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Original article

Correction of pediatric angular deformities in lower limbs through guided growth using a novel flexible plate system

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ABSTRACT

Introduction: Tension band plates (TBP) for guided growth (GG) are the gold standard treatment for angular deformities around the knee. EPIFLEX® is a novel flexible TBP that adjusts to the patient's bone anatomy.
Hypothesis: GG using a flexible TBP produces satisfactory correction rates with minor complications in the pediatric population with angular deformities around the knee.
Materials and methods: A retrospective evaluation of 33 patients (60 knees) treated for genu varum and valgum with hemiepiphysiodesis using a flexible TBP between 2017 and 2020 was performed. The study aimed to assess correction and complication rates; patients who completed treatment were included regardless of the follow-up times after implant removal.
Results: Thirteen females and 20 males with a median age of 10 years were included. The median treatment duration and follow-up were 10 and 22 months. The median monthly rate of change of mLDFA and mMPTA was 0.67° and 0.57°, respectively. A successful correction was achieved in 90% of the cases. There were no cases of infection or implant failure. Four cases presented overcorrection and two undercorrection; no significant relation with deformity or obesity was found.
Discussion: GG using this flexible TBP showed satisfactory correction rates with a low incidence of complications and no implant failure. It provides flexibility through good adaptability to the bone anatomy and mobility of the screws avoiding implant protrusion or breakage.
Level of evidence: IV; observational descriptive case series.

1. Introduction

Angular deformities of the lower limbs are frequent in pediatric orthopedic consultation [1]. Marked and progressive deformities around the knee, often associated with pathological conditions, can affect gait and produce pain or joint instability, requiring surgery [1,2]. Guided growth (GG) through physiodesis allows correction of angular deformities in skeletally immature patients by growth inhibition in a segment of the physis, replacing the osteotomies and minimizing the risk of complications [1–3]. The temporary hemiepiphysiodesis aims to achieve a regulated correction rate without permanently damaging the physis through other methods such as transphyseal screws, staples or tension band plates (TBP) [1–5], the latter the most currently used technique with satisfactory results [1,2].

In 2017, we began using a new flexible tension band, hypothesizing that GG using this device produces satisfactory correction rates with a low incidence of complications in the pediatric population with angular deformities around the knee. EPIFLEX® is a patented TBP developed in 2016 by Industrias Medicas Sampedro in Colombia. The device, made of biocompatible stainless steel (316 LVM) with two rigid ends joined by flexible cables, showed an average maximum resistance of 3183 ± 0.667 kN under tensile stress biomechanical tests. Considering that the approximate static equivalent loads born by the growth plates of the proximal tibia and distal femur are 0.5 kN each [4], the device presents a safety factor of 6, sufficient to resist the stress experienced during a GG process. Additionally, the flexibility of the plate allows divergence of the screws, avoiding the bending in 3 points, reducing the possibility of failure or breakage of the screws.

The clinical results of GG using EPIFLEX® have not been documented in the literature. The study's main objective was to evaluate the correction rates and complications of a series of patients with angular deformities around the knee treated using this device.

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2. Patients and methods

2.1. Patients

After approval by our institutional review board, we retrospectively reviewed the clinical charts of all consecutive patients who, since 2017, undergone surgical treatment for pathological angular deformities around the knee through GG using the flexible system EPIFLEX® (Industrias Médicas Sampedro, Medellín, Colombia). The implant was used in skeletally immature patients with deformities in the coronal plane. No cases were excluded based on follow-up time after plate removal.

We extracted demographic information, weight-to-age percentiles, etiologies and the type and degree of angular deformities diagnosed through full-length standing anteroposterior radiographs of both lower limbs with the patella facing forward. For bilateral compromise, each extremity was considered an individual unit.

The surgical planning followed the method described by Sabharwal et al. [6], considering the mechanical lateral distal femoral angle (mLDFA), mechanical medial proximal tibial angle (mMPTA), tibiofemoral angle (TFA) and by Stevens et al. [7], considering three zones for the mechanical axis deviation (MAD).

