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Research Paper

Novel abrasive and oscillating skin preparation device as pre-treatment of actinic keratosis in photodynamic therapy: A Single-center, prospective, open-label, randomized, split-site trial

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ABSTRACT

Background: Photodynamic therapy (PDT) is recommended as a first-line treatment for multiple actinic keratoses (AK) and field cancerized skin. When using PDT, skin preparation is recommended before application of photosensitizer cream to enhance absorption. Different physical methods exist to remove crusts and scales from the AK lesions. However, currently widely used methods can be time-consuming, unpleasant to the patient, or require expensive equipment.

Objectives: To investigate the performance, safety, and comfort of a novel skin preparation device consisting of a soft biocompatible abrasive pad attached to an oscillating device, compared to widely used methods such as curettage and manual microdermabrasion.

Methods: Before artificial daylight PDT (ADL-PDT) all patients (n = 22) underwent skin preparation with the oscillating abrasive device and either curettage (n = 11) or manual microdermabrasion with sandpaper (n = 11). Removal of hyperkeratotic skin and operation times were evaluated. Safety was defined through skin warming (SW), skin irritation (SI), and skin damage (SD). Device comfort was monitored by user and patient questionnaires. Skin preparation was repeated if needed on Day 14 before second ADL-PDT session. Patients determined pain using numerical rate scale (NRS) during skin preparation and ADL-PDT. AK clearance was measured with number and Olsen grade of AKs assessed on Day 0, Day 14, and at 4 months.

Results: **Primary outcomes:** Skin preparation times of AK lesions using the oscillating abrasive device was 15.2 s/10 cm^2 compared to manual sandpaper 26.6 s/10 cm^2 (P = 0.0136) and curettage 22.3 s/10 cm^2 (P = 0.1573). Hyperkeratotic lesions were easily removed with oscillating device for 95.5% (n = 21/22) of the patients. Corresponding values for curettage were 81.8% (n = 9/11, P = 0.10) and for sandpaper 54.5% (n = 6/11, P = 0.0096). More thorough work was required to remove hyperkeratotic lesions for 18.2% of patients (n = 2/11) in the curettage group and for 27.3% of patients (n = 3/11) in the sandpaper group. Some lesions remained on the skin area prepared with the oscillating device in one patient (4.5%, n = 1/22) and in two patients with sandpaper (18.2% n = 2/11). **Secondary outcomes:** Skin warming was reported more often with oscillating device (SW: n = 10/22), but caused less irritation (SI: n = 2/22) and skin damage (SD: n = 1/22), compared to curettage (SW: n = 1/11, SI: n = 5/11, SD: n = 8/11) and manual sandpaper (SW: n = 4/11, SI: n = 2/11, SD: n = 2/11). All reported cases of SW, SI and SD were mild. Device comfort was in general assessed by patients as neutral: oscillating device (n = 17/22), curettage (n = 8/11) and sandpaper (n = 9/11). Vibration of the oscillating device was assessed as neutral by many patients (n = 16), pleasant by four patients (n = 4) and unpleasant by two patients (n = 2). None of the patients found the vibration very unpleasant. The mean pain scores (NRS) were low during skin preparation (oscillating device 1.1, curettage 1.8, sandpaper 1.7) and even lower during ADL-PDT (oscillating device 0.6, curettage 0.4, sandpaper 1.0). Total number of AK lesions were 260 on Day 0, with a reduction to 56 AK lesions on Day 14 (Olsen grade 1: n = 46/108, Olsen grade 2: n = 10/116, Olsen grade 3: n = 0/35). All lesions were cleared at 4-month follow-up.

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Conclusions: The novel oscillating abrasive skin preparation device was as safe and as effective as curettage and manual microdermabrasion in preparation of AKs before ADL-PDT.

1. Introduction

Actinic keratosis (AK) is a precursor of invasive squamous cell carcinoma (SCC), which sometimes can be fatal. In AK, there is cellular atypia and hyperkeratosis of the outermost epidermis layer. The progression of AK to SCC is individual and rather unpredictable. The annual risk of progression of individual AK lesions to SCC ranges from 0.025 % to 16 %. It is currently not known which lesions will progress to invasive cancer. Thus, treatment guidelines recommend active treatment, especially in patients with multiple lesions and field cancerization [1–6].

AK treatment options include field-directed therapies, such as topically applied medication creams and photodynamic therapy (PDT); and lesion-directed therapies, e.g., cryosurgery, laser ablation, or locally applied solutions. Field-directed therapies can be used to treat areas with multiple or diffuse AKs and both visible and subclinical lesions. The choice of treatment also depends on the AK grade [7–11].

Methyl aminolevulinate (MAL) and 5-aminolevulinic acid (ALA) are topical compounds, used in PDT to treat AKs. PDT using a photosensitizer (MAL or ALA) is a flexible treatment strategy offering several options: red light, daylight, or artificial daylight. Artificial daylight enables treatment year-round, also in regions where using natural daylight is not possible [5,12–14].

Several studies have shown that preparing the skin before PDT to remove crusts and scales provides a significantly higher AK clearance compared to unprepared skin [15–21]. Skin preparation can be conducted pharmacologically or using physical methods, such as microneedling, curettage, superficial shaving, various lasers, plum-blossom needles, and microdermabrasion [8,18,22–24]. In clinical practice, curettage and microdermabrasion are widely used methods for skin preparation.

Current skin preparation methods can be time-consuming or require expensive specialty equipment, like different lasers. They can also be unpleasant or painful for the patient, causing side effects, such as pain, scarring, inflammation, and skin irritation, and often require manual treatment times, thus binding medical personnel [25]. A time-saving, patient-friendly skin preparation method suitable for larger areas would therefore be welcome in clinical practice.

