merete®

Guided Growth and Growth Arrest

PediatrOS™ FlexTack™ & RigidTack™

For Temporary Hemiepiphysiodesis

Faster and Easier Implantation, Reduced Fluoroscopy and Quicker Correction*

PediatrOS™
Merete® Pediatric Implants

*Compared to Two-Hole Plates and Blount Staples.

U.S. Patent No: 10,085,743

B. Vogt, R. Rödl
Department of Pediatric Orthopedics,
Deformity
Reconstruction and Podiatric Surgery,
Münster University Hospital,
in collaboration with:

Merete Technologies, Inc.
One Lincoln Centre
18W140 Butterfield Road, 15th Floor
Oakbrook Terrace, IL 60181

Customer Service Telephone: 855-637-3831

Introduction

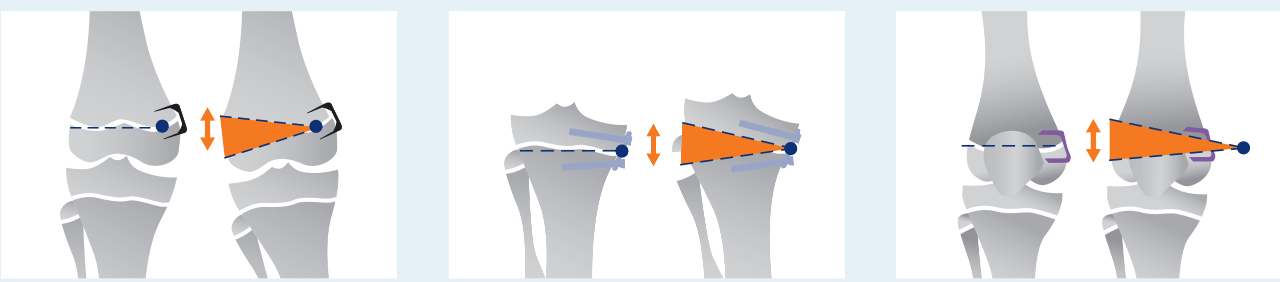
Treatments of angular deformities or differences in lengths in long bones are among the basic tasks of orthopedics. Historically, invasive transformational osteotomies with internal and external fixation systems were the only effective correction options. Often times these procedures were very stressful for patients and had non-negligible complication rates[1, 2]. Nowadays, the growth potential of the physes can be used to correct such deformities in children and adolescents through temporary or permanent arrest by epiphysiodesis (ED). Good experiences over several decades with the development of minimally invasive surgical techniques or modern, easy-to-install implants, ED now has a wide range of applications. Initially, Phemister[3-5] ED procedures were performed to influence growth permanently. However, subsequent painful conditions and restrictions of movement were not uncommon. High success rates were reported with Percutaneous[3] ED, though the irreversible procedure can cause premature, delayed or completely absent and asymmetrical stoppage of growth[3].

Figure 1: PediatrOS™ Staples. FlexTack™ 20mm (blue), 25mm (green) and 30mm (violet) a) and RigidTack™ (yellow) in 20, 25 and 30mm b).

Temporary Hemiepiphysiodesis (HED) is considered the preferred method for correcting mechanical axis deviations (MAD) and leg length discrepancies (LLD) during adolescence[1,2,6]. Generally, this is owed to the fact that a precise calculation of the time of intervention and knowledge of the residual growth potential are not mandatory[7] and that radiation exposure times are reduced. Modern implants, such as the Two-Hole Plates or conventional Blount staples, are used to induce temporary HED[1, 2, 6, 8, 9, 10]. Timely implant removal is crucial, and may lead to Iatrogenic MAD or LLD as well as rebound phenomena, if not executed correctly. Also, corrective procedures are often required due to implant-associated complications such as protrusions, loosening or breaking implants[2, 6, 9, 10]. Furthermore, inflexible Blount staples have an epiphyseal pivot point (Fig. 2a) and cause a rigid physis compression between the staple legs. Consequently, slow MAD correction rates are not unusual. Moreover, challenging positioning and removal procedures are necessary, often for multiple implants per site. Unlike staples, the Two-Hole Plates does not result in rigid compression of the epiphyseal plate, but creates a flexible tension-band effect to guide growth using an extra physeal pivot point (Fig. 2b)[1, 2, 6, 8, 9, 10]. However, the plate remains less than optimal in terms of design, surgical technique and biomechanical characteristics such as delayed correction[6, 8]. Additionally, Two-Hole Plates are not indicated for the LLD due to secondary deformities.

