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Retrospective Analysis

Percutaneous Ultrasound-Guided Tenotomy of the Iliotibial Band for Trochanteric Pain Syndrome: A Longitudinal Observational Study With One-Year Durability Results

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Background: Upper lateral hip pain is a common complaint in adults and is referred to as greater trochanteric pain syndrome (GTPS) and is more prevalent among older women. This is a debilitating condition that could result in lower physical activity and quality of life, and higher unemployment rate. GTPS is a clinical diagnosis, and many cases improve with conservative medical management (CMM). However, there is still a gap between patients not responding to CMM and those who are not good surgical candidates. Thus, percutaneous ultrasound tenotomy (PUT) may be a valuable treatment option to limit this gap.

Objectives: Demonstration of the one-year pain and functional outcomes, including sit to stand.

Setting: Academic tertiary care medical center.

Methods: Forty-eight consecutive patients with refractory trochanteric pain due to iliotibial band (ITB) tendinopathy. Fifty-six hips were treated; 8 patients underwent bilateral procedures. Electronic medical record review of consecutive patients who underwent ITB TENEX® was performed at Montefiore Medical Center from December 2019 to December 2021. Institutional guidelines recommended TENEX® for greater trochanteric pain refractory to conservative treatment and ultrasound (US) confirmed ITB tendinopathy (hypoechogenicity or thickened tendon > 6 mm). Pain level, as well as sit-to-stand, side-lying, and walking tolerance levels were evaluated at baseline preprocedure visit and one-year visit. Follow-up was performed by independent practitioners and corroborated by chart review.

Results: Numeric Rating Scale (NRS-11) improved by 4 points across all patients. Seventy percent of patients endorsed pain relief at one-year visit. Median preprocedure NRS-11 was 9. The reported median NRS-11at one year was 5 (Wilcoxon signed rank NRS-11 demonstrated a Z score of -6.042 with $P < 0.001$). One-year analysis among all patients revealed 57%, 78%, and 66% improvement in side-lying, sit-to-stand, and walking tolerance levels, respectively.

Limitations: We believe that our results must be confirmed with a randomized control trial with a control arm and more patients included.

Conclusions: PUT of the ITB using the TENEX® tissue remodeling device could be a safe and effective treatment for ITB tendinopathy-associated GTPS.

Key words: Surgery, novel, TENEX, iliotibial band, GTPS, function

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Upper lateral hip pain is a common complaint in adults with an incidence of 1.8 in 1,000 (1) and is referred to as the greater trochanteric pain syndrome (GTPS). The incidence of unilateral GTPS has been estimated to be as high as 15% in women and 6% in men aged 50 to 70 years (1). Women are particularly susceptible to this condition because of wider pelvis angles than men, which contributes to a higher degree of stress forces around the tendons which attach to the greater trochanter (GT) (2). Fearon et al (3), in 2014, reported that adults with GTPS have been found to have low levels of full-time work participation, high levels of pain and dysfunction negatively impacting physical activity, and a reduced quality of life. Given the relatively high incidence of GTPS, along with its dysfunctional impact on quality of life, effective treatments are needed. In order to appropriately direct an effective plan of care, it is important to distinguish between the most common causes of lateral hip pain: greater trochanteric bursitis (GTB), gluteal muscle tendinopathies, and iliotibial band (ITB) tendinopathy; as an aggregate some or all of these pathologies are referred to as GTPS (4-6).

