Evidence in focus
A systematic literature review and meta-analysis

Children

High treatment success rate with the TAYLOR SPATIAL FRAME in children
Purpose
To systematically evaluate the available evidence to determine the overall treatment success rate of TAYLOR SPATIAL FRAME® (TSF) in children with acute trauma, non-unions/mal-unions and deformities.

Background
TSF is an external device for limb correction, lengthening and/or straightening, with a long history of clinical use:

- More than 20 years of clinical use
- More than 200 publications detailing the use of TSF in adults and children

Methods

Literature search
A search for clinically relevant results was conducted using Embase and PubMed across three indications (September 6, 2018):

- Acute trauma
- Non-unions/mal-unions
- Deformity correction

Study suitability
Abstracts were analysed to determine study relevance. Additional studies were identified from other sources, such as by reviewing reference lists. To be considered eligible, a study had to fulfil the following criteria:

**Inclusion criteria:**
- Published from 2008 onwards in a peer-reviewed journal
- English language publication
- Paediatric population
- Proportion of successful cases identifiable in study

**Exclusion criteria:**
- Single case report
- Off-label product use
Only studies with >10 patients in the TAYLOR SPATIAL FRAME™ treatment group were included in the meta-analyses (Figure 1). Studies with 2-10 patients are reported in the Appendices.

- **Acute trauma**
  - Search term: "TAYLOR SPATIAL FRAME" and fracture
  - 138 studies identified:
    - Embase: 125
    - PubMed: 13
    - Other sources: 0
  - 134 studies excluded (not relevant)
  - 4 studies suitable for meta-analysis

- **Non-unions/mal-unions**
  - Search term: "TAYLOR SPATIAL FRAME"
  - 206 studies identified:
    - Embase: 188
    - PubMed: 18
    - Other sources: 0
  - 204 studies excluded (not relevant)
  - 2 studies excluded (<10 patients)
  - 1 study suitable for meta-analysis

- **Deformity correction**
  - Search term: "TAYLOR SPATIAL FRAME" and deformity
  - 122 studies identified:
    - Embase: 121
    - PubMed: 0
    - Other sources: 1
  - 103 studies excluded (not relevant)
  - 19 studies suitable for meta-analysis

Figure 1. Search strategy

**Meta-analyses**

The results of each suitable study were analysed to determine the proportion of patients treated with TSF who successfully achieved the treatment goal.

The goals used to indicate treatment success were:

- **Consolidation** in patients with acute trauma
- **Bony union** in patients with mal-unions/non-unions
- **Deformity correction**

Meta-analyses were then conducted to determine the overall success rate of TSF per indication.
Results

Total number of studies meeting the inclusion criteria with \( \geq 10 \) patients: 15 studies

**Combined treatment success**

The meta-analyses demonstrated consistently high success rates in acute trauma and deformity correction in children (Figure 2).

A proportional meta-analysis in non-unions/mal-unions for children was not possible as only one suitable study was identified with \( \geq 10 \) patients.

In four studies, **99%** of patients with acute trauma achieved consolidation\(^1-4\) (95% CI: 90-100%)

In eleven studies, **95%** of patients with deformities achieved correction\(^5-15\) (95% CI: 90-99%)

Figure 2. Combined treatment success in children treated with TSF.

Full details of studies included in the meta-analysis are included in the Appendices.

**Conclusion**

The TAYLOR SPATIAL FRAME\(^®\) has a long history of clinical use and has been reported in more than 200 peer-reviewed publications. These meta-analyses demonstrate consistently high success rates in children for the treatment of acute trauma and deformities. A meta-analysis was not possible in non-unions/mal-unions due to a lack of available studies.
Appendix 1. Literature review and meta-analysis in acute trauma

Table 1. Characteristics of relevant studies.

