THOMAS JEFFERSON UNIVERSITY
Sidney Kimmel Cancer Center

Assessing Patient Satisfaction and Confidence After Use of Educational Video to Augment Surgical Consent for Thyroid Surgery

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator:

Signed: _____ Date: _____

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Statement of Compliance

This study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and Thomas Jefferson University research policies

List of Abbreviations

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRO	Clinical Research Organization
CTCAE	Common Terminology Criteria for Adverse Events
DSMC	Data and Safety Monitoring Committee
DSMP	Data and Safety Monitoring Plan
FDA	Food and Drug Administration
FWA	Federalwide Assurance
GCP	Good Clinical Practice
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
N	Number (typically refers to participants)
NCI	National Cancer Institute
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PHI	Protected Health Information
PI	Principal Investigator
PRC	Protocol Review Committee
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SDS	Safety Data Sheet (formerly MSDS; Material Safety Data Sheet)
SKCC	Sidney Kimmel Cancer Center
SOP	Standard Operating Procedure

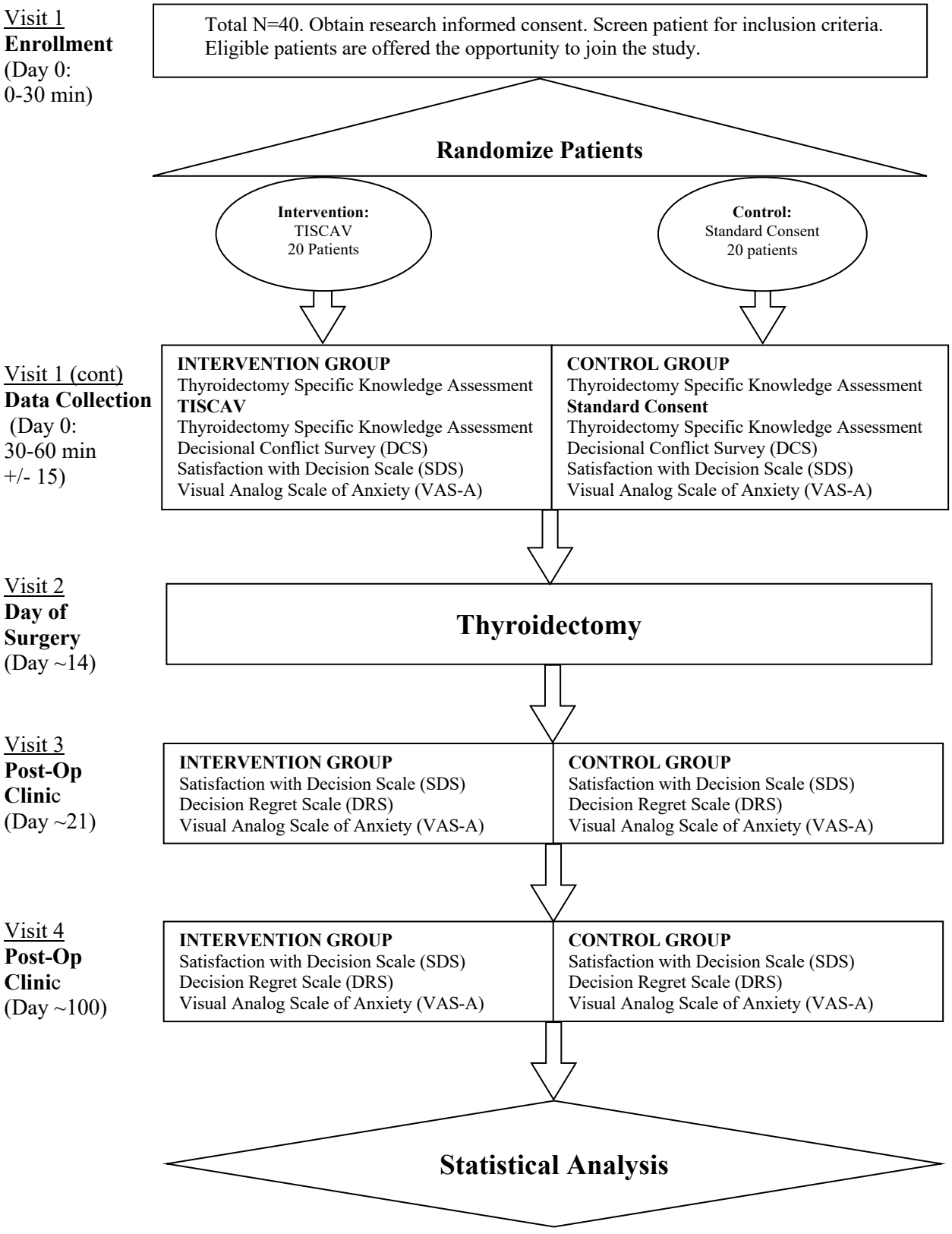
TJU	Thomas Jefferson University
UAP	Unanticipated Problem
HNSA	An Investigator-created Head and Neck-specific Surgical Assessment of Patient Comprehension ("Head and Neck Surgical Assessment")
TISCAV	Thyroid Informed Surgical Consent Augmenting Video
SC	Standard Consent
KA	Knowledge Assessment
DCS	Decision Conflict Survey
SDS	Satisfaction with Decision Scale
DRS	Decision Regret Scale
VAS-A	Visual Analog Scale for Anxiety

Study Summary

Title:	Reimaging Consent: Comprehension and Decision-Making in Thyroid Surgery
Précis:	This study is a Jefferson multi-site, randomized controlled trial to address limited retention and high rates of decision regret in thyroid surgery utilizing a Thyroid Informed Surgical Consent Augmenting Video (TISCAV) in a cohort of patients undergoing thyroidectomy. We aim to: 1) Establish the current levels of comprehension following standard thyroidectomy consent discussion compared with the enhanced TISCAV consent; and 2) Measure conflict, satisfaction, regret, and anxiety surrounding decision-making following thyroidectomy consent discussion using TISCAV. Study participants with newly diagnosed thyroid nodules will be recruited from clinic. Participants will be administered a series of surveys at the preoperative and postoperative visits to assess comprehension, anxiety, decision conflict, satisfaction, and regret. Based on preliminary findings from our ongoing work, we have found TISCAV to be an educational, understandable, and accessible resource. As such, we hypothesize that TISCAV will improve comprehension and mitigate decision regret in thyroidectomy. Study results will modernize an aspect of surgery which has remained unevolved to empower and educate patients.
Objectives:	We aim to: 1) Establish the current levels of comprehension following standard thyroidectomy consent discussion compared with the enhanced TISCAV consent; and 2) Measure conflict, satisfaction, regret, and anxiety surrounding decision-making following thyroidectomy consent discussion using TISCAV.
Population:	Patients > 18 years of age are eligible if they are opting to receive care at Jefferson Sidney Kimmel Cancer Center - City or at Jefferson Torresdale Hospital or at Yardley Otolaryngology involving thyroidectomy. They must agree to proceed with Head and Neck surgery from the Principal Investigator or the Co-Investigators
Number of Sites:	Multicenter Center Study: TJUH Center City, Jefferson NE, Jefferson Yardley
Description of Intervention:	Participants who agree to participate will be randomized to either receive the intervention, the Jefferson-produced, evidence-based Thyroid Informed Consent Augmenting Video (TISCAV) or undergo standard consent (SC). The intervention is a multimedia presentation that explains in simple language the indications, risks, and benefits, steps, and otherwise expectations patients should have regarding their upcoming thyroid surgery while displaying animated visualization tools.
Study Duration:	12 months
Participant Participation Duration:	3 months
Estimated Time to Complete Enrollment:	12 months

Schematic of Study Design

Schematic of Study Design



1 Introduction

1.1 Background Information

Due to the improved detection of thyroid nodules, the number of patients presenting for thyroid surgery is on the rise, with a 300% increase over the past 3 decades. Surgeons are estimated to perform 150,000 thyroidectomies annually in the United States. Patient education is an imperative component of surgical decision-making, and both legally and ethically, patients deserve to know their clinical diagnosis and available therapeutic options, including their risks and benefits, in order to participate in informed consent. Patients with newly diagnosed thyroid nodules have unique options, including the consideration of active surveillance, in addition to surgical choices. Although thyroidectomy has known risks, there is no standardized script for consenting and the conversation may vary significantly both between and within institutions.

