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Morphology of the knee after guided growth using tension-band devices: a retrospective multicenter study of 222 limbs and 285 implants

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Submitted 2023-08-16. Accepted 2023-11-08.

Background and purpose — Temporary hemiepiphysiodesis by tension-band devices is commonly applied to correct angular limb deformities in children. We aimed to evaluate knee joint morphology after guided growth using these devices.

Patients and methods — In a retrospective multicenter study we analyzed standardized anteroposterior long-leg radiographs of 222 limbs (285 implants) of patients treated by temporary hemiepiphysiodesis with either eight-Plates or FlexTacks for coronal angular deformities of the knee joint between 2013 and 2019. Femoral floor angle (FFA), femoral notch–intercondylar distance (FNID), and tibial roof angle (TRA) were measured pre- and postoperatively to assess the central knee joint morphology. Statistical exploratory analyses were performed using linear mixed models, t-tests, Wilcoxon signed-rank test, and Mann–Whitney U test.

Results — 217 FlexTacks (femur 106, tibia 111) in 104 children and 68 eight-Plates (femur 61, tibia 7) in 35 children were identified. Median time period under growth guidance was 11 months (range 4–42). No statistically significant change in the FFA was detected (eight-Plate: $P = 0.2$; FlexTack: $P = 0.3$). A statistically significant difference of the FNID was found in the eight-Plate group ($P = 0.02$), but not in the FlexTack group ($P = 0.3$). While TRA increased in both groups, a statistical significance was observed only in the FlexTack group ($P < 0.01$).

Conclusion — We found minor but clinically irrelevant changes in knee morphology after the treatment.

Growth modulation by means of staples or plates on one or both sides of an open physis is frequently used to correct angular deformities and limb length discrepancies (LLD) [1-4]. In 2007, guided growth by tension-band plating with eight-Plates was reported (Orthofix Medical Inc, Lewisville, TX, USA) and later the flexible staple called FlexTack (Merete GmbH, Berlin, Germany) was introduced [5,6].

Application of tension-band devices has become the gold standard for guided growth to correct angular deformities in the coronal plane of the lower limb in skeletally immature patients [7-9]. However, combined medial and lateral physeal arrest has also been used in LLD correction [7,8,10-13]. Recently a discussion erupted regarding possible changes in knee joint morphology after combined medial and lateral epiphysiodesis [14-17]. Because the common implants for epiphysiodesis decelerate growth in the periphery of the growth plate, leaving the central part of the physis available for further growth, it seems possible to induce changes in the central knee joint morphology. A decreasing tibial roof angle (TRA), decreasing femoral notch–intercondylar distance (FNID), and increasing femoral floor angle (FFA) might be possible. Even though theoretically this seems more probable in combined medial and lateral epiphysiodesis than in hemiepiphysiodesis, growth deceleration on just one side of the physis might also affect the knee joint morphology centrally and/or at the non-arrested side of the physis. It therefore remains controversial as to whether tension-band devices applied for angular deformity correction might affect the central knee morphology.

We aimed to assess knee joint morphology, i.e., FFA, FNID, and TRA, based on the established reference values on a large cohort before and after guided growth using 2 different implants, either eight-Plate or FlexTack.

DOI 10.2340/17453674.2023.34902

Patients and methods

The study was performed as an international retrospective multicenter cohort study. All patients undergoing hemiepiphysiodesis for correction of valgus deformity of the knee joint with eight-Plates at the Department of Children's Orthopedics, Aarhus University Hospital (AUH), Denmark between January 2015 and December 2019, or with FlexTacks at the Department of Pediatric Orthopedics, Deformity Reconstruction and Foot Surgery, Muenster University Hospital (MUH), Germany between December 2013 and September 2016 were included. Patients were identified using diagnosis and procedural codes in the electronic patient journals. Patients were excluded if appropriate radiographs were unavailable before or after angular correction, radiographs were of poor quality, or the limb had clearly changed positioning compared with the initial radiographs.

