

## Bone&JointOutcome Our Products in Clinical Studies

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# The TAYLOR SPATIAL FRAME\* for External Fixation

## A Systematic Review

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### Overview

## The TAYLOR SPATIAL FRAME<sup>+</sup> for External Fixation: A Systematic Review

Purpose of review The purpose of the current study was to conduct a thorough systematic literature review of the TAYLOR SPATIAL FRAME to improve the understanding of its clinical performance to date.

Background The TAYLOR SPATIAL FRAME (TSF) is an external fixator that uses computer software to simultaneously correct for length discrepancy and various aspects of deformity including angulation, translation, and rotation. We performed a systematic literature review of the TSF to improve the understanding of its clinical performance to date. Read more on page 4

Rating	•	
POOR QUALITY	MODERATE	HIGH QUALITY

Why this rating? This is a systematic review of Level III and IV evidence which includes prospective studies and case series. The evidence rating is moderate.

**Results** Twenty-five studies featuring data from 666 total patients were included in this study. Results of management with the TAYLOR SPATIAL FRAME were pooled based on the diagnosis into three groups of patients with: (1) acute trauma

(2) nonunion or malunion

(3) deformity (including studies with mixed pathology if >75% of patients had a developmental or congenital deformity). Read more on pages 6-23

### Key considerations

A systematic review of the literature found:

- High percentage of treatment goals achieved after initial treatment with use of TSF, shown in all three groups (100% in adults and 99.3% in children with acute trauma; 87.5% in adults and 98.6% in children with nonunion or malunion; 98.5% in adults and 93.3% in children with deformity)
- All complications excluding pin tract infections were pooled for each group (one complication in every 4.3 procedures in children with acute trauma; one in every 1.8 procedures in adults and 1.7 in children with nonunion or malunion; and one in every 5.4 procedures in adults and 2.7 in children with deformity).
- Time to external fixator removal:
- 14.0 and 14.9 weeks (acute trauma group);

- 33.0 and 11.2 weeks (nonunion and malunion group);
- 19.0 and 20.9 weeks (deformity group) for adults and children, respectively.
- Inconsistent reporting of clinical outcomes and surgical parameters amongst included studies, preventing the use of meta-analytic statistics.
- Need for additional studies with:
- Larger sample sizes.
- Consistent reporting amongst studies with regard to surgical parameters and clinical outcomes.
- Comparisons between the Ilizarov Ring Frame (current "gold standard") and the TAYLOR SPATIAL FRAME.
- Prospective, comparative designs with randomization to limit systematic bias.

### Background

External fixation plays a growing role in the primary treatment of unstable and high risk fractures, as well as in the reconstruction of congenital and acquired physical deformities [1]. The TAYLOR SPATIAL FRAME° (TSF) (Smith & Nephew, Memphis, Tennessee, USA) is a new generation of external fixator established on computer software that simultaneously corrects for length discrepancy and various aspects of deformity including angulation, translation, and rotation [2,3]. Based on the Ilizarov method, the TSF is used for corrections, lengthening, and straightening of both simple and complex deformities. It consists of two rings or partial rings connected by six telescopic struts at special universal joints to create a hexapod frame [4]. By adjusting strut lengths, one ring is repositioned with respect to the other [5]. The surgical technique is well described within current literature [4].

While the TSF is considered more cumbersome than the Ilizarov frame, it allows for easy application, immediate stabilization, access to soft tissues, and a reduced need for immobilization [1,2,5]. Furthermore, the TSF allows for both gradual and acute correction and has shown to be effective in correcting many deformities with varying severity in all limbs [4].

Figure 1: The TAYLOR SPATIAL FRAME.



Published studies on the TSF are mainly case series with small sample sizes and inconsistent reporting on varying bones and etiologies [6]. Thus, we performed a systematic review of the TSF to improve the understanding of its clinical performance to date. Primary outcomes were whether treatment goals were achieved and complications experienced. Secondary outcomes included data on surgical parameters and clinical outcomes. These outcomes were evaluated in three groups in which the TSF was used for: (1) acute trauma; (2) nonunion and malunion with or without deformity; and (3) deformity correction (when mixed pathology, included if >75% had a congenital or development deformity). Weighted means were obtained for adults and children separately.

### Methods

From 238 potentially eligible studies identified by a literature search, 213 did not meet the eligibility criteria for this review, leaving 25 eligible studies (**Figure 1**).

Please refer to *Appendix 1*: Methods for further detail on the eligibility criteria and literature search.

### Figure 2: Literature Review



ORIF = Open Reduction Internal Fixation

### **Study Characteristics**

Study characteristics are summarized in **Figure 2** with further detail found in **Tables 1, 2, and 3**. Note that in studies with mixed pathology of patients, the data was separated when possible. Otherwise, studies in which >75% of patients had a developmental or congenital deformity were reported solely in Group 3 (deformity correction).

Please refer to *Appendix 2*: Results for additional details on the study results.

### Surgical Parameters – Included Studies

Surgical parameters for the included studies are summarized in **Tables 4, 5, and 6**.

#### **Clinical Outcomes – Included Studies**

Clinical outcomes were inconsistently reported across included studies. **Tables 7, 8, and 9** summarize these results.

#### **Complications – Included Studies**

All Complications and revisions are summarized in **Tables 10**, **11**, **and 12**.

