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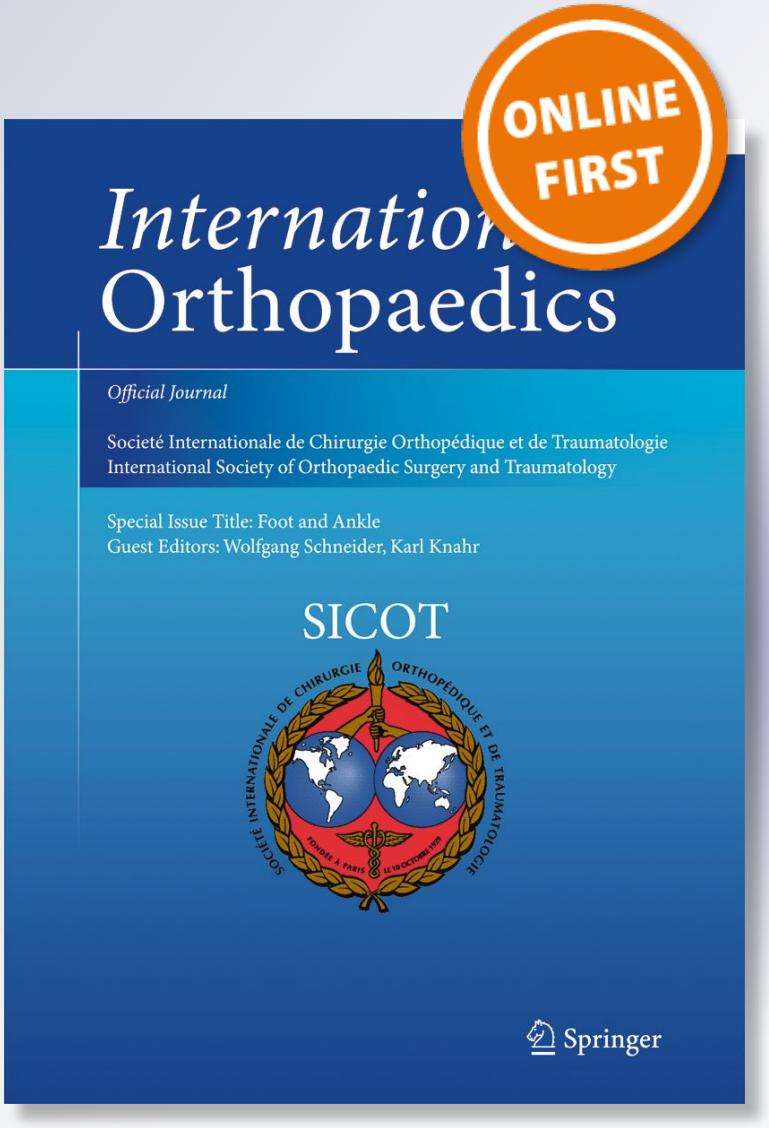

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REVIEW ARTICLE

Use of internal lengthening nails in post-traumatic sequelae

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Abstract External fixators are a well-established modality for treating fractures with bone defects, leg-length discrepancy, malunion, nonunion and other post-traumatic consequences. However, use of internal lengthening rods has remarkably increased recently for post-traumatic conditions. The main advantage of internal lengthening rods is eliminating pin-site complications. Internal lengthening rods are also associated with less pain. Motorised internal lengthening rods show promising performance in post-traumatic cases. Rigorous pre-operative planning is paramount to reducing lengthening-related complications. Certain types of internal lengthening rods offer bidirectional movement capability. Nail mechanism malfunction is a possibility with all kinds of nails. Direct doctor supervision is required, especially in the initial stages while the nail is lengthening. Internal lengthening nails are not as stiff as regular nails, with intricate internal mechanisms that can be broken under inattentive weightbearing activities. Preliminary positive outcomes indicate the role of internal lengthening rods in treating post-traumatic problems of leg-length discrepancy, malunion and nonunion.

Keywords Accordion manoeuvre · Fracture · Bone transport · Distraction osteogenesis · Internal lengthening nails · Implantable lengthening rods · Limb-length discrepancy · Nonunion

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Introduction

Cannulated interlocking intramedullary (IM) nails are the standard implants for operative fracture management of long bones. However, the role of internal lengthening rods as intramedullary stabilising devices is desirable in cases with limb-length inequality. Limb length discrepancy secondary to trauma can be due to bone loss, non-union, malunion or growth arrest.

