Paediatric lower limb deformity correction with the Eight Plate: adverse events and correction outcomes of 126 patients from an international multicentre study

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No large multicentre studies have yet been published on tension-band-like implants such as the Eight Plate to treat limb-length discrepancies and varus valgus deformities in children. Therefore, we carried out a retrospective international multicentre study including 126 patients to assess outcomes and to reliably quantify the incidence of implant-related and growth-plate related adverse events (AEs). Correction was achieved in 66% of varus valgus deformities and in 59% of limb-length discrepancies and maintained in 85%. Twenty (18%) patients experienced 43 AEs, which were primarily screw related. The AE rate of the Eight Plate is low; however, many of them could be avoided through tighter monitoring. *J Pediatr Orthop B* 00:000–000

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Introduction

Lower extremity angular deformities and limb-length discrepancies are among the most common nontraumatic conditions in children being referred to paediatric orthopaedists [1]. Recently, deformity correction through temporary (hemi) epiphysiodesis has gained widespread popularity [1–3]. This is primarily because providing gradual deformity correction may not only allow to avoid more extensive surgery (e.g. osteotomy), but it is also reversible, that is, it allows resumption of growth once the implant has been removed.

The latest developments in the area are implants acting as tension-bands that slow down growth at the implantation site. Consequently the procedure is named 'growth modulation'. To achieve sustainable deformity correction, correct timing for implantation and removal require precise calculation of the expected remaining growth [1]. To date, several studies on the use of tension-band type growth modulation implants have been published, but no multicentre study and only a few reports on patient cohorts greater than 30 patients are available [4–8].

Good correction success rates have been reported and complications and recurrence of deformity seem to be rare [5–11], but are still the major drawbacks of growth modulation. As a reliable quantification of rare events requires large sample sizes, we initiated an international multicentre study, reflecting the 'real-life use' of the Eight Plate.

The primary aim of our study was to quantify adverse events (AEs) related to growth plates or implants. Further analyses included evaluation of whether the planned correction was achieved and the achieved correction was maintained over time as well as the quantification of all other local AEs and additional surgeries.

Materials and methods

The study was carried out as a retrospective international multicentre study and registered with the *http://www.ClinicalTrials.gov* Identifier NCT01625975. Ethics approval was obtained at all sites before data collection commenced. Data were identified from hospital charts and entered into our REDCap database (v 4.1.3; Vanderbilt University, Nashville, Tennessee, USA) in an anonymized manner between October 2012 and December 2013. Consecutive patients from each participating hospital who had undergone implantation and removal of the Eight Plate (Orthofix, Bussolengo, Verona, Italy) for angular knee deformities and/or limb-length discrepancies (or if no removal was performed: who had reached skeletal maturity) within 5 years before the start of the study were included after they had been screened for inclusion and exclusion criteria (Table 1).

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Table 1 Inclusion and exclusion criteria

Inclusion criteria
Age range at implantation of the Eight Plate growth-modulation devices: 18 months to 17 years
Treatment with Eight Plate of varus valgus deformities of the knee and/or leg-length discrepancy because of any of the following:
Diseases or syndromes affecting the growth plate (e.g. Blount's disease)
Post-traumatic, affecting the growth plate
Postinfectious, affecting the growth plate
Idiopathic aetiology
Documented implantation of Eight-Plate system(s) within 5 years before study initiation
Documented explantation of all Eight-Plate system(s) (UK: according to the local standard of care not all implants were removed, in these cases: documentation of the timing of skeletal maturity)
Able to walk without walking aids before Eight-Plate implantation
Exclusion criteria
Any tumour possibly influencing the growth plate(s) before last follow-up visit considered for this study
Cerebral palsy
Total epiphyseal closure of the growth plates undergoing growth modulation at time point of initial Eight-Plate implantation

All patients were treated according to the local standard of care, which entailed obtaining erect long-standing radiographs before deciding to perform temporary epiphysiodesis. At the implantation site, single Eight Plates were inserted according to a previously described technique [6]. Implants were routinely removed after the desired correction had been achieved in all except one of the centres, where the timing of Eight Plate implantation was aimed at achieving correction at skeletal maturity.

