# Professional consensus on orthodontic risks: What orthodontists should tell their patients

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**Introduction:** Effective communication of risk is a requisite for valid consent, shared decision-making, and the provision of person-centered care. No agreed standard for the content of discussions with patients about the risks of orthodontic treatment exists. This study aimed to produce a professional consensus recommendation about the risks that should be discussed with patients as part of consent for orthodontic treatment. **Methods:** A serial cross-sectional survey design using a modified electronic Delphi technique was used. Two survey rounds were conducted nationally in the United Kingdom using a custom-made online system. The risks used as the prespecified items scored in the Delphi exercise were identified through a structured literature review. Orthodontists scored treatment risks on a 1-9 scale (1 = not important, 9 = critical to discuss with patients). The consensus that a risk should be discussed as part of consent was predefined as ≥70% orthodontists scoring risk as 7-9 and <15% scoring 1-3. **Results:** The electronic Delphi was completed by 237 orthodontists who reached a professional consensus that 10 risks should be discussed as part of consent for orthodontic treatment; demineralization, relapse, resorption, pain, gingivitis, ulceration, appliances breaking, failed tooth movements, treatment duration, and consequences of no treatment. **Conclusions:** A professional orthodontic consensus has been reached that 10 key risks should be discussed with patients as part of consent for orthodontic treatment. The information in this evidence base should be tailored to patients' individual needs and delivered as part of a continuing risk communication process. (Am J Orthod Dentofacial Orthop 2021;159:41-52)

Risk communication involves giving patients information about potential risks they may encounter as a result of a disease, a clinical procedure, or a particular behavior.[1] An orthodontist may be liable to legal action by the patient and disciplinary proceedings if a patient is not given sufficient, meaningful, and balanced information about the risks of treatment.[2] Effective communication of risk is a requisite for valid consent, shared decision-making, and the provision of person-centered care.[3]

The risks of orthodontic treatment have been defined broadly as any of the deleterious or iatrogenic effects of orthodontic treatment, or any potential adverse outcomes or consequences.[4] The communication of risk is particularly difficult in orthodontics as care is often elective, takes place over an extended period and is delivered as part of a triad (professional, patient, and primary carer).[5] Because of the considerable investments of time and resources, the potential harms must be carefully weighed against the anticipated benefits.

Landmark court rulings in the United States,[6] Canada,[7] United Kingdom,[8] and Australia[9] have shifted the way in which health care risks are communicated. This shift means that health practitioners are expected to provide patients with a reasonable amount of risk information in a patient-focused manner (which is likely to equate to a professional standard). In addition, the wants and needs of the particular patient must be identified and further information given relative to the material risks relevant to that subject elicited by their circumstances and response.[10] Although paternalism has no place within health care, neither does the abandonment of patients by health care professionals failing to contribute to the decision-making process. The principles of shared decision-making encourage health care

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professionals to use their expert opinion for the benefit of patients as part of the consent process. In addition, because of heuristic strategies to make quick and effortless decisions, patients often do not seek new information but rely heavily on health care professionals' advice about treatment.[5,11]

Laws in many countries have now formalized that consent is not simply a process of giving all information, regardless of relevance. However, no agreed standard for the content of discussions with patients about the risks of orthodontic treatment exists, and the development of orthodontic risk communication tools[12-14] have rarely been guided by an evidence base. Knowledge of a reasonable professional community standard pertaining to risk disclosure in orthodontics will allow clinicians to focus on and save energy for the additional risk information needs of the specific, individual patient. As such, this study aimed to gain a professional consensus on the risks that should be discussed as part of consent for orthodontic treatment.

## MATERIAL AND METHODS

Ethical approval was granted by the Cardiff University Dental School Research Ethics Committee (Ref no. 1507). A serial cross-sectional survey design using a modified electronic Delphi technique was used. Two survey rounds were conducted nationally in the United Kingdom.

The risks used as the prespecified items scored in the Delphi exercise were identified through a structured literature review. Search strategies focused on identifying articles reporting on the probability and nature of the risks of orthodontic treatment. As stated in the literature,[4,15] orthodontic treatment risks were defined broadly as any deleterious or iatrogenic effects of treatment, or any potential adverse outcomes or consequences. Risks associated with specific treatment modalities, such as headgear, miniscrew implants, and orthognathic surgery, were deemed to be outside the scope of this study and not included. Search strategies were developed using a combination of free-text terms, based on keywords and phrases, and controlled vocabulary in the form of appropriate subject headings. The databases Ovid MEDLINE (1946 to November 1, 2016), EMBASE (1947 to November 1, 2016), and PsycINFO (1806 to November 1, 2016) were searched, and search engines, such as Google (Google, LLC, Mountain View, Calif) and Google Scholar (Google, LLC), were also used. Key international orthodontic journals and the bibliographies of articles were used to identify additional studies and further search terms. Literature searches were kept up to date using e-mail notifications from Ovid MEDLINE (Wolters Kluwer Health 2016). Relevant risks were extracted from the studies using a reference table system, and 2 authors (J.P and H.P) generated a final list of risks by combining similar risk categories and resolving conflicts by discussion.