A family-owned Finnish company (Mirka Ltd, Jeppo, Finland) producing abrasives, tools, and polishing compounds, is developing a novel skin preparation device. The device consists of a soft, flexible biocompatible skin abrasive pad attached to an oscillating cordless handheld device, resulting in a gentle, easy-to-use, and time-efficient option compared to the existing skin preparation methods.

This study aims to investigate the performance and safety of the novel device in removing hyperkeratoses in AK patients before artificial daylight PDT (ADL-PDT) in comparison with two widely used skin preparation methods; curettage or manual microdermabrasion using sandpaper.

2. Materials and methods

2.1. Study design and randomization

This study was a single-center, prospective, open-label, randomized, split-body, comparative, pre-market investigation (NCT05356572) to evaluate the performance and safety of an abrasive pad in combination with an oscillating handheld device for the removal of hyperkeratotes in AK lesions and field cancerized skin, on adult volunteers.

In this two-arm study, before the first session of ADL-PDT on Day 0, all patients underwent interventions in randomized order with the oscillating device, and either curettage or manual microdermabrasion. Patients were followed up on Day 14 and at 4 months. On Day 14, skin preparation was repeated if remaining AK lesions occurred, and all patients received a second session of ADL-PDT treatment.

Randomization was performed before the start of the study by choosing the comparator (curettage or manual microdermabrasion), which method to start with (oscillating device or comparator), and which skin area to treat first (e.g., left or right side of the treatment area). Randomization allowed each patient to act as their own control. Sealed envelopes with pre-determined randomization were randomly placed into 22 sequentially numbered study material bags. On Day 0, the investigator found the pre-determined randomization for each patient when opening the sealed envelope.

The trial was conducted between September 2022 and September 2023 at the Department of Dermatology at Vaasa Central Hospital in the Wellbeing Services County of Ostrobothnia in Vaasa, Finland, in accordance with the Declaration of Helsinki principles, standard ISO 14,155:2020 guidelines, Medical Device Regulation 2017/745, Medical Devices Act 719/2021, and local regulatory requirements (Ethics Committee of the Hospital District of Southwest Finland approval 94/1801/2021).

2.2. Patients

Patients were enrolled from the patient population attending the investigational site for AK treatment with ADL-PDT. Other inclusion criteria were ages of 18–100 years and the ability to understand and sign the Informed Consent Form. All patients were informed of the nature, scope, and relevance of the study.

Exclusion criteria included known or suspected allergy or hypersensitivity to phenol formaldehyde or MAL cream, wound at the skin site to be treated, documented other skin disease in the treatment field at the time of enrolment, AK treatment within the last six months, and complications that would increase wound risks if the investigational product would be used.

2.3. Investigational device

The investigational device was a human skin abrader system, consisting of a coated soft cushioned biocompatible skin abrasive pad, attached to the backing pad of a cordless handheld device with an oscillating movement of 4000–8000 rpm (RPM). The device was intended for non-invasive skin preparation for eliminating parts of the hyperkeratotic skin and/or stratum corneum and was considered a microdermabrasion device. The device was non-sterile, and the abrasive pads and backing pad were single-use items.

The performance of the oscillating device was compared to two widely used skin preparation methods; curettage (Kai Medical disposable Dermal Curette) and manual microdermabrasion with sandpaper (Ambu® 2121 M Skin Prep Pads) [17,19,20,26,27].

2.4. Outcomes

Outcome measures are presented in detail in Table 1. The primary outcome was the performance of the investigational device in removing hyperkeratoses on Day 0 before ADL-PDT, measured by the time used for skin preparation and the investigator-assessed removal of the hyperkeratoses.

Secondary outcomes were safety, pain, and comfort experienced by the patient, user comfort, and AK lesion clearance at 4 months. Patients

Table 1
Primary and secondary outcome measures.

PRIMARY OUTCOMES	ASSESSMENT
Device performance (skin preparation on Day 0 before ADL-PDT)	User assessment of removed hyperkeratotic skin visually and by palpation and graded as all lesions removed easily, all lesions removed after thorough work, some lesions remained, or hyperkeratotic skin not removed at all
Device performance (time used for skin preparation)	Device operation times were assessed by mean difference in time per treated skin area to remove hyperkeratotic skin
SECONDARY OUTCOMES	**ASSESSMENT**
Safety (skin damage, skin irritation, and allergic reactions)	Graded by user as none, mild, moderate, or severe
Safety (skin warming)	Graded by patients as none, mild, moderate, or burning sensation
Pain (during skin preparation and during ADL-PDT at 30, 60, 90, and 120 min)	Graded by patients using NRS of 0–10
Patient comfort during skin preparation	Graded by patients as very pleasant, pleasant, neutral, unpleasant, or very unpleasant
Patient-reported vibration during skin preparation	Graded by patients as very pleasant, pleasant, neutral, unpleasant, or very unpleasant
User comfort during skin preparation (ease of use of the oscillating device)	Graded by user as clearly easier than comparator, easier than comparator, no difference, more difficult than comparator, clearly more difficult than comparator
User comfort during skin preparation (vibration of the oscillating device)	Graded by user as no sensation, mild, moderate, or disturbing
AK clearance	Number and Olsen grade (1, 2, or 3) of AKs were defined on Day 0, Day 14, and at 4 months. Clearance was assessed as the number of cleared AKs at 4 months divided by the AK number on Day 0.

rated pain during skin preparation and four times during ADL-PDT treatment and were also asked to assess skin warming and comfort during skin preparation.

The number and Olsen grade (1, 2, or 3) [28] of AKs were defined on Day 0, Day 14, and 4 months.

