Results of Hallux Abducto Valgus Surgical Correction Using Two 1.1mm Mini TightRope Constructs

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Hallux valgus represents an acquired foot deformity defined by medial deviation of the first metatarsal bone combined with lateral shift of the hallux and medial metatarsophalageal joint eminence enlargement. The functional impairment and metatarsalgia generated stem from the biomechanical imbalance which does not allow for normal transfer of weight trough the first ray during walking. The results generated with our experience with the 1.1mm Mini TightRope® Disposable Kitin the treatment of hallux valgus are analyzed in this paper. A total number of 24 feet (12 bilateral cases) with hallux valgus, surgically treated in our department were followed for a period of minimum twelve months and evaluated. The results showed an improvement of the mean preoperative IMA 14.6°to 7.9° postoperatively and 9.2° at six months after surgery. The preoperative measured HVA was reduced from 28.4to 14.2° at once and 16.1° after six months. The AOFAS hallux metatarsophalangeal-interphalangeal score resulted improvement reflects the functional benefits. These results confirm the good correction potential of the technique and support it as avalid treatment option for mild to moderate severity hallux valgus.

Keywords: Hallux valgus, intermetatarsal angle, metallic button, suspension system

Hallux abducto valgus is one of the most prevalent foot deformities addressed in orthopedic and podiatric practice. It comprises the medial eminence expansion of the first metatarsal head andthe biomechanical deficiency of the first ray in supporting body weight throughoutthe push-off step of normalgait.

This biomechanical imbalance is the expression of first metatarso-phalangeal joint alignment disruption, withmedial deviation of the metatarsal bone and lateral deviation of the corresponding phalanx combined with lateral displacement of the sesamoids.The inability of the first ray to transfer weight in a physiological manner generates overloading, mainly of the second metatarsal head and the other subsequent metatarsals manifested as metatarsalgia. Pain also results from the expanded medial eminence (bunion) conflicting with the footwear and the abnormal weight bearing on its head.The aesthetics concern prompted by the resulted deformity is another important element that weighs in on the decision for surgical correction.

Nowadays the etiology of hallux valgus is considered to be multifactorial and it involves a multitude of intrinsic and extrinsic factors. The suggested intrinsic factors are: genetic predisposition, first ray hypermobility, metatarsus primus varus, ligamentous laxity, metatarsal formula, metatarsal anatomy, pes planus and female gender. Out of the extrinsic factors, probably inadequate footwear is the most important issue that can exacerbate the abnormality, but does not represent a clear triggering factor [1-5].

The extent on which every factor influences the initiation of the deformity is still debated, but there is a general consensus on the multi-stepped and intricate pathogenesis of this malformation.A loss of axial alignment and stability ensues due to an altered balance between the dynamic and static stabilizers of the first metatarso-phalageal joint. The sequence of events leading to a symptomatic deformation includes: failure of the medial stabilizing structures (medial collateral ligament and sesamoid) of the joint; lateral sliding (subluxation or luxation) of the sesamoid plate relative to the medially displaced metatarsal head (metatarsus varus); valgization of the phalanx reinforced by the adductor hallucis tendon, flexor and extensor hallucis longus tendons; pronation and elevation of the medialized metatarsal head which is

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no longer capable of supporting plantar pressure [6-18]. In the management of hallux valgus the conservative options suggested usually include physiotherapy, accommodative footwear, insoles, separators, splints or orthoses. The results of these treatment methods have been proven questionable at best, regarding the radiological parameters and perceived deformity. Also it seems that conservative treatment does not alter the progression of the disease, with only limited positive effect on the symptoms [19-23].

In addition to a thorough history and physical examination with focus on some specific elements (tarso-metatarsal and metatarso-phalangeal mobility and static foot deformities), evaluation of affected patients involves radiographic examination with anteroposterior and weight-bearing views and specific measurements. The two most important measured angles that are taken into consideration for severity classification and management algorithm are the intermetatarsal angle (IMA) and hallux valgus angle (HVA). The first one is described between the diaphyseal axes of the first and second metatarsals with a pathological value over 9 degrees and the hallux valgus angle formed by the axis of the proximal phalanx and the diaphyseal axis of the corresponding metatarsal, with normal values under 15 degrees [24,25]. The present paper follows the results generated with our experience with button and wire cortical suspension systems in the treatment of hallux valgus.

