ORTHOPAEDIC SURGERY

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Poor compliance documenting informed consent in trauma patients with distal radius fractures compared to elective total knee arthroplasty

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complications, ethics, informed consent, orthopaedic surgery, trauma.

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Abstract

Background: The purpose of this study was (1) to evaluate the adequacy of informed consent documentation in the trauma setting for distal radius fracture surgery compared with the elective setting for total knee arthroplasty (TKA) at a large public hospital and (2) to explore the relevant guidelines in New Zealand relating to consent documentation.

Methods: Consecutive adult patients (≥16 years) undergoing operations for distal radius fractures and elective TKA over a 12-month period in a single-centre were retrospectively identified. All medical records were reviewed for the risks and complications recorded. The consent form was analysed using the Flesch Reading Ease Score (FRES) and the Simple Measure of Gobbledygook (SMOG) index readability scores.

Results: A total of 133 patients undergoing 134 operations for 135 distal radius fractures and 239 patients undergoing 247 TKA were included. Specific risks of surgery were recorded significantly less frequently for distal radius fractures than TKA (43.3% versus 78.5%, $P < 0.001$). Significantly fewer risks were recorded in the trauma setting compared to the elective (2.35 ± 2.98 versus 4.95 ± 3.33, $P < 0.001$). The readability of the consent form was 40.5 using the FRES and 10.9 using the SMOG index, indicating a university undergraduate level of reading.

Conclusions: This study has shown poor compliance in documenting risks of surgery during the informed consent process in an acute trauma setting compared to elective arthroplasty. Institutions must prioritize improving documentation of informed consent for orthopaedic trauma patients to ensure a patient-centred approach to healthcare.

Introduction

Healthcare professionals have an ethical, legal and regulatory requirement to obtain informed consent prior to any treatment. Although informed consent is a long-standing practice in medicine, the process of informed consent is evolving, and there remain challenges in implementing it effectively.[1,2] Not all physicians recognize the importance of informed consent, particularly in the field of orthopaedic surgery, where failure to obtain and document consent is a frequent cause of claims.[2–5]

In New Zealand, the legal pre-requisite for informed consent is set in the Code of Health and Disability Services Consumers' Rights under the Health and Disability Commissioner Act.[6] The Medical Council of New Zealand (MCNZ) is responsible for managing the standards of informed consent for doctors and recommends that patients are provided with all the information they need to help them make a fully-informed decision.[7] Furthermore, the information and specific risks in discussion during the consent process should be documented clearly and accurately in the patient notes. This is further supported by the Royal Australasian College of Surgeons (RACS) guidelines, which recommend 'a signed informed consent document with information specific to the patient, providing details of what was discussed'.[8]

Many articles have been published on informed consent; however, there is a paucity of those focused on orthopaedic trauma patients.[9–14] The process of obtaining informed consent in the setting of trauma is challenging and is complicated by time constraints and patient distress.[2,14] It is frequently tasked to a junior doctor to

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complete and document the consent process in the emergency room or the pre-operative holding area.[9,14] Distal radius fractures are the second most commonly treated fractures in orthopaedics, with a significant number resulting in complications and long-term morbidity.[15–19] Historically, these fractures have been managed conservatively with closed reduction and casting, however surgical management, specifically open reduction internal fixation (ORIF), is becoming more common.[16,17] For these reasons, patients undergoing surgery for distal radius fractures were chosen as the focus of this study.

In order to provide a comparison group in the elective orthopaedic setting, patients undergoing total knee arthroplasty (TKA) were also reviewed. In the elective environment, all patients participated in an outpatient clinic with their surgical team prior to their surgery and met with their surgeon(s) on the day of surgery. We hypothesised this would provide greater opportunities for discussion and documentation of the informed consent process, and there would be higher compliance recording consent in the elective surgery setting compared to acute surgery.

The purpose of this study was (1) to compare the adequacy of informed consent documentation in the trauma setting for distal radius fracture surgery compared to the elective setting for TKA at a large public hospital in New Zealand and (2) to explore the relevant guidelines in New Zealand relating to consent documentation.

