The Journal of Laryngology & Otology

cambridge.org/jlo

Consent for functional endoscopic sinus surgery: are we complying with the law?

H Raja and R Talwar

ENT Department, Luton and Dunstable University Hospital, Bedfordshire Hospitals NHS Foundation Trust, Luton, UK

Abstract

Objective. To assess the current standard of consent for functional endoscopic sinus surgery and determine whether it complies with the law following the Montgomery ruling.

Methods. Ten complications following functional endoscopic sinus surgery were identified as common or serious from a literature search. Using questionnaires, ENT surgeons were asked which of these complications they discussed with patients, and patients were asked how seriously they regarded those risks using a five-point Likert scale.

Results. Consent practice from 21 ENT surgeons and data from 103 patients were analysed. The 'reasonable patient' would expect to be consented for all risks, except for pain, and scarring or adhesions. Most ENT surgeons would routinely discuss all risks that were considered significant, except for facial paraesthesia (29 per cent) and damage to the nasolacrimal duct (24 per cent). A negative change in sense of smell was not mentioned by 29 per cent of surgeons.

Conclusion. This paper demonstrates that the current consent process for functional endoscopic sinus surgery is likely to be substandard medicolegally.

Main Article

Mr H Raja takes responsibility for the integrity of the content of the paper

Cite this article: Raja H, Talwar R. Consent for functional endoscopic sinus surgery: are we complying with the law? *J Laryngol Otol* 2023; **137**:81–84. https://doi.org/10.1017/S0022215122000974

Accepted: 12 April 2022
First published online: 21 April 2022

Key words:
Endoscopic Sinus Surgery; Informed Consent; Medicolegal Aspects; Communication; Rhinology

Author for correspondence:
Mr Haseem Raja, ENT Department, Luton and Dunstable University Hospital, Bedfordshire Hospitals NHS Foundation Trust, Lewsey Road, Luton LU4 0DZ, UK
E-mail: haseemraja@hotmail.com

Introduction

Functional endoscopic sinus surgery (FESS) is one of the most common ENT procedures performed, with approximately 19 000 cases conducted by the National Health Service (NHS) in England each year.[1] It is typically carried out to restore sinus ventilation and normal function, often in patients with chronic rhinosinusitis who do not respond adequately to medical treatment. Despite being a minimally invasive surgical technique, FESS is not without risks. The incidence of major complications such as orbital injury and meningitis has been reported to be approximately 0.5 per cent.[2] Discussion of these and other potential complications is critical to obtaining informed consent from patients.

In 2015, the UK Supreme Court case of 'Montgomery v Lanarkshire Health Board' changed the practice of informed consent.[3] In this case, the claimant gave birth to a boy with cerebral palsy as a result of shoulder dystocia and, despite her short stature and diabetes, was not warned of these rare risks (0.1 per cent and 9–10 per cent, respectively). In addition, an alternative option of a Caesarean section to reduce these risks was not discussed, as it was felt that it was not in her best interests. The claimant successfully sued for negligence, arguing that all risks should have been explained to her by the treating obstetrician, and she was awarded over £5 million in damages. This landmark case rejected the Bolam standard, defined as acting in accordance with a responsible body of medical opinion, that had long governed the surgical consent process.[4] Guidance from the General Medical Council (GMC) and Royal College of Surgeons of England was duly updated, with surgeons being required to provide information about all material risks relating to a procedure, including disclosing any risk to which the individual person would attach significance.[5]

Objectives

This study aimed to examine the consenting practice for FESS following the Montgomery ruling. We specifically focused on defining those FESS risks considered significant by the 'reasonable patient'. We also compared whether the 'reasonable patient' and ENT surgeon agreed about which risks should be discussed during the consent process.

