Professional consensus on orthodontic risks – what orthodontists should tell their patients

ABSTRACT

Introduction

Effective communication of risk is a requisite for valid consent, shared decision-making and the provision of person-centred 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 e-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 pre-specified 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). Consensus that a risk should be discussed as part of consent was pre-defined as ≥ 70% orthodontists scoring risk as 7-9 and <15% scoring 1-3.

Results

The e-Delphi was completed by 237 orthodontists who reached a professional consensus that ten risks should be discussed as part of consent for orthodontic treatment; demineralisation, 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 ten 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.

INTRODUCTION

Risk communication involves giving patients information about potential risks they may encounter as a result of a disease, a clinical procedure or a particular behaviour [1]. An orthodontist may be liable to legal action by the patient and to 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-centred 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] Due to 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 healthcare risks are communicated. This 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). Additionally, the wants and needs of the particular patient must be identified and further information given relative to the material risks relevant to that individual elicited by their circumstances and response.[10] While paternalism has no place within healthcare, neither does the abandonment of patients by healthcare professionals failing to contribute to the decision-making process. The principles of shared decision-making encourage healthcare professionals to use their expert opinion for the benefit of patients as part of the consent process. In addition, due to heuristic strategies to make quick and effortless decisions, patients often do not seek out new information but rely heavily on healthcare professionals advice about treatment.[5,11]

Law in many countries has now formalised 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 aims to gain a professional consensus on the risks that should be discussed as part of consent for orthodontic treatment.

MATERIALS AND METHODS

Ethical approval was granted by Cardiff University Dental School Research Ethics Committee (Ref 1507). A serial cross-sectional survey design using a modified e-Delphi technique was used. Two survey *rounds* were conducted nationally in the United Kingdom.

Survey development

The risks used as the pre-specified 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 of the deleterious or iatrogenic effects of treatment, or any potential adverse outcomes or consequences. Risks associated with specific treatment modalities, such as headgear, mini-screw 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 key words and phrases and controlled vocabulary, in the form of appropriate subject headings. The databases Ovid MEDLINE (1946 to 1 November 2016), EMBASE (1947 to 1 November 2016) and PsycINFO (1806 to 1 November 2016) were searched and search engines, such as Google (CA, USA) and Google Scholar (CA, USA), 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 email notifications from Ovid MEDLINE (Wolters Kluwer Health 2016). Relevant risks were extracted from the studies using a reference table system and two authors (JP and HP) generated a final list of risks, by combining similar risk categories and resolving conflicts by discussion.

Custom-made surveys using Key Survey (WorldAPP, Braintree, MA) 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 practising in a range of sectors (hospital and public and private practice) in South Wales (100% response rate). These individuals were chosen as a representative sample of professionals similar to those who would complete the Delphi exercise proper. 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 (Figure 1). To avoid weighting, risks were listed randomly in each round using a random number generator (Microsoft Office Excel).

Recruitment process and eligibility criteria

People with an email address registered on the British Orthodontic Society (BOS) membership database were deemed eligible to participate. Individuals registered as retired, international or core trainee members were excluded. Participant consent to be involved in the study was implicit on completion of the surveys and entry to a prize draw was offered to participants for completing the Delphi exercise.

Delivery and analysis

Round 1

The BOS disseminated the survey link directly to members. Two reminder emails were sent to participants, one and two weeks following initial contact. The survey was closed after a

further week. Email 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 were able to provide details in a free text box (Figure 1). A function was provided for participants to add extra risks they thought were relevant and that had not already been listed.

Round 1 analysis

Data were exported from Key Survey into Microsoft Office Excel and IBM SPSS Statistics (version 20, Armonk, NY) for analysis. The risk scores were reviewed against a pre-defined definition of consensus (Table 1). 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 analysed and coded by two authors (JP and HP), generating a list of specific circumstances for when each risk might apply.

The free text responses describing additional risks were analysed in a similar manner 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.

Round 2

Those participants who responded in Round 1 and provided a valid email address, were contacted and asked to complete the survey for Round 2. Similar to Round 1, reminder emails were sent and the survey was closed after three 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:

- Overall quartiles for the response scores from all participants.
- A reminder of their own score (if they scored the risk).

After taking the results of Round 1 into consideration, participants were asked to review the risks listed and re-score them. They were informed that for each risk they could change their score from Round 1 or keep it the same (Figure 2).

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.

Round 2 analysis

The definition of consensus was applied again, including only the responses from Round 2. Risks classified as *Consensus in,* following 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, the median score across risks from Round 1 was calculated for each participant. These scores were compared for those completing both rounds and those completing Round 1 only.

RESULTS

Identification of orthodontic treatment risks

The structured literature review identified 30 risks which were included in Round 1 of the Delphi exercise (Table 2).