Methods

All consecutive adult (16 years or older) patients who underwent surgery for acute distal radius fractures and elective TKA at a large public hospital in New Zealand over a 12-month period from October 2020 were included. Patients with distal radius fractures were excluded if they were referred to an external tertiary referral centre for treatment of complex fractures with extensive comminution. Patients undergoing TKA were excluded if they were revisions from unicompartmental knee arthroplasty to TKA, or were performed for neurological dysfunction limiting knee mobility or post-traumatic osteoarthritis with severe knee deformity.

Data relating to the patient, including age, sex and prioritized ethnicity (using the prioritization system developed for the New Zealand health and disability sector[20]), were recorded. Details of the distal radius fracture type (side, open/closed) and ORIF, pin fixation, external fixation, and manipulation under anaesthesia (MUA)) were collected.

All patient medical records were reviewed for documentation of informed consent regarding discussion of specific risks for the operation. This included outpatient clinical notes (i.e., pre-admission clinic), inpatient clinical notes (i.e., ward round notes), consent forms and operation notes.

In cases where patients were unable to consent, documentation of consent with the patients' welfare guardian or enduring power of attorney (EPOA) was used instead. The use of an interpreter during the consent process was also documented. All surgeries used the same institutional consent form for patients to sign (Supplementary Information 1). The risks that were discussed and documented for any operation were decided by the consenting doctor(s). There were no additional institutional information sheets given to patients that outlined specific risks for any operation. When medical abbreviations were used on the consent form, the terms used were recorded. Informed consent documentation for allograft bone and blood transfusion, which are documented with checkboxes on the consent form, was analysed separately. The grade of the consenting surgeon(s) and operating surgeon(s) was also collected.

Table 1 The Flesch Reading ease score (FRES), age group/education level, and New Zealand adult population literacy levels

Difficult to read[21]	FRES	Age group (y)/ education level	New Zealand population literacy levels[22]
Very difficult	0–30	University postgraduate	–
Difficult	30–50	University undergraduate	–
Fairly difficult	50–60	Year 12 secondary school	56%
Standard English	60–70	13–15	–
Fairly easy	70–80	12	–
Easy	80–90	11	86%
Very easy	90–100	10	95%

The readability of the institutional consent form was analysed using an open-source automated text reading programme to produce the Flesch Reading Ease Score (FRES)[21] (Table 1), the Simple Measure of Gobbledygook (SMOG) index,[23] the complex word count, and the total word count. In brief, the FRES is a function of syllables per word and words per sentence, while the SMOG index is based on the number of words of over three syllables per ten-word sample (Supplementary Information 2). These specific readability tests were used because of their reproducibility across the English language and medical literature.[24,25]

Significance testing and graphing were performed with Prism 8 (GraphPad, San Diego, CA, USA). Differences were determined with Fisher's exact test or Chi-squared tests for categorical data and t-tests for parametric continuous variables. Data are presented as mean ± standard deviation (STD), and a P-value <0.05 was significant. Ethics committee approval was obtained from the district health board involved in the study.

Results

For acute distal radius fractures, a total of 133 patients underwent surgery for 135 fractures in 134 operations over the study period. The majority (97%) of surgeries were ORIF procedures, while two were pin fixation and MUA, and one was external fixation. Of these injuries, 5.2% were open fractures. With regards to elective TKA, in total, 239 patients underwent 247 operations over the 12-month period. Patients undergoing distal radius fracture surgery were significantly younger (51.4 ± 16.8 versus 70.4 ± 8.7, $P < 0.001$) and more frequently New Zealand European (80.4% versus 48.5%, $P < 0.001$) compared to patients undergoing elective TKA. Patient demographics and operation details are shown in Table 2.

