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Formulation and Evaluation of Natural-based Cosmeceutical Ointments: An Approach to Manage Dry Scalp Dandruff

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

Abstract

Background: *Pityriasis capitis*, commonly known as dandruff, is a prevalent, chronic scalp ailment that affects over half of the world's population. Dry scalp dandruff is a type of dandruff. Ointments are good examples of pharmacological formulations that have emollient effects on the scalp and hair. Thus, this study aimed at formulating cosmeceutical herbal ointment as an approach to manage dry scalp dandruff disorder.

Methods: Phytochemical screening of Amla (*Phyllanthus emblica Linn*., family- Euphorbiaceae) powder and Avocado (*Persea americana* Mill., family- Lauraceae) oil was carried out. The ointments were formulated using shea butter as base. Physicochemical, cosmeceutical (conditioning) evaluations, draize skin irritancy test, and stability studies were also carried out.

Results: The natural-based ointment formulations were cream to brown in colour, the formulations had flowery smell, smooth and oily to gritty and dry texture, pH range of 4.8-7.4. Viscosity was in the range of 20433 to 28007 cp. Spreadability was in the range of 28.49 to 85.24 g.cm/sec. Loss on drying was in the range of 1.77 to 6.73 %. Globule size was in the range of 0.2 – 2.0 µm. The cosmeceutical or conditioning evaluation showed the average score for shine /oiliness, softness and washability to be 2.6 to 4.6, 2.6 to 3.6 and 3.0 respectively. Draize skin irritancy test showed that there was no inflammation, oedema and erythema observed. The formulations exhibited stability in terms of colour, smell, texture and there was no syneresis observed, but there was a difference in the pH (4.96-7.02) of all the formulations.

Conclusion: This study has shown that natural based cosmeceutical herbal ointment formulations may be used in managing dry scalp dandruff disorder through its conditioning activities.

Keywords: Natural-based, *Phyllanthus emblica*, *Persea americana*, *o*intment, dry scalp dandruff

INTRODUCTION

Pityriasis capitis, commonly known as dandruff, is a prevalent, chronic scalp ailment that has been known since antiquity and affects over half of the world's population (Limbu *et al*., 2021). It can be a stressful condition, starting around or after adolescence, primarily because of its chronic nature, obvious presence, and recurrence, which causes psychosocial humiliation for the affected person. Flaking, pruritus, and mild inflammation are the main symptoms of this scalp-specific ailment, which are linked to either oily (seborrheic) or dry scalp skin types (Limbu *et al*., 2021). There are four typical kinds of dandruff, which include: fungus-related, dry skin, oil-related, and disease-related (Roland, 2020).

People having dry scalp are susceptible to dry scalp dandruff. It occurs more frequently in the dry season.

Furthermore, the use of hot water can also dry out the scalp. With this type of dandruff, there is more hair loss reported. Increasing moisture and often moisturizing the scalp are the best and most efficient ways to treat dry scalp (Limbu *et al*., 2021).

The equilibrium of proteins, humectants, and emollients (PEH) is crucial. All of these elements are necessary for hair, but the exact amounts vary on the day and the condition of the hair. Thus, selecting the best care requires a lot of trial and error, but the rewards are worthwhile (Turkowski, 2023). Hygroscopic compounds called humectants draw in and hold onto water molecules in the hair. These materials are employed as components that control the proper degree of hydration. However, they need to work in tandem with emollients and should not be used alone. When used with emollients, they make the hair more pliable and moisturized. When humectants are used alone, they can exacerbate dryness of skin and hair. The most prevalent category of humectants consists of *Aloe vera*, glycerin, d-panthenol, niacinamide, urea, and hyaluronic acid (Turkowski, 2023).

Emollients create and preserve a healthy barrier around the hair. The emollients give hair a vital layer of protection against frizz and split ends. In this category, the most widely used materials include oils (coconut, argan), butters, waxes, fatty alcohols, silicones, paraffin, and lanolin. Emollients are present in a wide range of food and cosmetic goods, including butter, oil, and sunflower oil. Emollients are a staple of hair care products; they can found in many conditioners and hair mask (Turkowski, 2023).

