

Patient-Reported Outcomes with LASIK Symptoms and Satisfaction (PROWL-SS)

PROWL-SS Steward - H. Dunbar Hoskins Jr MD Center for Quality Eye Care, American Academy of Ophthalmology

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Note: The PROWL-SS was administered by web in the original studies.

Qualified Context of Use:

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The paper and electronic versions of the PROWL-SS can be used to assess satisfaction with vision and the existence, bothersomeness and impact on usual activities in the last 7 days of four visual symptoms – double images (8 items), glare (8 items), halos (8 items) and starbursts (8 items). The measure is designed to be used in patients undergoing LASIK surgery who meet the following conditions: 21 and older who speak and read English fluently, have not previously received any form of refractive surgery; are determined to be good candidates for LASIK based on their surgeon's assessment of medical and ophthalmic health, cognitive function, and physical function and social function; are undergoing the surgery for treatment of myopia, hyperopia and/or astigmatism; are undergoing the surgery for treatment of myopia, hyperopia and/or astigmatism; and are targeted to get a refraction of bilateral emmetropia or slight hyperopia (+0.25 Diopters). The four symptom scores may be used at baseline and post-surgery as secondary or additional safety assessment in clinical studies or observational studies to evaluate descriptively the subjects' visual perception. The satisfaction with vision scale may be used at baseline and post-surgery as an additional effectiveness endpoint to evaluate descriptively changes in satisfaction from baseline.

Note: While this questionnaire content covers symptoms and satisfaction, it would be important to measure dry eye symptoms and driving function, given that they have been found to be relevant to patients undergoing LASIK surgery.

This document provides the PROWL-SS questions for information purposes. There are six scores, each on a 0-100 possible range (0 = worse, 100 = best possible) (See PROWL-SS and Scoring Guide)

Satisfaction with Vision:	Question 1
Double-Image:	Questions 2-9
Glare:	Questions 10-17
Halos:	Questions 18-25
Starburst:	Questions 26-33

1. In general, how satisfied or dissatisfied are you with your present vision?

- Completely satisfied
- Very satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Very dissatisfied
- Completely dissatisfied

The next set of questions will reference the following images and their labels.

Double image



Glare



Halo



Starburst



INSTRUCTIONS: The next few questions are about *double images*, which some people call "*ghost*" or "*shadow*" images. By double images, we mean seeing a *distorted or blurry visual image*, such as the images shown below. These images may not represent exactly what you see and your symptoms may be more or less severe than what is shown.

No double image \longrightarrow Severe double image



2. In the last 7 days, have you seen any **double images**?

- Yes, but ONLY when NOT wearing glasses or contact lenses
- Yes, but ONLY when wearing glasses or contact lenses
- Yes, when wearing AND when not wearing glasses or contact lenses
- No, not at all

3. In the last 7 days, how often have you seen **double images** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Never
- Rarely
- Sometimes
- Often
- Always

4. In the last 7 days, how often have you seen **double images** when you are NOT wearing any vision correction (glasses or contact lenses)?

- Never
- Rarely
- Sometimes
- Often
- Always
- I always use glasses or contact lenses

5. In the last 7 days, how bothersome have the **double images** been when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome

6. In the last 7 days, how bothersome have the **double images** been when you are NOT wearing any vision correction (glasses or contact lenses)?

- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome
- I always use glasses or contact lenses

7. In the last 7 days, how much difficulty have you had doing your usual activities because you see **double images** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities

8. In the last 7 days, how much difficulty have you had doing your usual activities because you see **double images** when you are NOT wearing any vision correction (glasses or contact lenses)?

- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities
- I always use glasses or contact lenses

9. When you use your best vision correction (glasses or contact lenses) do the **double images** you see:

- I do not use glasses or contact lenses
- Go away completely
- Go away mostly
- Go away a little
- Not change
- Get a little worse
- Get a lot worse

INSTRUCTIONS: The next few questions are about *glare*. By glare, we mean *difficulty seeing well when there are bright lights like headlights or sunlight, such as shown in the images below. These images may not represent exactly what you see and your symptoms may be more or less severe than what is shown.*

No glare
→
 Severe glare



10. In the last 7 days, have you noticed any **glare**?

- Yes, but ONLY when NOT wearing glasses or contact lenses
- Yes, but ONLY when wearing glasses or contact lenses
- Yes, when wearing AND when not wearing glasses or contact lenses
- No, not at all

11. In the last 7 days, how often have you noticed **glare** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Never
- Rarely
- Sometimes
- Often
- Always

12. In the last 7 days, how often have you noticed **glare** when you are NOT wearing any vision correction (glasses or contact lenses)?

