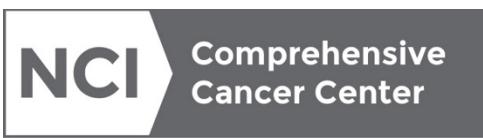




CASE
COMPREHENSIVE
CANCER CENTER



A Cancer Center Designated by the
National Cancer Institute

Study Number: CASE 6617

Study Title: The Use of 3D Printed Models in Mohs Micrographic Surgery

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INTRODUCTION

1.1 Overview

Perioperative anxiety in Mohs Micrographic Surgery (MMS) is associated with increased post-operative pain and decreased patient satisfaction. Optimum delivery of patient education has been suggested as a potential modality to decrease perioperative anxiety, but has not been conclusively demonstrated. A pilot study completed in July 2017 at University Hospital's Westlake Campus demonstrated that patient education completed with a 3D printed model and standardized script increased patients subjective understanding and decreased patient anxiety during the perioperative period. Despite these findings, the pilot study had notable limitations that included a small sample size and lacked an adequate control group. Our aim is to complete a comprehensive randomized control trial, with a larger cohort of patients and an adequate control group, to compare of our innovative counseling protocol to the current standard of care, verbal counseling. This work may help to provide an optimized educational delivery system for MMS at University Hospitals.

1.2 Background and Rationale

Non-melanoma skin cancer is frequently treated with MMS in the clinical setting. This procedure is completed under local anesthesia and the goals of treatment include complete removal of the cancer, perseveration of normal skin function and to provide patients an optimal cosmetic result. Cure rates of MMS have been cited above 95% for BCC & SCC.^{1-3, 6}

In previous studies, increased perioperative anxiety was associated with increased postoperative pain and decreased patient satisfaction.³⁻⁷ Prior literature has demonstrated efficacy of personalized intraoperative music and midazolam treatment to reduce perioperative patient anxiety in MMS.³⁻¹¹ It has been suggested that optimized delivery of patient education may be effective in decreasing patient anxiety, however, it has not been demonstrated.

The use of physical models, often created with 3D printing technology, have been effective in the delivery of medical education for patients, medical students and medical residents. In fact, most studies demonstrate that physical models outperform static (2D) or dynamic (3D), animated or digitized, representations for the delivery of medical education.¹²⁻¹⁸ In addition, the use of physical models for the delivery of medical education has been shown to decrease learner anxiety.^{12, 19}

In July 2017, a pilot study was completed in the University Hospitals Westlake MMS Clinic to determine if a 3D printed MMS model and standardized script protocol could enhance patient understanding of MMS and decrease perioperative patient anxiety.¹⁹ This pilot study included 25 patients and demonstrated that explanation with a 3D printed MMS model and standardized script patients had a statistically significant increase in understanding of MMS by 1.5 points and decrease in anxiety by 1.5 points using a Visual Analog Scale.¹⁹ Limitations of our initial study included lack of an adequate control group and small initial sample size.

Our aim is to complete a comprehensive randomized control trial, with a larger cohort of patients and adequate control group to investigate the effectiveness of our innovative counseling protocol featuring a standardized script and 3D printed MMS model.

2.0 OBJECTIVES

1. To investigate if patient education with a 3DP MMS model and standardized script protocol increases patient understanding of MMS more than current standard of care (control group) at the University Hospitals Cleveland Medical Center MMS Clinics.
2. To investigate if patient education with a 3DP MMS model and standardized script protocol decreases perioperative patient anxiety during MMS more than current standard of care (control group) at the University Hospitals Cleveland Medical Center MMS Clinics.
3. To evaluate if patient satisfaction with a 3DP MMS model and standardized script protocol increases patient satisfaction during MMS more than current standard of care (control group) at the University Hospitals Cleveland Medical Center MMS Clinics.

