Rehearsal's effect on recall and comprehension of orthodontic informed consent

Thesis

Presented in Partial Fulfillment of the Requirements for the Degree Master of Science in
the Graduate School of The Ohio State University

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2019

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Abstract

Introduction: Proper informed consent allows patients to take an active role in their own treatment decisions and may improve treatment outcomes due to enhanced compliance. The objective was to determine if hand-written rehearsal of core and custom consent items would increase short-term recall and comprehension. **Methods:** Ninety patient-parent pairs were randomly assigned to two groups. After case presentation, each subject was provided 10 minutes to read a modified informed consent document. Group A received visual printouts containing the four core elements (root resorption, decalcification, pain, and relapse/retention) likely to be encountered by all patients and up to four custom elements (e.g. impacted teeth, orthognathic surgery or other case specific treatment issues). Subjects identified and wrote what the image depicted and how it could affect treatment. Group B viewed a PowerPoint presentation on all 18 elements arranged from general to specific. All participants were interviewed, and each provided their socio-demographic data, as well as completed their literacy, health literacy, and state anxiety questionnaires. The groups were compared for recall and comprehension through an ANOVA. **Results:** Item scoring intra-rater reliability was excellent. Subject reliability ranged from fair to substantial. There were no significant differences between Groups A and B for socio-demographic variables, except Group A had a larger proportion of subjects classifying themselves as white. The rehearsal intervention

significantly improved recall and comprehension of the core elements ($p=0.001$) and improved both for the custom elements, but not significantly. For questions regarding the traditional domains of responsibility, risks, and treatment, Group B performed significantly better on treatment questions ($p=0.001$). Overall as anxiety increased, correct responses decreased. **Conclusions:** The rehearsal group improved recall and comprehension of the core and custom elements of informed consent, and as such, rehearsal and may be a more efficient method than an audiovisual presentation to provide informed consent.

Dedicated to my family

Acknowledgments

I would like Dr. Fields for all of the time and effort he gave me to develop and complete this project. I've learned a great deal of how much thought and consideration must be made in order to produce a quality research study from him. It's been wonderful to have you as a mentor and friend.

Also, thank you to Dr. Johnston, Dr. Firestone, and Dr. Robinson for being on my thesis committee and contributing their ideas and knowledge in each of their personal expertise. I am also appreciative for David Heinlein's contribution and legal expertise.

Sue Staples deserves a special thank you for being my research assistant, without whom, this project would not be possible. The commitment and time spent interviewing, recruiting subjects, and transcribing allowed me to see my patients in clinic!

Thank you to my fellow residents for their support and comradery in completing this project.

Finally, thank you to my wife, Lizzy whose constant love and support has fueled my efforts and continued learning. Thank you to my daughter, Elliotte, for always welcoming me home from a long day with a hug.

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(2017). Evaluation of Invisalign treatment effectiveness and efficiency compared with
conventional fixed appliances using the Peer Assessment Rating index. AJODO. 151(2):
259-266.

Fields of Study

Major Field: Dentistry

Specialty: Orthodontics

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Chapter 1. Introduction

Proper informed consent, providing possible risks and outcomes of treatment, allows patients to take an active role in their own treatment decisions. In order for patients to decide on their course of treatment, the options, risks, and benefits should be understood completely. Poor comprehension and recall among patients and their parents shows that current methods of orthodontic informed consent are insufficient.¹ A study found the overall recall rate for surgical orthodontic informed consent, one of our most invasive related procedures, to be 40%.²

Simply signing a document for legal purposes does not mean the patient understands the risks of treatment, and the provider can still be found to have not provided informed consent.^{3,4} Depending on the legal jurisdiction, the claim for “lack of informed consent” is a claim that can be separate and independent from a claim of dental malpractice. Even if there is no negligence in the performance of the dental procedure, a lack of informed consent claim may be able stand alone, as a separate tort. As such, assuring that the patient is informed of the nature, extent and risks of the procedure, is the essential component to “Consent” documents signed by that patient.

Treatment outcomes are likely to improve when patient understanding of home-instructions improves due to increased compliance.⁵ Poor recall and comprehension of information can be linked to current methods of informed consent. It is also correlated with the parent’s education level and vocabulary.¹ Patients and parents must have an understanding of the specific risks and reasons for treatment, procedures performed, and responsibilities for themselves in order for treatment to be successful.⁶ In order to

increase the chance of successful treatment, the recall of these factors is of significant importance.

Increasing patient and parent comprehension includes simplifying the informed consent document.⁷ Many informed consent documents contain dental jargon and are written at a much higher reading level than what the mean national literacy level is for adults; which is estimated to be at the 7th to 9th grade.^{8,9,10}

One study showed whether the information is given in a written, visual or verbal form has no effect independent of each other on retention, but further studies on combinations of the methods were proposed. A study comparing written, verbal, and visual methods of orthodontic informed consent demonstrated that none of these methods alone showed a difference in information retention. The authors recommended that the methods be combined to promote the best retention of informed consent materials.¹¹

Another study tested that approach and created an audiovisual (AV) presentation and compared that to only verbal explanation. They found that the AV group had better comprehension, even in patients with lower education levels.¹²

Modified informed consent documents with larger font, improved readability and processability used in a surgical study were more effective than the original form.⁷ A modified orthodontic consent form, with similar improvements, combined with an 18 element slide show demonstrated improved recall for both the patient and parent when compared to the standard American Association of Orthodontists (AAO) informed consent document.³ The time the staff/practitioner was increased for this method because they had to review each element separately.

Short-term memory may limit the number of novel items presented to 7 ± 2 according to previous research.¹³ The question becomes how do we deliver 18 elements needed for proper informed consent and still improve comprehension? A follow up study by Carr et al¹⁴, found through “chunking (presenting similar types of issues)” of elements (see Figure 1), those presented at the beginning or end of the slide show were understood better than those in the middle when presenting more than 7 items, demonstrating the serial position effect in memory.¹⁴ Pawlak et al¹⁵ compared a group receiving the modified informed consent, slide show and a short introductory video and found that no improvement was made in patient comprehension. The current best practice was found to be the Carr et al group which received modified informed consent and a customized slide show with chunking and information, which was ordered from general to specific issues.¹⁵

In addition to focusing on the grade level at which the consent is written, it is appropriate to begin evaluating the process of memory acquisition. Increasing participation of the patient can also increase memory and learning.¹⁶ A recent study showed that hand-writing notes increases memory and ability to understand information.¹⁷ Our visual attention is commonly restricted to precisely the point where the pen hits the paper during handwriting.¹⁸ We must also take into account that there are different processes responsible for storing information in our short or long term memory. Rehearsal can prevent the loss of information from short term memory and reinforce long-term consolidation of the material.¹⁹ Overall, the patient’s active participation in the process increases retention better than passive reception of that information.

Anxiety can be considered a factor in a patient's successful or failed attempt to remember and understand new information. While compliance can be induced by evoking a moderate level of fear arousal, high levels of fear can cause avoidance of the subject matter.²⁰

It has been shown that highly anxious subjects can store less new information in their working memory than those who were less anxious.²¹ One model proposes that the effectiveness of communication increases as anxiety increases. When combining these two functions, the result is that the actual communication effectiveness increases at first, then peaks and begins to fall as anxiety increases.²²

Correlations of childhood anxiety and underachievement in school have been found.²³ It was suggested that public health agencies should focus on presenting ways to deal with the issue rather than focus only on the dangers of the issue itself in order to increase public awareness and response and decrease anxiety.²⁰

Based on previous best practices according to Carr et al, we compared that method to a technique that incorporated greater patient interaction and rehearsal, emphasized the most important elements pertaining to each specific patient and required the subject's acknowledgement of the element's impact. The new informed consent methods were evaluated for recall and comprehension immediately after the consult.

Specific Aims

Our objective was to determine if hand-written rehearsal of core and custom consent items would increase short-term recall and comprehension.

Null Hypothesis

H₀₁: There is no significant difference in recall and comprehension between the current best practice and written rehearsal.

H₀₂: There is no significant difference in recall and comprehension between the current best practice and written rehearsal depending on question domains.

H₀₃: There is no significant difference in recall and comprehension between the current best practice and written rehearsal depending on state anxiety scores.

Chapter 2: Materials and Methods

This study investigated the orthodontic informed consent process and a possible improvement to this process by increasing the patient's understanding. It was a comparison between two groups of patient and parents. Group A had the treatment options and process explained, then had 10 minutes to read the Modified Informed Consent. Subjects received images illustrating the core (root resorption, pain, relapse/retention, and decalcifications) and up to four custom elements (e.g. impacted teeth, orthognathic surgery or other case specific treatment issues), on which they wrote what the image depicted and described the prevention or impact of the element. Group B was based on the current best practice as described by Carr et al. Instead of the images, an audiovisual PowerPoint presentation was administered. The presentation was chunked, which is grouping together similar factors, and represented the eighteen elements of orthodontic informed consent arranged from general to specific. The end of the slide show addressed up to four custom elements specific to that patient.

Human subject approval

The research protocol was reviewed and approved by The Ohio State University Institutional Review Board (IRB). All subjects (child patient and their parent) enrolled in this research stud completed the HIPAA authorization form, Consent, Assent, and Parental permission forms.

Modified informed consent document

The modified informed consent document (MIC) was developed by Kang et al ³ using the informed consent document for a major university orthodontic clinic and the American Association of Orthodontists Informed Consent for the Orthodontic Patient[®] document (AAO[®]) as a template. The MIC incorporated 18 common elements found in both the College of Dentistry (CoD) and AAO forms. These elements were:

1. Cavities, decalcification, gum disease
2. Discomfort
3. Injury from braces and injury from headgear
4. Health updates
5. Tobacco product use
6. Treatment time
7. Retainers
8. Impacted teeth and unerupted teeth
9. Root resorption
10. Large fillings and injured teeth that may need root canal therapy
11. Accidental injury during adjustment appointments
12. Abnormal jaw growth
13. Extractions and orthognathic surgery for severe crowding and mismatched jaws
14. Temporomandibular Joint Disorders
15. Tooth reshaping, interproximal reduction
16. Ceramic appliances and damage to enamel

17. Wisdom teeth

18. Allergies to orthodontic appliances

The MIC contained less medical/dental jargon, utilized an active voice, larger font size, and balanced white space.²⁴ This represented improved processability. The eighteen elements were divided into 1) preventable risks 2) possible limitations of treatment and 3) patient responsibilities. Each risk was followed by a recommended action for preventing the risk. Reading grade level of the MIC was determined to be 7th grade by the Fry Readability Formula.³ This represented improved readability when compared with the AAO informed consent document.