Ointments are good examples of pharmacological formulations that have emollient effects on the scalp and hair. Due to the claim that many natural ointments have little or no negative side effects and are therapeutically effective, they have been utilized for many years as an alternative medicine in many parts of the world. Natural plant products, whether in the form of standardized plant extracts or isolated chemicals, have opened up countless possibilities for novel therapeutic ingredients (Salako *et al*., 2017).

Dry scalp dandruff disorder is a type of dandruff disorder caused by dryness of the scalp (Limbu *et al*., 2021). Amla powder and Avocado pear oil are part of hair grooming ingredients which have been claimed to impact growth and conditioning properties. Hair conditioners entail two major ingredients which are humectants and emollients and they have been shown to combat dry scalp. Thus, this study aimed at formulating cosmeceutical herbal ointment as an approach to manage dry scalp dandruff disorder.

METHODOLOGY

Collection of the Plant material

Shea butter (*Vitelliaria paradox*, Family- Sapotaceae*)* was obtained locally from Oduwoye market in Mushin, Lagos state, Nigeria. Lavendar oil (*Lavandula angustifolia*, family- Lamiaceae), argan oil (*Argania spinosa*, family- Sapotaceae), coconut oil (*Cocos nucifera*, family- Arecaceae) and eucalyptus oil (*Eucalyptus globulus*, family- Myrtaceae) were sourced locally. Amla powder was obtained in its dry form, which had been already packaged in sachets by the producer.

Phytochemical Screening

Amla powder and avocado oil were tested for the presence of saponins, anthraquinones, cardiac glycosides, alkaloids, tannins, flavonoids, steroids, terpenoids using methods employed in earlier studies (Sofowora, 1998).

Formulation of Herbal Ointment

An amount of shea butter was triturated in a porcelain mortar and whipped using a fluid mixer until a creamy consistency was achieved. Then to a known quantity of whipped shea butter, a weighed quantity of amla powder was added, and triturated to get an homogenous mixture.

In another container, avocado pear oil, argan oil, eucalyptus oil, lavender oil and coconut oil in the required proportions were mixed to get a homogenous mixture. The oils were then added in aliquots to the shea butter and amla powder mixture. The mixture was triturated to get an even ointment (Kaushal and Upadhyaya, 2022). Lastly**,** the required quantity of honey was added to the mixture and triturated together. The ointment was then homogenized using a fluid mixer (Fluid Equipment, Islington, London) and transferred into a suitable container and labelled. The product was then stored at room temperature (25 ± 2 °C) for evaluation.

Table 1: Formulae for Formulation of Herbal Ointment

Formulations	Percentage of ingredients (%)							
	Avocado pear oil	Amla powder	Argan oil	Eucalyptus oil	Honey	Lavender oil	Coconut oil	Shea butter (base)
F1	0	5.0	2.0	2.0	5.0	1.0	10.0	75.0
F2	25.0	4.0	2.0	2.0	5.0	1.0	10.0	51.0
F3	30.0	3.5	2.0	2.0	5.0	1.0	10.0	46.5
F4	35.0	3.0	2.0	2.0	5.0	1.0	10.0	42.0
F5	40.0	0	2.0	2.0	5.0	1.0	10.0	40.0

Physicochemical Evaluation of the formulations

Organoleptic evaluation of the formulations

The colour of the formulations were checked visually; their odour were checked by smelling; their texture were felt by touching. Their ease of application, ease of removal and greasiness were also physically assessed (Goyal *et al*., 2024).

Measurement of pH

The measurement of pH of each formulation was done using a pH meter in duplicate and average values were taken (Goyal *et al*., 2024).

Viscosity

The viscosity of the formulations were determined using the CAP-2000 Brookfield viscometer. Test sample was taken in a clean and dry 250 ml beaker, and the viscosity of the test sample was determined by standard operating procedure of viscometer using spindle no 4. The spindle was used for finding the viscosity of the sample at speed of 20 revolution per minute. (Goyal *et al*., 2024).

