Timing of Penetrating Keratoplasty for Keratoconus

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Background:

Keratoconus is a noninflammatory, bilateral, irregular ectasia of the cornea normally, but not always, first diagnosed in the mid-teens to early twenties (Zadnik, et al., 1996). Occurring in anywhere from 4 (Duke-Elder and Leigh, 1965) to 120 (Hofstetter, 1959) persons per 100,000 people, keratoconus is a potentially sight threatening disease. In the United States the most often quoted number of patients affected with this disease is 50 persons per 100,000 people with the annual incidence rate being 2 persons per 100,000 people (Kennedy, et al., 1986).

Keratoconus findings can vary from mild irregular astigmatism to severe thinning and/or scarring of the cornea. As of now, there is no way to predict this unevenness and scarring nor even if anyone else in the family will acquire the disease. Currently, there is no certain way of predicting progression and hence no way of predicting if a keratoconic patient will require penetrating keratoplasty in his or her lifetime. This variable presentation is illustrated by some patients having a slow progression, others fast and still others no progression.

In the early stages of the disease, the patient may not require treatment, depending on the visual needs of the patient. However, as the disease progresses, glasses and soft contact lenses often provide adequate vision as long as the astigmatism is regular. When the astigmatism becomes irregular and the cornea becomes distorted with scarring and thinning, rigid contact lenses are often the only option.

If standard rigid contact lenses fail, there are many different forms of specialty lenses available for the keratoconic patient. These include multi-curve (Soper, Rose K and McGuire lens designs) and bitoric contact lenses. More recent advance fitting techniques include merging the benefits of topography with the irregular lens design needs of keratoconic patients. Z-Wave lenses are one such example wherein software allows for the creation of a multi-aspheric, multi-curve lens derived from the irregular corneal surface as measured by a Scout topographer.

Even with the best of intentions and efforts, often problems with rigid lens centration and comfort persist. In these cases, Softperm lenses attempt to marry the optics of a rigid center lens with the comfort of a soft skirt periphery. However, reduced tear exchange and extreme corneal irregularity can continue to cause comfort and fitting problems.

With the advent of affordable disposable high oxygen transmission silicon lenses, a piggyback contact lens system is regaining popularity for the more challenging keratoconic patients. In this scenario, a disposable soft lens is used as a base to provide comfort and stability for an overlying gas permeable lens.

When glasses and contact lenses fail, surgical intervention is usually the final option. Intacs have been tried with limited success to reduce corneal irregularity such that contacts can be worn again. Most often however penetrating keratoplasty is a more viable solution. Penetrating keratoplasty is often recommended when the visual acuity is worse than 20/40 or if there is contact lens intolerance, lens displacement and/or peripheral thinning of the cornea. Ocular pain is also a common complaint given by the patient when discussing the need for a corneal transplant.

One study, Dana, et al., sought to determine when contact lenses fail to help the keratoconus patient when should surgery be performed. This study discussed visual acuity, age, keratometry readings and duration of the disease. The conclusion made by this study was the longer the disease duration (more than 5 years) the more likely the patient will undergo penetrating keratoplasty for poor vision than for lens intolerance. This is similar to our study in that most patients underwent the transplant for poor vision. However, in our survey the transplant occurred, on average, 27.5 years after the initial diagnosis of keratoconus instead of the non-specific greater than 5 years done in above-mentioned study. Also, this study found keratometry readings averaged over 55D, average age was over 40 years and the duration of the disease was over 5 years. The above-mentioned data, on average, was taken 12 months after the initial presentation of keratoconus and before the patient underwent penetrating keratoplasty. (Dana, et. al., 1992). Although Dana, and similar studies have used visual acuity as the standard for measuring surgical success, often the patient's quality of life is more pertinent.

Quality of life became a topic of discussion starting in the mid-1970's (Flanagan, 1982). Visual acuity measures along with contrast sensitivity were found not to be poor indictors of patients' satisfaction and their ability to perform daily vision tasks. A subjective response and an analysis of this response allows for discrimination between the patients' perception of his or her overall health and the effectiveness of the treatment. Hence, quality of life surveys such as ours are often useful in predicting future outcomes, measuring changes over time and patient education. In order to measure quality of life after PKP for keratoconus we devised a survey modeled after the extensively studied and validated National Eye Institute Quality of Life survey used to assess the quality of life after cataract surgery.

