Gentle Guided Growth to Correct Knock Knees and Bowed Legs in Children

The Guided Growth™ System

eight-Plate®
quad-Plate™

ORTHOFIX®
INTRODUCTION

Children need gentle guidance and correction in many aspects of their life. For a significant number of children who do not spontaneously grow out of “bowed legs” or knock knees”, pain and/or difficulty in running may ensue. These children can benefit from a new, minimally invasive surgical procedure that involves the insertion of a small device called the eight-Plate.® The eight-Plate gently guides growth while allowing natural, safe and gradual correction of limb alignment. Growing up is tough enough on both children and their parents! Using the eight-Plate, your surgeon can accurately and selectively correct limb deformities so that your child can get on with growing up —strong and straight. Read on for more information about the correction of limb deformities using the eight-Plate and a procedure referred to as hemi-epiphysiodesis.

KNOCK KNEES AND BOWED LEGS

In normal skeletal growth, limbs are equal in length and are properly aligned from the hips to the ankles. Sometimes, however, congenital abnormalities, infection, injury or other conditions can cause long bones of the leg (e.g., tibia, femur) to grow out of alignment.
This misalignment often may result in joint deformities of the leg known as valgus (knock knees) or varus (bowed legs) deformities. In these situations, normal use of the leg is impaired and walking or running may be painful.

Unfortunately, bracing is not effective in the management of these conditions. The correction of limb deformities requires one of two surgical procedures: either an osteotomy [os-te-ot´o-me] or the minimally invasive hemi-epiphysiodesis [hemi-ep-i´fiz-e-o-de´sis] procedure.

**CORRECTIVE SURGICAL PROCEDURES**

Correction using the osteotomy method is a significant surgical procedure that involves cutting the misaligned bone, adding or removing a wedge of bone (depending on the type of deformity) and realigning the bone. The realigned bone must be fixed into place with pins or with a plate and screw combination followed by a cast. Another alternative is to fix the realigned bone in place using pins in the bone segments and connecting them to an external frame. In addition to the inherent risks of such a surgery, the child must endure a prolonged hospital stay and delayed weight bearing, followed by a course of physical therapy. In many cases, multiple osteotomy surgeries may be necessary to fully correct the leg’s alignment.

**epiphysiodesis** - an operation to stop the activity of a growth plate. The effects can be permanent or temporary

**hemi-epiphysiodesis** - to tether or restrain one side (medial or lateral) of the growth plate with an implant

**femur** - the long bone of the thigh

**tibia** - the larger leg bone between the knee and ankle (shin)

**normal alignment** - younger children should be able to stand with the knees and ankles touching simultaneously

**valgus** - an inward angulation of the knee in which the ankles are separated while the knees are touching; “knock knees”

**varus** - in outward angulation of the knee in which the knees are separated while the ankles are touching; “bowed legs”

**osteotomy** - cutting a bone into two segments
In contrast, correction using hemi-epiphysiodesis is a much less invasive surgical method for correcting pathological angular deformities. Epiphysiodesis is a term from the Greek in which “physis” means growth plate and “desis” means tether. This procedure, traditionally known as “epiphyseal stapling” utilizes surgical staples (typically 2 or 3) on one side of the physis, restricting its growth while permitting continued growth on the opposite, non-instrumented side. The goal is to permit realignment through growth. More simply put, bone growth is restricted on one side of the deformity while bone growth continues on the other side. Gradually, the bone realigns and the deformity is corrected. Since the bone is not cut (as with an osteotomy), there is no neurovascular risk, instability from the cut, or significant period of healing.

**physis** - growth plate near either end of the long bones (femur and tibia) which allow for elongation. These close naturally at maturity (girls at age 14, boys at age 16 approximately)

**implant** - device inserted into a tissue for a specified period of time which is not absorbed by the body

**lateral** - outer side, away from the middle or median plane

**medial** - inner side near the midline
Despite the fact that epiphyseal stapling has been used with success for more than 50 years, there are drawbacks and limitations to the use of staples. Staples are rigid, U-shaped implants that allow no flexibility during the growth and realignment of the bone. Additionally, the staples compress the growth plate on one side. Surgical planning for the precise placement of the staples is complicated. Furthermore, when rigid implants such as staples are confronted by the powerful forces generated by physis (growth), the staples may migrate, bend or break and compromise the outcome. Staple retrieval or revision may prove difficult, resulting in inadequate correction (or overcorrection) of the deformity.

**CORRECTION THROUGH GUIDED GROWTH USING THE ORTHOFIX EIGHT-PLATE**

The new eight-Plate technique of guided growth overcomes the drawbacks associated with traditional stapling and can give your child improved correction of their pathological angular deformity.