All patients had signed the institutional consent form with documentation stating the correct operation and side. However, 24.6% of patients undergoing distal radius fracture surgery had no further documentation of the risks of surgery that were discussed, which was significantly higher than for TKA (3.2%, $P < 0.001$),

Table 2 Patient demographics and operation details

	Acute distal radius fracture surgery, *n* (%)	Elective total knee arthroplasty, *n* (%)	*P*-value
Total patients	133	239	–
Sex			0.143
Female	92 (69.2)	146 (61.1)	
Male	41 (30.8)	93 (38.9)	
Age at surgery (y)			
Mean ± STD	51.4 ± 16.8	70.4 ± 8.7	<0.001*
Range	16–89	47–90	–
Ethnicity			<0.001*
New Zealand European	107 (80.4)	116 (48.5)	
Asian	15 (11.3)	54 (22.6)	
Māori	3 (2.2)	7 (2.9)	
Pacific Peoples	3 (2.2)	53 (22.2)	
Other	5 (4.9)	17 (7.1)	
Total operations	134	247	
Side			0.018*
Left	81 (60.0)	116 (47.0)	
Right	54 (40.0)	131 (53.0)	

*significant difference ($p < 0.05$).

Furthermore, non-specific descriptions of complications, for example stating 'risk and benefits were discussed', was recorded in 32.1% of patients for distal radius fractures, compared to 21.5% for TKA ($P < 0.001$). In the majority (78.5%) of TKA patients, specific risks of the surgery were recorded in the clinical documentation, compared to 43.3% of distal radius fracture patients ($P < 0.001$). For TKA patients, a discussion of the complications was recorded most often in outpatient pre-admission clinics. In contrast, for patients with distal radius fractures, this discussion was most frequently documented on the operation note (Table 3).

Patients undergoing TKA had a significantly higher number of specific risks recorded than those undergoing distal radius fracture surgery (4.95 ± 3.33 versus 2.35 ± 2.98, $P < 0.001$) (Table 3). The

Table 3 Risks and complications recorded for all clinical documentation (inpatient and outpatient clinical notes, consent form and operation note)

	Acute distal radius fracture surgery, *n* (%)	Elective total knee arthroplasty, *n* (%)	*P*-value
Total operations	134	247	–
Recorded complications			<0.001*
None	33 (24.6)	8 (3.2)	
Non-specific risks only	43 (32.1)	45 (21.5)	
Specific risks	58 (43.3)	194 (78.5)	
Discussion of complications			<0.001*
None	33 (24.6)	8 (3.2)	
Outpatient clinical notes	0 (0.0)	79 (32.0)	
Inpatient clinical notes	23 (17.2)	0 (0.0)	
Consent form	9 (6.7)	12 (4.9)	
Operation note	37 (27.6)	6 (2.4)	
Two of the above	29 (21.6)	98 (39.7)	
Three of the above	3 (2.3)	44 (17.8)	
Number of specific risks recorded			
Mean ± STD	2.35 ± 2.98	4.95 ± 3.33	<0.001*
Range	0–10	0–12	–

*Significant difference ($p < 0.05$).

most commonly recorded risks for distal radius fracture surgery were infection (38.8%), nerve injury (38.8%), vascular injury (36.6%), bleeding (28.4%) and need for further surgery (18.7%) (Fig. 1 and Supplementary Information 3). For elective TKA, the most common risk discussed with infection (76.9%), deep vein thrombosis/pulmonary embolus (DVT/PE) (69.6%), nerve injury (58.3%), bleeding (58.3%) and vascular injury (57.9%) (Fig. 2 and Supplementary Information 4).

The consent form was signed by the patient (or their welfare guardian/EPOA) in all operations. For distal radius fracture, most consent forms were completed by junior registrars (92.5%), whereas for TKA, the majority were completed by consultant orthopaedic surgeons (51.0%, $P < 0.001$). The consenting doctor was present in the operation in 22.4% of distal radius fracture surgeries, compared to 100% for TKA ($P < 0.001$). Checkboxes for allograft bone and blood transfusion consent were completed at similarly high rates for both acute distal radius fracture surgery (90.3% and 100%, respectively) and TKA (85.0% and 99.6%). Medical acronyms were used significantly more frequently on the consent form for acute distal radius fracture surgery than TKA (57.5% versus 11.7%, $P < 0.001$). Other details of the complications and acronyms recorded on the consent form are shown in Table 4.