Our survey (appendix 1) was created to collect data to help doctors and patients make an informed, educated decision when considering penetrating keratoplasty. This survey assessed the timing of penetrating keratoplasty and provided insight on the patient's vision and ocular comfort. Data detailing the number of patients functioning post-operatively with no correction, contact lenses, glasses or a combination of the three are also tallied. Lastly, we asked who first recommend the corneal transplant to the patient, an ophthalmologist, optometrist or some other person.

Method:

As our study involved human subjects, we had to obtain approval for the study from the Internal Review Board at the University of Michigan, wherein we describe our study and provided a sample consent form for the patients to be surveyed (appendix 2).

Our survey is being employed at five different study centers that have performed penetrating keratoplasty for keratoconus patients. Each center objectively measures visual acuities and keratometry as well as record the mode of correction and date of penetrating keratoplasty.

At the conclusion of the study we anticipate receiving 50 completed surveys from each center for a total of 300 surveys. Herein we report on the results collected thus far from one study center, the University of Michigan, Department of Ophthalmology and Visual Sciences. At the time of this writing we have received 25 surveys from the

University of Michigan. The following are tables with discussions on the 22 questions contained in the survey.

Results:

Age of patient when survey filled out	
Less than 30	0
30-39	5
40-49	2
50-59	10
60-69	8
70+	0
AVERAGE	53.3

The average age of the patient filling out the survey was 53.3 years old. Since keratoconus is normally first diagnosed in the mid-teens to early twenties, in our study it averaged over 30 years before the keratconus patient needed a transplant.

Gender of patient	
Male	14
Female	11

In this study the male/female ratio was fairly even, indicating keratoconus is not limited to a certain sex.

Current best corrected visual acuity at distance		
	Right eye	Left eye
20/15	1	0
20/20	7	8
20/25	0	4
20/30	4	0
20/40	2	0
Greater than 20/40	0	0
AVERAGE	20/24.72	20/22.40

The table above shows the average best corrected distance vision after the corneal transplant for the right eye is 20/24.72. Similarly, in the left eye the visual acuity averages 20/22.40. Therefore, patients undergoing penetrating keratoplasty at U of M can expect good vision after the transplant.

Current best corrected near vision		
	Right eye	Left eye
0.3	0	0
0.4	7	6
0.5	3	5
0.6	4	2
0.7-1.0	1	0
AVERAGE	0.511	0.500

Again the table above shows the average best correct near vision after the corneal transplant for the right eye has an average visual acuity of 0.511 with the left eye having a slightly less average at 0.500. Therefore, once again patients can expect good near vision results following a corneal transplant.

Pre-transplant best corrected distance visual acuity		
	Right eye	Left eye
20/15-20/25	1	2
20/30-20/40	4	3
20/50-20/70	6	5
20/80-20/100	0	0
20/200-20/300	2	3
20/400	1	0
Counting fingers	1	1
AVERAGE	20/119.61	20/98.40

The pre-transplant best-corrected visual acuity was generally poor. For the right eye the average pre-surgery visual acuity was 20/119.61 and the left eye average was 20/98.40. One person was counting fingers in both eyes.

Pre-transplant best corrected near visual acuity		
	Right eye	Left eye
0.0-0.4	0	2
0.5	3	0
0.6	2	4
0.7-0.9	5	1
1.0-1.5	1	3
1.6-2.0	2	1
2.0 or greater	0	0
Average	1.00	0.865

The pre-transplant best corrected visual acuity was generally poor. For the right eye the average pre-surgery visual acuity was 1.00 and the left eye average was 0.865.

When were you first diagnosed with keratoconus? (in months)	
Less than 100	0
100-219	3
220-389	9
390-510	5
510-630	1
AVERAGE	331.92

The average patient filling out this survey has been diagnosed with keratoconus approximately 27.5 years prior. The shortest time duration of the disease was 8.75 years and the longest time was 50 years.

When was a corneal transplant first suggested to you? (in months)	
Less than 100	0
100-199	8
200-299	5
300-399	1
400-499	3
AVERAGE	253.93

Twenty-one years ago was the average time a corneal transplant was first recommended to the patient. The shortest time was almost 8.5 years ago and the longest time was 40 years ago.

Who suggested that you undergo a corneal transplant?	
Ophthalmologist (MD)	23
Optometrist (OD)	0
Other	1
TOTAL	24

The vast majority of patients were recommended for the transplant by an ophthalmologist. However, these totals may reflect the older age of our respondents and the length of time since their original transplant. Patients considering transplants today may be more likely to have the recommendation made by an optometrist given the vast expansion of our scope of practice in the recent past.

