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Chronic deltoid ligament insufficiency repair with Internal Brace™ augmentation☆

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ABSTRACT

Background: Patients with chronic deltoid ligament insufficiency (CDLI) present a challenging situation. Although numerous procedures have been described, optimal treatment is still a matter of debate. While the treatment armamentarium ranges from simple ligament repair to complex reconstructions with or without realignment osteotomies, direct repair augmented with an Internal Brace™ device appears to be an attractive intermediate option. We investigated functional outcomes and complications in patients with CDLI operated on using Internal Brace™ augmentation.
Methods: A prospective study was conducted. Patients were included if they presented medial ankle pain and/or giving way, exhibited asymmetric flexible hindfoot valgus, failed conservative treatment, and had a positive MRI evaluated by an independent radiologist. Patients with stage IV flatfoot deformity, neuropathy and/or inflammatory arthritis were excluded. CDLI was confirmed intraoperatively with the arthroscopic drive-through sign. Patients were evaluated preoperatively and postoperatively using FAAM, SF-36 and grade of satisfaction. Paired t-tests were used to assess FAAM and SF-36 scores variation.
Results: Thirteen patients met inclusion criteria. No patient was lost to follow-up, with a mean follow-up time of 13.5 months (range 6-21). Preoperative FAAM and SF-36 scores improved from 58.7 to 75.3 and from 60.2 to 84.4 postoperatively, respectively ($p<.01$). Two implant failures were observed, with no apparent compromise of construct stability. No patient was re-operated.
Conclusions: Our results suggest that deltoid ligament repair with Internal Brace™ augmentation in patients with CDLI is a reliable option with good functional outcomes and high satisfaction grade in short term follow-up.
Level of evidence: Level IV.

1. Introduction

The deltoid ligament is the main stabilizer of the ankle joint, being the primary medial stabilizer and valgus restrainer. Moreover, not only restricts anterior translation of the talus, but lateral translation as well [1].

Several anatomic descriptions have been enunciated, being the division into superficial and deep components the most widely accepted [1–4]. Traditional anatomic knowledge describes three constant bands for the medial collateral ligament; namely, tibiospring and tibionavicular ligaments (superficial); and deep posterior tibiotalar ligament. Other ligaments have been variably described and include the superficial posterior tibiotalar ligament, tibiocalcaneal ligament, and deep anterior tibiotalar ligament [1,2,5,6]. However, more recent investigations suggest that this anatomic structure should not be falsely divided into these components, as they function anatomically and biomechanically as a single “unit”: the medial ligament complex; including the deltoid, spring ligament and posterior tibial tendon [7–9].

In such scenario, not only does the medial ligament complex stabilize the ankle against pronation, but also provides rotational stability [1,6]. Despite this anatomic and biomechanical relevance, the value of the medial ligament complex has been neglected by

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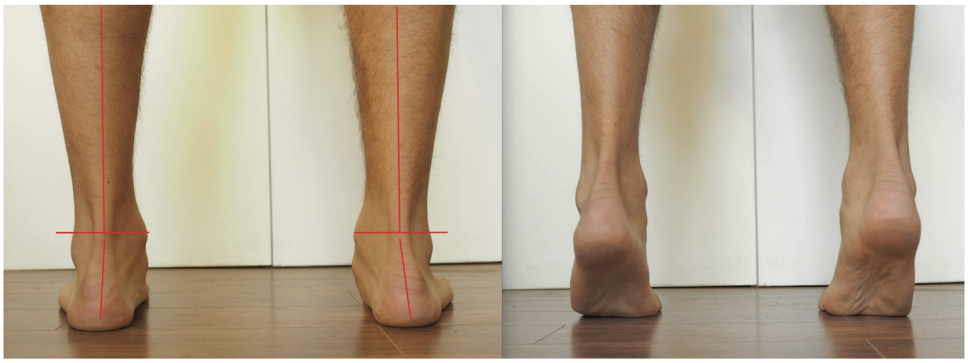


Fig. 1. Left asymmetric valgus with pronation of the forefoot that corrects with the activation of the posterior tibial tendon.

the orthopedic literature and only recently has come to orthopedic surgeon's attention [10–12]. In fact, anatomic repair in ankle fractures with deltoid rupture is the treatment of choice for many surgeons [13–15].

