ORIGINAL RESEARCH

Consent in Limb Lengthening Surgery: Predicting the True Incidence of Material Risk

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Abstract

Aim: The consent process involves supported decision-making between the surgeon and the patient. Both potential benefits and material risks of the procedure require explanation, with adequate time for reflection. The complexity of limb reconstruction surgery includes the potential for multiple types of complications. In an attempt to delineate the material risks in lower limb lengthening, a literature review was undertaken to ascertain the published rates of complications.

Materials and methods: A review of articles from 2003 to 2023 via PubMed and Google Scholar, including keywords 'lengthening', 'tibia', 'lengthening nail' and 'external fixator' was undertaken. Studies with a minimum of 20 patients, undergoing lengthening of the femur, tibia, or both by an external fixator and/or an intramedullary lengthening nail were included for analysis. Complications were reported according to Paley's problems, obstacles, and complications.

Results: Twenty-two papers met the inclusion criteria. The commonest complications listed following lengthening using an external fixator were pin site infections (52% in the femur and 18.8% in the tibia), delayed consolidation (8.3%), bone re-fracture (13%), and joint stiffness (18.8%). Following femoral lengthening using the intramedullary lengthening nails reported complication rates were lower, including implant issues (8%) and delayed consolidation (6%).

Conclusion: Patients require a full understanding of both benefits and potential harms when undergoing any surgical intervention. Our study has identified the published rates of complications following lower limb lengthening. These figures can be used to guide the consultation and enable surgeons to audit their own surgical results against the published literature.

Keywords: Complications, External fixators, Femoral lengthening, Informed consent, Intramedullary limb-lengthening system, Material risks, Tibial lengthening.

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Introduction

Faced with the prospect of surgery is always a daunting experience for any patient. The journey often starts with a concern that something may not be what it should be, escalating anxiety before confirmation of the quandary and the proposal of a treatment strategy. Limb reconstruction surgery may be summarised as that which restores alignment, length, and function of limbs. The spectrum of techniques ranges from simple insertion of physeal tethering plates that modulate growth,[1] to the use of external fixators to perform complex deformity correction and bone lengthening.[2] In these particular cases, due to the prolonged duration of treatment until the external fixator is removed, Paley devised a classification system that differentiated issues encountered during limb lengthening using Ilizarov frames into problems, obstacles, and complications.[3]

In November 2020, the UK's General Medical Council produced a document on Decision-making and Consent.[4] This highlights the need for an informed consent process to be undertaken with supported decision-making between the surgeon and the patient. Patients must be informed of the material risks associated with the proposed treatment. This may be defined as the risks that a reasonable person in the patient's position would attach significance to. The risks discussed should include any potential harm that the patient may receive during the treatment. This may not be classified as a complication by Paley but as a problem or obstacle. It would still be relevant to the discussion and be important to the patient. Furthermore, patients often ask what is the incidence of the particular risk occurring.

The aim of this paper was to undertake a literature review of lower limb lengthening to ascertain the published incidence of complications, with the intention of enabling surgeons to compare their own practice and better inform their patients of potential risks.

Materials and Methods

A comprehensive literature search was conducted in June 2023 via PubMed and Google Scholar using the Boolean operators (AND, OR, NOT), and the keywords searched included; 'lengthening',

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'tibia', 'femur', 'nail' and 'external fixation'. We limited our search to the last two decades to keep the papers current and relevant, and so only included those which were published from 2003 to 2023. The papers were then individually filtered to ensure they met our inclusion criteria.

Inclusion Criteria

- Studies reporting 20 or more patients/limbs of any age.
- Lengthening of the femur and/or tibia as site of surgery.
- The use of an external fixation and/or intramedullary lengthening nail, including papers using a combination of the two.
- Published between 2003 and 2023.

