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The TAYLOR SPATIAL FRAME◇ for External Fixation

A Systematic Literature Review Following 20 years of Clinical Outcomes

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The TAYLOR SPATIAL FRAME® for External Fixation: A Systematic Literature Review Following 20 years of Clinical Outcomes

Purpose of review

This systematic review was performed to evaluate and summarize the current evidence of the clinical performance of the TAYLOR SPATIAL FRAME (Smith & Nephew, Memphis, TN, USA).

Background

Since its introduction in 1996, several studies have reported positive clinical results with the TAYLOR SPATIAL FRAME external fixator. In order to obtain a more thorough understanding of this device's performance, we conducted a systematic review of the literature to collect data from studies reporting consolidation and complication rates. Studies looked at both adult and children receiving the TAYLOR SPATIAL FRAME for the following indications: acute trauma; non-union or malunion with or without deformity; and developmental or congenital deformity.

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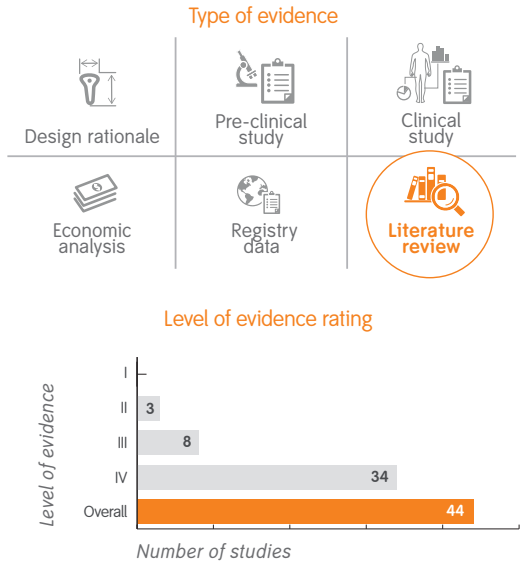
Evidence



Why this rating?

Although there are studies included of Levels II to IV evidence, all are considered Level IV. This is because only individual study arms from each of the higher-quality included studies were analyzed. They were therefore considered to be equivalent to case series and of a lower level of evidence (Level IV).

Study characteristics

Number of studies: **44**

Study designs included:
- **Case series**
- **Individual arms of higher-quality evidence, treated as case series**

Outcomes pooled into three groups for adults and children based on indication for use: Acute trauma (AT); nonunion or malunion with or without deformity (NMD); and developmental or congenital deformity (DCD)

Adults				Children		
AT	NMD	DCD		AT	NMD	DCD
24.5	26.3	36.1	Mean follow-up, months:	24.6	50.4	25.2
43.2	43.5	34.6	Mean age, years:	12.2	14.8	12.6
173	80	334	Sample size:	47	12	427

Key results and considerations

A systematic review of the literature found:
- **Consolidation rates for children in all three indications were 100%.**
- **Consolidation rates for adults with acute trauma, non/malunion, and deformities were 99.2%, 100%, and 100%, respectively.**
- **The majority of complications in adults (64.1%) and children (68.5%) were considered grade I, and did not require operative strategies to address.**

In conclusion, **the TAYLOR SPATIAL FRAME is a viable device for external fixation and deformity correction,** as confirmed by published clinical data in adults and children, with:
- High consolidation rates achieved in all groups
- Time to consolidation rates in line with expected averages for these indications
- Complication rates similar to those for other external fixators

Need for additional studies:
- High-quality randomized controlled trials (RCTs)
- Additional reporting of surgical parameters and clinical outcomes
- More studies in indications of acute trauma and non/malunion

Background

External fixation plays a growing role in the primary treatment of unstable and high risk fractures, non- and malunions, as well as in the reconstruction of congenital and acquired physical deformities.

TAYLOR SPATIAL FRAME (Smith & Nephew, Memphis, TN, USA; **Figure 1**) is an external fixator that uses computer software to simultaneously correct for leg length discrepancy and various aspects of deformity including angulation, translation, and rotation. TAYLOR SPATIAL FRAME consists of two rings or partial rings connected by six telescopic struts at special universal joints to create a hexapod frame. By adjusting strut lengths, one ring is repositioned with respect to the other.

Published studies on TAYLOR SPATIAL FRAME are primarily case series with small sample sizes. We performed a comprehensive systematic review of the published literature with TAYLOR SPATIAL FRAME to improve our understanding of this device's overall clinical performance, including complication rates, consolidation rates, time to consolidation, and rate of correction goals achieved (specific to deformities) following treatment with TAYLOR SPATIAL FRAME.

Figure 1: The TAYLOR SPATIAL FRAME®

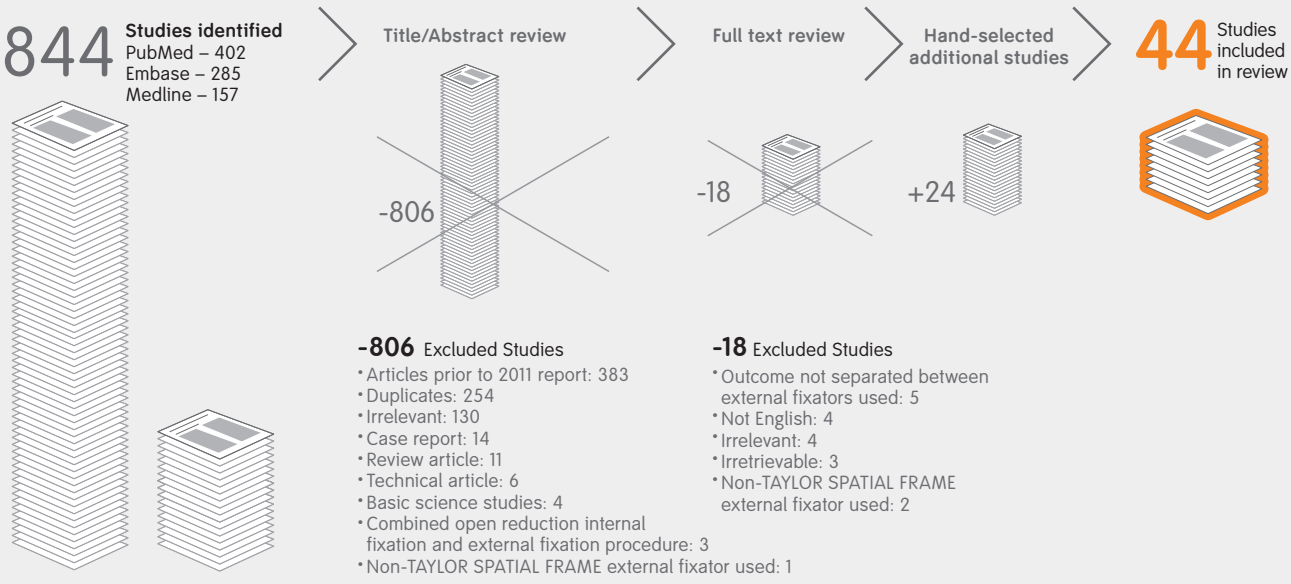
Methods

This review pools data from clinical studies reporting consolidation rates, time to consolidation, rate of correction goals achieved (specific to deformities), and complications following treatment with TAYLOR SPATIAL FRAME® in adults and children. Indications for use included acute trauma, non-union or malunion with or without deformity, and developmental or congenital deformity. From the 844 potentially eligible studies identified by a systematic search of the literature and manual search of relevant reference lists, 800 did not meet eligibility, leaving 44 eligible studies (**Figure 2**).[1–44]