Development of the computer-based slideshow

The original slideshow (2003, Microsoft Corporation, Redmond, WA) created by Kang et al³ provided audio and visual cues reviewing the eighteen elements of informed consent found in the MIC. For this study, we used a modified version that was used in the study by Carr et al¹⁴ in which the elements were divided into three “chunks.” The chunks were 1) “core” risks most commonly associated with orthodontic treatment: pain, external root resorption, decalcification, and retention/relapse, 2) “custom” risk factors that were specific to each patient (up to four selected by the orthodontist), and 3) the “general” or remaining risk factors. The slideshow was organized so that it progressed from general to more specific with the core and custom elements being placed at the end. The subjects were unaware of this arrangement and no attention was drawn to the importance or significance of the elements.

Measurement tool for informed consent

The measurement tool utilized a series of questions that focused on the eighteen elements of informed consent found in the MIC documents.^{25,26} Multiple choice questions allowed for recognition or recall processes to occur and allowed subjects to get 25% correct even by guessing. The comprehension questions were open-ended in an attempt to assess understanding rather than simple memorization of the information.²⁷ In order to measure subject comprehension, patients were asked how they would respond to certain scenarios. There were four rephrased questions aimed to test for internal reliability of subjects.

Interviewer training

A research assistant carrying out human subject research completed the Collaborative Institutional Training Initiative (CITI) program training and were IRB approved. The research assistant was trained on the research protocol, subject recruitment, consent process, and interview procedure. Interviews were conducted using a script that incorporated the measurement tool. The interviewer repeated and rephrased questions from the measurement tool as needed. The interviewer encouraged subjects to answer all questions without leading their response.

Interview recording, subject identification and interview transcription

All subject interviews were recorded using a digital voice recorder. Subjects were identified using a research ID that incorporated the intervention group, subject number (in order of recruitment) and participant type. “A” identified Group A participants, “B” identified Group B participants, “C” identified child participants, and “P” identified parent participants. All participant information was kept confidential and all identifiers removed. After initial recruitment, subjects were identified only by their research ID. Digital recordings of the interviews were stored as MP3 files on a secure local network and transcribed using an online transcription website.²⁸ They were then saved into a Microsoft® Word document.

Reading ability tests

The reading test portion of the Wide Range Achievement Test 3 (WRAT 3) (Wide Range in cooperation with PAR, Lutz, FL)²⁹, the Rapid Estimate of Adult Literacy in Medicine Short Form (REALM-SF)⁴² and Rapid Estimate for Adolescent Literacy in Medicine Short Form (REALM-TeenS)⁴³ were used to measure overall reading ability and the health literacy reading ability of both the parent and the patient subjects.

The WRAT3 measured a subject’s general reading ability and is for subjects age 5-75. Subjects were asked to read a list of forty-two words aloud.²⁹ If the subject incorrectly pronounced the first five words, he/she then read the letter portion of the test. The test was stopped if there were ten consecutive mispronunciations. The number of correct letters and words was summed and then correlated with a grade level. The test took 5-10 minutes to complete.

The REALM-SF correlated a reader's ability to correctly pronounce health-related words to a health literacy level.⁴² Each adult was given five seconds to read each word from a list of seven words with the total list taking less than a minute to complete. The number of words pronounced correctly was correlated to a health literacy grade level that ranges from the third grade and below to high school.

The REALM-TeenS correlated an adolescent's ability to pronounce health-related words to a health literacy level.⁴³ Each subject was asked to read aloud a list of ten health-related words and took less than a minute to complete. The number of correctly pronounced words was correlated to a health literacy grade level that ranges from the third grade and below to the tenth grade and above.

All of the instruments used in this study have been shown to be valid and reliable measures for the age groups in this study.^{25,30,42,43}

Self-administered questionnaire

A self-administered questionnaire gathered socio-demographic information and state anxiety level. This questionnaire was given after the reading literacy tests were administered. We obtained the subjects' age, sex, annual income, education obtained, employment status and whether they worked in a dental field, ethnicity, and whether they had previously undergone orthodontic treatment. Finally, the six-item Spielberger State-Trait Anxiety Inventory (STAI-6)³⁰ was given to determine each subject's state anxiety.

Sample size

Ninety patient-parent pairs (180 participants) attending the graduate orthodontic clinic were recruited by one author (BNS) or a research assistant at the time of the orthodontic records appointment or via a telephone call. Inclusion criteria were similar to that of Carr et al¹⁴ except that patients were as young as 11 years of age in this study compared with 12 years old in the earlier study. Eleven year old patients were included since many begin comprehensive treatment at that age which would make the results of the study more representative of the adolescent orthodontic population. The criteria for patients were: 11-18 years of age, could speak English, no previous orthodontic treatment, accompanied by a parent or guardian who could speak consent to both research and treatment and had legal guardianship for one year, no developmental disabilities or urgent medical conditions, no sibling who had been treated orthodontically within the past five years or was currently in treatment. The parent/guardian must also be able to speak English and have no developmental disabilities or urgent medical conditions.

A sample size of 45 per group was determined by power analysis based on data from a previous study by Carr et al with a non-directional $\alpha = 0.05$, and a $sd = 16.8$. This would yield a power of 0.80.

Subject allocation and procedures

The pairs were randomly allocated to one of the two study groups using a random number generator.³¹ The scripts used for recruitment, the interview, and questionnaires are in the Appendix. Group A (rehearsal group) underwent the regular consult process with their resident who explained the treatment process and alternative treatment options. The subject pairs were given the Modified Informed Consent document (MIC) and provided time to read it. The language of the MIC had previously been reviewed by University legal counsel. The subject pairs received printed images illustrating each of the four core informed consent elements and any additional (up to four) prioritized visual consent elements, and wrote on the image what the picture displayed and described the prevention or impact the risk poses. The four core elements, those that are the biggest risks for the general orthodontic patient population, given to each subject in Group A were:

- Root resorption (66%)^{32,33}
- Discomfort (95%)³⁴
- Cavities, decalcification, and gum disease (96%)^{35,36,37,38}
- Retainers/relapse (66%)^{39,40}

Up to four other custom elements were added depending on the individual case. (e. g. impacted tooth, abnormal jaw growth, interproximal reduction, wearing rubber bands, surgery etc.) This was deemed appropriate by legal counsel.

Group B (based on the Carr et al. Group B) had a similar explanation of their treatment and time to read the MIC. They viewed a supplemental slide show presentation that outlined items on the modified informed consent with visual and audio content. The slide show contained images and statements with audio and visual cues. The materials were chunked and represent the eighteen elements of orthodontic informed consent arranged from general to specific. The end of the slide show highlighted information regarding the four most common risks of orthodontic treatment as well as up to four customized risk factors for that specific patient, similar to the way customized risk factors were determined for Group A subjects.

Both patient and parent of each group pair were interviewed independently by the research assistant using an established measurement tool that utilizes open-ended questions that were developed to address each of the eighteen common elements of both informed consent documents. They then completed self-administered questionnaires to collect socio-demographic information and state anxiety level (STAI-6).⁴¹ Reading ability and health literacy were determined by administering the REALM-SF (Rapid Estimate of Adult Literacy in Medicine Short Form) to the parent subject, the REALM-TeenS (Rapid Estimate for Adolescent Literacy in Medicine Short Form) to each patient subject, and the reading test component of the WRAT 3 (Wide Range Achievement Test 3).^{42,43} At this point, if parents in either group agreed to treatment, the informed consent document was signed. The remainder of the orthodontic appointment was completed. The children and adolescents received a \$15 gift card for their participation.

Transcription and Coding

The interviews were transcribed by the research assistant and coded to blind the scorer. Using the previously established codebook from the research of Kang et al., one researcher scored all of the interviews after establishing inter-rater reliability. The inter-rater reliability was found by comparing the coding for 18 patient and parent interviews selected randomly from the data of Kang et al.³ Intra-rater reliability was also found by rescored a subset of 18 subjects two weeks later. Responses to the interview questions were scored for recall and comprehension as follows: “inappropriate response”, “don’t know/cannot remember”, or “question skipped/no response” were considered an incorrect response and questions scored as “on target response” were considered a correct response.

Data Analysis

Data were recorded in a spreadsheet (Microsoft® Office Excel, Microsoft Corporation, Redmond, WA) and statistical software (SAS, Cary, NC) was used to analyze it. Simple kappa statistics and 95% confidence intervals were used to determine intra-rater and inter-rater reliability as well as for internal reliability of the subjects with four rephrased concept questions. Between group differences in sociodemographic data, REALM-SF/REALM-TeenS scores, WRAT 3 scores, and STAI-6 scores were analyzed

using the Wilcoxon signed ranks test. The Fisher's exact test will be used to evaluate sex differences.

An ANCOVA was used to assess the following differences between groups A and B: mean percent of on-target responses for overall recall and comprehension; the domains of treatment, risk, and responsibility; and the relationship of the subjects of informed consent. This covariate analysis was performed with STAI-6 scores and ethnicity as covariates. A similar method to evaluate the differences between the core, custom, and general elements was performed.

A Bonferroni corrected t-test was used to resolve significant clinically important effects that had more than one degree of freedom.

