ORIGINAL ARTICLE

How Much Does Paediatric Femoral Lengthening Cost? A Cost Comparison between Magnetic Lengthening Nails and External Fixators

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Abstract

Aim: Motorised intramedullary lengthening nails are considered more expensive than external fixators for limb lengthening. This research aims to compare the cost of femoral lengthening in children using the PRECICE magnetic lengthening nail with external fixation.

Methods: Retrospective analysis of 50 children who underwent femoral lengthening. One group included patients who were treated with PRECICE lengthening nails, the other group included patients who had lengthening with external fixation. Each group included 25 patients aged between 11 and 17 years. The patients in both groups were matched for age. Cost analysis was performed following micro-costing and analysis of the used resources during the different phases of the treatments.

Results: Each group's mean patient age was 14.7 years. Lengthening nails were associated with longer operative times compared with external fixators, both for implantation and removal surgery (*p*-values of 0.007 and < 0.0001, respectively). Length of stay following the implantation surgery, frequency of radiographs and frequency of outpatient department appointments were all lower with lengthening nails. The overall cost of lengthening nails was £1393 more than external fixators, however, this difference was not statistically significant (*p*-value = 0.088).

Conclusion: The difference in the mean costs between femoral lengthening with lengthening nails versus external fixators was not statistically significant. Further research to review the effectiveness of the devices and the quality of life during the lengthening process is crucial for robust health economic evaluation.

Keywords: Cost analysis, Distraction osteogenesis, External fixator lengthening, Femoral lengthening, Hybrid lengthening, Intramedullary lengthening, Lengthening nail, Limb lengthening, Motorised implantable nail, Short stature.

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Take-Home Message

- Cost analysis is an important aspect of clinical research.
- When comparing the cost of treatment, it is important to assess the overall cost rather than the individual cost of implants.
- Lengthening nails and external fixators were comparable in the overall cost.

Introduction

Deformities of the lower limbs, including limb-length discrepancy (LLD), have been successfully treated with external fixation.[1] The frequent complications of external fixators and the emphasis on quality of life and the emotional well-being of patients have led to the development of fully implantable motorised lengthening nails.[1] PRECICE lengthening nails (NuVasive Specialized Orthopedics Inc. Aliso Viejo, California, United States) have become very popular for limb lengthening.[2] PRECICE nails are magnetic telescopic titanium intramedullary lengthening nails, with the nails being activated using an external remote control (ERC) to produce the required distraction. In the same way, they can be reversed to produce compression,[3] which is especially beneficial when considering the compression distraction (accordion) manoeuvre to accelerate bone formation. The concept of sleeper nails is another application of the reversible potential of PRECICE nails.[4]

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Lengthening nails are reported to be more convenient for patients and more effective in achieving the required length, in addition to having fewer complications than external fixators.[5–9] Limb lengthening is a high-cost process, not only because of the expensive fixation devices but also due to the need for multiple surgeries, complex rehabilitation, and management of adverse effects. As a result, NHS England has included lengthening nails and external fixators within the high-cost tariff-excluded device (HCTED) system. Motorised lengthening nails were commonly criticised for being more expensive than external fixators, however, the effect of this cost difference on the overall cost remained unclear. It is important when the cost is compared to look at the overall cost of the lengthening rather than the individual price of the devices.

Considering the financial pressure of limb reconstruction, it has become important to consider the cost when deciding on treatment options. This study compares the cost of femoral lengthening in children using magnetic lengthening nails to the cost of femoral lengthening with external fixation devices.

Methods

Motorised lengthening nails are currently being used off-label for children. Approval of this research was granted by the local Research and Development Department and NHS Health Research Authority (HRA) (IRAS number 241541).

Inclusion criteria consisted of the following: (1) age between 11 and 17 years old at the time of surgery, (2) femoral lengthening surgery using external fixator or PRECICE intramedullary limb lengthening system and (3) follow-up for a minimum of 12 months following the removal of the lengthening device.