3.0 RESEARCH SUBJECT SELECTION AND ELIGIBILITY

A total of 100 subjects between the ages of 18-90 years old, who are undergoing Mohs Micrographic Surgery at University Hospitals Cleveland Medical Center, Chagrin Highlands and Westlake Campus will be considered for the study. Patients will not be provided compensation for participation.

Eligible participants must be capable of reading and completing all subjective questionnaires including the State-Trait Anxiety Inventory (STAI), Visual Analog Scale (VAS), Post-Intervention Knowledge Survey and Satisfaction Survey. Patients will be ineligible for the study if they choose not to participate, or cannot complete the subjective or objective questionnaires described above.

4.0 RESEARCH SUBJECT ENTRY

Subjects will be recruited voluntarily from the University Hospitals Department of Dermatology Mohs Microsurgery Clinics. All patients who meet inclusion criteria will be eligible for the study. Patients will be randomized into experimental or control groups prior to onset of study protocol. All patients will undergo verbal consent in private patient rooms prior to the onset of the study protocol and will have the option to withdraw from the study at any time throughout the study. Verbal consent is preferred to written consent to prevent the collection of information classified as protected health information (PHI).

5.0 STUDY DESIGN AND METHODS

A total of 100 patients will be recruited from University Hospitals Department of Dermatology Mohs Micrographic Surgery Clinics at the Cleveland Medical Center, Chagrin Highlands and Westlake Locations. These patients will be randomly assigned to a control (50%) or experimental group (50%) prior to the onset of the study protocol. Patients in the control group will be educated on MMS according to the current standard of care, verbal counselling, with a standardized script (Appendix A). The experimental group will be educated on MMS with a standardized script in addition to a 3D MMS model (Appendix B).

Patients will initially undergo verbal consent in private patient rooms located within the Mohs Microsurgery Clinics prior to study initiation. As previously stated, verbal consent will prevent the

collection of any PHI during this study. Upon verbal consent, patients will fill out baseline testing including a State-Trait Anxiety Inventory (STAI) and Visual Analog Scale (VAS) to quantify their anxiety and understanding of the Mohs procedure (Appendices C, D, E). Following baseline testing, patients will undergo preoperative education. In the control group patients will be educated with a standardized script alone, and experimental group patients with a standardized script, in addition to a 3DP physical model demonstrating the MMS procedure. The total length of time to educate patients will be recorded.

After completion, patients will undergo standard of care procedures with the MMS team, including surgeon, and undergo the first stage of the MMS procedure. Patients will undergo post-testing following the first layer of MMS. This layout was chosen to ensure all patients to prevent study personnel from impeding the workflow of the MMS clinic, and is similar to a workflow used in previous studies.^{4,5}

Once complete, patients in both groups will fill out a post-intervention STAI, a VAS for anxiety and level of understanding of the Mohs Procedure. In addition, patients will receive an objective Mohs Quiz and subjective Satisfaction Survey (Appendices F, G). All of the data collected for the study will be de-identified, HIPPA-compliant and encrypted on a password protected Department of Dermatology server folder. These secure file folders are restricted and only research personnel have access to the files. In addition to de-identification, encryption and password protection, these data are also protected by University Hospitals firewall as well.

5.1 Design/Study Type

We propose a randomized control group format with 50% of patients randomized to the control limb and 50% of patients randomized to the experimental group.

5.2 Selection of Instruments

Pre-intervention and Post-intervention instruments

1) State-Trait Anxiety Inventory (STAI)

- a.** The STAI is a well-known, frequently used measure of patient anxiety within the clinical setting.^{5,8} This form consists of two forms to assess state anxiety and a patient's baseline trait anxiety. Each form consists of 20 Likert-type questions that can be easily answered by a patient with an average reading level. Estimated time for completion of these questions is approximately 2 minutes per form. This form has been used in 2 studies to date that assess intraoperative anxiety in Mohs.^{5,8}
- b.** We plan to use the anxiety State Form Y1, appendix A, at baseline and following completion of Stage 1 of MMS.
- c.** We plan to use the anxiety Trait Form Y2, appendix B, at baseline only to compare the baseline level of anxiety between the control and experimental groups.
- d.** Found in Appendices C, D