Chapter 3: Manuscript

Rehearsal's effect on recall and comprehension of orthodontic consent

ABSTRACT

Introduction: Proper informed consent allows patients to take an active role in their own treatment decisions and may improve treatment outcomes due to enhanced compliance. The objective was to determine if hand-written rehearsal of core and custom consent items would increase short-term recall and comprehension.

Methods: Ninety patient-parent pairs were randomly assigned to two groups. After case presentation, each subject was provided 10 minutes to read a modified informed consent document. Group A received visual printouts containing the four core elements (root resorption, decalcification, pain, and relapse/retention) likely to be encountered by all patients and up to four custom elements (e.g. impacted teeth, orthognathic surgery or other case specific treatment issues). Subjects identified and wrote what the image depicted and how it could affect treatment. Group B viewed a slideshow presentation on all 18 consent elements arranged from general to specific. All participants were interviewed, and each provided their socio-demographic data, as well as completed literacy, health literacy, and state anxiety questionnaires. The groups were compared for recall and comprehension through an ANCOVA. **Results:** The rehearsal intervention

significantly improved recall and comprehension of the core elements ($p=0.001$).

Rehearsal also improved custom recall and comprehension, but not significantly. Group B performed significantly better on treatment questions ($p=0.001$). Overall, as anxiety increased, correct responses decreased. **Conclusions:** The rehearsal group improved recall and comprehension of the core and custom elements of informed consent and proved a more efficient method than an audiovisual presentation to provide informed consent.

INTRODUCTION

Proper informed consent allows patients to take an active role in their own treatment decisions. In order for patients to decide on their course of treatment, the options, risks, and benefits should be understood completely. Poor comprehension and recall among patients and their parents showed that current methods of orthodontic informed consent are insufficient.¹

Simply signing a document for legal purposes does not mean the patient understands treatment, and the provider can still be liable for not informing the patient.^{3,4} Treatment outcomes are likely to improve when patient understanding of home-instructions improves due to increased compliance.⁵ Depending on the legal jurisdiction, the claim for “lack of informed consent” is a claim that can be separate and independent from a claim of dental malpractice. Even if there is no negligence in the performance of the dental procedure, a lack of informed consent claim may be able to stand alone, as a separate tort. Thus, documenting that the patient is informed of the nature, extent and risks of the procedure, is the essential component to “Consent” documents signed by that patient or parent/guardian.

Poor recall and comprehension of treatment information can be linked to current methods of informed consent. It is also correlated with the parent’s education level and vocabulary.¹ In order to increase the chance of successful treatment, understanding treatment is important.

Increasing patient and parent comprehension includes simplifying the informed consent document.⁷ Many informed consent documents contain dental jargon and are

written at a much higher reading level than what the mean national literacy level is for adults; which is estimated to be at the 7th to 9th grade.^{8,9,10}

One study showed that whether the information was given in a written, visual or verbal form had no effect on information retention, but further studies on combinations of the methods were proposed to promote the best retention of informed consent materials.¹¹ Another study tested that approach comparing an audiovisual (AV) presentation to only verbal explanation. They found that the AV group had better comprehension, even in patients with lower education levels.¹²

Modified informed consent documents with larger font, improved readability and processability used in a surgical study were more effective than the original form.⁷ A modified orthodontic consent form, with similar improvements and containing the necessary 18 elements found in the AAO form (Figure 1), combined with an 18 element slide show demonstrated improved recall for both the patient and parent when compared to the standard American Association of Orthodontists (AAO) informed consent document.³

Short-term memory may limit the number of novel items presented to 7 +/- 2 according to previous research.¹³ How to “package” the 18 elements to improve comprehension was examined in a follow up study by Carr et al. These investigators found grouping similar items together, or “chunking”, elements presented at the beginning or end of the slide show were understood better than items in the middle when presenting more than 7 items.¹⁴ The best practice was found to be the procedures reported

by Carr et al.: a modified informed consent and a customized slide show with chunking, which was ordered from general to specific issues.¹⁵

In addition to focusing on how the materials are presented, evaluating the process of memory acquisition should be considered. A recent study showed that hand-writing notes increases memory and ability to understand information.¹⁶ Visual attention is commonly restricted to precisely the point where the pen touches the paper during handwriting.¹⁷ Increasing participation of the patient can also increase memory and learning.¹⁸ Rehearsal can prevent the loss of information from short-term memory and can lead to long-term consolidation of the material.¹⁹ Overall, the patient's active participation in the process increases retention better than passive reception of that information.

Anxiety is a factor in a patient's ability to remember and understand new information. While compliance can be induced by evoking a moderate level of fear arousal, high levels of fear can cause avoidance of the subject matter.²⁰ When combining these two functions, the result is that the actual effectiveness increases at first then peaks and begins to fall as anxiety increases.²²

This study compared best practices presented by Carr et al. with a technique that incorporated greater patient interaction and rehearsal, emphasized the most important elements pertaining to each specific patient and required the subject's acknowledgement of the element's impact. The new informed consent methods were evaluated for recall and comprehension immediately after the consult. Our objective was to determine if

hand-written rehearsal of core and custom consent items would increase short-term recall and comprehension.

MATERIALS AND METHODS

The research protocol was reviewed and approved by the Institutional Review Board (2017B0330). Subjects were recruited as a convenience sample from new patients at a graduate orthodontic clinic by a research assistant during the orthodontic records appointment or by phone. A sample size of 45 per group was determined based on power analysis calculations from a previous study by Carr et al with a non-directional $\alpha = 0.05$, and a standard deviation = 16.8. This would yield a power of 0.80.

Ninety parent-patient pairs agreed to participate in the study. The inclusion criteria were: patients were age 11 through 18, patients had no previous orthodontic treatment or had no siblings currently in treatment or completed treatment in the past five years, both patient and parent able to communicate in English, both did not have any developmental disabilities or urgent medical conditions. Patients were accompanied by a parent or guardian who could consent to participation and had legal guardianship for at least one year. Forty-five parent-patient pairs were allocated at random via a random number generator to each of Groups A and B.³¹

A modified informed consent document (MIC) developed by Kang et al.³ and containing the 18 informed consent elements (Figure 1) was given to the subjects to read

for up to ten minutes after their consultation was completed. The MIC was written at a 7th grade reading level, contained less medical/dental jargon, had a larger font size, and well-proportioned white space (Figure 2). The subjects in Group A received printed images illustrating each of the four core informed consent elements and any additional (up to four) customized visual consent elements chosen by the orthodontist (e.g. impacted teeth, orthognathic surgery or other case specific treatment issues). Remaining elements not included in core and custom were considered general and as a group comprised Domain 1. Subjects wrote on the image what the picture displayed and described the prevention or impact the risk posed. The four “core” elements (and their percentage prevalence among treated patients in the literature) were root resorption (66%)^{32,33}, discomfort (95%)³⁴, cavities and decalcification (96%)^{35,36,37,38}, and retention/relapse (66%).^{39,40} Group B subjects instead watched a slide show as prepared by Carr et al¹⁴ explaining all 18 elements but “chunked” from general to specific and with the “core” elements followed by the “custom” elements at the end. The elements were also designated as either responsibility, risk, or treatment related (Domain 2).

Both groups were then interviewed and had their answers recorded by a trained research assistant using an open-ended script of questions developed and validated previously to analyze recall, the ability to provide specific pieces of information, and comprehension, the ability to understand and apply information.^{25,26,44} The script contained four rephrased recall questions to analyze subject reliability. The research assistant administered the reading portion of the Wide Range Achievement Test 3 (WRAT3)²⁹ to all subjects. The Rapid Estimate of Adult Literacy in Medicine Short

Form (REALM-SF) was administered to the parents/guardians, and the Rapid Estimate of Adolescent Literacy in Medicine Short Form (REALM-TeenS) was administered to the patients. The Steinberger State-Trait Anxiety Index – 6 item form (STAI-6) was given to parents and patients to determine state anxiety following the interview. All of the instruments used in this study have been shown to be valid and reliable measures for the age groups in this study.^{30,42,43} A self-administered questionnaire based on socio-demographic information was also completed by each subject. A gift card was given to each patient for participation.

A research assistant transcribed all interviews and deidentified the entries as well as scored the literacy tests. The calibrated orthodontist was blinded to any identifying information and scored each interview using the established codebook by Kang et al.

STATISTICAL ANALYSIS

Data were entered on a spreadsheet (Microsoft® Office Excel, Redmont, WA) and analyzed with statistical software (SAS, Cady, NC). Simple kappa statistics and 95% confidence intervals were used to determine intra-rater and inter-rater reliability as well as for internal reliability of the subjects with four rephrased concept questions. Between group differences in sociodemographic data, REALM-SF/REALM-TeenS scores, WRAT 3 scores, and STAI-6 scores were analyzed using the Wilcoxon signed ranks test. The Fisher's exact test was used to evaluate sex differences.

An ANCOVA was used to assess the following differences between groups A and B: mean percent of on-target responses for overall recall and comprehension; the domains of treatment, risk, and responsibility; and the relationship of the subjects of informed consent. This covariate analysis was performed with STAI-6 scores and ethnicity as covariates. A similar method to evaluate the differences between the core, custom, and general elements was performed.

A Bonferroni corrected t-test was used to resolve significant effects that had more than one degree of freedom.

RESULTS

Inter-rater reliability was used to determine the reproducibility for coding the interview data and was “excellent” ($\kappa = 0.88$; 95% CI: 0.65, 1.00). Intra-rater reliability for coding the interviews was “excellent” ($\kappa = 1.00$). Internal reliability (Table I) for all subjects was “moderate to substantial”⁴⁵ for three of the four questions with kappa scores ranging from 0.44-0.67. The question examining ankylosis had “fair” reliability with a kappa score of 0.22.

Group A had a significantly larger percentage of subjects identifying as white, while Group B had a larger percentage of subjects identifying as non-white. There was also a significant difference between the white/non-white (W/NW) groups and how their state anxiety affected the on-target response rate. Within Group B, the male parents were significantly older than the female parents ($p=0.01$). There are no significant differences

between Groups A and B for age, gender, education/grade level, parental income, REALM-SF, REALM-TeenS, WRAT3, or STAI-6 (Table II).