<table>
<thead>
<tr>
<th>Study, year</th>
<th>n</th>
<th>Age (years)</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shore et al, 2016¹</td>
<td>16</td>
<td>Mean: 13</td>
<td>Diaphyseal fractures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range: 6-18</td>
<td></td>
</tr>
<tr>
<td>Tafazal et al, 2014²</td>
<td>15</td>
<td>Mean: 13</td>
<td>Tibial fractures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range: 7-15</td>
<td></td>
</tr>
<tr>
<td>Blondel et al, 2010³</td>
<td>11</td>
<td>Mean: 12</td>
<td>Tibial fractures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range: 7-15</td>
<td></td>
</tr>
<tr>
<td>Zenios, 2013⁴</td>
<td>12</td>
<td>Mean: 12</td>
<td>Various</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Range: 8-15</td>
<td></td>
</tr>
</tbody>
</table>

n≥10; included in meta-analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Events</th>
<th>Total</th>
<th>Proportion</th>
<th>95% CI</th>
<th>Weight (fixed)</th>
<th>Weight (random)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blondel et al, 2010</td>
<td>9</td>
<td>11</td>
<td>0.82</td>
<td>[0.48; 0.98]</td>
<td>20.5%</td>
<td>21.8%</td>
</tr>
<tr>
<td>Shore et al, 2016</td>
<td>16</td>
<td>16</td>
<td>1.00</td>
<td>[0.79; 1.00]</td>
<td>29.5%</td>
<td>26.9%</td>
</tr>
<tr>
<td>Zenios et al, 2013</td>
<td>12</td>
<td>12</td>
<td>1.00</td>
<td>[0.74; 1.00]</td>
<td>22.3%</td>
<td>23.2%</td>
</tr>
<tr>
<td>Tafazal et al, 2014</td>
<td>15</td>
<td>15</td>
<td>1.00</td>
<td>[0.78; 1.00]</td>
<td>27.7%</td>
<td>26.9%</td>
</tr>
<tr>
<td>Fixed effect model</td>
<td>54</td>
<td></td>
<td>0.99</td>
<td>[0.92; 1.00]</td>
<td>100%</td>
<td>--</td>
</tr>
<tr>
<td>Random effects model</td>
<td></td>
<td></td>
<td>0.99</td>
<td>[0.90; 1.00]</td>
<td>--</td>
<td>100%</td>
</tr>
</tbody>
</table>

Heterogeneity: I² = 30%, t² = 0.0079, p=0.23

Figure 3. Proportional meta-analysis of studies (with ≥10 patients) assessing the use of TAYLOR SPATIAL FRAME® for acute trauma in paediatric populations

Abbreviations
CI = confidence interval
Appendix 2. Literature review and meta-analysis in non-unions/mal-unions

Table 2. Characteristics of relevant studies.

<table>
<thead>
<tr>
<th>Study, year</th>
<th>Level I: Randomised controlled trials</th>
<th>Level II: Prospective, comparative</th>
<th>Level III: Retrospective, comparative</th>
<th>Level IV: Case series</th>
<th>n</th>
<th>Age (years)</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>n≥10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Koren et al, 2016$^5$</td>
<td>13</td>
<td>Mean: 12</td>
<td>Range: 8-15</td>
<td>Post-traumatic mal-unions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n&lt;10, not included in meta-analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eidelman et al, 2010$^6$</td>
<td>4</td>
<td>Mean: 13</td>
<td>Range: 10-16</td>
<td>Mal-unions</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A proportional meta-analysis in non-unions/mal-unions for children was not possible as there was only one study found with ≥10 patients.

Appendix 3. Literature review and meta-analysis in deformity correction

Table 3. Characteristics of relevant studies.