2.2. Surgical procedure

For distal femoral valgus with mLDFA below 85° and MAD in zones -2 or -3, the plate was placed on the medial aspect of the distal femur, and for proximal tibial valgus with mMPTA greater than 90° and MAD in zones -2 or -3, it was placed on the medial aspect of the proximal tibia. When the deformity involved two centers of rotation of angulation (CORAs), two plates were placed medially, one on the femur and one on the tibia.

For distal femoral varus with mLDFA greater than 90° and MAD in zones +2 or +3, the plate was placed on the lateral aspect of the distal femur and for proximal tibial varus with mMPTA less than 85° and MAD in zones +2 or +3, it was placed on the lateral aspect of the proximal tibia. With two involved CORAs, one plate was placed on the lateral femur and one on the lateral tibia.

The surgical technique follows the same steps that of any TBP implanting. In brief, a skin incision is performed longitudinally over the anatomical segment to be corrected when the growth plate is located with the image intensifier. After dissecting and when the bone surface is appreciated, a 1.5 mm Kirschner pin is placed in the epiphysis. The not cannulated and not locked screw is longer than 50% of the epiphysis width and the plate size, so the metaphyseal hole housing the screw does not touch the physis. With the first epiphyseal screw in position, the plate is placed perpendicularly to the physis along the bone axis, attaching to the bone contour (Fig. 1). The second pin is inserted through the plate hole at the metaphysis set at an angle away from the growth line, avoiding damage and parallel to the epiphyseal screw. The metaphyseal screw, not cannulated and not locked, is also 50% or more of the width of the metaphysis. The proper position and length of the screws are verified in coronal and sagittal projections (Fig. 2).

2.3. Postoperative follow-up

All patients were allowed full knee mobility and weight-bearing without external support in the immediate postoperative period. Patients were periodically followed and the plates were removed when the correction was clinically and radiographically achieved.

We investigated any complications such as infection, implant breakage or failure that required revision surgery, implant discomfort during the treatment and the presence of over or undercorrection.

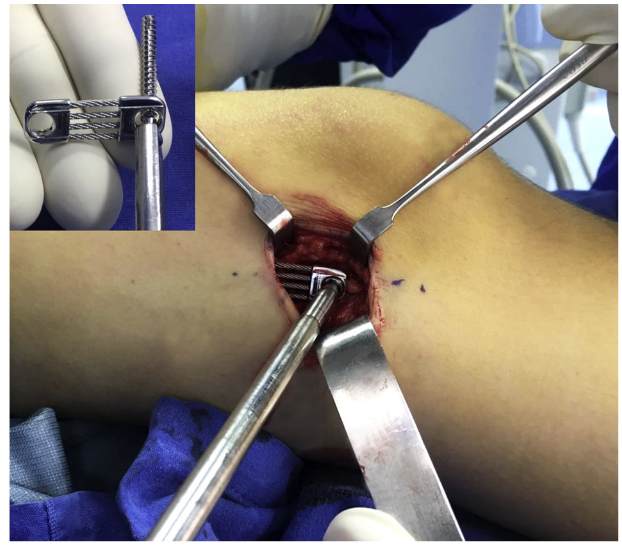

Fig. 1. Placement of the epiphyseal screw and plate to the femoral epiphysis above the periosteum. The insert shows the characteristics of the device and the position in which it is placed.

Fig. 2. The fluoroscopic view is used to verify the position of the screws; the plate fits the anatomy of the medial femur, attaching to its contour.

2.4. Statistical analysis

The statistical package for the social sciences (SPSS) software version 25.0 (IBM SPSS® Statistics, Chicago) was used. After the sample distribution evaluation, non-parametric tests were used for the analysis. The quantitative values were expressed as medians and ranges, and the qualitative as absolute frequencies. The magnitude and rate of correction were stratified by segments (tibia, femur, or both), deformity (varus or valgus) and the presence of obesity according to the center for disease control and prevention (CDC) weight-to-age percentiles [8]. The comparison of pre-surgical and last follow-up values was performed with the Wilcoxon Signed-Rank Test. The correction rates were correlated with age and weight-for-age percentiles and assessed according to sex and weight categories using the Spearman and Kruskal-Wallis tests. Values of $p < 0.05$ were considered statistically significant.