Traditionally, the Ilizarov method has been used for treating traumatic conditions associated with significant leg-length discrepancy. Papakostidis et al. [1] conducted a meta-analysis of 37 reports (898 patients) on using the Ilizarov method for treating lower-limb defects that showed 5% refracture rate and amputation rate of 2.9%. Surprisingly, more than half of these amputations were made upon patient request, which reflects low patient tolerability to external, frames particularly for prolonged periods. Conversely, these issues were not observed in a large cohort of patients who underwent multiple varieties of internal lengthening rods [2].

Early removal of external lengthening frame may leave the regenerate bone at risk of fracture. On the other hand, prolonged retention aiming for more consolidation is often resisted by tolerability issues. This tendency to minimise fixator time and the subsequent loss of protection created strategies such as lengthening and then nailing (LATN) and lengthening over a nail (LON) [3]. In these hybrid procedures, pathogens may gain access to the deep IM cavity through pin tracks [4, 5]. However, with internal lengthening devices, pin-site infection and soft tissue tethering can be effectively avoided [6]. Cost is a consideration with internal lengthening rods, as they are almost twice as costly as the hexapod fixator [7, 8].

Limb-lengthening surgery developed over time. As a result, a plethora of medical devices and surgical strategies are

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available. Many authors use certain terminology to describe these devices in terms of performance or efficacy. Distraction index, represented in millimetres per day, may reflect the ability of a device to generate a desired distraction rate clinically. Consolidation index defines the time (in days) required from implantation date for 1 cm of regenerate to adequately harden, allowing for full weight bearing. Consolidation index can be of great value when assessing external devices. Table 1 provides a summary of clinical measures related to the use of external and internal lengthening devices in post-traumatic pathologies based on published literature.

Internal lengthening rods

The preliminary work of Bliskunov in 1983 is recognised as the earliest reported IM lengthening device [16]. Bliskunov described an IM femoral nail proximally anchored to the ipsilateral iliac bone, which transforms the rotatory movements occurring at the pelvic girdle into linear nail movement. Betz and colleagues [17] introduced the basis of electronically motorised FITBONE® nail (Wittenstein Intens GmbH, Igersheim, Germany) in 1990. Guichet et al. [18] presented a mechanically activated lengthening nail that was tested initially on animals in 1992 [19]. Later, that nail was known commercially as the Albizzia® nail (DePuy, Villerubanne, France). In 2001, another mechanically activated lengthening nail system was developed by Cole et al. [4] and named the Intramedullary Skeletal Kinetic Distractor (ISKD®, Orthofix Inc., Mckinney, TX, USA). Phenix® nails (Phenix Medical, France), available in 2009, are magnetically actuated lengthening nails [2]. PRECICE® (Nuvasive, Aliso Viego, CA, USA), another magnetically actuated lengthening nail, was launched in 2011 [20].

Several varieties of implantable lengthening rods are available for clinical use (Table 2). The vast majority share a common structure of two telescopic cylinders that distract from each other, increasing the overall nail length, and a source of energy is needed. Internal lengthening nails can be classified into first (mechanically actuated) and second (motorised) generations. (Fig. 1).

ISKD and Albizzia/Guichet nails work by an interlocking ratchet mechanism that translates limb-twisting movements—performed by the patient or caregiver and often associated with excruciating pain [20]—into forward slippage of the nail male portion. Approximately 3–9° pivoting movements around the soft regenerate are required for ISKD and 20° for Albizzia/Guichet nails [4, 21], neither of which is commercially available in the USA.

FITBONE is a unidirectional lengthening motorised nail system empowered with electric energy generated at an external source and delivered through radiofrequency waves across the skin to a subcutaneous receiver–cable element attached to the nail end. Subsequently, the FITBONE motor unit forces the nail to move forward. US Food and Drug Administration (FDA) marketing approval had not been given in the USA at this writing [29, 30].

Phenix and PRECICE nails are magnetically motorised rods capable of lengthening and shortening long bones [20, 25]. Rod-length increase or decrease occurs in response to a portable external remote controller (ERC) placed superficially on the skin [31]. The PRECICE nail is driven magnetically by the ERC device, which contains two rotating magnet units creating coupled rotation of the inner PRECICE magnet, which leads to subsequent nail movement. The PRECICE nail is approved by the FDA; the Phenix is not, and thus is not available in the US market.