GTPS is a clinical diagnosis incumbent on point tenderness over the GT that often involves radiation to the lateral aspect of the thigh or buttock (7). Until recently, GTB was the main reported cause of GTPS. Bursitis is an inflammatory process of small, fluid-filled sacs (bursae) that cushion the peritrochanteric tendons and muscles commonly due to direct trauma, prolonged pressure, overuse, and arthritis. The trochanteric bursa lies between the tendon of the gluteus medius (GMed) and the posterolateral prominence of the GT. Studies (8,9) have concluded that bursal distension is uncommon and does not occur in the absence of GMed and gluteus minimus (GMin) tendon pathologies. Current literature (10) suggests that GMed, GMin, and ITB tendinopathy is the cause of GTPS, characterized by persistent localized tendon pain and loss of function commonly a result of repeated mechanical loading or overuse. GTPS is now believed to be a repetitive overload tendinopathy, both of which are primarily involved in hip abduction and pelvic stabilization in walking, stair climbing, sit-to-stand transfers, running, and standing on one leg (11). The ITB over the GT is in a location vulnerable to strain and may be implicated in many cases of refractory GTPS (12). Due to the close proximity of these structures to each other, magnetic resonance imaging (MRI) or ultrasound (US) image guidance is helpful to confirm painful pathology. US can define small peritrochanteric tears, as well as evaluate tendon integrity, which can be missed on MRI (11,13,14). MRI is suggested in cases to evaluate for tendinopathy and bursal effusions, for which surgical endoscopic trochanteric bursectomy and ITB release can be helpful. Where bursal pathology has a clear treatment algorithm, most patients with GTPS are not associated with a bursa so treatment strategies are ill-defined in these patients (10,15). Though many cases improve with conservative medical management (CMM), such as physical therapy (PT), nonsteroidal anti-inflammatory drugs (NSAIDs), and local steroid injections, many require long-term pharmacological management or surgery (5). However, a treatment gap exists between nonresponsive CMM and surgery, thus percutaneous US tenotomy (PUT) may be a valuable treatment option to limit this gap.

Open tendon release has been suggested when conservative measures fail (16-18). However, there are no durable treatment options for patients who refuse surgery or are not surgical candidates. Here, we describe the long-term outcomes of a novel PUT device to treat ITB tendinopathy-related GTPS.

Methods

Study Design

This retrospective analysis was approved by the institutional review board (IRB) at Montefiore Health System (IRB number 2019-10877). The study adhered to the standards of The Declaration of Helsinki.

A chart review of consecutive patients who underwent PUT of the hip at Montefiore Medical Center, from 12/31/19 to 12/31/21, were evaluated. Baseline data was obtained from electronic medical records (EMR). One-year data was collected by independent faculty during a phone questionnaire.

Forty-eight patients were identified. Bilateral procedures were performed on 8 patients. Fifty-six hips were assessed. At the time of the study, the procedure was only performed on patients with refractory GTPS who met the following criteria: 1) lateral hip pain which worsened with lying on the affected side more than 1 minute, 2) pain present for > 6 months, 3) reproducible tenderness to moderate palpation over the GT, 4) pain refractory to at least 8 sessions of PT and at least 2 different classes of oral medication management, 5) failed response to trochanteric steroid injection, 6) US evaluation or MRI performed prior to each procedure to evaluate for ITB, GMed, or GMin tendinopathy, and to confirm lack of a trochanteric bursitis, and 7) lateral hip pain provocation with application of pressure directly over the ITB using the US probe during ultrasonography to confirm ITB pain over other local tendinopathies, such as GMed or GMin. The patient was not included in the study if a trochanteric bursa was identified. Concurrently, confirmation was made by US visualization of hypoechoic ITB tendon, or thickened tendon (> 6 mm) suggesting tendinopathy (10) (Figs. 1-3). Normal tendon thickness is < 3.5 mm. All US scans and procedures were performed by the same physician. US tendon measurements were confirmed by an impartial observer. On the day of the procedure, US evaluation was repeated to confirm ITB pathology at the trochanter.

Hip pain Numeric Rating Scale (NRS-11) was the primary outcome measure at baseline and 12-month visits. Side-lying tolerance, walking tolerance, and sit-to-stand tolerance were evaluated as secondary

Fig. 1. *(A-C): (A) ^^^ Diseased tissue at the musculotendinous junction of the ITB. Note that the TENEX needle is approaching from the caudal-to-cranial direction. (B) 25-G needle introducing local anesthetic at the diseased site. (C) TENEX needle introduced with typical noise artifact seen on the US screen when the US energy is deployed (***).*
ITB, iliotibial band; US, ultrasound.

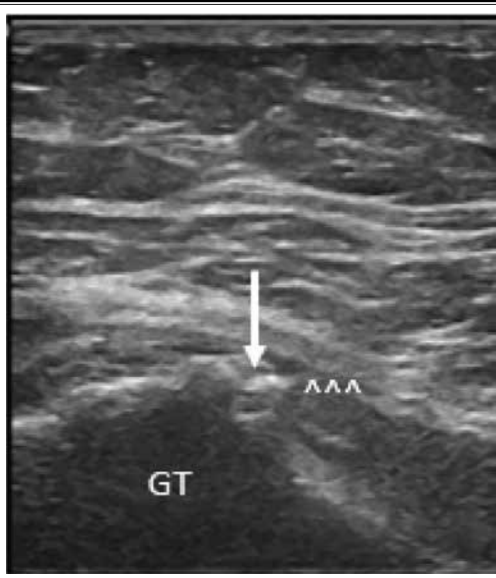

Fig. 2. *Osteophytic ridge seen at the inferior border of the trochanteric with diseased tendon (^^^) overlying structure.*

Fig. 3. *Thickened ITB. ITB, iliotibial band.*

outcome measures to validate the NRS-11 change (1) (Fig. 4). Post-PUT intervention was assessed by EMR valuation and patient questionnaire corroboration.