Although some of the 44 studies were of greater than Level IV evidence, for our purposes they are all considered Level IV case series. This is because only one study arm was included or the study arms were considered independently of one another.

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

Figure 2: Literature Review



Study Characteristics

Study characteristics are summarized in **Figure 3**. Details on the 44 included studies are provided in Tables 1-3, beginning on page 16.

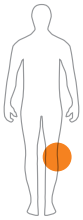
Please refer to *Appendix 2: Results* for additional details on the study results.

Figure 3: Study characteristics

Adults		Acute Trauma	Non/Malunion	Deformity
	Study designs included:	Retrospective comparative & case series	Retrospective comparative & case series	Prospective & retrospective comparative & case series
	Mean follow-up (months):	24.5	26.3	36.1
	Mean age:	43.2	43.5	34.6
	Sample size (mean):	173 (34.6)	80 (20)	334 (27.8)
	Number of fractures/ deformed limbs (mean)	178 (35.6)	80 (20)	385 (32.1)

Children				
	Study designs included:	Retrospective comparative & case series	Case series	Prospective & retrospective comparative & case series
	Mean follow-up (months):	24.6	50.4	25.2
	Mean age:	12.2	14.8	12.6
	Sample size (mean):	47 (11.8)	12 (12)	427 (18.6)
	Number of fractures/ deformed limbs (mean)	48 (12)	12 (12)	508 (22.1)

Consolidation Rates—Adults



In adults, mean consolidation rates were as follows for the three indications:

- Acute trauma: 99.2% (four studies reporting[1,27,30,37])
- Non/malunion: 100% (four studies reporting[18,25,36,41])
- Deformities: 100% (two studies[31,39])

Figure 4: Consolidation rates of TAYLOR SPATIAL FRAME® for three indications in adults.

Study (Operations)	Consolidation Rate (%)
Pooled Results, Acute Trauma; n=122	**99.2%**
Ahearn et al. 2014; n=21[1]	100%
Lahoti et al. 2013; n=7[2]	100%
Menakaya et al. 2014; n=37	100%
Sala et al. 2013; n=57	98.2%[3]
Pooled Results, Non/Malunion; n=80	**100%**
Feldman et al. 2003*; n=18	100%
Khunda et al. 2016*; n=40	100%
Sala et al. 2011; n=12	100%
Thiryayi et al. 2010; n=10	100%
Pooled Results, Deformities; n=60	**100%**
Nakase et al. 2016*; n=10	100%
Sokucu et al. 2013*[4]; n=50	100%

Percentages may not add to 100% due to rounding

[1] In the study, 21 out of 55 fractures were treated with TAYLOR SPATIAL FRAME

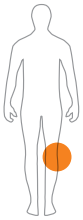
[2] Paper assesses TAYLOR SPATIAL FRAME on acute fractures and nonunions

[3] With initial treatment, 52 out of 57 fractures achieved union. Additional treatment led to union for remaining 5 fractures, but one of these was in a patient who had their TAYLOR SPATIAL FRAME exchanged for a plate, so it could not be attributed to the device.

[4] Two patients that did not achieve initial union underwent bone grafting. Paper reported that accurate and effective correction was achieved in all cases

*Includes both adults and children. Results could not be separated. Pooled with adults as average age was greater than 18 years

Time to Consolidation Rates—Adults



In adults, mean consolidation rates were as follows for the three indications:

- Acute trauma: 21.8 weeks (four studies[23,27,30,37])
- Non/malunion: 32.8 weeks (three studies[18,25,41])
- Deformities: 4.1 weeks (five studies[8,20,33,34,43])

Figure 6: Time to consolidation of TAYLOR SPATIAL FRAME® for three indications in adults.

Study (Operations)	Mean Time to Consolidation (Weeks)
Pooled Results, Acute Trauma; n=157	**21.8**
Henderson et al. 2015; n=56	28.4
Lahoti et al. 2013[1]; n=7	3.5
Menakaya et al. 2014; n=37	23.3[2]
Sala et al. 2013[5]; n=57	26.0[3] 28.0[4]
Pooled Results, Non/Malunion; n=68	**32.8**
Feldman et al. 2003*; n=18	18.5
Khunda et al. 2016*; n=40	45.6
Thiryayi et al. 2010; n=10	34.3
Pooled Results, Deformities; n=142	**4.1**
Docquier et al. 2008; n=2	6.6
Floerkemeier et al. 2011; n=2	4.1
Robinson et al. 2011; n=9	2.6[1]
Rozbruch et al. 2010*; n=122	4.9
Viskontas et al. 2006; n=7	2.1

Percentages may not add to 100% due to rounding
[1] Paper assesses TAYLOR SPATIAL FRAME on acute fractures and nonunions
[2] Value reported as a median, not mean
[3] Mean time to consolidate for tibia
[4] Mean time to consolidate for femur
[5] Time to consolidation was averaged for the 52 out of 57 fractures that achieved initial union. It does not incorporate times of the 5 remaining fractures that eventually achieved union with additional treatment
*Includes both adults and children. Results could not be separated. Pooled with adults as average age was greater than 18 years.

Consolidation Rates—Children

In children, mean consolidation rates were as follows for the three indications:

- Acute trauma: 100% (four studies[3,7,40,44])
- Non/malunion: 100% (one study[5])
- Deformities: 100% (two studies[4,38])

Figure 5: Consolidation rates of TAYLOR SPATIAL FRAME® for three indications in children.

