



Patient Satisfaction After Limb Lengthening With Internal and External Devices

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External fixation has long been used for limb lengthening but can result in many complications, such as tethering of the soft tissues, pain, decreased joint motion, scarring, and nerve injury. Recently, a controllable, telescopic, internal lengthening nail was developed to address many of these issues and hopefully improve the overall experience for the patient. The satisfaction rates of internal and external fixation for limb lengthening were compared in 16 patients, all of whom have experienced both methods. Thirteen out of 16 patients responded to a limb-lengthening questionnaire, developed by the authors for this patient population. Patients preferred the internal device with respect to overall satisfaction, reduced pain, ease of physical therapy, and better cosmetic appearance. When asked which device they would prefer if another surgery was required, all patients chose the internal device. From the patients' perspective, the internal lengthening device is an improvement over the traditional external fixator. (Journal of Surgical Orthopaedic Advances 24(3):174–179, 2015)

Key words: external fixation, internal lengthening, limb lengthening, satisfaction

Currently, external fixation is the most widely used method for limb lengthening (1). Lengthening with external fixation can result in many complications, including loss of joint range of motion. Herzenberg et al. demonstrated that it takes an average of 19 months before knee motion returns to preoperative levels after femoral lengthening (2). The technique for lengthening over an

intramedullary nail reduces the time in the external fixator, but the knee joint may still be significantly restricted. Paley et al. reported that only 77% of the preoperative knee flexion was regained 5 months after the fixator was removed (3). Other common complications include pin tract infection, scarring, soft-tissue contractures, and pain. Additionally, wearing the fixator for months at a time can be difficult for the patient to tolerate psychologically. Cleaning the pin sites can be painful, making it uncomfortable for the parent or caregiver to keep up with this daily task. Patients often require adaptive clothing to accommodate the external frame and need long-term pain management.

A fully implantable lengthening device with no wires or pins traversing soft tissues has been the holy grail of limb lengthening. Absence of pins and wires means no tethering of soft tissues, theoretically allowing patients to maintain better mobility and limb function (4). Additionally, with absent pin tracts, the potential for soft tissue or bone infection is greatly reduced (5). In late 2011, Ellipse Technologies, Inc., received U.S. Food and Drug Administration clearance for the PRECICE, an adjustable intramedullary rod containing a magnetic drive capable of lengthening or even shortening the bone (Fig. 1). An

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All human studies have been approved by our institutional review board ethics committee and were carried out in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. In addition, all persons gave their informed consent before their inclusion in this study.

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FIGURE 1 Anteroposterior view of the same patient after lengthening with the PRECICE. (Reprinted with permission.).

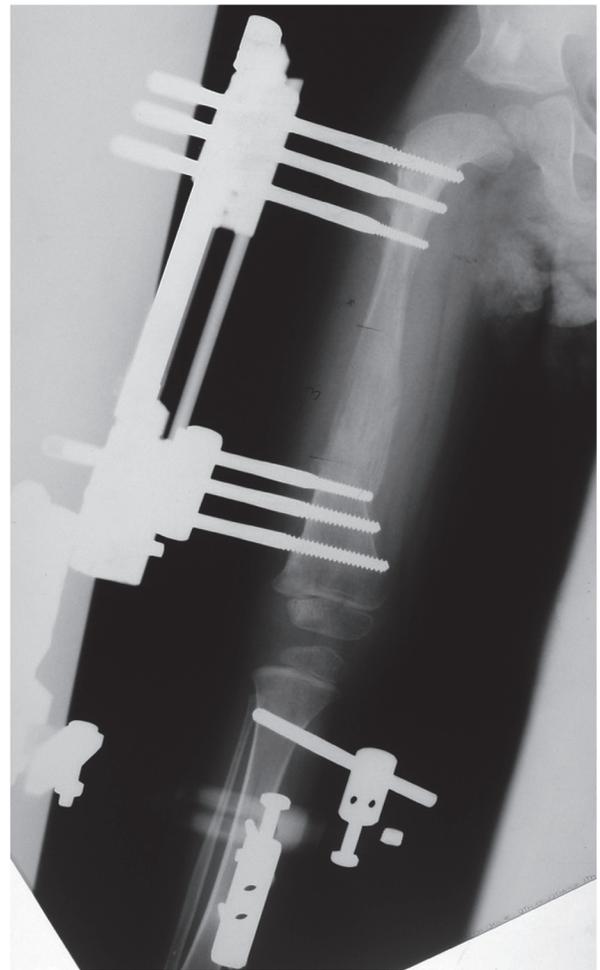


FIGURE 2 Anteroposterior view of patient lengthening with external fixation. (Reprinted with permission.).

external remote controller generates a magnetic field that activates the internal magnet. This controller is placed on the patient's leg several times throughout the day, using magnetic force to slowly and controllably distract the bone.

