■ CHILDREN'S ORTHOPAEDICS

Growth arrest: leg length correction through temporary epiphysiodesis with a novel rigid staple (RigidTack)

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Aims

Temporary epiphysiodesis (ED) is commonly applied in children and adolescents to treat leg length discrepancies (LLDs) and tall stature. Traditional Blount staples or modern two-hole plates are used in clinical practice. However, they require accurate planning, precise surgical techniques, and attentive follow-up to achieve the desired outcome without complications. This study reports the results of ED using a novel rigid staple (RigidTack) incorporating safety, as well as technical and procedural success according to the idea, development, evaluation, assessment, long-term (IDEAL) study framework.

Methods

A cohort of 56 patients, including 45 unilateral EDs for LLD and 11 bilateral EDs for tall stature, were prospectively analyzed. ED was performed with 222 rigid staples with a mean follow-up of 24.4 months (8 to 49). Patients with a predicted LLD of ≥ 2 cm at skeletal maturity were included. Mean age at surgery was 12.1 years (8 to 14). Correction and complication rates including implant-associated problems, and secondary deformities as well as perioperative parameters, were recorded (IDEAL stage 2a). These results were compared to historical cohorts treated for correction of LLD with two-hole plates or Blount staples.

Results

The mean LLD was reduced from 25.2 mm (15 to 45) before surgery to 9.3 mm (6 to 25) at skeletal maturity. Implant-associated complications occurred in 4/56 treatments (7%), and secondary frontal plane deformities were detected in 5/45 legs (11%) of the LLD cohort. Including tall stature patients, the rate increased to 12/67 legs (18%). Sagittal plane deformities were observed during 1/45 LLD treatments (2%). Compared to two-hole plates and Blount staples, similar correction rates were observed in all devices. Lower rates of frontal and sagittal plane deformities were observed using rigid staples.

Conclusion

Treatment of LLD using novel rigid staples appears a feasible and promising strategy. Secondary frontal and sagittal plane deformities remain a potential complication, although the rate seems to be lower in patients treated with rigid staples. Further comparative studies are needed to investigate this issue.

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Introduction

Treating leg length discrepancy (LLD) or excessive leg length in children with tall stature are among the challenging tasks in paediatric orthopaedic surgery. LLD and tall stature can be corrected surgically by manipulating the growth plates around the knee through permanent or temporary total epiphysiodesis (ED). Temporary ED, first proposed by Blount and Clarke[1] in 1949, inhibits epiphyseal growth through reversible stapling of an unharmed growth plate, where the inflexible staples produce firm physeal compression.[2] Many studies have shown the efficacy of this procedure using these traditional staples.[1,3-5] However, postoperative breakage, loosening, and migration of these staples,[4-6] along with secondary malalignment of the treated extremity,[6-8] have been reported. Percutaneous epiphysiodesis using transphyseal screws that provide improved

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Table I. Growth arrest subject population. Prospective cohort for rigid staples compared to two historic cohorts that received two-hole plates or Blount staples.

Variable	Rigid staples	Two-hole plates	Blount staples
Patients, n (M:F)	56 (38:18)	38 (21:17)	137 (84:53)
Implants, n	222	124	422 ED sites (2 to 3 staples)
Operated leg, n			
Right	27	21	69
Left	18	17	68
Bilateral	11	0	0
Location, n			
dF/pT	38	24	74
dF	18	8	42
pT	11	6	21
Mean age at implantation, yrs (range)	12.1 (8 to 14)	12.1 (10 to 16)	11.8 (6 to 16)
Mean LLD at implantation, mm (range)	25.2 (15 to 45)	26.7 (12 to 49)	29.3 (14 to 100)

dF, distal femur; ED, epiphysiodesis; LLD, leg length discrepancy; pT, proximal tibia.

Table II. Underlying conditions.

Condition	Rigid staples	Two-hole plates	Blount staples	Total
LLD, n				
Idiopathic	14	13	41	68
Congenital	15	10	37	62
Acquired	16	15	59	90
Tall stature, n				
Idiopathic	5	N/A	N/A	5
Congenital	6	N/A	N/A	6

LLD, leg length discrepancy; N/A, not applicable.

purchase, despite harming the growth plate, are an alternative.[9] However, screws and staples require timely implant removal and may lead to undesired effects such as secondary deformities if not executed correctly.[7,10,11] Furthermore, difficulty in positioning multiple staples per ED site can lead to inadequate placement with insufficient bone purchase and result in iatrogenic deformities. Mechanical axis shifts of more than 1 cm have been reported for up to 50% of stapling procedures,[6,8] as well as recurvatum deformity caused by placing the staples anterior of the fibular head.[8]

Based on excellent results reported for the treatment of angular deformities,[5,12] two-hole plates, introduced by Stevens[12] in 2007, have been adapted for ED in leg length corrections.[5,7,13-20] The non-locking plates are anchored with postoperatively deviating screws to decelerate growth, and successful equalization of LLD with reduced implant-associated complications has been reported.[5,7,14,15,20] Others, however, have described poor results in correcting LLD and have advised against the application of two-hole plates for this condition.[13,17-19,21,22] The guided implantation technique additionally improved positioning precision to prevent axis deviations and fibular head interferences. However, central knee deformations, best known as tibial "volcano effect",[7,23] as well as iatrogenic coronal[7,8,14,22] and especially sagittal deformities,[7,8,15,24] have been observed after the application of tension-band implants for ED. Correction of severe LLD can also lead to large screw divergence angles causing stress, bending, and ultimately failure of the implant, and revision procedures are frequently required due to screw breakage after long-term growth arrest.[7,8]

