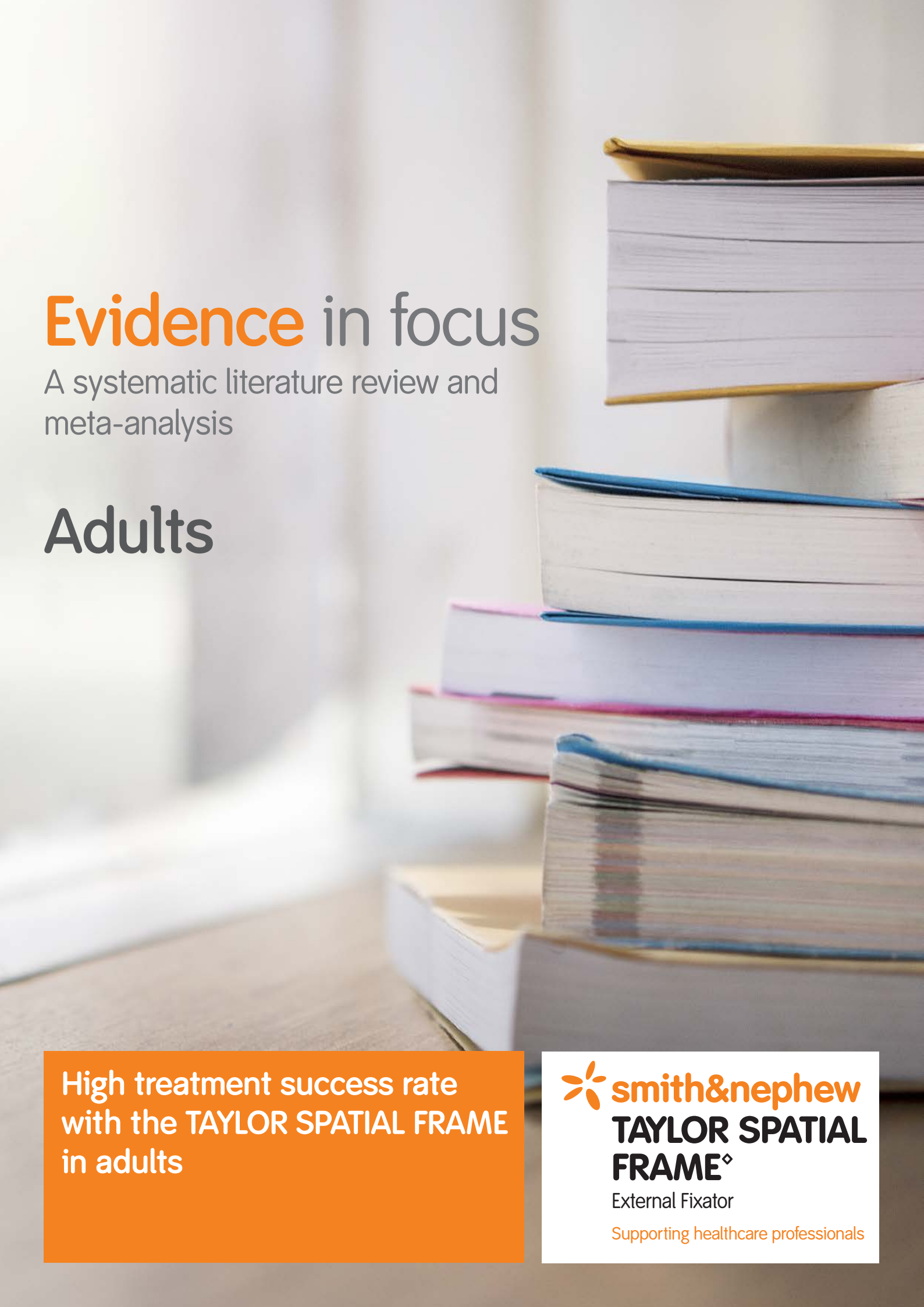


Evidence in focus

A systematic literature review and meta-analysis

Adults

High treatment success rate with the TAYLOR SPATIAL FRAME in adults

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 adults 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:

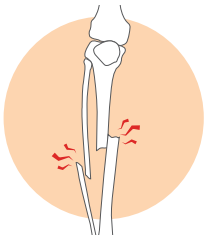
20
More than 20 years of clinical use

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

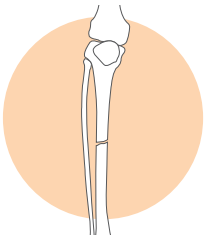
Methods

Literature search

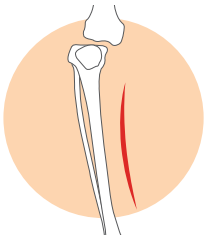
A search for clinically relevant results was conducted using Embase and PubMed across three indications (September 6, 2018):



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
- Adult 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.