Adults		Acute Trauma	Non/Malunion	Deformity
	Study designs included:	Case series	Case series	Case series and Prospective studies
	Mean follow-up range:	39.6 months	34.8 months	33.9 months
	Mean age: Mean sample size: Sample size range:	24.5 years 5 -	34.4 years 21 12–38	38.9 years 31.4 7–122

### Children

	Study designs included:	Case series	Case series	Case series and Prospective studies
Ð	Mean follow-up range:	19.4 months	16.5 months	21.2 months
	Mean age: Mean sample size: Sample size range:	11.8 years 9 6–11	12.7 years 3.5 3-4	12.4 years 30.5 5–129

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### Figure 3: Study characteristics

### Table 1: Study characteristics of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for acute trauma in adults and children.

Study Randomized studies Prospective studies	Case series Sample Size (Number of Fractures)	Mean Age (Years)	% Male	Included Limb(s)	Indication for Procedure	Length of Follow-up (Months)
Mean Adults	<b>5</b> (N=5)	24.5	76.9			39.6
Elbatrawy et al. 2009	5	24.5‡ (10–82)	76.9‡	Tibia (3) Femur (2)	Trauma (2 open fractures, 3 closed fractures)	39.6‡ (3–72)
Mean Children	<b>9</b> (N=27)	11.8	86.4			19.4
Al-Sayyad et al. 2006	10	12.3 (8.2–15.4)	100	Tibia	Traumatic, unstable tibial shaft fracture (2 compartment syndrome, 1 hemorrhagic blisters leading to failed reduction, 2 failed closed reduction, 5 open fractures).	37.2 (24–48)
Eidelman et al. 2006	6	11 (6–14)	NR	Tibia (5) Femur (1)	5 displaced tibial fractures, 1 displaced femoral fracture	9.0
Blondel et al. 2010	11	12 (7–15)	72.7	Tibia	Open tibial shaft fracture with contraindication or failure of nonoperative treatment (3 failed reduction after plaster cast, 3 open fractures, 4 associated fractures and closed head injury, 1 compartment syndrome); 1 proximal, 8 middle, 2 distal.	12 (4–32)

NR

Not reported Value reported for full sample size of patients in study ‡

Study Randomized studies Case series	Sample Size (Number of Fractures)		% Wale %	Included Limb(s)	Indication for Procedure	<b>1.</b> Length of Follow-up <b>36</b> (Months)
Feldman et al. 2003	18	29.6 (10–64)	61.1	Tibia	11 tibial malunions (1 proximal, 9 middle, 1 distal); 7 tibial nonunions (2 with osteomyelitis), 5 were atrophic and 2 were hypertrophic (1 proximal, 3 middle, 3 distal)	38.4 (24–50.4)
Kristiansen et al. 2006	20	31 (7–59)	55.0	Tibia	1 fibular hemimelia, 12 malunion, 1 hypoplasia tibiae, 2 pas equino varus + hypoplasia, 1 rheumatoid arthritis, 1 hyperphosphatemic rickets	NR
Rozbruch et al. 2008	38	43 (8–72)	78.9	Tibia	38 tibial nonunions – 6 proximal, 12 middle and 20 distal (10 closed, 26 open, 1 defect following bone tumor reconstruction, 1 osteomyelitis and bone defect following snake bite); 18 were atrophic, 14 were normotrophic, and 6 were hypertrophic; 19 were infected.	37 (16–63)
Elbatrawy et al. 2009	16	24.5‡ (10-82)	76.9‡	Tibia (14) Femur (2)	12 malunion, 4 nonunion	39.6‡ (3–72)
Sala et al. 2011	12	44 (19–79)	66.7	Tibia	12 Infected tibial atrophic nonunions (2 proximal, 4 middle, 6 distal)	24 (18–32)

## Table 2: Study characteristics of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for nonunions and malunions with and without deformity in adults and children.

Mean Children	<b>3.5</b> (N=7)	12.7	NR			16.5
Eidelman et al. 2006	3	12.3 (8–16)	NR	Tibia (2) Radius (1)	2 tibial malunion, 1 malunion and growth arrest of radius	9.0
Eidelman et al. 2010	4	13 (10–16)	NR	Tibia(3) Radius (1)	3 tibal malunion (1 middle, 2 distal); 1 radial malunion secondary to growth arrest.	24

NR Not reported

*‡* Value reported for full sample size of patients in study

ior deformation 3 m													
Struct Mean Adults	Randomized studies Prospective studies Case series	<ul> <li>Sample Size</li> <li>Number of Deformed Limbs)</li> </ul>		% Wale	Included Limb(s)	Included Limb(s) Indication for Procedure							
Viskontas et al. 2006		7	51.0 (36–72)	57.1 (4)	Knee (7)	7 primary diagnosis of medial compartment degenerative osteoarthritis of the knee	41.0						
Elbatrawy et al. 2009		8	24.5‡ (10–82)	76.9‡	Tibia (8)	2 multiple hereditary exostosis, 2 windswept deformity, 2 blount disease, 1 valgus deformity, 1 premature physeal growth arrest	39.6‡ (3–72)						
Nakase et al. 2009		10	28.8 (10–71)	NR	Femur (4), Tibia (6)	2 post-traumatic epiphyseal arrest; 3 malunion after fracture; 1 Bount disease; 1 Paget disease; 1 mal-union after ankle arthrodesis due to septic osteomyelitis; 1 hypo-phosphatamic rickets; 1 multiple hereditary exostosis	24 (11–41)						
Rozbruch et al. 2010		122	39 (5–72)	56.9	Tibia	Tibial deformities (72 nontraumatic cases: congenital, development, neurologic etiology; 30 posttraumatic malunions; 20 bilateral cases)	48 (10–98)						
Thiryayi et al. 2010		10	61.0 (48.0–71.0)	90.0 (9)	Ankle (10)	2 severe posttraumatic arthritis, 1 malunion, 1 non-union of pilon fracture, 1 infected ankle and 5 cases of previously failed surgical arthrodesis	16.7 (12.0–26.0)						

## Table 3: Study characteristics of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for deformities $\S$ in adults and children.