The readability of the consent form was 40.5 using the FRES, correlating to the literacy expected of a university undergraduate and classed as 'difficult to read' according to United States (US) Department of Health and Human Services classification.[21] The form scored 10.9 using the SMOG Index, correlating to a 12th grade level in the US education system, equivalent to Year 13 level using the New Zealand system. In total, the consent contained 517 words, with 44% that were unique and 22% having three syllables or more (classed as complex words).

Discussion

The main finding of this study was that there was significantly poorer compliance documenting the informed consent process in trauma patients undergoing distal radius fracture surgery compared to elective patients undergoing TKA. Only 43.3% of distal radius fractures surgeries had documentation of the specific risks discussed, compared to 78.5% of patients undergoing TKA, and significantly more risks were recorded on average for patients undergoing TKA. In 24.6% of distal radius fracture surgeries, the only documentation of the consent process was a signed generic consent form, compared to 3.2% of TKA. The institutional consent form was classed as 'difficult to read' and required a university undergraduate reading ability, implying many patients would not have the literacy level to understand it. Poor documentation of complications and risks may invalidate the consent and imply that the patient did not receive appropriate information prior to their treatment, with medico-legal implications.

Obtaining informed consent is an ethical, legal and regulatory obligation for all healthcare professionals.[6–8,26,27] The process embodies the ethical principles of autonomy, beneficence, and non-maleficence.[28] While the importance of informed consent has been enshrined in medicine for several decades, there are still many challenges to implementing the process effectively.[1,2] Modern medicine

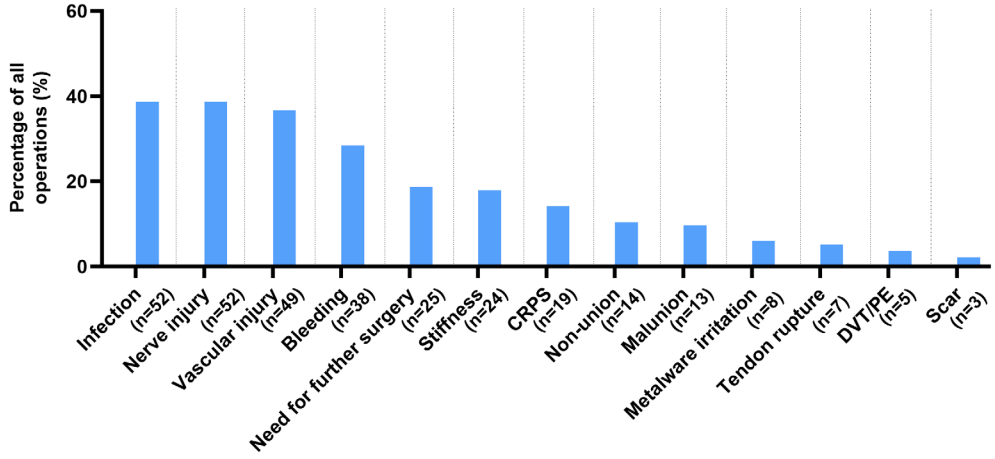

Fig. 1. Acute distal radius fracture surgery risks and complications recorded across all clinical documentation (clinical notes, consent form and operation note). *data not shown for specific risks recorded in less than 5% of operations. All recorded risks are shown in Supplementary Information 3. CRPS, chronic regional pain syndrome; DVT/PE, deep vein thrombosis/pulmonary embolus.

has shifted the focus of consent away from the Bolam principle, which was based on the collective opinion of experienced medical practitioners, towards the specific needs of a patient.[5,29] With this patient-centred approach, a surgeon is now required to explain all significant operative risks that a reasonable person in the patient's position would be likely to attach significance to.[2,26] This has since been refined through rulings such as the Roger v. Whitaker case in Australia[30] and the Montgomery v. Lanarkshire Health Board case in the United Kingdom.[31] These cases centre around doctors failing to provide adequate information to patients to make informed decisions on an individual basis.[32]

