Original article

Evaluation of the external fixator TrueLok Hexapod System for tibial deformity correction in children

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1. Introduction

Lower limb deformities are a common reason for visits to the paediatric orthopaedic surgeon. Studies have established that lower limb malalignment in childhood is a risk factor for osteoarthritis in adulthood [1]. A major goal is therefore to restore normal alignment in childhood whenever possible.

Many surgical techniques have been developed to correct tibial deformities. The most widely used is acute correction by a closing-wedge or opening-wedge tibial osteotomy. This technique is well established but extremely challenging to perform when the deformity involves multiple planes. In addition, in the event of a residual deformity, further surgery must be performed [2]. Furthermore, limb length discrepancy (LLD) cannot be corrected by wedge osteotomies. Management of the soft tissues may carry substantial risks. Finally, the loss of bone stock and risk of patella baja with this technique may compromise the feasibility of total knee arthroplasty in the future [3,4].

Distraction osteotomy for the gradual correction of limb deformities is a technique first described by Ilizarov. Several studies have assessed the hexapod external fixator Taylor Spatial Frame (TSF) (Smith & Nephew, Memphis, TN, USA) for applying distraction after...
a percutaneous osteotomy [5–7]. The complication rate was low and the treatment effective [8,9,6,10]. The six-axis concept allows for correction of complex deformities in all three planes, in a gradual manner that decreases soft tissue trauma. Compared to other methods, the TSF provides more accurate correction [11].

In 2012, the TrueLok Hexapod System (TL-HEXTM) (Orthofix S.R.L., Bussolengo, Verona, Italy) was introduced on the market. Similar to the TSF, the TL-HEXTM is a hexapod external fixator that allows the gradual correction of bone deformities. The main difference between the two devices lies in the radiographic analysis method and software used to determine the parameters for limb lengthening and deformity correction. Whereas the TSF has been proven effective in several studies, data on the TL-HEXTM are scant. Ferreira et al. compared radiographic outcomes between the two devices using a Sawbone® model [12]. However, no study has assessed clinical outcomes obtained with TL-HEXTM.

The main working hypothesis for this study was that the hexapod external fixator TL-HEXTM provided accurate correction of tibial deformities in children. The secondary hypothesis was that the complication rate was not higher with TL-HEXTM than with other hexapod external fixators. The objective of this study was to assess the clinical and radiological outcomes of TL-HEXTM tibial deformity correction in children.

2. Patients and methods

2.1. Study design

A retrospective study was conducted in two centres. Data were abstracted from the medical files of the children who underwent tibial deformity correction between November 2012 and September 2016. Inclusion criteria were age younger than 18 years, surgical tibial deformity correction using the TL-HEXTM external fixator, and a follow-up of at least 1 year.

In all, 26 patients with deformities in 31 tibias were identified, 11 (14 tibias) from the database of the Nationwide Children’s Hospital (Columbus, OH, USA) and 15 (17 tibias) from the database of the Timone Children’s Hospital (Marseille, France). Each patient was followed by one of the authors (C.A.I. or F.L). Demographic data were collected. There were 15 boys and 11 girls with a mean age at surgery of 11.9 years (range, 6–17 years). The tibial deformities were due to congenital defects in 11 (35%) cases, Blount’s disease in 9 (29%) cases, pseudo-achondroplasia in 4 (13%) cases; and other causes in 7 (23%) cases. Of the 31 tibias, 11 (35%) had had previous surgery.

2.2. Surgical management

The deformity was corrected gradually using the TL-HEXTM external fixator for all 31 tibias. A minimally invasive osteotomy involving the creation of drill holes then completion of the cuts using an osteotome was performed. This osteotomy technique ensures optimal preservation of the periostium, which should in theory enhance bone healing. The osteotomy site was the proximal third of the tibia in 16 (52%) cases, middle-third in 14 (45%) cases, and distal-third in 1 (3%) case. Additional procedures were performed in 18 cases and consisted of fibular syndesmotic screw insertion (n = 10), femoral lengthening (n = 2), epiphysiodysis about the knee (n = 3), supra-malleolar osteotomy for acute ankle valgus correction (n = 1), patellar reconstruction (n = 1), and osteochondroma excision (n = 1). Limb lengthening was assisted with elastic stable intramedullary nailing (ESIN) in 12 (39%) cases. The knee was included in the external fixator frame in 4 (13%) cases and the foot in 1 (3%) case.

2.3. Radiographic assessment

Radiographic parameters were assessed on long leg radiographs obtained pre-operatively and at last follow-up. Six parameters were measured: mechanical axis deviation (MAD), medial proximal tibial angle (MPTA), posterior proximal tibial angle (PPTA), lateral distal tibial angle (LDTA), anterior distal tibial angle (ADTA), and limb length discrepancy (LLD) [13] (Fig. 1). MAD was the distance in millimetres from the centre of the knee (tibial spines) to the mechanical axis of the lower limb (line connecting the centre of the hip to the centre of the ankle). The radiographic outcomes were compared to the MAD and LLD correction goals set pre-operatively.