§ In studies with patients of mixed pathology, entries were separated. When this was not possible, only those studies with >75% congenital or developmental deformity was included in this group.

NR Not reported

‡

Value reported for full sample size of patients in study

for deformities § in adults and children. (Cont.)												
Study	н С	Randomized studies Prospective studies	Case series	Sample Size (Number of Deformed Limbs)	Mean Age (Years)	% Male	Included Limb(s) Indication for Procedure					
Mean Children				<b>30.5</b> (N=336)	12.4	54.9			21.2			
Blondel et al. 2009				36	11.1 (3.0–18.0)	69.4	Tibia (26), Femur (6), Radius (2), Ankle (1), Knee (1)	17 congenital pathologies, 5 fractures, 2 post-traumatic pathologies, 3 post infectious sequelae, 3 achondroplasia and 6 "other".	21.3 (4.3–43.0)			
Feldman et al. 2003				22	9.9 (3–16)	68.4	Tibia	Tibia vara (8 infantile, 14 adolescent)	33.6 (24–45.6)			
Sluga et al. 2003				5	11.0 (6.0–16.0)	40.0 (2)	Femur (4), Tibia (1)	4 shortened or deformed femurs after fracture, osteomyelitis or a congenital short femur; 1 tibia with pseudoarthrosis	NR			
Fadel et al. 2005				22	16.5 (6–42)	36.4	Femur (4), Tibia (16), Feet (2)	4 tibia vara, 2 genu valgum, 3 congenital short femurs, 2 equinus feet, 5 short tibiae, 5 short and deformed tibia following trauma, 1 posttraumatic short femur	38.4 (30–54)			
Eidelman et al. 2006				22	12.0 (3.5–17)	NR	Tibia (14) Femur (11) Knee (4) Foot (4)	4 Blount disease, 1 growth arrest of ankle and most foot joints, 40mm shortening, severe valgus, 2 congenital short femur + fibular hemimelia, 1 spondyloepiphyseo-metaphyseal dysplasia, 1 DDH, distal femoral valgus and shortening, 1 growth arrest of tibia and 8 cm shortening, 1 fibrous dysplasia, distal femoral varus shortening, 1 rickets, 2 proximal tibial valgus, 1 osteogenesis imperfecta, excess external tibial torsion, 1 severe bilateral genu valgum, 1 Schmid-type skeletal dysplasia, 1 unilateral internal tibial torsion and genu varum, 1 arthrogyrposis and flexion contracture knee, 1 myelomeningocele and paralytic knee flexion contracture and clubfoot, 1 clubfoot and equinus and internal tibial torsion, 1 post-lengthening knee flexion contracture.	9			
Feldman et al. 2006				18	10.2 (3–16)	66.7	Tibia	Tibia vara (6 infantile, 12 adolescent)	24			
Manner et al. 2007				129	13.2‡ (2–49)	53.5‡	Femur, Tibia	Congenital deficiency (54 fibular hemimelia, 29 congenital femoral deficiency, 2 tibial aplasia) and acquired deformity (33 posttraumatic, 11 postinfectious, 26 idiopathic deformity, 16 hypo/pseudo/achondroplasia, 9 rickets, 8 syndromes, 4 enchondromatosis, 5 Blount's disease, 4 mucopolysacharidosis, 2 myelomeningocele, 2 peromelia, 1 multiple hereditary exostoses, 1 amniotic disease, 1 hemihypertrophy)	NR			

## Table 3: Study characteristics of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for deformities $\S$ in adults and children. (Cont.)

§ In studies with patients of mixed pathology, entries were separated. When this was not possible, only those studies with >75% congenital or developmental deformity was included in this group.

NR Not reported ‡ Value reported

Value reported for full sample size of patients in study.