Angular correction was considered achieved when corrected leg axis was obtained, or the physis had closed. All devices were removed after treatment.

Included patients were classified into 4 groups according to implant type and site: FlexTacks in the distal femur, eight-Plates in the distal femur, FlexTacks in the proximal tibia and eight-Plates in the proximal tibia.

To evaluate the impact of underlying conditions on primary outcomes, the FlexTack group was separated into 2 subgroups for both distal femur and proximal tibia: those with idiopathic valgus deformity and those with pathological conditions.

Medical records were reviewed for information concerning complications. Initial radiographs were all taken within 6 months prior to the insertion or removal of the tension-band device.

The study is reported according to STROBE guidelines.

Outcomes

In accordance with Sinha et al. [15], Tolk et al. [14], and Vogt et al. [18] the primary outcome measures were defined as the FFA, the FNID, and the TRA, which were assessed on standardized long standing anteroposterior radiographs with full knee extension and the patella pointing forward prior to insertion and removal of the implant (Figure 1).

Time period under growth guidance in months started with insertion and ended with the removal of the tension-band device or with physeal closure. Radiographic interval was defined as the time in months between the radiographs on which the pre- and postoperative measurements were conducted.

Measurements were performed using the Picture Archiving and Communication System (PACS) images (IMPAX 6.5, Agfa HealthCare NV, Mortsel, Belgium) (GE Healthcare, Chicago, USA) and the postprocessing software TraumaCad (Brainlab, Munich, Germany). Double measurements of all 3 outcome measures were performed by 2 raters (EH and AP) with at least 2 weeks in between to assess intra- and inter-rater reliability (IRR). Interclass correlation coefficients (ICC) were determined to evaluate IRR. A 2-way mixed effects model with absolute agreement was used.

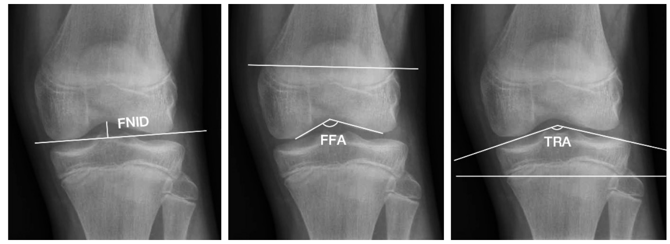


Figure 1. Femoral notch–intercondylar distance (FNID), femoral floor angle (FFA), and tibial roof angle (TRA).

Statistics

Statistical testing was performed with STATA/MP 17 (StataCorp LLC, College Station, TX, USA) and with SAS version 9.4 (SAS Institute, Cary, NC, USA). The data distribution was analyzed by histograms, QQ-plots, and Shapiro–Wilk test. Depending on normal distribution, data was analyzed using paired t-test, unpaired t-test, Wilcoxon signed-rank test, or Mann–Whitney U test.

All data is presented as medians, including minimum (min.), maximum (max.), and interquartile range (IQR) given as 25th and 75th percentile for easier comparison between parametric and non-parametric data. ICC values are given with 95% confidence interval (CI).

To analyze which variables have an influence on the difference between pre- and post-differences in the dependent variables FFA, TRA, FNID, mechanical axis deviation (MAD), mechanical lateral distal femur angle (mLDFA), and medial proximal tibia angle (MPTA), linear mixed models were fitted to account for the dependence in the data due to 2 legs from 1 patient. This was done with a random effect for the patient with a working correlation matrix with compound symmetry structure.

All analyses are exploratory: P values below 0.05 were considered as significant. Due to no correction for multiple testing all P values should be interpreted with caution and in connection with effect estimates and their corresponding confidence levels.

Ethics, data sharing, funding, and disclosures

The study has been approved by the responsible ethics committees at AUH and MUH (November 21, 2017, registration number 2017-491-f-S). The ethical approval does not permit data sharing. No external funding was obtained.