The medical records were reviewed for patients who met the inclusion criteria. Patients were divided into two groups according to the fixation device. The first had PRECICE lengthening nails, while the second had external fixation. Patients in the two groups were matched for age. Since the lengthening nails sample size was smaller than that of the external fixators group, matching was done by manually searching the external fixators database to include patients of the same age (±6 months) as the patients from the PRECICE nails group. Matching was undertaken blind of all other patient details, such as length of stay and outcomes.

This study focused on comparing the costs of femoral lengthening in children. Complications were reported to enable the calculation of the cost. The utilised resources for each patient were recorded and the costs were calculated using 2019/20 price levels. The identified resources included: the operative time (minutes) for each procedure, consumables (e.g., antibiotics, knee braces, plaster casts, etc.), length of hospital stay (LOS) following each surgery (days), radiographs that included unilateral limb or mechanical axis views and outpatient department (OPD) appointments. The units of costs for OPD appointments, radiographs, theatre utilisation, staff costs, hospital beds and hospital admission charges were all calculated according to the NHS England National Tariff. The prices of the components of the devices, medications and consumables were sourced from the supplier chain. The individual costs of the fixation devices varied between patients within the same group according to the type of nail (antegrade or retrograde) and the different components of the external fixators (numbers of rings, half-rings, rods, struts, wires, half-pins, bolts, etc.). The costs were calculated for individual patients according to the utilised resources rather than using the data from the patient level information costing system (PLICs), which might not reflect the variation in costs between patients. The costs of treatment of complications (medications, admission, LOS and any subsequent surgery) were calculated in the same way and presented as a separate cost category.

In our protocol, knee spanning seen with external fixators was replaced with night splints during the distraction phase with PRECICE nails. The distraction rate was 1 mm/day (0.25 mm four times/day for external fixation, and 0.33 mm three times/day with lengthening nails). The distraction rate was adjusted according to the quality of the regenerate, tolerance of the patients and nearby joints' range of motion. Full weight-bearing was allowed early following external fixation procedures, while non-weight-bearing was advised following lengthening nails procedures until adequate bone formation. Preoperative deformities were corrected either acutely or gradually with external fixators. Reverse planning,[10] acute correction and blocking screws[11] techniques were utilised when relevant to correct preoperative deformities with lengthening nails.

Multiple statistical tests were used to test the objectives of the study. At the first level of analysis, descriptive statistics were used. Mean and standard deviation were computed for the normally distributed continuous variables, otherwise, the median was computed, and frequencies or percentages were reported for categorical variables. At the second level, hypothesis testing was undertaken to examine the null hypothesis that there were no statistically significant differences in the mean of the two groups with regard to the individual outcomes (duration of the initial and removal surgeries, LOS following surgeries, numbers of radiographs and OPD appointments). Since the distribution of the individual outcomes was normal, paired *t*-test of differences in means was used to test the null hypothesis. However, the Mann–Whitney *U* test was also carried out on these variables for confirmation. But, for the difference in mean total cost in the two groups, a *t*-test was used. In all the statistical analyses, p-value < 0.05 was regarded as significant.

Results

Twenty-five cases were included in each group. The study included patients who were treated in a tertiary unit by multiple surgeons. The mean age was 14.7 years for each group. Each group had 11 children with congenital LLD, while the remaining 14 children had acquired indications for femoral lengthening. The external fixation group included 19 circular and 6 monolateral fixators, while the lengthening nails group included 13 trochanteric entry antegrade nails and 12 retrograde nails. All retrograde nails were inserted following the closure of the distal femoral physis. The patients were followed up for 12 months following the removal of the fixation device.

The target length was 4.8 cm and 4.5 cm for external fixators and lengthening nail groups, respectively. There was no significant difference in the length gained between the two groups ($p = 0.84$). Complications were significantly higher with external fixation than lengthening nails ($p < 0.0001$). The details of the complications are summarised and classified according to Paley's classification[12] in Table 1. Surgical treatment of the complications was required in one patient from the nail group to revise the lengthening nail to an intramedullary trauma nail for management of locking screw loosening and non-union. Meanwhile, surgery was required in 9 patients following lengthening with external fixations: 2 patients

to this journal's standard review procedures, with this peer review handled independently of this editorial board member and his research group.