Consequently, a new implant intended to be functionally equivalent to common two-hole plates, based on the simplicity of staples, was needed to satisfy users who required highest positioning precision, a fast surgery technique without the need for power equipment, and reduced intraoperative fluoroscopy times. These needs are all in combination with ideal biomedical alignment during implantation as well as easy removal during explantation. This is why the novel PediatrOS™ FlexTack™/RigidTack™ staples were developed (Fig. 1) by Merete and its clinical collaborators.

The implants are indicated for growth guidance in children and adolescents through temporary HED to 1) correct axis misalignment of the knee (genu varum/valgum, genu recurvatum/antecurvatum), the hip (varus), the ankle (varus/valgus, plantar flexion), the elbow (varus/valgus) and the wrist (varus/valgus) with FlexTack™ as well as 2) to correct LLD with RigidTack™. The anatomically preformed, titanium staples with a barbed surface along cannulated legs ensure that the implants are firmly anchored in the epiphysis and that surgery is performed precisely with optimal ease of use. Each of the three sizes for FlexTack™ and RigidTack™ has a 13-degree trapezoidal design adapted medially and laterally from the anatomical characteristics of the distal femur and proximal tibia. The staples either include a flexible crossbar (FlexTack™) that creates a tension-band effect to treat MAD through an extra epiphyseal pivot point (Fig. 2c) that leads to improved MAD correction rate or a rigid crossbar (RigidTack™) that arrests growth to treat LLD.



a) Blount Staples
- Rigid staple
- Epiphyseal pivot point
= Slow correction rate

b) Two-Hole Plates
- Rigid staple
-/+ Mid plate pivot point
= Mid range correction rate

c) FlexTack™
+ Flexible staple
+ Extra epiphyseal pivot point
= Enhanced correction rate

Figure 2: Tension Band Effect with varying MAD Correction Rates. Rigid Blount staples with an epiphyseal pivot point and slow MAD correction a), Two-Hole Plates with extra-epiphyseal pivot point and improved MAD correction rates b) and FlexTack™ also with extra-epiphyseal pivot point and enhanced MAD correction rates c).

Subject Population and Surgery Technique

A clinical study, with results that are currently under peer review, was completed to compare PediatrOS™ FlexTack™ with the performance of Two-Hole Plates to correct MAD, specifically for valgus, varus and flexion knees as well as valgus ankles and varus elbows. A prospectively compiled cohort of 405 consecutive FlexTack™ implantations in 187 patients with a mean follow-up time of 1.3 years (max. 2.6 years) was compared with a historical collective of 93 patients undergoing a total of 246 Two-Hole Plates implantations with a mean follow-up time of 1.0 years (max. 2.4 years). The number of implants, the side and location as well as the age at implantation were recorded (Tab 1).

Tab 1: MAD Subject Population and Implant Location. Prospective cohort for FlexTack™ and historic cohort for Eight Plates.

187 children (m 116, f 71), 405 FlexTack™ (~ 12.0 y) | 73 children (m 41, f 32), 156 Two-Hole Plates (~ 11.7 y)						
		Valgus Knee	**Varus Knee**	**Flexion Knee**	**Valgus Ankle**	**Valgus Elbow**
No. of patients (LLD)		138 (m 79, f 59)	41 (m 31, f 10)	3 (m 2, f 1)	2 (m 2, f 0)	3 (m 2, f 1)
		56 (m 31, f 25)	17 (m 10, f 7)	0	0	0
No. of implants		307	81	10	4	3
		123	33	0	0	0
Side (bilat., rt., lt.)		85, 29, 24	22, 9, 10	2, 0, 1	2, 0, 0	0, 2, 1
		36, 11, 9	9, 4, 4	0, 0, 0	0, 0, 0	0, 0, 0
Location dF/pT, dF, pT, dT, dH		85, 63, 75, 0, 0	20, 21, 22, 0, 0	0, 5, 0, 0, 0	0, 0, 0, 2, 0	0, 0, 0, 0, 3
		30, 25, 38, 0, 0	7, 9, 10, 0, 0	0, 0, 0, 0, 0	0, 0, 0, 0, 0	0, 0, 0, 0, 0
Age at implant		~ 12.0 y	~ 12.3 y	~ 11.7 y	~ 13.0 y	~ 7.3 y
		~ 11.7 y	~ 11.0 y	—	—	—

