

Leg Lengthening With a Motorized Nail in Adolescents

An Alternative to External Fixators?

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Abstract Leg lengthening by external fixation is associated with various difficulties. We evaluated eight adolescent patients who underwent leg lengthening with a motorized intramedullary lengthening device. We asked whether this method could reduce the time of hospitalization and rehabilitation and whether the incidence of complications commonly associated with external fixators could be reduced. We compared our preliminary results with those from other reports, with a focus on leg length achieved, time of rehabilitation, and rate of complications. The average leg-length discrepancy was 3.8 cm (range, 3–5 cm). The average lengthening distance was 3.8 cm (range, 2.9–4.7 cm). In six patients, leg lengthening was combined with successful correction of the mechanical axis alignment. The consolidation index averaged 26 days/cm (range, 19–41 days/cm). The average hospital stay was 9.6 days. No bone or soft tissue infections were observed. In comparison to other studies (1.0–2.8 complications/patient), our results suggest that the difficulties commonly

associated with external fixators can be reduced with this method. It also allows good angular correction in patients with mechanical axis deviation. These features combined with a short time of hospitalization and rehabilitation make it a promising procedure for limb lengthening.

Level of Evidence: Level IV Therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

Leg lengthening by external fixation is associated with various complications ranging from 1.0 to 2.8 per patient [10, 13, 28, 30, 31, 38]. Transfixation of soft tissue by pins or wires is intrinsic to the method and thus difficulties such as pain [14, 30, 41] and pin tract or deep infections [10, 30] are commonly encountered. Muscle contractures and joint stiffness are additional complications associated with this method [22, 30]. In cases in which callus distraction is combined with axis correction, secondary axial deformity [30, 38] and fractures of the newly formed bone [11, 30, 35] might occur. Restriction in joint mobility [22] and therefore increased disability accompany the long periods of treatment, which delay rehabilitation and return to normal daily activities.

In the past, several approaches were developed to deal with these problems [2, 7–9, 16–19, 31, 33, 39, 40]. In 1956, Bost and Larsen [8] described femoral lengthening using a combination of an external fixator for distraction and an intramedullary nail for stabilization. Leg lengthening with a temporary external fixator over an intramedullary nail reduced the time of external fixation and risk of pin tract infection by almost ½ [31, 33]. The time of external fixation and the number of pins transfixing

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the skin were believed responsible for these beneficial effects [31, 33]. Reducing the time of external fixation accelerates the return to a normal range of motion and reduces the risk of bone refractures [31]. The risk of pin tract infections and hence the risk for secondary osteomyelitis continue to be problems in methods using external fixators [29, 35].

Therefore, several groups [2, 16, 39] explored a purely intramedullary solution for leg lengthening in the 1970s. The disadvantage of these systems was the use of an external component connected with the intramedullary nail with a persisting risk for direct intramedullary infection [2, 16]. After use in two patients, another promising system [39, 40] managed by radio control later was abandoned because of insurmountable problems with the energy supply.

After these initial steps in intramedullary lengthening, at least three kinds of fully implantable devices [7, 9, 18] were designed during the last 20 years to solve these problems. Two of these systems are mechanically activated lengthening devices [9, 17–19, 21]. Betz et al. [7] developed the first fully implantable, motorized lengthening device with a subcutaneous receiver. In 1997, Baumgart et al. reported successful implantation and outcomes with no major complications in 12 adult patients for limb lengthening and bone transport [3]. Nonetheless, results in the literature are limited and require confirmation.

We therefore posed the following questions: (1) Does the use of a fully implantable, motorized intramedullary nail system accomplish therapeutic aims in terms of planned length achieved, correct mechanical axis alignment, and functional outcome?; (2) Does the use of a fully implantable, motorized intramedullary nail reduce the time of hospitalization and rehabilitation measured by the time of consolidation and time to full weightbearing?; And (3) can the incidence of complications commonly associated with external fixators be reduced with this method?