Custom-made surveys using Key Survey (WorldAPP, Braintree, Mass) were developed for the Delphi exercise and refined during steering group meetings of the research team. The surveys were based on previously reported Delphi methodology.[16] Pilot surveys were conducted with 23 orthodontic clinicians practicing in a range of sectors (hospital, public, and private practice) in South Wales (100% response rate). These subjects were chosen as a representative sample of professionals similar to those who would complete the Delphi exercise correctly. Feedback was obtained, and subsequent amendments to the survey layout and wording were made.

The risks identified in the structured literature review formed a template for the survey used in round 1 of the Delphi (Fig 1). To avoid weighting, we listed risks randomly in each round using a random number generator (Microsoft Office Excel; Microsoft, Redmond, Wash).

People with an e-mail address registered on the British Orthodontic Society (BOS) membership database were deemed eligible to participate. Subjects registered

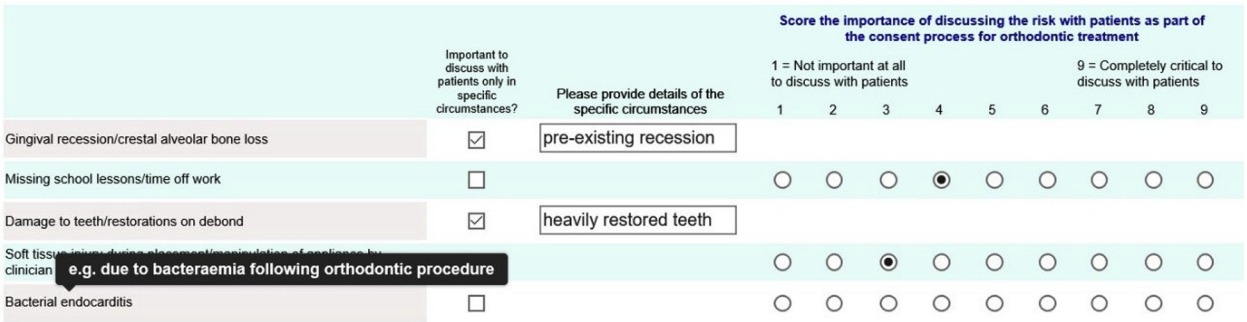


**Fig 1.** Round 1 online survey.

**Table I.** Definitions of consensus

| *Consensus classification* | *Description* | *Definition* |
|---|---|---|
| Consensus in | The consensus that risk should be discussed with patients as part of the consent process for orthodontic treatment | ≥70% participants scoring as 7-9 and <15% scoring 1-3 |
| Consensus out | The consensus that risk is not normally important to discuss with patients as part of the consent process for orthodontic treatment (but clinicians should use their discretion) | ≥70% participants scoring as 1-3 and <15% scoring 7-9 |
| No consensus | Uncertainty about the importance of discussing risk as part of the consent process for orthodontic treatment | Anything else |

as retired, international, or core trainee members were excluded. Participant consent to be involved in the study was implicit on completing the surveys, and entry to a prize draw was offered to participants for completing the Delphi exercise.

The BOS disseminated the survey link directly to members. Two reminder e-mails were sent to participants, 1 and 2 weeks after initial contact. The survey was closed after an additional week. E-mail addresses were collected for participation in round 2. It took participants approximately 10-15 minutes to complete round 1.

Participants were asked to score the importance of discussing each risk with patients as part of the consent process for orthodontic treatment. Risks were scored on an ordinal scale, from 1 to 9, with 1 being "not important at all" and 9 being "completely critical." Extra information to explicitly describe risks and avoid ambiguity was provided. If participants felt a risk only applied in specific circumstances, instead of scoring the risk, they could provide details in a free text box (Fig 1). A function was provided for participants to add extra risks they thought were relevant, which had not already been listed.

## Statistical analysis

Data were exported from Key Survey into Microsoft Office Excel and SPSS Statistics (version 20; IBM, Armonk, NY) for analysis. The risk scores were reviewed against a predefined definition of consensus (Table I). Risks classified as consensus in/out were not assessed in round 2.