PediatrOS™ RigidTack™ staples were additionally compared to Two-Hole Plates and Blount staples to investigate their performance when used in temporary HED for LLD. A prospective cohort with 119 RigidTack™ implantations in 37 patients with a mean follow-up time of 0.6 years (max. 1.3 years) was compared with a historical collective of 38 patients undergoing a total of 124 Two-Hole Plates implantations with a mean follow-up time of 1.0 years (max. 2.4 years). Also, a historical cohort of 137 patients with 1266 Blount staple (422 arrested physeal sites) implantations with a mean follow-up time of 1.9 years (max. 3.1 years) was taken into consideration for LLD. Again, the number of implants, the implantation site as well as the age at implantation were recorded (Tab 2)

Table 2: LLD Subject Population and Implant Location. Prospective cohort for RigidTack™ and historic cohort for Two-Hole Plates™ and Blount staples.

No. of patients (LLD)		37 (m 23, f 14)
		38 (m 21, f 17)
		137 (m 84, f 53)
No. of implants		119
		124
		1266
Operated leg (right, left)		21, 16
		22, 17
		69, 68
Location dF/pT, dFm pT		22, 11, 4
		24, 8, 6
		74, 42, 21
Age at implant		~ 11.9 y
		~ 12.3 y
		~ 11.9 y

The study documented intraoperative parameters such as duration of surgery (incision to suture) and intraoperative fluoroscopy time. Standard clinical and radiological follow-up examinations were conducted at 3 to 6 month intervals. Corrective speeds were analyzed for MAD and LLD correction per HED site. Complications were evaluated with a focus on implant-associated and biomechanical problems, though wound infections that needed revision, joint effusions as well as neurovascular complications and latrogenic deformities were also recorded. Statistical analysis was performed using the Mann-Whitney U-Test and the Fisher's Exact Test.

Instruments were designed for positioning precision, reduced surgery time and ease of use. Surgery steps as well as instrumentation are equal for both FlexTack™ and RigidTack™. Implantation was performed with following steps per site.

(Fig. 3): 1) First K-wire was inserted manually with a grip wrench, aligned parallel with the joint line or tangentially along the growth plate in a coronal view (validated with X-ray); 2) Second K-wire placed through the staple to avoid diverging legs along curved cortical bone of the epiphysis during 3) staple insertion with an impactor. Note that sub-periosteal bridge position may complicate explantation (no periosteum preparation needed, incision not through periosteum).

a) b) c) d)