RR receives royalties on the FlexTack licensed to Merete GmbH (Berlin, Germany). BV, RR, and JDR received payment from Merete GmbH and Orthofix Srl. (Bussolengo, Italy) for travel, presentations, and lectures that were not connected to the present study. The remaining authors have no conflicts of interest to declare. Complete disclosure of interest forms according to ICMJE are available on the article page, doi: 10.2340/17453674.2023.34902

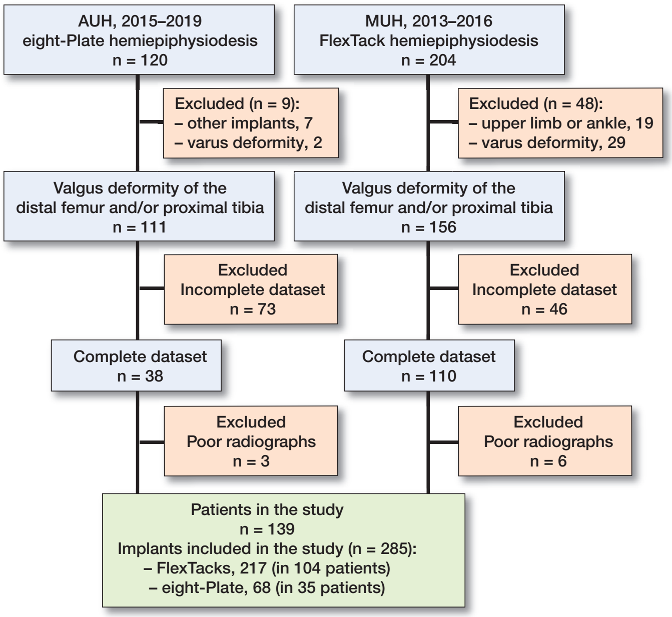


Figure 2. Flowchart of patient inclusion and exclusion. AUH = Aarhus University Hospital. MUH = Muenster University Hospital.

Results

A total of 222 lower limbs of 112 females and 110 males were eligible for inclusion in accordance with the STROBE guidelines. In total 285 implants (68 eight-Plates in 35 patients and 217 FlexTacks in 104 patients) had been used for medial temporary hemiepiphysiodesis of the distal femur or the proximal tibia to correct valgus deformity of the knee joint (Figure 2). Underlying pathologies of the patients are given in Table 1.

The median age was 13.1 years (3.2–18.4), with the oldest having a significantly delayed bone age and still open growth plates (Table 2). Treatment was completed after a median time under growth guidance of 11.0 months (3.8–41.8) following corrected leg axis or closed physis (Figure 3).

We observed changes in the femoral eight-Plate group for FNID (P = 0.02), and in the tibial FlexTack group for TRA (P < 0.01), but not in FFA. Comparing the femoral and tibial groups for the 2 devices, no differences were observed between the groups for the primary outcome measures FFA, FNID, and TRA.

In both the femoral and the tibial group, the time under growth guidance in the FlexTack group was shorter when compared with the eight-Plate group (femoral group P < 0.01, tibial group P = 0.03) (Table 2).

Changes in TRA and FFA did not show any dependance on either sex, the underlying condition, the device, the duration of growth guidance, or age (Table 4). FNID (P = 0.02, estimate: 0.55, CI 0.08–1.02), mLDFA (P = 0.01, estimate: –3.33, CI –5.94 to –0.71) and MPTA (P < 0.001, estimate: 4.12, CI 2.34–5.90) correlated significantly with the choice of implant (FlexTack or eight-Plate). The difference in MPTA also showed a significant dependence on the sex (P = 0.005, estimate 2.02, CI 0.62–3.41) and on age (P < 0.001, estimate 0.65, CI 0.35–0.94). Change in MAD correlated significantly with age (P = 0.02, estimate –1.13, CI –2.10 to –0.17) and sex (P = 0.04, estimate –4.89, CI: –9.48 to –0.30).