Data collection time points

Data collection included information documented at baseline, at all visits for additional surgery, at implant removal as well as at the final follow-up (FU). Final FU had to take place at a minimum of 6 months after device removal. In cases where implants were not removed, the respective documentation time point was skeletal maturity. The timing of the FU visits followed the local standard of care. AEs were documented throughout the entire period from Eight Plate implantation up to the final evaluation.

Baseline data

Collection of baseline data included patient demographics, indication and size and location of implants.

Outcome data

For evaluation of the incidence of growth-plate or Eight Plate-related AEs, data on all local AEs were collected from patients' charts and classified into previously defined categories.

Growth plate-related AEs were defined as premature partial or total epiphyseal closures or any other additional AE related to the growth plate. Premature closure was noted by means of radiographs if a physis was completely closed or markedly narrower than the contralateral physis or other nearby physes located in the same extremity. Premature closure was defined as partial if ossification had occurred in only a part of the physis and a partial gap was still visible and as complete if ossification had occurred in the complete physis and no gap was visible on the radiograph anymore. Eight plate-related AEs were defined as implant loosening (radiolucent lines around the implant or parts of the implant) or failure (breakage or bending of any part of the implant), screw migration through the growth plate or any other additional AE related to the Eight plate.

It is noteworthy that most other publications do not count epiphyseal closures, implant loosening or failure, or screw migration through the growth plate as complications.

Assessment of Eight Plate-related and growth plate-related AEs was performed clinically and radiologically by the investigators at the individual study sites according to the local standard of care.

Further outcome data included varus valgus deformities (VVD), limb-length discrepancies (LLD), functional deficits, any additional implant-related surgery and any additional local AE including 'failure of growth modulation devices other than an Eight Plate', 'worsening of deformity', 'functional knee deficit' and 'other local AEs'.

Deformity was evaluated by the local investigators, who categorized the mechanical axis by orthoradiogramm in 5° and 10 mm increments. Loss of correction, for example, through rebound (accelerated growth on the side of the physis that was temporarily restrained) [12], was defined if, after explantation, deformity recurred and the resulting varus or valgus was at least 5° or the length discrepancy was at least 10 mm.

Statistical analysis

Descriptive analysis was carried out on the full cohort of patients with one exception: in one centre, outcome on AEs was incomplete and it was not possible to complete it. Thus, data from this centre were altogether excluded from this analysis to minimize potential bias introduced through selective reporting. The statistical analysis was carried out using the software STATA, version 12 (Stata Corporation, College Station, Texas, USA).

Study population

The study comprises data of 126 patients. Slightly more boys (60%) than girls were included. The vast majority of patients (75%) had VVD, whereas in 18%, the reason for surgery was LLD and the remaining 7% were treated for both types of deformity. The mean BMI was 22.9 kg/m^2. The median age of the patients at index surgery was 12.4 years (first and third quartile: 10.6; 13.6). The age distribution was uniform over all centres except one, which indicates how cultural differences may influence the choice of timing of this procedure. Details on demography and indication are shown per individual study centre in Table 2. The planning and timing of

Table 2 Patient demographics and indication by study centre (all seven centres included)

