Does a Mohs Consent Video Improve Patient Reported Outcomes?

DATE: OCTOBER 7, 2016 PRESENTED BY: JUSTIN J. LEITENBERGER, M.D.

Background

- Why does informed consent matter?

- Can technology improve patient outcomes or clinic efficiency in dermatologic surgery?


“all of medical ethics is but a footnote to informed consent”
—Mark Kuczewski, PhD

Definitions

- Moral informed consent
  - patient *actually* having made an informed voluntary decision with an appropriate level of disclosure

- Legal informed consent
  - having gone through appropriate steps so that consent will be considered legally valid (e.g., signing documents)

Legal Standards for Risk Disclosure in USA

- Professional standard
  - Provider must discuss what another reasonable provider in same field would discuss in similar clinical context
  - AL, AZ, AR, CO, FL, ID, IL, IN, KS, KY, ME, MD, MI, MO, MT, NE, NV, NH, NY, NC, SC, TN, VT, VA, WY
- Reasonable patient
  - Provider must discuss what reasonable patient in similar clinical context would want to know to make decision
  - AK, CA, CT, DE, DC, GA, HI, IA, LA, MA, MN, MS, NJ, NM, ND, OH, PA, RI, SD, TX, UT, WA, WV, WI
- Subjective patient
  - Provider must discuss what individual patient wants to know to make decision
  - OK, OR

Data from King and Moulton. Note that legal standards are subject to change. Relevant statutory and common law must be consulted for most current information.

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Professional or Physician-based Standard

- Critiques
  - Standards may not be universally agreed upon in profession or exist
  - Provider's sense of loyalty to each other may limit participation for 'expert' witnesses
  - Fails to address patient needs
  - Providers, in general, disclose very little

Stoff, BK, et al. Reframing risk part I: Legal and ethical standards for medical risk disclosure JAAD, Volume 69, Issue 4, October 2013, Pages 634–636

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Reasonable Patient Standard

- Adopted in 23 states in response to criticisms of professional standard
- Typical patient standard

- Critiques
  - Highly variable among patients to determine what a reasonable patient would want to know
  - No resource for medical literature or colleagues to determine adequacy of disclosure content
  - Hypothetical reasonable patient may not satisfy needs of the individual patient (medical, cultural, religious)

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Subjective Patient Standard

- The health care provider obligated to discuss what the individual patient wants to know
- Applies in OK and OR
- Favored by authorities on biomedical ethics

- Critiques
  - Courts resist due to lack of objectivity or ‘adherence to standard’
  - Unreasonable for healthcare provider to probe deeply into value system of each patient
  - Most challenging as information must be tailored

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Multimedia Presentations

Review

Surgical Innovation
20(1) 13–23

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http://sri.sagepub.com
SAGE

The Use of Multimedia Consent Programs for Surgical Procedures: A Systematic Review

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Abstract

Objective. To compare multimedia and standard consent, in respect to patient comprehension, anxiety, and satisfaction, for various surgical/interventional procedures. **Data sources.** Electronic searches of PubMed, MEDLINE, Ovid, Embase, and Google Scholar were performed. Relevant articles were assessed by 2 independent reviewers. **Study selection.** Comparative (randomized and nonrandomized control trials) studies of multimedia and standard consent for a variety of surgical/interventional procedures were included. Studies had to report on at least one of the outcome measures. **Data extraction.** Studies were reviewed by 2 independent investigators. The first investigator extracted all relevant data, and consensus of each extraction was performed by a second investigator to verify the data. **Conclusion.** Overall, this review suggests that the use of multimedia as an adjunct to conventional consent appears to improve patient comprehension. Multimedia leads to high patient satisfaction in terms of feasibility, ease of use, and availability of information. There is no conclusive evidence demonstrating a significant reduction in preoperative anxiety.

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Multimedia Presentations

- Patient Satisfaction ↑
- Patient Knowledge ↑
- Anxiety ↔

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Multimedia interventions

- At least 9 randomized studies using adjunct multimedia in surgical consent
  - Scores for understanding, 59-82%
  - Mean improvement score, 13.6% compared to standard informed consent

- Pt satisfaction increased, but of those with poor outcomes, pts had poor recollection of key messages

Muslow et al. Beyond Consent – improving understanding in surgical patients. Am J. Surg 2012.