Patients failing non-operative treatment, including neuromuscular and proprioceptive training, for lateral chronic ankle instability will frequently undergo surgery, most commonly some sort of Brostrom repair. Nevertheless, about 26% will not be satisfied with the procedure at 9 years follow up [16]. In such scenario, possible failure causes must be ruled out; including technical errors, malalignment or unrecognized medial or multidirectional instability. A high index of suspicion must be maintained in those patients presenting with medial ankle pain, giving way sensation and asymmetric hindfoot valgus deformity that can be corrected by plantarflexion of the affected ankle [11,26] (Fig. 1). In those cases, multidirectional instability should remain as the main diagnostic possibility [10,17].

Surgical management of this pathology is still controversial. Most of the available evidence regarding medial ankle instability constitute a poor body of knowledge, including cases series with a small number of patients, cases report and standardization paucity [9,14,18–24]. Despite these inherited limitations, some authors will advocate tightening and repairing the native deltoid ligament to the medial malleolus. Moreover, some authors even suggest that complete rupture of the deltoid ligament could benefit from being acutely repaired if the lateral ligaments or syndesmosis are unstable [25].

However, some concern remains regarding quantity and quality of the residual ligament and the fact that repairing is not always possible, in particular in those patients with long term deformities.

For the above-mentioned reasons, other investigators have suggested that the medial ligament should be reconstructed using allograft or autograft. Several techniques have been reported in the literature [21–23,26], with no one demonstrating superiority over others. To complicate things more, it is hard to draw definitive conclusions from the available literature as most of these procedures are performed in conjunction with calcaneal and/or supramalleolar osteotomies.

We believe there is an intermediate alternative between repairing and reconstructing the deltoid ligament, without realignment osteotomies. However, clinical data of augmented medial ligament repair are lacking. Therefore, we designed a prospective case series to investigate functional performance of patients undergoing medial ligament repair with augmentation using Internal Brace (*Arthrex,Inc., Naples FL, USA*) and their surgical complications.

2. Methods

After obtaining IRB approval, a prospective study was conducted. Between January 2015 and October 2016, thirteen patients were operated on with this technique. Patients were included in the study if they presented clinical findings compatible with chronic medial insufficiency, failed conservative treatment, and had a MRI evaluated by an independent radiologist confirming medial complex disruption. No case with bilateral ankle instability was included in the study. All patients underwent a minimum of three months of non-operative treatment including physiotherapy with neuromuscular training. Patients with stage IV flatfoot deformity, neuropathy and/or inflammatory arthritis were excluded from the study. All patients underwent functional evaluation through Spanish version of 36 item short form survey (SF-36), Foot and Ankle Ability Measure (FAAM) and satisfaction survey. Finally, diagnosis was confirmed during surgery using the ankle drive through sign [27], which consists of introducing a 5 mm probe into the back of the ankle through the medial gutter during arthroscopy (Fig. 2).

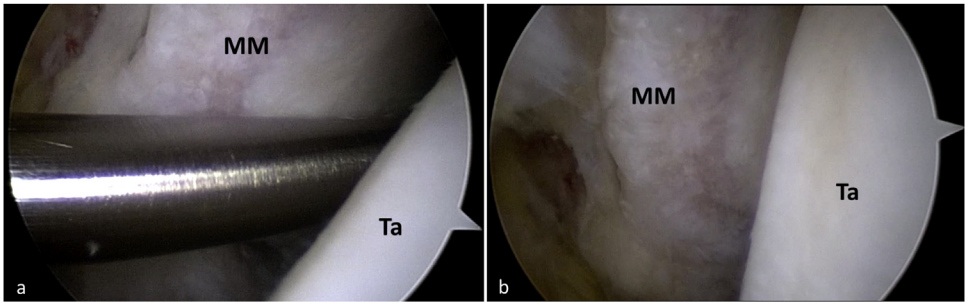


Fig. 2. a. Diagnosis was confirmed during surgery using the ankle drive through sign, which consists of introducing a 5 mm probe into the back of the ankle through the medial gutter during arthroscopy; b. denuded medial malleolus demonstrating the absence of medial ligament complex proximal insertions. MM = medial malleolus; MG = medial gutter; Ta = talus.

