ARAŞTIRMA MAKALESİ / RESEARCH ARTICLE

Kocaeli Med J 2024; 13 (2): 94-99, doi: 10.5505/ktd.2024.04710

# Pediatrik Hastalarda Akne Vulgaris Tedavisinde Kısa Süreli Temas Şeklinde Uygulanan Klindamisin ve Tretinoin Kombinasyonunun Etkinlik ve Tolere Edilebilirliğinin Standart Uygulama Şekli ile Karşılaştırılması

## Effectiveness and Tolerability of Short Contact Therapy with Topical Clindamycin and Tretinoin Combination Compared to Long Contact Therapy in the Treatment of Acne Vulgaris in Pediatric Patients

Sabir Hasanbeyzade

Dermatovenerology Clinic, Medicana International Ankara Hospital, Ankara, Türkiye.

## ÖZ

**Giriş:** Biz çalışmamızda, hafif ve orta şiddetli akne vulgaris tedavisinde klindamisin ve tretinoin kombinasyonunun standart ve kısa temas şeklinde kullanımının etkinlik ve yan etkilerini karşılaştırdık.

**Yöntem:** Çalışma için hastane klinik olmayan etik kurulundan onay alınmıştır. 01.09.2020-31.03.2021 tarihlerinde polikliniğe sivilce şikayeti ile ayaktan başvuran ve hafif-orta şiddetli akne tanısı alan, tedavisinde klindamisin-tretinoin kombinasyonu kullanılan, her grupta 240 hasta olacak şekilde toplam 480 hasta dosyası çalışmaya alındı. Kısa süreli temas şeklinde kullananlar ilacı sürdükten 1 saat sonra yıkarken, standart şekilde kullananlar gece sürüp sabaha kadar bekletip sabah yıkamışlardı.

**Bulgular:** İSGA skoru ve skordaki yüzdelik düşüş açısından gruplar arasında istatistiksel anlamlı fark bulundu (p 0.013). Standart uygulama grubunda İSGA ortalaması daha düşük ve İSGA düzelme yüzdesi daha yüksekti. Lezyon sayıları standart uygulamada daha fazla düzelme göstermekteydi (p <0.001). İki grup arasında yan etkiler açısından 1. ay sonunda fark bulundu (p <0.001). Yan etkiler standart uygulama şeklinde daha fazlaydı.

**Sonuç:** Standart uygulamanın kısa temas süreli uygulamaya göre daha etkili bulunması, 1. ay sonunda 2 grup arasında yan etkilerin standart grupta daha fazla görülmesi ve diğer aylarda düşerek diğer grupla eşitlenmesi tedaviye kısa temas süreli uygulama şeklinde başlanıp sonradan standart uygulamaya dönülmesinin etkinlik ve yan etki açısından daha verimli olacağını düşündürmektedir.

**Anahtar Kelimeler:** akne vulgaris, kısa temaslı, klindamisin, tretinoin, uzun temaslı

## ABSTRACT

**Objective:** In this study,the effectiveness and side effects were compared between the standard (long contact) and short contact use of clindamycin+tretinoin combination in the treatment of mild to moderate acne vulgaris.

**Method:** The study was approved by the hospital's nonclinical Ethics Committee.A total of 480 subjects were enrolled in the study and each group contained 240 subjects who were diagnosed with mild to moderate acne and treated with the combination of clindamycin+tretinoin between 01.09.2020-31.03.2021.Short contact users rinsed away the drug after 1 hour while standard users applied the drug at night,kept it until the next morning and then rinsed off.

**Results:** There was a statistically significant difference between the groups in terms of ISGA score and percentage reduction in the score (p 0.013).The average ISGA score was lower and percentage improvement in ISGA score was higher in the standard group.Number of lesions showed greater improvement in the standard use group (p <0.001).There was a difference between the two groups in terms of side effects by the end of 1st month (p <0.001).Side effects were higher in standard application group.

