

# Orthodontic informed consent considering information load and serial position effect



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**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 whether adding a short videotape presentation reiterating the issues related to informed consent to a modified informed consent document that emphasizes a limited number of core and patient-specific custom “chunks” at the beginning of an informed consent presentation improved the recall and comprehension of the risks, benefits, and alternatives of orthodontic treatment. A second objective was to evaluate the current related data for recommendable practices. **Methods:** Seventy patient-parent pairs were randomly divided into 2 groups. The intervention group (group A) patients and parents together reviewed a customized slide show and a short videotape presentation describing the key risks of orthodontic treatment. 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 the appropriateness of responses using a previously established codebook. Lastly, the patients and parents were given 2 reading literacy tests, 1 related to health and 1 with general content followed by the self-administered demographic and psychological state questionnaires. **Results:** There were no significant differences between the groups for sociodemographic 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. The positional effects were limited in impact. When compared with previous studies, these data further demonstrate the benefit of improved readability and audiovisual supplementation with the addition of “chunking.” **Conclusions:** There is no benefit to adding a short video to the previously established improved readability and audiovisual supplementation. There is a significant benefit of improved readability and audiovisual slide supplementation with the addition of “chunking” over traditional informed consent methods in terms of patient improvement in overall comprehension, treatment recall, and treatment comprehension. The treatment domain is the most affected. (*Am J Orthod Dentofacial Orthop* 2015;147:363-72)

Informed consent, one aspect of decision making in health care, including orthodontics, has experienced a shift from a paternalistic model to one driven by

patient autonomy.<sup>1</sup> 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” when presenting the choices to patients.<sup>2</sup>

Health literacy, “the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions,” plays a pivotal role in the informed consent process and is low in the United States.<sup>3</sup> These low rates are linked to, among other things, poor oral health.<sup>4,5</sup>

Health care providers often rely on written education materials to present consent information to their patients, and many are written beyond the average reading level of 8th to 9th grade in the United States, making them difficult to understand.<sup>6,7</sup> A consenting patient or parent who does not understand the treatment and

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its risks, benefits, and alternatives has not given valid “informed” consent, which may have legal implications.

Previous studies examining the medical informed consent process consistently have demonstrated low comprehension of the information presented.<sup>8,9</sup> At the same time, subjects also tend to overestimate their understanding when compared with other assessors’ measures.<sup>9</sup> Methods to improve understanding of consent information have been explored. Understanding among parents of children undergoing elective surgical procedures was greatly improved with a modified informed consent document. The modified form was changed to meet the lower target reading levels in addition to eliminating dense paragraphs in exchange for bullet points, boldface type and underlining for emphasis, and a column format for reading ease.<sup>10</sup> The authors of another study with a videotape to provide surgical patients with informed consent information found that it significantly increased their comprehension when compared with verbal explanations, especially in those with lower education levels.<sup>11</sup> When 2400 patients undergoing elective surgery, a significant surgery, or an elective diagnostic procedure were exposed to an interactive and illustrated online educational tool, Emmi solutions (Chicago, Ill), they demonstrated increased risk awareness, increased confidence in the provider, and increased understanding of the specifics of the treatment or procedure.<sup>12</sup>

Similar trends of poor understanding of consent information have been seen in orthodontics. In 2003, investigators 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.<sup>13</sup> 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.<sup>14</sup>

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.<sup>15</sup> Ways to improve the informed consent process in orthodontics have been explored. In a study by Kang et al,<sup>16</sup> a modified informed consent document combined with a computer-based slide show resulted in better recall and comprehension rates when compared with groups presented with the standard American Association of Orthodontics (AAO) form or the modified informed consent document alone. Carr et al<sup>17</sup> expanded on that research and used the principle of “chunking,” presenting like concepts together, as described by Doak et al.<sup>6</sup> Information was presented from general to specific in the computer-based slide

show. It was shown that subjects best understood the informed consent elements presented at the beginning or the end of the slide show. Carr et al also used a verbal explanation of the modified informed consent in 1 group and found some benefits.

Based on these studies, additional modifications to these newly developed procedures may improve the informed consent process even further. Placing the most important information first in the slide show could further improve the recall and comprehension rates. An audiovisual presentation as an alternative to the standard verbal explanation may support better understanding as well. The purpose of this study was to determine whether modified informed consent documents with emphasis on a limited number of core and custom issues at the beginning of an informed consent presentation, with the addition of a short videotaped presentation that reiterated the issues related to informed consent, could improve the recall and comprehension of the risks, benefits, and alternatives related to orthodontic treatment. By adjusting the already-proven novel approach and depending on the outcome of the study, it might be possible to shorten the informed consent process and not sacrifice recall and comprehension. A further purpose was to statistically compare the current and relevant previous studies to determine sound directions for implementation of informed consent.

## MATERIAL AND METHODS

The research protocols—study 1, which compared the 2 interventions, and study 2, which compared a current intervention with similar previous studies—were reviewed and approved by the institutional review board of Ohio State University.

In study 1, new patients planned for comprehensive treatment in the graduate orthodontic clinic at Ohio State University’s dental college were recruited to participate at the time of initial records or via telephone call before their consultation appointment. All patients met the following inclusion criteria as previously described by Carr et al<sup>17</sup>: 12 to 18 years of age, no previous orthodontic treatment, no sibling or immediate relative previously treated in the clinic, accompanied by a parent or legal guardian for at least 1 year, both patients and parents able to communicate in English, and no developmental disabilities or urgent medical conditions.

With a nondirectional alpha risk of 0.05 and assuming a standard deviation (SD) of 19.3 (Carr et al<sup>17</sup>), a sample size of 35 subjects per group was 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

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