Hallux Valgus Correction Using a Mini TightRope Device: A Report of the Short Term Outcomes in 3 Feet

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Objective: *Bony works seems to be base procedure for hallux valgus correction. Due to the challenge and possible complications of these procedures, these issues generate 'Foot and Ankle Society' to consider alternative procedures. The 'Mini TightRope' (Arthrex, Inc., Naples, FL) or interrosseous suture/button device was introduced in 2007 to address the above mentioned point. Although its feasibility and utilization were attractive, some reports revealed its drawbacks and limitations. The present report is to demonstrate short-term outcomes and information that might be useful for avoidance of potential complications from application of this device.*

Material and Method: *Three involved-feet in 2 patients with recalcitrant conditions and progressive hallux valgus, with at least a 6-month course of conservative treatment, were included. Limitation criteria for using 'Mini TightRope' were; non-athletic demand, good bone-stock, moderate severity of their hallux valgus (hallux-valgus-angle (HVA): 30-40, intermetatarsal-angle (IMA): 14-20), no hypermobility of first tarsometatarsal joint, and no signs of degenerative joint disease of first metatarsophalangeal/tarsometatarsal joint. Baseline data, American-Orthopaedic-Foot-and-Ankle-Society (AOFAS) scores, Visual-Analogue-Scale Foot-and-Ankle (VAS-FA) scores (including radiographic parameters) were collected at pre- and post-operative periods. The operations were carried out by a single surgeon. Precision in the creation of the interosseous-tunnel between 1st -2nd metatarsals was critical for this device. All patients strictly followed a similar postoperative-protocol, with austere prohibition of premature weight-bearing at forefoot-and-midfoot areas in 1-month postoperative-period.*

Results: *Although pre-postoperative (6-month) AOFAS/VAS-FA scores and radiographic angular differences were non-significant as to p-value: 0.10, there were satisfactory improvements of all scores and angular values in all postoperative periods. Patient number-two reported some tightness at 1st-2nd intermetatarsal area on left-foot. This was controlled with oral-medications in 1-month postoperative-period. Besides, there were no significant complications in the present report.*

Conclusion: *'Mini TightRope' might be of merit in hallux valgus correction for well-selected patients provided that technical implementation is precise and postoperative-protocol is followed with proper discipline.*

Keywords: *Mini TightRope, Interosseous suture and button device, Hallux valgus, Forefoot surgery, Short term, Outcome*

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Nowadays, there are many options in use for hallux valgus correction. Each procedure provides its characteristics of technique, advantages and disadvantages. Each patient will be considered for each procedure depending on his or her degree of deformity, age, activity level and underlying disease[1]. Other important considerations are osteopenic or osteoporotic conditions.

Distal or proximal osteotomy of the first metatarsal seems to be the mainstay procedure for the correction of the first intermetatarsal angle (IMA)[2]. By reasoning of the challenge and possible complications of these bony procedures; *i.e.* shortening, dorsiflexion angulations, delayed union, and non-union[2], these issues have motivated the foot and ankle surgeons to consider optional procedures. Joplin RJ proposed his concept about splay foot correction using a soft tissue sling via an adductor

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hallucis tendon transfer for the reduction of the first IMA[3]. According to the idea of Joplin RJ, the Mini TightRope (Arthrex, Inc., Naples, FL) was introduced placed between the first and second metatarsal for the creation of a structure acting as a ligament to restrain the first IMA, preventing medial migration of the first metatarsal[3-5]. Although there are many advantages of the Mini TightRope application in terms of avoiding of the complications from osteotomies; such as avascular necrosis, non-union, malunion, etc; there was a report of a second metatarsal stress fracture after using this device to correct hallux valgus[6]. This point led to the meticulous consideration of the Mini TightRope use, including the cautious selection of patients for a procedure using this device.

The present study is to report the short term outcomes of the correction of hallux valgus with moderate deformity in 2 selected patients, 3 feet in total, with good bone stock and no hypermobility of first tarsometatarsal joint or arthritic conditions of first metatarsophalangeal/ tarsometatarsal joint.