**Conclusion:** The fact that the standard application was found to be more effective than the short contact application,that the side effects were more common in the standard group at the end of the first month,and that they decreased and equalized with the other group in the following months,suggests that starting the treatment with a short contact application and then returning to the standard application would be more efficient in terms of effectiveness and side effects.

**Keywords:** acne vulgaris, clindamycin, long contact, short contact, tretinoin

**Sending Date:** 06.04.2023 **Acceptance Date:** 30.08.2024

**Correspondence:** Sabir Hasanbeyzade, Dermatovenerology Clinic, Medicana International Ankara Hospital, Ankara, Türkiye.
**E-mail:** dr.sabir.hasanov@gmail.com

**Cite as:** Hasanbeyzade S. Effectiveness and tolerability of short contact therapy with topical clindamycin and tretinoin combination compared to long contact therapy in the treatment of acne vulgaris in pediatric patients. Kocaeli Med J 2024; 13(2): 94-99, doi: 10.5505/ktd.2024.04710

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## INTRODUCTION

Acne vulgaris (AV) is an inflammatory disease of the pilosebaceous unit that primarily affects adolescents and is characterized by increased sebum production, epithelial hyperkeratinization, increased proliferation of Cutibacterium acnes and inflammation (1). There are three main treatment options for acne treatment: topicals, systemic antibiotics and systemic isotretinoin. Topical treatments are generally used alone or in combination for mild to moderate acne and include topical antibiotics, benzoyl peroxide, sodium sulfacetamide, retinoids and combinations of these. In this study, the effectiveness and side effects of long contact and short contact use of the combination of clindamycin and tretinoin were compared in the treatment of mild to moderate AV.

## MATERIALS AND METHODS

Study Design

The study was designed as a retrospective evaluation of patient files. The files were screened for patients with pimples presenting to the dermatology outpatient clinic between 01.09.2020-31.03.2021 and diagnosed with AV. The study involved patients between 12 and 18 years of age with mild to moderate acne as defined by the Investigator's Static Global Assessment (ISGA) score of 2-4 and treated with a combination of topical clindamycin phosphate 1.2% (12 mg/g) and tretinoin 0.025% (0.25 mg/g). Those who were previously treated with clindamycin-tretinoin combinations, who were diagnosed with severe acne with nodular-cystic lesions, who are below 12 and above 18 years old, who received other acne treatments within 3 months before presenting the clinic, who had a history of epilation or other interventions (energy bound device, peeling, dermabrasion, etc.) to the face, patients who was under systemic corticosteroid treatment, and facial cosmetics that contain retinol or acidic ingredients were excluded from the assessment. After all eliminations, a total of 480 patient files were included in the study with 240 subjects in each group.

The physical examinations, treatments and follow-ups and medical records were conducted by the same physician (study author). None of the patients discontinued the treatment due to side effects.

The study included the following information from patient files:

- Demographic characteristics such as age and gender
- Noninflammatory lesions that include open and closed comedones, inflammatory lesions including papules and pustules, and total number of lesions
- ISGA (Investigator's Static Global Assessment) scores (2):
  - 0 (clear) - normal, clear skin with no evidence of acne vulgaris
  - 1 (almost clear) - rare noninflammatory lesions present, with rare noninflamed papules (papules must be resolving and may be hyperpigmented, though not pink-red)
  - 2 (mild) - some noninflammatory lesions are present, with few inflammatory lesions (papules/pustules only, no nodulocystic lesions)
  - 3 (moderate) - noninflammatory lesions predominate, with multiple inflammatory lesions evident; several to many comedones and papules/pustules; there may or may not be one small nodulocystic lesion
  - 4 (severe) - inflammatory lesions are more apparent, many comedones and papules/pustules, there may or may not be a few nodulocystic lesions
  - 5 (very severe) - highly inflammatory lesions predominate, variable number of comedones, many papules/ pustules, and many nodulocystic lesions
- Patient satisfaction scores (1 – not satisfied, 2 – satisfied, 3 – very satisfied)
- Side effects:
  - Side effects as assessed by the physician: erythema (0 – none, 1 or mild – mild pink discoloration, 2 or moderate – redness, 3 or severe – significant bright red or dark red erythema) and dryness (0 – no scaling, 1 or mild – fine scales that are faint and limited to certain facial areas, 2 or moderate – scales all over the face, 3 or severe – scaling and peeling all over the face)
  - Side effects as assessed by the patient: burning/tenderness (0 – none, 1 – mild, 2 – moderate, 3 – severe)