2) Visual Analog Scale (VAS)

- a.** The VAS is a frequently employed Likert-type scale that is used to measure anxiety.^{5,8} This 0-10 scale documents the patients current state of anxiety and can be answered by patients with an average reading level. Estimated time of completion is under 30 seconds. This form has been used in 2 studies to date and

previously by experimental team to assess intraoperative anxiety in Mohs.^{5,8,19}

- b. In addition, because of the ease of use this tool has been converted to assess other objective measures including understanding. This was previously used by our experimental team to quantify patient's understanding of MMS.¹⁹
- c. We propose to use the VAS for anxiety and understanding at baseline and following completion of the first stage of MMS.
- d. Found in Appendix E

3) Objective Questionnaire & Patient Satisfaction Survey

- a. We have designed a short, questionnaire with 6 objective questions related to the patient's understanding of Mohs. This objective portion is to help to delineate objective differences in understanding between the control and experimental groups. This testing was created under the guidance of Dr. Margaret Mann (Mohs Surgeon) and similar objective surveys have been used to assess understanding following educational intervention.¹²⁻¹⁸ Our estimate is that this short quiz will take approximately 3 minutes for patients to complete.
- b. Following the objective questions, patients will be provided 3 subjective questions related to their satisfaction with the explanation of MMS that they received. These subjective questions will be used to help delineate subjective differences between the control and experimental groups. Similar objective surveys have been used to assess satisfaction following educational intervention.¹²⁻¹⁸
- c. We propose to hand out this questionnaire following completion of the first stage of MMS.
- d. See Appendix F & G

5.3 Description of Intervention

A standardized script including the counselling that patients would receive in both the control and experimental groups is included in the attached study documents. See Appendix A, B. This will allow for patients to receive the same information throughout the study, similarly to our recently completed pilot study.¹⁹ Patients in the experimental group will be educated with our 3D printed MMS model, in addition to the standardized script.

5.4 Data Collection

The same data will be collected from both groups of patients. This information will not include any data regarded as protected health information.

Data	At Baseline	Following Stage 1 of MMS
Age (excluding birthdate)	X	
Gender	X	
Subjective Response to "Previous History of Mohs"	X	
STAI Form Y-1	X	X
STAI Form Y-2	X	
VAS Anxiety	X	X
VAS Understanding of Mohs	X	X
Mohs Quiz		X
Satisfaction Survey		X

5.5 Description of Study Process

5.51 Instrument Administration

The instruments provided are self-administered questionnaires. Patients will be handed these questionnaires in private rooms during the study and will be supervised by the research team. Patients will be told about the instruments prior to administration of each questionnaire. Patients will be given adequate time to complete each questionnaire provided.

5.52 Intervention Administration

The educational intervention will be completed following baseline testing by the research assistant in a private patient room according to the standardized script. If patients have additional questions regarding the study at the time of intervention they will be answered by the research assistant. If these questions pertain to the patients' medical record, protected health information, or specific medical questions related to their MMS procedure the research assistant will defer to the medical team. Patients will receive educational intervention following baseline testing.

5.53 Special Concerns

If patients would not like to complete the study they can inform the research team at any time and there will be a discontinuation of all study procedures.

5.54 Compensation

Patients will not be compensated for participating in this study.

5.55 Adverse Reactions and Their Management

5.56 Reporting Adverse Events

No adverse events are expected.

5.57 Anticipated Reactions

No reactions are anticipated.

5.58 Reaction Management

If patients experience additional stress, discomfort, anxiety or other reactions to questionnaires the study can be ended at any time if the patient informs the research personnel.

6.0 STATISTICAL ANALYSIS

6.1

All patients will complete the study protocol on the day of their Mohs procedure. Patients will conclude the study protocol following administration of post-stage testing. Following conclusion, patients will undergo the remainder of their Mohs procedure according to standard of care.

