Orthodontic Informed Consent Considering Information Load and Serial Position Effect

THESIS

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By

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Abstract

Introduction: Previous research has demonstrated that current methods of informed consent are relatively ineffective as shown by poor recall and comprehension by adolescent patients and their parents. The purpose of this study was to determine if adding a short video reiterating the issues related to informed consent to a modified informed consent document that places emphasis on a limited number of core and patient specific custom “chunks” located at the beginning of an informed consent presentation improved the recall and comprehension of the risks, benefits and alternatives related to orthodontic treatment. Methods: 70 patient/parent pairs were randomly divided into two groups. The intervention group (Group A) patients and parents reviewed a customized slideshow and a short video describing the key risks of orthodontic treatment together. Group B followed the same protocol without viewing the video. All patients and parents were interviewed independently by research assistants using an established measurement tool with open-ended questions. Interviews were transcribed and scored for appropriateness of response using a previously established codebook. Lastly, the patients and parents were administered the REALM and WRAT questionnaires to establish health literacy and literacy in general, respectively, and completed the self-administered demographic and psychological state questionnaires. Results: No significant differences existed between the groups for socio-demographic variables. There were no significant differences
between the groups for overall recall and comprehension; recall and comprehension for the domains of treatment, risk and responsibility; and recall and comprehension for core, general and custom items. **Conclusions:** There was no benefit to adding a short video to the previously established improved readability and audiovisual supplementation. When compared to previous studies, these data further demonstrate the benefit of improved readability and audiovisual supplementation with the addition of chunking. Positional effects indicate the most important informed consent information should be presented last.
Dedicated to my Mother and Father, Henriet and Edward Pawlak
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Chapter 1: Introduction and Literature Review

Decision making in health care, including orthodontics, has experienced a shift from a paternalistic model to one driven by patient autonomy. In the past, it was expected that the clinician made the best treatment choice for the patient based on their expertise. Autonomy is defined as “living or acting according to one’s own rule, principle, or law.” Today’s patients desire to be active participants in decisions regarding treatment while exercising their right to an autonomous patient choice. Of course, it is not the patient’s responsibility to ensure they are informed regarding the risks and benefits of their treatment options. Rather, this duty falls on the health care provider, who is “obligat[ed] to communicate truthfully and effectively” when presenting the patient with their choices in order to obtain consent to treatment. Obtaining informed consent “is a vital step as it [acknowledges] a person’s freedom to choose independently” and “represents the most explicit respect for patient autonomy in everyday clinical practice.”

A person’s literacy level can have a dramatic impact on their daily life. From reading a recipe in a cookbook to keeping up with current events in the newspaper to determining the correct dosage from a prescription medication label, the ability to read and comprehend is crucial to function in our world. It has been shown the average American reading level is in the 8th to 9th grade range. One in five adult Americans
reads at 5th grade level or below, which is considered to be functionally illiterate. The National Center for Education Statistics method for literacy evaluation includes an assessment of prose literacy, document literacy and quantitative literacy graded at four levels: Below Basic, Basic, Intermediate and Proficient. Prose literacy is defined as the ability to “search, comprehend, and use information from continuous texts”, document literacy as the capacity to “search, comprehend, and use information from non-continuous texts in various formats”, and, finally, quantitative literacy as the ability of the individual to “perform computations using numbers embedded in printed materials.”

Application of all three of these literacy skills is necessary during orthodontic treatment from approving of the initial treatment plan and granting consent to correctly using over the counter medication when needed throughout treatment to reading dispensed literature describing a potential adjunctive procedure.

In 2003, 14 percent of Americans were considered Below Basic for prose literacy. Of this 14 percent, 39 percent were Hispanic, 20 percent were African American and 37 percent were Caucasian. Literacy levels can be further examined by educational attainment (categorized by still in high school, less than/some high school, GED/high school equivalency, high school graduate, vocational/trade/business school, some college, Associate’s/2-year degree, college and graduate studies/degree) and employment status (categorized by full time, part time, unemployed and not in the labor force). Surprisingly, average prose literacy levels actually decreased significantly between 1992 and 2003 for all education levels with the exception of adults still in high school or with a GED. Document literacy also showed a significant decrease in the some college,
Associate’s/2-year degree, college graduate and graduate studies/degree groups. Literacy levels can also directly impact the ability to attain and sustain employment. Fifty-one percent of adults with Below Basic prose literacy were not in the labor force in 2003. In contrast, 64 percent of adults with Proficient prose literacy and 54 percent of adults with Intermediate prose literacy were employed full time in 2003. Overall, literacy was lowest in all three categories for those adults who were not in the labor force.

Literacy can be further examined in terms of health, which obviously plays a pivotal role in a patient’s ability to make an informed, autonomous choice in regards to their dental decisions. Health literacy is defined as “the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.” Using the same Below Basic, Basic, Intermediate and Proficient ratings, the National Center for Education Statistics also evaluated health literacy in 2003. An astounding 88 percent of adults 16 years or older did not have proficient health literacy. As with general literacy, health literacy is greatly impacted by education level. Forty nine percent of adults who did not attend or never completed high school were rated with Below Basic health literacy versus only three percent of those with a 4-year college degree. Those with limited health literacy are greater consumers of health care services for treating the complications of disease as opposed to preventative services, and they are more likely to suffer from chronic conditions.
Fortunately, despite these deficiencies in literacy, the population does not reflect similar deficits in intelligence. That being said, the following are some important considerations. People with poor reading skills tend to take words literally instead of interpreting meaning. They read slowly, often one word at a time, which can cause them to forget the preceding words and miss the intended meaning of a sentence. Poor readers also skip over unknown words and are unable to infer the overall context of a passage. 

Despite these factors, it has been shown that patient health information documents are written at a level well beyond the majority of patients intended to utilize them. In 2000, Alexander examined the readability of a sample of 24 dental educational documents. He found that nearly half (41.7%) were written at a high school reading level, with one document reading as high as the 23rd grade level. Combined with the fact that the majority also contained excessive undefined medical and dental jargon, it would be nearly impossible for the average patient to understand them. Harwood et al conducted a study in 2004 to examine differences between various orthodontic patient education leaflets. Using a combination of Flesch Reading Ease scores and Flesch Kincaid Grade Level scores (with a range of very easy, easy, fairly easy, standard, fairly difficult, difficult and very difficult), all the American Association of Orthodontics (AAO) documents were written at fairly difficult to difficult reading levels. A popular method of obtaining informed consent in the United States is to use the AAO consent form. Clearly this poses a major issue to informed consent.

Studies examining understanding of informed consent exemplify the problem. In 2003, Tait et al conducted a study to gauge the understanding of 11 elements of
informed consent in clinical anesthesia and surgical studies for children. A total of 411 parents were presented verbal and written explanations of information and asked a series of open-ended questions. Parents significantly overestimated their overall understanding as high when compared to actual assessor’s measures of parental understanding 10. In a study of patients who had consented to participate in clinical oncology trials, Barrett found that an overwhelming half of the subjects failed to understand that the trial they consented to participate in was not the standard recommended treatment and possibly involved additional risks 11.

Similar trends of poor understanding of consent have been seen in orthodontics. In 2003, Baird and Kiyak (12) found that both children and their parents recalled considerably fewer reasons for treatment as well as risks of treatment than were explained by the orthodontist using a series of open ended interview questions. 12 Parent vocabulary level was most significantly correlated with the amount of recalled reasons for treatment. Also in 2003, Mortenson et al. (13) evaluated low income and ethnic minority children and their parents for their understanding of the purpose of planned early orthodontic treatment. 13 They found similar results, with both children and their parents recalling significantly fewer reasons for treatment, orthodontic procedures to expect, risks associated with treatment and responsibilities of the child during treatment than were explained in the prior presentation. Furthermore, retention of information presented seems to continuously diminish as time progresses. Enst et al. 14 administered a questionnaire to orthodontic patients and their parents at least six months following
treatment start and found poor recall of risk factors such as decay, root resorption, retention and length of retention.

So, how can we improve methods of consent to ensure patients are making an informed decision? In 2005, Tait et al. 15 presented parents of children undergoing elective surgical procedures with several possible forms of consent including a standard or modified consent form. The modified form was changed to meet lower target reading levels in addition to eliminating dense paragraphs in exchange for bullet points, boldfacing and underlining for emphasis and using a column format for reading ease. It was shown that overall understanding was greater with the modified form, and in addition, when shown both forms 81.2% of parents preferred the modified form. The “Repeat-back” method (RB), in which patients recount what they’ve been told in order to display understanding, has been suggested as another way to enhance informed consent 16. In a randomized controlled trial, Fink et al determined that the RB technique significantly improved consent comprehension scores among surgical patients, with the minimal additional time spent on consent being acceptable to providers. Another study examined the effects of using a videotape to provide surgical patients with informed consent information and found it significantly increased comprehension when compared to verbal explanation17. Perhaps even more noteworthy, the video was of most benefit to patients of lower education levels. In a study by Sobel et al., 2400 patients undergoing procedures selected to represent an elective surgery, a significant surgery and an elective diagnostic procedure were exposed to an interactive and illustrated online educational
tool, Emmi solutions. Increased risk awareness, increased confidence in the provider and increased understanding of treatment/procedure specifics were reported 18.

The literature clearly demonstrates many alternative methods for improving comprehension of informed consent in healthcare, but what has been done specific to the field of orthodontics? In 2007, Kang et al. 19 conducted a pilot study to develop a tool for better and more consistent measurement of recall and comprehension of informed consent. The measurement tool contained questions about the 18 elements found in the AAO form, covering a range of risks and limitations of treatment, and was validated by orthodontists. This measurement tool was later used in a second phase of study to evaluate and compare 3 methods of informed consent: the AAO form, a modified informed consent document (MIC) or the MIC paired with a computer-based slideshow for improved processability. The MIC incorporated the 18 elements with the use of less medical and dental jargon, active voice, 7th grade reading level, larger font size and balanced white space. The narrated computer-based slideshow (PowerPoint 2003, Microsoft Corporation, Redmond, WA) was developed with audio and visual cues to the 18 elements. Levels of recall and comprehension were similar for the AAO group and MIC only group. The MIC and slideshow group showed better levels of recall and comprehension for patients and parents, demonstrating the possibility that alternative methods to consent might be valuable to improve understanding 19.

Limitations of Kang’s study indicated the need for further research. The large amount of material subjects had to review during the informed consent process violates a previously accepted educational standard of limiting the number of new concepts
presented in a given time period to seven 20. While it has been shown that reiterating key points can aid in retention of information in the long-term, the possibility that too much repetition leads to confusion and is exhaustive also exists 4. The sheer volume of material and multiple presentation modalities spanning a substantial length of time could have inhibited short-term memory and therefore potentially affected subject recall and comprehension. Presenting all of the critical information in a clear, concise yet effective way has continued to prove challenging.

In a follow-up study by Carr et al. 21, two groups viewed a customized version of the computer-based slide show, with the eighteen elements divided into three “chunks”. Doak et al. 4,22 has previously demonstrated the concept of “chunking”, or presenting like concepts together, in order to expand short-term memory capabilities. The three chunks were: 1) four most common core risks to orthodontics, 2) up to four custom risks that applied to the particular subject and 3) the remaining general risk factors. In addition, group A received a verbal explanation of the MIC by the resident orthodontist, while group B did not.

The four most common risks to orthodontic treatment have been established as enamel decalcification & gingival disease, external root resorption, pain and post-treatment change. The risk of clinically detectable areas of demineralization better known as decalcification or white spots have long been recognized as a risk of orthodontic treatment 23. In a literature review, Mitchell et al. 24 found prevalence as high as 96% for white spot lesions among orthodontic patients. Another study demonstrated enamel decalcification in 25% of teeth in 53 adolescent patients, with the most frequently
affected being anterior teeth and premolars. Also confirmed by Gorelick 25, maxillary incisors followed by mandibular posterior teeth exhibited the highest number of white spot lesions following debonding. A study by Kloehn and Pfeifer 26 showed that inflammatory and hyperplastic changes occur within the periodontium during orthodontic treatment and the severity of these issues was directly related to oral hygiene. A link between plaque accumulation and gingivitis as well as possible progression of gingivitis to periodontitis has been established 27, and orthodontic appliances allow for increased plaque build-up, especially in the absence of good oral hygiene practices.