The variation in informed consent practices commonly results in inadequate patient understanding. Medical information discussed during the clinical visit is poorly recalled, reportedly forgotten at a rate as high as 80%. The longer the time interval between discussion and intervention, the worse retention becomes. Poor preoperative understanding has been demonstrated in the field of otolaryngology. Although patients report satisfaction with the amount of information disclosed, at the time of the procedure half are unable to list a single potential surgical complication. Furthermore, patients with head and neck cancer often report poor understanding of anticipated surgical consequences, even when endorsing adequate understanding of the procedure. Endocrine surgery is not excluded from these challenges, half of patients with thyroid cancer report low satisfaction with the overall amount of information received about their diagnosis and treatment options.

The discrepancy between physician teaching and patient education is critical to reconcile in order to attain quality patient education and shared decision-making. This inconsistency underscores patient factors, with those who are particularly vulnerable being those patients with language barriers, older age, low education levels, poor health literacy and anxiety during the clinical encounter. Utilization of technology for the delivery and augmentation of medical information is innovative. From a health system perspective, limited clinical time in busy surgical clinics in addition to the evolving complex diagnostic and treatment options makes adequate and quality surgical counselling a challenge. Many written tools such as pamphlets, information sheets, and websites have attempted to improve patient education, but have shown variable effect without obvious superiority. In patients undergoing thyroidectomy, the utilization of printed materials only demonstrated a recollection rate of 50%. One challenge with the adoption of printed materials is the elevated reading level at which they are commonly written, often exceeding that of the fourth to sixth grade reading level recommended by the NIH by multifold. In otolaryngology, it has been reported that 10% of patients have inadequate health literacy, and this, in combination with the complexity of anatomy and pathology in our specialty, can limit the accessibility of written resources.

Multimedia educational resources have more consistently demonstrated improvement in patient comprehension. Within the field of otolaryngology where complex anatomy can contribute to poor patient understanding, multimedia has been found to be an effective and preferable tool to improve comprehension. Audiovisual content as an adjunct to routine informed consent discussion in various otolaryngology subspecialities, including rhinology and facial plastics, has been shown to improve retention. In head and neck oncologic patients, multimedia has been associated with improved education, satisfaction and lessened anxiety levels. As highlighted in **Figure 1**, improved patient understanding can have impact beyond recall to improve patient satisfaction and treatment adherence.

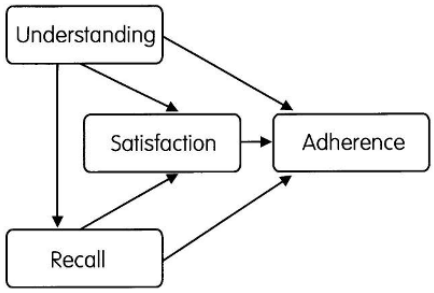


Figure 1. Ley's model on interactions between patient-related factors and outcomes.[1]

As healthcare becomes increasingly patient-centered, patient education efforts have been targeted to improve decision-making and patient-centered care. Decision regret is defined as remorse or distress with regard to a treatment decision. High rates of decision regret have been shown in patients with cancer where active surveillance has been considered to be a reasonable treatment option. In otolaryngology, elevated rates of decision regret have been reported within the head and neck cancer patient population, and it has been shown that patients who are more informed experience less decision regret, even in the face of complication**.** [37–39]

Preoperative anxiety is common and has been shown to influence patients to avoid a planned operation. Higher levels of anxiety have been reported prior to otolaryngology procedures compared to other surgical specialties, and elevated perioperative anxiety has been associated with low satisfaction. Anxiety has been shown to influence treatment decision in patients with cancer, where those patients with high levels of anxiety have been more likely to pursue surgical intervention over active surveillance. Historically, patient education efforts have been met with some resistance, driven largely by concern for heightening anxiety. However, many modern studies have demonstrated that information prior to medical procedures does not elevate anxiety levels. In fact, improving patient understanding prior to surgical intervention has been shown to decrease anxiety. The literature has demonstrated a beneficial role for video education in the reduction of patient anxiety.

Though many studies have examined some aspects of decision-making in the perioperative period, there has been wide variability in methods and cohorts. There remains a paucity of work in patient education and decision-making in the field of endocrine surgery. This study proposes the use of formative knowledge assessment, validated decision-making surveys to utilize a surgeon-designed Thyroid Informed Surgical Consent Augmenting Video (TISCAV). Through the proposed longitudinal randomized trial, this study seeks to improve patient education and shared decision-making in patients pursuing thyroid surgery.

1.2 Rationale for Proposed Study

Our proposal, based upon preliminary results, will test several hypotheses that are vital to modernizing the informed consent conversation prior to thyroidectomy. While previous studies have demonstrated poor understanding and retention in endocrine surgery patients prior to surgical intervention, literature has not demonstrated a superior intervention to improve comprehension. Therefore, our findings will provide insight into the role of a surgeon-designed TISCAV to improve comprehension and further appreciate decision-making in thyroid surgery.

First, we will test the hypothesis that a surgeon-created patient education video improves baseline comprehension prior to thyroidectomy. Our preliminary findings suggest our video is a feasible and accessible intervention that is able to improve patient knowledge and confidence. Further analysis will allow us to identify superiority to traditional verbal patient consent.

Second, we will test the hypothesis that informed patients are more confident in, more satisfied with, and experience less regret with their decision to pursue surgery. Utilizing several validated survey tools, this research will further examine decision-making for patients pursuing thyroid surgery, and further analysis will allow us to study the impact of state anxiety on this process.

These proposed studies will be examined over the course of perioperative thyroid care though 3-month follow-up. This approach will assess multiple aspects of patient education and consideration during the perioperative period, and will inform interventions to improve comprehension and decision-making in patients undergoing thyroid surgery.

1.3 Potential Risks and Benefits

1.3.1 Potential Risks

- Multimedia presentations: dizziness, confusion, loss of consciousness, seizures, palpitations, SOB, panic, anxiety.
- Healthcare-information: Panic, Anxiety, Loss of Consciousness, Seizures, Palpitations, SOB, Dizziness, Confusion.

1.3.2 Benefits

- Knowledge of avenues for quality improvement in surgical care for thyroidectomy
- By formative assessment, knowledge of current state of patient comprehension prior to thyroid surgery
- Efficacy data of multimedia interventions for patient comprehension for thyroid surgery

- Confidence of Surgery-Specific Knowledge using validated survey, knowledge of current state of patient confidence of their thyroid surgery knowledge
- Decisional conflict using validated survey related to decision to pursue thyroid surgery
- Satisfaction with decision to pursue thyroid surgery using validated survey

2 Study Objectives

2.1 Primary Objectives

AIM 1: Establish the current levels of comprehension following standard thyroidectomy consent discussion compared with the enhanced TISCAV consent.

AIM 2: Measure conflict, satisfaction, regret, and anxiety surrounding decision-making following thyroidectomy consent discussion using TISCAV.

2.2 Endpoints/Outcome Measures

We have demonstrated feasibility of the TISCAV to educate patients prior to thyroidectomy. However, the role of augmented consenting compared to standard discussion is unknown. To address this gap, we propose a prospective, randomized controlled trial recruiting 40 patients consenting for partial or total thyroidectomy. A survey will be administered to assess sociodemographic and clinical characteristics, as well as to measure comprehension using an investigator-created 10-item formative assessment. This will be administered at two time points: first at the onset of the clinic visit prior to consent, and again after consent at the conclusion of the preoperative clinic visit for both control and intervention arms. We expect that TISCAV will be associated with improved post-video comprehension compared to standard consent. Our findings will inform thyroid surgeons to better educate patients when deciding to pursue thyroidectomy.

