The use of 3-dimensionally printed models to optimize patient education and alleviate perioperative anxiety in Mohs micrographic surgery: A randomized controlled trial

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Background: Perioperative patient anxiety in Mohs micrographic surgery (MMS) is associated with increased postoperative pain and decreased satisfaction.

Objective: To determine whether a 3-dimensionally printed MMS model with standardized education (SE) improves perioperative patient understanding and anxiety.

Methods: An unblinded, randomized controlled trial was conducted, with patients randomly assigned to receive the MMS model plus SE or SE alone. Baseline and poststage understanding and anxiety were evaluated with the Visual Analog Scale (VAS) and State-Trait Anxiety Inventory (STAI). Additionally, patients completed a 6-item knowledge assessment.

Results: Eighty-two patients were enrolled, 42 in the MMS model and 40 in the SE group, with similar group mean age (67.8 years), sex (59.8% male), and previous MMS experience (47.6%). Both groups experienced significant reductions in VAS anxiety and State-Trait Anxiety Inventory scores and significant increases in VAS understanding. Compared with SE alone, the MMS model group had larger VAS anxiety reduction (change, −1.31; approaching significance) than the SE group (change, −0.52; $P = .052$) and 5.59 (93.25%) correct responses versus 5.15 (85.83%) correct responses in the SE group ($P < .028$).

Limitations: Overestimations of baseline patient anxiety in our population and 91.1% recruitment of the intended study population limited study power.

Conclusion: A 3-dimensionally printed MMS model with SE may improve patient understanding of MMS and decrease perioperative anxiety. (J Am Acad Dermatol 2019;81:1339-45.)

Key words: 3D printing; Mohs micrographic surgery; patient anxiety; patient education.

Performing Mohs micrographic surgery (MMS) under local anesthesia spares patients the risks of general anesthesia but may increase perioperative patient anxiety.[1-3] Factors that may contribute to perioperative patient anxiety include concerns related to skin cancer diagnosis, fear of intraoperative or postoperative pain, procedural complications, and cosmetic result.[1-3] Optimizing the patient experience is of utmost importance because perioperative anxiety in MMS is associated with increased postoperative pain and decreased patient satisfaction.[1,2] Perioperative anxiety is

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considered to be a critical component of patient care in MMS, much like pain is often regarded as the sixth vital sign.

In attempts to optimize perioperative anxiety in MMS, pharmacologic and nonpharmacologic interventions have been investigated.[4-8] Recently, the use of the peanut butter cup analogy was suggested to improve patient education and decrease anxiety during MMS.[9] Analogies remain an important tool in medical education. Three-dimensional printing (3DP) technology has enabled the development of widely accessible, fully customizable models that improve delivery of medical education and learner anxiety.[10] The proposed mechanism by which educational models improve anxiety is by decreasing the cognitive load associated with the desired material,[10,11] thereby making information more understandable to the learner. Because verbal counseling is frequently used as the vehicle for delivering medical information, this information can be condensed into a standardized education (SE) protocol and delivered to patients. In our randomized controlled trial, we sought to determine if a 3DP MMS model in conjunction with an SE protocol was more effective than SE alone in improving patient understanding, presumably by decreasing cognitive load and thereby serving as a mechanism to reduce perioperative anxiety in MMS.

CAPSULE SUMMARY

- Perioperative anxiety in Mohs micrographic surgery is associated with poor outcomes and patient dissatisfaction.
- A 3-dimensionally printed Mohs micrographic surgery model with standardized education enhanced patient understanding of the procedure and decreased perioperative anxiety. This noninvasive, low-cost strategy may improve patient satisfaction and outcomes in Mohs micrographic surgery.

METHODS

Trial design

A single-center, randomized controlled trial was completed from March 27, 2018, through June 28, 2018, at an outpatient dermatology office affiliated with an urban, academic medical center. A total of 88 patients were assessed for eligibility and randomly assigned 1:1 to the 3DP MMS model or SE groups. Six patients declined to participate or met exclusion criteria before baseline testing. Eighty-two patients completed the experimental protocol, 42 in the MMS model group and 40 in the SE group, and were included in final analysis (Fig 1).