According to Killaney 28, many patients who undergo orthodontic tooth movement will demonstrate at least a small degree of external root resorption. One study of 400 patients showed that 88% experienced a millimeter or greater of external root resorption with 5% experiencing severe shortening of greater than 5 mm 29. Possible risk factors for root resorption have been established. One study linked a history of trauma to the incisors with significantly increased risk for root resorption 30. In another study, the extent of root resorption in teeth with blunt or pipette shaped roots was significantly higher than for those with normal root morphology 31. One study indicated a 2 to 3 month pause in treatment might decrease total root resorption 32.

Pain is a concern for many patients undergoing orthodontic therapy 33. In a series of self-administered questionnaires, 65% of 170 orthodontic patients reported experiencing pain 4 hours after orthodontic appliance placement. That number increased to 95% with an average intensity of 42 on a 0-100 pain scale at the 24-hour mark. Using a visual analogue scale (VAS) of 10 cm, Ngan assessed the pain experience of 65 patients
following the placement of separators and 57 patients following the placement of an initial arch wire. Increased pain with biting and chewing was experienced at 4 hours and 24 hours in both groups when compared to a control group.

Following orthodontic treatment, major concern of the orthodontist and patient alike is the stability and long-term retention of the treatment outcome. Regardless of treatment approach, it has been shown that arch length and width decrease in the post-treatment phase. Mandibular anterior crowding post-treatment persists to the 40-year age bracket and beyond, demonstrating the importance of long-term retention. Propensity for occurrence of these possibilities at the individual level is impossible to ascertain. While relapse potential for all patients exists post-treatment, it is especially likely in those with continued growth, males and those with the most severe pre-treatment occlusions.

The remaining “chucks” in Carr’s study were up to four risks specific to the patient as determined by the resident orthodontist prior to treatment consultation and all remaining elements that did not fall into the previous two categories. The information was presented in order from general to specific, with the core and custom risks at the end.

It was shown that there was little benefit to verbal review of the informed consent by the orthodontist, with the exception of risks with the patient group. Carr et al. also showed that subjects best understood the informed consent elements presented at the beginning or end of the slide show. Recall was better than comprehension for patients and parents. It was suggested that if more than 7 elements are to be addressed, those with the highest importance be presented at the beginning or end of the slideshow.
Clearly, continued study may further improve the informed consent process for maximum recall and comprehension in orthodontic patients and their parents. The concept of chunking was also applied in this research. The purpose of this study was to determine if modified informed consent documents using emphasis on a limited number of specific and custom issues located at the beginning of an informed consent presentation and a standardized short video reiterating the key elements of informed consent improved the recall and comprehension of the risks, benefits and alternatives related to orthodontic treatment.

**Null Hypothesis**

H$_0$: There is no significant difference in recall and comprehension when a standardized short video reiterating key elements of informed consent is added to modified informed consent documents using emphasis on a limited number of specific and custom issues located at the beginning of an informed consent presentation.

**References**


Chapter 2: Materials and Methods

By way of the introduction, this study will determine if modified informed consent documents using emphasis on a limited number of specific and custom issues located at the beginning of an informed consent presentation and specific information regarding risk improve the recall and comprehension of the risks, benefits and alternatives related to orthodontic treatment. This study will compare two Groups. Following a verbal review of their proposed treatment with the resident orthodontist, Group A and Group B participants will view a customized computer-based slideshow presentation demonstrating the four most common risks of orthodontic treatment, followed by up to four custom risks specific to the patient and finally the remaining elements previously identified as key risks to orthodontic treatment. In addition, Group A participants will view a video presentation outlining the elements of informed consent presented in the Modified Informed Consent (MIC) document regularly utilized by the division and developed by Kang et al. ¹.

Human subject approval

The research protocol was evaluated and approved by the University Institutional Review Board (IRB). All residents, research assistants and volunteers were compliant with IRB mandated training. All patients and parents completed appropriate forms
including Consent, Assent, Parental Permission and HIPPA authorization forms. The consent forms are in the Appendix.

**Modified informed consent document**

Using the informed consent document from a university orthodontic clinic in conjunction with the American Association of Orthodontics Informed Consent for the Orthodontic Patient© (AAO), Kang et al.\(^1\) developed the MIC to include 18 common elements found in the existing forms. The MIC was also used in previous research by Carr et al.\(^2\). Differences between the MIC and previous consent documents included less medical/dental jargon, utilizing active voice, larger font and more balanced white space\(^3\). Utilizing the Fry Readability Formula\(^4\), the MIC was created at the 7\(^{th}\) grade reading level. The 18 risks described were divided into either preventable risks followed by a description for prevention or possible limitations of orthodontic treatment. The MIC is in the Appendix. The 18 elements are as follows:

1. Cavities, decalcification and gum disease
2. Discomfort
3. Injury from braces and injury from headgear
4. Heath Updates
5. Tobacco product use
6. Treatment time
7. Retainers
8. Impacted 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 and interproximal reduction

16. Ceramic appliances and potential damage to enamel

17. Wisdom teeth

18. Allergies to orthodontic appliances

Development of the computer-based slideshow

The PowerPoint (2003, Microsoft Corporation, Redmond, WA) slideshow (PPT) developed by Kang et al. ¹ utilized audio and visual cues to review the 18 elements of informed consent found in the MIC, arranged in order from general to specific. In this study, the 18 elements were divided into “chunks”, as suggested by Doak et al. ³. Similar methodology was employed by Carr et al. ², with a differing order from the current study. The “chunks” were presented in the following order for groups A and B: 1) the four most common “core” risks to orthodontic treatment: (i) cavities, decalcification & gum disease, (ii) pain, (iii) root resorption and (iv) post-treatment change, 2) Up to four custom risks specific to the patient as selected by the treating orthodontic resident and 3)
the remaining “general” risk factors. The subjects were not informed of the particular slideshow order or significance of any elements.

**Informed consent video**

As determined by Carr et al. $^2$, it is possible that verbal explanation of the MIC can impact subject recall and comprehension of informed consent. Therefore, in this study, a standardized videotape presentation by the chair of the orthodontic department was recorded. The script for the videotape was created using the MIC and is included in the Appendix.

**Measurement tool for recall/comprehension**

A measurement tool, using a series of open-ended questions and focusing on the 18 elements of informed consent in the MIC, was developed by Kang et al. $^5,6$. Utilizing open-ended questions is thought to better assess recall and comprehension of the information presented $^7$. Recall questions directly asked subjects about a specific element, such as “What are the risks to teeth and gums with braces on?” Conversely, comprehension questions described a scenario and asked the subjects how they would handle the presented situation, such as “Amy just got her braces a few days ago. Her teeth are sore, especially when she is eating. What would you do?” The interview script is in the Appendix.
**Personnel Training**

All research assistants and resident orthodontists participating in this human subject research study completed the required CITI (Collaborative IRB training initiative) training and were approved by the IRB. All received appropriate training regarding research protocol, subject recruitment, obtaining consent to participate and interview procedures. An interview script using the aforementioned measurement tool was utilized. Interviewers were instructed to repeat questions as needed as well answer any questions without leading subject response.

**Interview and transcription process**

All interviews were recorded using a digital voice recorder and later transcribed word for word into a dedicated Microsoft© word document for later scoring. Subjects were assigned a unique research ID stated at the beginning of the interview using their subject number as determined by recruitment order, intervention group “A” or “B” and child “C” or parent “P” participant. Subject information was kept confidential and any identifiers were removed as subjects were only identified by their research ID after initial recruitment.

**Literacy Assessment**

Two measurements of literacy were used for all subjects: the reading portion of the Wide Range Achievement Test 3 (WRAT 3) (Wide Range in cooperation with PAR,
Lutz, FL)\(^8\) and the Rapid Estimate of Adult Literacy in Medicine (REALM) (Terry Davis, Louisiana State University Medical Center, Shreveport, LA)\(^9\), which allowed for assessment of overall reading ability as well as health literacy levels. The WRAT 3 is applicable to ages 5-75 and can therefore be applied to virtually all subjects of this study. Subjects were asked to read letters and words aloud and could stop when five consecutive words could not be pronounced. Typically the WRAT took 5 to 10 minutes to complete. The number of correct responses was totaled and an age-matched reading level was determined for each subject. As the name implies, the REALM was created to assess adult health literacy levels. However, since no equivalent measurement tools for children exist, it was applied to the child participants of this study. Each subject was asked to read the list of 66 words aloud, taking 5 seconds for each. The total number of correct responses was scored using a grading scale with a range from 3rd grade to high school. The WRAT3 and REALM are in the Appendix.

**Anxiety Measures**

The Spielberger State-Trait Anxiety Inventory (STAI)\(^10\) was used to assess both state anxiety, or anxiety about a specific event, and trait anxiety, or anxiety level as a personal characteristic. Participation in the research study as well as anticipation regarding discussed orthodontic treatment had the potential to impact the state anxiety levels of the subjects. A condensed self-administered six-question inventory (STAI-6) was used to measure state anxiety levels of all subjects. The STAI-6 is in the Appendix.
**Questionnaire**

All subjects completed a self-administered questionnaire in order to gather socio-demographic data including age, gender, income, education level, employment status, dentally related employment, ethnicity and previous orthodontic treatment. A visual analogue scale (VAS) of 0 to 10 was also included for self-assessment of understanding of risks, benefits and limitations of orthodontic treatment. The questionnaire is in the Appendix.

**Sample size and randomization**

Patients planned for comprehensive orthodontic treatment at The Ohio State University graduate orthodontic clinic and their respective parent or guardian were recruited by residents at the time of their orthodontic records or prior to their orthodontic consultation via telephone call. With a non-directional alpha risk of 0.05 and assuming a standard deviation of 19.3 (Carr et al.²), a sample size of 35 subjects per group would be required to demonstrate a difference of 15 percentage points in on-target responses with a power of 0.893. This was based on the variable from the previous study with the greatest variability, the MIC Risk. This was a convenience sample of available subjects. Inclusion criteria for subject recruitment in the study were:

- Patients at least 12 years old (approximately in the 7th grade) and not older than 18 years of age
• Patient accompanied by a parent or guardian who could sign consent for research and treatment and had legal guardianship for at least one year

• Patient and parent do not have any developmental disabilities or urgent medical conditions

• Patient and parent able to communicate in English

• Patient do not have a sibling or relative that is currently being treated or has previously been treated at the clinic in the past five years

Patient/parent pairs were assigned randomly to Group A or Group B prior to their consult appointment using a true random number generator (Random.org) ™; the randomness in the generator of the numbers came from atmospheric noise. Atmospheric noise generates randomness by physical phenomenon, such as tuning a radio to static.

**Study Sequence**

**Group A**

1. Patient/parent assented/ consented to participate with the research assistant.

2. The case presentation was presented by the patient’s assigned resident orthodontist. This included discussion of the patient’s orthodontic problems and the treatment option(s) (including no treatment) that would address these problems. Approximate duration of treatment was also discussed. Questions regarding treatment were answered.
3. Resident orthodontist completed clinical portion of the appointment as necessary. For example, placing separators.

4. Patient/parent returned to consult area and viewed the customized computer-based slide show presentation.

5. Patient/parent viewed the short standardized video describing the key risks for orthodontic treatment as listed on the MIC.

6. Patient/parent independently interviewed by research assistants. All interviews were recorded.

7. Research Assistants administered the WRAT3 and REALM for patient/parent independently.

8. Patient/parent completed STAI6 and questionnaire with optional demographic questions.

9. Patients were compensated for their participation with a $10 gift card.

10. Resident orthodontist answered any questions regarding consent information and obtained parent/guardian signature on the MIC document.

Group B

All of the previously described steps were completed for Group B with the exception of the standardized video presentation.

Scoring of interviews
A previously developed codebook was used to recognize key words and phrases signifying correct recall and comprehension responses \(^1\). One rater was used in this study and received extensive training by the previous rater to ensure proficiency when scoring interviews. According to the codebook, four scores for responses were possible: 1) inappropriate 2) on-target/correct 3) I don’t know/don’t remember 4) question skipped or no response. Only the on-target/correct or inappropriate (which included types 1, 3 and 4 answers) were used for data evaluation.