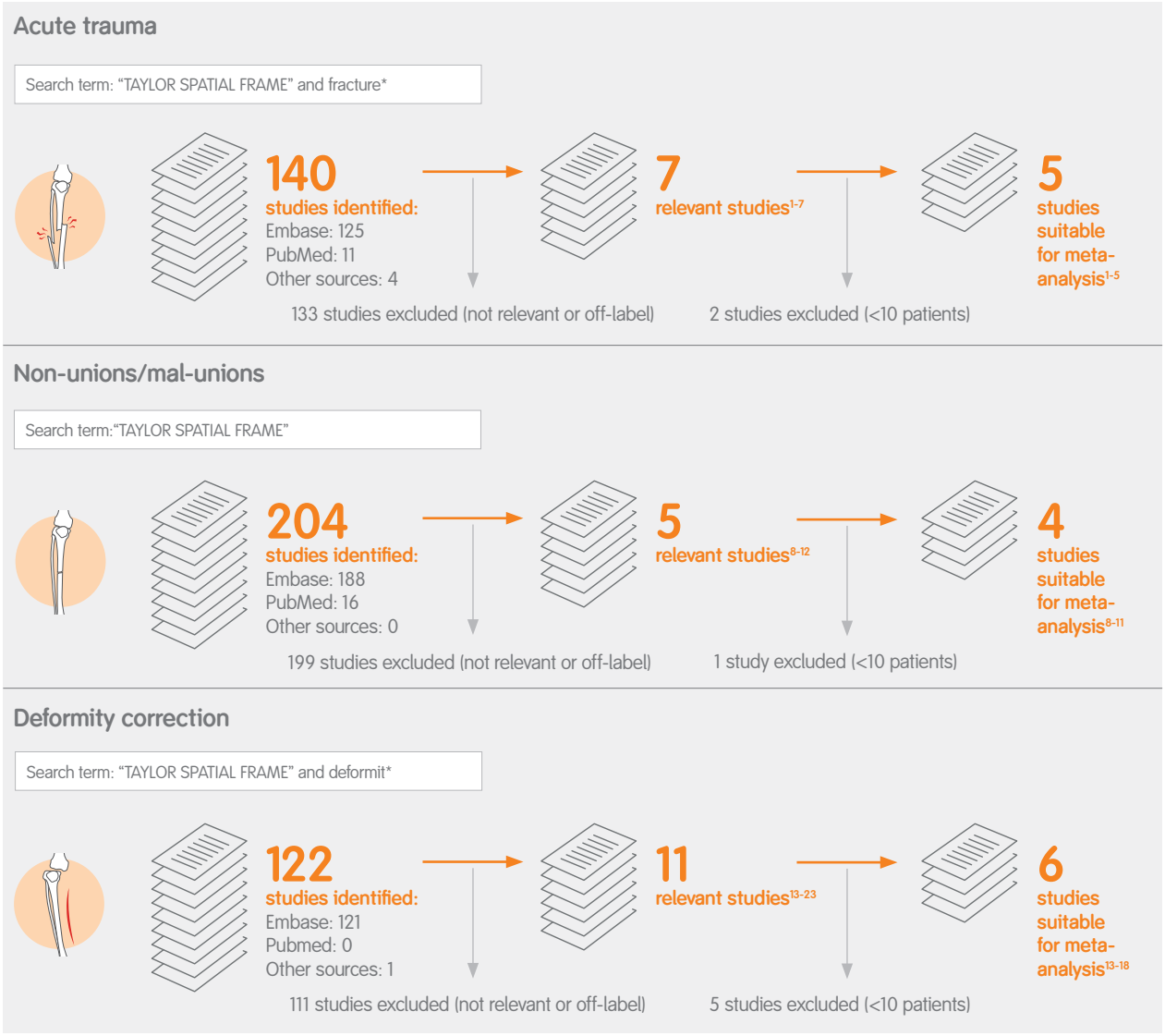


Figure 1. Search strategy

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

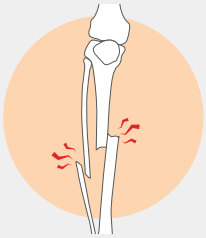
Total number of studies meeting the inclusion criteria with **≥10 patients**

15 studies

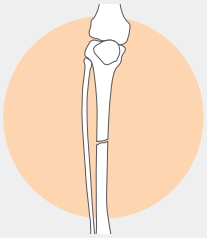
Combined treatment success

Across all three indications in adult patients, the meta-analyses demonstrated consistently high treatment success rates (**Figure 2**).