6.2

Several instruments will be used during the study to detect differences between the control and experimental group. Our power analysis was designed to determine the number of patients per group required to determine a difference between the control and experimental group's results of the STAI Form Y1 (Appendix A). This form detects the differences in patient's current state of

anxiety at the time of completion. This form consists of 20 questions, with each question worth between 1-4 points, with patients at minimum scoring 20 to indicate a minimum level of anxiety and 80 to indicate a maximum state of anxiety. Our aim is to detect a minimum difference in the STAI Form Y1 of 5 points between the control and experimental groups.

Based on data from prior studies⁵, we anticipate that the mean STAI score will be approximately 38.7 +/- 10. We anticipate that a 6 point difference between the experimental and control groups would represent statistical significance. Considering these constraints sample size analysis was done to determine the number of patients needed to detect a 6 point difference, with a standard deviation of approximately 10, significance set to .05 and power of 80%. Within these constraints we estimate approximately 45 patients would be needed per group using 2-sided T-test (nQuery Advisor). Assuming a rate of 10% attrition per every 100 patients, we estimate we will need approximately 50 patients per group during the study.

In a prior pilot study, approximately 7 patients were enrolled per MMS clinic. Based on estimates from this study, we anticipate that it will take approximately 12-20 MMS clinics to recruit patients for this intended study. Clinics are held on average 2 days per week, and thus we anticipate completion from 3-5 months from the beginning of the study.

6.3

In subgroup analysis patients will be stratified based on age, gender, and prior experience with MMS or not. We anticipate that patients who have previously undergone MMS will have lower anxiety scores across all measures and increased understanding of the procedure, based on the results of our pilot study. This is anticipated based on the results of the previous pilot study and other literature.⁵

Patients will be randomly selected according to day of the study, every other day randomization. We anticipate that there will be no significant differences between groups based on age, gender and prior experience with MMS based on randomization protocol. All patients from a given clinic will be allocated to the control or experimental group prior to onset of the day.

6.5

If patients are unable to complete the experimental protocol, their data will be discarded prior to final analysis. Patients may drop out from the study at any time, according to the guidelines of the protocol. This will not impact outcome of their procedure.

6.6

Ineligible patients for the study fall under one or more of the below criteria:

- Under 18 years of age
- Over 90 years of age
- Cannot complete the survey measures independently for any reason

6.7

Statistical analyses for this randomized control trial will be completed under the supervision Dr. Pingfu Fu, Dr. Margaret Mann and Dr. Daniel Popkin. This analysis will use basic statistical measurements in order to determine differences between the control and experimental groups. Demographic information including age (but excluding birth date), gender and response to prior

MMS treatment will be compared between control and experimental groups. STAI, VAS, Objective Questionnaire and Patient Satisfaction Questionnaire responses will be recorded and results including median and mean data will be determined. Pre- and post-surgery measurements will be compared using paired T-test. To compare experimental and control groups, T-test will be used after checking normality assumption. In addition, to compare subgroups of the experimental and control groups (> 2 groups) ANOVA followed by Tukey pairwise procedure will be used. If normality assumption is violated, Wilcoxon rank signed test and Kruskal-Wallis test will be used.

6.8

In patients who did not complete the experimental protocol, data would be discarded as stated previously. If a complete dataset were to be lost for a patient whom completed the entire protocol, data would be handled according to the digression of the study team. In patients missing only one value, median data point would be applied. If patients were missing one or more values, data would need to be discarded.

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8.0 APPENDICES

File	Appendix ID
1) Standardized Script	A
2) 3D Printed Mohs Micrographic Surgery Model	B
3) STAI Form Y1	C
4) STAI Form Y2	D
5) VAS Anxiety & Understanding	E
6) Mohs Quiz	F
7) Satisfaction Survey	G

Appendix A - Standardized Script

What is Skin Cancer?

