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Improved comfort in lower limb lengthening with the intramedullary skeletal kinetic distractor

Principles and preliminary clinical experiences

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Abstract *Introduction:* Limb lengthening by external fixators is associated with many problems such as pain at the pin tracts, muscle transfixation, pin tract infections, reduced joint motion, and prolonged fixation time. The intramedullary skeletal kinetic distractor (ISKD) is a new internal, mechanically activated implant, which distracts by mild rotations of 3°. *Material and methods:* In a prospective clinical study, four patients with an mean age of 29 years (18–36 years) underwent intramedullary lengthening via ISKD. The average lengthening of three femora and one tibia was 31 mm (26–40 mm). *Results:* All patients performed the rotations for the distraction themselves without any significant problems. One patient took mild analgesics during the first days of distraction, whereas three patients did not require any analgesics. The average patient discharge occurred 10 days (8–11 days) postoperatively with no complications during the hospital stay. The planned length of distraction was achieved in all patients with normal alignment and normal joint orientation. Full weight bearing was performed on average after 10 weeks (7–14 weeks). Consolidation was noted 80 days (51–111 days) postoperatively with an average consolidation index of 2.9 days/mm. No complications were observed during the follow-up period of 14 months. The Enneking score was 26.8 points, and according to the classification of Paley all patients had an excellent result. *Conclusions:* From these preliminary results we conclude that the comfort of limb lengthening with the ISKD is increased by the elimination of fixator-associated complications and by the simple distraction mechanism, which is well tolerated by the patients. Further advantages of the ISKD are early full weight bearing and excellent limb function.

Keywords ISKD · Lengthening · Nail · Monitor · Comfort

Introduction

Callus distraction by external fixation allows for regeneration of a high amount of new bone even in patients with severe bone loss [20]. However, callus distraction by external fixation is associated with many problems. Soft tissue transfixation by pins and wires can cause muscle contractures and joint stiffness [15, 20], pain [11, 29], and infections [6, 20]. Furthermore, lengthening by external fixators can lead to secondary axial deformity [20, 28] and refractures of the regenerated bone [7, 20, 27]. The long period of time for external fixation delays rehabilitation and return to normal daily activities. The total rate of problems and complications during limb lengthening by external fixation ranges from 1.0 to 2.8 per patient [6, 9, 18, 20, 21, 28].

A combination of an intramedullary nail and a temporary external fixator, which is only applied during distraction, can reduce the time of external fixation and the risk of infection [21, 24]. Due to early removal of the external fixator, return to normal range of motion is accelerated and the risk of refractures is reduced [21]. However, the risk of pin tract infections continues to represent a significant problem. Severe osteitis may occur if treated improperly [19, 26]. This concern is also known from intramedullary nailing after previous external fixation of femoral fractures [25].

Fully implantable devices have been developed within the last few decades to solve these problems. Betz and Baumgart developed the first motorized lengthening device with a subcutaneous receiver [4], which was successfully implanted to many patients for limb lengthening and bone transport [3]. This motor-driven device is not authorized for general use to our knowledge.

Guichet et al. designed the first mechanically activated lengthening device (Albizzia nail). In this device, lengthening is achieved by rotations of 20° around the longitu-