Spreadability

A 0.5g of the ointment was placed on a glass slide and a circle was made around it. A second slide was placed over it and a predetermined weight was put on it for a specific period of time. Spreadability was noted as g-cm/sec (Goyal *et al*., 2024). This can be expressed as:

Spreadablility = M*L/T

Where, M = weight of the object; L = length of the slide; T = time

Loss on Drying:

A weighed quantity of ointment was put inside a weighed petri dish. The petri dish was put in an oven for drying at 57-62 °C for 60 minutes. The formula below can be used for the calculation of loss on drying Salako *et al*., 2024):

$$\text{Percentage of loss on drying} = \frac{(\text{Weight before heat} - \text{weight after heat})}{\text{weight before heat}} x100$$

Determination of globule size

A sample of the ointment was smeared on the glass slide mounted on a light microscope and examined at a magnification of x10 x100 x2. The smallest and largest globule per field of view was counted and sized with the aid of the Olympus binocular digital camera microscope (Mendonsa *et al*., 2019).

Conditioning properties

Human hair samples were collected and washed with natural black soap and allowed to dry. Then 0.5g of ointment was applied to 5g of hair. This was done for all five ointment formulations, a blank and Damatol® as a marketing standard. Damatol was used because it is a commercially available haircare product being used for itching and dandruff and it also contains coconut oil. The hair samples were then subjected to random inspection by five random test observers for shine or oiliness, hair softness and washability after washing off ointments with natural black soap and rated on a scale of 1-5, with 1 being the lowest ranking score and 5 the best ranking score (Hanwate and Tambe, 2023).

Draize skin irritancy test

Mice were collected from the animal house of the College of Medicine, University of Lagos. The mice were housed in cages at ambient temperature (25±2 °C) under controlled light/dark cycles of 12h/12h and fed standard mouse chow and water ad libitum. They were acclimatized to the laboratory environment for about 1 week. A section of their skin on the dorsal region was shaven. The ointment samples were then applied topically and the skin was observed for signs of irritation (inflammation, oedema or erythema) after 30 minutes, 1hour, 2hours, and 24hours (Nyigo *et al*., 2015).

Stability studies

All the developed formulations were subjected to stability testing for 10 weeks at room temperature (25 ± 2 °C). The parameters of the formulation such as colour, odour, texture, pH and presence of syneresis were determined for all the formulations (Revansiddappa *et al*., 2018).

RESULTS

Phytochemical Screening

The results of the phytochemical screening of avocado pear oil and amla powder are presented in Table 2.

Organoleptic evaluation of the formulations

The formulations were evaluated and their organoleptic properties presented in Table 3.

The pH of the ointment formulations were measured and presented in table 4

Table 2: Phytochemical screening of avocado pear oil and amla powder

Test	Amla powder	Avocado oil
Saponins	Positive	Positive
Anthraquinones	Negative	Positive
Cardiac glycosides	Positive	Positive
Alkaloids	Positive	Positive
Tannins	Positive	Negative
Flavonoids	Positive	Positive
Steroids	Negative	Positive
Terpenoids	Positive	Positive

Table 3: Organoleptic evaluation of the formulations

Formulation	Colour	Smell	Texture	Ease of application	Ease of removal	Greasiness
F1	Brown	Flowery smell	Gritty and dry	Easy	Easy	Slightly greasy
F2	Pale brown	Flowery smell	Gritty and oily	Easy	Easy	Slightly greasy
F3	Pale brown	Flowery smell	Smooth and oily	Easy	Easy	Greasy
F4	Pale brown	Flowery smell	Smooth and oily	Easy	Easy	Greasy
F5	Cream	Flowery smell	Smooth and oily	Easy	Easy	Greasy

F1 **F2** **F3** **F4** **F5**

Figure 1: Picture of the ointment formulations

Table 4: pH of the ointment formulations

Formulation	PH
F1	7.4 ±0.3
F2	5.7 ±0.1
F3	5.3 ±0.2
F4	5.1 ±0.3
F5	4.8 ±0.22
Standard (Damatol®)	4.28 ±0.23

Viscosity

The viscosity of the formulations at a temperature of 24.5^{o} C, and 20 rotations per minute using spindle size 4 is presented in Table 5.

