

## **Treatment of telangiectasia on the cheeks with a compact yellow (585 nm) semiconductor laser and a green (532 nm) KTP laser: a randomized double-blinded split-face trial**

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## ABSTRACT

**Objectives:** The primary objective of this study was to compare a traditional green KTP laser to a new investigational yellow laser (PhotoLase) in the treatment of facial telangiectasia in terms of the treatment outcomes. The secondary objective was to assess the functionality and reliability of the PhotoLase system from the perspective of the user.

**Study Design/Methods:** The study was a randomized split-face double-blinded study that compared the treatment efficacy of the 532-nm KTP laser and the investigational 585-nm PhotoLase laser. One or two treatments were given based on the response of the first treatment. The improvement of telangiectasia was graded according to a 7-point Telangiectasia Grading Scale (TGS) by the subjects and blinded physicians. The subjects assessed the amount of pain during the treatments using Visual Analogue Scale (VAS), and evaluated adverse effects 2–3 days after the treatment(s) using a self-assessment form.

**Results:** At least 50% improvement was seen in 15/18 subjects after the first PhotoLase treatment, and a similar result was observed for KTP, as assessed by the blinded physicians ( $p=0.29$ ). In the subjects' assessment, 7/18 subjects had at least 50% improvement after the first PhotoLase treatment, whereas at least 50% improvement was observed for 10/18 subjects in the KTP side, the difference being significant ( $p=0.008$ ). The amount of pain was higher with PhotoLase compared to KTP (67.7 vs. 34.6,  $p<0.001$ ). There was no difference in the frequency of erythema, crusting or purpura between the devices, but more blistering and less edema were seen after PhotoLase treatment ( $p<0.05$ ). Treatment with PhotoLase was evaluated to be 4.7-fold faster than with KTP and the PhotoLase system was more compact, narrower, lighter and easier to carry than KTP.

**Conclusions:** The investigational PhotoLase laser enables significantly faster treatments, but the process is somewhat more painful than with KTP, otherwise providing a similar clinical outcome in the treatment of facial telangiectasia.

**Keywords:** Telangiectasia; KTP laser; green laser; yellow laser; semiconductor disk laser technology; comparative study

## INTRODUCTION

Millions of people worldwide are affected by facial telangiectases, small dilated blood vessels with diameters between 0.1 to 1.0 mm. Predisposing conditions include rosacea, photodamage, topical steroid use and genetic factors. Discomfort and psychological distress drive patients to seek help, and telangiectasia treatments are among the most common dermatological laser procedures.<sup>1,2</sup> Treatment of superficial vascular lesions is based on selective photothermolysis, where the target chromophore is the intravascular oxyhaemoglobin in red blood cells. Absorption of laser light heats the chromophore leading to vessel wall damage. Several lasers are used for vascular indications, but the standard lasers are yellow pulsed dye laser (585- or 595-nm) and green potassium-titanyl-phosphate (KTP) laser (532-nm), because their wavelengths are close to the  $\alpha$  and  $\beta$  absorption peaks (542 and 577 nm) of oxyhaemoglobin.<sup>3</sup>

The original PDL (577-nm) had a short pulse duration of 0.3 ms, causing frequently post-operative purpura. Modern PDLs, such as Cynergy™ (Cynosure) and VBeam® (Syneron Candela) operate at wavelengths of 585 and 595 nm, respectively, and have micropulse mode and adjustable pulse durations up to 40 ms for less purpura.<sup>2</sup> Spot sizes in Cynergy™ and VBeam® range from 3 to 12 mm. Currently available KTP devices have adjustable pulse durations from 0.05 to 2000 ms and spot sizes from 0.2 to 12 mm. One KTP system, Aura XP (Laserscope), can be equipped with a SmartScan scanner (Laserscope).