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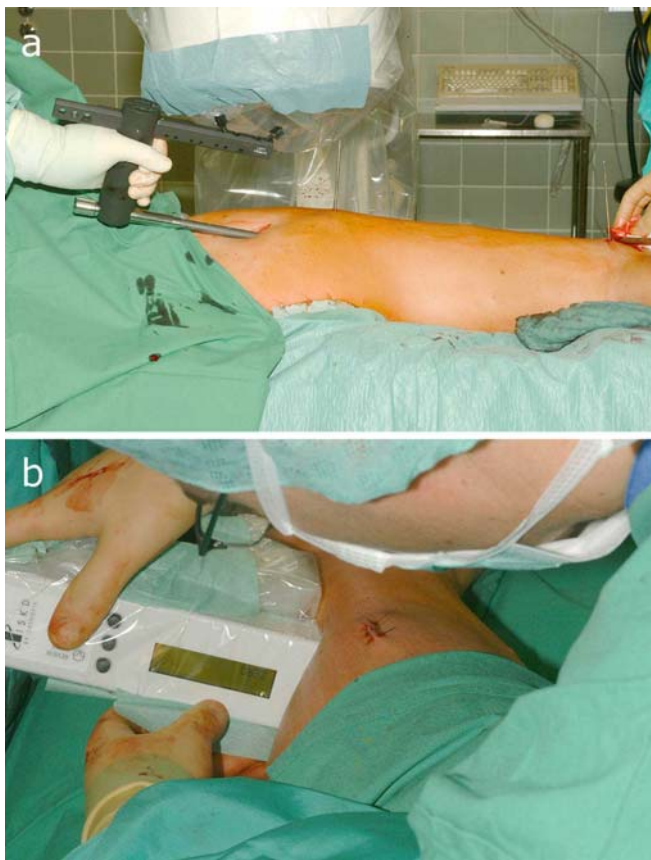


Fig. 1 a, b Minimally invasive implantation of a femoral ISKD through a 2-cm-long skin incision. Intraoperative control of the distraction mechanism of the implanted ISKD with an external handheld monitor

dinal axis of the bone. Mechanical testings of the nail revealed comparable characteristics to conventional intramedullary nails [12]. One major drawback of this device is the induction of severe pain in several individuals, induced by the large degree of rotation necessary for distraction [10, 13].

The intramedullary skeletal kinetic distractor (ISKD) is a mechanically distracting intramedullary nail designed for the femur and tibia [5]. Its proximal and distal part is internally connected with a threaded rod by two one-way clutches. These clutches are activated by rotations of 3–9°. These oscillations are part of the physiological gait process. A distraction of 1 mm is achieved by 160 rotations of 3°. The actual amount of distraction is controlled by an external handheld monitor, which measures the orientation of a magnet on the distal part of the internal threaded rod (Fig. 1). The patients measure the daily distraction at a minimum of five times per day. If the distraction length is insufficient, the leg is rotated under the control of the monitor until the desired distraction length is reached. The maximal distraction length by the ISKD is 80 mm. The ISKD is available for both the femur and the tibia [5, 10, 12, 13].

Patients and methods

After approval of the local ethics committee (approval no. 2948), a prospective study was performed on four patients with a leg discrepancy who were operated between 16 July and 30 July 2002. Inclusion criteria were patients with the need of 20–80 mm lengthening for limb length discrepancy due to short femur or tibia, a minimal patient age of 18 years, compliant patients who understand the nature of the device, and no history of osteitis for at least 1 year. Exclusion criteria were patients who cannot bear weight on the contralateral limb, patients in whom an osteotomy cannot be made in the proximal or mid-third of the shaft of the bone, deformities that require multilevel osteotomies, and patients with systemic bone diseases.

Every 2 weeks during distraction, and every 4 weeks during consolidation, radiographs were taken in anteroposterior (AP) and lateral directions. Additionally, at these time points the use of analgesics was recorded, range of motion of the hip and knee joint, and any problems or complications. The duration of the hospital stay and time to full weight bearing was analyzed.

Preoperatively and at follow-up examination, the functional status was assessed by the Enneking score (function, pain, emotional acceptance, supports, walking, and gait 5 points each, maximum 30 points) [8] and by Paley's classification (range of motion, leg discrepancy, gait, joint orientation, pain, and ability to perform activities; maximum 100 points; excellent=95–100 points, good=75–94 points, fair=40–74 points, and poor=less than 40 points) [21].