Indications

Limb-length discrepancy is the primary indication of internal lengthening by implantable rods. Post-traumatic leg-length discrepancy could stem from multiple conditions. Injury to the growth plate could lead to delayed limb-length discrepancy secondary to growth arrest. Remarkable limb shortening might occur with complex long bone fracture accompanied by significant bone defects. Fracture management for acute shortening requires a subsequent lengthening session. Stump elongation of residual limbs is attainable with some internal lengthening rods dedicated for that purpose.

Promising outcomes have been observed using internal lengthening rods in the field of bone transport surgery. Shortening capability of some telescopic nails may be employed in situations of nonunion where compression is required. Also, shortening can reverse the undesirable effect of overdistraction and subsequently offers a protective measure for soft tissue conditions that may arise, and the accordion manoeuvre can be accomplished with bidirectional internal lengthening rods to enhance the healing potential of poor regenerate. Additionally, deformity correction using internal lengthening rods is possible to a certain degree. Some potential applications of internal lengthening devices can be considered as off-label uses. Acute lengthening through the fracture site is possible but has not been reported to date. Reactivation of a pre-implanted sleeper lengthening nail may also be conducted.

Contraindications

Implantation of internal lengthening rods in long bones with significant deformity, narrow-diameter canals or obliterated medullary cavities is contraindicated. The main portion of the nail intended to occupy the IM canal is straight. Also, they must not be implanted in with active infection. Using a

Table 1 Outcomes of available lengthening devices used in traumatic conditions

Study	Implant	No. cases	Procedure	Healing (days)	Consolidation Index (days/cm)	Lengthening (cm)
Sangkaew et al., 2004 [9]	AO/ASIF conventional external fixator	70	Lengthening	244.7	43.7	5.6
Nakase et al., 2007 [10]	Ilizarov / monolateral fixator	14	Lengthening	190	51.4	3.7
Ganger et al., 2010 [11]	TSF	24	Lengthening	180	66.6	2.7
Lenze et al., 2011 [12]	FITBONE	11	Lengthening ± deformity correction	123	40	3.3
Wang et al., 2012 [13]	ISKD	16[a]	Lengthening	152	47.8	3.5
Abuomira et al., 2016 [14]	Ilizarov/TSF	30	Bone transport	418	59.1	7.6
Abuomira et al., 2016 [14]	Ilizarov	25	Bone transport	359	63	6.5
Hammouda et al., 2017 [15]	PRECICE	17	Lengthening	119	31.9	3.8

AO/ASIF Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation, *ISKD* intramedullary skeletal kinetic distractor, *TSF* Taylor spatial frame

[a] 15 of 16 had post-traumatic conditions

piriformis entry site should be avoided in patients <12 years, as it carries the risk of damage to blood supply of the femoral head; trochanteric nailing is preferred in adolescents if indicated [32].

In general, magnetic resonance imaging (MRI) compatibility status has not yet been determined for internal lengthening rods. Patients who need MRI for any reason should have this performed prior to implantation of the magnetically driven rod

Table 2 Literature review of internal lengthening rods

Study	No.	No. trauma cases	Implant	Conditions	Outcomes	Complications[a]
Guichet et al., 2003 [21]	41	11	Albizzia	LLD	All segments reached target length and healed eventually with frequent interruptions	13 segments required ratcheting under anesthesia 11 complications required surgical interventions. 3 mechanical failure
Thonse et al., 2005 [22]	91	Unspecified	ISKD	LLD	70% satisfactory distraction	20% too slow distraction 10% too rapid distraction
Krieg et al., 2011 [8]	32	9	FITBONE	LLD/deformity	30/32 reached target length 35 days/cm femoral CI 48 days/cm tibial CI	1 mechanical failure 3 backwinding
Schiedel et al., 2014 [23]	26	Unspecified	PRECICE	LLD	24/26 reached target length 97% accuracy rate	2 mechanical failure 10 ERC errors
Kirane et al., 2014 [24]	24	Unspecified	PRECICE	LLD	96% accuracy rate 96% precision rate	4% implant failure 24% nonimplant complication
Shabtai et al., 2014 [7]	21	Unspecified	PRECICE	LLD	0.91 months/cm healing index	7 complications required surgical intervention
Thaller et al., 2014 [25]	10	7	Phenix	LLD/deformity	8/10 reached target length 0.85 mm/day distraction rate 27 days/cm weightbearing index	3 mechanical failures
Paley et al., 2014 [26]	65	6	PRECICE	LLD	0.83 mm/day distraction rate 125.3 days healing time	3 nail fractures
Birkholtz et al., 2016 [27]	11	7	PRECICE	LLD	45.18 mm target length 103% accuracy rate	1 mechanical failure 1 nail-tip protrusion
Accadbled et al., 2016 [28]	26	11	FITBONE	LLD	88% achieved target length 73 days/cm femoral healing index 83.5 days/cm tibial healing index	15.4% complication rate

