ORIGINAL RESEARCH

Re-use of Motorised Intramedullary Limb Lengthening Nails

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Abstract

Aim: This study reviews the re-use of implanted motorised intramedullary lengthening nails previously used for limb lengthening.

Materials and methods: A retrospective review was performed on the re-use of motorised intramedullary lengthening nails. All patients had a magnetically controlled intramedullary lengthening nail in the femur, tibia, or humerus previously utilised for either lengthening or compression. Patients were included if the magnetically controlled intramedullary lengthening nail underwent attempted re-use either in the same lengthening episode or in a temporally separate lengthening treatment requiring another corticotomy.

Results: Ten patients with 12 lengthening episodes were analysed including five tibial, five femoral and two humeral segments. Overall, seven of 12 nails (58%) were successfully re-deployed without the need for nail exchange. Two of three nails were successfully retracted and re-used for continued distraction in the same lengthening treatment. Five of nine nails (56%) were successfully reactivated in a subsequent, later lengthening episode.

Conclusion: Re-use of a magnetically controlled limb lengthening nail is an off-label technique that may be considered for patients requiring ongoing or later lengthening of the femur, tibia or humerus. Regardless of whether the nail is used in the same lengthening episode or separate lengthening episode, surgeons should be prepared for exchange to a new implant.

Clinical significance: Re-use of a magnetically controlled intramedullary lengthening nail will reduce surgical trauma and save implant cost in limb lengthening treatment but may only be possible in half of attempted cases.

Keywords: Limb length discrepancy, Motorised intramedullary lengthening, Sleeping nail, Sleeper nail.

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INTRODUCTION

Lengthening of long bone segments was first described by Ilizarov by his method of distraction osteogenesis utilising external fixators.^{1,2} Limb lengthening techniques have undergone a transition from external fixation-based techniques to largely all-internal implants primarily with motorised intramedullary lengthening nails. Motorised intramedullary limb lengthening (MILL) has been reported for the surgical lengthening of femoral, tibial, and humeral segments.^{3–5}

Some patients require separate episodes of lengthening to achieve limb length equalisation either because of the magnitude of discrepancy or the need to temporally separate lengthening treatments. In these cases, a MILL device can be re-used. To accomplish this, the distal interlocking screws are removed, the telescoping portion of the nail is reversed, the nail is relocked, and the nail is redeployed for further lengthening.

This procedure may be performed in two situations: to continue an ongoing treatment for cases in which the nail is maximally deployed but further lengthening is desired, or to use a "sleeping nail" technique.⁶ In this technique, the index lengthening site is allowed to consolidate. When further lengthening is desired at a later time, the nail is retracted and re-locked, then a corticotomy is performed at separate site from the previous lengthening site. A new lengthening then begins with the same device.

Studies reporting the outcomes of nail reutilisation remain sparse. If successful, this strategy could avoid the additional trauma of implant exchange and can save the cost of an additional lengthening device. We review our experience with re-use of motorised intramedullary lengthening nails for limb lengthening in children. In this report, the terms re-use and redeployment are ¹⁻³Department of Orthopaedic Surgery, Gillette Children's Specialty Healthcare, St. Paul; Department of Orthopedic Surgery, University of Minnesota, Minneapolis, Minnesota, United States of America

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used interchangeably to denote a nail that was retracted and then distracted by any timeline. The term "reactivation" is used to denote a specific subset of nails that were dormant for a period and then re-used or re-deployed for a second, later lengthening treatment.

MATERIALS AND METHODS

This study was Institutional Review Board (IRB) approved and a waiver of consent obtained. Patients were eligible if they had undergone reversal of a previously deployed MILL nail (PRECICE[®], Nuvasive, San Diego, CA, USA) between 2015 and 2022 by a single surgeon with the intention to re-deploy the implanted intramedullary device for lengthening. Variables of interest included length of time the nail was inactive, magnitude of previous lengthenings, specific implant considerations (diameter,

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Figs 1A to D: (A) A 13-year-old boy with a post-infectious physeal arrest and large humeral length inequality was undergoing retrograde humeral lengthening and had reached the end of available implant stroke; (B) Under general anaesthesia, a two-pin spanning external fixator was placed and the proximal interlocking bolt was removed. The patient was awoken, and for several hours the family retracted the nail with the external remote control until sufficient retraction was appreciated on radiographs; (C) Under a separate anaesthetic episode on the same date, the nail was re-locked and another 3 cm lengthening was achieved (D). After the advent of the "fast distractor device", a nail retraction of this type could be performed under anaesthesia within a few minutes. Notice the modification of the implant, including cutting of the large diameter end of the nail to decrease implant length, and the single interlocking screw in the supracondylar humerus was placed through a guided growth implant with a separate screw outside of the lengthening implant, with the intent of providing additional fixation

length, and "stroke"), timing of nail interlocking screw removal and retraction, complications associated with re-deployment of the nail, and the amount of lengthening achieved with the second use of the nail. Complications specific to the nail re-use were categorised according to the modified Clavien-Dindo classification for orthopaedic surgery.⁷