Table 5: Viscosity of the formulations

Formulation	Viscosity (cp)
F1	28007.00 ±23
F2	22356.00 ±26
F3	23870.67 ±5
F4	20433.00 ±31
F5	22984.67 ±28
Standard (Damatol®)	25657.50 ±16

4.2.4 Spreadability

The spreadability coefficient of each formulation was calculated and presented in Table 6.

Table 6: Spreadability of the formulations.

Formulation	Mass (gram)	Length (cm)	Time (seconds)	Spreadability (g.cm/sec)
F1	200	5.2	36.5	28.49
F2	200	5.2	29.2	35.61
F3	200	5.2	24.4	42.62
F4	200	5.2	17.3	60.12
F5	200	5.2	12.2	85.24

Loss on drying

The percentage loss on drying is for each formulation is presented in Figure 2.

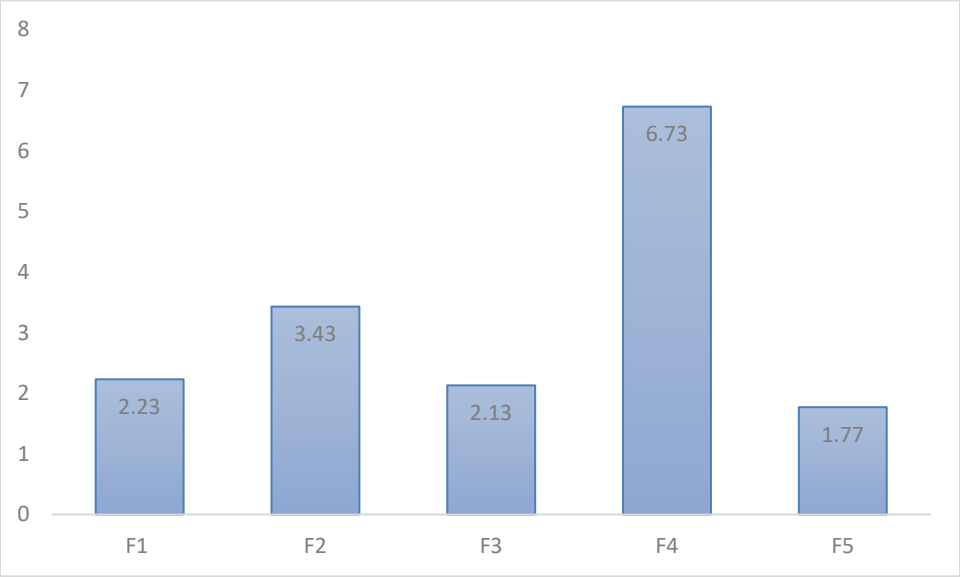

Figure 2: Bar chart representing percentage loss of the formulations

Determination of globule size

The range of globule size of each formulation is presented in Table 7.

Table 7: Globule Size Range of the Formulation

Formulation	Globule size range (µm)
F1	0.2 – 1.2
F2	0.2 – 1.2
F3	0.2 – 2.0
F4	0.2 – 1.6
F5	0.2 – 1.8

Conditioning properties

The conditioning properties of the ointment formulations, together with a blank and a standard (Damatol®) was subjected to review by 5 randomly selected hair ointment users. They scored the conditioning characteristics on a scale of 1-5 with 1 being the lowest ranking score and 5 the best ranking score. The average score of each property is presented in Table 8.

Table 8: Conditioning properties of the ointment formulations, a blank and a standard (Damatol)

Formulation	**Shine/oiliness**	**Softness**	**Washability**
F1	3.6	3.2	3.0
F2	4.6	2.8	3.0
F3	3.4	3.6	3.0
F4	3.2	2.8	3.0
F5	3.4	3.0	3.0
Blank	2.2	2.4	3.0
Standard (Damatol®)	3.2	3.0	3.0

Draize skin irritancy test on mice

The observations made in the Draize skin irritancy test using mice post 30 min, 60 min, 2 h and 24 h are presented in Table 9.