	Study centre [*n* (%)]							
Characteristics	Center 1 (*N* = 19)	Center 2 (*N* = 9)	Center 3 (*N* = 17)	Center 4 (*N* = 13)	Center 5 (*N* = 28)	Center 6 (*N* = 6)	Center 7 (*N* = 34)	Total (*N* = 126)
Sex								
Female	7 (37)	2 (22)	9 (53)	4 (31)	11 (39)	3 (50)	14 (41)	50 (40)
Male	12 (63)	7 (78)	8 (47)	9 (69)	17 (61)	3 (50)	20 (59)	76 (60)
Age at visit (years)								
Mean	12.6	12.0	8.1	12.3	12.4	13.9	11.3	11.6
SD	1.8	3.5	3.4	2.9	2.4	2.1	3.0	3.1
Median	12.4	12.4	8.7	12.7	13.0	13.7	12.2	12.4
Q1; Q3	11.1; 13.6	11.8; 14.3	5.9; 10.9	11.8; 13.6	11.6; 13.7	13.0; 15.3	10.8; 13.3	10.6; 13.6
Minimum; maximum	10.1; 16.5	5.3; 15.9	1.8; 14.1	4.8; 16.5	5.1; 15.8	10.9; 17.0	2.8; 14.7	1.8; 17.0
BMI (kg/m^2)								
Mean	22.9	25.2	23.3	22.2	19.8	23.9	19.8	22.9
SD	3.7	6.0	6.9	5.2	5.8	6.1	5.6	3.7
Median	22.0	27.6	25.8	20.5	16.9	24.8	17.9	22.0
Q1; Q3	20.1; 24.5	20.1; 28.4	17.8; 27.3	17.9; 28.0	15.1; 27.1	18.7; 28.2	16.9; 21.4	20.1; 24.5
Minimum; maximum	18.4; 30.4	15.7; 31.6	11.8; 33.4	17.9; 28.0	13.6; 27.8	16.9; 31.1	12.0; 41.8	18.4; 30.4
Indication for Eight Plate								
LLD	7 (37)	2 (22)	0 (0)	6 (46)	1 (4)	1 (17)	6 (18)	23 (18)
VVD	11 (58)	6 (67)	17 (100)	6 (46)	24 (86)	5 (83)	25 (74)	94 (75)
LLD and VVD	1 (5)	1 (11)	0 (0)	1 (8)	3 (11)	0 (0)	3 (9)	9 (7)

LLD, limb-length discrepancy; Q1, first quartile; Q3, third quartile; VVD, varus valgus deformity.

surgery was based on the present discrepancy and not on the expected discrepancy at maturity.

The reason for deformity was idiopathic in most children (72%), whereas in 19%, a disease or syndrome had led to the deformity. In 6%, a previous trauma and in 2% a previous infection was the cause. Details on the causes of deformity stratified by indication are shown in Table 3.

In children operated for VVD alone, the angular deformities ranged from 24° of valgus to 29° of varus. In 83%, both legs were treated. Of the children with VVD, 27.7% were operated on the tibia, 45.7% on the femur and 26.6% on the femur and tibia.

The majority (68%) of children operated for LLD had a preoperative limb-length discrepancy of 20–29 mm, whereas in 32%, the length difference was 10–19 mm. A discrepancy of 7 mm has been recommended as a threshold for surgical correction [13]. Of the children operated for LLD, 4.5% were operated on the tibia, 36.4% on the femur and 59.1% on the tibia and femur. Details on the extent of angular deformity and limb-length differences at baseline are presented by indication in Figs 1 and 2, respectively. Of the children operated for VVD and LLD simultaneously, 44.4% underwent surgery of both legs. In children with both VVD and LLD, the limb-length discrepancy ranged from 0 to 49 mm and the alignment deformity ranged from 19° valgus to 9° of varus. In 33.3%, only the tibia was operated and in 66.7%, surgery was performed on both the tibia and the femur.

