Albertan Orthodontists' Perceived Challenges and Strategies to Obtain Adult Patients' Informed Consent

by

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ABSTRACT

Introduction: Informed consent (IC) is a communication process between a patient and a doctor that often leads to agreement or permission for health care management. For the IC process to be effective, provision of appropriate and accurate information to patients is fundamental and must be followed by patients' understanding and ability to remember information that had been previously discussed with the health care provider. Evidence on informed consent processes for orthodontic treatments suggests that patients' comprehension and recollection rates should be a cause for concern.

Objectives: This study was designed to better understand, from a provider's perspective: 1) how orthodontic informed consents are obtained from adult patients in Alberta; 2) identify the barriers orthodontists perceive when obtaining informed consent from their adult patients; and 3) identify the strategies employed by these professionals to improve patients' comprehension or recollection of treatment information.

Method: An exploratory investigation using qualitative description was conducted. Participants were recruited through a combination of purposeful and snowball sampling. Data were collected until saturation was reached, through audio-recorded, semi-structured interviews. Data were analyzed using thematic analysis. Quality and credibility were achieved by employing the strategies of member checks, memo writing, and analyst triangulation.

Results: Final sample consisted of 12 orthodontists working in 8 different cities in Alberta. Three themes were identified: the flow of the orthodontic informed consent process, challenges interfering with the informed consent process, and strategies to optimize information delivery and communication.

Conclusion: This study described the rich experience of orthodontists practicing in Alberta, Canada, in obtaining informed consent from adult patients. The participants reported barriers that may be overlooked in the daily routine of orthodontic practices. Finally, information was provided that may serve as guidance for orthodontists to overcome or minimize these challenges, improving the quality of consent processes, and increasing the chances of having more informed patients.

PREFACE

This thesis is an original work by Narjara Conduru Fernandes Moreira. The research project, of which this thesis is part, received research ethics approval from the University of Alberta Research Ethics board, Project name “Informed consent in orthodontics: comprehension and recollection of adult patients”, number Pro00075250, September 2017.

Chapter 2 of this thesis (with the exception of sections ‘6. Systematic Review Update’ and ‘7. Review of the Orthodontic Literature’) has been published as N.C.F. Moreira, C. Pacheco-Pereira, L. Keenan, G. Cummings, C. Flores-Mir, “Informed consent comprehension and recollection in adult dental patients: a systematic review”, *Journal of the American Dental Association*, 2016, vol. 147, issue 8, 605-619.e7. I was responsible for study conception and design, data collection, data analysis and interpretation, drafting of the manuscript, and critically revision of the manuscript, and I was the first reviewer. C. Pacheco Pereira worked on study conception and design, data collection, data analysis and interpretation, and critically revised the manuscript, and she was the second reviewer. L. Keenan worked on study conception and design, data analysis and interpretation, and critically revised the manuscript. G. Cummings worked on study conception and design, data analysis and interpretation, and critically revised the manuscript. C. Flores-Mir worked on study conception and design, data analysis and interpretation, and critically revised the manuscript, and he was the third reviewer.

DEDICATION

This thesis is dedicated to God Almighty and to my beloved family.

To the Lord, who provided me with the gift of life, and the strength I needed at several moments during this journey.

To my parents, my very first and eternal enthusiasts, who never stopped believing in me.

To my beloved husband, who has been by my side for every step of the way, from the hardest times to the glory days, I could never make it without you.

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For all the twelve orthodontists who took time out of their immensely busy schedules to participate in this study, I am truly appreciative.

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CHAPTER 1: INTRODUCTION

1. INFORMED CONSENT

Dentists have to provide patients with all of the significant information about the prescribed treatment before any procedures begin. The patients must have the opportunity to examine the facts and provide their informed consent (IC) prior to undergoing any oral health treatment. However, identifying the legally defined scope of information disclosure can be difficult because it may vary between different jurisdictions. Although IC law continues to evolve, patient-centered disclosure standards are more often being adopted by courts, with the duty to disclose information being measured by the amount of information that a reasonable patient would need to make an informed decision.[1] Information to be provided includes, but is not limited to, the nature of the treatment, risks, benefits, treatment alternatives and costs.[2]

The principle of autonomy in dentistry is the right of an individual to determine one's own oral health condition and one's own perceived and/or real need for treatment. This has been protected and recognized as primordial within the dental codes of ethics. While respecting patients' right of autonomy, it is the dentist's duty to involve patients in their treatment decisions in a meaningful way.[2,3]

When patients provide consent for a treatment, it must be voluntary and they must have the competence to understand information that is imparted.[4] Solely providing information and having the consent document signed does not truly accomplish full informed consent goals and cannot be considered valid if the consent process does not include the patient's true comprehension of that information.[5,6]

Although patients often presume that they understand the information provided,[7-9] this may not always be the case.[10] Moreover, evidence suggests that objectively assessed patients' comprehension and/or recollection rates can be quite low.[11,12] Additional support media, such as leaflets, videos and decision boards, applied to IC processes have been suggested to improve adult dental patients' comprehension and recollection rates.[11,13-15] However, there is a lack of data on whether this enhancement is maintained long-term.[16]

2. INFORMED CONSENT IN ORTHODONTICS

When compared to other dental specialties, orthodontic treatment scenarios are marked by prolonged treatment times and follow-up, demanding capability for longer and more solidified recollection/comprehension by patients. This usually involves significant treatment changes that can only be perceived after considerable treatment time. Therefore, patients' initial understanding and ability to remember information that had been previously discussed with the orthodontist's team would need to be substantial and retained over a long-time period. Clinically relevant information varies depending on each individual patient and often involve complex information, such as skeletal and dental aspects of occlusion, and the understanding that orthodontic treatment outcomes are also dependent on not only the clinician's diagnostic and treatment skills,[17] but also on the individual's own craniofacial growth,[18] individual response to treatment and compliance with treatment instructions.[19] This explains the large variability in expected treatment times and outcomes.

It has been suggested that informed patients have more reasonable expectations of treatment outcomes[20] and tend to be more satisfied when their treatment results are closely related to their initial motives to undergo treatment,[21] while insufficient provision of information has been related to patient dissatisfaction[22] and subsequent outcome disputes.[23] Thus, it is rational to assume that an orthodontic treatment that is based on miscommunication between the patient and orthodontist's team may result in outcomes that differ from what the patient would expect.

With the purpose to help its members, professional organizations such as the American Association of Orthodontists have set guidelines to guide orthodontists through the process of properly informing patients and obtaining their informed consent for orthodontic treatment.[24,25] The Canadian Association of Orthodontists, on the other hand, has not implemented their own set of recommendations for obtaining patients' consent for treatment.

3. STATEMENT OF PROBLEM

Consistent with findings within medical[26,27] and dental literature,[16] orthodontic consent processes suggest that patients' comprehension and recollection rates should be a cause for concern.[28-30] However, few studies have examined why low levels of understanding and recollection still occur, and therefore this issue remains unclear and needs to be explored. Because of this, we have decided to explore the informed consent processes from the perspective of the providers, to try to understand the challenges as faced by the orthodontists when communicating with patients, which could interfere in patients' understanding and recall of information provided during consent processes, and what strategies they found to be useful to overcome those challenges.

4. QUALITATIVE RESEARCH METHOD

Quantitative research methods, in its majority, and to a lesser extent qualitative methods have both been applied to the multidimensional aspects of the informed consent processes in orthodontics. Qualitative research evidence has focused exclusively on the decision-making processes of patients considering orthognathic surgery.[31,32] Quantitative analysis has mostly been aimed at measuring patients' and parents' understanding or recall of orthodontic information provided during informed consent processes,[28-30] or testing the effectiveness of different methods of information delivery and their impact on patients' abilities to understand or recall treatment information.[33-37]

However, these studies typically contain generic questions that provide limited insight into the factors that might interfere with the processes of informed consent and contribute to inadequate levels of patients' comprehension and recollection.

Therefore, this study provided an exploratory investigation of orthodontic informed consent processes from the perspective of the orthodontists, using qualitative description. This provided a comprehensive summary of human experience in the everyday context of participants' lives,[38] and a deeper understanding of the challenges orthodontists experience when communicating with their patients during their daily practices. Ultimately, listening to insiders' own voices allowed interaction with their subjective interpretation of their own particular experience, offering researchers a promising scenario that brought a whole new and insightful perspective to the phenomenon under analysis.[39]

5. RESEARCH GOALS

This study was designed to address the following objectives: 1) Describe orthodontic consent processes for adult patients in Alberta; 2) Identify barriers Canadian orthodontists perceive with respect to adult patients' understanding or recollection of treatment information; 3) Identify strategies employed by these professionals to improve patients' comprehension or recollection of treatment information.

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CHAPTER 2: LITERATURE REVIEW

MANUSCRIPT: INFORMED CONSENT COMPREHENSION AND RECOLLECTION IN ADULT DENTAL PATIENTS: A SYSTEMATIC REVIEW

1. INTRODUCTION

People have the right to self-determination through the informed consent process.[1,2] Despite the importance of legal aspects of informed consent,[3,4] attention also should be given to providing patients with appropriate information needed to make an autonomous choice that best represents their own interests.[5] Important issues related to the patient's treatment, including risks, benefits, treatment alternatives, and costs, have to be explained fully by the health care professional and understood by the patient, so the patient can make an informed decision.[1] However, available evidence shows that even after being informed, a high proportion of patients do not understand fully the proposed treatment explanations and associated risks and benefits.[6] The patient's or guardian's complete comprehension of information shared during the informed consent process is of paramount importance[6,7]; otherwise, the signed document may represent the patient's acceptance of a partially comprehended procedure.[5]

Although comprehensive reviews about this topic in the medical literature point to an overall unsatisfactory patient understanding[8,9] and recollection[9] of the information presented during informed consent processes, investigators in only a few empirical studies in dentistry[10-12] have explored these issues. Although results of these studies suggest that similar problems occur in the dental field during the informed consent process, the reality is that the informed consent process in dental settings is not necessarily similar to that in medical settings. Several relevant factors are different: multiple oral health problems may occur simultaneously,[13] there often is an aesthetic effect, and there is a fee-for-service aspect of dental services. To our knowledge, no attempt has been made to synthesize available evidence of the effectiveness of the informed consent process in dentistry. In this systematic review, we assess available evidence regarding adult dental patients' ability to comprehend effectively the oral health treatment information provided during informed consent processes and to recollect that information immediately or more than 1 week after the informed consent process was completed.

2. METHODS

This systematic review adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[14] We registered this systematic review protocol at PROSPERO under the protocol number CRD42015020345.

Eligibility Criteria

Inclusion criteria were as follows:

- Original studies, regardless of the methodology used, in which the investigators assessed adult patients' ability to comprehend effectively the oral health treatment information provided during informed consent processes and to recollect that information immediately or more than 1 week after the informed consent process was completed;
- Studies in which the investigators compared standard informed consent processes with different kinds of information delivery, such as multimedia or smart consents;
- No language restriction.

During phase 2, the reviewers added 1 extra inclusion criterion:

- Studies in which the investigators included personal interaction between the dental care provider and patient before an assessment of their informed consent comprehension or recall was completed.

Exclusion criteria were as follow:

- Studies in which the investigators analyzed informed consent for participation in research trials and exclusively assessing readability of consent forms;
- Studies in which the investigators included patients with cognitive deficit or impairment, as well as letters, reviews, and personal opinions.

Information sources

We comprehensively searched the following databases: MEDLINE via OvidSP, PubMed, Cochrane Library, Embase, LILACS (Literatura Latino Americana em Ciências da Saúde), and Web of Science up to the first week of April 2015; we used detailed individual search strategies for each database. We performed a partial gray literature search by using Google Scholar and limited it to the first 100 most relevant articles. We also checked reference lists of included articles and conducted hand searches for additional citations that were not identified during the electronic searches.

Search

We adapted truncation and word combinations according to each specific database search (eTable 2.1, available online at the end of this article). We managed all references by using reference manager software (RefWorks-COS, ProQuest) and removed all duplicates.

Study Selection

We completed study selection in 2 phases. In phase 1, 2 of us (N.C.F.M., C.P.P.) independently assessed the titles and abstracts of all identified electronic database citations. We selected all abstracts that met the inclusion criteria and retrieved full-text articles for phase 2. Whenever abstracts did not provide enough information to make a decision, we obtained the full-text articles to support a final decision. In phase 2, the same 2 reviewers independently reviewed the full-text articles and applied the same selection criteria to confirm eligibility. In both phases, disagreements about whether a study met the inclusion criteria were settled by discussion between the 2 reviewers. A third author (C.F.M.) was involved when an initial agreement was not possible.

Data items

We extracted the following data elements from each included study: authors, year of publication, sample size, study objectives, methods, dental procedure performed or dentistry area (when the procedure was not clear), results related to outcomes of interest, methodology of standard informed consent within the study, experimental informed consent method of comparison (when applicable), and time frame for information recall. If any required data were not available, we tried to contact the authors to retrieve any missing information.

Data Collection Process

One author (N.C.F.M.) collected all required information from each selected article. A second author (C.P.P.) cross-checked the retrieved information. Following a systematic process, we resolved any disagreement by means of discussion. The third author (C.F.M.) was involved when an agreement could not be reached.

Risk of bias in individual studies

We used 4 tools for risk of bias assessment to evaluate the methodology of individual included studies: the Cochrane Collaboration's tool[15] for assessment of randomized studies; the National Heart, Lung, and Blood Institute tool[16] for cross-sectional studies; the methodological index for nonrandomized studies tool[17] for the case series; and the Critical Appraisal Skills Programme tool[18] for qualitative studies. We used a combination of these tools to assess mixed-methods studies. Two of us (N.C.F.M., C.P.P.) independently assessed the risk of bias in each selected study. The third reviewer (C.F.M.) resolved any disagreement if a final decision was required.

Summary measures and Synthesis of results

We considered comprehension or recollection of informed consent by the adult patient using any type of summary measurement (categorical or continuous variables) to be the primary outcome. We planned a meta-analysis, provided that data were sufficiently homogeneous.

3. RESULTS

Study Selection

Among the 35 full-text articles considered, 4 were not identified from an electronic database. We retrieved 2 by cross-checking reference lists, 1 from a journal monthly update, and 1 directly identified by searching the local library. Subsequently, we excluded 16 articles because they did not meet the inclusion criteria (eTable 2.2, available online at the end of this article). Ultimately, we included 19 articles in this review (Figure 2.1[14]).[10,12,19-35]

Study characteristics

Although some studies included audio or visual information such as leaflets[10,24,31-33] or use of multimedia devices[19,25,26,33,35] to help informed consent processes, only 4 had a methodology to evaluate the effectiveness of these auxiliary methods of information transfer during informed consent processes.[19,31,32,35] The investigators assessed decision-making aids in 2 other studies[27,29]; the investigators evaluated the usual informed consent process already in use in a specific clinical setting (Table 2.1[10,12,19-35]) in 9 studies.[12,20-23,25,28,30,34] Tables 2.1[10,12,19-35] and 2.2[10,12,19-35] present summaries of characteristics of the included articles.

Risk of bias within studies

We assessed the reported methodological quality of randomized studies as unclear to high risk of bias. For example, attrition was a domain with less risk of bias. Similarly, we assessed cross-sectional studies as poor to fair quality. Investigators in only 1 study justified their sample size,[20] and none reported adjustment for confounding variables. We assessed the case series as fair quality. Although the initial intention was to assess risk of bias in the mixed-methods studies by using 2 different tools according to their methodology, the quantitative methodology part of these studies did not provide assessment of any of the outcomes of interest; therefore, we assessed only the qualitative portion for quality. Methodologically, the studies were heterogeneous, and the quality of the qualitative studies varied significantly, from poor[23] to good[25] (Table 2.3[10,12,15-35] and eTables 2.3-2.6,[10,12,15-35] available online at the end of this article).

Synthesis of results

Assessed comprehension and recollection

Investigators in 11 studies[10,12,19,22,24,27,29-32,35] objectively assessed patient comprehension or recollection. Of those assessing information provided by means of conventional approaches (that is, direct professional-patient interaction), patient understanding ranged from 27% to 85%,[12,19,27,29,32] and recollection fluctuated between 20% and 86%.[22,30,31,35] However, when explanation interventions such as leaflets, multimedia, or decision boards were included as adjuncts to the informed consent process, understanding ranged from 44% to 93%[19,27,29,32] and recollection from 30% to 94%.[10,24,31,35] In studies in which the investigators compared conventional with enhanced processes,[19,27,29,31,32,35] all showed significantly better results for the intervention groups. The only exception was a group that received a leaflet without any prompting to read the provided material.[32]

Self-reported understanding

Investigators in some studies assessed patients' subjective understanding of information provided for informed consent.[10,20,21,23,25,26,28,33,34] Most presented similar findings—for instance, 100% of the patients ranked their understanding as favorable or very favorable,[20] felt they understood the information that was provided,[33] or rated their understanding as very good or excellent.[26] In other studies, 92% self-reported that they understood all or most of the information,[10] and 83% self-reported that they fully understood the explanations.[23]

Patients' perceptions of the process

Investigators in some studies used qualitative analysis to assess informed consent processes performed in the usual way within a clinical setting[21,28,34]; among these studies, investigators in 1 found that some patients did not remember having received any kind of information.[21] Patients in another study reported that previous experience with dental treatment made them feel that they already understood it anyway, whereas other patients stated that when dentists were rushed there was no time for explanations or questions.[28] Not all patients had access to accurate and complete information; some chose not to attend to information that was presented, and few patients were able to report postoperative or long-term complications related to the surgery they were about to undergo.[34]

Timing of assessment

Among all included studies, investigators in only 1 objectively assessed the outcomes of interest more than once over time.[32] However, they did not assess time effects directly on recollection or understanding, just the effect of introducing a leaflet to facilitate recollection.

Risk of bias across studies and additional analysis

Data from the included studies were notably heterogeneous. Therefore, we did not consider a meta-analysis suitable.

4. DISCUSSION

Informed consent is an essential component of the decision-making process. In this study, we sought the best evidence regarding understanding or recollection of adult dental patients when presented with information related to their planned dental treatment. Limited evidence suggests that patients' comprehension or recollection of that information is not always adequate, particularly when explanations are given in verbal format only. Although most of the time patients indicated that they understood the information, when assessed objectively, they did not perform as well. This discrepancy is an important clinical consideration when assessing the real effect of informed consent processes in dental clinical practice.

The identified evidence was of limited strength because all the studies in which the investigators assessed the outcomes objectively were classified as having unclear to high risk of bias. Investigators in the 1 good quality methodology study[25] only assessed the outcomes subjectively. Another limitation is that investigators in only 1 study[32] used a validated instrument to measure outcomes, weakening the strength of the results overall.