All the patients had used the combination of clindamycin and tretinoin in the evening. Patients using short contact therapy washed the product away after 1 hour while standard users applied the drug at night, kept it overnight and washed it the next morning. All the patients applied a moisturizing agent after washing their faces and applied sunscreens 2 times a day in the morning and at noon. The product was not applied around the mouth and eyes. These aspects partly eliminate the potential differences between the groups in terms of dryness and those due to the sun exposure.

Statistics: All the data drawn from patient files that are mentioned above were entered in the software SPSS Statictics 25 (IBM© Corp., Armonk, NY, USA) and analyzed. P value <0.05 was considered statistically significant. Discontinuous variables were expressed in numbers and percentages while continuous variables were expressed in mean +/- standard deviation. Chi-squared test was used to investigate independent variables for discontinuous variables. Whether the groups conformed normal distribution in terms of continuous variables was assessed using Kolmogorov-Smirnov test. Mann-Whitney U test was used to investigate the difference in terms of continuous variables in independent groups not conforming normal distribution and Wilcoxon test for the difference in continuous variables in dependent groups not conforming normal distribution.

## RESULTS

The mean age was 15.45 +/- 1.81 and 88 (36.7%) of the subjects were male and 152 (63.3%) were female in the long contact group. In the short contact group, these data were 15.22 +/- 1.73, 96 (40%) and 144 (60%), respectively. No statistically significant difference was found between the groups in terms of age and gender (p 0.094 and 0.453, respectively). There was no statistically significant difference between the groups in terms of pretreatment ISGA values, open comedones, closed comedones,

noninflammatory lesions, papules, pustules, inflammatory lesions and the total number of lesions (p 0.642, 0.504, 0.138, 0.437, 0.110, 0.051, 0.086, 0.141, respectively). These data are summarized in Table 1.

**Table 1. Baseline Characteristics and Pretreatment Values of Study Subjects.**

| Mean +/- sd | Standard application (n=240) | Short contact application (n=240) |
|---|---|---|
| Age (years)<br>*min.-max.* | 15.45 +/- 1.81<br>*12-18* | 15.22 +/- 1.73<br>*12-18* |
| Gender (n / %):<br>male<br>female | <br>88 / 36.7%<br>152 / 63.3% | <br>96 / 40%<br>144 / 60% |
| Initial ISGA values | 2.88 +/- 0.78 | 2.88 +/- 0.76 |
| ISGA subgroups (n / %):<br>2<br>3<br>4 | <br>90 / 37.5%<br>90 / 37.5%<br>60 / 25% | <br>85 / 35.4%<br>100 / 41.7%<br>55 / 22.9% |
| NNL[1]<br>*open comedone*<br>*closed comedone* | 42.85 +/- 9.45<br>*10.90 +/- 3.19*<br>*31.95 +/- 6.33* | 43.28 +/- 9.41<br>*11.16 +/- 3.32*<br>*32.13 +/- 6.28* |
| NIL[2]<br>*papule*<br>*pustule* | 37.25 +/- 5.84<br>*13.75 +/- 1.57*<br>*23.50 +/- 4.34* | 37.71 +/- 5.96<br>*13.91 +/- 1.67*<br>*23.68 +/- 4.26* |
| TNL[3] | 80.11 +/- 15.28 | 80.88 +/- 15.13 |

[1]NNL-Number of Noninflammatory Lesions, [2]NIL-Number of Inflammatory Lesions, [3]TNL-Total Number of Lesions.