Materials and methods

Design and setting

A cross-sectional study was performed at Bedfordshire Hospitals NHS Foundation Trust between 1 January 2020 and 28 February 2020. We completed a literature search to identify 10 complications listed as common or serious following FESS (Table 1).[2,6–10]

Two questionnaires were devised to record the following: (1) how routinely ENT surgeons discussed the 10 complications during the consent process; and (2) how seriously

Table 1. Incidence of common FESS complications

Complication	Incidence (%)
Bleeding	0.2–21.1
Infection	1–10.1
Pain	0.7–4
Scarring or adhesions	0.5–5
Orbital injury leading to double vision or blindness	0.06–0.5
Damage to nasolacrimal duct leading to watery eye	0.1–1.7
Facial paraesthesia	0.3–3
CSF leak & meningitis	0.06–2.3
Negative change in sense of smell	0.4–9
Recurrence of symptoms requiring further surgery	6–15

FESS = functional endoscopic sinus surgery; CSF = cerebrospinal fluid

patients regarded each of these complications using a five-point Likert scale. ENT surgeons were asked to provide any reasons for omitting complications from their consent process. At the time of questionnaire completion in clinic, both authors (HR and RT) were present to answer any queries that patients may have had about the complications listed.

We defined the 'reasonable patient' as being representative of the views of at least 50 per cent of patients. The standard of a 'responsible body of medical opinion' was similarly defined as those views representative of at least 50 per cent of ENT surgeons.

Participants

Patients were identified through attendance at adult ENT clinics. ENT surgeons were primarily identified from those working at the Trust, with a smaller proportion being contacted via e-mail from other centres across England.

Main outcome measures

The main outcome measure was the association between risks deemed as serious or very serious by the 'reasonable patient' and risks routinely discussed by the ENT surgeon with patients during the consent process.

Data analysis

Statistical analysis was carried out using IBM SPSS Statistics version 21.0 software (IBM, Armonk, New York, USA). Results from the two groups (ENT surgeons and patients) were compared using the test of proportions, with statistical significance set at $p < 0.05$.

Ethical considerations

Completion of the questionnaires was voluntary and all responses were anonymised. The NHS Research Ethics Committee review confirmed that no ethical approval was required.

Results

We received 21 out of 24 questionnaire responses (84 per cent) from ENT surgeons (11 consultants and 10 registrars). All complications were routinely discussed by surgeons, except for the following: damage to the nasolacrimal duct leading to epiphora (24 per cent), facial paraesthesia (29 per cent), scarring or adhesions (38 per cent), pain (52 per cent), and a negative change in sense of smell (71 per cent) (Table 2).

The most common reason given by ENT surgeons for not routinely consenting for damage to the nasolacrimal duct and facial paraesthesia was that these were infrequent complications of FESS (9 out of 16 (56 per cent)) and 6 out of 15 (40 per cent) respectively). Similarly, 50 per cent (3 out of 6) of those ENT surgeons who did not mention a negative change in sense of smell as a potential complication cited its low incidence post-surgery as their reason. In addition, around 31 per cent of ENT surgeons (5 out of 16) who did not consent for damage to the nasolacrimal duct attributed their reasoning to it being a complication that should never occur during routine FESS.

A total of 103 questionnaires were completed by patients. The 'reasonable patient' deemed all complications serious or very serious, except for pain (34 per cent), and scarring or adhesions (48 per cent) (Table 2).

Discussion

Obtaining informed consent for a procedure is a vital part of surgical practice. It is a process that, under English common law and GMC guidance, requires the surgeon to fully disclose all relevant treatment options (including no treatment), and state their respective risks and benefits to a patient, allowing the patient to make a fully informed decision. This requires time, patience and good communication skills.

To the best of our knowledge, this is the first study to assess the consent process for FESS and determine whether ENT surgeons are complying with the law following the Montgomery ruling. We found a significant difference between the FESS complications that ENT surgeons routinely discuss with patients and those that the 'reasonable patient' would want to know about during the consent process. Two potential complications routinely omitted by ENT surgeons were damage to the nasolacrimal duct leading to epiphora and facial paraesthesia. Another important complication not discussed often enough by ENT surgeons was a negative change in sense of smell. Several studies have reported the negative impact of these complications on quality of life.[11,12] Wolf *et al.* also found that only a small proportion of ENT surgeons disclose the risk of anosmia and epiphora as possible complications of FESS.[13]