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Multimedia interventions - MMS

- Migden, M, Chavez-Frazier A., Nguyen T. The use of high definition video modules for delivery of informed consent and wound care education in the Mohs Surgery Unit. Semin Cutan Med Surg. 2008 Mar ; 27(1): 89-93.
- Mohs educational video and after-care video
- Patients in video group preferred this over physician/nurse discussion alone.

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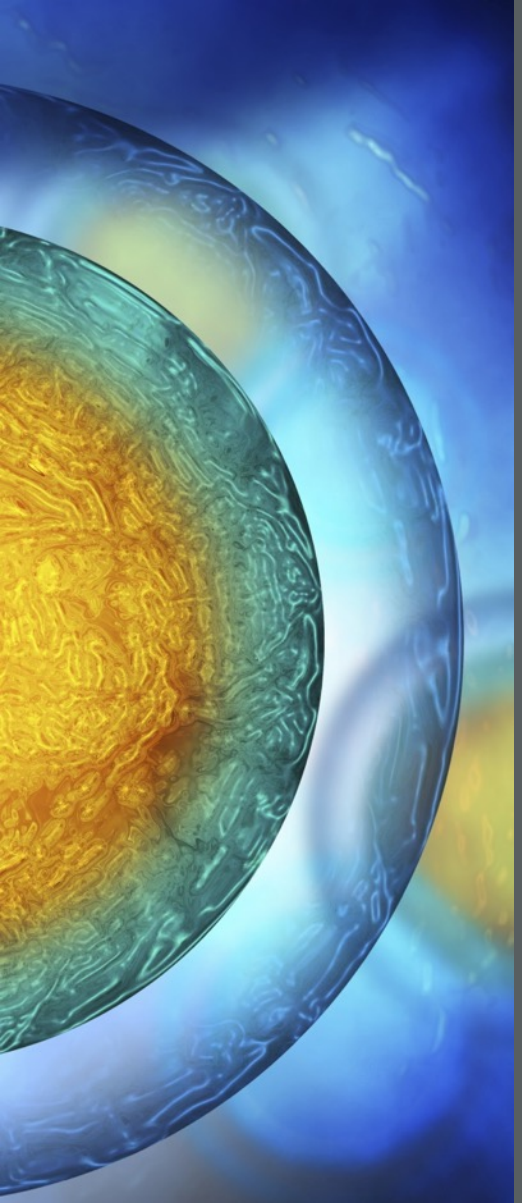

A problem

- Patients typically perceive the informed consent process as an overwhelming formality and ultimately feel disempowered
- .

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Project Aims

- We developed a multimedia presentation aimed at informing patients of the risks and potential complications, benefits and alternatives to Mohs surgery

- To determine the effect of using a multimedia presentation during the informed consent process on patient anxiety, understanding and satisfaction when compared to the conventional informed consent process

Mohs Consent Process

- Patients are mailed a Mohs Surgery pamphlet
- On the day of surgery, the surgeon performs a consultation and informed consent about the procedure
- Patient signs the informed consent form and procedure begins

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Mohs Consent Video

- Approximately 2 minute video produced at OHSU
- A longer 6 minute version is available online at the department website
- Outlines the risks, benefits and alternative treatments prior to Mohs surgery

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Study Design

- Study population is OHSU Mohs surgery patients during October-December 2015

- 2 study groups
  - Control group: mailed standard preoperative pamphlet plus day-of verbal informed consent process

  - Study group: receives above plus watches additional 2-minute multimedia video

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Study Design

- Randomized to 1 of 2 groups using online randomizer tool at Randomizer.org
- Sticker used to denote intervention group

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Study Protocol

- Control group met with surgeon for review of RBA and informed consent signed
- Intervention group watched video prior to first Mohs stage in addition to above
- All participants received questionnaire after their first Mohs stage to complete in waiting room
- Questionnaire returned when roomed for closure/next stage

