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Post-retrieval functionality testing of PRECICE lengthening nails: The "Sleeper" nail concept

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ABSTRACT

Introduction: PRECICE intramedullary magnetic lengthening nails, introduced in 2011, have changed the landscape of long bone limb lengthening. The implants have a stroke ranging from 5 to 8 cm, but it may be desirable to perform part of the lengthening at one treatment, allow bone healing, leave the implant in place, dormant, and then return one or more years later to re-lengthen with the same implant. We call this the "sleeper" nail concept. This strategy may be gentler for the joints and soft tissues. Would the nail mechanism still be functional one or more years later?

Methods: We tested 102 intact, consecutively explanted nails. Using a "fast magnet," the male part was lengthened to 5 mm short of its maximum stroke capacity and retracted back to 35 mm (all nails start with the male part exposed 30 mm). The nails passed the test if the male part succeeded in lengthening to 5 mm short of the maximum stroke capacity and back to 35 mm (or only retract in case fully deployed at testing). During our testing, the nails were prevented from reaching their full capacity of lengthening/retraction to avoid jamming the gears. Failure was defined as the inability or partial ability to complete the process.

Results: Eighty-six nails (84.3%) performed successfully according to our testing standard. When comparing successful and failed nails in terms of nail type, generation, diameter, length and in vivo interval, there was no statistical significance. Comparing both groups in terms of status at testing (fully deployed or not) showed statistical significance with 9 of the 16 failed nails fully deployed at testing ($p < 0.001$).

Conclusion: Dormant PRECICE nails can be reactivated for further lengthening. The results imply that full deployment may damage the mechanism, making future re-use by retracting and then re-lengthening unsuccessful. The candidate nails for this purpose should not have any signs of clear damage (bending or breakage) and should not have been fully deployed. However, surgeons and patients should be aware of the need for possible nail exchange if the "sleeper" nail fails to wake up.

Level of evidence: Level IV case series analysis of retrieved surgical implants.

1. Introduction

Telescopic intramedullary magnetic lengthening nails have eliminated many of the drawbacks of traditional external fixators such as pin-site infections and tethering of muscles and skin by the external fixation wires/half-pins.[1–3] Nonetheless, complications of distraction osteogenesis during limb lengthening are still present, including muscle contractures, joint instability, neurovascular compromise, nonunions, and other serious complications.[4–9] In an attempt to reduce such complications, staged lengthening might be a solution.[10] It may be desirable to perform a portion of the bone lengthening at one treatment, allow the bone to heal and the soft

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tissues to recover, and then return at a later stage to cut the bone and complete the lengthening. As an example, if a patient requires 8 cm of lengthening, it may be technically easier, more successful, and better tolerated to undergo two sequential 4-cm lengthenings, separated by a few years apart. Such a strategy may be gentler for the soft tissue and joints.[11]

With internal lengthening options, the most commonly implanted device worldwide is the PRECICE nail (NuVasive Specialized Orthopedics, San Diego, CA, USA) with over 10,000 implantations to date (company data, August 2019). The routine protocol for these lengthening nails calls for their planned, elective removal approximately 1 year after the lengthening surgery, provided there is solid, circumferential healing of the lengthened regenerate bone.[1] Instead of removal, these nails could potentially be used to re-lengthen in the same patient; however, this potential use has not yet been systematically studied (Fig. 1). It should be noted that this type of strategy is considered off-label usage. We attempted to answer this question by testing the functionality of routinely (per protocol) explanted PRECICE nails when tested ex-vivo to determine the possibility of using the nail for a second lengthening session, months or years after the first lengthening procedure.

2. Methods

This project was exempt from IRB review as it does not meet the criteria for human subjects research. We studied a consecutive group of 102 PRECICE nails that were explanted from 83 patients between May 2013 and June 2016. Before any testing, all nails were washed with antibacterial soap and water, dried, and stored in plastic bags until testing. The male part of the telescopic nail measures 30 mm in all nails in the non-lengthened state and is able to lengthen 50, 65, or 80 mm depending on the nail model. In vivo, these nails are lengthened with the use of an External Remote Controller (ERC); however, the manufacturer (NuVasive Technologies) provides a "fast magnet" apparatus that can quickly ascertain if the mechanism is still functional. This device spins faster than the clinically available ERC, making testing more expeditious and convenient. "Functional" was defined as the ability to lengthen 5 mm short of the nail's full stroke capacity and retract back to 35 mm. We did not test the nails to their full stroke capacity in order to prevent possible gear damage. "Failure" was defined as the inability or partial ability to complete this process of lengthening and retraction.