Complications of pain and bleeding associated with FESS exist on a spectrum, ranging from mild to severe. This was discussed with patients if specific questions arose regarding their severity during questionnaire completion. For example, in the case of a severe nosebleed, patients would be informed about the possible need for nasal packing, blood transfusion (if applicable), or a return to the operating theatre to arrest the bleeding. The 'reasonable patient' in our study did not consider pain to be a serious or very serious risk of FESS. Navaratnam and colleagues have reported, however, that unnecessary pain is one of the most frequently cited reasons for rhinology litigation.[14] It would therefore seem prudent, in addition to managing patients' expectations before surgery and offering good post-operative analgesia, still to include pain on the FESS consent form, to mitigate potential claims.

We found that most ENT surgeons opted against discussing complications such as facial paraesthesia and a negative change in sense of smell primarily because of their perceived

https://doi.org/10.1017/S0022215122000974 Published online by Cambridge University Press

Table 2. FESS complications routinely discussed by surgeons *vs* complications viewed as serious by patients

Complication	Complication deemed serious or very serious by patients (%)	Complication routinely discussed by surgeons with patients (%)	*P*-value for test of proportions
Complication deemed serious or very serious, & routinely consented for			
– Bleeding	50	100	<0.0001
– Infection	81	100	0.0278
– Orbital injury leading to double vision or blindness	94	100	0.2585
– CSF leak & meningitis	95	95	0.9840
– Negative change in sense of smell	62	71	0.4179
– Recurrence of symptoms requiring further surgery	83	90	0.3681
Complication deemed serious or very serious, & not routinely consented for			
– Damage to nasolacrimal duct leading to watery eye	83	24	<0.0001
– Facial paraesthesia	85	29	<0.0001
Complication not deemed serious or very serious			
– Pain	34	52	0.1118
– Scarring or adhesions	48	38	0.4295

FESS = functional endoscopic sinus surgery; CSF = cerebrospinal fluid

low incidence and severity. A recent study exploring the consent process in septoplasty found that a significant proportion of ENT surgeons do not meet patients' expectations regarding risk disclosure for similar reasons.[15] In addition, a few ENT surgeons specifically did not consent for damage to the nasolacrimal duct because they felt it should never occur during routine FESS. These explanations, whilst possibly meeting the Bolam test, fail to adhere to the new legal standard defined by the 'Montgomery v Lanarkshire Health Board' case. This landmark case transformed the consent process towards a more patient-centred approach, placing responsibility on the surgeon to tailor the consultation accordingly and to inform patients of any material risks associated with a procedure. Patients' expectations have generally increased; they frequently now expect to be informed about all possible risks, irrespective of their incidence and severity, so that they can consider information and make informed personal decisions. The burden of proof for informed consent has been shifted in favour of the patient, so it is of paramount importance that surgeons are fully aware of these changes.

Litigation in NHS hospitals has also significantly increased over the last decade.[16] A total of 727 NHS ENT clinical negligence claims were made between April 2013 and April 2018.[14] Of these, around 15 per cent were related to the consent process, amounting to approximately £17 342 685, at a mean cost per claim of £162 081.[14] Around 23.5 per cent (171 out of 727) of all claims were related to rhinology, with 27 per cent of those (46 out of 171) attributable to FESS.[14] This, in keeping with practice from the USA, makes it the most common rhinology operation associated with litigation claims.[17] Despite insufficient data to determine how many of those claims arose from lack of informed consent, specifically failure to disclose all material risks, a separate study found that over a third of negligence claims relating to FESS injuries are due to such reasons.[18] Furthermore, fraught with potentially serious complications given its intimate location to important structures such as the orbit and anterior skull base, FESS has the highest mean cost per claim (£172 978) compared to other ENT procedures.[14] These figures provide a glaring and timely reminder that surgeons are open to litigation claims if their consent practice falls below the expected standard, particularly as FESS is a common procedure owing to the high prevalence of chronic rhinosinusitis. In addition, limiting the costs of litigation may be crucial for the overall financial sustainability of the NHS.