Materials and Methods

Between August 2003 and May 2005, we prospectively enrolled eight patients (six males and two females) with an average age of 15.7 years (range, 13–18 years). These patients underwent leg lengthening with a fully implantable, motorized intramedullary nail system (FITBONE[®] Telescope Active Actuator nail [TAA]; WITTENSTEIN intens[®] GmbH, Igersheim, Germany) (Fig. 1) introduced by Baumgart et al. [4–6]. Patients were selected according to the following criteria. We included patients with a maximum age of 18 years with a minimum leg-length discrepancy of 3 cm who were able to understand and handle the system. We excluded patients with a history of

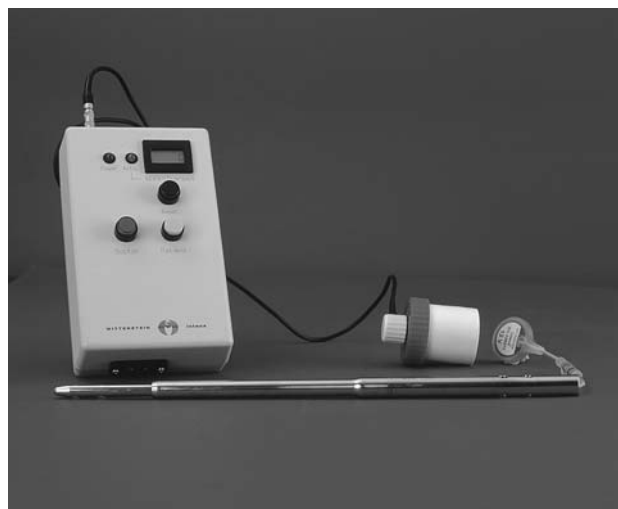


Fig. 1 A FITBONE[®] TAA with control and transmitter unit is shown. (Reproduced with permission of WITTENSTEIN intens[®] GmbH, Igersheim, Germany.)

deep infection or osteomyelitis within the last 2 years, patients with insufficient stability of the joints adjacent to the bone to be lengthened, and patients with an extension deficit of the knee or pes equinus.

Before surgery, we (AHK, BKF) measured leg-length discrepancy, preoperative alignment of the mechanical axis, and joint orientation on plain radiographs. These measurements were made under conditions based on the preoperative standard protocol for retrograde corrective planning described by Baumgart et al. [4, 6]. Different from conventional trauma nails, the femoral FITBONE[®] TAA is straight, which must be considered in preoperative planning. To achieve a correct mechanical axis and therefore avoid early arthritis after limb and joint malalignment, it is essential to perform supracondylar femoral or proximal tibial displacement and/or angulation osteotomies at the time of insertion.

The preoperative level of difficulty was assessed according to a scale for femoral lengthening with external fixators devised by Paley et al. [31]. A total score is derived from this scale, which is based on 12 parameters that influence risk and difficulty of the individual lengthening procedure. In patients with correction of the tibia, we (AHK) used a modified version of the classification described by Paley et al. (Table 1). The preoperative level of difficulty in our patients was an average of 6.6 points (range, 3–10 points).

The nails were implanted into six femurs and two tibias. The average leg-length discrepancy was 3.8 cm (range, 3–5 cm). Five femurs and one tibia had a valgus deformity resulting in an average mechanical axis deviation of +22 mm (range, 10–35 mm). One of the femurs (Fig. 2) had a translation of one bone diameter (Fig. 2A–C). The

Table 1. Classification scale for the level of difficulty of the tibial lengthening procedure*†

Parameter	0 Points	1 Point	2 Points	3 Points
Planned tibial lengthening (each cm of lengthening = 1 point)				
Age (years)	5–19	20–29	30–50	> 50
Complexity of correction of deformity at level of lengthening	None	Angulation > 5° < 20°, rotation > 10° < 30°, translation < 50% of bone diameter or MAD 1–3 cm	Angulation > 20°, rotation > 30°, translation ≥ 50% of bone diameter or MAD > 3 cm	Combination of deformities at one level or multilevel deformities
Other levels of treatment in same bone	None	One additional level mild complexity	One additional level moderate complexity	One additional level of severe complexity or ≥ 2 levels
Associated femoral lengthening (cm)	None	1–3	3.1–6	> 6
Stability of joint (ankle + knee)	None	Grade I	Grade II	Grade III
Fixed plantar flexion deformity of the ankle (degrees)	0	1–5	5–15	> 15
Plantar flexion of the ankle (degrees)	> 30	20–30	10–19	< 10
Osteoarthritis of the joints	None	Marginal osteophytes, subchondral sclerosis	Narrowing of joint space	Loss of joint space
Quality of bone	Normal	Ollier's disease, mild osteoporosis, nonunion	Radiation neurofibromatosis, osteogenesis imperfecta	Osteonecrosis, infection
Quality of soft tissue	Normal	Spastic, obese muscular	Fibrotic, postradiation, small open wound	Tissue necrosis, infection, large open wound
Medical problems and medication	None	Smoking, hypertension, rheumatoid arthritis, or other systemic arthritis	Diabetes, hemophilia, sickle cell anemia, mild immunosuppression, bone-inhibiting medications	Moderate immunosuppression, antimetabolic chemotherapy