Table 1
Basal characteristics by type of deformity.

	Genu valgum (38 Knees)			*p*-value	Genu varum (22 Knees)			*p*-value
	Tibia (8)	Femur (18)	Both segments (12)		Tibia (14)	Femur (4)	Both segments (4)	
[b]Sex								
Male	4	9	10	0,148	10	4	0	0,008[c]
Female	4	9	2		4	0	4	
[a]Age (years)	10 (3–11)	9 (4–13)	4 (3–14)	0,041[c]	12 (4–13)	11 (9–13)	10,5 (9–12)	0,568
[b]Etiology				0,010				0,062
Idiopathic	8	13	4		10	4	2	
Secondary to overcorrection					2			
Blount's disease					2			
Rickets								
Congenital pseudoarthrosis			1					
Cerebral palsy		1						
Morquio disease			4					
Multiple congenital exostoses		4						
Epiphyseal dysplasia/Post-axial hypoplasia			3					
[a]Weight-for-age percentile (kg)/age	83 (69–99)	88 (23–99)	22 (1–99)	0,105	49 (1–83)	67 (61–73)	19 (10–28)	0,299
[b]Obesity (according to weight-for-age percentile)	3	7	3	0,847				-
[a]Treatment lenght (months)	9,5 (8–17)	10 (6–12)	13 (6–18)	0,037[c]	10 (6–17)	9,5 (8–11)	18 (11–25)	0,137
[a]Follow-up (months)	24 (14–24)	16 (14–24)	24 (12–24)	0,133	14 (12–24)	20,5 (18–23)	27 (26–29)	0,007[c]

[a] Values expressed as medians (min-max).
[b] Values expressed as absolute frequencies.
[c] Statistical significance ($p < 0{,}05$).

3. Results

Thirty-three patients (60 knees) with a median age of 10 years (range, 3–14) were included. There were 38 femoral and 36 tibial segments involved. The median treatment duration and follow-up were 10 (6-25) and 22 (12-29) months. The basal characteristics stratified by deformity are described in Table 1.

The median monthly rate of change of mLDFA and mMPTA was 0.67°(0.3°-1.4°) and 0.57°(0.18°-1°), respectively. The median time to achieve correction was 10 months (range; 6-12 for distal femur and 6-17 for proximal tibia). When both segments were involved, the median monthly correction rate of mLDFA and mMPTA was 0.64°(0.2°-1.92°) and 0.68°(0.33°-1.25°), respectively and the time to achieve correction was 13 (6-25) months. The correction rates were not significantly different when one or two segments were involved. The pre-surgical and post-surgical measurements at the last follow-up are displayed in Table 2 and two representative cases are shown in Figs. 3 and 4.

The magnitude of correction and the correction rates did not differ in the bi-variate analysis by either sex, etiology, obesity, or age ($p > 0.05$).

There were no cases of infection or implant failure. Localized pain associated with the device occurred in one case; a 13-year-old non-obese patient with an idiopathic deformity presented pain at the end of treatment and the plate was removed without consequences. There were four overcorrection cases and two undercorrection with no significant relation to the deformity or obesity.

4. Discussion

The treatment of angular deformities around the knee in skeletally immature patients with TBP has shown high efficacy and low complication rates [9–11]. In this series of 60 coronal deformities, GG using this novel flexible band showed satisfactory correction rates, 90% successful alignment, a few complications and zero implant failures.

TBP is the most popular treatment method for angular deformities around the knee, acting as a focal hinge at the perimeter of the physis with an extraperiosteal rigid plate that hardly adapts to the patient's anatomy secured with two screws free to pivot in the holes while the physis grows [2,9,12]. When present, implant failure is caused by metaphyseal screw extrusion or breakage due to a 3-point flexion mechanism, mainly in obese patients with Blount disease [10]. There is plenty of evidence about the efficacy of the different TBP among all pediatric age groups and etiologies [9,10,13,14]. In a systematic review, Kumar et al. [9] found mean mLDFA and mMPTA correction rates of 0.87° and 0.72° per month, an average treatment duration of 15.3 months and successful correction and complications rates of 91.2% and 5.6%, respectively. Additionally to the high effectiveness of the TBP, Shin et al. [10] showed a significant association between cannulated screws and increased body weight with implant-related complications, suggesting that more flexible systems could decrease the risk of device failure at the screw-bone interface (Table 3).

