Evidence in focus

A systematic literature review and meta-analysis

Children

High treatment success rate with the TAYLOR SPATIAL FRAME in children

smith&nephew

TAYLOR SPATIAL FRAME◇

External Fixator

Supporting healthcare professionals

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:

20

More than 20 years of clinical use

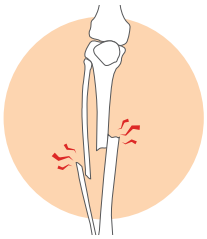
200

More than 200 publications detailing the use of TSF in adults and children

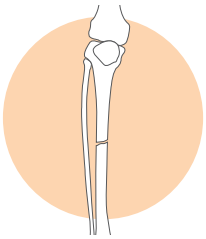
Methods

Literature search

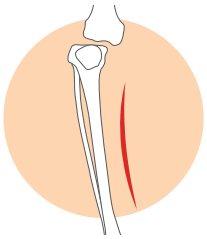
A search for clinically relevant results was conducted using Embase and PubMed across three indications (September 6, 2018):



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.

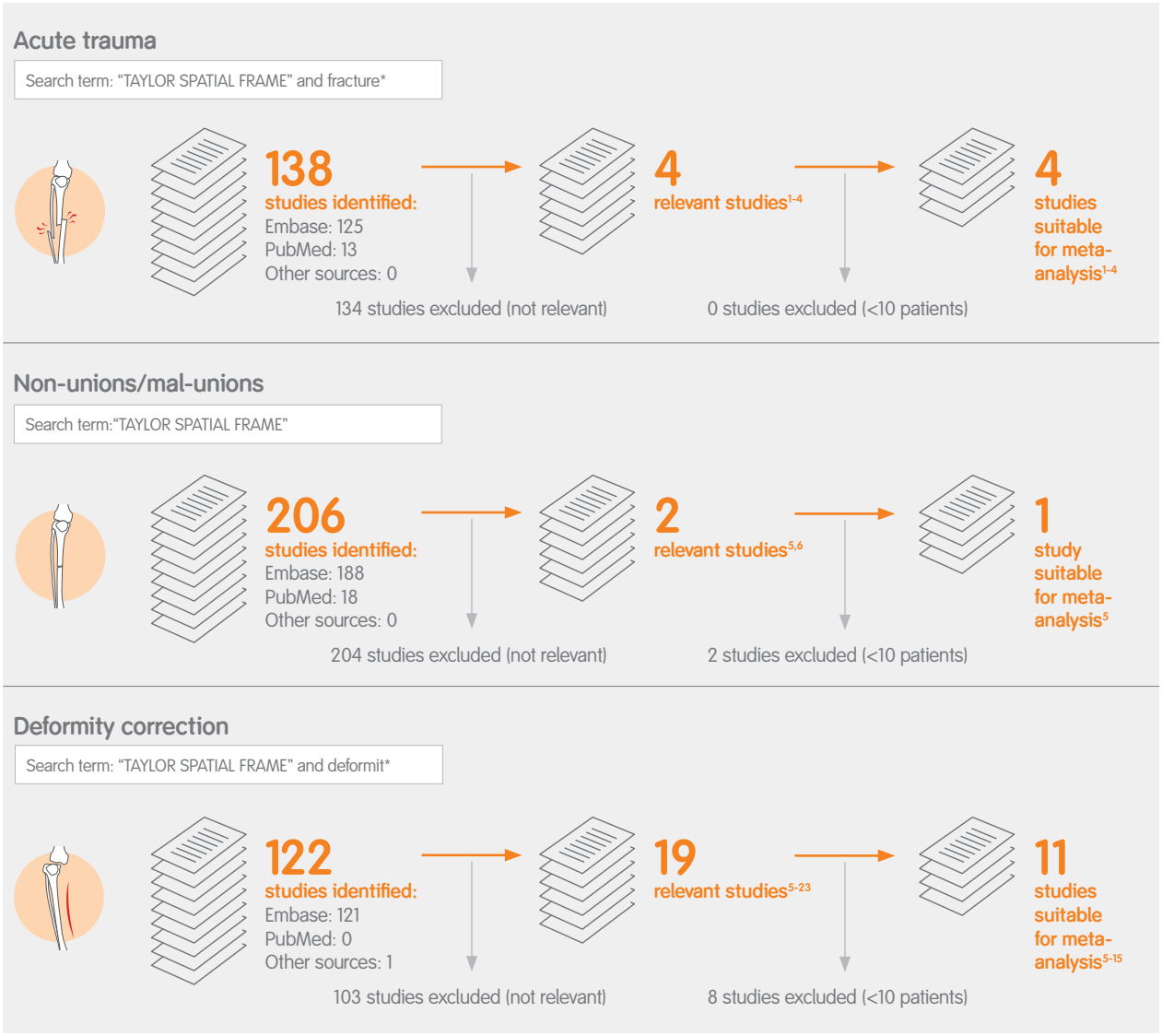


Figure 1. Search strategy

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 **≥10 patients**

15 studies

Combined treatment success

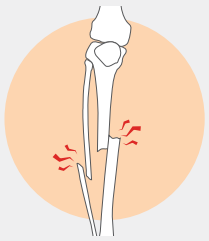
The meta-analyses demonstrated consistently high success rates in acute trauma and deformity correction in children (**Figure 2**).
A proportional meta-analysis in non-unions/mal-unions for children was not possible as only one suitable study was identified with ≥10 patients.

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%)

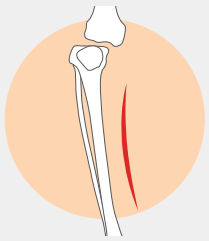