The summary of the ANCOVA is provided for Domain 1 (core, custom, or general) (Table III). The effect of STAI by ethnicity (W/NW) was statistically significant ($p=0.044$). The relationship effect (parent vs child patient) was highly significant ($p=0.001$). Domain 1 was found to have a significant interaction with intervention (Group A vs B) and type (recall vs comprehension) for knowledge retained ($p<0.001$) (Table IV). ANCOVA tests compared Group A and B's on-target response rate for recall and comprehension and for Domain 1. Group A had a significantly higher on-target response rate in the "core" domain than Group B ($p=0.021$). Although there were no significant differences in the "custom" domain, Group A outperformed Group B (Figure 3).

The summary of the ANCOVA is provided for Domain 2 (responsibility, risk, and treatment elements) (Table V). The effect of STAI by ethnicity (W/NW) was statistically significant ($p=0.009$). The relationship effect was highly significant ($p=0.001$). Further, Domain 2 was found to have a significant interaction with intervention and type of knowledge retained ($p<0.001$) (Table VI). The on-target response rate for recall and comprehension and the domains of responsibility, risk, and treatment were examined (Figure 4). Group B had a significantly better on-target response rate on questions in the domain, "treatment" ($p=0.0001$). A decrease in correct response rate occurred as state anxiety (STAI) increased, at different rates for whites and non-whites (Figure 5). This was true for both domains.

DISCUSSION

Domain 1 covered the core, custom, and general elements of orthodontic informed consent. Our results showed that rehearsal (Group A) significantly improved correct response rate of “core” questions compared to the slideshow (81% rehearsal, 71% slideshow). Rehearsal also improved the correct response rate for the “custom” element questions (43% rehearsal, 37% slideshow), although not significantly. “General” questions were answered at about the same rate (46% rehearsal, 50% slideshow).

Group A, compared to Carr et al’s slideshow group and Kang et al’s original group, correctly answered more questions based on the “core” elements.^{3,14} However, neither Group A or Group B performed as well as previous studies for the “custom” element. The two groups are very similar for all demographic metrics, such as literacy and education levels.

The best practices method generally performed at a lower level in this study than in Carr et al’s original work, with a similar patient and parent pool. But further examination of the data for all domains were well within Carr et al’s Group B standard deviations. Therefore, we conclude that the method of Carr et al. is robust.

Some elements are intrinsically harder to grasp, such as questions about “ankylosis and interproximal reduction”. It is possible that a different ratio of difficult to

easy questions were asked to each group, resulting from the different treatment plans and selection of the “custom” elements.

Domain 2 covered the responsibility, risk, and treatment elements of orthodontic informed consent. Group B had a significantly better correct response rate for the “treatment” questions compared to Group A (41% slideshow, 30% rehearsal). Rehearsal showed a higher, but insignificant, correct response rate for “responsibility” questions (77% rehearsal, 70% slideshow) and they were the same for “risk” elements (49% rehearsal, 49% slideshow).

Group A’s correct response rate was similar to Carr et al’s results for “risk” and “responsibility” elements; but worse for the “treatment” elements.

In this sample, the “core” domain was generally the highest scoring, followed by the “responsibility” domain for both parents and patients. It is likely that these domains resulted in the highest on-target response rates because some of the elements, like brushing to prevent cavities or discomfort with braces, are most likely to be considered common knowledge by the general public, even to those not undergoing orthodontic treatment. The rehearsal method enhanced the correct response rate for these domains. In this sample, the “treatment” domain performed worst.

When rehearsal is compared to Kang et al’s AAO form group, rehearsal improved the recall correct response rate for both parents (65% vs 58%) and patients (52% vs 42%), whereas comprehension was not as greatly affected.³ Rehearsal may be a more successful method of getting the parent and patient to “parrot” back the recall information, but doesn’t appear to help with understanding of the consent elements.

Parents performed better than the patients in both domains and in overall recall and comprehension, which is consistent with previous studies.^{3,13,14} Parents and patients correctly answered 66% and 52% of recall questions, respectively, and only 51% and 42% of comprehension questions, respectively. Similarly, recall questions have been shown in previous studies to have a higher on-target response rate than more thought-provoking comprehension questions due to the ability to repeat word for word the correct answer in the former.^{3,13,14}

In this study, internal reliability scores were very similar to those found by Kang et al and Carr et al. The ankylosis questions are about complex phenomenon and resulted in only fair reliability. As shown in Carr et al., calibrating new researchers is possible as demonstrated by the high intra- and inter-rater reliabilities.

We found that those identifying as white or non-white were both affected by state anxiety. A higher state anxiety resulted in worse performance on the interview. Other studies have shown the association of higher levels of anxiety to poorer academic performance.^{46,47} This is in contrast to the findings in Kang et al, who reported no relationship between anxiety scores and correct response rates.³ Increased anxiety negatively affected those identifying as white more than those identifying as non-white. This is not consistent with some existing data that reports that anxiety is more detrimental to minorities.⁴⁸

We did find a general trend toward underperforming as anxiety increased as has been reported.²² This could have been in anticipation of the impending interview, or concern about the potential painfulness of some of the impending treatment. This also

shows that an improvement in recall and comprehension may be made by decreasing the family's anxiety during the consult.

Participants who were 11 and 12 years old may have been handicapped by the level of the presentation (7th grade), but participants in both groups would have been negatively affected. Further, care must be taken in generalizing results from a convenience sample.

This study supports an alternative method for obtaining informed consent through rehearsal of the core and custom elements. Assigning up to four custom elements along with the mandatory core elements and having the parent and patient write out the depiction and how it affects their treatment causes the number of novel elements learned to within the 7 +/- 2 principle.¹³ It also confirms that the audiovisual presentation and rehearsal methods outperform the commonly used AAO form.³

The rehearsal method takes less time than the audiovisual presentation and focuses on the elements that the patient is most likely to encounter during their treatment. This allows for patients and parents to focus on the most important elements that will pertain to their situation and not get distracted by details most unlikely to affect them. This method did not threaten the understanding of the other elements needed for complete informed consent.

The long term results of these two methods at a 6-month recall appointment are unknown. Little data are available for long term results in dentistry or orthodontics. Although some of the elements may be repeated over multiple appointments to patients

and parents during treatment (e.g. oral hygiene and appliance care), it is unknown how responses would be impacted.

We suggest that in order to improve this process further, it would be advisable to increase repetition of the most relevant elements in order to consolidate the new consent information from short term into long term memory.

CONCLUSIONS

1. Rehearsal significantly improves recall and comprehension of the core elements of orthodontic informed consent.
2. Rehearsal improves recall and comprehension of the custom elements of orthodontic informed consent, although not significantly.
3. An audiovisual enhanced readable and processable consent significantly improved recall and comprehension of the treatment elements of orthodontic informed consent.
4. An increase in state anxiety negatively affects recall and comprehension of the orthodontic informed consent, but is more detrimental to subjects identifying as white.
5. Written rehearsal is a potentially more efficient way to provide informed consent material than an audiovisual presentation.

6. Rehearsal and the audiovisual presentation both outperformed the historic data associated with the AAO informed consent.

1. Cavities, decalcification, gum disease
2. Discomfort
3. Injury from braces or injury from headgear
4. Health updates
5. Tobacco product use
6. Treatment time
7. Retainers
8. Impacted teeth and unerupted teeth
9. Root resorption
10. Large fillings and injured teeth that might need root canal therapy
11. Accidental injury during adjustment appointments
12. Abnormal jaw growth
13. Extractions and orthognathic surgery for severe crowding and mismatched jaws
14. Temporomandibular joint disorder (TMD)
15. Tooth reshaping and interproximal reduction
16. Ceramic appliances and damage to enamel
17. Wisdom teeth
18. Allergies to orthodontic appliances

Figure 1. Eighteen orthodontic informed consent elements

YOUR CONSENT FOR ORTHODONTIC TREATMENT (BRACES)

Orthodontic treatment (braces) can help you have a pleasing smile. You should know that treatment with braces has limits and possible risks. All health treatments, including braces, have some limits and risks. Your treatment with braces usually goes as planned but results cannot be guaranteed. The good news is that the risks with braces are usually minor and do not happen very often, but you should know about them before choosing braces. The following are possible risks and how you can help reduce the risks.

RISKS**WHAT YOU CAN DO**

Cavities, Decalcification, Gum disease You can get cavities (tooth decay), gum disease, or decalcification (permanent white or brown spots on your teeth) if you eat foods with a lot of sugar or do not clean your teeth often and properly. Your gums can bleed, get puffy, red, and infected (gingivitis). You can also lose the bone that holds your teeth (periodontal disease). The chance of having these problems is greater when you have braces.	<ul style="list-style-type: none">▪ Watch your diet - Avoid sugar and sticky foods.▪ Remove the plaque (build up of food and germs) from your teeth by brushing and flossing your teeth every day.▪ Get regular dental check ups with your dentist while you are in braces.
Discomfort Getting braces and having adjustments to straighten your teeth can make your teeth and mouth sensitive or sore. Everyone is different, but in general, the soreness usually lasts 24 to 48 hours.	<ul style="list-style-type: none">▪ You can take over-the-counter nonaspirin pain medicine to help relieve soreness if allowed by your doctor. Otherwise, use what your doctor recommends.▪ Tell us right away if anything seems unusual.
Damage to braces or teeth Parts of your braces may become loose or break if you get hit in the mouth or face from sports or horseplay. Eating hard foods can also break your braces. Mouth jewelry and piercings around the lips can damage your gums, lips and teeth.	<ul style="list-style-type: none">▪ Wear a mouthguard when you are playing any sport.▪ A mouthguard can protect your teeth and braces from breaking or getting loose.▪ Avoid hard foods.▪ Avoid piercing or keeping a piercing in your tongue, lip, or any part of your mouth.
Injury from braces Your braces may poke or scratch your mouth. Also, if parts of your braces become loose or break they may be swallowed or inhaled (breathed into the lungs). Injury from headgears Even though headgears have a safety system, they can be dangerous. They can hurt your eyes and face.	<ul style="list-style-type: none">▪ Tell us if your braces are hurting you or are loose or broken.▪ Do not wear your headgear outside of the house, during horseplay, or while playing sports.▪ Follow your orthodontist's directions.
Health updates Many medical problems can affect your progress with braces.	<ul style="list-style-type: none">▪ Tell us about your health and all medications.▪ Tell us when there are any changes to your health, including pregnancy and medications.
Using Tobacco Products Using tobacco (smoking or smokeless tobacco) can increase your chance of getting gum disease and slows down healing in your mouth. Tobacco can also increase your chance of getting sores in your mouth and hurt your health.	<ul style="list-style-type: none">▪ Avoid using tobacco products.▪ If you continue to use tobacco, you should know that you may get a less than ideal result with your braces.