**Subject Reliability**

Four of the recall questions in the measurement tool were rephrased in order to test reliability of the subjects. They were: health updates, retention/post-treatment change, temporomandibular joint disorders and impacted/unerupted teeth. Simple kappa statistics with 95% confidence intervals were used. Subject reliability results are in Table I.

**Rater Reliability**

Scoring 10 randomly selected patient and parent interviews and comparing the obtained scores to those completed by Carr tested inter-rater reliability, which was excellent \(^1^1\) (\(K=0.86\) [95% CI, 0.83-0.86]). Rescoring the same 10 patient and parent interviews 2 weeks later and comparing them to the previous scores tested intra-rater reliability, which was also excellent (\(K=0.99\) [95% CI, 0.97-01.0]).
Comparisons made in this study

Comparison between Groups A and B will evaluate the outcome of viewing the scripted video in addition to the customized slideshow and address the possible benefit of a shortened informed consent presentation.

For purposes of the discussion, comparison will also be made between group B of this study, Kang’s AAO, Kang’s slideshow and Carr’s streamlined groups. In the Kang et al. \(^1\) study, the AAO subject group reviewed the previously described AAO consent form only. The Kang et al. \(^1\) slideshow group used the MIC form and viewed the slideshow. In the Carr et al. \(^2\) study, the streamlined group viewed a customized slideshow with the following order for the “chunks”: general risk factors of orthodontic treatment, the 4 most common core risks and up to four custom risks and were presented the MIC form without resident review. Comparisons between these four groups will examine the benefits of the MIC form and multimedia presentation versus a traditional informed consent format and determine whether the order in which information is “chunked” and presented impacts recall and comprehension.

Data analysis

All data was processed using Microsoft \(^\circ\) Office Excel spreadsheets (Microsoft Corporation, Redmond, WA) and statistical software (SAS) (SAS Institute Inc., Cary, North Carolina). Responses coded as “on target” were counted towards the percentage
correct while the others (“inappropriate”, “don’t know/can’t remember”) counted towards percentage incorrect or missing data (“question skipped/no response”).

Simple Kappa statistics with 95% CI were calculated for inter-rater (Carr et al. ² vs. our study), intra-rater and subject reliability. Descriptive statistics were calculated for socio-demographic data, WRAT3 scores, REALM scores, STAI-6 scores and VAS self-assessment scores.

Between Group differences (Group A vs. B) were calculated based on the following analysis: analysis of variance (ANOVA) for age and VAS self-assessment scores, the Mann-Whitney-Wilcoxon test for WRAT3, REALM and STAI-6 scores, the chi-square test for sex and the Fisher exact test for ethnic group and grade (Table II). Between group differences in mean percentage of on-target responses for overall recall and overall comprehension; the domains of treatment recall, risk recall, responsibility recall, treatment comprehension, risk comprehension and responsibility comprehension; and core recall, general recall, custom recall, core comprehension, general comprehension and custom comprehension were assessed using analysis of variance. Spearman correlation coefficients with p-values corrected by the step-down Bonferroni method of Holm were used to calculate the correlations between REALM, WRAT3, STAI-6 and VAS self-assessment scores and various outcome variables. Chi square tests were used to evaluate positional differences between custom and general issues in the current study. An α level of 0.05 was selected.

Among Group differences (1 vs. 2 vs. 3 vs. 4) were calculated based on the following analysis: analysis of variance (ANOVA) for age, the Mann-Whitney-
Wilcoxon test for WRAT3, REALM and STAI-6 scores, the chi-square test for sex and the Fisher exact test for ethnic group and grade (Table II). Among group differences in mean percentage of on-target responses for overall recall and overall comprehension; the domains of treatment recall, risk recall, responsibility recall, treatment comprehension, risk comprehension and responsibility comprehension; and core recall, general recall, custom recall, core comprehension, general comprehension and custom comprehension were assessed using analysis of variance (Tables VI-VIII).


Introduction: Previous research has demonstrated that current methods of informed consent are relatively ineffective as shown by poor recall and comprehension by adolescent patients and their parents. The purpose of this study was to determine if adding a short videotape presentation reiterating the issues related to informed consent to a modified informed consent document that places emphasis on a limited number of core and patient specific custom “chunks” located at the beginning of an informed consent presentation improved the recall and comprehension of the risks, benefits and alternatives related to orthodontic treatment. Methods: 70 patient/parent pairs were randomly divided into two groups. The intervention group (Group A) patients and parents reviewed a customized slideshow and a short videotape presentation describing
the key risks of orthodontic treatment together. Group B followed the same protocol without viewing the videotape. All patients and parents were interviewed independently by research assistants using an established measurement tool with open-ended questions. Interviews were transcribed and scored for appropriateness of response using a previously established codebook. Lastly, the patients and parents were administered the REALM and WRAT questionnaires to establish health literacy and literacy in general, respectively, and completed the self-administered demographic and psychological state questionnaires. **Results:** No significant differences existed between the groups for socio-demographic variables. There were no significant differences between the groups for overall recall and comprehension; recall and comprehension for the domains of treatment, risk and responsibility; and recall and comprehension for core, general and custom items. **Conclusions:** There was no benefit to adding a short video to the previously established improved readability and audiovisual supplementation. When compared to previous studies, these data further demonstrate the benefit of improved readability and audiovisual supplementation with the addition of chunking. Positional effects indicate the most important informed consent information should be presented last.

**Introduction**

Decision making in health care, including orthodontics, has experienced a shift from a paternalistic model to one driven by patient autonomy. In the past, it was expected that
the clinician made the best treatment choice for the patient based on their expertise.\textsuperscript{1}

However, today’s patients desire to be active participants in decisions regarding treatment. The duty of providing information regarding risks, benefits and alternatives to treatment falls on the health care provider, who is “obligat[ed] to communicate truthfully and effectively”\textsuperscript{2} when presenting the patient with their choices.

Health literacy, defined as “the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions”\textsuperscript{3} also plays a pivotal role in the informed consent process. Health literacy rates in America are low and are linked to lower consumption of preventative health care services, greater incidence of chronic health conditions and poorer oral health\textsuperscript{4,5}.

Health care providers often rely on written education materials to present consent information to their patients. It has been shown that a great number of these documents are written well beyond the average United States reading level of 8\textsuperscript{th} to 9\textsuperscript{th} grade and contain undefined dental jargon, making them very difficult to understand.\textsuperscript{6,7} A consenting patient, parent, or often a minor, as is the case with many patients receiving orthodontic treatment, who does not understand the treatment and its risks, benefits and alternatives has not given valid ‘informed’ consent, which may have legal implications if there are negative sequelae of treatment.

Previous studies examining the medical informed consent process consistently demonstrate low comprehension of the information presented\textsuperscript{8,9}. At the same time, subjects also tend to overestimate their understanding when compared to other
Because of this reality, methods to improve understanding of consent information have been explored. One study found that understanding among parents of children undergoing elective surgical procedures was greatly improved when using a modified informed consent document. The modified form was changed to meet lower target reading levels in addition to eliminating dense paragraphs in exchange for bullet points, boldfacing and underlining for emphasis and using a column format for reading ease. Another study examined the effects of using a videotape to provide surgical patients with informed consent information and found it significantly increased comprehension when compared to verbal explanation, especially in those with lower education levels. When 2400 patients undergoing procedures selected to represent an elective surgery, a significant surgery or an elective diagnostic procedure were exposed to an interactive and illustrated online educational tool, Emmi™ solutions, they demonstrated increased risk awareness, increased confidence in the provider and increased understanding of treatment/procedure specifics.

Similar trends of poor understanding of consent information have been seen in orthodontics. In 2003, one study found that both children and their parents recalled considerably fewer reasons for treatment as well as risks of treatment than were explained by the orthodontist, with parent vocabulary level most significantly correlated with the amount of recalled reasons for treatment. Another study found that low income and ethnic minority children and their parents recalled significantly fewer reasons for treatment, orthodontic procedures to expect, risks associated with
treatment and responsibilities of the child during treatment than were described in the case presentation \(^{14}\).

Although not a major focus of malpractice claims, orthodontics accounts for approximately 4% of claims according to a 2006 survey and must be taken seriously for risk management purposes. \(^{15}\) As such, ways to improve the informed consent process in orthodontics have been explored. In a study by Kang et al. \(^{16}\), a modified informed consent (MIC) document in combination with a computer-based slideshow resulted in better recall and comprehension rates when compared to groups presented with the standard American Association of Orthodontics (AAO) form or MIC document alone. Carr et al. \(^{17}\) expanded upon that research and employed the principle of “chunking”, presenting like concepts together, as described by Doak et al. \(^{6}\). Information was presented from general to specific in the computer-based slideshow. It was shown that subjects best understood the informed consent elements presented at the beginning or end of the slideshow. Carr et al. \(^{17}\) also used a verbal explanation of the MIC in one of the groups and found some benefits.

Based on these previous studies, additional modification to these newly developed procedures may improve the informed consent process even further. Placing the most important information first in the slideshow, could further improve recall and comprehension rates. Other methods of audiovisual presentation as an alternative to standard verbal explanation may support better understanding as well. The purpose of this study was to determine if modified informed consent documents using emphasis on a limited number of core and custom issues located at the beginning of an informed
consent presentation with the addition of a short videotaped presentation, which reiterated the issues related to informed consent, could improve the recall and comprehension of the risks, benefits and alternatives related to orthodontic treatment.

**Materials and Methods**

The research protocol was reviewed and approved by a University-based institutional review board.

New patients planned for comprehensive treatment in the graduate orthodontic clinic at a University-based dental college were recruited to participate by resident orthodontists at the time of initial records or via telephone call prior to their consultation appointment. All patients met the following inclusion criteria as previously described by Carr et al. 17: 12 to 18 years of age, no previous orthodontic treatment, no sibling or immediate relative previously treated in the clinic, accompanied by parent or legal guardian of at least 1 year, patients and parents able to communicate in English and no developmental disabilities or urgent medical conditions. With a non-directional alpha risk of 0.05 and assuming a standard deviation of 19.3 (Carr et al. 17), a sample size of 35 subjects per group would be required to demonstrate a difference of 15 percentage points in on-target responses with a power of 0.893. Patient/parent pairs were randomly allocated to the 2 intervention groups using a random number generator based on atmospheric noise (Random.org) 18. Due to one withdrawal mid-study, Group A consisted of 34 patient/parent pairs and Group B consisted of 35 patient/parent pairs.
The original slideshow (PowerPoint version 2003; Microsoft, Redmond, Wash), containing audio and visual cues for the 18 elements of informed consent (Fig. 1), was developed by Kang et al.\textsuperscript{16}. As previously mentioned, the study by Carr et al.\textsuperscript{17} modified the slide show, presenting “chunks”\textsuperscript{6} in the following order: (1) General risk factors, (2) the 4 most common core risks of orthodontic treatment according to the literature: enamel decalcification & gum disease\textsuperscript{19-23}, external root resorption\textsuperscript{24-28}, pain\textsuperscript{29,30} and retention/relapse\textsuperscript{31-33} and (3) up to 4 custom patient specific risk factors as determined by the treating orthodontist e.g. such as the need for interproximal reduction or abnormal jaw growth. The present study also employed the concept of “chunking” in the following order: (1) the four most common core risks; (2) up to 4 custom patient specific risks and; (3) all other remaining general risk factors.

Research assistants were trained in research protocol which included subject recruitment, the consent process and the interview procedure. Interviews were conducted using a script that incorporated a previously validated measurement tool\textsuperscript{34,35}. Based on the 18 elements of informed consent in the AAO document, the open-ended nature of the questions was designed to better assess recall and comprehension\textsuperscript{34-36}. Knowledge-based questions, such as “What are the risks to the teeth and gums with braces on?”\textsuperscript{34,35} measured recall while scenario-based questions such as “Amy just got her braces and her teeth are sore. What would you do?”\textsuperscript{34,35} measured comprehension. Interviewers repeated and rephrased questions as needed but were instructed not to lead subject responses. Four recall questions were rephrased and repeated to assess subject reliability.
For Groups A and B, the orthodontic resident first reviewed the recommended treatment plan as well as any alternatives and answered all questions concerning treatment. Patients and parents in both groups then viewed the customized computer-based slide show. Group A subjects also viewed a video presentation summarizing the 18 elements of informed consent, designed to standardize the verbal explanation used in the study by Carr et al. 17. All subjects then participated in the recorded interview with the research assistants.