2.4. Complications

Complications that developed during limb lengthening were classified according to Paley [13] as mild (full resolution without surgery), moderate (full resolution with surgery), and major (residual impairments after surgery).

2.5. Statistical analysis

The data are described as mean (range). Mean values before surgery and at last follow-up were compared by applying Student’s t-test for paired data. To compare patients managed with and without ESIN, Student’s t-test for independent samples was chosen. The Chi2 test was used to compare qualitative data. Fisher’s test was applied instead when required by small sample sizes. Values of P smaller than 0.05 were taken to indicate significant differences.

3. Results

3.1. Radiographic outcomes

Table 1 reports the results of the radiographic analysis. Pre-operatively, 16 (52%) tibias had varus deformity, 14 (45%) valgus deformity, and 1 (3%) no deformity in the coronal plane. At last follow-up, significant decreases were found in mean MAD (32.1 mm to 10.2 mm, P < 0.001) and mean LLD (36.8 mm to 9.1 mm, P < 0.001).

![Image](https://example.com/image.png)
Table 1

Radiographic outcomes. The MAD and LLD were significantly improved at last follow-up. The proportion of patients with normal MPTA and PPTA values was significantly higher at last follow-up.

<table>
<thead>
<tr>
<th></th>
<th>Pre-operatively</th>
<th>At last follow-up</th>
<th>t-test</th>
<th>Chi²</th>
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<tr>
<td></td>
<td>Mean</td>
<td>Normal</td>
<td>Abnormal</td>
<td>Mean</td>
</tr>
<tr>
<td>MAD (mm)</td>
<td>32.1</td>
<td>–</td>
<td>–</td>
<td>10.2</td>
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<tr>
<td>MPTA (°)</td>
<td>85.1</td>
<td>8 (26%)</td>
<td>22 (73%)</td>
<td>88.2</td>
</tr>
<tr>
<td>PPTA (°)</td>
<td>80.6</td>
<td>12 (40%)</td>
<td>18 (60%)</td>
<td>81.1</td>
</tr>
<tr>
<td>LDTA (°)</td>
<td>85.2</td>
<td>17 (65%)</td>
<td>9 (35%)</td>
<td>86.8</td>
</tr>
<tr>
<td>ADTA (°)</td>
<td>84.8</td>
<td>10 (38%)</td>
<td>16 (62%)</td>
<td>82.9</td>
</tr>
<tr>
<td>LLD (mm)</td>
<td>36.8</td>
<td>–</td>
<td>–</td>
<td>9.1</td>
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</tbody>
</table>

MAD: mechanical axis deviation; MPTA: medial proximal tibial angle; PPTA: posterior proximal tibial angle; LDTA: lateral distal tibial angle; ADTA: anterior distal tibial angle; LLD: limb length discrepancy.

Fig. 2. An 11-year-old girl with hemimelic epiphyseal dysplasia of the left lower limb. History of multiple surgical procedures including femoral and tibial lengthening and distal femoral osteotomy. A. Pre-operative long leg radiograph: LLD = 100 mm (right tibia, 360 mm/left tibia, 300 mm); MAD = 31 mm; MPTA = 112°. B. Radiograph taken immediately after surgery. C. Radiograph 3 months after surgery: gradual 7-cm distraction with gradual correction of the valgus tibial deformity. D. Long leg radiograph 1 year after surgery and 4 months after removal of the TL-HEXTM: LLD = 30 mm (right tibia, 360 mm/left tibia, 370 mm); MAD = 0 mm; MPTA = 94°.

In the tibias managed with proximal osteotomy (Fig. 2), the MPTA improved significantly, from 80.6° pre-operatively to 88.5° at last follow-up (P = 0.006). The PPTA showed no significant change in this group (81.6° vs. 80.3°, P = 0.56). In the groups of tibias with middle-third or distal-third tibial osteotomy, neither MPTA nor PPTA changed significantly (91.4° vs. 88.0°, P = 0.11; and 79.6° vs. 81.9°, P = 0.18; respectively).

For all 31 tibias, the MAD and LLD goals set pre-operatively were achieved.

3.2. Clinical outcomes and complications

Pain control was achieved using only a step 1 analgesic in 26 (84%) cases. In the remaining 5 (16%) cases, a step 2 analgesic was required. Mean duration of external fixator use was 163.5 days (range, 90–241 days). Mean time to full weight bearing was 44.9 days (range, 7–82 days).