a d Limbs)	
Study Study Randomized studi Prospective studi Case series Sample Size (Number of Deforme Mean Age (Years) Male Included Limb(s) Included Limb(s) Length of Follow-u	(Months)
Docquier et al. 2008619.3 (12.7-30.9)NRTibia (4), Femur (1), Foot (2)1 tibia with infectious epiphyseodesis, 1 femur and 1 tibia with Ollier's disease, 1 idiopathic tibia, 1 tibia with vitamin D-resistant hypophosphataemic rickets, 1 calcaneus case with sequel of clubfoot and 1 foot with severe burn1 tibia with infectious epiphyseodesis, 1 femur and 1 tibia with Ollier's disease, 1 idiopathic tibia, 1 tibia with vitamin D-resistant hypophosphataemic rickets, 1 calcaneus case with sequel of clubfoot and 1 foot with severe burn12 (4.7-	2.9 -22.0)
Eidelman et al. 2008158 (3.5-14)61.5FootVarious foot deformities (6 residual clubfoot deformities, 3 arthrogryposis with rigid equinovarus (2 bilateral); 2 foot 	11
Marangoz et al. 20082213.9 (5.9-24.6)40.0 (8)Femur (22)7 post-traumatic, 6 developmental (idiopathic), 2 multiple enchondromatosis, 2 rickets, 2 congenital femoral deficiency, 1 spondyloepiphyseal dysplasia, 1 congenital pseudohypoparathyroidism and 1 multifocal osteomyelitis.15 (4.5-	5.7 -35.0)
Naqui et al.10.758.5Tibia (44), (1.0–16.0)10 congenitally short limbs, 5 fibular hemimelia, 4 congenital talipes equinovarus, 3 neurofibromatosis pseudarthrosis, 4 tibia valgus, 2 diaphyseal aclasia-tibia vara, 2 metaphseal 	2.0 –59.0)
Eidelman et al. 20101413 (8–17)NRTibia (11); Femur (3)9 tibial valgus (5 proximal, 3 distal, 1 proximal and distal); 2 	24
Iobst 20101511.9NRTibia/Fibia, Femur, FootLimb shortening (4 fibular hemimelia, 3 infantile Blount's disease, 2 congenital short femur, 2 fibrous dysplasia, 1 traumatic growth arrest, 1 clubfoot, 1 malunion, 1 vascular malformation)	6.5
Floerkemeier et al. 2011915.9 (8.0-29.0)28.6 (2)Feet (9)7 cases of pes equinovarus, cavus and adductus. 1 bilateral pes cavus and 1 occurred bilaterally.22 (13.4-	1.5 –34.2)

## Table 3: Study characteristics of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for deformities § in adults and children. (Cont.)

was not possible, only those studies with >75% congenital or developmental deformity was included in this group.

Value reported for full sample size of patients in study ‡

### Table 4: Surgical parameters of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for acute trauma in adults and children.

Approximation Strategy Weighted Mean Adults	Total Operative Time (min)	Lengthening Time (Weeks)	Time to External Fixator Removal (Weeks)	Preoperative AP / Frontal Malalignment (Degrees)	Postoperative AP / Frontal Malalignment (Degrees)	Preoperative Lateral / Sagittal Malalignment (Degrees)	Postoperative Lateral / Sagittal Malalignment (Degrees)	Average Leg Lengthening (mm)	Lengthening/External Fixation Index (Days/cm)	Average Time to Discharge (Days)	Smith & Nephew Web-based Software Used?
Elbatrawy et al. 2009	NR	NR	14 (7–24)	NR	NR	NR	NR	NR	NR	7.9 (3–22)	YES

Weighted Mean Children		NR	14.9					10	NR		
Al-Sayyad et al. 2006	122 (110–141)	NR	19 (12–33)	14.5 (4–35)	1 (0-3)	9 (0-9)	1 (0–3)	NR	NR	NR	YES
Eidelman et al. 2006	NR	NR	9.8 (7–14)	NR	NR	NR	NR	10	NR	NR	NR
Blondel et al. 2010	NR	NR	14 (8.6–20.9)	NR	4 (0–10)	NR	5 (0–12)	NR	NR	8 (3–18)	YES

NR

Not reported Value reported for full sample size of patients in study. ‡

### Table 5: Surgical parameters of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for nonunions and malunions with and without deformity in adults and children.

<b>Struct</b> Weighted Mean Adults	Total Operative Time (min)	<b>11</b> Strut Adjustment/Limb Lengthening Time (Weeks)	Time to External Fixator Removal (Weeks)	Preoperative AP / Frontal Malalignment (Degrees)	Postoperative AP / Frontal Malalignment (Degrees)	Preoperative Lateral / Sagittal Malalignment (Degrees)	Postoperative Lateral / Sagittal Malalignment (Degrees)	Average Leg Lengthening (mm)	Lengthening/External Fixation Index (Days/cm)	Average Time to Discharge (Days)	Smith & Nephew Web-based Software Used?
Feldman et al. 2003	)][( NR	NR	18.5 (12–32)	11.7 (0–24)	1.4 (0–3)	10.3 (0–57)	0.9 (0-2)	NR	NR	NR	YES
Kristiansen et al. 2006	NR	NR	29.2 (14.8–61)	NR	NR	NR	NR	15 (5–60)	73.2 (24.4– 256.2)	NR	YES
Rozbruch et al. 2008	NR	18.9 (2.1–68.6)	41.3 (17–102.1)	NR	NR	NR	NR	67 (25–160)†	NR	NR	YES
Elbatrawy et al. 2009	NR	NR	14‡ (7–24)	NR	NR	NR	NR	NR	NR	7.9‡ (3–22)	YES
Sala et al. 2011	NR	14.6 (7–24)	59.7 ± 14.1 (42.9–85.7)	NR	NR	NR	NR	80 (30–120)	61 (33.6–122)	NR	YES
Weighted Meen											

Weighted Mean Children		NR	11.2					10.8	NR		
Eidelman et al. 2006	NR	NR	12.7 (11–15)	NR	NR	NR	NR	8.5 (8–9)	NR	NR	NR
Eidelman et al. 2010	NR	NR	10 (9–11)	NR	NR	NR	NR	12.5 (10–15)	NR	NR	YES

NR

Not reported Value reported for full sample size of patients in study. ‡

## Table 6: Surgical parameters of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for deformities $\S$ in adults and children.