Technique: Continuation of Ongoing Lengthening

Lengthening nails that were to be retracted and re-deployed to continue the same lengthening episode were handled in the following manner. Under general anaesthesia, a temporary external fixator was placed to maintain length and alignment of the regenerate (Fig. 1). Interlocking bolts were removed from the male portion of the nail and the patient was then awoken from anaesthesia. The family completed retraction of the nail with the external remote control over a period of hours. Once retraction was radiographically confirmed, the patient returned to the operating room for nail re-locking and resumption of lengthening at the same site. During the study period a "fast-distractor" device was developed by the manufacturer, allowing for up to 7 mm/minute of nail compression or distraction. After the advent of the fast distractor, the nail could be quickly retracted and relocked by the surgeon under the same anaesthetic episode.

Technique: Reactivation of a "Sleeping Nail"

When nails were to be re-used after the consolidation of a previous lengthening, several technical strategies were employed and this

was termed nail "reactivation". If bony overgrowth of interlocking screws was suspected or anticipated, male interlocking screws were removed and the nail was either retracted at that time or left in its deployed position for later use. In a majority of cases, the male interlocking screws were left *in situ* and would be removed at the time of attempted nail reactivation.

At the time of later surgery for attempted nail re-use, locking bolts were removed and the nail retracted with the fast distractor if this had not been performed previously (Fig. 2). If the nail did not retract with the fast distractor, the nail was exchanged in standard manner. If the nail was successfully retracted, a low-energy osteotomy was performed at a distant site with osteotomes and curved corticotomes under fluoroscopic confirmation (Fig. 2D). Interlocking bolts were then reapplied and reactivation of the nail was confirmed. The patient then continued lengthening after a sufficient latency period and at the rate and rhythm prescribed by the surgeon.

Results

Ten patients (with 12 lengthening episodes) were included over an 8-year period (2015–2022). Five tibial segments, five femoral segments, and two humeral segments were included. The mean age at surgery was 14.0 years old (9.3–19.6 years old). The aetiology of the limb length discrepancy included congenital short femur (n = 2), post-infectious growth arrest (n = 2), post-traumatic growth arrest (n = 2), fibular hemimelia (n = 1), ischaemic growth arrest



Figs 2A to F: (A) A 15-year-old boy with a congenital short femur had undergone an uncomplicated antegrade 2.8 cm femoral lengthening 18 months prior to reoperation, with an 8-cm stroke nail; (B) In a single anaesthetic episode, his interlocking bolts were removed; (C) The nail was retracted and relocked; (D) A new corticotomy was performed and (E) The nail was tested; (F) An additional 3 cm of lengthening was performed

(n = 1), Ollier disease (n = 1), and congenital pseudarthrosis of the tibia (CPT, n = 1).

Seven of 12 nails (58%) were successfully re-used. This was attempted at a mean of 29.6 months from index placement of the MILL nail (1.4–84.0 months). Successful second use of the nail occurred at a mean of 17.6 months after insertion compared with 46.4 months for nails that failed re-use. In four cases, the nails underwent the distal interlocking screw removal in a prior, temporally separate procedure (mean 22.6 months, range 13.1–43.0 months), and three of these nails were successfully re-deployed (75%). Three nails (two humeral and one femoral) underwent attempted re-use to extend the same lengthening treatment, two successfully.

Eleven nails were 8.5 mm in diameter and one nail was 10.7 mm in diameter. Overall implant lengths ranged from 150 to 305 mm. All nails were P2 generation (a technical detail meaning the nails were composed of a single male and female component with a crown moulding at the telescopic junction, in distinction to the first generation of nails, P1, which were assembled from multiple parts without crown moulding). The average first lengthening was 3.6 cm (-0.5-7.6 cm) and two of the three nails reaching their maximum deployment were successfully re-used. The mean lengthening prior to attempted redeployment was 2.8 cm among nails that were successful, compared with 4.5 cm among nails not successfully re-deployed. The mean second lengthening was 3.4 cm (1.2–5 cm).

One nail was first placed in compression mode (viz., partially deployed) to achieve compression and healing of a refractured congenital tibial pseudarthrosis prior to successful reactivation for lengthening. No complications directly referable to re-used nails were identified intraoperatively or in the subsequent lengthening treatment.