Material and Method

Baseline data collection

Two patients; with recalcitrant conditions and progressive hallux valgus, following in at least a 6-month course of standard, conservative treatment; were included in the present report. The baseline data collection was recorded (Table 1). The American Orthopaedic Foot and Ankle Society (AOFAS)[7], Visual Analogue Scale-Foot and Ankle (VAS-FA)[8] score, radiographic measurements by a radiologist (WA) in terms of the hallux valgus angle (HVA), intermetatarsal angle (IMA) and distal metatarsal articular angle (DMAA) were collected preoperatively and immediately postoperative. Further data was collected at the 1-month, 3-month and 6-month postoperative period. During the postoperative periods; the AOFAS and VAS-FA scores, including additional evaluations were obtained by another physician (SK) who was not an attending surgeon at time of the operation. The criteria for the using the Mini TightRope device were patients with non-athletic demand, good bone stock, moderate severity of hallux valgus (HVA: 30-40, IMA: 14-20)[9,10], no hypermobility of first tarsometatarsal joint, and no evidence of degenerative joint diseases of the first metatarsophalangeal/tarsometatarsal joint.

Surgical procedure

The operations were carried out by the same surgeon (CA) in 2010. The surgical procedures were performed with the patient in a supine position with a padded tourniquet applied to the ipsilateral thigh with proper anesthesia technique. The modified McBride bunionectomy, including removal of medial eminence and release of the adductor tendon in the first intermetatarsal space was performed in all cases. The 1.2 mm guide wire was placed from the 2nd metatarsal across and through the 1st metatarsal. This augments the simplicity of accurately bisecting the 2nd metatarsal in reference to the dorsal and plantar portions of the metatarsal. Then the 2.7 mm Cannulated Drill Bit was used to drill the tunnel for the Mini TightRope over the Guide wire in a medial to lateral direction. Proper placement was confirmed with a C-Arm x-ray machine. The authors recommendation is to avoid making more than 1-2 attempts to create the proper interosseous tunnel. More attempts may increase the weakening of the stress riser through previously unused tunnels which could precipitate postoperative stress fractures of the metatarsals. The 1.6 mm guide pin was passed with a pull-through suture, attached to the Mini TightRope, from the lateral (2nd metatarsal) to the medial (1st metatarsal) and stopping before the button entered the drill hole. The pull-through suture was advanced while the guide pin was pulled medially. At the same time, the lateral tension was applied on the blue suture just behind the oblong button[12]. The oblong button

Table 1. The demographic data characteristics of patients

Patients /Side of involved foot	Age (years)	Gender	Occupation	Follow-up (weeks)	Complication
1/right	41	Female	Housewife	26	None
2/right	31	Female	Police officer	24	None
2/left	31	Female	Police officer	24	Tightness at 1st-2nd IMA*

*This symptom was reported by a patient in 1-month postoperative period. IMA: intermetatarsal area

was turned over upon exiting the medial side of the 1st metatarsal cortex at the area just proximal to the medial eminence[12]. The 1st metatarsal and the 2nd metatarsal were manually reduced to each other to correct the intermetatarsal angular deformity using a point reduction clamp. The temporarily corrected IMA was measured and confirmed by C-arm. The trailing round button was tightened down by applying gradual tension on the remaining two strands of blue suture. Then, 2-3 half hitches were tied and the suture was cut[11]. Eventually, a medial capsular plication was performed, wound closure was done, a bandage was then applied and maintained in a corrected position of the hallux[5].

Postoperative care

During the 4-week postoperative period, the patient was advised to use a controlled-ankle motion walker on the involved foot with weight-bearing on the heel more than on the mid and/or forefoot areas. Then, the patient was allowed to use a stiff-soled shoe for a period of 2 weeks. Thereafter, the patient was instructed to wear a shoe with a wide toe box[5]. A toe spacer was used during the entire 12-week postoperative period.

Statistical analysis

Statistical analysis was implemented using the SPSS 13.0 (SPSS: Chicago, IL). The Wilcoxon signed rank test was used to compare the AOFAS/VAS-FA scores and radiographic angular values between the preoperative and 6-month postoperative period. The statistical significance was identified at $p < 0.05$ level.

Results

The demographic data

The data characteristics included age, gender, occupation, follow-up time and complications are as shown in Table 1. There were two patients of which three feet with hallux valgus were included in the present study.

Score results

Table 2 indicates the score results and the comparison between the preoperative and postoperative AOFAS scores and VAS-FA scores. Although non-significant differences were shown at p-value: 0.10 for all score types between the pre-and-postoperative periods, there were satisfactory improvements of the postoperative AOFAS and VAS-FA scores in all periods of follow-up.