Table 1. Etiology of valgus deformity

Type	FlexTack	eight-Plate	Total (%)
Idiopathic	120	63	183 (82)
Congenital	28	0	28 (139
Post traumatic	5	0	5 (2.3)
Post tumor	2	0	2 (0.9)
Metabolic	1	0	1 (0.5)
Syndromic	1	0	1 (0.5)
Post infectious	1	0	1 (0.5)
Iatrogenic	1	0	1 (0.5)

The ICC values based on 2 independent raters were excellent for all measurements (FFA 0.93, CI 0.86–0.96; FNID 0.94, CI 0.54–0.98; TRA 0.89, CI 0.70–0.96).

All patients in the eight-Plate group had an idiopathic valgus deformity. Analysis of FNID revealed an increase (P = 0.02) in the pathological FlexTack group. Additionally, a statistically significant increase in TRA for both idiopathic (P < 0.01) and pathological deformities (P < 0.01) was observed (Table 3).

In the femoral group, the pathological deformity group had a significant increase in FNID (P = 0.02), younger age (P < 0.01), shorter treatment period (P = 0.04), and longer radiographic interval (P < 0.01) when compared with the idiopathic group. In the tibial group, similar findings prevailed for patient characteristics, and a difference in increase for TRA was observed (P = 0.02).

Complications

No breakage of the implants was reported in either group. In 1 patient, the screws on an eight-Plate were replaced due to them backing out of the femur, resulting in insufficient growth inhibition of the physis. 1 female patient still presented valgus deformity of the knee joint in both legs at the age of 18 years with closed growth plates. She underwent osteotomy, and the femoral eight-Plates were not removed until the procedure was performed. 2 FlexTack patients experienced postoperative infections, 1 wound infection and 1 septic knee arthritis.

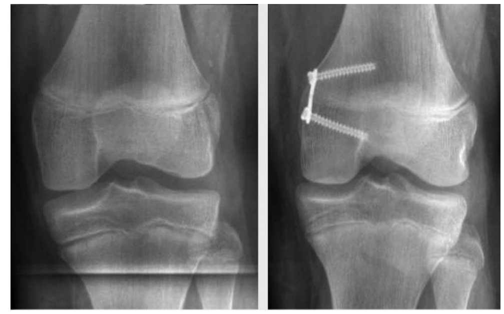
Discussion

We aimed to evaluate knee joint morphology after guided growth using FlexTack and eight-Plate. Our study showed no difference in FFA, indicating absence of central femoral overgrowth. Conversely, an increase in the TRA in the FlexTack group was found, while no change was observed in the eight-Plate group. An increase in FNID was observed in the eight-Plate group and in the pathological FlexTack group.

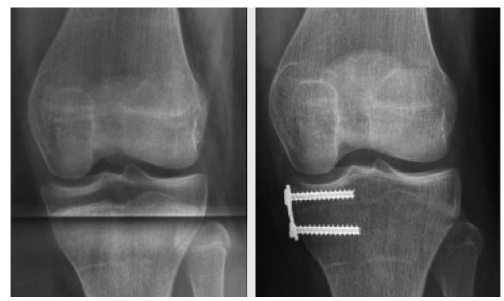
Table 2. Descriptive statistics for the 4 patient groups