Our ongoing research suggests that TISCAV positively impacts confidence in the decision to pursue thyroidectomy. We propose a survey to assess decision-making during the consent process. At the initial preoperative visit, both groups will be administered the Decisional Conflict Survey (DCS) and Satisfaction with Decision Scale (SDS). The DCS is a 15-question validated survey and the SDS is a 6-question validated survey, and both are used to evaluate aspects of surgical decision-making. During the first (~1 week) and second (~3 months) postoperative visits, the SDS and the 5-question validated Decision Regret Scale (DRS) will be administered to assess patient response to their decision to pursue surgery. Additionally, at all timepoints, patients will be assessed using the Visual Analog Scale for Anxiety (VAS-A) to measure state anxiety. This aim seeks to assess patient reaction to their decision to pursue thyroidectomy after experiencing the consequences of this decision. We expect that TISCAV will be associated with lower rates of decision regret, higher rates of confidence and satisfaction, and comparable levels of anxiety. Assessing patient factors affecting decision-making will guide thyroid surgeons to better guide preoperative conversations

3 Study Design

The manner in which to improve perioperative patient understanding in the setting of informed consent remains unknown. To address this gap, this study proposes a prospective longitudinal investigation of the consent process in patients undergoing thyroidectomy. Survey research will examine the understanding,

confidence, anxiety, decision regret, and satisfaction associated with traditional and augmented informed consent for thyroidectomy. Participants will be assessed at 3-time points in order to assess knowledge and decision-making throughout the perioperative period: diagnosis, initial post-operative visit, and 3-month follow-up visit.

3.1 Study Population.

Eligible participants will include patients (1) with newly diagnosed thyroid nodule; (2) age ≥18 years; (3) who undergo thyroid lobectomy or total thyroidectomy. Participants will be excluded if they are unable to speak or read the English language.

3.2 Recruitment, Accrual, and Feasibility

The Thomas Jefferson University Hospital Jefferson Thyroid and Parathyroid Center evaluates more than 1,000 new patients annually. Surgeons perform over 215 thyroid surgeries each year, which equates to approximately 18 thyroid surgeries per month. We will identify eligible patients using the electronic medical record to evaluate the outpatient appointment calendars of our involved surgeons and recruit using a clinic-based approach. We plan to enroll 40 patients during months 2 through 7. Data collection will continue throughout month 10. This sample size is reasonable based on the number of patients seen annually. Feasibility was previously defined at a threshold value of 80% based on prior unpublished work. In this preliminary study, feasibility was been measured at 93%. The study size of 40 participants will provide ample precision for the feasibility estimate. If we observe a similar proportion, then a Clopper-Pearson Exact 95% confidence interval will be (86%, 98%).

Our central hypothesis is that the utilization of TISCAV will be associated with improved surgery-specific comprehension and decision-making during perioperative consent for thyroid surgery. Two specific aims are proposed to test the central hypothesis.

Aim 1: Establish the current levels of comprehension following standard thyroidectomy consent discussion compared with the enhanced TISCAV consent.

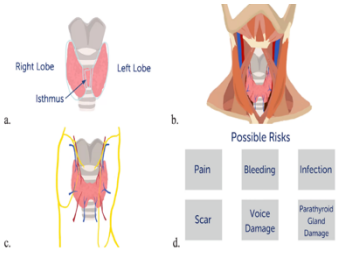


Figure 2. Animation screenshots taken from surgeon-designed TISCAV.

Preliminary Data. In a pilot study involving 30 patients, overall knowledge was significantly improved (+1.3) after viewing the TISCAV. Patients also reported increased confidence in understanding risks of surgery (+1.2) after watching the video.

Methods. Eligible individuals will be approached to discuss study participation and, if interested, will undergo informed research consent. A survey including sociodemographic information, clinical characteristics, and an investigator-created 10-item formative assessment will be administered to study participants at initial visit prior to randomization, and again after consent at the conclusion of the preoperative clinic visit.

Sociodemographic Information and Clinical Characteristics. Age, sex, marital status, race, ethnicity, education level, and employment status will be obtained from patients. The electronic medical record will be used to obtain medical history and endocrine data.

Thyroid Informed Surgical Consent Augmenting Video (TISCAV). The TISCAV is an animated 8 minute and 38 second video with surgeon voiceover. The video was scripted and recorded by the project

mentor with illustrations contributed by Sidney Kimmel Medical College students. It has been approved by Jefferson Creative Services for use of branding, and by the Department of Otolaryngology for content. **Figure 2** depicts animations from the TISCAV, which describes surgical anatomy, indications, benefits, and possible risks to both thyroid lobectomy and total thyroidectomy.

Formative Assessment. The assessment will be administered prior to patient education and again after consenting is finished to assess patient understanding. This 10-question multiple-choice survey has been reviewed by our endocrine surgery team for content. The assessment has been calculated at a Flesh-Kincaid Grade level 3.5, correlating to a 7th grade reading level.

Aim 2: Measure conflict, satisfaction, regret, and anxiety surrounding decision-making following thyroidectomy consent discussion using TISCAV.

Preliminary Data. In preliminary studies using a single question survey, patients report 98% satisfaction with the TISCAV.

Methods. As described above, eligible individuals will be approached to discuss study participation and, if interested, will undergo informed research consent. A survey including sociodemographic information, clinical characteristics, and an investigator-created 10-item formative assessment will have been previously be administered to study participants. Following randomization at initial visit, patients will be administered a survey containing the decision-making tools. Following thyroid surgery, the patient will be administered a set of surveys at two subsequent timepoints: the first postoperative visit (1-2 weeks following surgery) and the 3-month postoperative visit.

Sociodemographic Information and Clinical Characteristics. As previously described, age, sex, marital status, race, ethnicity, education level, and employment status will be obtained from patients, and the electronic medical record will be used to obtain medical history and endocrine data.

Decision-Making Survey Instruments. Several validated survey instruments will be utilized in this study as shown in **Table 2**. The Decisional Conflict Survey (DCS) is a measurement of 5 dimensions of decision making using a 16-item question format. Measured on a 5-point scale, where each question is scored 0 to 4. The total score is calculated out of 64, with five subcategories separated by question. These categories include uncertainty, informed, values clarity, support, and effect decision.[60,61] The Satisfaction with Decision Scale (SDS) is a 6-item scale used to assess patient satisfaction with a healthcare decision. This is rated on a scale where each statement is scored 1 (not satisfied) to 5 (very satisfied). Total score is calculated out of 30, with higher scores indicating higher decision satisfaction.[62] The Decision Regret Scale (DRS) is a 5-item statement scale used to evaluate regret after healthcare decision making. Each statement is measured 1 (strongly agree) to 5 (strongly disagree). Total score is calculated out of 25, with higher scores indicating high decisional regret.[33] The Visual Analog Scale for Anxiety (VAS-A) is a simple and rapid assessment of anxiety using a single question, which has demonstrated adequate reliability, validity, and sensitivity.[63] The VAS-A has been shown to be advantageous when multi-item inventories such as State-Trait Anxiety Inventory (STAI) may be burdensome, and it has been shown to correlate with the STAI in the perioperative setting.[46]

Table 2. Decision-Making Survey Instruments

Measure	Domain	Description
Decisional Conflict Survey (DCS)[60,61]	**Conflict**	• 16-items (scored 0-64) to assess decisional conflict • Higher scores indicate higher decisional conflict • Five categories of subscores are calculated: uncertainty, informed, values clarity, support, and effective decision

Satisfaction with Decision Scale (SDS)[62]	**Satisfaction**	• 6-items (scored 6-30) to assess decision satisfaction • Higher scores indicate higher decision satisfaction
Decision Regret Scale (DRS)[33]	**Regret**	• 5-items (scored 5-25) to assess decision regret • Higher scores indicate higher decisional regret
Visual Analog Scale for Anxiety (VAS-A)[63]	**Anxiety**	• Single question visual scale to assess state anxiety • Range from not at all anxious to extremely anxious

3.3 Data Management and Statistical Analysis

Surveys will be administered by a Research Associate via a tablet (or paper format if requested) using RedCap, a HIPAA-compliant survey data system. Data analysis will be performed using SPSS (27). Exploratory data analysis will be used to describe variables of interest and identify data anomalies that may invalidate the results. Data will be screened for outliers and will be assessed for their influence on results. Descriptive statistics will be utilized and a two-sided t-test will be constructed at α=0.05 to evaluate significance of the means.