Risks stated by the majority of participants (>50%) as applying only in specific circumstances were forwarded for assessment in round 2. The free-text responses for these risks were thematically analyzed and coded by 2 authors (J.P and H.P), generating a list of specific circumstances for when each risk might apply.

The free-text responses describing additional risks were analyzed similarly but coded according to the original risk list. Risks not already represented were included in the list of risks forwarded for assessment in round 2.

Those participants who responded in round 1 and provided a valid e-mail address were contacted and asked to complete the survey for round 2. Similar to Round 1, reminder e-mails were sent, and the survey was closed after 3 weeks. It took participants approximately 5-10 minutes to complete round 2.

Participants were provided with the following results from round 1 for each risk carried forward: (1) overall quartiles for the response scores from all participants; and (2) a reminder of their score (if they scored the risk).

After considering the results of round 1, participants were asked to review the risks listed and rescore them. They were informed that for each risk, they could change their score from round 1 or keep it the same (Fig 2).

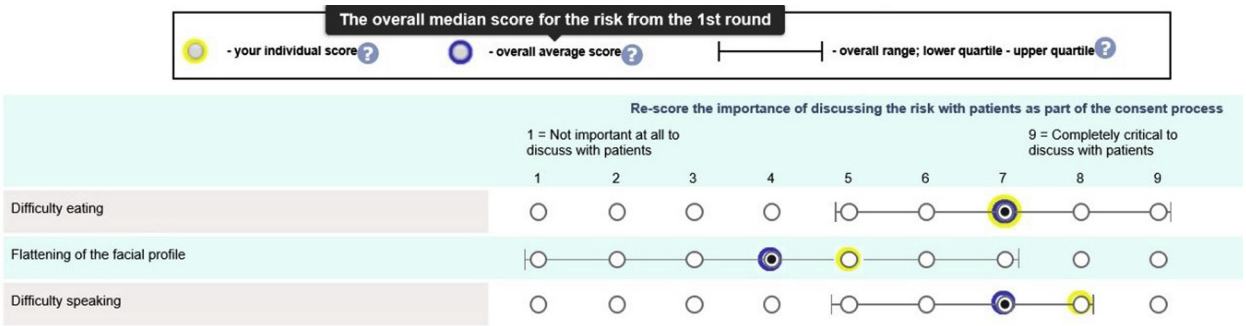


**Fig 2.** Round 2 online survey.

**Table II.** Risks included in Delphi exercise with orthodontist opinion and evidence in the literature

| *Risk highlighted by study (+/− specific circumstances when risk might apply)* | *Orthodontist opinion (% of participants scoring risk 1-3, 7-9)* | *Evidence in the literature* |
|---|---|---|
| Demineralization | Consensus in (0, 99) | • May affect 60%-75% of patients[17]<br>• Severity varies from white spot lesions to frank cavitation[4] |
| Relapse | Consensus in (1, 98) | • Ninety percent of patients affected 20 years after treatment[18]<br>• Can influence patient satisfaction[19] |
| Length of treatment | Consensus in (1, 95) | • Influenced by nonadherence to clinical recommendations, individual variation in rates of tooth movement[20] and poor attendance[21] |
| Root resorption | Consensus in (2, 93) | • May affect 90% of patients[22]<br>• Severe root shortening may affect 5% of patients[23] |
| Pain/discomfort | Consensus in (3, 89) | • May affect >50% patients after appointments[24]<br>• May affect adolescents more than other age groups[25] |
| Consequences of doing nothing | Consensus in (5, 86) | • Patients with overjets >4 mm have twice the odds of incisal trauma[26]<br>• Ectopic canines may undergo cystic change and cause resorption of adjacent incisors[27] |
| Appliances breaking | Consensus in (4, 85) | • The majority of patients have breakages at >10% of appointments[28] |
| Failure to achieve desired tooth movement(s) | Consensus in (9, 76) | • May occur because of persistent residual spacing, poor compliance,[15] or ankylosis[29] |
| Gingivitis | Consensus in (7, 76) | • Treatment can result in 0.23 mm increased pocket depth[30] |
| Cuts and ulcers | Consensus in (4, 75) | • May affect 75%-95% of patients[31] |
| *Gingival recession and/or crestal alveolar bone loss* | | |
| With patients with a preexisting periodontal condition | Consensus in (0, 99) | • Thirty-six percent of patients may have ≥1 anterior tooth surface with ≥2 mm of bone loss[32]<br>• Risk factors: a thin gingival biotype, excessive labiolingual movement of the mandibular incisors,[33] preexisting recession,[34] and adult age[35] |
| If there are specific anatomic considerations | Consensus in (1, 90) | |
| With adult patients | Consensus in (5, 72) | |
| If using certain treatment modalities | No consensus (4, 67) | |
| *Unfavorable growth* | | |
| With specific skeletal patterns/malocclusions | Consensus in (0, 96) | • May occur in 15% of patients with Class II malocclusion[36]<br>• May occur because of a hypoplastic maxilla/prognathic mandible in patients with Class III malocclusion[37]<br>• May have a strong genetic predisposition[38]<br>• May necessitate a surgical approach |
| *Development or worsening of black triangles between teeth* | | |
| With patients with preexisting periodontal conditions/black triangles | Consensus in (0, 96) | • May appear unaesthetic and cause chronic food retention<br>• Prevalence in adult patients of 40%[39]<br>• Risk factors: adult patients and those with triangular-shaped crown form, preexisting periodontal conditions,[40] or preorthodontic crowding[39] |