Skin cancer is the most common form of cancer and over one million people in the United States develop skin cancer per year. The majority of these skin cancers are either called either basal cell carcinoma (BCC), or squamous cell carcinoma (SCC), based on the cell type the cancer originates from.

Patients will either then be counseled using **¶1 – for BCC ¶2 – for SCC**

¶1 - for BCC: This is the most common skin cancer and almost never spreads, therefore it is very rarely life threatening. This type of tumor can be very locally destructive and can become problematic when it involves structures on the face and neck. As they increase in size, they become more complex to remove and have the potential to invade into bone and other tissues.

¶2 - for SCC: This is the second most common form of skin cancer and has the potential to be aggressive, but usually only once they reached a size over 2 cm in diameter. With this tumor type there is concern for invasion into the surrounding tissue, which is why prompt removal of this type of skin cancer is recommended.

These tumors are commonly described by patients as the “pimple that does not go away” or “scab that just won’t heal” prior to seeking care from a dermatologist. Often times the tumor has been growing for several months to years, prior to recognition by patients and treatment. Although a skin cancer may appear small from the surface, in many cases the cancer undergoes extensive growth below the skin, former, deeper root-like branching patterns and thus the visible tumor maybe only represent the “tip of the iceberg.”

Why people get skin cancer?

Long-term exposure to sunlight, especially during the teenage years and early adult decades, is the single most important factor in the formation of skin cancer. After years of ultraviolet light damage to sun-exposed areas, normal skin cells may transform into cancer cells. As a collective group, these cells will divide more rapidly than the surrounding skin cells, until they become readily visible to patients and dermatologists as a skin cancer.

What are the treatment options for skin cancer?

Depending on the specific characteristics of your skin cancer, a number of different treatments can be used. These treatments include excision of the tumor, curettage and electrodessication, and Mohs Surgery.

What is Mohs Micrographic Surgery?

Mohs micrographic surgery is the gold treatment of choice in basal and squamous cell carcinoma, when they become large in size and/or effect important functional areas like the head and neck. The goals of this procedure are to completely remove the cancer, preserve normal skin function and are to provide an optimal cosmetic result. Overall, this treatment has a 97-99% cure rate for skin cancer.

The Mohs Procedure

The Mohs procedure entails a series of repeated “stages” to ensure complete cancer removal. During each stage, a layer of tissue is removed, processed and examined under the microscope to determine if any residual cancer remains.

Before the Mohs procedure, an area surrounding the skin cancer will be numbed with local anesthetic. Once numbed, a thin, “saucer-shaped” layer of tissue is removed. A small portion of healthy tissue around the skin cancer is taken, in attempt to clear the tumor during the first stage of the procedure. This takes approximately 5 minutes, after which time your wound will be bandaged.



Figure 1: Left: Demonstrates the irregular appearance of skin cancer compared to healthy tissue. **Middle:** Demonstrates an example of the first layer of tissue take during MMS with residual tumor tissue. **Right:** Demonstrates the residual tumor embedded in the surrounding tissue.

*Figures included for IRB review board only, demonstrate how models will be used. For more information see supplemental document

The tissue specimen is then taken to the lab, marked and processed. Using a map of the cancer cells in relation to the healthy tissue, the surgeon can determine during microscopic examination if there are remaining cancer cells. The entire stage takes about 1 hour. Approximately half of patients will need additional stages during the procedure. These stages are completed in a similar manner, which will increase the time needed to complete the procedure.

Following complete removal of the cancer, your surgeon will determine the best method to treat your wound. Options include allowing the wound to heal naturally, using stitches to sew the wound closed, using a skin grafting to cover the surgical wound, or by using a flap procedure to close the wound. This will be discussed more extensively with your surgeon during the procedure, based on the size and location of your skin cancer.

What are the advantages of Mohs?

The major advantages to Mohs Surgery are that this procedure has the highest cure rate for skin cancer, removes a minimal amount of healthy tissue, provides the opportunity to achieve an optimal cosmetic outcome with minimal scarring, and eliminates the need for general anesthesia or hospitalization.