This study received approval from the Case Comprehensive Cancer Center institutional review board and University Hospitals Cleveland Medical Center institutional review board and was registered to ClinicalTrials.gov (no. NCT03461965). Informed consent was obtained from patients before initiation of the study protocol, and all patient data remained deidentified.

Participants

All patients between the ages of 18 and 90 years and having MMS for removal of nonmelanoma skin cancer were eligible. Patients were excluded if they were unable to complete study questionnaires independently, did not have MMS, or were administered anxiolytic medication during the perioperative period. Patients self-reported age, sex, and prior history of MMS. All procedures for were performed by the same female surgeon, Dr Mann, at the University Hospitals Cleveland Medical Center Department of Dermatology.

Interventions

Patients in both groups were educated by a male (Dr Biro) or female (Ms Huynh) member of the research team. Participants randomly assigned to the SE group received verbal counseling about MMS from a standardized script written by Dr Biro under supervision of Dr Mann. Research team members were instructed to present information from the script and defer procedural questions to the medical team, and they were allotted 5 minutes to complete the SE educational protocol. Participants randomly assigned to the MMS model group received verbal counseling about MMS from the SE script with addition of a physical demonstration with a 3DP MMS model (Fig 2). The 3DP MMS model was developed by Dr Biro using Blender 2.7 software (Blender Foundation, Amsterdam, Netherlands) printed with a Makerbot Replicator 2 Printer (Makerbot Industries, Brooklyn, New York) and contained 2 skin layers for simplification, a layer of removed tissue, and residual tumor embedded in the bottom layer of skin. The same instructions and constraints for the SE group were applied to the MMS model group.

Outcomes

Patients had baseline testing before the assigned intervention, either the SE or MMS model, and post-testing after completion of the first MMS stage. The primary outcome was reduction of patient anxiety, which was determined using 2 well-validated anxiety

Abbreviations used:

3DP: 3-dimensionally printed
MMS: Mohs micrographic surgery
SE: standardized education
STAI: State-Trait Anxiety Inventory
VAS: visual analog scale

measures, the visual analog scale (VAS) and State-Trait Anxiety Inventory (STAI).[4,6,12] The VAS is a 10-cm line, with 11 evenly spaced intervals ranging from *No Anxiety* to *Extreme Anxiety*. Patients marked their anxiety levels from 0 to 10, and values between intervals were rounded to the nearest 0.5 between values, as described in the experimental protocol.

The STAI[12] combines 2 20-question assessments: Form Y-1 measuring the patient's state, or dynamic, anxiety and Form Y-2 measuring patient's trait, or static, anxiety. State anxiety inventory items had preassigned values ranging from 1 to 4, where 1 represented *not at all*, 2 represented *somewhat*, 3 represented *moderately so*, and 4 represented *very much so*. Trait anxiety inventory items had preassigned values ranging from 1 to 4, where 1 represented *almost never*, 2 represented *sometimes*, 3 represented *often*, and 4 represented *almost always*. Total scores for each inventory ranged from 20 to 80, with increasing scores associated with higher levels of anxiety. Data for trait anxiety were collected only at baseline to ensure similar characteristics among groups. After consent, patients completed the VAS and both STAI questionnaires, and during posttesting patients completed only the VAS and STAI state anxiety questionnaire.

Secondary outcomes included patient understanding and satisfaction. Because no standardized measure of patient understanding exists for MMS, subjective and objective measures were used to analyze patient understanding. To assess patients' perceptions of their knowledge, the research team used a VAS entitled "My Current Comfort Level With My Understanding of the Mohs Procedure" that ranged from *Not at All Comfortable* to *Extremely Comfortable*, with values ranging from 0 to 10 at 0.5 intervals, similar to VAS anxiety scores. To assess objective knowledge, a 6-item test with multiple choice questions was created by investigators and included information discussed in the standardized script. Patients filled out the VAS assessing understanding at baseline and posttesting and the 6-item test at completion of posttesting. To gauge patient satisfaction, a 3-item Likert-like scale questionnaire was distributed to patients after completion of the protocol. This scale included questions regarding satisfaction with the explanation of the MMS procedure, if the explanation used could be improved, and if they recommended that other patients be provided a similar explanation of MMS.