Mean healing index was 39.3 ± 5.7 days/cm (range, 32–58 days/cm) overall, 36.1 ± 4.0 days/cm (range, 33–46 days/cm) in cases with ESIN, and 44.1 ± 9.1 days/cm (range, 32–58 days/cm) in cases without ESIN. The difference between the groups with and without ESIN was statistically significant (P = 0.04). Mean healing index was significantly higher for tibias with vs. without previous surgery (42.1 vs. 35.1 days/cm, P = 0.02). The group with previous surgery had a significantly longer duration of external fixator use (184.6 vs. 151.3 days, P = 0.04).

Complications included a fracture in 2 (6.5%) cases, superficial pin tract infection in 16 (51.6%) cases, and deep-seated infection in 1 (3.2%) case. The overall complication rate was 61.3%, with 11 unplanned visits. Of the 19 complications, 17 were minor and 2 moderate; no major complications were recorded. Unplanned revision surgery was performed in 3 cases, with 1 case each of repeat tibial osteotomy required by early healing of the initial osteotomy, internal fixation of a femoral fracture, and Achilles tenotomy during hardware removal. In 6 cases, problems arose with the external fixator, involving the wires or half pins (n = 2), a ring (n = 1), or the struts (n = 3). None of these problems required revision surgery.

4. Discussion

Hexapod external fixators have been proven effective in various indications [14]. Thus, in several studies these devices used to treat fractures produced good outcomes in terms of both healing rates and residual deformity [15–17]. The TSF has been assessed in other indications such as tight non-union [18] and three-dimensional deformities [6,10,11]. To our knowledge, no study has assessed the effectiveness of the hexapod external fixator TL-HEXTM for correcting tibial deformities in children.
Radiographic outcomes were assessed by measuring the parameters typically used in tibial deformities [19,20]. The TL-HEXTM was effective in correcting LLD, leaving a residual difference of 9 mm at last follow-up. MPTA reflects proximal tibial geometry and is a good parameter for evaluating proximal tibial deformities in the coronal plane. MPTA showed no significant change in the overall study population. However, dividing patients based on the osteotomy site showed that MPTA improved significantly in the group with proximal tibial osteotomy. This finding is consistent with the presence in this group of proximal tibial deformities responsible for abnormal MPTA values before surgery. TL-HEXTM therapy proved effective in treating these deformities. There was a single case of distal tibial osteotomy, precluding a meaningful statistical analysis of LDTA.

This study has several limitations. The retrospective design precludes definitive conclusions about the effectiveness of the study treatment. However, the vast majority of published studies on the same topic are retrospective, and our data provide a similar level of evidence. There was no control group: TL-HEXTM was not compared to another fixation device. The outcomes were comparable to those reported with other hexapod external fixators, suggesting similar effectiveness of the TL-HEXTM device. However, a comparative study is required to confirm this possibility. Finally, the small sample size limits the statistical power of the study. Nevertheless, our finding that correction goals were achieved consistently demonstrates that TL-HEXTM is effective for limb lengthening and tibial deformity correction.

The 61% overall complication rate is consistent with earlier data [21]. Most of the complications were minor, i.e., resolved fully without surgery. The most common complication was superficial infection of wire and half pin insertion sites, which is common with all external fixators. Local care was effective, in keeping with previous reports [22]. There was a single deep-seated infection, which responded to long-term antibiotic therapy and did not require surgical revision.

The healing index was significantly lower in patients treated with versus without ESIN. Similarly, in an experimental study in dogs, Popkov et al. reported better healing with intramedullary K-wires [23]. In contrast, the healing index was higher for tibias with a previous history of surgery, probably due to poorer bone quality.

The effectiveness of a hexapod external fixator for correcting tibial deformities has been convincingly demonstrated. Most studies, however, used the TSF [6–10]. A clinical evaluation of TL-HEXTM in this indication was therefore timely. An experimental study by Ferreira et al. showed fundamental differences between the TSF and TL-HEXTM, among which the most important resided in the software used to compute the amount of correction over time [12]. TSF software relies on the relative positions of the rings, whereas TL-HEXTM software uses bone segment position as the reference. Consequently, the method used to compute ring position within the frame and relative ring motion during correction is not the same. This difference in computation methods has not been evaluated in clinical practice and may cause errors. Nevertheless, our findings suggest that TL-HEXTM provides accurate correction with a significant improvement in MAD (from 32.1 mm to 10.2 mm). At last follow-up, only 11 patients had an MAD value greater than 10 mm. These results are similar to those reported with the TSF device [10,11,14].

This is the first study to focus specifically on the clinical and radiographic effectiveness of TL-HEXTM for the multplanar correction of tibial deformities in children. This external fixator was effective in correcting the angular abnormalities, lengthening the operated limb, and restoring the mechanical axis. The complication rate was similar to those reported with other hexapod external fixators. ESIN was associated with a better healing index. Consequently, ESIN should be considered routinely for patients requiring tibial lengthening with an external fixator.

Disclosure of interest

The authors declare that they have no competing interest.

References