Two measurements of literacy were used for all subjects: the reading portion of the Wide Range Achievement Test 3 (WRAT 3) (Wide Range in cooperation with PAR, Lutz, FL) 37 and the Rapid Estimate of Adult Literacy in Medicine (REALM) (Terry Davis, Louisiana State University Medical Center, Shreveport, LA), 38. These instruments allowed for assessment of overall reading ability as well as health literacy levels, respectively.

All subjects completed a self-administered questionnaire in order to gather socio-demographic data. The questionnaire also included a visual analogue scale (VAS) of 0 to 10 for self-assessment of understanding of risks, benefits and limitations of orthodontic treatment and a condensed six-question inventory (STAI-6) used to measure state anxiety levels 39. Patients then received a $10 gift card in recognition of their time of participation.

The recorded interviews were transcribed and blindly scored using a codebook of key words and phrases signifying correct recall and comprehension responses previously developed by Kang et al 16 and used by both Kang et al. 16 and
Carr et al. 17. One rater was used in this study and received extensive training by the previous rater to ensure proficiency when scoring interviews. According to the codebook, four scores for responses were possible: 1) inappropriate 2) on-target/correct 3) I don’t know/don’t remember 4) question skipped or no response. Inter-rater reliability was measured by scoring 10 randomly selected patient and parent interviews and comparing the obtained scores to those completed by a previous rater from another study. Rescoring the same 10 patient and parent interviews 2 weeks later and comparing them to the previous scores measured intra-rater reliability. For final data evaluation, answers were coded as on-target/correct or wrong.

**Statistical Analysis**

Simple Kappa statistics with 95% CI were calculated for inter-rater (Carr et al. 17 vs. the present study), intra-rater and subject reliability. Descriptive statistics were calculated for socio-demographic data, WRAT3 scores, REALM scores, STAI-6 scores and VAS self-assessment scores.

Between group differences (Group A vs. B) were calculated based on the following analysis: analysis of variance (ANOVA) for age and VAS self-assessment scores, the Mann-Whitney-Wilcoxon test for WRAT3, REALM and STAI-6 scores, the chi-square test for sex and the Fisher exact test for ethnic group and grade (Table II). Between group differences in mean percentage of on-target responses for overall recall and overall comprehension; the domains of treatment recall, risk recall, responsibility recall, treatment comprehension, risk comprehension and responsibility
comprehension; and core recall, general recall, custom recall, core comprehension, general comprehension and custom comprehension were assessed using analysis of variance. Spearman correlation coefficients with p-values corrected by the step-down Bonferroni method of Holm were used to calculate the correlations between REALM, WRAT3, STAI-6 and VAS self-assessment scores and various outcome variables. Chi square tests were used to evaluate positional differences between custom and general issues in the current study. An α level of 0.05 was selected.

**Results**

Inter- and intra-rater reliability for scoring interview data were excellent\(^4\) (K=.86 [95% CI, 0.83-0.86]) and (K=.99 [95% CI, 0.97-0.10]), respectively.

Subject reliability (Table I) for the children was fair to moderate, with kappa values ranging from 0.30 to 0.47 and an overall kappa score of 0.41. The parent overall kappa score was also 0.41, however, the kappa score range was larger (0.17 to 0.70), resulting in slight to substantial reliability.

For within study comparisons, the Groups were referred to as A and B. There were no significant differences between Groups A and B for sex, age, gender, ethnicity, grade or education level, WRAT3, REALM or STAI-6 scores (Table II).

The results for percentage of correct responses showed no significant differences between Groups A and B for the patients or parents in the following categories: overall
recall and overall comprehension (Table III); the domains of treatment recall, risk recall, responsibility recall, treatment comprehension, risk comprehension and responsibility comprehension (Table IV); and core recall, general recall, custom recall, core comprehension, general comprehension and custom comprehension (Table V).

Group A and B data were combined for chi square tests to analyze positional effects because there were no group differences. For the patients, percentage of correct comprehension responses regarding extractions and orthognathic surgery for severe crowding and mismatched jaws were much improved when presented earlier as a custom issue (position 4-8) versus as a later general issue (position 13) (38.9% versus 8.0%, \( p=0.0137 \)). For parents, a similar trend was seen for percentage of correct comprehension responses regarding large fillings and injured teeth that may require root canal therapy as a custom issue (position 4-8) versus a general issue (position 14) (69.2% custom versus 25.6% general, \( p=0.0015 \)). No other positional differences for recall or comprehension were detected.

Group A and B data again were combined for correlation calculations because there were no group differences. WRAT 3 scores were positively correlated with percentage of correct responses for overall recall among patients (\( r_s=0.39, p=0.0256 \)). VAS self-assessment scores were positively correlated with percentage of correct response for core recall and general comprehension among the parent group (\( r_s=0.40, p=0.0186; r_s=0.44, p=0.0064 \)). No significant correlations were seen between REALM scores and STAI-6 scores.
Discussion

Results from this study can be used to address two factors affecting the informed consent process: the benefit of a standardized overall videotaped presentation of the informed consent issues and the effects of “chunked” information positioning in the informed consent process.

The standardized supplemental video presentation viewed by this study’s Group A had no effect on: overall recall and comprehension; all domains of recall and comprehension; and core, general and custom recall and comprehension. In Carr et al.’s study, a verbal explanation improved outcomes for selected areas. While it was hypothesized that an additional standardized audiovisual format might have further improved patient and parent understanding, it is possible that reiteration of the previously presented material fatigued them or provided information overload inconsistent with good practices in the provision of information. It seems the addition of the video served only to add time to the informed consent process and proved unnecessary.

The positional evaluation indicated there were few significant differences among the comparisons (8% showed significant differences). For the child patients, comprehension improved when information regarding extractions and orthognathic surgery for crowded teeth and mismatched jaws was presented as a custom issue in the later early third of the presentation rather than the in the later third as a general issue. For parent comprehension, information regarding large fillings or injured teeth at risk
for root canal therapy was also better understood as a custom issue presented in the later early third to early middle third than in the later third as a general issue. These differences were minor and contradict the results of Carr et al. 17 because the improvement was for issues embedded in the center of presentation rather than at the beginning or end, which should have reduced understanding of these issues. Patients and parents were not conscious of the customization of the slideshow and how the material was chunked. Perhaps, the core and custom issues would have been of a different benefit if the subjects were made aware of the significance of the chunks and how they applied to their treatment.

Subject reliability ranged from slight to substantial. These scores were comparable with the previous research using the same MIC forms16,17. While slight patient reliability on the topic of ankylosis may be due to the complexity of the topic, slight parent reliability on the topic of retainers is less understandable.

Inter-rater and intra-rater reliabilities were excellent and comparable to those of previous studies. This demonstrates the validity of the employed measurement tool and the ease in which other researchers can be trained to use it.

Statistically significant positive correlations between WRAT3 scores and patient overall recall as well as VAS self-assessment scores and parent core recall and general comprehension were noted. WRAT3 scores of 8th grade to high school reading levels were in accordance with the average patient age and are indicative of the impact literacy level has on informed consent understanding. The positive correlation of parent self-assessment disagrees with previous research in which subjects over-
estimated their understanding of informed consent information\textsuperscript{9} and is the first time there has been evidence of knowledge self-awareness by either patients or parents. Despite their statistical significance, these correlations may not be clinically meaningful predictors of patient and parent understanding due to their relatively low values.

In order to facilitate discussion of the results of the present study with those of similar preceding studies, we compared our results through a combined analysis with selected intervention groups from those of Kang et al.\textsuperscript{16} and Carr et al.\textsuperscript{17} (Tables VI-VIII). Although these study groups have some selected differences in their demographics, they are, for the most part highly comparable (Table II) and were all performed in the same clinical setting with similar procedures. These combined results make discussion easier since the similarities and differences, with caveats, are focused and objective. Essentially, it is the basis of a context for discussion of the usefulness of the modified interventions that have been recently tested.

For among study comparisons, Group 1 was defined as Group B from the current study because there were no between group differences for A and B, and it represented a more streamlined consent process using a readable form, audiovisual supplementation and “chunked” issue presentation from specific to general. Group 2 was defined as Kang et al.’s\textsuperscript{16} AAO consent group, arguably the most common method used in US orthodontic practices. Group 3 was defined as Kang et al.’s\textsuperscript{16} slideshow and MIC group, which used a more readable form and supplemental audiovisual presentation. Group 4 was defined as Carr et al.’s\textsuperscript{17} custom slideshow without verbal explanation
group. This represented a readable form, supplemental audiovisual materials and “chunk” issue presentation from general to specific.

The following cautions must be recognized and weighed when making these Group comparisons. Groups 1, 3 and 4 were comparable for socio-demographics, WRAT, REALM, STAI-6 and VAS self-assessment scores. There were significant differences in WRAT3 scores, with Group 2 having significantly lower literacy levels (2nd grade vs. 8th grade for patients; 3rd grade vs. high school to post-high school for parents). Interestingly, there were no differences in REALM scores, which is more specific to health literacy, but still considered to have both general and health literacy components. In reality, a lack of REALM differences might mitigate the WRAT3 differences because they are usually correlated, e.g., 0.77 for patients and 0.42 for parents in the Kang et al. study. There were also significant differences in ethnicity distribution for Group 2.

Noting the above, the Group comparisons can help inform us in general about the various interventions. For instance, improved readability and supplemental audiovisual slide presentation compared with the standard AAO form (Group 2 vs. 3) had multiple significant impacts. Patient overall recall and parent overall comprehension were both improved. The domains of patient responsibility recall and treatment comprehension were significantly increased, as were parent treatment recall and treatment comprehension. Clearly, these improvements demonstrate the advantages of an alternative informed consent format.
Chunking, added to a readable form and audiovisual presentation (Group 1 vs. 3 and 3 vs. 4), appears to have specific and limited effects. Patient overall comprehension, treatment recall and treatment comprehension were all significantly improved. No significant differences were evident in the parent groups. Perhaps, if patients and parents were made aware of the significance of the “chunks”, a more profound effect would be noticed.

Chunking, a readable form and audiovisual slide presentation, when used as an alternative to the AAO form, (Group 1 vs. 2 and 2 vs. 4) had a great impact. Overall recall and comprehension were significantly improved for both patients and parents. The patient domains of treatment recall, risk recall, treatment comprehension and responsibility comprehension significantly improved. Treatment recall, risk recall and treatment comprehension for parents significantly improved. Uniformly, core recall and comprehension as well as general recall and comprehension significantly improved for patients and parents. These results demonstrate the dramatic benefit of grouping like concepts as opposed to providing a comprehensive list with little organization as seen with more traditional informed consent format.

Adjusting the order effect (Group 1 vs. 4) demonstrated mixed results and depended on perspective. Patients and parents generally performed significantly better on custom recall and comprehension questions when the information was presented at the end as in the Group 4 slideshow. Not surprisingly, in the current study, the same custom information being presented in the middle of the Group 1 slideshow resulted in much lower patient custom recall and parent custom comprehension rates.
For specific consent issues, there were dramatic and significant improvements of 30-40% but with limited impact because it only affected 8% of the outcomes when the occupied different positions. It appeared that moving material forward was beneficial, but the new position was less than optimal in terms of our previous results because it was near the middle of the presentation. This contradicted previous results by Carr et al.\textsuperscript{17} in which patients and parents best remember information shown at the beginning and end of a presentation.

These results are consistent with the phenomenon known as the primacy effect\textsuperscript{17,42-46}. The order in which information was presented clearly had a significant impact on patient and parent understanding and should be considered when formulating a customized informed consent format. Even with an alternative audiovisual format and customization of the informed consent process, there is still a significant amount of information (18 elements) to be presented. Previous research in learning indicates that the short-term memory is limited to recall of 7±2 new concepts\textsuperscript{41}. With “chunking” and positional effects considered, this still poses the continued challenge of providing a large amount of information, which may not be completely retained or understood, to consenting parents prior to the start of orthodontic treatment. One alternative would be presenting the most significant treatment and risk issues particular to the patient at the initial consultation and saving more general information for another time or format. In other words, the result might be different if only the core and custom issues were included instead of the total spectrum of consent issues.
It was most difficult to affect the domains of responsibility and risk even with multiple enhancements to the consent process, while treatment is more responsive. Treatment issues were more positively affected and probably more tangible to the patient and parent. It is possible information specific to the treatment domain was also emphasized in the case presentation immediately prior to informed consent process. While it is discouraging that the risk and responsibility domains are not greatly influenced, it still imperative to review these issues prior to starting treatment. Fortunately, this information also tends to be reiterated and emphasized throughout treatment e.g. good oral hygiene practices or wearing rubber bands, so less influence of these domains might not be as detrimental.