2.1. Surgical technique

All patients were operated on in the supine position. After antibiotic prophylaxis was administered and the extremity was prep and draped, gravity exsanguination was performed and maintained through a thigh tourniquet. Ankle arthroscopy was realized though standard anteromedial and anterolateral portals using a 2.9 mm, 30° arthroscope (*Arthrex*, *Inc*., *Naples FL*, *USA*).

Systematic examination of the ankle joint through Ferkel's points was performed and the anterior chamber was evaluated for soft/bony impingement. The talar dome and tibial plafond were inspected for osteochondral lesions and ligamentous tears were ruled out from the lateral gutter.

Chronic deltoid insufficiency diagnosis was confirmed after visualizing a denuded medial malleolus; proving the absence of the proximal insertion of the medial ligamentous complex (Fig. 2). Thereafter, the ankle drive through sign was performed in all cases. All intraarticular pathology was addressed during this time. A curved incision was performed starting 1 cm proximal to the tip of the medial malleolus toward the medial aspect of the talonavicular joint. The posterior tibial tendon was identified and protected. A medial ankle arthrotomy was then performed, elevating the medial ligamentous complex and the periosteum of the distal tibia to perform a pants-over-vest repair at the end of the procedure. (Fig. 3). A rongeur was used to prepare the anterior aspect of the malleolus for ligament reattachment. In anticipation for medial ligament repair augmentation using Internal Brace™ (*Arthrex*, *Inc*., *Naples FL*, *USA*), three fixation tunnels were prepared using a 3.4 mm drill bit: the intercollicular groove of the medial malleolus, the sustentaculum tali and the talar neck. While the first two tunnels are easily recognized in normal anatomy, the tunnel at the talar neck must be performed 1 cm from posterior to anterior on the medial bend of the articular surface of the talar trochlea, where the deep deltoid footprint is located (Fig. 4). When preparing the sustentaculum tunnel, the surgeon should aim away from the subtalar joint by angling the drill bit plantarly 15° and posteriorly to avoid the subtalar joint (Fig. 7). In a similar manner, when preparing the talar tunnel, the surgeon should aim to the talar body in order to achieve optimal anchor purchase.

Additionally, another 3.4 mm tunnel is performed in the anterior colliculus to insert a 5.0 mm corkscrew anchor with four strands of Fiberwire suture ® (*Arthrex*, *Inc*., *Naples FL*, *USA*), which will be used for deltoid repairing (Fig. 5). Before repairing the medial ligament complex, a 4.75 mm SwiveLock® anchor (*Arthrex*, *Inc*., *Naples FL*, *USA*) loaded with one FiberTape® is introduced into

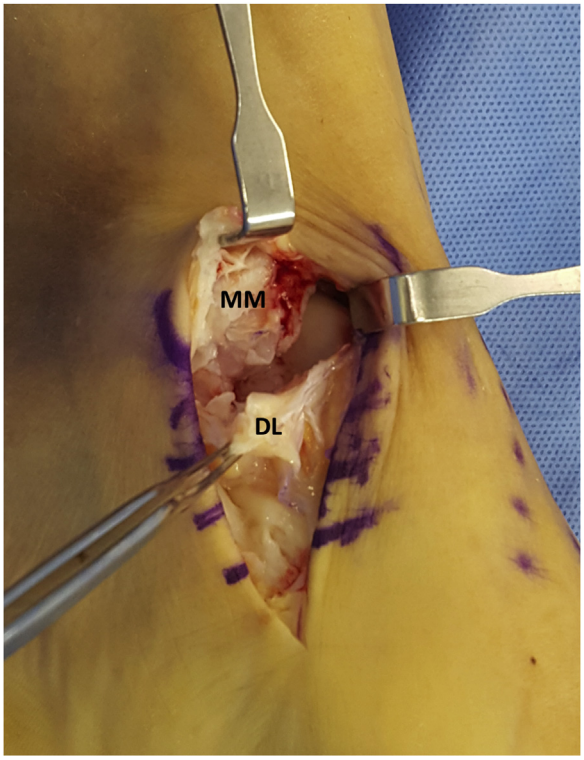


Fig. 3. Medial arthrotomy. The anterior surface of the medial malleolus is prepared to receive the re-insertion of the deltoid ligament and internal brace augmentation. Proximal attachment of the ligament at the medial malleolus is elevated to perform a pants-over-vest at the end of the procedure. MM = medial malleolus.