We included a wide array of designs: randomized clinical trials, observational cross-sectional studies, case series, qualitative studies, and mixed-methods studies. This diversity allowed this review to provide different insights that a specific study type alone would not be able to provide. The downside is that a wide range of study designs is not suitable for an all-inclusive meta-analysis.

We found that literature about informed consent commonly used the following terms interchangeably: understanding, comprehension, knowledge, recollection, and recall. We considered objectively assessed knowledge[19,27,29,32] as the same as understanding or comprehension. Recollection or recall commonly was assessed together with recognition either by prompting the patient when not able to recall spontaneously[24,30,31] or by showing patients all possible options and asking them if they could remember them.[10] In other words, most studies in which the investigators attempted to assess recollection of consent information used assessment methods that essentially prompted the patient’s response.

Therefore, it is questionable to imply that they really assessed what the patient actually recalled.

Educating patients is not only fundamental but also an essential part of the informed consent process. Although some studies in which the investigators appraised recall of information in patient education by using different methods exist in the literature,[36-38] we decided not to include studies in which the investigators did not attempt to include a professional-patient interaction in some way because we believe that patient education alone should not be considered a comprehensive informed consent process. Historically, the courts and higher courts considered the professional-patient relationship to be the core of informed consent, whereas the extent of information to be disclosed varies significantly in different countries.[39]

Although objectively assessed understanding ranged significantly (27-85%),[12,19,27,29,32] most of the time patients self-rated their understanding rather high.[10,20,23,26,33] More interesting would be having both objective and self-reported understanding assessments within the same study so that the quality of the information delivery could be compared equally. This method is foundational because there could be significant clinical decision implications if there are differences between what patients think they understood compared with what they actually were told.

Eli and colleagues[40] assessed the effect of anxiety on a person's ability to recollect information. They found statistically higher values related to patients' self-reported understanding when compared with real knowledge in both stressful and nonstressful situations. In our systematic review, investigators in only 1 study[10] evaluated both recall and self-reported understanding, showing an assessed recollection of 70%, whereas 92% of the patients felt that they understood all or most of the information presented. Although this difference may, at a glance, seem similar, an in-depth analysis of their methodology revealed that the method they used to assess recollection biased patients to have higher levels of recall than normally expected. The researchers asked patients questions regarding their recollection, but at the same time showed them all the possible responses, which made it more of a recognition assessment than a natural recall. The patients' true recollection actually may have been lower than the value measured with their instrument. Other studies also had a design that asked the patients to recognize information instead of recalling it. In those studies, patients were prompted whenever they could not recall the information spontaneously, making the results sound more optimistic than they would have been if no prompting was provided.[24,30,31] This assumption is supported by the findings from Layton[30] who recorded the patients' total overall recall (prompted and unprompted) as 86%; however, the reported unprompted findings accounted for only 36% of their recall.

Although participant reports from prospective studies seemed to be positive most of the time,[10,23,26,33] this was not always the case when retrospective informed consents were conducted in the standard way within a clinical setting, from the patients' point of view, without involvement of the researchers or any attempt to standardize the process in any way. According to the results of some of these studies, few patients firmly stated that they had not been informed,[21] others commented that sometimes dentists were rushed and there was not always time for explanations or questions, and occasionally assumptions were made that patients understood when they did not.[28] Although these findings were from studies in which the investigators did not attempt to intervene in the standard informed consent process performed in that particular clinical setting, they cast doubt on whether all the dentists always take time to inform patients when they are not being evaluated. Findings obtained from qualitative analysis help confirm the importance of qualitative design research when there is a need to understand patients' perspectives better. However, the authors could not determine how well the information was presented to the patients; they could not identify whether the flaw was in the information delivery process or as a direct result of the patients' ability to process the information that was provided.

Differences in points of view between patients and professionals may have critical consequences in the decision-making process, particularly when it comes to elective treatments. In other words, if patients cannot comprehend risks and benefits of an elective treatment fully, they will not be able to weigh all relevant information and make the decision that best applies to their values. This discrepancy may result in patients undergoing an intervention only because of professional recommendation, increasing the likelihood of feeling regret and dissatisfaction at the end.[41,42]

Health literacy becomes a potential and relevant patient-related barrier within informed consent processes because it directly affects how well patients can process and understand the basic health information needed to make proper health decisions.[43] However, none of the eligible included studies addressed this issue.

It was not possible to assess whether time influenced a patient's recollection because the only study in which the investigators assessed recollection more than once over time did not assess how time affected patients' recall of information.[32] To our knowledge, there is no study in the dental literature in which the investigators have appraised this issue. Although medical findings[44,45] show that recall tends to decrease over time, regardless of interventions used to enhance understanding, the same cannot be stated in dentistry.

The dental literature points toward the concept that additional media likely should be added to the dental informed consent process: leaflets, interactive or noninteractive multimedia, and decision boards. These tools yield significantly more positive results than do the conventional standard process of verbal explanations. Although the studies included were not free of bias, all of them in which the investigators aimed to assess the effectiveness of these tools showed similar results regarding this issue,[19,27,29,31,32,35] with only 1 of the intervention groups showing an improvement that was not statistically significant.[32] However, the favorable results in our review regarding the effectiveness of these adjunct interventions were obtained together with verbal explanations from a dental care provider. Therefore, how effective those same additional media would be in the absence of verbal explanations is unknown and could be answered only by a study that specifically addresses both informed consent strategies.

It also could be argued that clinicians should face the informed choice process as an opportunity for teaching patients how to weigh the risks and benefits for the current decision and for future health care decisions. This initial investment of education time with the patient implies their value as an equal partner in the decision-making process.[46]

On the basis of the available evidence, clinicians should endeavor to include adjunct resources, such as leaflets, decision boards, and audiovisual material, when sharing important treatment information with patients. Dentists should not rely solely on patients' self-reported comprehension of information imparted because it might not be representative of their real understanding. Although the wide range of patients' comprehension (27-93%) and recollection (20-94%) in this review precludes affirming that, in general, dental patients demonstrate appropriate levels of comprehension and recall, the informed consent process in dentistry has room for improvement.

Future research in the following areas would be relevant to dental practitioners. Researchers should evaluate whether adults' comprehension and recollection improved if the informed consent process was repeated periodically over a long-term treatment period. This repetition would be of particular interest in orthodontics and periodontics because of the long-term treatment or long-term follow-up, respectively, which are key factors to treatment success. Researchers should assess whether improved informed consent processes enhance comprehension and recollection among patients with low health literacy. In-depth investigation of patients' perspectives on the barriers and facilitators to the comprehension and recollection of information shared during the informed consent process also would be useful.

5. CONCLUSION

According to the available literature, adult dental patients do not always show adequate levels of understanding and information recollection from their informed consent processes, although they usually think that they understood the information provided well. Usually, an immediate improvement of understanding and recall capabilities among adult dental patients was gained when adjunct information methods were used. No data are available regarding long-term information recollection capabilities in adult dental patients after the process has been completed.

6. SYSTEMATIC REVIEW UPDATE

Since we had published this systematic review of the adult dental literature in 2016,[47] two papers fitting the eligibility criteria have been published.[48,49] Johnstone and colleagues[48] assessed the recall of potential complications immediately after 144 patients have been through their standard verbal process of informed consent for endodontic treatment. Nineteen percent of their patients could not be assessed immediately, and instead had to mail their completed questionnaires at a later date, which according to the authors did not affect recall. The authors suggested that when asked how much information about complications patients understood, 63% of the patients indicated that they understood "all of it". However, 91% of the patients in their study could only recall 2 or fewer risks out of 5, and 11% of them were not able to remember any risks. The authors concluded that, under these circumstances, patients presented a poor level of recall following their consultations.[48]

Yusoff and colleagues[49] evaluated the recall of potential complications in 120 patients going through informed consent processes for a lower wisdom tooth removal. Patients were randomly assigned to either a verbal information group or the same verbal information supplemented by a leaflet group. Patients' recall was measured at 3 different times: at first consultation; pre-operatively, at the day of surgery; and seven days after surgery. The authors suggested that there was no statistically significant difference in the recall rate between the two experimental groups, and that both groups presented similar attrition in the recall rate over time. Finally, the researchers concluded that the practice of obtaining informed consent with verbal intervention is equivalent to the verbal and written intervention.[49] It has to be noted that the authors were not clear on how patients were approached when receiving the leaflets, the authors only mentioned that the patients in the written group have received additional information leaflets, without mentioning whether the patients were prompted to read the leaflets. In our systematic review,[47] studies that compared conventional with enhanced informed consent processes all showed significantly better results for the intervention groups, the only exception was a group that received a leaflet without any prompting to read the material provided.[32] It is not clear whether this was also the case in Yusoff et al.'s[49] research, but apparently handling printed information to patients without directing them to read it would be equivalent to not providing any printed material.

Yusoff and colleagues[49] were the only researchers that investigated the effect of time on the recall rate of adult dental patients. They observed a statistically significant decline in the recall rate in both groups, especially from immediate to postoperative phase, decreasing from 64% to 57% in the verbal group, and from 71% to 64%, in the leaflet group.

7. REVIEW OF THE ORTHODONTIC LITERATURE

This section provides an additional review of the literature to the systematic review presented in the previous sections. Since no orthodontic paper fit the eligibility criteria to be included in the previous systematic review, an overview of the orthodontic scenario was missing. Therefore, this section summarizes the evidence published on informed consent processes for orthodontic treatments. Most published research attempting to study the issues of comprehension and recollection of information shared during orthodontic informed consents focused on child or adolescent patients and their parents.

Previous research evaluating patients' and their parents' recollection of treatment information suggested that a poor recall of treatment-related information also occurs in orthodontics.[11,50,51] Although some studies may have included adult patients, [51-57] none of them separately analyzed data from adult patients. Therefore, no direct conclusion can be drawn regarding comprehension and recollection skills of the adult orthodontic patient. In fact, the mean age of patients in these studies ranged from 13.2 to 14.5 years of age. Patel, Moles and Cunningham[52] were the only ones to include age as an independent variable, suggesting that age did not significantly affect recall of orthodontic information. It is worth noting that the majority of patients in this study was between 11 and 13 years of age.[52]

Other attempts by Patel, Moles and Cunningham,[52] Kang et al.,[53] Carr et al.,[54] Pawlak et al.,[55] Aljabaa, McDonald and Newton[56], Ahn et al.[57], Thomson, Cunningham and Hunt[58] and Thickett and Newton[59] assessed the effectiveness of different methods to improve the informed consent process among orthodontic patients and their parents. The researchers evaluated the following methods of information delivery: verbal explanations, written information in various formats, visuals, and computer simulations. There was minimal consensus regarding the best way to provide information to patients, varying from study to study.

Most studies that evaluated recall of information in different points in time did so immediately and at 6-8 weeks after the initial consultation[52,57-59]; only one study included a more extended follow-up period of 18 weeks.[56] Some of these studies were designed to compare the effectiveness of different methods of delivering information in the short- and long-term, without assessing the impact of time in the retention rate.[58,59] The studies that analyzed the effect of time on information retention suggested that it does not significantly impact the recall of orthodontic information.[52,56,57]

To the best of our knowledge, researchers have not yet attempted to individually assess orthodontic informed consent processes and comprehension and recollection of information shared during these processes in adult patients.

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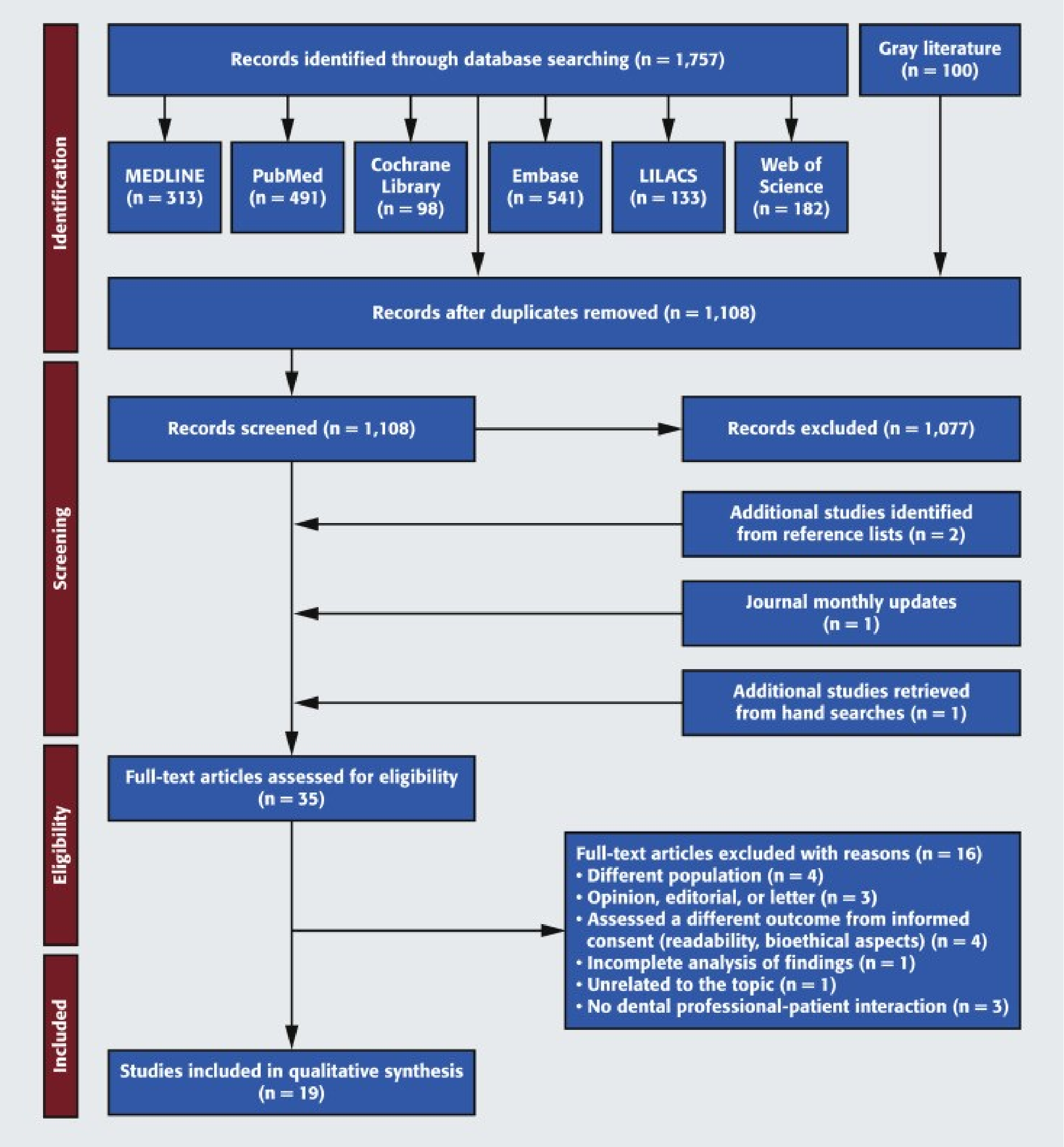

Figure 2.1. Flowchart showing the results of the search process. LILACS: Literatura Latino Americana em Ciências da Saúde. Source: *Moher and colleagues*.[14]

Table 2.1. Summary of descriptive characteristics of included articles.

Study, Country	Sample Size (N)	Study Design	Psychometric Tool Related to Understanding and Recall	Dental Procedure, Dentistry Field, Clinical Setting	Informed Consent Process (No. of Patients)	Recollection Time Frame	Calibrated Information Given to the Patients[*]
Ader and Colleagues,[19] 1992 United States	60	Randomized clinical trial	Multiple-choice quiz	Third-molar extraction surgery Tertiary care hospital	Surgeon only (n = 25) Interactive videodisc and surgeon (n = 18) Noninteractive videotape and surgeon (n = 17)	Immediate	The multimedia groups were calibrated, but the surgeon group was unclear.
Layton,[30]1992 United Kingdom	100	Cross-sectional	Structured, open-ended questions interview (prompted whenever necessary)	Mandibular third-molar extraction surgery under general anaesthesia NHS[†] hospital dental clinic	Structured verbal warnings about specific complications or risks Group preadmission: warned 10 d before the operation at a preadmission clinic Group on admission: warned 1 d before the operation on their admission to the hospital	13 or 22 d after the informed consent process	Yes
Layton and Korsen,[31]1994 United Kingdom	94 and control group (n = 100) from their previous study	Cross-sectional	Structured, open-ended questions interview (prompted whenever necessary)	Mandibular third-molar extraction surgery under general anaesthesia NHS hospital	Control group: structured verbal warnings about specific complications or risks Experimental group: verbal explanation similar to the control groups' and a written sheet (same warnings, in lay language) Both control and experimental groups were divided into 2 groups:	Group A: 19 to 26 d after consent Group B: 13 d after consent	Yes

Study, Country	Sample Size (N)	Study Design	Psychometric Tool Related to Understanding and Recall	Dental Procedure, Dentistry Field, Clinical Setting	Informed Consent Process (No. of Patients)	Recollection Time Frame	Calibrated Information Given to the Patients*
					- Group A: verbal warning and a warning sheet to read and take home, then bring back and sign on admission (1-2 wks before the operation) **-** Group B: verbal warning and a warning sheet to read and sign on admission (1 d before the operation)		
O'Neill and Colleagues,[32] 1996 United Kingdom	66	Randomized clinical trial	Wisdom Tooth Knowledge Scale (a previously validated questionnaire)	Third-molar extraction surgery under local anaesthesia University dental hospital	Verbal explanation (all groups) in addition to the following: **-** Wisdom Tooth Leaflet and prompt group (n = 16): the wisdom tooth information leaflet was provided and patients were verbally prompted to read it **-** Wisdom Tooth Leaflet group (n = 18): the wisdom tooth information leaflet was provided, without prompting Control 1 group (n = 16): a dental health education leaflet unrelated to the surgery procedure was	Timing 1: immediately after the verbal explanation (at first consultation) Timing 2: 2 wks later, just before surgery	Yes

Study, Country	Sample Size (N)	Study Design	Psychometric Tool Related to Understanding and Recall	Dental Procedure, Dentistry Field, Clinical Setting	Informed Consent Process (No. of Patients)	Recollection Time Frame	Calibrated Information Given to the Patients*
					provided, without prompting Control 2 group (n = 16): no reading material was provided		
King,[28]**2001** United Kingdom	50 (12 of them were approached qualitatively)	Mixed-methods: cross-sectional and qualitative	Structured fixed choice questionnaire and interview	Different types of dental treatment within the NHS scope NHS dental clinics	Usual informed consent process conducted by different NHS dentists across different cities	Not available	No
Atchison and Colleagues,[21] **2005** United States	34	Qualitative	Focus group discussion using open-ended interview style	Third-molar extraction surgery under general anaesthesia or treatment for a mandibular fracture County hospital for minority patients	Third-molar patients: routinely informed at a separate preparation clinic visit Fracture patients: informed in emergency department or in the in-patient ward (emergent nature)	Unclear; it seems to have ranged among participants, with an example of a patient who underwent surgery more than 7 mo earlier	No
Johnson and Colleagues,[27] **2006** United States	67	Randomized clinical trial	Questionnaire	Endodontic treatment or extraction (with possible tooth replacement) University dental clinic	4 residents were trained for an EndoDB.[‡] In both the standard informed consent process (usual care) and EndoDB, the nature of information presented was the same.	Immediate	The EndoDB was calibrated before its use, and usual care informed consent was not.
Stirling and Colleagues,[34] **2007** United Kingdom	59	Mixed-methods: cross-sectional and qualitative	Patient questionnaire and semistructured telephone interviews	Orthognathic treatment 4 different clinics	Usual informed consent process conducted by different dentists across the 4 assessed clinics	Prospective patients: 4 wks after first consultation Retrospective patients: 18 to 42	No