There was a statistically significant difference in both groups between ISGA values at baseline and at 3 months (p <0.001 for both), i.e. both groups showed improvement with treatment by the end of the 3rd month (Table 2).

There was a statistically significant difference between the groups after treatment in terms of ISGA scores and the percentage reduction in the scores (p 0.013). The mean ISGA score was lower and the mean percentage improvement in ISGA was higher in the standard application group compared to short contact group, indicating a higher effectiveness. Similarly, statistically significant differences were observed between the groups in terms of open comedones, closed comedones, noninflammatory lesions, papules, pustules, inflammatory lesions and the total number of lesions (p <0.001). All of these variables show greater improvement with the standard application. All of these data are detailed in Table 2.

A statistically significant difference was found between the two groups by the end of 1st month in terms of erythema, dryness and the sense of burning/stinging (p <0.001 for all). These side effects are observed higher with the standard use. Severe erythema was observed to be higher by the end of 1st month in patients using standard application while no statistically difference was seen in terms of side effect severity (p 0.230). The severity of side effects was found to be different at 1st month in patients with dryness and burning/stinging (p 0.041, <0.001, respectively). Severe dryness and severe sense of burning were significantly higher in the patient group using standard application (Table 3).

At the 2nd month, no statistically significant difference was found between the two groups in terms of erythema, dryness and sense of burning (p 0.559, 0.631, 0.687, respectively). Similarly, no difference was seen between the groups in terms of erythema, dryness and sense of burning by the end of 3rd month (p 0.736, 0.793, 0.815, respectively). The data are presented in Table 3.

A statistically significant difference was found between two groups in terms of patient satisfaction (p 0.001). Despite the fact that the number of satisfied patients were similar in both groups, the ratio of patients that were satisfied was higher in standard group while the proportion of those who were very satisfied was higher in the short contact group (Table 4).

## DISCUSSION

Most of the patients in this study were female; the proportion of male subjects in the standard application and short contact application were 36.7% and 40%, respectively. This difference is thought to be due to the fact that women care more about appearance and are affected more by factors that negatively affect their appearance and therefore visit hospital more often.

The ISGA values, percentage changes in ISGA, open and closed comedones, papules and pustules, , total number of non-inflammatory lesions, total number of inflammatory lesions and the total number of all lesions after 3 months were found to be statistically significantly different between the groups and the effectiveness was higher in the group using standard application.

The side effects at the end of 1st month were different among the two groups and were higher in the standard use group. However, no difference was seen between the groups by the end of the 2nd and 3rd months, and the insidence of side effects were reduced in both groups compared to the end of the first month.

A research of PubMed did not reveal a study that compared the short contact and long contact use of clindamycin-tretinoin combination in terms of effectiveness and side effects. Most of the studies had been conducted using standard application and compared the combination either with other topical agents, with placebo, or with clindamycin and/or tretinoin. A comparison of the applications with short contact and standard use was noted in one study and the product used in this study was in the form of triplet combination (mentioned later in the text).

In their 52-week study investigating the safety of the combination with clindamycin phosphate 1.2% and tretinoin 0.025%, Kircik et al. observed side effects in 32 (7.2%) of 442 subjects; the most frequent side effect was acne flares (29/442, 7%) followed by sunburn (12/442, 3%), hypersensitivity (7/442, 2%), contact dermatitis (5/442, 1%) and desquamation in the application site (3/442, 1%). Erythema and scaling were increased in the 1st month of treatment (mild erythema 25.2%, scaling 22.6%; moderate erythema 52%, scaling 4%; severe erythema 0.7%,

scaling 0.5%) and gradually decreased with continuing treatment. Similarly, inflammation (8.5%) and prickling/stinging (5.7%) were also seen in the 1st month and these rates decreased as the treatment continued (3). In the other two studies conducted by the same author using the same active substances with a cleansing agent containing 5% and 5.5% benzoyl peroxide, these side effects were shown to increase during the 4th and 2nd weeks, respectively, followed by decline as the treatment continued (4, 5).