Consolidation was defined when the distraction gap was corticalized on three of four sides as seen on AP and lateral radiographs. The distraction index was calculated from the length of the radiographic distraction gap divided by the time between beginning to the end of the distraction. The consolidation index was calculated from the interval of the operation date to the date of radiographic consolidation divided by the length of the distraction gap. Pre- and postoperative alignment, joint orientation, and leg length were measured on digital bilateral leg standing radiographs with special computer software (MediCAD version 2.0, Hectec, Altfrauenhofen, Germany) and compared to the normal values described by Paley et al. [22].

Three femoral and one tibial ISKD (Orthofix, Valley, Germany) were implanted into one female and three male patients with an average age of 29 years (18–36 years). Two femora had a complex deformity with a combined 7° varus and 28° rotational deformity and a 12° varus and 41° rotational deformity. A third femur had a mild valgus deformity of 5°. Apart from these three post-traumatic deformities, one congenital tibial shortening was addressed with an ISKD. Preoperatively, the adequate length and diameter of the ISKD was determined on plain radiographs. Different from conventional femoral nails, the femoral ISKD is straight, which has to be considered in preoperative planning. The final follow-up investigation was made 14.2 months postoperatively (14.0–14.5 months).

Intraoperatively, the rotation was controlled by two 3.0-mm Kirschner wires, which were placed parallel in the proximal and distal segments. For femoral osteotomy a multiple drill hole technique was used: with control by the image intensifier, transverse drillings were made through a lateral stab incision, and the osteotomy was completed with a small osteotome. For tibial osteotomy, a Gigli saw was used [23]. Special attention was paid to create transverse, straight osteotomies, which allowed rotational movements for the distraction of the ISKD. If necessary, rotation was corrected under the control of the angle between the Kirschner wires in the proximal and distal fragments. Corrections in the frontal plane were performed with the "cable technique" [16]. Due to the straight design of the femoral ISKD, the medullary canal of the femur has to be overreamed 2.0 mm, whereas the tibia has to be overreamed 1.5 mm. Postoperatively, the patients controlled distraction by the external monitor at a minimum of five times per day.

