

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:

https://www.fda.gov/media/150166/download?utm_medium=email&utm_source=govdelivery

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 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?

- 1 Completely satisfied
- 2 Very satisfied
- 3 Somewhat satisfied
- 4 Somewhat dissatisfied
- 5 Very dissatisfied
- 6 Completely dissatisfied

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

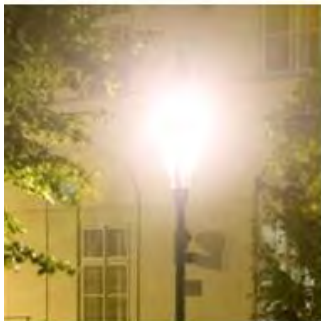
Double image



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**?

- 1 Yes, but ONLY when NOT wearing glasses or contact lenses
- 2 Yes, but ONLY when wearing glasses or contact lenses
- 3 Yes, when wearing AND when not wearing glasses or contact lenses
- 4 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)?

- 6 I do not use glasses or contact lenses
- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 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)?

- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 Always
- 6 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)?

6 I do not use glasses or contact lenses

- 1 Extremely bothersome
- 2 Very bothersome
- 3 Somewhat bothersome
- 4 A little bothersome
- 5 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)?

- 1 Extremely bothersome
- 2 Very bothersome
- 3 Somewhat bothersome
- 4 A little bothersome
- 5 Not at all bothersome
- 6 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)?

- 6 I do not use glasses or contact lenses
- 1 No difficulty at all
 - 2 Very little difficulty
 - 3 Moderate difficulty
 - 4 A lot of difficulty
 - 5 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)?

- 1 No difficulty at all
- 2 Very little difficulty
- 3 Moderate difficulty
- 4 A lot of difficulty
- 5 So much difficulty that I can no longer do some of my usual activities
- 6 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:

- 7 I do not use glasses or contact lenses
- 1 Go away completely
 - 2 Go away mostly
 - 3 Go away a little
 - 4 Not change
 - 5 Get a little worse
 - 6 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**?

- 1 Yes, but ONLY when NOT wearing glasses or contact lenses
- 2 Yes, but ONLY when wearing glasses or contact lenses
- 3 Yes, when wearing AND when not wearing glasses or contact lenses
- 4 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)?

- 6 I do not use glasses or contact lenses
- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 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)?

- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 Always
- 6 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)?

- 6 I do not use glasses or contact lenses
- 1 Extremely bothersome
- 2 Very bothersome
- 3 Somewhat bothersome
- 4 A little bothersome
- 5 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)?

- 1 Extremely bothersome
- 2 Very bothersome
- 3 Somewhat bothersome
- 4 A little bothersome
- 5 Not at all bothersome
- 6 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)?

- 6 I do not use glasses or contact lenses
- 1 No difficulty at all
- 2 Very little difficulty
- 3 Moderate difficulty
- 4 A lot of difficulty
- 5 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)?

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

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

- 7 I do not use glasses or contact lenses
- 1 Go away completely
- 2 Go away mostly
- 3 Go away a little
- 4 Not change
- 5 Get a little worse
- 6 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**?

- 1 Yes, but ONLY when NOT wearing glasses or contact lenses
- 2 Yes, but ONLY when wearing glasses or contact lenses
- 3 Yes, when wearing AND when not wearing glasses or contact lenses
- 4 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)?

- 6 I do not use glasses or contact lenses
- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 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)?

- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 Always
- 6 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)?

6 I do not use glasses or contact lenses

1 Extremely bothersome

2 Very bothersome

3 Somewhat bothersome

4 A little bothersome

5 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)?

1 Extremely bothersome

2 Very bothersome

3 Somewhat bothersome

4 A little bothersome

5 Not at all bothersome

6 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)?

6 I do not use glasses or contact lenses

1 No difficulty at all

2 Very little difficulty

3 Moderate difficulty

4 A lot of difficulty

5 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)?

1 No difficulty at all

2 Very little difficulty

3 Moderate difficulty

4 A lot of difficulty

5 So much difficulty that I can no longer do some of my usual activities

6 I always use glasses or contact lenses

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

7 I do not use glasses or contact lenses

1 Go away completely

2 Go away mostly

3 Go away a little

4 Not change

5 Get a little worse

6 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**?

- 1 Yes, but ONLY when NOT wearing glasses or contact lenses
- 2 Yes, but ONLY when wearing glasses or contact lenses
- 3 Yes, when wearing AND when not wearing glasses or contact lenses
- 4 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)?

- 6 I do not use glasses or contact lenses
- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 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)?

- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often
- 5 Always
- 6 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)?

- 6 I do not use glasses or contact lenses
- 1 Extremely bothersome
- 2 Very bothersome
- 3 Somewhat bothersome
- 4 A little bothersome
- 5 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)?

- 1 Extremely bothersome
- 2 Very bothersome
- 3 Somewhat bothersome
- 4 A little bothersome
- 5 Not at all bothersome
- 6 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)?

- 6 I do not use glasses or contact lenses
- 1 No difficulty at all
- 2 Very little difficulty
- 3 Moderate difficulty
- 4 A lot of difficulty
- 5 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)?