2.5. Study protocol

The participant flow is described in Fig. 1. On day 0, before skin preparation, the investigator assessed the number and Olsen classification of the lesions. Photographs of the AKs were taken before and after skin preparation, treatment areas were drawn on a transparent template, and an electronic case report form (eCRF) was filled.

After skin preparation, the removal of hyperkeratotic skin was visually assessed and by palpation by the investigator. Thereafter, treatment continued according to normal clinical routines, including application of 16 % (160mg/g) MAL cream (Metvix®, Galderma Nordic), and after 30 min of MAL application the patients were exposed to two hours of illumination in a daylight room (Indoor Lux©, Gerdes Medical AG).

At the first follow-up visit (Day 14), patients obtained a second session of ADL-PDT. If AK lesions from Day 0 remained, the same Day 0 skin preparation method was applied before ADL-PDT. Before skin preparation and the second ADL-PDT session, the investigator assessed possible redness, irritation, and allergic reactions, as well as taking photographs of the skin.

At four months, during the last follow-up visit, the previously drawn transparent templates were used for guidance to document the AK clearance, and electronic case report forms were filled. Photographs were taken of the treated skin areas.

2.6. Sample size calculation

The primary outcome was the assessment of hyperkeratotic skin removal on day 0. It was estimated to observe improvement in removal grade for at least 25 % of the patients against the comparators. Using power analysis, with a power of 80 % and a significance level of 5 %, 20 patients were required for the study set-up using a standard deviation of 20 %.

2.7. Statistical analysis

Categorical outcome variables were analysed using Fisher's exact test. The analysis was applied to removal grade, irritation, skin damage, and skin warming. All analyses were performed in overall and pair-wise comparisons of the oscillating device to curettage and the oscillating device to sandpaper. P-values <0.05 were considered statistically significant. All analyses were performed using R version 4.4.0 (R Core Team 2024, R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Patients

Twenty-two patients were enrolled, with a mean age of 79.2 years. Baseline demographic and clinical characteristics are presented in Table 2. Most of the patients were men ($n = 16$). Fourteen patients had previously been treated for AK, and many of these patients ($n = 12$) had received ADL-PDT treatment before, whereas a few had experienced conventional red light PDT treatment ($n = 4$), and one patient had been treated with Cryotherapy ($n = 1$). Time elapsed since previous ADL-PDT treatment for the twelve patients were in months (M) as follows: 6M-12 M ($n = 4$); 15 M ($n = 2$); 25M-26 M ($n = 2$); 36M-40 M ($n = 2$); 46M-51 M ($n = 2$). AK lesions were located on the face ($n = 13$), scalp ($n = 5$), lower extremity ($n = 1$), upper extremity ($n = 2$), or upper body ($n = 1$). Table 2 shows the details regarding area of skin preparation and the mean number of AK lesions per patient for each Olsen grade. Treatment field area (cm^2), mean ± SD, for each skin preparation device was 28.4 ± 10.1 for the oscillating device, 32.5 ± 10.6 for curettage, and 25.8 ± 9.9 for sandpaper. In total, 260 AK lesions were included in this study, representing the three Olsen grades as follows: Olsen grade 1 (41.5 %), Olsen grade 2 (44.6 %), and Olsen grade 3 (13.9 %).

3.2. Device performance

As assessed by the investigator, all hyperkeratotic lesions were easily removed with the oscillating device on 95.5 % of the patients ($n = 21$). Comparatively, lesions were easily removed with curettage on 81.8 % of the patients ($n = 9$) ($P = 0.10$), and with sandpaper on 54.5 % of the patients ($n = 6$) ($P = 0.0096$). The removal of lesions required more thorough work on two patients (18.2 %) in the curettage group and on three patients (27.3 %) in the sandpaper group. Some lesions remained in the area prepared with the oscillating device on one patient (4.5 %) and in the area prepared with sandpaper on two patients (18.2 %).

The duration of skin preparation is shown in Fig. 2. Skin preparation times ranged from 18 s to 113 s, depending on the treatment size and the skin preparation device used. The calculated skin preparation times for each device (seconds), mean ± SD, were for the oscillating device 35.5 ± 9.4; for curettage 62.9 ± 21.4; and for sandpaper 57.8 ± 26.2. The preparation of the hyperkeratotic skin was, on average, faster with the oscillating device (15.2 s/10 cm^2) than with the comparators (curettage 22.3 s/10 cm^2, sandpaper 26.6 s/10 cm^2). The difference in skin preparation time between the oscillating device and sandpaper was statistically significant ($P = 0.0136$). The corresponding value for oscillating device versus curettage was not statistically significant ($P = 0.1573$).