The EPIFLEX® flexible design allows excellent adaptability of the non-rigid plate to the bone anatomy, assembling adequately even in patients with bone pathologies and avoiding a possible failure due to a 3-point flexion mechanism and the consequent metaphyseal screw breakage. The system uses non-cannulated screws that provide resistance to torsion and flexion, allowing correction without failures or discomfort related to the device. Our results provide evidence that the flexible band produces similar correction rates to other devices of its class, with a median mLDFA and mMPTA correction rates of 0.67° and 0.57° (one segment) and 0.64° and 0.68° (two segments) per month and a median treatment duration of 10-13 months and a successful correction rate of 90%. We did not find differences among patients who were intervened in only one segment

Table 2
Comparative presurgical and post-surgical measurements.

	Tibia			Femur			Both segments		
	Presurgical	[a]Postsurgical	*p*-value	Presurgical	[a]Postsurgical	*p*-value	Presurgical	[a]Postsurgical	*p*-value
Genu valgum (38 knees)									
mLDFA				82 (70–86)	88 (87–92)	0.000[b]	80 (66–84)	88 (86–89)	0.002[b]
mLDFA correction rate					0.65 (0.30–1.40)			0.57 (0.33–1.92)	
mMPTA	96 (92–96)	89 (82–90)	0.010[b]				96 (88–105)	90 (82–90)	0.007[b]
mMPTA correction rate		0.67 (0.35–1)						0.55 (0.33–1.25)	
TFA	11.5 (10–14)	5.5 (4–7)	0.011[b]	10.5 (8–22)	5 (3–7)	0.000[b]	15 (9–26)	6 (3–7)	0.002[b]
MAD	-2 ((-2)-(-2))	-1 ((-1)-1)	0.007[b]	-2 ((-3)-(-2))	1 ((-1)-1)	0.000[b]	-3 ((-3)-(-2))	-1 ((-1)-1)	0.003[b]
Genu varum (22 knees)									
mLDFA				93 (92–94)	87 (87–88)	0.059	94.5 (92–98)	89.5 (88–90)	0.068
mLDFA correction rate					0.59 (0.55–0.75)			0.29 (0.20–0.55)	
mMPTA	83 (80–85)	88.5 (83–90)	0.001[b]				83 (80–84)	94 (89–98)	0.068
mMPTA correction rate		0.50 (0.18–0.83)						0.74 (0.45–1.06)	
TFA	1 ((-23)-3)	5 (4–7)	0.001[b]	3 (2–3)	7 (6–7)	0.046[b]	-1 ((-5)-3)	8.5 (7–10)	0.063
MAD	2 (2–3)	1 (1–1)	0.000[b]	2 (2–2)	1 (1–1)	0.04[b]	3 (3–3)	-0.5 ((-2)-1)	0.063

All values are expressed as medians (min–max).
[a] Postsurgical values at the last follow-up.
[b] Statistical significance ($p < 0.05$).