<b>Strug</b> Weighted Mean Adults	Total Operative Time (min)	G Strut Adjustment/ Limb O Lengthening Time (Weeks)	<b>16</b> Time to External Fixator <b>66</b> Removal (Weeks)	Preoperative AP/ Frontal Malalignment (Degrees)	Postoperative AP/ Frontal Malalignment (Degrees)	Preoperative Lateral/ Sagittal Malalignment (Degrees)	Postoperative Lateral/ Sagittal Malalignment (Degrees)	Average Leg Lengthening <b>.11</b>	Lengthening / External Fixation Index (Days/cm)	Average Time to Discharge (Days)	Smith & Nephew Web-based Software Used?
Viskontas et al. 2006	NR	2.1 (1.0–3.6)	23.0 (16.0–36.0)	8.3 (2.0–13.0)	3.4 (2.0–6.0)	NR	NR	NR	NR	0.0–1.0	YES
Elbatrawy et al. 2009	NR	NR	14 (7–24)	NR	NR	NR	NR	NR	NR	7.9 (3–22)	YES
Nakase et al. 2009	NR	NR	19.7 (10.9–31.1)	NR	NR	NR	NR	29 (12–60)	57.8 (30.2–96.9)	NR	YES
Rozbruch et al. 2010	NR	4.9 (1–14.1)	18.6 (10.1–50.7)	NR	NR	NR	NR	10 (0–66)	NR	NR	YES
Thiryayi et al. 2010	NR	8.4 (4.0–25.0)	24.0 (8.0–44.0)	NR	NR	NR	NR	NR	NR	NR	YES

Weighted Mean Children		6.1	20.9					41.6	41.4		
Blondel et al. 2009	NR	9.1 (5.0–15.4)	26.1 (7.9–52.1)	13.5	NR	14.2	NR	45.0 (28.0–83.0)	38.2 (24.2–45.2)	NR	YES
Feldman et al. 2003	150 (180–240)	NR	14.6 (9–24)	16.5 (8–50)	0 (-2–2)	12.2 (2–21)	0.1 (-2–3)	NR	10	5.2 (3–9)	YES
Sluga et al. 2003	NR	13.5 (4.9–20.0)	40.7 (23.1–52.0)	NR	NR	NR	NR	59.0 (17.0–72.0	48.4 (35.1–95.3)	NR	NR
Fadel et al. 2005	90–180	NR	22.9 (8.7–39.2)	NR	NR	NR	NR	50 (35–80)	42 (33–48)	NR	YES
Fadel et al. 2005	90–180	NR	22.9 (8.7–39.2)	NR	NR	NR	NR	50 (35–80)	42 (33–48)	NR	YES

§ In studies with patients of mixed pathology, entries were separated. When this was not possible, only those studies with >75% congenital or developmental deformity was included in this group.

NR Not reported

*t* Value reported for full sample size of patients in study.

## Table 6: Surgical parameters of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for deformities $\S$ in adults and children. (Cont.)

Study	Total Operative Time (min)	Strut Adjustment/ Limb Lengthening Time (Weeks)	Time to External Fixator Removal (Weeks)	Preoperative AP/ Frontal Malalignment (Degrees)	Postoperative AP/ Frontal Malalignment (Degrees)	Preoperative Lateral/ Sagittal Malalignment (Degrees)	Postoperative Lateral/ Sagittal Malalignment (Degrees)	Average Leg Lengthening (mm)	Lengthening / External Fixation Index (Days/cm)	Average Time to Discharge (Days)	Smith & Nephew Web-based Software Used?
Eidelman et al. 2006	NR	NR	13.6 (8–20)	NR	NR	NR	NR	34 (10–40)	NR	NR	NR
Feldman et al. 2006	NR	NR	14.3 (9–24)	16.1 ± 9.5 (7–49)	1.3 ± 1.1 (0-4)	9.6 ± 6.0 (1–20)	1.9 ± 1.4 (0-5)	NR	NR	NR	YES
Manner et al. 2007	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	YES
Docquier et al. 2008	NR	NR	9.2 (5.3–15.7)	NR	NR	NR	NR	30.9 (0.0–60)	NR	NR	YES
Eidelman et al. 2008	NR	NR	13.2 (10–20)	NR	NR	NR	NR	NR	NR	NR	YES
Marangoz et al. 2008	NR	NR	27.0 (11.3–82.8)	15 (genu valgum) 11.9 (genu varum)	2.1 (genu valgum) 1.5 (genu varum)	23.0	0.8	49.0 (15.0–90.0)	67.1 (15.3–109.8)	3.0-5.0	YES
Naqui et al. 2008	NR	3.8 (0.6–13.0)	25.0 (12.0–92.0)	17.5 (7.0–50.0)	NR	22.3 (3.0–58.0)	NR	NR	NR	15.0 (3.0–40.0)	YES
Eidelman et al. 2010	NR	NR	13 (9–24)	NR	NR	NR	NR	18.8 (1–40)	NR	NR	YES
lobst 2010	NR	NR	30.4	NR	NR	NR	NR	41.3	54.6	NR	YES
Floerkemeier et al. 2011	NR	4.3 (3.1–7.0)	9.2 (4.8–13.1)	NR	NR	NR	NR	NR	NR	18.0 (9.0–26.0)	NR

§ In studies with patients of mixed pathology, entries were separated. When this was not possible, only those studies with >75% congenital or developmental deformity was included in this group.

NR Not reported

‡

Value reported for full sample size of patients in study.