In five studies,
95%
of patients with acute trauma achieved consolidation[1-5]
(95% CI: 85-100%)



In four studies,
91%
of patients with non-unions/ mal-unions achieved bony union[8-11] (95% CI: 80-98%)



In six studies,
98%
of patients with deformities achieved correction[13-18]
(95% CI: 93-100%)

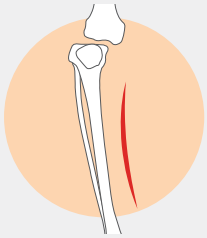


Figure 2. Combined treatment success in adult patients treated with TSF.

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 adult patients for the treatment of acute trauma, mal-unions/non-unions and deformities.

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							
Ahearn et al, 2014[1]			■		21	Mean: 44* Range: 17-78*	Unstable bicondylar tibial plateau fractures
Menakaya et al, 2014[2]			■		37	Mean: 45* Range: NR*	Various
O'Neill et al, 2016[3]			■		15 fractures	Mean: 39* Range: 16-79*	Various
Rampurada et al, 2008[4]				■	26	Mean: 40 Range: 22-59	Tibial plateau and pilon fractures
Sala et al, 2017[5]				■	20	Mean: 37 Range: 11-72	Open supracondylar-intracondylar femoral fractures
n<10; not included in meta-analysis							
Lahoti et al, 2013[6]				■	7	Mean: 38 Range: 15-70†	Various
Sharma and Nunn, 2013[7]				■	2	Mean: 54 Range: 48-60	Open tibial fractures

Forest plot for consolidation in acute trauma

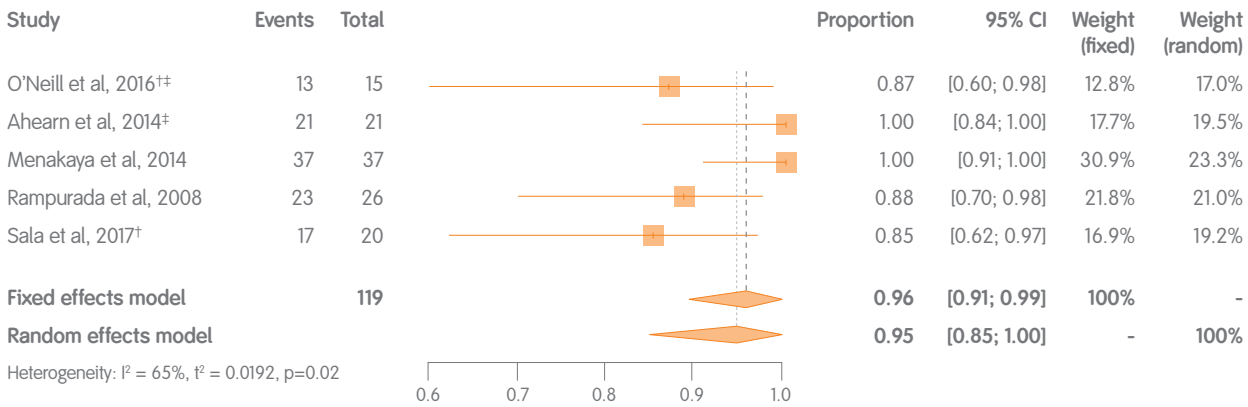


Figure 3. Proportional meta-analysis of studies (with ≥10 patients) assessing the use of TSF for acute trauma

* Mean age and range of overall patient population.
† Data for adults and children not separated but mean age >18 years.
‡ Data shown is for number of fractures successfully treated.

Abbreviations

CI = confidence interval; NR = not reported

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; included in meta-analysis							
Arvensen et al, 2017[8]					37	Mean: 50 Range: NR	Deformities associated with distal tibial non-unions
Khunda et al, 2016[9]					40	Mean: 40 Range: 9-69*	Non-unions
Napora et al, 2017[10]					75	Mean: 46 Range: NR†	Infected posttraumatic non-unions of the tibia
Rozbruch et al, 2008[11]					38	Mean: 43 Range: 8-72*	Tibial non-unions
n<10; not included in meta-analysis							
Schoenleber & Hutson, 2015[12]					5	Mean: 38† Range 22-51†	Non-unions/mal-unions