Sample size

Our sample size, determined before initiation of the experiment, was 90, with 45 participants in each group. This calculation was based on a previous study[4] in which STAI state mean scores were approximately 38.7 at baseline, and it assumed that after the intervention we would be able to detect a 6-point difference on the STAI state anxiety form between the MMS model and SE group, with a power of 80% and a 5% rate of type I error.

Randomization

Based on a coin-flip randomization, patients who had MMS on Tuesdays were assigned to the MMS model group and those on Thursdays were assigned to the SE group. Tuesday and Thursday patients were from the same patient pool and presented to the same clinic location, and all procedures were completed by the same surgeon, Dr Mann.

Statistical analysis

All data analysis was completed in GraphPad Prism 7 (GraphPad Software, San Diego, CA) and SAS, version 9.14 (SAS Institute, Cary, NC) software. The associations of between-categorical variables, including patient sex, history of previous MMS, the 6-item knowledge assessment, and the 3-item Likert-like satisfaction survey, were analyzed using chi-square tests. The differences of continuous variables, including patient age and baseline and posttest VAS and STAI scores between treatment groups (MMS vs SE), were examined using the *t* test, and the differences of pretest (baseline) and posttest VAS and STAI scores within each treatment group were analyzed using the paired *t* test after checking normality. Wilcoxon rank-sum test or Wilcoxon signed-rank test was used instead if normality was violated. *P* values were not adjusted for multiple tests across different endpoints. All tests were 2-sided, and a *P* value of less than .05 was considered statistically significant.

RESULTS

The mean age of patients enrolled was 67.8 years (standard deviation, ±12.1 years), 59.8% of the patients enrolled were male, and 52.4% of the patients had not previously had MMS. No baseline differences existed between group demographics, anxiety, or subjective understanding, as summarized in Table I. Subgroup analysis showed that no significant differences existed based on which research

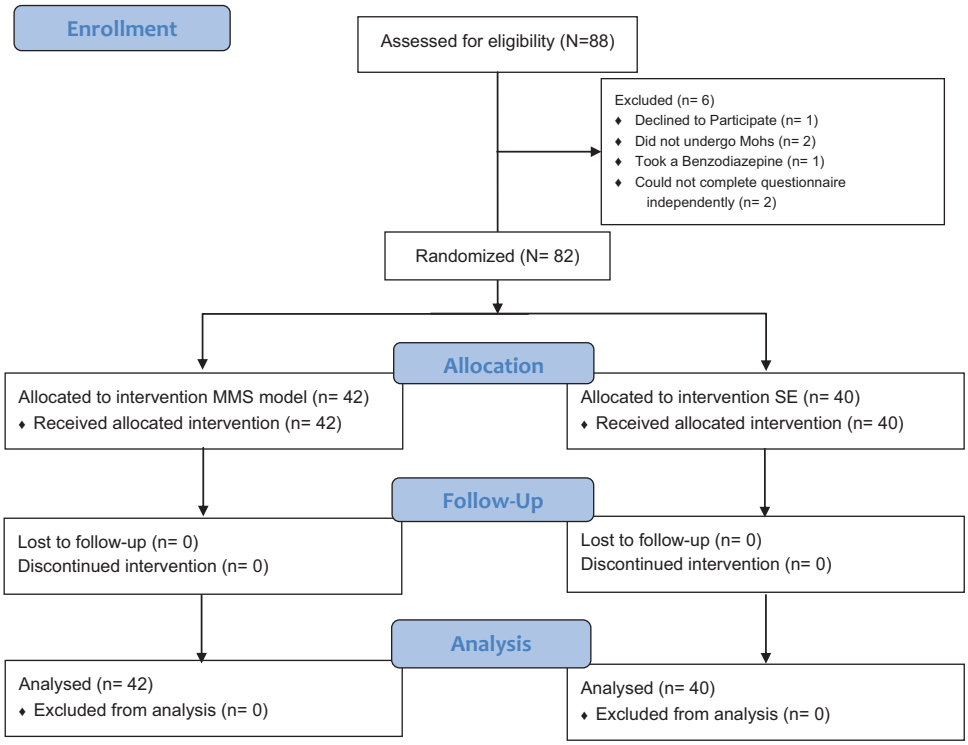

Fig 1. Participant recruitment and randomization. *SE*, standardized education.

