

1 **fTitanium elastic nails versus Spica cast in pediatric femoral shaft fractures:**
2 **A Systematic Review and Meta-analysis of 1012 patients.**

3 **ABSTRACT:**

4 **BACKGROUND**

5 There is a general consensus on the management of femoral fractures in children
6 younger than two years and adolescents older than sixteen years. The best
7 treatment for patients younger than sixteen years of age is still debatable. Titanium
8 Elastic Nails (TEN), is widely used with some evidence, nonetheless, we
9 performed a systematic meta-analysis to synthesize evidence from published
10 studies about the efficacy of TEN compared to Spica cast for the management of
11 femoral shaft fracture in children aged between 2 to 16 years old.

12 **METHODS**

13 A computer literature search of PubMed, Scopus, Web of Science, CINAHL and
14 Cochrane Central was conducted using relevant keywords. We included clinical
15 trials and observational studies that compared TEN versus Spica cast; Records
16 were screened for eligible studies and data were extracted and synthesized using
17 Review Manager version 5.3 for Windows. Our search retrieved 573 unique
18 articles. Following the abstract and full text screening, 12 studies with a total of
19 1012 patients were eligible for the final analysis

20

21 **RESULTS**

22 In terms of union (in weeks), the reported effect sizes favoured the TEN group
23 in two included studies only. Moreover, the overall standardized mean difference
24 in sagittal (SMD -0.48, 95% CI [-0.70 to -0.26], $P < 0.001$) and coronal angulations
25 (SMD -0.66, 95% CI [-1.00 to -0.31], $P < 0.001$) favored TEN fixation in
26 management of femoral fractures younger than 16 years. The reported length of
27 hospital stay was not consistent across studies. The overall risk ratio of
28 malalignment (RR=0.39, 95% CI [0.27 to 0.57], $P < 0.001$) favored the TEN as well
29 as walking independently. Based on our analysis, TEN treatment is superior
30 to traction and hip spica for femoral-shaft fractures in children younger than 16
31 years old.

32 **CONCLUSION**

33 Based on our analysis we recommend the use of TEN fixation in management of
34 pediatric femoral fractures in patients younger than 16 years.

35 **KEYWORDS**

36 Femoral fractures, spica cast, titanium elastic nails, flexible nails

37 **1. INTRODUCTION**

38 Femoral shaft fractures represent 1.4 % to 1.7 % of all pediatric fractures (1).
39 There is a bimodal pattern being more in early childhood and mid-adolescence and
40 more common among boys than girls (2). The reported annual incidence is up to
41 1/5000- they represent the most frequently pediatric fracture requiring a hospital
42 admission. There are different mechanisms of injury described; this includes but
43 not limited to road traffic accidents, falls, Non-accidental injuries, incidental
44 findings, sports related injuries and pathologic fractures (3). In children less than 4
45 years and toddlers, child abuse would be a main concern (4). In mid-adolescence
46 motor vehicle accidents represent a common cause (5).

47 When choosing the treatment modality in this age group, several issues including
48 the final outcome ought to be considered; as they have impact on psychological
49 and developmental effects: on the child, family and social ramifications and
50 financial implications (if a parent has to take time off work).

51 There is a general consensus on the management of femoral fractures in children
52 younger than two years and adolescents aged 16 or more (6). The ideal treatment
53 for patients between two and sixteen years of age is debatable (7). Closed
54 reduction and Spica cast (CRSC) (6, 8-12), external fixation (13-16), plate and

55 screws (17, 18), intramedullary nails (19-25) and flexible intramedullary nails (26-
56 29) have been described for management of femoral fractures in this age group.

57 Titanium Elastic Nails (TEN) is used globally for the operative fixation of femoral
58 fractures in children younger than 16 years old, despite the paucity of studies
59 evaluating their risks and benefits (26-29). TEN have been used in Europe since
60 the eighties (30) and historically stainless-steel Ender nails have been used
61 elsewhere (31). The surge of TEN in North America has led to an over- spill in
62 their use (32).

63 We performed a systematic review and meta-analysis to analyse the evidence about
64 the efficacy of flexible nails compared to Spica cast for the management of femoral
65 fracture in children younger than 16 years old.