In a 12-week randomized controlled trial investigating the effectiveness of clindamycin phosphate + tretinoin and clindamycin phosphate + salicylic acid combinations and clindamycin lotion in the topical treatment of mild to severe acne, NilFroushzadeh et al. found that clindamycin phosphate + tretinoin combination was 67% effective in reducing the number of open comedones, 60.94% in reducing closed comedones, 71.67 in reducing papules, 76.19% in reducing pustules, 72.20% in reducing the total number of lesions and 73.73% in reducing the acne severity index (ASI). The proportion of side effects was 21.42% in this group and most were tolerable in severity (6).

Draelos et al. investigated tolerability in a study in which they conducted using clindamycin phosphate 1.2% - tretinoin 0.025% gel and a cleansing agent containing 4% benzoyl peroxide. The rate of side effects in the study was 3%. These side effects were generally mild and decreased after 1-2 weeks (7).

Seven side effects associated with clindamycin-tretinoin combination were identified in 20 subjects in the single center, randomized, bilateral 3-week study by Aschoff et al. comparing the effectiveness and tolerability of clindamycin-tretinoin combination and benzoyl peroxide-adapalene combination. At the end of treatment, the number of noninflammatory lesions decreased by 65.4% and the number of inflammatory lesions decreased by 54.9%. Erythema, dryness, burning and stinging complaints were increased in all patients at the first week visit but then decreased again during the treatment course (8).

In a 12-week double-blind, randomized, multicenter study with clindamycin-tretinoin combination, Lawrence et al. observed reduction of 39.26% in the total number of lesions at the end of the treatment with a 36.8% reduction in mild acne, 39.7% in moderate acne and 40.3% reduction in severe acne. The side effects showed an increase in the 2nd week of the treatment but decreased during the treatment (9). In two other studies, improvements of similar rates were observed (42-43.2% in noninflammatory lesions, 54-56.5% in inflammatory lesions and 54-56.5% in total lesion number) (10, 11).

Callender et al found an improvement of 67% at 12 weeks in patients with dark skinned acne and development of hyperpigmentation due to acne in their study investigating the effectiveness of combination therapy with clindamycin phosphate and tretinoin (12).

In their randomized, double-blind, controlled study on 2219 individuals, Leyden et al reported that combination of clindamycin phosphate+tretinoin reduced the number of inflammatory lesions by 53.4%, noninflammatory lesions by 45.2% and total lesions by 48.7%, that patients achieving a score of 0 and 1 were 37% in total, side effects were 19% in total, and the rates of dryness, desquamation and erythema were 9%, 8% and 6%, respectively, with burning/stinging seen at a similar rate (13).

Chang et al, in their randomized, double-blind, placebo controlled study conducted on 43 subjects with rosacea, found no difference in the number of papules and pustules and mean percentage of improvement before and after the treatment with 12 weeks of clindamycin-tretinoin combination. Increased disease severity, scaling of the skin, burning and redness were seen in 17.5%, 15%, 9% and 18.1% of the subjects, respectively (14).

Bertolani et al compared the effectiveness and tolerability of short and standard contact applications of a product containing 0.02% tretinoin, 0.8% clindamycin 4% glycolic acid in 46 subjects with mild to moderate acne in a randomized controlled, two-center study. After 8 weeks of study, scores of effectiveness and tolerability showed significant differences in patients receiving short contact therapy. The patients better tolerated the agent in the short contact group. GAGS was reduced by 55% in the short contact group at 8 weeks to become 8.5 at average, which was statistically significantly lower than the average in standard application group (15). 6 out of 23 subjects (26%) in the standard application group discontinued treatment due to toleration problems while only 2 of the 23 subjects (8%) in the short contact group discontinued treatment due to side effects (15).