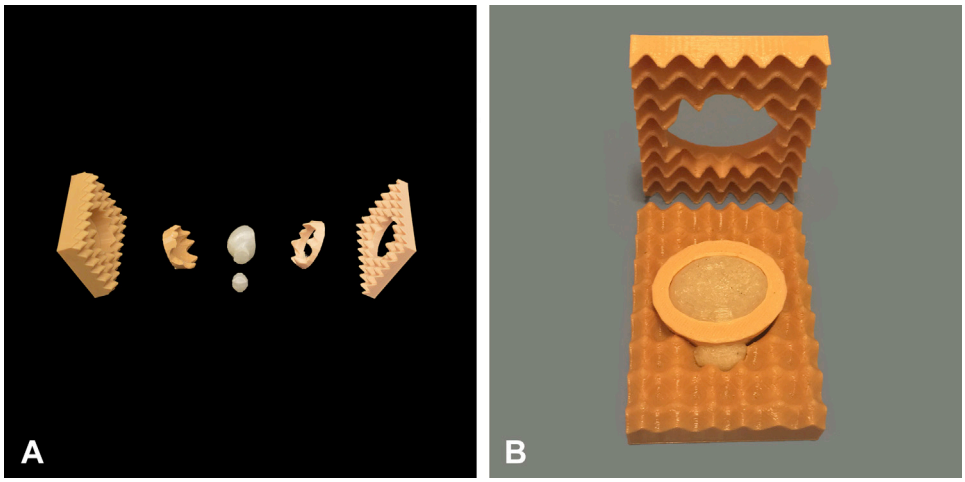

Fig 2. The 3DP MMS model, expanded view. **A**, Assembly of the 3DP MMS model. Complete 6-piece model costs $4.00 in plastic material and can be printed in 3 hours or less. An expanded view of the 6 components used in the model is shown. **B**, An overhead view, as presented to the patient, showing the tumor extending beyond the surgical margins. *3DP*, 3-Dimensionally printed; *MMS*, Mohs micrographic surgery.

team member completed the protocol. The MMS model group had decreased VAS anxiety scores, from 3.00 to 1.7 (change, −1.3; $P < .0001$), and STAI state anxiety scores, from 32.7 to 27.8 (change, −4.9; $P < .0001$), whereas the SE group had decreased VAS anxiety scores, from 2.5 to 2.0 (change, −.5; $P < .04$) and STAI state anxiety, from 33 to 29.7 (change = −3.3, $P < .03$). Larger reductions in anxiety were observed in the MMS model group, but only the VAS for anxiety approached statistical significance ($P = .052$) (Fig 3 and Table II). When subgroup analysis was completed for the VAS for anxiety and the STAI, a significant difference was observed for reduction in anxiety in the

Table I. Patient characteristics in randomly assigned groups*

Characteristic	Control group	Experimental group	Total	*P* value
Patients, n (%)	40 (48.88)	42 (51.12)	82 (100)	
Age in years, mean (SD)	67.83 (12.89)	67.83 (11.34)	67.83 (12.10)	.92
Patient sex, n (%)				
Male	25 (62.5)	24 (57.14)	49 (59.76)	.62
Female	15 (37.5)	18 (42.86)	33 (40.24)	
Patients who previously had MMS, n (%)				
Mohs experience	19 (47.5)	20 (47.62)	39 (47.56)	.99
No Mohs experience	21 (52.5)	22 (52.38)	43 (52.44)	
Baseline STAI form Y-2, "Trait Anxiety," mean (SD)	31.1 (8.85)	29.8 (7.53)	30.5 (8.28)	.65

MMS, Mohs micrographic surgery; *SD*, standard deviation; *STAI*, State-Trait Anxiety Inventory.
*There were no significant differences between the control and experimental groups.