There is a need for novel ED devices, with improved biomechanical stability and sufficient bone purchase, that enable adequate positioning and induce symmetrically arrested growth without harming the physis. We postulated that the advantages of established two-hole plates and traditional Blount staples could be combined in a single device. Therefore, we have developed an implant for temporary ED with a reinforced crossbar and barbed, cannulated prongs for guided insertion to provide surgical simplicity, secure bone purchase, and improved clinical outcomes. Recently Hillebrand et al[25] have found a comparable efficacy between Blount staples and novel rigid staples in an animal model.

In our study, we have evaluated the clinical efficacy and potential complications of this novel implant in patients with LLD and also those of tall stature. We then compared our findings to historical cohorts of patients treated for correction of LLD with two-hole plates and Blount staples.

Methods

A prospective study for the clinical use of novel rigid staples according to guidelines defined for Stage 2a of the IDEAL framework was performed.[26] This study was approved by the ethical committee of the University of Muenster (registration number 2020-319 f-S).

All patients recruited into the study from 2014 to 2019 gave informed consent to participate and to be treated with novel rigid staples (RigidTack; Merete, Germany). A further group of patients was retrospectively analyzed who had been treated in our department with either Blount staples (Stryker, Germany), from 1970 to 2006 or with two-hole plates (eight-Plate; Orthofix, USA) from 2006 to 2014. The numbers of patients, implants, and implantation sites were recorded as well as the patient age at implantation (Table I). The mean follow-up was 24.4 months (8 to 49) in patients treated with rigid staples, 36.0 months (7 to 83) in patients with two-hole plates, and 27.8 months (6 to 94) in patients with Blount staples. No difference in age at intervention, operated leg sides, arrested growth plates, and underlying conditions was found between the groups (Table II). The mean LLD before treatment was 25.2 mm (15 to 45) in patients with rigid staples, 27.4 mm (12 to 49) in patients with two-hole plates, and 29.3 mm (14 to 100) in patients with Blount staples.

Children and adolescents who showed adequate residual growth potential for equalization or reduction of a predicted LLD of ≥ 2 cm at skeletal maturity were included. Tall stature interventions were indicated for patients with a projected overall height three standard deviations above their sex-specific mean. Patients with a predicted LLD of < 2 cm at skeletal maturity were excluded. Underlying conditions of LLD and tall stature are given in Table II.

Surgical technique. The design criteria for the rigid staples inserted in the prospective cohort included a sagittal trapezoidal contour for optimal epiphyseal fit. Staples were available in sizes of 20, 25, and 30 mm with reinforced crossbars, adjusted to be equivalent in strength to three Blount staples, which maintained sustained compression across the physis through

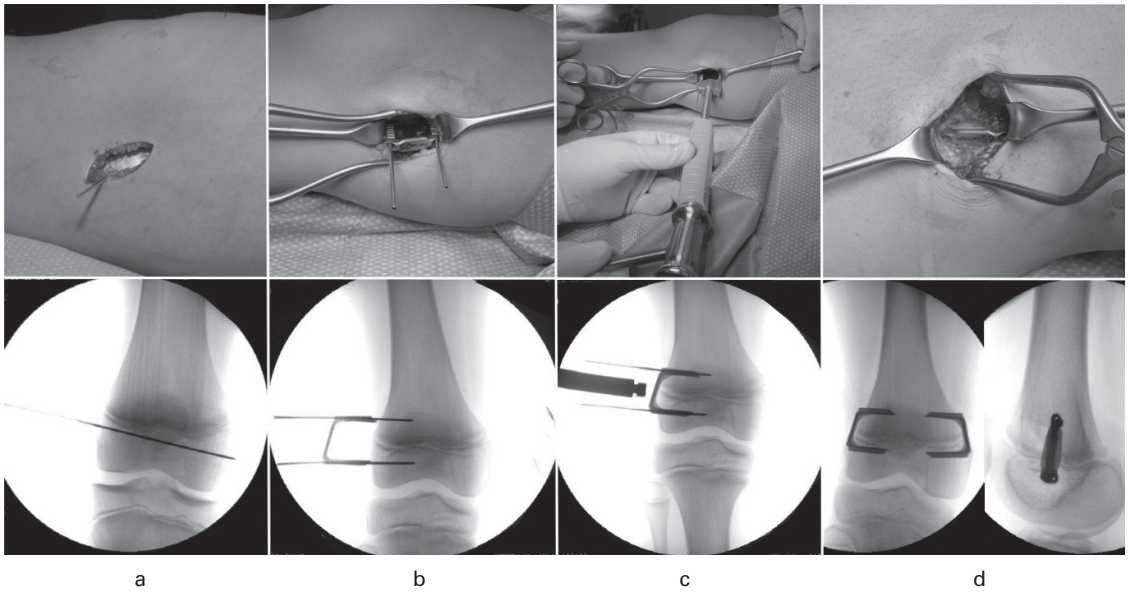

Fig. 1

Implantation of rigid staples. a) Incision was followed by manual insertion of a first Kirschner wire, to guide the staple, and b) a second wire is inserted through the vacant, cannulated prong. c) Then, the crossbar is impacted until each staple was d) fully immersed in bone.

parallel staple prongs during growth. Barbed and cannulated staple prongs were employed for secure sub-periosteal bone purchase and Kirschner (K)-wire guided insertion was used in order to ensure adequate and safe placement.[25,27] The surgeons, who were authors of this study, performed the procedures, and the duration of surgery (incision to suture) and fluoroscopy time were recorded.