Figure 2. Combined treatment success in children treated with TSF.

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.

Study, year	Level I: Randomised controlled trials	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	n	Age (years)	Indication
n≥10; included in meta-analysis							
Shore et al, 2016[1]			■		16	Mean: 13 Range: 6-18	Diaphyseal fractures
Tafazal et al, 2014[2]			■		15	Mean: 13 Range: 7-15	Tibial fractures
Blondel et al, 2010[3]				■	11	Mean: 12 Range: 7-15	Tibial fractures
Zenios, 2013[4]				■	12	Mean: 12 Range: 8-15	Various

Forest plot for consolidation in acute trauma

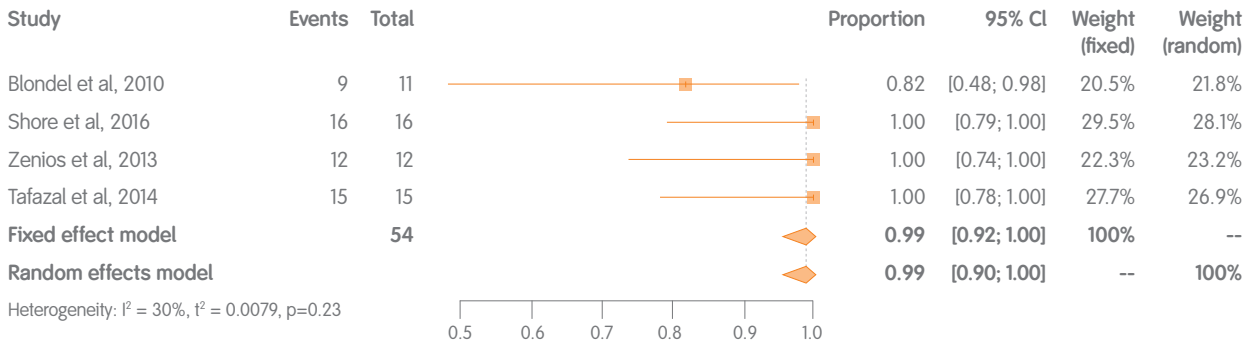


Figure 3. Proportional meta-analysis of studies (with ≥10 patients) assessing the use of TAYLOR SPATIAL FRAME® for acute trauma in paediatric populations

Abbreviations
CI = confidence interval

Appendix 2. Literature review and meta-analysis in non-unions/mal-unions

Table 2. Characteristics of relevant studies.

Study, year	Level I: Randomised controlled trials	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	n	Age (years)	Indication
n≥10							
Koren et al, 2016[5]				■	13	Mean: 12 Range: 8-15	Post-traumatic mal-unions
n<10; not included in meta-analysis							
Eidelman et al, 2010[6]				■	4	Mean: 13 Range: 10-16	Mal-unions

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.