Exclusion Criteria

- Studies written up any other language other than English.
- Animal studies.
- Studies including other sites of surgery.
- Systematic reviews and meta-analysis.
- Studies which included cases with plate assisted lengthening.
- Studies which included treating acute osteomyelitis or acute trauma alongside lengthening, including bone transport techniques.
- Studies with inadequate description of complications or, lack of a reporting the figures of each complication.

Patients were not subdivided into paediatric and adult cases. Complications were listed according to Paley's classification.[3] Problems required no surgical intervention to resolve, whereas obstacles did require surgery. Intraoperative complications and those obstacles that remained after frame removal and completion of lengthening were accepted as true complications. The affected areas could be further subdivided into soft tissue, bone, or general conditions, such as pain and difficulty with activities of daily living.

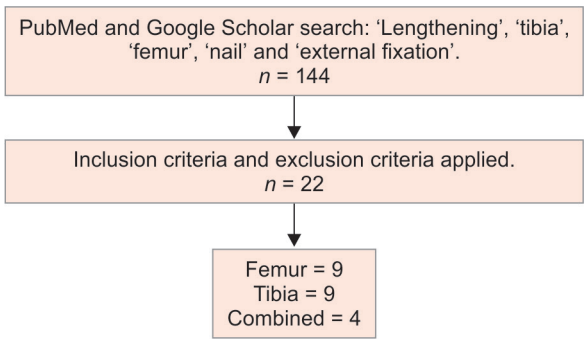
We grouped the complications, reported by the included papers, into either soft tissue, bony or implant. Soft tissue complications included pin site infection, muscle contracture, neurological injury, vascular injury, compartment syndrome, deep vein thrombosis, joint luxation, and joint stiffness. Muscle contracture and joint stiffness were reported separately as listed in the separate papers. Bony complications included osteomyelitis, re-fracture, premature consolidation, delayed consolidation, and deformity. Implant complications included pin loosening and/or breakage, and external fixator or intramedullary nail failure.

Results

A total of 144 papers were identified. And 22 papers published between 2008 and 2022 met the inclusion criteria. Many of the studies from the primary search were excluded either, due to less than 20 or more patients reported in the study, or for not documenting complications. The papers included nine reporting femoral lengthening,[5–13] nine tibial lengthening[14–22] and four combined lengthening (Including lengthening nails and external fixators) (Flowchart 1).[23–26] Femoral lengthening was undertaken in 356 patients, tibial lengthening in 649 patients, and papers reporting both femoral and tibial lengthening included 265 patients.

The complications reported following femoral lengthening with an external fixator are given in Table 1, with the highest complication reported as pin site infections in 52% and bone re-fracture following frame removal in 13% of 100 cases. Complications in femoral lengthening with an intramedullary lengthening nail are listed in Table 2. The complication rate was low, with the highest reported being technical issues with the implants in 8%, delayed consolidation in 6% and premature consolidation in 4% of 301 cases.

Flowchart 1: Methodology



Following tibial lengthening, the complication rate following external fixation is given in Table 3. Similar to femoral lengthening, pin site complications are most commonly seen in 18.8% of 649 patients. Joint contracture was seen in 15.9% and delayed consolidation in 8.3%. In the papers reporting the outcome of both femoral and tibial lengthening using external fixators, similar complication rates were seen, including pin site infections in 44.7%, joint contracture in 16.3%, regenerate deformity in 17.8% and re-fracture following frame removal in 11.5%.

The overall results are summarised in Table 4, including the extremely low rates of vascular injury, compartment syndrome, deep vein thrombosis, joint subluxation/dislocation, and osteomyelitis, all have reported rates of less than 1%.

Discussion

The process of informed medical consent includes a full discussion of potential treatments, including the option of no treatment, highlighting the relevant material risks significant to the patient. When discussing treatment, the information that a patient requires includes the diagnosis and prognosis of their condition, any uncertainties requiring further investigation, the desired outcome with potential benefits, and the risks of harm following treatment.[4] This should be performed in an objective way to ensure full understanding by the patient without assuming their needs or what they feel is significant. This supported decision-making between the doctor and patient relies on the patients feeling comfortable to voice their opinions and be listened to. They should be able to make an informed decision free from coercion and in line with their own values and wishes. Unwanted harm that may result from the treatment could be translated as a risk of complications. Our study has identified and listed the published rates of complications following lengthening of the femur and tibia with the aim that limb reconstruction surgeons may use these values as a baseline for patient information and also as a comparison against their own practice.

