Comparison of Temporary Epiphysiodesis With RigidTacks™ and Blount-Staples in a Porcine Animal Model Using Magnetic Resonance Imaging

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ABSTRACT: RigidTack™ is a newly developed implant for total temporary epiphysiodesis. The implant combines the technical advantages of the traditionally used rigid Blount-staples and the newer flexible eight-plates™. Thus, the implant is rigid like the Blount-staples, which may be a biomechanical advantage in temporary epiphysiodesis, and has an easy and guided implantation technique like the eight-plate™. As in eight-plates™, supposedly only two RigidTacks™ are sufficient for temporary epiphysiodesis compared to six Blount-staples in traditional treatment. The goal of this study was to compare Blount-staples and RigidTacks™ in regard to the total potential of growth arrest, the occurrence of postoperative implant-associated complications, secondary angular deformities, and central joint deformations. Twelve pigs were allocated in two groups (n = 6) for treatment of the proximal tibia. Total temporary epiphysiodesis was performed with either four Blount-staples or two RigidTacks™. Magnetic resonance imaging (MRI)-scans were performed before and 14 weeks after surgery, and the amount and distribution of growth arrest were evaluated by measuring the interphyseal distance in nine defined zones. Total temporary epiphysiodesis with two RigidTacks™ resulted in a similar amount of growth arrest as that of four Blount-staples. No significant coronal or sagittal angular deformities or joint deformities were observed in either group; however, one secondary loosening of a Blount-staple occurred. The study concluded that Blount-staples and RigidTacks™ are adequate implants for total temporary epiphysiodesis. Whether or not the precise implant-placement through the guided implantation technique of RigidTacks™ and a reduced number of implants indeed lead to a reduction of secondary angular deformities has to be investigated in further clinical trials. © 2019 The Authors. Journal of Orthopaedic Research™ published by Wiley Periodicals, Inc. on behalf of Orthopaedic Research Society. J Orthop Res 38:946–953, 2020

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Leg length discrepancy (LLD) is an impairing condition that frequently requires surgical treatment. Moderate discrepancies of 2–5 cm can be treated by growth arrest through epiphysiodesis in skeletally immature patients. Permanent percutaneous procedures8–10 and temporary techniques11–13 are widely used. Permanent methods are based on the destruction of the growth plate and therefore limited in accuracy and restricted to interventions in later growth periods.4,6,9 Total temporary epiphysiodesis (TTE) is based on placement of implants on the medial and lateral side of the physis. The need for hardware removal, however, is a disadvantage of temporary methods. Additionally, initial malpositioning, secondary loosening, breakage and migration of implants can lead to secondary angular deformities (AD). These implant-associated complications were frequently observed, especially when using four to six traditional rigid Blount-staples (BS)1,8,9,11,14,15 (Fig. 1A). Therefore, alternative implants have been developed. Métairieau proposed the transphyseal application of cannulated screws.16 However, implant-associated complications and iatrogenic AD still frequently occur and the temporary nature is always called into question as the screws cross the physis.17 In 2005, Stevens introduced the eight-Plate™ (Orthofix GmbH, Lewisville, TX) with its flexible tension band effect for guided growth.13 This implant provides a guided implantation technique through cannulated screws and only one implant is inserted per arrested site.13,18 Good results without relevant implant-associated problems were reported when using the device for correction of AD.11,13,14,18,19 and as a consequence, its range of indication was extended to the treatment of moderate LLD.20,21 Unfortunately, the biomechanical behavior of flexible implants can result in problems such as inefficient growth arrest and central joint deformations.1,12,20,22,23

To our knowledge, no secondary central joint deformations have been reported when performing TTE with rigid implants. Following this, the biomechanical properties of rigid implants seem to be more suitable for TTE.

Consequently, to combine the desired biomechanical behavior of rigid implants with the precise implantation technique of the eight-Plate™, the RigidTack™ (RT) was developed (Fig. 1E).

Through changes of implant design, the developers hope to achieve the following advantages. (i) By a
k-wire-guided implantation technique similar to the eight-Plate™ a lower rate of primary malpositioning might be achieved. (ii) A rigid implant-design similar to BS is a promising step to enable a complete and evenly distributed growth arrest over the entire physis. (iii) Due to the reinforced rigid crossbars, the number of needed implants just as the number of implant-failure might be reduced. (iv) The barbed legs of the RT are designed to anchor the implant in the bone to decrease the risk of secondary implant-loosening. (v) The anatomical shape with an angled crossbar is supposed to align better along the proximal tibia. Currently, there is insufficient evidence to assess whether or not these changes in implant-design and implantation technique have resulted in a lower number of implant-associated complications. The present study intends to address this problem and was designed to answer the following questions: (i) Does TTE with two RT result in the same amount of growth arrest as four BS? (ii) Does RT lead to a significant reduction of implant-associated complications and secondary AD in comparison to BS? (iii) Do rigid implants produce central joint deformations when performing TTE?

