Treatment of leg length discrepancy

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Recent review date: 1/2022

Next review date: 5/2023

Policy contains: Ilizarov distraction osteosynthesis; intramedullary nail; leg length discrepancy; leg length inequality; PRECICE; FITBONE; shoe lift.

Coverage policy

Treatment of leg length discrepancies is clinically proven and, therefore, medically necessary when any of the following criteria are met, based on the magnitude of the discrepancy (Quinones, 2018):

- Custom-fitted shoe lifts for a discrepancy of 2 to 6 cm.
- Surgical treatment:
  - For a discrepancy of 2 to 6 cm: Leg shortening (epiphysiodesis or bone resection).
  - For a discrepancy of 5 to 20 cm: Leg lengthening (distraction osteosynthesis, may be combined with other procedures).
- Prosthetic fitting for a discrepancy of greater than 20 cm.

Limitations

Use of surgical leg lengthening treatments for cosmetic purposes or to correct short stature is investigational.

No other limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Leg length discrepancy, or leg length inequality, is a relatively common condition. Clinically significant leg length discrepancy usually appears in childhood. Some children are born with this discrepancy. Other children develop the condition due to injury (a broken leg bone may grow faster than normally when healing); bone illness (dysplasias); or other illness (neurologic or inflammatory conditions such as juvenile arthritis). Abnormal size of the femur and/or tibia is associated with a large majority of cases (American Association of Orthopaedic Surgeons, 2021).

Some patients may develop leg length discrepancy after surgery. A review of 21 studies (n = 39) of children undergoing anterior cruciate ligament reconstruction showed that more than 70% (29 of 39) developed leg length discrepancy, the most common reason being limb overgrowth (Collins, 2016).

Only 10% of the population has exactly equal lower leg lengths, with the large majority of the other 90% having a discrepancy of < 1 cm, which is considered insignificant (Gordon, 2019). The degree of discrepancy in clinically significant cases is typically 3.5% to 4% of total leg length, or 4 cm (1.7 inches) in the average adult. Any discrepancy in excess of these thresholds often causes limping and other walking-related difficulties.

Leg length discrepancy may be identified when the child is screened for scoliosis (even though discrepancy may not be caused by scoliosis). A physical examination for suspected cases will include observation of gait during walking, and measurement of the discrepancy when the child is standing barefoot. Gait abnormalities are often observed when the deviation is over 1 cm, and the greatest impact is observed as the deviation grows (Khamis, 2017). Sometimes a block is placed under the shorter leg until the hips are level (American Association of Orthopaedic Surgeons, 2021).

Further diagnostic information can be obtained from imaging studies. These include X-rays or scanograms, which are a series of three X-rays and a ruler to measure the length of a leg bone. In some cases, a computerized axial tomography scan of the bone and soft tissue in the legs will be taken. Growing children with leg length discrepancy are monitored over time to assess changes in the discrepancy.

Treatments for minor leg length discrepancies (typically 2 to 6 cm) without any deformity are non-surgical (Quinones, 2018). These treatments can include periodic surveillance during childhood, or wearing a lift fitted to the inside or outside of the shoe. Lifts are not costly and can be removed easily. Major discrepancies can be addressed in some cases by surgery to slow or stop the growth of the longer limb; shorten the longer limb; or lengthen the shorter limb. Types of surgery include (American Association of Orthopaedic Surgeons, 2021):

- **Epiphysiodesis.** The growth plate is destroyed by drilling or scraping, decreasing the discrepancy. In some cases, a metal staple or metal plate with screws is placed around the sides of the growth plate to slow or stop growth in the longer leg, to be removed when leg lengths are even.
- **Limb shortening.** A section of bone is removed from the middle of the longer limb, and metal plates and screws or a rod are inserted to hold the bone in place. Major shortening may weaken leg muscles; thus, limb shortening cannot be used for significant limb length discrepancies (i.e., more than three inches in the femur or more than two inches in the tibia).
- **Limb lengthening — external (major discrepancies only; viewed as a treatment of last resort).** This approach, called distraction osteosynthesis, involves cutting the bone in the shorter leg in two, and applying an external fixator connected to the bone by wires and pins to gradually lengthen the limb at a controlled rate across the osteotomy site. Intramedullary nails may be used. When the bones are pulled apart, new bone will grow in the space created. The bone can be lengthened by about one inch per month.
- **Limb lengthening — internal.** This procedure involves cutting the bone in the shorter leg and implanting an expandable metal rod in the bone. As the intramedullary rod gradually expands, a space

is created, and new bone grows to fill the space without the need for external pins or wires. The expandable intramedullary rod can be controlled through a mechanical stimulus or through movement (kinetic activation). The only kinetically-activated intramedullary distractor approved for the U.S. market, the Intramedullary Skeletal Kinetic Distractor (ISKD, Orthofix, McKinney, Texas), is no longer sold in the United States (U.S. Food and Drug Administration, 2015).