- Never
- Rarely
- Sometimes
- Often
- Always
- I always use glasses or contact lenses

13. In the last 7 days, how bothersome has the **glare** been when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome

14. In the last 7 days, how bothersome has the **glare** been when you are NOT wearing any vision correction (glasses or contact lenses)?

- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome
- I always use glasses or contact lenses

15. In the last 7 days, how much difficulty have you had doing your usual activities because you noticed **glare** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities

16. In the last 7 days, how much difficulty have you had doing your usual activities because you notice **glare** when you are NOT wearing any vision correction (glasses or contact lenses)?

- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities
- I always use glasses or contact lenses

17. When you use your best vision correction (glasses or contact lenses) does the **glare** you notice:

- I do not use glasses or contact lenses
- Go away completely
- Go away mostly
- Go away a little
- Not change
- Get a little worse
- Get a lot worse

INSTRUCTIONS: The next few questions are about *halos*. By halos, we mean *seeing a fuzzy cloud of light around lighted objects*, such as the ones shown in the images below. These images may not represent exactly what you see and your symptoms may be more or less severe than what is shown.

No halos —————> Severe halos



18. In the last 7 days, have you seen any **halos**?

- Yes, but ONLY when NOT wearing glasses or contact lenses
- Yes, but ONLY when wearing glasses or contact lenses
- Yes, when wearing AND when not wearing glasses or contact lenses
- No, not at all

19. In the last 7 days, how often have you seen **halos** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Never
- Rarely
- Sometimes
- Often
- Always

20. In the last 7 days, how often have you seen **halos** when you are NOT wearing any vision correction (glasses or contact lenses)?

- Never
- Rarely
- Sometimes
- Often
- Always
- I always use glasses or contact lenses

21. In the last 7 days, how bothersome have the **halos** been when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome

22. In the last 7 days, how bothersome have the **halos** been when you are NOT wearing any vision correction (glasses or contact lenses)?

- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome
- I always use glasses or contact lenses

23. In the last 7 days, how much difficulty have you had doing your usual activities because you see **halos** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities

24. In the last 7 days, how much difficulty have you had doing your usual activities because you see **halos** when you are NOT wearing any vision correction (glasses or contact lenses)?

- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities
- I always use glasses or contact lenses

25. When you use your best vision correction (glasses or contact lenses) do the **halos** you see:

- I do not use glasses or contact lenses
- Go away completely
- Go away mostly
- Go away a little
- Not change
- Get a little worse
- Get a lot worse

INSTRUCTIONS: The next few questions are about *starbursts*. By *starbursts*, we mean *seeing rays of light coming out from lighted objects*, such as in the car headlights in the images below. These images may not represent exactly what you see and your symptoms may be more or less severe than what is shown.

No starbursts
→
 Severe starbursts



26. In the last 7 days, have you seen any **starbursts**?

- Yes, but ONLY when NOT wearing glasses or contact lenses
- Yes, but ONLY when wearing glasses or contact lenses
- Yes, when wearing AND when not wearing glasses or contact lenses
- No, not at all

27. In the last 7 days, how often have you seen **starbursts** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Never
- Rarely
- Sometimes
- Often
- Always

28. In the last 7 days, how often have you seen **starbursts** when you are NOT wearing any vision correction (glasses or contact lenses)?

- Never
- Rarely
- Sometimes
- Often
- Always
- I always use glasses or contact lenses

29. In the last 7 days, how bothersome have the **starbursts** been when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome

30. In the last 7 days, how bothersome have the **starbursts** been when you are NOT wearing any vision correction (glasses or contact lenses)?

- Extremely bothersome
- Very bothersome
- Somewhat bothersome
- A little bothersome
- Not at all bothersome
- I always use glasses or contact lenses

31. In the last 7 days, how much difficulty have you had doing your usual activities because you see **starbursts** when you are wearing your best vision correction (glasses or contact lenses)?

- I do not use glasses or contact lenses
- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities

32. In the last 7 days, how much difficulty have you had doing your usual activities because you see **starbursts** when you are NOT wearing any vision correction (glasses or contact lenses)?

- No difficulty at all
- Very little difficulty
- Moderate difficulty
- A lot of difficulty
- So much difficulty that I can no longer do some of my usual activities
- I always use glasses or contact lenses

33. When you use your best vision correction (glasses or contact lenses) do the **starbursts** you see:

- I do not use glasses or contact lenses
- Go away completely
- Go away mostly
- Go away a little
- Not change
- Get a little worse
- Get a lot worse