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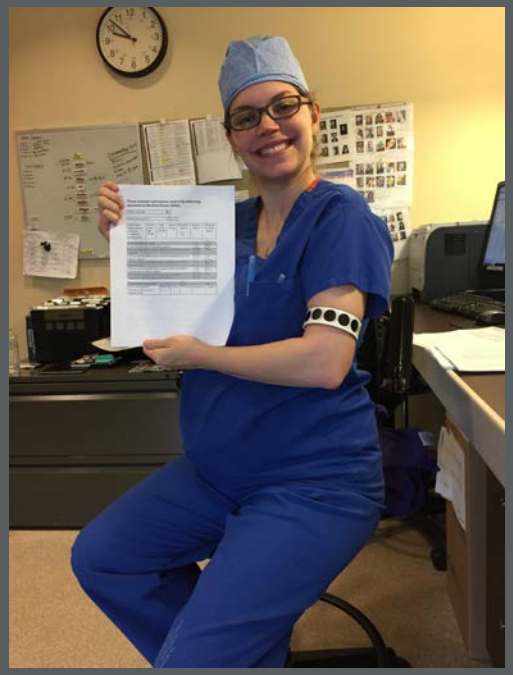
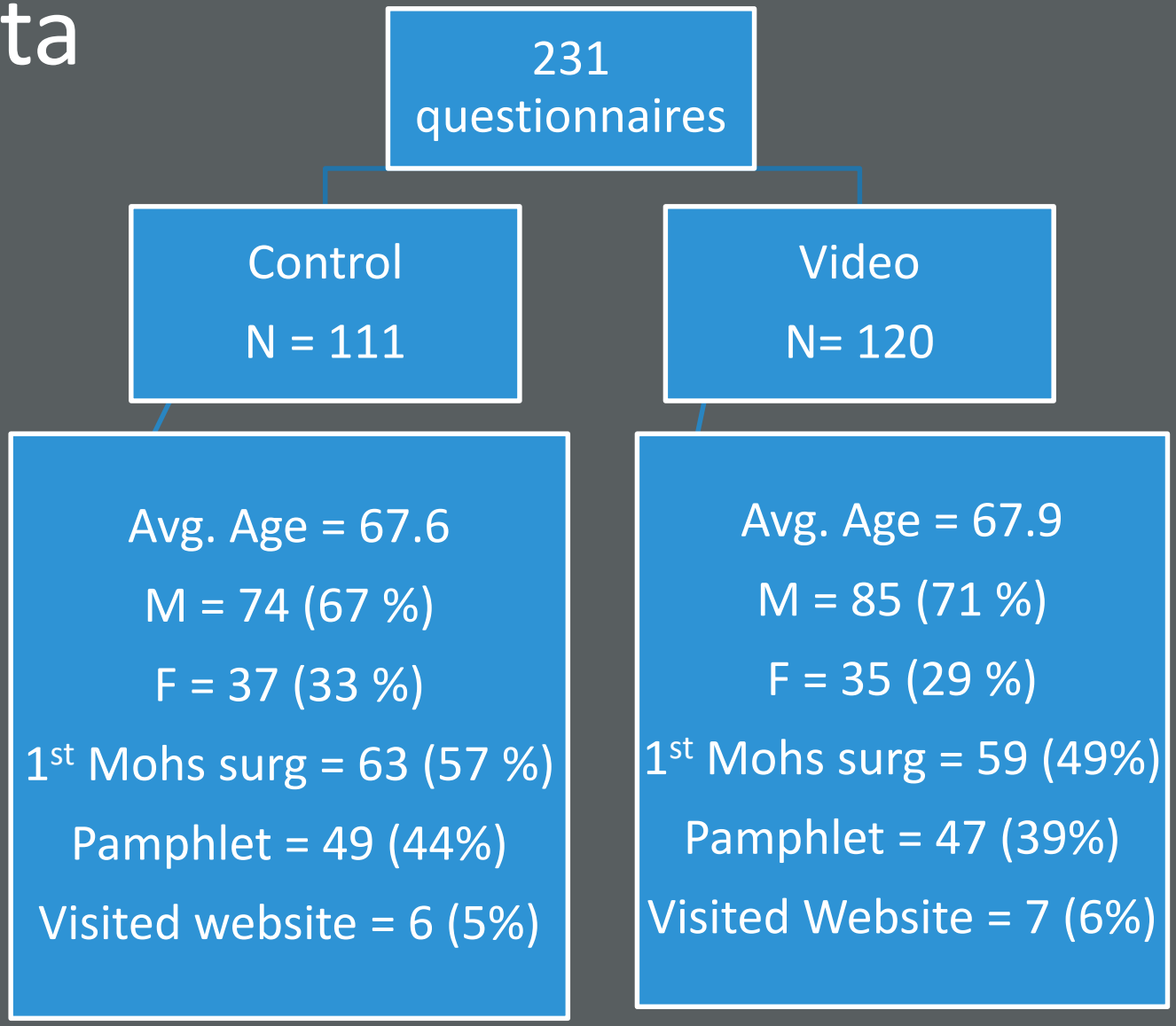
Questionnaire

