

## Orthofix approach to Evidence Based Medicine:

For years, clinical decision-making was based primarily on physician knowledge and expert opinion. Now, the medical community is searching for measurable outcomes “validating” efficacy of treatments. Evidence Based Medicine (EBM) is an approach that integrates individual clinical expertise with the best available evidence when making decisions about patient treatment. (Nierengarten MB et al. Using Evidence Based Medicine in Orthopaedic Clinical Practice: The Why, When, and How-To Approach. Medscape Orthopaedics & Sports Medicine. 2001; 5[1]). Over the last few years, there has been a significant growth in Evidence Based Medicine.

## DISCLAIMER

This document is designed as a scientific tool for surgeons. As such, it reviews medical literature focusing on the “eight-Plate,” with the specific aim to collect scientific evidence on the performance of the system, as published by independent studies. This document is not intended to substitute the instructions for use (leaflet), nor any product claims can be taken from it. For information and guidelines for its correct use please refer to the “eight-Plate” instructions for use (leaflet).

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# 1. PRODUCT OVERVIEW

The Orthofix eight-Plate or “guided growth plate” is a unique, figure-eight-shaped device about the size of a paper clip that gently guides growth, while allowing natural, safe, and gradual correction of limb alignment.

Procedures for treatment may include:

- \* Knock knees
- \* Bowed legs
- \* Varus deformity of the elbow
- \* Flexion/extension deformities of the knee
- \* Flexion/extension deformities of the ankle
- \* Flexion/extension deformities of the wrist
- \* Radial/ulnar deviation

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. Due to the flexibility of the plate, the chances of the plate or screws bending or breaking under the forces of bone growth are virtually eliminated.



## Applications

The Guided Growth Technique with the eight-Plate may be used for any growing child or adolescent (age range: 18 months to 17 years) with any angular deformity, regardless of the etiology.

## Benefits to Surgeons

- \* Simple, minimally invasive technique
- \* Learning curve = 1 to 2 cases
- \* Addresses multiple/complex deformities simultaneously
- \* Modular correction – repeat as indicated

## Benefits to Patients

- \* Outpatient procedure – minimal impact on school/work schedule
- \* Reduced surgical pain/risks
- \* Immediate mobilization/rehabilitation
- \* Flexible implant will tether (not compress) the physis, allowing more rapid correction

For further information on the eight-Plate and quad-Plate components, characteristics, and guidelines for its use, please refer to the following documents:

- \* eight-Plate/quad-Plate – Operative Technique (EP-1107-OPT)
- \* eight-Plate Catalogue (EP-1004-PL)
- \* Clinical Cases (EP-0607.1-PL, EP-0607.2-PL, EP-0607.3-PL)
- \* Patient Information Brochure (EP-0601-PL)



### 2.1 PATHOLOGICAL GENU VALGUM

We thank Dr. Boero, Istituto Giannina Gaslini, Genoa, Italy, for kindly providing the following x-rays and case details.

#### X-RAYS PRE-OPERATIVE



9-year-old girl with multiple hereditary exostosis;  
Bilateral genu valgum;  
Deformity: 10°

#### X-RAYS POST-OPERATIVE



#### X-RAYS DURING TREATMENT



Image at 15 months of treatment;  
Initial correction achieved

#### X-RAYS AT THE END OF TREATMENT



Image at 24 months of treatment;  
Minimal overcorrection  
in the right leg and good  
alignment in the left leg;  
Note how the screws progressively  
diverged during treatment



## 2.II PATHOLOGICAL ANKLE VALGUS

We thank Prof. Stevens, University of Utah, Salt Lake City, Utah, USA for kindly providing the following x-rays and case details.

### X-RAYS PRE-OPERATIVE



4-years-old child with spina bifida;  
bilateral ankle valgus:  
LDFA angle: Right: 75°  
Left: 70°

### X-RAYS AT THE END OF TREATMENT



Image at 24 month of treatment  
LDFA angle: Right: 85°  
Left: 94°

The short (16 mm) epiphyseal screws were employed because they fit best;  
Overcorrection into mild varus (up to LDFA 85°) is permitted in anticipation of rebound deformity which is more common at the ankle than at the knee