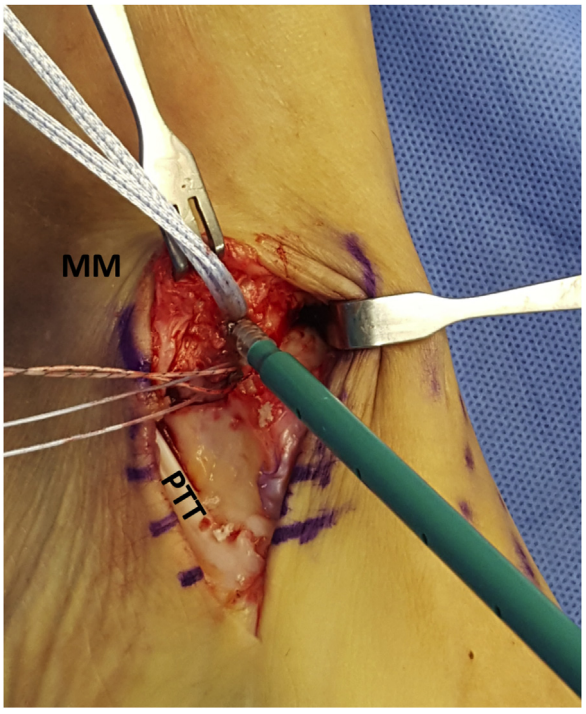


Fig. 4. Once the tunnel has been performed into the intercollicular groove, one 4.75 × 15 mm SwiveLock® anchor will be introduced into the medial malleolus and the FiberTape® will be passed through the proximal deltoid ligament using a free needle. This step will assure that the tape lies over the top of the native ligament repair and not intra-articular. MM = medial malleolus, PTT = posterior tibial tendon.

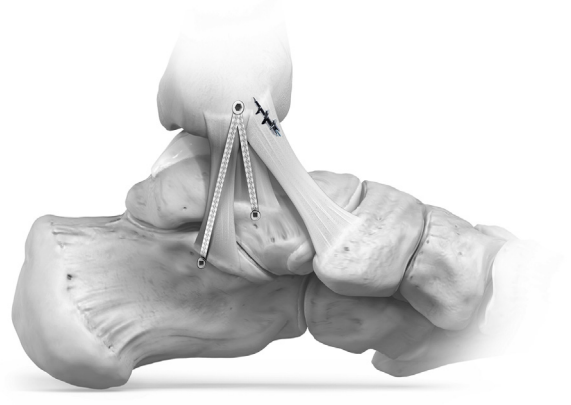


Fig. 5. Drawing of the final appearance and tunnel position of an internal brace augmentation for a deltoid repair. Note how the bracing is on top of the repair, preventing joint contact with the synthetic material. A bröstrom-type repair of the medial ligament is performed in advance of the augmentation and fixed with an anchor to the anterior colliculus.

the intercollicular groove and using a free needle, the tape will be developed anteriorly to the native deltoid tissue, superficial to the repair and not intra-articular. This step leave two FiberTape® arms coming from the medial malleolus: one for the talus (tibiotalar) and another for the sustentaculum tali (tibiocalcaneal), which aim to resemble the deep and superficial deltoid ligament during augmentation, respectively.

A 21 G needle is placed through the deltoid ligament into the talar tunnel to facilitate finding its location after the repair has been performed. This step will facilitate blind fixation of the tibiotalar arm of the augmentation.