Table 1: Adverse events of femoral lengthening

	External fixation [n (%)]		*PRECICE nail [n (%)]*	
	Events	*Affected patients*	*Events*	*Affected patients*
Problems				
• Pin-site infection	12 (63.2%)	9 (36)	0	0
Obstacles				
• Deep infection	1 (5.2)	1 (4)	0	0
• Screw failure	0	0	1 (33.3)	1 (4)
• Pin loosening	1 (5.2)	1 (4)	0	0
• Non-union	2 (10.5)	2 (8)	1 (33.3)	1 (4)
• Contractures	1 (5.2)	1 (4)	0	0
• Loss of length	0	0	1 (33.3)	1 (4)
Complications				
• Fracture post removal	1 (5.2)	1 (4)	0	0
• Joint subluxation	1 (5.2)	1 (4)	0	0
Total adverse events and affected segments	19	16 (64)	3	1 (4)

Discussion

The cost of healthcare continues to rise, but the resources available to meet these demands are restricted. Obtaining the best-possible clinical outcomes and patient satisfaction remains the main clinical priority for both clinicians and their patients. Economic factors do play an increasingly important role in the development, management and evaluation of health systems.[13] The use of novel devices requires careful assessment of the cost implications of these devices in addition to their clinical outcomes. Multiple authors reported the clinical outcomes of limb lengthening with motorised lengthening nails, [7,9,14–16] however, most of these studies included adults and children population. Despite the increased cost of the lengthening nails, there was no evidence comparing the overall cost of this recent intervention to the traditional treatment with external fixators in children.[8] Richardson et al.[17] compared the costs of femoral lengthening with magnetic lengthening nails to lengthening with external fixation over a nail. The study focused on adults and followed a macro-costing approach. The authors concluded quicker union and fewer procedures per patient in the magnetic lengthening nails group. There was no statistically significant difference in the overall cost of treatment between the two groups despite the lower surgeons' fees with magnetic nails. These results echoed the reports from the same institute, which compared tibial lengthening with magnetic lengthening nails to lengthening with external fixation and then nailing.[18] Yet, it was not clear whether the extra cost of lengthening nails could result in reducing the overall treatment cost in children. As a result, this study focused on the cost analysis of the lengthening nails and external fixators for femoral lengthening in children.

Table 2: List of NHS resources

	External fixation group		*Lengthening nail group*		*Difference (external fixation – lengthening nails)*	*p-value*
Resources	*Mean*	*SD*	*Mean*	*SD*	*Mean*	
Number of patients	25		25			
Duration of osteotomy surgery (min)	153.56	28.55	180.04	37.17	–26.48	0.007
Length of stay following osteotomy surgery (days)	9.24	5.78	4.19	3.35	5.08	<0.0001
Radiographs unilateral (*n*)	11.48	3.11	4.16	3.41	3.56	0.0001
Mechanical axis radiographs (*n*)	2.88	1.83	1.31	0.55	1.56	0.0003
Outpatient department appointments (*n*)	11.84	3.05	7.92	3.23	3.84	<0.0001
Duration of removal of fixation devices (min)	42.4	11.07	110.54	29.57	–68.88	<0.0001
Length of stay following device removal surgery (days)	0.16	0.62	0.96	0.98	–0.8	0.0001

required manipulation under anaesthesia for stiff joints, 1 had debridement of deep infection, 1 required replacement of a half-pin, 2 were treated with bone grafts for non-union, 1 patient required internal fixation of a fracture following removal of the fixator, while the last patient required hip reconstruction to treat subluxation.

Lengthening nails were associated with longer operative times for both implantation ($p = 0.007$) and removal ($p < 0.001$) of the devices compared with external fixators. Unlike the external fixators, lengthening nails led to shorter LOS following the implantation surgery ($p < 0.0001$), fewer OPD appointments (p-value < 0.0001) and radiographs ($p = 0.0001$ and 0.003 for focused views and mechanical axis views, respectively). Length of hospital stay following the device removal was longer with lengthening nails ($p = 0.0001$) than with external fixators. Table 2 describes the NHS resource utilisation.