The safety and efficacy of PDL and KTP have been demonstrated in numerous studies, and both are suggested as first line treatments for facial telangiectases by the European Society for Laser Dermatology. At least 50–90% improvement can be expected after 1–3 treatments.<sup>3</sup> For facial capillary malformations, PDL is still the gold standard therapy<sup>4</sup>, but modern large spot size KTPs seem also effective and can be considered first line regimen.<sup>5,6</sup>

The advantage of the yellow PDL compared to the green KTP is the longer emission wavelength, enabling deeper penetration and treatment of larger vessels. In addition, oxyhaemoglobin has higher absorption for yellow than for green wavelengths. Yellow wavelengths also have lower melanin absorption, allowing treatment of darker skin phototypes with lower risk of epidermal damage.<sup>2</sup>

However, the yellow PDL has some intrinsic disadvantages such as large size and high annual maintenance costs. To address the needs of the dermatologic community a novel laser technology, namely optically pumped semiconductor disk laser (SDL), has emerged to provide a compact and cost-effective alternative for a yellow laser source. SDLs, also known as VECSELs (vertical external-cavity surface-emitting lasers), are recognized for their power scaling abilities, transverse mode control and the ability to tailor the emission wavelength according to specific application needs.<sup>7,8</sup> With the addition of wavelength selective components and suitable laser cavity configurations, SDLs can also be designed to emit narrow linewidth<sup>9</sup> and have a wavelength tuning range up to tens of nanometers.<sup>10</sup> Light pulses down to a few hundred nanometers can be easily achieved by directly modulating the pump laser of an SDL.<sup>11</sup> Another pulsing method, possibly more attractive for medical applications, is to use a continuous wave SDL as a source and guide it through a handheld scanning device capable

of producing different pulse lengths and treatment patterns by moving the laser beam to a different spot. In this case the pulse duration is limited by the mechanical capability rather than by the intrinsic modulation features of the semiconductor, which are much faster.

The primary objective of this pilot study was to compare the efficacy of a yellow laser system based on SDL technology to the traditional green KTP laser in the treatment of facial telangiectasia. This included comparing the treatment outcome and the adverse effects caused by the treatment. The secondary objective was to assess the functionality of the new yellow laser from the point of view of the treating investigators.

## **MATERIALS AND METHODS**

### **Study Design**

The study was a split-face comparative double-blinded study without a separate control group. It was designed to enable a comparison between a traditional green laser and an investigational yellow laser. The split-face design eliminated individual biases and the randomization eliminated possible small variations in the symmetry of the telangiectases on the face. The double-blinded assessment eliminated subjective and objective biases of the investigators and the subjects. The protocol was approved by the Ethics Committee of Tampere University Hospital (Reg. No. R17111). The protocol followed the principles of the Declaration of Helsinki and its amendments.

### **Devices**

The study employed two different laser systems: the traditional green KTP laser (Aura XP, Laserscope) and the investigational yellow laser called PhotoLase. The KTP laser emits 532-nm radiation up to 15 W, and was equipped with a Laserscope SmartScan scanner, which delivered 127 spots with a diameter of 1.0 mm, forming a hexagon pattern and covering an area of ~1.1 cm<sup>2</sup> in 17.5 seconds.

The PhotoLase laser (Fig. 1a) was developed at the Optoelectronics Research Centre (ORC), Tampere University of Technology in collaboration with the French National Institute of Health and Medical Research (INSERM). It emits 585-nm yellow radiation up to 8 W in continuous wave operation, delivered via a multimode optical fiber with a diameter of 200 μm. The device was equipped with a MedArt scanner (Fig. 1b) capable of delivering the laser light in different patterns (single spot, line, square, and hexagon). One scan covered an area of ~1.0 cm<sup>2</sup> in less than a second and included 37 spots with a diameter of 1.4 mm. The pulse duration was adjustable in the range 10–100 ms. Only the hexagon shape (Fig. 1c) was used to enable a more accurate comparison of the two laser systems. The pulse duration was fixed to 25 ms based on pre-clinical tests indicating good clinical end-point. A detailed description of the system can be found in Kantola et al. 2019 (in press).

The study also employed a Canfield Visia Imaging System to assess the effectiveness of the laser treatments. The imaging system produces high quality multi-spectral images with standardized lighting and facial positioning.