- Questionnaire included 4 sections
  - Patient characteristics (12 questions)
  - Knowledge Assessment (10 questions)
  - Short STAI-Y anxiety scale (10 questions)
  - Patient satisfaction (8 questions)

Data Collection



Data


231 questionnaires
Control
N = 111
Video
N= 120
Avg. Age = 67.6
M = 74 (67 %)
F = 37 (33 %)
1st Mohs surg = 63 (57 %)
Pamphlet = 49 (44%)
Visited website = 6 (5%)
Avg. Age = 67.9
M = 85 (71 %)
F = 35 (29 %)
1st Mohs surg = 59 (49%)
Pamphlet = 47 (39%)
Visited Website = 7 (6%)

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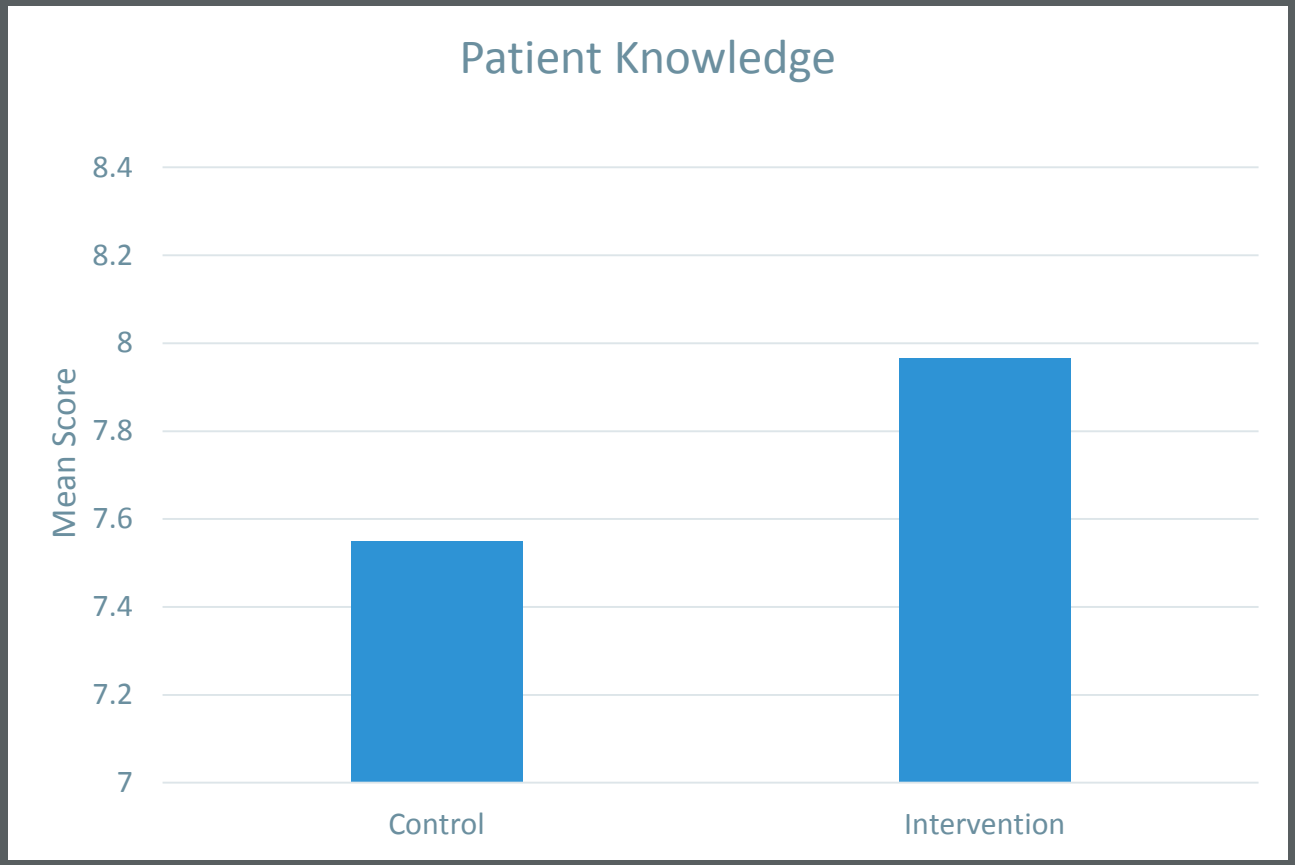
Patient Knowledge