Study (Operations)	Consolidation Rate (%)
Pooled Results, Acute Trauma; n=48	**100%**
Al-Sayyad 2006; n=10	100%
Blondel et al. 2010; n=11	100%
Tafazal et al. 2014; n=15	100%
Zenios 2013; n=12	100%
Pooled Results, Non/Malunion; n=12	**100%**
Al-Sayyad 2012; n=12[1]	100%
Pooled Results, Children; n=29	**100%**
Al-Sayyad 2011; n=24	100%
Sluga et al. 2003; n=5	100%

Percentages may not add to 100% due to rounding
[1] One subject was treated with two TAYLOR SPATIAL FRAME devices on their forearm

Time to Consolidation Rates—Children

In children, mean time to consolidation was as follows for the three indications:

- Acute trauma: 16.4 weeks (two studies[40,44])
- Non/malunion: Not reported
- Deformities: 8.8 weeks (four studies[4,6,8,20])

Figure 7: Time to consolidation of TAYLOR SPATIAL FRAME for two indications in children.

Study (Operations)	Mean Time to Consolidation (Weeks)
Pooled Results, Acute Trauma; n=25	**16.4**
Tafazal et al. 2014; n=15	14.8
Al-Sayyad 2006; n=10	18.0
Pooled Results, Deformities; n=103	**8.8**
Al-Sayyad 2011; n=24	15
Blondel et al. 2009; n=67	5.5
Docquier et al. 2008; n=5	10.3
Floerkemeier et al. 2011; n=7	4.4

Percentages may not add to 100% due to rounding

Correction Goals Achieved—Adults and Children

The total number of correction goals achieved, a commonly reported outcome in the indication of deformities, was 98.1% for adults (7 studies[2,8,15,20,26,34,43]) and 94.3% in children (14 studies[6,8-14,16,17,19,20,22,35]).

Figure 8: Rate of correction goals achieved with TAYLOR SPATIAL FRAME° for deformities in adults and children.

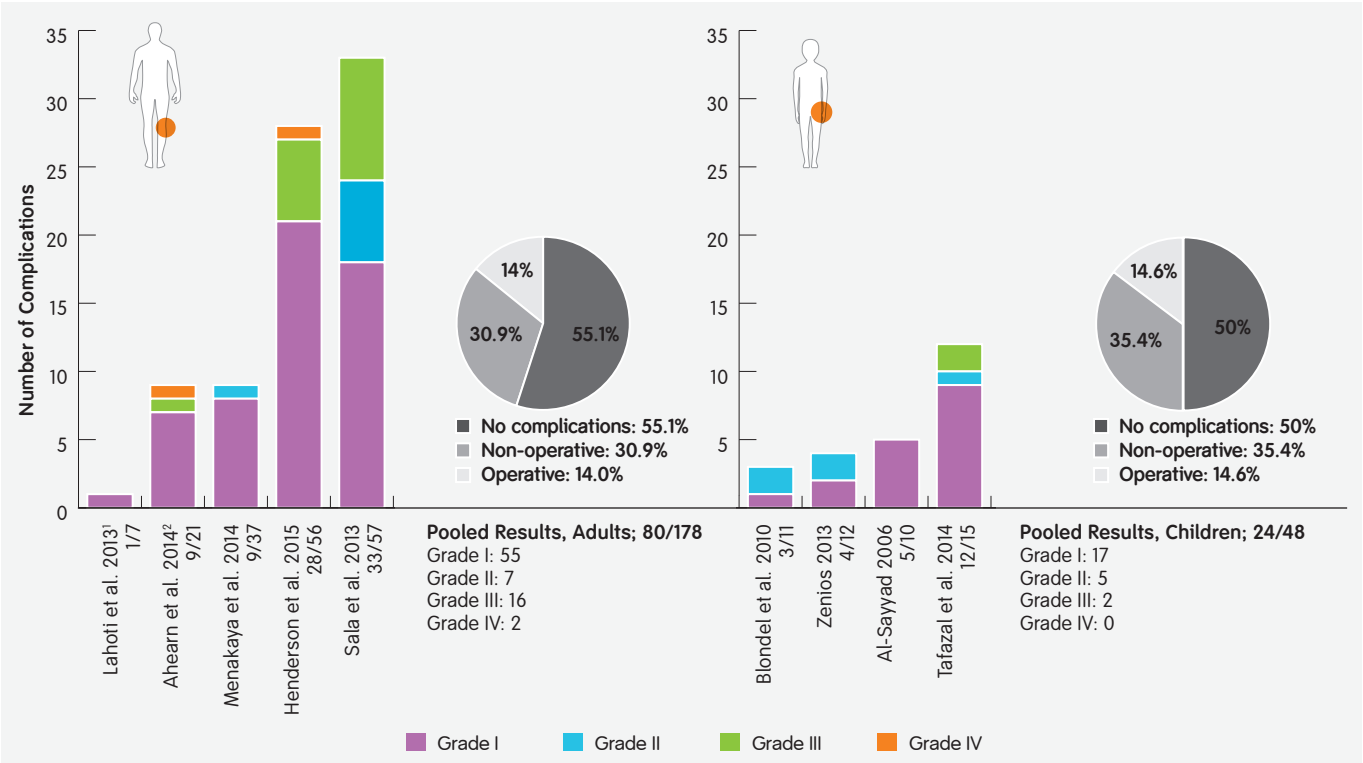
Study (Year)	Rate of Correction Goals Achieved (%)
Pooled Results, Adults; n=255	**98.1%**
Alexis et al. 2015*§; n=80	99%
Docquier et al. 2008; n=2	100%
Elbatrawy et al. 2009*; n=29	100%
Floerkemeier et al. 2011; n=2	50%
Kristiansen et al. 2006*; n=20	95%
Rozbruch et al. 2010*; n=122	99%
Viskontas et al. 2006; n=7	86%
Pooled Results, Children; n=336	**94.3%**
Blondel et al. 2009; n=67	91%
Docquier et al. 2008; n=5	100%
Eidelman et al. 2006; n=44	100%
Eidelman et al. 2008; n=15	87%
Eidelman et al. 2010; n=18	100%
Eidelman et al. 2011; n=8	100%
Eidelman et al. 2011; n=10	100%
Eidelman et al. 2012; n=9	100%
Fadel et al. 2005^; n=22	91%
Feldman et al. 2003; n=22	95%
Feldman et al. 2006; n=18	94%
Floerkemeier et al. 2011; n=7	100%
Hassan et al. 2012; n=11	100%
Naqui et al. 2008; n=55	95%
Sachs et al. 2015[1]; n=11	82%
Sachs et al. 2015[2]; n=14	86%

Percentages may not add to 100% due to rounding
[1] Paper reports on the group with fibular osteotomy
[2] Paper reports on the group with no fibular osteotomy
* Adults and children included. Results could not be separated. Pooled with adults, as average age was greater than 18 years.
^ Includes both adults and children. Results could not be separated. Pooled with children, as average age was less than 18 years.
§ Paper reports on donated TAYLOR SPATIAL FRAME devices that were previously used
≠ Value reported for full sample size of patients in study

Complication Rates

Total number of complications were pooled from the included articles that investigated TAYLOR SPATIAL FRAME®. For all three indications combined, the overall rate of complications per fracture or deformity was 43.0% and 54.2% in adults and children, respectively. These complications were classified according to severity using a modified grading system by Donnan et al[45] (see Appendix). Grade I complications do not require operative interventions, whereas Grades II–IV do. Incidence rates were developed for the following categories: no complications, non-operative complications, and operative complications. Results from individual studies and pooled incidence rates are presented in Figures 9–11.