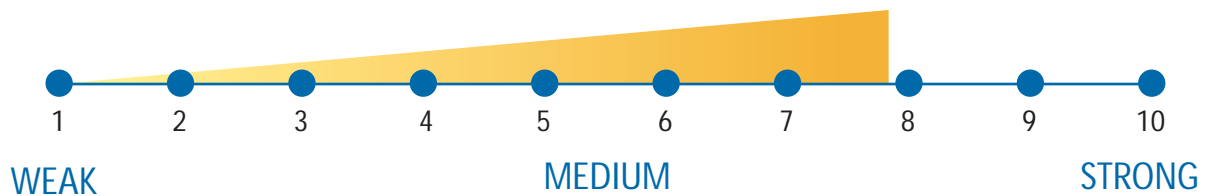
#### 3.1.A REFERENCES

1. Correcting genu varum and genu valgum in children by guided growth: temporary hemiepiphysiodesis using tension band plates. Ballal MS, Bruce CE, Nayagam S. *J Bone Joint Surg Br [Br]* (2010) Feb; 92(2): 273-276.
2. Early experience with medial femoral tension band plating in idiopathic genu valgum. Guzman H, Yaszay B, Scott VP, Bastrom TP, Mubarak SJ. *J Child Orthop* (2011) Feb; 5(1): 11-17.
3. Use of the eight-Plate for angular correction of knee deformities due to idiopathic and pathologic physis: initiating treatment according to etiology. Boero S, Michelis MB, Riganti S. *J Child Orthop* (2011) 5(3): 209-216.
4. Anterior distal femoral stapling for correcting knee flexion contracture in children with arthrogryposis – preliminary results. Palocaren T, Thabet AM, Rogers K, Holmes Jr. L, Donohoe M, King MM, Kumar SJ. *J Pediatr Orthop* (2010) Mar; 30(2): 169-173.
5. Failure of Orthofix eight-Plate for the treatment of Blount disease. Schroerlucke S, Bertrand S, Clapp J, Bundy J, O. Gregg F. *J Pediatr Orthop* (2009) Jan-Feb; 29(1): 57-60.
6. Guided growth for angular correction. A preliminary series using a tension band plate. Stevens PM. *J Pediatr Orthop* (2007) Apr-May; 27(3): 253-259.
7. Temporary hemiepiphysiodesis with the eight-Plate for angular deformities: mid-term results. Burghardt RD, Herzenberg JE. *J Orthop Sci* (2010) Sep; 15(5): 699-704.
8. Temporary hemiepiphysal arrest using a screw and plate device to treat knee and ankle deformities in children: a preliminary report. Burghardt RD, Herzenberg JE, Standard SC, Paley D. *J Child Orthop* (2008) Jun; 2(3): 187-197.
9. Guided growth for fixed knee flexion deformity. Klatt J, Stevens PM. *J Pediatr Orthop* (2008) Sep; 28(6): 626-631.



### 3.1.B METHODOLOGICAL EVALUATION

| CRITERIA                                   | Ballal [1] | Guzman [2] | Boero [3] | Palocaren [4] | Schroerlucke [5] | Stevens [6] | Burghardt [7] | Burghardt [8] | Klatt [9] |
|--|------------|------------|-----------|---------------|------------------|-------------|---------------|---------------|-----------|
| 1 Inclusion and exclusion criteria defined | 0          | 1          | 0         | 0             | 0                | 0           | 0             | 0             | 0         |
| 2 RCT or prospective study                 | 1          | 0          | 0         | 0             | 0                | 1           | 0             | 0             | 0         |
| 3 Clear primary outcome                    | 1          | 1          | 1         | 1             | 1                | 1           | 1             | 1             | 0         |
| 4 Evaluated endpoints                      | 1          | 1          | 1         | 1             | 1                | 1           | 1             | 1             | 1         |
| 5 Adequate sample size                     | 1          | 1          | 1         | 1             | 1                | 1           | 1             | 1             | 1         |
| 6 Consistent follow-up times (≥3 months)   | 1          | 1          | 1         | 1             | 1                | 1           | 1             | 1             | 1         |
| 7 Complete follow-up > 80%                 | 1          | 1          | 1         | 1             | 1                | 1           | 1             | 1             | 0         |
| 8 Statistical analysis                     | 1          | 1          | 1         | 1             | 1                | 0           | 0             | 0             | 0         |
| 9 International peer reviewed journal      | 1          | 1          | 1         | 1             | 1                | 1           | 1             | 1             | 1         |
| 10 Publication year (last 5 years)         | 1          | 1          | 1         | 1             | 1                | 1           | 1             | 1             | 1         |
| Score                                      | 9          | 9          | 8         | 8             | 8                | 8           | 7             | 7             | 7         |