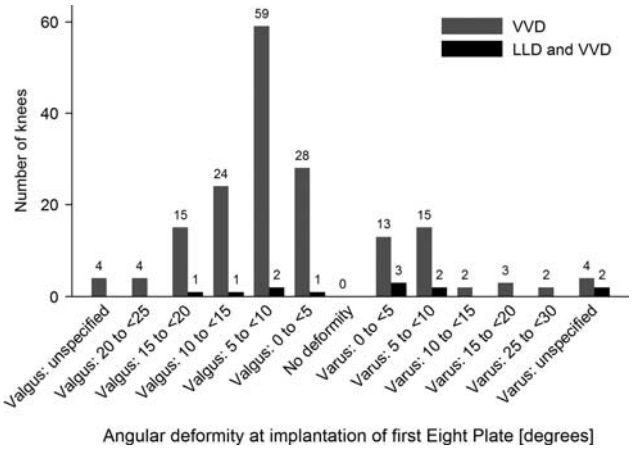
The mean in-situ time of the implant was 25.3 months in patients operated for VVD and LLD simultaneously, 18.9 months in patients operated for LLD and

Table 3 Causes of deformity (all seven centres included)

	Indication for Eight Plate [*n* (%)]			
Characteristics	LLD (*N* = 23)	VVD (*N* = 94)	LLD and VVD (*N* = 9)	Total (*N* = 126)
Primary cause of deformity	23	94	9	126
Idiopathic	10 (43)	76 (81)	5 (56)	91 (72)
Previous trauma affecting the growth plate	4 (17)	3 (3)	1 (11)	8 (6)
Previous infection affecting the growth plate	0 (0)	1 (1)	2 (22)	3 (2)
Syndrome or disease affecting the growth plate:	9 (39)	14 (15)	1 (11)	24 (19)
Syndromes	2	6	1	9
Klippel–Trenaunay (1), Schwachmann Diamond (1), Ellis van Crefeld (1), Loeys–Dietz (1), unspecified dysmorphia (1), (multiple) epiphyseal dysplasia (2), dysostosis cleido cranialis (1), achondroplasia (1)				
Perthes disease	3	0	0	3
Longitudinal defect	2	0	0	2
Genetic [multiple exostoses (1), cystnosis (1)]	0	2	0	2
Tumour	1	0	0	1
Rickets	0	5	0	5
Other	1	1	0	2
Amniotic constriction (1), tethering lateral femur (1)				

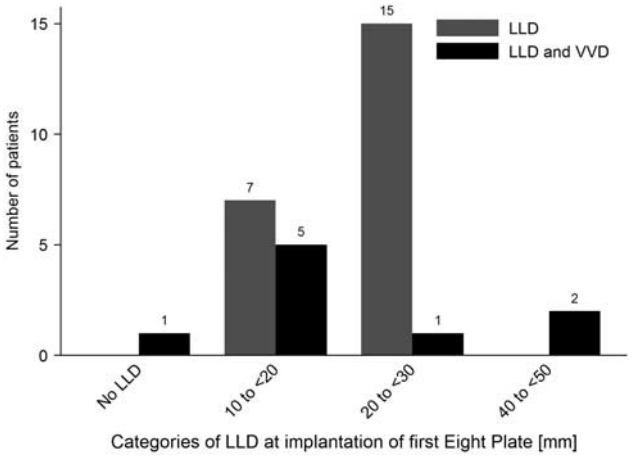
LLD, limb-length discrepancy; VVD, varus valgus deformity.

Fig. 1



Summary of angular deformity at implantation of the first Eight Plate for patient by indication for growth-modulation surgery involving varus valgus deformity (VVD) (all seven centres included).

Fig. 2



Summary of limb-length discrepancy (LLD) at implantation of the first Eight Plate for patient by indication for growth-modulation surgery involving LLD (all seven centres included).

14.2 months in patients operated for VVD. In nine (7%) patients all from the same centre, the Eight Plate was not removed according to the local standard of care.

Results

Adverse events

Information on AEs was available from all except one centre and is presented in Table 4. In total, 43 AEs occurred in 20 (18%) patients and nine patients experienced more than one AE.

With one exception, premature epiphyseal closures always occurred in both legs and usually subsequent to a neglected implant exchange or removal. Similarly, implant-related complications typically occurred in a clustered manner. For example, in one patient, all four implanted screws and in another patient, two of four implanted screws bent. In a further patient, two screws broke during explantation and in one patient a screw was initially reported as bent and then broke during explantation (Fig. 3). Only in two patients (one screw breakage, Fig. 4, and one screw bending) did isolated implant-related complications occur.