Figure 9: Complications, graded by severity, in TAYLOR SPATIAL FRAME for acute trauma in adults and children.



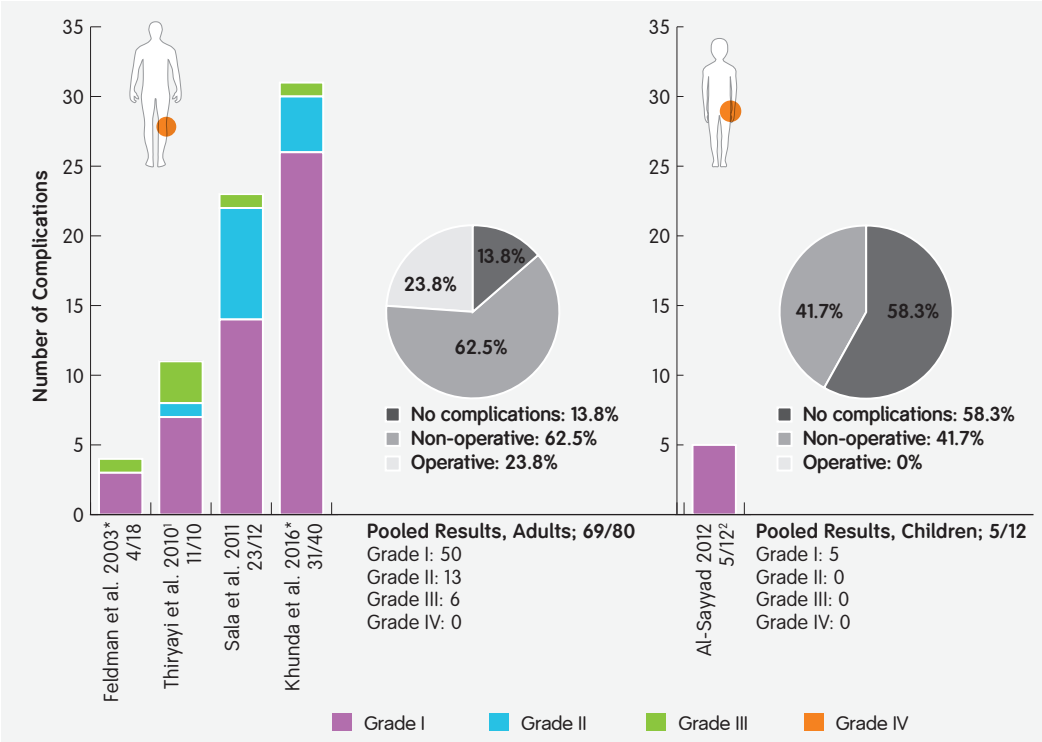
Individual study data are presented as the number of complications over the total impacted limbs analyzed. Percentages may not add to 100% due to rounding. Incidence rates for no complications, non-operative complications, and operative complications are basic averages. Multiple complications could have occurred for individual patients.

[1] In the study, 21 out of 55 fractures were treated with TAYLOR SPATIAL FRAME. Results were separated.

[2] Paper assesses TAYLOR SPATIAL FRAME on acute fractures and nonunions

Complication Rates for Non/Malunion

Figure 10: Complications, graded by severity, in TAYLOR SPATIAL FRAME° for nonunions and malunions with and without deformity in adults and children.



Individual study data are presented as the number of complications over the total impacted limbs analyzed. Percentages may not add to 100% due to rounding. Incidence rates for no complications, non-operative complications, and operative complications are basic averages. Multiple complications could have occurred for individual patients.

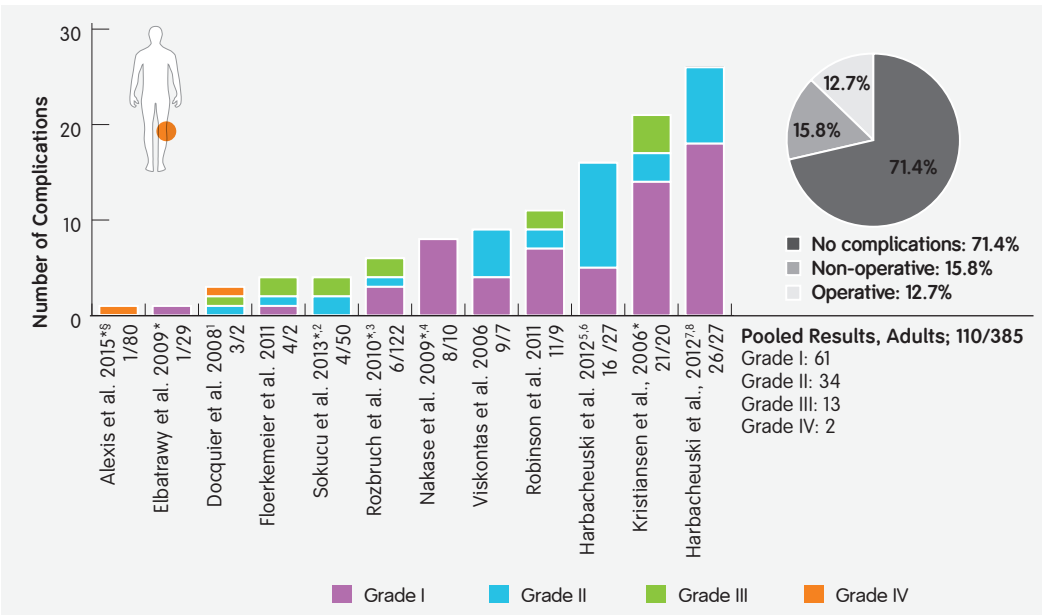
[1] All 7 pin site infections were successfully treated with oral antibiotics or in combination with local debridement and were classified under Grade I as results were not separated

[2] One subject was treated with two TAYLOR SPATIAL FRAME devices on their forearm

* Includes both adults and children. Results could not be separated. Pooled with adults as average age was greater than 18 years.

