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CORR Insights®: What Are the Potential Benefits and Risks of Using Magnetically Driven Antegrade Intramedullary Lengthening Nails for Femoral Lengthening to Treat Leg Length Discrepancy?

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Where Are We Now?

The indications and techniques for limb lengthening continue to evolve. The basic understanding of distraction osteogenesis as described by Ilizarov has stood the test of time [6]. The prerequisites for a healthy lengthening include a 5-day to 10-day latency period following a low-energy osteotomy, then a controlled gradual lengthening of the bone ends at a certain rate and rhythm, followed by waiting (consolidation phase) for the lengthening regenerate to mature and get stronger before the patient can resume unrestricted activities. The discomfort of having a bulky external device on the limb, typically for several months, along with frequent pin tract infections, limited joint mobility secondary to transfixation of musculotendinous units by pins and wires, and the fear of bending or fracture of the lengthening callus soon after removal of the external fixator has led to the search of more user-friendly limb-lengthening devices [1].

But this quest to develop newer limb-lengthening tools and techniques that address some of the external fixator–related problems has been a roller coaster ride. While lengthening over nails decreases time spent in an external fixator, it exposes patients to other complications such as deep infections related to the close proximity of internal and external fixation devices [8]. Likewise, the initial success with lengthening nails was followed by several reports of problems, including "runaway nails" that caused painful, uncontrolled lengthening and non-union caused by malfunctioning of the lengthening mechanism and valgus malalignment related to lengthening along the anatomic, rather than mechanical, axis of the femur [7, 10].

Designers of motorized telescopic lengthening nails have attempted to address some of the previously reported problems like implant malfunction and breakage at the modular junctions. Orthopaedic surgeons and their industry partners continue to examine further improvements with the goal of enhancing patient comfort and safety [7]. One such enhancement was an attempt to make the motorized lengthening nail stronger by changing the metal from titanium to stainless steel to allow for earlier weightbearing during limb lengthening. However, as demonstrated by recent reports of corrosion and radiolucencies [14], unanticipated problems may surface several months or years after an "improved" implant has been introduced.

In this well-performed study, Frommer and colleagues [3] analyzed the radiographic results of patients with ≥ 2 cm of limb shortening who underwent femoral lengthening using an antegrade, trochanteric-entry titanium lengthening nail. An experienced group of limb lengtheners employed a standardized surgical technique in a very select group of patients in this

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report. They excluded patients with deep infections, those < 8 years of age, those with angular deformities, and those with a femoral dimension too small to accommodate the smallest available lengthening nail.

The authors noted that adjustment of distraction rate was the most common (27%; 24 of 90) complication. Other untoward events included temporary restriction of knee motion (20%; 18 of 90), delayed consolidation (6%; 5 of 90), premature consolidation/insufficient distraction (6%; 5 of 90), nonunion (4%; 4 of 90), periprosthetic fractures (3%; 3 of 90), deep infection (3%; 3 of 90), and knee subluxation (1%; 1 of 90), resulting in multiple trips to the operating room and inability to achieve the desired goal, likely with worsening function than started. Overall, 18 of 90 (20%) patients had unplanned return to the operating room in addition to the 90% of this group undergoing elective removal of the lengthening nail several months following the nail insertion (the authors' intention was to remove 100% of them, but this did not occur). A history of prior infection or post-infectious limb length discrepancy was associated with higher odds of unplanned return to additional surgery, although with a very wide CI [3].

Where Do We Need To Go?

Despite the findings in the current study, several unanswered questions remain. Are these results from an experienced group of limb lengtheners equally valid for surgeons who have not yet gone through a learning curve [2]? What about surgeons who have not received enough training in the field of limb lengthening and deformity correction?

For starters, it would be better if we could come to a shared language as to what defines a "complication" in a patient undergoing limb lengthening. Currently, it seems very much in the eye of the beholder. Obviously, the complexity of the preoperative deformity and host factors matter [12]. That being said, is temporary loss of knee motion that is regained with physical therapy in a patient undergoing limb lengthening enough of a setback to be labeled as a complication? Can such temporary impediments be lumped together with, say, an irreducible knee dislocation during lengthening a congenitally short femur? Results from a previous study suggested that we categorize such events based on reversibility of the untoward occurrence and attainment of the intended goal that was set out preoperatively [13].

As we strive to improve the clinical outcomes of a heterogenous group of patients undergoing limb lengthening using a variety of techniques that are performed by surgeons with varying clinical skills and training, we need to come up with a system that can help us assess and report the results accurately across such a diverse group. Having a relevant, reliable, and sensitive patient-reported outcome measure that is applicable to such a broad group of individuals with limb deformities would be helpful in comparing results across different patient populations.

Furthermore, we need more clarity on when and whether we ought to remove magnetically controlled internal lengthening nails. Is this recommendation related to concerns with the proximity of the magnet to other devices, or is the longevity and strength of the nail the issue? Can we come up with stronger nails that are safe to leave in for a patient's lifetime?

Finally, can we make these or similar implants more affordable such that they can be used by surgeons working in resource-limited environments where there is a substantial unmet need among children and adults with lower limb deformities?

How Do We Get There?

The field of limb lengthening and deformity correction involves not only a diverse group of patients with varied etiologies, but also surgeons with different subspecialty interests, training backgrounds, and practice settings. Thus, we need to agree on a common language for quantifying the complexity of the limb deformity [12], untoward events [2, 13] including device-related problems, and patient-reported outcomes.

In an attempt to classify implant-related complications related to internal lengthening nails, Lee et al. [9] classified untoward events into three broad categories: distraction control-related (runaway nail, nondistracting nail), stability-related (nail bending/breakage or rotational instability), and other device-related events (corrosion, adverse reaction to tissues). Each of these groups were then subcategorized as problems, obstacles, and sequalae as suggested by Paley [13]. Using such a classification system will allow one to compare safety profile and performance between different internal lengthening implants. However, we also need broader outcome measures so that we can compare limb-lengthening results between internal versus external fixators.

Investigators are also working on coming up with a set of valid, reliable, and accurate patient-reported outcome measures that are specific to individuals with limb deformities [4]. Once such a measure has gone through scientific scrutiny and sensitivity testing across a diverse group of patients, it would be helpful to have clinicians agree on one

or two such measures and adopt these in their clinical practice. Researchers should also be encouraged by leaders in the scientific community and subspecialty societies to report their findings using such measures when submitting their clinical research. In time, having a critical volume of such consistent reporting measures across different clinical scenarios will help us compare outcomes between various lengthening techniques and can be subjected to pooled analysis. After ensuring scientific rigor, such large datasets can help address questions such as the need for elective removal of a lengthening nail and the impact of a surgeon's case volume and training background on their clinical outcomes for such procedures.

As stakeholders in the global orthopaedic community, including educators and office-bearers of various professional societies, start to acknowledge "limb lengthening and deformity correction" as a distinct subspecialty [11], greater resources should become available to support the educational, research, and product development efforts in this growing field. Developing low-cost implants for limb lengthening, similar to what has been done for intramedullary fixation of long bones, would be extremely beneficial for a large segment of the global population that is currently underserved [5]. Strengthening alliances among clinicians, scientists, and innovators who use the same "deformity" language across the globe should go a long way toward providing safe, effective, and appropriate care to this unique and growing population of patients.

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