MATERIALS AND METHODS

Study Design, Animals, and Implants

Twelve 10-week-old skeletally immature female Danish domestic pigs were included in the sample. All animals were raised under the same conditions and were housed individually in single pens. Prior to the study, a power analysis was performed using the G*Power-version 3.1.9.2 (HHU, Duesseldorf, Germany). A repeated measures within-between interaction was chosen. The number of groups was set to 2 (RT and BS) and the number of measurements at 18 per animal. The correlation between repeated measures was set at 0.6 corresponding to moderate to high correlation. This resulted in a total sample size of twelve pigs ($2 \times n = 6$).

At baseline, the mean weight of the pigs was 28.2 kg (24.0–33.0 kg). The pigs were randomly allocated into two equally sized groups treated with unilateral TTE either using two BS (Vitallium alloy; crossbar 16 mm, both legs 22 mm; Stryker-Trauma GmbH, Schoenkirchen, Germany) (Fig. 1A–D) or one RT (Titanium alloy [TiAl6V4 ELI]; crossbar 20 mm, epiphyseal leg 22 mm, metaphyseal leg 19.5 mm, stiffness 200 N/15°; Merete GmbH, Berlin, Germany) (Fig. 1E–H) per arrested site. The proximal tibia was chosen, as a high risk of secondary AD has especially been reported when performing tibial TTE. The size of the implants was chosen to suit the proximal tibia. As the study relied on commercially available implants, a slight size difference between BS and RT remained. In accordance with a porcine animal study by Gottliebsen et al., a time period of 14 weeks for TTE was determined. MRI scans of the tibiae were performed 1–2 two days before implantation and after 14 weeks of TTE directly after hardware removal (Fig. 2).

The experimental protocol was in accordance with the European directive 2010/63/EU for animal experiments and the Danish Animal Research guidelines. The research proposal was approved by the Danish Animal Experiment Committee (File-number 2015-15-0201-00761).

Anesthesia and Analgesia

The MRI scans at baseline were performed on sedated pigs after intramuscular application of 0.12 ml/kg Zoletil® (tiletamine, zolazepam; Virbac, Carros, France). All surgeries as well as the second MRI scans were conducted on living, ventilated animals under general anesthesia. Anesthesia and postoperative assessment was provided according to established protocols previously published by our group.

Surgery

All surgical interventions were executed using aseptic dressing and procedures. The implantation and removal procedures were performed following the manufacturer’s guidelines.
MRI scans of both tibiae were obtained using a 3-Tesla scanner (MAGNETOM® Skyra; Siemens AG, Munich/Berlin, Germany) at baseline and directly after removal to avoid implant-related artifacts. The following multiple-slice sequences were run on each leg using a 366×174 mm diameter flexible surface coil applied to the lower leg: T1-weighted sequence of the whole tibia (acquisition time 5.21, resolution matrix 256×256, FoV read 230 mm, FoV phase 100%, slice thickness 0.9 mm, repetition time 2,300 ms, echo time 2.32 ms, number of averages 1.0, receiver bandwidth 200 Hz, voxel-size 0.9×0.9×0.9 mm, interpolated voxel-size 0.45×0.45×0.9 mm); T2-weighted (acquisition time 5.09, resolution matrix 256×256, FoV read 230 mm, FoV phase 100%, slice thickness 0.9 mm, repetition time 3,200 ms, echo time 408 ms, number of averages 1.0, receiver bandwidth 725 Hz, voxel-size 0.9×0.9×0.9 mm, interpolated voxel-size 0.45×0.45×0.9 mm).