	Femur			Tibia		
Factor	FlexTack	eight-Plate	P value [a]	FlexTack	eight-Plate	P value [a]
Patients	67	34		73	4	
Knees	106	61		111	7	
Sex (F/M)	55/51	33/28		51/60	4/3	
Age, median	13.5	12.5	0.01	13.4	14.2 [b]	0.4
(IQR)	(12.2–14.5)	(11.3–13.8)		(12.1–14.4)	–	
range	4.1–18.1	5.3–18.4		3.2–18.1	5.3–14.3	
Months under growth guidance						
median	9.4	12.4	< 0.001	10.4	12.1 [b]	0.03
(IQR)	(7.2–12.7)	(10.6–15.2)		(7.2–16.3)	–	
range	3.8–41.8	6.2–26.0		3.8–39.8	12.0–16.3	
Radiographic interval, months						
median	10.0	12.7	0.01	11.3	15.4 [b]	0.3
(IQR)	(7.6–13.4)	(10.3–14.4)		(8.5–18.1)	–	
range	3.9–31.9	7.5–33.5		3.9–40.3	10.1–17.2	
FFA before, °						
median	144	141				
(IQR)	(139–147)	(137–145)				
range	121–163	125–153				
FFA after, °						
median	144	139				
(IQR)	(139–147)	(136–144)				
range	127–166	121–153				
FFA difference (after–before)						
median	0.0	–0.9	0.8			
(CI)	(–1.0 to 0.0)	(–1.6 to 1.2)				
P value [c]	0.3	0.2				
FNID before, mm						
median	8.0	8.3				
(IQR)	(6.9–8.9)	(7.6–9.4)				
range	2.5–12.7	4.4–12.3				
FNID after, mm						
median	8.1	8.6				
(IQR)	(6.6–9.1)	(7.4–10.4)				
range	2.2–12.6	4.7–14.4				
FNID difference (after–before)						
median	0.1	0.2	0.1			
(CI)	(–0.1 to 0.3)	(–0.2 to 0.8)				
P value [c]	0.3	0.02				
TRA (before), °						
median				144	153 [b]	
(IQR)				(141–147)	–	
range				122–154	122–161	
TRA (after), °						
median				145	152 [b]	
(IQR)				(142–147)	–	
range				126–155	125–161	
TRA difference (after–before)						
median				1.0	2.0	0.8
(CI)				(0.5 to 1.5)	(–1.0 to 3.0)	
P value [c]				< 0.001	0.09	

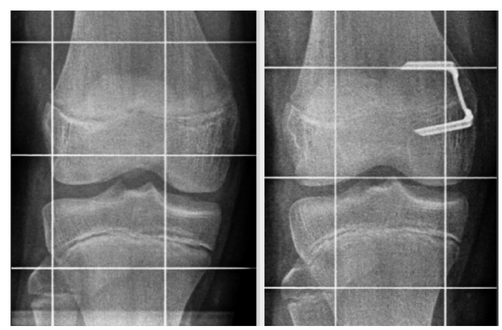
[a] P value FlexTack vs. eight-Plate
[b] Due to low number of patients in group it was not possible to calculate IQR.
[c] P value of difference
FFA = femoral floor angle.
FNID = femoral notch–intercondylar distance.
TRA = tibial roof angle.
IQR = interquartile range.
CI = confidence interval



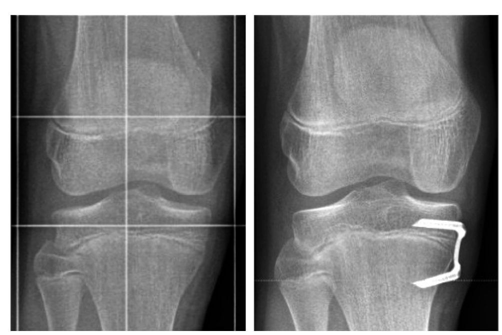
12-year-old male patient treated with an eight-Plate on the medial femur on the left leg. The difference measured –5.2° in FFA, and 2.1 mm in FNID.



13-year-old female patient treated with an eight-Plate on the medial tibia on the left leg. The difference in TRA measured 2.2°.



13-year-old male patient treated with a FlexTack on the medial femur on the right leg. The difference measured 2.0° in FFA, and –0.3 mm in FNID.



14-year-old male patient treated with a FlexTack on the medial tibia on the right leg. The difference in TRA measured –2.7°.

Figure 3. Examples of patients included in the cohort and their measured changes in relevant primary outcome after treatment.