Clearly, these data tell a story of incremental improvement greatly enhanced by a readable form and audiovisual slide presentation. Adding Chunking resulted in some additional modest benefit to these former strategies, but the improvement using all three modifications together is marked compared with the AAO form alone. These methods substantially improve the AAO form for recall and comprehension for all consenters involved by about 12-16%. The domains are positively and significantly affected by 4-30%, while the core and general issues were significantly enhanced by 14-27%.

While the AAO will not provide exact figures for the number of orthodontists currently using their informed consent document for confidentiality reasons, it was confirmed as one of their most popular member used practice management tools (personal communication, AAO marketing, 2014). Demonstrated low recall and comprehension rates make its widespread use questionable. The current and previous
studies have clearly established that audiovisual alternatives to traditional informed consent documents tremendously improve patient and parent understanding. Use of the best available informed consent methods to ensure parents make a knowledgeable decision regarding their child’s care is an important responsibility of the dental healthcare professional.

These updated methods of informed consent demonstrated better recall and comprehension among patients and parents immediately following the case presentation, but no long-term evaluation of understanding, for traditional and alternative formats alike, has been completed to date. Patient and parent recognition of all risks and benefits of treatment is equally important at the end of treatment. This is a possibility for further study.

There are limitations to our study. The lower recall and comprehension rates seen among patients and parents in the AAO informed consent document group may not be solely attributable to informed consent format. Significantly lower literacy levels for the patient and parent subjects of group 2 as well as a different ethnic distribution must be considered as confounding factors. Additionally, low reliability has consistently been demonstrated by child and adult subjects.

Conclusions

1. There was no benefit to adding a short video to the previously established improved readability and audiovisual supplementation.
2. These data further demonstrate the benefit of improved readability and audiovisual slide supplementation with the addition of chunking.

3. The benefits of chunking were most significantly reflected in patient improvement in overall comprehension, treatment recall and treatment comprehension.

4. Positional effects indicate the most important information should be presented last.

5. The treatment domain is the most affected.

6. The significant amount of information to be presented (18 elements) defies the concept of presenting 7 ± 2 new concepts for short term memory optimization. Presenting less significant information at a later time could be considered.


41. MILLER GA. The magical number seven plus or minus two: Some limits on our capacity for processing information. *Psychol Rev.* 1956;63(2):81-97.


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 at risk for 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

Fig 1. Eighteen elements of informed consent
Table 1. Internal Reliability of Patients and Parents

<table>
<thead>
<tr>
<th>Question</th>
<th>Parent kappa (CI)*</th>
<th>Reliability</th>
<th>Patient kappa (CI)</th>
<th>Reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retainers</td>
<td>0.17 (-0.21-0.55)</td>
<td>Slight</td>
<td>0.32 (0.06-0.58)</td>
<td>Fair</td>
</tr>
<tr>
<td>Health updates</td>
<td>0.24 (-0.10-0.58)</td>
<td>Fair</td>
<td>0.30 (0.09-0.52)</td>
<td>Fair</td>
</tr>
<tr>
<td>TMJ/TMD</td>
<td>0.70 (0.53-0.88)</td>
<td>Substantial</td>
<td>0.52 (0.29-0.75)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Ankylosis</td>
<td>0.13 (-0.09-0.34)</td>
<td>Slight</td>
<td>0.47 (0.27-0.66)</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

*Lower 95% to upper 95% CI
Table 2: Sociodemographic data, REALM, WRAT3, STAI-6 and self-assessment scores for patients and parents

<table>
<thead>
<tr>
<th>Subject</th>
<th>Group</th>
<th>Sex (%)</th>
<th>Age Mean (SD)</th>
<th>Education Level (Median)</th>
<th>Ethnicity* (%)</th>
<th>REALM (Median)</th>
<th>WRAT3 (Median)</th>
<th>STAI-6 (Median)</th>
<th>Self assessment VAS Mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>A (n=34)</td>
<td>54.3 F 45.7 M</td>
<td>14.5 (1.8)</td>
<td>8th grade</td>
<td>68.8 WNH 15.6 BNH 6.3 mixed 3.1 WH, SA,EA</td>
<td>7th to 8th grade</td>
<td>8th grade</td>
<td>10</td>
<td>7.75 (1.9)</td>
<td>0.0839</td>
</tr>
<tr>
<td></td>
<td>B/1 (n=35)</td>
<td>42.9 F 57.1 M</td>
<td>14.4 (1.6)</td>
<td>8th grade</td>
<td>60.0 WNH 17.2 EA 11.4 BNH, WH</td>
<td>7th to 8th grade</td>
<td>High school</td>
<td>9</td>
<td>7.54 (1.65)</td>
<td>0.8801</td>
</tr>
<tr>
<td>2 (n=31)</td>
<td>71.0 F 29.0 M</td>
<td>14.3 (1.6)</td>
<td>**</td>
<td>**</td>
<td>7th to 8th grade</td>
<td>2nd grade</td>
<td>10</td>
<td>**</td>
<td>0.7141</td>
<td></td>
</tr>
<tr>
<td>3 (n=30)</td>
<td>43 F 57 M</td>
<td>14.6 (1.7)</td>
<td>8th grade</td>
<td>73.3 WNH 20.0 BNH 3.3 WH 3.3 mixed</td>
<td>High school</td>
<td>High school</td>
<td>10</td>
<td>7.46 (1.7)</td>
<td>0.5586</td>
<td></td>
</tr>
<tr>
<td>4 (n=40)</td>
<td>55 F 45 M</td>
<td>14.3 (1.6)</td>
<td>8th grade</td>
<td>72.5 WNH 17.5 BNH 7.5 mixed 2.5 WH</td>
<td>High school</td>
<td>High school</td>
<td>9.5</td>
<td>8.30 (1.69)</td>
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<tr>
<td>Subject</td>
<td>Group (n=34)</td>
<td>Sex (%)</td>
<td>Age Mean (SD)</td>
<td>Education level (Median)</td>
<td>Ethnicity* (%)</td>
<td>REALM (Median)</td>
<td>WRAT3 (Median)</td>
<td>STAI-6 (Median)</td>
<td>Self assessment VAS Mean (SD)</td>
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<td></td>
</tr>
<tr>
<td>Parents</td>
<td>A</td>
<td>67.7 F</td>
<td>44.7 (10.5)</td>
<td>4 years of college</td>
<td>69.7 WNH</td>
<td>High school</td>
<td>Post-high school</td>
<td>9</td>
<td>9.65 (1.25)</td>
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<tr>
<td></td>
<td>B/1 (n=35)</td>
<td>82.9 F</td>
<td>45.9 (9.0)</td>
<td>&lt; 4 years of college</td>
<td>65.7 WNH</td>
<td>High school</td>
<td>Post-high school</td>
<td>10</td>
<td>8.7 (1.28)</td>
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</tr>
<tr>
<td></td>
<td>17.1 M</td>
<td></td>
<td></td>
<td></td>
<td>14.3 BNH, WH</td>
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<tr>
<td></td>
<td>2 (n=31)</td>
<td>74.2 F</td>
<td>43 (7.2)</td>
<td>**</td>
<td>19.4 WNH, WH</td>
<td>High school</td>
<td>3rd grade</td>
<td>8</td>
<td>**</td>
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<td></td>
<td>25.8 M</td>
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<td>16.1 EA</td>
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<tr>
<td></td>
<td>3 (n=30)</td>
<td>80 F</td>
<td>42 (6.6)</td>
<td>&lt; 4 years of college</td>
<td>73.3 WNH</td>
<td>High school</td>
<td>High school</td>
<td>7</td>
<td>9.02 (1.09)</td>
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<tr>
<td></td>
<td>20 M</td>
<td></td>
<td></td>
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<td>17.5 BNH</td>
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<td></td>
<td>4 (n=40)</td>
<td>80 F</td>
<td>43.8 (8.2)</td>
<td>&lt; 4 years of college</td>
<td>75 WNH</td>
<td>High school</td>
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<td>9</td>
<td>9.17 (0.94)</td>
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<tr>
<td></td>
<td>20 M</td>
<td></td>
<td></td>
<td></td>
<td>17.5 BNH</td>
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</table>

Continued
Group A Current study group A with customized slideshow with “chunks” organized from more specific to general and short video presentation; Group 1 Current study group B with customized slideshow with “chunks” organized from more specific to general; Group 2 Kang et al. data for AAO document; Group 3 Kang et al. data for non-customized slideshow; Group 4 Carr et al. data for customized slideshow with “chunks” organized from general to specific

F=Female; M=Male; VAS= visual analogue scale

*WNH=white, non-Hispanic; WH=White Hispanic; BNH=black, non-Hispanic; BH=black Hispanic; EA= East Asian or Pacific Islander; SA= south Asian; ** data not available
Table 3 Mean (SD) percentages of overall on-target recall and comprehension for patient and parent groups A and B

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>A vs. B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall recall</td>
<td>55 (14.7)</td>
<td>54.1 (14)</td>
<td>0.7847</td>
</tr>
<tr>
<td>Overall Comprehension</td>
<td>51.5 (20.3)</td>
<td>52.3 (16)</td>
<td>0.8433</td>
</tr>
<tr>
<td><strong>Parent</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall recall</td>
<td>71.5 (14.4)</td>
<td>70.1 (11.9)</td>
<td>0.6643</td>
</tr>
<tr>
<td>Overall Comprehension</td>
<td>66 (13.7)</td>
<td>68.6 (13)</td>
<td>0.4425</td>
</tr>
</tbody>
</table>

*Statistically significant difference as indicated by $P<0.05$*
Table 4. Mean (SD) percentages of on-target responses for consent domains for groups A and B

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>Parents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tx Recall</td>
<td>45.4 (22.7)</td>
<td>50.2 (20.4)</td>
</tr>
<tr>
<td>Risk Recall</td>
<td>59.8 (18.7)</td>
<td>59.4 (22.3)</td>
</tr>
<tr>
<td>Resp Recall</td>
<td>61.8 (19.1)</td>
<td>60.7 (18.3)</td>
</tr>
<tr>
<td>Tx comp</td>
<td>41.7 (25.8)</td>
<td>47 (25.6)</td>
</tr>
<tr>
<td>Risk comp</td>
<td>43.4 (24.5)</td>
<td>38.4 (18.8)</td>
</tr>
<tr>
<td>Resp comp</td>
<td>67 (24.1)</td>
<td>69.8 (18.6)</td>
</tr>
<tr>
<td><strong>Parents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tx recall</td>
<td>67 (25.2)</td>
<td>70.1 (19.7)</td>
</tr>
<tr>
<td>Risk recall</td>
<td>71.7 (15.6)</td>
<td>65.7 (17.4)</td>
</tr>
<tr>
<td>Resp recall</td>
<td>82 (16.5)</td>
<td>80 (15.8)</td>
</tr>
<tr>
<td>Tx comp</td>
<td>55 (22.6)</td>
<td>57 (18.6)</td>
</tr>
<tr>
<td>Risk comp</td>
<td>53.6 (22.2)</td>
<td>57.2 (18.7)</td>
</tr>
<tr>
<td>Resp comp</td>
<td>86.1 (13.1)</td>
<td>87.8 (14.3)</td>
</tr>
</tbody>
</table>

* Group A Slideshow and video; Group B slideshow only

Tx=Treatment; Resp=Responsibility

* Statistically significant difference as indicated by P<0.05
Table 5. Mean (SD) percentages of on-target responses for recall and comprehension of core, custom and general issues for patient and parent Groups A and B