Radiographic angular measurements

Table 3 shows the comparisons between the preoperative and postoperative radiographic variables. Although the pre-postoperative angular differences were not significantly different at p-value: 0.10 between the pre-and-postoperative periods, there were the satisfactory improvements of the 6-month postoperative IMA, HVA and DMAA as compared with the preoperative values (Fig. 1 and 2). There were no migrations of the internal buttons as evidenced from radiographic follow-up. In the radiographs at the 1-month follow-up, interosseous tunnels were filled with bridging trabeculae in all three feet involved.

The second patient reported some tightness at the 1st-2nd intermetatarsal area on the left foot during 1-month postoperative period; however, this symptom resolved uneventfully, alleviated with oral medications. Besides, there were no significant complications or need for device removal in the present reports as far as the 6-month follow-up. In addition to the postoperatively improved AOFAS and VAS-FA scores, both patients subjectively reported their quality of life to be

Table 2. Score results and the comparisons between the preoperative and postoperative period

Patients/Side of involved foot	Score Types	Preoperative	Immediate postoperative	1-month postoperative	3-month postoperative	6-month postoperative*
1/right	AOFAS	39	69	82	87	97
	VAS-FA	61.5	64.9	77.8	83.6	86.7
2/right	AOFAS	37	65	87	89	89
	VAS-FA	28.8	39.3	69.9	75.5	79.6
2/left	AOFAS	42	65	82	85	87
	VAS-FA	30	38.05	69.2	76	80

*Non-significant differences between the pre-and-postoperative (6-month follow-up) results were shown as p-value: 0.10 for all score types

Table 3. The results of radiographic angular measurements

Patients/Side of involved foot	Angular Types*	Preoperative	Immediate postoperative	1-month postoperative	3-month postoperative	6-month postoperative**
1/right	First IMA	20	6	8	9	10
	HVA	32	0	12	12	12
	DMAA	21	0	6	8	9
2/right	First IMA	18	4	5	6	7.5
	HVA	35	2	7	8	8
	DMAA	33	0	5	7	7
2/left	First IMA	17	8	8	10	10
	HVA	23	12	12	15	15
	DMAA	26	6	10	12	12

*The unit of each type is degree
**Non-significant differences between the pre-and-postoperative (6-month follow-up) results were shown as p-value: 0.10 for all angular types

Fig. 1 (A, B) Preoperative radiographs show moderate deformity of the hallux valgus of the right foot (case 1). The six-month postoperative radiograph shows a satisfactory correction with a healed interosseous tunnel

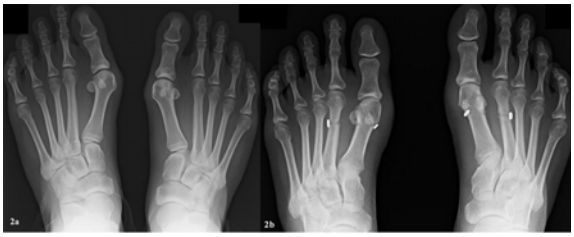

Fig. 2 (A, B) Preoperative radiographs show a moderate deformity of the hallux valgus of the both feet (case 2). The six-month postoperative radiographs show satisfactory correction with a healed interosseous tunnel of each foot

satisfactory postoperatively. This was evidenced with unnecessary postoperative splinting (longer than a month), immediate postoperative weight-bearing on their heels and early use of shoes at 1-month post surgery.

Discussion

Nowadays, there are more than 100 procedures to correct the deformity of hallux valgus[12]. Normally, if the deformity presents with a mild degree abnormality, it may be corrected with a distal osteotomy, while with proximal procedures, arthrodesis, or combined osteotomies are utilized for the patients with more progressive, severe deformities[10]. With several procedural options, cautious decision should be considered for the most proper surgical treatment. The surgeon should realize all the drawbacks and possible jeopardy with each procedure. The possibility of the many complications of the fore mentioned osteotomies and arthrodesis were reported such as; shortening of the first metatarsal, dorsiflexion malunion, delayed union, non-union, recurrence of the deformity, incomplete correction, osteonecrosis of the capital fragment and hallux varus[12-14]. The idea of the correction via soft-tissue transfer may be necessarily re-considered to avoid the complications of bony procedures. Tendon transfers were proposed for use as slings to reconstruct the deformity and prevent the recurrence of the hallux valgus[3,15]. In 2007, the Mini TightRope or interosseous suture/button device was

launched for use as an artificial sling between the first and second metatarsal in accordance to the fore mentioned concept[3-6]. In cadaveric studies, repair with this device has been proven with no differences in IMA measurements compared with using the chevron osteotomy[6]. According to the recommendation of the device manufacturers, a patient is able to mobilize with full weight-bearing in a stiff-soled shoe immediately after repair[11,16]. An increasing utilization of this device may be originated from the above mentioned benefits. However, some reports propose the complications and drawbacks from the application of this device such as; stress fractures of the second or forth metatarsals, hallux varus and recurrences of the deformity[5,6]. These complications might be related with an increase in stress at the intraosseous tunnel or distal level of the second metatarsal purchase point[5,6].