Study, Country	Sample Size (N)	Study Design	Psychometric Tool Related to Understanding and Recall	Dental Procedure, Dentistry Field, Clinical Setting	Informed Consent Process (No. of Patients)	Recollection Time Frame	Calibrated Information Given to the Patients*
						mo after patient had made treatment choice	
Hu and Colleagues,[26] **2008** People's Republic of China	174	Case series	Questionnaire	Prosthodontic treatment 2 offices in a public general dental hospital and 4 individual clinics	3 different times: - Baseline: dentist-patient interaction with no media assistance - First visit: dentist-patient interaction assisted by computer, using a dental multimedia system - Second visit: after treatment was performed, dentist-patient interaction assisted by computer, using a dental multimedia system	Immediate	Yes
Brons and Colleagues,[22] **2009** The Netherlands	24	Cross-sectional	Multiple-choice and open-ended question questionnaire	Orthognathic surgery University dental clinic	1 surgeon verbally provided explanation and illustrated by pictures and drawings	Immediate	Yes
Brosnam and Perry,[10]**2009** United Kingdom	75	Cross-sectional	Multiple-choice questionnaire and 1 open-ended question for suggestions	Third-molar extraction surgery under local or general anaesthesia University dental clinic	1 surgeon and 3 leaflets to take away and read	Immediately after the first consultation or immediately after the second consultation, if applicable	Yes
Alfaro-Carballido and Garcia-Rupaya,[20]**2011**	49	Cross-sectional	Self-applied questionnaire	Oral surgery, periodontics, endodontics,	Usual informed consent process in	Patients received informed consent before	No

Study, Country	Sample Size (N)	Study Design	Psychometric Tool Related to Understanding and Recall	Dental Procedure, Dentistry Field, Clinical Setting	Informed Consent Process (No. of Patients)	Recollection Time Frame	Calibrated Information Given to the Patients*
Peru				prosthesis, orthodontics University dental clinic	that clinical setting No details provided	questionnaire Sometimes more than 6 appointments before the survey application date	
Ferrus-Torres and Colleagues,[24] **2011** Spain	87	Cross-sectional	Postoperative open-ended question interview (prompted whenever necessary)	Impacted third-molar extraction surgery University dental clinic	A trained resident verbally explained the risks and provided an informative leaflet to read (not to take home) with the same information in lay language.	7 d after surgery	Yes
Ryan and Colleagues,[33] **2011** United Kingdom	30	Cross-sectional	Questionnaire	Orthognathic treatment University dental hospital	Verbal and visual information (leaflets and DVD) Unclear regarding whether all patients were able to take home a DVD	Immediate	Yes
Singh and Colleagues,[12] **2012** India	500	Cross-sectional	Structured interview schedule generating scores according to the responses	Different outpatient departments Tertiary care dental teaching hospital	Usual care process in that hospital	Unclear	No
Clayton and Colleagues,[23] **2013** United States	24	Qualitative, multimethod approach	Semistructured interviews and direct observation	Included, but not limited to, routine cleaning, restorations, extractions, crowns, bridges, or endodontic treatment Private practices	Usual informed consent process conducted by different dental professionals across the different assessed clinics	Unclear; it seems to have varied because most of the patients were not in active treatment	No

Study, Country	Sample Size (N)	Study Design	Psychometric Tool Related to Understanding and Recall	Dental Procedure, Dentistry Field, Clinical Setting	Informed Consent Process (No. of Patients)	Recollection Time Frame	Calibrated Information Given to the Patients[*]
				and at a school of dental medicine			
Kupke and Colleagues,[29] 2013 Germany	81	Randomized clinical trial	Questionnaire	Class II defect treatment University dental clinic	DB[§] group: the student left DB with the patient for at least 5 min. After that, the patient and the student made a conjoint decision on further treatment. Non-DB group: the treatment options were discussed without using the DB. Completion of the informed consent took place in a separate room in the absence of the student on finalization of the treatment session.	Immediate	Yes. All students received training in shared decision making as part of their routine curriculum, and it was used irrespective of whether a DB was used.
Flett and Colleagues,[25] 2014 United Kingdom	10	Qualitative, cross-sectional	Semistructured interviews	Orthognathic surgery Dental teaching hospital	Patients underwent the regular initial consultation in that department and British Orthodontic Society DVD taken home	2 wks after consultation and immediately to up to 2 wks after watching the DVD (because the DVD was received at the day of consultation)	No
Choi and Colleagues,[35] 2015 South Korea	51	Randomized clinical trial	Open-ended questions questionnaire	Impacted third-molar extraction surgery Military dental clinic	Control group: Korean Dental Association informed consent document and verbal explanation Audiovisual group: Korean Dental Association informed	1 wk after the operation and provision of information	Yes

Study, Country	Sample Size (N)	Study Design	Psychometric Tool Related to Understanding and Recall	Dental Procedure, Dentistry Field, Clinical Setting	Informed Consent Process (No. of Patients)	Recollection Time Frame	Calibrated Information Given to the Patients[*]
					consent document and verbal explanation and slide-show presentation		

⁎ Researchers warranted that information given to the participants was calibrated previously or attained a minimum level required to be tested.
† NHS: National Health Service.
‡ EndoDB: Endodontic decision board.
§DB: Decision board.

Table 2.2. Summary of results of included articles.

Study	Country	Outcomes	Statistical Findings Related to Outcome of Interest	Conclusion
Ader and Colleagues,[19] 1992	United States	Mean percentage of quiz surgeon only group: 40% Interactive video disk and surgeon group: 72.6% Noninteractive videotape and surgeon group: 85%	Analysis of variance: $P < .0001$ Tukey test: difference between each of them	Interactive video disk participants were better informed than those in the surgeon group but less informed than videotape participants.
Layton,[30] 1992	United Kingdom	Number of warnings recalled (with or without prompting): - 5 (all): 61% - 4: 20% - 3: 11% - 2: 5% - 1: 1% - 0: 2% Overall patients' recall[*]: - Recalled unprompted: 35.8% - Recalled prompted: 49.8% - Total recall: 85.6% - Total overall of patients with no recall: 14.4% Overall percentage of patients with no recall and timing of consent[*]: - Preadmission group (n = 49): 17.2% - On admission group (n = 51): 11.6%	χ^2 test and Yates correction Patients with no recall comparing the different timing of consent groups (preadmission versus on admission): None of the warnings were significantly different between the groups.	There is no difference to patients' recall of information, whether this information is given at a preadmission clinic or on admission.
Layton and Korsen,[31] 1994	United Kingdom	Total overall of patients' recall (with or without prompting)[*]: - Written and verbal: 93.6% - Verbal only: 85.6% Overall patients with no recall[*]: - Written and verbal: 6.4% - Verbal only: 14.4% Overall patients with no recall in the written and verbal group[*]: - Group A (n = 51): 4.7%	χ^2 test and Yates correction Patients with no recall: Written and verbal group versus verbal-only group: - Dysesthesia lip: $P < .01$ - Dysesthesia tongue: $P < .001$ - Swelling, trismus, pain: NS[†] Group A versus group B: None of the warnings were significantly different between the groups.	Written preoperative information improved the quality of the informed consent process.

Study	Country	Outcomes	Statistical Findings Related to Outcome of Interest	Conclusion
		- Group B (n = 43): 9.3%		
O’Neill and Colleagues,[32] 1996	United Kingdom	Preleaflet mean (SD[‡]) score (ranging from 0 to 58) Postleaflet mean (SD) score Increase in knowledge WTL[§] and prompt group: 26.81 (1.87) 29.00 (1.63) 2.19 WTL group: 25.50 (4.32) 27.28 (1.74) 1.78 Control group 1: 25.19 (2.48) 25.31 (2.94) 0.12 Control group 2: 26.56 (2.66) 26.81 (2.29) 0.25	Kruskal-Wallis: $P > .25$ Analysis of variance: $P < .001$ Paired *t* tests and Bonferroni correction WTL and prompt: $P < .001$ WTL: $P = .059$ Control 1: $P = .841$ Control 2: $P = .596$	A well-designed information leaflet resulted in increased knowledge in patients undergoing third-molar extraction in a clinical setting.
King,[28]2001	United Kingdom	Some people felt that they understood reasonably well what was explained to them. With previous experience of treatment, some felt that they already understood what to expect. Sometimes, assumptions were made that people understood when they did not. Patients mentioned that when dentists were rushed, there was not always time for explanations or questions.	No statistical analysis related to the outcome of interest	There is a wide variation in consenting practice, from patients who feel that they have given consent freely to those who feel that it is the dentist who takes control.

Study	Country	Outcomes	Statistical Findings Related to Outcome of Interest	Conclusion
Atchison and Colleagues,[21] 2005	United States	20 (of 34) patients recorded being given treatment risk information. 5 fracture patients stated firmly that they had not been informed.	No statistical analysis regarding the outcome of interest	Informed consent perception varied among patients, with some feeling adequately prepared, whereas communication was not always ensured to others.
Johnson and Colleagues,[27] 2006	United States	Mean knowledge scores (SD) (ranging from 0 to 5) Pretrial (run in): 4.09 (1.03) Usual care group: 4.26 (0.78) EndoDB[¶] group: 4.63 (0.55)	Analysis of variance: $P = .03$ t test: Pretrial × usual care: $P = .47$ EndoDB × usual care: $P = .03$ χ^2 test (to analyze whether there were differences in specific questions): $P = .07$	The EndoDB improved knowledge regarding treatment information.
Stirling and Colleagues,[34] 2007	United Kingdom	Overall patients' perception of consequences of treatment[*]: - Positive consequences: 63.33% - Short-term negative consequences: 42.33% - Postoperative negative consequences: 17% -Long-term negative consequences: 10.33% 90% of the patients provided positive comments about the information. 46% were unhappy with aspects of the information. Some statements suggest that not all patients had access to accurate and complete information before making their choices, whereas others chose not to attend to information that was presented. In general, few patients mentioned negative consequences of treatment.	No statistical analyses presented Frequency data were generated from qualitative analysis	Some patients receiving orthognathic treatment do not appear to be making informed decisions about their treatment.
Hu and Colleagues,[26] 2008	People's Republic of China	Understanding of the decision and treatment plan rated as excellent: (P1,[#] P2,[**] P3[††]): 37.4%, 50.6%, 54% (on a 6-point scale, no responses in	Understanding of the decision and treatment plan rated as excellent (odds ratio [95% confidence interval]): P2 versus P1:	The introduction of the dental multimedia system appeared to have positive effects on professional-patient

Study	Country	Outcomes	Statistical Findings Related to Outcome of Interest	Conclusion
		the lowest 4 levels) Preferred the multimedia system–assisted approach over the traditional communication pattern (P2 and P3): 70.1% and 70.1%	10.646[‡‡] (4.812-23.550) P3 versus P1: 5.492[‡‡] (2.567-11.749)	communications, improving the mutual understanding between them.
Brons and Colleagues,[22] 2009	The Netherlands	Overall percentage of recall[*]: - Consequences and possible complications of operation: 47.5% - Reasons for treatment: 15.38% - Reasons to refrain from surgical intervention: 25% Total overall: 29.29%	No statistical analysis presented	Recall rate of risks and complications immediately after an informed consent interview for surgical orthodontic treatment was 42%.
Brosnam and Perry,[10]2009	United Kingdom	Overall percentage of patients' awareness of complications: ≈69.5%[*] Patients' awareness of the risk of complications: 87% knew about *all* or *some* of the risks. Information understood: 92% understood *all* or *most of it*.	Patients who had a second consultation were significantly more aware of "bleeding" and "infection": Fisher exact test, $P < .01$	The criterion standard in the informed consent process was met only partially in most cases, yet most patients felt that the process had been appropriate for their needs.
Alfaro-Carballido and Garcia-Rupaya,[20]2011	Peru	17 (35%): Very favorable 32 (65%): Favorable 0: Unfavorable	No statistical analysis considering patient participants separately	The patients had a clear perception of the informed consent and the planned treatment.
Ferrus-Torres and Colleagues,[24] 2011	Spain	Recall of complications Overall percentage: ≈80.5%[*] (70 patients)	No statistical analysis presented	Patients did not remember most of the information received before providing informed consent.
Ryan and Colleagues,[33] 2011	United Kingdom	100% of patients felt they understood the information given.	No statistical analyses presented	The new style of clinic consistently provided a high level of information to help patients in the decision-making process.
Singh and Colleagues,[12] 2012	India	Overall understanding score: 53.1%	Patients with higher education levels understood better ($P < .01$)	Current consent procedures seem inadequate.

Study	Country	Outcomes	Statistical Findings Related to Outcome of Interest	Conclusion
		Author's classification of the patients' level of understanding: - Poor: 17% - Unsatisfactory: 33% - Satisfactory: 32% - Good: 18%		
Clayton and Colleagues,[23] 2013	United States	20 patients *fully* understood the explanations. 3 patients asked questions whenever they did not understand. 1 patient sometimes did not understand.	None	Patient education should be integrated meaningfully into the workflow shared by dentists, their team members, and patients to maximize its outcomes.
Kupke and Colleagues,[29] 2013	Germany	Total knowledge score mean (SD) (ranging from 0 to 15) DB[§§] group (n = 50): 10.04 (3.5) Non-DB group (n = 31): 4.16 (2.5)	Mann-Whitney *U* test (DB versus non-DB): $P < .0001$ Mann-Whitney *U* tests and Bonferroni correction (difference between the groups within single questions) Survival rate, total costs, self-payment, treatment time: $P < .0001$ Characteristics: $P = .226$ Wilcoxon test (Total costs versus share of self-payment, regardless of the group) Total costs less than self-payment (reported as significant but no *P* value provided)	The use of a DB yielding information regarding treatment options led to a significantly higher level of patient knowledge compared with that in those who received consultation alone.
Flett and Colleagues,[25] 2014	United Kingdom	The virtual animations seemed to improve the participants' understanding of what the surgery involved. Patients commented that the moving images were better than the explanation in the clinic. Most people felt the DVD was important to watch before coming to a decision because they felt they gained knowledge and information that they did not gain from the clinical consultations or other sources.	None	The DVD was useful, providing information that patients could not get or process from professional or external sources; therefore, if used properly, it has a role in the decision-making process.

Study	Country	Outcomes	Statistical Findings Related to Outcome of Interest	Conclusion
Choi and Colleagues,[35] 2015	South Korea	Overall recall[*]: Control group: 20.19% Audiovisual group: 30%	From 8 potential postoperative complications, the audiovisual group significantly recalled trismus and allergic reactions more than did the control group (χ^2 test: $P < .05$).	The audiovisual slide presentation reduced anxiety and improved patient knowledge of the potential postoperative complications involved in surgical extraction of an impacted mandibular third molar.

* Calculated from the article's data.
† NS: No significant difference.
‡ SD: Standard deviation.
§ WTL: Wisdom Tooth Leaflet.
¶ EndoDB: Endodontic decision board.
# P1: Baseline.
⁎⁎ P2: First visit.
†† P3: Second visit.
‡‡ Statistical significance.
§§ DB: Decision board.

Table 2.3. Risk of bias assessment of included studies.[*]

Study	Study Design	Risk of Bias or Quality
Ader and Colleagues,[19] 1992	Randomized clinical trial	High risk of bias[†]
Layton,[30] 1992	Cross-sectional	Fair quality[‡]
Layton and Korsen,[31] 1994	Cross-sectional	Poor quality[‡]
O'Neill and Colleagues,[32] 1996	Randomized clinical trial	Unclear risk of bias[†]
King,[28] 2001	Mixed methods	Moderate risk of bias[§¶]
Atchison and Colleagues,[21] 2005	Qualitative	Moderate risk of bias[§¶]
Johnson and Colleagues,[27] 2006	Randomized clinical trial	Unclear risk of bias[†]
Stirling and Colleagues,[34] 2007	Mixed methods	Moderate risk of bias[§¶]
Hu and Colleagues,[26] 2008	Case series	Moderate risk of bias[¶#]
Brons and Colleagues,[22] 2009	Cross-sectional	Fair quality[‡]
Brosnam and Perry,[10] 2009	Cross-sectional	Poor quality[‡]
Alfaro-Carballido and Garcia-Rupaya,[20] 2011	Cross-sectional	Poor quality[‡]
Ferrus-Torres and Colleagues,[24] 2011	Cross-sectional	Poor quality[‡]
Ryan and Colleagues,[33] 2011	Cross-sectional	Fair quality[‡]
Singh and Colleagues,[12] 2012	Cross-sectional	Poor quality[‡]
Clayton and Colleagues,[23] 2013	Qualitative	High risk of bias[§¶]
Kupke and Colleagues,[29] 2013	Randomized clinical trial	Unclear risk of bias[†]
Flett and Colleagues,[25] 2014	Qualitative	Low risk of bias[§¶]
Choi and Colleagues,[35] 2015	Randomized clinical trial	Unclear risk of bias[†]

[*] For more details, see eTable 2.3, eTable 2.4, eTable 2.5, and 2.6 (available online at the end of this article).
[†] Source: Higgins and Greene.15
[‡] Source: National Heart, Lung, and Blood Institute.16
[§] Source: Critical Appraisal Skills Programme.18
[¶] Risk of bias gradation attributed by the authors. For more details, see eTables 2.5 and 2.6, available online at the end of this article.
[#] Source: Slim and colleagues.17

eTable 2.1: Databases and search terms.