66

67 **2. METHODS**

68 We followed the PRISMA statement guidelines for the preparation of this review
69 and meta-analysis.

70 **2.1. Inclusion and Exclusion criteria**

71 Those studies satisfying the following criteria were included in the present study: 1
72 Clinical trials and observational studies that compared titanium elastic nails versus
73 hip spica; 2 studies whose population was children below the age of 16 years with
74 femoral shaft fractures; 3 studies where the experimental/observation group
75 underwent titanium elastic nails/ flexible intramedullary nails; 4 studies with
76 control group receiving immediate hip Spica cast or traction followed by Spica; 5-
77 studies that were prospective or retrospective studies; and 6 studies whose
78 outcomes were presented as continuous outcomes reliable for analysis; and 7
79 studies reporting the outcomes of hospital stay, union duration, sagittal
80 angulations, malunion, complications, parents satisfaction, coronal angulations,
81 malalignment, and independent walking milestones. We excluded studies that were
82 not available in English language, theses, conference abstracts, and studies whose
83 data were not reliable for extraction and analysis.

84

85

86 2.2. Literature Search Strategy

87 A computer literature search of PubMed, Scopus, Web of Science, CINAL and
88 Cochrane Central was conducted using the following keywords: (((“Bone
89 Nails”[Mesh] OR “Titanium”[Mesh] OR (titanium elastic nailing)) AND (“Casts,
90 Surgical”[Mesh] OR (hip spica casting) OR (spica cast) OR “Traction”[Mesh] OR
91 (conservative management)) AND (“Femur”[Mesh] OR pediatric femur fracture
92 OR femur shaft fracture))) OR ((Bone Nails AND Traction AND “Fractures,
93 Bone”[Mesh])). Additionally, we hand-searched references of the identified
94 articles. Two authors screened the titles and abstracts of the retrieved citations.
95 Eligibility criteria were performed in two steps. An initial abstract screening was
96 commissioned followed by a full-text retrieval of eligible articles and further
97 screening for eligibility to meta-analysis.

98 2.3. Data Extraction

99 Two authors extracted the data independently using an online data extraction form.
100 The extracted data included the following: 1) study design; 2) study population; 3)
101 risk of bias domains; and 4) specific study outcomes: hospital stay, time to union,
102 sagittal angulations, coronal angulations, malalignment, and walking
103 independently; Disagreements were resolved by consensus.

104 2.4. Quality assessment

105 The quality of the Randomized Clinical Trials was assessed according to the
106 Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 (updated
107 March 2011) using the quality assessment table provided in the same book (Part 2,
108 Chapter 8.5). The Cochrane risk of bias assessment tool includes the following
109 domains: sequence generation (selection bias), allocation sequence concealment
110 (selection bias), blinding of participants and personnel (performance bias), blinding
111 of outcome assessment (detection bias), incomplete outcome data (attrition bias),
112 selective outcome reporting (reporting bias) and other potential sources of bias.
113 The authors' judgment is categorized as 'Low risk', 'High risk' or 'Unclear risk' of
114 bias. The NOS contains eight items, categorized into three dimensions including
115 selection, comparability, and—depending on the study type—outcome (cohort
116 studies) or exposure (case-control studies). For each item a series of response
117 options is provided. For observational studies, we used the Newcastle-Ottawa
118 Scale (NOS) for quality assessment (33). NOS is based on a star system and is
119 used to allow a semi-quantitative assessment of study quality. The NOS ranges
120 between zero up to nine stars.

121 2.5. Measures of treatment effect

122 The primary outcomes were union duration, malunion rate, the length of stay,
123 independent walking, angulations (Sagittal and coronal) in both groups. The
124 secondary outcomes were: complications and parents' satisfaction.

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130 2.6. Dealing with missing data

131 In the case of missing Standard deviation (SD) of mean change from baseline,
132 calculations were performed using the standard error or 95% confidence interval
133 (CI), according to Altman (34).