* Modification of the Paley et al. [31] classification for femoral lengthening; †mild = 0–6 points, moderate = 7–11 points, severe = ≥ 12 points; MAD = mechanical axis deviation.

deformities and leg-length discrepancies were caused by congenital disease in four patients and by infection in two patients and were secondary to trauma in two patients. The minimum followup was 18 months (mean, 33.5 months; range, 18–36 months) (Table 2). We had prior approval of the Women's and Children's Hospital Ethics Committee; informed consent for participation in the study was obtained from all patients.

For lengthening, we used the FITBONE® TAA, a fully implantable, motorized intramedullary nail that is available in various sizes and different designs for the femur and the tibia [6, 37]. The femoral nail is a straight stainless steel nail with a maximum distraction length of 40 to 80 mm. The tibial version of the TAA is available as a straight nail or with the typical proximal Herzog angulation of tibia nails. In its proximal part, the nails contain a motor that, through a thin flexible wire, is connected to a subcutaneous reception antenna. High-frequency electric energy induced by an external transmitter through the skin is the power source for the motor. The patient places the transmission antenna on the skin

directly over the palpable reception antenna. The impulses are triggered manually at the external unit. The motor delivers the torque that, through a gear and spindle mechanism, is transformed into a unidirectional, axial movement. The sound of the motor can be controlled simultaneously with the help of a stethoscope. This gives important feedback regarding motor function and motor load. The daily distraction is modifiable on each use depending on callus formation. In our patients, we started distraction with three sessions per day producing a distraction rate of 1 mm per day. At this time, the device is available only to centers certified by the manufacturer.

During surgery, we (AHK, BKF) controlled rotational alignment by two parallel 3.0-mm Kirschner wires in the proximal and distal segments. The osteotomy was made using a drill-hole corticotomy technique. Mechanical axis and joint alignment in the frontal plane were maintained or adjusted with the help of radiolucent rulers attached to the operating table. Straight reamers were used to enlarge the medullary canal to 0.5 mm larger than the nail's diaphyseal diameter. This allows easy insertion of the nail without



Fig. 2A–K (A) Anteroposterior and (B) lateral radiographs are shown of a 17-year-old boy who sustained a supracondylar displaced femur fracture after nonoperative treatment in Africa. (C) He had a leg-length discrepancy of -5 cm. (D) Postoperative anteroposterior and (E) lateral radiographs show a FITBONE[®] 13 TAA nail with the subcutaneous antenna. (F) Anteroposterior and (G) lateral radiographs were obtained after a distraction phase of

49 days; lengthening of 47 mm was achieved. Three months postoperatively, (H) anteroposterior and (I) lateral radiographs show good callus formation and the patient started full weightbearing. He achieved full range of motion in the knee. Two years postoperatively, after removal of the implant, (J) anteroposterior and (K) lateral radiographs show the pelvis was equal and the patient had an excellent functional outcome.

force and avoids bending moments that could interfere with the function of the device or alter the desired alignment. The subcutaneous reception antenna subsequently was connected with the motor in the proximal part of the nail through an insulated, thin flexible wire. In the femur, the wire is placed through a drill hole in the lateral side of the cortex to avoid an intraarticular position.

Postoperatively, we used the categorical outcome scoring system devised by Paley et al. [31] which they used for lengthening with external fixators over an intramedullary nail at the femur. We modified this scoring system for patients with tibia correction (Table 3) by exchanging the

femur angles with reference tibia angles [31]. At clinical appointments every week during distraction and after 3, 6, 9, 12, and 18 months, we (AHK, BKF) recorded the use of analgesics; range of motion of the hip, knee, and ankle; and any problems or complications.