**Table II.** Continued

| *Risk highlighted by study (+/− specific circumstances when risk might apply)* | *Orthodontist opinion (% of participants scoring risk 1-3, 7-9)* | *Evidence in the literature* |
|---|---|---|
| With patients with specific tooth anatomy | Consensus in (1, 87) | |
| With adult patients | Consensus in (4, 74) | |
| With patients with anterior crowding | No consensus (18, 45) | |
| *Bacterial endocarditis* | | |
| With patients whose physicians recommend antibiotic prophylaxis | Consensus in (3, 92) | • NICE[41] guidance states: "Antibiotic prophylaxis against infective endocarditis is not recommended *routinely* for people undergoing dental procedures"<br>• High-risk patients: the history of infective endocarditis or prosthetic/repaired heart valves<br>• Orthodontists should liaise with the patient's physician if concerned |
| With patients with a history of cardiac disease | No consensus (18, 57) | |
| *Negative effect on playing wind/brass instrument* | | |
| With patients who are wind/brass instrumentalists | Consensus in (5, 79) | • Brass instrumentalists commonly affected and effects normally transient[42] |
| *Tooth wear caused by opposing brackets* | | |
| If using certain appliance types | Consensus in (5, 78) | • Often affects maxillary incisal edges and canine tips[4]<br>• May be problematic in patients with bruxism,[43] if an increased overbite is present,[4] or when ceramic brackets are used |
| With patients with specific occlusal features | Consensus in (6, 76) | |
| With patients with bruxism | No consensus (8, 64) | |
| Problems eating | No consensus (7, 67) | • Appliances may affect mastication and diet[44] |
| Periodontitis | No consensus (10, 61) | • Treatment may have small detrimental effects on periodontal health in long-term[30] |
| Devitalization of teeth | No consensus (8, 61) | • Previously traumatized teeth may be at increased risk of devitalization during treatment[45] |
| Problems speaking | No consensus (11, 55) | • Appliances may affect speech[46] |
| Missing school lessons/time off work | No consensus (11, 48) | • Patients may require time out from school or employment to attend appointments[2] |
| Damage to teeth or restorations on debonding | No consensus (11, 26) | • Can occur on the removal of appliances and excess cement[47]<br>• Care if using ceramic brackets and in patients with heavily restored dentitions[4] |
| Flattening of the facial profile | No consensus (35, 12) | • No conclusive evidence to demonstrate a relationship between extractions and changes to the facial profile[48] |
| Risks associated with tooth extraction(s) | No consensus (69, 7) | • Clinicians may discuss several complications associated with dental extractions |
| Teasing, embarrassment, impact of the appliance on interpersonal relationships | No consensus (6, 7) | • Young patients may be teased by their peers and embarrassed because of appliance appearance[49] |
| Temporomandibular dysfunction | No consensus (48, 7) | • A causal link has not been established with orthodontic treatment[50]<br>• Symptoms may resolve, remain the same, or become more severe during treatment |

