Misleading information before lower third molar surgery – 40 years of failing our patients?

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Key points

The author contends that the research previously used is erroneous and misleading.

This research has been superseded by modern imaging techniques and change in interpretation is now required to fulfil the requirements of the Montgomery judgement. It is incumbent on practitioners to provide real and accurate information to patients for valid consent. Present processes fail to do this, which calls into question the validity of the consent process in many cases.

Abstract

Lower third molar removal is a common surgical procedure that, like all surgery, carries with it inherent risks. One primary risk of significance is inferior dental nerve injury, which can have a significant impact on patients' lives. Conventional consenting usually involves the generic discussion of risks of inferior dental nerve injury but without any substantive personalised risk assessment. Following the Montgomery judgement, these warnings have to be considered both inadequate and potentially misleading, as they are based on population research that is inherently flawed; pre-surgical risk assessments should be focused on the individual. This paper will consider the inadequacy of current consenting protocols and will suggest how we might offer clearer guidance to our patients when seeking valid consent for third molar surgery.

Background

The landmark March 2015 Supreme Court Montgomery judgement¹ has precipitated any number of doomsday-esque expositions in both the medical^{2,3,4} and dental^{5,6,7} press with respect to its purported impact on the day-today delivery of clinical care. This paper intends to stimulate discussion among colleagues and to – hopefully – encourage reflection upon our present practise. Its content and opinions may challenge contemporary protocols to a perhaps uncomfortable degree but the author considers the time to be right for such views to be aired.

At present, consenting procedures for mandibular third molar removal would generally be expected to focus upon discussion of the risks of inferior dental and lingual nerve injury. That these risks exist is a given; they have been reported upon almost *ad*

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infinitum. There is a substantial back catalogue of available publications, many basically duplicating previous studies, yet it appears that little substantive progress in quantifying the legitimate risks to patients has been made over the decades. In the view of the author, such studies have minimal merit. Their methodology is frequently flawed, their comparisons are inappropriate and their interpretations misleading. In reality, these compare apples with pears and yet somehow purport to cultivate prize tomatoes. The opinion of the author is that contemporaneous concepts used in disclosure of the risks of nerve injury during mandibular third molar surgery are fundamentally unsound and indeed, potentially misleading. Moreover, ill-founded anxieties and misconceptions in relation to these risks can give rise to defensive and potentially inappropriate treatment recommendations by clinicians and misguided choices by patients.

Introduction

UK non-criminal (civil) law can be conveniently divided into statutory and so-called common law components. Statutory law is essentially that set out in Acts of Parliament and other similarly cherished tomes, whereas, by way of contrast, common law (sometimes also referred to as case law) is that which has instead evolved organically on the principle of precedent and is extrapolated from decisions reached in comparable historic cases. In other words, statutory law is that constructed by parliament and common law is that developed by judges, albeit in the main by extremely senior judges.

The vast majority of claims for compensation in relation to medical and dental procedures are brought in the tort (aka a civil wrong) of negligence. For the actions and/or omissions of a doctor or dentist to be considered negligent by a judge, it is necessary for the plaintiff's (patient's) representative to demonstrate firstly, that the clinician breached their duty of care to the patient and then, that this breach of duty in turn directly caused the loss or harm being alleged. The greater part of the legal playing field upon which medical and dental negligence cases are contested is framed within the boundaries of common law.

Almost all readers will be familiar with the Bolam⁸ judgement. This iconic 1957 benchmark case enshrined in common law the doctrine that a clinician could not be considered to have breached their duty of care to their patient if they had acted in accordance with an accepted body of relevant contemporary professional medical (or of course, dental) opinion. This is possibly the earliest example of peer review in

action, with the requisite legal yardstick being entirely profession-driven.