Immediately before your most recent corneal transplant, did you wear contact lenses?		
	Right eye	**Left eye**
Soft	1	1
Rigid	19	18
Softperm	1	1
Piggyback	0	0
None	3	4

Most patients before the transplant surgery wore rigid gas permeable contact lenses due to the scarring and irregular astigmatism associated with severe keratoconus. More patients (7) wore no prescription than soft contact lenses. As discussed above, this could be due to the irregular cornea making the contact lens not fit properly, ocular pain or discomfort, poor vision even with treatment and/or poor education to the patient on different possibilities of contact lenses.

If you did not wear contact lenses prior to surgery why not?	
Poor Vision	0
Cost	0
Poor Comfort	4
I didn't know it was an option	1
Other	1

As you can see, for the majority of patients that did not wear contact lenses prior to surgery (4) poor comfort was the main reason they did not wear any contact lenses though one person was not educated on the option of contact lenses and one person marked other.

Prior to having your corneal transplant, which problems did you experience ?		
	Right eye	**Left Eye**
Decreased ability to read at near	11	11
Decrease reading road signs or other distance details	12	13
Reading a computer monitor	4	6
Light sensitivity	7	9
Discomfort with contact lenses	10	9
Poor vision with contact lenses	9	8

Most keratoconus patients complained of decrease in vision at distance though decrease in vision at near was a close second as problems experienced before eye surgery. Reading a computer was the least troublesome (based on average age, many patients may not use a computer on a regular basis). Discomfort and poor vision with the contact lenses came in a close third and fourth.

What was the most significant factor in your decision to proceed with a corneal transplant?	
Poor vision	18
Poor comfort	5
Other	4

Poor vision was the most common compliant. This may be attributed to hampering a person's everyday lifestyle. Comfort and other reasons were also a factor to a handful of patients.

Do you feel the timing of your transplant was appropriate?		
	Right eye	Left eye
Too early	1	0
Appropriate timing	15	13
Too late	2	3

Most patients felt the timing of their penetrating keratoplasty was appropriate with more patients wishing they had had it sooner than later. This may be attributed to the high success rate of the surgery center.

If you wish that you had your corneal transplant sooner or later, what timing would you have preferred?		
	Sooner	Later
3 months	1	0
6 months	1	0
1 year	2	0
Other	1	0

Everyone that wished they had it sooner would have liked it performed a year or sooner than when it was actually done since they great success with the transplant.

Do you wear vision correction for distance?		
	Right eye	Left eye
None	3	3
Soft contact lenses	0	0
Rigid contact lenses	15	17
Glasses and contact lenses	6	3
Softperm contact lenses	1	0
Piggyback contact lenses	0	0
Glasses only	0	1

After the surgery, most patients wear rigid gas permeable contact lenses due to the fact the corneal transplant can leave the cornea irregular. More people than before the surgery are wearing glasses and three people are not wearing any correction. There is more data here since it is for both eyes no matter if that eye had a transplant or not.

How do you feel your best corrected distance vision compares to pre-transplant vision?	
Significantly better	22
Slightly better	1
Slightly worse	1
Significantly worse	0
No change	1

After the surgery, the majority of patients felt their distance vision was significantly better than before the surgery and one person felt like it has not changed at all. Only one person felt the vision was slightly worse and no one felt their vision after the transplant was significantly worse.

In general, how satisfied are you with your transplant?	
Very satisfied	22
Slightly satisfied	1
Slightly dissatisfied	1
Very dissatisfied	0

Everyone besides one person was satisfied or very satisfied with the surgery with one person only being slightly dissatisfied.

Do you feel you were educated appropriately before the transplant?	
Yes	23
No	2

Of the two patients who did not feel they were educated appropriately, one stated he or she felt the terminology given for the procedure was too technical.

Discussion:

In assessing the timing of the penetrating keratoplasty and the subjective responses of the keratoconus patients' vision and ocular comfort with and without correction, before and after surgery, we are able to gain better insight, knowledge and decision making capabilities concerning the timing of the procedure. This insight will be valuable when recommending and counseling penetrating keratoplasty to the keratoconus patient as well as to help focus future studies concerning the treatment of keratoconus. Subjective and partial objective measurements, ascertained in the survey, gives us valuable information such as being able to state that most patients can expect significantly improved visual acuities after the surgery. However, contact lenses may still be required post-operatively.

This study indicates patients undergoing PKP at the University of Michigan (UM) feel they are well informed prior to the procedure and that they are being referred appropriately. Moreover, our data show poor lens comfort is not the main reason patients are referred for penetrating keratoplasty, rather a decrease in visual acuity is the primary reason.