134 2.7. Data Synthesis

135 Hospital stay, time to union, sagittal angulations, coronal angulations, malunion
136 and walking independently were pooled as standardized mean difference (SMD) in
137 the random effect model meta-analysis described by Der-Simonian and Laird(35).
138 The incidence of malalignment in both groups was pooled as relative risk (RR) in
139 the meta-analysis model using the Mantel-Haenszel (M-H) method. Statistical
140 analyses were conducted using Review Manager 5.3 for Windows.

141 2.8. Assessment of heterogeneity

142 Heterogeneity was assessed by visual inspection of the forest plots and measured
143 by I-square and Chi-Squared tests. According to the Cochrane Handbook of
144 Systematic Reviews and Meta-analysis of interventional studies, the Chi-squared

145 test assesses whether observed differences in results are compatible with chance
146 alone. According to Higgins 2002 (36) and Higgins 2003 (37), the heterogeneity
147 test I-squared is calculated from the following equation: $\left[\frac{Q-df}{Q}\right] \times 100\%$ where Q is
148 the chi-squared statistic and df is its degrees of freedom. I-squared test can be
149 interpreted as follows: 0% to 40%: might not be important; 30% to 60%: may
150 represent moderate heterogeneity; 50% to 90%: may represent substantial
151 heterogeneity; and 75% to 100%: considerable heterogeneity.

152 2.9. Publication bias

153 According to Egger *et al.* (38), publication bias assessment is not reliable for less
154 than 10 pooled studies. Therefore, in this study, we could not assess the existence
155 of publication bias by Egger's test for funnel plot asymmetry.

156 **3. RESULTS**

157 **3.1. Search results**

158 Our search retrieved 573 unique articles. Following the abstract and full text
159 screening, 12 studies(28, 32, 39-49) with a total of 1012 patients were eligible for
160 the final analysis (See PRISMA flow diagram; [**Figure 1**]). The reasons for study
161 exclusion are shown in **Supplementary File no.1**.

162 Of the 12 included studies, two studies were randomized controlled studies; the
163 summary of the included studies and their main results are shown in [**Table 1**].

164 **3.2. Quality of included studies**

165 The quality of the included studies was from moderate to high quality according to
166 the Cochrane risk of bias assessment tool and the NOS. Therefore; included studies
167 have acceptable quality for inclusion in our review. The summary of quality
168 assessment domains of included studies is shown in supplementary file.

169 Primary Outcomes

170 **3.3. Duration to Union (in weeks)**

171 **In terms of duration till union (in weeks)**, reported effect sizes were heterogeneous
172 and were not reliable for pooling in a meta-analysis model to give an overall effect
173 estimate [**Figure 2**]. The duration till union was significantly less in the TEN

174 group than the control group in two studies (40), (41); while in the third study of
175 (39).

176 3.4. Malunion

177 The pooled risk ratio of malunion showed less rate of malunion in the TEN group
178 compared with the Spica group (RR 0.43, 95% CI [0.26, 0.71], $P < 0.001$, [Figure
179 3]. Pooled studies were homogenous ($P > 0.1$; I-square=0%).

180 3.5. Sagittal Angulations

181 The overall standardized mean difference in sagittal angulations favored TEN
182 group than the control group (SMD -0.48, 95% CI [-0.70 to -0.26], $P < 0.001$,
183 [Figure 4]. Pooled studies were not heterogeneous (Chi square $P = 0.90$; I-
184 square=0%).

185 3.6. Coronal Angulations

186

187 The overall standardized mean difference in coronal angulations favored TEN
188 group than the control group (SMD -0.66, 95% CI [-1.00 to -0.31], $P < 0.001$,
189 [Figure 5]. Pooled studies were not heterogeneous (Chi square $P = 0.14$; I-
190 square=48%).

191

192 3.7. Hospital stay (days)

193 Three retrospective studies favored the CRSC group over the TEN group. The
194 remaining retrospective study did not favor either of the two groups. The two
195 RCTs (42), (43) reported a statistically significant difference favoring shorter
196 hospital stay in the case of TEN than the CRSC group (Mean Difference = -13.60
197 days, 95% CI [-16.25 to -10.95], and Mean Difference = -12.28 days, 95% CI [-
198 13.26 to -11.30], respectively). The overall effect estimates did not favor any of the
199 two groups (Mean Difference = -3.13, 95% CI [-7.44, 1.18], P =0.15, [Figure 6]);
200 the pooled effect estimate was highly heterogeneous (Chi square P <0.001; I-
201 square=99%)

202 3.8. Malalignment

203 The overall risk ratio of malalignment favored TEN group than control group
204 (RR=0.39, 95% CI [0.27 to 0.57], P<0.001, [Figure 7]). Pooled studies were not
205 heterogeneous (Chi-square P=0.40 and I-square=0%).