In New Zealand, the MCNZ is responsible for registering doctors and managing standards of informed consent,[7] based on the Health and Disability Commissioner Act.[6] The MCNZ states treatment should not occur until the patient has been given information about their treatment options, including the risks and benefits[7] and refers to the Roger v. Whitaker case.[30] Importantly, the MCNZ guidelines require that clear and accurate patient records should be made of the information discussed, any specific risks highlighted, any requests or concerns expressed, any decisions made, and the reasons for them. The RACS also states that standard consent forms may not be enough in themselves to provide informed consent and recommends surgeons provide patients with specific and individualized information.[8]

The process of informed consenting in patients undergoing acute surgery for traumatic injury can be compromised by acute pain and psychological distress and the effects of analgesia or sedation.[14,28] Previous studies reported that patients undergoing emergency surgery are less likely to remember signing a consent form and less likely to be satisfied with the consent process than elective patients.[13,33,34] In the elective orthopaedics setting (i.e., arthroplasty surgery), informed consent is not a single event but a process developed from the first consultation with the surgical team until the operation begins.[14,27,35] This process is often supported by consultation with supporting staff, including nurses and physical therapists.[36] These steps enable patients to develop a fuller understanding of the risks and benefits of surgery. Our study supports these findings with significantly more risks of surgery discussed during the consent process for elective patients compared to trauma patients. Furthermore, specific risks for TKA were most often recorded in outpatient clinical notes than on consent forms or operation notes.

For distal radius fractures, the types of recorded risks were similar to a previous study[9]; however, overall, the rates of risks recorded were significantly lower. Some risks, including failure of surgery and deep vein thrombosis/pulmonary embolus (DVT/PE), were discussed more commonly in the previous study.[9] The complication rate of distal radius fractures varies widely in the literature, from 6% to 80%.[16,17] Loss of motion, delayed union/non-

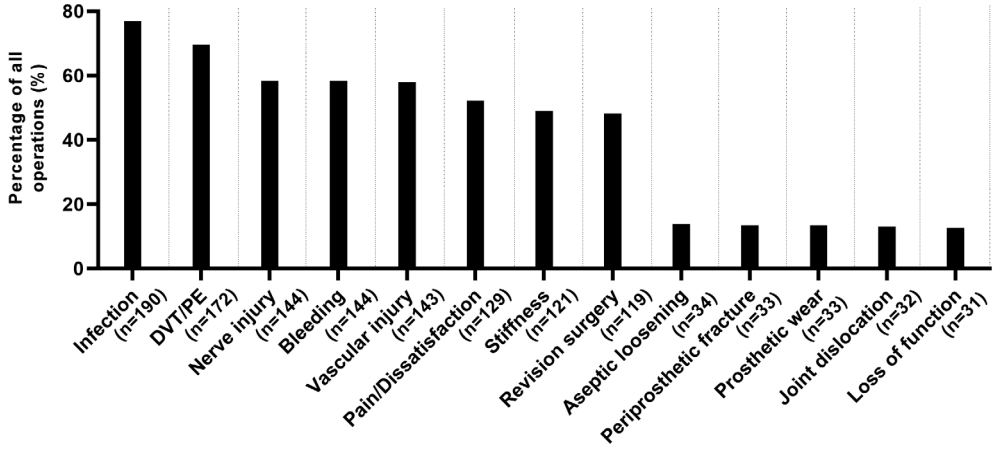

Fig. 2. Elective total knee arthroplasty risks and complications recorded across all clinical documentation (clinical notes, consent form and operation note). *Data not shown for specific risks recorded in less than 5% of operations. All recorded risks are shown in Supplementary Information 4. DVT/PE, deep vein thrombosis/pulmonary embolus.

Table 4 Risks and complications recorded on consent form only

	Acute distal radius fracture surgery, *n* (%)	Elective total knee arthroplasty, *n* (%)	*P*-value
Total consent forms	134	247	–
Grade of consenting surgeon			<0.001*
Junior registrar	124 (92.5)	42 (17.0)	
Senior registrar	4 (3.0)	52 (21.1)	
Fellow	0 (0.0)	27 (10.9)	
Consultant	6 (4.5)	126 (51.0)	
Consenting surgeon in operation	30 (22.4)	247 (100.0)	<0.001*
Interpreter used	6 (4.5)	27 (10.9)	0.036*
Patient unable to consent	4 (3.0)	0 (0.0)	0.015*
Allograft bone consent	121 (90.3)	210 (85.0)	0.156
Blood transfusion consent	134 (100.0)	246 (99.6)	>0.999
Used of acronyms in consent	77 (57.5)	29 (11.7)	<0.001*
Type of acronyms used			<0.001*
ORIF	77 (57.5)	0 (0.0)	
TKA or TKJR	0 (0.0)	19 (7.7)	
'R' or 'L'	13 (9.7)	20 (8.1)	
#	4 (3.0)	0 (0.0)	
MUA	2 (1.5)	0 (0.0)	