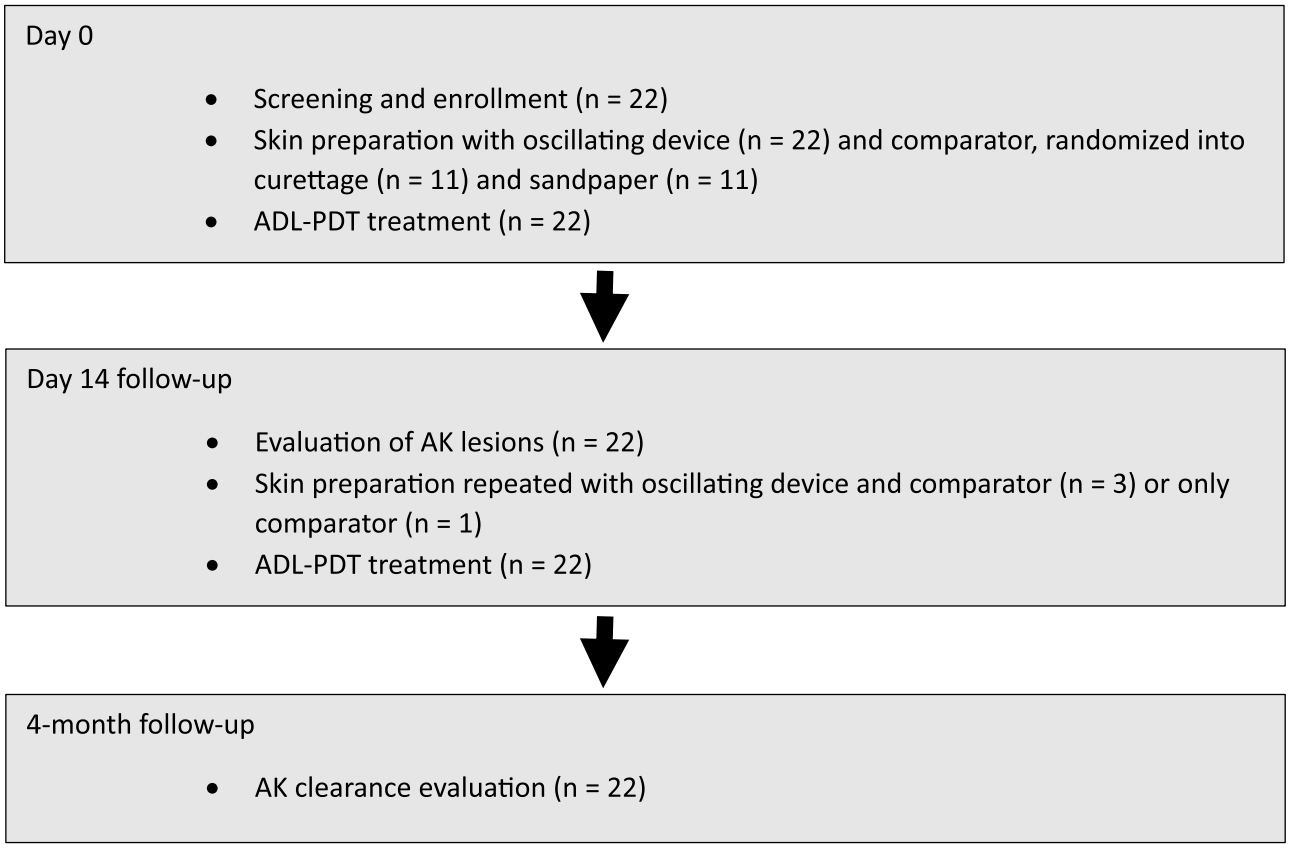

Fig. 1. Participant flow.

3.3. Device safety

Skin warming was reported by 45.5 % of the patients ($n = 10$) in the oscillating device prepared skin area, 9.1 % of the patients ($n = 1$) in the curettage-prepared area (compared to the oscillating device, $P = 0.054$), and 36.4 % of the patients ($n = 4$) in the sandpaper-prepared area (compared to the oscillating device, $P = 0.72$). Patients experienced only mild warming, i.e., no burning sensation was reported. Irritation was observed in 9.1 % of patients ($n = 2$) in oscillating device-prepared skin areas, 45.5 % of patients ($n = 5$) in curettage-prepared skin areas (compared to the oscillating device, $P = 0.027$), and 18.2 % of patients ($n = 2$) in sandpaper-prepared skin areas (compared to the oscillating device, $P = 0.59$). Skin damage was reported in 4.5 % of patients ($n = 1$) in oscillating device-prepared skin areas, 72.7 % of patients ($n = 8$) in curettage-prepared skin areas (compared to the oscillating device, $P < 0.0001$), and 18.2 % of patients ($n = 2$) in sandpaper-prepared skin areas (compared to the oscillating device, $P = 0.25$). All observed skin damage and irritation were reported as mild, for example, minor bleeding and skin redness. Allergic reactions were not detected. Figs. 3 and 4 show photographs of two patients before and after skin preparation on Day 0. What was considered mild irritation and mild skin damage after skin preparation on Day 0 is presented in the photographs in Fig. 3b (patient of curettage-group) and Fig. 4e (patient of sandpaper-group).

Fig. 5 presents adverse effects assessed by the investigator and the patients. Data on skin warming, irritation and skin damage are summarized in Fig. 5a, and pain scores during skin preparation assessed by the patients are found in Fig. 5b No pain was reported during skin preparation by 50.0 % of patients prepared with the oscillating device ($n = 11$), 18.2 % of patients prepared with curettage ($n = 2$), and 36.4 % of patients prepared with sandpaper ($n = 4$). During skin preparation, the mean pain score for each skin preparation method was <2 (oscillating device 1.1, curettage 1.8, sandpaper 1.7). During PDT, the mean pain score for the skin area treated with the oscillating device was 0.6, for curettage 0.4, and for sandpaper 1.0. Pain scores assessed by patients during ADL-PDT treatment can be found in the supplementary materials.

No other adverse events were reported, and no serious adverse events, serious adverse device effects, or device deficiencies occurred.

3.4. Assessment of comfort

In most cases (67.3 %, $n = 15$), the investigator felt no vibration using the oscillating device. A mild vibration was reported in six ($n = 6$) skin preparation sessions and moderate vibration in only one case ($n = 1$). Vibration was not considered disturbing during any of the treatment sessions. The investigator evaluated the use of the oscillating device as easier ($n = 9$) or clearly easier ($n = 13$) than the comparators. The investigator described the oscillating device as more efficient, lighter, and faster, and reported that the abrasive pad of the oscillating device was not immediately filled with dead skin, as with the sandpaper used as a comparator. Importantly, the investigator did not assess the oscillating device as harmful to any of the patients.