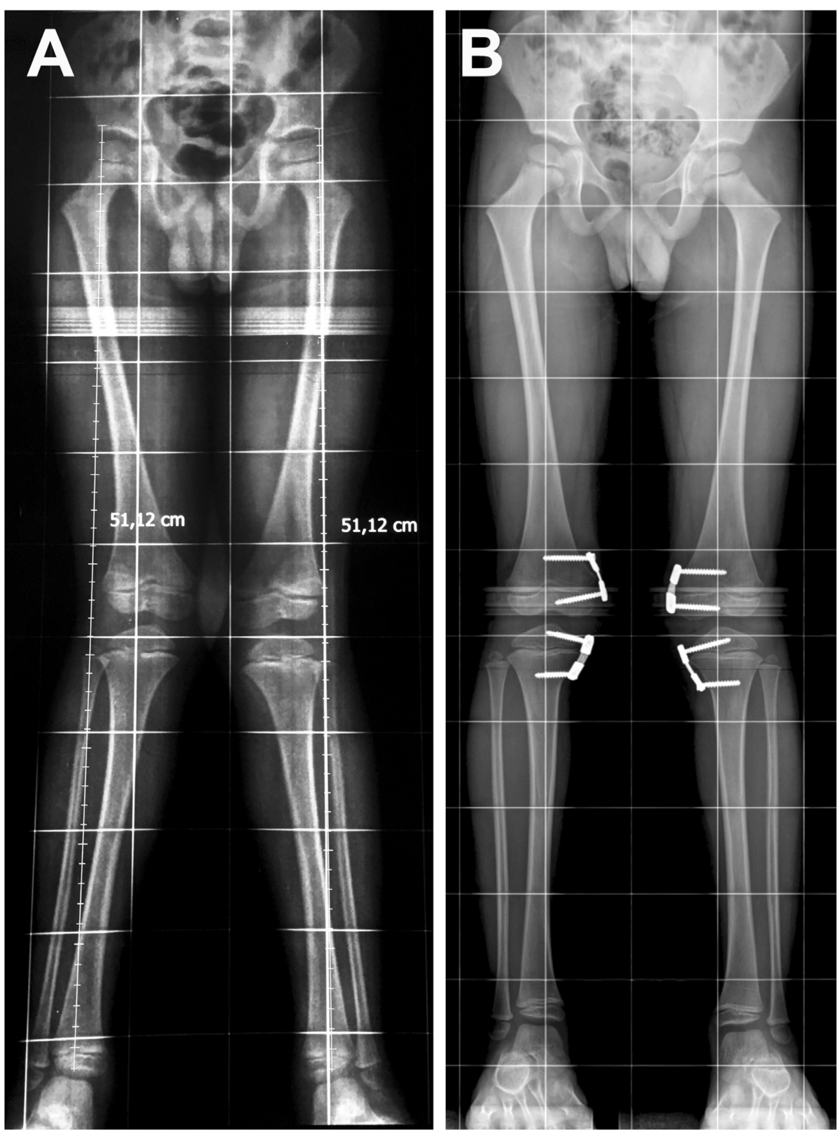

Fig. 3. Presurgical X-rays (A) of a 4-year-old patient with idiopathic genu valgus with a MAD in zone -3. Post-surgical X-rays (B) show the anatomical angles correction and normalization of the MAD to zone 1.

Table 3
Overview of results of GG with different devices for correction of coronal deformities around the knee.

Author (year)/Type of study	*n* patients/*n* studies	Etiology (*n* [%] studies or knees)	Device (N knees)	Age (years/range)	Follow-up (months/range)	Correction success (%)	Correction rates (per month)	Complications (*n*/%)
Kumar (2016) [4]/Pospective series	37 (63 knees)	Skeletal dysplasia (4)	TBP:		24			Failure:
		Idiopathic genu valgum (38)	8-P (31)	7.3 (3.5–12)		93.5%	1.4° (1°–2°)	6.5%
		Post-rachitic genu valgum (11)/varum (8)	Staples (32)	7.8 (4–12)		93.75%	1.2° (0.75°–2.33°)newline (*p*-value = 0.71)	12.5%newline (*p*-value = 0.43)
		Congenital deformity (2)						Migration (staples) 6.25% (*p*-value = 0.49)
Shin (2018) [10]/Retrospective series	52 (115 plates)	NA	TBP: PP (63) 8-P (30) HP (22)	11.7	18.4	81.7%	0.51°±0.42° 0.55°±0.33° 0.39°±0.44°newline (*p*-value = 0.43)	4/63 3/30 0/22newline (*p*-value = 0.92) Total: 6.1%
Kumar and Sonanis (2018) [9]/Systematic review	215 (350 knees)/7 studies	Idiopathic 33% Pathological 67%	TBP (8-P)	9.5 (2–16)	18.9 (12.4–24)	91.2% (196/215)	mLDFA 0.87° (0.65°–1.3°) mMPTA 0.72° (0.5°–1°)newline Deformity cor-rectionnewline 1.28° (0.93–1.53)	Hardware problems (5) Overcorrection/leg length difference (5)newline Infection (1)newline Stiffness (1)newline Total: 5.6%
Burghardt (2018) [13]/Systematic review	~260 (345 knees)/12 studies	Blount's disease		2–16	12–48			Migration or breakage
			Staples (235) TBP (8-P 102/Pediplates 8)			50–88% 0–89%	10.1°–11.9°/year 5°–9.5°/year	Staples: (15–27%) TBP: (25–50%)
							MAD/year: Staples (12.7 mm) TBP (8.9 mm)	Overcorrection (3 studies with staples)
Danino (2019) [11]/Retrospective multicentre series	206 (372 plates)	Idiopathic	TBP	12.5 ± 2.3	16 ± 2.2	93% (mLDFA) 92% (mMPTA)	mLDFA 0.85° mMPTA 0.78°	Infection 1% Early limited ROM 1%
Knapik (2019) [5]/Systematic review	252 (501 knees)/11 studies	Idiopathic genu valgum						Recurrent deformity