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Figure 2. Modified informed consent (MIC) document (copyright 2008, The Ohio State University)

Continued

Figure 2 continued

<u>RISKS</u>	<u>WHAT YOU CAN DO</u>
<p>Treatment time Your time in braces is only an estimate. The actual time in braces may be longer. The following can affect your time in braces and affect the end result: how you grow, how well you wear your rubber bands and other parts of your braces, and if you come to all of your scheduled appointments.</p>	<ul style="list-style-type: none"> ▪ Wear your rubber bands and other parts of your braces as instructed by your orthodontist. ▪ Come to all of your scheduled appointments. ▪ Come to your appointments on time.
<p>Retainers When you get your braces off, your teeth will want to move back toward their starting positions. Your teeth and bite are always changing throughout life. Teeth may change because you are still growing or you have oral habits. There may also be other unknown reasons.</p>	<ul style="list-style-type: none"> ▪ You should wear a retainer to help keep your teeth straight. ▪ Retainers should be worn for as long as you want to keep your teeth straight.

LIMITS

Our goal is to give you the best result possible. There are limits to what braces can do and some things are uncontrollable. The following are the possible limits of braces and other things you should know about braces.

- **Impacted teeth** (teeth that are stuck in the jaw) and **unerupted teeth** (teeth that have not come into the mouth) can be problems. They can cause loss of teeth, gum problems, and shortening of roots. Sometimes these teeth can be pulled into the mouth. Some teeth become ankylosed (tooth fused to the bone) and will not move. These teeth may have to be removed. These problems mean you may be in braces longer.
- Having braces can sometimes cause the roots of your teeth to get shorter. This is called **root resorption**. A past injury of your teeth can increase your chances of having this happen. In general, shortened roots are not a severe problem but can sometimes lead to early loss of the teeth that are affected. If you get root resorption, we may stop or slow down your treatment for a while.
- A large filling or an injury to a tooth from a past accident can **damage the nerve** inside the tooth. Straightening injured teeth can sometimes irritate the nerve and you may need to have a root canal on that tooth.
- Sometimes the dental instruments we use in your mouth can accidentally poke, scratch, or bump your mouth, gums, or teeth.
- **Abnormal jaw growth** can affect your end result and change your treatment. If your teeth and jaws do not grow as expected, your bite will change. If you have braces when this happens, you might need to be in braces longer or have jaw surgery. If abnormal tooth or jaw growth happens after you get your braces off, you may need to have braces again. Abnormal growth is something we cannot predict or control.
- You may need to have some **teeth removed or orthognathic surgery (jaw surgery)** as part of your treatment. This is usually needed to fix severe crowding or severe mismatch of the jaws.
- Problems can occur in the jaw joints making it hard to open your mouth, giving you joint pain, headaches, ear aches, or pain when chewing. These are sometimes called **Temporomandibular Joint Disorders (TMD or TMJ)**. If you have any of these problems, please tell us right away. We may send you to a specialist to have these problems treated. Braces do not cause or cure TMD or TMJ.
- **Braces alone may not provide the best result.** The best result may require changing the shape and size of your teeth. These may include reshaping or flattening some of your teeth by grinding the enamel or adding filling material to make your teeth a different size. Your dentist can help make these changes and answer your questions about these procedures.

2/3

Continued

Figure 2 continued

- **Clear or tooth-colored braces** have been known to break and damage teeth. When the braces are taken off, they can crack or cause flaking of the teeth. There is a risk of swallowing or inhaling the bracket if it breaks.
- **Wisdom teeth** can sometimes cause problems with your teeth and jaws. We will let you know if they need to be removed. Your dentist may also discuss wisdom teeth with you. Please let us know what your dentist recommends before you have anything done.
- Some patients are **allergic to the materials in the braces and rubber bands**. The braces may need to be stopped. Sometimes, special braces can be used or we may have to do a different plan for your teeth. You may need to see a medical doctor to control the allergy.

POSSIBLE OPTIONS

Getting braces is a choice for you to make. There may be more than one good way to fix your teeth and mouth. Sometimes there is only one good choice. You do not have to change your mouth and teeth.

CONSENT TO HAVE ORTHODONTIC TREATMENT (BRACES)

I have read, understood and have had all of my questions answered about the risks and limits of braces. I have been told by my orthodontist about the problems they have found and how they can be fixed. My orthodontist has also told me about any problems that may come up during my treatment with braces. I understand that things can change while I am in braces and the risk of continuing with braces may become greater than the benefits. The braces should be stopped if this happens. I know that treatment generally goes as planned but my results are not guaranteed. I understand that extra dental procedures, like jaw or gum surgery, implants, root canals, reshaping teeth and/or fillings are a separate cost from the braces. All of the information I need to make a decision has been given to me. I was able to ask all of my questions about my treatment and this form. I consent (give my permission) to having treatment.

USE OF RECORDS AGREEMENT

The Ohio State University Orthodontic Clinic is a patient treatment and learning center. I know that during my appointments, there may be other people observing for learning purposes. My records (pictures of my face and teeth, x-rays, or models of myself) may be used for consultations, teaching, publication in dental books and journals, or for display at scientific meetings. My name will not be included with the records. I consent to the use of my records by The Ohio State University Section of Orthodontics for these purposes.

KEEPING MY BRACES AND TEETH CLEAN (ORAL HYGIENE AGREEMENT)

I know that it is my responsibility to keep my braces and teeth clean. I must see my family dentist at least every 6 months. If I do **NOT** keep my braces and teeth clean while I have my braces, I know that any or all of the following bad things may occur: permanent discoloration of my teeth, cavities, or gum disease. If any of the above things occur because my braces and teeth are not clean, I know that I may need treatment by my family dentist or a dental specialist.

KEEPING MY APPOINTMENTS

If I cannot keep my appointment, 24 hours notice is required and I must cancel my appointment by calling (614) 292-9100. This helps the staff schedule another patient to take my place. If I cancel an appointment less than 24 hours in advance or do not show for an appointment, it will be considered a **no-show**. A **no-show** hurts 4 people: a patient that could have used my time, my orthodontist, the faculty supervising my care, and myself. After 3 **no-shows**, I will be considered uncooperative. I may not be able to continue being a patient in this clinic. My care in this clinic will be reconsidered.

URGENT PROBLEMS

If I have an urgent problem with my braces between 4:30 pm and 7:30 am, Monday to Friday or anytime on weekends, I can page my orthodontist. If s/he is unavailable, I can call (614) 293-8000 and ask for the GPR Resident on call.

Patient, Parent or Legal Guardian Signature _____ Date: _____ Resident _____ Date: _____

Figure 3. On-target response rate for the domains of core, custom, and general questions

*Values are significantly different from each other (“Core”; $p=0.0208$)

Figure 4. On-target response rate for the domains of responsibility, risk, and treatment

*Values are significantly different from each other ("Treatment"; $p=0.0008$)

Figure 5. The effect of STAI on correct responses; regression equations:

Domain 1: NW; % Correct = $49.79 + 0.0752 \times \text{STAI6}$

Domain 1: W; % Correct = $68.55 - 1.12 \times \text{STAI6}$

Domain 2: NW; % Correct = $55.44 - 0.623 \times \text{STAI6}$

Domain 2: W; % Correct = $65.17 - 1.06 \times \text{STAI6}$

Table 1. Internal reliability of subjects

<i>Question</i>	<i>Subject kappa (CI)*</i>	<i>Reliability⁴⁵</i>
Retainers	0.45 (0.20-0.69)	Moderate
Health updates	0.44 (0.28-0.60)	Moderate
TMJ/TMD	0.67 (0.56-0.78)	Substantial
Ankylosis	0.22 (0.07-0.37)	Fair

TMJ/TMD, Temporomandibular joint/temporomandibular disorder.

* Lower 95% to upper 95% confidence bounds.

⁴⁵Landis and Koch.

Table 2. Sociodemographic data, REALM-TeenS, REALM-SF, WRAT 3, STAI-6 for patients and parents

<i>Subject</i>	<i>Group</i>	<i>Sex</i>	<i>Age (y)</i> (mean [$\pm$ SD])	<i>Educational</i> <i>level (median)</i>	<i>Ethnicity*</i> (%)	<i>Income</i> (median)	<i>REALM-TeenS</i> (median)	<i>REALM-SF</i> (median)	<i>WRAT 3</i> (median)	<i>STAI-6</i> (median)
Patient	A	55.6% F	14.8 (2.0)	9 th grade	70.0 WNH		8 th -9 th		Post high	8.0
	n=45	44.4% M	14.3 (2.1)		15.0 mixed		grade		school	
					7.5 BNH 2.5 BH 2.5 WH 2.5 EA					
	B	55.6% F	14.2 (2.2)	9 th grade	48.8 WNH		8 th -9 th		Post high	9.0
	n=45	44.4% M	15.0 (1.9)		29.3 BNH 7.3 mixed 7.3 SA 4.9 WH 2.4 BH		grade		school	
<i>P</i> value		>.99	>.99	0.38	0.03		0.24		0.58	0.16
Parent	A	80% F	42.3 (8.3)	<4 years	75.0 WNH	\$25,000-		High	Post high	9.0
	n=45	20% M	47.2 (8.1)	college	12.5 mixed	\$49,999		school	school	
					7.5 BNH 2.5 BH 2.5 EA					
	B	77.8% F	42.1 (8.1)	<4 years	53.7 WNH	\$25,000-		High	Post high	9.0
	n=45	22.2% M	51.0 (9.4)	college	29.3 BNH 7.3 WH 4.9 SA 2.4 BH 2.4 mixed	\$49,999		school	school	
<i>P</i> value		0.80	0.12**	0.20	<.01	0.39		0.80	0.96	0.88

F, Female; *M*, male.