Even though keratoconus is normally first diagnosed in the mid-teens to early twenties, the average age for a corneal transplant was 53.3 years old. Therefore, based on our data, when explaining keratoconus to a newly diagnosed patient, we can explain to them the progression of the disease and if a transplant is needed the average timing is 30 years after the initial diagnosis.

So far, the data indicates about 5.5 years after being first diagnosed with keratoconus, patients are first educated on penetrating keratoplasty. Most of the patients (15) reported the timing of the penetrating keratoplasty was appropriate and only one person stating he or she thought it was done too soon and 5 people thought it was performed too late. Of the five that wished they had it sooner, two felt they would have liked to have it a year sooner, one six months sooner, one three months sooner and one marked other. Twenty-two people stated they were very satisfied with the surgery while one was slightly satisfied and only one person was slightly dissatisfied. Again, this indicates the U of M doctors are educating their patients well and referring them appropriately for the transplant.

Poor comfort was the main reason patients did not wear contact lenses prior to surgery and one patient was not educated on contact lenses being an option. A possible explanation for this is that that person may not have been able to be fit with contact lenses. The majority of patients wore some form of a rigid gas permeable contact lens before surgery. Interestingly, of the problems experienced prior to surgery, decrease in road signs or other distance details was the main complaint with decrease in near vision and discomfort with the contact lenses as other complaints. After surgery, most of the patients wear rigid gas permeable lenses, some (9) wear glasses and contact lenses and six wear no correction at all.

Anecdotally, when the patients were asked about advice they would give to other patients considering a transplant for keratoconus, the general consensus was to go ahead with the surgery since it was worth it with minimal discomfort and quick recovery, though one must be patient with the post-operative healing time. Other advice they

would offer to other potential penetrating keratoplasty patients include: educate yourself, trust your doctor and make sure he or she knows all the potential problems, respect your doctor's opinion on the timing of the penetrating keratoplasty and be ready emotionally. Another piece of advice, given by a patient, was for the person having the surgery have an empathetic, non-rushed, person debrief him or her on the surgery itself and the expected results. This advice was given to try to prevent any miscommunication between the doctor and patient.

From a doctor's standpoint, it is helpful to learn about average pre-operative and post-operative visual acuity, though more extensive measurements have been done in other studies. It is interesting to note of the 25 surveys we have received so far, 24 of the patients were referred by ophthalmologists with no optometrists referring the patient for surgery. However, this number could be skewed by the older age of the patients in our study.

New and improved surgical techniques such as interrupted sutures and relaxing incisions are decreasing the amount of irregular astigmatism experienced after the transplant. Thus, better outcomes can be expected with the surgery as well as less people needing to wear correction, such as rigid gas permeable contact lenses, after the operation.

Our study was hampered by the small sample size. Given this small sample, scientific data analysis (ie. Chi squared) would be unreliable. However, this study does provide insight into what we may find when the data from all the study centers is received and analyzed.

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Appendix 1 – Sample Survey Form

Timing of Penetrating Keratoplasty for Keratoconus

1. Today's Date: ___/___/___ (MM/DD/YY)

2. Institution (circle one)
    1. UM
    2. UCBSO
    3. UI
    4. NYU
    5. UCLA

3. Date of birth: ___/___/___ (MM/DD/YY)

4. Gender: 1 Male 2 Female

5. Today's Best-corrected distance VA: OD 20/__ __ OS 20/__ __

6. Today's BCNVA OD .40/__ __ OS .40/__ __

7. Pre-Transplant: Best-corrected distance VA OD 20/__ __ OS 20/__ __

8. Pre-Transplant: BCNVA OD .40/__ __ OS .40/ __ __

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START HERE:

9. When were you first diagnosed with Keratoconus? ___/___ (MM/YY)

10. When was a corneal transplant first suggested to you? ___/___ (MM/YY)

11. Who suggested that you undergo a corneal transplant?

    1 Ophthalmologist (MD)

    2 Optometrist (OD)

3 Other _____

12. What is the date of your most recent corneal transplant?

1. Right eye ___/___/___ (MM/DD/YY)
2. Left eye ___/___/___ (MM/DD/YY)

13. Immediately before your most recent corneal transplant, did you wear contact lenses?

Right eye: **Left Eye:**

1 None 1 None

2 Soft 2 Soft

3 Rigid 3 Rigid

4 Softperm 4 Softperm

5 Piggyback 5 Piggyback

14. If you did not wear contact lenses prior to surgery, why not?

1 Poor vision

2 Cost

3 Poor comfort

4 I didn't know it was an option

5 Other _____

15. Prior to having your corneal transplant, which problems did you experience in your **RIGHT** eye? (please check all that apply):