At testing, the explanted nails were first measured with a ruler. Specifically, we measured the length that the male end was deployed in centimeters. We also recorded the serial number and the specific nail (diameter, length, type). The explanted PRECICE nail then was mounted on the fast magnet bench testing device. A mark was made with a permanent fine point marker on the male end of the telescopic rod where the male end enters the female component. The fast magnet then was activated for lengthening to 5 mm short of full stroke capacity and then shortening back to 35 mm.

We excluded nails that did not have associated basic demographic data of the patient from whom it was extracted. Furthermore, we excluded one broken nail in which the male part was sliding loose in the female part. The final group consisted of 102 nails from 83 patients.

Basic demographic information was collected for each nail: patient name (HIPAA protected by coding), diagnosis, type of PRECICE nail and serial number, date of insertion and removal, and amount of clinical lengthening achieved. A comparison between the successful and failed nails was performed according to nail type (antegrade femur, retrograde femur, and tibia), generation (P1 vs. P2), diameter (8.5, 10.7 and 12.5 mm), lengths, status at testing (fully deployed or not), and in vivo interval (duration spent inside the body).

All data were inputted into an electronic spreadsheet (Microsoft Excel, Microsoft Office, Redmond, Washington). Comparison

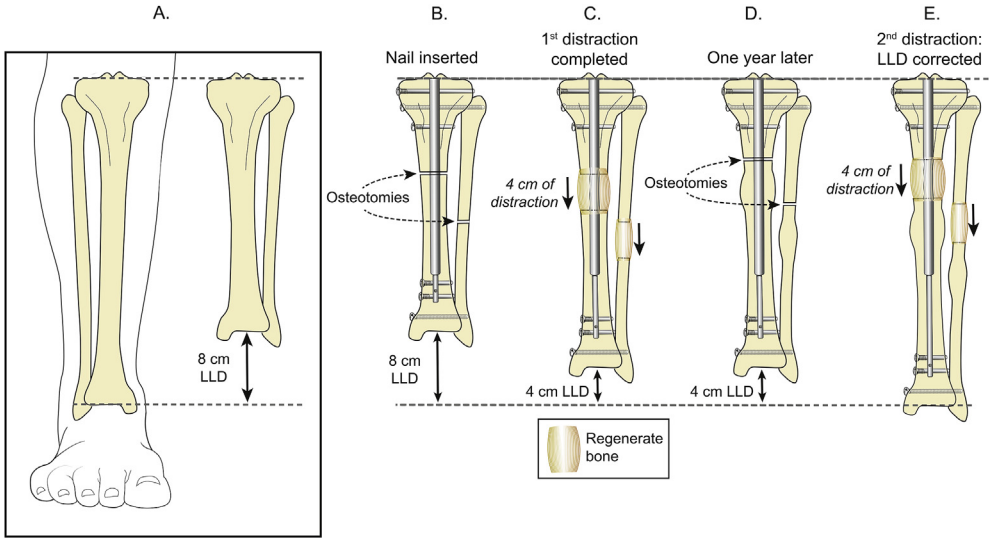

Fig. 1. A, Normal right tibia with short left tibia (8-cm limb length discrepancy [LLD]).
B, Insertion of magnetic lengthening nail (245 mm) with potential stroke of 80 mm.
C, After lengthening 4 cm, LLD is now reduced to 4 cm.
D, One year later, regenerate bone is well healed. The original nail has been "sleeping" and is now "awake" and reactivated after cutting the tibia and fibula in different locations.
E, After an additional 4 cm of lengthening, LLD is now zero. The advantage for the patient was that it is potentially easier for the soft tissues and bone to tolerate two modest lengthenings (4 cm each) rather than one heroic lengthening (8 cm).

between successful and failed nails was calculated using Chi Square and Mann Whitney methods (IBM SPSS Statistics for Windows, version 22, IBM Corp., Armonk, N.Y., USA).