Table 3 (*Continued*)

Author (year)/Type of study	*n* patients/*n* studies	Etiology (*n* [%] studies or knees)	Device (N knees)	Age (years/range)	Follow-up (months/range)	Correction success (%)	Correction rates (per month)	Complications (*n*/%)
			TBP (152) Staples (349)		11.9 ±1.9 12.8 ± 7newline (p = 0.80)		0.64°±0.3° 0.73°±0.4°newline (p = 0.61)	8.8% vs. 3% (p = 0.05) Device failurenewline 0% vs. 1.7%newline Overcorrection-newline 0% vs. 2.1% (p = 0.12)newline Undercorrection-newline 0.9% vs. 0% (p = 0.95)
Martínez (2017 and 2019) [15,16]/2 retrospective series	22 (44 knees)	Idiopathic genu valgum	Screws and suture (24 knees) 8-P (20 knees)	11.5 (8–14)	12.3 (9.2–22.3) 16.5 (11.6–25.2)	100%	0.45° (1.0–3.75) 0.54° (0.21–1.48) (p = 0.33)	SS: surgical wound dehiscence (1) 8-P: No complications
Jain (2020) [14]/Retrospective series/Systematic review	40 (61 knees) in the series[a]/	Blount's disease	TBP:newline 8-P (18)/Pediplate (43)[a]	[a]9.6 (3.3–14.8)	[a]38 (8–119)			[a]Surgical/Mechanical failure (41%/11%)newline Associated with plate material (p = 0.023)
	8 studies (127 patients, 179 knees)		8-P (5 studies)/Pediplate (3 studies)	Early-onset (3 studies)/Late-onset (8 studies)	5–70			Surgical/Mechanical failure (11–72.2%/0–50%)
Our study	33 (60 knees)	Idiopathic (41) Blount's disease (2) Morquio disease (4) Multiple congenital exostoses (4)newline Other (9)	Flexible TBP	10 (3–14)	22 (12–29)	90%	mLDFA 0.67° (0.3–1.4) mMPTA 0.57° (0.18–1)	Localized pain (1) Overcorrection (4) Undercorrection (2)

TBP: Tensión band plates; PP: Peanut plate; 8-P: Eight-plate; HP: Hinge plate; SS: Screw and suture; DC: Dynamic compression plate; ROM: Range of movement.

[a] Data from the case series.