CI consolidation index, *ERC* external remote controller, *ISKD* intramedullary skeletal kinetic distractor, *LLD* leg-length discrepancy,

[a] Complications represent the entire reported complications for the referred study including traumatic and nontraumatic cases

Fig. 1 First- [intramedullary skeletal kinetic distractor (ISKD)] and second- (PRECICE) generation internal lengthening nails

[33]. Based on the PRECICE manufacturer manual, implanted electronic devices such as pacemakers, implantable cardiac defibrillator and infusion pumps may be altered by the rod's magnetic field and hence should not be used conjunctively. Internal lengthening rods are not considered suitable for managing polytraumatised patients in the acute setting. Driving mechanisms are not expected to function properly in individuals with a body mass index >35. Wide soft tissue interval >5–7 cm may interfere with external remote controller function of the PRECICE magnetically motorised nail [23].

Distraction

All internal lengthening rods were developed to offer distraction osteogenesis for bone-lengthening purposes. Distraction velocity should be adjusted within safe physiological margins, maintaining regenerate well-being: rapid distraction could harm the regenerate, leading to delayed or nonunion; slow distraction may result in premature consolidation. A lengthening rate of 1 mm/day is generally acceptable, which is a subject to minor adjustment as dictated by regenerate condition. Clinical and radiological evaluation is recommended on a weekly basis during the distraction period [34].

Successful attempts of residual limb-lengthening using internal lengthening rods were reported using FITBONE TAM implant [34, 35]. Residual limbs with remarkably limited IM space do not accommodate standard internal lengthening rods. However, rod miniaturisation may have a role in stump elongation surgery [26].

At our institute, we have used ISKD rods for internal lengthening purposes in >200 segments [36]. After FDA recall of ISKD in 2012, we shifted to PRECICE nails. Lengthening with PRECICE nails was conducted in 17 post-traumatic limb-shortening cases with 2.2-year follow-up duration (Figs. 2 and 3). Average lengthening of 3.8 cm (2.3–6.0 cm) was achieved. Mean consolidation index was 32 days/cm (16–15 days/cm). Non-implant-related complications were encountered in 18% of cases, mainly pertaining to premature consolidation and soft tissue complications [15].

Fig. 2 A 28-year-old male patient with left tibia post-traumatic leg-length discrepancy. **a** Healed tibial fracture with 4-cm shortening. **b** PRECICE nail lengthening above the fracture area. **c** Full healing of the lengthening area after removal of PRECICE hardware

Compression

Compression is possible using the shortening mode of implantable rods, although shortening capability is limited to specific types. Currently, PRECICE is the only available rod in the USA with bidirectional mechanical function [26]. Satisfactory preliminary outcomes were reported in Europe with Phenix M2 nail system, which has both lengthening and shortening modes. Researchers used the shortening option on one occasion for distraction-induced neurological deficit of the foot, which recovered eventually [25]. Likewise, shortening may help ameliorate other distraction-related complications, such as joint subluxation and progressive soft tissue contractures. Based on the compression concept, Paley reported a case of simultaneous ankle arthrodesis and distal tibia lengthening using PRECICE nail [20].

Deformity correction

Intra-operative correction of mild, pre-existent angular deformities can be attempted with internal lengthening rods [20, 37, 38]. External fixator should be applied to maintain the corrected position until the nail is fully seated [26]. Blocking screws are useful adjuncts to stabilise the nail in the desired location. A uniformly straight passageway for the nail may be fashioned in the best favourable direction within the confines of the medullary canal using a rigid reamer guided by preplaced blocking screws, as indicated [2, 39]. Correcting rotational deformity can be obtained around the internal lengthening rods as far as the surrounding soft tissues remain unharmed [24].