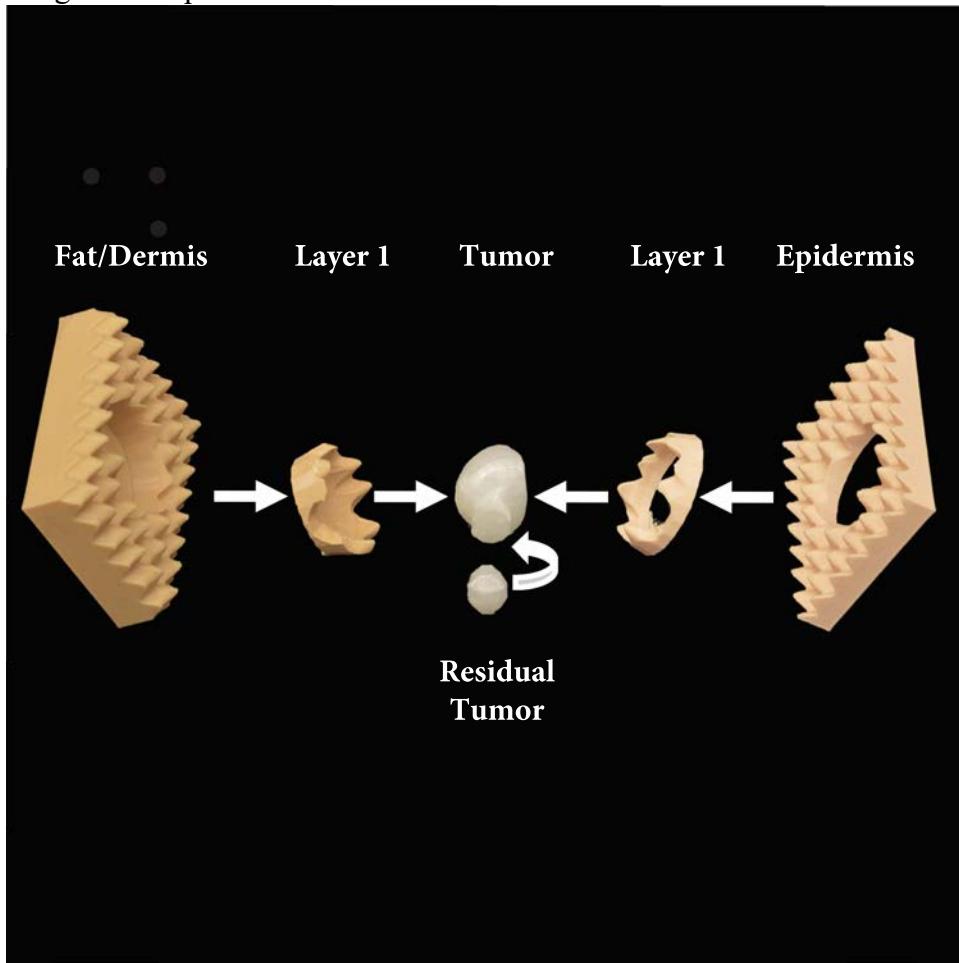
What are the risks of Mohs?

The risks of surgery, as with any trauma to the skin, risks include bleeding, bruising around the surgical area, a risk of infection below 1% and local numbness. In addition, there is often a need to extend surgical incisions approximately 3 times the length of the initial incision to facilitate optimal closure of the surgical wound. Again, these risks are shared by excisional procedures, whether MMS or non-MMS.