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>A vs. B*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core recall</td>
<td>58.5 (17.2)</td>
<td>53.8 (18.5)</td>
<td>0.2635</td>
</tr>
<tr>
<td>Gen recall</td>
<td>52.5 (14.5)</td>
<td>52.7 (15.2)</td>
<td>0.9434</td>
</tr>
<tr>
<td>Cust recall</td>
<td>36.2 (32.7)</td>
<td>36.2 (36.1)</td>
<td>0.9991</td>
</tr>
<tr>
<td>Core comp</td>
<td>68.9 (25.9)</td>
<td>69.4 (23)</td>
<td>0.9344</td>
</tr>
<tr>
<td>Gen comp</td>
<td>39.4 (22.6)</td>
<td>41.3 (17.9)</td>
<td>0.692</td>
</tr>
<tr>
<td>Cust comp</td>
<td>30.8 (33.3)</td>
<td>31.3 (40.3)</td>
<td>0.97</td>
</tr>
<tr>
<td><strong>Parents</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Core recall</td>
<td>75.4 (18.9)</td>
<td>73.5 (17)</td>
<td>0.6584</td>
</tr>
<tr>
<td>Gen recall</td>
<td>71.2 (17.2)</td>
<td>71 (11.7)</td>
<td>0.9536</td>
</tr>
<tr>
<td>Cust recall</td>
<td>54.6 (30.6)</td>
<td>60.8 (32.1)</td>
<td>0.437</td>
</tr>
<tr>
<td>Core comp</td>
<td>79.4 (20)</td>
<td>84.5 (14.9)</td>
<td>0.2271</td>
</tr>
<tr>
<td>Gen comp</td>
<td>58 (17.9)</td>
<td>61 (16.9)</td>
<td>0.4656</td>
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<tr>
<td>Cust comp</td>
<td>39.1 (36.8)</td>
<td>37.2 (36.5)</td>
<td>0.8429</td>
</tr>
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</table>

*Statistically significant difference as indicated by P<0.05

*Group A customized slideshow and video; Group B customized slideshow only
Gen= general; cust= custom
Table 6. Mean (SD) percentages of on-target responses for recall and comprehension of core, custom and general issues for patient and parent groups A and B

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Recall</td>
<td>54.1 (14)</td>
<td>42.3 (13)</td>
<td>52.6 (14.4)</td>
<td>57.4 (13.4)</td>
<td>0.0035*</td>
<td>0.973</td>
<td>0.7207</td>
<td>0.0194*</td>
<td>&lt;0.0001*</td>
<td>0.4708</td>
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<tr>
<td>Overall Comprehension</td>
<td>52.3 (16)</td>
<td>37.9 (13.6)</td>
<td>44.1 (16.7)</td>
<td>53.6 (13.3)</td>
<td>0.0006*</td>
<td>0.1225</td>
<td>0.9838</td>
<td>0.3332</td>
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<td>0.0450*</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Recall</td>
<td>70.1 (11.9)</td>
<td>58.1 (15.6)</td>
<td>67.3 (16.8)</td>
<td>70.6 (13.9)</td>
<td>0.0049*</td>
<td>0.8557</td>
<td>0.9987</td>
<td>0.065</td>
<td>0.0021*</td>
<td>0.7681</td>
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<tr>
<td>Overall Comprehension</td>
<td>68.6 (13)</td>
<td>54.7 (17)</td>
<td>66.3 (16.6)</td>
<td>69.2 (15.2)</td>
<td>0.0017*</td>
<td>0.9333</td>
<td>0.9976</td>
<td>0.0170*</td>
<td>0.0006*</td>
<td>0.8573</td>
</tr>
</tbody>
</table>

*Statistically significant difference as indicated by $P<0.05$

**Group 1** Current study group B with customized slideshow with “chunks” organized from more specific to general; **Group 2** Kang et al. data for AAO document; **Group 3** Kang et al. data for non-customized slideshow; **Group 4** Carr et al. data for customized slideshow with “chunks” organized from general to specific
Table 7. Mean (SD) percentages of on-target responses for consent domains for all groups and comparisons among groups

<table>
<thead>
<tr>
<th>Patients</th>
<th>G1</th>
<th>G2</th>
<th>G3</th>
<th>G4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tx Recall</td>
<td>50.2 (20.4)</td>
<td>28.5 (19.4)</td>
<td>36.7 (22.9)</td>
<td>48.9 (19)</td>
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<tr>
<td>Risk Recall</td>
<td>59.4 (22.3)</td>
<td>39 (21.7)</td>
<td>51.3 (20.3)</td>
<td>52.4 (18.5)</td>
</tr>
<tr>
<td>Resp Recall</td>
<td>60.7 (18.3)</td>
<td>57.8 (20.2)</td>
<td>70.7 (18.3)</td>
<td>68.6 (18.5)</td>
</tr>
<tr>
<td>Tx comp</td>
<td>47 (25.6)</td>
<td>18 (16.7)</td>
<td>32.7 (23.8)</td>
<td>39 (20)</td>
</tr>
<tr>
<td>Risk comp</td>
<td>38.4 (18.8)</td>
<td>28.2 (17.9)</td>
<td>28.1 (19.7)</td>
<td>38.9 (18.5)</td>
</tr>
<tr>
<td>Resp comp</td>
<td>69.8 (18.6)</td>
<td>61.1 (20.2)</td>
<td>68.2 (23)</td>
<td>78.2 (15.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parents</th>
<th>G1</th>
<th>G2</th>
<th>G3</th>
<th>G4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tx recall</td>
<td>70.1 (19.7)</td>
<td>46.3 (21.9)</td>
<td>62.3 (24.5)</td>
<td>62.1 (27)</td>
</tr>
<tr>
<td>Risk recall</td>
<td>65.7 (17.4)</td>
<td>57.2 (15.6)</td>
<td>66 (22)</td>
<td>69.6 (19.3)</td>
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<tr>
<td>Resp recall</td>
<td>80 (15.8)</td>
<td>77 (22.1)</td>
<td>80.5 (17.8)</td>
<td>80.8 (15.9)</td>
</tr>
<tr>
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<td>29.8 (21.3)</td>
<td>56.4 (24.1)</td>
<td>59.6 (26.4)</td>
</tr>
<tr>
<td>Risk comp</td>
<td>57.2 (18.7)</td>
<td>46.2 (21.9)</td>
<td>52.2 (21.1)</td>
<td>57.5 (20.5)</td>
</tr>
<tr>
<td>Resp comp</td>
<td>87.8 (14.3)</td>
<td>78.8 (22.1)</td>
<td>87 (18.3)</td>
<td>86.8 (13.1)</td>
</tr>
</tbody>
</table>

* Statistically significant difference as indicated by *P* < 0.05

Group A Current study group A with customized slideshow with “chunks” organized from more specific to general and short video presentation; Group 1 Current study group with customized slideshow with “chunks” organized from more specific to general; Group 2 Kang et al. data for AAO document; Group 3 Kang et al. data for non-customized slideshow; Group 4 Carr et al. data for customized slideshow with “chunks” organized from general to specific

Tx=Treatment; Resp=Responsibility
Table 7. Mean (SD) percentages of on-target responses for consent domains for all groups and comparisons among groups (cont.)

<table>
<thead>
<tr>
<th>Patients</th>
<th>G1 vs. G2</th>
<th>G1 vs. G3</th>
<th>G1 vs. G4</th>
<th>G2 vs. G3</th>
<th>G2 vs. G4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tx Recall</td>
<td>0.0001*</td>
<td>0.0378*</td>
<td>0.9828</td>
<td>0.3875</td>
<td>0.0002*</td>
</tr>
<tr>
<td>Risk Recall</td>
<td>0.005*</td>
<td>0.3863</td>
<td>0.9928</td>
<td>0.0905</td>
<td>0.0014*</td>
</tr>
<tr>
<td>Resp Recall</td>
<td>0.9171</td>
<td>0.1371</td>
<td>0.9749</td>
<td>0.0359*</td>
<td>0.0749</td>
</tr>
<tr>
<td>Tx comp</td>
<td>&lt;0.0001*</td>
<td>0.0394*</td>
<td>0.2625</td>
<td>0.0422*</td>
<td>0.0004*</td>
</tr>
<tr>
<td>Risk comp</td>
<td>0.1148</td>
<td>0.1147</td>
<td>0.366</td>
<td>1</td>
<td>0.0742</td>
</tr>
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<td>Resp comp</td>
<td>0.2474</td>
<td>0.9859</td>
<td>0.0993</td>
<td>0.4625</td>
<td>0.0013*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parents</th>
<th>G1 vs. G2</th>
<th>G1 vs. G3</th>
<th>G1 vs. G4</th>
<th>G2 vs. G3</th>
<th>G2 vs. G4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tx recall</td>
<td>0.0003*</td>
<td>0.5379</td>
<td>0.4469</td>
<td>0.0393*</td>
<td>0.0266*</td>
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<tr>
<td>Risk recall</td>
<td>0.2465</td>
<td>0.9999</td>
<td>0.7972</td>
<td>0.2463</td>
<td>0.0288*</td>
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<tr>
<td>Resp recall</td>
<td>0.9002</td>
<td>0.9995</td>
<td>0.9963</td>
<td>0.8646</td>
<td>0.7924</td>
</tr>
<tr>
<td>Tx comp</td>
<td>&lt;0.0001*</td>
<td>0.9996</td>
<td>0.9563</td>
<td>&lt;0.0001*</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Risk comp</td>
<td>0.1232</td>
<td>0.7526</td>
<td>0.9999</td>
<td>0.646</td>
<td>0.0932</td>
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<tr>
<td>Resp comp</td>
<td>0.1372</td>
<td>0.9877</td>
<td>0.9945</td>
<td>0.2291</td>
<td>0.1954</td>
</tr>
</tbody>
</table>

Group A Current study group A with customized slideshow with “chunks” organized from more specific to general and short video presentation; Group 1 Current study group with customized slideshow with “chunks” organized from more specific to general; Group 2 Kang et al. data for AAO document; Group 3 Kang et al. data for non-customized slideshow; Group 4 Carr et al. data for customized slideshow with “chunks” organized from general to specific

Tx=Treatment; Resp=Responsibility  * Statistically significant difference as indicated by P<0.05
Table 8. Mean(SD) percentages of on-target responses for recall and comprehension of core, custom and general issues for all patient and parent groups and comparisons among all groups

<table>
<thead>
<tr>
<th></th>
<th>G1</th>
<th>G2</th>
<th>G3</th>
<th>G4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core recall</td>
<td>53.8 (18.5)</td>
<td>45.6 (17.8)</td>
<td>62.5 (20.9)</td>
<td>65.7 (17.9)</td>
</tr>
<tr>
<td>Cust recall</td>
<td>36.2 (36.1)</td>
<td></td>
<td></td>
<td>55.7 (33.3)</td>
</tr>
<tr>
<td>Gen recall</td>
<td>52.7 (15.2)</td>
<td>37.9 (17.6)</td>
<td>47.2 (14.5)</td>
<td>51.8 (15.3)</td>
</tr>
<tr>
<td>Core comp</td>
<td>69.4 (23)</td>
<td>43.9 (21.9)</td>
<td>60.7 (22.7)</td>
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<td>0.0485*</td>
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*Table 8. Mean(SD) percentages of on-target responses for recall and comprehension of core, custom and general issues for all patient and parent groups and comparisons among all groups (cont.)*
Table 8. Mean(SD) percentages of on-target responses for recall and comprehension of core, custom and general issues for all patient and parent groups and comparisons among all groups

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</table>

* Statistically significant difference as indicated by $P<0.05$

*Group A Current study group A with customized slideshow with “chunks” organized from more specific to general and short video presentation; Group 1 Current study group with customized slideshow with “chunks” organized from more specific to general; Group 2 Kang et al. data for AAO document; Group 3 Kang et al. data for non-customized slideshow; Group 4 Carr et al. data for customized slideshow with “chunks” organized from general to specific
Chapter 4

Conclusions

1. There was no benefit to adding a short video to the previously established improved readability and audiovisual supplementation.

2. These data further demonstrate the benefit of improved readability and audiovisual slide supplementation with the addition of chunking.

3. The benefits of chunking were most significantly reflected in patient improvement in overall comprehension, treatment recall and treatment comprehension.

