

**FEATURES
SECTION**

Current Products and Practice

An audit of the current consent practices of consultant orthodontists in the UK

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Abstract

Objective: To collect information on the current consent practices of consultant orthodontists for orthodontic and joint orthognathic treatment.

Design: Postal questionnaire.

Subjects and Methods: The questionnaire was sent to all 222 consultant orthodontists held on the database of the British Orthodontic Society. The questionnaire consisted of five multi-part questions requiring tick-box responses.

Outcome: A total of 199 questionnaires were returned.

Results: Written information on orthodontic treatment was provided by 56 per cent of respondents whilst 41 per cent obtained written consent. Written information on joint orthognathic treatment was provided by 47.5 per cent of respondents, whilst 20 per cent obtained joint written consent. Most who obtained written consent for orthodontics and joint orthognathic treatment used 16 years as an appropriate age for patients to provide their own consent.

Conclusions: Consent practice amongst consultant orthodontists varies, with 35 per cent providing neither written information nor seeking written consent prior to orthodontic or joint orthognathic treatment.

Index words:

Consent, Consultant
Orthodontist,
Orthodontics,
Orthognathic Surgery.

Received 7 February 2002; accepted 23 May 2002

Introduction

Medical consent varies from country to country and in some cases from state to state¹ and is frequently changed by new case law or occasionally as the result of pressure created by worldwide issues such as Human Rights.²

In the United States of America (USA), where the population is more litigious than in the UK, the medical and legal professions have, for some time, placed great importance on informed consent. As early as 1972 some states in the USA employed a 'prudent patient' test.³ This changed the emphasis from 'what a responsible body of medical opinion would tell people' to 'what a reasonable person would want to know about their treatment'.

In 1992 the Australian High Court went beyond the 'prudent patient' test and indicated that the Doctor

should disclose all information to the particular patient that they would think significant if he or she knew it existed.⁴ The same year in Canada the Supreme Court characterized the doctor–patient relationship as fiduciary.⁵ This implies that the relationship is based on trust, with the doctor having superior power and knowledge that he/she will exercise only for the patients good or in their best interest.

Meanwhile in Europe the European Human Rights Legislation was being proposed in the hope it would harmonize the countries of the European Economic Community (EEC) given that all member states still maintained their own domestic legal system. Some countries such as the Netherlands pre-empted this by updating their own Medical Acts. Interestingly in a recent paper on consent from the Netherlands the results indicate that patients are not always happy that their

dentist informs them of the possible treatment risks and alternatives.⁶ It could be argued that this may be because the levels of litigation have not increased sufficiently in Europe to focus the clinicians on this issue to the extent that it has in North America.

The English law on consent is still based around case law, although as part of the EEC the European Human Rights Legislation also applies. The Bolam Test,⁷ which is the basis for English case law on medical consent, states that a clinician 'must act in accordance with a practice accepted as proper by a responsible body of medical men skilled in the art'. In future, courts will be expected to take into account the case law of the European Court of Human Rights in Strasbourg, as well as English case law. In March 2001, the Department of Health in England (DOH) produced a 'Reference Guide to Consent for Examination or Treatment'⁸ up-dating healthcare professionals on the current position within English law. In addition, the English DOH is currently developing a new standardized NHS consent form. Although it is too early to predict how the European Human Rights Act will affect English medical law, the current advice provided in the Reference Guide is compatible with both European and English laws.

Consent for examination or treatment is a very topical issue in the United Kingdom. Recent events highlighted by the press and other media have made the public more aware of their right to be informed and involved in the consent process. The signature on a consent form should be a written record of that process.

There is a legal and an ethical reason to obtain consent before carrying out any medical or dental treatment.⁹ The legal reason is to avoid a criminal charge of battery or a civil claim of trespass to the person. The ethical reason is that the understanding, co-operation, and confidence of the patient are important to help ensure a successful outcome.

Orthodontic treatment carries risks that include failure to complete treatment, decalcification and root resorption. A treatment time-scale of 18–24 months may make it difficult for individuals to remember what was included in the consent process. A written record may therefore become legally important and also helpful in reinforcing a patient's commitment to treatment.

Orthodontic treatment within the United Kingdom is provided by four main groups.

1. General Dental Practitioners (GDP) who work as part of the General Dental Services (GDS) under the National Health Service Regulations. They may also

choose to work under private contract with each patient.

2. Specialists Practitioners in Orthodontics on the Specialist List who also may work within the GDS or in private practice, or both. They are a secondary referral point for the GDP.
3. Community Orthodontists who are generally salaried, work as part of the GDS, and whose role is designed to target disadvantaged groups.
4. The hospital-based Consultant Orthodontist who can be a secondary or tertiary referral point for the GDP or Specialist. They provide advice and treatment for the most severe malocclusions, train the future orthodontic specialists, co-ordinate orthodontic services within their area including the educational and training needs of the GDP, and provide outreach and multi-disciplinary treatment.