Database	Search Terms
MEDLINE **Cochrane Library** **Embase**	1. informed consent.mp. or exp Informed Consent/ 2. consent.mp. 3. consent∗.mp. 4. exp Geriatric Dentistry/ or exp Dentistry, Operative/ or exp Dentistry/ or exp Public Health Dentistry/ or dentistry.mp. 5. dental care.mp. or exp Dental Care/ 6. dent∗.mp. 7. orthodontics.mp. or exp Orthodontics, Corrective/ or exp Orthodontics/ 8. orthodont∗.mp. 9. endodontics.mp. or exp Endodontics/ 10. endodont∗.mp. 11. prosthodontics.mp. or exp Prosthodontics/ 12. prosthodont∗.mp. 13. periodontics.mp. or exp Periodontics/ 14. periodont∗.mp. 15. exp Dental Implants/ or exp Dental Implantation/ or implantology.mp. 16. oral surgery.mp. or exp Surgery, Oral/ 17. exp Radiography, Dental/ or oral radiology.mp. 18. (oral medicine and pathology).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] 19. oral pathology.mp. or exp Pathology, Oral/ 20. oral medicine.mp. or exp Oral Medicine/ 21. dental surgery.mp. 22. comprehension.mp. or exp Comprehension/ 23. comprehend∗.mp. 24. understanding.mp. 25. understand∗.mp. 26. exp Mental Recall/ or exp Memory/ or recollection.mp. 27. recollect∗.mp. 28. retention.mp. or exp “Retention (Psychology)”/ 29. recall.mp. 30. recall∗.mp. 31. retrieval.mp. or exp “Information Storage and Retrieval”/ 32. retriev∗.mp. 33. remembering.mp. 34. remembrance.mp. 35. remember∗.mp. 36. reminding.mp. 37. remind∗.mp. 38. knowledge.mp. or exp Knowledge/ 39. 1 or 2 or 3 40. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 41. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 42. 39 and 40 and 41
Pubmed	((((“Informed Consent”[MeSH]) OR (((informed consent) OR consent) OR consent*))) AND ((((((((((((((((((((((((((“Dentistry”[MeSH] OR “Public Health Dentistry”[MeSH] OR “Geriatric Dentistry”[MeSH] OR “Dentistry,

	Operative”[MeSH])) OR dentistry) OR dent*) OR (“Orthodontics”[MeSH] OR “Orthodontics, Corrective”[MeSH])) OR orthodontics) OR orthodont*) OR “Dental Care”[MeSH]) OR “Surgery, Oral”[MeSH]) OR oral surgery) OR dental surgery) OR “Dental Implants”[MeSH]) OR implantology) OR endodontics) OR endodont*) OR prosthodontics) OR prosthodont*) OR periodontics) OR periodont*) OR (oral and maxillofacial surgery)) OR dental care) OR dental implant*) OR oral medicine) OR oral pathology) OR (oral medicine and pathology)) OR dental public health)) AND (((((((((((((((((((((“Comprehension”[MeSH]) OR comprehension) OR comprehend*) OR understanding) OR understand*) OR understood) OR recollection) OR recollect*) OR retention) OR “Mental Recall”[MeSH]) OR recall) OR recall*) OR (“Information Storage and Retrieval”[MeSH])) OR retrieval) OR retriev*) OR remember*) OR remembrance) OR remind*) OR knowledge)) OR “Memory”[MeSH])
LILACS*	consentimento esclarecido OR consentimento livre e esclarecido OR consentimiento informado OR informed consent OR consentimento OR consentimiento OR consent OR consent$ [Palavras] and odontologia OR odontología OR dentistry OR ortodontia OR ortodoncia OR orthodontics OR endodontia OR endodoncia OR endodontics OR cirurgia oral OR cirurgia buco OR cirugía maxilofacial OR cirugía bucal OR cirugía oral OR oral surgery OR dental surgery OR prótese OR prostodoncia OR prótesis dental OR prosthodontics OR periodontia OR periodoncia OR periodontics OR implantodontia OR implantología OR implantology OR implant dentistry OR radiologia oral OR oral radiology OR dental radiology OR patologia oral OR patología bucal OR oral pathology OR dent$ [Palavras] and compreensão OR compreend$ OR comprensión OR comprehension OR comprehend$ OR entendimento OR entend$ OR entendimiento OR understand$ OR lembr$ OR record$ OR recuerdo OR recollect$ OR recall$ OR remember$ OR retriev$ OR remind$ OR conhecimento OR conocimiento OR knowledge [Palavras]
Web of Science	(TOPIC: (informed consent) *OR* TOPIC: (consent) *OR* TOPIC: (consent*)) AND (TOPIC: (dentistry) *OR* TOPIC: (dent*) *OR* TOPIC: (orthodontics) *OR* TOPIC: (orthodont*) *OR*TOPIC: (endodontics) *OR* TOPIC: (endodont*) *OR* TOPIC: (oral surgery) *OR* TOPIC: (oral and maxillofacial surgery) *OR* TOPIC: (dental surgery) *OR* TOPIC: (dental care) *OR*TOPIC: (prosthodontics) *OR* TOPIC: (prosthodont*) *OR* TOPIC: (periodontics) *OR* TOPIC: (periodont*) *OR* TOPIC: (implantology) *OR* TOPIC: (dental implant*) *OR* TOPIC: (oral radiology) *OR* TOPIC: (dental radiology) *OR* TOPIC: (oral medicine and pathology) *OR*TOPIC: (oral medicine) *OR* TOPIC: (oral pathology)) AND (TOPIC: (comprehension) *OR*TOPIC: (comprehend*) *OR* TOPIC: (understanding) *OR* TOPIC: (understand*) *OR* TOPIC: (understood) *OR* TOPIC: (recollection) *OR* TOPIC: (recollect*) *OR* TOPIC: (retention) *OR*TOPIC: (recall) *OR* TOPIC: (recall*) *OR* TOPIC: (retrieval) *OR* TOPIC: (retriev*) *OR* TOPIC: (remember*) *OR* TOPIC: (remembrance) *OR* TOPIC: (remind*) *OR* TOPIC: (knowledge))
Google Scholar	Any idiom; Without patents and citations; Classified by relevance (100 most relevant articles). (“informed consent” OR consent) (dentistry OR dental OR orthodontics OR endodontics OR “oral surgery” OR “oral and maxillofacial surgery” OR prosthodontics OR periodontics OR “dental implant”) (comprehension OR understanding OR recollection OR recall)
*LILACS: Literatura Latino Americana em Ciências da Saúde.	

eTable 2.2. Excluded articles and reason for exclusion.

Study	Reason
Witt and Bartsch,[e1]1993	Different assessed population (parents, dentists, nonpatient volunteers)
Schouten and Frielle,[e2]2001	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Schouten and Colleagues,[e3] 2002	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Naidoo,[e4] 2004	Personal opinions, letters, reviews, or editorials
Knobel and Hassfeld[e5]2005	No dental professional-patient interaction
Wolf and Colleagues,[e6]2006	Unrelated to the topic
Eli and Colleagues,[e7]2008	No dental professional-patient interaction
Padron Chacon and Colleagues,[e8] 2008	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Ghafurian,[e9] 2009	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Amarilla Guirland,[e10]2011	Different assessed population (parents, dentists, nonpatient volunteers)
Avramova and Yaneva,[e11] 2011	Different assessed population (parents, dentists, nonpatient volunteers)
Sharma and Colleagues,[e12] 2011	Personal opinions, letters, reviews, or editorials
Cleeren and Colleagues,[e13] 2014	No dental professional-patient interaction
Di Prospero,[e14] 2014	Personal opinions, letters, reviews, or editorials
El Azem and Colleagues,[e15] 2014	Different assessed population (parents, dentists, nonpatient volunteers)
Valenza and Colleagues,[e16] 2014	Incomplete analysis of findings

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eTable 2.3. Risk of bias assessment of included randomized studies.[*]

Criterion	Ader and Colleagues,[19] 1992	O'neill and Colleagues,[32] 1996	Johnson and Colleagues,[27] 2006	Kupke and Colleagues,[29] 2013	Choi and Colleagues,[35] 2015
Random Sequence Generation (Selection Bias)	UN[†]	UN	LR[‡]	UN	UN
Allocation Concealment (Selection Bias)	HR[§]	UN	UN	LR	UN
Masking of Participants and Personnel (Performance Bias)	UN	UN	UN	LR	UN
Masking of Outcome Assessment (Detection Bias)	UN	UN	LR	UN	UN
Incomplete Outcome Data (Attrition Bias)	UN	LR	LR	LR	UN
Selective Reporting (Reporting Bias)	UN	LR	LR	LR	UN
Other Bias	HR	LR	LR	LR	UN
Overall Rating	HR	UN	UN	UN	UN

∗Source: Higgins and Greene.[15]
†UN: Unclear risk.
‡ LR: Low risk.
§ HR: High risk.

eTable 2.4. Risk of bias assessment of included cross-sectional studies.[*]

Criterion	Layton,[30] 1992	Layton and Korsen,[31] 1994	Brons and Colleagues,[22] 2009	Brosnam and Perry,[10] 2009	Alfaro-Carballido and Garcia-Rupaya,[20] 2011	Ferrus-Torres and Colleagues,[24] 2011	Ryan and Colleagues,[33] 2011	Singh and Colleagues,[12] 2013
Was the Research Question or Objective in This Article Clearly Stated?	N[†]	Y[‡]	Y	Y	Y	Y	Y	Y
Was the Study Population Clearly Specified and Defined?	Y	Y	N	N	CD[§]	Y	CD	Y
Was the Participation Rate of Eligible People at Least 50%?	NR[¶]	NR	NR	Y	NR	NR	NR	Y
Were All the Participants Selected or Recruited From the Same or Similar Populations (Including the Same Period)? Were Inclusion and Exclusion Criteria for Being in the Study Prespecified and Applied Uniformly to All Participants?	Y	N	Y	Y	Y	Y	CD	NR
Was a Sample Size Justification, Power Description, or Variance and Effect Estimates Provided?	N	N	N	N	Y	N	N	N
For the Analyses in This Article, Were the Exposures of Interest Measured Before the Outcomes Being Measured?	N	N	N	N	N	N	N	N
Was the Time Frame Sufficient So That One Could Reasonably Expect to See an Association Between Exposure and Outcome if It Existed?	Y	Y	Y	Y	CD	Y	Y	NR

Criterion	Layton,[30] 1992	Layton and Korsen,[31] 1994	Brons and Colleagues,[22] 2009	Brosnam and Perry,[10] 2009	Alfaro-Carballido and Garcia-Rupaya,[20] 2011	Ferrus-Torres and Colleagues,[24] 2011	Ryan and Colleagues,[33] 2011	Singh and Colleagues,[12] 2013
Were the Exposure Measures (Independent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	Y	Y	N	N	N	Y	Y	Y
Were the Outcome Measures (Dependent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	Y	Y	Y	N	CD	Y	N	Y
Were Key Potential Confounding Variables Measured and Adjusted Statistically for Their Effect on the Relationship Between Exposures and Outcomes?	N	N	N	N	CD	N	N	CD
Classification	Fair	Poor	Fair	Poor	Poor	Poor	Fair	Poor

∗ Source: National Heart, Lung, and Blood Institute.[16] We removed 4 original criteria because they were not applicable: “For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?”; “Was the exposure(s) assessed more than once over time?”; “Were the outcome assessors blinded to the exposure status of participants?”; and “Was loss to follow-up after baseline 20% or less?”

† N: No.

‡ Y: Yes.

§ CD: Cannot determine.

¶ NR: Not reported.

eTable 2.5. Risk of bias assessment of included nonrandomized studies.*

Criterion	Hu and Colleagues,[26] 2008†
A Clearly Stated Aim	2
Inclusion of Consecutive Patients	2
Prospective Collection of Data	2
End Points Appropriate to the Aim of the Study	2
Unbiased Assessment of the Study End Point	0
Follow-up Period Appropriate to the Aim of the Study	2
Loss to Follow-up Less Than 5%	2
Prospective Calculation of the Study Size	0
Total	12 of 16

∗ Source: Slim and colleagues.[17]
† 0: Not reported. 2: Reported and adequate.

eTable 2.6. Risk of bias assessment of included qualitative methodology studies.*

Criterion	King,[28] 2001	Atchison and Colleagues,[21] 2005	Stirling and Colleagues,[34] 2007	Clayton and Colleagues,[23] 2013	Flett and Colleagues,[25] 2014
Was There a Clear Statement of the Aims of the Research?	Yes	Yes	Yes	Yes	Yes
Is a Qualitative Methodology Appropriate?	Yes	Yes	Yes	Cannot tell	Yes
Was the Research Design Appropriate to Address the Aims of the Research?	Cannot tell	Yes	Yes	Cannot tell	Yes
Was the Recruitment Strategy Appropriate to the Aims of the Research?	No	Yes	Yes	Yes	Yes
Were the Data Collected in a Way That Addressed the Research Issue?	Cannot tell	Yes	No	No	Yes
Has the Relationship Between Researcher and Participants Been Considered Adequately?	Yes	Yes	No	No	Yes
Have Ethical Issues Been Taken Into Consideration?	Yes	Yes	Yes	Yes	Yes
Was the Data Analysis Sufficiently Rigorous?	No	No	No	No	Yes
Is There a Clear Statement of Findings?	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Yes
How Valuable Is the Research?	Yes	Yes	Yes	Yes	Yes
Overall Rating	5 of 10	8 of 10	6 of 10	4 of 10	10 of 10

∗ Source: Critical Appraisal Skills Programme.[18]

CHAPTER 3: THE METHOD OF INQUIRY

1. INTRODUCTION

The dental research has been dominated by a positivist perspective, an epistemological approach that assumes there is only one truth, which can be discovered through empirical experimentalist methodologies. In contrast, the ontological and epistemological questions underpinning qualitative paradigm are viewed differently. More specifically, the constructivist perspective used in this study maintains that there are many realities and truths, which are constructed and influenced by several factors.[1]

This study was conducted and analyzed from relativist and subjectivist ontological and epistemological views, which means that knowledge is considered to be constructed in an ever-changing manner as a consequence of human activity. "Realities exist in the form of multiple mental constructions, socially and experientially based, local and specific, dependent for their form and content on the persons who hold them".[1(p27)] Such realities can be uncovered by subjective interaction between participant and researcher, with findings being a consequence of the process of interaction between them. So, when using constructivist lens to explore a phenomenon, such phenomenon is not controlled or predicted, as it would if a positivist approach was taken, but it is actually reconstructed through the eyes and minds of those living it and interacting to reveal it.[1]

As described in the literature review, different experimental approaches have been very useful in revealing that patients' ability to comprehend and recollect information related to their orthodontic treatment may be a cause for concern. However, the stories behind these numbers are not yet well understood, especially because as health care deals with people, and people are more complex than other type of subjects considered in natural sciences. Based on this paradigm, experimental methods may become less suitable to fully comprehend these issues, and there remain many unanswered questions about human interactions and how people interpret interactions.[2]

As such gaps in knowledge become clearer, there is a growing recognition of the importance of qualitative health research, especially due to the fact that not all research objectives lend themselves to quantitative methods.[3] Indeed, qualitative inquiry has proven itself valuable to reach the areas that cannot be reached by other methods, through striving to interpret or understand the meaning people attach to their lived experiences.[2,4]

2. QUALITATIVE DESCRIPTION AS A RESEARCH METHOD

The present study is an exploratory investigation using qualitative description, as it intends to explore, identify and describe recurring patterns of experiences among our participants. Qualitative description was selected as the methodological approach because it allows a comprehensive summary of human experience in the everyday context of participants' lives.[5]

The method can be applied using a reasonable combination of different sampling strategies, data collection, data analysis, and data re-presentation techniques, and is the method of choice when a purer description of a phenomenon is desired. Descriptive renderings are straighter and closer to the data, and much less transformed when compared to other qualitative methods that are more theoretically-driven. Whereas representations are closer to the data as it is given, it is worth mentioning that data alone never speak for themselves, and researcher interpretation, just like in any other qualitative method, will always be an inevitable part of the process, yielding a thorough and nuanced final interpretive account.[5,6]

3. STUDY OBJECTIVES

Our study did not set out to prove or disprove hypotheses or to test a theory; rather, it sought to generate descriptive data from which a better understanding of the phenomenon might be developed.

This study was designed to address the following objectives: 1) Describe orthodontic consent processes for adult patients in Alberta; 2) Identify challenges Canadian orthodontists perceive with respect to adult patients' understanding or recollection of treatment information; 3) Identify strategies employed by these professionals to improve patients' comprehension or recollection of treatment information.

4. CHOOSING THE SAMPLE

Participants were recruited using a combination of purposeful sampling, snowball sampling and maximum variation strategy. In other words, participants were selected for their abilities to inform the phenomenon of interest, and the criteria used to maximize variation of lived experiences was experience level in the orthodontic field.[7] In practice, we sought to include participants within a wide range of experience as an orthodontist in Canada, working in a private practice environment, from entry-level specialists all the way up to close-to-retire professionals. Participants were divided into less than 5 years of experience as an orthodontist in Canada, 6 to 15 years, 16 to 25 years, 26 to 35 years, and 35 years and over, while ensuring to have participants in all ranges of expertise. This allowed a broad range of different lived experiences when obtaining adult patients' consent for orthodontic treatment.

The characteristics and contact details of the participants were obtained from a combination of different strategies. Initially, a list of all orthodontists working as clinical instructors at the Department of Orthodontics in the University of Alberta was obtained. Simultaneously, an online search of all orthodontic offices in Alberta was conducted. Additionally, the main researcher directly asked participants and some of her acquaintances to indicate other potential participants.

Eligibility criteria included professionals who are certified as orthodontists by the Royal College of Dentists of Canada, practicing in the province of Alberta.

In qualitative research, the determination of sample size is directed by data saturation, which is defined as “the point at which no new information or themes are observed in the data”.[8(p59)] The relative homogeneity of our population and fairly structured content of our interview guide may have contributed to reaching saturation of data at an earlier point than what would be needed should unstructured interview techniques have been used instead.[8] Moreover, the fact that all Canadian orthodontists undergo the same overall licensing exam, and likely come from accredited orthodontic graduate programs should be considered.

5. DATA COLLECTION

Respondents (n=12) were recruited from September 2018 through May 2019, through either emailing or mailing a letter of initial contact inviting them to take part in our research study (Appendix 1). Participants that indicated they were willing to participate received a copy of our study information letter (Appendix 2), which described the study procedures in more detail.

The main researcher interviewed each informant once. Interviews were audio-recorded and conducted either face-to-face or by phone. Preference was given to face-to-face interviews in a location that respected participants' privacy. However, at first contact all participants were also given the option to be interviewed by phone should they find it more convenient. Only three participants (25%) preferred to be interviewed by phone. Interviews were conducted using an open-ended questions semi-structured interview guide (Appendix 3), prompting participants to describe any experiences involving either patients' understanding or recollection of treatment information, with the ultimate goal of encouraging unanticipated statements. The interviewer was also attentive to identify misunderstandings based on different terminology that may have been used to imply the main thesis goal to explore informed consent processes from the providers' point of view. Interviews lasted an average of twenty-three minutes, with most of them (n= 10) ranging from eleven minutes to twenty-five minutes.

Data were collected and analyzed continuously and simultaneously, until new data collected produced little to no changes to the analysis, or in other words, until no new themes emerged. Saturation was observed to occur around the 10th interview. However, researchers decided to carry on with participants recruitment and data collection, to ensure that there would be no changes to the analysis, and saturation had indeed been reached. After 12 interviews, the researchers decided that new themes were indeed not emerging to justify collecting any additional data.