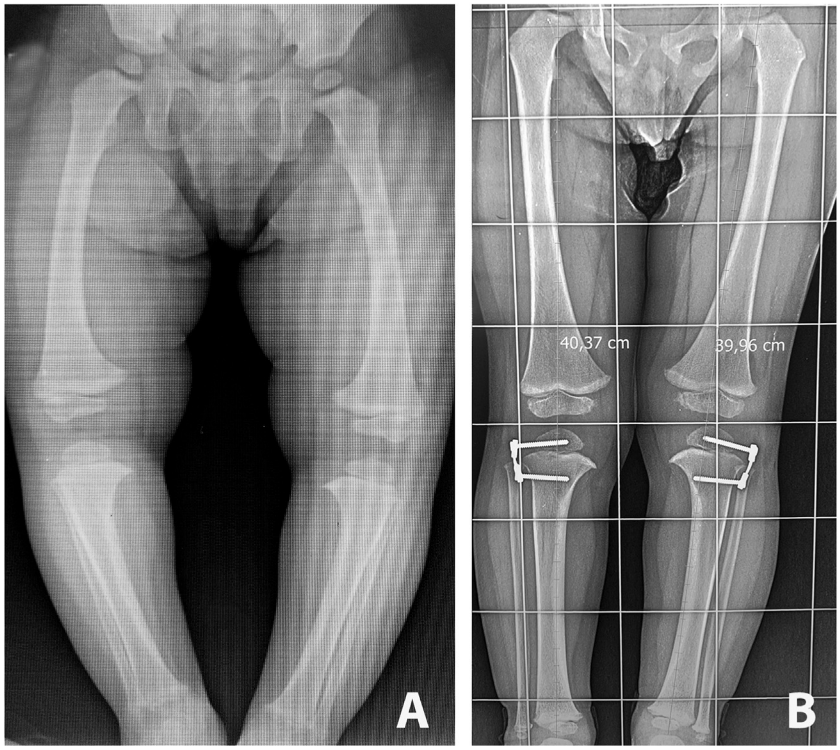

Fig. 4. Presurgical X-rays (A) of a 3-year-old patient with Blount's disease (genu varus) with medial peak in the tibial plateau and MAD in zone -3. Post-surgical X-rays (B) of the correction 7 months after the procedure with adequate alignment of the limb and MAD in zone -1.

compared to those with two segments involvement, demonstrating that the device achieves satisfactory results in more complex deformities. Additionally, we did not find differences in the correction rates between patients with idiopathic and non-idiopathic deformities; however, it must be carefully interpreted as the ratio was 41:19 cases.

There was only one case of implant discomfort in a patient with femoral genu varum associated with dissecting osteochondritis; at the end of treatment, having achieved the desired correction, the pain at the implant site-without limitation to mobility-improved after the plate removal, not affecting the outcome.

Some authors have shown higher complication rates in patients with pathological physis like Blount disease [9,13,14]. Likewise, childhood obesity associated with varus deformity has been linked with high surgical failure rates [13,14]. In our study, the inclusion of only one non-obese patient (2 knees) with Blount disease and 13 segments from obese patients, all with valgus deformity, could explain the absence of complications. Despite having patients with compromised physis, none presented complications or failures and their correction rates were similar to those with idiopathic deformities.

Six cases (10%) failed to achieve the desired correction. Overcorrection was planned in one patient with epiphyseal dysplasia, foreseeing a possible rebound in the long-term and in two patients (three segments), it occurred due to a delay in the follow-up and plate removal caused by the pandemic lockdown. Undercorrection occurred in a 12-year-old patient with idiopathic tibial valgus who skeletally matured earlier; however, the MAD remained in a borderline area.

Our outcomes are comparable to those shown by other authors using different devices such as staples [12] or more affordable ones like screws and non-absorbable filament used by Martínez et al. [15,16] in patients with genu valgum (Table 3).

Our study had some limitations. The retrospective design could have introduced a selection bias and compromised the data quality; it was controlled by including and following all consecutive patients using the plate. A possible assessment bias must be considered as the senior surgeons planned and evaluated their cases. However, the principal author, a fellow of children's orthopedics, accompanied the whole process of each patient, controlling this bias.

5. Conclusion

This flexible TBP provides adaptability to the bone anatomy and mobility of the screws, avoiding failure due to a 3-point flexion, preventing implant protrusion or breakage and making it functional for the whole treatment length. It is an effective alternative for GG to treat coronal angular deformities around the knee; whether it is superior to other systems or effective in correcting different deformities is a matter of further comparative studies.

Disclosure of interest

Doctors Quintero and Gil declare that they have no competing interest.

Doctor Galban received royalties from Industrias Medicas Sampedro as a consultant and participated in developing the EPI-FLEX device.

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None.

Authors' contribution

Daniel Quintero: data acquisition, analysis, interpretation and drafting of the article.

Miguel Galbán: conception and design of the study, drafting the article and final approval of the version to be submitted.

Cesar Gil: conception and design of the study, drafting the article and final approval of the version to be submitted.

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