3. Results

Eighty-six (84.3%) nails passed the test successfully (Fig. 2). Table 1 shows the demographic information for all implants, and Table 2 shows the specific demographic information of the 16 failed implants. Thirty-seven first generation P1 nails and 65 second generation P2 nails were tested. In the P1 group, 29 nails (78.4%) passed testing successfully. Eight nails (21.6%) failed testing; all had been fully deployed. In the P2 group, 57 nails (87.7%) passed testing. Eight nails (12.3%) failed testing, only one of which was fully deployed.

Table 3 shows the comparison between successful and failed nails and the level of significance. The results showed no significance in terms of nail type ($p = 0.75$), generation ($p = 0.214$), diameter ($p = 1.000$), length ($p = 0.331$), and in vivo interval ($p = 0.519$). Comparing both groups in terms of status at testing (fully deployed or not) showed that those that were fully deployed had significantly higher failure rates ($p < 0.001$).

4. Discussion

PRECICE nails have been shown in numerous studies to be an effective method for limb lengthening.[12–14] The PRECICE nail has made limb lengthening easier and more comfortable for patients with limb length discrepancy.[15] This is done by eliminating external fixators, external fixator pins, pin-site infections, and tethering of the muscles and skin by the external fixator pins.[1,2] However, the basic challenges of limb lengthening remain: stretching of the soft tissues, bone formation, and decreased joint motion.[4–7] For these reasons, it may be desirable to break down a specific lengthening into two parts: For example, instead of a single 6-cm lengthening, one could undergo two 3-cm lengthenings, performed 1–2 years apart. It may be easier and potentially safer for a patient to endure a 3-cm lengthening twice than a single 6-cm lengthening. Knowing that staged lengthening is better tolerated, we examined whether the PRECICE nail could be successfully awoken after sleeping for months and continue functioning for the remainder of the stroke capacity and determined that 84% of the evaluated nails were successful.

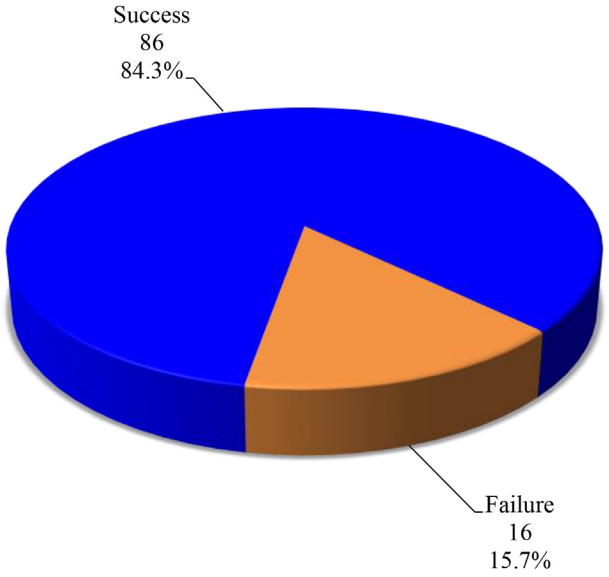

Fig. 2. Distribution of successful and failed nails.

Theoretically, any magnetic-powered device should function as long as the power supply is available. The magnet inside the PRECICE nail is susceptible to multiple factors, which may lead to partial or complete damage to the sensitive magnetic core. Various external forces such as hammering upon insertion and excessive weight bearing prior to healing of the regenerate bone may have detrimental effects. In addition, exogenous magnetic fields could potentially interfere with the nail's magnet. It is known that exposing a PRECICE nail to an MRI can degauss the magnet within the nail, rendering it ineffective.[16] Those factors are variable and difficult to measure. Additionally, a recent retrieval analysis study of 15 nails showed macroscopic and microscopic corrosion of the nails[17] which may have implications for potential re-use of the nails for subsequent lengthening.