The ratio of dissatisfied patients was higher in the standard application group while satisfied patients was higher in the short contact group. This shows that the side effects that develop due to treatment is important for the patients (most of the patients not satisfied were those experiencing severe side effects). Although the effectiveness was lower in the short contact group compared to standard application, the drug was found to be still effective also in this group. Therefore, the higher patient satisfaction in the short contact group is thought to be related to lower rates of side effects and severity. Thus, side effects and their severity resulting in a convenient treatment course is as important as effectiveness for patients.

Taking into consideration that standard application was more effective than short contact therapy in this study and that side effects were higher in the group receiving standard application compared to the other group at 1 month which then became equal to the short contact group during the following months suggests that starting the treatment with short contact application and later switching to standard use will be more efficient in terms of effectiveness and side effects. In this way, both the effectiveness and patient satisfaction are increased and the side effects are reduced. Further studies are needed regarding such modes of application.

Limitations of the Study

The drawbacks of the study include the retrospective design of the study and the timing of patient treatment that coincide with relatively colder seasons like fall, winter and spring (side effect severity and patient satisfaction due to this might be different during summer). The findings cannot be extrapolated to the entire world since the study included patients admitted to the dermatology outpatient clinic of a given hospital in a certain country. Since patients with severe acne were not included in the study, the study results are not valid for them. The results cannot be generalized to other age groups since the study was conducted on patients within the age group 12-18 only.

**Table 2. Monthly Data for ISGA Measurements, Lesion Numbers and Reduction Percentages.**

| mean +/- sd | Standard application | | | Short contact application | | |
|---|---|---|---|---|---|---|
| | End of 1st m | End of 2nd m | End of 3rd m | End of 1st m | End of 2nd m | End of 3rd m |
| ISGA value | 1.79 +/- 1 | 1.21 +/- 0.87 | 0.88 +/- 0.88 | 2.08 +/- 0.86 | 1.42 +/- 0.86 | 1.08 +/- 0.96 |
| *Reduction percentages* | *37.85 +/- 32.52* | *57.64 +/- 30.20* | *69.79 +/- 30.10* | *27.43 +/- 24.31* | *51.39 +/- 27.53* | *62.95 +/- 31.95* |
| NNL[1] | 24.88 +/- 14.05 | 16.42 +/- 12.26 | 8.96 +/- 10.80 | 30.42 +/- 10.68 | 22.04 +/- 11.26 | 15.33 +/- 11.52 |
| *Reduction percentages* | | | *80 +/- 23.22* | | | *65.04 +/- 26.18* |
| Open comedone | 6.50 +/- 3.97 | 4.42 +/- 3.57 | 2.85 +/- 3.19 | 8.25 +/- 3.28 | 6.33 +/- 3.34 | 4.87 +/- 3.62 |
| *Reduction percentages* | | | *74.87 +/- 27.44* | | | *56.81 +/- 31.54* |
| Closed comedone | 18.38 +/- 10.24 | 12 +/- 8.81 | 6.12 +/-7.69 | 22.17 +/- 7.59 | 15.71 +/- 8.14 | 10.46 +/- 8.16 |
| *Reduction percentages* | | | *81.63 +/- 22.29* | | | *67.81 +/- 25.02* |
| NIL[2] | 20.88 +/- 11.51 | 12.29 +/- 10.16 | 6.08 +/- 8.48 | 24.62 +/- 9.27 | 15.75 +/- 9.30 | 9.67 +/- 7.94 |
| *Reduction percentages* | | | *84.07 +/- 21.75* | | | *74.75 +/- 21.07* |
| Papule | 7.83 +/- 3.95 | 4.92 +/- 3.91 | 2.71 +/-3.45 | 9.42 +/- 3.10 | 6.50 +/- 3.44 | 4.33 +/- 3.42 |
| *Reduction percentages* | | | *80.65 +/- 24.25* | | | *69.23 +/- 24.8* |
| Pustule | 13.04 +/- 7.72 | 7.37 +/- 6.38 | 3.38 +/- 5.22 | 15.21 +/- 6.68 | 9.25 +/- 6.13 | 5.33 +/- 4.77 |
| *Reduction percentages* | | | *86.10 +/- 21.01* | | | *77.96 +/- 19.62* |
| TNL[3] | 45.75 +/- 25.28 | 28.71 +/- 22.10 | 15.04 +/- 19.17 | 55.04 +/- 19.36 | 37.79 +/- 19.78 | 25 +/- 19.08 |
| *Reduction percentages* | | | *81.87 +/- 22.42* | | | *69.60 +/- 23.16* |