### **Subject inclusion and exclusion criteria**

Finnish speaking volunteering adults with symmetrical facial telangiectasia, and a Fitzpatrick's skin phototype I–IV, were included in the study. Exclusion criteria were unbalanced chronic disease, pregnancy, lactation, haemophilic condition, being under guardianship, alcohol or drug abuse and significant tanning less than 6 weeks prior to the study. All volunteers gave their informed consent.

### **Treatment Protocol**

The subjects were randomized to receive KTP treatment on one side of the face and PhotoLase on the contralateral side. The randomization was performed in blocks of two using a web-based validated program (Research Randomizer). The investigators T.K. and A.K. randomized and enrolled all the participants. One to two treatments were performed at 1- to 2-month intervals depending on the recommendation of the investigators and preferences of the subjects. Prior to the first treatment, the investigators assessed each subject and categorized the severity of their telangiectasia into mild, moderate or severe (Fig. 2).

Treatment parameters were selected to achieve the same clinical end-point of vessel disappearance or clot formation within the vessel. Double passes were used when needed. KTP settings were 20–30 J/cm<sup>2</sup> at 10-ms pulse duration and the PhotoLase settings were 5.6–8.1 J/cm<sup>2</sup> at 25-ms pulse duration. No topical anesthesia or cooling was used.

### **Efficacy Assessments**

The primary endpoint of this study was the 7-point Telangiectasia Grading Scale<sup>13</sup>, which was assessed by the subjects and the blinded investigators (T.K. and A.K.). The TGS is scored: -1 = condition worsened; 0 = no change; 1 = some improvement (<25%); 2 = intermediate improvement (25–50%), 3 = significant improvement (50–75%); 4 = very significant improvement (>75%); 5 = complete resolution of telangiectasia. The investigators assessed the TGS using the Visia images taken prior and 1–2 months after the treatment(s). The assessment was

performed as a consensus assessment by the investigators T.K. and A.K. Even though T.K. and A.K. also performed the treatments, the efficacy assessments can be regarded blinded, since the Visia images did not show information about which device was used in either side of the face. In addition, the subjects gave their own best assessment of the clinical outcome using a mirror.

### **Safety Assessments**

Assessment of adverse effects was conducted 48–72 hours after the treatment(s) through a self-assessment form given to the subjects. Visual Analogue Scale (VAS, 0–100) was used for pain and a 4-point scale (0=absent, 1=mild, 2=moderate, 3=severe) for erythema, edema, crusting, purpura and blisters.

### **Sample Size Calculation**

The sample size calculation assumes, that a clinically important difference, as measured by a 7-point Telangiectasia Grading Scale (-1–5), is 2. With an alpha error of 0.05, power of 0.80 and a sigma value of 2, we arrived at a sample size of 16 with a sample size calculator comparing two independent samples<sup>13</sup>. Assuming that there will be a few dropouts during the study, a sample size of 20–30 subjects is warranted.

### **Statistical Analysis**

Statistical comparisons between the KTP and PhotoLase treatments were made using the McNemar test, Wilcoxon signed ranks test and permutation test with exact p-values. Stata 15.1 (StataCorp LP; College Station, Texas, USA) statistical package was used for the analysis.

## **RESULTS**

### **General**

Twenty-four subjects participated and completed the study. Six subjects were excluded from the analysis, since their telangiectases were not assessable using the Visia images. The mean age of the subjects was 48 years (range 27–63 years), sixteen (89%) females and two (11%) males. Nine subjects received KTP on the left cheek and PhotoLase on the right cheek, and nine subjects vice versa. Five subjects (28%) received a single treatment and thirteen subjects (72%) received two treatments. The Fitzpatrick's skin phototypes were I, II or III in 6/8/4 subjects, respectively. The baseline telangiectasia grades were I, II, or III in 4/9/5 subjects, respectively, and the grades were symmetrical in all of the subjects.

