to Akshun ultra gel though not completely. With the evidence of the patients who reported perceivable relief from pain within 10 minutes clearly suggest the analgesic effect of Akshun ultra gel. Prolonged usage, multiple time usage etc., may offer greater relief where the oral medicament can be reduced.

The sensorial counter irritant responses such as stinging, tingling, cooling and numbing were also perceived by all the patients within 10 minutes of product usage that suggest the possible rapid permeation of a actives into the skin.

In the present clinical investigation we have also analysed the thermal image response in the pain region before and after application of the product by thermal camera.[9] During pain due to systemic cause, the region would endure muscle spasm/ contraction and compression/cramping of nearby blood vessels, besides vasoconstriction, deep vessel dilation and superficial vessel compression. The above changes bound to alter the blood flow and the same when photographed would appear less reddish. When an effective topical pain relieving product is applied with ingredients known to offer

1. Vasodilatation
2. Counter irritancy
3. Tingling sensation
4. Cool and numb effect

would naturally increase the blood perfusion and increased vasodilatation. The subsequent imaging would provide deep reddish appearance of the skin clearly indicating the increased blood flow. Our present clinical investigation on all patients (both gender) suffering from different kinds of pain has shown a distinct increase in cherry red appearance in the skin region where they had applied the product relieve the pain. And the difference between the images before and after treatment was obvious and conspicuous. Further all the patients in the group clearly reported complete to significant reduction in pain. In the light of the above finding we confirm the pain relieving

mechanism of the product may include vasodilatation and increased blood flow.[10]

Our comparative evaluation of yet another formulation devoid of mat over emulsion technology but with actives of same proportion did not offer significant pain relief nor any hemodynamic change over skin (data on file). The clinical trial findings clearly show Akshun ultra gel can instantly relieve various kinds of pains and continuous usage may help to keep the pain at abeyance and also may help in reducing oral medicaments and associated side effects.

REFERENCES

1. Binder AI. Cervical spondylosis and neck pain. BMJ. 2007 Mar 10;334(7592):527-31. doi: 10.1136/bmj.39127.608299.80. PMID: 17347239; PMCID: PMC1819511.
2. Pandelani FF, Nyalunga SLN, Mogotsi MM, Mkhatshwa VB. Chronic pain: its impact on the quality of life and gender. Front Pain Res (Lausanne). 2023 Sep 13;4:1253460. doi: 10.3389/fpain.2023.1253460. PMID: 37781217; PMCID: PMC10534032.
3. Ghlichloo I, Gerriets V. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) [Updated 2023 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK547742/
4. Harirforoosh S, Asghar W, Jamali F. Adverse effects of nonsteroidal antiinflammatory drugs: an update of gastrointestinal, cardiovascular and renal complications. J Pharm Pharm Sci. 2013;16(5):821-47. doi: 10.18433/j3vw2f. PMID: 24393558.
5. Liam J. O'Neil, Deshiré Alpízar-Rodríguez, Kevin D. Deane. Rheumatoid Arthritis: The Continuum of Disease and Strategies for Prediction, Early Intervention, and Prevention. The Journal of Rheumatology Apr 2024, 51 (4) 337-349; DOI: 10.3899/jrheum.2023-0334
6. Moore RA, Derry S, McQuay HJ. Topical analgesics for acute and chronic pain in adults. Cochrane Database Syst Rev. 2010;(7):CD008609. doi: 10.1002/14651858.CD008609. Update in: Cochrane Database Syst Rev. 2017 May 12;5:CD008609. doi: 10.1002/14651858.CD008609.pub2. PMID: 25411557; PMCID: PMC4234085.
7. Jorge LL, Feres CC, Teles VE. Topical preparations for pain relief: efficacy and patient adherence. J Pain Res. 2010 Dec 20;4:11-24. doi: 10.2147/JPR.S9492. PMID: 21386951; PMCID: PMC3048583.
8. Garg, Vandana. (2022). Counterirritants and sensory profiling of pain-relieving patches. International Journal Of Pharmaceutical And Bio-Medical Science. 02. 466-478. 10.47191/ijpbms/v2-i11-01.
9. Erel VK, Özkan HS. Thermal camera as a pain monitor. J Pain Res. 2017 Dec 14;10:2827-2832. doi: 10.2147/JPR.S151370. PMID: 29276403; PMCID: PMC5734233.
10. Aruna V, Amruthavalli GV, Gayathri R. Peripheral Blood Flow: A New Indicator for Measuring the Analgesic Effect of Dolowhite Emulsion. Research and Reviews: A Journal of Unani, Siddha and Homeopathy. 2017; 4(1): 1–3p.

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