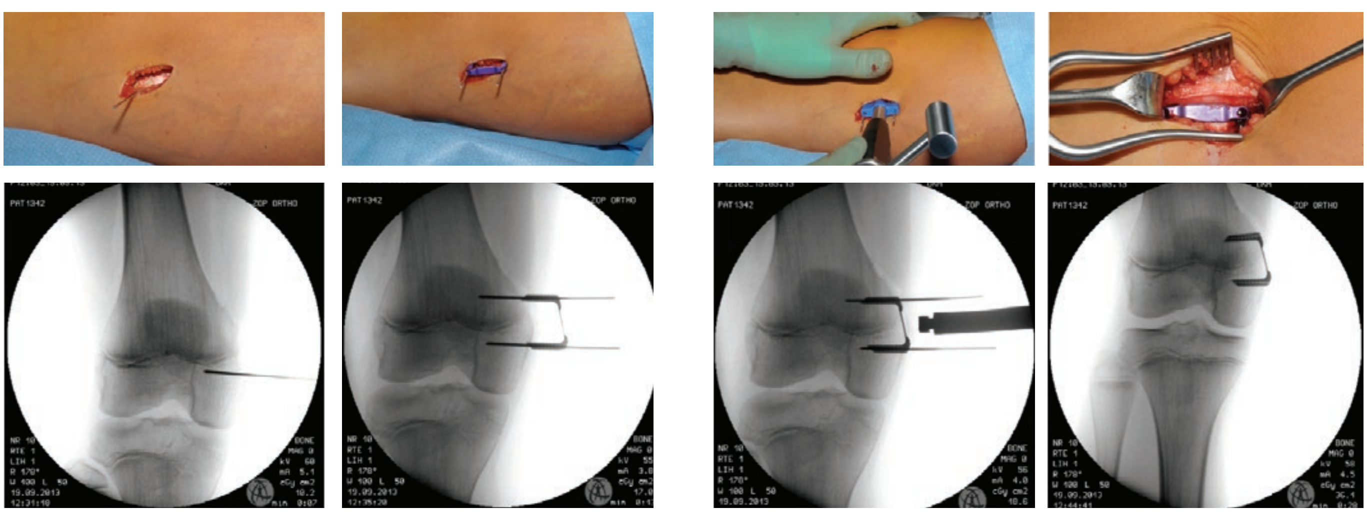


Figure 3: Implantation. Guide wire placement with grip wrench a) and; through staple legs b) to impact till c) the staple legs are fully immerse in bone d).

Preliminary Results

Implanting PediatrOS™ FlexTack™/RigidTack™ involved significant reductions in both surgery and fluoroscopy times when compared to the Two-Hole Plates and Blount staples (Fig. 5a and 5b) FlexTack™ brought about valgus correction which began comparatively sooner and progressed significantly faster (Fig. 5c) with an average MAD correction rate of 3.02 mm/month compared to 1.50 mm/month for Two-Hole Plates. Thus, implantation was possible at a later age with FlexTack™ (~ 12.0 y) than with Two-Hole Plates (~ 11.7 y). However, no significant speed differences were seen in varus correction. LLD correction rates were 1.01 mm/month with RigidTack™ compared to Two-Hole Plates with 0.45 mm/month and Blount staples with 0.66 mm/month (Fig. 5d). RigidTack™ and Blount staples were implanted at on age of 11.7 years and Two-Hole Plates at 12.0 years on average.

Differences in complication rates across groups were not significant for wound infections, joint effusions and neurovascular complications. Implant-associated complications were significantly different (Fig. 6). When used to correct MAD: only two implant-associated complications involving one staple breakage and one laterally loosened staple leg (joint side) accompanied by soft-tissue irritation were observed on distal femur sites in subsequent follow-up examinations conducted on FlexTack™ patients. This leads to a complication rate of 1.1%. In the MAD group, implant-associated complication rates for Two-Hole Plates were 10.8% mainly due to fracturing screws (Fig. 6a) and secondary deformities. Conventional Blount staples showed 34.6% due to breaking, migrating or malpositioned staples that led to secondary deformities. When used to correct LLD (Fig. 6b), implant–associated complication rates were 2.7% for RigidTack™, 10.5% for Two-Hole Plates and 14.6% for conventional Blount staples. Latrogenic deformities were reduced in the prospective cohort (Fig. 4), seven legs (9.8 %) treated with rigid staples showed secondary deformities in the frontal plane during follow up. Five (7.0 %) mechanical axis deviations (MAD), thus zone changes between postoperative and follow-up radiographs into varus and two into valgus (2.8 %) position, were recorded. The subgroup of 47 LLD patients, included two legs (4.3 %) that were in varus position and none in valgus. Three somatomegaly patients (two bilateral, one unilateral) showed secondary frontal plane deformities. A total of six out of 38 patients (15.8 %) treated with two-hole plates that showed secondary deformities (valgus 3/38, 7.9% and varus 3/38, 7.9%) during follow-up. Blount staples led to a total of 47 frontal plane deformities (47/137, 34.3 %), 35 (25.6%) varus and 12 (8.8%) valgus positions were recorded. Therefore, the number of MAD zone shifts is reduced in LLD patients that received rigid staples, if bilateral somatomegaly intervention (12 out of 71 legs) are excluded. Additionally, recurvation deformities occurred in 15 out of 31 subjects with two-hole plates (48.4%) and 33 out of 84 with Blount staples (39.3%), in contrast to one rigid staple (1.4 %) TED out of 71 legs.

Thus far, completed axis correction has been documented in 90 patients (40.91%), whose FlexTacks™ were removed without difficulty after 1.84 years (1-3.6 years) (Fig. 7).

Figure 4: Secondary Frontal Plane Deformities. Clinical outcome comparison between rigid staples, two-hole plates and Blount staples for mechanical axis zone changes into valgus and varus.