There has been recent reform of the consent process in the United Kingdom following Montgomery vs the Lanarkshire Health Board in 2015.[27] The need to tailor the discussion to the individual patient and their personal material risks requires the doctor to try and find out what matters to the patients and avoid a conversation where a patient may state 'if I knew that before, I never would have had the surgery'. The surgeon should discuss reasonable alternative treatment, with no expectation to undertake treatment that would be viewed as inappropriate, recently highlighted in the McCulloch vs Forth Valley Health Board.[28] Whereas most clinicians have heard

Table 1: Complications following femoral lengthening with an external fixator

		Soft tissue								*Bone*						*Implant*
Study	*Number of patients*	*Pin site infection*	*Muscle contracture*	*Neurological injury*	*Vascular injury*	*Compartment syndrome*	*DVT*	*Joint luxation*	*Joint stiffness*	*Osteomyelitis*	*Re-fracture*	*Premature consolidation*	*Delayed consolidation*	*Deformity*	*Pin loosening*	*Breakage/ Failure*
Sangkaew[5]	51	26	–	–	–	–	–	–	3	–	10	4	–	–	–	1
Gordon et al.[6]	37	19	–	–	–	–	–	4	–	4	3	4	–	–	–	2
Laubscher et al.[7]	12	7	–	–	–	–	–	–	4	–	–	–	–	–	–	–
Total	100	52.0%	–	–	–	–	–	4.0%	7.0%	4.0%	13.0%	8.0%	–	–	–	3.0%

Table 2: Complications following femoral lengthening with an intramedullary lengthening

		Soft tissue								*Bone*					*Implant*	
Study	*Number of patients*	*Pin site infection*	*Muscle contracture*	*Neurological injury*	*Vascular injury*	*Compartment syndrome*	*DVT*	*Joint luxation*	*Joint stiffness*	*Osteomyelitis*	*Re-fracture*	*Premature consolidation*	*Delayed consolidation*	*Deformity*	*Pin loosening*	*Breakage/ Failure*
Simpson et al.[8]	33	N/A	–	–	–	–	–	–	–	–	–	–	2	–	N/A	1
Kenawey et al.[23]	45	N/A	–	–	–	–	–	–	–	1	–	4	11	–	N/A	1
Lee et al.[9]	26	N/A	–	–	–	–	–	–	–	–	–	–	1	–	N/A	–
Kirane et al.[10]	17	N/A	–	–	–	–	–	–	–	–	–	1	–	–	N/A	1
Laubscher et al.[7]	20	N/A	–	–	–	–	–	–	4	–	–	–	–	–	N/A	–
Lecoanet et al.[11]	28	N/A	2	–	–	–	–	2	–	–	1	4	1	–	N/A	4
Calder et al.[12]	107	N/A	6	–	–	–	–	–	–	–	–	1	3	–	N/A	17
Laufer et al.[13]	25	N/A	–	–	–	–	–	1	1	1	1	2	–	–	N/A	–
Total	301	–	2.7%	–	–	–	–	1.0%	1.6%	0.7%	0.7%	4.0%	6.0%	–	–	8.0%