3.4 Potential Pitfalls and Alternative Strategies

We acknowledge volunteer bias as a potential limitation to our study, as patients interested in participating in this survey may be those who are more interested or eager to be involved in their health and surgical decision-making. Although such bias would be expected to be present across both treatment arms. Furthermore, the study is performed at a single tertiary care academic center with a predominantly White and non-Hispanic population, which may yield limited generalizability. We acknowledge a potential pitfall of insufficient accrual within the study time frame. If that occurs, we will address by extending our recruitment time if necessary.

3.5 Future Directions

Utilization of novel surgeon-created multimedia technologies for perioperative information delivery is a feasible, accessible, and effective intervention to address current limitations in the preoperative healthcare setting. The findings from this project can be further extrapolated to specifically study those most vulnerable populations previously identified. Beyond written information or clinical encounters, audiovisual materials may be uniquely applied to address health literacy barriers. We look to adapt this multimedia presentation to languages beyond English, including Spanish and Mandarin, both of which are commonly spoken by patients in our clinic. The data collected from these proposed studies will inform patient education and decision-making in thyroid surgery, and seek to empower and educate patients, including those with low health literacy who are most vulnerable in standard consenting. Through insight into patient comprehension and decision-making factors, we can advance an aspect of surgery which has remained unevolved.

3.6 Number of Participants

40 participants

3.7 Duration of Therapy

N/A

3.8 Duration of Follow Up

N/A

3.9 Treatment Assignment Procedures

3.9.1 Randomization Procedures

Subjects that consent to the study will be randomized into the intervention or control group. Subjects will be randomized using a coin flip program.

3.9.2 Masking Procedures

N/A

3.10 Study Timeline

3.10.1 Primary Completion

12 months

3.10.2 Study Completion

12 months

4 Study Enrollment and Withdrawal

4.1 Eligibility Criteria

4.1.1 Inclusion Criteria

Individuals must meet all of the following inclusion criteria in order to be eligible to participate in the study:

- Patients who opt to receive care at Jefferson Sidney Kimmel Cancer Center or at Jefferson Torresdale Hospital or at Yardley Otolaryngology from the Principal Investigator or the Co-Investigators.
- Patients ≥ 18 years of age
- Patients diagnosed with thyroid disease for which thyroidectomy is indicated.
- Patients who provide verbal informed consent for the clinical trial.
- Patients who are willing to comply with all study procedures and be available for the duration of the study
- Patients who read and speak fluent English
- Patients who do not meet any of the exclusion criterion.

4.1.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:
Patients opting to review the TISCAV but otherwise unwilling to comply with all study procedures for the duration of the study

- Patients who cannot read or speak English fluently

- Patients with a known history of adverse reactions to multimedia presentations or videos of potentially emotionally distressing nature
- Patients < 18 years of age
- Patients who, for any other reason, are suspected to be unable to complete assessment and survey-based materials in the context of this study.

4.2 Gender/Minority/Pediatric Inclusion for Research

We will not exclude potential subjects from participating in this study based on ethnic origin or socioeconomic status. Every attempt will be made to enter all eligible patients in this protocol and therefore address the study objectives in a patient population representative of the disease population at Jefferson Sidney Kimmel Cancer Center, Jefferson Hospital Torresdale, and Yardley Otolaryngology. Thyroid cancer has a predominance of females to males. Thus, we expect to an enrollment pattern that reflects these epidemiologic facts for Thyroid-related studies.

4.3 Strategies for Recruitment and Retention

Eligible patients are identified and recruited at the three participating institutions: Jefferson SKCC, Jefferson Torresdale Hospital, Yardley Otolaryngology. Subjects from Center City will have an ID number. To aid the Principal and Co-Investigators in identifying eligible participants, the clinic-designated research assistant will review the weekly clinic roster to identify patients who may be eligible for study participation. Eligible patients will be preliminarily identified based on clinical factors suggesting a high-likelihood of thyroid surgery recommendation. The clinic-designated research assistant will meet face-to-face with the Principal and Co-Investigators to discuss potential eligibility. Identified patients will be approached with an eligibility interview addressing inclusion and exclusion criteria. Eligible patients who meet inclusion criteria will be randomized into the intervention protocol arm or the control arm. Patients will complete surveys and either TISCAV or SC followed by open discussion with the surgeon. Patients will then be contacted by phone for postoperative survey timepoints.

4.4 Participant Withdrawal

4.4.1 Reasons for Withdrawal

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may terminate a study participant's participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

4.4.2 Handling of Participant Withdrawals and Participant Discontinuation of Study Intervention

Patients can withdraw at any time during the study if they no longer want to participate in the trial. If a subject withdraws consent to participate in the study, permission will be sought to use data pertaining to the subject in the analysis as far as they participate, and they will be removed from subsequent analyses.

Specific reasons for discontinuing a subject from this study are:

1. Voluntary discontinuation by the subject who is at any time free to discontinue their participation in the study, without prejudice to further treatment.
2. Safety reasons as judged by the investigator.
3. Patient inability to participate in the counselling component of the intervention
4. Subject lost to follow-up
5. Death

4.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the principal investigator. If the study is prematurely terminated or suspended, the principal investigator will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants.
- Insufficient adherence to protocol requirements.
- Data that is not sufficiently complete and/or evaluable.
- Determination of futility.

5 Study Intervention

5.1 Study Product

The investigational product in this study is an educational intervention. TISCAV will be used to teach patients about the indication, risks, benefits of Thyroid Surgery and provide details about the surgical procedure as well. The TISCAV was scripted and recorded by the Principal Investigator and illustrations were created by Sidney Kimmel Medical College students. The TISCAV is roughly 10 minutes in duration and is approved by Jefferson Creative Services for use of Logo/Brand, Fonts, and Color Schemes. After initially viewing the TISCAV in clinic, patients also can review at their convenience on YouTube.

5.1.1 Acquisition

Product is an electronic video and is available with unlimited use at zero cost. The TISCAV is approved by Jefferson for use of Logo/Brands/Fonts/Patients at their convenience on YouTube at the following location:

https://www.youtube.com/watch?v=52lpC4YTSC0

5.1.2 Study Behavioral or Social Intervention(s) Description

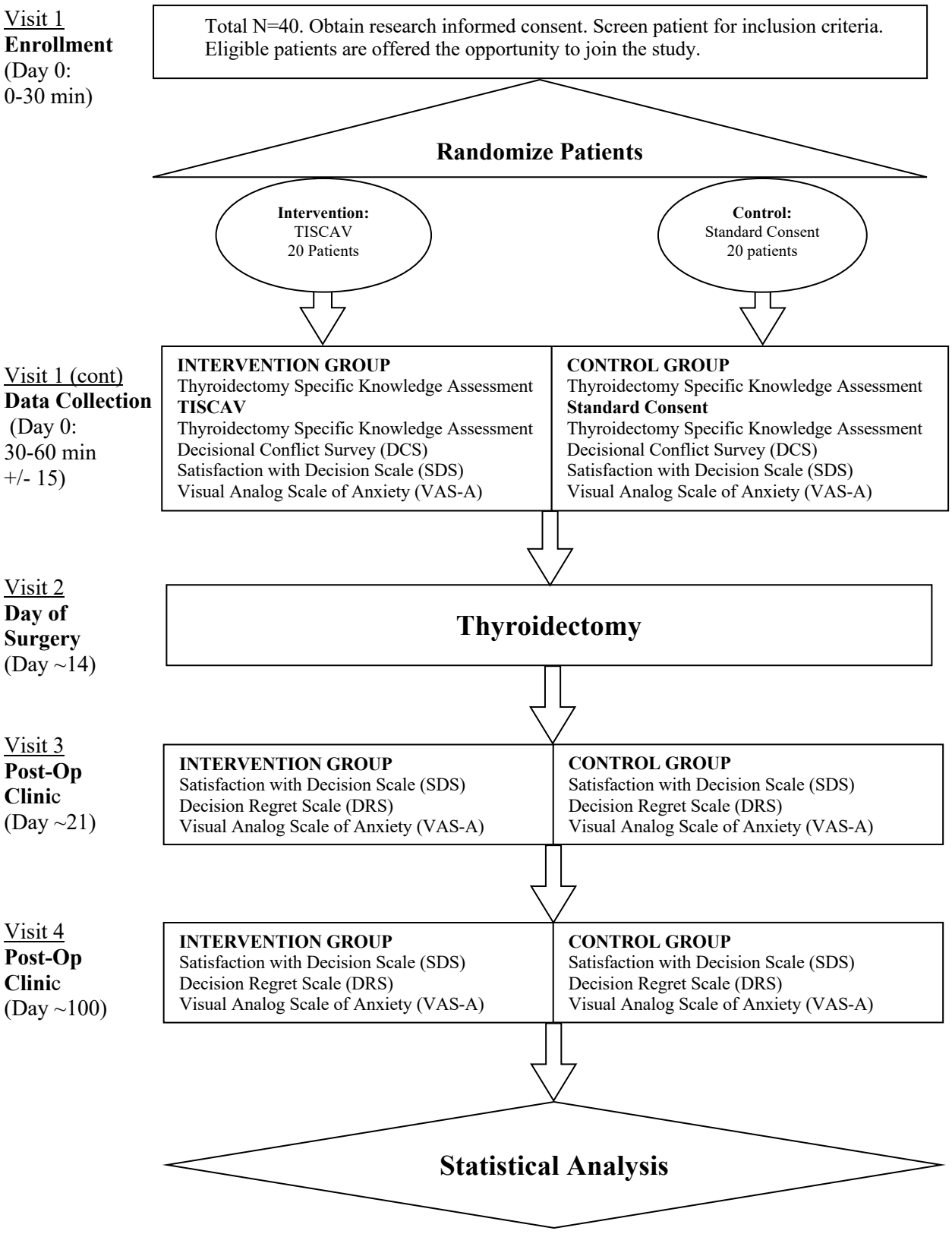
N/A

5.2 Study Procedural Intervention(s) Description

See 6.2

5.3 Administration of Procedural Intervention

Schematic of Study Design



6 Study Schedule

6.1 Pretreatment Period/Screening

- **Visit 1, Day 0, 0 – 30 minutes**
  - Eligible patients are identified by a clinical-designated research assistant.
  - Clinic-designated research assistant meets face-to-face with the PI and Co-I to potentially eligible subjects
  - Patients who consent for thyroid surgery are approached with eligibility interview questions of inclusion and exclusion criteria
  - Patients are randomized

6.2 Enrollment/Baseline

- **Visit 1, Day 0, 30-60 minutes +/- 15 minutes**
  - INTERVENTION ARM:
    - Patients complete the initial KA
    - **** Patients review the TISCAV****
    - Patients complete the post-intervention KA
    - Patients complete the DCS, SDS, VAS-A
  - CONTROL ARM:
    - Patients complete the initial KA
    - **** Patients undergo SC****
    - Patients complete the post-intervention KA
    - Patients complete the DCS, SDS, VAS-A

6.3 End of Treatment Study Procedures

- **Visit 2, Day ~21 – Postop Visit 1**
  - INTERVENTION ARM:
    - Patients are phoned around the time of their initial postoperative visit
    - Patients complete the SDS, DRS, and VAS-A
  - CONTROL ARM:
    - Patients are phoned around the time of their initial postoperative visit
    - Patients complete the SDS, DRS, and VAS-A
- **Visit 3, Day ~100 – Postop Visit 2**
  - INTERVENTION ARM:
    - Patients are phoned around the time of their 3 month postoperative visit
    - Patients complete the SDS, DRS, and VAS-A
  - CONTROL ARM:
    - Patients are phoned around the time of their 3 month postoperative visit
    - Patients complete the SDS, DRS, and VAS-A

6.4 Long Term/Survival Follow-up

N/A

6.5 Withdrawal Visit/Discontinuation of Therapy

If a subject withdraws consent to participate in the study, permission will be sought to use data pertaining to the subject in the analysis as far as they participate, and they will be removed from subsequent

analyses. Subjects will be called by phone at least on three occasions, phone calls at least twice will be carried out to the next-of-kin and certified letters will be sent twice. If follow-up is not obtained after the previously listed attempts have been carried out the subject will be considered lost to follow-up.

7 Study Procedures and Evaluations

7.1 Study Procedures/Evaluations

Decision-Making Survey Instruments. Several validated survey instruments will be utilized in this study. The Decisional Conflict Survey (DCS) is a measurement of 5 dimensions of decision making using a 16-item question format. Measured on a 5-point scale, where each question is scored 0 to 4. The total score is calculated out of 64, with five subcategories separated by question. These categories include uncertainty, informed, values clarity, support, and effect decision. The Satisfaction with Decision Scale (SDS) is a 6-item scale used to assess patient satisfaction with a healthcare decision. This is rated on a scale where each statement is scored 1 (not satisfied) to 5 (very satisfied). Total score is calculated out of 30, with higher scores indicating higher decision satisfaction. The Decision Regret Scale (DRS) is a 5-item statement scale used to evaluate regret after healthcare decision making. Each statement is measured 1 (strongly agree) to 5 (strongly disagree). Total score is calculated out of 25, with higher scores indicating high decisional regret.[33] The Visual Analog Scale for Anxiety (VAS-A) is a simple and rapid assessment of anxiety using a single question, which has demonstrated adequate reliability, validity, and sensitivity. The VAS-A has been shown to be advantageous when multi-item inventories such as State-Trait Anxiety Inventory (STAI) may be burdensome, and it has been shown to correlate with the STAI in the perioperative setting.

7.2 Laboratory Procedures/Evaluations

7.2.1 Clinical Laboratory Evaluations

N/A

7.2.2 Special Assays or Procedures

N/A

7.2.3 Specimen Preparation, Handling, and Storage

N/A

7.2.4 Specimen Shipment

N/A

8 Evaluation of Safety

8.1 Specification of Safety Parameters

8.1.1 Unanticipated Problems

Unanticipated problems (UAPs) include, in general, any incident, experience, or outcome that meets the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;

UAPs are considered to pose risk to participants or others when they suggest that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.1.2 Adverse Events

An adverse event (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the study. That is considered related to the study-specific treatment. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are adverse events if the abnormality:

- Results in study withdrawal
- Is associated with a serious adverse event
- Is associated with clinical signs or symptoms
- Leads to additional treatment or to further diagnostic tests
- Is considered by the investigator to be of clinical significance

8.1.3 Serious Adverse Events

Adverse events are classified as serious or non-serious.

A **serious adverse event** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening but are clearly of major clinical significance. They may jeopardize the subject and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization or intensive treatment of bronchospasm in an emergency department would typically be considered serious. All adverse events that do not meet any of the criteria for serious should be regarded as **non-serious adverse events**

8.2 Safety Assessment and Follow-Up

The PI will follow adverse events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator (or designee) will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3 Recording Adverse Events

At each contact with the subject, the investigator will seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events related to the intervention arm of this study will be recorded immediately in the source document, and in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results should be recorded in the source document, though should be grouped under one diagnosis.

All adverse events related to the intervention occurring during the study period will be recorded. Adverse events will be reported from both study sites using the online reporting system.

The clinical course of each event will be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period will be followed up to determine the outcome. Any serious adverse event that occurs after the study period and is possibly related to the study treatment or study participation will be recorded and reported immediately.

8.3.1 Relationship to Study Intervention

The relationship to study intervention or study participation must be assessed and documented for all adverse events. Evaluation of relatedness must consider etiologies such as natural history of the underlying disease, concurrent illness, concomitant therapy, study-related procedures, accidents, and other external factors.