The native deltoid is approximated to the medial malleolus using two Mason-Allen stitches using the 5.0 corkscrew anchor. After finishing the native ligament repair, the tibiotalar arm will be fixed. For this step, load a 4.75 mm Swivelock with one of the FiberTape® arms and insert it into the talar tunnel. The 21 G needle previously introduced into the tunnel should guide the surgeon into the proper location and orientation for fixation. Two considerations must be taken to avoid over tensioning the FiberTape®. First, the amount of tape that will be introduced into the tunnel should be marked using the laser line in the screwdriver. Secondly, a mosquito clap underneath the tape will further prevent overtightening. To fix the tibiocalcaneal arm of the augmentation, the same precautions should be taken. Load another 4.75 mm SwiveLock with the remaining FiberTape® arm and introduce it into the sustentacular tunnel while holding the hindfoot in slight eversion. A very important step is to drive the tape underneath the posterior tibial tendon, avoiding impingement over it though malposition (Fig. 6).

Wounds are closed in a layered fashion and patients typically are not immobilized. Once the wounds are clean and dry, typically by their third postoperative visit, stitches are removed, and patients are encouraged to start early rehabilitation with controlled active and passive range of motion. The physiotherapy is continued until patient has recovered full muscular strength and ankle range of motion and proprioception are restored. Athletic activities are allowed at 12 weeks.

2.2. Statistical analysis

Data was analyzed using Stata software version 13.0 for Windows. Normal distribution was assessed by the Saphiro Wilk test, and the variables were found to be normally distributed. Paired *t*-tests were used to assess the pre and postoperative FAAM and SF-36 scores. The significance was set at $p < 0.05$.

3. Results

Thirteen patients met inclusion criteria on which 10 were men and 3 women with a mean age of 32.4 years (range 18–61) at the time of the evaluation. The mean total follow-up was 13.5 months (range 6–21). There were 8 right and 5 left ankles included, with no bilateral cases. Five patients presented multidirectional instability and two patients had concomitant osteochondral lesion which were addressed at the same surgical procedure, with debridement/micro fractures and Modified Brostrom Gould ligament repair, respectively. The mean SF-36 score improved from 60.2 (range 32–70) preoperatively to 84.4 (range 53–95) at the final follow-up ($p < 0.01$). The mean FAAM score improved from 58.7 (range 3–70) preoperatively to 75.3 (range 32–93) postoperatively ($p < 0.01$) (Graph 1). When they were asked if they would recommend the surgery to a close friend or a family member; or if they would undergo the procedure again, all of the patients answered yes. In the present series, there were no complications including nerve injuries, delayed wound healing or infections. Intraoperatively, two implant failures (anchor breakage during insertion) were observed but had no apparent compromise of construct stability. In this short time frame, no patients were re-operated.

4. Discussion

Our study is the first to suggest that medial ligament complex repair with *Internal Brace™* augmentation in patients with CDLI is a reliable alternative with good functional outcomes and high satisfaction grade in the short-term follow-up.