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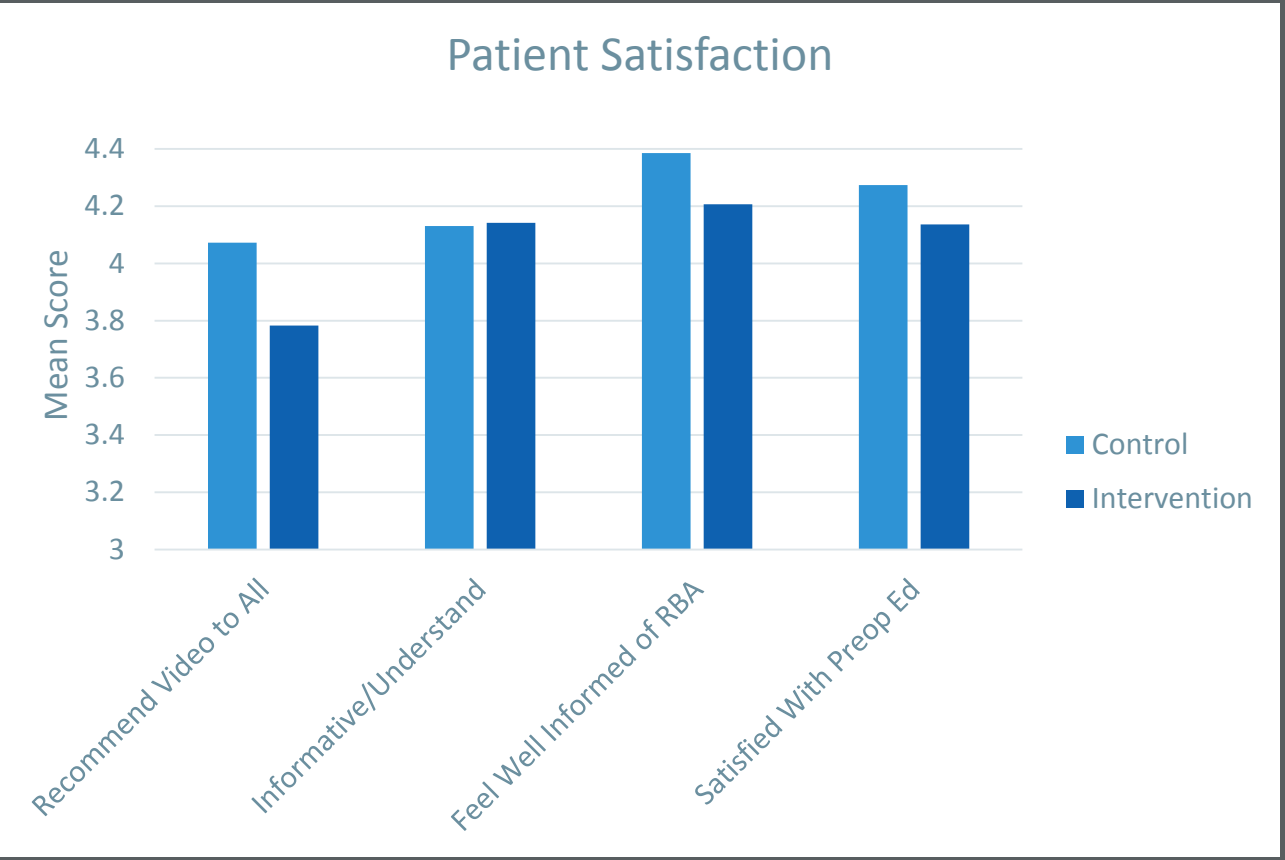
Patient Satisfaction