Forest plot for bony union in mal-unions/non-unions

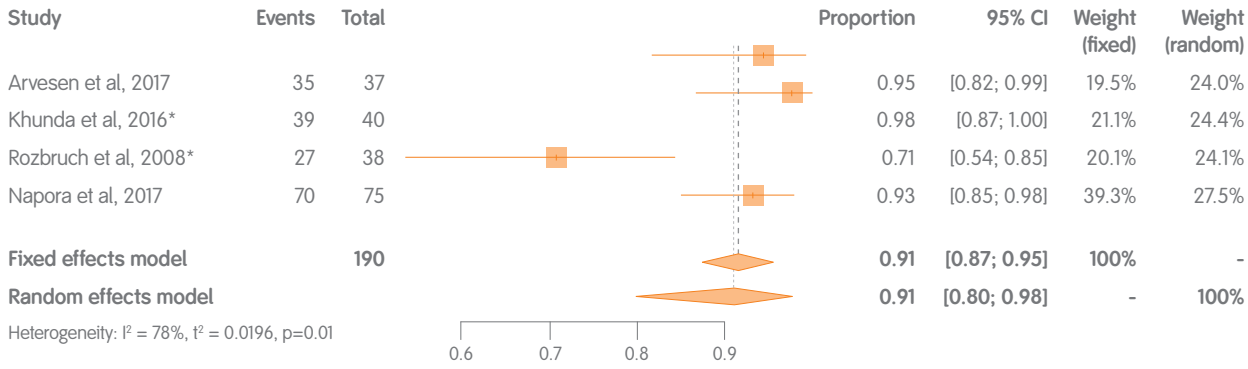


Figure 4. Proportional meta-analysis of studies (with ≥10 patients) assessing the use of TSF for non-unions or mal-unions

* Data for adults and children not separated but mean age >18 years.

† Mean age of overall patient population.

Abbreviations

CI = confidence interval; NR = not reported

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							
Ashfaq et al, 2012[13]			■		57*	Mean: 39 Range: 21-72	Proximal tibia varus
Horn et al, 2011[14]				■	52	Mean: 44 Range 18-79	Various
Nakase et al, 2009[15]				■	10	Mean: 29 Range: 10-71†	Various
Rozbruch et al, 2010[16]				■	102 (122 tibiae)	Mean: 39 Range: 5-72†	Various
Sokucu et al, 2013[17]				■	37 (50 limbs)	Mean: 23 Range: 10-58†	Various deformities around the knee
Thiryayi et al, 2010[18]				■	10	Mean: 59 Range: 48-71	Various
n<10; not included in meta-analysis							
Manggala et al, 2017[19]			■		7	Mean: 43 Range: 18-63	Foot and ankle deformities
Baumgartner and Weber, 2017[20]				■	6	Mean: NR Range: NR	Post-infectious bony malalignments
Docquier et al, 2008[21]				■	2	Mean: 27 Range 24-31	Various
Robinson et al, 2011[22]				■	9	Mean: 49 Range: 37-59	OA deformities
Tawari et al, 2018[23]				■	2	Mean: 64 Range: 63-64	Tibial deformities

Forest plot for deformity correction

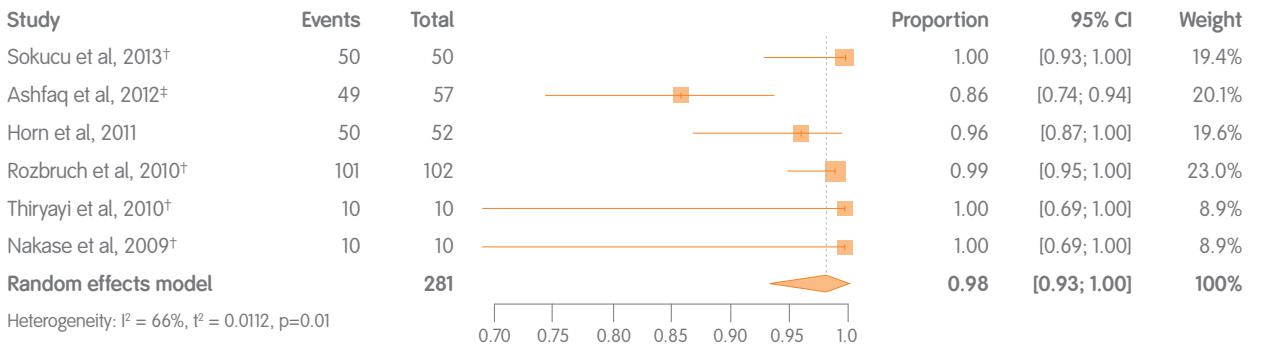


Figure 5. Proportional meta-analysis of studies (with ≥10 patients) assessing the use of TSF for deformity correction in adults

* Two n values are given in this study. n=55 is described in the Materials & Methods. n=57 is calculated from treatment success in the results section and has therefore been used in the meta-analysis.

† Data for adults and children not separated but mean age >18 years.

‡ Data reported as number of limbs rather than patients.

Abbreviations

CI = confidence interval; NR = not reported; OA = osteoarthritis

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