In today's clinical practice, a great deal of importance is placed on how the patient views his or her individual experience (6). Furthermore, patient satisfaction is likely to become an important factor in how physicians and health care facilities are reimbursed financially. In the past, physicians have emphasized clinical and radiographic results as a way to determine the success of a procedure. The new paradigm includes the patient perspective and satisfaction.

The authors' center has used external fixation extensively for more than two decades (Fig. 2). Although the final clinical outcome in patients is generally good, the overall experience for the individual can be painful, may result in a high rate of complications, and is socially disruptive for the family. Since the authors began using the

TABLE 1 Patient demographic information, clinical results, and related complications

Patient	Gender	Etiology	External Fixator					Internal Lengthening				
			Age (years)	Bone	Amount (cm)	Complications	Healing Index (month/cm)	Age (years)	Bone	Amount (cm)	Complications	Healing Index (month/cm)
1	f	Neonatal sepsis	7.8	F	6.4	1	0.8	13	F	5	0	0.96
2	m	CFD	2.9	F	5	0	0.8	9.10	F	6.5	0	0.82
3	m	Ollier disease	16	F+T	10 (5,5)	0	1.3	18.10	F	6	0	1
4	m	Growth arrest	7	F	5	1	NA	11.3	F	3.4	2	0.89
5	f	CFD	3	F	7	3	0.8	10.4	F	6.1	0	0.93
6	f	Achondroplasia	12.10	F+T	14 (8,6)	4	0.92	15.3	F	5.7	0	1.16
7	f	FH + CFD	12	F+T	6 (3,3)	1	1.6	15.5	F	4.5	3	1.5
8	f	CFD	11	F+T	8	5	0.9	27.6	F	6.5	0	1
9	m	FH + CFD	9	F+T	NA	6	NA	15	T	4.3	0	1.5
10	m	CFD	8	F	4	0	1	15	F	5.5	7,8	0.9
11	f	FH + CFD	7	T	5	9	1	14.7	F+T	7.5	0	1.2
12	m	Neonatal sepsis	7.6	F+T	7.7	10, 1	0.9	11.7	F	5	0	0.82
13	f	CFD	10.10	F	8	0	0.65	16.9	F	2.5	11	1.1
14	f	FH + CFD	10.10	F+T	6.4	12	0.93	14.10	F	4.6	8	0.93
15	f	Achondroplasia	10	F+T	9.5 (6,3.5)	10	0.77, 1.3	17	F+T	13	0	0.9
16	m	CFD	8	F	5	0	1	18.7	F	2.7	0	1.2

FH, fibular hemimelia; CFD, congenital femoral deficiency; f, female; m, male; F, femur; T, tibia; NA, not available.

Complication key: 0, none; 1, pin tract infection; 2, tarsal tunnel syndrome; 3, knee flexion contracture; 4, scar contracture; 5, post external fixation removal fracture; 6, femoral fracture due to fall during lengthening; 7, hip subluxation; 8, delayed nonunion; 9, deep infection; 10, premature consolidation; 11, rotatory subluxation of knee; 12, hip flexion contracture.

PRECICE, in January 2012, it was noted that the patient and family experiences were much improved. As these impressions were purely anecdotal, a survey was developed to report patient satisfaction in a quantifiable way. It was decided to study specifically those patients who had undergone prior lengthening with an external fixator and then returned for an additional lengthening with the PRECICE. The following questions were addressed:

1. Is there a difference in patient satisfaction when comparing treatment with internal and external fixation in patients who have had both?
2. If patients required an additional lengthening surgery, which device would they prefer?

Materials and Methods

After obtaining institutional review board approval, a retrospective chart analysis was performed to identify patients who had two prior lengthenings: with external fixation initially, and more recently, with the PRECICE internal lengthening nail. Only patients who fit the criteria described above were included in this study, regardless of age or etiology. Sixteen patients were identified, and a questionnaire was developed to assess patient satisfaction. Patients were contacted by telephone or were asked to

complete the questionnaire during a regularly scheduled clinic visit.