* *WNH*, White non-Hispanic; *WH*, White Hispanic; *BNH*, Black non-Hispanic; *BH*, Black Hispanic; *EA*, East Asian or Pacific Islander; *SA*, South Asian

** Males were older ($P<.01$) than the females in the parents in B intervention group

Group A = Rehearsal; Group B = Best practice group (slideshow) Carr et al¹⁴

Table 3. Domain 1 interactions

Source of Variation	Numerator Degrees of Freedom	Denominator Degrees of Freedom	F-ratio	P-value
STAI6 x WorNW	2	155.73	3.193	0.0437 †
Intervention (I)	1	155.73	2.944	0.0882
Relationship (R)	1	155.75	36.148	<.0001 †
I x R	1	155.93	0.613	0.4349
Type	1	777.92	89.911	<.0001
I x Type	1	777.92	0.062	0.8040
R x Type	1	777.92	1.794	0.1808
I x R x Type	1	777.92	0.935	0.3338
Domain1	2	780.45	239.397	<.0001
I x Domain1	2	780.45	7.779	0.0005 ‡
Relationship x Domain1	2	780.44	1.979	0.1389
I x R x Domain1	2	780.44	0.741	0.4769
Type x Domain1	2	777.92	7.836	0.0004 ‡
I x Type x Domain1	2	777.92	0.930	0.3949
R x Type x Domain1	2	777.92	0.242	0.7853
I x R x Type x Domain1	2	777.92	0.290	0.7486

‡Significant 2-way interactions that required covariance

†Significant 1-way interactions

Table 4. Pairwise interactions for Domain 1

Intervention	Type	Domain 1	_Int	_Type	_Domain 1	Estimate	StdErr	Bon_p*
A	Comp	Core	A	Comp	General	0.4249	0.03405	0
A	Comp	Core	A	Comp	Custom	0.3956	0.03456	0
A	Comp	General	A	Comp	Custom	-0.02929	0.03456	1
A	Recall	Core	A	Recall	General	0.2598	0.03405	0
A	Recall	Core	A	Recall	Custom	0.358	0.03456	0
A	Recall	General	A	Recall	Custom	0.09817	0.03456	0.06923
B	Comp	Core	B	Comp	General	0.2482	0.03384	0
B	Comp	Core	B	Comp	Custom	0.3216	0.03384	0
B	Comp	General	B	Comp	Custom	0.0734	0.03384	0.46685
B	Recall	Core	B	Recall	General	0.1738	0.03384	0.00001
B	Recall	Core	B	Recall	Custom	0.346	0.03384	0
B	Recall	General	B	Recall	Custom	0.1722	0.03384	0.00001

*Bonferroni adjusted p-value

Table 5. Domain 2 Interactions

Source of Variation	Numerator Degrees of Freedom	Denominator Degrees of Freedom	F-ratio	P-value
STAI6 x WorNW	2	155	4.896	0.0087 †
Intervention (I)	1	155	0.238	0.6260
Relationship (R)	1	155	36.277	<.0001 †
I x R	1	155	0.315	0.5754
Type	1	785	112.347	<.0001
I x Type	1	785	1.374	0.2415
R x Type	1	785	1.600	0.2063
I x R x Type	1	785	1.374	0.2415
Domain2	2	785	387.943	<.0001
I x Domain2	2	785	20.907	<.0001 ‡
Relationship x Domain2	2	785	0.984	0.3742
I x R x Domain2	2	785	1.278	0.2791
Type x Domain2	2	785	34.509	<.0001 ‡
I x Type x Domain2	2	785	1.481	0.2281
R x Type x Domain2	2	785	0.280	0.7562
I x R x Type x Domain2	2	785	0.147	0.8632

‡Significant 2-way interactions that required covariance

†Significant 1-way interactions

Table 6. Pairwise interactions for Domain 2

Intervention	Type	Domain 2	_Int	_Type	_Domain 2	Estimate	StdErr	Bon_p*
A	Comp	Responsibility	A	Comp	Risk	0.3733	0.02818	0
A	Comp	Responsibility	A	Comp	Treatment	0.5283	0.02818	0
A	Comp	Risk	A	Comp	Treatment	0.155	0.02818	0
A	Recall	Responsibility	A	Recall	Risk	0.1858	0.02818	0
A	Recall	Responsibility	A	Recall	Treatment	0.4246	0.02818	0
A	Recall	Risk	A	Recall	Treatment	0.2387	0.02818	0
B	Comp	Responsibility	B	Comp	Risk	0.3516	0.02801	0
B	Comp	Responsibility	B	Comp	Treatment	0.3581	0.02801	0
B	Comp	Risk	B	Comp	Treatment	0.006577	0.02801	1
B	Recall	Responsibility	B	Recall	Risk	0.07235	0.02801	0.14941
B	Recall	Responsibility	B	Recall	Treatment	0.2351	0.02801	0
B	Recall	Risk	B	Recall	Treatment	0.1628	0.02801	0

*Bonferroni adjusted p-value

Chapter 4: Conclusions

1. Rehearsal significantly improved recall and comprehension of the core elements of orthodontic informed consent.
2. An audiovisual enhanced readable and processable consent improved recall and comprehension of the treatment elements of orthodontic informed consent.
3. An increase in state anxiety affected both white and non-white participants and resulted in an overall decrease in performance in recall and comprehension of the orthodontic informed consent, but was more detrimental to subjects identifying as white.
4. Written rehearsal is a potentially more efficient way to give informed consent material than an audiovisual presentation.
5. Rehearsal and the audiovisual presentation both outperformed the historic data associated with the AAO informed consent.
6. Since this was a convenience sample for Columbus, Ohio, this study should be replicated in other national samples.

References

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Appendix A. Assent

ASSENT
Behavioral/Social Science

IRB Protocol Number: 2017B0330
IRB Approval date: 09/06/17
Version: 1.0

The Ohio State University Assent to Participate in Research

Study Title: Orthodontic informed consent considering effect of rehearsal of treatment risk on short and long term recall and comprehension

Researcher: Henry W. Fields, Jr.

Sponsor: Delta Dental Master's Thesis Grant

- You are being asked to be in a research study. Studies are done to find better ways to treat people or to understand things better.
- This form will tell you about the study to help you decide whether or not you want to participate.
- You should ask any questions you have before making up your mind. You can think about it and discuss it with your family or friends before you decide.
- It is okay to say "No" if you don't want to be in the study. If you say "Yes" you can change your mind and quit being in the study at any time without getting in trouble.
- If you decide you want to be in the study, an adult (usually a parent) will also need to give permission for you to be in the study.

1. What is this study about?

We want to know how much our patients and parents understand about their orthodontic treatment.

2. What will I need to do if I am in this study?

You will be randomly assigned (by chance) to one of two research study groups. You will need to listen to the presentation by your orthodontic resident. The resident will explain what they plan to do to treat you. You may also read a few papers that talk about all the possible risks and your responsibilities when you are in treatment. We will also ask you to watch a short informational slide show or write what you've just learned on some pictures. Then you will complete a questionnaire, read a list of words, and then be interviewed. In the interview we will ask you some questions about what you just heard and read. We will also ask questions about how you are feeling, such as if you are feeling relaxed or worried.

3. How long will I be in the study?

The study will take approximately 45-60 minutes for the first appointment and 20-30 min for the second appointment at 6 months.

4. Can I stop being in the study?

You may stop being in the study at any time.

5. What bad things might happen to me if I am in the study?

There are no bad things that can happen if you are in the study.

6. What good things might happen to me if I am in the study?

There are no good things that can happen to you if you are in the study. It can help other people in the future because we can make our papers and presentations easier to understand.

7. Will I be given anything for being in this study?

You will be given a \$15 gift certificate for participating after the first interview and another \$15 gift card for you and your parent after the 6 month interview.

8. Who can I talk to about the study?

For questions about the study you may contact Dr. Henry Fields or Dr. Brennan Skulski.

Henry Fields
The Ohio State University College of Dentistry
Section of Orthodontics
4088 F Postle Hall
305 W. 12th Ave, PO Box 182357
Columbus, Ohio 43210-2357
614-292-1120

Brennan Skulski
The Ohio State University College of Dentistry
Section of Orthodontics
305 W. 12th Ave, PO Box 182357
Columbus, Ohio 43210-2357
614-292-9100

To discuss other study-related questions with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

Signing the assent form

I have read (or someone has read to me) this form. I have had a chance to ask questions before making up my mind. I want to be in this research study.

Signature or printed name of subject Date and time AM/PM

Investigator/Research Staff

I have explained the research to the participant before requesting the signature above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining assent Signature of person obtaining assent

Date and time AM/PM

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.

Appendix B. Parental Permission

PARENTAL
PERMISSION
Behavioral/Social
Science

IRB Protocol Number: 2017B0330
IRB Approval date: 09/06/17
Version: 1.0

The Ohio State University Parental Permission For Child's Participation in Research

Study Title: Orthodontic informed consent considering effect of rehearsal of treatment risk on short and long term recall and comprehension

Researcher: Henry W. Fields, Jr.

Sponsor: Delta Dental Master's Thesis Grant

This is a parental permission form for research participation. It contains important information about this study and what to expect if you permit your child to participate.

Your child's participation is voluntary.

Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate. If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose: We would like to know how well we are communicating with our patients and their parents during our consultation appointment and improve this if needed.