Table 4 Summary of adverse events at the patient level (data from six centres)

Characteristic present[a]	Total ($N=109$) Patients [n (%)]	95% CI
Total adverse events related to growth modulation	20 (18)	11.6–26.9
Adverse events related to growth plates or Eight Plate	13 (12)	6.5–19.5
Premature partial or total epiphyseal closure	5 (5)	1.5–10.4
Premature partial epiphyseal closure	5 (5)	1.5–10.4
Premature total epiphyseal closure	1 (1)	0.0–5.0
Adverse events related to Eight Plate	10 (9)	4.5–16.2
Screw loosening	2 (2)	0.2–6.5
Screw breakage	1 (1)	0.0–5.0
Screw bending	5 (5)	1.5–10.4
Screw migration through growth plate	2 (2)	0.2–6.5
Plate bending or breakage	0 (0)	0.0–3.3
Intraoperative complications (screw breakages at explantation)	2 (2)	0.2–6.5
Further adverse events		
Worsening of deformity	4 (4)	1.0–9.1
Functional deficits of knee (extension deficit, dorsal implant)	1 (1)	0.0–5.0
Other local adverse events	5 (5)	1.5–10.4
Superficial skin irritation	1 (1)	0.0–5.0
Superficial wound infection	3 (3)	0.6–7.8
Deep wound infection, perioperative haematoma/seroma, pseudobursa or knee joint effusion	0 (0)	0.0–3.3
Stiff knee (trapped soft tissue, treated with manipulation under anaesthesia and physiotherapy)	1 (1)	0.0–5.0
Unspecified adverse event	1 (1)	0.0–5.0

[a]The same patient can contribute towards more than one category.

Further surgery

In 21 patients, 25 surgical procedures between first implantation and final explantation of the Eight Plate took place. Fourteen of these surgeries were staged implantations or removals, that is, it had been intentional to implant or remove different plates in separate surgeries. Other reasons for additional surgeries were screw bending in one and screw loosening in two patients. Further additional surgeries were performed for newly emerging indications including rebound in four patients. Table 5 presents an overview about all additional surgeries.

Treatment success

In 66% of patients treated for VVD and in 59% of patients treated for LLD, no deformity remained at the time of implant removal. In patients treated for both,

Fig. 3

Male patient with Klippel–Trenaunay syndrome operated with 16 mm Eight Plates and 32 mm cannulated screws for limb-length discrepancy at the age of 11. The patient was lost to follow-up. Three years after initial Eight Plate implantation, the patient showed up again. At that time, both screws of the medial Eight Plate had migrated through the growth plate and screw bending was observed. In addition, the patient had developed a valgus deformity of the left leg and a partial premature epiphyseal closure, which resulted in a complete premature epiphyseal closure seven months later. During implant removal surgery, the head of the bent lateral proximal screw broke off. The thread was not removed and remained *in situ*. Supracondylar correction osteotomy of the distal femur was performed to correct the valgus deformity.

complete alignment correction was achieved in 67%, whereas complete length correction was achieved in 78%.

In 99 of 103 patients whose indications involved VVD, the Eight Plate was removed. Figure 5 presents an overview of the angular deformities at implant removal.

In patients whose indications involved LLD, the Eight Plate was removed in 27 of 32 patients. Figure 6 shows the length discrepancies remaining at implant removal.

In 81 patients, an FU examination was performed. The median age at final FU was 14.5 years (first and third quartile: 12.9; 15.8). Overall, in 15% of patients, a deviation from the initially achieved correction was noted at FU. The correction was maintained in 85 and 89% of patients treated for limb-length discrepancy and VVD, respectively, whereas in patients with a combined indication, the correction only lasted in 63%.