Orthognathic treatment is almost exclusively carried out as part of a multi-disciplinary team where the Consultant Orthodontist can work closely with the Consultant Maxillo-Facial Surgeon. Orthognathic treatment is one overall plan and yet it is the authors' perception that consent is often obtained separately for the orthodontics and the surgery, and insufficient emphasis placed on the fact that a stable result usually relies on the surgery being undertaken.

Aim

To collect information on the current consent practices of UK Consultant Orthodontists for orthodontic treatment and joint orthognathic treatment by means of a postal questionnaire.

Method

Following a small pilot survey completed by four Liverpool Consultant Orthodontists, a single-sided A4 questionnaire was sent by post to every consultant orthodontist on the British Orthodontic Society database in January 2001. There was a request to enclose an example of any consent form currently used and any written information provided.

Although the results of the survey were anonymized, a record was kept of those who replied in order to follow up non-responders. Two-hundred-and-twenty-two questionnaires were sent out and after 4 weeks a reminder was sent to the non-responders. In total 199 replies were eventually received, giving an excellent

response rate of 90 per cent. Over 50 of these replies enclosed an example of their written consent form.

Results

The questionnaires were analysed by the audit team at Warrington Hospital, and the results listed in Tables 1 and 2

Discussion

Written information on the benefits/risks of treatment

Written information allows patients to assimilate knowledge in their own time, reinforces verbal information, and can be referred to at a later date. Written information on the benefits/risks of orthodontic treatment was provided by 56 per cent of consultants as part of the consent process. While it is important to take time

to explain to patients the benefits and risks of treatment, it is very difficult for the patient and relatives to remember all the information and advice provided at consultation. Information leaflets are valuable in reinforcing this information and some are produced by the British Orthodontic Society including one on the benefits/risks of orthodontic treatment.

Routine written consent for orthodontic treatment

Written consent was routinely obtained for orthodontic treatment by 41 per cent of consultants. There is no requirement in English law (apart from some special circumstances³) to obtain written consent for treatment procedures. Consent can be equally valid whether implied or expressed, oral or written. A signature on a consent form does not indicate a valid consent if insufficient information has been provided to enable a considered choice to be made. Nevertheless, a signed consent form

Table 1 Response to questions on written information and written consent on orthodontic treatment and joint orthognathic treatment

Question	Yes	No	No response
1. Do you provide written information on the benefits/risks of orthodontic treatment?	111 (56%)	88 (44%)	0 (0%)
2a. Do you routinely obtain written consent for orthodontic treatment?	81 (41%)	118 (59%)	0 (0%)
3. Do you use a purpose designed consent form?	73 (37%)	8 (4%)	0 (0%)
4a. Do you provide written information on the benefits/risks of combined orthognathic treatment as part of a consent process?	95 (47.5%)	99 (50%)	5 (2.5%)
4b. If yes, is it made clear that failure to have the orthognathic surgery is likely to compromise the final outcome?	60 (30%)	32 (16%)	3 (1.5%)
5a. Do you routinely obtain consent for both the orthodontic treatment and the orthognathic surgery as one combined procedure?	39 (20%)	150 (75%)	10 (5%)
5b. If yes, who would normally obtain such consent?	Orthodontist 16 (42%)	Surgeon 7 (16%)	Both 16 (42%)

Table 2 Response to questions on the age at which consultants consider it appropriate for the patient to sign his/her own written consent

Question	Age	Number	Percentage
2b. If yes to Question 2a, at what age do you normally ask the patient to give his or her own written consent to orthodontic treatment?	12	3	4%
	15	1	1%
	16	68	84%
	17	2	2%
	18	4	5%
	16–21	3	4%
5c. If yes to Question 5a, at what age do you normally ask the patient to give his or her own written consent to combined orthodontic treatment and orthognathic surgery?	12	1	2.5%
	16	19	49%
	18	5	13%
	16–21	3	7.5%
	No Response	11	28%

following an informed discussion of the benefits and risks with an individual patient can be a useful written record of that consent process.

Written information on the benefits/risks of treatment followed by written consent

From this audit, 78 per cent of consultant orthodontists who obtained written consent also provided written information, whereas 59 per cent of those who did not obtain written consent did not provide written information either.

Age at which written consent is given for orthodontic treatment

Of those who obtained written consent for treatment 84 per cent asked patients to sign their own consent form at the age of 16; a few chose to obtain written consent from patients of a younger or older age (Table 2). In English law, individuals aged 16 or over have, under Section 8 of the Family Law Reform Act 1969, a statutory right to consent to their medical, surgical or dental treatment. Individuals below 16 years of age can provide valid consent if the clinician believes they have sufficient understanding of what is involved in the proposed treatment proposed i.e. they are Gillick-competent.¹⁰

Purpose designed consent form

The British Orthodontic Society developed and promoted the use of a purpose design consent form in 1995. In this audit, where written consent was obtained, 90 per cent of respondents reported using a purpose designed consent form. The majority returned with the audit were produced by the British Orthodontic Society or were almost identical in layout. The remainder appeared to be standardized NHS consent forms used throughout each Trust for a variety of medical procedures. Finally a few forms were specific to orthodontics and some of these also contained written information on orthodontics and produced multiple carbon copies for retention by the patient and hospital administration. Some clinicians recorded what was discussed in the clinical notes. This allows for individualization of the consent process, but does not allow the patient the opportunity to see what was written unless they specifically request access to the clinical case notes.