4. Positional effects indicate the most important information should be presented last.

5. The treatment domain is the most affected.

6. The significant amount of information to be presented (18 elements) defies the concept of presenting $7 \pm 2$ new concepts for short term memory optimization. Presenting less significant information at a later time could be considered.
Bibliography


## Appendix A: Modified Informed Consent (MIC) document
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**SECTION OF ORTHODONTICS**

**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

<table>
<thead>
<tr>
<th>Risks</th>
<th>What You Can Do</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cavities, Decalcification, Gum disease</strong>&lt;br&gt;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.</td>
<td>• Watch your diet - Avoid sugar and sticky foods.&lt;br&gt;• Remove the plaque (build up of food and germs) from your teeth by brushing and flossing your teeth every day.&lt;br&gt;• Get regular dental check ups with your dentist while you are in braces.</td>
</tr>
<tr>
<td><strong>Discomfort</strong>&lt;br&gt;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.</td>
<td>• You can take over-the-counter nonaspirin pain medicine to help relieve soreness if allowed by your doctor. Otherwise, use what your doctor recommends.&lt;br&gt;• Tell us right away if anything seems unusual.</td>
</tr>
<tr>
<td><strong>Damage to braces or teeth</strong>&lt;br&gt;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.</td>
<td>• Wear a mouthguard when you are playing any sport.&lt;br&gt;• A mouthguard can protect your teeth and braces from breaking or getting loose.&lt;br&gt;• Avoid hard foods.&lt;br&gt;• Avoid piercing or keeping a piercing in your tongue, lip, or any part of your mouth.</td>
</tr>
<tr>
<td><strong>Injury from braces</strong>&lt;br&gt;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).</td>
<td>• Tell us if your braces are hurting you or are loose or broken.</td>
</tr>
<tr>
<td><strong>Injury from headgears</strong>&lt;br&gt;Even though headgears have a safety system, they can be dangerous. They can hurt your eyes and face.</td>
<td>• Do not wear your headgear outside of the house, during horseplay, or while playing sports.&lt;br&gt;• Follow your orthodontist’s directions.</td>
</tr>
<tr>
<td><strong>Health updates</strong>&lt;br&gt;Many medical problems can affect your progress with braces.</td>
<td>• Tell us about your health and all medications.&lt;br&gt;• Tell us when there are any changes to your health, including pregnancy and medications.</td>
</tr>
<tr>
<td><strong>Using Tobacco Products</strong>&lt;br&gt;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.</td>
<td>• Avoid using tobacco products.&lt;br&gt;• If you continue to use tobacco, you should know that you may get a less than ideal result with your braces.</td>
</tr>
</tbody>
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1/3
RISKS

<table>
<thead>
<tr>
<th>WHAT YOU CAN DO</th>
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<tr>
<td>Treatment time</td>
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<tr>
<td>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.</td>
</tr>
<tr>
<td>• Wear your rubber bands and other parts of your braces as instructed by your orthodontist.</td>
</tr>
<tr>
<td>• Come to all of your scheduled appointments.</td>
</tr>
<tr>
<td>• Come to your appointments on time.</td>
</tr>
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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.

• 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.
• 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: ____________

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Appendix B: Custom Slideshow elements

Please ID at most 4 increased risk factors that you would highlight in the informed consent for this specific patient.

- Treatment time
- Health updates
- Tobacco product use
- Ceramic appliances and damage to enamel
- Accidental injury during adjustment appointments
- Wisdom teeth
- Impacted teeth and unerupted teeth
- Allergies to orthodontic appliances
- Large fillings and injured teeth that may need root canal therapy
- Extractions and orthognathic surgery for severe crowding and mismatched jaws
- Injury from braces and injury from headgear
- Abnormal jaw growth
- Temporomandibular Joint Disorders
- Tooth reshaping, interproximal reduction
Appendix C: Consent

The Ohio State University Consent to Participate in Research

Study Title: Orthodontic Informed Consent Considering Information Load and Social Position Effect
Principal Investigator: 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. 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 participate.

- Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?
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.

2. How many people will take part in this study?
We hope to have 180 people in this study.

3. What will happen if I take part in this study?
You and your child will be randomly assigned (by chance, like flipping a coin) to one of two research study groups. You will have your normally scheduled consultation appointment with your orthodontic resident. The resident will review all the information about your child’s
orthodontic problem and how to best treat it. You and your child may watch a short video.
You and your child will be asked to watch a short informational slide show, to complete a
questionnaire and then be interviewed separately on what the resident discussed with you.
Both of you will also be asked to read a list of words that may or may not be familiar to you.
You also will be asked how you feel.

4. How long will I be in the study?
The study will take approximately 15-40 minutes in addition to your regularly scheduled
appointment. Patients and parents will also be invited to an interview regarding their recall
and understanding of the informed consent issues at 12 months and 24 months or the end of
treatment, whichever occurs first.

5. Can I stop being in the study?
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.

6. What risks, side effects or discomforts can I expect from being in the study?
There are minimal anticipated risks, side effects or discomfort from being in the study. All
information will be kept confidential in locked cabinetry and on secure network computer
servers, and the possibility of a loss of confidentiality is minimal. A coding system will be
used to ensure names are not associated with any study information.

7. What benefits can I expect from being in the study?
You will not expect to have any benefits from the study. This study may benefit others in the
future.

8. What other choices do I have if I do not take part in the study?
You may choose not to participate without penalty or loss of benefits to which you are
otherwise entitled. You will have your consultation appointment as regularly scheduled if
you choose not to participate.

9. Will my study-related information be kept confidential?
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;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician’s office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?
There are no costs for taking part in this study.

11. Will I be paid for taking part in this study?
Your child will receive a $10 gift card for taking part in this study. They will also receive a $10 gift card for participating at 12 months and 24 months or the end of treatment, whichever comes first.

12. What happens if I am injured because I took part in this study?
If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.
The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?
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.
You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

The 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.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Henry Fields or Dr. Caroline Pawlak.

Henry Fields
The Ohio State University College of Dentistry
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4088 F Yost Hall
337 W. 12th Ave.
Columbus, Ohio 43210-3357
614-292-1120

Caroline Pawlak
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337 W. 12th Ave.
Columbus, Ohio 43210-3357
614-292-9100

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 1-800-678-0751.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Henry Fields or Dr. Caroline Pawlak.

Henry Fields
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Section of Orthodontics
4088 F Yost Hall
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Columbus, Ohio 43210-3357
614-292-1120
CONSENT

Caroline Pestak
The Ohio State University College of Dentistry
Section of Orthodontics
315 W. 12th Ave
Columbus, Ohio 43210-1357
614-292-6100

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

----------

Printed name of person authorized to consent for subject (when applicable)

Signature of person authorized to consent for subject (when applicable)

Date and time

----------

Relationship to the subject

----------

Witness(es) - May be left blank if not required by the IRB

Printed name of witness

Signature of witness

Date and time

----------
Appendix D: HIPPA Authorization

THE OHIO STATE UNIVERSITY
AUTHORIZATION TO USE
PERSONAL HEALTH INFORMATION IN RESEARCH

Title of the Study: Orthodontic Informed Consent Considering Information Load and Serial Position Effect
OSU Protocol Number: 2011H0184
Principal Investigator: Henry W. Fields, Jr.

Subject Name________________________________________

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, X-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University’s Notice of Privacy Practices or the study before signing this form.

Initials/Date: ____________________

Page 1 of 3
Those Who May Use, Share And Receive Your Information As Part Of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.

- Those who oversee the study will have access to your information, including:
  - Members and staff of the Ohio State University’s Institutional Review Boards, including the Western Institutional Review Board
  - The Office for Responsible Research Practices
  - University data safety monitoring committees
  - The Ohio State University Research Foundation

- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
  - The Food and Drug Administration
  - The Office for Human Research Protections
  - The National Institutes of Health
  - The Ohio Department of Human Services

Those researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study:

- The research sponsor and companies owned or connected with the sponsor: Delta Dental Master’s Thesis Grant

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Initials/Date______________
If you have any questions relating to the research, please contact

Henry Fields
The Ohio State University College of Dentistry
Section of Orthodontics
4081 F Postle Hall
333 W. 12th Ave.
Columbus, Ohio 43210-2357
614-292-1120

Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Henry W. Fields, Jr. and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature
(Subject or Legally Authorized Representative)

Name
(Print name above)
(If legal representative, also print relationship to subject.)

Date ________ Time ________ AM / PM
Appendix E: Parental Permission

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

Study Title: Orthodontic Informed Consent Considering Information Load and Serial Position Effect
Principal Investigator: Henry W. Field, 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.
- 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.
- Your child’s participation is voluntary. You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.
- Your child may or may not benefit as a result of participating in this study. Also, as explained below, your child’s participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.
- You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue 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. You are being asked to consider permitting your child to participate in this study for the reasons explained below.

1. Why is this study being done?
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.

2. How many people will take part in this study?
We hope to have 180 people in this study.
3. What will happen if my child takes part in this study?
You and your child will be randomly assigned (by chance) to one of two research study
groups. Your child will have their normally scheduled consultation appointment with his/her
orthodontic resident. The resident will review all the information about your child’s
orthodontic problem and how to best treat it. Your child may be asked to watch a short video.
Your child will review a short slideshow. Your child will be asked to complete a
questionnaire and then interviewed on what the resident discussed with you. The both of you
will also be asked to read a list of words that may or may not be familiar to you. We will also
ask questions about how you are feeling, such as if you are feeling relaxed or worried.

4. How long will my child be in the study?
The study will take approximately 15-40 minutes beyond your regularly scheduled
appointment time.

5. Can my child stop being in the study?
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.

6. What risks, side effects or discomforts can my child expect from being in the study?
There are no anticipated risks, side effects or discomforts from being in the study.

7. What benefits can my child expect from being in the study?
Your child will not benefit directly from participating in the study. The study may benefit
others in the future.

8. What other choice: does my child have if he/she does not take part in the study?
You or your child may choose not to participate without penalty or loss of benefits to which
you are otherwise entitled.

9. Will my child’s study-related information be kept private?
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;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your child’s medical care, your child’s study-related information may be placed in their permanent hospital, clinic, or physician’s office records. Authorized Ohio State University staff not involved in the study may be aware that your child is participating in a research study and have access to your child’s information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your child’s protected health information.

10. What are the costs of taking part in this study?
Participating in this study may make your appointment longer than normal.

11. Will I or my child be paid for taking part in this study?
Your child will be given a $10 gift certificate. By law, payments to subjects are considered taxable income.

12. What happens if my child is injured because he/she took part in this study?
If your child suffers an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if your child should obtain medical treatment at The Ohio State University Medical Center.
The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my child’s rights if he/she takes part in this study?
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.
123 You and your child will be provided with any new information that develops during the 124 course of the research that may affect your decision whether or not to continue participation in 125 the study.
126
129 You or your child may refuse to participate in this study without penalty or less of benefits to 130 which you are otherwise entitled.
131 An Institutional Review Board responsible for human subjects research at The Ohio State 132 University reviewed this research project and found it to be acceptable, according to 133 applicable state and federal regulations and University policies designed to protect the rights 134 and welfare of participants in research.
136
138 14. Who can answer any questions about the study?
139
140 For questions, concerns, or complaints about the study you may contact Dr. Henry Fields or 141 Dr. Caroline Pawlak.
142
143 Henry Fields
144 The Ohio State University College of Dentistry
145 Section of Orthodontics
146 408S F Vesle Hall
147 305 W. 13th Ave.
148 Columbus, Ohio 43210-2357
149 614-292-1120
150
151 Caroline Pawlak
152 The Ohio State University College of Dentistry
153 Section of Orthodontics
154 305 W. 13th Ave.
155 Columbus, Ohio 43210-2357
156 614-292-9100
157
158 159 For questions about your child’s right as a participant in this study or to discuss other study- 160 related concerns or complaints with someone who is not part of the research team, you may 161 contact Ms. Sandi Meadows in the Office of Responsible Research Practices at 1-800-678- 162 6251.
163 If your child is injured as a result of participating in this study or for questions about a study- 164 related injury, you may contact Dr. Henry Fields or Dr. Caroline Pawlak.
165
166 Henry Fields
167 The Ohio State University College of Dentistry
168 Section of Orthodontics
PARENTAL PERMISSION

IRB Protocol Number:

IRB Approval date: 8/21/12

Version: 2.8

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614-292-1120

Caroline Pawlak
The Ohio State University College of Dentistry
Section of Orthodontics
305 W 12th Ave
Columbus, Ohio 43210-2357
614-292-9100

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

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

Page 6 of 8 Form date: 09/26/09
**Witness(es)** - May be left blank if not required by the IRB

<table>
<thead>
<tr>
<th>Witness</th>
<th>Printed name of witness</th>
<th>Signature of witness</th>
<th>Date and time</th>
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**PARENTAL PERMISSION**

**Biomedical/Cancer**

**IRB Protocol Number:** 2012H0184

**IRB Approval date:** 8/21/12

**Version:** 2.0
Appendix F: Assent

The Ohio State University Assent to Participate in Research

Study Title: Orthodontic Informed Consent Considering Information Load and Serial Position Effect

Researcher: Henry W. Fields, Jr.