206 3.9. Walking independently

207 Four studies (two retrospective studies and two RCTs) investigated the ability of
208 patients to walk independently. All the four studies reported a statistically
209 significant difference in walking independently favoring the TEN group than the
210 control group [Figure 8].

211 Secondary Outcomes

212 3.10. Parent Satisfaction

213 Two studies reported parent satisfaction; both studies showed higher satisfaction
214 rate following TEN than Spica. The pooled RR of parent satisfaction did not
215 significantly favored the TEN group than the Spica group (RR 1.65, 95% CI [0.94,
216 2.88], P =0.08, [Figure 9].

217

218 3.11. Complications

219 The complications of each procedure are mutually independent. Therefore, we
220 cannot compare both procedures for the same complications. Therefore, the
221 percentages could not be expressed as Risk Ratio between the two groups.
222 Summary of complications is summarized in [Table 2] and [Table 3].

223

224 **4. DISCUSSION**

225 Our analysis showed a statistically significant difference favoring the TEN group
226 in the **duration of union** when compared with CRSC - as well as malunion, sagittal
227 and coronal angulations in the management of femoral fractures in patients
228 younger than 16 years old. We report a statistically significant difference favoring
229 shorter hospital stay in the case of TEN when compared to the CRSC group.
230 Likewise, the overall risk ratio of malalignment favored TEN group than CRSC.
231 Similarly, we have observed a statistically significant difference in independent
232 walking and parents' satisfaction favoring the TEN group than the CRSC group.
233 Subsequently, based on our observations, the results showed significant benefits of
234 TEN compared to CRSC in the treatment of femoral-shaft fractures in children
235 younger than 16 years old.

236 Traditionally, conservative treatment was the method of choice for diaphyseal
237 fractures in children and adolescents, because it avoided surgical risks. However,
238 spica use requires lengthy immobilisation and a higher risk for limb length
239 discrepancy (LLD). TEN fixation thus superseded other surgical options in the
240 pediatric population, as it is: simple, effective, reproducible and minimally
241 invasive. It allows: a stable fixation, rapid healing and a prompt return to normal
242 activity [32, 37, 41, 48]

243 4.1. Overall completeness of evidence

244 Shemshaki *et al.* (42) compared spica cast with TEN in management of peadiatric
245 femoral fractures and reported superior results in the TEN group with earlier
246 discharge from hospital ($P < 0.001$), return to independent walking ($P < 0.001$),
247 return to school ($P < 0.001$) and better parent satisfaction ($P = 0.003$); the two
248 groups were similar in baseline characteristics. The Range of knee motion was
249 138.7 ± 3.4 and 133.5 ± 13.4 degrees in the CRSC and the TEN groups
250 respectively ($P = 0.078$). Malunion was observed three patients (13.0%) in the
251 CRSC group compared with none in the TEN group ($P = 0.117$). Postoperative
252 infection was observed in three patients (13.0%) in the TEN group.

253 Similarly, Soleimanpour *et al.*(43) reported superior results in the TEN group in
254 regards to absence time from school, length of hospital stay, time needed for
255 walking and angular deviation (varus or valgus) were when compared with the
256 CRSC group. They observed no statistically significant difference between the two
257 groups in regards to malunion, wound complications and hospital charges.

258 4.2. Union

259 Heffernan *et al.* (39) showed no statistical significant difference between the two
260 groups in regards to the time to union. However, Sasseendar *et al.* (41) and Flynn

261 *et al.* (32) showed a statistically significant difference favoring the TEN group than
262 the control group.