To become more familiarized with data collected, the main researcher listened to the audio recorded interviews before transcribing the recordings. The interviews were transcribed verbatim, with the first five interviews being transcribed by the main researcher and the following seven interviews using professional transcription services. When transcription services were used, the main researcher engaged in listening to the audio-recorded interviews at least twice to check the transcripts for accuracy. Data collection and data analysis happened simultaneously throughout the research process.[4]

6. DATA ANALYSIS

Data from interviews were analyzed using thematic analysis as described by Braun & Clarke.[9,10] The authors describe a flexible foundational method that is not tied to any particular theory and can be used within various epistemological and ontological frameworks to systematically approach the data set, in order to identify, analyze and report patterns across such set of data. Pattern-based analysis assumes that recurring ideas across a data set reflect something psychologically or socially substantial.[10]

Although other versions of thematic analysis do exist in the literature, the method used in this study, as developed by the authors mentioned above, involves a systematic step-by-step process to deal with the data. Data were analyzed inductively with all codes and themes generated from the data. It is worth mentioning that although described linearly, the process of data analysis actually is recursive in practice, with the researcher moving back and forth as needed, throughout its phases.

Data familiarization

The process of immersion in the data should be the very first step in qualitative data analysis. This was accomplished by engaging with the data, through both interactive data collection, listening the audio-recordings before transcription, and repeated reading the transcripts in an active way, searching for meanings and patterns. During this phase, the researcher would also jot down initial ideas regarding what she was seeing in the data, before any initial coding was actually started.

Generating codes

Once well acquainted with the data, the coding process was started. Coding is the process of identifying and labeling accordingly chunks of data that can be relevant for answering the research question. Whereas coding can be done either selectively or completely, we chose the latter approach to be used in our study. Complete code aims to identify each and every instance within the entire data set that can be relevant or interesting to answer the research question, with the researcher becoming selective only later in the analytic process. Codes were data-driven and, therefore, reflected the explicit content found within the data.

Coding was done through a combination of manual coding on the transcript hard-copies and organizing codes using a word-processing file. Analysis began by systematically reviewing the first transcript before proceeding to the next, until all transcripts have been coded. Fragments of data were coded in as many ways as they were found to fit, which means that the same chunk of data could be labeled entirely or partially under different codes.

Each coded fragment of data was collated into a table within the word-processing file, as they were coded. As the process of coding evolved, new fragments of data would either be assigned to an existing code, to a new code, or to an existing code that would be slightly modified to incorporate the new identified material.

Searching for themes

This phase consisted of identifying broader patterns (themes) across the data set. A theme “captures something important about the data in relation to the research question, and represents some level of patterned response or meaning within the data set”.[9(p82)] In general, themes reported in our study were developed from combination of codes, in an active process of examining the codes and coded data to create potential patterns. Codes were printed and cut into individual pieces to provide a visual representation of the big picture of codes and potential patterns found across the data set. Codes were sorted into groups that formed provisional themes, which were revised or refined as the analysis progressed. At the end of this stage, provisional themes were organized into a table with all relevant coded data extracts collated to each of them.

Reviewing themes

This stage involved two different levels of review and refinement of the provisional themes. First, the researcher re-read each set of coded and collated data that combined to form one of the provisional themes, to make sure that the theme worked in relation to those coded data, until all themes have been revised and refined as needed. Second, the researcher went back to the entire data set and re-read the transcripts to check whether the provisional themes grasped the meaning of the entire set of data collected in relation to the study’s research question. The resultant was an elaborated, coherent and relevant portrait of the dominant patterns found in the data that would address the study’s research question. Data extracts (direct quotes) illustrate the participants’ perceptions of the issues that influence effective communication of treatment information with their patients.

7. QUALITY AND CREDIBILITY IN QUALITATIVE RESEARCH

Research value is dependent upon the credibility of its findings. Credibility was achieved through *member checks*, by providing verbatim transcripts to all participants, which enabled them to check whether the interview was an accurate representation of their lived experiences.[11] Additionally, after the researcher interpreted the data, three participants were given the results to check the accuracy of the interpretation and to validate that the results were a true representation of the communicated lived experience.[12] No changes were requested.

Memo writing, which is the process of taking notes of analytic insights throughout the analytical phase of the research,[10] took place as soon as analytic ideas were coming up. These memos established an audit trail of the researcher's assumptions, thoughts, and ideas throughout the study, ensuring transparency from the outset of the study, and helping to reduce the researcher's preconceptions on the developing knowledge construction.[13] Memos are 'informal analytic notes' that work as a pivotal step between data collection and write-up of final report.[14(p72)]

Another technique used to contribute to verification and validation of the qualitative analysis employed was *analyst triangulation*. This was accomplished by having an experienced qualitative researcher (LK) analyze the data independently and then compare her findings with the first researcher, which provided a control on selective perception and blind interpretive bias.

8. ETHICAL CONSIDERATIONS

This study has been reviewed for its adherence to ethical guidelines and received approval by a Research Ethics Board at the University of Alberta (Appendix 4). Ethical considerations guiding the research included full description of the research process, informed consent, respect for free choice to participate, confidentiality and anonymity, data storage, and protection from harm.

All participants were treated with respect and dignity, through respecting their right of autonomy to decide whether to take part in the research, and their privacy and identity. Participants were not coerced to participate in the study. In some instances, potential participants indicated that they were willing to participate, but did not reply when further contacted. In these cases, candidates' right of autonomy was respected, and they were no longer contacted. All interviews were conducted in a private space within the venue chosen by the participants.

Participants were fully informed about the nature of our study and its involved procedures. Participants received the Study Information Letter (Appendix 2) in advance to the interview day. At the day of the interview, participants received an additional printed copy of the Study Information Letter and had an opportunity to ask questions, so that they could make an informed choice about their participation. Following the discussion, each participant was asked to read and sign a consent form (Appendix 5) and received a copy of their signed document.

Participants were reassured about their right to withdraw from the study at any time, or have the audio recorder stopped during the interview, without any consequences, and have their data destroyed. To maintain confidentiality, any identifying information that could link participants to the research was removed from the transcripts and report, and participant’s anonymity was safeguarded by assigning pseudonyms. Only the principal researchers had access to the master list containing participants’ identifiers.

Audio-recordings will be erased from recorder devices at the conclusion of the study, and their encrypted files will be deleted from the secure computer after five years. There were no known risks associated with participating in this study.

9. SUMMARY

A qualitative descriptive method was chosen to explore orthodontic informed consent processes in Alberta, and the barriers faced by Canadian orthodontists when communicating treatment information to adult patients, as well as the strategies implemented by such professionals to augment their patients' comprehension and recollection of information received. Purposive sampling was used to select orthodontists with different levels of experience in the field. Twelve interviews were conducted, mainly face-to-face, or by telephone, and were transcribed verbatim. Data were analyzed systematically for recurring patterns (themes), using thematic analysis, and interpretive skills were used to organize these themes into a comprehensive description of the process. Attention was given to ensure rigor throughout the research process.

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CHAPTER 4: FINDINGS

1. INTRODUCTION

The findings of this study are presented in multiple sections. The first section consists of the demographic information of study participants. The next three sections describe the themes commonly found after analyzing the lived experiences of all the participants.

The first theme describes the flow of the orthodontic informed consent process for adult patients, and how treatment related information is communicated to patients before they give their consent to proceed with treatment in a sample of orthodontic practices in Alberta, Canada.

The second theme deals with the challenges faced by the participants during the process of informing their patients about their orthodontic treatments, with regards to barriers that may interfere in patients' comprehension and recollection of such information. Three subthemes are outlined: patients' internal barriers, patients' external barriers, and financial barriers.

The third theme discusses strategies to optimize information delivery and communication employed by the participants to improve the informed consent process. Four subthemes were identified: tailoring content to be delivered, communication fashion, communication timing, and being accommodative.

2. STUDY PARTICIPANTS

A total of 12 practitioners (Table 4.1), licensed orthodontists working in 8 different cities across Alberta, were included in the study. Eight participants were male. In total, years of experience as a Canadian licensed orthodontist ranged from 3 to 43 years, with an average of 19.3 years. Only two participants preferred not to work together with treatment coordinators in their private practices.

3. THEMES

A. The Flow of the Orthodontic Informed Consent Process

Participants described the flow of treatment related information given to adult patients in their private practices before they decide whether to undergo orthodontic treatment. An overall description of such processes is described below, illustrating the most recurrent patterns along with some of the variations among participants.

The nature of information given to a patient to enable them to make an informed decision that is in agreement with the patients' best interests would entail but not be limited to: diagnostic findings; general risks and benefits of an orthodontic treatment; patient specific risks; treatment options, including no treatment; treatment plan and goals; limitations; reasonable expectations; importance of compliance; estimated treatment time; importance of retention; retention protocols; and financial costs.

There is some variation regarding the sequence of steps a patient goes through in the process of receiving information before giving consent to be treated, among the participants' private offices. Usually most or all of the information related to the informed consent process is provided at initial consultation. Some offices will have another formal sit-down consultation at a later time point, after the orthodontist has finalized a patient's treatment plan.

Patient's records are either obtained at initial consultation in full or just as a preliminary set (radiographs and photographs) with the remaining records obtained in a later appointment, or in some cases they are obtained in full at a later appointment. Some participants prefer that their patients go home and reflect on what had been discussed before they make a decision to proceed with treatment. “We want them to go home, we want them to think about it” (Orthodontist #2).

Patients are informed using a combination of different strategies. Verbal explanations may be accompanied by the patient’s own records, and/or examples of other patients’ before and after photographs, as well as orthodontic models of appliances. Written information included a copy of the consent form to patients, or sometimes a letter with a summary of what was discussed in layman terms, or informative material, such as brochures and pamphlets. In some cases, patients were directed to the office’s website for a review of additional information. Videos were commonly used, with most participants referring to those available through commercial imaging software.

The duty of informing patients is shared between the orthodontist and either a treatment coordinator (TC) (N= 10), or a registered dental assistant (RDA) (N= 2). The participants stated that as the orthodontist, they were usually responsible for communicating the general information related to orthodontic treatments: the diagnostic findings, treatment plan and options, and risks and benefits. The other staff member was usually responsible for showing the videos and appliances models, and delivering more specific details related to the treatment, such as oral hygiene recommendations, foods to avoid, retention protocols, frequency and length of orthodontic appointments, etcetera. Costs involved with the treatment were communicated by TCs, RDAs or in some cases by a financial coordinator.

To ensure crucial information is delivered appropriately and accurately, participants may selectively choose to convey specific information themselves because they wanted to make sure patients understood.

> But I highlight the diagnostic findings that are important. […] you know, the big things that we wanna make sure, that I wanna know that they 100% understand. […] So, I highlight the key diagnostic findings, and then, I highlight the key risks or considerations or options. So, I wanna look in their eyes and know whether or not they care about their facial asymmetry, or their midline, or the things I'm saying 'I can't fix it without surgery', and I wanna know how much that matters, I wanna feel that, so I do. (Orthodontist #3)

All of the participants indicated that they would verbally check the patient's level of understanding of information, either by asking patients directly whether they understood what had been explained, or by asking if the patient had any questions.

One participant (Orthodontist #2) specifically mentioned that in the past a letter would be sent out to his/her patients after 4 months of treatment, questioning if they remembered what had been previously discussed during the informed consent process, and asking other questions along that line, with a very low response rate.

As part of the process of informing their patients, participants describe how they will tell their patients that they are free to ask questions at any time, during or after their consultations.

> We ask if they have any questions. And we also tell them that if they don't understand anything that we're explaining at the moment that we're doing the explanation, they can interrupt and ask any time. (Orthodontist #7)

Consent form contents used varied. Some participants used standard forms that were "very thorough and comprehensive", with no additional specific details. Instead they would actually skip the parts of the consent form that did not apply to a certain patient.

Other participants would have a standard form that included generic information that applied to all orthodontic treatments, but they would add an additional customized page solely dedicated to describing the specific issues that were related to that patient’s unique presentation, in lay terms.

One participant (Orthodontist #12) specifically mentioned the consent form provided by the American Association of Orthodontists, which contains general considerations and risks involved with any orthodontic treatment, with some space at the end for patient specific details. This participant believed that informed consent forms should be customized for each patient, although at his/her office they only use a standard consent form.

A second participant stated to believe that presenting general risks and limitations should not be considered adequate informed consent.

> By just telling you that you may get root resorption is not an informed consent decision. An informed consent decision is: ‘you may get root resorption and you have short roots to begin with’. That's an informed consent decision. And from what I've seen, most people just use a general form. I don't, because there are specific either to the patient’s presentation or to the stuff you're going to do to them. (Orthodontist #6)

B. Challenges Interfering with the Informed Consent Process

The participants shared a variety of challenges that interfered with the informed consent process: a) patients’ internal barriers; b) patients’ external barriers; and c) financial barriers.

a) Patients’ Internal Barriers

Participants stated that barriers to patient comprehension of treatment information would often be imposed by the patients themselves. They also suggested that, in some circumstances, difficulties were beyond patients' own control. The internal barriers that were identified by the participants fall into 5 categories: i) background; ii) personalities and attitudes; iii) expectations; iv) taking responsibility; and v) limitation of memory.

i) Background

Patients' background factors, such as their ethnicity and their subsequent language barriers, as well as their education level, were frequently described by participants as reasons for misunderstandings occurring during professional-patient interactions.

According to one participant, ethnicity could potentially influence the manner in which patients understood treatment related information.

> There are some patients from certain populations, or certain cultures. They are usually more, you know, they accept, they understand the treatment more than other cultures. So, I still believe the patient ethnicity plays a role in the understanding processes. (Orthodontist #12)

Lack of proficiency in English was the most frequently mentioned barrier that may prevent patients from understanding treatment related information.

> Language is a big one. […] Language being like English versus another language. (Orthodontist #3)
>
> Barriers would be language barriers, especially. That's definitely we have to work hard to overcome those. (Orthodontist #5)

Educational background would also impact patients' abilities to properly grasp treatment information, with educated patients having an adequate understanding of the information that was provided.

> Their education level. So, we have to be cautious of our language that we use and make sure we explain things in detail. (Orthodontist #5)

> The first thing is the level of knowledge, like the level of education. We have some patients that are highly educated patients. Those patients usually they understand our concepts, right? What we're talking about. So, the level of education plays a key role. […] Usually higher educated people will understand our treatments, and they will, you know, be on the same page, right? (Orthodontist #12)

ii) Personalities and Attitudes

Patients' personalities and attitudes may impose a challenge that prevents them from properly comprehending information related to their orthodontic treatments. Different personalities may deal differently with information received; some personality traits may influence the way one processes information. For instance, "some people are not good listeners [laugh]" (Orthodontist #5).

Choosey patients may also absorb information differently, according to one participant.

> Their nature is very, you know, picky people. So usually, even if we provide enough information, they still, you know, have the same expectations during their treatment. (Orthodontist #12)

Participants stated another obstacle that may prevent patients from understanding what is explained during an orthodontic consultation: their emotional state. When patients are stressed, or feel pressured or distracted, their comprehension and recollection abilities may become impacted.

> Sometimes their personality or emotional well-being. Sometimes they're just not in a headspace where they want to accept what you're telling them. So, you might tell them, but they don't really internalize something. […] So, you really have to try and gauge and check in with that person to make sure they're actually hearing you, or at a time where they're even willing to listen and that they're understanding, so that they are not just rushing through. (Orthodontist #5)

Occasionally, patients are disinterested in treatment related information, and all that matters to them is “getting started”. In these cases, patients do not want to hear any details that are not needed to go ahead with treatment.

> There are, of course, personalities where they just wanna get started, they don't really care what you're saying. We still go through it maybe a little bit quicker than others. (Orthodontist #1)

> There are some (patients) who know that ‘Hey! I know you're the doctor’, and then ‘I know you'll do a good job, I just want braces’. (Orthodontist #8)

> [Sometimes] people will have less time and they don't want to hear all the details, and you can tell when they're becoming impatient. (Orthodontist #5)

In other instances, patients may not be able to focus on what is being said. That may happen in daily circumstances within a dental office, such as when individuals are rushing: “If they are in a hurry, if they are trying to get somewhere after the appointment, that’s a barrier, they are not gonna be listening” (Orthodontist #4).

iii) Expectations

Patients may have higher expectations about the final esthetic results of their orthodontic treatments than the orthodontist is capable of accomplish with the proposed treatment plan. In such cases, even being given treatment information, they may overlook it, as the image of their final results that they had formed inside their minds is one that is not easily deconstructed, so they may not be able to truly understand the realistic results that can be accomplished. One participant stated, “You have to make sure that the (professional) and the patients are on the same page, in terms of the expectations, what they are expecting with the treatment, and what they're expecting at the end” (Orthodontist #12).

> I guess another good example would be phase one patient. So, patient had significant crowding in the maxillary arch. We were doing expansion and upper partial braces. I'm trying to make room for canines to drop-down. […] And throughout the treatment I'm kind of giving mom an update: 'Look, we'll make room. Look at this, bla bla bla'. But at the day the braces are gonna come off she is like: 'I got another opinion from my friend who works in Ortho and this is not finished and-…', you know, '…I don't like it, my child looks ugly!', and I'm trying to explain: 'No, this is just, you're right, is not finished. It's a phase one', you know. We explain that it is just a phase one and the goals are these and, you know, my goals are to make the canines coming be healthy and the goals are not to deal with what is unaesthetic at this point etcetera, etcetera. […] In her mind, she had a vision of her daughter getting braces and having a beautiful smile, and in my mind, I had a vision of her daughter getting braces and having room for canines to come in. And we did not end up consenting enough for us to understand each other's expectations. (Orthodontist #3)

iv) Taking responsibility

"Responsibilities" and "need for compliance" were described by participants as critical components of any orthodontic treatment. In some situations, a patient is not willing to take their share of responsibility for the success of their orthodontic treatment; they may decide to just ignore the explanations given by the orthodontist during their consultations.

> When you explain a lot of these things to a patient, and if that patient does not want to take responsibility to get to that end result, they may just tune you right out. So, in other words, you could be talking about what's ideal or what's limited, what all these different options that you can provide for that patient, but they may end up, you know, just, they've come in with a focus in mind and they're not listening to you as you're talking about all that stuff. (Orthodontist #2)

v) Limitation of memory

Participants have acknowledged that difficulties in understanding and recollecting treatment related information may partially be due to "human nature". Patients were said to frequently "forget" what was discussed as a result of "limited memory". Since orthodontic treatments are frequently lengthy in nature, poor recollection issues could potentially be exacerbated by the time span needed to complete such treatments: “It's a long treatment for some people, some patients wear their braces for 3 years. So, they don't remember what was all said” (Orthodontist #5).