Some surgeries to correct leg length discrepancies are needed after procedures that bring on discrepancies; these surgeries include total knee or total hip arthroplasty, along with anterior cruciate ligament repair.

Findings

The Pediatric Orthopaedic Society of North America issued a guideline about leg length discrepancy, covering patient history, epidemiology, symptoms, diagnosis (especially imaging studies), causes, and treatment. The guideline states that no treatment is needed for discrepancies under 2 cm, and shoe lifts are appropriate for discrepancies from 2 to 6 cm, with surgical interventions used for larger discrepancies (Quinones, 2018). The American Academy of Orthopaedic Surgeons (2016, updated in 2021) produced a similar document. A guideline from Germany indicated that shoe lifts may be used if the discrepancy is from 2 to 5 cm, with surgery appropriate for larger discrepancies (Vogt, 2020).

Shoe lifts

A systematic review of 10 studies (n = 349), including only one randomized controlled trial, of shoe lifts used in adults with leg length discrepancy and low back pain, scoliosis, and osteoarthritis, determined 88% of patients experienced partial or complete pain relief (Campbell, 2018).

A systematic review of 23 studies (n = 377 asymptomatic patients) observed that heel lifts of 10 mm decreased duration of swing phase; those at least 5 cm decreased velocity during walking; those of 15 mm decreased maximum ankle dorsiflexion angle; and those of 12 and 18 mm decreased gastrocnemius muscle tendon unit length during running. Few effects were statistically significant (Rabusin, 2019).

Numerous articles on shoe lifts and foot orthoses as a treatment for leg length discrepancy have been published. One study of 300 patients with lower back pain indicated that more than 70% had lower leg discrepancy. Use of underfoot wedge correction or heel rises resulted in reduced discrepancy by an average of 8 mm, and a corresponding reduction in lower back pain (D'Amico, 2012).

A study of 369 children age 5 to 17 years with scoliosis included those with a discrepancy of 0.5 cm (n = 27), 1 cm (n = 329), 1.5 cm (n = 9), and 2 cm (n = 4). An external or internal shoe lift was applied to each. During the first follow-up examination within two weeks, the spine adjusted and the curve corrected in 83.7% (n = 316). In 14.7% (n = 53), the correction was observed later and accompanied by slight low back pain. An average of 11.3 months was needed to equalize the discrepancy. Authors conclude that leg length discrepancy equalization, in minor cases, "equals elimination of scoliosis" (Raczkowski, 2010).

Surgical treatment

A systematic review/meta-analysis compared patients undergoing classical (n = 457) and integrated (n = 488) leg lengthening. Integrated lengthening, which combines internal and external fixation methods, had a superior external fixator index (P = .0001) and bone healing index (P = .0146), plus shorter mean time spent in frame (P = .0015), fewer problems (P = .000) and fewer sequelae (P = .001) (Sheridan, 2020).

A systematic review and meta-analysis of four studies (n = 354 limbs) compared two methods of lower limb lengthening — the conventional Ilizarov external leg lengthening method alone (n = 171) versus Ilizarov leg lengthening followed by intramedullary nailing (n = 183). No significant difference between the two groups in gained length was observed (P = .16). The complication rate was significantly lower for the Ilizarov followed by

nailing group, mainly attributed to lower rates of pin tract infection (*P* = .0002). The nailing group had a superior external fixation and consolidation index (both *P* < .00001) (Xu, 2017).

A systematic review of 18 studies (n = 547) of adolescents who underwent leg lengthening were followed for an average of 4.3 years after the procedure. Superior outcomes were identified for patients with achondroplasia/hypochondroplasia compared to those with Turner's syndrome or constitutional short stature in terms of mean height gained, healing index, and complication rate per segment (Kim, 2014).

Another systematic review investigating the efficacy of intramedullary nailing for children age 6 to 12 years with femur fractures found low complication rates, high union rates, low re-fracture rates, low average hospital stays, and early return to function (Baldwin, 2011).