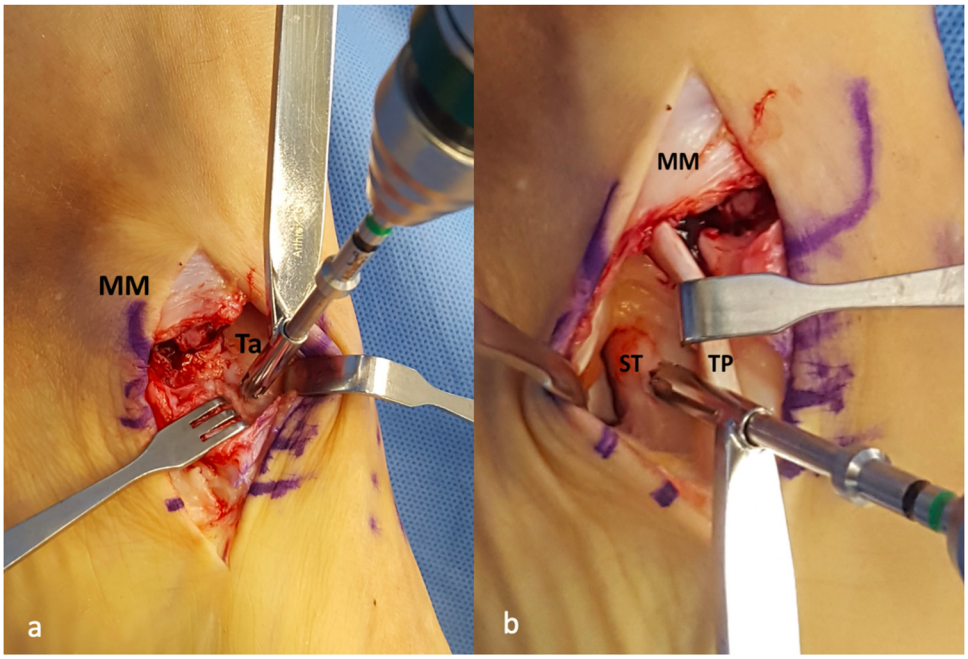
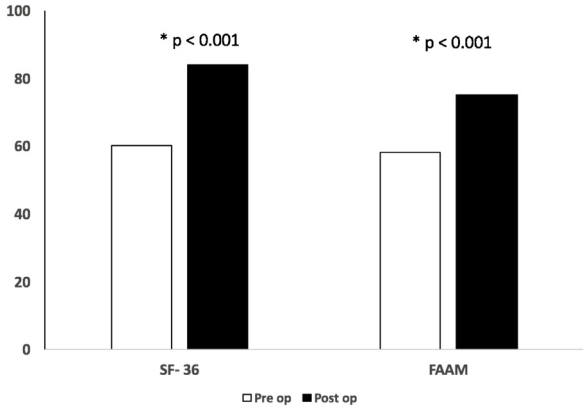


Fig. 6. a. Preparation of the talar tunnel. b. After developing the interval between the posterior tibial tendon and flexor digitorum longus, the sustentaculum tali is nicely exposed to safely perform the tunnel. MM = medial malleolus, PTT = posterior tibial tendon, ST = sustentaculum tali.

Fig. 7. Final view of repair and augmentation of the medial ligament complex. MM = medial malleolus.



Graph 1. Pre and postoperative functional outcomes after deltoid ligament repair with Internal brace augmentation.

Hintermann et al. repaired 52 medial complex ligaments after arthroscopically confirming medial instability diagnosis in a similar fashion as described in this series. They report significant functional improvement at 4 years. As a third of their series underwent concomitant calcaneal osteotomy, their results cannot be compared to our findings [10]. We believe that only repairing the medial ligament complex is insufficient to counteract valgus forces alone and therefore, consideration should be given to perform concomitant realignment osteotomies. In cases in which the hindfoot deformity is actively correctible, an intermediate option with FiberTape augmentation will let surgeons set appropriate ligament tension at time zero, allowing safe return to physical rehabilitation and sporting, decreasing rehabilitation times. We indicate axis realignment procedures if deformities are not passively correctable and/or have more than 6 months since the time of injury. The authors prefer not to change hindfoot axis unless this is strictly necessary, as sporting activities can be severely affected by this procedure. However, if other deformities such as rigid flatfoot or forefoot abduction do not correct, osteotomies or arthrodesis should be performed.

Yasuda et al. operated on 23 ankles undergoing simultaneous medial collateral ligament repair with lateral collateral ligament reconstruction with a complex palmaris longus autograft technique [24]. They did not augment their medial repair. Similarly, Buchhorn et al. repaired medial and lateral ligaments in 81 patients with adequate function and pain reduction at one year follow up [18]. Only five patients from our series underwent a modified Brostrom-Gould repair. The other six patients on which isolated deltoid ligament repair with augmentation was performed, had no residual lateral ankle instability. Surgeons should be prepared to address multidirectional instability of the ankle in any case.

To the best of our knowledge, there is only one report about deltoid ligament augmentation in which the authors performed the procedure percutaneously [28]. In our hands, identifying the exact position of the sustentaculum tali tunnel and managing the FiberTape underneath the posterior tibial tendon are critical to avoid impingement and make the percutaneous technique less appealing.

Several reconstruction techniques have been described to address medial ankle instability [21,23]. However, all of which represent complex procedures, with unpredictable results and questionable reproducibility. The authors believe that reconstruction should be reserved for situations in which native tissue is insufficient to provide an adequate repair.