The average age at the time of the external fixation lengthening surgery was 9 years (range, 2–16 years) and 15 years (range, 9–27 years) at the time of the internal lengthening surgery. Patients in this study population had the following etiologies: congenital limb deficiency (10), achondroplasia (two), distal femoral physal growth arrest (three), and Ollier’s disease (one). Table 1 summarizes patients’ demographic information, clinical results, and related complications. The healing index for external fixator lengthening was defined as time (months) from the index surgery until frame removal, divided by amount of lengthening achieved (in centimeters). The healing index for internal lengthening was defined as time (months) from the index surgery until three or four cortices were bridged divided by amount of lengthening achieved.

The questionnaire was designed to assess which device was preferred in regard to pain during lengthening, ability to weight bear, social and functional mobility, cosmetic acceptance, perceived complications, and preferred method of lengthening if required in the future (Table 2). If patients were too young at the time to remember their first lengthening, parents were asked to complete the questionnaire on their behalf.

TABLE 2 Patient questionnaire**Questions:**

1. On a 0–10 scale (10 being the worst), how much pain did you have in general over the course of lengthening?
2. In general, which device made physical therapy (PT) more challenging?
3. To the best of your recollection, how many weeks did you take prescription pain medicine (such as oxycodone, Oxycontin, Valium)?
4. In general, how long was it until you were full weight bearing w/o crutches/walker? (weeks)
5. What device gave you a better result cosmetically? (scarring)
6. Which device resulted in fewer complications?
7. Which device allowed quicker return to full knee range of motion?
8. Which device was easier to deal with on a day-to-day basis?
9. Which device allowed quicker return to social activities (including visiting w/ friends, family)?
10. Which device allowed quicker return to physical activities (walking, sports, etc.)?
11. Overall, which device were you more satisfied with?
12. If you had to do it all again, which device would you choose?

Comments:**Results**

Sixteen patients met the inclusion criteria of having undergone both external fixator and internal (PRECICE) lengthening at this institution. Two patients had outdated contact information and could not be reached. One patient declined participation. Seven male and six female patients were included in the study. Eight out of 16 patients had both the femur and the tibia lengthened during the external fixation lengthening, while only two out of 16 patients had both bones lengthened with internal fixation. All patients achieved their lengthening goal during both the external and internal fixation treatments.

Average follow-up from the time the external fixator was applied was an average of 65 months (range, 30–96 months). The average follow-up after the internal device surgery was 15 months (range, 12–22 months).

Subjective patient experience comparing external with internal methods of lengthening showed striking differences. Pain was assessed using a 10-point scale, where 0 represented no pain and 10 represented excruciating pain. The average pain score with external fixation was 7/10 (range, 2–10), while the average pain level reported with the internal device was 3 (range, 0–6) ($p = .0010$). The length of time that patients required prescription pain medication was significantly shorter with the internal device, averaging 5.2 weeks (range, 1–12 weeks), compared with an average of 11.4 weeks (range, 3.5–20 weeks) with the external fixator ($p = .001$). All patients (100%) reported that lengthening with the internal device was easier to manage on a day-to-day basis, made physical

therapy less challenging, allowed for quicker return to full range of motion in the joints, and resulted in fewer complications. All patients (100%) were more satisfied with the cosmetic result after surgery with the internal lengthening method. Every patient (100%) responded that it was easier to deal with the internal device as compared with the external method with daily activities such as sleeping, going to the bathroom, and getting dressed. Although not statistically significant, social mobility (visiting friends and family) was reported to be better with the internal rod (8 out of 13 chose the PRECICE). Five patients reported no difference in the amount of time it took to return to social activity. Quicker return to physical activity, including sports, was not significantly different, although six patients reported this return to be quicker with the internal lengthening. One patient reported quicker return to physical activity after external fixation, while three reported no difference between the devices. In two cases, this question was not applicable because of patients not fully weight bearing for reasons that were not related to the device. Overall, all patients (100%) were more satisfied with their lengthening experience with the internal device than with the external fixator. All patients responded that they would use the internal device if another lengthening was required in the future.