Sponsor: Delta Dental Master’s Thesis Grant

1. 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.
2. This form will tell you about the study to help you decide whether or not you want to participate.
3. 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.
4. 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.
5. 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 find out how much information you keep from what you are taught at your orthodontic treatment session.

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 test you. You may also watch a video that talks 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 and complete a questionnaire, read a list of words, and then interview you. 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 15-40 minutes in addition to your regularly scheduled
appointment. You will be asked to watch a short informational slideshow, complete a
questionnaire and complete an interview on what the resident discussed with you. You may
be asked to watch a short video. You will read from a list of words that may or may not be
familiar to you. You will be asked how you feel. In the future, you will also be invited to an
interview that will ask you similar questions 12 months into your treatment and at 24 months
or the end of your treatment whichever occurs first.

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?
All information about you will be kept private, but there is a small risk it may not stay private.
We will use a code matched with your information instead of your name to prevent this from
happening. All information will be kept in locked cabinets or on protected computers.

6. What good things might happen to me if I am in the study?
You will not benefit from being in this study, but we might learn something that could help
others.

7. Will I be given anything for being in this study?
You will be given a $10 gift certificate for participating. You will also get a $10 gift card if
you participate in the study at 12 months and 24 months or the end of you treatment.

8. Who can I talk to about the study?
For questions about the study you may contact Dr. Henry Fields or Dr. Caroline Pawlak.

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305 W. 12th Ave. PO Box 122357
Columbus, Ohio 43210-2357
614-292-1120

Caroline Pawlak
The Ohio State University College of Dentistry
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 1-800-678-4251.

**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**

**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**

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.
Appendix G: Video Script

Informed Consent Video Script

I’m Dr. Henry Fields, Chairman of the Department of Orthodontics at The Ohio State University. Today I will be reviewing some of the risks associated with orthodontic treatment.

One of the most common risks of orthodontic treatment is discomfort. Your mouth and teeth will be sensitive and sore. This typically lasts 24 to 48 hours after getting the braces put on as well as every time they are adjusted to make your teeth straight. You can take over-the-counter non-aspirin pain relievers if allowed by your doctor. Following a soft diet will also help with soreness.

Another risk associated with braces is root resorption. This means the roots of your teeth can become slightly shorter due to the treatment. If your teeth have been previously injured, this increases the chances for root resorption. Usually the shortened roots do not affect the long term health of your teeth, but if the root resorption is severe, these teeth can be lost early. If signs of root resorption are detected, your treatment may be slowed down or stopped for a period of time.

During braces, the teeth are at increased risk for cavities, decalcification and gum disease. If you eat a lot of sugary foods or do not properly clean your teeth often enough, you can get tooth decay or permanent white and brown staining of the teeth, which is known as decalcification. Your gums can get puffy, sore, red and bleed easily. Brushing and flossing will remove the plaque, which is the build-up of food and bacteria, which causes these problems. It is also important to continue regular visits with your general dentist during braces.

After your braces are removed, it is important to wear a retainer as long as you want to keep your teeth straight. Your teeth and bite are always changing throughout your life, and your teeth will want to go back to their starting positions.

Braces may poke or scratch your mouth. If parts of your braces become loose, you could swallow them or breathe them into your lungs.

Using tobacco products (smoking or smokeless tobacco) can increase the chances of getting gum disease and slow down healing in your mouth. Tobacco also increases the chance of getting sores in your mouth and is bad for your health. Don’t smoke or you could get a less than ideal result from your braces.
Sometimes impacted teeth, which are teeth that are stuck in the jaw, and unerupted teeth, which are teeth that have not come into the mouth, can cause problems like loss of teeth, gum problems and shortened roots. Sometimes these teeth can be pulled into the mouth. Some teeth become ankylosed, or fused to the bone, and will not move. These teeth may have to be removed and can make time in braces longer.

Abnormal jaw growth can affect your end result and change your treatment. Sometimes your teeth and jaws do not grow as expected and your bite will change. This may mean you need braces for longer or jaw surgery. If it happens after your braces are off, you may need braces again. We cannot predict or control abnormal jaw growth.

If you have a large filling or a past injury to a tooth, there may be nerve damage inside that tooth. Straightening teeth with braces can sometimes irritate the nerve, and you may need a root canal.

Tempromandibular Joint Disorders (TMD or TMJ) are problems with your jaw joints that can include pain, headaches, ear aches and pain when chewing. Braces do not cause or cure TMD or TMJ. If you have any of these problems, let us know right away.

The risk of damage to tooth enamel is greater with ceramic or tooth-colored braces. When they are removed, they can cause cracking or flaking of the teeth. If the bracket breaks, there is a risk of inhaling or swallowing it.

Some people are allergic to the material in the braces or rubber bands. If this happens, braces may need to be stopped. Sometimes special braces can be used or a different plan of treatment may need to be used. A medical doctor may be needed to help control the allergy.

These are only some of the risks associated with orthodontic treatment.
Appendix H: 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 and 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 and 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 and 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 and 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]

Administrating the REALM
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.]

Administrating 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.]
Script for Main study interview (Subject – Child)
This interview is a way for us to find the best method to communicate with and teach our patients and parents. This is not a test. There is no right or wrong answer. Your 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 similar. 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 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 and 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 and 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 and 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©
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 J: Rapid Estimate of adult literacy in medicine (REALM©)

<table>
<thead>
<tr>
<th>List 1</th>
<th>List 2</th>
<th>List 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>fat</td>
<td>fatigue</td>
<td>allergic</td>
</tr>
<tr>
<td>flu</td>
<td>pelvic</td>
<td>menstrual</td>
</tr>
<tr>
<td>pill</td>
<td>jaundice</td>
<td>testicle</td>
</tr>
<tr>
<td>dose</td>
<td>infection</td>
<td>colitis</td>
</tr>
<tr>
<td>eye</td>
<td>exercise</td>
<td>emergency</td>
</tr>
<tr>
<td>stress</td>
<td>behavior</td>
<td>medication</td>
</tr>
<tr>
<td>smear</td>
<td>prescription</td>
<td>occupation</td>
</tr>
<tr>
<td>nerves</td>
<td>notify</td>
<td>sexually</td>
</tr>
<tr>
<td>germs</td>
<td>gallbladder</td>
<td>alcoholism</td>
</tr>
<tr>
<td>meals</td>
<td>calories</td>
<td>irritation</td>
</tr>
<tr>
<td>disease</td>
<td>depression</td>
<td>constipation</td>
</tr>
<tr>
<td>cancer</td>
<td>miscarriage</td>
<td>gonorrhea</td>
</tr>
<tr>
<td>caffeine</td>
<td>pregnancy</td>
<td>inflammatory</td>
</tr>
<tr>
<td>attack</td>
<td>arthritis</td>
<td>diabetes</td>
</tr>
<tr>
<td>kidney</td>
<td>nutrition</td>
<td>hepatitis</td>
</tr>
<tr>
<td>hormones</td>
<td>menopause</td>
<td>antibiotics</td>
</tr>
<tr>
<td>herpes</td>
<td>appendix</td>
<td>diagnosis</td>
</tr>
<tr>
<td>seizure</td>
<td>abnormal</td>
<td>potassium</td>
</tr>
<tr>
<td>bowel</td>
<td>syphilis</td>
<td>anemia</td>
</tr>
<tr>
<td>asthma</td>
<td>hemorrhoids</td>
<td>obesity</td>
</tr>
<tr>
<td>rectal</td>
<td>nausea</td>
<td>osteoporosis</td>
</tr>
<tr>
<td>incest</td>
<td>directed</td>
<td>impetigo</td>
</tr>
</tbody>
</table>

SCORE
List 1 ________________
List 2 ________________
List 3 ________________
Raw Score ________________
RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE

The Rapid Estimate of Adult Literacy in Medicine (REALM) is a screening instrument to assess an adult patient's ability to read common medical words and lay terms for body parts and illnesses. It is designed to assist medical professionals in estimating a patient's literacy level so that the appropriate level of patient education materials or oral instructions may be used. The test takes 2 to 3 minutes to administer and score. The REALM has been correlated with other standardized tests.

<table>
<thead>
<tr>
<th>Correlation of REALM with SORT, PIAT-R, and WRAT-R</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIAT-R</td>
</tr>
<tr>
<td>Recognition</td>
</tr>
<tr>
<td>Correlation Coefficient</td>
</tr>
<tr>
<td>P Value</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reliability Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test-Retest</td>
</tr>
<tr>
<td>(n = 100)</td>
</tr>
<tr>
<td>.99</td>
</tr>
</tbody>
</table>

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

   "I want to hear you read as many words as you can from this list. Begin with the first word on List 1 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 longer than five 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/her pronounce only known words.

3. Count as an error any word not attempted or mispronounced. Score by marking a plus (+) after each correct word, a check (✓) after each mispronounced word, and a minus (-) after words not attempted. Count as correct any self-corrected word.

4. Count the number of correct words for each list and record the numbers in the "SCORE" box. Total the numbers and match the total score with its grade equivalent in the table below.
<table>
<thead>
<tr>
<th>Raw Score</th>
<th>Grade Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-18</td>
<td>3rd Grade and Below</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>19-44</td>
<td>4th to 6th Grade</td>
</tr>
<tr>
<td></td>
<td>Will need low literacy materials; may not be able to read prescription labels.</td>
</tr>
<tr>
<td>45-60</td>
<td>7th to 8th Grade</td>
</tr>
<tr>
<td></td>
<td>Will struggle with most patient education materials; will not be offended by low literacy materials.</td>
</tr>
<tr>
<td>61-66</td>
<td>High School</td>
</tr>
<tr>
<td></td>
<td>Will be able to read most patient education materials.</td>
</tr>
</tbody>
</table>

Used with permission of Terry Davis, Louisiana State University.
Appendix K: Wide range achievement test 3 (WRAT 3®)

BLUE READING

ABOSE RTHUP IVZJQ

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
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.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Not at all</th>
<th>Some what</th>
<th>Moderately</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel calm</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I am tense</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I feel upset</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. I am relaxed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. I feel content</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. I am worried</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Please make sure that you have answered all the questions.
Appendix M: Parental Questionnaire

QUESTIONNAIRE FOR MAIN STUDY (SUBJECT-PARENT)

Parent/Guardian Questionnaire
Research ID_____________ P Date____________

1. What is your age in years and months? ______________Years____________Months

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
   - $10,001-$24,999
   - $25,000-$49,999
   - $50,000-$74,999
   - $75,000-$99,999
   - $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?
   - 8th grade or less
   - 9th grade
   - 10th grade
   - 11th grade
   - 12th grade or GED

   - 2 years of college or technical school
   - Less than 4 years of college
   - 4 year College graduate
   - Graduate school
   - 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
12. Below is a line with a 0 on the left and 10 on the right. Please place a mark on the line that best describes how much you understand about the risks, benefits, and limitations of orthodontic treatment for your child.

0 10
Not at all I understand completely
Appendix N: Child Questionnaire

QUESTIONNAIRE FOR MAIN STUDY (SUBJECT-CHILD)

Child Questionnaire
Research ID ______________ C Date ____________

1. What is your age in years and months? _________________Years_____________Months

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?
   6th grade
   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? ____________________________________________
7. Below is a line with a 0 on the left and 10 on the right. Please place a mark on the line that best describes how much you understand about the risks, benefits, and limitations of your orthodontic treatment.

| 0 | 10 |

Not at all  I understand completely