### 3.1.C DEMOGRAPHIC DETAILS

| Author           | Design        | Patients   | Age  | Deformities  | Bone          | Follow-up                              |
|------------------|---------------|--|--|--|---------------|--|
| Ballal [1]       | Prospective   | 25 patients<br>(37 legs, 51 segments)<br>Females: 40%              | Avg. age:<br>11.6<br>(range: 5.5 to 14.9)<br>years   | Symptomatic genu varum or genu valgum  | Femur + tibia | 12.4*<br>(range:<br>6 to 32)<br>months |
| Guzman [2]       | Retrospective | 25 patients<br>(47 valgus deformities of the knee)<br>Females: 64% | Avg. age:<br>12.5<br>(range: 10 to 16)<br>years      | Idiopathic genu valgum (IGV)   | Femur + tibia | 12.7*<br>months                        |
| Boero [3]        | Retrospective | 58 patients<br>Females: 48%  | Avg. age:<br>10.10<br>(range: 2.3 to 14.11)<br>years | Idiopathic group: 30 patients<br>Pathological group: 28 patients                   | Femur + tibia | 21*<br>(range:<br>8 to 39)<br>months   |
| Palocaren [4]    | Retrospective | 10 patients (16 knees)<br>Females: 50%                             | Avg. age:<br>7.7<br>(range: 4.3 to 11.8)<br>years    | Arthrogyposis  | Femur         | 24*<br>(range:<br>24 to 36)<br>months  |
| Schroerlucke [5] | Retrospective | 23 patients (31 angular deformities of the knee)                   | Avg. age:<br>11<br>(range: 7 to 14)<br>years         | Blount's disease: 16 patients<br>Genu varum: 2 patients<br>Genu valgum: 5 patients | Femur + tibia | 17*<br>months                          |



| Author        | Design        | Patients  | Age   | Deformities  | Bone          | Follow-up                             |
|---------------|---------------|---|---|--|---------------|---------------------------------------|
| Stevens [6]   | Prospective   | 34 patients<br>(65 deformities)                           | Avg. age:<br>10.5<br>(range: 1.7 to<br>17.8) years  | Idiopathic group: 17 patients<br>Pathological group: 17 patients | Femur + tibia | (range:<br>14 to 26)<br>months        |
| Burghardt [7] | Retrospective | 43 patients<br>(54 physes, 51<br>limbs)<br>Females: 44.2% | Avg. age:<br>9.7<br>(range: 4 to<br>14.3) years     | Genu valgum: 39 patients<br>Genu varum: 4 patients               | Femur + tibia | 26*<br>(range:<br>18 to 30)<br>months |
| Burghardt [8] | Retrospective | 11 patients<br>Females: 54.5%                             | Avg. age:<br>10.2<br>(range: 4.11 to<br>13.8) years | Genu valgum: 9 patients<br>Genu varum: 2 patients                | Femur + tibia | 9.5*<br>(range:<br>5 to 13)<br>months |
| Klatt [9]     | Retrospective | 18 patients<br>(29 deformities)                           | Avg. age:<br>10.8<br>(range: 4 to<br>17) years      | Pathological group: 18 patients                                  | Femur         | 14*<br>(range:<br>6 to 28)<br>months  |

\* Avg. follow-up



### 3.1.D RESULTS

**PRE-/POST-OPERATIVE ANGLES** (TFA, tibial femoral angle; mL DFA, mechanical lateral distal femoral angle; MPTA, medial proximal tibial angle)

#### Ballal [1]:

Median angle of deformity treated: 8.3°

| Parameter                      | Pre-op mean degrees                     | Post-op mean degrees |
|--------------------------------|---|----------------------|
| Range of deformity             | 53° of genu verum to 17° of genu valgum | n.a.*                |
| Mean deformity for genu varum  | 28.8° (range: 11.1° to 53.3°)           | n.a.*                |
| Mean deformity for genu valgum | 8.4° (range: 3° to 25°)                 | n.a.*                |

\*n.a.: not available

#### Guzman [2]:

| Angle | Pre-op mean degrees       | Post-op mean degrees      |
|-------|---------------------------|---------------------------|
| TFA   | 11.2° (range: 5° to 16°)  | 6.0° (range: 0° to 14°)   |
| aLDFA | 78.7° (range: 74° to 84°) | 83.7° (range: 75° to 91°) |

#### Boero [3]:

Mean  $\pm$  SD of correction required: 11°  $\pm$  4.9° (range: 0° to 25°)

| Patient's group | Pre-op mean TFA         | Post-op mean TFA      |
|-----------------|-------------------------|-----------------------|
| Idiopathic      | 14° (range: 10° to 20°) | 5° (range: 4° to 8°)  |
| Pathological    | 22° (range: 14° to 30°) | 9° (range: 5° to 25°) |

#### Palocaren [4]:

Pre-operative knee deformity (mean): 50.1° (range: 20° to 90°)

Post-operative knee deformity (mean): 32.5° (range: 0° to 90°)

#### Schroerlucke [5]:

Mean angular deformity in patients with genu varum: 9.5°

#### Stevens [6]:

Pre-operative knee deformity: 7° to 30° as measured by LDFA and MDTA

#### Burghardt [7]:

Average improvement:

mLDFA: 10° (range: 1° to 18°)

MPTA: 7.78° (range: 0° to 14°)



**PRE-/POST-OPERATIVE ANGLES** (TFA, tibial femoral angle; mL DFA, mechanical lateral distal femoral angle; MPTA, medial proximal tibial angle)