### **Safety**

The amount of pain, as measured using VAS, was higher with PhotoLase when compared to KTP, 67.7 (SD 22.9) vs. 34.6 (SD 16.9), respectively. There was no difference in the frequency of erythema, crusting or purpura between KTP and PhotoLase, as assessed using a 0–3 scale, 2–3 days after the treatments. More blistering and less edema were seen after PhotoLase treatment ( $p < 0.05$ , Table 1). A small superficial atrophic scar was noted in two subjects on the PhotoLase side.

### **Efficacy**

In the blinded investigators' assessment, fifteen subjects (83%) had a TGS value of 3 or larger, indicating at least 50% improvement after the first PhotoLase treatment, and a similar result was observed for KTP ( $p=0.29$ ). In the subjects' assessment, seven subjects (39%) had at least 50% improvement after the first PhotoLase treatment, whereas at least 50% improvement was observed for ten subjects (56%) in the KTP side, the difference being significant ( $p=0.008$ ).

The potential benefit of the optional second treatment was also assessed by the subjects and the blinded investigators. Based on the subjects' assessment, 11/13 benefited from the second KTP treatment, and 10/13 from the second PhotoLase treatment. The difference between the devices was insignificant ( $p=0.54$ ). Based on the blinded investigators' consensus assessment, 9/13 subjects benefited from the second KTP treatment, and 8/13 from the second PhotoLase treatment. The difference between the devices was insignificant ( $p=0.81$ ).

Figs. 3 and 4 show the before and after Visia images of a female subject with moderate telangiectasia. Photographs were taken before and after the treatments. The left side was treated with KTP and the right side with PhotoLase. In this case, the improvement in TGS was 4 on the KTP side and 3 on the PhotoLase side after the first treatment and 4 on both sides after the second treatment.

### **Functionality of the investigational device**

The secondary objective of the study was to assess the functionality of the investigational device. The evaluation was performed by the investigators (T.K. and A.K.) based on their user-experience during the study. The most obvious difference in functionality was observed in the scanning speeds of the scanners, 17.5 seconds per 1.1 cm<sup>2</sup> for the SmartScan scanner (KTP) and less than one second per 1.0 cm<sup>2</sup> for the MedArt scanner

(PhotoLase). Assuming a mean of three seconds between the scans, this yields a 4.7-fold difference in treatment speed favouring PhotoLase. The SmartScan scanner was also larger, bulkier and heavier. The button that was pressed to initiate the scanning was integrated to the SmartScan scanner, but the MedArt scanner was used with a foot pedal. The investigators favored the hand-button for easier administration of the pulses. The investigational device PhotoLase appeared to be more compact, narrower, lighter and easier to carry compared to the KTP laser. Both laser systems were stable during the trial period and no malfunctions were noted.

## DISCUSSION

To our knowledge, this is the first head-to-head study to compare a 585-nm yellow SDL to a traditional 532-nm green KTP laser in the treatment of facial telangiectasia. We were able to recruit the desired number of subjects with full compliance throughout the study period, and both laser systems were shown similarly effective.

Recently Kapicioglu et al. (2018) reported a non-controlled case series using a 577-nm yellow SDL for the treatment of erythematotelangiectatic rosacea, facial erythema and facial telangiectasia. They achieved over 80% cure rate for facial erythema and telangiectasia in 76.6% of subjects after first treatment, whereas we achieved over 50% cure rate in 83.3% of cheeks treated with PhotoLase or KTP. Our parameters for KTP were 20–30 J/cm<sup>2</sup> at 10-ms pulse duration and for PhotoLase 5.6–8.1 J/cm<sup>2</sup> at 25-ms pulse duration. In comparison, Kapiciogly et al. used 16–22 J/cm<sup>2</sup> fluences with the 577-nm laser. There are probably two main reasons for the cure rate difference. Firstly, our trial was conducted in private sector, where typically milder presentations of telangiectasia are treated, compared to hospital conditions. Only 28% of our subjects had severe telangiectasia. Secondly, we chose not to use topical anesthesia or cooling to prevent possible vasoconstriction in the treatment area, which resulted in limitation to use higher PhotoLase fluences due to pain.