Possibly somewhat surprisingly, the Bolam principle with respect to the nature and standard of treatment being delivered was not extended to include the obtaining of what is now generally referred to as valid consent until as relatively recently as the Sidaway9 judgement in 1985. This confirmed that those risks a clinician is required to disclose to a patient as part of the consenting procedure were, yet again, confined to those which a reasonable body of relevant medical opinion would consider to be material under the particular circumstances. As such, it can readily be seen that the relevant legal yardstick remained wholly profession-driven. It should nevertheless be noted that Sidaway was a 4-to-1 majority decision reached in the House of Lords. In his eerily prophetic sole dissenting judgement, Lord Scarman opined that 'the test of materiality is whether...a reasonable person in the patient's position would be likely to attach significance to the risk'.9 In other words, the venerable law lord was of the view that the touchstone was not necessarily simply relevant professional medical opinion taken in isolation, but rather that which the reasonable patient would wish to know. While this dissenting judgement did not, by definition, come to reflect UK law at the time, it nevertheless slightly cracked open the door, so to speak, to at least the possibility of an objective patient-driven test with respect to the disclosure of risks associated with treatment subsequently being introduced.

It is beyond the scope of this article to consider in any detail those cases which might have in any way served to undermine or otherwise 'chip away' at the Sidaway doctrine in the interim. Be this as it may, there can be little doubt that, by 2015, UK life and society were in a multitude of ways unrecognisable from that which had prevailed a mere three decades earlier, back in 1985. In particular, information - including that pertaining to medical treatment and the potential risks associated with this - had become infinitely easier for members of the public to access. As a consequence, patients were rightly considered to be better informed and no longer dependent exclusively on a patriarchal medical hierarchy to direct and/or control its flow.

On this basis, the circumstances in the now almost equally familiar Montgomery¹ judgement were readily distinguished from any fading echoes of the bygone Sidaway era. The Supreme Court wholeheartedly embraced the doctor-patient professional relationship as having inexorably evolved and patients no longer being simply passive recipients of 'doctor knows best' medical care. They were instead considered to be informed consumers actively exercising rights and choices, as indeed properly befits the aspirations of the eBay and Netflix generation. It was accordingly determined that, in order for consent to be considered valid, a clinician must be able to demonstrate having disclosed all material risks associated with the treatment being proposed. Furthermore, the Montgomery test of materiality was not confined to only those risks which the reasonable patient might wish to know, but extended to those which the particular patient under consideration might wish to know. This requirement is an entire order of jurisprudential magnitude beyond even that intimated by Lord Scarman's monumentally insightful, dissenting judgement back in the analogue age of Sidaway. As a consequence, the requisite standard in terms of disclosing risks as part of a consenting procedure is now no longer profession-driven. It is not even the objective, patient-driven standard tentatively mooted by Lord Scarman almost four decades ago. It is instead a subjective patient-driven standard, with the profession on the face of matters seemingly having involuntarily relinquished all control. However, despite this apparently seismic shift and the perceived concomitant increased burden inflicted on clinicians, Montgomery has, in reality, done little more than to bring the common law in line with pre-existing professional standards. By way of illustration, the General Dental Council has instructed registrants since as early as 2013 well in advance of the Montgomery judgement - that 'you should find out what your patients want to know, as well as what you think they need to know?10

The problem

Prior to undertaking lower third molar surgery, it is usual practice to warn patients of the risks of both inferior dental and lingual nerve injury (although, anecdotally at least, the latter appears to be less comprehensively addressed). Such warnings are generally accompanied by a discussion of other impacts of the proposed surgery, such as swelling, bruising, pain and trismus. Such considerations might more correctly be considered as side effects or consequences, not complications, that occur as a result of surgery, or indeed any injury, at any anatomical site. Additional complications, such as intractable infection and, rarely, fracture of the mandible, may also be considered.