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

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

- 7 I do not use glasses or contact lenses
- 1 Go away completely
- 2 Go away mostly
- 3 Go away a little
- 4 Not change
- 5 Get a little worse
- 6 Get a lot worse

Scoring Guide

Recode out-of-range values or n/a responses, if necessary, to missing (.)

Item Numbers	Change original response category:	To recoded value of:	Note
I3, I4, I5, I6, I7, I8, I11, I12, I13, I14, I15, I16, I19, I20, I21, I22, I23, I24, I27, I28, I29, I30, I31, I32.	6	. (n/a)	"6" is the first response listed in survey for items 3, 5, 7, 11, 13, 15, 19, 21, 23, 27, 29, 31.
I9, I17, I25, I33	7	. (n/a)	"7" is the first response listed in survey for items 9, 17, 25, 33.

All scales are scored so that a higher score is more positive. To accomplish this, we rescore all items, when necessary, to be in the positive direction prior to combining them. Note that items that are **reverse-coded** (e.g., I1 below) will have **_rev** appended to their name while other **recoded** items (e.g., I2 below) will have **_rec** appended to their names to differentiate them from their original.

Item Numbers	Change original response category	To recoded value of:	New Items
I1, I9, I17, I25, I33	1	6	I1_rev, I9_rev, I17_rev, I25_rev, I33_rev
	2	5	
	3	4	
	4	3	
	5	2	
	6	1	
I2, I10, I18, I26	4	4	I2_rec, I10_rec, I18_rec, I26_rec
	1	3	
	2	2	
	3	1	

Item Numbers	Change original response category	To recoded value of:	New Items
I3, I4, I7, I8, I11, I12, I15, I16, I19, I20, I23, I24, I27, I28, I31, I32	1	5	I3_rev, I4_rev, I7_rev, I8_rev, I11_rev, I12_rev, I15_rev, I16_rev, I19_rev, I20_rev, I23_rev, I24_rev, I27_rev, I28_rev, I31_rev, I32_rev
	2	4	
	3	3	
	4	2	
	5	1	
I3_rev ^{s1} , I4_rev ^{s1} , I5 ^{s1} , I6 ^{s1} , I7_rev ^{s1} , I8_rev ^{s1} , I11_rev ^{s2} , I12_rev ^{s2} , I13 ^{s2} , I14 ^{s2} , I15_rev ^{s2} , I16_rev ^{s2} , I19_rev ^{s3} , I20_rev ^{s3} , I21 ^{s3} , I22 ^{s3} , I23_rev ^{s3} , I24_rev ^{s3} , I27_rev ^{s4} , I28_rev ^{s4} , I29 ^{s4} , I30 ^{s4} , I31_rev ^{s4} , I32_rev ^{s4}	1	1	I3_rec, I4_rec, I5_rec, I6_rec, I7_rec, I8_rec, I11_rec, I12_rec, I13_rec, I14_rec, I15_rec, I16_rec, I19_rec, I20_rec, I21_rec, I22_rec, I23_rec, I24_rec, I27_rec, I28_rec, I29_rec, I30_rec, I31_rec, I32_rec
	2	2	
	3	3	
	4	4	
	5	5	
	(screener s#=4)	6	
items have 5-response levels but are expanded to six categories using corresponding screener (s1=I2, s2=I10, s3=I18, s4=I26): if screener=4 (no symptom) then recode item to 6 (best possible response).			
I9_rev ^{s1} , I17_rev ^{s2} , I25_rev ^{s3} , I33_rev ^{s4}	1	1	I9_rec, I17_rec, I25_rec, I33_rec
	2	2	
	3	3	
	4	4	
	5	5	
	6	6	
	(screener s#=4)	7	
items have 6-response levels but are reverse coded and expanded to 7 categories using corresponding screener (s1=I2, s2=I10, s3=I18, s4=I26): if screener=4 (no symptom) then recode to 7 (best possible response).			

Transform items to 0-100 possible range (i.e., subtract minimum possible, divide by possible range, and then multiple by 100). Then combine as follows.

	# of items	After recodes per above instructions, calculate average of items for each scale
<i>New measures of visual aberrations</i>		
Double image	8	I2_rec, I3_rec, I4_rec, I5_rec, I6_rec, I7_rec, I8_rec, I9_rec.
Glare	8	I10_rec, I11_rec, I2_rec, I3_rec, I4_rec, I5_rec, I6_rec, I7_rec.
Haloed	8	I18_rec, I19_rec, I20_rec, I21_rec, I22_rec, I23_rec, I24_rec, I25_rec.
Starburst	8	I26_rec, I27_rec, I28_rec, I29_rec, I30_rec, I31_rec, I32_rec, I33_rec.
<i>Measure of satisfaction</i>		
Satisfaction with vision	1	I1_rev.