**Burghardt [8]:**

| Angle                                  | Pre-op mean degrees | Post-op mean degrees | Mean change           |
|--|---------------------|----------------------|-----------------------|
| mL DFA in case of medial distal femur  | 82°                 | 91°                  | 9° (range: 5° to 11°) |
| mL DFA in case of lateral distal femur | 103°                | 93°                  | 10° (both limbs)      |
| MPTA in case of medial proximal tibia  | 94°                 | 87°                  | 7° (range: 4° to 10°) |
| MPTA of the normal contralateral limb  | 83°                 | 90°                  |                       |

**Klatt [9]:**

Mean pre-operative flexion contracture: 23.4° (range: 10° to 50°)

**RATE OF CORRECTION** (degrees/month)

**Ballal [1]:**

Distal femur: 0.7° (range: 0.3° to 1.5°)  
 Proximal tibia: 0.5° (range: 0.1° to 1.0°)  
 Femur and tibia treated concurrently: 1.2° (range: 0.1° to 2.2°)

**Guzman [2]:**

aL DFA: 0.32° (3.8° in a year)

**Boero [3]:**

Mean ± SD: 0.93° ± 0.82° (range: 0° to 6°)

**Schroerlucke [5]:**

Mean correction for genu varum and genu valgum: 0.42°

**Burghardt [7]:**

Mean mL DFA improvement: 0.65° (range: 0.05° to 1.22°)  
 Mean MPTA improvement: 0.58° (range: 0.13° to 1.67°)

**Klatt [9]:**

Fixed knee flexion deformity (FKFD) correction: 1.3° (range: 0° to 4.8°)

**PERCENTAGE OF SUCCESS (= complete correction of deformities)**

Boero [3]: 89.7%

Stevens [6]: 97%

Burghardt [7]: 92.6%

**DURATION OF TREATMENT**

Ballal [1]:

Mean: 16.1 (range: 7 to 37.3) months

Boero [3]:

Average plate removal: 14 months

Idiopathic group: 11 months

Pathological group: 18 months

Stevens [6]:

11 months

Burghardt [8]:

Average time of plate removal: 9.5 (range: 5 to 13) months



### COMPLICATIONS/REMOVALS/REVISIONS

#### Ballal [1]:

Radiological evidence of plate and screw migration: 1 patient (4%)  
Deep infection: 1 patient (4%)  
Rebound deformity: 1 patient (4%)

#### Guzman [2]:

No complications; rebound deformity: 2 cases (8%)

#### Boero [3]:

Uncorrected deformity: 1 patient (1.7%) in the pathological group  
Rebound deformity: 2 patients (3.8%) in the pathological group

#### Palocaren [4]:

Implant removal: 2 patients (20%); 1 each (10%) due to prominence of hardware and loosening of screws

#### Schroerlucke [5]:

Breakage of the tibial metaphyseal screw: 8 of 31 (26%) constructs in Blount disease patients

#### Stevens [6]:

Bilateral rebound growth and recurrent deformity: 4 patients (11.8%)  
Revision of fixation: One of the 2 recalcitrant Blount patients (due to screw loosening)

#### Burghardt [7]:

No complications

#### Burghardt [8]:

No complications

#### Klatt [9]:

Mild knee effusion: 1 patient (5.6%)  
Superficial wound infection: 1 patient (5.6%)



### 3.I.E WHAT THE AUTHORS SAY... CONCLUSIONS

"The procedure is technically simple and has significant potential for treating genu varum and genu valgum for many children without the need for osteotomy." **Ballal [1]**

"We consider the eight-Plate the best solution for the treatment of pediatric angular deformities, be they idiopathic or due to an underlying pathological condition." **Boero [3]**

"The eight-Plate has the potential to extend the indication for hemiepiphyseal stapling to a younger age group because it has a reduced risk of breakage and extrusion." **Burghardt [7]**

"The eight-Plate effectively treats angular deformities in growing children and is less likely to extrude spontaneously than the Blount staple. We have not observed growth disturbance or other complications related to this device." "Because of the easy and precise technique of insertion, its reversibility, and the decreased risk of spontaneous extrusion, the eight-Plate has widely replaced the Blount staple in our center." **Burghardt [8]**

"Problems observed with stapling, including hardware failure or slow correction, have been successfully circumvented by switching to the flexible construct of the eight-Plates." "Based on the low complication rate, patient acceptance, and the rapidity of improvement, we now use this technique as our treatment of choice." **Klatt [9]**