Patients assessed comfort for oscillating device and the randomized comparator. Most patients ($n = 14$) rated skin preparation as neutral for both the oscillating device and the randomized comparator device (curettage group $n = 6$ and sandpaper group $n = 8$). Three patients ($n = 3$) rated skin preparation as pleasant when the oscillating device was used and two patients ($n = 2$) when sandpaper was used. One patient ($n = 1$) found skin preparation very pleasant with oscillating device as well as curettage. Many patients ($n = 16$) also rated the vibration of the oscillating device as neutral, and four patients ($n = 4$) found the vibration pleasant. Two patients ($n = 2$) with the treatment area either around the eyes or on the scalp rated the vibration as unpleasant. None of the patients found the vibration very unpleasant.

A deviation from the randomization protocol regarding the first

Table 2
Baseline demographic and clinical characteristics.

	Total $n = 22$	Oscillating device $n = 22$	Curettage $n = 11$	Sandpaper $n = 11$
Age in years, mean ± SD (range)	79.2 ± 7.1 (57–86)			
Gender, n (%)				
Female	6 (27.3)			
Male	16 (72.7)			
Fitzpatrick skin type, n (%)				
Type II	8 (36.4)			
Type III	14 (63.6)			
Previous AK treatment received, n (%)				
Yes	14 (63.6)			
ADL-PDT	12 (54.5)			
Conventional PDT	4 (18.2)			
Cryotherapy	1 (4.5)			
Location of AK lesions, n (%)				
Face	13 (59.1)			
Scalp	5 (22.7)			
Lower extremity	1 (4.5)			
Upper extremity	2 (9.1)			
Upper body (front)	1 (4.5)			
Total of all AK lesions, n (%)	260	132	64	64
Olsen grade 1	108 (41.5)	50	29	29
Olsen grade 2	116 (44.6)	60	26	30
Olsen grade 3	35 (13.9)	22	9	5
AK lesions per patient, mean ± SD				
Number of all AK lesions	11.8 ± 3.1	6.0 ± 1.9	5.8 ± 1.1	5.8 ± 1.7
Olsen grade 1	4.9 ± 2.4	2.3 ± 1.5	2.6 ± 1.0	2.6 ± 1.4
Olsen grade 2	5.3 ± 1.5	2.7 ± 0.7	2.4 ± 1.0	2.7 ± 1.0
Olsen grade 3	1.6 ± 1.8	1.0 ± 1.2	0.8 ± 0.7	0.5 ± 0.8
Treatment field area (cm^2), mean ± SD		28.4 ± 10.1	32.5 ± 10.6	25.8 ± 9.9

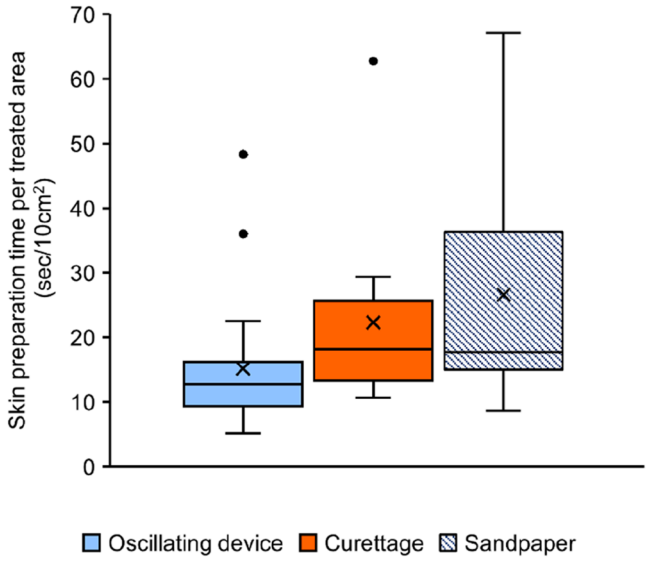

Fig. 2. Boxplots of preparation times of hyperkeratotic skin per treated area for oscillating device ($n = 22$), curettage ($n = 11$), and sandpaper ($n = 11$).

treatment method was observed during the study, resulting in fewer cases of starting with sandpaper. Corrections were made, however, this may have slightly affected patient-reported pain in patients treated with sandpaper. The deviation did not affect the performance assessment.

3.5. Follow-up

On Day 14, none of the patients showed irritation in the skin area prepared with the oscillating device. The investigator reported mild irritation (slight redness) in one patient (4.5 %) in the sandpaper-prepared skin area. The same patient showed mild irritation and skin damage after skin preparation with sandpaper at Day 0 (Fig. 4e). Skin preparation was repeated for three patients on both the sandpaper-prepared skin area as well as on the oscillating-prepared skin area. For one patient, skin preparation was repeated only with curettage. Mild irritation and skin damage were observed by the investigator on one patient in the sandpaper-prepared area. Two patients experienced mild skin warming with the oscillating device and sandpaper. Total amount of AK lesions on Day 14 was $n = 56$, with Olsen grade 1 lesions ($n = 46$) and Olsen grade 2 lesions ($n = 10$). AK lesion clearance on Day 14 was 78.0 % in the areas prepared with the oscillating device, and 78.9 % in the areas prepared with the comparators.

At the 4-month follow-up visit, all areas prepared using any method showed 100 % of AK clearance ($n = 22$). In other words, the actinic keratoses included in this study were cured at 4-month follow-up visit. In Figs. 3 and 4, photographs from the 4-month follow-up visit of two patients are presented for comparison to Day 0. Both the investigator and patients visually evaluated the aesthetic outcome of the treatment areas. No difference in the aesthetic outcome was noticed between the used skin preparation methods in any of the patients. Mild erythema of treated skin area was still visible for two patients at 4-months follow-up. One patient that had obtained Cryotherapy treatment for AKs nine years earlier had obtained new AKs during the 4-month follow-up period on skin areas not included in the study.