Certain deformity patterns are predictable with different kinds of osteotomies and nailing approaches. Angulation

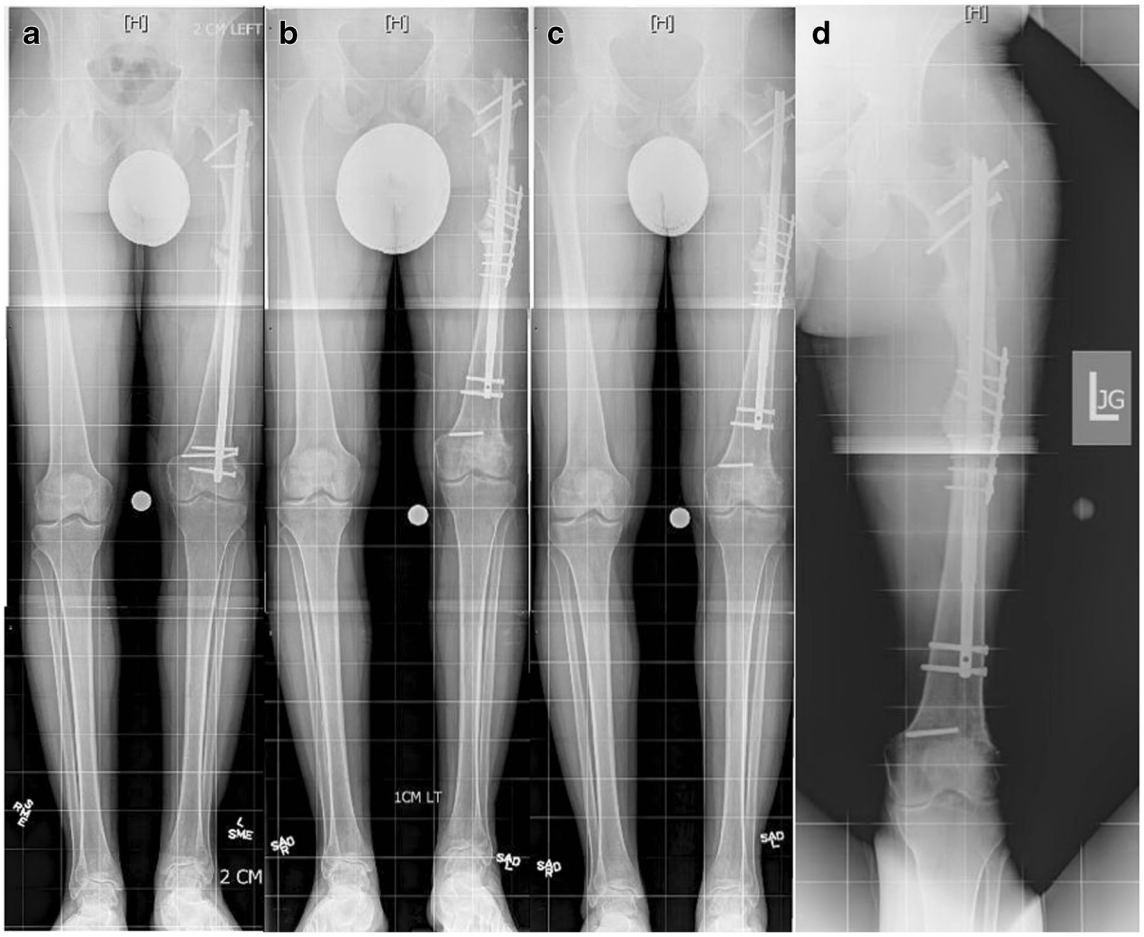

Fig. 3 **a** Femoral nonunion with 2-cm shortening. **b** Concurrent plate osteosynthesis of nonunion site and PRECICE lengthening through an osteotomy above the nonunion site. **c** Correction of limb-length discrepancy. **d** Healing of nonunion site and the regenerate segment

typically occurs in the short metaphyseal segments, which tend to have a loose nail grip within their wide IM cavities. Retrograde femoral lengthening tends to develop procurvatum and varus deformity, whereas antegrade tibial lengthening is associated with procurvatum and valgus malalignment [34]. Blocking screws should be placed intra-operatively at the concave side of the IM canal whenever deformity development is anticipated [39].

Theoretically, femoral lengthening with IM rods can alter the limb's mechanical axis, as it follows the line of femoral anatomic axis pushing the knee centre towards midline. This is not expected to occur with tibial lengthening, where anatomic and mechanical axes are parallel. Clinical significance of lengthening-induced mechanical axis deviation is a controversial issue. Unlike lengthening by external devices, internal lengthening rods lack adjustability options once they are in place. For this reason, potential for mechanical axis deviation should be taken in consideration [40]. It is estimated that each 1-cm length gain is coupled with ~1 mm lateral mechanical axis deviation [41]. Reverse planning method may be useful in this situation [42].