Evaluation and Measurement

The MRI images were examined using an OsiriX DICOM viewer (Pixmeo SARL, Bernex, Switzerland). The images were presented on T1 and T2 weighted sequences to detect any possible injury on the physis. The interphyseal distance (ID) between the proximal and the distal tibial growth plate was measured to compare the potential of growth arrest between the two devices and to evaluate the distribution of growth arrest in different bone areas. Due to the better demarcation of the physis, T1-weighted sequences were used for the ID measurements. The tibial MRI images were reformatted along the coronal, sagittal, and transverse plane to assure a centered alignment of the tibiae before measuring the ID (Fig. 3A–D). First, the exact middle of the tibia was applied in the sagittal plane, then parallel lines were drawn from the most lateral and medial part of the distal physis in the coronal plane. A third measurement was conducted in the exact middle of the two lines (Fig. 3A). The same procedure was conducted 5 slices (5×0.9 mm) anterior and posterior from the centered measurements (Fig. 3B). This led to a 3×3 grid of regions of interest (ROI) (L1–L9), equally spaced from anterior to posterior and from medial to lateral. The mean values of the ID of all nine ROI (L1–L9) were calculated to compare the overall potential of the growth arrest of the two devices (Fig. 3C). The sagittal ID was evaluated at medial, central, and lateral locations as the average ID from combined locations regions. The sagittal medial zone (SMZ) was defined by the average measure across L1, L2, and L3, the sagittal central zone (SCZ) was defined by the average measure across L4, L5, and L6 and the sagittal lateral zone (SLZ) was defined by the average measure across L7, L8, and L9 (Fig. 3D). In accordance, the coronal ID was measured at the anterior, central, and posterior locations. The coronal anterior zone (CAZ) was defined by the average measure across L1, L4, and L7, the coronal central zone (CCZ) was defined by the average measure across L2, L5, and L8 and the coronal posterior zone (CPZ) was defined by the average measure across L3, L6, and L9 (Fig. 3E).

To investigate coronal AD and central joint deformations, the zones within the sagittal plane (SMZ, SCZ, SLZ) were compared just as the coronal zones (CAZ, CCZ, CPZ) were compared to detect sagittal AD. The reliability of the measurements was tested by two raters, HH performed an additional 90 measurements. This correlates with a double-measurement rate of over 40%. Intraclass correlation coefficients (ICC) were used to determine the inter-rater reliability. A two-way mixed-effects model using absolute agreement definition was used. The estimated ICC values were excellent for all ROI, ranging from 0.94, 95% confidence interval (CI) (0.79–0.98) to 0.99, 95% CI (0.89–0.99). Regardless of the zone, the

Figure 2. Flowchart showing treatments and assessments across the follow up for the RigidTack™ (RT) and Blount-stable (BS) group.
The overall ICC value for all 90 measurements was 0.97, 95% CI (0.96–0.98), \( p < 0.001 \).

The information on the DICOM images was removed before processing. However, even after removal surgery, traces of the implants were visible on the images and complete blinding could not be ensured (Fig. 4A and B).

### Statistics

To test for equal means of ID in the right and left tibia of each pig at baseline of the study, we conducted a paired samples \( t \) test.

To test for the differences in total growth arrest between treated and untreated leg (type) and between the groups (BS and RT) at baseline and after 14 weeks of growth (time), a factorial repeated-measures analysis of variance (ANOVA) with type and time as within-subject factors and group as a between-subjects factor were conducted. The analysis was followed by posthoc analyses that were Bonferroni corrected to account for multiple comparisons.

To test for possible secondary coronal or sagittal AD or central joint deformations, differences of growth arrest within the coronal plane (SMZ, SCZ, SLZ) (Fig. 3B) and the sagittal plane (CAZ, CCZ, CPZ) were examined (Fig. 3E). A repeated-measures ANOVA with position as a within-subject factor and group (BS vs. RT) as a between-subject factor was conducted.

The level of significance was set at \( \alpha < 0.05 \). All statistical tests were conducted using SPSS 25 (IBM, Armonk, NY).

### RESULTS

Paired samples \( t \) tests confirmed that there were no baseline differences in ID between the right and left tibia within each pig (BS: mean diff. = 0.3 mm; 95% CI (0.66–0.98), \( p > 0.05 \)).
CI: −0.8–0.18 mm; \( p = 0.217 \); RT: mean diff. = 0.4 mm; 95% CI: −1.16–1.99 mm; \( p = 0.599 \) (Fig. 5A).

The three-way repeated-measures ANOVA showed that there was a significant main effect of time, \( F(1, 10) = 465.409, p < 0.001 \). Thereby, the ID were significantly lower at baseline than after 14 weeks across all tested tibiae. The main effect of the group (RT vs. BS) was not significant, \( F(1, 10) = 4.140, p = 0.069 \). Furthermore, there was a significant interaction effect between the time and type, \( F(1, 10) = 151.770, p < 0.001 \). In particular, the treated tibiae showed less growth from baseline to week 14 than the not-treated tibiae (Fig. 5A and B). There was no significant interaction effect between time and group, \( F(1, 10) = 0.742, p = 0.409 \), and between time, type and group, \( F(1, 10) = 0.064, p = 0.858 \). Hence, the growth was same in the BS and the RT group and across treated and untreated tibiae.