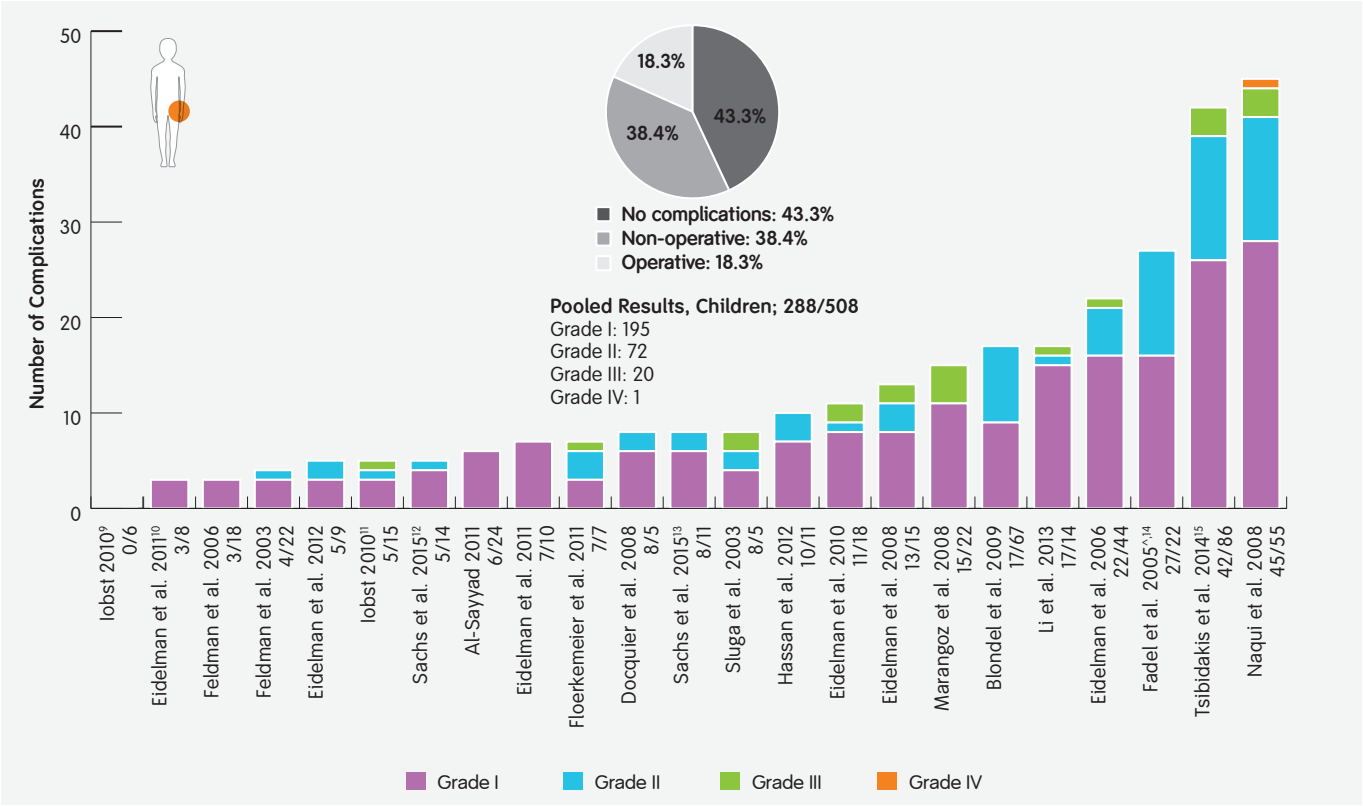
Complication Rates for Deformities

Figure 11a: Complications, graded by severity, in TAYLOR SPATIAL FRAME for developmental or congenital deformity in adults.



Complication Rates for Deformities Cont.

Figure 11b: Complications, graded by severity, in TAYLOR SPATIAL FRAME° for developmental or congenital deformity in children.



Individual study data are presented as the number of complications over the total impacted limbs analyzed. Percentages may not add to 100% due to rounding. Incidence rates for no complications, non-operative complications, and operative complications are basic averages. Multiple complications could have occurred for individual patients.

[1] Algoneurodystrophia was classified as Grade IV
[2] Results do not include number of pin-site infections as the paper only indicated "some" cases had pin-side problems
[3] 1Results do not include number of pin-site infections as the paper only indicated "most" patients had superficial pin infections
[4] All 3 superficial pin-site infections were classified under Grade I as treatment with oral or intravenous antibiotics, or removal of the pins were not separated
[5] Paper reports on the LAP treatment with TAYLOR SPATIAL FRAME (retrospective case-matched comparison study)
[6] Regenerate collapse in 7 cases were classified as Grade II
[7] Paper reports on the classic treatment with TAYLOR SPATIAL FRAME (retrospective case-matched comparison study)
[8] Regenerate collapse in 6 cases were classified as Grade II
[9] Paper reports on lengthening with TAYLOR SPATIAL FRAME rings and Ilizarov clickers
[10] All 3 pin-tract infections were classified under Group I as treatment of the infections were not provided
[11] Paper reports on lengthening with TAYLOR SPATIAL FRAME rings and struts
[12] Paper reports on the group with no fibular osteotomy
[13] Paper reports on the group with fibular osteotomy
[14] Pin tract inflammation occurred in all 22 patients but only 12 infections required antibiotics and were classified as Grade I
[15] Study does not specify how the complications were treated. Pin tract infections and software changes were classified as Grade I; delayed consolidation and all obstacles were classified as Grade II; and complications were classified as Grade III
* Adults and children's results could not be separated. Pooled with adults as average age was greater than 18 years.
^ Includes both adults and children. Results could not be separated. Pooled with children, as average age was less than 18 years.
§ Paper reports on donated TAYLOR SPATIAL FRAME devices that were previously used
≠ Value reported for full sample size of patients in study

Discussion

This systematic review of the TAYLOR SPATIAL FRAME® assessed its use in the indications of acute trauma, nonunion and malunion, and deformity correction. It observed the following key results:

- Consolidation rates for children with either acute trauma or non/malunion were 100%.
  - Only one study reported nonunion and malunion for children.
- Consolidation rate for adults with acute trauma or non/malunion were 99.2% and 100%, respectively.
- Consolidation rate for adults and children with deformities were both 100%.
  - Children in all groups were able to achieve consolidation.
- The overall rate of complications per fracture or deformity was 43.0% and 54.2% in adults and children, respectively.
- Grade II-IV complications requiring operative strategies to address were as follows across the three main indications:
  - Acute trauma
    - Adults: 14.0%
    - Children: 14.6%
  - Non/malunions
    - Adults: 23.8%
    - Children: 0%
  - Deformities
    - Adults: 12.7%
    - Children: 18.3%

Conclusion

The TAYLOR SPATIAL FRAME appears to be a viable device for external fixation and deformity correction, as high consolidation rates were achieved in all groups. The rates of Grade II-IV complications requiring operative strategies to address was low across indications, ranging from 12.7% to 23.8% in adults and 0% to 18.3% in children.

