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Efficacy of castor oil cream in treating infraorbital hyperpigmentation: An exploratory single-arm clinical trial

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Abstract

Introduction: Infraorbital hyperpigmentation represents one of the most prevalent conditions in cosmetic dermatology. To treat this condition, many patients prefer natural remedies. This study explored the efficacy of topical castor oil cream in treating patients with infraorbital hyperpigmentation.

Methods: We conducted an exploratory single-arm clinical trial at the Shahid Faghihi Dermatology Clinic and Molecular Dermatology Research Center of Shiraz University of Medical Sciences, Shiraz, Iran, during 2021–2022. Using the convenience sampling method, we enrolled 25 patients with infraorbital hyperpigmentation. We instructed the patients to apply topical castor oil cream twice daily for 2 months. The darkness, melanin, and erythema levels were evaluated by VisioFace® 1000 D and SkinColorCatch® devices. We used a visual analog scale to assess skin laxity, wrinkles, and patient satisfaction. Data analysis was done with Stata version 14.2.

Results: The data of 22 patients with a mean age of 40.92 ± 7.33 years were analyzed. The VisioFace® scores decreased significantly by the end of the study [right eyes: mean difference (MD): -5.63 (95% CI: -7.12 to -4.15), p < 0.001; left eyes: MD: -5.91 (95% CI: -7.46 to -4.36), p < 0.001]. Moreover, castor oil cream significantly reduced the melanin level, wrinkles, and skin laxity in the infraorbital region (p < 0.05).

Conclusions: Castor oil cream seems to be an effective alternative for treating infraorbital hyperpigmentation. Randomized clinical trials are needed to confirm our findings.

KEYWORDS castor oil, cosmetics, darkness, hyperpigmentation, pigmentation disorders

1 | INTRODUCTION

Infraorbital hyperpigmentation (periorbital darkness, periorbital melanosis, infraorbital dark circles, infraorbital darkness) refers to

hyperpigmented patches beneath the eyes, which are usually bilateral, and predominantly affect women.¹ Infraorbital hyperpigmentation makes patients look tired, old, and sad, adversely impacting their quality of life besides giving rise to significant cosmetic costs.²

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Multiple factors can cause infraorbital hyperpigmentation. Since the infraorbital skin is thin and has little subcutaneous tissue (collagen, elastin, and glycosaminoglycans), it is susceptible to early aging and can signal the start of age-related skin changes. The thin skin in this region may appear dark due to the prominence of the underlying muscles and vasculature.^{3,4} With aging, orbicularis oculi hypertrophy and suborbicularis oculi pseudo-herniation occur, and subcutaneous fat and volume are lost in the malar region, contributing to hyperpigmentation. The accumulation of eyelid fluid below the eye may also contribute, considering the presence of hemosiderin and biliverdin, which permeate the vasculature secondary to pathologic or age-related processes.^{3–5} Systemic diseases, hormonal changes, inflammation, skin reactions, nutritional deficiencies, sleep disorders, ultraviolet light exposure, and medications (e.g., contraceptive pills or ophthalmic prostaglandin) may also induce periorbital darkness.⁴

Treatments for infraorbital hyperpigmentation include lasers, creams, serums, fillers, chemical peels, carboxytherapy, plasma-rich platelets, blepharoplasty, and normobaric oxygen. The treatment approach should consider the etiology. If volume loss is the main cause, it can be addressed effectively with soft tissue fillers and autologous fat grafts. In the case of extreme skin laxity, a blepharoplasty procedure is indicated. Pigment-based darkness can be treated using creams and chemical peels, while laser-based modalities offer some relief from vascular or pigment-related etiologies.^{5,6}

Castor has long been used in Persian medicine as a treatment for skin diseases such as hyperpigmentation.⁷ Derived from *Ricinus communis*, castor oil is recognized for its laxative properties, though it also offers antimicrobial, anti-inflammatory, antinociceptive, analgesic, antioxidant, wound healing, and vasoconstrictive activities and promotes uterine contractions and lipid metabolism.⁸ Ricinoleic acid is castor oil's most important fatty acid,⁹ besides linoleic, linoleic, oleic, stearic, dihydroxy stearic, palmitic, and arachidonic acid.¹⁰ Castor oil has no genotoxic effects and is safe for FDA-approved indications.⁸

Evidence showed that many patients with dermatologic conditions prefer using complementary and alternative remedies rather than or in adjuvant with chemical agents.^{11,12} However, the efficacy of topical castor oil in treating skin hyperpigmentation conditions has been sparsely investigated. Therefore, this study evaluated the efficacy of castor oil cream in treating infraorbital hyperpigmentation.