In seven of nine patients whose indication included VVD and who lost correction after implant removal, the reason was rebound, whereas this was only the case in one of three patients with LLD as an indication. The ages of patients with and without rebound were similar, with 14.0 and 14.3 years, respectively. Boys experienced rebound twice as often as girls; however, the low rebound incidence did not allow performing analytical statistics.

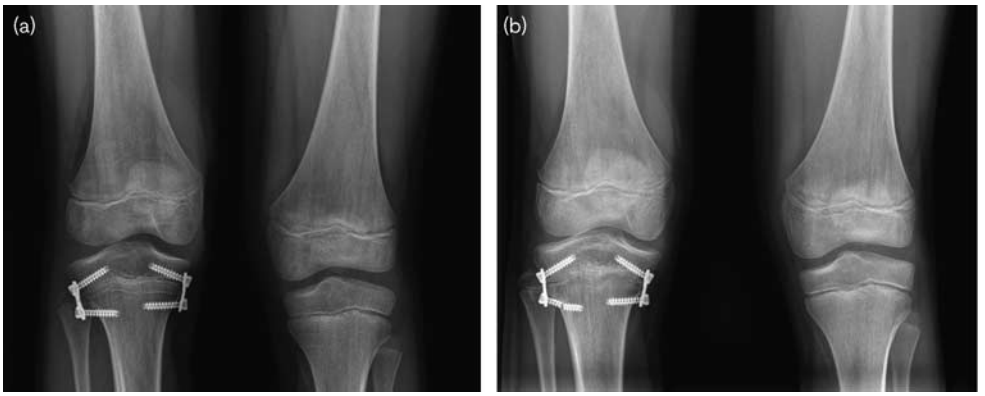
Discussion

Our primary aim was to quantify AEs and we found that the most common AEs were related to screws.

In 2% each, screw loosening or migration occurred. Loosening and migration have been reported at comparable rates by other researchers. Burghardt and Herzenberg [8] reported loosening in 2% and Stevens [6] reported loosening in 3% of patients; Ballal *et al.* [9] reported implant migration in 4% of patients.

Screw breakage in-situ occurred in one of our patients. Breakage of screws in-situ has so far mainly been reported in Blount patients [14,15] and has been attributed to the combination of excess weight and the altered structure of the physis, which are typical for Blount disease [15]. As we did not have any Blount patients in our series,

Fig. 4



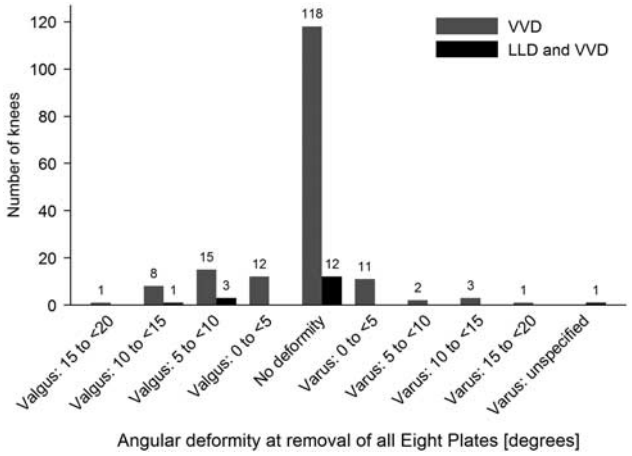
Male patient operated with 12 mm Eight Plates and 24 mm cannulated screws for a limb-length discrepancy of 2.5 cm because of fibular hemimelia at the age of 8. Uneventful postoperative course with normal radiograph findings 15 months after intervention (a), but screw breakage after 2.9 years (b). The aimed correction was achieved; the thread of the broken screw was not removed at Eight Plate explantation and remained *in situ*.