The multivariate test of secondary AD in the sagittal plane showed no significant effects. In particular, the main effect of the position (CAZ, CCZ, CPZ) was not significant, \( F(2, 4) = 4.674, p = 0.09 \) as well as the main effect of the group, \( F(1, 5) = 0.217, p = 0.661 \), and the interaction effect of the position and the group, \( F(2, 4) = 2.558, p = 0.193 \) (Fig. 6A and B).

Furthermore, no secondary AD or central joint deformations occurred in the coronal plane. Accordingly, the main effect of the position (SMZ, SCZ, SLZ) was not significant, \( F(2, 4) = 1.87, p = 0.267 \), as well as the main effect of the group, \( F(1, 5) = 0.269, p = 0.626 \), and the interaction effect of the position and the group, \( F(2, 4) = 4.327, p = 0.1 \) (Fig. 7A and B).

The graphical presentation of the data confirms the overlap of the confidence intervals and therefore the non-significance of the effects (sagittal plane: Fig. 6A and B; coronal plane: Fig. 7A and B).

A similar clinical outcome was observed in both groups. All pigs tolerated the surgery well and showed no alternations in dietary habits or level of mobility.
Additionally, no infections or wound problems occurred in either group; however, one secondary loosening of a BS in the lateral posterior position was observed during removal surgery (Fig. 8). No implant-associated complications occurred using RT.

DISCUSSION
TTE has developed into one of the main treatments of moderate LLD in skeletally immature patients. For many years, rigid implants like BS have been the only devices available for this procedure. As several implant-associated complications were reported,1,9,15,27 alternative implants developed. Positive results without significant implant-associated complications were published for flexible implants in the treatment of AD.11,15,18,19 As the guided implantation technique and a reduced number of implants have been shown to be advantageous over BS, their range of indication was extended to TTE for LLD correction. Unfortunately, the biomechanical behavior of flexible implants does not seem appropriate for TTE and may lead to central joint deformations1,23 and insufficient growth arrest.20,22 Rigid implants such as BS seem to provide a more suitable, evenly distributed growth arrest throughout the entire physes. Modern rigid implants like RT combine the surgical benefits of flexible eight-plates™ (i.e., guided implantation technique, only one implant per site) with the biomechanical advantages of rigid implants,28 a synthesis which might reduce the number of implant-associated complications resulting in iatrogenic AD while assuring an equally efficient growth arrest compared to BS.

The study shows that the amount of growth arrest after TTE with two RT is not different to four BS. The authors believe, in accordance with previous studies, that the main reason for secondary AD is asymmetric growth arrest due to primary malpositioning or secondary loosening and migration.9,14 In particular, iatrogenic tibial varus malalignment can be caused by primary malpositioning at the lateral aspect of the proximal tibia where the fibula head does not leave much space.1,9 By reducing the number of needed implants from up to three BS to only one RT per site and by using a guided implantation technique, a precise and sustainably stable placement is easier to achieve. However, when using only a single implant per arrested site, the mechanical strength of growth arrest is concentrated on only two fixed points—namely, the lateral and medial aspect of the proximal tibia. Therefore, when using fewer implants, an accurate central placement is of great importance to assure an evenly distributed growth arrest throughout the entire physes. Consequently, a possible guided implantation technique is an important technical improvement in TTE for all surgeons, and not just those with less experience. The guided implantation technique of RT simplifies a central placement, which leads to a constant distribution of growth arrest throughout the entire physis. BS resulted in a comparable growth arrest without significant differences in the examined tibial zones. As a result, no significant secondary AD after 14 weeks of growth arrest was found in either group (Figs. 6A and B and 7A and B). Interestingly, numerical differences of growth arrest between the measured tibial zones for the coronal and sagittal plane were seen in both groups. A larger \( \Delta ID \) between the medial and lateral zone was detected in the BS group (Fig. 7A). This might lead to tibial varus malalignment when

Figure 7. Growth arrest after 14 weeks of total temporary epiphysiodesis (\( \Delta ID \) = difference of the mean interphyseal distance between the treated and untreated tibia in mm; 95% confidence interval is given) of (A) Blount-staples (BS) and (B) RigidTack™ (RT) within the coronal plane (sagittal medial zone [SMZ], sagittal central zone [SCZ], sagittal lateral zone [SLZ]).