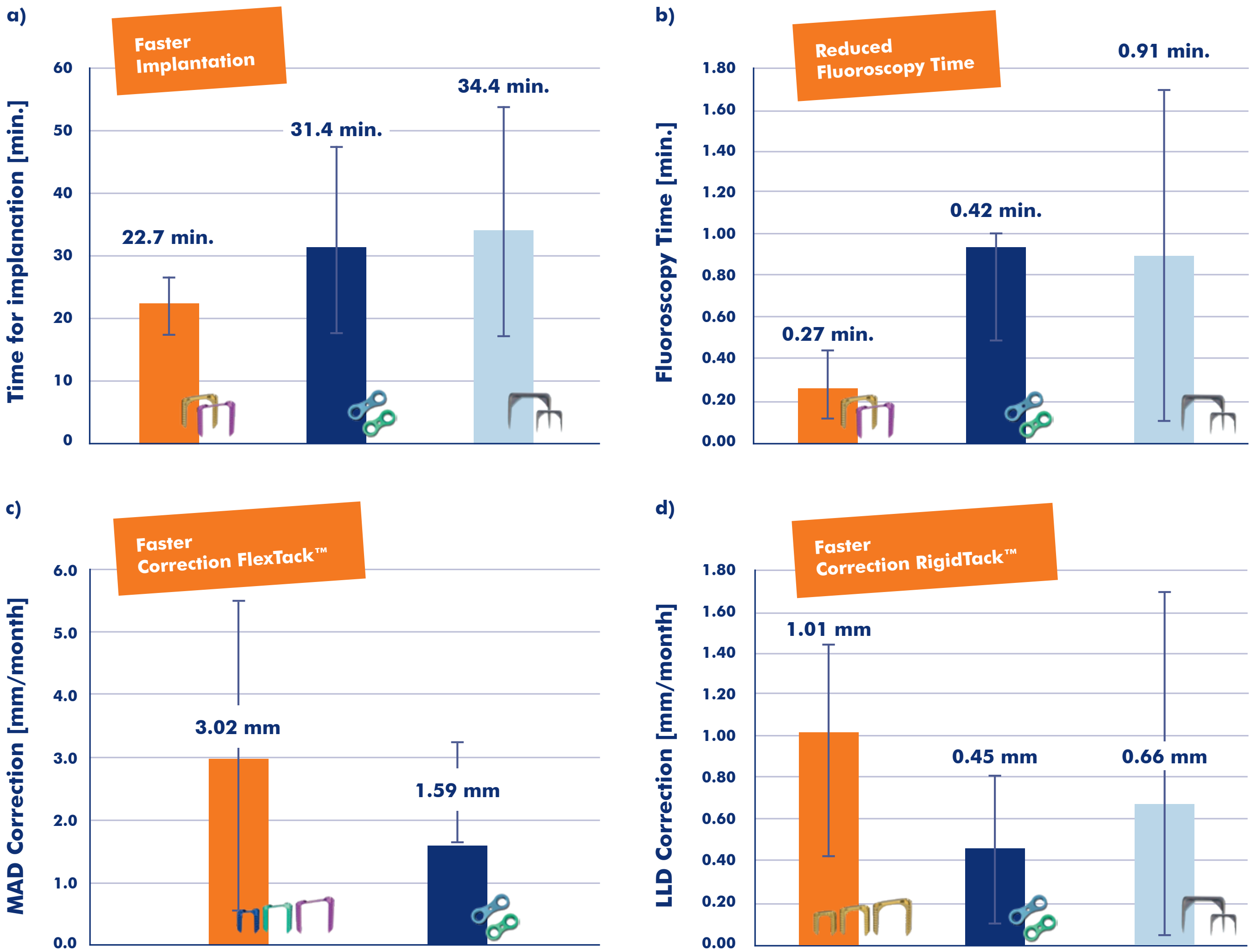


Figure 5: Performance Comparison. Implantation times (Incision to suture) per epiphysiodesis site a) and fluoroscopy times for the entire collective with correction rates b) for MAD c) and LLD d) .