Table 3: Complications following tibial lengthening with an external fixator

		Soft tissue								*Bone*					*Implant*	
Study	*Number of patients*	*Pin site infection*	*Muscle contracture*	*Neurological injury*	*Vascular injury*	*Compartment syndrome*	*DVT*	*Joint luxation*	*Joint stiffness*	*Osteomyelitis*	*Re-fracture*	*Premature consolidation*	*Delayed consolidation*	*Deformity*	*Pin loosening*	*Breakage/ Failure*
Rozbruch et al.[14]	66	–	21	–	–	–	–	–	–	2	–	2	–	–	–	–
Novikov et al.[15]	124	5	26	6	–	–	–	1	–	3	1	–	6	9	–	–
Borzunov et al.[16]	38	8	–	2	–	–	–	–	–	–	–	–	1	1	–	4
Donnan et al.[17]	50	26	–	1	–	–	–	–	–	–	5	–	–	2	–	1
Jennison et al.[18]	58	38	–	–	–	–	–	–	–	–		–	4	–	–	–
Laufer et al.[19]	21	4	–	–	–	–	–	–	–	–	3	2	5	–	2	2
Nguyen and Le Van[20]	208	IS	56	–	–	–	–	–	–	–	–	1	36	IS	–	–
Balci et al.[21]	27	6	–	–	–	–	–	–	–	–	4	–	–	–	–	–
Chowdhury et al.[22]	57	17	–	–	–	–	–	–	–	–	1	–	2	2	–	1
Total	649	18.8%	15.9%	1.4%	–	–	–	0.2%	–	0.8%	2.2%	0.8%	8.3%	5.0%	0.3%	1.2%

Table 4: Summary of published lower limb-lengthening complications

	Soft tissue								*Bone*					*Implant*	
	Pin site infection	*Muscle contracture*	*Neurological injury*	*Vascular injury*	*Compartment syndrome*	*DVT*	*Joint luxation*	*Joint stiffness*	*Osteomyelitis*	*Re-fracture*	*Premature consolidation*	*Delayed consolidation*	*Deformity*	*Pin loosening*	*Breakage/ Failure*
Complications of femoral lengthening with intramedullary nailing	N/A	2.7%	–	–	–	–	1.0%	1.6%	0.7%	0.7%	4.0%	6.0%	–	N/A	8.0%
Complications of femoral lengthening with external fixation	52.0%	–	–	–	–	–	4.0%	7.0%	4.0%	13.0%	8.0%	–	–	–	3.0%
Complications of tibial lengthening with intramedullary nailing	N/A	8.3%	–	–	8.3%	–	–	–	–	–	–	–	–	N/A	–
Complications of tibial lengthening with external fixation	18.8%	15.9%	1.4%	–	–	–	0.2%	–	0.8%	2.2%	0.8%	8.3%	5.0%	0.3%	1.3%
Complications of femoral and tibial lengthening with external fixation	44.7%	16.3%	4.8%	–	1.0%	–	0.5%	–	0.5%	11.5%	5.8%	2.9%	17.8%	–	–

of the Montgomery report, there is still evidence that poor consent practice continues.[29] A review of 111 patient notes recorded poor documentation of specific patient risk was noted in 50% in cycle 1 of a service improvement study. Following an education programme highlighting poor practice and surgical risk of litigation, a further review of 96 patient notes recorded an improvement of up to 60% in cycle 2 of the study. Other findings included risks of the specific procedure improving from 42 to 76%, and alternative procedures documented initially in 48% increasing to 76%. Most alarmingly, evidence of written documentation provision was noted in 14% of patients in cycle 1, but this was reduced to only 8% in cycle 2.