Radiographs in anteroposterior and lateral views were taken once per week during the distraction phase and every 4 weeks during the consolidation phase. At the end of the distraction phase, achieved leg length, postoperative alignment of the mechanical axis, and joint orientation were measured on plain radiographs (Fig. 2F–G). The distraction index was calculated as time of distraction per

Table 2. Patient characteristics and results

Patient Number	Gender	Age (years)	Etiology	Bone	Preoperative difficulty score*	Leg-length discrepancy (mm)	Gain of length (mm)	Planned length achieved (%)	Followup (months)	Axis correction (months)	Distraction period (days)	Axis preoperatively (MAD, mm)	Axis postoperatively (MAD, mm)	Postoperative outcome score†
1	Male	18.1	Postinfection	Femur	6 (mild)	36	35	97.2	36		37	5	2	100 (excellent)
2	Male	16.5	Congenital	Femur	6 (mild)	35	34	97.1	36	Varisation	31	10	0	80 (good)
3‡	Male	15.4	Congenital	Femur	10 (moderate)	40	27		35	Varisation	34	18	2	85 (good)
4	Male	16.8	Congenital	Tibia	6 (mild)	35	29	82.9	32	Varisation	30	-4	0	75 (good)
5§	Female	14.4	Congenital	Tibia	3 (mild)	30			36			25	10	40 (fair)
6	Male	17.1	Posttraumatic	Femur	5 (mild)	50	45	90	24	Varisation	49	12	7	95 (excellent)
7	Female	13.6	Postinfection	Femur	10 (moderate)	44	39	88.6	24	Varisation	45	35	8	75 (good)
8	Male	14.0	Posttraumatic	Femur	2 (mild)	37	37	100	18	Varisation	50	32	0	90 (excellent)

* According to the Paley et al. [31] classification system for femoral lengthening and our modification of it for tibial lengthening (Table 1); † according to the Paley et al. [31] outcome scoring system for femoral lengthening and our modification of it for tibial lengthening (Table 3); ‡ patient with jamming of the nail and breakage after consecutive trauma; §distraction stopped because of pain syndrome and device failure; MAD = mechanical axis deviation.

millimeters distraction gap (days/mm). Consolidation was defined when the distraction gap was corticalized on three of four sides as seen on anteroposterior and lateral radiographs and the patient started full weightbearing without crutches (Fig. 2H–I). The consolidation index was calculated as the time to consolidation per centimeter of distraction gap (days/cm).

Results

Six of eight patients achieved successful bone lengthening in terms of achieved leg length and postoperative alignment of the mechanical axis. Two patients (Patients 3 and 5) were excluded from consolidation and distraction analysis because of device failure in one and nail breakage in the other.

The average lengthening distance was 38.1 mm (range, 29–47 mm). Planned length was achieved to an average of 93% (range, 83%–100%). The average distraction period was 40.3 days (range, 30–50 days) with a distraction index of 1.1 mm per day (range, 0.9–1.2 mm). In patients in whom lengthening was combined with corrective osteotomy (n = 6), improvement of the mechanical axis deviation was obtained from preoperatively + 22 mm (range, 10–35 mm) to postoperatively + 5 mm (range, 0–10 mm). The average correction distance from valgus to normal mechanical axis deviation was 18 mm (range, 5–32 mm).

Three patients achieved excellent outcome scores, four had a good score, and one had a fair score. The average functional outcome score was 80 points. Preoperative knee function was restored and even showed improvement in one case. Only during the distraction phase was knee flexion reduced to an average of 70° (± 20°). At the latest followup, no extension deficit was observed in any of the patients. There was no reduction in hip function. The lengthening nail had been removed in all patients after an average of 20 months.

The average hospital stay was 9.6 days (range, 5–14 days). Full weightbearing was resumed between 2.5 and 4 months depending on the length of the distraction period. Radiographic consolidation was observed 94 days (range, 70–120 days) postoperatively on average. The average consolidation index was 26 days/cm (range, 19–41 days/cm). The average consolidation of the five femur lengthenings was 88 days (range, 70–96 days).