[1]NNL-Number of Noninflammatory Lesions, [2]NIL-Number of Inflammatory Lesions, [3]TNL-Total Number of Lesions.

**Table 3. Side Effect Data.**

| n / % | Standard application | | | Short contact application | | |
|---|---|---|---|---|---|---|
| | End of 1st m | End of 2nd m | End of 3rd m | End of 1st m | End of 2nd m | End of 3rd m |
| Erythema | 24 / 10% | 7 / 2.9% | 5 / 2.1% | 7 / 2.9% | 5 / 2.1% | 4 / 1.7% |
| mild | 4 / 1.7% | 3 / 1.3% | 4 / 1.7% | 2 / 0.8% | 4 / 1.7% | 4 / 1.7% |
| moderate | 2 / 0.8% | 2 / 0.8% | 1 / 0.4% | 2 / 0.8% | 1 / 0.4% | 0 |
| severe | 18 / 7.5% | 2 / 0.8% | 0 | 3 / 1.3% | 0 | 0 |
| Dryness | 27 / 11.3% | 10 / 4.3% | 8 / 3.3% | 10 / 4.3% | 8 / 3.3% | 7 / 2.9% |
| mild | 3 / 1.3% | 4 / 1.7% | 6 / 2.5% | 4 / 1.7% | 6 / 2.5% | 6 / 2.5% |
| moderate | 4 / 1.7% | 3 / 1.3% | 2 / 0.8% | 3 / 1.3% | 2 / 0.8% | 1 / 0.4% |
| severe | 20 / 8.3% | 3 / 1.3% | 0 | 3 / 1.3% | 0 | 0 |
| Burning/stinging | 32 / 13.3% | 14 / 5.9% | 10 / 4.1% | 14 / 5.9% | 12 / 5% | 9 / 3.7% |
| mild | 2 / 0.8% | 5 / 2.1% | 8 / 3.3% | 6 / 2.5% | 10 / 4.2% | 8 / 3.3% |
| moderate | 2 / 0.8% | 5 / 2. 1% | 2 / 0.8% | 4 / 1.7% | 2 / 0.8% | 1 / 0.4% |
| severe | 28 / 11.7% | 4 / 1.7% | 0 | 4 / 1.7% | 0 | 0 |

| Table 4. Patient Satisfaction Data. | | |
|---|---|---|
| n / % | Standard application | Short contact application |
| Not satisfied | 20 / 8.3% | 4 / 1.7% |
| Satisfied | 85 / 35.4% | 71 / 29.6% |
| Very satisfied | 135 / 56.3% | 165 / 68.8% |

**Ethics Committee Approval:** The study was approved by the non-clinical research ethics committee of Medicana International Ankara Hospital ( approval date 10.07.2021 and number BSH-2021/19).

**Author Contributions:** All authors contributed to the article.

**Conflict of Interest:** The study has no conflicts of interest (due to single author).

**Funding:** Organisation or person supporting the research other than the authors: no funding resources.

**Informed Consent:** Consent has been obtained from all participants for the use of data

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