The following guidelines are used to assess relationship of an event to study intervention:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.
    d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
    a. There is no temporal relationship between the intervention and event onset.
    b. An alternate etiology has been established.

8.3.2 Expectedness

The PI is responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention. Risk information to assess expectedness can be obtained from preclinical studies, the investigator's brochure, published medical literature, the protocol, or the informed consent document.

8.3.3 Severity of Event

Adverse events will be graded for severity according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

8.3.4 Intervention

Any intervention implemented to treat the adverse event must be documented for all adverse events.

8.4 Safety Reporting

8.4.1 Reporting to IRB

8.4.1.1 *Unanticipated Problems*

All incidents or events that meet criteria for unanticipated problems (UAPs) as defined in Section 8.1.1 Unanticipated Problems require the creation and completion of an unanticipated problem report form (OHR-20).

UAPs that pose risk to participants or others, and that are not AEs, will be submitted to the IRB on an OHR-20 form via the eazUP system within 10 working days of the investigator becoming aware of the event.

UAPs that do not pose risk to participants or others will be submitted to the IRB at the next continuing review.

8.4.1.2 *Adverse Events*

Grade 1 AEs will be reported to the IRB at continuing review.

Grade 2 AEs will be reported to the IRB at the time of continuing review.

8.4.1.3 *Serious Adverse Events*

SAEs will be reported to the IRB on OHR-10 forms via the electronic reporting system (eSAEy) according to the required time frames described below.

Grade 3-4 AEs that are unexpected and deemed to be at least possibly related to the study will be reported to the IRB within 2 working days of knowledge of the event.

Grade 3-4 AEs that are deemed unrelated to the study will be reported to the IRB within 5 working days.

Grade 5 AEs will be reported to the IRB within one working day of knowledge of the event.

All SAEs will be submitted to the IRB at continuing review, including those that were reported previously.

8.4.2 Reporting to SKCC DSMC

All AEs and SAEs, safety and toxicity data, and any corrective actions will be submitted to the DSMC per the frequency described in the SKCC DSMP. The report to the SKCC DSMC will also include any unanticipated problems that in the opinion of the PI should be reported to the DSMC.

For expedited reporting requirements, see table below: DSMC AE/SAE Reporting Requirements

8.4.3 Reporting of Pregnancy

8.5 Halting Rules

9 Study Oversight

In addition to the PI's responsibility for oversight, study oversight will be under the direction of the SKCC's Data and Safety Monitoring Committee (DSMC). The SKCC DSMC operates in compliance with a Data and Safety Monitoring Plan (DSMP) that is approved by the NCI.

10 Clinical Site Monitoring and Auditing

Clinical site monitoring and auditing is conducted to ensure that the rights of human participants are protected, that the study is implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods are maintained. Monitoring and auditing for this study will be performed in accordance with the SKCC's Data and Safety Monitoring Plan (DSMP) developed by the SKCC Data and Safety Monitoring Committee (DSMC). The DSMP specifies the frequency of monitoring, monitoring procedures, the level of clinical site monitoring activities (e.g., the percentage of participant data to be reviewed), and the distribution of monitoring reports. Some monitoring activities may be performed remotely, while others will take place at the study site(s). Appropriate staff will conduct monitoring activities and provide reports of the findings and associated action items in accordance with the details described in the SKCC DSMP.

11 Statistical Considerations

11.1 Study Hypotheses and Analysis Plans

To estimate the efficacy of TISCAV for increasing surgery-specific comprehension. Patient surgery-specific comprehension will be measured by formatively using KA. Means and standard deviations of KA scores will be computed. A two-sided paired t-test will be constructed at the α=0.05 level to evaluate the statistical significance of mean changes in KA scores between timing of tests. A two-sided two-sample t-test will be constructed at the α=0.05 level to evaluate the statistical significance of the difference in mean HNSA scores between the groups. This will be further applied to the DCS, SDS, DRS, and VAS-A across timepoints and between groups

11.2 Interim Analyses and Stopping Rules

There are no interim analyses planned for this pilot study.

11.3 Sample Size Considerations

Feasibility was previously defined at a threshold value of 80% based on prior unpublished work. In this preliminary study, feasibility was measured at 93%. The study size of 40 participants will provide ample precision for the feasibility estimate. If we observe a similar proportion, then a Clopper-Pearson Exact 95% confidence interval will be (86%, 98%).

11.3.1 Accrual Estimates

We will aim to recruit 3-4 patients per month over the course of 12 months for a total of 40 study participants.

12 Source Documents and Access to Source Data/Documents

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, and regulatory and institutional requirements for the protection of confidentiality of participant information. Study staff will permit authorized representatives of SKCC and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

13 Quality Control and Quality Assurance

The investigator will allocate adequate time for monitoring activities. The Investigator will also ensure that compliance or quality assurance reviewers are given access to all the above noted study-related documents and study related facilities (e.g., pharmacy, diagnostic laboratory, etc.), and has adequate space to conduct the monitoring visit.

14 Ethics/Protection of Human Participants

14.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

14.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

14.3 Informed Consent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to participants and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the participant. Consent forms will be IRB-approved, and the participant is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the participant and answer any questions that may arise. The participant will sign the informed consent document prior to any study-related assessments or procedures. Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. The consent process will be documented in the clinical or research record.

14.4 Exclusion of Women, Minorities, and Children (Special Populations)

Women and minorities will be included in this study. Children will be excluded from this study as pediatric populations less than 18 years of age are legally not allowed to purchase nicotine products and they are not included in the study population.

14.5 Participant Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study.
- Who will have access to that information and why.

- Who will use or disclose that information.
- The rights of a research subject to revoke their authorization for use of their PHI.

If a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

14.6 Future Use of Stored Specimens and Other Identifiable Data

N/A

15 Data Handling and Record Keeping

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study participants, including accurate case report forms (CRFs), and source documentation.

15.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the investigator. All source documents and laboratory reports will be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the investigator or designee.

15.2 Data Capture Methods

Electronic surveys and questionnaires will be distributed to all patients at each study visit. Survey responses will be populated into REDCap by the research coordinator. Documents will be collected and stored for all patients in a secure area.

15.3 Types of Data*

Clinical data regarding patient medical history, social history and history of disease will be de-identified and collected in a dual-factor authentication protected password encrypted database. Outcomes measures collected in the form of surveys will be collected on paper assessments which will be evaluated and stored in a locked cabinet in 925 Chestnut St. 6th floor.

15.4 Study Records Retention

All study essential documents will be retained by the investigator for 2 years after the completion of the study.

15.5 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the participant, the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly. All deviations from the protocol must be addressed in study participant source documents and promptly reported to the IRB and other regulatory bodies according to their requirements.

16 Study Finances

16.1 Funding Source

This study will be financed through a grant if available.

16.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All Jefferson University Investigators will follow the TJU Conflicts of Interest Policy for Employees (107.03).

16.3 Participant Stipends or Payments

N/A

17 Publication and Data Sharing Policy

An Executive Committee consisting of all investigators will be responsible for developing publication procedures and resolving authorship issues. The Principal Investigator will hold the primary responsibility for publication of the any results of the study. Approval will be obtained from the primary responsible party before any information can be used or passed on to a third party. Costs associated with data sharing and publication will be paid for by the Sidney Kimmel Cancer Center. This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