4. Discussion

This study demonstrated that hyperkeratotic parts of AK lesions were as easily and safely removed using the novel oscillating skin preparation device as using the currently widely used methods, such as curettage and sandpaper. Skin preparation using the oscillating device was faster than sandpaper, and gentler than curettage. The larger the area to be treated, the more pronounced the differences in treatment duration in the oscillating device's favour. The oscillating device could therefore save time, especially in the treatment of larger skin areas.

According to Heusinkveld et al., [15] the advantages of using sandpaper compared to other physical skin preparation methods include comfort to the patient, ease of use, low cost, and efficiency of topical cream uptake. In a study by Bay et al., [19] removal of hyperkeratoses and the stratum corneum barrier before conventional PDT showed to increase the uptake of the light sensitizer with AFXL pretreatment as the superior skin preparation method, followed by microdermabrasion, microneedling, and curettage. Microdermabrasion was performed using the same sandpaper as in our study. The performance and time-saving aspects of the oscillating device are of value in clinics where expensive skin preparation equipment, such as lasers, is not an option.

Dermal curettes are used for their extremely sharp ring blades, enabling the precise removal of tissues with minimal damage to surrounding skin. During the curettage of a larger skin area, such as the preparation of field cancerized skin before daylight PDT, there is always a risk that the sharp blade will go through the epidermis and cause pinpoint bleeding [29]. This bleeding needs to be stopped before applying the photosensitizing topical cream and will prolong the already time-consuming PDT treatment. Although mild irritation and skin damage were observed using the oscillating device, it did not cause more irritation and damage compared to sandpaper and caused less irritation and damage than curettage. No bleeding or damage to deeper skin layers was observed using the oscillating device.

A clear advantage of the oscillating device is the easy and gentle preparation of large skin areas and the need for only one skin preparation method. Fargnoli et al., [30] suggests using curettage to remove

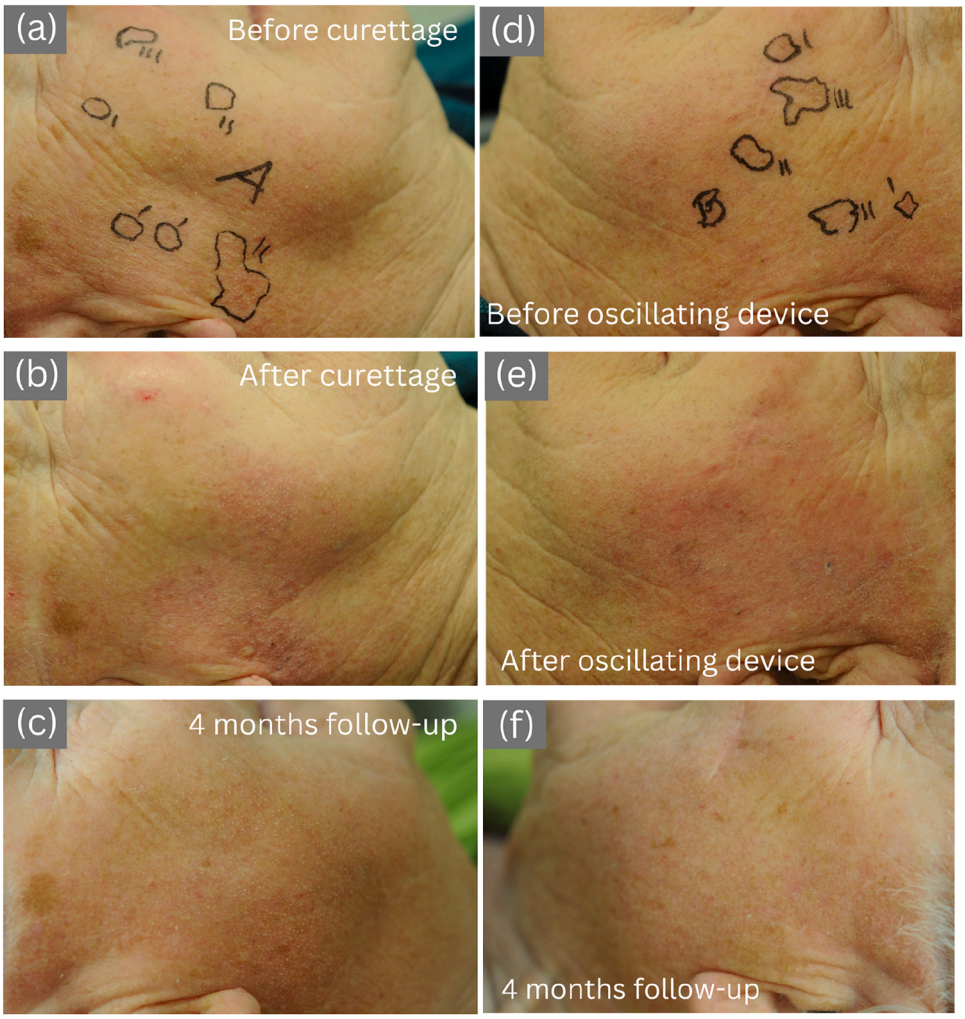

Fig. 3. Photo documentation of patient in the curettage-group: skin area A (curettage) and skin area B (oscillating device) before skin preparation (3a and 3d), and after skin preparation (3b and 3e) on day 0, and at 4-months follow-up visit (3c and 3f).

individual lesions and then continuing with common field skin preparation methods, such as a skin abrasive pad or keratolytics. Skin warming due to the friction of the oscillating movement of the investigational device was believed to be potentially uncomfortable for the patients. However, based on the answers from the 22 patients in our study, we can conclude that this was not the case. The duration of skin preparation with the oscillating device was faster than with sandpaper. Although skin warming was reported more often using the oscillating device, none of the patients who experienced skin warming rated it as unpleasant, and no skin damage due to skin warming was observed. A correlation of skin warming on irritation and skin damage was not found for the oscillating device, irritation together with skin warming was reported in only one patient. In most cases, the patients considered skin preparation with all methods used as neutral.