A patient's decision to undertake a procedure should be appropriately documented. The time to reach this decision can be variable, depending on several factors including the complexity or severity of the condition, the relevant risks and treatment options with the likelihood of a successful outcome, and the patient's level of understanding. Patients should be given a reasonable time and space to reach a decision. Ideally, the patient should sign the consent form after this period. This would allow a patient to receive a copy of the signed form alongside all relevant information, for reference and reflection. This would include the relevant correspondence from the surgeon. At the time of admission, the surgeon can confirm with the patient that nothing has changed. If there has been a significant delay from the original signing, then the surgeon can sign in the relevant area to confirm the consent, the patient is not required to sign a second time. It is possible to sign the consent form on the same day, as long as the patient has a complete understanding of the procedure and the relevant material risks. There should be no changes to the consent or planned procedure discussed. If there is a change to the planned procedure or further information is given then, in this scenario, adequate time and space are needed for the patient to make an informed decision on the changes suggested. There have been several cases resulting in litigation following negligent consent, the most expensive being Hassell vs Hillingdon Hospitals.[30] In this particular case, there was evidence of previous discussion including relevant risks. The consent form was signed on the day of surgery and the potential risk of paralysis was added. The procedure was unfortunately complicated by paralysis. The court found that the consent process was negligent, importantly, with no evidence that the surgery was performed negligently. If the consent process had been performed properly, with adequate time and space for the patient to reflect on the risk of paralysis, then the patient would have deferred surgery to consider the options in more detail. The case was settled for £4.4 million.

The complexity of limb reconstruction surgery is associated with several complications, which range from minor pin site infections to potential limb-threatening compartment syndrome or life-threatening deep vein thrombosis and pulmonary embolus. Whereas every patient will have their own individual material risk priorities, the common problems, obstacles, and complications highlighted by Paley[3] should be discussed. As demonstrated in this study, the risk of pin site infections when using external fixation is high, in 26–50% of cases. However, there is a very low incidence reported of vascular injury, compartment syndrome, deep vein thrombosis, joint subluxation/dislocation, and osteomyelitis. In the case of deep vein thrombosis, the low incidence has been previously demonstrated in a review of elective use of external fixators in limb reconstruction.[31] It is also accepted that the risk of joint subluxation and/or dislocation is much higher in lengthening undertaken in congenital limb deficiency, with absence of cruciate ligaments and knee instability.[32,33] The risk may be predicted to be lower in other aetiologies. Ultimately, it will be the surgeon's decision in partnership with the patient to decide which risks are relevant.

There are several limitations to this study. We have only used one search engine which brings into bias with potential studies that have been missed and additional data that could alter our results. There was no separation of paediatric and adult patients. It may be accepted that paediatric patients have different biological responses and therefore may be more or less vulnerable to potential complications. However, the complications discussed during the consent process would be the same. The complications listed in the literature often lacked detail, such as differentiation of superficial pin site infection treated by oral antibiotics compared with deep pin site infection requiring surgical debridement. It was not possible to differentiate muscle contracture and joint stiffness, which were therefore reported separately. Furthermore, some of the papers report implants that have been withdrawn from clinical use due to unwanted complications.[8,9,11] These results may skew the data presented. We therefore accept that a generalised discussion would take place from the data presented. It is not possible to state that the incidence of the complications listed in this review will be the same risk to the individual patient undergoing a specific treatment, that is to say, the demographic of the patient in the clinic matches exactly the patients involved in the published studies and so have the same risk. This is due to the heterogeneous make-up of the studies reviewed and the inability to break down the individual cases reported to match the patient being counselled, which further supports that this information should be used to guide the conversation. The published risk of certain complications can be used to inform patients of potential harm that could occur during surgery. Surgeons can use the figures as a baseline to compare their own results, potentially highlighting trends of unwanted complications and instigate a review of surgical technique and postoperative rehabilitation.

In conclusion, we have demonstrated the published rates of complications following lower limb lengthening of the femur and tibia. We recommend the figures be used as a guideline during discussions with patients for these complex procedures, relaying the material risk of complications as part of the informed consent process. They could also be used by surgeons as a service review of their own practice to benchmark against the published evidence. Further reviews could be undertaken to look at other results of distraction osteogenesis, such as bone transport or for the treatment in long bone infection.

Availability of Data and Material

Raw data available on request from the primary author.

Author Contributions

Makvana S carried out data collection, data analysis, and paper write-up. Robertsion A performed data collection and analysis. Britten S was involved in data analysis, paper write-up and editing. Calder P contributed to the designing study, data analysis, paper write-up and editing.

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