The cost analysis reflected the difference in the utilisation of resources between the two groups. The costs of the individual items are summarised in Table 3.

Figure 1 illustrated the total cost, by component, for each group. The mean costs of the lengthening device were £11,428 (SD 550) and £7,745 (SD 1324) for lengthening nails and external fixators, respectively. The mean total cost of femoral lengthening was £19,374.55 (SD 2,306.1) with PRECICE nails and £17,980.68 (SD 3,261.68) with external fixators. The cost difference between the two groups was not statistically significant ($p = 0.088$).

This study included the first 25 femoral lengthening nails in our unit. We found that the duration of surgery was longer with the lengthening nails compared with external fixators. External fixation is a mature technology that surgeons are experienced in using. However, as lengthening nails were a relatively new technology then, one can argue that surgeons had not yet optimised their skills, and so the length of surgery might have been longer than would be expected once it became more routinely used. However, the duration of surgery did not reduce as expected when more patients were treated. The increased duration of lengthening nail surgery is likely due to the essential requirement to accurately correct the deformities intraoperative due to the limited potential for postoperative correction with lengthening nails. Reverse planning, acute correction, fixator-assisted nailing and Poller screws can be

Table 3: List of cost of the components of treatment

	External fixation group		*Lengthening nail group*		*Difference*
Cost component	*Mean*	*SD*	*Mean*	*SD*	*(External fixation – nails)*
Cost of theatre utilisation during osteotomy surgery, including staff cost (£)	2375.57	441.69	2785.22	575.09	–409.65
Cost of the length of stay following osteotomy surgery (£)	3632.42	2273.31	1635.38	1341.22	1997.04
Cost of radiography (£)	509.31	97.34	322.75	123.63	186.56
Cost of clinic appointment (£)	1326.08	341.68	896	358.57	430.08
Cost of the fixation device (includes the cost of knee brace for the lengthening nails patients) (£)	7745.66	1324.22	11428.02	550.29	–3682.36
Cost of complications (£) (include the cost of any medications, surgery and hospitalisation)	1390.15	2384.71	177.44	887.2	1212.71
Cost of theatre utilisation for the device removal surgery (£) (include plaster cast, if required)	644.93	171.22	1721.5	463.06	–1076.57
Cost of length of stay following the device removal surgery (£)	145.17	235.11	408.24	354.06	–263.07
Total cost (£)	17980.689	3261.6818	19374.55	2306.14	–1393.86

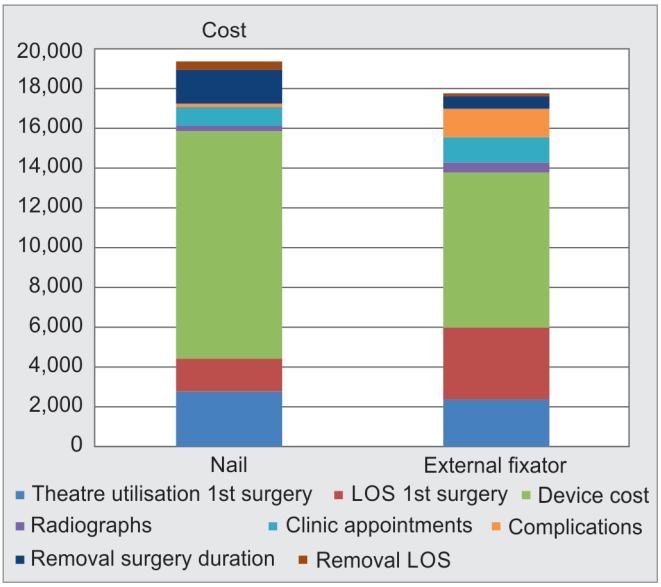

Fig. 1: Stacked bar chart of the total cost, by component, for each group

used to correct the deformities. These techniques usually add more time to the surgery. Following the surgery with external fixation, most patients required intensive training to learn about pin-site care and to become more familiar with the devices and the planned adjustments, this might explain the longer length of hospital stay that was reported with external fixators. Lengthening nails had significantly fewer complication rates than external fixators. The lower rate of complications with lengthening nails is believed to reduce the need for outpatient appointments and radiographs. Removal of external fixators was routinely done as minor day case procedures, whereas removal of lengthening nails was a more time-consuming procedure, and some patients required overnight stay.