Rigid staple implantation, preserving the periosteum, included the following steps: first, a K-wire was inserted manually, using a grip wrench, 5 mm from the growth plate towards the joint (Figure 1a). Staples were then manually guided over the first K-wire and a second guide wire was introduced through the vacant second cannulation (Figure 1a). Note that collinear paraphyseal guidewires lie parallel to the tangent of the entire growth plate and joint line (Figure 1b) in order to facilitate alignment and to ensure parallel staple prongs during medial and lateral insertion with an impactor (Figure 1c), until a physeal bridge position is reached (Figure 1d).[27]

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Removal of the rigid staples was performed at skeletal maturity or at the time of LLD equalization. Explantation involved exposure of the cannulated staple legs (Figure 2a) to insert threaded K-wires to guide a U-profile chisel collinear along the guide wires and over each staple prong (Figure 2b). This cleared the bone-implant interface and allowed subsequent extraction of the staple with a sliding hammer (Figure 2c) without leaving any residual bone on the implant surfaces (Figure 2d). Note that the periosteum had been preserved during implantation.[27]

Both two-hole plates and Blount staples were inserted and removed as has previously been described.[1,12]

Clinical and radiological evaluation. Standardized clinical and radiological follow-up examinations were conducted at six-month intervals in both the prospective and historical cohorts. All radiographs were performed taking into account vertical adjustment to avoid hyperextension or flexion of the knee joint. Inaccurate radiographs were repeated to enable standardization and comparable radiographs. Pre- and postoperative long-standing anteroposterior radiological measurements were obtained between the most superior portion of the femoral head and the centre of the tibial plafond using a calibrated digital radiology system (Centricity PACS and TraumaCad). These were compared at equivalent follow-up examinations to determine the rate of LLD correction (reduction of length difference per month). Changes in the mechanical axis, defined as a line drawn between the femoral head and the centre of the tibial plafond, towards varus and valgus positions were recorded, according to Gorman et al.[6] Absolute shifts of the mechanical axis and changes in its position in relation to defined zones -3 to 3 were measured (Figure 3). Every shift of the mechanical axis ≥ 1 cm was considered clinically important, as it represents a large change and is greater than the measurement inaccuracy. The mean distance between the knee joint centre and the border of the zones 1 and 2 was 1.6 cm. Therefore, not every clinically important shift of the mechanical axis ≥ 1 cm led to a zone change. An absolute shift < 1 cm, however, could result in a zone change if the initial position of the mechanical axis was

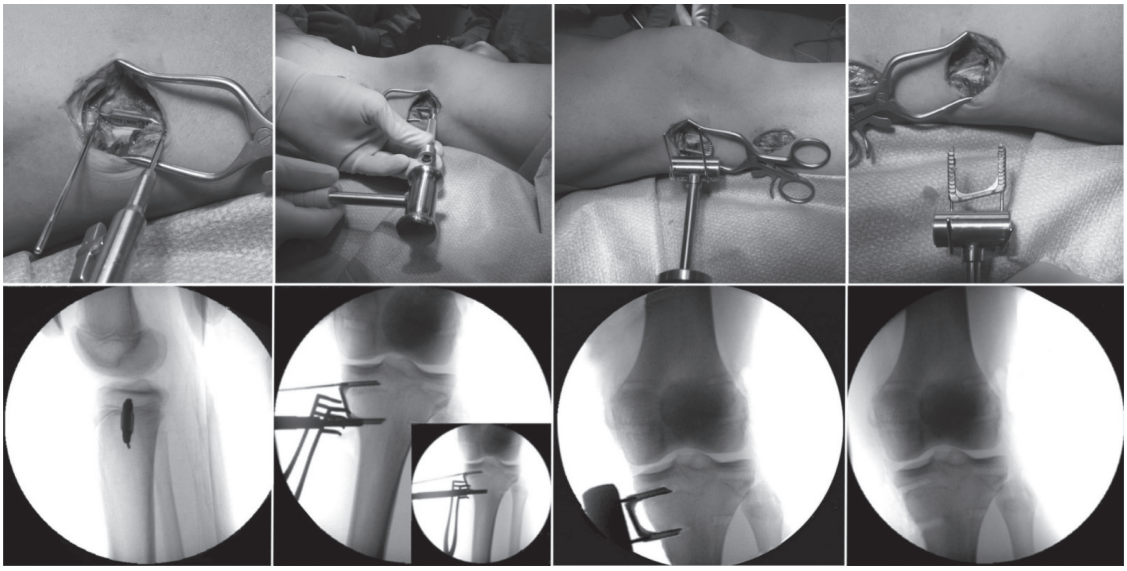

Fig. 2

Explantation of a rigid staple (same patient shown in Figure 7). a) Kirschner wire threaded into the staple prongs after exposure followed by b) chisel insertion to clear the interface and c) extraction with sliding hammer to d) fully remove the staple without residual bone.