Experimental part

Materials and methods

A number of 12 cases of bilateral hallux valgus, surgically treated in our department were followed for a period of minimum twelve months during this study. All the patients were females with ages ranging from 26 to 64 years old. This encompasses a total number of 24 feet managed using the 1.1mm Mini TightRope® Disposable Kit with two constructs per foot after failure of a trial, non-operative course of treatment. The exclusion criteria were a diagnosis of severe deformity defined by an IMA greater than 20° and/or a HVA greater than 40°, arthritic involvement of the metatarsophalangeal or tarsometatarsal joint, coexisting neuromuscular or rheumatic pathology. The evaluation process consisted of radiographic examination and HVA and IMA measurements before and after surgery, at six weeks and six months. Also, assessment using the American Orthopedic Foot and Ankle Society (AOFAS) hallux metatarsophalangeal-interphalangeal scale before correction and at six months postoperatively was performed. We encountered two cases with associated hammertoe which had to be addressed during surgery.

The applied surgical technique combines a soft tissue procedure on the first metatarsophalangeal joint with correction of the enlarged intermetatarsal angle using two fixed loop suspension systems. Every 1.1mm Mini TightRope® Disposable Kit contains 2 constructs, each with two preloaded 2.6 mm oblong buttons on the 2.0 FiberWire® suture loops made of ultra high molecular weight polyethylene and polyester, with silicone elastomer coating, two free oblong buttons and multiple 1.1 mm suture passing K-wires.

The first step was the release of the tight lateral capsule at the level of firstmetatarsophalangeal joint combined with release of the deep transverse ligament and the adductor hallucis phalangeal insertion. The fibular sesamoid is also freed of any adhesions and detached from the capsule allowing the return of the sesamoid plate to the normal position during the realignment of the ray. All this is achieved through a dorsal skin incision in the first metatarsal webspace. Using a medial approach of the joint,bunionectomy and excision of the redundant capsule is carried out, with care not to remove the sesamoid groove by excessive resection. A small, third incision for access to the lateral second metatarsal neck is centered in the second web space. Trough dorso-plantar adjustments and under fluoroscopic guidance a 1.1mm tapered suture passing K-wire is inserted through the second metatarsal starting at a point centered on the shaft, at 2-3 millimeters proximal to the neck and then through the first metatarsal, exiting just proximally to the resection surface of the medial eminence. A number two suture wire is passed from lateral to medial using the end loop of the K-wire and then the free end of the Mini TightRope construct is passed back from medial to lateral, allowing for the knots over the second button to be places laterally in the intermetatarsalwebspace. A second construct is placed at 5-7 millimeters proximal to the first one and, after correcting the IMA under fluoroscopic control the systems are tightened and secured with a minimum of three knots. The postoperative recovery protocol allows walking with only heel weight-bearing for the first six weeks because the achieved stability is dependent to some extent on soft tissues scarring to preserve correction and unload the device. If early weight-bearing on the first ray is initiated, because of the high tension on the system, the second metatarsal may react comparably to a stress fracture with pain and prolonged edema.

Results and discussions

In terms of radiology correction results, the mean preoperative IMAof 14.6°± 2.6° was improved to 7.9°± 2.2° postoperatively and maintaineda mean value of 9.2°± 2.4°registered at six months after surgery. The preoperative

measured HVA was reduced from 28.4°± 8.6° to 14.2°± 6.3° after surgery with a mean improvement after six months at 16.1°± 6.8°. These values confirm the good correction potential of the technique, with the minimal loss of reduction registered after the first six months being attributed to redistribution and final setting of the tension which is gradually and partially taken up by the soft tissues healing.

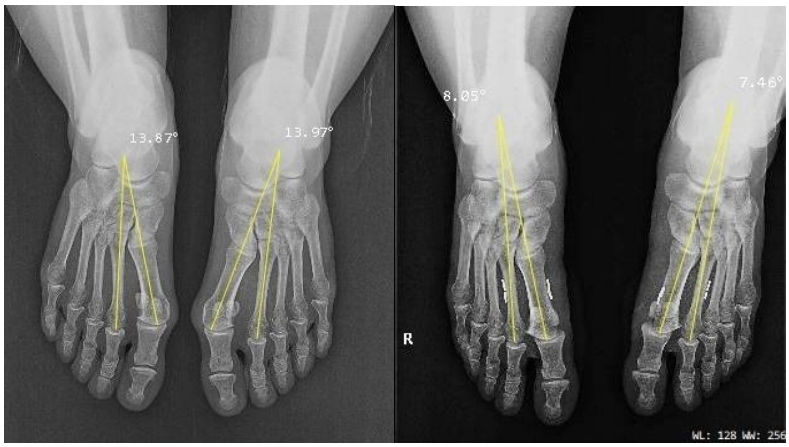

Fig.1 Preoperative and postoperative measurements of IMA angles show good correction and improved position of the sesamoid bones - 42 years old female

Although some small changes is the position of the metallic buttons can be detected no important displacement was noted or failure of the constructs. One case presented subsidence of a single distal, first metatarsal button because of the tunnel exit point was placed in the area of exostosectomy, where the remaining cancelous bone cannot support the pressure concentration under the button.No second metatarsal fracture occurred in our series maybe because we gave special attention to surgical technique accuracy which states that precise placement of the bone tunnels, especially trough the second metatarsal, at equal distance between the dorsal and plantar cortex ensures the lowest risk for this specific complication.