263 Sela *et al.* (44) reported 100% union rate, less than 8% rate of LLD and a
264 complication rate of less than 5% with CRSC. Only one of the 151 patients treated
265 with CRSC needed a re-operation. Assaghir *et al.* (40) retrospectively evaluated
266 104 pediatric femoral fracture in children with a mean age of 4.5 years managed
267 with either TEN or spica cast followed up for a minimum of 3 years. TEN was
268 statistically better in terms of union ($P < 0.001$), and shortening ($P = 0.016$)
269 subsequently leading to earlier weight bearing ($P < 0.001$). Saseendar *et al.* (41)
270 demonstrated that fracture union happens earlier in the TEN group (6 weeks) than
271 in the spica group (8 weeks) ($P = 0.001$).

272 Heffernan *et al.* (39) performed a multicenter retrospective analysis of 215 patients
273 aged 2 to 6 Years. Although there was no significant difference in healing times
274 between TEN and the spica groups ($P=0.652$), they recommended that TEN is a
275 reasonable option for treatment of femur fractures in young children when
276 compared with CRSC with shorter time to independent ambulation and full
277 activities ($P=0.023$). They strongly recommended the utilization of TEN in high-
278 energy mechanism fractures.

279

280 4.3. Complications

281 In our analysis, reported complications in TEN group included: painful nail ends,
282 pin migration, superficial infection, painful scar and painless limb. On the other
283 hand, complications in CRSC group ranged from: sores, ulcers, infected pin,
284 wedging of the spica, revision and limbing.

285 Sela *et al.* (44) reported that CRSC were associated with more side effects- mainly
286 contact dermatitis. The main complication was the risk of re-manipulation due to
287 loss of reduction. They also had 10.5% more LLDs (>2 cm shortening or <1 cm
288 lengthening). Similarly, Flynn *et al.* (32) reported that the rate of complications
289 associated with TEN compared favorably with that associated with CRSC. In their
290 cohort, none of the children treated with TEN had more than one cm of LLD
291 compared to 2/35 (4%).

292 Say *et al.* (45) detected no significant differences in regard to complications and
293 results. Although the complications are statistically alike in both procedures, they
294 highlighted that the complications of TEN are more challenging.

295 4.4. Malunion, sagittal, and coronal angulation

296 Our analysis showed lower rate of malunion in the TEN group compared with the
297 CRSC group. Similarly, the overall standardized mean difference in sagittal
298 angulation (P<0.0001) and coronal angulation (P=0.0002) favored TEN group than

299 the CRSC group. Acceptable angulation in pediatric shaft femoral fractures has
300 been set by Kasser (50): angulation of 30° in both planes, 20° on the sagittal plane
301 and 15° on the coronal plane and 10° on the coronal plane and 15° on the sagittal
302 plane in patients younger than 2 years, between 2 and 5 and between 5 and 10
303 years, respectively. When angulations during spica cast treatment occur beyond
304 these ranges, different strategies must be considered - such as cast wedging (3).
305 Loss of acceptable angulation after reduction of femoral fracture in children treated
306 with spica casting has been reported (28, 32, 41). Assaghir *et al.* (40) reported
307 statistically significant differences in favor of TEN over CRSC in regards to
308 shortening (P =0.016); sagittal angulation (P =0.018); coronal angulation (P
309 =0.022); rotation (P =0.014).

310 Heffernan *et al.* (39) reported lingering angulation was higher in the CRSC vs.
311 TEN group in both the sagittal plane (P =0.002) and coronal plane (P =0.006).
312 Similarly, outcome success represented by coronal and sagittal angulation less than
313 10° and shortening less than 15 mm was attained in 92 % of the TEN group
314 compared to 67% in the CRSC group (odds ratio for TEN group 9.28 (1.6–54.7); p
315 = 0.0138) (28). Saseendar *et al.* (41) demonstrated that Spica casting led to
316 increased coronal plane angulation (P = 0.001), higher rotational malalignment (P=
317 0.001), higher limb length discrepancy at 1-year follow-up (P<0.001) when
318 compared with the TEN group.