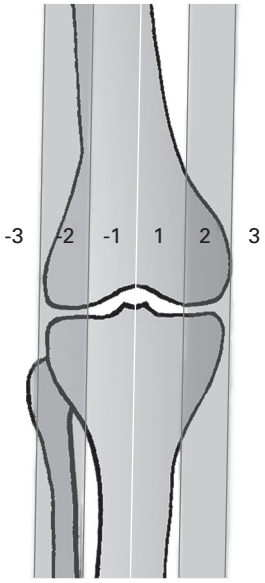

Fig. 3

Zones of the mechanical axis. The neutral mechanical axis (white line) divides the central knee joint area in the frontal plane into zones 1 and -1. Zones 2 and 3 are the more medial (varus), and zones -2 and -3 are the more lateral (valgus) zones, their boarders are tangent to the medial and lateral femoral condlyes.

close to a border between two zones. Additionally, a clinically important shift ≥ 1 cm and a zone change does not necessarily entail biomechanical consequences (change between zone -1 and 1). On the other hand, a zone change away from zone -1 or 1 was considered to be more clinically relevant than just an absolute shift of the mechanical axis ≥ 1 cm, because it represents a biomechanically relevant deviation from the normal weight-bearing axis. Clinical sagittal plane examinations to measure recurvatum angles postoperatively and during follow-up were documented in all rigid staple patients, in 30 of 38 two-hole plate patients (78.9%) and in 84 of 137 Blount staple patients (61.3%). Changes > 10° were also validated radiologically and recorded as clinically relevant. Implant placement, bone purchase, and failure were reviewed to record breakage, loosening, and migration to estimate implant-associated complications. Wound infections that needed revision, and joint effusions, as well as neurovascular complications, were also recorded. LLD and body height at skeletal maturity were predicted using the multiplier method.[28,29]

Statistical analysis. Variables were analyzed using descriptive statistics only to detect reduction of LLD and changes within the observed group. Comparison between novel rigid staples and historical cohorts of two-hole plates and Blount staples were also performed descriptively focusing on mean levels due to different study designs.

Results

Rigid staples. All patients completed treatment of LLD and tall stature. Hardware was removed after a mean of 23.3 months (4 to 49) in LLD patients (Figure 4b). Residual LLD ≤ 1 cm was found in 23/45 patients (51.1%), between 1 cm and 2 cm in 13/45 patients (28.9%), and > 2 cm in 9/45 patients (20.0%). A residual LLD of > 2 cm was observed mainly in patients who already had acquired damage to the contralateral femoral and tibial growth plates. LLD was remarkably reduced from 25.2 mm (15 to 45) before treatment to 9.3 mm (6 to 25) at follow-up (Figure 4a).

In tall stature patients, a relevant reduction of the initially predicted body height by a mean of 18.3 cm (4.0 to 31.9) was achieved after treatment, whereas no relevant difference in