Written information on the benefits/risks of combined orthodontic/orthognathic treatment and consent as one procedure

Written information about orthognathic cases was provided by 47 per cent of respondents and 30 per cent emphasized that without surgery a satisfactory stable result was unlikely to be achieved. Only 20 per cent of consultants routinely obtained consent as one combined procedure. This is important, as sometimes following preparatory orthodontic treatment, when the upper and lower arches are aligned, patients will question the need to proceed to the surgical procedure and some may decide to abandon further treatment. It is essential that patients understand the 'combined approach' necessary to achieve the optimum result, with the best chance for stability. Written information and combined consent would help to reinforce in patients' minds the necessity for both the orthodontics and surgery that are required to obtain the best result. Inevitably, surgeons will wish to obtain their own consent immediately prior to surgery or perhaps the original consent could be updated to reinforce the surgical risks.

Who obtains consent for joint orthognathic treatment?

This was either the orthodontist alone (42 per cent) or with the surgeon (42 per cent). In a minority of cases (16 per cent) the surgeon alone obtained consent for the joint treatment. Ideally, the consent process should take place at a joint clinic with both orthodontist and surgeon in attendance. However, as long as the process is documented, the signing of the consent form can take place at a subsequent orthodontic clinic prior to treatment starting. This allows time for patients to assimilate the information and provide informed consent.

Age at which written consent is given for joint orthognathic treatment

Of those who obtain written consent for joint orthognathic treatment, 49 per cent asked patients to give their own consent at 16 years of age (Table 2); one consultant indicated 12 years of age, but it is debatable whether the average 12-year-old would be considered Gillick-competent in these circumstances.

Summary and recommendations

The National Audit Office report on clinical negligence¹¹ expressed concern at the cost of settling current

and future clinical negligence claims. It is likely that Orthodontics, although not a high-risk speciality will follow this trend.

Many consultant orthodontists already appear to be providing written information on the benefits/risks of treatment. Some appear to have written their own information leaflets whilst others use the British Orthodontic Society standard leaflets on various aspects of orthodontic treatment.

A number of respondents indicated pressure from their Trusts to use the standardized NHS consent form and this is a trend that is likely to continue. Some consultants appear to be using consent forms that produce multiple copies. The practice of providing a copy for the patient, and another copy that can be stored safely in the department or office in the event the clinical notes are lost, has much to recommend it.

If consent is considered appropriate for orthodontic treatment, then patients can sign their own consent forms under case law below the age of 16 if they are Gillick-competent. It is thought to be unlikely that such a scenario would arise for routine orthodontics, bearing in mind the fact that most patients will be commencing orthodontic treatment between 10 and 14 years of age, well below the age of 16.

The potential morbidity/mortality is increased with a combined orthodontic/surgical approach. Therefore, it would appear especially important that adequate information is provided and that the consent is for the combined procedure at the outset. This can be updated/reinforced by the surgeon immediately prior to surgery. The age of consent for treatment is more relevant in this group. Individuals may start orthodontic preparation prior to surgery at 14 or 15 years of age, and could therefore only sign for themselves if Gillick-competent. Under current statute, individuals are entitled to sign for themselves at 16 or 17 years of age, although those with parental responsibility can still sign on their behalf. It must be remembered that once patients are 18, then no one can sign on behalf of that person other than the individuals themselves, provided they are competent. In the case of incompetent patients then healthcare professionals must act in the patients' best interest, as it is their common law duty to do so.

Recommendations

1. As part of the consent process, written consent should be obtained for routine orthodontic treatment on a standardized NHS consent form with appropriate written information leaflets provided. One copy of the written consent should be given to the patient another retained in the case notes, and a third copy kept safe within the department or office in case the clinical notes go missing.
2. Many national associations (for example, the British Orthodontic Society) produce high quality leaflets and it would seem logical for reasons of consistency that these are adopted.
3. Special consideration should be given when seeking consent from patients undergoing a combined orthodontic/orthognathic surgery approach. Written consent to include the orthodontics, and the anticipated surgery should be obtained following a consultation on a combined clinic with both surgeon and orthodontist. The consent for surgery can be repeated immediately prior to the surgical procedure.

Acknowledgements

The authors would like to thank Mrs Veronica Brash for assistance with the tables, Mrs Beryl Mooney for secretarial support, and all those consultants who participated in the survey.

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