In 2011, Britten and colleagues11 undertook a survey of colleagues, including consultant oral and maxillofacial surgeons, which demonstrated that warnings of risks of injury to these particular nerves were provided but that a significant proportion (16%) did not quantify these risks and that the majority did not document any detail of such warnings, either on the consent form and/or within the clinical records. Some surgeons provided patients with information leaflets which included generalised risk statistics. The current patient information leaflet produced by the British Association of Oral Surgeons quotes risks of 2-20% with respect to temporary changes in sensation and 0.5-2% with respect to permanent change12 but does not specifically distinguish between the lingual and inferior dental nerve distributions. The patient information leaflet produced by the British Association of Oral and Maxillofacial Surgeons quotes similar, if slightly lower, figures.13

Thus, given the contemporaneous data provided by the specialist associations and the large number of papers supporting this, it might reasonably be stated that lower third molar surgery is considered to carry a risk of between 0.5-2% for permanent inferior dental nerve injury and less than 0.5% for permanent lingual nerve injury. As noted in the introduction, over the decades, a vast number of papers have been published reviewing nerve injuries associated with lower third molar surgery14,15,16,17,18,19,20,21,22,23 and many have sought to quantify the associated risk factors. From Kipp14 and Mason24 in the 1980s, to Carmichael and McGowan¹⁵ in the 1990s and the recent Cochrane review of 2020,25 these risks have seemingly not significantly changed. There has similarly been no specific evidence of preference of one surgical approach over another, with the exception perhaps of avoidance of lingual tissue retraction, and this lack of change is reflected in the latest Royal College of Surgeons guidance document for third molar surgery.²⁶ One might wonder why, with so many publications considering this matter, there has been no movement forwards in effectively managing the risk profile associated with third molar surgery.

There are two probable reasons for this lack of progress. First and entirely unsurprisingly, the primary factor to be considered is the surgical anatomy of the third molar site. In a

proportion of patients, the lower third molar roots will be in contact with the inferior dental neurovascular canal or may even encompass it. The lingual nerve invariably lies in a specifically vulnerable setting. Nothing will change the reality of this anatomy.

The second factor is the structure and expectations of the studies themselves. These are almost exclusively population studies of one form or another. Some papers look at the outcomes of thousands of surgical procedures and some barely a hundred. Yet, the ensuing information is nevertheless merged in an attempt to produce a figure that can be applied to each and every individual patient. This is entirely missing the point of population studies. While these remain viable public health tools, their outcomes cannot be simply extrapolated to apply to a specific patient. In other words, they are remarkably blunt instruments which simply lack sufficient precision to be legitimately applied to individual risk assessment. Every patient is concerned with only the specificity of issues of their own circumstances. In other words, the patient wants to know 'am I the one who will experience permanently altered sensation?', which is of course the key question, not how many people in any given population group are likely to suffer a similar fate. Many publications, such as those by Chung et al.21 and Nyguen et al.,22 do attempt to identify higher risk category individuals. Most papers that attempt to derive this detail from their data report that the cases with increased risk are those associated with increased surgical difficulty, such as those with clear evidence of inferior dental canal impingement and/or distoangular impaction, with greater patient age and with the experience of the operator. Yet, in these papers, again as stated in the introduction, the author is not comparing like with like; the relationship of the root apices to the inferior dental neurovascular canal is the key issue, not the tooth angulation, the patient's age or any other factor. By way of example, Carmichael and McGowan15 included a number of erupted teeth unlikely to lead to complications, yet distorting (reducing) the risk profile. In a more typical paper, Jerjes et al.27 reviewed 1,087 extractions of lower third molars, yet in more than 20% of their cases, the roots of the teeth were greater than 2 mm from the inferior dental canal and as such, were not associated with any realistic likelihood of subsequent inferior dental nerve injury. Simply put, such study designs lack the necessary level of sensitivity to meaningfully quantify the risk of inferior dental nerve injury in any specific instance and in the cold light of day, give rise only to a largely unhelpful assemblage of information that cannot be called upon when advising a specific patient of the particular risks associated with their proposed surgery.

Hasegawa and colleagues²⁸ attempted a multivariate analysis in an attempt to pin down the relevant risk factors. While most of their findings are of limited or no help in identifying the real risk group, their analysis did however reveal a strong association between altered sensation and the radiographic overlap of the inferior dental neurovascular canal by the third molar roots. Those with complete, or almost complete, overlap and loss of the radiographic border of the canal were associated with higher risk of inferior dental nerve injury. Neither of these findings should be in the least surprising.