Another split-face study by Uebelhoer et al. (2007) compared KTP (Gemini, Laserscope) and 595-nm PDL (VBeam<sup>®</sup>) for facial telangiectases. The PDL settings were a 10-mm spot, a fluence of 7.5 J/cm<sup>2</sup>, a 10-ms pulse duration, optional pulse stacking, and dynamic nitrogen cooling spray. The KTP settings were mostly 10 J/cm<sup>2</sup> at 18 ms and 9 J/cm<sup>2</sup> at 23 ms with 5- and 10-mm spot sizes, respectively, and a sapphire contact cooling. The percentage of improvement was 62% with KTP, and 49% with PDL after the first treatment, being slightly lower than cure rates in our study. Tanghetti et al. (2012) used a 595-nm PDL (V-Star<sup>®</sup>, Cynosure) for facial telangiectases with Zimmer air cooling and could use fluences as high as 8.1–14.5 J/cm<sup>2</sup> with 10- and 40-ms pulse durations. In their study, about 80% of subjects reached a 50% or higher cure rate with 1–2 treatments, a result that we reported after the first treatment with PhotoLase.

Like the yellow SDLs, modern large spot size KTPs can challenge the gold standard role of PDLs, as shown by Uebelhoer et al. More recently, Kwiek et al. (2017, 2018) showed the efficacy of large spot size KTP (ExcelV<sup>®</sup>, Cutera) in patients with facial capillary malformations. The settings were a 5- to 10-mm spot size, a fluence of 8–11.5 J/cm<sup>2</sup> and pulse duration 4 to 9 ms. An integrated sapphire glass contact cooling was used. The median improvement was 70.4% after a mean of 7.1 treatments in previously non-treated patients<sup>5</sup>, and 59.1% after a mean of 6.2 treatments in previously treated patients<sup>6</sup>.

No serious side effects were reported during the present study. More blistering, but less edema was observed for the PhotoLase system compared to KTP. A small superficial atrophic scar resulting from a blister was noted in the PhotoLase side in two subjects, which is an unwanted adverse effect that we want to eliminate in the future. Instead of a fixed pulse duration, we will tailor the pulse duration for the vessel caliber in the future. In addition, epidermal cooling will be included to prevent epidermal damage and to optimize treatment parameters. We are planning to use either an updated scanner with an integrated contact cooling, or air cooling in our future trials.

The 4.7-fold faster treatment time using the MedArt scanner can be considered a major benefit compared to SmartScan scanner. The power reserve of PhotoLase also makes it possible to increase the scanning area of one illumination sequence while still applying sufficient fluence on the treatment area. This would further reduce the time of treatment, especially for larger treatment areas. We acknowledge that the present study would be stronger, if the PhotoLase system was compared to a modern PDL or large spot size KTP. The functionality and speed of modern devices are on a different level than that of Aura XP with SmartScan. Newer KTP devices with large spot size can also treat telangiectases with lower fluencies due to deeper penetration and even distribution of energy, reducing the cooling effect of blood flow.<sup>6</sup> On the other hand, we still consider it fair to compare the clinical outcome of the present devices, since the scanning patterns were similar and the spots sizes were close to each other in terms of diameter.

The strengths of the present study are the randomized split-face design, high-quality Visia images and excellent subject compliance. Some discrepancy can be seen in the subjects' TGS assessment compared to blinded investigators' consensus assessment. We believe that such a difference resulted from the insensitivity of the TGS assessment tool, which has relatively large 25% grading steps. Subjects might easily give different curing scores, if they notice even a slight difference in the erythema between face sides. Experienced clinicians, then again, will not let too small differences distract the overall assessment. Also, the subjects' assessment was based on their

memory, whereas the blinded investigators had high-quality standard and erythema-weighted images to compare the results very systematically.