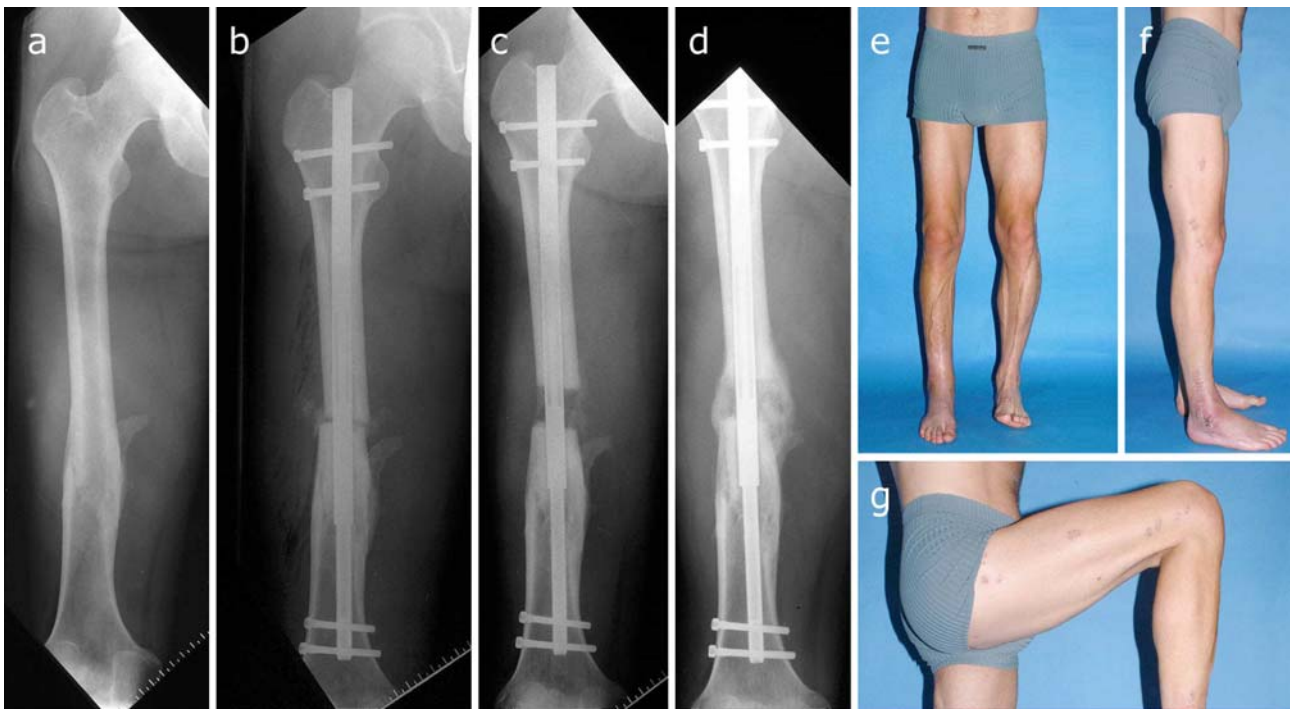


Fig. 2 **a** A 36-year-old man with a post-traumatic femoral shortening of 30 mm and 5° valgus deformity. **b** Postoperative radiograph after multiple drill hole osteotomy, reaming, and implantation of an ISKD. Note the reaming debris at the osteotomy site. **c** Complete distraction of the femur after 4 weeks under partial weight bearing (distraction index 1.8 mm/day). **d** Consolidated callus after 12 weeks. Full weight bearing had been allowed after 8 weeks. **e–g** Clinical photographs 4 weeks postoperatively at the end of the distraction phase demonstrating correct axial alignment and full range of motion of the knee and hip joint. Only small incisions and minimal soft tissue damage is necessary for limb lengthening with the ISKD

Results

The mean operation time was 108 min (range: 90–145 min) and total intraoperative blood loss 230 ml (100–320 ml). No intraoperative problems or complications occurred. In three patients additional operations were performed (removal of osteophytes $n=1$, implant removal $n=2$, tenotomy $n=1$).

Mobilization was started on the 1st postoperative day. From the 5th day, a daily distraction of 1 mm was intended. One patient required analgesics during the first 3 days of the distraction. The other patients had only mild pain during distraction and did not need any analgesics. The patients were discharged from hospital after an average of 10 days (8–11 days) postoperatively.

All patients completed the planned lengthening with an average distraction index of 1.2 mm/day (0.9–1.8 mm/day) (Fig. 2, Fig. 3, Fig. 4). The average lengthening was 31 mm (26–40 mm). At an average of 10 weeks (7–14 weeks) full weight bearing was allowed. Average hip flexion measured 123° (105–135°) preoperatively, 116° (95–135°) after distraction, and 122° (105–140°) at follow-up exami-



Fig. 3 a–d Radiographs of an 18-year-old man with a tibial shortening of 28 mm. **a** Postoperative radiograph after percutaneous Gigli saw osteotomy, intramedullary reaming, and insertion of the ISKD. **b** Daily distraction of 1.0 mm/day. No need for analgesics during the distraction procedures. **c** Consolidated callus after 4 months. **d** Early stage of remodeling at 9 months postoperatively

nation. Mean knee flexion decreased from 126° (105–140°) preoperatively to 107° (70–125°) after distraction and normalized to 124° (105–135°) at follow-up.