# 3. LITERATURE APPRAISAL & REVIEW

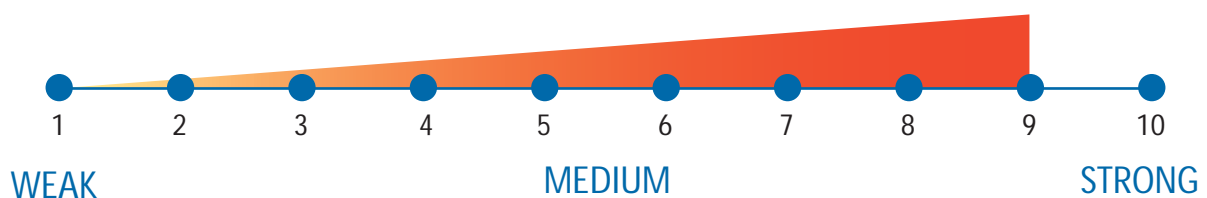
## 3. II ANKLE

### 3.II.A REFERENCES

1. Guided growth for ankle valgus. Stevens PM, Kennedy JM, Hung M. *J Pediatr Orthop* (2011) Dec; 31(8): 878-883.

### 3.II.B METHODOLOGICAL EVALUATION

| CRITERIA |   | Stevens [1] |
|----------|---|-------------|
| 1        | Inclusion and exclusion criteria defined      | 1           |
| 2        | RCT or prospective study                      | 0           |
| 3        | Clear primary outcome                         | 1           |
| 4        | Evaluated endpoints                           | 1           |
| 5        | Adequate sample size                          | 1           |
| 6        | Consistent follow-up times ( $\geq 3$ months) | 1           |
| 7        | Complete follow-up > 80%                      | 1           |
| 8        | Statistical analysis                          | 1           |
| 9        | International peer reviewed journal           | 1           |
| 10       | Publication year (last 5 years)               | 1           |
| Score    |   | 9           |







### 3.II.C DEMOGRAPHIC DETAILS

| Author      | Design        | Patients                                  | Age  | Deformities                     | Bone          | Follow-up                     |
|-------------|---------------|---|--|---------------------------------|---------------|-------------------------------|
| Stevens [1] | Retrospective | 33 patients (57 ankles)<br>Females: 39.4% | Avg. age: 10.4<br>(range: 6.1 to 14.6) years | Around 35 different deformities | Femur + tibia | 27 (range: 12 to 57.5) months |

### 3.II.D RESULTS

#### PRE-/POST-OPERATIVE ANGLES (LDTA, lateral distal tibial angle)

Pre-operative LDTA: 78.7° (range: 68° to 85°)  
Post-operative LDTA: 90° (range: 76° to 103°)

#### RATE OF CORRECTION (DEGREES/MONTH)

LDTA: 0.6° (range: 0.15° to 1.6°)

#### COMPLICATIONS/REMOVALS/REVISIONS

Deep infection: 2 cases (6.1%)  
Hardware revisions: 2 cases (6.1%)

### 3.II.E WHAT THE AUTHORS SAY... CONCLUSIONS

"The ease and efficacy of this minimally invasive form of treatment have rendered osteotomy unnecessary in this series. It is safe, well tolerated, and may readily be combined with other treatments." **Stevens [1]**



## 4. A COMPARISON BETWEEN... EIGHT-PLATES AND STAPLES

4.1 Hypophosphatemic Rickets: The Role of Hemiepiphyodesis. Novais E, Stevens PM. *J Pediatr Orthop* (2006) Mar-Apr; 26(2): 238-244.

### 4.1.A STUDY DETAILS

|                        |  |
|------------------------|--|
| <b>Patients:</b>       | 9 patients with hypophosphatemic rickets   |
| <b>Avg. age:</b>       | 7.7 (range: 2.8 to 13.3) years   |
| <b>Bone:</b>           | Femur + tibia  |
| <b>Devices:</b>        | eight-Plates and staples (the authors do not describe the type of treatment used for each patient) |
| <b>Mean follow-up:</b> | 7.8 (range: 4.5 to 12) years   |

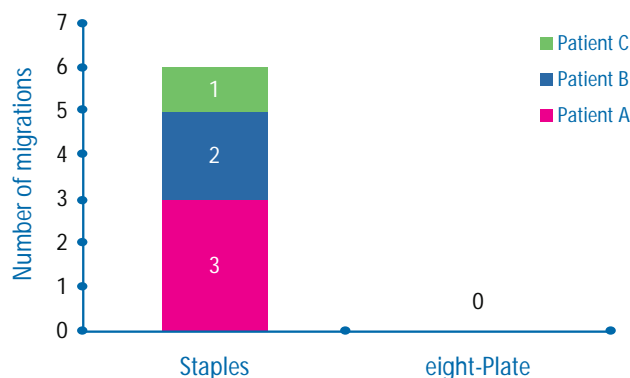
### 4.1.B RESULTS

Hemiepiphyodesis was completely successful, restoring a neutral mechanical axis and normal ranges for LDFA and MPTA in 4 patients, partially successful in 3 patients, and no correction was noted in 2 patients.

### 4.1.C COMPLICATIONS

The only complication seen was staple migration.

FIGURE 1. HARDWARE MIGRATIONS



**Figure 1.** Staple migration occurred in 3 patients: 3 times in patient A who had loose staples replaced, twice in patient B who had 2 staples removed and once in patient C who had loose staples and went on to have osteotomies and subsequent restapling.