Our study is the largest of its kind, with 285 implants in 222 patients investigating not only tibial, but also femoral changes in the knee joint after growth guidance. It is the

Table 3. Descriptive statistics for patient groups treated with FlexTacks divided into underlying pathology: idiopathic or pathological

Factor	FlexTack femur idiopathic	FlexTack femur pathological	P value [a]	FlexTack tibia idiopathic	FlexTack tibia pathological	P value [a]
Patients	47	20		49	24	
Knees	84	22		84	27	
Sex (F/M)	41/43	14/8		42/42	9/18	
Age, median	13.9	11.2	< 0.001	13.8	9.8	< 0.001
(IQR)	(12.9–14.6)	(9.7–12.5)		(12.7–14.4)	(6.5–12.7)	
range	6.5–18.1	4.1–16.0		6.5–18.1	3.1–16.2	
Months under growth guidance						
median	9.4	10.5	0.048	9.6	13.4	0.005
(IQR)	(7.1–11.4)	(7.9–17.0)		(6.6–13.5)	(8.4–23.1)	
range	3.8–26.5	5.5–41.8		3.8–39.8	5.5–34.9	
Radiographic interval, months						
median	9.7	11.2	0.01	10.9	13.4	0.005
(IQR)	(7.4–12.4)	(9.7–18.0)		(7.4–15.7)	(9.9–24.8)	
range	3.9–23.2	5.7–31.9		3.9–40.3	5.7–35.7	
FFA before, °						
median	143	147				
(IQR)	(139–147)	(143–155)				
range	127–152	121–163				
FFA after, °						
median	143	149				
(IQR)	(138–146)	(142–152)				
range	127–152	131–166				
FFA difference (after–before)						
median	0.0	–0.5	0.6			
(CI)	(–1.5 to 1.0)	(–2.0 to 2.1)				
P value [b]	0.3	0.8				
FNID before, mm						
median	8.3	6.2				
(IQR)	(7.4–9.2)	(4.4–7.1)				
range	5.6–12.7	2.5–11.0				
FNID after, mm						
median	8.4	6.7				
(IQR)	(7.2–9.3)	(5.7–7.5)				
range	5.9–12.6	2.2–11.2				
FNID difference (after–before)						
median	0.0	0.5	0.02			
(CI)	(–0.2 to 0.2)	(0.0 to 0.8)				
P value [b]	0.9	0.02				
TRA (before), °						
median				145	140	
(IQR)				(142–147)	(135–145)	
range				126–154	122–147	
TRA (after), °						
median				145	142	
(IQR)				(143–148)	(137–147)	
range				126–155	126–149	
TRA difference (after–before)						
median				1.0	1.8	0.02
(CI)				(0.3 to 1.4)	(0.7 to 2.8)	
P value [b]				0.001	< 0.001	

[a] P value idiopathic vs pathological
[b] P value of difference
For Abbreviations, see Table 2

Table 4. Mixed models (type 3 tests of fixed effects) for the changes in tibial roof angle (TRA), femoral floor angle (FFA), femoral notch–intercondylar distance (FNID), mechanical lateral distal femoral angle (mLDFA), medial proximal tibial angle (MPTA) and mechanical axis deviation (MAD). Reference was the right leg, the male sex, the "pathological" condition and the FlexTack