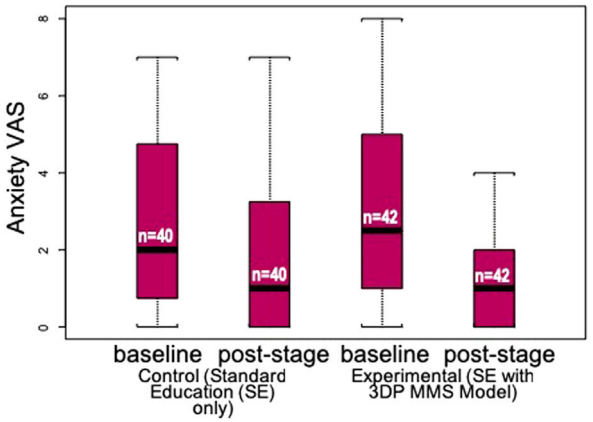

Fig 3. Patient-reported anxiety by VAS showed greater improvement in the experimental versus control group. A greater magnitude of improvement was observed for patient volunteers randomly assigned to the group that used a 3DP model during counseling versus the group randomly assigned to received standard of care with the handout only, summarized in a boxplot. Bold black bars indicate the medians, red boxes show the 25th to 75th percentiles, brackets encompass the entire range, and dot-dash whisker lines highlight outliers. P = .052 when comparing the improvement in anxiety (poststage minus baseline) between the experimental and control groups (Student t test). *3DP*, 3-Dimensionally printed; *SE*, standardized education; *VAS*, visual analog scale.

experimental group across both measures: VAS anxiety decreased from 3.0 to 1.5 ($P < .01$); STAI state anxiety decreased from 36 to 29.22 ($P < .01$), which was not observed in the control group; VAS anxiety decreased from 3.0 to 2.45; and STAI state anxiety decreased from 32.7 to 30.3. Both groups had significant improvements in VAS for understanding scores: from 6.17 to 8.63 (change, 2.56: $P < .0001$) for the MMS group (the experimental group) and from 7.21 to 9.04 (change, 1.83; $P < .0001$) for the SE group (the control group). Differences in subjective understanding were not statistically significant between the groups. For the 6-item knowledge assessment, the MMS model group averaged significantly higher scores than the SE group (MMS model, 5.59 [93.25%] correct responses vs SE group, 5.15 [85.83%] correct responses; $P < .028$). Finally, overall satisfaction was significantly higher on the 3-item Likert-like scale assessment in the MMS group ($P < .03$).

DISCUSSION

Optimal management of perioperative anxiety in MMS is an increasingly important element of patient care. In our randomized controlled trial, we found that preoperative counseling with a 3DP MMS model, along with standardized verbal counseling, provided patients with greater objective understanding of the procedure and was associated with reductions in patient VAS anxiety that approached statistical significance ($P = .052$). Several studies have assessed pharmacologic and nonpharmacologic interventions to alleviate perioperative patient anxiety in MMS. These studies have shown anxiolytic effects of midazolam and personalized patient music in MMS. Ravitskiy et al[5] found a significant decrease in patient VAS anxiety at 60 minutes after a 1-time dose of 10 mg midazolam syrup compared with placebo alone. Although this therapy was effective at 60 minutes, anxiolytic effects of therapy were nonsignificant after 120 minutes.[5] Vachiramon et al[4] found that patients who listened to personalized music during MMS had a significant decrease in VAS anxiety and STAI state anxiety compared with those who did not.[4] Compared with our results, these trials had similar patient demographics, including patient age and prior MMS experience. One limitation of both of these studies was that the proposed intervention was compared with placebo or no intervention alone, whereas our patients were provided the same verbal

Table II. Summary of primary and secondary outcomes*

Outcome	Control	Experimental	*P* value
VAS: Anxiety			
Baseline VAS: Anxiety, mean (SD)	2.48 (1.99)	3.00 (2.36)	.38
Poststage VAS: Anxiety, mean (SD)	1.95 (2.12)	1.69 (2.03)	.61
P value compared with baseline	.038	<.0001	—
Change in anxiety VAS (poststage minus baseline), mean (SD)	−.53 (1.54)	−1.31 (2.00)	.052
STAI: Anxiety			
Baseline STAI form Y-1, "State Anxiety," mean (SD)	33.0 (10.79)	32.7 (8.80)	.93
Poststage STAI form Y-1, "State Anxiety," mean (SD)	29.7 (9.61)	27.8 (8.16)	.54
P value compared with baseline	.03	<.0001	—
Change in Anxiety "State Anxiety" (poststage minus baseline), mean (SD)	−3.3 (9.37)	−4.95 (6.95)	.352
VAS: Understanding			
Baseline VAS: Understanding, mean (SD)	7.21 (2.63)	6.17 (2.96)	.11
Poststage VAS: Understanding, mean (SD)	9.04 (1.24)	8.63 (1.53)	.31
P value compared with baseline	<.0001	<.0001	—
Change in Understanding VAS (poststage minus baseline), mean (SD)	1.83 (2.34)	2.46 (2.22)	.208
Correct quiz responses, n (%)	206 (85.83)	235 (93.25)	.007
Incorrect quiz responses, n (%)	34 (14.17)	17 (6.75)	