#### 4.I.D WHAT THE AUTHORS SAY... CONCLUSIONS

"Although we accomplished the goal of restoring alignment with staples in several patients, we observed some drawbacks, including staple migration (6/38 staples, 16%) and, when performed too late, limited response."

"Consequently, it is now our preferred practice to use a two-hole plate and screws."

"Using an extraperiosteal two-hole plate and screws may avert the problems of implant loosening or migration."



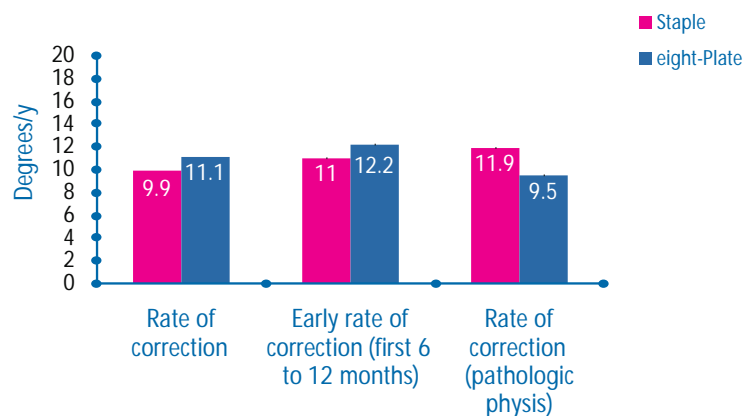
4.II Physeal stapling versus eight-Plate hemiepiphysiodesis for guided correction of angular deformity about the knee. Wiemann JM 4th, Tryon C, Szalay EA. *J Pediatr Orthop* (2009) Jul-Aug; 29(5): 481-485.

### 4.II.A STUDY DETAILS

|                        |   |
|------------------------|---|
| <b>Patients:</b>       | 63 hemiepiphysiodesis performed on 38 patients<br>Staples group: 39<br>eight-Plate group: 24  |
| <b>Avg. age:</b>       | Staples group: 12.6 (range: 8.5 to 16.7) years<br>eight-Plate group: 11.1 (range: 5.2 to 16) years<br>Difference in age between the two groups was statistically significant ( $P = 0.04$ ) |
| <b>Bone:</b>           | Femur + tibia   |
| <b>Mean follow-up:</b> | Staples group: 16.2 (range: 5 to 34) months<br>eight-Plate group: 14.1 (range 6 to 27) months   |

### 4.II.B RESULTS

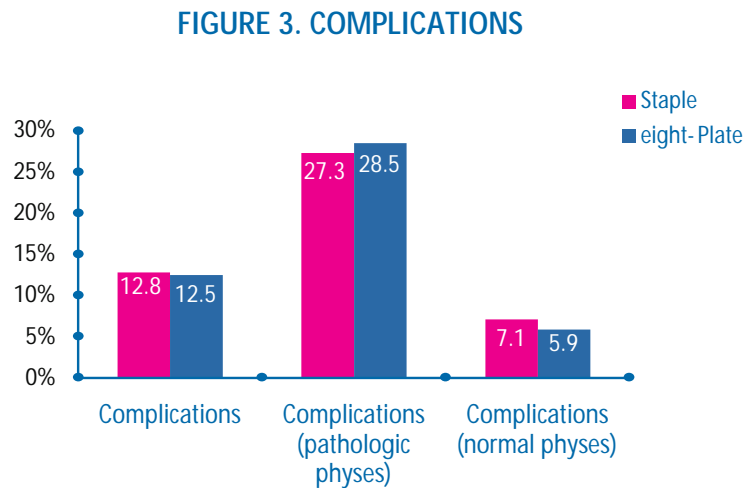
FIGURE 2. MEAN RATE OF CORRECTION



**Figure 2.** The mean overall rate of correction for patients treated with staples was 9.9° per year and that for the eight-Plate group was 11.1°. This difference was not statistically significant. The difference in mean rate of correction within the first year after surgery was also not statistically significant (11.0° per year in the staple group and 12.2° per year in the eight-Plate group).



## 4.II.C COMPLICATIONS



**Figure 3.** No statistically significant differences were observed among staple and eight-Plate group.

## 4.II.D WHAT THE AUTHORS SAY... CONCLUSIONS

"The eight-Plate is as effective as staple hemiepiphysiodesis for correction of angular deformities in children."

"The eight-Plate is our preferred technique for temporary hemiepiphysiodesis because of its precise surgical technique and ease of insertion, even in younger patients."



4.III Hemiepiphyodesis for posttraumatic tibial valgus. Stevens PM, Pease F. *J Pediatr Orthop* (2006) May-Jun; 26(3): 385-392.

The eight-Plate can be used for posttraumatic deformities provided that the growth plate has not closed.