We think that repair and augmentation is reasonable technique to attempt a less aggressive option, as this decision will not burn

bridges for future reconstructions, if needed. Although differentiating the superficial and deltoid ligaments as separate entities for repairing is anatomically appealing, we feel that fixing the deep deltoid portion is difficult and not possibly reproducible in every case. Considering this limitation, our technique relies in the concept that reattaching of the superficial deltoid to its native location should place the deep deltoid in an adequate position to heal.

Nevertheless, an important take home message is that the Fibertape is not the answer for all cases of ligament instability. This construct will not replace the native ligament, but we believe is extremely useful to allow the native ligament to heal with a "check-rein "over the repair to protect it while it heals, which can prompt early rehabilitation because of the strength at the time zero. If the residual ligament is deemed insufficient for repair, patients have failed previous surgery or are hyperlax, have a high demanding labor/sports practice or present with BMI >30 [19,20,29] consideration should be given to an allograft reconstruction.

Understanding instability of the ankle is complex and not fully understood. We agree that when the anterior talofibular and calcaneofibular become insufficient and peroneal muscle eversion forces are overcomed, the talus fails into anterolateral shifting and inversion. Pathologic motion in these two planes explains why instability of the ankle joint is an external rotatory problem; leading to abnormal joint mechanics and to articular degeneration if not promptly addressed. On the other hand, instability at the medial side of the joint produce abduction (deep deltoid failure) and anteromedial shifting of the talus (superficial deltoid insufficiency), both abnormalities leading to pathologic internal rotation. In addition, the anatomic and functional connection of the deltoid ligament, spring ligament complex and posterior tibial tendon can produce an additional flatfoot deformity, which complicate things furthermore.

Although both entities could produce similar symptoms, medial ankle instability is a challenging diagnosis and the surgeon must be aware of this possibility when evaluating an unstable ankle. Physical examination could not be overemphasized in this situation. Flexible, asymmetric valgus deformity of the hindfoot leads to medial ankle pain and giving-way sensation and must be ruled out. Not addressing medial ankle instability could lead to accelerated articular degeneration, producing a worse scenario for the patient. However, both entities (medial and lateral instability) can coexist and generate a multidirectional instability, a complex situation which often cause more severe symptoms. In such cases, isolate lateral repair can produce premature failure of the procedure, as pointed out by the study of Maffulli et al. [16]. Lastly, ankle instability most common sequalae are chronic pain and articular degeneration, both of which are believed to be more common with medial ankle instability. For the aforementioned reasons, we believe diagnosis and treatment of this situation is of paramount importance.

Our study is not without any limitations. First, the lack of a control group prevents any comparison and definitive conclusions to be drawn from our findings. Secondly, the number of patients is quite small and follow up could be longer. We acknowledge that it is not easy to quantify the extend of deltoid incompetence and more reliable criteria than the passage of a 5 mm probe and/or arthroscopic view of the medial malleolus should be replaced by future investigations. Furthermore, we failed to follow up patients with weigh bearing X-rays demonstrating the absence of a valgus hindfoot or talar tilt. Nevertheless, chronic medial instability in the absence of flatfoot deformity is not a frequent finding. Having said this, this study presents a standardized, organized and unique approach to this challenging pathology and we believe this is a strong and reproducible technique in the short term.

5. Conclusion

Our results suggest that deltoid ligament repair with Internal Brace™ augmentation in patients with CDLI is a reliable option with good functional outcomes and high satisfaction grade in short term follow-up. Consideration should be given to residual tissue feasibility to achieve and adequate repair, which can be augmented using suture taping. If residual ligament is deemed insufficient for repair, patients have failed previous surgery, are hyperlax, have a high demanding labor or sports practice or present with a BMI >30; surgeons should favor allograft reconstruction.

Conflict of interest

Dr. Pellegrini and Dr. Carcuro are paid consultants for Arthrex Inc. Dr. Huertas is Medical Senior Specialist for Arthrex Inc. Dr. Cuchacovich, Dr. Muñoz and Dr. Torres have nothing to disclose.

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