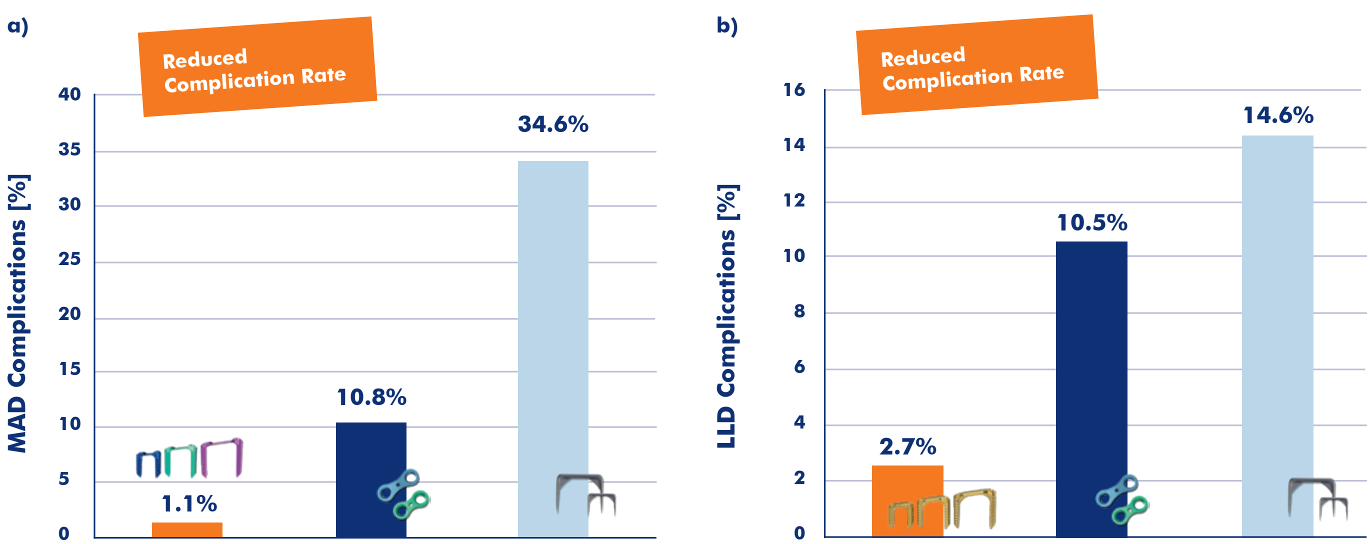
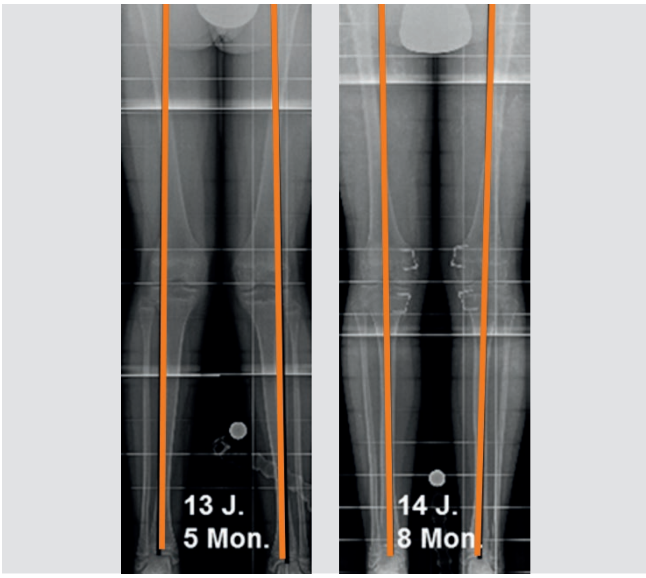


Figure 6: Implant-associated Complication Rates. Compared for MAD a) and LLD b).

Explantation involved (Fig. 8) 1) Exposure of the cannulated staple legs to insert threaded K-wires; 2) Driving a U-profile chisel collinearly over the guide wires into the epiphysis to clear the bone-implant interface; and 3) extracting the staple with a slap hammer.

a)



b)