Given the complexity of informed consent and the potential for litigation with FESS, we offer the following suggestions to improve compliance with the law and patients' experience of the consent process, as follows.

First, use a standardised consent form for FESS that includes all complications listed in this study. Surgeons would have a framework for discussion and not be expected to remember all complications. This will ensure errors of omission do not occur, whilst providing more time for explanation, and appropriate safety-netting and advice on how to manage potential complications, including details of what to do if the patient needs further review in the post-operative period. A standardised consent form would reap further rewards by nullifying the potential litigation risk stemming from poor legibility. Most importantly, extra space should be provided on the consent form to include additional material risks that may emerge during the patient–doctor dialogue.

Second, provide high-quality information regarding FESS. Whilst the provision of materials, written or online, should be routine practice for all surgeons, these need to be quality-assured and designed for the layperson, meeting universal health literacy guidelines. A good option that meets these criteria would be the patient leaflet entitled 'About Functional Endoscopic Sinus Surgery (FESS)' produced by ENT UK (the professional membership body representing ENT in the UK). This will help patients to better understand the procedure, to deliberate and to re-confirm their decision to proceed with FESS.

Third, keep clear, detailed and contemporaneous notes of all patient discussions. ENT surgeons need to be mindful that a claim for clinical negligence relating to inadequate consent for FESS can be brought at any time. This can be without warning and sometimes many years after surgery was performed. It is therefore imperative to keep clear and detailed notes of all patient discussions. This should include details that the surgeon has considered all material risks that are relevant to the individual patient, discussed other treatment

https://doi.org/10.1017/S0022215122000974 Published online by Cambridge University Press

options including no treatment, and the patient has understood and considered all of this at the time of surgery. Failure in doing so can result in surgeons finding it very difficult or impossible to defend a subsequent claim relating to a patient not being informed about potential complications.

Fourth, consider extending the time of consultations. Obtaining informed consent should be viewed as a multi-stage process, rather than a tick-box exercise that is rushed. In a study of 575 patients scheduled for elective surgery, Fink and colleagues found that total consent time was the strongest predictor of patient comprehension. The authors reported that comprehension was maximised when the consent process took between 15 and 30 minutes.[19] Surgeons may therefore need to consider extending the time of their consultations, particularly as they are often required to work in busy and time-pressured out-patient clinics. It is important to acknowledge that this may have ramifications on service provision, such as a reduction in reviews for newly referred patients and failure to meet strict pathway targets, both of which can incur financial losses within the NHS.

Limitations

Our study has some limitations. First, our questionnaire was limited to 10 complications. It is plausible that the 'reasonable patient' may have deemed other complications as serious or very serious. Second, the association of these complications with patients who have had FESS, to determine what the patients felt was relevant or important to them, was not established before questionnaire formulation. This additional level of information could provide further robustness regarding those risks that the 'reasonable patient' considers serious or very serious.

- Functional endoscopic sinus surgery (FESS) is a commonly performed ENT procedure associated with a range of serious risks
- ENT litigation has increased, with approximately 15 per cent of all clinical negligence claims related to lack of informed consent
- The case of 'Montgomery v Lanarkshire Health Board' has transformed the practice of informed consent
- ENT surgeons should discuss nasolacrimal duct damage, facial paraesthesia and impaired sense of smell as potential FESS complications
- Surgeons should keep clear, detailed and contemporaneous notes of all patient discussions relating to the informed consent process

Finally, questionnaires were sent to a relatively small number of surgeons, with a near equal split between registrars and consultants. In light of their added clinical experience and heightened awareness of malpractice claims, we appreciate that consultants may be more risk-aware compared with registrars, disclosing a potentially broader and more complete range of risks. This would likely result in an underestimation of complications disclosed by the 'responsible body of medical opinion' in our study. However, to best reflect what happens in everyday NHS clinical practice, we thought it was important to include both consultants and registrars.

Conclusion

Functional endoscopic sinus surgery is one of the most commonly litigated ENT procedures given the potential risks involved. This study has demonstrated that a significant proportion of surgeons do not routinely mention all the risks that the 'reasonable patient' would want to know before undergoing FESS. ENT surgeons should take the necessary steps to ensure their consent practice for FESS is robust, including a thorough explanation of all material risks, to mitigate potential medicolegal claims.