Table 9: Draize skin irritancy test on mice

Formulation	Inflammation	Oedema	Erythema
F1	None observed	None observed	None observed
F2	None observed	None observed	None observed
F3	None observed	None observed	None observed
F4	None observed	None observed	None observed
F5	None observed	None observed	None observed

Stability studies

The result of the stability studies carried out 10 weeks post formulation at room temperature (25 ± 2 ℃) is presented in Table 10 below.

Table 10: Stability Studies

Formulations	Colour	Smell	Texture	Syneresis	pH at formulation	pH after 10 weeks at room temperature
F1	Brown	Flowery smell	Gritty and dry	Absent	7.4 ±0.30	4.96 ±0.21
F2	Pale brown	Flowery smell	Gritty and oily	Absent	5.7 ±0.10	5.59 ±0.22
F3	Pale brown	Flowery smell	Smooth and oily	Absent	5.3 ±0.20	5.41 ±0.13
F4	Pale brown	Flowery smell	Smooth and oily	Absent	5.1 ±0.30	7.02 ±0.33
F5	Cream	Flowery smell	Smooth and oily	Absent	4.8 ±0.22	6.38 ±0.10

DISCUSSION

The phytochemical analysis of amla powder revealed that it contains saponins, cardiac glycosides, alkaloids, tannins, flavonoids, and terpenoids. Avocado pear oil revealed the presence of saponins, anthraquinones, cardiac glycosides, alkaloids, flavonoids, steroids as well as terpenoids. Phytochemicals have been shown to have a role in managing hair loss, and to have hair growth stimulating properties (Kesika *et al*., 2023).

The formulations were evaluated based on their organoleptic properties as seen in table 1. They all had a flowery smell with colours ranging from cream to brown as seen in figure 1. The texture of F1 and F2 were gritty while that of F3, F4 and F5 were smooth. Also, F1 and F2 were less greasy when compared with F3, F4 and F5. All the formulations had good ease of application and removal. The flowery smell of the formulations is an advantage over the standard Damatol® which has a partially choking peppermint smell. The organoleptic properties are necessary to ensure good aesthetics of the formulation and ensure ease of use by the end users.

The pH range of the formulations ranged from 4.8 to 7.4. Only F1 was alkalinic while F2, F3, F4 and F5 were acidic within the range of the pH of the skin which is 4.1 – 5.8 (Costa and Horswill, 2022). Alkaline pH may cause an increase in the negative electrical charge of the hair fiber surface which will cause increased friction between the hair fibers. This increased friction may cause damage to the cuticle and breakage of fiber. Lower pH of hair formulations on the other hand may cause less frizzing thereby generating less negative static electricity on the fiber surface (Gavazzoni Dias *et al*., 2014).

The British Pharmaceutical Codex defines an ointment as a semisolid that, under shear stress, typically behaves like a viscoelastic material. Ointments'

rheological behavior and structure are intimately associated. Thus, the concentration of the waxy components and the stiffness of the matrix govern the flow characteristics of ointments. The viscosity of the formulations ranged from 20433cp to 28007cp. F1 has the highest viscosity while F4 has the lowest viscosity. Viscosity could result in the ointments having varied flow rates and cutaneous absorption characteristics. The consistency of therapy and the delivered dose of a semisolid therapeutic product can be influenced by its rheological behavior, which is dependent on its viscosity (Jin *et al*., 2023; Ueda *et al*., 2010).

The result of spreadability is inverse to viscosity. The lower, the viscosity of an ointment, the lower the surface tension and the more the ointment is easily spread and absorbed into the skin. The spreadability of the formulations helps in the uniform application of the ointment on the scalp and hair. Research has shown that spreadability is a very important property in the development of semisolid preparations for topical application. It is responsible for the overall performance of a formulation (Szulc-Musioł *et al*., 2017).