Bone transport

Internal lengthening rods may provide a less-invasive mode of bone transport. The main advantage is lack of external pins cutting through the skin and underlying tissues in a full-thickness manner to the same degree the moving segment is transported. A bone transport version of FITBONE nail exists [34, 43, 44]. Kold et al. reported a successful bone transport distance of 4 cm in a posttraumatic tibial defect with FITBONE TSA device [6]. Custom-built Phenix nails are claimed to be able to run monofocal and bifocal modes of bone transport procedures [2].

Accordion manoeuvre

Accordion manoeuvre comprises subjecting the regenerate tissue to a fluctuating pattern of distraction-compression-distraction cycles for the sake of enhancing bone formation. The device must have the dual function of lengthening and shortening. Paley et al. [45] reported successful healing of

delayed union following lengthening osteotomies in two tibias and one femur using the accordion manoeuvre exclusively without bone grafting.

Pre-operative evaluation

Measuring leg-length discrepancy and deformity should be determined on the basis of full-length standard radiographs consisting of anteroposterior and lateral views marked with a calibration indicator [31]. Rotational deformity can be judged clinically. However, computed tomography (CT) imaging is the modality of choice to delineate rotational malalignment if needed [33]. Nail type, entry and length is defined accordingly. Piriformis nail entry should be avoided in adolescents to preserve femoral head blood supply [3].

Surgical technique

Surgical placement of internal lengthening rods is accomplished in a very similar manner to that of IM nailing. Nevertheless, additional specific guidelines should be implemented. Osteotomy site should be preplanned individually, as indicated, and carefully chosen to ensure the entire regenerate bone plus an additional 3 cm is protected by the driving section of the nail. Venting the IM canal at the osteotomy site is advocated before reaming to minimise the risk of fat embolism and allow leak of bone graft and reaming around the osteotomy site [34]. IM canal overreaming by 2-mm larger than the planned nail size is required to facilitate PRECICE nail insertion. Fixator-assisted nailing is recommended during insertion to maintain the proper alignment for bone healing [26]. Blocking screws should be considered selectively wherever deformity potential is a concern [39]. Vigorous nail insertion is harmful to the inner drive mechanism [33]. Testing the nail mechanism intra-operatively is crucial to confirm nail functionality [4, 32].

Post-operative care

Delay of five days post-operatively is usually allowed to initiate the operational program. Weekly evaluation should be ensured, particularly during nail activity. Mechanical failure and other emerging complications must be detected and managed on a timely manner. Patient education is essential, especially with regard to weight-bearing precautions. Case-specific physical therapy is encouraged as soon as possible. Mechanically actuated internal lengthening nails like ISKD and Albizzia/Guichet are driven by the patient's physical activity and therefore should be tailored accordingly. Motorised nails with patient-operated external units are subject to operational errors. Optimising the distraction rate is essential to build healthy regenerate. Skin-surface remarking while lengthening is necessary to maintain optimal external magnet communication.

Complications

First-generation rods were associated with poorly controlled lengthening rate and pain secondary to the required limb rotation [21, 46]. Variable degrees of mechanism malfunction have been observed in almost all kinds of rods [43]. Rod fractures are often related to excessive weight bearing; this risk grows as the rod lengthens. Experimental bending-strength tests showed that stiffness of a fully distracted 10-mm ISKD titanium nail is comparable with the stiffness of an 8-mm regular titanium nail [4]. PRECICE nail manufacturer claimed improved bending strength four times higher than the initial version by eliminating welds and modular parts [20]. Lengthening-induced pain has been substantially reduced with the second-generation nails by eliminating rotational lengthening.

Future consideration

It can be predicted that IM lengthening rods may dominate the field of bone transport owing to its capability to drag the target transport segment internally without the need for external pins transfixing the surrounding tissues and communicating with the outside environment [20]. In the same context, efforts are underway to target implantable lengthening nails towards specific uses. Miniaturised lengthening rods might fit small IM canals, expanding indications for their application.

Conclusion

Telescopic nails are minimally invasive, versatile IM devices. Meticulous pre-planning is crucial for optimal outcomes. Frequent clinical and radiological evaluations are encouraged, particularly during the distraction period. Extra precautions should be paid to weightbearing to protect nail function and integrity.

Compliance with ethical standards

Conflict of interest HA and MG do not report any conflicts of interest. JC reports being a paid consultant for Biomet, Depuy Synthes, and Cerament. JC receives royalties from University of Florida. JC receives research support from Acelity, CD Diagnostics, Microbion Corporation. JC receives fellowship support from Biocomposites.

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