We identified no intraoperative problems or complications. No bone or soft tissue infection was observed. No wound healing problems were observed. After the acute postoperative phase, five patients were completely pain-free. Three patients experienced discomfort, which in one was caused by locking bolts and in the other by the

Table 3. Scoring system for outcome of tibial lengthening*†

Parameter	Additions (number of points to be added to derive total score)			Subtractions (number of points to be subtracted from the total score)				
	Excellent (25)	Good (20)	Fair (10)	Poor (0)	Excellent (0)	Good (5)	Fair (20)	Poor (30)
Range of motion of the knee	Fixed flexion deformity = 0°, flexion > 120°, or flexion ≥ 90% of preoperative flexion	Fixed flexion deformity ≤ 5°, flexion 101°–120°, or flexion 67%–89% of preoperative flexion	Fixed flexion deformity = 6°–15°, flexion 70°–100°, or flexion 50%–66% of preoperative flexion	Fixed flexion deformity > 15°, flexion < 70°, or flexion < 50% of preoperative flexion				
Amount of lengthening	Within 1 cm of goal	Within 1.1–3 cm in goal	Within 3.1–5 cm of goal	> 5 cm of goal				
Gait (preoperative to postoperative points)‡	0, 1 to 1	1, 2 to 1	0 to 1 or 1, 2 to 2	0 to 2				
Medial proximal tibia angle (degrees)	85°–90°	80°–84°, 91°–95° or > 5% axis deviation of preoperative angle	75°–79°, 96°–100° or > 10% axis deviation of preoperative angle	< 75°, > 100° or > 15% axis deviation of preoperative angle				
Pain (preoperative to postoperative points)§					0, 1, 2 to 0 or 1 to 1	0, 2, 3 to 1	1 to 2 or 2 to 3	0 to 2, 3 or 1 to 3
Ability to perform activities of daily living or to work (preoperative to postoperative points)¶					0, 1, 2 to 0	1, 2 to 1	1 to 2 or 0 to 1	0 to 2

* Modification of the Paley et al. [31] outcome scoring system for femoral lengthening; † excellent = 95–100 points, good = 75–94 points, fair = 40–74 points, poor = < 40 points; ‡ 0 points = no limp, 1 point = slight limp, 2 points = moderate limp; § 0 points = no pain, 1 point = slight pain, 2 points = moderate pain, 3 points = severe pain; ¶ 0 points = full activity and full-time work, 1 point = reduced activity and work, 2 points = no activity and work.

antenna. Neither of the two patients required any specific pain medication. Neither reported any problems after regular removal of the nail with the antenna 2 years post-operatively (Fig. J–K). The third patient with the failed device developed a complex regional pain syndrome. After removal of all metal, this patient reported mild pain at the latest followup (36 months).

We encountered two obstacles resolved by additional surgery. After an antegrade implantation of a FITBONE[®] TAA 12/10 in a femur, the nail jammed after 28 days with a distraction gap of 25 mm. After manipulation, the nail rejammed at a distraction gap of 27 mm. This patient went back to full weightbearing 13 weeks after surgery and had an unprotected fall, which resulted in nail breakage. We removed the nail and stabilized the femur with an AO trauma nail maintaining the distraction gap of 24 mm. Four months after the revision, the patient resumed a normal life with full mobility. Leg-length discrepancy remained at 1.2 cm. In another patient, we observed antenna cable breakage 12 months after implantation at the femur. We arthroscopically removed the subcutaneous antenna and the broken cable. All patients were satisfied with the comfort and ease of handling with this new system.

Discussion

Callus distraction by intramedullary lengthening has become an alternative treatment method for limb lengthening during the last 5 years [4, 6, 9, 14, 19, 21, 27, 37]. Few data have been published concerning the FITBONE[®] TAA for intramedullary leg lengthening [4, 6, 37]. The concept that led to the development of techniques using intramedullary nails for callus distraction was to achieve leg lengthening with faster rehabilitation and a lower rate of complications [3, 9, 19]. We explored whether functionality and outcome support these concepts.

This ongoing study is limited by the small number of selected patients treated with this method. The results might be biased by the fact that patients were selected for this procedure. The complexity and the novelty of this method afforded selection according to the criteria described in the Materials and Methods. Also, we lacked matched control subjects who were treated with external fixators. The fact that the maximum distraction length was 45 mm in our study also might have positively influenced our results. In consideration of these limitations, conclusions from the current study can be seen as a general trend.

The use of external fixators is associated with a high rate of severe complications between 24% and 117% [1, 10, 12, 13, 28, 30, 31, 38]. Combinations of intramedullary nails and external fixators also show a high rate of complications

in adults [15, 25, 26, 31, 35]. A lower complication rate of 11% was reported in children [34].

The occurrence of complications is not limited to the time a fixator is attached. Even after removal, additional complications such as malalignment and refractures often occur [31, 36, 38].

The complication rate of external fixators in adults seems to depend on three main factors: the length of distraction, the number of pins, and the age of the patient [1, 10, 13, 28, 30, 31, 38]. In children, length of distraction seemed to have little effect on the consolidation index, whereas an increase of angular corrections greater than 30° was related to poor consolidation index [12].