*Significant benefit was observed from the use of the 3-dimensionally printed model regarding anxiety and understanding.

information during counseling with the standardized script protocol.

Two prior studies have investigated the role of patient education for the reduction of anxiety in MMS. Sobanko et al[6] conducted a trial to determine if a preoperative educational telephone call 1 week before surgery compared with no call would decrease perioperative patient anxiety in MMS and found no difference. A limitation may have been that the intervention was too temporally distant from surgery to have the desired anxiolytic effect. Additionally, Hawkins et al[7] found decreased perioperative anxiety with explanatory video modules in MMS. These results must be interpreted with caution, however, because anxiety data were provided for only 2 of the 4 total experimental groups, and comparison data were unavailable.

A key strength of our trial includes the standardized script protocol used in both groups, which allowed us to assess the impact of standardized verbal education alone versus the additional benefit of the 3D MMS model. Other strengths include the use of 2 well-validated markers of patient anxiety, the VAS and STAI, and similar baseline characteristics in both groups.[4,6,12] Despite these strengths, there are limitations to report. First, our trial was powered to detect differences in STAI scores with 45 patients in each group, but the goal enrollee number was not reached. Despite this limitation, we recruited 91.1% of our intended population, 93.3% of the MMS model group and 88.9% of the SE group. Completion of recruitment would unlikely have significantly affected our primary outcome. Administrative delays prevented completion of recruitment, which may, in part, explain the group differences of 0.5 points at baseline for VAS for anxiety and 1.0 points for VAS for understanding. Similar small differences in baseline VAS anxiety have been observed in previous studies, and the clinical importance of this is unknown.[4] Second, anticipated baseline patient anxiety may be overestimated in our patient population based on previous studies.[4] Our power calculation was based on the trial by Vachiramon et al,[4] in which patients had a higher baseline STAI anxiety of 38.7 in their experimental group versus 32.7 in our MMS model group. Possible explanations for the decreased anxiety in our study population include increased access to educational resources between diagnosis and MMS, increased awareness of the procedure, or education status of the patient population.

Additional limitations include the lack of a well-validated instrument to measure patient understanding. Our previous pilot data[13] suggested that the VAS can be used to evaluate patients' perceptions of their understanding, similar to the VAS for anxiety. To compare patients' perceptions of their understanding and objective understanding, we developed a 6-item knowledge assessment to measure patient understanding. Patients did not have statistically significant differences in the VAS for understanding; however, the application of this knowledge was significantly greater in the experimental group. This suggests that patients educated with a 3DP MMS model have increased short-term understanding of MMS versus patients educated with verbal education alone. We hypothesize that the mechanism for this is a reduction in cognitive load of the provided material. Whether this has an impact on long-term

learning, willingness to adhere to recommended follow-up skin examinations, or future MMS procedures remains to be investigated. The authors have made the model files used from the study available at the NIH 3D print exchange https://3dprint.nih.gov/discover/3dpx-007848 (National Institutes of Health, Washington DC).

CONCLUSION

Patient education with a 3DP MMS model along with SE before surgery increased patient understanding and decreased perioperative anxiety compared with SE alone. Because preoperative anxiety during MMS has been associated with increased pain and lower patient satisfaction, there is an increasing need to address perioperative anxiety. Here, we propose a low-cost, noninvasive tool that can be used in combination with other noninvasive treatments, such as music, to decrease perioperative patient anxiety in MMS. Our 3DP MMS model may decrease cognitive load, allowing patients to gain a greater understanding of a complex procedure and improving the counseling experience. Future investigation may address the long-term impact of this useful tool and whether similar interventions are applicable to other dermatologic and nondermatologic procedures.

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