Effect	Estimate (CI)	P value
TRA		
Side of leg	–0.06 (–0.85 to 0.73)	0.9
Sex	0.05 (–0.82 to 0.92)	0.9
Underlying condition	–0.41 (–1.61 to 0.80)	0.5
Device	–0.01 (–2.12 to 2.11)	0.99
Duration	0.05 (–0.01 to 0.11)	0.09
Age	–0.15 (–0.32 to 0.02)	0.09
FFA		
Side of leg	0.89 (–0.07 to 1.85)	0.07
Sex	–0.23 (–1.75 to 1.28)	0.8
Underlying condition	0.85 (–1.51 to 3.21)	0.5
Device	–1.73 (–3.54 to 0.07)	0.06
Duration	0.10 (–0.03 to 0.23)	0.1
Age	–0.08 (–0.41 to 0.26)	0.7
FNID		
Side of leg	–0.09 (–0.27 to 0.09)	0.3
Sex	–0.41 (–0.79 to –0.02)	0.04
Underlying condition	–0.39 (–0.99 to 0.20)	0.2
Device	0.55 (0.08 to 1.02)	0.02
Duration	–0.01 (–0.04 to 0.02)	0.6
Age	–0.03 (–0.12 to 0.05)	0.5
MLDFA		
Side of leg	0.10 (–0.47 to 0.67)	0.7
Sex	1.14 (–0.88 to 3.15)	0.3
Underlying condition	–2.51 (–5.38 to 0.36)	0.09
Device	–3.33 (–5.94 to –0.71)	0.01
Duration	–0.09 (–0.23 to 0.06)	0.3
Age	0.03 (–0.39 to 0.45)	0.9
MPTA		
Side of leg	0.18 (–0.53 to 0.89)	0.6
Sex	2.02 (0.62 to 3.41)	0.01
Underlying condition	1.41 (–0.62 to 3.43)	0.2
Device	4.12 (2.35 to 5.90)	< 0.001
Duration	–0.08 (–0.19 to 0.02)	0.1
Age	0.65 (0.35 to 0.94)	< 0.001
MAD		
Side of leg	0.94 (–1.22 to 3.10)	0.4
Sex	–4.89 (–9.48 to –0.30)	0.04
Underlying condition	–5.53 (–12.1 to 1.05)	0.10
Device	0.58 (–5.40 to 6.55)	0.9
Duration	–0.08 (–0.42 to 0.25)	0.6
Age	–1.13 (–2.10 to –0.17)	0.02

first to include patients treated with the flexible staple, FlexTack, and to compare the results with established reference values of the knee joint [18]. Our findings were compared with previous studies on this subject by Tolk et al. and Sinha et al. [14,15], who investigated patients treated with tension-band plates only. However, one-to-one comparisons of the studies are hindered by their heterogeneity regarding treatment indications.

Neither central overgrowth of the femur nor any difference in FFA was found in our study following temporary hemiepiphysiodesis with either of the 2 devices. A small increase in FNID was observed in the eight-Plate group. This is com-

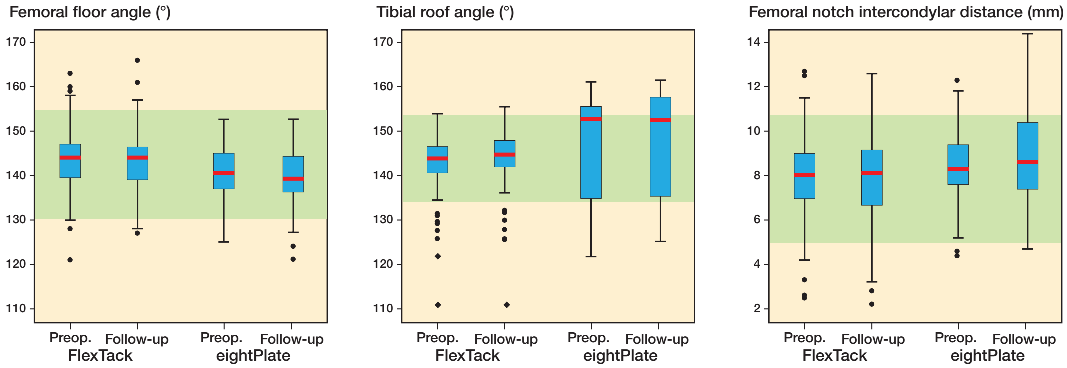


Figure 4. FFA, TRA, and FNID for the 2 devices FlexTack and eight-Plate before and after hemiepiphysiodesis. Red line = median, boxes = interquartile range, whiskers = range of values that lie within 1.5 x interquartile range, and dots are outliers defined as higher/lower than 1.5 x interquartile range. The green area marks the radiographic reference values as established by Vogt et al. (2023) [18].

parable with the observations reported by Tolk et al. However, their mean time under growth guidance in the femoral group was longer than ours, which is explained by their aim to correct LLD instead of angular deformity [14]. Our femoral pathological FlexTack cohort also showed an increase in the FNID. This group was younger and has a longer treatment period than the idiopathic group. Furthermore, distances are very likely to change over time with growth in contrast to angles, and this finding is therefore not unexpected.