DISCUSSION

In this series, 58% of magnetically controlled intramedullary lengthening nails were successfully re-used. Statistical conclusions

associated with failure were not possible due to the small number of patients, heterogeneity of implant sizes, absolute and relative lengthening magnitudes, time until re-use attempts, and differences in timing of interlocking screw removal.

Eltayeby et al. performed a study of MILL nails in which explanted devices were retracted and re-deployed ex vivo.⁶ Their results suggested that 84% performed successfully according to a standardised protocol and concluded that full deployment to the maximum nail stroke could damage the internal mechanism and decrease the likelihood of successful re-use. In another study of patients with achondroplasia undergoing lower extremity lengthening, Alonso-Hernandez et al. utilised a planned twostage lengthening strategy in which magnetically controlled intramedullary lengthening nails were unlocked after the first stage of lengthening, reversed and locked again followed by a second lengthening as part of one continuous treatment.⁴ In that series, 92% of nail successfully retracted. Three case reports (two in femoral lengthening and one in tibial lengthening) re-deployed the MILL nail in the same lengthening episode.⁸⁻¹⁰ When a rest period is desired between lengthenings, it is possible to await consolidation of a first lengthening, and follow with a later osteotomy and continue nail deployment without retraction if sufficient stroke is still available.¹¹

In our series, a majority of nails (58%) were successfully re-used. A similar majority (55%) of the subset of "sleeping nails" were successfully "re-activated" after prolonged quiescence. Postulated reasons for failure of reactivation are multiple. It seemed that the successfully re-used nails had been implanted for a shorter duration and had smaller lengthenings, well below the maximum stroke, although two of three nails which had reached maximum deployment were still successfully re-used.

Bony ingrowth into interlocking screw holes may have given resistance to an otherwise functioning nail, preventing the nail from retracting or re-deploying. For example, in one procedure a tibial nail had had distal interlocking bolts removed as a separate procedure 43 months prior (Case ID 6). At the time of attempted re-use, the nail did not retract, *in vivo* and a nail exchange was performed. However, intraoperative examination of the extracted





Figs 3A to D: (A and B) A 19-year-old girl with complete fibular hemimelia had undergone a previous 4.7 cm tibia lengthening and distal interlocking bolts had been removed 43 months prior to attempted nail re-use; (C and D) At the time of attempted re-use, the nail would not retract intraoperatively, so the implant was exchanged to a new nail and a subsequent lengthening was performed in standard manner. However, on the back table of the operating room, the nail, which would not retract *in vivo*, easily retracted *ex vivo*, suggesting that the bony ingrowth into locking holes of the implant had resisted the still functioning nail mechanism

device revealed that the nail functioned properly both retracting and re-deploying (Fig. 3). It is likely that the nail failed to retract *in vivo* because bone had filled the vacant distal interlocking holes. The authors suggest that if MILL nail re-use is planned, all interlocks could be filled at index lengthening and maintained until future surgery, to mitigate the likelihood of bony ingrowth, particularly if the dormant period will be long. Not all nails were systematically tested *ex vivo*, so the authors cannot comment about other nails that failed attempted re-use.

In principle, re-use of a functioning medical device can save the burden of tissue dissection, minimise operating room and anaesthetic time, and decrease cost of care. No complications directly related to nail re-use were recognised in this study; therefore, an attempt at nail reactivation prior to exchanging to another lengthening nail may be beneficial. Other authors caution against reactivation of early generation PRECICE nails (P1) due to corrosion in the nails and concern for mechanical failure.¹¹ However, macroscopic analysis of retrieved P2 nails in the above study demonstrated no corrosion.

This study is limited by is retrospective nature and small numbers. Owing to these factors, statistically significant predictors for successful re-use could not be determined. In addition, this is an off-label use of the PRECICE nail as it was not specifically designed for such re-deployment. Consequently, specific discussions are performed with each patient who is a candidate for reactivation of a motorised internal lengthening nail.

CONCLUSION

This study demonstrates that retraction and re-deployment of magnetically controlled intramedullary lengthening nails is successful in 58% of cases. Goal lengthening was successfully achieved among all re-used nails.

Clinical Significance

The practice of re-using a magnetically controlled intramedullary lengthening nail is supported by this study. This strategy avoids additional surgical trauma and the cost of an additional implant. Furthermore, no complications from re-use were recognised and standard lengthening proceeded as planned. Patients should be notified that this practice is an off-label use and that failure to re-deploy the nail in the operating room is an indication for exchanging to a new device.

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