Concerns have been raised about increases in leg length discrepancy after total hip arthroplasty. A review of six arthroplasty techniques found no statistically significant difference between groups in the frequency of patients with excess leg length discrepancy (Domb, 2015).

External fixation surgery to lengthen limbs, while successful, results in the consolidation of regenerate bone while in the fixation device. Some patients require bone stimulation to correct this situation. In a meta-analysis of seven studies (n = 153), patients with bone stimulation healed significantly faster than those using comparison methods (average 33.7 days versus 45.4 days, *P* = .003) (Jauregui, 2016).

<u>Leg length discrepancy associated with other leg disorders</u>

A meta-analysis of four studies (n = 302) comparing effects of closing-wedge and opening-wedge high tibial osteotomies on change in leg length. Because the change in leg length was much less and did not cause clinical concerns, the opening-wedge approach is preferred if a large correction is required (Lee, 2019).

A systematic review of 216 children with distal femur tumors undergoing limb salvage with expandable prosthesis revealed 36% had leg length discrepancy, a figure that increased significantly with longer follow-up (*P* < .001). The group averaged 4.4 lengthening procedures and 43 mm lengthened (Portney, 2020).

In a review of 3,026 persons age 50 to 79 with or at high risk for knee osteoarthritis, subjects with leg length discrepancy ≥ 1 cm (versus < 1 cm) had greater odds of knee osteoarthritis (based on radiographic findings) in the shorter leg (53% versus 36%) but not the longer leg (38% versus 36 %). Similarly, at a threshold of 2 cm, the differences were greater for the shorter leg (68% versus 37%) but not different for the longer leg (42% versus 37%). Subjects with leg length discrepancy ≥ 1 cm had greater odds of knee osteoarthritis for both the shorter leg (15% versus 9%) and longer leg (13% versus 9%) based on symptoms (Harvey, 2010).

One review included 3,012 persons with complete data on chronic knee symptoms (pain, aching, or stiffness on most days), 3,007 with complete data on chronic hip symptoms (pain, aching, or stiffness on most days, or groin pain), and 206 subjects with leg length discrepancy of > 2 cm. The leg length discrepancy group had a significantly greater chance of having knee symptoms (56.8% versus 43.0%, *P* < .001), and (borderline significant) greater chance of having hip symptoms (49.5% versus 40.0%, *P* = .09) (Golightly, 2009, 2010).

A mail survey of 1,114 persons who had had total hip replacement five to eight years earlier revealed 30% (n = 329) reported a leg length discrepancy. However, imaging showed only 36% of these 329 patients had an anatomical discrepancy. Patients reporting a leg length discrepancy had a significantly worse Oxford hip score (*P* < .001) (Wylde, 2009).

In 2022, we added four systematic reviews (Angelini, 2020; Axelrod, 2021; Frost, 2021; Masci, 2021) examining the safety and efficacy of internal expandable rod systems, combined internal and external fixation, and external fixation alone in various populations. There is no consensus on the optimal surgical technique for correcting leg length discrepancy. We modified the coverage criteria to align with the treatment criteria from the Pediatric Orthopaedic Society of North America (Quinones, 2018).

The Ilizarov circular frame with or without lengthening over an intramedullary nail have been the most studied methods and appear to offer optimal results with few complications. Other external fixation options appear to achieve satisfactory leg lengthening outcomes, and, where reported, the number of revision operations per limb appears similar across methods. There is an absence of evidence on functional outcome scores or duration of fixation that may be more clinically relevant to the patient.

Regarding internal leg lengthening methods, the magnetically-controlled PRECICE® Bone Transport System (NuVasive Specialized Orthopedics, Inc., Aliso Viejo, California) and the motorized FITBONE® TAA (Orthofix WITTENSTEIN intens GmbH, Germany) have been the most studied methods for femur or tibial lengthening in adults and children. The available evidence consists of small, low- to moderate- quality nonrandomized studies that enrolled populations with mixed etiologies, skeletal maturities, target limbs; studies varied with respect to follow-up duration and reported outcomes, making complication rates and relative effectiveness difficult to quantify (Axelrod, 2021, n = 13 studies with 725 patients; Frost, 2021, n = 41 studies with 782 patients; Masci, 2021, n = 5 studies with 131 pediatric patients). While both methods appear to have comparable outcomes, the current evidence does not support a clear advantage of these methods in the duration of lengthening and in the risk of reoperation relative to external methods.

References

On October 18, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “leg length inequality (MeSH),” “bone lengthening (MeSH),” “Ilizarov technique (MeSH),” and “leg length discrepancy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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