The cost difference of £1393 between the two interventions for each patient was not statistically significant. The increased costs of the nails and operative duration in this group were largely offset by the reductions in length of hospital stay, outpatient appointments and number of radiographs. The more frequent complications with external fixators resulted in increased costs due to frequent appointments, admissions and surgical procedures.

Osteolysis, periosteal reaction and pain have been reported to be associated with a recent version of lengthening nails (the PRECICE STRYDE nails).[19] Unlike the titanium PRECICE nails, STRYDE nails are made of stainless steel, with the purpose to allow immediate weight-bearing. Corrosion at the telescopic junction of the STRYDE nails is thought to be responsible for these bony changes, which have led the STRYDE nails to be recalled for further research. No osteolytic changes have been observed in association with the use of the PRECICE nails in this study sample.

Economic evaluation is a central component of technology appraisals and clinical guidelines developed by the National Institute for Health and Clinical Excellence (NICE).[20–22] Economic evaluation is a comparative analysis of alternative treatment options in terms of both their costs and outcomes. Cost-utility analysis (CUA) is the type of analysis that is favoured by NICE. This is because the costs in monetary units are compared with the outcomes in quality-of-life adjusted years (QALYs).

Limb lengthening is mainly directed towards improving the quality of life rather than focusing on a single outcome. As a result, it is more useful to utilise cost-utility analysis for the economic evaluation of the different limb-lengthening devices. However, the outcomes in terms of QALYs between the two interventions have not yet been studied yet.[8] There are no published reports on the outcome of lengthening nails that used a validated health-related quality-of-life assessment (HR-QOL).[8] Some authors used locally developed patient satisfaction questionnaires.[14,23] Nevertheless, it is important to use validated HR-QOL to enable calculating the QALYs.

This study tried to avoid some of the limitations of previous research. It is focused only on children. Both groups had the same mean age and number of congenital indications for lengthening. The study followed micro-costing that is known to be more accurate than macro-costings. This study had some limitations. Firstly, the study represents a non-randomised comparison. However, matching was undertaken to make the two groups as similar as possible. The patients' selection was based on their ages and diagnoses only before reviewing the notes to identify complications and outcomes. Secondly, the retrospective design of this research was chosen to enable the recruitment of a sufficient sample size in

the external fixator group, this is because the number of patients who are treated with external fixators has dropped due to the increased demand for lengthening nails. Relying on retrospective notes review might have resulted in under-reporting the frequency of mild adverse events as these may not have been recorded. Having performed many thousand external fixators for lengthening at our unit, we are comparing an established technique with a novel surgical procedure, and this may underrepresent the complications seen in the fixator group. Third, some of the NHS resources were not included in this research, such as community physiotherapy, occupational therapy, hospital transport and medications supplied by primary care. Another limitation was the price of the individual devices and the fact that resources were calculated according to the NHS supply chain; a different supplier or healthcare service might have different prices.

Conclusion

The difference in the mean overall costs between the two interventions was not statistically significant. As a result, lengthening nails are not cost-prohibitive devices for femoral lengthening despite their apparent increased cost. This is the only research that has undertaken detailed costing of all aspects of hospital care relating to lengthening nails in comparison with external fixation.

Patient satisfaction and quality of life, both perioperatively and post surgery, are the most important factors in introducing new surgical interventions, and further research is needed in this area with validated outcomes. This is in addition to clinical outcomes and their cost analysis to further support the safety and efficacy of lengthening nails. However, our study provides valuable data on the costs of lengthening nails and external fixators in children.

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