Discussion

The aim of this study was not to compare the clinical and complication rates associated with these methods of lengthening. It has been reported that 23% of the general population has a limb length discrepancy of 1 cm or more (7). The primary goal of surgical equalization of lower extremity limb length discrepancy (LLD) is to enhance the quality of life of patients by improving gait, function, appearance, and pain, secondary to compensation of the LLD. Patients who have LLD resulting from disorders in the lower extremities are at greater risk of developing back and hip pain (8). Treatment objectives include obtaining limb length equality, producing a level pelvis, and improving function, hopefully with a technique that is tolerable for the patient. Standard guidelines for treatment of limb length inequality generally recommend the following: for LLD of 2 cm or less, no treatment or an internal shoe lift. For LLD of 2 to 6 cm, epiphysiodesis or shortening of the longer limb is considered. For LLD of 6 to 15 cm, a lengthening procedure is considered (7, 8). These guidelines are not absolute.

A limb length discrepancy of more than 7.5 cm generally requires staged lengthening, epiphysiodesis combined with lengthening, or amputation (9). The patients in this series began with large amounts of limb length discrepancy, requiring more than one surgery to address the issue.

Over the past 15 years, there has been an increasing use of and interest in internal lengthening devices. Potential advantages of intramedullary lengthening devices include the reduced risk of contractures and infections, better maintenance of axial correction, a lower rate of refracture, reduction of pain resulting from the elimination of soft tissue transfixation, and an earlier return to daily activities (10).

The previously available intramedullary skeletal kinetic distractor (ISKD) was mechanically driven, which required twisting rotations of the limb to lengthen the rod. This action can result in a significant amount of pain and discomfort to the patient (5). Devices such as the Albizzia nail, not approved for use in the United States, can result in a complication rate that ranges from 22% to 29%, which does not include patients who required general anesthesia for distraction (4, 5, 10). In 27% of the patients with implanted ISKDs, mobilization under general anesthesia was required during the distraction phase (11). Complications ranging between 11% and 47% were reported with the ISKD (10–13).

Over the past few years, more emphasis has been placed on patient satisfaction, although the relationship between patient satisfaction and treatment outcome is debatable (14). Patient satisfaction is increasingly used to measure quality of care. Objective assessments of surgical outcome by the physicians do not always correlate with patient assessments. While surgeons often pay more attention to objective analysis of various parameters, patients focus on their functional ability (15). It has also been observed that quality of care from the patient's perspective does not always correlate with the technical quality of the medical team's work (16). Harris et al. studied patients with a lower extremity trauma and found that surgeon satisfaction is driven by objective data, which does not correlate with patient satisfaction (17). Toole et al. concluded in their study involving 463 patients treated for lower extremity injuries that patient satisfaction is determined by function, pain, and presence of depression at the end of 2 years (18). For these reasons, it is important for the surgeon to take all these factors into account before devising a treatment plan.

This study is the first of its kind, assessing patient preference and satisfaction in regard to lower extremity lengthening. With the introduction of the new PRECICE intramedullary lengthening device, the authors felt it important to compare the results using external and internal lengthening, from a patient perspective.

The results of this questionnaire indicate that the new, internal method of lengthening is associated with significantly greater patient satisfaction, reduced pain, better tolerance with physical therapy, better perceived cosmetic appearance, and a more tolerable experience for the patient. The new method has no statistical advantage over

external lengthening with reference to the amount of time it took for the patient to become fully weight bearing or the perception of a quicker return to social and sports activities.

Major limitations of this study include a small sample size, relatively short follow-up, and lack of randomization. Another weakness of this study is the use of a nonvalidated questionnaire. However, there are no currently available validated scores for this unique patient population. An additional weakness of the study is that it is retrospective, and we asked patients to report satisfaction when the index surgery was performed. All patients in this retrospective study had external fixation first at a younger age, and then a repeat lengthening using the internal lengthening system with a mean difference in age of approximately 6 years.

Additionally, as most patients had lengthening with the external fixator many years before completing the questionnaire, their perception of their experience may be distorted through the lens of time and would result in recall bias. When patients were too young (2/13) to remember their first experience, parents were asked to complete the questionnaire. Although this may be seen as a limitation of the study, it allows for representation of the experience from a parent or caregiver perspective. Despite these drawbacks, the study is the first of its kind, providing objective data that heavily favor internal methods of lengthening from the patient and caregiver perspective. Further studies that include a larger group with long-term follow-up would help to confirm these initial findings.

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