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SUPPLEMENTAL MATERIALS

Appendices

At a Glance

Estimated New Cases in 2020	52,890
% of All New Cancer Cases	2.9%

Estimated Deaths in 2020	2,180
% of All Cancer Deaths	0.4%

5-Year Relative Survival
98.3%
2010–2016

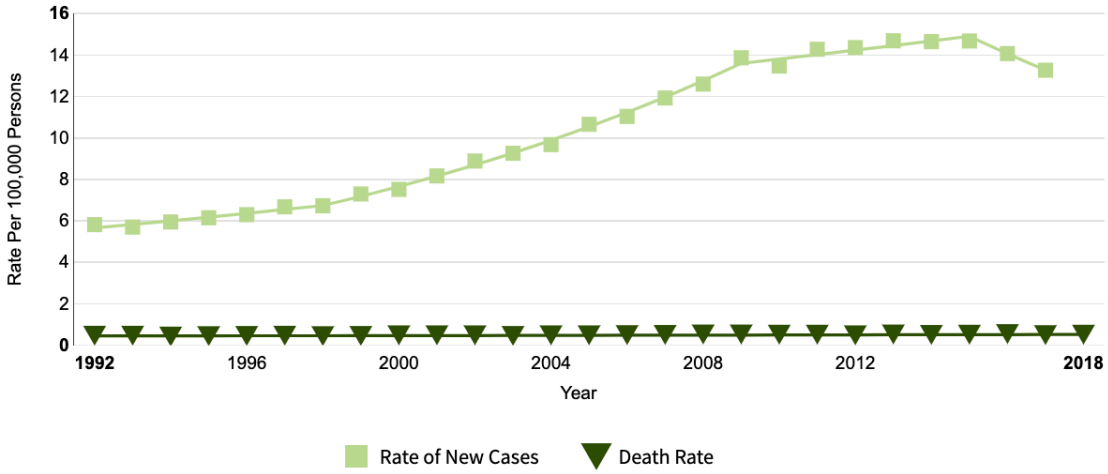

FIGURE 1: Thyroid Cancer GENDER: Recent Trends in SEER Age-Adjusted Incidence Rates, 2000-2017

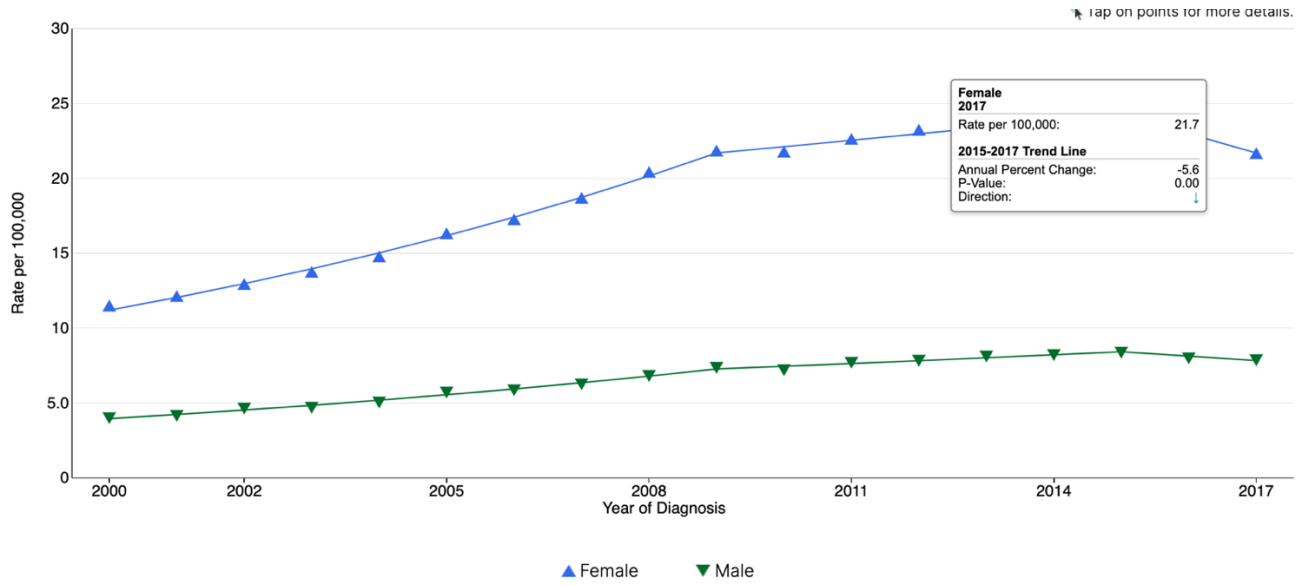

FIGURE 2: Thyroid Cancer GENDER: Recent Trends in SEER Age-Adjusted Incidence Rates, 2000-2017

Table Display: Trends Rates

Sex	Annual Percent Change			
	Year Range	Estimate (%)	P-Value	Direction
Female	2000-2009	7.6	0.00	↑
	2009-2015	1.9	0.00	↑
	2015-2017	-5.6	0.00	↓
Male	2000-2009	7.0	0.00	↑
	2009-2015	2.5	0.00	↑
	2015-2017	-3.6	0.16	Stable

TABLE 1: Thyroid Cancer: Recent Trends in SEER Age-Adjusted Incidence Rates, 2000-2017

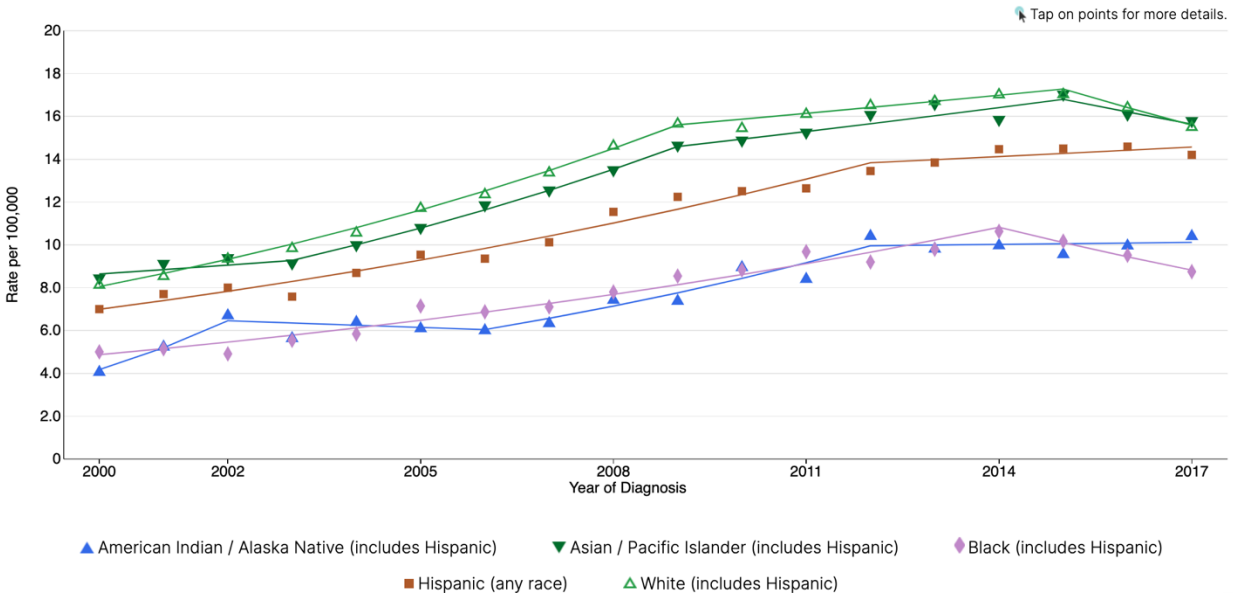

FIGURE 3: Thyroid Cancer RACE: Recent Trends in SEER Age-Adjusted Incidence Rates, 2000-2017