The reasons for the observed femoral morphological changes remain unclear. Based on these findings we refute the theoretical consideration that flattening of the femoral condyles occurs following hemiepiphysiodesis, and it is assumed that the changes are too small to have clinical impact.

Jain et al. report a non-significant change in mean TRA of 4° for guided growth. However, their patients were very young and the number of patients was low (n = 35) [17], resulting in a significant risk of type 2 errors.

The use of FlexTack on the proximal tibia resulted in a statistically significant median increase in TRA of 1.0°. No statistically significant change was observed in the group treated with eight-Plates. However, the finding in the eight-Plate group is based on 7 patients only and should thus not be generalized. Nonetheless, our results differ from previous studies by Tolk et al. and Sinha et al. who reported a reduction in TRA, supporting the development of volcano-like changes [14,15]. This is possibly due to the simultaneous treatment of both medial and lateral sides of the physis in cases of LLD. Ballhause et al., whose methodology was similar to ours, also found an increase in TRA of 1.0° when investigating angular deformity correction, though this was not statistically significant [16].

Considering that hemiepiphysiodesis is usually performed for a short period of time until the angular correction is achieved and not as long as is needed for an equalization of LLD, it does not seem likely to produce large changes in the central knee joint. Supporting this hypothesis, larger changes in TRA are observed the longer the physis is under growth guidance. The reason why this dependence is not observed in FFA or FNID is yet to be investigated.

Regarding the 2 epiphysiodesis devices, only slight differences in FNID and TRA changes were found. Implant-related changes in FNID, mLDFA, and MPTA were significant, but not homogeneous. We hypothesize these implant-related changes to be of minimal importance. The lack of a significant difference in change of MAD suggests both implant devices to be equally successful in correcting axis deviation.

Despite the detection of variations in changed knee joint morphology between FlexTacks and eight-Plates we do not believe that a change of 1–2° has any clinical implications, as they keep within the physiological variation and measurement error (Figure 4) [18].

Limitations

First, only 7 patients were included in the tibial eight-Plate group, rendering it difficult to draw conclusions from these findings. Second, the morphological changes were evaluated in 1 plane only, the coronal plane radiographs, as sagittal plane radiographs are not routinely part of the follow-up protocol. Ballhause et al. included sagittal plane analysis of the tibia and did not report any changes in knee joint morphology in this plane [16]. Third, the study addresses radiological evaluations of the changes in knee joint morphology and not clinically significant changes. Fourth, the study does not account for differences in patient positioning or malrotation of the limb, which may affect measurements [19]. However, long standing radiographs were assessed and grossly malrotated images were discarded from further analyses.

Conclusion

The effect of temporary hemiepiphysiodesis using tension-band devices (eight-Plate or FlexTack) to correct coronal angular deformities of the knee on the radiographic joint morphology seems to be minimal and without clinical implications.

Study design, conceptulization, methods: all authors; resources: GG, BMM, RR; supervision: JDR, GG; BMM, AAA, RR, AF, BV; data collection: EH, CA, AM, MM, BV, JDR, AL, GT, AF; data analysis: VWE, BV, EH, JDR, AF; interpretation of results: all authors; writing the first draft: EH, CA, BV, JDR, AF; critical revision: GG, BMM, AAA, VWE, AL, GT, RR; revision after peer-review: EH, CA, VWE, BV, AF, JDR.

Handling co-editor: Ilkka Helenius
Acta thanks Elhanan Bar-On and Jaap J Tolk for help with peer review of this manuscript.

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