**Table II.** Continued

| *Risk highlighted by study (+/− specific circumstances when risk might apply)* | *Orthodontist opinion (% of participants scoring risk 1-3, 7-9)* | *Evidence in the literature* |
|---|---|---|
| Soft tissue injury during placement or manipulation of the appliance by the clinician | Consensus out (70, 10) | • May be caused by clumsy instrumentation and chemical and thermal burns[4] |
| The negative effect of the appliance on sleeping patterns | Consensus out (74, 9) | • Appliances may affect sleeping patterns[51] |
| Radiation exposure | Consensus out (70, 9) | • One person/2.5 million lateral cephalometric, 1 person/half-million panoramic, and 1 person/40,000 cone-beam computed tomography exposures may be at risk of fatal cancer[52] |
| Airway or ingestion risks | Consensus out (72, 8) | • A fifth of orthodontists may have managed an aspiration/ingestion incident[53]<br>• May result in gastrointestinal perforation/infection, oropharyngeal laceration, and airway obstruction[54]<br>• Face masks may reduce dust inhalation to a safe level[55] |
| Allergies to orthodontic materials | Consensus out (83, 5) | • Latex allergy prevalence of <1% in the general population but may be higher in atopic subjects and those with spina bifida[56]<br>• Risk factors for nickel allergy include female sex, asthma, and piercings[57] |
| Cytotoxic effects and mutagenic potential of orthodontic materials | Consensus out (91, 2) | • Commonly used materials have not been reported to have cytotoxic effects in vivo[58-60] |

Note. Legend (1 = not important at all and 9 = completely critical): Consensus in = consensus that risk should be discussed with patients; ≥70% participants scoring as 7-9 and <15% scoring 1-3; No consensus = uncertainty about the importance of discussing risk; risk not classified as Consensus in/out; Consensus out = consensus that risk is not normally important to discuss (but clinicians should use their discretion); ≥70% participants scoring as 1-3 and <15% scoring 7-9.

Participants were also asked to score the risks that had previously been identified as applying only in specific circumstances according to the list of circumstances defined in round 1.

The definition of consensus was applied again, including only the responses from round 2. Risks classified as consensus in, after either round (and not identified as applying only in specific circumstances), were included in a core set of risks.

To identify whether attrition in round 2 would introduce bias, we calculated the median score across risks from round 1 for each participant. These scores were compared for those completing both rounds and those completing round 1 only.

## RESULTS

The structured literature review identified 30 risks, which were included in round 1 of the Delphi exercise (Table II).

Of the total BOS membership (n = 1906), 1479 members were confirmed eligible and invited to participate in round 1. Of those members invited, 345 (23%) responded to round 1. Of those subjects who participated in round 1, 321 (93%) provided a valid e-mail address and were invited to participate in round 2. Of those 321 subjects who were invited to participate in round 2, 237 (74%) responded.

The male:female ratio of respondents was equal (Table III). Three quarters of participants had practiced orthodontics for at least 11 years, and the remaining participants practiced for 10 years or less. Over half of the respondents that worked mainly in the public health system were BOS practice group members and had research experience involving patients and treated adults or a mix of patients. The proportion of respondents working in Southeast England decreased in round 2, whereas the proportion of respondents working in other regions was similar in both rounds.

Using the definition of consensus (Table I), we classified 9 risks as consensus in (demineralization/caries, relapse, length of treatment, root resorption, pain/discomfort, consequences of doing nothing, appliances breaking, failure to achieve desired tooth movement(s),

**Table III.** Participant Characteristics

| Characteristics | Round 1 respondents (% of round 1 respondents) | Round 2 respondents (% of round 2 respondents) |
|---|---|---|
| *Sex* | | |
| Male | 168 (49) | 121 (51) |
| Female | 177 (51) | 116 (49) |
| *No. of years practicing orthodontics* | | |
| 0-10 | 91 (26) | 65 (27) |
| >11 | 254 (74) | 172 (73) |
| *Type of clinical practice* | | |
| NHS | 202 (59) | 147 (62) |
| Private/mixed | 143 (41) | 90 (38) |
| *BOS group* | | |
| Hospital/community | 148 (43) | 113 (48) |
| Practice | 197 (57) | 124 (52) |
| *Age of patients* | | |
| Children | 127 (37) | 85 (36) |
| Adults/mixed | 218 (63) | 152 (64) |
| *Experience of research involving patients* | | |
| Yes | 192 (56) | 139 (59) |
| No | 153 (44) | 98 (41) |
| *Work location* | | |
| Southeast England | 92 (27) | 48 (20) |
| North England | 70 (20) | 53 (22) |
| East England | 45 (13) | 33 (14) |
| West England and Wales | 91 (26) | 66 (28) |
| Scotland and Northern Ireland | 47 (14) | 37 (16) |

*NHS*, National Health Service.

gingivitis) and 4 risks as consensus out (Figs 3 and 4; Table II). These risks were excluded from round 2.