<table>
<thead>
<tr>
<th>Study, year</th>
<th>Level I: Randomised controlled trials</th>
<th>Level II: Prospective, comparative</th>
<th>Level III: Retrospective, comparative</th>
<th>Level IV: Case series</th>
<th>n</th>
<th>Age (years)</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>n≥10; included in meta-analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reitenbach et al, 2016$^7$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>33</td>
<td>Mean: 15</td>
<td>Range: 2-54$^*$</td>
</tr>
<tr>
<td>Sachs et al, 2015$^8$</td>
<td></td>
<td>23 (2 tibias)</td>
<td>Mean: 15</td>
<td>Range: 13-21$^*$</td>
<td>Blount disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blondel et al, 2009$^9$</td>
<td></td>
<td></td>
<td>Mean: 11</td>
<td>Range: 3-18</td>
<td>Various aetiologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eidelman and Katzman, 2008$^{10}$</td>
<td></td>
<td></td>
<td>Mean: 8</td>
<td>Range: 4-14</td>
<td>Complex foot deformities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eidelman et al, 2010$^6$</td>
<td></td>
<td></td>
<td>Mean: 13</td>
<td>Range: 8-17</td>
<td>Deformities secondary to growth arrest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eidelman et al, 2012$^{11}$</td>
<td></td>
<td></td>
<td>Mean: 15</td>
<td>Range: 11-18</td>
<td>Clubfoot deformities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horn et al, 2017$^{12}$</td>
<td></td>
<td></td>
<td>Median: 14</td>
<td>Range: 4-18</td>
<td>Various aetiologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Koren et al, 2016$^5$</td>
<td></td>
<td></td>
<td>Mean: 12$^+$</td>
<td>Range: 2-16$^+$</td>
<td>Various</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Küçükkaya et al, 2009$^{13}$</td>
<td></td>
<td></td>
<td>Mean: 17</td>
<td>Range: NR$^*$</td>
<td>Various aetiologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naqui et al, 2008$^{14}$</td>
<td></td>
<td></td>
<td>Mean: 11</td>
<td>Range: 1-16</td>
<td>Various aetiologies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tsibidakis et al, 2014$^{15}$</td>
<td></td>
<td></td>
<td>Mean: 11</td>
<td>Range: 3-16</td>
<td>Various aetiologies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3. Characteristics of relevant studies (cont.).

<table>
<thead>
<tr>
<th>Study, year</th>
<th>Level I: Randomised controlled trials</th>
<th>Level II: Prospective, Comparative</th>
<th>Level III: Retrospective, Comparative</th>
<th>Level IV: Case series</th>
<th>n</th>
<th>Age (years)</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barnes et al, 2010&lt;sup&gt;16&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td>Mean: 14</td>
<td>Tibial growth arrest after trauma</td>
</tr>
<tr>
<td>Docquier et al, 2008&lt;sup&gt;17&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>Mean: 17</td>
<td>Various aetiologies</td>
</tr>
<tr>
<td>Domzalski, et al 2009&lt;sup&gt;18&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>Mean: 14</td>
<td>No clear aetiological factor</td>
</tr>
<tr>
<td>Eidelman and Katzman, 2011&lt;sup&gt;19&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7</td>
<td>Mean: 11</td>
<td>Varied arthrogrypotic foot deformities</td>
</tr>
<tr>
<td>Eidelman et al, 2011&lt;sup&gt;20&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8</td>
<td>Mean: 14</td>
<td>Various aetiologies</td>
</tr>
<tr>
<td>Hassan and Letts, 2012&lt;sup&gt;21&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9</td>
<td>Mean: 9</td>
<td>Various aetiologies</td>
</tr>
<tr>
<td>Seybold et al, 2008&lt;sup&gt;22&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>Mean: 14</td>
<td>Pseudo-Madelung deformities after epiphyseal fracture</td>
</tr>
<tr>
<td>Siapkara et al, 2008&lt;sup&gt;23&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Mean: 16</td>
<td>Anterior growth arrest and recurvatum deformity</td>
</tr>
</tbody>
</table>

Figure 4. Proportional meta-analysis of studies (with ≥10 patients) assessing the use of TAYLOR SPATIAL FRAME<sup>®</sup> for deformity correction in children.

- Data for adults and children not separated but mean age <18 years.
- Mean age and range of overall patient population.
- Data for 4 non-union cases excluded.
- Six of the original 25 patients were excluded because TSF was only used acutely before progressing on to a different treatment regime.
- Data reported as number of tibia rather than patients.

**Abbreviations**
- CI = confidence interval
- NR = not reported
References