Procedures/Tasks: You and your child will be randomly assigned (by chance) to one of two research study groups. You and your child will need to listen to the presentation by your orthodontic resident. The resident will explain what they plan to do to treat your child. You and your child may also read a few papers that talk about all the possible risks and your responsibilities when you are in treatment. We will also ask you and your child to watch a short informational slide show or write what you've just learned on some pictures. Then you both will complete a questionnaire, read a list of words, and then be interviewed. In the interview we will ask you both some questions about what you just heard and read. We will also ask questions about how you and your child are feeling, such as if you are feeling relaxed or worried.

Duration: The study will take approximately 45-60 minutes for the first appointment and 20-30 min for the second appointment at 6 months.

Your child may leave the study at any time. If you or your child decides to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to

which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits: There are minimal anticipated risks, side effects or discomforts from being in the study.

Your child will not benefit directly from participating in the study. The study may benefit others in the future.

Confidentiality:

Efforts will be made to keep your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law. Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Incentives: Your child will be given a \$15 gift certificate for participating after the first interview and another \$15 gift card for you and your child after the 6 month interview. By law, payments to research participants are considered taxable income.

Participant Rights:

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel your child has been harmed as a result of study participation, you may contact Dr. Henry Fields or Dr. Brennan Skulski.

Henry Fields
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For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject

Printed name of person authorized to provide permission for subject

Signature of person authorized to provide permission for subject

Relationship to the subject

Date and time AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time AM/PM

Appendix C. Consent

CONSENT
Behavioral/Social Science

IRB Protocol Number: 2017B0330
IRB Approval date: 09/06/17
Version: 1.0

The Ohio State University Consent to Participate in Research

Study Title: Orthodontic informed consent considering effect of rehearsal of treatment risk on short and long term recall and comprehension

Researcher: Henry W. Fields, Jr.

Sponsor: Delta Dental Master's Thesis Grant

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose: We want to know how much our patients and parents understand about their orthodontic treatment.

Procedures/Tasks: You will be randomly assigned (by chance) to one of two research study groups. You will need to listen to the presentation by your orthodontic resident. The resident will explain what they plan to do to treat you. You may also read a few papers that talk about all the possible risks and your responsibilities when you are in treatment. We will also ask you to watch a short informational slide show or write what you've just learned on some pictures. Then you will complete a questionnaire, read a list of words, and then be interviewed. In the interview we will ask you some questions about what you just heard and read. We will also ask questions about how you are feeling, such as if you are feeling relaxed or worried.

Duration: The study will take approximately 45-60 minutes for the first appointment and 20-30 min for the second appointment at 6 months.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits: There are no bad things that can happen if you are in the study. There are no good things that can happen to you if you are in the study. It can help other people in the future because we can make our papers and presentations easier to understand.

Confidentiality:

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Incentives:

You will be given a \$15 gift certificate for participating after the first interview and another \$15 gift card for you and your parent after the 6 month interview.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact Dr. Henry Fields or Dr. Brennan Skulski.

Henry Fields
The Ohio State University College of Dentistry
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4088 F Postle Hall

CONSENT
Behavioral/Social Science

IRB Protocol Number: 2017B0330
IRB Approval date: 09/06/17
Version: 1.0

305 W. 12th Ave, PO Box 182357
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For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____ Printed name of subject	_____ Signature of subject
	_____ Date and time
	AM/PM
_____ Printed name of person authorized to consent for subject (when applicable)	_____ Signature of person authorized to consent for subject (when applicable)
_____ Relationship to the subject	_____ Date and time
	AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____ Printed name of person obtaining consent	_____ Signature of person obtaining consent
	_____ Date and time
	AM/PM

Appendix D: Customized Slideshow Elements

Data Identification for Selection of Customized Informed Consent

Patient name_____.

Research ID_____.

Date of consult_____.

Phone number_____.

Age_____.

First sibling with ortho treatment_____.

Speaks English_____.

Mental disabilities_____.

_____.impacted tooth

_____.mouth guard

_____.allergic reaction

_____.head gear

_____.smoking

_____.unerupted tooth

_____.large filling or previous trauma to a tooth

_____.abnormal jaw growth

_____.reshaping teeth (buildups or IPR)

_____.ceramic brackets

_____.wisdom teeth

_____.TMJ disorder

Appendix E: Script for invitation to participate

The script is "We are asking you and your child to participate in a research study for one of our residents, Dr Brennan Skulski's master's degree. We are looking at ways to improve patient understanding of their orthodontic treatment and its risks and limitations. Please plan on an additional 45 mins after your consult appt for the study. Your child will receive a \$15 target gift card at this appt and the same parent and child will each receive a \$15 gift card at the 6 month interview."

Appendix F: Parental interview script

INTERVIEW SCRIPT FOR MAIN STUDY (SUBJECT-PARENT)

Script for main study interview (Subject – Parent)

This interview will help us find the best way to communicate with our patients and parents. This is not a test. There is no right or wrong answer. Your child's treatment will not be influenced by how you answer questions during this interview. This part of the study will be tape recorded so the information can be analyzed later by the research investigators. Some of the questions may sound the same. Please answer each question as best as you can.

[Turn tape recorder on]

The research ID is [state the research ID].

[Informed Consent Questions]

1. What are the risks to the teeth and gums with braces on?
How can you prevent these things from happening?
2. What are the risks to the tooth roots during braces?
What could make it worse?
If the orthodontist notices some changes to the tooth roots what would the orthodontist do?
3. What are the risks to your child's teeth if ceramic braces are taken off?
4. When your child is done with braces, what does your child need to do to keep their teeth straight?
5. Some people have jaw pain or what they call "TMJ" or "TMD". How is this related to the braces or orthodontic treatment?
6. What problems can an injured tooth or a tooth that had a large cavity cause during braces?
7. What can you expect your child to feel after getting their braces on or having an adjustment on their braces?
Is there anything you can do about this?
8. What are some things that could happen while the orthodontist or assistant is working in your child's mouth with instruments?
9. When something comes loose in your child's mouth what should you do?

10. How do we fix mismatched jaws?
How do we fix crowded teeth?
11. Please name some of the things that can happen if your child's jaws do not grow as we expect or grow abnormally?
12. If there are teeth that are stuck in the jaws or fused to the bone, what can happen?
Can these teeth be pulled into the mouth?
13. How long is your child estimated to be in braces or have orthodontic treatment?
What are some things that could affect the treatment time?
Name some responsibilities you and your child have during treatment.
14. Braces may not be enough to perfectly fix your child's teeth. What else may need to be done to make them look right?
15. What are some important things your orthodontist needs to know about your child's health?
16. What is your orthodontist going to do about your child's wisdom teeth?
17. What would happen if your child developed an allergy to the materials in the braces?
18. What is your orthodontist's recommendation about smoking or using smokeless tobacco?
Why?
- R19. Does your child have to wear anything after their braces are taken off?
What are their responsibilities?
How long do they have to wear it?
- R20. When your child comes in for an appointment, what does the orthodontist need to know about their health?
- R21. "TMJ" or "TMD" is associated with jaw pain. How does orthodontic treatment affect "TMJ" or "TMD"?
- R22. Sometimes teeth are stuck or fused to the jaw bone and won't come into the mouth. What can be done about this? What are the risks?

Scenarios

I will now read to you a situation and ask you how you would handle the situation.

Amy got her braces a few days ago. Her mouth is sore especially when she is eating. What would you do?

Dr. Smith, your child's orthodontist, just showed you an x-ray of your child's teeth. She said that your child has root resorption of a few teeth in the upper jaw. What would you see?

You were checking your child's teeth to make sure he was brushing well and you noticed that his gums were bleeding. What is the reason for this? What would you do?

Your orthodontist just took Billy's braces off. There are white spots and circles on the front of each tooth that don't wipe off. What has happened? What can be done about this? What could have prevented this?

Your child has a tooth that needed to be pulled into the mouth. The tooth was being pulled into the mouth slowly, but all of a sudden it stopped moving. What could be the reason? What should be done about this?

Sara had her braces taken off 5 years ago. She is now 22 and her teeth do not fit together. In fact, her teeth don't come together at all when she closes her mouth. What happened?

Becky had a lot of cavities filled a year ago. The dentist told her that one cavity was really deep. She is now in braces and her teeth are sore. That one tooth is really throbbing. What could be happening to the tooth?

While eating dinner, your child finds a bracket loose in his mouth. What should you do?

Betsy was expected to be in braces for only 1 and a half years. It is now almost 2 years since she had her braces first put on. What could have happened?

John has two small teeth with spaces between them. He was told by his orthodontist that the spaces may not be closed. Why?

Jenny recently got her braces taken off and has retainers. She is wondering how long she is going to have to wear the retainers. What do you tell her?

Andrew has had braces for a year now and has been having some jaw soreness. He thinks the braces caused his jaw to be so sore. What would you say?

When Annie was 6, she tripped and chipped her front tooth. What might happen to that tooth now that she is getting braces?

Robert went to his doctor for a yearly check up. He has to take a new medication. Today he is going to his orthodontist for an adjustment appointment. What should he do at the appointment?

When someone has extremely crooked teeth or mismatched jaws what may need to be done?

[Turn off the tape recorder]

Administering the REALM-SF®

Start on the left at the top and read down. This helps us understand how familiar you are with the words we plan to use. [Have subject read each word out loud. They can attempt to read it several times. If they get stuck on a word, ask them to skip to the next one. Have them attempt all of the words.]

Administering the WRAT 3®

Start on the left at the top and read to the right. This helps us understand how familiar you are with the words we plan to use. [Have subject read each word out loud. They can attempt to read it several times. If they get stuck on a word, ask them to try anyway. If they do not pronounce at least five words correctly, have them read the 15 letters in the Letter Reading section after completion of the Word Reading section. If they miss 10 words in a row, stop.]

[Ask the parent to complete the questionnaire.]