Participants

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 individuals who participated in Round 1, 321 (93%) provided a valid email address and were invited to participate in Round 2. Of those 321 individuals who were invited to participate in Round 2, 237 (74%) responded.

The gender ratio of respondents was equal (Table 3). Three quarters of participants had practiced orthodontics for at least eleven years and the remaining for ten years or less. Over half of respondents worked mainly in the public health system, were BOS practice group members, had research experience involving patients and treated adults or a mix of cases. The proportion of respondents working in South-East England decreased in Round 2, whilst the proportion working in other regions was similar in both rounds.

Round 1

Using the definition of consensus (Table 1), nine risks were classified as *Consensus in* (demineralisation/caries, relapse, length of treatment, root resorption, pain/discomfort, consequences of doing nothing, appliances breaking, failure to achieve desired tooth movement(s), gingivitis) and four risks as *Consensus out* (Figures 3, 4 and Table 2). These risks were excluded from Round 2.

Of the risks that had not reached consensus (n=17), four 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, two risks were identified that had not already been represented and these were included in the list of risks forwarded for assessment in Round 2.

Round 2

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

Using the lists defined in Round 1, six risks (four original and two additional) were scored according to specific circumstances. Participants reached *Consensus in* when these risks were scored according to all but four of the specific circumstances (Table 2).

When comparing the median scores across risks from Round 1, those participants who completed Round 1 only, did not represent extreme views when compared to those participants completing both rounds (Figure 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 ten risks forming the consensus recommendation include; demineralisation, relapse, resorption, pain, gingivitis, ulceration, appliances breaking, failed tooth movements, treatment duration and consequences of no treatment. Delphi methods were deemed appropriate as healthcare professionals' communication of risk involves a blend of scientific evidence, social values and expert judgement.[17] The Delphi technique has been used to investigate risk disclosure for medical procedures,[18] develop clinical guidelines[19] and criteria to assess orthodontic outcomes[20] and assess the impact of reducing orthodontic treatment availability[21]. 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 3) and provided greater participant anonymity than these alternative methods would have allowed.[22] 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 2). 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.[11,12,23-25] This study suggests that orthodontists may not routinely communicate a number of treatment risks that are important to patients, such as problems eating and speaking.[12,26-29] These findings are in agreement with previous studies[30] that have shown patients and professionals to 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 effectively explain orthodontic risks to patients.

Direct to consumer companies and poorly trained orthodontic treatment providers lack the necessary education and focus on risk communication to provide effective consent for orthodontic treatment. (reference) This 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 whilst providing participant anonymity.[22] An ordinal scale of 1-9 was decided upon as it has been used effectively in previous Delphi studies[31,32] and is reliable for statistical analysis.[33] This scale was decided upon through steering group meetings of the research team which included a medical statistician (DF). A level of consensus was defined a priori based on previously reported Delphi methodology[32] as currently there are no guidelines for determining an acceptable level of consensus in Delphi studies.[34] 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.[32,35] 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[34] and therefore, the majority of the BOS membership were invited to ensure a sample size that would yield a meaningful statistical analysis. In addition, many techniques were used to maximise the response to the electronic questionnaires.[36] While participants' demographics differed between the rounds the views of non-responders to Round 2 were 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 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. A number of 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 be used to guide the development of risk communication tools, professional guidelines and patient resources.

CONCLUSIONS

A professional orthodontic consensus has been reached that ten 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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TABLES

Table 1: Definitions of consensus

Consensus classification	Description	Definition
Consensus in	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	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 own discretion)	≥ 70% participants scoring as 1-3 AND <15% scoring 7-9
No consensus	Uncertainty about importance of discussing risk as part of the consent process for orthodontic treatment	Anything else

Table 2: 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**
Demineralisation		Consensus in (0, 99)	• may affect 60-75% of patients[37] • severity varies from white spot lesions to frank cavitation[4]
Relapse		Consensus in (1, 98)	• 90% of patients affected 20 years after treatment[38] • can influence patient satisfaction[39]
Length of treatment		Consensus in (1, 95)	• influenced by non-adherence to clinical recommendations, individual variation in rates of tooth movement[40] and poor attendance[41]
Root resorption		Consensus in (2, 93)	• may affect 90% of patients[42] • severe root shortening may affect 5% of patients[43]
Pain/discomfort		Consensus in (3, 89)	• may affect >50% patients after appointments[44] • may affect adolescents more than other age groups[45]
Consequences of doing nothing		Consensus in (5, 86)	• patients with overjets >4mm have twice the odds of incisal trauma[46] • ectopic canines may undergo cystic change and cause resorption of adjacent incisors[47]
Appliances breaking		Consensus in (4, 85)	• majority of patients have breakages at >10% of appointments[48]
Failure to achieve desired tooth movement(s)		Consensus in (9, 76)	• may occur due to persistent residual spacing, poor compliance,[15] or ankylosis[49]
Gingivitis		Consensus in (7, 76)	• treatment can result in 0.23mm increased pocket depth[50]
Cuts and ulcers		Consensus in (4, 75)	• may affect 75-95% of patients[51]
Gingival recession/crestal alveolar bone loss	with patients with a pre-existing periodontal condition	Consensus in (0, 99)	• 36% of patients may have ≥1 anterior tooth surface with ≥2mm of bone loss[52]