Although skin preparation was not completely painless, the oscillating device did not cause more pain or discomfort than the comparative methods. The mean pain scores reported were similar to, or even lower than those reported in other studies evaluating skin preparation methods such as curettage [29], microdermabrasion, and ablative fractional laser [19,20]. The oscillating movement seemed to be gentle to the skin even on elderly patients. Microdermabrasion has been reported to improve the absorption of drugs applied to the skin [15,17,19]. Our study showed that the investigational device with its oscillating movement and a soft-cushioned abrasive pad can be a fast and efficient method for removing hyperkeratotic skin.

This study had some limitations. As there was only one user, having more users for the oscillating device could have produced user data with different experiences. Sample sizes for the comparators were small, and in most cases, the treatment area was on the head. However, the results of this study showed a 100 % AK clearance comparable to other studies [13,31–35]. where the face and scalp were treated with one or two sessions of ADL-PDT. One must consider that the time between two sessions of PDT treatment, the skin preparation methods, the photosensitizers, the light sources, the illumination times, and included AK grades in the below-referred studies vary. Kellner et al. [31] reported AK clearance rates of 93 % at a three-month follow-up visit for the PDT group exposed to simulated daylight (SDL) in a randomized two-session split-face clinical trial of conventional PDT versus SDL-PDT, including AK Olsen grades 1 and 2. A two-session PDT treatment protocol was conducted one week apart, and the hyperkeratoses were removed by slight curettage. The simulated daylight source in that study was the same as in our study, a so-called daylight room, but BF-200 aminolaevulinic acid gel (Ameluz®, Biofrontera) was used as a photosensitizing agent. Drumm et al. [32] reported AK clearance rates (mean ± SD) of 66.4 ± 21.4 % (natural DL-PDT) and 61.6 ± 24.3 % (simulated DL-PDT), using two sessions of PDT one week apart with MAL cream, but did not mention if crusts and scales had been removed. Noteworthy is that the number of AK lesions (mean ± SD) in the study of Drumm et al. was considerably higher (45.0 ± 18.1) compared to our study (11.8 ± 3.1). Creusot and Mordon [33] reported a reduction of 238 AK Olsen

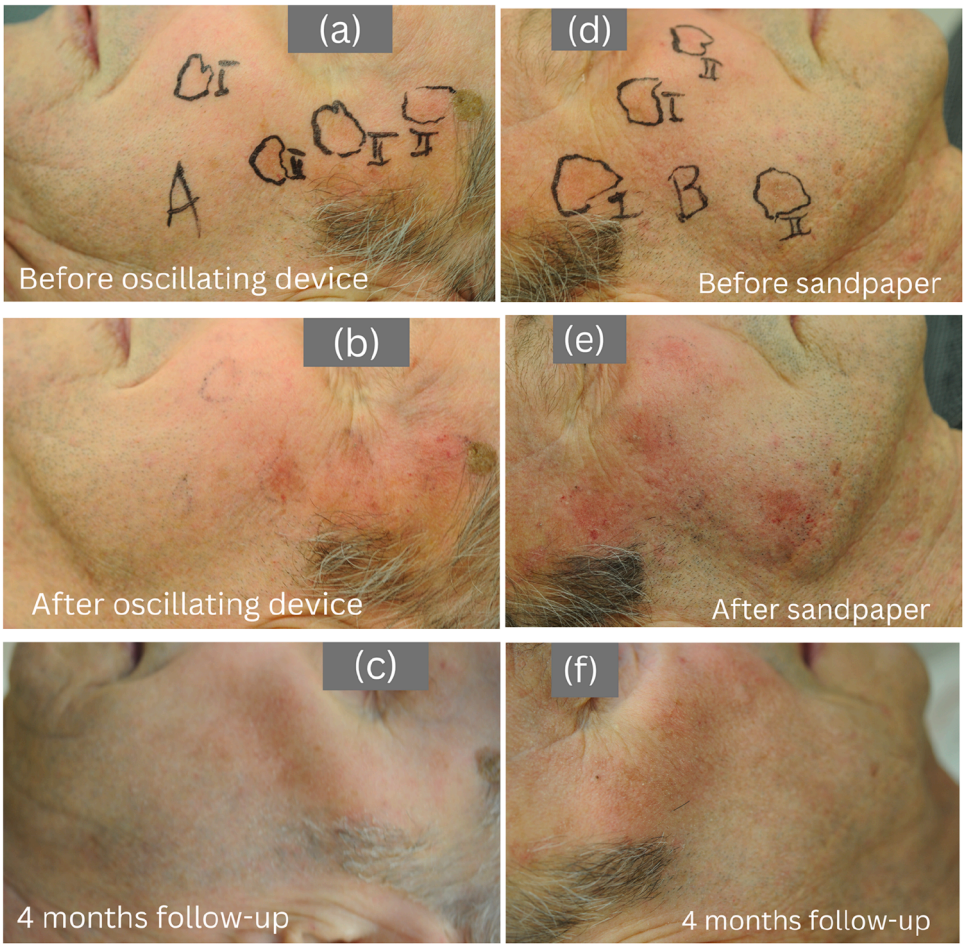

Fig. 4. Photo documentation of patient in the sandpaper-group: skin area A (oscillating device) and skin area B (sandpaper) before skin preparation (4a and 4d), and after skin preparation (4b and 4e) on day 0, and at 4-months follow-up visit (4c and 4f).