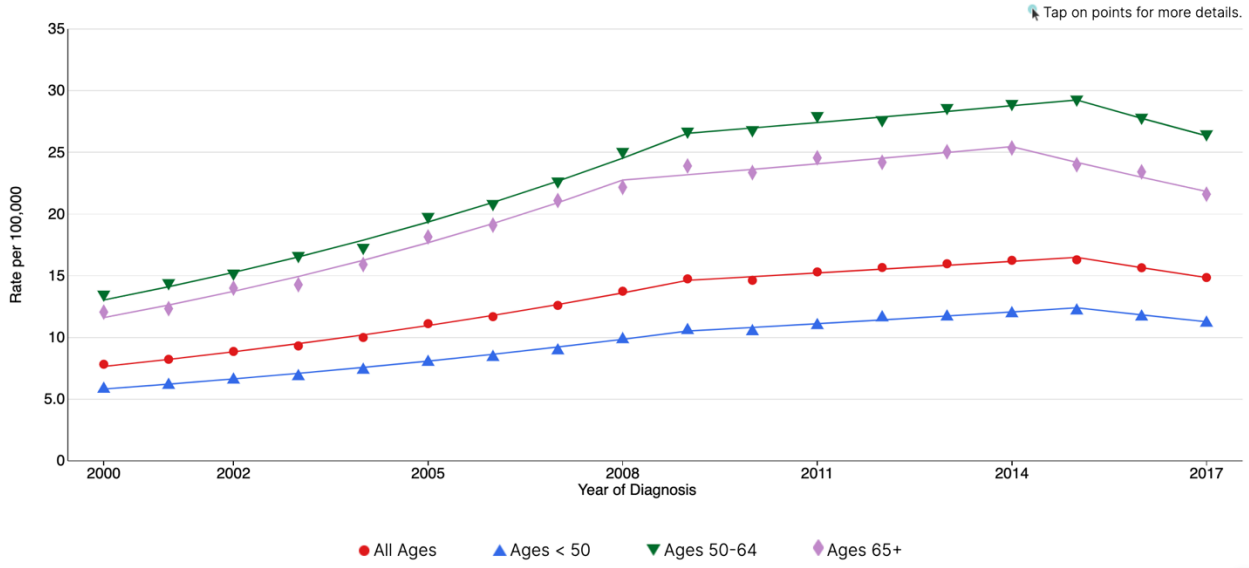

FIGURE 4: Thyroid Cancer AGE: Recent Trends in SEER Age-Adjusted Incidence Rates, 2000-2017

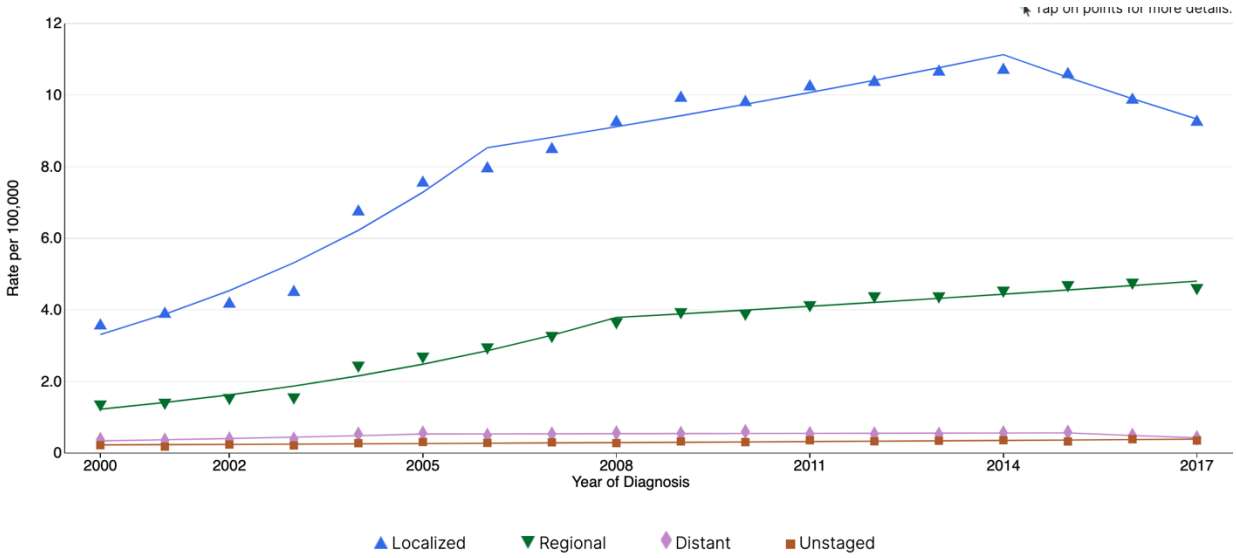

FIGURE 5: Thyroid Cancer AGE: Recent Trends in SEER Age-Adjusted Incidence Rates, 2000-2017

Understanding Your Upcoming Thyroid Surgery
Formative Assessment

1. Which of the following is a reason to have thyroid surgery?
    a. Suspicious thyroid nodule
    b. Overactive thyroid gland
    c. Very enlarged thyroid gland
    d. Cancer in a thyroid nodule
    e. All of the above

2. Steps of thyroid surgery include all of the following **EXCEPT**:
    a. Incision in the skin
    b. Removing the parathyroid
    c. Opening the muscles in the neck
    d. Sealing the blood vessels that supply the thyroid gland

3. Which of the following is a risk of thyroid surgery?
    a. Injury to the parathyroid glands
    b. Injury to the nerves to the vocal cords
    c. Bleeding
    d. Pain
    e. All of the above

4. Pain after thyroid surgery most commonly includes all of the following **EXCEPT:**
    a. Sore throat
    b. Sore muscles in neck and back
    c. A small amount of pain at the incision
    d. Severe pain at the incision

5. The _____ is in charge of balancing calcium levels in the body:
    a. Thyroid
    b. Parathyroid
    c. Pancreas
    d. Liver

6. The risk of having low blood calcium levels is greatest after which of the following surgeries:
    a. Hemithyroidectomy (half of the thyroid)
    b. Isthmusectomy (middle part of the thyroid)
    c. Total thyroidectomy (all of the thyroid)
    d. Same for all of the above

7. Significant bleeding after surgery occurs in____.
    a. More than half of patients (>50%)
    b. About half of patients (50%)
    c. 1 in 4 patients (25%)
    d. Less than 1 in 100 patients (<1%)

8. True or False: In the rare event of having bleeding after surgery, a second surgery may be needed to remove the collection of blood.
    a. True
    b. False

9. True or False: Most patients will require antibiotics after surgery.
    a. True
    b. False

10. The risk of permanent damage to the nerve to the vocal cord after thyroid surgery is:
    a. More than half of patients (>50%)
    b. About half of patients (50%)
    c. 1 in 4 patients (25%)
    d. Less than 1 in 100 patients (<1%)

FIGURE 6: Knowledge Assessment

Decisional Conflict Survey (DCS)

	Yes	Probably Yes	Unsure	Probably No	No
Do you know which options are available to you?	0	1	2	3	4
Do you know the benefits of each option?	0	1	2	3	4
Do you know the risks and side effects of each option?	0	1	2	3	4
Are you clear about which benefits matter most to you?	0	1	2	3	4
Are you clear about which is more important to you (the benefits or the risks and side effects)?	0	1	2	3	4
Do you have enough support from others to make a choice?	0	1	2	3	4
Are you choosing without pressure from others?	0	1	2	3	4
Do you have enough advice to make a choice?	0	1	2	3	4
Are you clear about the best choice for you?	0	1	2	3	4
Do you feel sure about what to choose?	0	1	2	3	4
Is this decision easy for you to make?	0	1	2	3	4
Do you feel you have made an informed choice?	0	1	2	3	4
Does your decision show what is important to you?	0	1	2	3	4
Do you expect to stick with your decision?	0	1	2	3	4
Are you satisfied with your decision?	0	1	2	3	4

FIGURE 7: Decisional Conflict Survey

Decision Regret Scale (DRS)

Please think about the decision you made about your thyroid surgery after talking to your surgeon. Please show how you feel about these statements.	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
It was the right decision.	1	2	3	4	5
I regret the choice that was made.	1	2	3	4	5
I would go for the same choice if I had to do it over again.	1	2	3	4	5
The choice did me a lot of harm.	1	2	3	4	5
The decision was a wise one.	1	2	3	4	5

FIGURE 8: Decisional Regret Scale

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Satisfaction with Decision Scale (SDS)

	Not Satisfied				Very Satisfied
I am satisfied that I was adequately informed about the issues important to my decision.	1	2	3	4	5
The decision I made was the best decision possible for me personally.	1	2	3	4	5
I am satisfied that my decision was consistent with my personal values.	1	2	3	4	5
I expect to successfully carry out (or continue to carry out) the decision that I made.	1	2	3	4	5
I am satisfied that this was my decision to make.	1	2	3	4	5
I am satisfied with my decision.	1	2	3	4	5

FIGURE 9: Satisfaction with Decision Scale