Abbreviations: MUA, Manipulation under anaesthesia; ORIF, Open reduction and internal fixation; 'R' or 'L', right or left; TKA/TKJR, Total knee arthroplasty/Total knee joint replacement; #, fracture;

*Significant difference ($p < 0.05$).

union, nerve compression/neuritis, pain syndromes and hardware complications have the highest incidence of reported complications.[16,17] Despite this high incidence, the recorded discussion of these complications ranged from 6% (metalware irritation) to 39% (nerve injury). Long term risks, including post-traumatic arthritis, complex regional pain syndrome (CRPS), and tendon rupture, were rarely recorded, and no patients had recorded a risk of grip strength reduction or distal radioulnar joint pain, despite their relatively high incidence.[16,37]

The recorded risks for TKA were also comparable to previous studies reviewing the consenting process.[38,39] The most common (2–5%) complications listed in joint registries after TKA include infection, loosening and instability, which were recorded at highly variable rates from 12.9% (instability/dislocation) to 76.9% (infection).[40–42] Other rare (<1%) complications were discussed highly frequently, including nerve damage (58.3%) and vascular injury (57.9%).

In the acute setting, the majority (93%) of informed consents in this study were obtained by junior registrars, and the consenting surgeon was only present in the operation 22% of the time. Whereas for elective TKA, junior registrars rarely completed written consents (17%), the majority (51%) of consents were obtained by the orthopaedic consultant surgeon operating, and the consenting surgeon was present in all operations. The MCNZ cautions against using junior doctors to obtain consents unless acting under the direct supervision of a more experienced colleague and states the doctor undertaking the treatment is responsible for the overall informed consent process.[7] This aligns with international jurisprudence in the English-speaking world.[2,5,32,43] Due to the acuity of orthopaedic trauma surgery, informed consent discussions are mostly held on the hospital floor, the emergency room or in the pre-operative holding area by junior doctors.[44]

It is likely that the high usage of junior registrars to complete the written consenting process contributed to the poor documentation of the informed consent process. Previous studies have demonstrated registrars, or residents, may not have sufficient clinical experience to anticipate potential surgical complications and risks or have adequate communication skills to explain the information in adequate detail.[45–47] The consenting surgeon should be aware of all the potential complications and their appropriate management. One study recommended developing training for junior doctors at induction sessions for consenting common trauma procedures.[46] It is also the responsibility of the operating surgeon to receive a clear handover that the consent process has been performed adequately, if not performed by themselves, and review the quality of the consent recorded before surgery. Because of the wide variability in procedure-based complications and risks, the British Orthopaedic Association has endorsed an online orthopaedic-based procedure guideline, OrthoConsent, to guide junior doctors in consenting trauma cases.[41]

This study demonstrated that the institutional consent form is not as easy to read and understand as recommended by the New Zealand Ministry of Health guidelines.[48] In New Zealand, 44% of adult New Zealanders do not have the literacy to understand dense or lengthy texts, and 56% have poor health literacy skills, scoring below the minimum required to meet the demands of everyday life and work.[22,49] Other patient factors include visual impairment and language barriers, with 6% and 11% of patients requiring an interpreter for consent in the acute and elective setting, respectively, yet all signed an English language consent form. Therefore, patients cannot be expected to comprehend written text, and there cannot be an over-reliance on written information for informed consent. Other studies in the Australia and United Kingdom have reported poor readability of orthopaedic patient information leaflets and consent forms.[24,50,51]