1 Decreased ability to read at near

2 Decreased reading road signs or other distance details

3 Reading a computer monitor

4 Light sensitivity

5 Discomfort with contact lenses

6 Poor vision with contact lenses

16. Prior to having your corneal transplant, which problems did you experience in your **LEFT** eye? (please check all that apply):

1 Decreased ability to read at near

2 Decreased reading road signs or other distance details

3 Reading a computer monitor

4 Light sensitivity

5 Discomfort with contact lenses

6 Poor vision with contact lenses

17. What was the most significant factor in your decision to proceed with a corneal transplant?

1 Poor vision

2 Poor comfort

3 Other_____

18. Do you feel the timing of your transplant was appropriate?

1 Too early

2 Appropriate timing

3 Too late

19. If you wish that you had your corneal transplant sooner or later, please check the timing you would have preferred:

1 three months

2 six months

3 one year

4 Other (please indicate how long):

20. Do you wear vision correction for distance in your right eye?

1 None 5 Softperm contacts

2 Soft contacts 6 Piggyback contact lenses

3 Rigid contacts 7 glasses only

4 glasses and contacts

21. Do you wear vision correction for distance in your left eye?

1 None

2 Soft contacts

3 Rigid contacts

4 glasses and contacts

5 Softperm contacts

6 Piggyback contact lenses

7 glasses only

22. How do you feel your best corrected distance vision compares to pre-transplant vision?

1 Significantly better

2 Slightly better

3 Slightly worse

4 Significantly worse

23. In general, how satisfied are you with your corneal transplant?

1 Very satisfied

2 Slightly satisfied

3 Slightly dissatisfied

4 Very dissatisfied

24. Do feel you were educated appropriately before the transplant?

1 Yes

2 No

25. If no, please explain:

26. Do you have any advice for patients considering a transplant for keratoconus:

Appendix 2: Sample Internal Review Board Approved Consent Form

Project Title: **Timing of Penetrating Keratoplasty for Keratoconus**

Research Team:

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WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have had a penetrating keratoplasty for keratoconus at least 18 month ago, but not more than 12 years ago. The purpose of this research study is to evaluate keratoconus patients' perceptions of the timing and perceived benefits of corneal transplants and to determine how the surgery changed patients' vision and/or ocular comfort.

HOW MANY PEOPLE WILL PARTICIPATE?

300 patients are anticipated to participate nationwide.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for the length of time it takes you to complete the survey, approximately 10 - 15 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be given a survey to complete. The person administering your survey will enter information about your pre and post transplant visual acuity. You will complete the

remainder of the survey regarding questions about your transplant experience. You may skip any questions you would prefer not to answer. Upon completion of your survey, you will return it to the investigator. The survey will be kept separate from your medical record and a separate investigator will analyze the data. The survey does not contain your name or an ID number.

WHAT ARE THE RISKS OF THIS STUDY?

There are no foreseeable risks to participating in this study

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit personally from being in this study. However, we hope that, in the future, other keratoconics might benefit from this study by determining optimal keratoplasty timing, from the patient perspective.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The Center for Keratoconus is funding this research study. No one on the research team will receive a direct payment or an increase in salary from The Center for Keratoconus for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, federal government regulatory agencies, and a University Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. This informed consent document will be placed in your chart. If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. The research team will access or create health information about you, as described in this document, for purposes

of this research study. The research team will keep your study-related health information indefinitely for purposes of the research. Once your health care provider has disclosed your protected health information to the research team, it may no longer be protected by federal privacy regulations.

The research team may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff. If the research team shares your health information with others, it may not be protected by federal privacy regulations.

You cannot participate in this study unless you permit your health information to be used by the research team. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give the research team permission to use or create health information about you.

You may withdraw your permission for the research team to use your health information for this research study by sending a written notice to: Christine W Sindt OD 200 Hawkins Drive Iowa City, IA 52242. However, the research team may still use your health information that was collected before withdrawing your permission. Also, if the research team has sent your health information to a third party, such as the study sponsor, or has removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Christine W Sindt OD 319-356-4816

If you have questions about the rights of research subjects or research related injury, please contact the Human Subjects Office, 300 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso.

QUESTIONS

I have been told that I may contact the principal investigator, Christine W Sindt O.D. with questions about this research study. I have been told that I may contact the Human

Subjects Office, 335-6564, with questions about my rights as a research subject or about research-related injury.

_____ _____

Signature of Subject Date

_____ _____

If applicable, Signature of Parent, Guardian, or Date

Legally Authorized Representative

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

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(Signature of Person who Obtained Consent) (Date)