Table 5 Additional surgeries, that is, surgeries taking place between first implantation and final explantation of the Eight Plate (all seven centres included)

	VVD ($N=94$)	LLD ($N=23$)	LLD and VVD ($N=9$)	Total ($N=126$)
Patients with one additional surgery	9	1	7	17
Staged implantation	1	–	3	4
Staged implantation combined with staged removal	0	–	1	1
Staged removal	6	–	2	8
Staged removal combined with definitive epiphysiodesis according to Canale	0	1	–	1
Removal of loose screw with suspected infection (but negative culture)	1	–	–	1
Exchange of bent screw	1	–	–	1
Repositioning of loose screw		–	1	1
Patients with two additional surgeries	3	1	0	4
Additional growth-modulation surgery because of newly developed indication including rebound	3	1	–	4

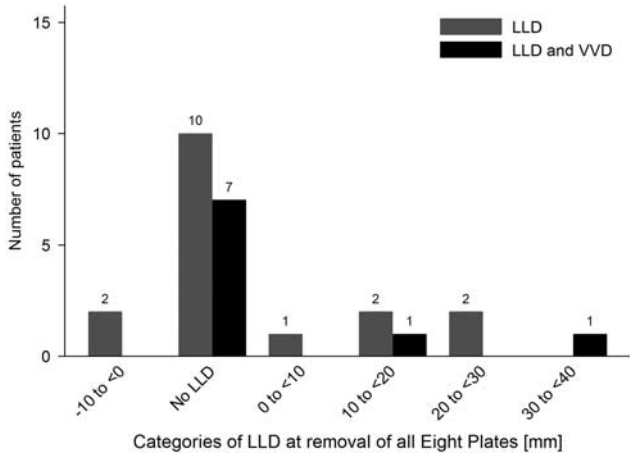
LLD, limb-length discrepancy; VVD, varus valgus deformity.

Fig. 5



Summary of angular deformity at removal of all Eight Plates for patient by indication for growth-modulation surgery involving varus valgus deformity (VVD) (all seven centres included).

Fig. 6



Summary of limb-length discrepancy (LLD) at removal of all Eight Plate of first Eight Plate for patient by indication for growth-modulation surgery involving LLD (all seven centres included).

the low rate of screw breakage is what would be expected.

In 5% of our patients, screws bent. No other reports of screw bending are known to us, but then, even though bent screws often precede implant failure, they do not always entail clinical problems, which makes us assume that this may be under-reported. It is noteworthy that the underlying mechanisms leading to screw bending are still unclear. In the situation of pronounced screw divergence, it seems obvious that with continuing growth, screw bending impends; thus, it is clearly advised to replace such a screw to avoid bending, future migration through the growth plate or even premature epiphyseal closure.

The second common AE was premature epiphyseal closure, which occurred in 5% of our patients.

We are not aware of other reports of premature epiphyseal closures with the Eight Plate.

Both screw-related events and premature closures often occurred clustered in our series, typically in patient presenting with several AEs who had not been seen by the treating surgeon for an extended time.

Tighter monitoring would have most probably allowed detection of these adverse developments early enough to take appropriate measures to halt them. The importance of tight postoperative monitoring seems to be crucial and has also been emphasized by other authors [12].

The majority of our patients had VVD. Of these, only 66% achieved full correction. This rate appears to be lower than the rates published from smaller cohorts in single-centre settings, which range between 82 and 94% [6–8,11,16]. As the patients included in this study reflect our first experience with the implant, the learning curve certainly contributed toward the relatively low correction rate. The highest reported correction rate can be found in the publication by Stevens in 2007. This prospective study included 34 patients and, except for two patients with adolescent Blount disease, all patients corrected their deformities, neutralizing the mechanical axis while preserving a horizontal knee to within 3° on a standing anteroposterior radiograph [6]. Tight quarterly

postoperative controls were carried out, which certainly contributed towards the excellent treatment success and the low complication rate (one reoperation to add a plate and replace a loose screw and one infection). This again indicates the importance of continuous patient monitoring after surgery.