Of the risks that had not reached consensus (n = 17), 4 were stated by the majority of participants as applying only in specific circumstances. Analysis of the free-text responses provided a list of specific circumstances for when each risk might apply. These risks and their specific circumstances were included in the list of risks forwarded for assessment in round 2.

In total, 107 participants provided 237 free-text responses describing potential additional risks. From these responses, 2 risks were identified that had not already been represented, and these were included in the list of risks forwarded for assessment in round 2.

In round 2, 19 risks were listed. Of these, 13 risks were not scored according to specific circumstances, and of this subset 1 risk was classified as consensus in (mucosal ulceration/laceration while wearing appliance) and 2 risks as consensus out (Figs 3 and 4; Table II). On average, participants changed their scores from round 1 for 30% of the risks (the median, range 0%-100%). In total, 3 participants (1%) changed all their risk scores, and 33 participants (14%) made no changes.

Using the lists defined in round 1, we scored 6 risks (4 original and 2 additional) according to specific circumstances. Participants reached consensus in when these risks were scored according to all but 4 of the specific circumstances (Table II).

When comparing the median scores across risks from round 1, those participants who only completed round 1 did not represent extreme views when compared with those participants completing both rounds (Fig 5).

## DISCUSSION

This study used the Delphi technique to produce a professional consensus recommendation about the risks that should be discussed with patients as part of consent for orthodontic treatment. The 10 risks forming the consensus recommendation include demineralization, relapse, resorption, pain, gingivitis, ulceration, appliances breaking, failed tooth movements, treatment duration, and consequences of no treatment. Delphi methods were deemed appropriate as health care professionals' communication of risk involves a blend of scientific evidence, social values, and expert judgment.[61] The Delphi technique has been used to investigate risk disclosure for medical procedures,[62] develop clinical guidelines,[63] and criteria to assess orthodontic outcomes[64] and the impact of reducing orthodontic treatment availability.[65] Other consensus development methods include the nominal group technique and consensus conferences. However, the Delphi technique used in this study has captured the views of a large number of orthodontists from a variety of backgrounds (Table III) and provided greater participant anonymity than these alternative methods would have allowed.[66] It should be acknowledged that consensus reached using any of these methods does not mean that the correct answer has been found but rather that participants have agreed on an issue to a specific level.

An orthodontic patient has a high likelihood of being affected by the majority of the risks that the professional participants agreed should be communicated (Table II). This high probability is reflected by qualitative research reports of orthodontic patients' risk experiences, including issues with pain, caries, gingivitis, appliances breaking, ulceration, and relapse.[11,12,67-69] This study suggests that orthodontists may not routinely communicate several treatment risks that are important to patients, such as problems eating and speaking.[12,44,70-72] These findings are in agreement