## CONCLUSION

To conclude, we demonstrated non-inferiority of the novel yellow semiconductor disk laser, PhotoLase, in the treatment of facial telangiectasia compared to the traditional green KTP laser. A major benefit of the PhotoLase is the significant decrease of treatment time, which could be further decreased by enlarging the scanning area for single illumination. The PhotoLase system can also be considered more user-friendly in the present setting. However, larger studies with optimized cooling, laser parameter tailoring, and comparison to modern PDL or KTP devices are warranted in the future.

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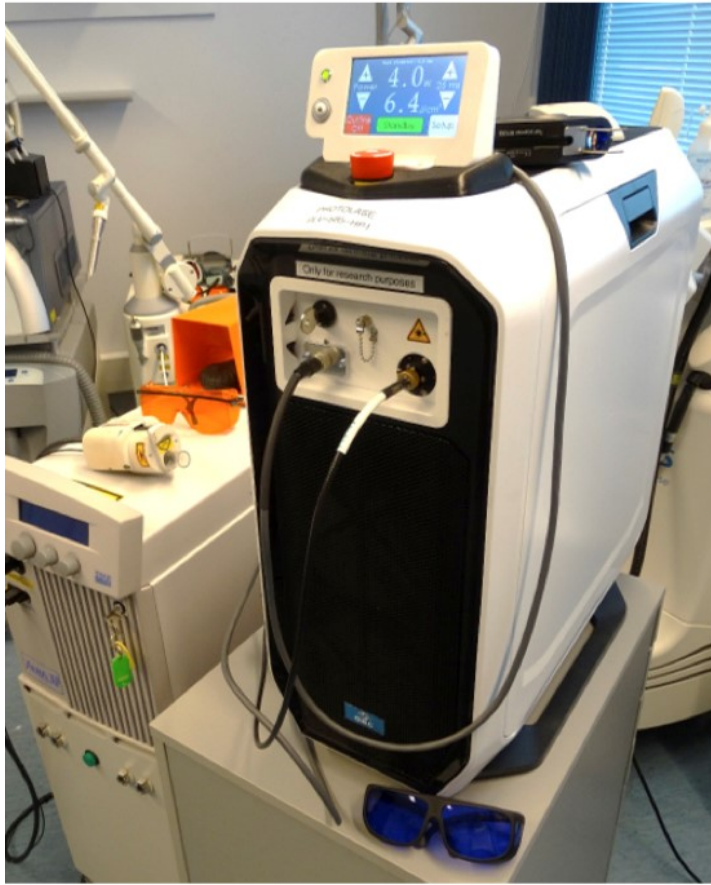
## TABLES AND FIGURES

Table 1. The frequency of treatment reactions of the first treatment with KTP and PhotoLase. The intensity of the reactions was scaled: 0=absent, 1=mild, 2=moderate, 3=severe.

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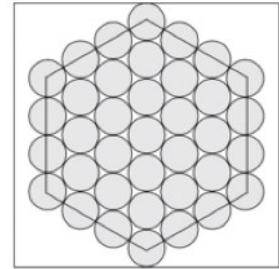
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(a)