2 | PATIENTS AND METHODS

2.1 | Study design

We conducted an exploratory, single-arm, open-label clinical trial on patients with infraorbital hyperpigmentation referring to the Shahid Faghihi Dermatology Clinic and Molecular Dermatology Research Center affiliated with Shiraz University of Medical Sciences from September 2021 to February 2022. This study is registered with the Iranian Registry of Clinical Trials (ID: IRCT20150825023753N16; link: https://www.irct.ir/trial/42994).

2.2 | Sample size

The study population included all patients with infraorbital hyperpigmentation. We used the "sampsi" module of Stata software version 14.2 to estimate the minimum sample size. In line with the Nilforoushzadeh MA et al. study,¹ considering the value of 11.18 for the mean baseline darkness level measured by VisioFace® and decreasing 4 points as the minimum clinically important change after the intervention, 24 patients were calculated for the minimum sample size. This calculation considered alpha equal to 0.05, study power 80%, and 20% potential loss to follow-up.

2.3 | Inclusion and exclusion criteria

This study included adults (>18) with infraorbital hyperpigmentation confirmed by a dermatologist to be unrelated to systemic or vascular diseases. On the other hand, the patients who reported hypersensitivity reactions to castor oil, pregnant and lactating women, patients with a positive history of systemic diseases including diabetes mellitus, hypertension, kidney/liver diseases, hyperthyroidism/hypothyroidism, and individuals wishing not to participate in the study were excluded. In addition, we asked all the participants to discontinue using topical medications to treat periorbital darkness from 1 month before enrolling in the study.

2.4 | Preparation of castor oil topical cream

An oil-in-water cream containing filtered castor oil (yielded by coldpressing caster seeds) at a concentration of 10% extracted oil was prepared at the Medicinal Plants Processing Research Center (Shiraz University of Medical Sciences).

2.5 | Gas chromatography/mass spectroscopy for the analysis of fatty acid profile

The gas chromatography device, manufactured by Agilent Technologies, USA, model 7890B, with a capillary column as BPX70 type (length 50 m and inner diameter 0.32 mm) were employed in this investigation. The standard marker was Supelco 37 Component FAME Mix (standard code 47855) which was injected directly into the device. The sample of castor oil for injection must be diverted to the form of methyl ester. For this purpose, 0.3g of oily sample was mixed with 7 mL of normal hexane, then 2 mL of saturated methanolic- potassium was added. It was completely mixed for 1 min to form two phases. Subsequently, 1 mL was taken from the upper phase and injected into the GC (according to the National Standard Organization of Iran, No. 4–13 126). The type of injector is Split/Splitless, which was set to Split mode with a ratio of 1:50. The temperature of the glass tube was 250°C and that of the FID detector was 270°C. The temperature of the glass tube causes the sample to vaporize and enter the column by means of nitrogen carrier gas (flow rate of 0.5 mm/min). The temperature program of the oven started with 50°C and remained at this temperature for 1 min. It reached a temperature of 160°C for 15 min at a rate of 10°C/min, then remained at 240°C/min for 7 min (rate of 6°C/min). The injected sample burned and turned into ions (ionized), affecting by the electron circuit. Finally, the chromatograms were plotted by the processor.

2.6 | Intervention

We instructed the patients to apply castor oil cream to their infraorbital areas twice daily for 2 months. In addition, we asked the patients to wash their faces with water before using the cream.

2.7 | Data collection, primary, and secondary outcome measurements

At baseline, we recorded demographic features like age, sex, marital and occupational status, educational level, and medical history. Before beginning the study and 2 months after starting the treatment, the dermatologist evaluated the primary and secondary outcomes of the study.

The study's primary outcomes were the patients' infraorbital darkness, melanin, and erythema levels. Changes in the color (ΔE) of the patients' infraorbital areas were measured by VisioFace® 1000 D Full Face Skin Analysis Device (PC-based device), manufactured by CK Electronic Cologne Germany. The melanin and

erythema levels in the specified region were measured using a SkinColorCatch® device (Serial number DCC1008, Delfin Technologies Ltd, Finland).

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Secondary outcomes included skin laxity, wrinkles, and patient satisfaction. A dermatologist evaluated skin laxity and wrinkles in the patients' infraorbital areas before and after the treatment on a visual analog scale (VAS). Furthermore, as an indicator for assessing patient satisfaction, we asked the patients' opinions regarding the level of infraorbital darkness using a VAS.