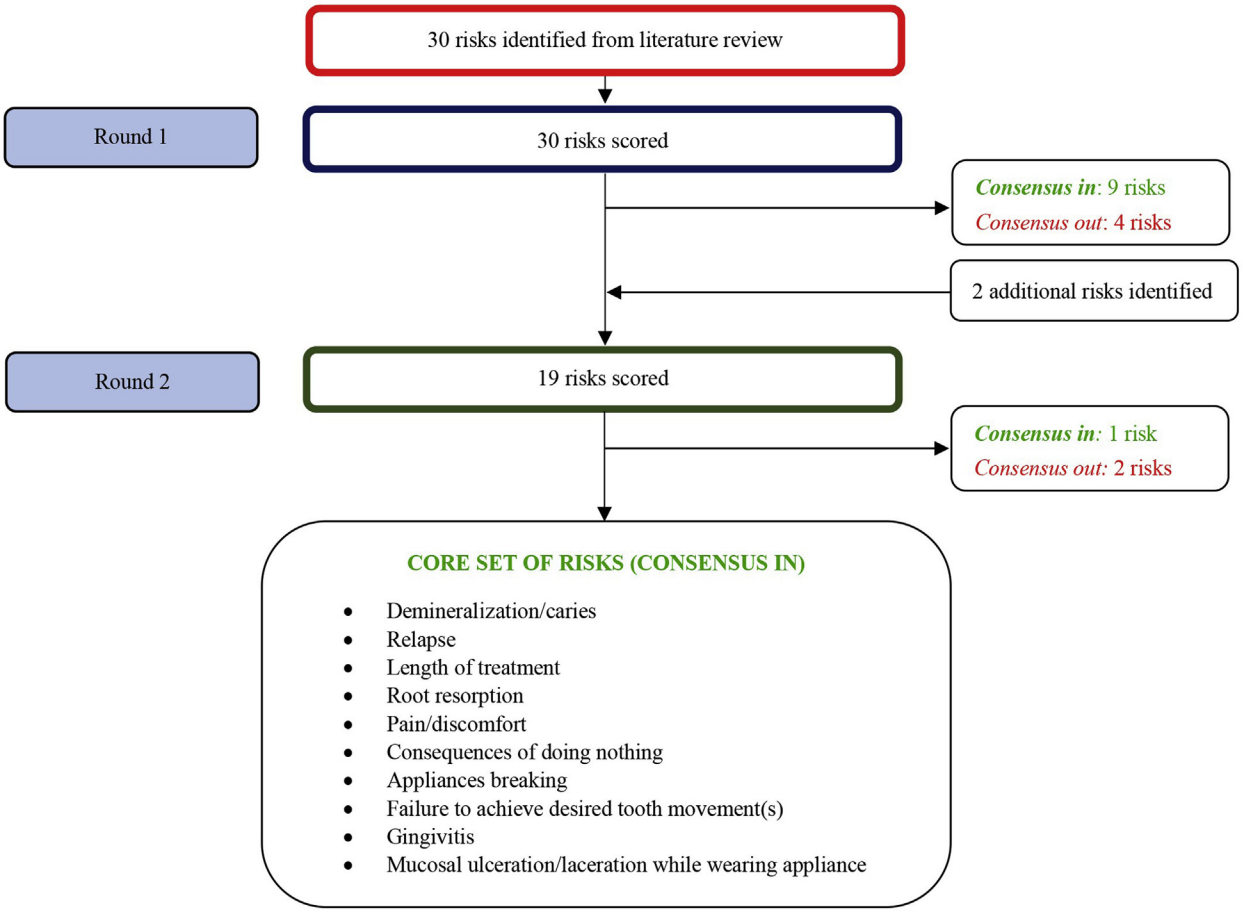


**Fig 3.** Flow diagram of the Delphi exercise.

with a previous study[73] that showed that patients and professionals have different views about orthodontic problems and highlight that patients may require additional information about other material risks to be communicated.

The results of this study support the need for treatment providers to have the necessary knowledge and communication skills to explain orthodontic risks to patients effectively. Direct to consumer companies and poorly trained orthodontic treatment providers are likely to lack the necessary education and focus on risk communication to provide effective consent for orthodontic treatment.[74] This finding has important implications for dental regulators who exist to protect patients and their autonomous right to make informed decisions about their care.

The Delphi technique used in this study has captured the views of a large number of orthodontists while providing participant anonymity.[66] An ordinal scale of 1-9 was decided on as it has been used effectively in previous Delphi studies[75,76] and is reliable for statistical analysis.[77] This scale was decided on through steering group meetings of the research team, which included a medical statistician (D.F). A level of consensus was defined a priori based on previously reported Delphi methodology[76] as currently there are no guidelines for determining an acceptable level of consensus in Delphi studies.[78] Although the response rate from BOS members to round 1 of the Delphi exercise was low, it is similar to that reported in other Delphi surveys.[76,79] Securing professionals' responses to surveys can often be problematic, and it was gratifying that the majority of participants were retained in both rounds. There is no standard method for sample size calculation in studies using the Delphi technique.[78] Therefore, the majority of the BOS membership was invited to ensure a sample size that would yield a meaningful statistical analysis. In addition, many techniques were used to maximize the response to electronic questionnaires.[80] Although participants' demographics differed between the rounds, the views of nonresponders to round 2 were