The most useful conclusion based on statistical analysis was our comparison of successful versus failed nails in terms of their pre-testing status (fully deployed or partially deployed): almost 50% of the fully deployed nails in the study failed the test. Therefore, we conclude that, in some cases, deploying the nail fully may damage the internal mechanism, rendering it unuseable for reactivation later on. When planning a staged "sleeper nail" lengthening strategy, the surgeon must be aware not to lengthen the nail to its maximum during the first procedure. We also recommend that if the nail is to be shortened in vivo ("choking up on the nail") then it should not be fully retracted to the zero position (3 cm male tip exposed). We suggest that in cases short of maximum nail length, "sleeper" nails can be used later on by first allowing full healing of the regenerate bone. Then the patient can return to surgery to remove the distal locking screws, and the patient can retract the male end of the nail in vivo. Subsequently, another return trip can be made to the operating room to insert the distal locking screws, osteotomize the bone, and lengthen again.

Regarding the seven failures in the seven P2 nails that were not fully deployed, an explanation for this might be the creation of a biofilm on the latest generation of the PRECICE nails that might hinder the nail excursion.[17] Comparing the mean in vivo duration of implantation, we found no significance in our study. According to those results, the PRECICE nails can be reasonably expected to be capable of reactivation for a second lengthening procedure, no matter how long they were implanted in the body, so long they were not fully deployed at reactivation. Although not planned as a staged lengthening, a recent study by Couto et al. described a case report of a patient with residual leg length discrepancy after the contralateral limb continued with its normal growing process.[18] A second successful lengthening procedure was performed with the same lengthening device.[18]

This study has several limitations. It may be inappropriate to draw conclusions about whether a magnetic nail can be reactivated for additional lengthening in vivo based on nails that were extracted and remained outside the human body for a period of time. Truly "sleeping" nails would have experienced daily body loading forces during the interim preceding the reactivation test. Furthermore, the nails were not tested against body weight. Therefore, loaded testing or a clinical study may provide more useful information. Moreover, patients in whom the "sleeper" nail strategy is planned would not be eligible for any kind of MRI studies if indicated later on. Additional argument may arise from the safety profile of "sleeper" nails inside the human body. For example, metallosis has been reported from magnetically-controlled growing rods used to correct scoliosis.[19] In fact, keeping these devices implanted after union without adequate clinical justification is not indicated. However, the potential for a "sleeper" nail strategy can decrease the surgical and economic burden for patients, while

Table 1
Demographics of nails that successfully passed the "sleeper" test.

Generation	Nail type	Diameter, mm	Length, mm	In Vivo/months (Std. Dev)	Status at testing, months	Results
P1 (n = 37)	AG (n = 21) RG (n = 5) Tib (n = 11)	10.7 (n = 32) 12.5 (n = 5)	230 (n = 25) 255 (n = 5) 280 (n = 2) 305 (n = 1) 330 (n = 2) 355 (n = 2)	18.6 (7.91)	FD (n = 14) Not FD (n = 23)	Success (n = 29) Fail (n = 8)
P2 (n = 65)	AG (n = 37) RG (n = 9) Tib (n = 19)	8.5 (n = 22) 10.7 (n = 33) 12.5 (n = 10)	195 (n = 6) 215 (n = 4) 230 (n = 3) 245 (n = 23) 275 (n = 9) 305 (n = 14) 335 (n = 5) 365 (n = 1)	15.4 (6.58)	FD (n = 3) Not FD (n = 62)	Success (n = 57) Fail (n = 8)

AG, Antegrade; RG, Retrograde; Tib, Tibial; Std Dev, Standard Deviation; FD, Fully Deployed.

Table 2
Demographics of nails that failed the "sleeper" test.

Generation	Nail type	Diameter, mm	Length, mm	In Vivo/months (Std. Dev)	Status at testing, months
P1 (n = 8)	AG (n = 4) RG (n = 2) Tib (n = 2)	10.7 (n = 7) 12.5 (n = 1)	230 (n = 6) 255 (n = 1) 330 (n = 1)	18.5 (n = 3.29)	FD (n = 81 Not FD (n = 0)
P2 (n = 8)	AG (n = 4) Tib (n = 4)	8.5 (n = 3) 10.7 (n = 4) 12.5 (n = 1)	195 (n = 1) 230 (n = 1) 245 (n = 1) 275 (n = 3) 305 (n = 1) 335 (n = 1)	14.6 (n = 6.58)	FD (n = 1) Not FD (n = 7)

AG, Antegrade; RG, Retrograde; Tib, Tibial; Std Dev, Standard Deviation; FD, Fully Deployed.