2.8 | Study ethics

The protocol of this study was approved by the Research Ethics Committee of Shiraz University of Medical Sciences (Ethics code: IR.SUMS.MED.REC.1399.246). This protocol was clearly explained to all study participants, who signed a written informed consent form before entering the study.

2.9 | Statistical analysis

We used Stata version 14.2 (StataCorp LLC, College Station, Texas, USA) for statistical analysis, reporting the gathered data as mean and standard deviation (SD) for quantitative data and frequency and percentage for categorical data. We compared measures before and after the intervention with the paired t-test. For estimation of the size of the differences, we used mean difference (MD) and standard mean difference (SMD), consisting of Hedges's G, with a 95% confidence interval (CI). *p* values ≤0.05 were regarded as significant.

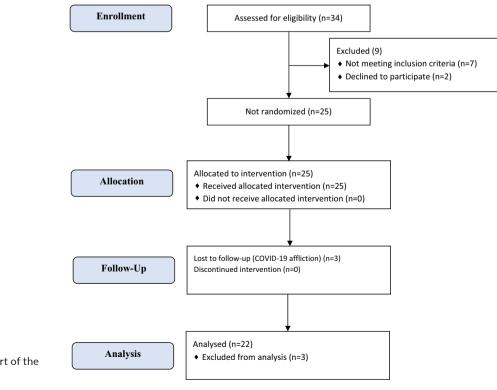


FIGURE 1 CONSORT flowchart of the study.

3 | RESULTS

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3.1 | The fatty acid profile of castor oil using gas chromatography/mass spectroscopy

According to the results of GC/FID chromatogram, series of main fatty acids in the extracted oil were respectively from Ricinoleic acid ($C_{18}H_{34}O_3$, $C_{18:1}$, 67.6%), Linoleic acid ($C_{18}H_{32}O_2$, $C_{18:2}$, 11.3%), Oleic acid ($C_{18}H_{34}O_2$, $C_{18:1}$, 8.6%), Linolenic acid ($C_{18}H_{30}O_2$, $C_{18:3}$, 5.3%) as well as Palmitic ($C_{16}H_{32}O_2$, $C_{16:0}$), and Stearic acid ($C_{18}H_{36}O_2$, $C_{18:1}$) with less than 3% of abundance.

3.2 | Study participants

This study involved 25 patients (23 women and 2 men) with a mean age of 40.92 ± 7.33 years, though three were lost to follow-up because of COVID-19 affliction. Hence, 22 patients completed the study and were included in the data analysis (Figure 1). Table 1 shows the demographic characteristics of the patients enrolled in the study.

3.3 | Primary outcomes

As shown in Table 2, over 2 months, the castor oil cream significantly decreased the darkness below both the right (from 12.91 ± 2.18 to

TABLE 1 Demographic characteristics of the study participants.

| Variable | Frequency (%)/ mean±SD |
|-----------------------------|------------------------|
| Age, years | 40.92±7.33 |
| Sex | |
| Man | 2 (8) |
| Woman | 23 (92) |
| Marital status | |
| Single | 4 (16.67) |
| Married | 20 (83.33) |
| Educational status | |
| Under diploma or diploma | 6 (24) |
| Academic education | 19 (76) |
| Occupational status | |
| Housewife | 7 (28) |
| Governmental employee | 9 (36) |
| Non-governmental | 9 (36) |
| Medical history | |
| Taking contraceptive agents | O (O) |
| Using topical sunscreen | |
| Yes | 13 (52) |
| No | 12 (48) |
| Using sunglasses | |
| Yes | 19 (76) |
| No | 6 (24) |
| | |

7.27±3.21, p < 0.001) and left (from 12.23 ± 2.34 to 6.32 ± 2.53 , p < 0.001) eyes, as measured by the VisioFace® device. Furthermore, the results of the colorimeter (SkinColorCatch) analysis indicated that the level of melanin reduced significantly beneath both the right (from 783.59±83.36 to 699.77±72.48, p < 0.001) and left (from 742.23±76.70 to 699.77±72.48, p = 0.004) eyes. However, there was no significant change in erythema below either eye (p > 0.05). Figure 2 shows the before and after measurements made using the VisioFace® 1000 D device for four participants.

3.4 | Secondary outcomes

The patients scoring of their infraorbital darkness before and after using the topical cream of castor oil, which could indicate patients' satisfaction with the treatment, showed that the darkness decreased from 7.32 ± 2.03 to 4.59 ± 2.11 (p<0.001). Moreover, according to the dermatologist's assessment, skin laxity and wrinkles in the specified area significantly improved after using the castor oil cream (p=0.004 and p<0.001, respectively) (Table 2). Finally, compliance with treatment was more than 85%.