It is important to note that the articles included in this review had inherent limitations due to study design and sample size; thus, further higher-quality, large clinical studies are required to validate the conclusions made regarding the beneficial outcomes following TAYLOR SPATIAL FRAME use. Consistent reporting of surgical parameters and clinical outcomes is needed to aid in future systematic review initiatives. 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	Limitations
• A thorough and systematic search of the literature was conducted. • Explicit inclusion and exclusion criteria • Demonstrated reproducibility of selection and quality of assessment of criteria	• 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 • Lack of reporting on functional and quality of outcomes.

Review at a glance

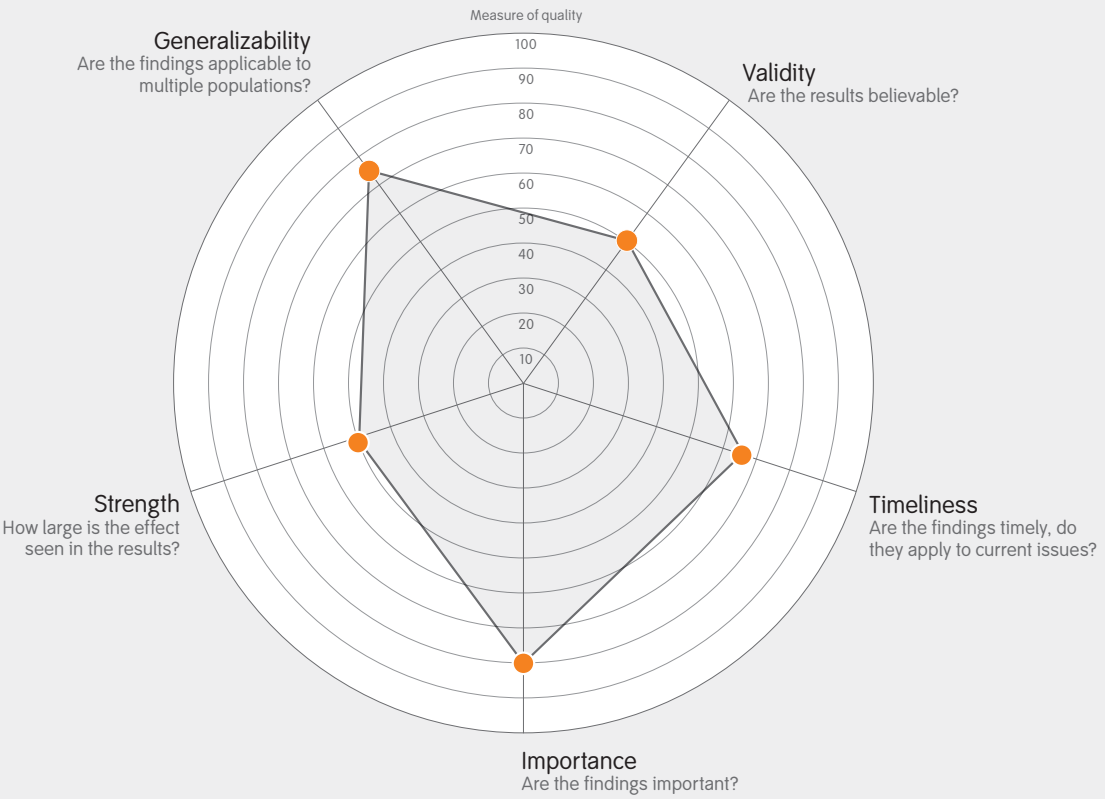
Generalizability
75 out of 100. The included studies assess the TAYLOR SPATIAL FRAME® for external fixation as management in lower and upper limbs for the indications of acute trauma, non-union or malunion with or without deformity, and developmental or congenital deformity. Also, the cumulative sample included a very broad demographic, allowing the findings to be applied to a larger population with similar characteristics.

Validity
50 out of 100. This review of moderate strength evidence contained inconsistent reporting of clinical outcomes and time to consolidation.

Timeliness
65 out of 100. The TAYLOR SPATIAL FRAME presents an option in external fixation treatment that is effective for a broad range of indications. All studies in this review were published within the past 13 years.

Importance
80 out of 100. This evidence provides valuable insight into the use of the TAYLOR SPATIAL FRAME to successfully achieve desired outcomes for managing and correcting a variety of injuries and deformities.

Strength
50 out of 100. Data from 44 studies were included in this study. The evidence is of moderate strength, including Level II, III, and IV studies with relatively small sample sizes.



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REVIEW

Study Characteristics for Three Main Indications—Acute Trauma

Table 1: Study characteristics of nine included studies for acute trauma in adults and children.

Study, Year	Level I: RCTs	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	Sample size (Number of fractures)	Mean age, years (Range)	% Male	Included limb(s)	Indications for procedure	Mean length of frame wear (Weeks)	Mean length of follow-up (Months)
Mean Results, Adults 					**173 (178)**	**43.2**	**72.3**			**27.5**	**24.5**
Ahearn et al., 2014[1]		■			21 (21)	44.0[1] (17-78)	72.7[1]	Tibia	Displaced bicondylar tibial plateau fracture	NR	31 (12-58)
Menakaya et al., 2014[30]		■			37 (37)	48.0[3] (40-57)	62.2	Tibia	High energy fracture	23.3[3]	NR
Henderson et al., 2015[23]				■	56 (56)	42.8 (14-78)	73.2	Tibia	Tibial shaft fracture	NR	(12-NR)
Lahoti et al., 2013[27]				■	7[2] (7)	38.4 (15-70)	71.4	Tibia	Tibial fracture and infected tibial nonunion	31.7 (25.7-40.7)	NR
Sala et al., 2013[37]				■	52 (57)	43.0 (11-81)	76.9	Femur (25), Tibia (32)	Multiple traumatic lower-limb fracture	NR	18 (13-33)
Mean Results, Children 					**47 (48)**	**12.2**	**87.2**			**16.1**	**24.6**
Tafazal et al., 2014[40]		■			15 (15)	12.7 (7-15)	86.7	Tibia	Acute tibial fracture	14.8	(24-NR)
Al-Sayyad, 2006[3]				■	9 (10)	12.3 (8.2-15.4)	100	Tibia	Unstable tibial fracture	19 (12-33)	37.2 (24-48)
Blondel et al., 2010[7]				■	11 (11)	12 (7-15)	72.7	Tibia	Open physis presenting a tibial shaft fracture and with contraindication/failure of non-operative treatment	14 (8.6-20.9)	12 (4-32)
Zenios, 2013[44]				■	12 (12)	12 (8-14)	91.7	Tibia	Unstable tibial fracture	16.5 (8-36)	(12-NR)

Abbreviations: NR= not reported.
Percentages may not add to 100% due to rounding
[1] Reported values are for the entire study, as 34 patients were treated with locking plate and 21 were treated with TAYLOR SPATIAL FRAME. Results were not reported separately.
[2] Paper assesses TAYLOR SPATIAL FRAME on acute open fractures (5 cases) and infected nonunions (2 cases). Nonunions were treated with open reduction and internal fixation initially, which resulted in skin necrosis and breakdown with a soft tissue defect equivalent to a Gustilo IIIB fracture. Results were not reported separately.
[3] Value is reported as a median, not mean.