319 Shemshaki *et al.* (42) reported a 13.0% of nonunion in the CRSC group whereas
320 none occurred in the TEN group in their randomized controlled trial ($P = 0.117$). In
321 the younger age groups. Assaghir *et al.* (40) retrospectively evaluated femoral
322 fracture in children with a mean age of 4.5 years. TEN was statistically better in
323 terms of sagittal angulation ($P = 0.018$), coronal angulation ($P = 0.022$), rotation (P
324 $= 0.014$).

325 4.5. Cost effectiveness

326 Buechsenschuetz *et al.* (46) retrospectively undertook a cost analysis comparing
327 both modalities. They looked at different aspects including hospital, physicians,
328 physiotherapy and facility costs. Inpatient costs were higher in the TEN group
329 regarding the overall surgeon's and physiotherapy costs paid ($p < 0.001$). The
330 metalwork removal procedure was included as well in the TEN group. Facility
331 costs, however, were higher in the spica group ($p < 0.015$), resulting in a slight
332 difference in overall inpatient costs between the two groups ($p < 0.047$). Finally,
333 they reported that the total overall costs of femoral shaft fractures with TEN was
334 significantly less expensive (average, \$11,077) than traditional CRSC approach
335 (average, \$13,490), with a value of $p < 0.04$. On the other hand, Clinkscales and
336 Peterson(48) reported that costs for patients in the traction group were equal to the
337 intramedullary nail group. Similarly, Flynn *et al.* (32) and Soleimanpour *et al.* (43)
338 reported that costs for the two treatment options were similar. Flynn *et al.* (32)

339 demonstrated that although the surgical costs is significantly higher in the TEN
340 group ($P<0.0001$), the hospitalization cost was significantly higher in the CRSC
341 group ($P<0.001$), yielding to insignificant total costs' differences between both
342 groups.

343 4.6. Parent satisfaction

344 Two studies (40, 46) reported parent satisfaction. Both studies showed higher
345 satisfaction rate following TEN than Spica. Also similar to our findings, there was
346 lower parent satisfaction in the CRSC group, with superior parental acceptance of
347 the TEN treatment. This was also reported by Clinkscales and Peterson(48). This
348 observation could be attributed to the various social and psychological aspects of
349 treating femoral fractures with spica casts that was highlighted by different studies
350 (51-53)

351 Buechsenschuetz *et al.* (46) reported that nearly all of the children in the TEN
352 group were reintegrated with their social environment sooner than their CRSC
353 counterparts. Patients in the TEN group were able to return to school within 2 to 3
354 weeks of their surgery, and in some cases even before the CRSC group patients
355 were released from their initial hospitalization. They showed that two children in
356 the CRSC group had to repeat a school grade. This led to parental dissatisfaction
357 and had adverse implications on the child. One parent felt their child was

358 “emotionally scarred” during the cast period, and another child ultimately needed
359 psychiatric counseling after removal of the cast. Though these observations cannot
360 be generalized, this is inferred as a direct consequence of the CRSC procedure, as
361 was previously reported by Streissguth and Streissguth (54).

362 4.7. Length of hospital stay

363 Two RCTs (42, 43) reported a statistically significant difference favoring shorter
364 hospital stay in the case of TEN than the CRSC group. Shemshaki *et al.* (42)
365 reported a short length of stay in the TEN group when compared with the CRSC
366 group with a mean of 6.9 ± 2.9 days in the TEN group to 20.5 ± 5.8 days in the
367 CRSC group ($P < 0.001$). Likewise, Soleimanpour *et al.* (43) and Flynn *et al.* (32)
368 reported a shorter hospitalization in the TEN group, when compared with CRSC
369 group ($p < 0.05$) and ($p < 0.0001$) respectively. Flynn *et al.* reported a mean of 5
370 days of hospitalization in the TEN group compared to 24 days in the CRSC group.

371 However, the remaining included studies reported different results with shorter
372 hospital stay in the CRSC group. Our pooled effect estimate did not favor any of
373 the two group

374 4.8. Independent walking and return to school

375 Similar to our findings, Shemshaki *et al.* (42) reported a short time interval to
376 independent walking in the TEN group when compared with the CRSC group.