grade 1 and 2 from a total AK number of 293 at baseline, at three months after a single session of SDL-PDT, corresponding to an AK clearance rate of 81.2 %. Patients with remaining AK lesions at three months underwent a second SDL-PDT session, and the cure rate of AK lesions was 93 % at the six-month follow-up for all patients in the study. In the study of Arisi et al. [13] crusts and scales were removed using a mildly abrasive pad before application of MAL cream in conventional PDT versus indoor DL-PDT. The second PDT session was conducted at the three-month follow-up visit only for patients with an incomplete response. The number of AKs and area of AK lesions were well documented with a 2D and 3D camera, and there was a significant reduction at the three-month follow-up with no difference between conventional PDT and indoor DL-PDT. Reduction of AK lesions and AK area were presented as box plot graphs, but with numbers missing. Therefore, a direct comparison to the above-referred studies is not possible. Antonetti et al. [34] did not report any data on skin preparation. However, one session of indoor DL-PDT resulted in equivalent efficacy of 1 hour versus 2 h of illumination on clearance rates at the three-month (72.9 % vs 71.1 %) and six-month (76.2 % vs 78.9 %) follow-up. In the paper of Fredman et al. [35], superficial curettage was used for skin preparation and the median complete lesion response at Day 30 after a single MAL ADL-PDT treatment of the face or decolletage was 92 %. Data on AK lesions at a later follow-up visit were not available in that publication.

Future studies should investigate the use of the oscillating device on larger skin areas in larger sample sizes and include more than one clinician. Due to the financial challenges that healthcare is currently facing, future studies should also examine the time-saving properties of the oscillating device and its potential reduction in treatment duration per patient. While some skin preparation methods require a physician, the oscillating device can also be operated by nurses. Future studies should therefore also clarify the potential benefits of the oscillating device as a less user-dependent treatment for removing hyperkeratotic skin.

This study demonstrated that the cordless soft-cushioned oscillating abrasive skin preparation device operates as intended in removing hyperkeratotic skin as pre-treatment for PDT in AK, is safe for the patient, and prepares the skin as effectively as curettage and in less time than microdermabrasion with manual sandpaper. The oscillating skin preparation device also caused less irritation and skin damage compared to curettage, was easier to operate for the user than the comparators and did not get clogged during use as was the case with the manual sandpaper.

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CRediT authorship contribution statement

Johanna H. Hagman: Writing – review & editing, Resources, Methodology, Investigation, Data curation, Conceptualization. **Teresa Czuryszkiewicz:** Writing – review & editing, Visualization, Project administration, Methodology, Formal analysis, Data curation, Conceptualization.

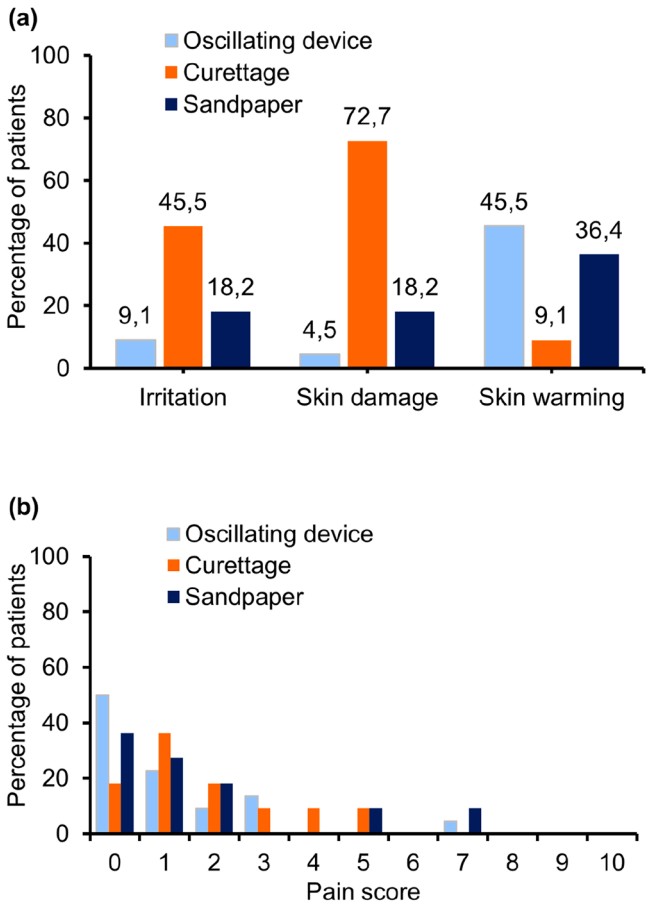

Fig. 5. (a) The percentage of patients who experienced irritation, skin damage, or skin warming during skin preparation (oscillating device $n = 22$, curettage $n = 11$, sandpaper $n = 11$). The irritation and skin damage were assessed by the physician, and the patients were asked to rate the sensation of skin warming. All adverse effects were assessed as mild. (b) Bars show the percentage of patients who rated the pain with a given pain score during skin preparation (oscillating device $n = 22$, curettage $n = 11$, sandpaper $n = 11$). The mean pain score for the oscillating device was 1.1, for curettage 1.8, and for sandpaper 1.7.

Declaration of competing interest

Johanna H. Hagman has no conflict of interest to declare.
Teresa Czuryszkiewicz is an employee at Mirka Ltd.

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Supplementary materials

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