3.5 | Adverse event

The patients reported no adverse events during this study.

4 | DISCUSSION

This preliminary study demonstrated that topical castor oil cream effectively treats patients with infraorbital hyperpigmentation. In addition, this herbal remedy significantly improved infraorbital wrinkles and skin laxity, and patient satisfaction was acceptable.

Castor oil is a promising option for treating certain dermatology conditions. Some studies have confirmed its efficacy in treating dry skin,^{13,14} while others revealed that topical castor oil could be effective in skin tissue regeneration and reepithelialization.¹⁵⁻¹⁷ Piamphongsant T. demonstrated that using a phenol-castor oil component during the peeling process adjuvant with an anti-melasma cream was effective in skin hyperpigmentation conditions.¹⁸ Another study demonstrated that topical, periocular application of castor oil improved blepharitis symptoms such as eyelash matting, eyelid margin thickening, telangiectasia, cylindrical dandruff, madarosis, and lid wiper epitheliopathy.¹⁹ Furthermore, Pakkang et al. developed a compound herbal remedy consisting of castor and sunflower oil as a safe makeup remover product.²⁰

According to the VisioFace® analysis results, topical castor oil decreased the level of infraorbital darkness by more than five points; these changes were statistically significant. This improvement could be considered large and conclusive due to the large values of the effect sizes and the narrow ranges of the corresponding confidence intervals. Furthermore, SkinColorCatch® TABLE 2 Outcomes measures before and after 2 months of using castor oil cream for infraorbital hyperpigmentation.

| | Measured value | | | | |
|---|-------------------|--------------------|-------------------------------|----------------------------|---------|
| Outcome | Before | After | Mean difference (90% CI) | Hedges's G (90% CI) | p-Value |
| Visiofasce Color (ΔE) | | | | | |
| Right eye | 12.91±2.18 | 7.27±3.21 | -5.63 (-7.12 to -4.15) | -2.02 (-2.73 to -1.29) | <0.001 |
| Left eye | 12.23 ± 2.34 | 6.32 ± 2.53 | -5.91 (-7.46 to -4.36) | -2.38 (-3.14-1.60) | <0.001 |
| Colorimeter (SkinColorCate | h®) | | | | |
| Melanin | | | | | |
| Right eye | 783.59±83.36 | 699.77±72.48 | -83.82 (-118.43 to -49.21) | –1.05 (–1.67 to –0.43) | <0.001 |
| Left eye | 742.23±76.70 | 699.77±72.48 | -42.45 (-70.11 to -14.80) | –0.56 (–1.15 to 0.04) | 0.004 |
| Erythema | | | | | |
| Right eye | 459.86±14.64 | 454.68 ± 15.49 | -5.18 (-11.85 to 1.49) | -0.34 (-0.92 to 0.25) | 0.121 |
| Left eye | 456.5 ± 14.01 | 453.09 ± 12.83 | -3.40 (-10.72 to 3.90) | -0.25 (-0.83 to 0.34) | 0.343 |
| Patients' score for their dark circle eyes using a visual analog scale (VAS) | 7.32±2.03 | 4.59±2.11 | -2.72 (-3.62 to -1.84) | -1.29 (-1.93 to -0.65) | <0.001 |
| Skin laxity | 6.18 ± 3.00 | 4.40 ± 2.77 | -1.77 (-2.93 to -0.62) | -0.60 (-1.19 to -0.004) | 0.004 |
| Wrinkle | 2.45 ± 0.91 | 1.64±0.79 | -0.82 (-1.20 to -0.44) | -0.94 (-1.55 to -0.32) | <0.001 |

measurements indicated that the infraorbital melanin level decreased significantly, and the reduction was within the moderate range. On the other hand, there were no significant changes in the erythema values, possibly due to the short time of the study. Accordingly, we expect that the effects of the topical use of castor oil will become more clear as the duration of use increases. From the viewpoints of the patients who participated in our study, the infraorbital darkness was reduced after 2 months of topical castor oil. This result could indicate acceptable satisfaction with using the product among patients.