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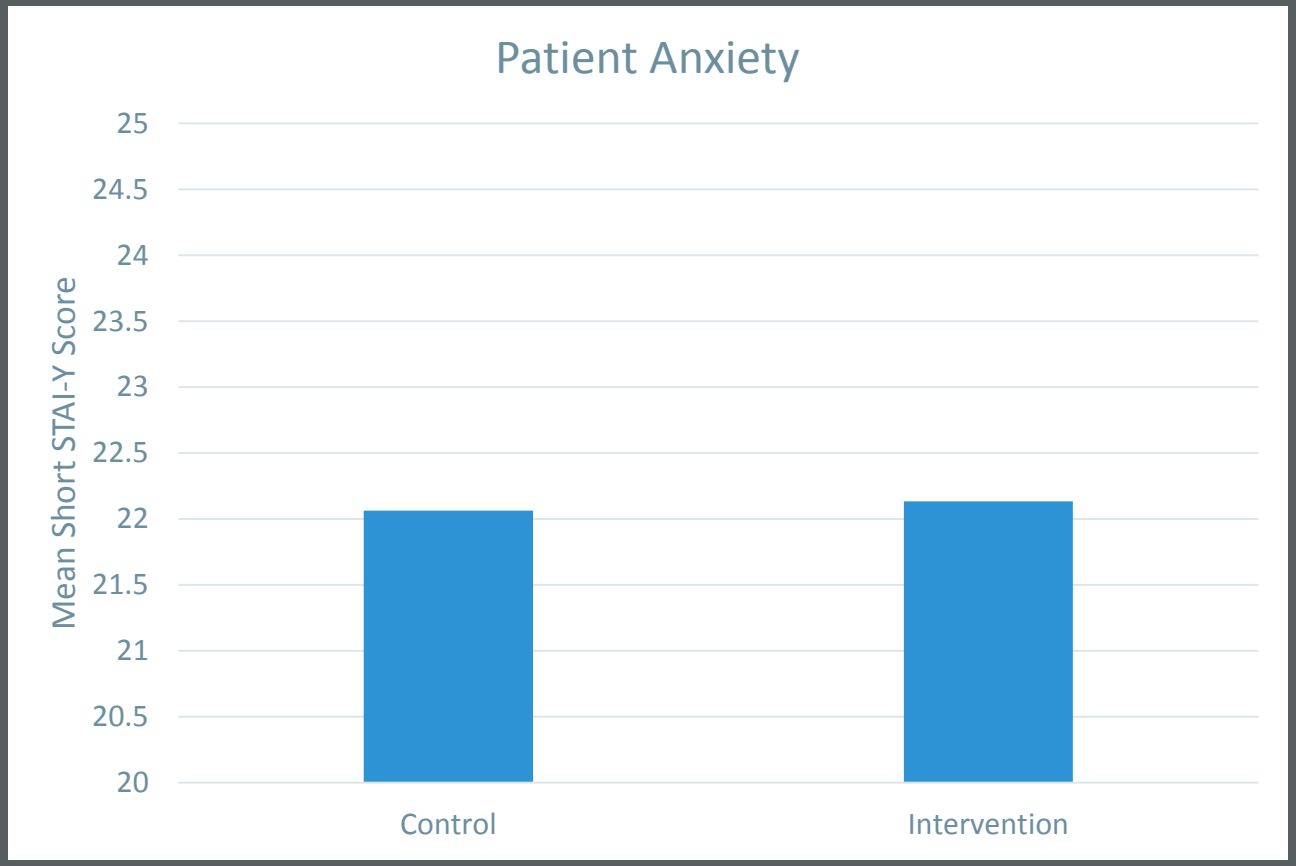
Patient Anxiety



Conclusions

- Overall a well-received tool
  - Integrated well into workflow
  - Include more/additional video re: wound care
- Impact limited by brevity and lack of depth
- Decreased face to face time with patient prior to procedure

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Thank you!