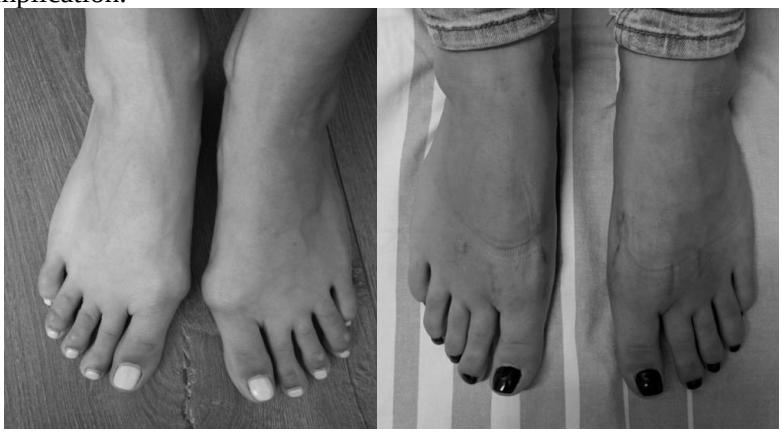

Fig.2 Case: 26 year old patient: aesthetic results at six weeks after surgical correction

The the American Orthopaedic Foot and Ankle Society (AOFAS) hallux metatarsophalangeal-interphalangeal scale before correction showed an overall value of 54.76 (40-73) with an improvement at six months postoperatively to 92.21 (83-98). The patient satisfaction reflected by these numbers was fairly distributed between all of the score subcomponents like pain perception, function and alignment. Two patients experienced persistent metatarsalgia with one case of complete resolution after a few months after surgery. No repeated interventions were needed to this moment for recurrence or other critical complications except for one case that needed excision of reactive soft tissue developed over one of the medial buttons.

Choosing the optimal surgical treatment of hallux valgus is done on individual basis after considering the severity of the malformation, joint congruency, bonemorphology, degenerative status of the metatarsophalageal joint, tarsometatarsal hypermobility and comorbidities. There is still controversy regarding the most appropriate surgical treatment algorithm and ideal technique out of more than one hundred options described in the literature. Despite this great variety of correction techniques, a few basic concepts incorporate all these variations: metatarsophalangeal or tarsometatarsal joint arthrodesis (modified Lapidus procedure), metatarsal osteotomies (chevron, Mitchell, crescentic, scarf) or soft tissue procedures (modified McBride) [26-32]. The last two decades have brought an increasing appeal for minimally invasive

surgical techniques like Bosch or SERI techniques, which promise consistent results with least complications. Despite the promising results longstanding and comparative evaluation of this group of interventions needs to be performed [33-35].

Based on the idea that varization of the first metatarsal represents an essential element of the disease pathogeny and its stability plays an important role in the recurrence of hallux valgus the majority of correction techniques aim to address these issues. Furthermore the fact that the overall results do not prove absolute superiority for any given technique, attention has been given to the development of soft tissue approaches which would achieve correction, stabilization and avoid recurrence, without the added complications and invasiveness ofthe osteotomy techniques. The prototype for this group of procedures is the so called syndesmosis procedure which relies on osteodesis (fibrous connection) between the first two metatarsals combined with cerclage for maintaining the correction of the intermetatarsal angle. [36-38] The latest variation of this surgical correction principle which has gained popularity nowadays is the technique that combines a soft tissue procedure (modified McBride) with fixation of corrected IMA using a system of buttons and high strength suture loop attached like MTR (Mini TightRope®, AthrexInc, Naples, Florida), acting as a intermetatarsal cerclage.

Usually the disease severity dictates the two main classical concepts for surgical correction. For mild to moderate deformities the treatment option can rely on soft procedure alone or in conjunction with a distal metatarsal osteotomy. For moderate to severe cases the most frequently deployed strategy is either metatarsal base osteotomy or tarsometatarsal fusion. All these procedures carry a consistent risk ofvarious complications like malunion, nonunion, transfer metatarsalgia, recurrence, excessive metatarsal shortening or avascular necrosis of the first metatarsal head [39]. The MTR surgical technique used for cases of mild to moderate hallux valgus (HVA<40° and IMA<20°) not only manages to correct the deformity without the use of osteotomies, avoiding the associated risks, but also deals with the challenge of high recurrence rates related to soft tissue procedures alone and the problem of first metatarsal stabilization.