Appendix B

3D Printed Mohs Micrographic Surgery Model

Images of 3D printed MMS model



Appendix C

SELF-EVALUATION QUESTIONNAIRE STAI AD Form Y-1

Please provide the following information:

Age _____ Previous Mohs (Circle) Y N Gender (Circle) M F

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then blacken the appropriate circle to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

Very Much So
Moderately So
Somewhat
Not At All

1	I feel calm	1	2	3	4
2	I feel secure	1	2	3	4
3	I am tense	1	2	3	4
4	I feel strained	1	2	3	4
5	I feel at ease	1	2	3	4
6	I feel upset	1	2	3	4
7	I am presently worrying over possible misfortunes	1	2	3	4
8	I feel satisfied	1	2	3	4
9	I feel frightened	1	2	3	4
10	I feel comfortable	1	2	3	4
11	I feel self-confident	1	2	3	4
12	I feel nervous	1	2	3	4
13	I am jittery	1	2	3	4
14	I feel indecisive	1	2	3	4
15	I am relaxed	1	2	3	4
16	I feel content	1	2	3	4
17	I am worried	1	2	3	4
18	I feel confused	1	2	3	4
19	I feel steady	1	2	3	4
20	I feel pleasant	1	2	3	4

Appendix D

SELF-EVALUATION QUESTIONNAIRE STAI AD Form Y-2

DIRECTIONS:

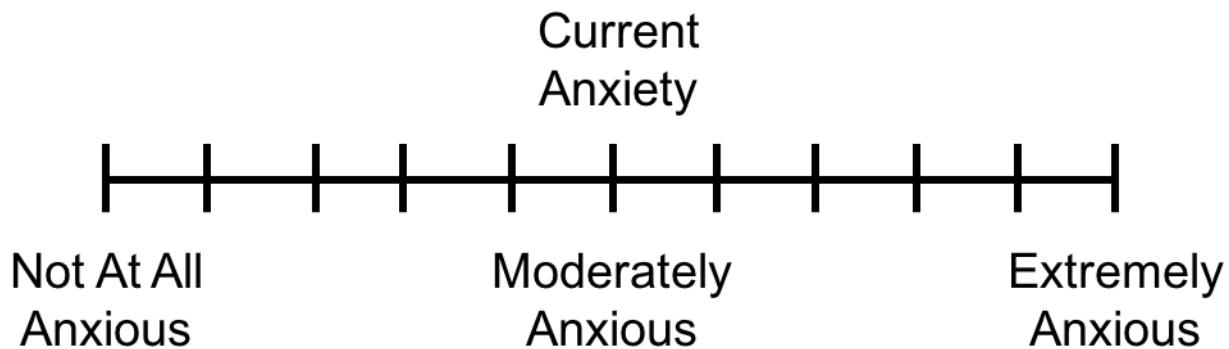
A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate you generally feel.

Almost
Always
Often
Sometimes
Never
Almost

21	I feel pleasant	1	2	3	4
22	I feel nervous and restless	1	2	3	4
23	I feel satisfied with myself	1	2	3	4
24	I wish I could be as happy as others seem to be	1	2	3	4
25	I feel like a failure	1	2	3	4
26	I feel rested	1	2	3	4
27	I am "calm, cool, and collected"	1	2	3	4
28	I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29	I worry too much over something that really doesn't matter	1	2	3	4
30	I am happy	1	2	3	4
31	I have disturbing thoughts	1	2	3	4
32	I lack self-confidence	1	2	3	4
33	I feel secure	1	2	3	4
34	I make decisions easily	1	2	3	4
35	I feel inadequate	1	2	3	4
36	I am content	1	2	3	4
37	Some unimportant thought runs through my mind and bothers me	1	2	3	4
38	I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39	I am a steady person	1	2	3	4
40	I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