Appendix G: Child interview script

INTERVIEW SCRIPT FOR MAIN STUDY (SUBJECT-CHILD)

The research ID is [state the research ID].

[Informed Consent Questions]

1. What are the risks to the teeth and gums with braces on?
How can you prevent these things from happening?
2. What are the risks to the tooth roots during braces?
What could make it worse?
If the orthodontist notices some changes to the tooth roots what would the orthodontist do?
3. What are the risks to your teeth when ceramic braces are taken off?
4. When you are done with braces, what do you need to do to keep your teeth straight?
5. Some people have jaw pain or what they call “TMJ” or “TMD”. How is this related to the braces or orthodontic treatment?
6. What problems can an injured tooth or a tooth that had a large cavity cause during braces?
7. What can you expect to feel after getting your braces on or having an adjustment on your braces?
Is there anything you can do about this?
8. What are some things that could happen while the orthodontist or assistant is working in your mouth with instruments?
9. When something comes loose in your mouth what should you do?
10. How do we fix mismatched jaws?
How do we fix crowded teeth?
11. Please name some of the things that can happen if your jaws do not grow as we expect or grow abnormally?
12. If there are teeth that are stuck in the jaws or fused to the bone, what can happen?
Can these teeth be pulled into the mouth?
13. How long are you estimated to be in braces or have orthodontic treatment?
What are some things that could affect the treatment time?
Name some responsibilities you have during treatment.
14. Braces may not be enough to perfectly fix your teeth. What else may need to be done to make them look right?

15. What are some important things your orthodontist needs to know about your health?
16. What is your orthodontist going to do about your wisdom teeth?
17. What would happen if you developed an allergy to the materials in the braces?
18. What is your orthodontist's recommendation about smoking or using smokeless tobacco? Why?
- R19. Do you have to wear anything after your braces are taken off?
What are your responsibilities?
How long do you have to wear it?
- R20. When you come in for an appointment, what does the orthodontist need to know about your health?
- R21. "TMJ" or "TMD" is associated with jaw pain. How does orthodontic treatment affect "TMJ" or "TMD"?
- R22. Sometimes teeth are stuck or fused to the jaw bone and won't come into the mouth. What can be done about this? What are the risks?

Scenarios

I will now read to you a situation and ask you how you would handle the situation.

Amy got her braces a few days ago. Her mouth is sore especially when she is eating. What would you do?

Dr. Smith, your orthodontist, just showed you an x-ray of your teeth. She said that you have root resorption of a few teeth in the upper jaw. What would you see on the x-ray?

You were checking your teeth to make sure you were brushing well and you noticed that your gums were bleeding. What is the reason for this? What would you do?

The orthodontist just took Billy's braces off. There are white spots and circles on the front of each tooth that don't wipe off. What has happened? What can be done about this? What could have prevented this?

You had a tooth that needed to be pulled into the mouth. The tooth was being pulled into the mouth slowly, but all of a sudden it stopped moving. What could be the reason it stopped moving? What should be done about this?

Sara had her braces taken off when she was 15 years old. She is now 22 and her teeth do not fit together. In fact, her teeth don't come together at all when she closes her mouth. What happened?

Becky had a lot of cavities filled a year ago. The dentist told her that one cavity was really deep. She is now in braces and her teeth are sore. That one tooth is really throbbing. What could be happening to the tooth?

While eating dinner, you find a bracket loose in your mouth. What should you do?

Betsy was expected to be in braces for only 1 and a half years. It is now almost 2 years since she had her braces first put on. What could have happened?

John has two small teeth with spaces between them. He was told by his orthodontist that the spaces may not be closed. Why?

Jenny recently got her braces taken off and has retainers. She is wondering how long she is going to have to wear the retainers. What do you tell her?

Andrew has had braces on for a year now and has been having some jaw soreness. He thinks the braces caused his jaw to be sore. What would you say?

When Annie was 6, she tripped and got a large chip on her permanent front tooth. She is now 14 and getting braces. What might happen to that tooth now that she is getting braces?

Robert went to his doctor for a yearly check up. He has to take a new medication. Today he is going to his orthodontist for an adjustment appointment. What should he do at the appointment?

When someone has extremely crooked teeth or mismatched jaws what may need to be done?

[Turn off the tape recorder]

Administering the REALM-TeenS®

Start on the left at the top and read down. This helps us understand how familiar you are with the words we plan to use. [Have subject read out loud each word. They can attempt to read it several times. If they get stuck on a word, ask them to skip to the next one.]

Administering the WRAT 3®

Start on the left at the top and read to the right. This helps us understand how familiar you are with the words we plan to use. [Have subject read out loud each word. They can attempt to read it several times. If they get stuck on a word, ask them to try anyway.]

[Ask the child to complete the questionnaire.]

Appendix H: Parental questionnaire

Parent/Guardian Questionnaire
 Research ID _____ P _____ Date _____

1. What is your birth date? Month _____ Day _____ Year _____

Please circle the best answer for the following questions

2. What is your gender? Male _____ Female _____

3. What was your total household income before taxes in the past year (including wages, social security, alimony, child support, and any other income)?

\$10,000 or less	\$50,000-\$74,999
\$10,001-\$24,999	\$75,000-\$99,999
\$25,000-\$49,999	\$100,000 or more

4. Who is living in your household? (check as many as you need to)

Single _____

With spouse or partner _____

With other adults: how many? _____

With own children: how many? _____

With parents: how many? _____

With children of spouse/partner/others': how many? _____

5. Have you ever had braces or orthodontic treatment?

Yes _____ No _____

6. Are there other people in the household who have had braces or orthodontic treatment, or are currently in treatment?

Yes _____ No _____

7. What is the highest grade of school or year of college that you finished?

8 th grade or less	2 years of college or technical school
9 th grade	Less than 4 years of college
10 th grade	4 year College graduate
11 th grade	Graduate school
12 th grade or GED	Professional school (MD, DDS, JD, DO)

8. What is your working status right now?

Working full time

Working part time

Stay at home parent

Retired

Unemployed, looking for work

Unemployed, not looking for work

Unable to work

Full or part time student

9. Do you have or have you ever had a dentally related job (Dental assistant, EFDA, Dental hygienist, Dentist)?

Yes

No

10. What ethnic group or groups would you identify **yourself** with? (Circle as many as you need)

Black, Hispanic

Black, Non-Hispanic

White, Hispanic

White, Non-Hispanic

South Asian

East Asian, Pacific Islander

Native American

Mixed

11. What ethnic group would you identify your **child** with?

Black, Hispanic

Black, Non-Hispanic

White, Hispanic

White, Non-Hispanic

South Asian

East Asian, Pacific Islander

Native American

Mixed

Appendix I: Child questionnaire

Child Questionnaire
Research ID _____ C Date _____

1. What is your birth date? Month _____ Day _____ Year _____

Please circle the best answer for the following questions.

2. Are you male or female? Male Female

3. Have you had braces or orthodontic treatment?
Yes No

4. What grade of school are you in right now?
7th grade
8th grade
9th grade
10th grade
11th grade
12th grade
GED
Technical School
College
Associate training

5. Do you have a part time job?
Yes No

6. What is your job title? _____

Appendix J: REALM-SF

REALM-SF Form

Patient name _____ Date of birth _____ Reading level _____

Date _____ Examiner _____ Grade completed _____

Menopause	☐
Antibiotics	☐
Exercise	☐
Jaundice	☐
Rectal	☐
Anemia	☐
Behavior	☐

Instructions for Administering the REALM-SF

1. Give the patient a laminated copy of the REALM-SF form and score answers on an unlaminated copy that is attached to a clipboard. Hold the clipboard at an angle so that the patient is not distracted by your scoring. Say:

"I want to hear you read as many words as you can from this list. Begin with the first word and read aloud. When you come to a word you cannot read, do the best you can or say, 'blank' and go on to the next word."
2. If the patient takes more than 5 seconds on a word, say 'blank' and point to the next word, if necessary, to move the patient along. If the patient begins to miss every word, have him or her pronounce only known words.

Scores and Grade Equivalents for the REALM-SF

<u>Score</u>	<u>Grade Range</u>
0	Third grade and below; will not be able to read most low-literacy materials; will need repeated oral instructions, materials composed primarily of illustrations, or audio or video tapes
1-3	Fourth to sixth grade; will need low-literacy materials, may not be able to read prescription labels
4-6	Seventh to eighth grade; will struggle with most patient education materials; will not be offended by low-literacy materials
7	High school; will be able to read most patient education materials

Appendix K: REALM-TeenS

REALM-TeenS Score Sheet

Patient ID #: _____ Date: _____ Examiner Initials: _____

diabetes	_____
exercise	_____
prevention	_____
asthma	_____
nausea	_____
fatigue	_____
adolescent	_____
anemia	_____
tetanus	_____
bronchial	_____
TOTAL SCORE	_____

Administering the REALM-TeenS

Suggested Introduction:

"Providers often use words that patients don't understand. We are looking at words providers often use with their patients in order to improve communication between health care providers and patients. Here is a list of medical words.

Starting at the top of the list, please read each word aloud to me. If you don't recognize a word, you can say 'pass' and move on to the next word."

Interviewer: Give the participant the word list. If the participant takes more than 5 seconds on a words, say "pass" and point to the next word. Hold this scoring sheet so that it is not visible to the participant.

Appendix L: STAI-6

Self-evaluation questionnaire (Y-6 item)

Research ID _____ Date _____

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

	Not at all	Some what	Moderately	Very much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered *all* the questions.

Appendix M: WRAT3

WRAT3

BLUE READING

A B O S E R T H U P I V Z J Q

in	cat	book	tree
how	animal	even	spell
finger	size	felt	split
lame	stretch	bulk	abuse
contemporary	collapse	contagious	triumph
alcove	bibliography	horizon	municipal
unanimous	benign	discretionary	stratagem
seismograph	heresy	itinerary	usurp
irascible	pseudonym	oligarchy	covetousness
heinous	egregious	omniscient
assuage	disingenuous	terpsichorean	

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