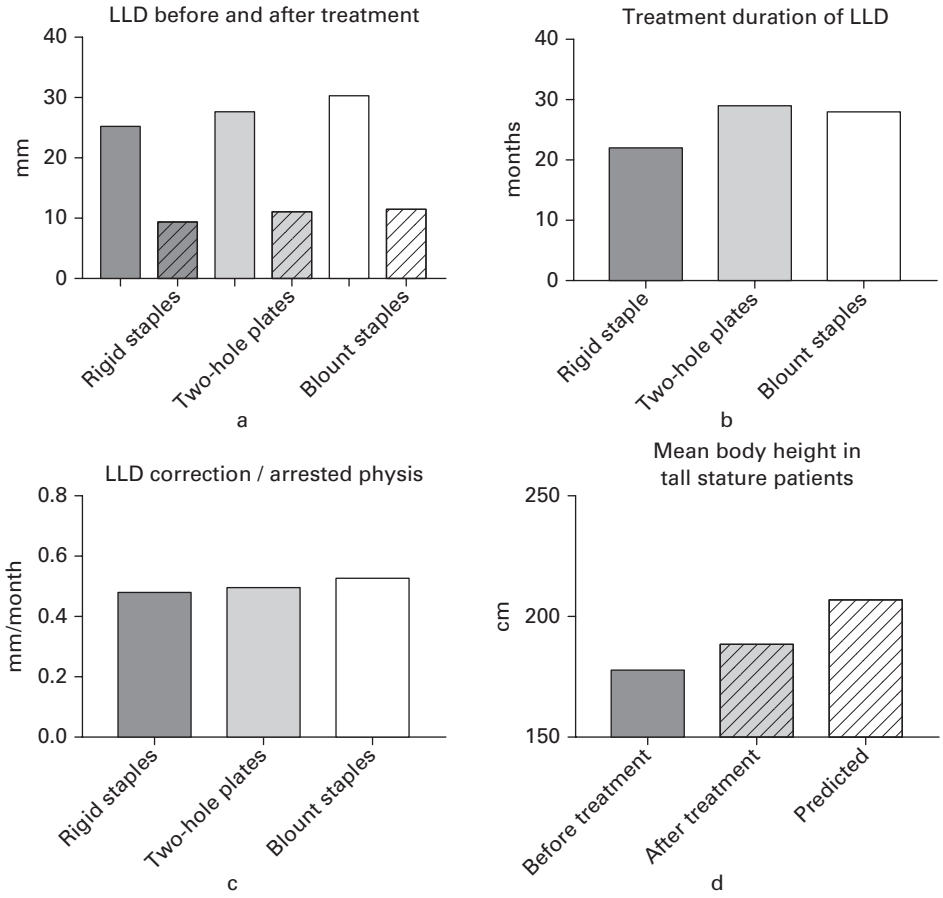

Fig. 4

Treatment outcome of leg length discrepancy (LLD) and tall stature. a) Differences in LLD before and after treatment (shaded), b) treatment durations in months, and c) LLD correction speed rates in mm/month. d) Mean body height of tall stature patients before and after treatment with rigid staples are compared to predicted body height.

Table III. Complication rates.

Complication	Rigid staples, n (%)	Two-hole plates, n (%)	Blount staples, n (%)
Implant-associated (breakage, loosening, migration)	4 (7.1)	4 (10.5)	20 (14.6)
Haematoma/joint effusion	2 (3.6)	1 (2.6)	7 (5.1)
Neurovascular	0 (0)	0 (0)	1 (0.7)

body height was found after treatment compared to before treatment (Figure 4d).

Complications. Implant-associated complications are shown in Table III. Breakage, loosening, or migration during treatment were observed in 4/56 patients (7.1%). Haematoma and joint effusions occurred in 2/56 patients (3.6%). No wound infections or neurovascular complications were detected.

The absolute shift of the mechanical axis after treatment was 6.1 mm (0 to 26) (Figure 5). In total, 12/67 legs (17.9%) showed secondary deformities in the frontal plane during follow-up: 8/67 mechanical axis changes (11.9%) between postoperative and follow-up radiographs towards varus and 4/67 (6.0%) towards valgus position. A subgroup analysis of 45 LLD patients included 4/45 legs (8.9%) that changed to varus and 1/45 (2.2%) to valgus position (Figure 5b, Table IV). In contrast, 5/11 tall stature patients (45.5%) showed secondary frontal plane deformities in one or both legs.

Zone changes were registered in 7/45 LLD patients (15.6%). Clinically important zone changes were found in 4/45 patients (8.9%) (Figure 5c). Moreover, hyperextension of the knee as a clinical result of a sagittal deformity occurred in 1/45 LLD patients (2.2%) (Figure 5d, Table IV). The risk for secondary deformity was not linearly correlated to treatment duration or arrested physis (femoral/tibial). No patient with a procurvatum deformity or flexion contracture of the knee was detected.

In conformity with the IDEAL guidelines the implantation technique was modified throughout the study period. In 15 patients, collinear paraphyseal guidewires were applied during implantation to collinearly align lateral and medial cannulated staple prongs parallel to the joint line for biomechanically optimal growth inhibition (Figure 6a). None of the LLD patients treated with this technique developed secondary deformities.

Perioperative parameters. The mean time from incision to suture for implantation was 21.9 minutes (11.0 to 38.0);