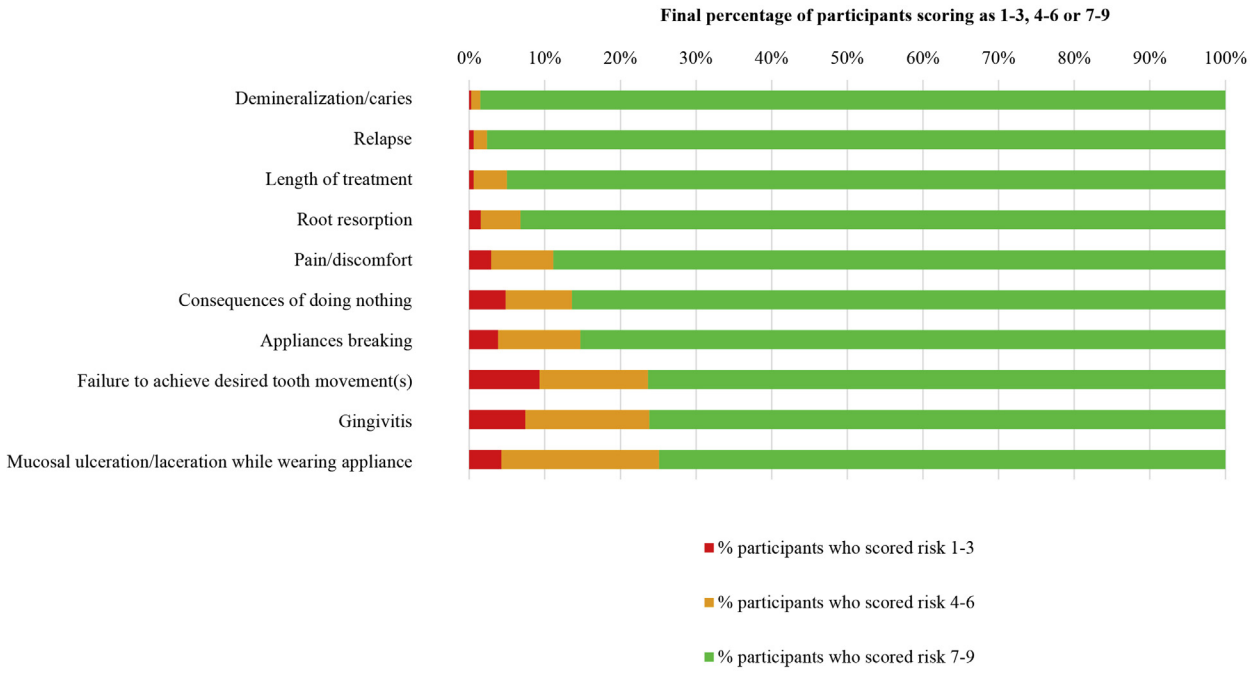


**Fig 4.** The core set of risks (classified as consensus in during Delphi). Percentage of participants scoring as 1-3, 4-6, or 7-9.

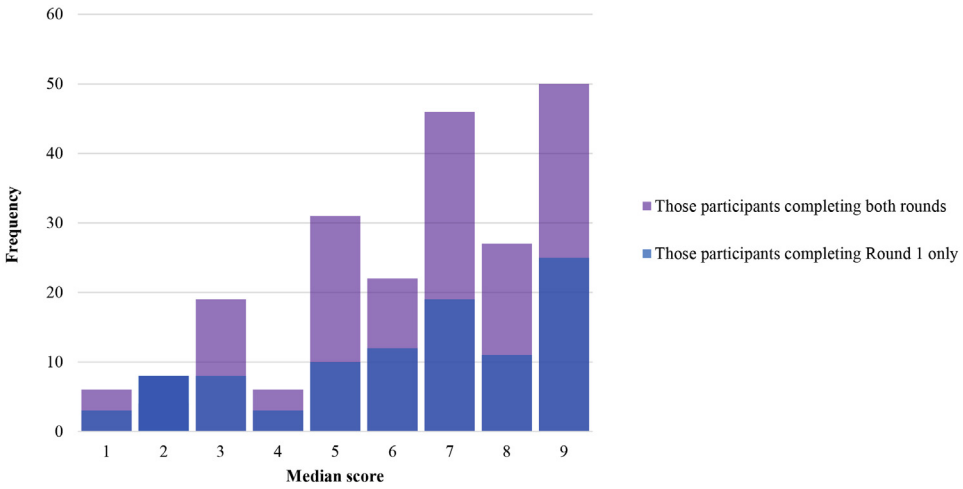


**Fig 5.** Comparison of median scores across risks from round 1; for participants completing both rounds (n = 237) and those participants completing round 1 only (n = 108).

not extreme, suggesting that attrition bias had not been introduced.

After receiving feedback from the whole group, the majority of Delphi participants changed their risk scores. This finding suggests the Delphi, as opposed to a one-off survey, was a useful exercise. By round 2, the responses for the remaining risks were stable, and a third round was deemed unnecessary.

Deciding what risk information should be given to orthodontic patients is a common clinical dilemma and has been made more complex by developments in consent law. To assist consent discussions, clinicians should consider discussing the salient risk information highlighted in this study. Several risks have been identified that are likely to be of significance to patients in specific contexts, and the data relating to these risks can help

orthodontists tailor their discussions to the individual needs and values of patients. This information can also guide the development of risk communication tools, professional guidelines, and patient resources.

## CONCLUSIONS

A professional orthodontic consensus has been reached that 10 key risks should be discussed with patients as part of consent for orthodontic treatment. The information in this evidence base should be tailored to patients' individual needs and delivered as part of a continuing risk communication process.

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