Several comments were made by participants that highlight general circumstances in which they recognized that patients tended to frequently forget information that they have previously received.

> Sometimes, you might have to say that during the new patient exam process. You might have to continue that when they sign up for treatment, when they're actually signing the informed consent. And then sometimes even during the course of treatment. So, because again, human nature, we tend to forget things. (Orthodontist #8)
>
> There's always gonna be somebody that you will explain, you know, it hasn't happened very often. Okay? But I can recall, very rarely, the instance where I will explain something and then they will ask me the same question again. And then maybe, a third time. (Orthodontist #9)

In other instances, participants were more specific when they described particular situations in which they have experienced patients’ lack of recollection or understanding, regardless of providers’ efforts to keep them informed.

> It happened once. A patient that had a root resorption and then I explained the process, what's happened and I showed, and I also noted that it was explained in the beginning, and she said: ‘No, I don't remember’. And then I had to bring back the signed informed consent that she actually signed the informed consent, and that was explained at that time. So, it can happen, that down the road they will forget. (Orthodontist #7)
>
> Especially if you say: ‘Well, we can do this, but there's a risk of, say, maybe that we won't have to take any teeth out, but maybe there's a chance we might have to take teeth out’. And then a year down the road, then you have to take teeth out and say: ‘Do you remember we had this conversation?’, ‘Well, no I don't really remember that’. [laughs] (Orthodontist #10)

Although participants recognized that repeating information to patients may help overcome their poor retention of information, other times regardless of how often they attempted to review essential information with patients, it was never enough, and they would not succeed.

> And I try to explain what that means to have small lateral incisors, and you explain that they will need bonding or build up at the end of treatment, and then 'Your dentist will have to do veneers'. We talk about the cost of that in addition to the orthodontics, how that plays out, the timing of it and how it affects retainers. And mid-treatment, I will remind while they say: 'Why are there spaces around those teeth?', I'll explain: 'Cos we're going to need to do some build ups at the end of the treatment'. And still sometimes at the end, like: 'Oh, the braces came off today and there still a space there' [laughs], and 'Yes. And you're going to get your dentist to fix that'. So, it's amazing how they don't remember, but they don't. (Orthodontist #5)

Often at the end of their treatments, patients will have forgotten what was discussed regarding the need for retainers or the retention protocols.

> 'You didn't tell me I had to wear a retainer'. But we do tell everyone about retention, but they don't remember. (Orthodontist #5)

Participants commented that in some instances, patients may deliberately choose to forget or remember specific information.

> It's just that, you know like, sometimes you forget, or sometimes they choose to forget too. (Orthodontist #8)
>
> They always remember how long- if- when you tell them how long it's gonna take. They always remember that. So, if you tell them it's gonna take eighteen months, and it's now twenty months or twenty-four months, they remember that for sure. [laughs] (Orthodontist #10)

Most of the above-mentioned barriers to patients' comprehension are quite explicit; however, in some cases there might be implicit barriers, those that are unvoiced or not obvious on the surface of the doctor-patient interaction. This seems to be the case when patients struggle to admit or sometimes even realize that they have not understood information given to them.

> Even if they say they completely understood, sometimes, I feel that they're saying that just because they don't wanna look that they had some questions. (Orthodontist #7)
>
> I'll always say: ‘Do you have any-’, well I'll assume if they have any questions. But again, I guess that's not really-, I mean, some people: ‘Oh no, no, I understand’. And they have no idea. [laughs] (Orthodontist #10)

b) Patients’ External Barriers

Participants acknowledged that times have changed in some aspects of orthodontic practice, bringing along new obstacles to the daily routine of the professionals in the field. Modern life is becoming more complex and that seems to bring along new challenges to the orthodontic practice as well. Participants identified 3 categories that affect the informed consent process: i) free consultations; ii) self-education and unrealistic expectations; and iii) volume of information.

i) Free consultations

Participants described how the increase in competitivity in the industry may translate in some orthodontists providing free orthodontic examinations, and how such professionals are more likely to avoid spending too much time educating patients, which may end up reflecting on the overall patients’ comprehension of information related to their orthodontic treatments.

> We do not provide free examinations, we have a professional fee for adults and kids. When you have people that have free exams, and I did this for a while, but we’re not competing with all the other orthodontic offices. If you do a free examination, then I'm wondering: ‘Why do I wanna spend an hour or an hour and a

> half of our clinic time doing this detailed explanation for somebody that is just kicking tires to find out what's the cheapest way to do it?'. I want my patients to be educated clients, and so, they have to understand they're coming here for a different experience. And so, you're gonna go to some offices, where they have no cost exams, they may take a panorex, they may take photos, and they may sit them down and try and run it like a car dealership: 'If you start today, we will give you $500 off'. We are not interested in that. (Orthodontist #2)

> I find in other offices, patients are somewhat ignorant or naïve. The patients in other, some offices, were not given that kind of information. See, sometimes they would come to me for a second opinion, and they would tell me: 'Oh, gee. I only had an appointment, an exam at some other office. And I was in there for 10 minutes, and it was done'. Here in our office it was well over an hour, and, or sometimes more, and we gave them all, a ton of information, a lot of information. And informed, they could make a more intelligent decision. (Orthodontist #11)

ii) Self-education and unrealistic expectations

The participants have found that patients have been frequently self-educating themselves with the help of easily accessible and widespread information from the internet or from friends/relatives, which becomes an obstacle when such information is distorted or does not apply to their specific case scenarios. Most patients will not have the skills one would need to filter out the non-reliable or irrelevant sources of information.

> And the other thing that we see a lot more of nowadays, is the patients are self-educated on the internet. So, they have a preconceived notion of how certain things should be and how 'I saw this [clear aligners] treatment on the internet and that's what I want'. And different things like this or, you know, braces, or whatever or some obscure appliance like a Daytime-Nighttime-Activator appliance, a DNA Appliance that some people talk about. So, you know, people search out things on the internet nowadays, and they do self-educate and self-medicate themselves. And, so, sometimes, their expectations are based on their internet searches. And from an experiential perspective, you've got kind of show them, you know, maybe the good and the bad of those types of things. (Orthodontist #2)

> Dr. Google is a big impediment. […] Because they go online and they get information from there, and it's not accurate, and it's certainly not necessarily pertinent to them or to their bite, or to their occlusion. So, they come in sometimes with preconceived ideas, and they're sometimes shocked as to how come it takes so long to treat. (Orthodontist #11)

Misleading orthodontic advertisement is one of the factors that may influence patients and result in confusion: “Because when you go on Google, you'll find people out there claiming they can move teeth in three months, in six months”. And that is why patients sometimes get “shocked because they didn't realize how long it takes to treat the patient.” (Orthodontist #11).

> I think misinformation, you know, and not from us (orthodontists) but, you know, there's a lot of advertising going on, right? Especially with [clear aligners]. And, people are hearing that [clear aligners] can fix every type of bite. And so, if they come in and that's all they want and yet they're a surgical case. So, I think that would definitely be a barrier for them… (Orthodontist #9)

Online accessible information can quite often jeopardize the process of educating patients: one participant stated that it is “often fraught with error, and that has been probably one of the more difficult things to have to deal with in practice over the years”. The same participant commented on the time prior to the internet when “people that were interested, and they would read up on something in the past, but it's not like that, it's not like the information that they can get off of the web these days. And much of it is erroneous or false” (Orthodontist #11).

Indeed, such misinformation may still lead patients to have unrealistic expectations, which in turn becomes a barrier when it is time for them to focus on and understand trustworthy information given by professionals during their consultations.

> Some patients have a high expectation, those patients are difficult to satisfy at the end. […] So usually, even if we provide enough information, they still, you know, have the same expectations during their treatment. Because those guys always have higher expectations, they do their search, they Google, you know, they do the search before they come, and they see other examples that might not be good examples. (Orthodontist #12)

iii) Volume of information

Participants recognized that in some cases, even the right amount of information can already be quite overwhelming for patients.

> This is often overwhelming. (…) And, so, you would ask the question earlier on ‘Is it too much or too little (information)?’. I've always been of the opinion that you're going to cover everything. (Orthodontist #2)
>
> Too much information. So, overload. We did find that initially, cause we used to do the consents at the same day as the exam, and now we’ve pulled them into the start appointment. But we don’t put them through that consent process until they’re actually coming in to start. And that's because they’ve already heard the price, the timeline, the options of different types of treatment. It’s too much stuff. I worried that they were losing their ability to concentrate. So, I pulled those two pieces apart. So, too much information is definitely a barrier. (Orthodontist #3)

Some participants have acknowledged that, frequently the volume of information exchanged during the initial orthodontic consultations may overwhelm patients and they might not be able to process it all.

> Maybe the amount of information. They won't absorb as much, because it's a lot of stuff, a lot of information. So, they can maybe understand at the moment that’s being explained, but they don't absorb it. (Orthodontist #7)
>
> Like we give them too much information, that nobody can absorb all of that information. […] And I think that's often what happens, is we just give them so much information. There's no way they can absorb it all or remember it all. (Orthodontist #10)

However, it seems that although the load of information may be overwhelming to patients, often participants mentioned that they would prefer to err on the side of giving patients too much information rather than the opposite.

> The more information, the better. I don't think that there's anything that we consciously leave out. We pretty much provide everything. Honestly, we if anything, give them too much information. There's nothing we, like, we don’t ever skimp on information to the patient. (Orthodontist #4)

Further to the regular load of information to be provided to patients before they make a decision to be treated orthodontically, depending upon case complexity, an even greater load of information may need to be given to them. Participants stated that this is all too common when treating adults, because “the majority of adult patients that we see in our office, a lot of them are multidisciplinary” (Orthodontist #2). One participant expressed concern over the need for additional dental interventions: “It's not just an orthodontic plan. Often for adults, they will need other doctors involved and they should know the plan from every doctor” (Orthodontist #5).

> The complexity of the case also plays a role. Like, if the case is simple, usually patients understand that we're going to align the teeth and stuff. If the case is complicated, then even if you explain, sometimes the patients don't understand the concepts, right? (Orthodontist #12)

Finally, it is noteworthy to say that although most of the participants have at some point acknowledged that the amount of orthodontic information provided to patients is often times overwhelming, when they were directly asked to identify barriers to patients understanding of information, only very few of them categorized the information load as a barrier.

c) Financial barriers

Costs involved with orthodontic treatments were negatively portrayed by participants in two different ways: i) as a barrier that limits patients’ understanding of information; and ii) as an impediment to proceed with the treatment.

From time to time, “patients come in and all they want to know is: ‘How much will it cost.’” (Orthodontist #9). Therefore, there might be instances in which individuals may struggle to concentrate on orthodontic treatment information that is being given to them, especially if they are truly concerned about the potential costs involved with such treatments.

> The other thing that's a barrier for some patients, is quite frankly the only thing they're thinking of is: ‘How much is all of this gonna cost me?’. So, the financial thought process for that patient ongoing in the back of their mind will, sometimes, be clouding their perception, their receiving of the information and/or their judgement… (Orthodontist #2)

However, presenting the fees up front, in an attempt to avoid patients’ concerns about discovering the potential costs during the informed consent, may still not solve the issue if patients dislike those.

> Maybe you just presented the fee, they didn’t like the fee, and now you present them with the informed consent. Maybe it’s different from if you’d presented the informed consent first, then not knowing the fee, then you show the fee afterwards. So, maybe sequence of how you or of when you actually go over the informed consent may help. (Orthodontist #1)

Costs will sometimes act as an impediment, deterring patients from undergoing orthodontic treatment.

> Patients ultimately don't want to put the time in for that, or they don't want to put their money into it. So, expense could be an impediment, right? It's often times money. (Orthodontist #11)

Participants explained that adult patients would frequently require additional interventions, such as implants or crowns, with other dental specialists, which could easily build up to the overall cost of treatment. They emphasized that it is crucial that patients are aware from the very beginning, even though it may result in them refusing to engage in the complex and lengthy treatment.

> Because it's not just an orthodontic plan often for adults, they will need other doctors involved and they should know the plan from every doctor and the total cost of everything. Cos it can be 40 or $50,000. Then my utter 8 to $10,000 fee is not inconsequential, but it's only a small part of what they're signing up for. So, I always make sure that they have that information from the other doctors as well. (Orthodontist #5)

C. Strategies to Optimize Information Delivery and Communication

In this section, there are 4 subthemes that encompass the major strategies shared by the participants to improve the informed consent process, and enhance patients' understanding and recollection of treatment: a) tailoring the content to be delivered; b) communication fashion; c) communication timing; and d) being accommodative.

a) Tailoring the Content to be Delivered

Participants suggest that patients' comprehension and recollection of treatment information can be improved if the content of information to be communicated can be tailored to each individual patient. While each patient requires the basic information needed to make an informed decision, participants suggest that the patient's individual interests should serve as the road map for providers, guiding orthodontists to customize the depth of information and the richness of details provided to each patient.

Participants often described attempts to gauge the amount of extra information that they provide to match each patients' level of interest. Interested patients and those with a more inquisitive behavior usually do get an extra amount of information when compared to those adopting a more neutral or indifferent stance, even though everyone gets the basic information. "So, a lot of it is directed by the patient". (Orthodontist #10)

> Some people are very, very detailed, they need an extra appointment to get through the whole consent, because they wanna know any possibilities. (Orthodontist #3)

> It varies from patient to patient. So, if they have specific questions… […] So a lot of it is guided by the patient too. […] We try not to overwhelm them with too much, unless they want to know it. [laughs] (Orthodontist #10).

> We provide basic details for everyone. We go into more details for specific patients who request this information, or if they have questions after we finish the consult. […] And the patients' interest, whether they're interested in learning more or not… (Orthodontist #12)

Participants often talked about the need to provide the appropriate amount of information to patients, so they are fully informed. Participants consistently mentioned that they make sure to highlight potential risks, especially in the case of any complications coming true during the course of treatment. In such cases, not only do the participants feel that they are protected legally, but also their patients would be able to deal with those complications in a smoother way because they were informed beforehand.

> If you run into problems and you haven't told them that you're likely to run into the problem at the beginning, then you're at fault. If you have told them at the beginning that this particular thing may be a problem for them, then you're a genius. And so that's why we tell them everything. (Orthodontist #6)

Although information to be provided may depend on the specifics of each case presentation, and the unique treatment needs of each individual, participants suggested that orthodontists should keep their explanations as simple as possible and avoid unnecessary details, making it easier for patients to comprehend. "Talk basics, don't go into detail" (Orthodontist #8). Participants mentioned that they try to be more general, and not to overwhelm their patients, unless patients demand or request more details.

> Because if you go into a really lengthy, wordy conversation you can tell quite clearly if the patient is not understanding. (Orthodontist #9)

> We don't go into too much details that will make the patients feel, you know, intimidated, or feel a little, you know, worried or threatened. (Orthodontist #12)

b) Communication Fashion

Participants suggested that the way in which information is communicated to patients may interfere with their understanding or recollection of such information.

First, provide patients with information in a slow and careful manner, so that patients comprehend the treatment plan before they get started. One participant emphasized that each patient needs “somebody walking through with them, so they have the opportunity to ask questions as they go” (Orthodontist #6). Some participants have emphasized the importance of investing time in patients’ education.

> It’s time well spent [laugh] in the beginning. It makes for much smoother treatments. (Orthodontist #5)

> It takes more time, but it’s totally worth it in the end. (Orthodontist #4)

Appealing to patient’s learning style, while trying to match it could be useful to help patients to adequately grasp the sense of what is being explained.

> Some people are visual people, others are auditory, some need to make notes, some like to record information. So, whatever works for them to make sure that they're getting all the information. […] So, it is individual. But we try to reach many people and see what they need, and try to understand what they need to understand to make sure that they’re understanding. (Orthodontist #5)

Participants mentioned that jargon and technical language should be avoided at all costs when talking to patients, as it limits patients’ comprehension. Instead, layman’s terms should be used whenever communicating with patients, to facilitate their understanding. There was a clear consensus among the participants: “Always speak in layman's terms as much as possible to make sure that (patients) understand” (Orthodontist #5).

> If we use scientific language, then we see that patients don’t understand what we're saying. (Orthodontist #12)

Meanwhile, some participants also found it useful to provide patients with written material, which they could revisit at home or at their convenience.

> And then we also follow up with written material for them to take home. We have information sheets on the different appliances, braces. So, they get a package of information to take home. We also refer them to our website, which we have a lot of information on there. (Orthodontist #5)

Participants almost unanimously mentioned that using visual media helped patients comprehend information more effectively than solely relying on verbal explanations that may be difficult for them to conceptualize: “The visual says it all” (Orthodontist #9); and “Just words are difficult to know what it is, what image (patients) are forming in their mind when they hear your words” (Orthodontist #3).

According to our participants, visual aids can take various shapes, including but not limited to showing patients software videos, interactive media, before and after treatment pictures, patients’ own records and models, etc.

> So, it's very easy for staff and doctors to talk about recession, but what is recession? What does recession really mean to the patients when they are hearing it? That's why I use a video, I show recessions. So, now your eyes see what recession is, when you’re using those words. (Orthodontist #3)
>
> I think that if they can see. So, if you're saying you need an appliance or retainer for them to be able to see it, I think really helps people. Otherwise they have really no visual idea what you're talking about. (Orthodontist #10)

Finally, another visual resource that participants liked to use to augment patients’ comprehension of treatment related information is showing patients similar cases that had been treated by the participant. This strategy helped their patients visualize the benefits that are attainable and were specific to their cases, so they could clearly understand the end goals of their orthodontic treatments.

> I find that when I show them similar cases […] then they understand that they're getting the same result, and that's what it's gonna happen at the end. (Orthodontist #12)

c) Communication timing

This sub-theme discusses the most appropriate timing in which information should be provided to patients, to overcome their lack of recollection issues. Due to the long-term nature of orthodontic treatments, participants stated that the process of informing patients about crucial aspects related to their treatments should happen on an ongoing basis. The orthodontist or orthodontic team should communicate treatment related information to patients throughout the course of their orthodontic treatments, by repeating information, giving patients reminders, and coaching them throughout their treatments.

Repeating and/or reiterating information was a strategy frequently mentioned by the participants to help patients recollect information that is essential to their treatments. Sometimes participants would reiterate important information on the first day of treatment, just before the treatment started, in order to make sure that the patient understood what had been agreed before.

> And often, too, even when patients have gone through all this process and they've signed the consent forms, and they're ready to get their treatment started, on the day of treatment that they're starting, I will often say to them: 'So, do you understand that you are going to need in addition to some braces for 2 years, you will also need these implants and prosthetics?' (Orthodontist #5)

> And a lot of the times, I will bring up: 'So, you know, I'm putting your front braces on this way, because what we decided was we're going to put some crowns on them. So, when you notice your teeth moving, on the next it'll be you might notice that

> your front teeth look a little bit shorter than the ones beside them', and (patients) will be nodding: 'Mm-hmm, mm-hmm', you know. And that to me, make sure that we've again reiterated: 'We all agree on this plan you're getting crowns, when we're all done'. (Orthodontist #3)

Other times participants choose to give little reminders or review information while patients are in the chair during the course of a patient's treatment, "so you'd have to sometimes remind (patients) what you're doing in the mouth" (Orthodontist #11).