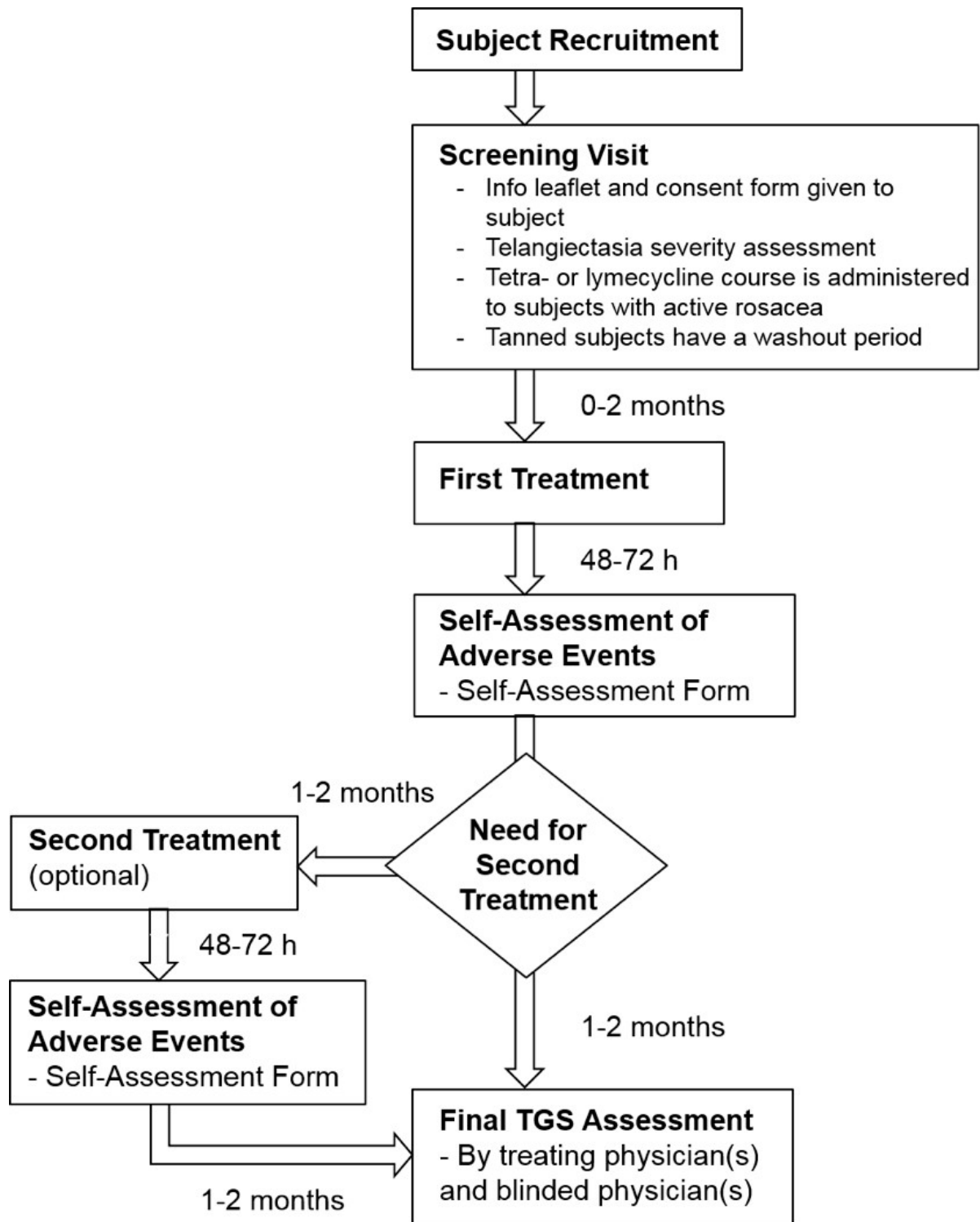


(b)



(c)







Adverse effect	Treatment reactions 2-3 days after KTP treatment (%)	Treatment reactions 2-3 days after PhotoLase treatment (%)	P-value
<b>Erythema</b>			0.87
0	1 (6)	2 (11)	
1	7 (39)	7 (39)	
2	8 (44)	6 (33)	
3	2 (11)	3 (17)	
<b>Crusting</b>			0.55
0	11 (61)	9 (50)	
1	4 (22)	5 (28)	
2	3 (17)	3 (17)	
3	0 (0)	1 (6)	
<b>Edema</b>			0.007
0	2 (11)	3 (17)	
1	1 (6)	7 (39)	
2	5 (28)	6 (33)	
3	10 (56)	2 (11)	
<b>Purpura</b>			0.12
0	11 (61)	14 (78)	
1	3 (17)	3 (17)	
2	1 (6)	1 (6)	
3	1 (6)	0 (0)	
<b>Blistering</b>			0.023
0	15 (83)	10 (56)	
1	3 (17)	3 (17)	
2	0 (0)	3 (17)	
3	0 (0)	2 (11)	

P-values calculated with Wilcoxon signed ranks test.