In combined LLD and VVD diagnoses, we achieved complete alignment correction in 67% and complete length correction in 78% of patients. To the best of our knowledge, no other report on growth modulation for such combined diagnoses exists so far; thus, we cannot compare our results with others.

Finally, in children undergoing surgery for LLD, our success rate was 59%. Several other reports on the use of tension-band-like devices for LLD have been published. Lauge-Pedersen and Hägglund aborted an RSA study on the Eight Plate after they had observed almost no effect on growth retardation in their first two patients. On the basis of results from a previous study, they supposed that the time to observe the desired effect might have been too short; however, if this was indeed the case, the method should be labelled unpredictable. They also emphasized the risk of permanent physiodesis when leaving the plate in place for more than 18–24 months [17]. Stewart *et al.* [18] compared the Eight Plate to physeal ablation with drilling and curettage and found that growth arrest was significantly superior in the ablated physes. Gaumetou *et al.* [4] also noted that growth arrest after Eight Plate implantation was much lower than reported previously with percutaneous epiphysiodesis using transphyseal screws. Lykissas *et al.* [19] compared the safety and effectiveness of three mechanical devices (percutaneous transphyseal screws, tension band plates and staples) for the correction of limb-length discrepancies and found no significant difference among the three devices in terms of discrepancy reduction. Pendelton *et al.* achieved a final LLD of 0.5 cm or less in only 26% of patients with the Eight Plate and emphasize that growth modulation for length correction needs to be initiated sufficiently long before skeletal maturity [5].

Our experience is in line with the current opinion that growth modulation with Eight Plates is difficult to predict and has to be initiated earlier before skeletal maturity than when performing a permanent epiphysiodesis. This is based on the fact that using Eight Plates does not aim to induce a complete growth arrest but to modulate, that is, slow down, the growth. This makes timing of the procedure just before skeletal maturity difficult and is the main reason why close monitoring of growth is essential for success. The success of the Eight Plate relies on taking immediate measures such as screw exchange or explantation before complications such as migration of screws through the endplates or partial/complete closure of the physis become manifest.

In 85% of our patients, the achieved correction was maintained. The most common cause for loss of correction was rebound. Rebound has also been reported in other studies [6,7,9]. However, neither our study nor the other studies followed their patients up to skeletal maturity; therefore, caution needs to be exercised when interpreting such data until large prospective studies with long-term FU until skeletal maturity are available.

Our study also has limitations, which are mainly because of the retrospective multicentre study design. This entailed that all patients were treated according to the local standard of care; thus, the timing of FU examinations was not standardized and in one centre, implant removal was not always performed. In addition, FU information was not available from all patients; thus, interpretation of maintenance of correction requires caution. Also, we had not defined for how long patients needed to be followed. Even though the median age at final FU was as high as 14.5 years, it is obvious that many patients must have been skeletally immature at the time of study closure; thus, the definite outcome is not available.

Nevertheless, only this study design enabled us to gather data on the largest population published on the Eight Plate so far, allowing us to provide robust AE incidence estimates, which probably reflect the true AE incidence better than any other previously published study from more homogeneous single-site studies.

Nonetheless, the fact that our study used broad inclusion and exclusion criteria and thus its outcomes reflect the 'real-world use' of the implant in different cultural settings is, at the same time, a drawback because such a heterogeneous population could affect the validity of the study.

Conclusion

Our study is the first to present outcomes and Eight Plate-related AEs in a multicentre setting. Overall, treatment success was lower than reported previously. Considering the type of the most common AEs, which were mainly screw-related, and their clustered occurrence, we believe that the majority of AEs could have been avoided through tighter monitoring.

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Conflicts of interest

J.D. has received support (current relationship) for travel for AO education task force meetings, payment for lectures as a member of the AO faculty international and payment for development of educational presentations for the AO education task force. L.W.'s institution has received money in the past for his participation in review activities. A.J. is an employee of AO Clinical Investigation and Documentation and receives employment income. For the remaining authors there are no conflicts of interest.

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