Finally, participants sometimes coached their patients throughout their treatments, guiding them through the upcoming steps, and reminding them about what is expected to come next, which made for straightforward treatments.

> Reminding them, coaching them throughout the treatment. So, that they don't have surprises, and they don't forget what they were told 2 years ago[…] It just makes it a lot smoother and a lot happier people at the end. Because they are not being surprised by things they've forgotten. (Orthodontist #5)

d) Being Accommodative

Providers emphasized that they, as the orthodontists, would absolutely be willing to call back patients to provide clarification if needed, and that patients seemed to welcome their willingness to solve their queries.

> And if they don't understand you just say: 'Hey, let me know, give me a call. If you don't understand, I can always go over something with you over again'. I think they appreciate that. (Orthodontist #1)

> Now, if they would phone back and my staff, receptionist, or my dental assistants couldn't answer a question that they had, I would get back to them in the evening with a phone call to them: take the chart home and phone them up, and try and answer their questions over the phone. (Orthodontist #11)

Being accommodative to individual needs by offering additional consultation time at no charge to patients should they need it, was also cited by our participants as helpful, especially if a lot of information was conveyed or if discussion involved complicated information.

> And if people are short for time or overwhelmed, we offer additional consult time. So, when I have a case that's complex, could have surgery could not have surgery, implants, a lot of overwhelming information, we usually tell the patients that […] they can come in for an in-office consultation. (Orthodontist #5)

> And if the patient, you know, calls me and ask me to review, you know, we will either have a telephone consultation to review or if the patient wants to come back in and have another sit-down consultation just to review. Because we do give a lot of information… […] And we don't charge for an additional consult because, uh, you know, we do give a lot of information. (Orthodontist #9)

One participant stated that sometimes non-native English speaking patients will show up to the consultation accompanied by someone who is proficient in English, which becomes a useful resource to overcome their language barrier. So, whenever information provided is too complex, or patients present such language barriers, he/she will suggest to patients that “they can bring a spouse, they can bring a friend, someone to help them make sure that they understand everything. (Orthodontist #5)

> In our favor, sometimes our adults that have poor English skills, they will often bring their teenagers. Which is a great resource. They'll either bring a friend or more often they bring their, you know, older teen children. And that's great to help with communication, because they can translate. (Orthodontist #5)

Finally, two participants mentioned that for patients that are considering orthognathic surgery, they believe it would be advantageous to have the opportunity to talk to someone that went through the same kind of procedure. So, they managed to have some of their previously treated surgical patients available to discuss their experiences with the new patients.

> Sometimes patients who are recommending jaw surgery, we will actually let them talk to other patients who have had the jaw surgery, and that helps them get an idea of, you know, to talk to somebody who actually went through it. I think patients find that helpful. (Orthodontist #10)

4. SUMMARY

The above sections outline the main themes that emerged from the interviews with Canadian licensed orthodontists who shared their experiences and perceptions with informed consent processes for orthodontic treatment of adult patients. They described the flow of consent processes used in their private practices, including the nature of information provided, the means used to delivery information, the presenters and their share in the information delivery process, as well as the consent forms they use. In the sequence, they identified barriers that they believe may interfere with patients' comprehension and recollection of information provided, and those were: patients' internal barriers, patients' external barriers, and financial barriers. Finally, participants have discussed strategies that they find useful to overcome or mitigate some of the later barriers, making for a smoother informed consent process: tailoring content to be delivered, communication fashion, communication timing, and being accommodative.

Table 4.1. Demographic profile of study participants

Demographic Characteristic		Number of Participants
Gender		
	Male	8
	Female	4
Experience		
	≤ 5 years	3
	6-15 years	3
	16-25 years	2
	26-35 years	1
	≥ 35 years	3
Treatment Coordinator		
	Yes	10
	No	2

CHAPTER 5: DISCUSSION AND CONCLUSIONS

1. INTRODUCTION

In this study a sample of Canadian licensed orthodontists practicing in Alberta, Canada, described the processes used by them to communicate treatment related information to their adult patients before obtaining their signed informed consent for treatment. They also expressed the challenges that they faced regarding their patients' comprehension and recollection of information received during the informed consent processes, together with strategies they used in their daily routines to try to overcome or mitigate such challenges.

This chapter integrates the results of this study with the available literature on informed consent processes and patients' understanding and recall of information received during such processes. The existing body of knowledge on orthodontic informed consents for adult patients is significantly lacking, therefore the discussion incorporates appropriate evidence from related healthcare fields and non-adult orthodontic populations. Limitations of the study are identified along with recommendations for future research at the end of this chapter.

Discussion about the flow of orthodontic informed consent process will be followed by challenges interfering the informed consent process and finally strategies to optimize information delivery and communication will be facilitated.

2. DISCUSSION

A. The Flow of the Orthodontic Informed Consent Process

Even though all orthodontists are required to pass the same licencing board exams to become licensed within Canada, the orthodontists that participated in this study described variations in the process of providing information to patients before they made their decision and consented to orthodontic treatment. Some variation with regards to timing of consent form signing, number of appointments before signing consent forms, or consent form documents content was noted. This may be suggestive to the fact that no specific orthodontic informed consent document supported by the Canadian Association of Orthodontics is available. However, general rules concerning ethics and professionalism, and overall guidelines related to the informed consent process are discussed and assessed during the orthodontists' graduate training and examined during their orthodontic licencing examination. We observed that the interviewed professionals adjusted those generally implied informed consent guidelines, which lead to a variance in the informed consent process among the orthodontists, based on their experience and individual patient needs. At the end of the day, these participants (licensed orthodontists) have to respond to their licensing body if problems arise due to inadequate consent processes.

Despite the variations in the initial orthodontic consultations, the participants routinely communicated and highlighted the risks that were specific to each patient's presentation. The majority of our participants disclosed the most likely potential irreversible conditions that patients needed to understand before they decided to embark on an orthodontic treatment.

Allowing patients time to absorb information received was seen as a fundamental step by some of the participants. One participant changed and adapted the consent processes in his/her clinic to allow the patients more time to process the information before signing the consent form because the patients appeared to be “losing their ability to concentrate” after receiving all the information needed to make a decision. Orthodontists do not specifically have an expectation that the informed consent is signed immediately. Since orthodontic care occurs over a couple of years, with frequent follow-up appointments (every four to eight weeks), orthodontist have many opportunities for patients to come back and ask questions should they arise. The fact that orthodontic treatments are most frequently elective in nature if compared to some other dental needs likely enable such flexibility. This would also allow patients plenty of time to absorb information and think about it before deciding to have an orthodontic treatment.

The majority of orthodontists interviewed preferred to work closely with their treatment coordinators, with some variation regarding the level of informed consent related information that was delegated to these staff members. Variations ranged from delegating the obtaining of the patient’s consent solely to the treatment coordinator, to treatment coordinators that would be limited to repeating and illustrating what was previously explained by the orthodontist. The most common pattern was the provision of general treatment information performed by the orthodontist, while treatment coordinators would be responsible for showing videos and orthodontic appliances or models, while delivering more detailed information, such as oral hygiene and diet recommendations. Orthodontists would likely be available, if needed, to further clarify any additional doubt that may arise.

It appears that treatment coordinators do play a significant role in the informed consent process among this sample of Canadian orthodontic offices. Although most orthodontic offices have treatment coordinator positions, details of their scope of work and level of responsibility varies between offices. It is noteworthy that treatment coordinators are not guided by a set of rules or standards in Canada. This differs from other orthodontic staff members such as the dental assistants (DA); they have specific requirements to become licensed in most Canadian provinces.[1] It is the orthodontist's duty to use competent personnel, training and supervising them adequately, with the orthodontist being solely responsible for the quality of information delivered during an informed consent process.[2] Finally, during orthodontic treatment, DAs might be expected to reinforce some of the information associated with some patient's behaviors (i.e., oral hygiene, compliance with the use of removable devices). For this reason, it can be argued that in Orthodontics, the informed consent process could be seen as a continuous flow of reinforcement, with a formal process of signing a consent occurring before starting the treatment. Charting of related discussions would normally ensue further supporting the point of a continuous process.

It seems that the participants preferred method of determining their patients' understanding was by verbal checking: asking patients directly if they understood the information or had any questions. One participant sent surveys in the past to assess his/her patients' comprehension and recall of information discussed, with a low response rate. Another participant used non-verbal checking in addition to verbal checking: analyzing patient's eyes and facial expressions during consent discussions. Bensing, Kerssens and

Parsch[3] described non-verbal cues as a useful resource for decoding a patient's hidden feelings.

Participants believed that they gave their patients plenty of opportunities to ask questions, by asking their patients close-ended questions, such as "Do you understand?" or "Do you have any questions?". Farrel[4] et al.'s study argued that close-ended questions like the ones used by our study's participants seemed to be less effective and less encouraging for patients than open-ended questions such as "What questions do you have?" or "What parts of this discussion are hard to understand?". Farrel et al.[4] also stated that depending on the timing of such questions during the consultation, practitioners might leave too much of the conversation unassessed. Korsch, Gozzi and Francis[5] suggested that although pediatricians believed that they gave parents ample opportunities to ask questions, 25% of parents stated that they would like to have an opportunity to ask more questions.

Menendez et al.'s[6] research suggested that questions often go unasked when patients have inadequate health literacy skills, which is the inability to access, understand and use health information, which affects 60% of adults in Canada.[7] However, patients do not need to have low literacy skills to have limited health literacy.[7] Parikh et al.[8] suggested that patients with low literacy skills may not admit that they struggle to understand what they had read, with some of them admitting feeling ashamed to confess that they have troubles reading or understanding what they read. Some patients may likely benefit if delivering of information and assessment of understanding are structured with the expectation that even those who are well-educated may still struggle with health-related information.

Furthermore, patients or their parents often overestimate their understanding of information received,[9-11] so clinicians should not rely solely on patients' reported understanding, particularly when crucial information is involved. For this purpose, teaching-back, which is a technique whereby patients are prompted to restate in their own words the information that was conveyed, and receive clarifying feedback from the provider, has been suggested as a helpful method to assess patients' understanding. Teaching back also gives professionals an opportunity to correct misunderstandings,[12] close the gaps of health literacy between patients and doctors,[13] and effectively improves patients' comprehension of medical information.[14] Kupst et al.[12] also reported that parents on the teach-back group were more satisfied as they felt the doctor took time to make sure that they understood the information. The teach back method may be time consuming, depending on the amount of information that is being provided. Therefore, future research would be needed to investigate whether the benefits are clinically relevant for the orthodontic informed consent processes to justify the time burden that may occur. Another alternative would be for the DA or the treatment coordinator could take on this task.

B. Challenges Interfering with the Informed Consent Process

a) Patients' Internal Barriers

Ethnicity was described by one of the participants as a barrier that may affect patients' understanding of treatment related information. Not all cultures share the same Western scientific view of the human body, which is often more objective and value-free. In a multicultural society like Canada, many patients may hold culturally different views of dental health and its perceived value.[15] This may influence the way they value orthodontic information, or more importantly for the informed consent process, how they interpret the risks. Furthermore, immigrants in Canada are among the minorities that score much lower in terms of health literacy when compared to the national Canadian average.[7] This could explain the hurdles that the participants experienced with some of these patients when explaining health-related information. However, Patel, Moles and Cunningham[16] and Carr et al.[10] suggested that ethnic factors have no significant impact on patients' and parents' comprehension and recollection of orthodontic information.

Communication between an orthodontist and their patient can be exceptionally challenging when they do not fully speak the same language. Canada has a multilingual society of over 200 different mother tongues.[17] Therefore, it is expected that language barriers will occur between patients and health providers. In fact, most participants encountered language-related communication barriers in their daily practices, with language being the most frequently cited barrier in this study. Goldsmith, Slack-Smith and Davies[18] indicated that similar realities are seen in other multicultural societies, with some dental patients potentially accepting treatment without questioning as a result of their language barriers, even when they bring someone to help with translation. The push to get an aesthetic smile may "muddle" the perceived importance of the conveyed risks and jeopardize the essence of the informed consent processes.

According to participants, patients' education level may interfere with their understanding of orthodontic information. On the other hand, orthodontic literature suggested only a marginal correlation between parents' educational level and their abilities to recall orthodontic treatment risks.[19] This may be related to the concept simplification that providers consistently use when explaining informed consent. Kang et al.[9] found no relationship between the patients' education levels and their comprehension and recollection of treatment related information.

In this study, participants suggested that patients' personalities and moods, and their subsequent attitudes and emotional well-being, may interfere with their understanding of information. There is a lack of evidence in the orthodontic literature reporting this type of challenge faced by orthodontists when informing their patients about their treatments. This might be due to the fact that most studies about orthodontic informed consent processes have been quantitative, limited to measuring patients' or parents' understanding or recall of information,[19-21] or comparing the effectiveness of different methods of information delivery.[9,10,16,22-24] By simply quantifying patients' recall and understanding or comparing different methods of information delivery and their impact on patients' ability to recall information, the personal aspects influencing decision making may be overlooked, which may affect those processes.

The participants in our study indicated that patients may have an attitude of disinterest toward treatment related information, especially if they are only interested in the outcomes of the treatment. Stirling et al.[25] also found that patients admit that sometimes they diligently choose not to pay attention to information that is presented to them before they make an informed decision, because they just want to have the orthognathic surgery done without giving too much thought to "additional" detailed information. Flett et al.[26] reported that sometimes potential orthognathic patients may get bored when information is provided in a presentation format, and they consciously skip parts of it. It is also possible that patients perceive orthodontic treatments as non-threatening and without significant repercussions, further reducing their interest in the information that is being presented.

While it is suggested that orthognathic treatment patients are happier with the treatment outcomes when they have realistic expectations,[25] similar orthodontic literature on whether patients' previous expectations may impact their understanding of subsequent orthodontic information is lacking. Participants in our study suggest that this may be the case. If this is proven to be true, confirmation bias could be playing a key role, which is the tendency that individuals have to interpret information in a biased manner to confirm their pre-existing beliefs or expectations, ignoring or neglecting any facts or instances that are inconsistent to those beliefs.[27]

The present study suggests that patients tend to forget information received during their informed consent processes, which has also been well documented in the dental[11] and orthodontic literature.[19-21] This may happen regardless of the many attempts of orthodontists to repeat or review essential information. According to participants, 'human nature' and patients' 'limited memory' could help to explain patient's tendency to forget things. The evidence concerning the effect of time on orthodontic patients' and parents' ability to recall information suggested that time did not interfere significantly with information recall, when measured at 6 to 8 weeks[16,24] and 18 weeks[23] after information delivery.

Orthodontic treatments last an average of 24 months, which are much longer than the time spans assessed in many studies that focus on medical procedures that are completed within a day, which could exacerbate patients' poor recollection. It is also possible that within the long-term timeframes in which orthodontic treatments happen, patients' expectations may vary or become different from their initial ones. On the other hand, the frequency in which follow-ups are scheduled in practice also offers orthodontists, support clinical staff, and patients the advantage of regular contact, and multiple opportunities to revisit crucial information, which could mitigate issues related to limited memory and ensure orthodontist and patient are in general agreement about the treatment plan. However, when Baird and Kiyak[19] interviewed kids and parents who have been through their informed consent processes 6 to 36 months before the interviews, they found that even the ones that had experienced some sort of complication during their orthodontic treatments could still not recall previously discussed risks.

This study also suggests that patients may have selective memory, with poorer recollection abilities toward particular types of information. Orthodontic patients need retainers, and the ‘retention protocols’ were among commonly forgotten information in everyday practices of participants in this study, which has also been suggested by Williams et al.[28] and Ernst et al.[21] Indeed, Ley[29] has shown that patients recall best what they tend to consider most important.

b) Patients’ External Barriers

Participants in this study suggested that with the increase in competitivity seen in the orthodontic business, some professionals may feel pushed to offer free consultations, which in turn could increase the chances that these professionals feel tempted to spend less time informing their patients. Medical evidence indicates that patients are more satisfied and sue less when doctors spend more time to communicate and educate them.[30] Franklin[31] stated that the need for prudent risk management is also necessary because of the increasingly litigious society, which is less tolerant of doctor errors.

While participants indicated that they discussed verbally the individual risks during the initial consultations, several participants still did not specifically document those risks on the forms that were signed by their patients, which potentially made them vulnerable to professional liability if one of those risks occurred during the course of treatment,[31,32] since the general presumption for documentation is that “if it is not in the chart, it did not happen”.[33(p130)] On the other hand, some other participants in this study were clear with regards to ensuring the charting of specific individualized treatment risks in the forms signed by patients during consent processes.

Findings from this study suggest that nowadays additional challenges are faced as a result of the easy access to the web and its widely disseminated network of information. Unfortunately, not all sources of information readily available out there are sound or even relevant to each specific patient. Hence, it is not surprising that the ordinary patient in most situations will not automatically hold the skills one would need to filter out the non-reliable or irrelevant sources of information.

The present study also suggests that orthodontists take a dim view of patients’ behaviour when searching information online and self-educating themselves through the web, because the information available is often unreliable and non-specific to the patients’ presentation. Quite frequently such sources contain misleading orthodontic advertisements, raising unreasonable expectations and threatening a proper patient education process. Flett et al.[26] found that patients considering orthognathic surgery who also searched Google and Wikipedia, acknowledged that information on the web could be wrong and sensationalistic, while information received in the clinic was specific to their cases. They also considered that the DVD received from the surgical team as a more trustable source of information. Thus, it is possible that directing and guiding patients to trustable sources of online information may help to build their knowledge, without relying on their information filtering skills.

From participants' statements, it seems that there is a very fine line between providing patients with the right amount of information or too much information. They indicated that it was not easy to reduce the amount of information because they preferred to err on the side of giving patients too much information rather than the opposite. Knowing which patients may benefit for more or less details could be seen as more of an art than a science. Several participants provided more detailed information for those patients that seemed to be more interested or asked more questions.

The issue becomes more complicated for adult orthodontic treatments because they often involve multidisciplinary teams, involving different professionals from other dental specialties. Since the critical information cannot always be shortened, researchers have recommended that dentists start with the most important information, because patients tend to have better recall of information that was presented first.[10,29]

c) Financial Barriers

Costs were also suggested to be a deterrent to patients and to patients' understanding of the provided information. Almost all Canadians are responsible for financing their own dental care, including orthodontic care costs, either through private insurance or through direct payment, in contrast to a largely publicly funded medical system. Costs increase substantially when additional treatment is needed from other dental specialties, building up on the overall cost of treatment, not uncommon when treating adult patients, according to some of the participants. However, participants indicated that cost was a challenging barrier to overcome because it could negatively impact their patients' understanding of information, regardless of whether fees were presented at the beginning or at the end of the consent process. Whether patients from different socioeconomic status may be affected differently by such information was not clear.