Our findings align with the study conducted by Cao et al., which demonstrated that a microemulsion gel of polyoxyethylene hydrogenated castor oil improved skin hyperpigmentation. According to that study, the castor oil product could inhibit melanocyte tyrosinase activity, thereby decreasing the rate of melanin synthesis in A375 human melanocytes.²¹ Moreover, an in-vivo study declared castor wax beads safe for cleaning recalcitrant oily skin contamination, suggesting it as an alternative medicinal remedy for skin protection.²²

Castor oil contains certain chemical compositions that could benefit skin care, offering skin protection, clearing, wound healing, and moisturizing properties. Constituents like triricinolein, phenolic compounds, and linoleic, ricinoleic, palmitic, stearic, and oleic acid give castor oil anti-inflammatory, antioxidant, and antibacterial features.^{14,23-25} The GC/FID analysis conducted in our study revealed that ricinoleic acid, linoleic acid, and oleic acid were the predominant fatty acid compositions in the castor oil that we used. This result was in line with the results of previous studies. The clinical findings of our study could be related to the bioactivity effects of these fatty acids, particularly ricinoleic acid, of castor of castor oil, as evidenced by previous research.²⁶⁻²⁹

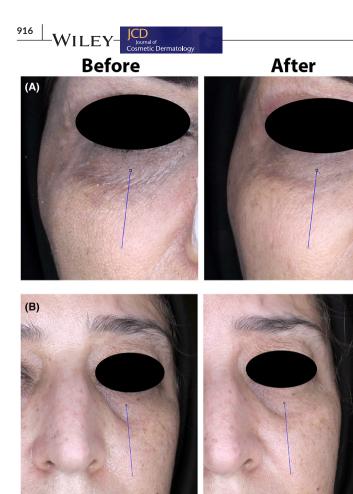
In this study, the patients reported no side effects. This result aligns with other evidence that castor oil does not have remarkable transdermal absorption, meaning that adverse events because of topical application of castor oil will be rare.³⁰ In addition, another study showed that periocular application of castor oil did not have any side effects.¹⁹ However, as some evidence claims castor oil has cytotoxic effects on conjunctival cells,²⁷ we emphasized that the patients should prevent direct contact of their eyes with castor oil cream.

This project was the first to examine the efficacy of a topical castor oil product in treating patients with infraorbital hyperpigmentation, though some limitations existed. First, our investigation was a single-arm, open-label, exploratory clinical trial with a small sample size, so we recommend extensive randomized clinical trials. Second, the duration of this study was short, so we suggest longer study durations. While we evaluated the efficacy of castor oil cream in treating infraorbital hyperpigmentation, we recommend evaluating this product's efficacy in treating other hyperpigmentation skin conditions, such as chloasma and post-inflammatory hyperpigmentation. Next, other forms and doses of this herbal remedy should

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| Image | ΔL | ΔE |
|-------|--------|-------|
| 1 | -11.00 | 11.00 |
| 2 | -9.00 | 9.00 |



| Image | ΔL | ΔE |
|-------|-------|------|
| 1 | -9.00 | 9.00 |
| 2 | -4.00 | 5.00 |

FIGURE 2 Photography of the patients before and after receiving castor oil cream for 2 months.

be evaluated for treating skin hyperpigmentation conditions alone or adjuvant with other conventional medications. Finally, the use of dermoscopy and subclinical imaging, which were not used in this study, should also be advised to improve the evaluation of the outcomes in future research.

CONCLUSION 5

Overall, the results of our study demonstrated that castor oil cream could be a safe alternative cosmetic agent for treating patients with infraorbital hyperpigmentation. This natural product is also expected to be effective in treating other skin darkness conditions, such as melasma. Therefore, studies should delineate the mechanisms of action through which castor oil treats skin hyperpigmentation conditions. Moreover, extensive randomized clinical trials should be conducted to confirm our findings.

AUTHOR CONTRIBUTIONS

Mohammad Mahdi Parvizi, Nasrin Saki, Mohammad Mehdi Zarshenas, designed the study. Mohammad Mahdi Parvizi, Nasrin Saki, RZ, Soodabeh Samimi, Mohammad Miaad Shahrizi collected the data. Mohammad Mahdi Parvizi, Soodabeh Samimi, Mohammad Mahdi Parvizi drafted the manuscript. Mohammad Mahdi Parvizi,

Mohammad Mehdi Zarshenas, Nasrin Saki finalized the manuscript. All authors reviewed the manuscript and approved the final version. They take full responsibility for the content and writing of this article.

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CONFLICT OF INTEREST STATEMENT

Nothing to declare.

DATA AVAILABILITY STATEMENT

The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

The protocol of this study was approved by the Ethics Committee of Shiraz University of Medical Sciences (Ethics code IR.SUMS. MED.REC.1399.246). In addition, this study was registered on the Iranian Registry of Clinical Trials website (Registration code: IRCT20150825023753N16).

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