### Table 7: Clinical outcomes of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for acute trauma in adults and children.



man	et	al.	200

	idelman et al. 2006	96.7‡	37.0 +/- 7.8‡	NR	NR	NR
Blondel et al. 2010         100         NR         NR         5 (0–12)         Pain V.	londel et al. 2010	100	NR	NR	5 (0–12)	Pain VAS

NR Not reported ‡

Value reported for full sample size of patients in study.

LLD Leg-Length Discrepancy. NR

NR

NR

All < 2 out of 10

### Table 8: Clinical outcomes of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for nonunions and malunions with and without deformity in adults and children.

		Were	Score	rative	erative	Clinical Outcome Scores			
Apnts Weighted Mean Adults		<b>22</b> Treatment Goals <b>5.</b> Achieved (%)	External Fixator	Average Preoper LLD (mm)	Average Postope LLD (mm)	Measure	Pre-op Score	Post-Op Score	
Feldman et al. 2003	0	94.4	NR	6.8 (5-30)	0.4 (-3–3)	NR	NR	NR	
Kristiansen et al. 2006		95	NR	NR	NR	NR	NR	NR	
			t ASAMI bony outcome			SF-36 Physical Function	19	51	
Rozbruch et al.		71.1	24 excellent, 12 good, 2 poor	31	18 ± 20 (0–68)	SF-36 Physical Role	21	51	
2008			20 excellent, 14 good, 2 fair, 2 poor	(10-57)		AAOS Lower Limb Module Score	56	82	
Elbatrawy et al. 2009		100	NR	31.4‡ (0–53)	< 3‡ (except for 1 with LLD = 15)	NR	NR	NR	
Sala et al. 2011		100	ASAMI bony outcome: 10 excellent, 2 good ASAMI functional outcome: 6 excellent, 5 good, 1 fair	NR	NR	NR	NR	NR	
Weighted Mean Children		98.6							

NR Not reported			† Onl	y in 22 of 38 patients			
Eidelman et al. 2006	96.7‡	37.0 +/- 7.8‡	NR	NR	NR	NR	NR
Al-Sayyad et al. 2006	100	NR	9.3 (0–20)	1.1 (0-4)	NR	NR	NR
	ЛЦ						

Value reported for full sample size of patients in study ‡Value reported for full sanLLDLeg-Length Discrepancy.

Only in 22 of 38 patients

These scores were taken after revision surgeries were conducted. Both poor † results were due to amputation.

### Table 9: Clinical outcomes of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for deformities § in adults and children.

		Were	Score	ative LLD	srative		Clinical Outco	ome Scores	
Study	0	Treatment Goals Achieved (%)	External Fixator	Average Preopel (mm)	Average Postope LLD (mm)	Measure		Pre-op Score	Post-Op Score
Weighted Mean Adults		98.5							
Viskontas et al. 2006		80.0 (4/5)	NR	NR	NR	Lower Extrer	nity Measure (LEM)	NR	94.0%
Elbatrawy et al. 2009		100	NR	31.4‡ (0–53)	< 3‡ (except for 1 with LLD = 15)		NR	NR	NR
Nakase et al. 2009		100	NR	NR	NR		NR	NR	NR
							Physical functioning	47 (0–100)	66 (10–100)
							Role physical	39 (0–100)	65 (0–100)
							Bodily pain	47 (0–100)	66 (0–100)
						SE 36	General health	74 (20–100)	75 (22–100)
						31 – 30	Vitality	52 (10–90)	62 (5–100)
							Social functioning	62 (0–100)	78 (0–100)
Rozbruch et al. 2010		99.2	NR	NR	NR		Role emotional	67 (0–100)	79 (0–100)
							Mental health	68 (16–100)	79 (40–100)
						Knon DOM	Extension	0 (-30-20)	0 (–10–10)
						Knee KOW	Flexion	126 (60–140)	125 (70–145)
							Dorsiflexion	10 (-30-30)	11 (0–30)
							Plantar flexion	40 (20–70)	38 (0–70)
						AAOS Iov	wer limb module	76 (5–100)	86 (51–100)
Thiryayi et al. 2010	1	100.0	NR	NR	NR	50-point American College of Foo and Ankle Surgeons		5.0	34.0
						10-Point	Numeric Scale	8.0	2.5

was not possible, only those studies with >75% congenital or developmental deformity was included in this group.

Value reported for full sample size of patients in study

LLD Leg-Length Discrepancy.

### Table 9: Clinical outcomes of included studies assessing the TAYLOR SPATIAL FRAME° Fixator for deformities § in adults and children. (Cont.)