### 4.III.A STUDY DETAILS

|                        |  |
|------------------------|--|
| <b>Patients:</b>       | 19 hemiepiphyodesis performed on 12 patients                   |
| <b>Avg. age:</b>       | Avg. age: 4.11 (range: 1.3 to 9.4) years                       |
| <b>Bone:</b>           | Tibia only (most patients), and rarely in femur (2 cases only) |
| <b>Devices:</b>        | eight-Plates or staples  |
| <b>Mean follow-up:</b> | 45 (range: 12 to 120) months                                   |

### 4.III.B RESULTS

The LPTA after hemiepiphyodesis improved from a pre-operative average of 17° valgus to 6° after last intervention, and was 8° at the last follow-up, compared with an average of 1.5° in the contralateral limb, which did not change during treatment.

FIGURE 4. AVERAGE TIBIAL FEMORAL ANGLE

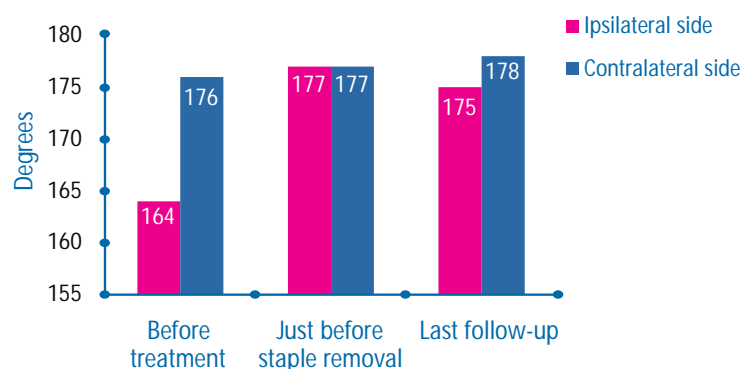
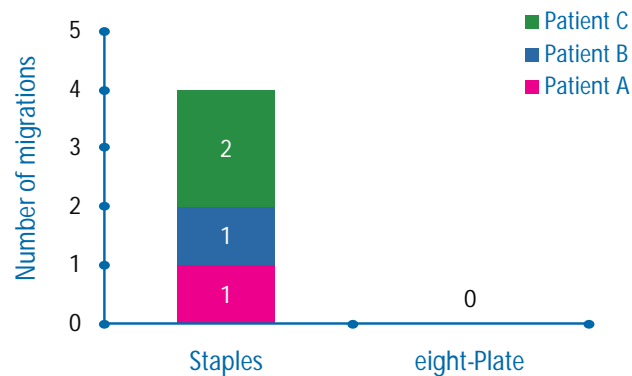


Figure 4. The average improvement was 11°.



### 4.III.C COMPLICATIONS

FIGURE 5. HARDWARE MIGRATIONS



**Figure 5.** Staple migration occurred in 3 patients: patient A and B were restapled once and patient C was restapled twice and when a rebound deformity occurred, it was decided to use eight-Plate.

### 4.III.D WHAT THE AUTHORS SAY... CONCLUSIONS

"We recognize the potential for staple extrusion in young children, and this was the only significant complication in this series (4 times in 3/12 patients). We now prefer to use a two-hole plate and screws, a construct that is flexible yet secure, accommodating the dynamic and ever-changing physis while promoting angular correction."

"Our current preference is to use the nonlocking plate and screw construct rather than a rigid staple. This avoids the vexing problem of premature staple migration; correction of alignment is more rapid, and rebound growth is less likely."



4.IV Guided growth for pathological physes. Radiographic improvement during realignment. Stevens PM, Klatt JB. J Pediatr Orthop (2008) Sep; 28(6): 632-639.

### 4.IV.A STUDY DETAILS

|                  |  |
|------------------|--|
| <b>Patients:</b> | 14 patients with rickets   |
| <b>Bone:</b>     | Femur + tibia  |
| <b>Devices:</b>  | eight-Plates and staples (the authors do not describe the type of treatment used for each patient) |

### 4.IV.B RESULTS

In cases wherein the fixation remained in situ, consistent narrowing of the width of the physes was observed during the months after extraphyseal instrumentation.

This phenomenon occurred not only at the distal femur and proximal tibia/fibula but also at the hip and ankle.

As the mechanical axis deviation was corrected and perhaps as a consequence of the normalization of gait, the physes were closer to normal in appearance, although there was no change in the medical regimen.

### 4.IV.C COMPLICATIONS

Staple migration and recurrent deformity were frequent complications; the other complications were rare.