The use of medical abbreviations was found to be more common in the acute trauma setting, compared to the elective setting, with terms describing the operation ('ORIF' and "TKA/TKJR') or side ('L' or 'R') frequently used. Abbreviations are commonly used in surgical practice for time convenience and brevity of documentation in medical records. As well as being unintelligible to patients, abbreviations are poorly understood outside of their medical subspeciality and carry risks to patient safety.[52,53] Despite this, several studies have shown they are still widely used in orthopaedics and other medical clinical documentation.[9,46,53] Regularly auditing and reviewing a service's practice has been shown to reduce abbreviation usage.[46]

At this study hospital, consent for blood transfusion and human allograft bone is included as a checkbox on the institutional consent form. This likely contributed to high rates of documentation compliance of these two risks in both the acute and elective settings. For this reason, they were analysed separately from other specific risks. Media reports have heightened public awareness of the risk of allograft, and other studies have reported poor compliance of documenting consent for its risks.[54,55] The recording of consent for the use of human allograft bone was introduced onto the institutional consent form (Supplementary Information 1) in 2018 after a patient complaint that led to an enquiry by the New Zealand Health and Disability Commissioner.[56] The case centred on a patient who underwent spinal surgery

with allograft and complained that they were not consented pre-operatively for the use of allograft. Importantly, although a surgeon claimed to have discussed this risk with the patient before surgery, this was not documented in the clinical notes, and the responsible consultant was found to have breached the Right 6[1] of the Code of Health and Disability Services Consumers' Rights.[6] This re-affirms the importance of informed consent documentation in medical records and highlights the utility of a checklist to improve documentation compliance in consenting.[9,14,46,57]

The main strength of this study is that it reviewed all medical records of all consecutive patients undergoing distal radius fracture surgery and TKA over 12 months for documentation of informed consent. There are inherent limitations to this study. Informed consent is a broad practice; we chose to focus only on the recorded documentation around consent and did not investigate the patient's recall or understanding of the consent process. This study was also performed retrospectively, so we could not audit which complications and risks surgeons may have discussed but not recorded. It is possible repetition of the consent process in the elective arthroplasty outpatient setting may have reinforced risk documentation compared to the trauma setting, where the types of surgery can vary widely. One limitation of the FRES and SMOG scores is that opaque but short medical terms such a 'carpal' escape the 'gobbledygook' test by not being polysyllabic words, despite being not well understood by the lay reader. This study used a blank consent form without any risks listed for readability analysis, and therefore adding a list of specific risks, by nature of the FRES and SMOG formulae,[21,23] would likely reduce the readability further.

Overall, this study has shown significantly poorer compliance documenting the informed consent process in an orthopaedic trauma setting compared to an elective arthroplasty setting. Poor documentation of consent places institutions and individual surgeons at risk of complaints and litigation. In the acute trauma setting, there was an over-reliance on a generic consent form for documenting informed consent, which was set at a literacy level many patients would struggle to understand. Future studies should evaluate interventions that can improve compliance, including registrar educational resources on consent documentation or modification of consent forms (i.e., checkboxes for specific risks). Surgeons and their institutions must prioritize the process and documentation of informed consent for orthopaedic trauma patients and ensure a patient-centred healthcare approach is followed.

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Conflict of interest

None declared.

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Author contributions

Scott M. Bolam: Conceptualization; data curation; formal analysis; investigation; methodology; project administration; software; writing – original draft; writing – review and editing. **Leigh Munro:** Data curation; formal analysis. **Mark Wright:** Conceptualization; formal analysis; methodology; supervision; writing – original draft; writing – review and editing.

Ethics approval

The study has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki.

Data availability statement

This manuscript has associated data in a data repository available on request from the corresponding author.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Supplementary Information 1. The institutional generic consent form for orthopaedic surgery.
Supplementary Information 2. Readability formulae for the Flesch Reading Ease Score (FRES) and the Simple Measure of Gobbledygook (SMOG) index.
Supplementary Information 3. All recorded risks and complications for distal radius fracture surgery across all clinical documentation (clinical notes, consent form and operation note).
Supplementary Information 4. All recorded risks and complications for total knee arthroplasty across all clinical documentation (clinical notes, consent form and operation note).