Figure 8. T2-weighted magnetic resonance image of traces of a loose Blount-staple after removal surgery. The growth plate shows a curved appearance when compared to the tibiae shown in Figure 5.
continuing TTE for a period longer than 14 weeks. Our findings are in agreement with the results of the clinical trials by Gorman et al. and our own group’s description of iatrogenic tibial varus AD after TTE with BS. In contrast, RT showed a slight tendency to a larger growth arrest at the lateral site, possibly leading to valgus malalignment when continuing TTE. However, the measured differences in our study are not statistically significant and can only be interpreted therefore as tendencies to secondary AD.

Regarding the sagittal plane, RT led to an evenly distributed growth arrest even when only one implant per site was inserted; thus, possibly reducing the risk of secondary sagittal AD.

In contrast, BS showed higher potential for growth arrest in the anterior zone (Fig. 6A), which could possibly lead to secondary recurvation malalignment when continuing TTE.

In one out of six cases, secondary loosening of the lateral posterior positioned BS occurred (Fig. 8). Our observations support previous studies that describe a loosening or dislocation rate of BS of up to 35%. In this study, RT showed a better anchoring in the bone. This might result because of the barbed structure of the legs (Fig. 1E) and the anatomically shaped crossbar, as the metaphyseal leg of the BS seemingly tends to get loose (Fig. 8). No secondary deformities of the central joint occurred in either group (Fig. 7A and B). The maintenance of the joint architecture is an important advantage of rigid implants, demonstrated by the results of this study.

BS and RT are both adequate implants for TTE, and a precise placement of the implants is of paramount importance in preventing secondary AD. Therefore, the advantages of RT (i.e., the guided implantation technique and the reduced number of needed implants) are important technical improvements, as a reduced number of implants simplifies accurate placement within a limited anatomical space, especially on the proximal lateral tibia. In combination with the k-wired guided implantation technique, the changes of implant design might reduce the number of secondary AD after TTE.

This study has to be seen with the following possible limitations in mind. (i) The authors are aware that results of animal model studies (specifically those due to the anatomical differences between growing children and immature domestic pigs) cannot directly be transferred to clinical praxis. Nevertheless, our results can add valuable knowledge for further clinical research in this topic. (ii) Fourteen weeks of growth arrest may have been too brief a period to produce significant secondary AD. Previous studies have shown, however, that only 9 weeks of temporary hemiepiphysiodesis produce significant AD in a porcine model. Therefore, the authors are confident that the 14-week period for growth arrest was sufficient to produce reliable results. (3) Even though a power analysis showed a sufficient number of subjects, due to a small sample size, the generalizability of the results may be questionable. (4) As we used the contralateral limb as control within the same pig, we cannot assure if this affected the results. Still, the study model does not affect the biomechanical properties of the two tested implants. Therefore, we don’t believe that our results were influenced by this limitation. (v) Slight differences in implant-size were used; this might have influenced the results. Still, both implants suited the local anatomy. The anatomical shaped design of the RT leads to different sizes of legs, which is an important difference between the two implants (Fig. 1E). Furthermore, commercially available standard sizes were used to reflect the clinical reality. (6) To our knowledge, this is the first study that evaluates AD after TTE by ID measurements in MR images. As previous studies show, ID is a good indicator for the measurement of total growth arrest after TTE in pigs. If the ID measurements are suitable for the detection of AD, further studies have to follow this. To our knowledge, there are no studies that correlate ID measurements in the MRI with conventional X-ray measurements. The great advantage of this method is that through reformatting, an exact alignment along the anatomy can be achieved. Mistakes caused by wrong positioning of the examined extremity can be avoided through this method. Although the possible limitations described above need to be considered, it is important to remember the study’s goal was to provide surgeons with additional options when treating skeletally immature patients with moderate LLD.

In conclusion, the results of this porcine animal model indicate that BS and RT are adequate implants for TTE. Both rigid implants do not produce central joint deformations. Whether or not the precise implant-placement through the guided implantation technique of RT and a reduced number of implants indeed lead to a reduction of secondary AD has to be investigated in further clinical trials.

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H.H. and J.S. contributed to the acquisition, analysis, and interpretation of data, drafting of the paper, approval of the submitted, and final version. B.V., G.G., B.M.M., O.R., R.R., M.G., and A.F. contributed to research design, interpretation of data, and revising the paper and approval of the submitted and final versions. H.H., J.S., and A.A.A. carried out the experiment and contributed to the acquisition and analysis of data. All authors have read and approved the final submitted manuscript.

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