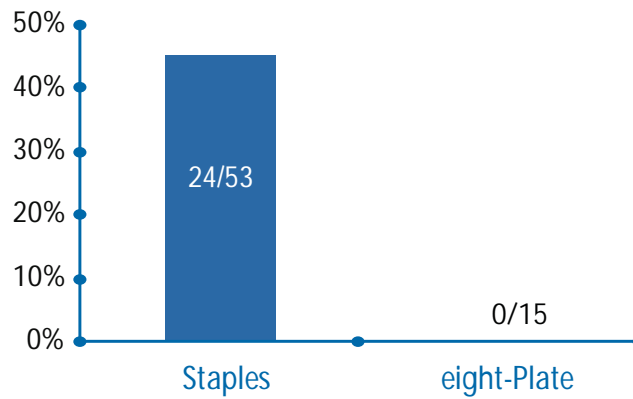
The authors switched to eight-Plate due to occasional and challenging problems related to staple migration.

Superficial wound infection in a patient was resolved with oral antibiotics; deep infections in 2 patients required 3 additional procedures, including staple removal.



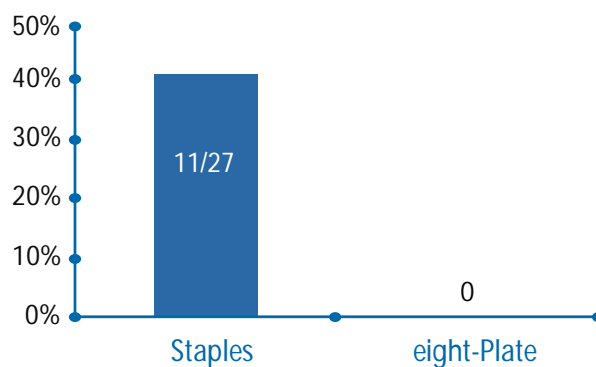


FIGURE 6A. MIGRATION



**Figure 6A.** Additional revision surgery was frequently performed in children with staples. Due to staple migration, eight-Plate was used. Patients treated with eight-Plate demonstrated neither a failure or migration of their hardware nor premature physal closure.

FIGURE 6B. REBOUND DEFORMITY



**Figure 6B.** No rebound deformity was observed in patients treated with eight-Plates (follow-up: 12 months).



#### 4.IV.D WHAT THE AUTHORS SAY... CONCLUSIONS

"The juxtaposition of one or more rigid staples against the dynamic physis, in the presence of soft bone, may lead to slow correction or hardware migration, necessitating revision surgery."

"By switching from staples to the eight-Plate, we have noted more rapid correction and averted problems with hardware migration, reducing the need for revision surgery."

"In our opinion, the eight-Plate solves the problems experienced with staples, including hardware migration."



**The following articles have not been analyzed as they pertain to animal studies, reviews, case reports and articles not in English which are not applicable to our scoring system used for the article evaluation.**

### **Animal studies:**

- Hemiepiphyseal arrest in a porcine model. Burghardt RD, Kanellopoulos AD, Herzenberg JE. *J Pediatr Orthop* (2011) Jun; 31(4): e25-e29.
- Temporary hemiepiphyseal arrest with Blount staples and eight-Plates in pigs. Kanellopoulos AD, Mavrogenis AF, Dovris D, Vlasis K, Burghardt R, Soucacos PN, Papagelopoulos PJ, Herzenberg JE. *Orthopedics* (2011) Apr 11; 34(4): 263.
- Correction of bone angular deformities: Experimental analysis of staples versus eight-Plate. Goyeneche RA, Primomo CE, Lambert N, Miscione H. *J Pediatr Orthop* (2009) Oct-Nov; 29(7): 736-740.

### **Reviews:**

- Mechanical failures of eight-Plate guided growth system for temporary hemiepiphyseal arrest. Burghardt RD, Specht SC, Herzenberg JE. *J Pediatr Orthop* (2010) Sep; 30(6): 594-597.
- Guided growth for the correction of pediatric lower limb angular deformity. Saran N, Rathjen KE. *J Am Acad Ortho Surg* (2010) Sep; 18(9): 528-536.
- Advances in growth plate modulation for lower extremity malalignment (knock knees and bow legs). Goldman V, Green DW. *Current Opin Pediatr* (2010) Feb; 22(1): 47-53.
- D.D.S.H. Developmental dysplasia of the spastic hip: strategies of management in cerebral palsy. A new suggestive algorithm. Portinaro N, Panou A, Gagliano N, Pelillo F. *Hip International* (2009) Jan-Mar; 19(Suppl 6): S69-S74.
- Guided growth: 1933 to the present. Stevens PM. *Strat Traum Limb Recon* (2006) Dec; 1(1): 29-35.

### **Case Report:**

- Orthopaedic manifestations of Navajo Familial Neurogenic Arthropathy. Woiczik MR, D'Astous JL. *J Pediatr Orthop* (2010) Apr-May; 30(3): 289-295.

### **Article in German:**

- [Correction of angular deformity of the knee in growing children by temporary hemiepiphyseal arrest using the eight-Plate]. Niethard M, Deja M, Rogalski M. *Z Orthop Unfall* (2010) Mar; 148(2): 215-221.

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