	if there are specific anatomical considerations	Consensus in (1, 90)	• risk factors: a thin gingival biotype, excessive labio-lingual movement of the lower incisors,[53] pre-existing recession[54] and adult age[55]
	with adult patients	Consensus in (5, 72)	
	if using certain treatment modalities	No consensus (4, 67)	
Unfavourable growth	with specific skeletal patterns/malocclusions	Consensus in (0, 96)	• may occur in 15% of class II patients[56] • may occur due to a hypoplastic maxilla/prognathic mandible in class III patients[57] • may have a strong genetic predisposition[58] • may necessitate a surgical approach
Development/worsening of black triangles between teeth	with patients with pre-existing periodontal conditions/black triangles	Consensus in (0, 96)	• may appear unaesthetic and cause chronic food retention • prevalence in adult patients of 40%[59] • risk factors: adult patients and those with triangular-shaped crown form, pre-existing periodontal conditions,[60] or pre-orthodontic crowding[59]
	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[61] guidance states: “Antibiotic prophylaxis against infective endocarditis is not recommended *routinely* for people undergoing dental procedures” • high risk patients: history of infective endocarditis or prosthetic/repaired heart valves • 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 [62]
Tooth wear caused by opposing brackets	if using certain appliance types	Consensus in (5, 78)	• often affects maxillary incisal edges and canine tips[4] • may be problematic in patients with bruxism,[63] 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[29]
Periodontitis		No consensus (10, 61)	• treatment may have small detrimental effects on periodontal health in long-term[50]
Devitalisation of teeth		No consensus (8, 61)	• previously traumatised teeth may be at increased risk of devitalisation during treatment.[64]
Problems speaking		No consensus (11, 55)	• appliances may affect speech[65]
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/restorations on debond		No consensus (11, 26)	• can occur on removal of appliances and excess cement[66] • 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[67]
Risks associated with tooth extraction(s)		No consensus (69, 7)	• clinicians may discuss a number of complications associated with dental extractions
Teasing/embarrassment/impact of appliance on interpersonal relationships		No consensus (6, 7)	• young patients may be teased by their peers and embarrassed because of appliance appearance[68]
Temporomandibular dysfunction		No consensus (48, 7)	• a causal link has not been established with orthodontic treatment[69] • symptoms may resolve, remain the same, or become more severe during treatment

Soft tissue injury during placement/manipulation of appliance by clinician	Consensus out (70, 10)	• may be caused by clumsy instrumentation and chemical and thermal burns[4]
Negative effect of appliance on sleeping patterns	Consensus out (74, 9)	• appliances may affect sleeping patterns[70]
Radiation exposure	Consensus out (70, 9)	• 1 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[71]
Airway/ingestion risks	Consensus out (72, 8)	• a fifth of orthodontists may have managed an aspiration/ingestion incident[72] • may result in gastrointestinal perforation/infection, oropharyngeal laceration and airway obstruction[73] • face masks may reduce dust inhalation to a safe level[74]
Allergies to orthodontic materials	Consensus out (83, 5)	• latex allergy prevalence of <1% in general population but may be higher in atopic individuals and those with spina bifida[75] • risk factors for nickel allergy include female gender, asthma and piercings[76]
Cytotoxic effects/mutagenic potential of orthodontic materials	Consensus out (91, 2)	• commonly used materials have not been reported to have cytotoxic effects in vivo[77-79]

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 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 own discretion); ≥ 70% participants scoring as 1-3 AND <15% scoring 7-9

Table 3: Participant characteristics

		Round 1 respondents (% of Round 1 respondents)	Round 2 respondents (% of Round 2 respondents)
Gender	Male	168 (49)	121 (51)
	Female	177 (51)	116 (49)
Number of years practising 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	South-East England	92 (27)	48 (20)
	North England	70 (20)	53 (22)
	East England	45 (13)	33 (14)
	West England & Wales	91 (26)	66 (28)
	Scotland & Northern Ireland	47 (14)	37 (16)

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Figure captions:

Figure 1: Round 1 online survey

Figure 2: Round 2 online survey

Figure 3: Flow diagram of Delphi exercise

Figure 4: Core set of risks (classified as Consensus in during Delphi); percentage of participants scoring as 1-3, 4-6 or 7-9

Figure 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)