	Were	Score	rative LLD	erative	Clinic	al Outcome S	cores
Study	Treatment Goals Achieved (%)	External Fixator	Average Preope (mm)	Average Postope LLD (mm)	Measure	Pre-op Score	Post-Op Score
Weighted Mean Children	93.3						
Blondel et al. 2009	91.0	NR	50.0	38.0 (0.0–103.0)	NR	NR	NR
Feldman et al. 2003	100	Schoenecker's Criteria: 22 good	NR	NR	NR	NR	NR
Sluga et al. 2003	60.0	NR	NR	NR	NR	NR	NR
Fadel et al. 2005	NR	Tucker Score: 18 excellent, 2 good, 2 fair	NR	NR	NR	NR	NR
Eidelman et al. 2006	96.7‡	37.0+/- 7.8‡	NR	NR	NR	NR	NR
Feldman et al. 2006	100	NR	17.2 (11–30)	2.1 (-5–10)	NR	NR	NR
Manner et al. 2007	90.7	NR	NR	NR	NR	NR	NR
Docquier et al. 2008	100.0	NR	NR	NR	NR	NR	NR
Eidelman et al. 2008	84.6	NR	NR	NR	NR	NR	NR
Marangoz et al. 2008	100.0	NR	NR	NR	NR	NR	NR
Naqui et al. 2008	94.5	NR	NR	<15	NR	NR	NR
Eidelman et al. 2010	100	NR	NR	NR	NR	NR	NR
lobst 2010	100	NR	NR	NR	NR	NR	NR
Floerkemeieret al. 2011	85.0	Unknown measure: 8 good, 1 poor	NR	NR	NR	NR	NR

In studies with patients of mixed pathology, entries were separated. When this was not possible, only those studies with >75% congenital or developmental § deformity was included in this group.

Not reported

NR Value reported for full sample size of patients in study.

‡ LLD Leg-Length Discrepancy.

### Table 10: Complications experienced by patients who received TAYLOR SPATIAL FRAME° Fixator for acute trauma in adults and children.

Study	R	Sample Size (N)	Number of Pin Tract Infections	Other Complications Experienced	Number of Other Complications*	Total Number of Revision Procedures
Weighted Mean Adults		5.0	1		0	0
Elbatrawy et al. 2009		5	1‡	None	0	0
Weighted Mean Children		9.0	2.7		2.1	0
Al-Sayyad et al. 2006		10	5	None	0	0
Eidelman et al. 2006		6	2	1 delayed union, 1 transient peroneal nerve palsy	2	0
Plandal at al. 2010		11	1	1 residual flexum (8 degrees); 1 overgrowth (7mm);	Λ	0

2 intraoperative compartment syndromes

Blondel et al. 2010

Other complications refers to any reported complication that is not a pin tract infection.

11

1

Value reported for full sample size of patients in study. ‡

4

0

## Table 11: Complications experienced by patients who received TAYLOR SPATIAL FRAME° Fixator for nonunions and malunions with and without deformity in adults and children.

Strong Weighted Mean Adults	Sample Size (N)		Other Complications Experienced	Number of Other FTL Complications*	Total Number of Revision Procedures
Feldman et al. 2003	18	3	1 delayed union.	1	0
Kristiansen et al. 2006	20	0	13 joint contractures requiring physiotherapy; 1 premature consolidation; 4 reduced callus formation requiring bone transplant; 3 fracture after frame removal	21	8
Rozbruch et al. 2008	38	0	11 persistent nonunions (4 re-treated with TSF, 3 intramedullary rodding, 2 plate fixation, 2 amputation)	11	11
Elbatrawy et al. 2009	16	1‡	None	0	0
Sala et al. 2011	12	10	3 half pin breakage; 3 equinus ankle contractures; 1 peroneal artery pseudoaneurysm; 2 LLD (15 mm and 20 mm); 3 regenerate bending (< 5 degrees)	12	0

Weighted Mean Children	3.5	2.6		2.1	0
Eidelman et al. 2006	3	2	1 delayed union, additional 2 months in cast	1	0
Eidelman et al. 2010	4	3	3 superficial pin tract infections	3	0

 Other complications refers to any reported complication that is not a pin tract infection.

LLD Leg-Length Discrepancy.

*‡* Value reported for full sample size of patients in study.

## Table 12: Complications experienced by patients who received TAYLOR SPATIAL FRAME° Fixator for deformities $\S$ in adults and children.

Study	Sample Size (N)	Number of Pin Tract Infections	Other Complications Experienced	Number of Other Complications*	Total Number of Revision Procedures
Weighted Mean	31.0	4.1		5.7	1.9
Viskontas et al. 2006	7	5	2 pin breaks; 1 delayed union	3	2
Elbatrawy et al. 2009	8	1‡	None	0	0
Nakase et al. 2009	10	3	3 transient decrease of range of motion of the nearby joint; 2 deep infections	5	2
Rozbruch et al. 2010	122	Most patients (number NR)	2 cellulutis; 3 peroneal nerve neurapraxia; 1 delayed union resulting in some loss of correction after frame removal	6	2
Thiryayi et al. 2010	10	7	1 ankle pain on weight bearing; 1 L5 sensory neuropathy; 1 tarsal tunnel syndrome; 1 external fixator failure	4	1

Weighted Mean Children	27.9	10.8		10.2	5.3
Blondel et al. 2009	36	8	1 deep infection; 3 bone regenerate fractures	4	1
Feldman et al. 2003	22	3	1 delayed union.	1	0
Sluga et al. 2003	5	2	2 knee stiffness; 2 broken pins; 1 coxitis and osteomyelitis	5	1
Fadel et al. 2005	22	22	6 adjustment under general anesthesia necessary (3 for early consolidation, 3 to all repeat corticomy); 2 fracture of the regenerated bone; 1 deep vein thrombosis; 2 needing second attempt; 3 loosening of frames	14	13
Eidelman et al. 2006	22	10	1 bleeding after injury of genicular artery by half-pin, 1 delayed union of femoral site, 4 fracture of femur, 1 residual deformity on femur, 1 talus subluxation	8	1
Feldman et al. 2006	18	3	None	3	0
Manner et al. 2007	129	0	12 persisting axial deformity	12	NR
Docquier et al. 2008	7	3	2 transient equinus deformity; 1 hamstring retraction; 1 botryomycoma; 1 callus fracture; 1- non-union; 1 plantar aponeurosis; 1 reflex sympathetic dystrophy	9	2

§ In studies with patients of mixed pathology, entries were separated. When this was not possible, only those studies with >75% congenital or developmental deformity was included in this group.