In the present report, the authors' patients were selected and counselled with cautious consideration as for the application of this device. The additional indications were; good bone stock, non-athletic demands, no hypermobility of first tarsometatarsal joint and no signs of degenerative joint diseases of the first metatarsophalangeal/ tarsometatarsal joint. For techniques of the application, the present report recommends avoidance of making more than 1-2 attempts for the appropriate interosseous tunnel. More attempts may increase the frailty of the stress riser through previously unused tunnels which may precipitate postoperative stress fractures of the metatarsals. After the surgery, our patients strictly followed our postoperative protocol, especially the protocols of prohibition of premature weight-bearing at the forefoot and/or midfoot areas in the 1-month postoperative period. In consideration of at least the 6-month follow-up, although the pre-postoperative scores and radiographic angular differences were non-significant, there were little decreases in correction (re-elevation of IMA, HVA and DMAA degree), with satisfactory improvements of AOFAS/VAS-FA scores in all postoperative periods of follow-up. The non-significant differences of the pre-and-postoperative findings in terms of AOFAS/VAS-FA scores and angular values might be created from the small number of patients and short follow-up period in the present report. In terms of other findings, there were no serious complications or the need for device removal. The interosseous tunnels of all involved the feet were re-filled with trabeculae at 1 month following the surgery. The good bone stock of our patients might play a role in this rapid recovery which may prevent stress fractures of the metatarsals. Therefore, bone conditions might be a factor with need for further investigation to the effects of the outcomes after the application of the interosseous suture/button device.

Although recognition of the limitations of the authors present report, in terms of the few numbers of involved feet or the short period (6-month) of follow-up. All of the results provide that the worthwhile information; well-selected patients, precision in the technical procedure and postoperative awareness of the risk of premature weight-bearing might help avoid the potential, early complications of using of the Mini TightRope or interosseous suture/button device in hallux valgus correction. An additional amount of patients and a longer follow-up period is needed in subsequent studies to help clarify the significant improvements from the application of this device.

Conclusion

The Mini TightRope or interosseous suture/ button device may be of merit in hallux valgus correction for the appropriate patients, provided that the technical implementation is precise and the postoperative protocol is followed with the proper disciplines.

Potential conflicts of interest

None.

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การผ่าตัดแก้ไขภาวะผิดรูปแบบโก่งออกนอกของนิ้วหัวแม่เท้าโดยใช้อุปกรณ์พิเศษชนิดกระดุมมินิไทต์โรป: รายงานผลการรักษาระยะสั้นจาก 3 เท้า ที่ได้รับการผ่าตัด

ชญานิน อ่างทอง, ศุภกิจ คณิตเนตร, วิรณา อ่างทอง

วัตถุประสงค์: *ปัจจุบัน การผ่าตัดแก้ไขโดยการตัดหรือเชื่อมกระดูกเท้าเป็นวิธีการหลักในการรักษาภาวะผิดรูปแบบโก่งออกนอกของนิ้วหัวแม่เท้า อย่างไรก็ตามงานวิจัยหลายงานบอกถึงความยากลำบากสำหรับขั้นตอนของการผ่าตัดดังกล่าวรวมทั้งภาวะแทรกซ้อนที่ตามมา จากจุดนี้ได้ทำให้วงการศัลยแพทย์เท้าและข้อเท้าศึกษาหาวิธีผ่าตัดทางเลือกอื่นๆขึ้น อุปกรณ์พิเศษชนิดกระดุมมินิไทต์โรปได้รับการคิดค้นขึ้นใน พ.ศ.2550 และแม้ว่าจะมีข้อดีในแง่ของการใช้งานที่ง่ายและมีประโยชน์ในการผ่าตัดรักษาด้วยอุปกรณ์ดังกล่าว กลับพบว่ามีการรายงานถึงผลข้างเคียงและข้อจำกัดของอุปกรณ์นี้เช่นกัน การศึกษานี้มีจุดประสงค์เพื่อรายงานผลการรักษาระยะสั้นและข้อมูลที่เป็นประโยชน์ในการหลีกเลี่ยงภาวะแทรกซ้อนจากการผ่าตัดรักษาที่ใช้อุปกรณ์นี้*