The Albizzia[®] nail (DePuy, Villeurbanne, France), the ISKD[®] (Orthofix Inc, Valley, Germany), and the FITBONE[®] TAA and Slide Active Actuator (SAA) nails are the only intramedullary lengthening devices currently used for limb lengthening [3–5, 14, 19–21, 27, 35, 37]. An important difference between the FITBONE[®] nails and the other two devices is their motorized mechanism. The ISKD[®] and Albizzia[®] nails are mechanical devices. In the Albizzia[®] nail, the required rotations for lengthening have caused pain and discomfort [19]. Numerous patients with Albizzia[®] nails (22%–39%) were readmitted to the hospital, and rotations of the nail under general or epidural anesthesia were necessary at some stage of the lengthening because of the severe pain and discomfort the extensive rotations had caused at the osteotomy site [14, 19]. The complication rate after treatment with the Albizzia[®] nail ranges from 22% to 29% if the need for general anesthesia for distraction is not considered [14, 19]. In 27% of the patients with implanted ISKD[®] nails, mobilization under general anesthesia was required during the distraction phase [27]. Complications of 11% to 47% were reported with the ISKD[®] [9, 27].

A complication rate of 13% was described in a larger number of patients (n = 150) using the FITBONE[®] SAA and TAA nails [6]. In that series, none of the patients experienced infections and only 3% of the patients had the nail exchanged. The motorized FITBONE[®] TAA does not require any external manipulation or patient activity, which increases the patient's comfort. At the time of discharge of our patients, seven of eight were pain-free and did not require any pain medication. During followup, two of those patients experienced mild irritations, which disappeared after removal of the system.

At the end of the lengthening, the mechanical axis and joint alignment must be correct to avoid early arthritis. In contrast to external fixators, elongation with the FITBONE[®] TAA is performed along the anatomic axis. The position of the nail after the operation defines the final alignment after lengthening. Axis adjustments during distraction are still possible with the external fixator.

This is not possible with an intramedullary lengthening nail.

Retrograde planning [3, 4, 6] takes the preoperative, postoperative, and postlengthening states into consideration. In cases with mechanical axis deviation and/or joint malalignment, intraoperative corrections in the form of bone displacement and/or angulatory corrections may be required (Fig. 2D–E). In our series, the mechanical axis deviation was corrected from 22 mm preoperatively to 5 mm postoperatively.

Intramedullary lengthening devices showed a reamed intramedullary nail does not disturb bone formation in a distraction gap. Ilizarov emphasized the importance of preserving the endosteal blood supply in distraction osteogenesis with an external fixator for better bone healing [23, 24]. Donnan et al. [12] reported an average consolidation index of 43.6 days/cm in children with external fixators. Baumgart et al. [3] observed a consolidation index of 42 days/cm with the FITBONE® SAA nail. With a consolidation index of 35.2 days/cm, the Albizzia® nail appears faster [14]. The consolidation index in the ISKD® ranged from 21 to 29 days/cm [21, 27]. In our group with the FITBONE® TAA, the consolidation index was 26 days/cm.

The short time of an average of 9.6 days of hospitalization and the fast rehabilitation of our patients are important aspects in favor of the TAA [3, 19, 37]. Without transfixation of skin and muscles, the TAA facilitates physiotherapy before and during the distraction phase. We required early postoperative mobilization and partial weightbearing, which were possible for our patients. After 3 to 4 weeks in the consolidation phase, the patients returned to full weightbearing. Many patients who were treated with an external fixator often reported discomfort caused by pin cleaning, serious sleeping problems, clothing restrictions, painful soft tissue transfixation and consequently decreased joint mobility, and the overall long disability caused by external fixation accompanied by delayed return to normal daily activities and work [22, 32, 41].

Our initial experiences with the FITBONE® TAA in this group of adolescent patients suggest some patients could benefit from its use. In comparison to external fixators, its advantages are simple handling, the programmable motor with exact control, early full weightbearing, faster rehabilitation, and excellent functional results already present during the consolidation phase. Potential advantages of intramedullary lengthening devices include the reduced risk of contractures and infections, better maintenance of axis correction, a lower rate of refractures, reduction of pain resulting from the elimination of soft tissue transfixation, and an earlier return to daily activities.

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