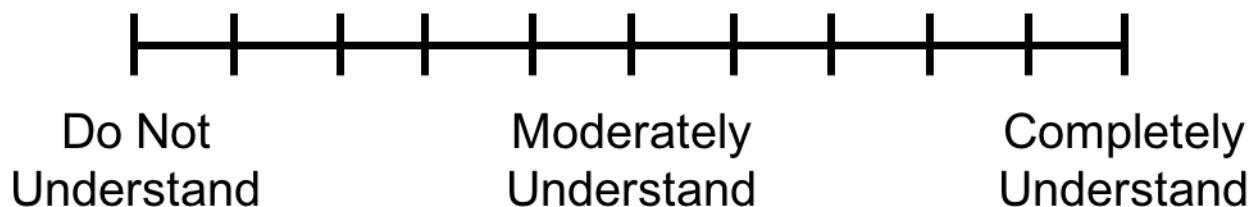
Appendix E

VAS Patient Anxiety



VAS Patient Understanding of Mohs

My Current Level of Understanding
of The Mohs Procedure



Appendix F

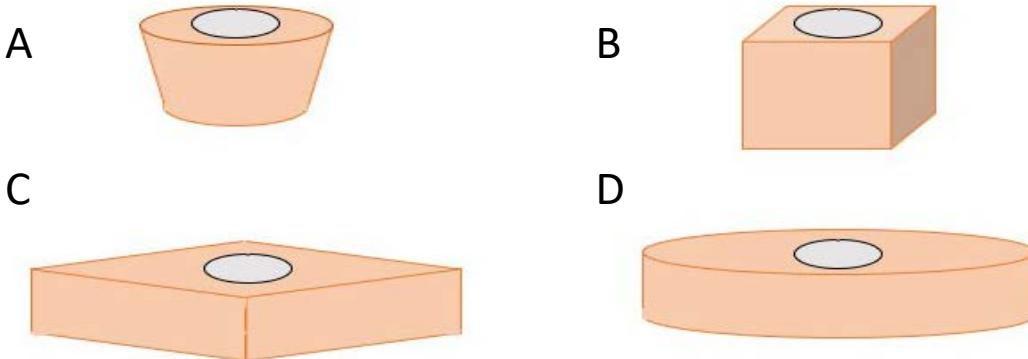
Mohs Quiz

Thank you for your participation in our study! We ask you to fill out the quiz and choose the best answer for each question. Do not worry about your score, as you cannot fail.

1. What are the main benefits of the Mohs procedure compared to other treatments?

- A) The procedure is faster
- B) The procedure allows for easier repair of the wound
- C) The recovery time is faster
- D) Mohs removes the entire cancer in one procedure and has a higher cure rate.

2. How is the cancer removed in the first stage of the Mohs procedure?



3. How can my doctor be sure that all cancer cells are removed?

- A) You will find out your results in one week after a pathologist views the specimen
- B) A special dye is added that “lights up” in cancer cells
- C) Based on the size of the visible tumor
- D) Your doctor examines the skin under the microscope and maps out any remaining cancer

4. Do all patients require a second stage of cancer removal?

- A) No, a second stage is not necessary if all of the cancer was removed
- B) Yes, a second stage is always removed to help close the surgical wound
- C) No, the Mohs procedure is completed in one layer always
- D) Yes, a few extra millimeters of extra healthy tissue are always removed

5. What are the reasons for a layer-by-layer approach when removing the cancer?

- A) To ensure that the surgical wound can be closed easily
- B) To remove a minimal amount of healthy skin, while removing the whole cancer
- C) There is less bleeding with this approach
- D) To prevent infection

6. Why do Mohs surgeons remove an area of healthy skin around the cancer?

- A) To try to remove all of the cancer in one stage
- B) The visible portion of the cancer is the only portion of the cancer that matters
- C) None of the skin surrounding the cancer is “healthy”
- D) The skin is going to die because it is so close to the cancer

Appendix G

Satisfaction Survey

1. Overall how satisfied are you with today's explanation of the Mohs Procedure?

- A) Not at All Satisfied
- B) Somewhat Satisfied
- C) Neutral
- D) Moderately Satisfied
- E) Entirely Satisfied

2. Do you feel that this explanation can be improved?

- A) Disagree
- B) Somewhat Disagree
- C) Neutral
- D) Somewhat Agree
- E) Strongly Agree

3. Would you recommend that patients be provided an explanation in a similar manner?

- A) Disagree
- B) Somewhat Disagree
- C) Neutral
- D) Somewhat Agree
- E) Strongly Agree