Study Characteristics for Three Main Indications—Non/Malunion

Table 2: Study characteristics of five included studies for non-unions and malunions with and without deformity in adults and children.

Study, Year	Level I: RCTs	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	Sample size (Number of non/ malunions)	Mean age, years (Range)	% Male	Included limb(s)	Indications for procedure	Mean length of frame wear (Weeks)	Mean length of follow-up (Months)
Mean Results, Adults 					**80 (80)**	**43.5**	**70.0**			**37.1**	**26.3**
Sala et al., 2011[36]			■		12 (12)	44 (19-79)	66.7	Tibia	Infected non-unions	59.7 (42.8-85.7)	24 (18-32)
Feldman et al., 2003[18]				■	18 (18)	29.6* (10-64)	61.1	Tibia	Post-traumatic malunions and nonunions	18.5 (12-32)	38.4 (24-50)
Khunda et al., 2016[25]				■	40 (40)	39.5* (9-69)	70	Tibia	Complex tibial non-unions	46.1 (13.6-170.7)	26 (3-70)
Thiryayi et al., 2010[41]				■	10 (10)	61[6] (48-71)	90	Tibiotalar joint	Ankle arthrodesis	24 (8-44)	16.7 (12-26)
Mean Results, Children 					**12 (12)**	**14.8**	**100**			**21.3**	**50.4**
Al-Sayyad, 2012[5]				■	12[1] (12)	14.8 (8-18)	100	Humeral (8), Radial (4)	Upper extremity pathologies	14 (11-17)[2] 14 (13-15)[3] 15 (14-16)[4] 42[5]	50.4 (24-84)

Percentages may not add to 100% due to rounding

* Includes both adults and children. Results could not be separated. Pooled with adults as average age was greater than 18 years.

[1] One subject was treated with two TAYLOR SPATIAL FRAME devices on their forearm.

[2] Group 1: distal humeral deformity (6 patients)

[3] Group 2: humeral shaft deformity (2 patients)

[4] Group 3: distal radius deformity (3 patients)

[5] Group 4: bone defect requiring bone transport (1 patient)

[6] Value is reported as a median, not mean.

Study Characteristics for Three Main Indications—Deformities

Table 3: Study characteristics of 31 included studies for developmental or congenital deformities in adults and children.

Study, Year	Level I: RCTs	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	Sample size (Number of deformities)	Mean age, years (Range)	% Male	Included limb(s)	Indications for procedure	Mean length of frame wear (Weeks)	Mean length of follow-up (Months)
Mean Results, Adults 					**334 (385)**	**34.6**	**55.4**			**19.0**	**36.1**
Kristiansen et al., 2006[26]		■			20 (20)	31* (7-59)	55	Tibia	Congenital or acquired deformity	28.7 (15-60)	NR
Harbacheuski et al., 2012[21]			■		25 (27)	41.1 (36.1-46.2)	68	Tibia (21), Femur (6)	Deformity requiring osteotomy[1]	26.6 (15-51)	80 (25-140)
Harbacheuski et al., 2012[21]			■		25 (27)	41.3 (35.9-46.8)	40	Tibia (21), Femur (6)	Deformity requiring osteotomy[2]	19.3 (7-45)	45 (28-63)
Alexis et al., 2015[2]				■	69*§ (80)	NR	39.1	Femur, Tibia, Fibula	Congenital, developmental, posttraumatic, and complex multiplanar deformities, limb length discrepancy, bone deficit following osteomyelitis, deformities involving poor soft-tissue tolerance, and acute fractures	NR	NR
Docquier et al., 2008[8]				■	2 (2)	27.4 (23.9-30.9)	NR	Tibia (1), Foot (1)	Deformity of bones in the lower limb	12.1 (9.4-14.7)	10.5 (6.7-14.3)
Elbatrawy et al., 2009[15]				■	26 (29)	24.5* (10-82)	76.9	Tibia (25), Femur (4)	Lower limb deformity	14 (7-24)	39.6 (3-72)
Floerkemeier et al., 2011[20]				■	2 (2)	24.5 (20-29)	0	Foot	Severe deformity of the lower limb	8.6 (7.8-9.4)	22.4 (16-28.5)
Nakase et al., 2009[31]				■	10 (10)	28.8* (10-71)	80	Tibia (6), Femur (4)	Lower limb deformity	19.7 (10.8-31.1)	24 (11 -40.8)
Robinson et al., 2011[33]				■	9 (9)	48.7 (37-59)	100	Tibia	Medial compartment OA and varus deformity	18[7] (12-37)	19[7] (15-35)
Rozbruch et al., 2010[34]				■	102 (122)	39* (5-72)	56.9	Tibia	Tibial congenital deformities	18.6 (10.1-50.7)	48 (10-98)
Sokucu et al., 2013[39]				■	37 (50)	23* (10-58)	56.8	Tibia (33), Femur (17)	Deformities around the knee	20.3 (4-36)	32 (15-54)
Viskontas et al., 2006[43]				■	7 (7)	51.0 (36-72)	57.1	Knee	Medial compartment OA of the knee with varus alignment	23 (16-36)	41

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Study Characteristics for Three Main Indications—Deformities Cont.

Table 3: Study characteristics of 31 included studies for developmental or congenital deformities in adults and children. Cont.