C. Strategies to Optimize Information Delivery and Communication

a) Tailoring the Content to be Delivered

The present study suggests that customizing information to the individual patients may improve their level of understanding and recollection. In practical terms, it was described as keeping explanations simple, avoiding unnecessary details, while providing extra or more detailed information only for those patients that asked more questions or demonstrated a higher interest in further information. Participants consistently stated that as a general rule, every patient gets the basic information needed to make a decision, including risks (general and specific), which are almost always highlighted by the orthodontists themselves during consultations. An important fact to bear in mind is that even basic information may change according to individual case presentations and treatment needs, and it might involve complex information such as skeletal and dental problems, which can still be difficult for some patients. Understanding of the involved risks with orthodontic treatment not only would allow patients to make a more informed treatment decision, but also seems to make treatments run smoother if any said complication arises, fulfilling both ethical and legal aspects of a consent for treatment.[34,35]

b) Communication Fashion

Taking the time to educate patients, slowly and carefully explaining information, and appealing to the patient's learning style were all strategies that the participants used to engage patients and improve their understanding and recollection of information. As everyone learns differently, ideally orthodontists should assess each patient individually to discover what would likely work best for them. Then they should be able to adapt information delivery resources to individual learning preferred styles.[36] However, in reality, this may be difficult and time-consuming to achieve in busy everyday practices. Thus, the provision of information in multiple formats may increase the chances of matching the learning preferences of individual patients, increasing the likelihood that the delivered information will be understood and retained by a particular patient.[35]

Jargons and technical terms should be avoided when communicating to patients, as they are more likely to understand information that is delivered in plain language. Other studies have also reported patients' struggles to understand the message delivered due to the use of technical terminology.[25,26]

Providing patients with written material that they can take home was also suggested as a way to help their understanding and retention of treatment information. Williams et al.[28] reported that while not all patients were able to remember that they were provided with printed information, such as leaflets during their clinical visits, approximately 93% of those found the leaflets helpful. Stirling et al.[25] also found that written material helped patients by answering important questions that they may have forgotten to address during their consultation, and also by raising new questions that they could ask in future consultations. As suggested by participants, it is possible that the opportunity of referring back to the information itself can be helpful. Flett et al.[26] provided information to their patients using a DVD format and their patients specifically mentioned benefits from being able to take the material home: the convenience of revisiting the information as many times as they would like, and the ability to watch the material at their own pace. It would be important to carefully consider the design of any written material given to patients, to make sure it contains information that is easy to read, understand, and is targeted at the appropriate age level. This may imply more than one version of any given informational material. Also, consideration should be given to the fact that these studies did not specifically targeted orthodontic scenarios, so their conclusions may not fully apply to the intricacies of orthodontic informed consent processes.

Although written information improves dental patients' recollection and comprehension,[37,38] Patel, Moles and Cunningham[16] suggested that when compared to more visual means of orthodontic information delivery, the latter yields better results. Indeed, the use of media to clarify verbal information was suggested by most of the participants in our study to help improve patients' comprehension of information. Flett et al.[26] suggested that some potential orthognathic patients found a DVD easier to understand than the explanations that they had received from the clinic they attended. Among the various visual means of providing information to patients reported in our study, our participants used before and after pictures of similar cases treated by the same professional. Although, before and after treatment images are likely to be helpful for patients,[26,28] Flett et al.[26] found that some patients were confused after seeing pre-treatment pictures in profile being compared to frontal images of post-treatment faces. Therefore, caution is recommended when presenting before and after treatment images to patients with regards to the organization and presentation of such images, to reduce the complexity of the process further complex for patients. It should also be noted that patients are likely to focus on frontal aesthetic changes over profile characteristics. Orthodontists, on the other hand, seem to put a significant value on profile changes.

c) Communication Timing

Orthodontic treatments occur over long time periods, with some treatments lasting over 36 months. Therefore, sustained retention of information would be essential. Delivering information on an ongoing basis, through repetition, reminders and/or coaching patients throughout the course of their treatments, were suggested to be important strategies for mitigating patients' poor recollection abilities, and reinforcing crucial information. Medical literature has suggested that although repeating information once during consultation increases immediate parents' recall of information, retention is not sustained after 6 weeks.[12] It has to be considered that orthodontic appointments are usually spaced in periods over 6-8 weeks long. To the best of our knowledge, it is not known whether repeating information at different points in time throughout the treatment would significantly impact patients' recollection of information, but it seems to help close gaps of communication and make treatments smoother.

d) Being Accommodative

Participants have mentioned instances when they would go above and beyond to accommodate patients' needs with the intention of improving the quality of information delivered: calling back patients to answer their questions; offering additional consultation time if patients want it; suggesting patients bring someone to help patients understand complex information or translate explanations; and arranging for patients considering orthognathic surgery to meet patients that have been through a similar procedure.

Indeed, it may be easier to understand complex information if patients bring a family member or friend, according to participants. Flett et al.[26] also emphasized that potential orthognathic patients found it useful to have the opportunity to reflect on delivered information and discuss it with relatives. When patients are non-proficient in English, having an interpreter to help to translate information provided during informed consent consultations would be necessary. Use of informal interpreters, usually family members of patients, was reported by our participants and has also been suggested by Goldsmith, Slack-Smith and Davies.[18] However, family members and friends may not be able to translate key terms that are necessary for obtaining informed consent.[36] Furthermore, it is not clear how subsequent appointments are handled, when those family members are not likely to be present. Communication between doctor-staff-patient remains as fundamental during the consult day as in any future appointments and has been suggested by Pacheco-Pereira et al.[39] to be strongly related to orthodontic treatment outcome satisfaction.

Two participants noted that providing patients who are considering orthognathic surgery with an opportunity to talk to someone that has undergone a similar procedure may be helpful to patients. Williams et al.[28] reported that 95% of the patients that had this opportunity found it useful, and helped them to decide on whether to proceed with surgery or not. Cunningham, Hunt and Feinmann[40] reported that 23.5% of patients that had orthognathic surgery felt poorly or very badly informed, and would like to have met someone who had undergone a similar procedure prior to undergoing surgery themselves. Similarly, potential orthognathic patients that have watched a DVD containing real stories of patients who underwent similar treatment found it useful to hear other patients' experiences.[26] However, in some instances, patients complained about the fact that patients recorded in the video did not talk about specific details that they wanted to learn about.[26] There is a disadvantage to patients that are not given the opportunity to ask questions immediately after watching recorded educative materials, which makes it less effective than giving patients the opportunity to meet other patients directly. However, the DVD may be a reasonable substitute when the first option is not feasible. This may be relevant when orthodontists need to educate their patients who are considering orthognathic surgery and need to make a decision. The orthodontist or treatment coordinator should provide the answers to the patient's questions after the DVD is viewed.

3. SUMMARY

In the previous sections, the flow of information delivery during informed consent processes for adult orthodontic patients in Alberta, Canada, was described. The participants identified barriers that they may experience when communicating treatment related information to patients, with regards to their comprehension and recollection of information. As a result of this study, there are recommendations for improving the informed consent processes for patients and minimizing the challenges that orthodontists face in delivering information.

Information should be tailored to each individual patient's needs before they can make a comprehended choice about their orthodontic treatment. Information should be provided to patients in an unhurried and attentive fashion, using plain language, visual media to illustrate verbal explanations, and easy-to-read supplementary material. Communication with patients should happen on an ongoing basis, throughout the treatment, reviewing crucial information and reminding patients about essential aspects of their treatment, as well as preparing them for the upcoming steps in their treatment.

Orthodontists can use the following strategies to accommodate patients' needs: calling patients back to determine if they have concerns or questions to be addressed after their consultations; extending or offering additional consultation time if patients require it; suggesting that patients bring someone who may help them understand complex procedures or translate the information; and arranging for patients considering orthognathic treatment to meet with patients who had similar procedures.

4. LIMITATIONS OF THE STUDY

The findings of our study are not intended to be representative of the entire population; they represent the characteristics of a small group of Canadian orthodontists, working in Alberta, Canada. The participants were trained in different orthodontic schools and hence were likely exposed to different levels of information in regards to orthodontic informed consent. A minimal set of guidelines would have been provided to all of them as part of their licensing requirement. The goal of this study was to provide a rich description of the phenomenon of informed consent processes for adult patients as perceived by the participants. This allowed gaining a deeper understanding of the barriers that these professionals may have experienced when communicating treatment related information to patients and obtaining their informed consent, as well as the strategies that these orthodontists used to try to overcome or minimize these barriers. This is especially important because previous research attempts have only focused on quantifying the different aspects of orthodontic informed consents, while qualitative methods, such as the one used in this study, give voice to study participants, which may help to bring to light issues that may otherwise go unnoticed.

Additionally, the cross-sectional and non-experimental nature of the design used in this research study makes it impossible to establish causal relationships. Thus, the barriers and strategies reported here are the orthodontists' perceptions of their patients' understanding or recollection of information delivered by the participants.

Finally, qualitative interviewing the orthodontists who take part in an orthodontic informed consent process exclusively, and not including interviews with the treatment coordinators or the dental assistants, while still providing a deeper understanding of the concerns reported in previous studies, it did not allow a fuller picture of the information consent process that the patients experience. On the other hand, interviewing patients instead would likely have disclosed a different, although no more or less important, scenario of experiences.

5. RECOMMENDATIONS FOR FUTURE RESEARCH

This study provided a preliminary glimpse into orthodontists' perceived barriers and strategies to obtaining informed consent from adult patients. As the nature of this study was qualitative, and the sample consisted of a small population of orthodontists in Alberta, Canada, there certainly are opportunities to obtain quantitative data on a larger sample of the orthodontic population in Canada. This would allow experimental research to be designed with the purpose of testing whether such barriers and strategies significantly impact patients' comprehension and recollection of information received during informed consent processes. Moreover, further exploring the complex involvement of other staff members from the orthodontic team in the informed consent processes, such as the treatment coordinators and the dental assistants, might provide additional clarification on the process. Finally, using a similar methodology to give voice to orthodontic patients, to understand their perspectives on the issue, may disclose barriers that are overlooked by orthodontists. Following those leads would likely contribute to closing some of the gaps in the literature concerning the problems around orthodontic informed consent processes.

6. CONCLUSION

Ensuring that patients are genuinely informed before making a decision to proceed with treatment should be a significant concern for a healthy orthodontic practice. The increasing body of literature documenting young patients' and their parents' limited comprehension and recollection of information delivered during orthodontic informed consent processes demonstrates that these consent processes have room to be improved. This study described the rich experiences and perceptions of orthodontists practicing in Alberta, Canada, in obtaining informed consent from adult patients. The flow of information provided during the consent processes, the specific challenges they face when communicating treatment related information to patients, and their strategies for improving the consent processes, are presented and compared to the literature. With this research being the first of its kind in orthodontics, the results provide a useful initial resource to help to identify barriers that may be overlooked in the daily routine of orthodontic practices. Finally, this study offers information that may serve as guidance for orthodontists to overcome or minimize these challenges, improving the quality of consent processes, and increasing the chances of having more informed patients.

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APPENDIX 1

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LETTER OF INITIAL CONTACT

Dear Dr. _______________,

I am a graduate student at the University of Alberta under Dr. Carlos Flores-Mir's supervision.

I would like to invite you to participate in our research project titled '**Informed consent in orthodontics: comprehension and recollection of adult patients**" (University of Alberta Ethics ID: Pro00075250).

Our research is focused on orthodontic informed consent processes. Our ultimate goal is having an improved understanding of how orthodontic informed consent processes are conducted within private orthodontic practices in Alberta.

Participation would involve an interview that may last up to 30 minutes. I would really appreciate the opportunity to talk to you and have your insights about your overall informed consent clinic's routine enriching our research project. Data will be anonymized and only presented as a summary of findings.

I am available to chat over the phone or in person at the time and day that works for your schedule.

I am looking forward to hearing from you,

Best regards,

Narjara Moreira

APPENDIX 2

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INFORMATION LETTER

Informed consent in orthodontics: Toward an understanding of adult patients' experiences and perceptions of their comprehension and recollection

Principal Investigator:	**Graduate Student:**	**Co-Supervisor:**
Carlos Flores-Mir	Narjara Moreira	Louanne Keenan
5528 Edmonton Clinic	5083 Edmonton Clinic	2115 Edmonton Clinic
Health Academy	Health Academy	Health Academy
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cf1@ualberta.ca	narjara@ualberta.ca	lkeenan@ualberta.ca
780-492-7409	780-919-5723	780-492-1418

Background

- ☐ You are being invited to be part of this study because communicating orthodontic treatment related information to patients is part of your professional routine.
- ☐ Overall it is important to understand the barriers and facilitators that affect how well patients comprehend treatment information received during their initial orthodontic consultation.

Purpose

- ☐ The objective of this study is to find out how patients are informed regarding their potential orthodontic treatments, and how it may affect the way they comprehend such information received during initial orthodontic consultations.
- ☐ The results from this study are expected to improve our understanding of the way patients are informed about their orthodontic treatments.
- ☐ This study's results will be used in support of Dr. Narjara Moreira's Master's (Dentistry) thesis.

Study Procedures

- ☐ You will be interviewed about how patients are informed regarding their orthodontic treatment information before they eventually consent to be treated at your clinic.
- ☐ The interview may last up to 30 minutes.
- ☐ The interview, either in-person or by phone, will occur at your earliest convenience, and in a location that respects your privacy.
- ☐ It is possible that a short follow-up interview is needed to clarify provided information.
- ☐ Each interview will be audio-recorded and transcribed word for word but kept anonymous in any related future report.

Version: May 25, 2018

Benefits

- We hope that the findings from this study will help to understand how orthodontic teams communicate treatment related information to patients before they consent to be treated. This should help our understanding and lead to improvements in the orthodontic consent processes.
- You will receive a $25 gift card to thank you for your participation, even in the event that you decide not to complete the study.

Risks

- There are no known risks to being involved with this study.
- If we learn anything during the research that may affect your willingness to continue being in the study, we will communicate it to you right away.

Voluntary Participation

- Your participation is completely voluntary.
- You are not obliged to answer any specific question during this study.
- You can ask me to turn off the audio recorder anytime.
- You may choose to withdraw at any time during this study, without any penalty.
- If you withdraw from the study, you can ask to have your data excluded from the reports, and destroyed.

Confidentiality & Anonymity

- A pseudonym will be used to protect your identity. This will be used to identify any data from your interviews.
- Data from this study will only be used for research and educational purposes.
- Your name will never be mentioned. Sometimes your words will be used *ad verbatim* so that your ideas will be clear.
- Only the investigators listed above and the transcription professional will have access to the raw data from our conversation.
- Any electronic data will be encrypted and/or password protected.
- Data will be kept in a locked, secure location for a minimum of five years and may be used for future research upon ethical approval.
- If you are interested, you can have a copy of the final report.

Further Information

- If you have any further questions regarding this study, please do not hesitate to contact me, Narjara Moreira, or the Principal Investigator, Carlos Flores-Mir.
- The plan for this study has been reviewed for its adherence to ethical guidelines by a Research Ethics Board at the University of Alberta (University of Alberta Ethics ID: Pro00075250). For questions regarding participant rights and ethical conduct of research, contact the Research Ethics Office at (780) 492-2615.

APPENDIX 3

Interview Guide

- How long have you been practicing as a Canadian licensed Orthodontist?

Means of providing treatment information

- Could you describe how the flow of treatment related information given to a patient, before they consent to be treated, works in your practice?
- At your clinic, what means are used to provide treatment information to patients?
    - (verbal, video, written, etc.)
- Who provides treatment information to patients at your private practice?
    - The orthodontist or a treatment coordinator?
        - If both, what information is usually provided by the orthodontist and what information would be provided by the treatment coordinator, or both?

Nature of information provided to patients

- Describe the information that is provided to your patients before they decide whether to undergo an orthodontic treatment.
- Describe how you make a decision regarding which information is important to be provided to a specific patient before they decide to undergo an orthodontic treatment.
- Describe how you decide the amount of information that you provide to each orthodontic patient
    - Probing Question: (When information is too much or too little?)
- Do you usually use any means to double check whether a patient understood the information provided to them?

Perception of importance of treatment information provision

- Describe how the information that a patient receives about his/her orthodontic treatment impacts the success of their treatment or their experience during their treatment.

Barriers and facilitators to patient's comprehension of information provided

- From your experience, what barriers prevent patients from understanding treatment information provided to them?
- From your experience, what seems to help patients to better understand treatment information that is provided to them?
- Would you be able to describe a situation in which you experienced, regardless of efforts put to provide treatment information to a patient, any issues or barriers related to lack of comprehension or recollection of information that had indeed been previously discussed with that patient before?

APPENDIX 4

Health Research Ethics Board

308 Campus Tower
University of Alberta, Edmonton, AB T6G 1K8
p. 780.492.9724 (Biomedical Panel)
p. 780.492.0302 (Health Panel)
p. 780.492.0459
p. 780.492.0839
f. 780.492.9429

Approval Form

Date:	September 19, 2017	
Study ID:	Pro00075250	
Principal Investigator:	Carlos Flores Mir	
Study Title:	**Informed consent in orthodontics: Toward an understanding of adult patients' experiences and perceptions of their comprehension and recollection**	
Approval Expiry Date:	Tuesday, September 18, 2018	
Approved Consent Form:	Approval Date 9/19/2017	Approved Document Revised Informed Consent Form

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel. Your application, including the following, has been reviewed and approved on behalf of the committee;

- Revised Letter of Invitation (9/12/2017)
- Initial Interview Guides (9/3/2017)
- Research Proposal (9/12/2017)

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. It has been determined that the identification of participants described in the ethics application is a chart review for which subject consent for access to personally identifiable health information would not be reasonable, feasible or practical. Subject consent therefore is not required for access to personally identifiable health information described in the ethics application.

In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (Tuesday, September 18, 2018), you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health approvals should be directed to (780) 407-6041. Enquiries regarding Covenant Health approvals should be directed to (780) 735-2274.

Sincerely,

Anthony S. Joyce, PhD.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

APPENDIX 5

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CONSENT

Title of Study: Informed consent in orthodontics: Toward an understanding of adult patients' experiences and perceptions of their comprehension and recollection
Principal Investigator(s): Carlos Flores-Mir **Phone Number(s):** 780-492-7409
MSc Student: Narjara Moreira **Phone Number(s):** 780-919-5723

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time, without having to give a reason, or without penalty?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your study records?	☐	☐

Who explained this study to you? ____

I agree to take part in this study:

Signature of Research Participant ____

(Printed Name) ____

Date: ______________________________

Signature of Witness ____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee _______________________________ Date _______________

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT

Version: May 1, 2018