Fig. 4 **a** A 27-year-old man with a post-traumatic leg shortening of 63 mm, an external rotational deformity of 45°, and varus deformity of 12° of the femur. **b** Multiple drill hole osteotomy of the femur at the apex of the deformity, correction of the malalignment, and stabilization by an ISKD. **c** Successive lengthening of the femur of 40 mm (distraction index 0.9 mm/day). **d, e** Radiographs 6 and 9 months postoperatively demonstrating consolidation and maturation of the callus tissue. **f** Preoperative single leg standing radiograph: external rotational deformity of 45° and varus deformity of 12° of the femur and internal rotational deformity of the tibia of 41°. **g** The single leg standing radiograph taken 6 months postoperatively demonstrates realignment of the lengthened leg

Complete radiographic consolidation was observed 80 days (51–111 days) postoperatively. The mean consolidation index was 2.9 days/mm (1.8–4.1 days/mm). Leg standing radiographs on follow-up examination showed normal alignment and joint orientation [22]. The mechanical lateral distal femur angle (mLDFA) averaged 92.2° (88.5–96.5°) prior to surgery and 88.3° (85.5–90°) at follow-up. Mechanical axial deviation (MAD) was corrected from 21.7 mm (12–31 mm) preoperatively to 8.2 mm (3–13 mm). No hardware failures, infections, non-unions, or malunions were observed.

According to Paley's classification all patients had excellent results. The functional outcome measured by the Enneking score increased from 13.3 points preoperatively to 26.8 points postoperatively.

Discussion

Callus distraction by external fixation has become a widely accepted treatment method for limb lengthening [1, 2, 11, 17, 18, 21]. However, it was discussed by experts that “complications are the rule rather than the exception” [14]. Removal of the fixator is a critical step, and malalignment and refractures can occur [20]. Many patients dislike the external fixator because of the painful soft tissue transfixation, decreased joint mobility, and long disability caused by external fixation accompanied by delayed return to normal daily activities [15, 29]. Studies of external lengthening devices have demonstrated a rate of severe complications between 24% and 117% [1, 6, 9, 18, 20, 21].

Potential advantages of intramedullary lengthening devices include the reduced risk of contractures and infections, prophylaxis of axis deviation and refractures, reduction of pain due to the elimination of soft tissue transfixation, and earlier return to daily activities. To the best of the authors' knowledge, the Albizzia nail and the ISKD are the only intramedullary lengthening devices, which are now in general use for limb lengthening [10]. The complication rate of external limb lengthening ranges from 24% to 117% depending in particular on the length of distraction, experience of the surgeon, and age of the patients [1, 6, 9, 18, 20, 21]. In contrast, the complication rate after treatment with the Albizzia nail ranges only from 22% to 29%, if the need for general anesthesia for distraction is

not considered [10, 13]. The designer of the ISKD reported even fewer complications with a rate of 11% after 18 lengthenings [5].

In a study of Guichet et al., a considerable number of patients with an Albizzia nail were readmitted to the hospital and rotations of the nail were performed under general anesthesia at some stage of the lengthening because the extensive rotations at the osteotomy site caused severe pain and discomfort [13]. In another the study, 12% of the femoral lengthenings with the Albizzia nail were incomplete because these patients refused epidural anesthesia for the distraction [10].

A limitation of this study is the small number of patients. However, only one publication exists about the ISKD so far, which was published by the designer of the implant [5]. Furthermore, this study analyses on the distraction phase, which can be a very painful period of time for the patients [10, 11, 13, 29]. The analysis of the first four European ISKD patients showed that the ISKD is a relatively simple device, which was well understood by the patients. The mild rotations of 3° were well tolerated enabling the patients to perform the distraction themselves. Furthermore, the ISKD offered the advantages of early rehabilitation, early full weight bearing, and excellent functional results. It provided a high quality of regenerated bone and stable intramedullary fixation.

Nevertheless, several aspects have to be considered in the treatment with an ISKD. Since the ISKD cannot be shortened or corrected in the postoperative course, exact preoperative planning and implantation is essential. Furthermore, good compliance of the patients and understanding are mandatory for successful treatment. The costs of this new implant are higher than those of external fixators. In consideration of the low rate of complications and the reduction in hospital stay due to ambulatory distraction, the ISKD appears to be a very attractive and cost-effective implant. However, prospective, randomized studies have to prove this hypothesis.

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