Study, Year	Level I: RCTs	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	Sample size (Number of deformities)	Mean age, years (Range)	% Male	Included limb(s)	Indications for procedure	Mean length of frame wear (Weeks)	Mean length of follow-up (Months)
Mean Results, Childern 					**427 (508)**	**12.6**	**54.3**			**18.4**	**25.2**
Blondel et al., 2009[6]		■			36 (67)	11.1 (3-18)	69.4	Tibia (26), Femur (6), Radial (2), Knee (1), Ankle (1)	Isolated limb lengthening >=4 cm, lengthening with axis correction, axis correction only	26.1 (8-52)	21.3 (4.3-43)
Sachs et al., 2015[35]		■			10 (11)	15.6 (12-21)	90.9	Tibia	Tibia vara[3]	15.9 (12-24)	NR
Sachs et al., 2015[35]		■			13 (14)	15.1 (13-18)	92.9	Tibia	Tibia vara[4]	14.1 (12-24)	NR
Feldman et al., 2006[19]			■		18 (18)	10.2 (3-16)	66.7	Tibia	Tibia vara	14.3 (9-24)	(NR-24)
Iobst, 2010[24]			■		15 (15)	11.9	NR	Tibia, Fibula, Femur, Foot	Correction of limb length and deformity: Fibular hemimelia (4), infantile Blount's disease (3), congenital short femur (2), fibrous dysplasia (2), traumatic growth arrest (1), clubfoot (1), malunion (1), vascular malformation (1)[5]	30.4	16.5
Iobst, 2010[24]			■		6 (6)	11.3	NR	NR	Correction of limb length and deformity: fibular hemimelia (2), congenital short femur (2), traumatic growth arrest (1), congenital pseudoarthritis (1)[6]	24.4	24.1
Al-Sayyad, 2011[4]				■	24 (24)	16 (6-18)	95.8	Tibia (14), Femur (10)	Neglected malaligned fracture (old fractures with callus allowed to proceed to heal in poor position)	17 (13-25)	36 (24-60)
Docquier et al., 2008[8]				■	4 (5)	16.9 (16.4-17.5)	NR	Tibia (3), Femur (1), Foot (1)	Deformity of bones in the lower limb	22.5 (7.6-37.6)	15.3 (4.7-22)
Eidelman et al., 2006[9]				■	31 (44)	12.2 (3.5-17)	71.0	Tibia (27), Femur (13), Foot (3), Radius (1)	Deformity	12.5 (8-20)	9
Eidelman et al., 2008[10]				■	13 (15)	8 (3.5-14)	61.5	Foot	Foot deformity	13.2 (10-20)	11

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Review of study characteristics Cont.

Study, Year	Level I: RCTs	Level II: Prospective, comparative	Level III: Retrospective, comparative	Level IV: Case series	Sample size (Number of deformities)	Mean age, years (Range)	% Male	Included limb(s)	Indications for procedure	Mean length of frame wear (Weeks)	Mean length of follow-up (Months)
Eidelman et al., 2010[11]				■	18 (18)	13.1 (8-17)	NR	Tibia	Post-traumatic deformity	12.3 (8-24)	NR (24-NR)
Eidelman et al., 2011[12]				■	8 (8)	13.7 (8-22)	87.5	Tibia	Tibia varus, severe equinus, shortening	13.6 (12-16)	NR
Eidelman et al., 2011[13]				■	7 (10)	10.6 (4-16)	42.9	Foot	Arthrogrypotic foot deformity	16.1 (14-18)	29 (14-62)
Eidelman et al., 2012[14]				■	9 (9)	14.3 (11-18)	77.8	Foot	Deformity	15 (12-20)	34.3 (16-60)
Fadel et al., 2005[16]				■	22 (22)	16.5^ (6-42)	36.4	Tibia (14), Femur (4), Foot (2)	Lower limb deformity	22.6 (6-39)	38.4 (30-54)
Feldman et al., 2003[17]				■	19 (22)	9.9 (3-16)	68.4	Tibia	Tibia vara	14.6 (9-24)	33.6 (24-45.6)
Floerkemeier et al., 2011[20]				■	7 (7)	13.4 (9-17)	42.9	Foot	Severe deformity of the foot	9.0 (4.7-12.7)	21.2 (13-34.2)
Hassan et al., 2012[22]				■	9 (11)	9.2 (6-14)	22.2	Foot	Foot deformity	21.4 (13-30)	32.6[8] (4-48)
Li et al., 2013[28]				■	14 (14)	13 (12-18)	64.3	Tibia	Deformity	16.3 (11.4-23.7)	14 (12-24)
Marangoz et al., 2008[29]				■	20 (22)	13.9 (5.9-24.6)	40	Tibia	Femoral deformity	26.6 (11.1-81.4)	15.7 (4.5-35)
Naqui et al., 2008[32]				■	53 (55)	10.7 (12-16)	58.5	Tibia (44), Femur (11)	Deformity	25 (12-92)	22 (12-59)
Sluga et al., 2003[38]				■	5 (5)	11 (6-16)	40	Femur (4), Tibia (1)	Deformity	40.7[8] (23.1-52)	NR
Tsibidakis et al., 2014[42]				■	66 (86)	11.2 (3-16)	54.5	Tibia	Multi-planar tibia deformity	NR	54.2 (16-84)

Abbreviations: NR= not reported; OA = osteoarthritis.
Percentages may not add to 100% due to rounding
[1] Paper reports on the classic treatment with TAYLOR SPATIAL FRAME® (retrospective case-matched comparison study).
[2] Paper reports on the LAP treatment with TAYLOR SPATIAL FRAME (retrospective case-matched comparison study).
[3] Paper reports on the group with fibular osteotomy.
[4] Paper reports on the group with no fibular osteotomy.
[5] Paper reports on lengthening with TAYLOR SPATIAL FRAME rings and struts.
[6] Paper reports on lengthening with TAYLOR SPATIAL FRAME rings and Ilizarov clickers.
[7] Value is reported as a median, not mean.
[8] Paper reports slightly different value as this was calculated from Table 1.
* Includes both adults and children. Results could not be separated. Pooled with adults, as average age was greater than 18 years.
^ Includes both adults and children. Results could not be separated. Pooled with children, as average age was less than 18 years.
§ Paper reports on donated TAYLOR SPATIAL FRAME devices that were previously used
≠ Value reported for full sample size of patients in study

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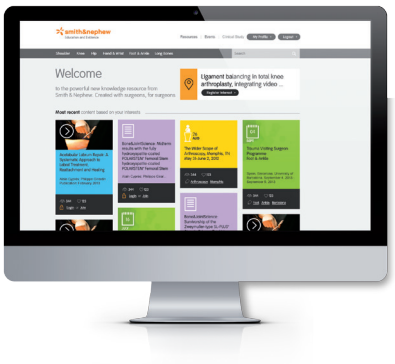
Appendices

Appendices

Visit **www.smith-nephew.com/** for appendices or use this QR code. The following appendices provide further detail:

Appendix 1: Methods
Appendix 2: Results

Notes



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