Competing interests. None declared

References

1 NHS Digital. Hospital Episode Statistics, Admitted Patient Care, England – 2019–20: Main procedures and interventions. In: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2019-20 [15 December 2021]
2 Krings JG, Kallogjeri D, Wineland A, Nepple KG, Piccirillo JF, Getz AE. Complications of primary and revision functional endoscopic sinus surgery for chronic rhinosinusitis. *Laryngoscope* 2014;**124**:838–45
3 The Supreme Court. Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland). In: https://www.supremecourt.uk/cases/uksc-2013-0136.html [15 December 2021]
4 Brahams D. Doctor's duty to inform patient of substantial or special risks when offering treatment. *Lancet* 1985;**1**:528–30
5 Royal College of Surgeons of England. Consent: Supported Decision Making. In: https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/ [15 December 2021]
6 ENT UK. Functional Endoscopic Sinus Surgery. In: https://www.entuk.org/functional-endoscopic-sinus-surgery-fess [15 December 2021]
7 Dalziel K, Stein K, Round A, Garside R, Royle P. Endoscopic sinus surgery for the excision of nasal polyps: a systematic review of safety and effectiveness. *Am J Rhinol* 2006;**20**:506–19
8 Suzuki S, Yasunaga H, Matsui H, Fushimi K, Kondo K, Yamasoba T. Complication rates after functional endoscopic sinus surgery: analysis of 50,734 Japanese patients. *Laryngoscope* 2015;**125**:1785–91
9 Shah SJ, Hawn VS, Zhu N, Fang CH, Gao Q, Akbar NA *et al*. Postoperative infection rate and associated factors following endoscopic sinus surgery. *Ann Otol Rhinol Laryngol* 2022;**131**:5–11
10 Hosemann W, Draf C. Danger points, complications and medico-legal aspects in endoscopic sinus surgery. *GMS Curr Top Otorhinolaryngol Head Neck Surg* 2013;**12**:Doc06
11 Blomqvist EH, Brämerson A, Stjärne P, Nordin S. Consequences of olfactory loss and adopted coping strategies. *Rhinology* 2004;**42**:189–94
12 Shin JH, Kim YD, Woo KI; Korean Society of Ophthalmic Plastic and Reconstructive Surgery (KSOPRS). Impact of epiphora on vision-related quality of life. *BMC Ophthalmol* 2015;**15**:6
13 Wolf JS, Chiu AG, Palmer JN, O'Malley BW Jr, Schofield K, Taylor RJ. Informed consent in endoscopic sinus surgery: the patient perspective. *Laryngoscope* 2005;**115**:492–4
14 Navaratnam AV, Hariri A, Ho C, Machin JT, Briggs TW, Marshall A. Otorhinolaryngology litigation in England: 727 clinical negligence cases against the National Health Service. *Clin Otolaryngol* 2021;**46**:9–15
15 Raja H, Talwar R. Consent for septoplasty: are we meeting patients' expectations? *Med Leg J* 2021;**89**:237–40
16 Lane J, Bhome R, Somani B. National trends and cost of litigation in UK National Health Service (NHS): a specialty-specific analysis from the past decade. *Scott Med J* 2021;**66**:168–74
17 Tolisano AM, Justin GA, Ruhl DS, Cable BB. Rhinology and medical malpractice: an update of the medicolegal landscape of the last ten years. *Laryngoscope* 2016;**126**:14–19
18 Lynn-Macrae AG, Lynn-Macrae RA, Emani J, Kern RC, Conley DB. Medicolegal analysis of injury during endoscopic sinus surgery. *Laryngoscope* 2004;**114**:1492–5
19 Fink AS, Prochazka AV, Henderson WG, Bartenfeld D, Nyirenda C, Webb A *et al*. Predictors of comprehension during surgical informed consent. *J Am Coll Surg* 2010;**210**:919–26

https://doi.org/10.1017/S0022215122000974 Published online by Cambridge University Press