The author would argue that the reality here is that the subgroup most likely to experience (permanent) inferior dental nerve injury is that where the relationship of the third molar root apices to the inferior dental neurovascular canal is extremely close. In many respects, all third molars falling outside this subgroup are irrelevant to understanding the actual risks to the inferior dental nerve. Consequently, the author contends that those cases where inferior dental nerve injury occurs are confined to a very small group with the highest anatomical risk and that the real, numerically adjusted risk to these cases is substantially higher than those quoted. These might be termed the 'prize tomatoes' and are the ones that really need identification and appropriate risk analysis.

Can we identify this subgroup?

Selvi and colleagues²⁹ reviewed nerve injuries against cone beam computerised tomography (CBCT) assessment of the third molar roots and their relationship to the inferior dental neurovascular canal. They were able to show a more precise understanding of the relationship from a structural and anatomical perspective when related to neve injuries. In their study, not only was the loss of the cortex of the inferior dental neurovascular canal associated with increased risk of inferior dental nerve injury, which would make logical sense, but also the size of the defect in the cortex of the canal. A 3 mm or greater defect of the canal cortex was strongly associated with increased risk of nerve injury. Once again, this of course makes complete sense. A nerve injury does not just appear out of thin air. It is almost

always a consequence of an unintended interaction between the third molar root and the nerve. As such, the greater the exposure of the nerve to damage through a defect in the canal cortex, the more likely it is that an injury will occur. This is supported by work from Susarla and colleagues³⁰ in 2010, who suggested that the magnitude of the cortical defect of the inferior dental neurovascular canal on CBCT assessment was fundamental in determining visual nerve exposure in the canal during surgery, although they were not seeking to demonstrate that such exposure would automatically give rise to nerve injury (and indeed it did not). Inferior dental nerve injury is an unpredictable outcome and a case series by Bozkurt and Görürgöz³¹ did not demonstrate a strong link between canal cortical defect on CBCT and nerve injury, whereas a similar but larger study by Wang et al.32 suggested a moderate but not consistent correlation. A recent study by Kubota and colleagues³³ has attempted to develop a risk stratification, proposing three areas of significance in the development of inferior dental nerve injury: lingual or inter-radicular position of the canal; multiple roots perforating the canal; and patient age of 30 or more.

These conclusions should not be in the least surprising and point to the crux of the risk assessment: when is close too close? This is not yet absolutely clear, although the abovementioned papers provide helpful guidance. There are probably a number of additional influencing variables, such as bone flexibility and density and resilience of the nerve structures, which may explain the finding that those patients over 30 years of age may have higher risk of inferior dental nerve injury, a finding that would appear to have no other logical derivation. This question - when is close too close - should perhaps be the driver for prescribing CBCT,³⁴ but there is clear evidence that use of CBCT does not improve the outcomes from third molar surgery.35,36,37 One might justifiably then ask: what is the point of CBCT? The answer seems to be to identify those cases with significant loss of structure of the inferior dental canal and to aid in decision-making and/or surgical planning. This, in turn, enables patients to be advised where appropriate of the associated significant risk of inferior dental nerve injury.

The key point, therefore, is that the risk of inferior dental nerve injury is in fact concentrated in a very small cohort and those patients who are not in this cohort

probably do not have any significant risk of such injury. As such, to simply quote a generic (population-based) risk percentage in all cases is inappropriate and might, were it to be tested, be construed in legal terms as being misleading, which brings the rationale full circle back to the Montgomery judgement.