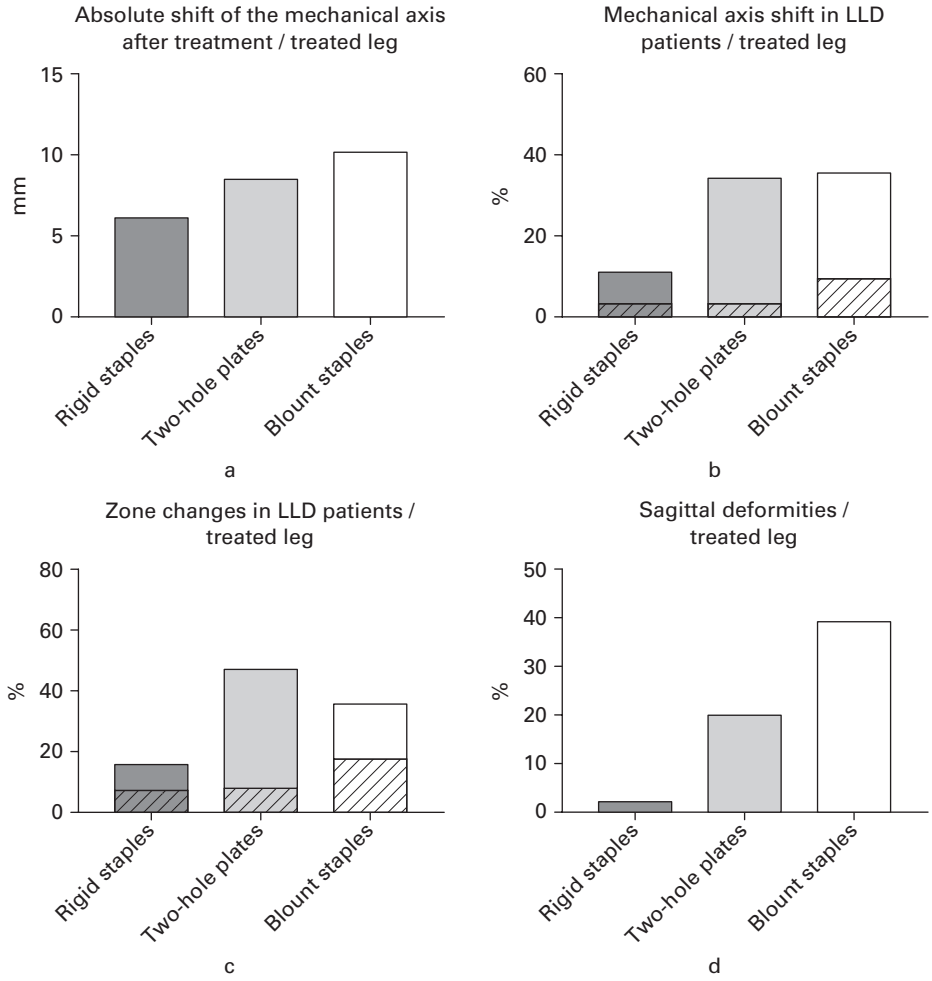

Fig. 5

Secondary deformities. a) Absolute shift of the mechanical axis after treatment per treated leg between rigid staples, two-hole plates, and Blount staples including tall stature patients and b) secondary frontal plane deformities with mechanical axis shifts ≥ 1 cm into varus and valgus (shaded) in leg length discrepancy (LLD) patients. c) Zone changes in treated LLD patients with a share of biomechanically relevant zone changes away from zone 1/-1 (shaded) and d) secondary sagittal deformities in LLD patients per treated leg are presented.

Table IV. Secondary deformities in leg length discrepancy patients.

Variable	Rigid staples	Two-hole plates	Blount staples
Coronal, n (%)			
Varus	4 (8.9)	1 (2.6)	35 (25.5)
Valgus	1 (2.2)	12 (31.6)	12 (8.8)
Total	5 (11.1)	13 (34.2)	47 (34.3)
Sagittal, n (%)	1 (2.2)	6/30 (20.0)	33/84 (39.3)

Table V. Absolute leg length discrepancy after treatment.

Absolute LLD	Rigid staples, n (%)	Two-hole plates, n (%)	Blount staples, n (%)
≤ 1 cm	23 (51.1)	18 (47.3)	79 (57.7)
1 cm to 2 cm	13 (28.9)	8 (21.1)	33 (24.1)
> 2 cm	9 (20.0)	12 (31.6)	25 (18.2)

LLD, leg length discrepancy.

fluoroscopy time at implantation was 0.28 minutes (0.06 to 0.68). At explantation, the mean time from incision to suture was 18.1 minutes (10.0 to 34.0) with a mean radiation exposure time of 0.01 minutes (0.005 to 0.07). Figure 7 illustrates a typical radiological progression of a LLD patient treated with rigid staples.

Comparison of rigid staples with two-hole plates and Blount staples. The three patient cohorts (rigid staples, two-hole plates, Blount staples) had comparable patient demographic data regarding age at intervention, operated leg sides, arrested growth plates, and aetiology (Table II). The mean LLD before treatment was lower in patients treated with rigid staples compared to 26.7 mm (12.0 to 49.0) in two-hole plates and 29.3 mm (14.0 to 100.0) in Blount staples (Figure 4, Table I). Furthermore, treatment duration was lower in patients treated with rigid staples compared to the historical cohorts (Figure 4b). LLD was reduced to 11 mm (2 to 38) using two-hole plates and 11.4 mm (2.0 to 75.0) with Blount staples (Figure 4a). For each of the three implants, equivalent LLD correction rates were detected during the treatment period (Figure 4c). Compared to two-hole plates and Blount staples no difference in residual LLD after treatment using rigid staples was found (Figure 4, Table V).

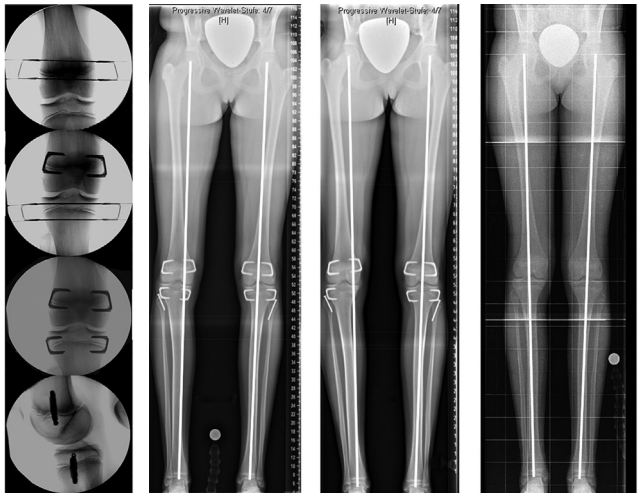

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Fig. 6

Secondary deformity complication management. a) Parallel guidewires during implantation of rigid staples may reduce iatrogenic deformities due to precise placement in the frontal and the sagittal plane. b) Iatrogenic deformities such as this varus deformity of the proximal tibia of the right knee (b1) can be corrected through premature removal of the concave-sided implant (b2) achieving correction at the end of growth arrest (b3).