Stemming from our experience with this specific surgical technique and also based on the published results in the literature it is clear that the corrective potential have been demonstrated by the improved radiological parameters that maintain a fair degree of reliability, at least on the observed term. Also the functional, aesthetic and life quality improvements have been validated by the specific score results assessments. The important debate comes from the particular complications associated with this technique. So far the main, specific complications recognized are: second metatarsal fracture, loss of correction due to implant failure or button migration, overcorrection with subsequent hallux varus and persistent forefoot edema. A 2015 published paper by Dayton et al. performs a systematic review of the results and especially of the complications reported in 9 journal articles, regarding the use of Mini TightRope implants for hallux valgus correction. It highlighted a 25% overall complication rate and 13.6% incidence rate for second metatarsal fracture, out of 132 cases. It presumed that this type of intervention would not be a very satisfactory surgical option due to mainly a high percent of complications [40]. This conclusion is in our opinion questionable at least. The main reasons which make a relevant conclusion impossible are: the variations in surgical technique used in the pooled studies, the low number of reported cases and the relative novelty of the implants, procedure with short follow-up time periods.

The same kind of suture loop and button constructs have been used with good results for stabilization of acromio-clavicular and ankle syndesmotic injuries and applied for a long time in knee cruciate ligaments reconstruction surgery. Similar suture materials combined with different types of anchors have been used for repair of shoulder Bankart lesions and for reconstruction of medial patellofemoral ligament. The implementation of the materials and construct principles in hallux valgus correction surgery rely on the long-term experience with this type of systems and the proven reliability in terms of material resistence and biocompatibility. The low profile of the implants eliminates the need for a second removal procedure and allows magnetic resonance imaging and any other kind of imaging technique, which sometimes can be required for non-tumoral or tumoral pathology later in life [41-45]. Amidstthe unique complications associated with MTR the second metatarsal fracture is the most frequent and most scrutinized. Combining the published information and gained experience it can be fairly stated that this problem is much more complex than perceived and its elucidation is unachievable at this moment. First of all, multiple types of solutions used for hallux valgus have changed and present some variations. The first generation of implants needed a 2.7mm diameter drill hole in the metatarsal bone for passage of only one construct per forefoot that supported all the tension, and the majority of papers associated with the highest number of second metatarsal fractures used this solution. A decrease to 1.1mm for the suture bone tunnels diameter in the new generation of implants minimizes the induced fragility of the second metatarsal shaft [46-49]. Another improvement of the system design aimed at reducing the risk for fracture is the addition of a special metallic, 43 millimeters long buttress plate on which the two 2.6 millimeters lateral buttons disperse the pressure on a higher supporting surface which is placed between them and the second metatarsal cortical bone. A well recognized element of surgical technique is the careful placement of the bone tunnel, centered on the second metatarsal diaphysis in order not to increase the risk for iatrogenic fracture. Furthermore the bone quality of the patient associated with advanced age can be of concern when

analyzing the fracture risk. The paper reporting the largest number of second metatarsal fractures, written by Weatherall et al. also includes the patients population with the highest mean age and presumably the lowest bone quality [50].

The second most frequent complication, in the form of hardware failure (an overall 7.6% in the literature review) has been attributed to hardware failure. This designation can be argued because sometimes it is hard to differentiate pure material failure from deficient surgical technique with knot untying. Also the application of two construct for every case can may lead, in our opinion to a more reliable and stable fixation with a decreased future risk for hardware failure, because of load sharing. [51-55]

Relative novelty and progressive evolution of the technique have not yet established a steady learning curve and a stable set of rules in order to have conclusive overall results on the medium and long-term. Our experience shows that, at present time a good level of confidence can be maintained in this technique and its advantages but also we accept and support the need for further testing and analysis of results of homogenous case series.[56-58] Some of the characteristic problems that need to be studied, in our opinion are: standardization of the implant characteristics and kits, clearer surgical indication rules based on radiological parameters, age, bone mineral density and coexisting forefoot deformities, soft tissue reactivity to the long term presence of the systems (biocompatibility) and employment of implant removal rules and salvage procedures. All these can ensure the implementation of a uniform surgical technique and learning curve and will allow an accurate evaluation process of the results on the long run, relative to other procedures.

Conclusions

The good short-term, functional and radiological results combined with a better understanding and improvement of the implants and technique maintains a good potential for this osteotomy sparing method. Until long-term follow-ups and extensive implementation of the matured surgical technique are not available, this remains a promising treatment option for mild to moderate severity hallux valgus.

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