Consequent on the Montgomery judgement, it may be tempting for clinicians to attempt to 'cover all bases' by warning all lower third molar surgery candidates of the risk of inferior dental nerve injury. However, to do so would not be rational, appropriate or reasonable and it would indeed run contrary to the doctrine. The clinician instead needs to make a significantly more effective (accurate) risk judgement: assessing the individual factors applicable to the patient concerned rather than blandly quoting population risk figures. If the risk to the inferior dental nerve is considered significant, then this should be clearly stated. An instance where the inferior dental neurovascular canal is largely encompassed by a third molar root will probably present a close to 100% risk of nerve injury, not a 0.5-2% risk. If the risk is low, then this should similarly be stated, without alarming and misleading the patient with information that distorts the reality of their position and may lead to compromised decision-making.

However, to fulfil the requirements of the Montgomery doctrine, disclosure of not only the risks of nerve injury is required, but also the implications should those risks come to fruition. To simply state that there may be changes in sensation (however worded) may well not be sufficiently comprehensive or descriptive for many patients to properly assimilate. In their discussion, having reflected upon the relative importance of altered sensation in the lip to patients, Britton et al.¹¹ suggested that for many, altered sensation may not necessarily be all that troublesome but could have far greater impact upon others. Publications^{38,39,40,41,42,43,44} over the years suggest that such impact is a largely unquantifiable factor but, despite the small anatomical area involved, the effect upon quality of life of protracted inferior dental sensory disturbance can be devastating. It is, therefore, incumbent upon the clinician to explore this area with the patient as part of the consenting process. The inevitable next question is, where does this discussion stop?

Inferior dental or lingual nerve injury may lead to a range of outcomes, from relatively minor hypoaesthesia to very painful posttraumatic trigeminal neuropathy or complete anaesthesia. While the mild end of this spectrum may be largely insignificant, more severe symptoms require robust clinical management and many patients may wish to know in advance how such a scenario might be managed. Functional changes may include deterioration in the quality of speech, eating and taste. There may be concomitant impacts on work, social and personal aspects of life, giving rise to psychological issues, including those relating to physical relationships. Indeed, many hospital pre-surgery information forms

Questions may also be about how the treatment might affect your future state of health or style of life, for example:

- Will I need long-term care?
- · Will my mobility be affected?
- Will I still be able to drive?
- Will it affect the kind of work I do?
- Will it affect my personal/sexual relationships?
- Will I be able to take part in my favourite sport/exercises?
- Will I be able to follow my usual diet?

Health care professionals should welcome your views and discuss any issues so they can work in partnership with you for the best outcome.

Patient Notes

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Appendix 1 An excerpt from a hospital consent form

offer guidance to patients in this respect. Appendix 1 shows an excerpt from a hospital consent form drawing patients' attention to these factors. The significant obstacle remains that it is impossible to identify in advance which patients are at the greatest risk of substantial psychological impact. Clinicians consequently need to be transparent with the patient, indicating the impossibility of predicting such outcomes with any accuracy, yet at the same time offering insight into the impact of significant complications.

Conclusion

Many published studies looking at the risk of inferior dental nerve injuries consequent on lower third molar surgery are flawed and fail to properly identify and consider subgroups of variable (higher) risk within populations, yet for years have been the cornerstone upon which advice to patients concerning risks associated with the surgery has been based. Plain film and CBCT assessment targeted to the correct subgroup can provide greater accuracy of assessment of the specifically high-risk case, with evidence to show how these may be used. Blunt and simplistic quoting of the outcome of population studies fails to appropriately inform patients of their particular level of risk, rendering consent invalid and should accordingly be discarded. Those patients who are legitimately at real risk of inferior dental nerve injury should be clearly identified and appropriately informed and the discussions should include consideration of the impact of the potential outcomes of inferior dental and lingual nerve injury and potentially their management. For those who do not have substantive risk of inferior dental nerve injury, an accurate and true risk assessment should be given and patients should not be misled by a generic consenting process quoting averaged figures based on flawed research.

In the final analysis, Shelford Gawain,⁴⁵ a general medical practitioner who, when diagnosed with bowel cancer, summed up the issue concisely: 'the information that I want is not that one in ten patients will benefit, but whether I am that one'.

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Ethics declaration

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