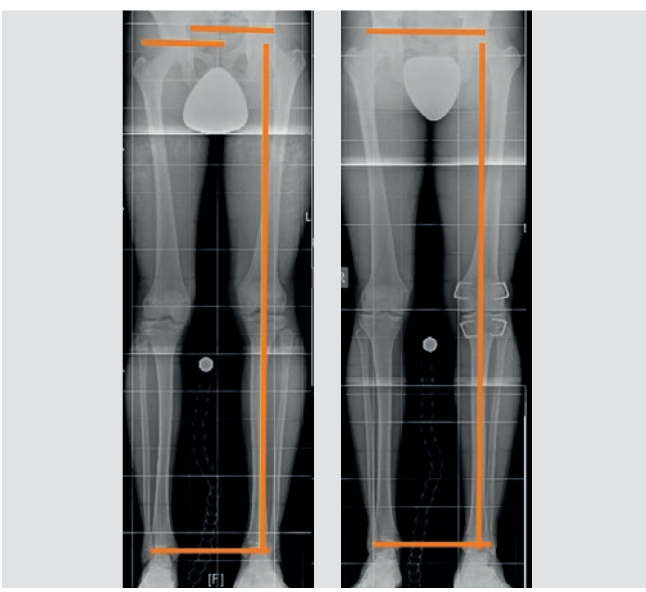
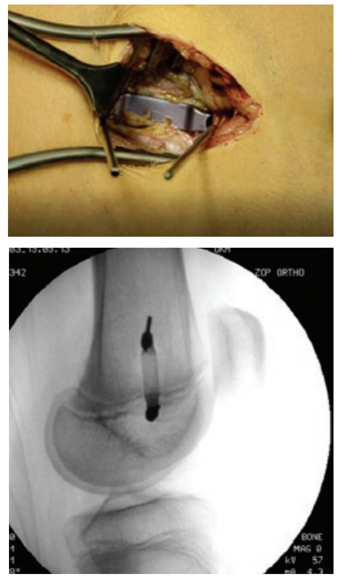


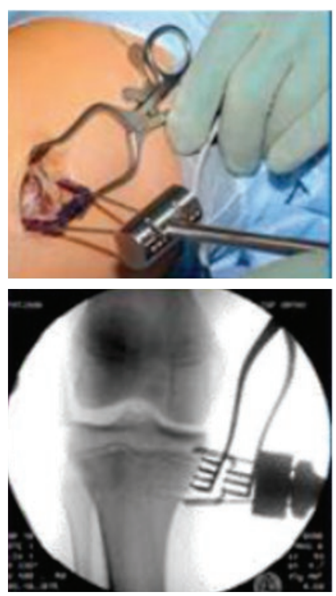
Figure 7: Completed MAD and LLD correction. Completed Performed for Genum valga with FlexTack™ at 13 years and 5 months, top-left, corrected after 21 months at 15 years and 2 months of age, top-right a). And performed for LLD with RigidTack™ at 11 years and 1 month, bottom-left, corrected after 3 years and 7 months at 14 years and 8 months of age, bottom-right b).

a)



b)

c)



d)

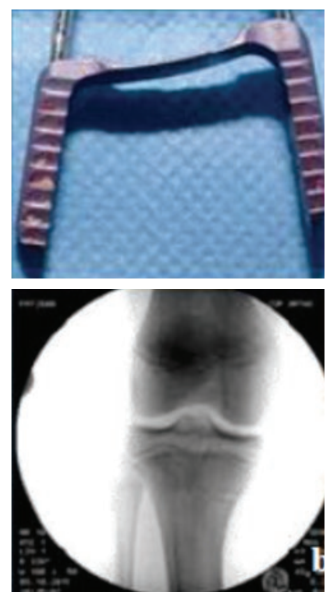


Figure 8: Explantation. K-Wire Placement a); Chisel insertion b); and extraction with slide hammer to fully remove the PediatrOS™ staple without residual bone lead to complete c), complication-free removal without bone loss d).

Discussion

PediatrOS™ was first introduced in Germany in 2013. Since then, FlexTack™ has been successfully used more than 1,700 times and RigidTack™ more than 900 times. The preliminary results above focus on temporary HED with this novel product line to illustrate the superior performance when compared to competitors such as Two-Hole Plates and Blount staples.

Implantation time, recorded across users of varying experience levels, was significantly faster compared to either Two-Hole Plates (8.7 min) or Blount staples (11.7 min). Intraoperative fluoroscopy time was reduced by 0.20 min compared to Two-Hole Plates and by 0.64 min compared to Blount staples. Thus, patients will not be strained with long surgeries or extended radiation exposure. Primarily, this is owed to an improved surgery technique and optimally usable instruments with a minimum number of necessary components. MAD correction rates were improved nearly twofold from 1.59 mm/month with Two-Hole Plates to 3.02 mm/month with FlexTack™. RigidTack™ LLD correction rates out-performed Two-Hole Plates by 0.56 mm/month and Blount staples by 0.35 mm/month. This allows surgeons to intervene at a later age to correct MAD or LLD in patients closer to skeletal maturity which limits possible rebound effects. Furthermore, the total amount of foreign bodies was reduced from three, e.g. two screws and a compression plate or three staples per HED site to one with PediatrOS™ FlexTack™/RigidTack™.