Other complications refers to any reported complication that is not a pin tract infection.

NR Not reported

*‡* Value reported for full sample size of patients in study.

infection.

## Table 12: Complications experienced by patients who received TAYLOR SPATIAL FRAME° Fixator for deformities § in adults and children. (Cont.)

Study	Sample Size (N)	Number of Pin Tract Infections	Other Complications Experienced	Number of Other Complications*	Total Number of Revision Procedures
Eidelman et al. 2008	15	7	1 talar subluxation, 1 metatarsophalangeal joint subluxation mof second toe, 2 undercorrection of severe clubfeet, 1 residual mild supination, 1 residual equinus and forefoot adduction, 1 premature consolidation	7	1
Marangoz et al. 2008	22	6	4 stiff knees; 2 delayed unions; 2 posterior subluxations	8	0
Naqui et al. 2008	55	24	2 breakage of wires; 11 fixed flexion deformity; 2 delayed union requiring dynamization; 2 non-unions; 2 ipsilateral supracondylar fractures; 1 osteomyelitis; 1 pseudoaneurysm	21	10
Eidelman et al. 2010	14	5	1 angulation of regenerate, 1 transient peroneal nerve palsy, 1 delayed union	8	1
lobst 2010	15	3	1 knee flexion contracture; 1 joint subluxation	2	0
Floerkemeier et al. 201 <sup>2</sup>	1 9	1	1 skin ulcer; 1 wound healing problem; 1 relative shortening of the tendon of the flexor digitorum longus and temporary paresthesias; 1 nerve paresthesia; 1 deep infection; 1 hematoma infection; 1 ulcer; 1 secondary arthritis	8	4

In studies with patients of mixed pathology, entries were separated. When this was not possible, only those studies with >75% congenital or developmental deformity was included in this group.
 \* Other complications refers to any reported complication that is not a pin tract

NR Not reported

*t* Value reported for full sample size of patients in study.

ESULTS

### Conclusions

This systematic review assesses the TAYLOR SPATIAL FRAME° Fixator for three important uses and patient populations including: • acute trauma

- nonunion and malunion and
- deformity correction.

The TAYLOR SPATIAL FRAME Fixator appears to be a viable alternative to the Ilizarov Frame for external fixation, as suggested by the favorable percentage of treatment goals being achieved in all groups. The rates of complications observed were similar to those found for other external fixators, considering the severity and complexity of the injuries and deformities.

While a formal comparison to the Ilizarov frame is not within the scope of this paper, it should be noted that a custommade frame system for differing cases is less time-consuming with the TSF. Furthermore, the software-generated adjustment schedule allows for an overview of the correction over time [22]. Disadvantages for the TSF compared to the Ilizarov frame may include the learning curve associated with a new external fixator.

It is important to note that the articles included in this review had inherent limitations and further high-quality, large clinical studies are required before definitive conclusions regarding the outcomes using the TSF can be made. Studies comparing the llizarov frame to the TSF are recommended. Furthermore, consistent reporting of surgical parameters and clinical outcomes is needed. We did note the use of validated quality of life and functional outcome questionnaires in a few studies, which if incorporated consistently in future research could allow for robust comparisons of the effectiveness of external fixators, possibly via meta-analyses.

#### Strengths

- A thorough and systematic review of the literature was conducted.
- Explicit inclusion and exclusion criteria.
- Demonstrated reproducibility of selection and quality of assessment criteria.
- Data from 666 patients were included with a broad age range, and a variety of limbs and indications for surgery, yielding a relatively high generalizability.
- A relatively large sample size indicating high levels of success of the TSF across a variety of populations, injuries, and deformities.

### Limitations

- Lack of level I and II evidence.
- Poor methodology utilized allowing for large amounts of systematic bias.
- Inconsistent reporting across studies and variable patient populations preventing the ability to utilize meta-analytic techniques.
- Small sample sizes.
- Lack of reporting on functional and quality of life outcomes.

### Review at a glance

#### Generalizability

75 out of 100. The included studies assess the TAYLOR SPATIAL FRAME° for external fixation as management for a large number of indications in multiple limbs. Also, the cumulative sample included a very broad demographic, allowing the findings to be applied to a larger population with similar characteristics.

#### Validity

60 out of 100. Systematic review of moderate evidence, with inconsistent reporting on surgical parameters and clinical outcomes between included studies. A large amount of bias is present although consistent findings were obtained.

#### Timeliness

65 out of 100. The TAYLOR SPATIAL FRAME Fixator presents a new alternative in external fixation treatment that is used effectively for a broad range of indications. All studies in this review were published within the past eight years.

#### Importance

80 out of 100. The evidence is important in providing patients, orthopaedic surgeons, and healthcare payers information regarding the success in achieving desired outcomes when using the TAYLOR SPATIAL FRAME to manage and correct a variety of injuries and deformities.

#### Strength

60 out of 100. Data from 25 studies were included in this study. The evidence is moderate, including Level III and IV studies with relatively small sample sizes.



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## Appendices

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