377 They reported a mean 17.6 ± 10.2 days to supported walking in the TEN group
378 compared to 65.6 ± 10.7 in the CRSC group ($P < 0.001$). Additionally, they
379 demonstrated that the children in the TEN group took a shorter time to return to
380 school sooner. It took the patients in the TEN group a mean of 31.5 ± 13.4 to
381 return back to school compared to 64.3 ± 19.6 days in the CRSC group ($P < 0.001$).
382 Similarly, Flynn *et al.*(32) reported an earlier return to supported walking and
383 independant walking in children in the TEN group, and a quicker return to school
384 and these differences were significant when compared with CRSC group (48 days
385 in the TEN compared to 103 days in the CRSC group ($p < 0.0001$)). The same
386 observations were reported by Soleimanpour *et al.* (43); they demonstrated that
387 mean non-attendance time from school, time needed for walking with and without
388 help were significantly lower in the group treated by TEN ($p < 0.05$). Assaghir *et*
389 *al.* (40) demonstrated TEN was statistically better in terms of earlier weight
390 bearing ($P < 0.001$), and earlier return to nursery ($P = 0.000$) in children less than 6
391 years old.

392 4.9. Quality of the evidence

393 The quality of this evidence is credible as it is based on high quality studies as
394 indicated by the quality assessment. Search methods and eligibility criteria were
395 well defined. We followed PRISMA checklist to prepare this study, and we
396 performed all the steps in strict accordance with the Cochrane Handbook for

397 Systematic Reviews of Interventions. We should mention that in our study, we
398 combined data from RCTs and observational studies. However, most effect
399 estimates were pooled without significant heterogeneity. Furthermore, the effect
400 estimates of RCTs were not significantly different from those of observational
401 studies except in terms of hospital stay. Therefore, we believe that evidence
402 obtained from our analysis is robust.

403 4.10. Limitations

404 This meta-analysis included retrospective and observational studies together with
405 two RCTs. It is well established that RCTs are the gold standard comparative
406 studies providing class one evidence. Given this, we recommend further RCTs
407 comparing the TEN with Spica hip. Additionally, the included studies did not study
408 comprehensively different aspects of femoral shaft fractures and subsequently, this
409 has been under-reported in our meta-analysis. These include factors like fracture
410 type, patients' skeletal maturity and associated co-morbidities in those children. As
411 these are important factors that should be considered when choosing the preferred
412 treatment method.

413

414

415 4.11. Authors' conclusions

416 Based on our analysis we recommend the use of TEN fixation in management of
417 pediatric femoral fractures in patients younger than 16 years old. The results imply
418 that a child with a femoral fracture when treated with a TEN, achieves recovery
419 milestones significantly faster than a child treated with traction and spica cast.
420 Further studies with longer follow-ups and comparison of TEN with other surgical
421 methods, such as external fixation, in children's femoral fractures are required.

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424 selection of studies.

425 **CONFLICT OF INTEREST**

426 All authors confirm no financial or personal relationship with a third party whose
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430

431 **Figures Legend**

432 Figure 1 shows PRISMA flow diagram for study selection.

433 Figure 2 shows the standardized mean difference between the two groups in the
434 **duration to union** (in weeks) with 95% confidence intervals. IV=Inverse variance

435 Figure 3 shows the risk ratio of malunion between the two groups with 95%
436 confidence intervals. M-H=mantel Haenzel

437 Figure 4 shows the standardized mean difference between the two groups in the
438 sagittal angulations with 95% confidence intervals.

439 Figure 5 shows the standardized mean difference between the two groups in the
440 coronal angulations with 95% confidence intervals.

441 Figure 6 shows the mean difference between the two groups in the length of
442 hospital stay with 95% confidence intervals. IV=Inverse variance

443 Figure 7 shows the risk ratio between the two groups in the rate malalignment with
444 95% confidence intervals.

445 Figure 8 shows the standardized mean difference between the two groups in the
446 walking independently with 95% confidence intervals. IV=Inverse variance

447 Figure 9 shows the risk ratio between the two groups in the parent satisfaction with
448 95% confidence intervals.

449

450 **- TABLES**

451 Table 1: Summary of included studies.

452 Table 2 Complications for the TEN group

453 Table 3: Complications for the Cast Group

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455

456

457

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