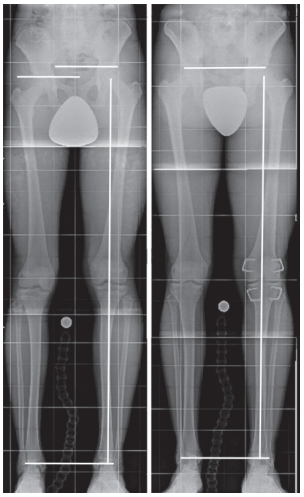

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Fig. 7

Radiographs before and after treatment with rigid staples (same patient shown in Figure 2). Left: 4.2 cm leg length discrepancy in a male patient at 11 years and one month. Right: Corrected leg length after three years and seven months at 14 years and eight months of age.

Implant breakage, loosening, or migration during treatment was recorded in 4/38 patients (10.5%) treated with two-hole plates and 20/137 patients (14.6%) treated with Blount staples. Haematoma or joint effusion occurred in 1/38 patients (2.6%) with two-hole plates and in 7/137 patients (5.1%) with Blount staples (Table III).

Shifts of the mechanical axis were observed with a mean of 8.4 mm (0 to 23) using two-hole plates and 10.2 mm (0 to 16) using Blount staples (Figure 5a). Overall, 13/38 patients (34.2%) treated with two-hole plates developed secondary mechanical axis changes (varus 31.6% and valgus 2.6%) during follow-up. In 47/137 patients (34.3%) treated with Blount staples, frontal plane deformities were registered (varus 25.5% and valgus 8.8%) (Figure 5b, Table IV). Zone changes were detected in 18/38 patients (47.4%) treated with two-hole plates and in 48/137 patients (35.0%) treated with Blount staples. Clinically important zone changes were found in 3/38 patients (7.9%) with two-hole plates and in 24/137 patients (17.5%) with Blount staples (Figure 5c). Sagittal deformities were observed in 6/30 patients (20.0%) treated with two-hole plates and in 33/84 patients (39.3%) treated with Blount staples (Figure 5d, Table IV).

The mean time from incision to suture at implantation was 34.6 minutes (11 to 80) using two-hole plates and 34.9 minutes (10 to 162) using Blount staples. Mean fluoroscopy time at implantation was 0.49 minutes (0.10 to 1.58) using two-hole plates and 0.81 minutes (0.06 to 2.50) using Blount staples. Mean times at explantation were detected with 23.8 minutes (18 to 32) using two-hole plates and 30.8 minutes (15 to 50) using Blount staples. Mean levels of radiation exposure at explantation were detected with 0.05 minutes (0.01 to 0.1) in two-hole plates and 0.28 minutes (0.01 to 1.5) in Blount staples. These findings were higher or similar to the outcome of the novel rigid staple.

Discussion

ED used to surgically effect growth has been available for over 80 years, during which time substantial methodological and technical progress has been achieved.[7,10] Indications have increasingly been expanded due to successful application of both permanent and temporary procedures. Open permanent techniques have now become obsolete and minimal invasive percutaneous methods are used successfully to achieve total arrest of epiphyseal growth, with drilling and curettage being the most common procedure for irreversible ED.[7,10] Temporary ED is an effective alternative with a variety of implants available to treat moderate LLD with manageable complications.[7,10,17,21] Blount staples though have been reported to result in breakage, loosening, and migration of implants, because of their implant design and the need to position up to three staples per ED site.[4-6] Also with Blount staples, secondary frontal plane deformities have been reported in up to every second patient.[4,6-8] Consequently, two-hole plates were introduced,[5,7,13-20] even though the biomechanical properties seem to be less than optimal in length corrections and implant failures have been widely reported.[13,17-21,25] Recent reviews have described two-hole plates as having limited efficacy and increased complication rates, especially in long-lasting LLD interventions.[17,21]

Because of these issues, we have developed a novel rigid staple to reduce the level of complications recorded by established implants for temporary ED. Following a recent animal study, describing equivalent potentials of growth arrest between Blount and rigid staples in a porcine model,[25] we have used these novel rigid staples in patients and found similar LLD correction rates in the three groups studied, implying equivalent efficacy levels between the three implants. Furthermore, similar amounts of residual LLD following treatment were observed

in the three groups, which was comparable to outcomes previously reported.[6,15] The duration of treatment was lower using rigid staples compared to two-hole plates and Blount staples, which is probably because of the more precise level of prediction of LLD as well as improved screening of patients with LLD by paediatric orthopaedic surgeons. We found that the ratio of lower amount of correction and lower treatment duration results in the same correction rates using either rigid staples, two-hole plates, or Blount staples and we speculate that the shorter treatment time led to a lowered risk for secondary deformities.

One of the principal concerns when performing temporary ED for treating LLD is the risk of secondary mechanical axis deviations, which have been previously reported using two-hole plates[13] and Blount staples.[6] In our study, the rigid staple was associated with a lower incidence of secondary frontal plane deformity when solely investigating patients with LLD. However, we did use the rigid staple initially in patients with tall stature and a higher incidence of axis deviation was observed in this group than in the entire study population.