Table 3
Comparison between the studied groups according to demographic data.

	Total (n = 102)	Success (n = 86)	Failure (n = 16)	Test of sig.	p
Type					
AG	58 (56.9%)	50 (58.1%)	8 (50%)	$\chi^2 = 0.710$	0.747
RG	14 (13.7%)	12 (14%)	2 (12.5%)		
Tibia	30 (29.4%)	24 (27.9%)	6 (37.5%)		
Generation				$\chi^2 = 1.547$	0.214
P1	37 (36.3%)	29 (33.7%)	8 (50%)		
P2	65 (63.7%)	57 (66.3%)	8 (50%)		
Diameter, mm				$\chi^2 = 0.168$	1.000
8.5	22 (21.6%)	19 (22.1%)	3) 18.8%)		
10.7	65 (63.7%)	54 (62.8%)	11 (68.8%)		
12.5	15 (14.7%)	13 (15.1%)	2 (12.5%)		
Length, mm				$\chi^2 = 11.060$	0.331
195	6 (5.9%)	5 (5.8%)	1 (6.3%)		
215	4 (3.9%)	4 (4.7%)	0 (0%)		
230	28 (27.5%)	21 (24.4%)	7 (43.8%)		
245	23 (22.5%)	22 (25.6%)	1 (6.3%)		
255	5 (4.9%)	4 (4.7%)	1 (6.3%)		
275	9 (8.8%)	6 (7%)	3 (18.8%)		
280	2 (2%)	2 (2.3%)	0 (0%)		
305	15 (14.7%)	14 (16.3%)	1 (6.3%)		
330	2 (2%)	1 (1.2%)	1 (6.3%)		
335	5 (4.9%)	4 (4.7%)	1 (6.3%)		
355	2 (2%)	2 (2.3%)	0 (0%)		
365	1 (1%)	1 (1.2%)	0 (0%)		
Status					
FD	17 (16.7%)	8 (9.3%)	9 (56.3%)	$\chi^2 = 21.408$*	<0.001*
Not FD	85 (83.3%)	78 (90.7%)	7 (43.8%)		
In Vivo interval, months					
Median (Min. – Max.)	15.0 (4.0–47.0)	15.0 (4.0–47.0)	16.50 (5.0–26.0)	U = 618.00	0.519
Mean ± SD.	16.54 ± 7.23	16.50 ± 7.55	16.75 ± 5.42		

AG, Antegrade; RG, Retrograde; Tib, Tibial; FD, Fully Deployed.
χ^2: **Chi square test**, U: **Mann Whitney test**.
p: p value for comparing between the two groups.
*: Statistically significant at $p \leq 0.05$.

having the potential back-up strategy for re-inserting a new nail if the retained nail fails to provide adequate lengthening.

5. Conclusion

Most of the PRECICE nails that have been retained in place after full healing can be theoretically reactivated for further lengthening across a new osteotomy if indicated. The candidate nails for this strategy should not have any radiographic evidence of damage (e.g., bending, breakage) and should still have adequate stroke remaining (not have been fully deployed). We strongly recommend that patients in whom a lengthening of a large segment is planned should be considered for the "sleeper" nail strategy. Surgeons, patients, and patients' families should be aware of the possibility of a "sleeper" nail not waking up and functioning, which would require a nail exchange to salvage the situation. There are clear advantages to the "sleeper" strategy, such as decreased cost. However, the cost savings should be balanced with the possible need for an additional outpatient surgery to remove the distal interlocks to allow the nail to be then gradually re-wound. In some cases, this interval surgery would not be required, such as when there is adequate residual stroke in the implanted nail. Finally, we recognize that the sleeper nail concept is considered an off-label use of this device.

Disclosures

JEH is a clinical advisor for Bonus BioGroup and a consultant for NuVasive Specialized Orthopedics, OrthoPediatrics, Orthofix, OrthoSpin, Smith & Nephew, and WishBone Medical.

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Declaration of competing interest

HHE and HMA declare that they have no conflicts of interest. JEH is a consultant for NuVasive Specialized Orthopedics.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcot.2020.06.005.

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