วัสดุและวิธีการ: *การศึกษานี้ได้รวบรวมผู้ป่วยที่มีภาวะผิดรูปแบบโก่งออกนอกของนิ้วหัวแม่เท้าจำนวน 2 ราย (ทั้งหมด 3 เท้า) ซึ่งมีความผิดรูปมากขึ้นแม้ได้รับการรักษาแบบอนุรักษ์นิยมมาแล้วอย่างน้อย 6 เดือน ข้อบ่งชี้อื่นๆ ของการผ่าตัดด้วยวิธีนี้ คือ การใช้งานแบบไม่ใช่นักกีฬา, สภาพกระดูกที่ดี, ความรุนแรงของการผิดรูปแบบ ปานกลาง (มุม hallux-valgus-angle (HVA): 30-40 องศา, มุม intermetatarsal-angle (IMA): 14-20 องศา), ไม่มีพิสัยการเคลื่อนไหวของข้อ first tarsometatarsal ที่มากผิดปกติ และ ไม่มีการเสื่อมของข้อ first metatarsophalangeal/tarsometatarsal การศึกษานี้ได้รวบรวมข้อมูลพื้นฐานของผู้ป่วยรวมทั้งคะแนนประเมินของเท้าและข้อเท้า (American-Orthopaedic-Foot-and-Ankle-Society (AOFAS) scores, Visual-Analogue-Scale Foot-and-Ankle (VAS-FA) scores) และค่ามุมจากการประเมินผลทางภาพถ่ายรังสีวิทยาโดยบันทึกข้อมูลทั้งก่อน-หลังผ่าตัด การผ่าตัดกระทำโดยศัลยแพทย์เท้าและข้อเท้า 1 ท่านซึ่งเน้นเรื่องของความแม่นยำในการทำช่องระหว่างกระดูก 1st-2nd metatarsals ขณะทำการผ่าตัด ผู้ป่วยทุกคนจะได้รับคำแนะนำลักษณะเดียวกันในการปฏิบัติตนอย่างเคร่งครัดหลังผ่าตัดและเน้นย้ำถึงการหลีกเลี่ยงการลงน้ำหนักที่บริเวณเท้าส่วนกลาง-ปลายในช่วง 1 เดือนแรกหลังการผ่าตัด*

ผลการศึกษา: *การเปรียบเทียบความแตกต่างระหว่างก่อน-หลังผ่าตัดในส่วนของคะแนนประเมินของเท้าและข้อเท้า (AOFAS, VAS-FA scores) และค่ามุมจากการประเมินผลทางภาพถ่ายรังสีวิทยา พบว่าไม่มีนัยสำคัญที่ p-value: 0.10 อย่างไรก็ดี การศึกษานี้พบว่า ค่าคะแนนและค่ามุมทางรังสีวิทยาดีขึ้นอย่างเป็นที่น่าพอใจในทุกช่วงเวลาหลังผ่าตัด ผู้ป่วยรายที่ 2 มีอาการตึงๆที่บริเวณ 1st-2nd intermetatarsal ของเท้าซ้ายโดยที่อาการดังกล่าวดีขึ้นหลังได้รับยาบรรเทาอาการในช่วง 1 เดือนแรกหลังการผ่าตัด นอกจากนี้ไม่มีรายงานถึงภาวะแทรกซ้อนอื่นๆในการศึกษานี้*

สรุป: *อุปกรณ์พิเศษชนิดกระดุมมินิไทต์โรปนั้นอาจมีประโยชน์มากในการนำมาใช้ในการผ่าตัดแก้ไขภาวะผิดรูปแบบโก่งออกนอกของนิ้วหัวแม่เท้าในผู้ป่วยที่ได้รับการพิจารณาก่อนผ่าตัดเป็นอย่างดีแล้วถึงข้อบ่งชี้และความเหมาะสมโดยเฉพาะอย่างยิ่งเมื่อทำการผ่าตัดด้วยเทคนิคที่ถูกต้องแม่นยำรวมทั้งการแนะนำให้ผู้ป่วยปฏิบัติตนหลังผ่าตัดอย่างเหมาะสมและเคร่งครัด*