The total number of mechanical axis deviations observed after treatment was lower using rigid staples in LLD patients compared to two-hole plates or Blount staples. On the one hand, treatment with two-hole plates and Blount staples resulted in more zone changes, while the incidence of clinically relevant secondary frontal plane deformities using rigid staples did not differ from that of two-hole plates. Higher rates of secondary deformities using two-hole plates and Blount staples though have been previously described.[6,13] It is of note that fewer secondary deformities were observed when rigid staples were used only in LLD patients, and that neither two-hole plates nor Blount staples were used in tall stature operations. Almost half of tall stature patients treated with rigid staples (45.5%) showed a clinically important mechanical axis deviation. This might be explained by an extended time of treatment for bilateral ED, though we did not observe any correlation between treatment duration and the risk for secondary deformities. Higher growth potential of growth plates in tall stature patients may increase the risk for secondary deformities, although we acknowledge that this is a hypothesis. One of the main advantages of temporary ED is the ability to remove the implant when achieving equal leg length or observing and treating secondary deformities. Interestingly only 2.6% of mechanical axis deviations have been reported in tall stature patients using permanent ED.[30] If permanent ED is performed accurately, temporary ED appears inferior as a treatment option for tall stature patients. Therefore having considered the literature and according to the IDEAL framework, we have abandoned temporary ED for the treatment of patients with tall stature in favour of permanent ED.

Whichever implant was used, most of the observed secondary deformities were in varus position, as similarly described by Gorman et al.[6] As the exact implant placement, especially on the lateral physeal site of the proximal tibia, can be difficult, eventual malposition of multiple implants may, in contrast to novel rigid staples, lead to insufficient and asymmetrical growth arrest, resulting in varus deviations.[6,8,25] The physeal compression through adequately positioned and reinforced rigid staples might hinder recurvatum deformities and lessen the incidence of frontal plane deformities. Nevertheless, secondary frontal plane deformities have yet to be resolved in ED. In accordance with the IDEAL guidelines, collinear paraphyseal guidewires during implantation of rigid staples were used to collinearly align lateral and medial cannulated staple prongs, parallel to the joint line for biomechanically optimal growth inhibition. However, this technique was adopted too late in our study to significantly reduce secondary deformities, but none of the 15 LLD patients we treated with this refined technique developed secondary deformities, and requires further investigation. Collinear paraphyseal guidewire positioning needs to be performed precisely, as transverse placement in the axial plane can lead to secondary frontal plane deformities. In the lateral plane, exact central guidewire placement is mandatory in order to prevent development of sagittal plane deformities.

If iatrogenic angular deformities occur in the frontal plane, they can be managed by premature implant removal on the concave side (Figure 6b), which is a notable advantage over permanent ED, where secondary deformities can only be corrected by an osteotomy. Fewer iatrogenic recurvation deformities were observed using rigid staples compared to two-hole plates and Blount staples. A single one-piece implant per ED site may facilitate central placement in the sagittal plane and prevent hyperextension, which is beneficial especially along the proximal lateral tibia in order to prevent fibular head interferences.

Mechanical implant failure is a frequent problem of two-hole plates and Blount staples occurring in up to 58%.[17] While the rate of complications for two-hole plates and Blount staples was lower in our study, compared to the literature, there was a numerical reduction in the complication rate using novel rigid staples. Due to the design with reinforced crossbars and barbed prongs which improved bone purchase, the novel rigid staple might be more resistant to breakage, loosening, and migration. However, the rigid staples can still bend slightly during long-lasting arrest (Figure 6b). So far, no biomechanical comparison study has yet evaluated the fatigue strength and pull-out force of different ED implants and these require further investigation. Regarding central joint deformities, observations of rigid staples in a porcine model have shown promising results with no newly occurred 'volcano effect'.[25] However, further long-term studies are needed to see if this assumption is applicable to patients treated for LLD.

This study has several limitations. First, a limited number of patients with LLD caused by different underlying diseases were treated with rigid staples. This led to a high variation of the residual growth potential of the non-treated leg. Second, this study lacks a true control group because all reported cases included two clinical indications. The inclusion of tall stature patients in the prospective cohort elevated the rate of secondary frontal plane deformities. Retrospectively studied data were compared to a prospective cohort and as such are subject to recall and selection bias, but we would argue that this comparison is useful to classify efficacy and safety of the novel rigid staples.

Successful treatment of LLD by growth arrest also depends on appropriate timing of the interventions and thorough monitoring through follow-up visits irrespective of the type of implant used. As these aspects of managing LLD by temporary ED have greatly improved over the period of this study, through the use of growth prediction and the calculation of ED timing, both factors may be potential confounders in assessing success of different ED implants. These issues could be addressed in future by prospective comparative studies. Rigid staples and two-hole plates are single devices

that need to be be applied precisely to avoid secondary deformities. Improved positioning of implants and better understanding of the clinical reaction in the physis during temporary ED may also influence the development of secondary deformities.

In conclusion, our results show that temporary ED using rigid staples for the treatment of growing patients with LLD appears to be both feasible and promising. We have described an easy-to-use technique with guided surgery which may reduce the number of required implants and implantation space. ED using this rigid staple design seems to be safe and efficacious, resulting in successful correction of LLD, and may reduce secondary deformities and overall complications. In patients who seek treatment for tall stature, ED using rigid staples resulted in a high rate of secondary deformities and complications. Thus, rigid staples should be used with caution and we suggest that consideration should be given to perform permanent ED in tall stature patients.

Take home message

- The clinical use of rigid staples appears to be safe and efficacious.
- Further research including randomized controlled trials is needed to evaluate their adaption into clinical practice to treat leg length discrepancies.
- However, independent of the device used, we advise caution when applying temporary epiphysiodesis in long-lasting growth arrest. The use of permanent techniques might be more advisable for treatment of tall stature.

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