The Orthofix eight-Plate or ‘guided growth plate’ is a unique, figure-eight shaped device about the size of a paper clip, that allows gradual correction of your child’s limb deformity. The eight-Plate holds one side of the growth plate. As the opposite side of the physis continues to expand and grow, the screws diverge within the plate, effectively serving as a hinge. This hinge action also avoids compressing the growth plate that is being guided. And because of its flexibility, the chances of the plate or screws bending or breaking under the forces of bone growth are considered very low.
THE SURGICAL PROCEDURE

Implantation of the eight-Plate is performed under anesthesia and takes about an hour. During the procedure, the surgeon will make a 2-3 cm (approximately 1”) incision at the physis of the bone to be corrected. The eight-Plate is secured to the bone with two small titanium alloy screws. For “knock knees” the eight-Plate is placed on the medial side of the bone (i.e., inner side); for bowed legs, the eight-Plate is placed on the lateral side of the bone (i.e., outer side). Multiple deformities can be addressed during the same procedure, inserting one eight-Plate per physis. The incision is closed, generally with resorbable sutures. After recovery from anesthesia, your child may be taken home.

POSTOPERATIVE RECOVERY

The eight-Plate technique of guided growth involves minimal surgical trauma and pain when compared to an osteotomy. There is no cast; crutches are optional (for comfort) and physical therapy is seldom required. Your child is encouraged to walk and resume activities as tolerated, including sports when comfort permits, which is typically within 3 weeks.

Trevan, who has a hereditary skeletal dysplasia, presented at age 2 with short stature, waddling gait and activity-related hip and knee pain. He received eight-Plate guided growth treatment, and at one year his legs had straightened and his symptoms were resolved. The eight-Plate has allowed Trevan to receive treatment at an earlier age, and his deformities were corrected without major surgeries, without osteotomy and without hospital stays or casting. He is now enjoying a normal, active childhood.
**CORRECTION OCCURS GENTLY OVER TIME**

The eight-Plate temporarily restrains growth on one side of the bone plate while natural growth is allowed to continue on the opposite side. Gradually over time, (typically from several months up to one year) the deformity is corrected. To ensure timely and adequate correction, your child needs to be seen by the surgeon every 3 months for a check-up. If your child cannot return to the surgeon every 3 months, due to distance for example, another doctor should take x-rays of the legs (the most accurate film is a full length view taken in the standing position). Send these x-rays to the surgeon who implanted the eight-Plate. When the deformity is corrected, the surgeon will remove the eight-Plate, under anesthesia, in an outpatient surgery.

Sometimes, our children need a little extra correction. And if that correction is needed for a joint deformity, rest assured that you and your child are not alone. We understand that surgery on our little ones is traumatic for you and the child, but consistent correction and gratifying clinical results have been achieved with guided growth using the eight-Plate.
FREQUENTLY ASKED QUESTIONS

Question: Is the eight-Plate meant to be permanent?
Answer: No, it should be removed when the deformity is corrected.

Question: How long can the eight-Plate safely be left in place?
Answer: As long as it is required, pending correction of the deformity. The typical range is 6-18 months.

Question: What are the indications for eight-Plate application?
Answer: Any angular deformity that would otherwise warrant an osteotomy in a patient with open growth plates, or any length discrepancy that would otherwise merit epiphysiodesis.

Question: Is a cast required after eight-Plate application?
Answer: No cast is required.

Question: Can the patient go home on the day of surgery?
Answer: Yes, generally patients go home after surgery on the same day.

Question: Are there any limitations or precautions in terms of weight-bearing?
Answer: Typically patients are encouraged to carry out immediate weight-bearing and early motion as advised by their doctor.

Question: How often does the patient have to come back for a check-up?
Answer: Patients should be seen at least every 3 months to monitor their growth and determine when to remove the plate.

Question: Are there any contraindications to the eight-Plate?
Answer: The eight-Plate should not be used for adult deformities (when the growth plates have closed) or where the growth plate has closed, such as due to trauma or infection.

Question: What is the recommended age and/or size for a patient to have an eight-Plate implant?
Answer: Since the eight-Plate does not bear any body weight after it is implanted, patient size really doesn’t matter. The eight-Plate can be used successfully in patients as young as 18 months or as old as 17 years, as long as the child is still growing (skeletally immature).

Question: Is the use of the eight-Plate limited to knock knees and bowed legs?
Answer: No, it may be used to correct other angular deformities such as flexion or extension deformities of the knee; valgus, extension or flexion deformities of the ankle; varus deformity of the elbow; and wrist flexion/extension deformities or radial/ulnar deviation.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the “Instructions for Use” supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions, information and sterilization.