SAS code:

```

*set 6 to missing for 6-level items;
array skip6 I3 I4 I5 I6 I7 I8
           I11 I12 I13 I14 I15 I16
           I19 I20 I21 I22 I23 I24
           I27 I28 I29 I30 I31 I32;
do over skip6;
if skip6=6 then skip6=.n;
end;

*set 7 to missing for 7-level items;
array skip7 I9 I17 I25 I33;
do over skip7;
if skip7=7 then skip7=.n;
end;

/*****
/* recode/reverse items as necessary */
*****/

* reverse 6-level items (1-6 -> 6-1);
* I9, I17, I25, I33 later get a 7th level;

array six    I1 I9 I17 I25 I33;
array rev6   I1_rev I9_rev I17_rev I25_rev I33_rev;
do over m6;
rev6=(7-six);
end;

* special adjust4;
array f4      I2 I10 I18 I26;
array f4_rec  I2_rec I10_rec I18_rec I26_rec;
do over f4;
if f4=4 then f4_rec=4; else
if f4=1 then f4_rec=3; else
if f4=2 then f4_rec=2; else
if f4=3 then f4_rec=1;
end;

* reverse 5-level items before adding a 6th level (1-5 ->
5-1);
array five
I3 I4 I7 I8
I11 I12 I15 I16

```

```
I19 I20 I23 I24
I27 I28 I31 I32;
```

```
array rev5
I3_rev I4_rev I7_rev I8_rev
I11_rev I12_rev I15_rev I16_rev
I19_rev I20_rev I23_rev I24_rev
I27_rev I28_rev I31_rev I32_rev;
```

```
do over five;
rev5=(6-five);
end;
```

```
* Create an extra level in items for aberration scales;
```

```
I3_rec=I3_rev; I4_rec=I4_rev;
I5_rec=I5;      I6_rec=I6;
I7_rec=I7_rev; I8_rec=I8_rev; I9_rec=I9_rev;
```

```
I11_rec=I11_rev; I12_rec=I12_rev;
I13_rec=I13;      I14_rec=I14;
I15_rec=I15_rev; I16_rec=I16_rev; I17_rec=I17_rev;
```

```
I19_rec=I19_rev; I20_rec=I20_rev;
I21_rec=I21;      I22_rec=I22;
I23_rec=I23_rev; I24_rec=I24_rev; I25_rec=I25_rev;
```

```
I27_rec=I27_rev; I28_rec=I28_rev;
I29_rec=I29;      I30_rec=I30;
I31_rec=I31_rev; I32_rec=I32_rev; I33_rec=I33_rev;
```

```
if I2=4 then do;
  I3_rec=6; I4_rec=6;
  I5_rec=6; I6_rec=6;
  I7_rec=6; I8_rec=6; I9_rec=7;
end;
```

```
if I10=4 then do;
  I11_rec=6; I12_rec=6;
  I13_rec=6; I14_rec=6;
  I15_rec=6; I16_rec=6; I17_rec=7;
end;
```

```
if I18=4 then do;
  I19_rec=6; I20_rec=6;
  I21_rec=6; I22_rec=6;
  I23_rec=6; I24_rec=6; I25_rec=7;
```

```
end;
if I26=4 then do;
  I27_rec=6;  I28_rec=6;
  I29_rec=6;  I30_rec=6;
  I31_rec=6;  I32_rec=6; I33_rec=7;
end;

/* end create extra level code */

/* Transform items to a 0-100 possible range.
The general formula is: new_score = (original_score - min)
x 100 / (max - min)  */

* items coded 1-4 get recoded to: 0, 100/3, 200/3, 100;
array four  I2_rec I10_rec I18_rec I26_rec;
do over four;
four=(four-1)*100/(4-1);
end;

* items coded 1-7 get recoded to:
  0, 100/6, 200/6, 50, 400/6, 500/6, 100;
array seven I9_rec I17_rec I25_rec I33_rec;
do over seven;
seven=(seven-1)*100/(7-1);
end;

* items coded 1-6 get recoded to: 0, 20, 40, 60, 80, 100;
array six I1_rev
  I3_rec I4_rec I5_rec I6_rec I7_rec I8_rec
  I11_rec I12_rec I13_rec I14_rec I15_rec I16_rec
  I19_rec I20_rec I21_rec I22_rec I23_rec I24_rec
  I27_rec I28_rec I29_rec I30_rec I31_rec I32_rec;
do over six;
six=(six-1)*100/(6-1);
end;

label I1_rev = "satisfaction with vision";

/* Create scales by averaging items together(SAS mean
function will calculate score if at least one non-missing
item is present,
otherwise result is missing)  */
```



```
dimage8  =mean(of I2_rec I3_rec I4_rec I5_rec I6_rec
I7_rec I8_rec I9_rec);
glare8   =mean(of I10_rec I11_rec I12_rec I13_rec I14_rec
I15_rec I16_rec I17_rec);
halos8   =mean(of I18_rec I19_rec I20_rec I21_rec I22_rec
I23_rec I24_rec I25_rec);
starbrst8 =mean(of I26_rec I27_rec I28_rec I29_rec I30_rec
I31_rec I32_rec I33_rec);

label
dimage8  = "double image"
glare8   = "glare"
halos8   = "halos"
starbrst8 = "starburst";
```