Compared to the best competitor, implant-associated complication rates were reduced by an order of magnitude for MAD and fourfold for LLD. More specifically, complication rates were reduced from ~10% in Two-Hole Plates interventions to 1.1% with FlexTack™ in MAD and 2.7% with RigidTack™ in LLD. Axis misalignments corrected over an extend amount of time with Two-Hole Plates generally lead to diverging screws in situ, subsequently screws "hit a hard stop" within the two-hole plates and deform until fracture. Additionally, screws migrate and loosen within the plate through increasing axial pull-out forces induced by the growth plate a period after plate. Moreover, the use of Two-Hole Plates functionally allows medial growth within the physis through diverging screws within the plate after bilateral arrest during the treatment of LLD. Secondary deformities (volcano effect) are the consequence. Blount staples and Two-Hole Plates are often accompanied by iatrogenic deformities (genu recurvatum) caused by ventral implantation locations necessary in the proximal tibia to avoid fibular head interferences.

No secondary deformities were recorded with FlexTack™/RigidTack™. The two implant-associated FlexTack™ complications (loosening, breakage) were most likely owed to user-errors due to a steep implantation angle and trapped cartilage while staples were impacted towards the periosteum. This was suggested postoperatively by a fluoroscopically visible fissure line within the bending zone of the staple that fractured postoperatively.

No iatrogenic secondary deformities were recorded with FlexTack™. The two implant-associated FlexTack™ complications (loosening, breakage) were most likely owed to user-errors due to a steep implantation angle and trapped cartilage while staples were impacted towards the periosteum. This was suggested postoperatively by a fluoroscopically visible fissure line within the bending zone of the staple that fractured postoperatively. Additionally, postoperative zone changes, thus, secondary varus/valgus deformities were reduced with RigidTack™ due to an improved central positioning across the physis within the frontal plane and the improved cortical fixation with barbed staple prongs. Growth arrest with Blount-Staples lead to frequent implant dislocations along the distal non-barbed staple prong within the tibia, wherefore, the correction is lost unilaterally. Rectangular Blount-staples do not adapt to the local anatomy, specifically along the medial tibia. Consequently, non-barbed staple legs that are only partially immersed in bone migrate postoperatively and introduce elevated secondary varus deviations (25.6%). Two-hole plates were fixated with threaded compression screws, thus, dislocations are migrations with subsequently zone changes are less pronounced (7.9%). However, parallel screw alignment for homogenous arrest across the physis was difficult to adjust intraoperatively.

Conclusion

The PediatrOS™ FlexTack™/RigidTack™ represents a logical synthesis of staples and cannulated screw/plate systems. Its simplified surgical technique reduces both surgery times and radiation exposure. Its biomechanical improvements resulted in faster correction with almost no implant-associated complications.

Examples




References

[1] Stevens PM., Klatt JB. (2007). J Pediatr Orthop. 27: 253-259.
[2] Wiemann JM., Tryon C. et. al. (2009) J Pediatr Orthop. 29:481-485.
[3] Hasler CC (2000). Orthopade 29:766–774.
[4] Phemister D (1933). J Bone Joint Surg Am 15:1–15.
[5] Raab P, Wild A, Seller K et al (2001) Eur J Pediatr 160:668–674.
[6] Vogt B., Schiedel F. et. al. (2014). Orthopäde. 3:267-284.
[7] Stevens PM, Maguire M, Dales MD et al (1999). J Pediatr Orthop. 19:645–649.
[8] Burghardt RD:, Herzenberg JE. et al. (2008) J Child Orthop. 2:187-197.
[9] Schroerlucke S., Bertrand S. et. al. (2009). J Pediatr Orthop. 29:57-60.
[10] Ballal MS., Bruce CE. Et. al. (2010). Bone a. Joint J. 92:273-276..

Distributed by

Merete Technologies Inc. (MTI)
One Lincoln Center
18W140 Butterfield Rd., 15th Floor
Oakbrook Terrace, IL 60181

Phone: 630-869-1019
Fax: 630-445-1752

order@merete-medical.com
www.mereteUSA.com

Manufactured by

Merete GmbH
Alt-Lankwitz 102
12247 Berlin
Germany

Tel.: +49 (0)30 77 99 80 - 0
Fax: +49 (0)30 76 68 03 61

service@merete.de
www.merete.de