The percentage loss on drying of the formulations showed that the values ranged from 1.77 % to 6.73 %. F5 had the lowest moisture content amongst the formulations. A high percentage of moisture content could make the formulation susceptible to microbial deterioration. Low percentage loss on drying implies that the formulations may not be susceptible to microbial deterioration and that the formulations are highly lipophilic and hydrophobic; hence, they can help to lock down moisture in the scalp. Shea butter which is the base of the ointment have been shown to form a barrier that helps seal moisture into the scalp. Therefore, these ointments may also help protect, relieve, and prevent chapping and dryness even during dry seasons (Fuller, 2024).

The globule size of the ointment formulations ranged between 0.2 - 2.0 µm. The smaller the difference between the smallest and largest globule in a formulation, the better the homogeneity.

Globule size gives an insight into the particle size distribution of the ointment. Globule size can also can impact the texture and sensory properties of topical formulations by affecting stability, spreadability and appearance (Nishka, 2023).

Hair conditioning is a very important property to look at in hair care, the importance of good conditioned hair includes good manageability, enhancement of lustrous look of hair, reduction of friction between the hair strands to allow easier brushing and combing (Waghmare and Tambe, 2024). All these affects the overall health of the hair.

The conditioning activity of the formulations were rated on the basis of shine and oiliness, hair softness and washability. The ratings were subjective and were based on the view of the observers who were users of hair ointments.

All the formulations showed a level of shine/oiliness higher than that of the negative control (blank) and their results were comparable with that of the positive control (Damatol®) which is a commercially available hair care ointment brand in Nigeria. Formulation F2 had the highest rating being higher by 1.4 above that of the positive control. If the shine score is too low, it means that the scalp is dry, and lacks moisture. This will lead to flaky scalp and eventually dry scalp dandruff. However, when the oil content is too high; this can lead to easy dirt attraction, making the hair stick together and also even cause the oily type of dandruff (Mayo *et al*., 2023). Thus, a good shine/oiliness score is one that is just optimum.

The hair softness showed that all the formulations had a level of hair softness higher than that of the negative control (blank) and their results were comparable with that of the positive control (Damatol®), with formulation F3 having the highest rating being higher by 0.6 above that of the positive control. Softness of hair shows that more moisture was locked into the hair as a result of the formulations; optimum moisture content can help prevent dry scalp dandruff. However, it is important to note that if the hair gets too soft, it can lead to hair breakage and if it is too hard, it can be very discomforting to the owner and may also lead to breakage when trying to comb. Hence, optimum softness is needed (Mysore and Arghya, 2022).

Washability result showed that all the formulations, negative and positive controls had washability rating of 3.0. They were all equally washable with natural black soap, leaving no significant traces of the ointment on the hair samples. Good washability property implies that upon washing the hair after use of the ointment, there will be no clogging of hair pores by the ointment. Clogging of hair pores could lead to black head, growing lumps, abscesses, odors and scars (Pallavi, 2020)**.**

There have been claims that amla powder helps makes the hair softer, shinier and voluminous and also stimulates hair growth (Dalela, 2019). Avocado oil has also been shown to be a hair growth promoter (Kei, 2023)**.**

Based on the evaluation carried out, all the formulations exhibited stability in terms of colour, smell, texture and there was no syneresis, but there was a difference in the pH of all the formulations. This can be addressed by addition of a natural pH stabilizer or buffer to the formulations (Shaw and Gregory, 2022).

The ointment formulations were applied directly to shaven mice skin. This was done to test for visible signs of irritation such as inflammation, oedema or

erythema. After 30 min, 60 min, 2hours and 24 hours, there was no visible sign of irritation on the skin of the mice. This indicates that the formulations are mild enough for the skin and scalp and may not cause irritation on human skin.

CONCLUSION

The study has shown that natural based cosmeceutical herbal ointment can be as effective as market standard synthetic ointment (Damatol®) in the management of dry-scalp related dandruff. The study has also shown the usefulness of avocado pear oil and amla powder in the management of dry-scalp related dandruff. More research should be carried out on the use of natural-based cosmetic products to combat the occurrence of adverse effects caused by synthetic ingredients.

ETHICAL CONSIDERATIONS

Ethical approval was obtained from College of Medicine, University of Lagos Animal Care and Use Research Ethics Committee with registration number NHREC/CMUL ACUREC/19/08/2019.

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