Study, year	Level I: Randomised controlled trials	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	n	Age (years)	Indication
n≥10; included in meta-analysis							
Reitenbach et al, 2016[7]			■		33	Mean: 15 Range: 2-54*	
Sachs et al, 2015[8]			■		23 (25 tibias)	Mean: 15 Range: 13-21*	Blount disease
Blondel et al, 2009[9]				■	36	Mean: 11 Range: 3-18	Various aetiologies
Eidelman and Katzman, 2008[10]				■	13	Mean: 8 Range: 4-14	Complex foot deformities
Eidelman et al, 2010[6]				■	14	Mean: 13 Range: 8-17	Deformities secondary to growth arrest
Eidelman et al, 2012[11]				■	11	Mean: 15 Range: 11-18	Clubfoot deformities
Horn et al, 2017[12]				■	117	Median: 14 Range: 4-18	Various aetiologies
Koren et al, 2016[5]				■	38	Mean: 12† Range: 2-16†	Various
Küçükkaya et al, 2009[13]				■	19	Mean: 17 Range: NR*	Various aetiologies
Naqui et al, 2008[14]				■	53	Mean: 11 Range: 1-16	Various aetiologies
Tsibidakis et al, 2014[15]				■	66	Mean: 11 Range: 3-16	Various aetiologies

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

Table 3. Characteristics of relevant studies (cont.).

Study, year	Level I: Randomised controlled trials	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	n	Age (years)	Indication
n<10; not included in meta-analysis							
Barnes et al, 2010[16]				■	5	Mean: 14 Range: 11-16	Tibial growth arrest after trauma
Docquier et al, 2008[17]				■	4	Mean: 17 Range: 16-17	Various aetiologies
Domzalski, et al 2009[18]				■	2	Mean: 14 Range: 14-15	No clear aetiological factor
Eidelman and Katzman, 2011[19]				■	7	Mean: 11 Range: 4-16	Varied arthrogrypotic foot deformities
Eidelman et al, 2011[20]				■	8	Mean: 14 Range: 8-22	Various aetiologies
Hassan and Letts, 2012[21]				■	9	Mean: 9 Range: 6-14	Various aetiologies
Seybold et al, 2008[22]				■	2	Mean: 14 Range: 13-14	Pseudo-Madelung deformities after epiphyseal fracture
Siapkara et al, 2008[23]				■	3	Mean: 16 Range: 15-16	Anterior growth arrest and recurvatum deformity

Forest plot for deformity correction

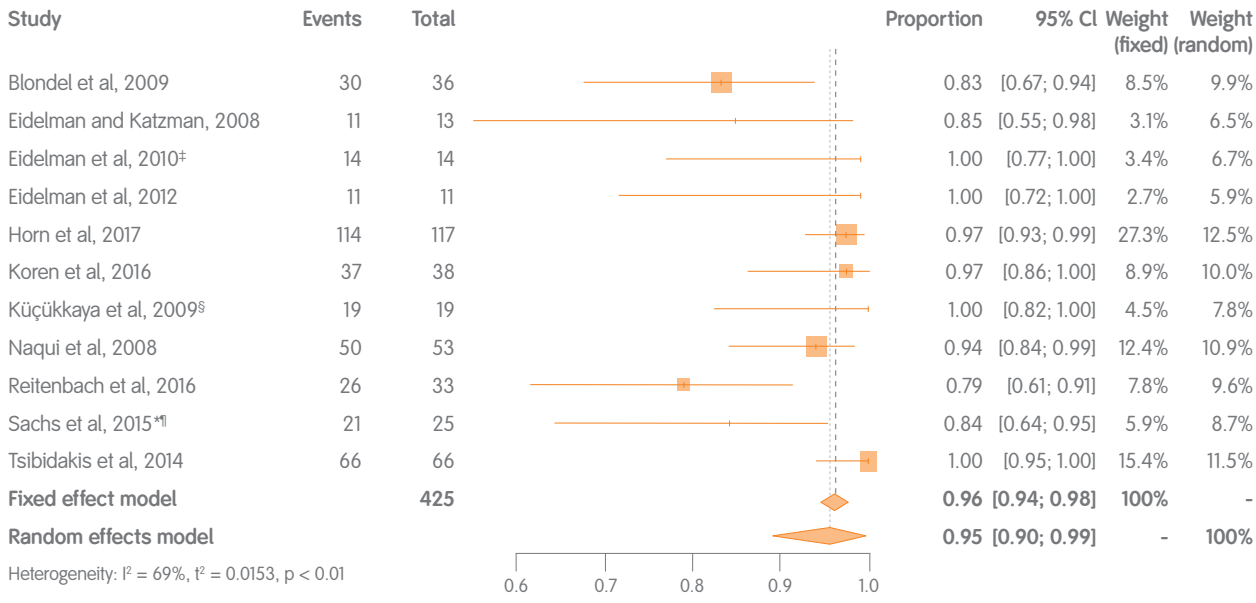


Figure 4. Proportional meta-analysis of studies (with ≥10 patients) assessing the use of TAYLOR SPATIAL FRAME® for deformity correction in children.

* 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

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