Surgical Technique and Postoperative Care

Patients were placed in the lateral decubitus position with the affected side up. Manual palpation identified the trochanter and US examination was performed to identify important landmarks for the procedure (GT, GMed/GMin tendons, and ITB), as well as visualize the anterior-posterior and cephalo-caudal dimensions of the trochanter. After the area was appropriately marked, it was sterilized using a 2% chlorhexidine gluconate/70% isopropyl alcohol (Chloraprep®) solution and covered with a sterile drape. A 500 mL 0.9% sodium chloridebag was attached to the tenotomy device to lavage the tissue and to improve the US dynamics during the procedure. A sterile draped 10 MHz linear US probe was then primed and positioned to identify the midline of the trochanter and tensor fascia lata tendons in a long-axis view. With the US in place and muscular landmarks in view, a 1.5-inch, 25-G needle was used to anesthetize a tract using an in-plane trajectory along the diseased tendon and the subcutaneous tissue with 6-10 mL of 2% lidocaine. Next, 1-2 cm distal to the US probe, an #11 scalpel was used to create a 2-4 mm skin puncture, large enough to accommodate the tenotomy needle (TENEX®, TENEX Health, 26902 Vista Terrace, Lake Forest, CA). Following the initial tract created with local anesthetic, the tenotomy device was introduced through the puncture site and advanced to make contact with the diseased tendon (Figs. 5 and 6). Once the tip of the instrument was confirmed to be on the site of the pathologic tissue, the tenotomy device ultrasonic energy was deployed and the tenotomy was performed along its length and width across the trochanter. First, the midline portion of the tendon was addressed, using an oscillatory motion, from distal to proximal. Next, the US was angled slightly to visualize and address the anterior and posterior portions of the tendon in a similar fashion. The needle tip was kept within 1-2 mm of the ITB and in view throughout the entirety of the procedure to ensure treatment of the ITB. The number of passes and cutting time were recorded during each procedure. After appropriate debridement of the tissue (7 minutes of working time), the surgical tip was used to suction the remaining fluid from the tissues. The tenotomy device was then with-

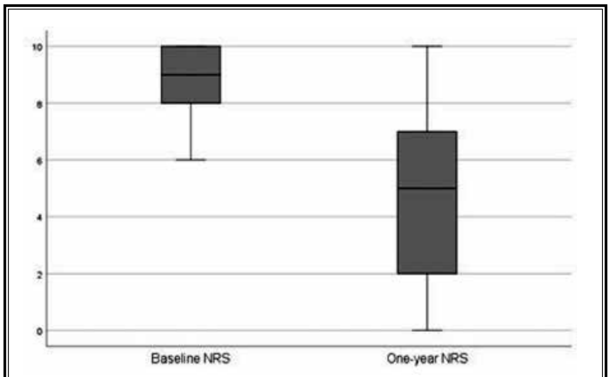

Fig 4. *Box and whisker plot showing composite NRS-11 data for baseline and one-year visits,*

Fig. 5. *The insertion of TENEXTM needle in the lateral decubitus position. Please note the insertion of the needle is in at a 70° angle pointing toward the opposite hip and caudal-to-cephalad approach.*

drawn from the patient. Excess subcutaneous fluid was expressed from the entry site by manual massage and hemostasis was obtained. Steri-Strips were used to approximate the skin at the incision site and covered with a clear pressure dressing (Fig. 6).

Patients were asked to keep the pressure dressing dry for 2 days to prevent superficial infection of the percutaneous entry site. No activity restrictions were placed on the patient after the procedure. Figures 5 and 6 show the positioning of the patient, insertion of needle, local anesthetic, and postprocedure wound.

Data was collected one year after the procedure by a group of independent faculties who had no engagement in the patient's medical care.

Ex Vivo Evaluation Tendon Evaluation

The investigators performed PUT on 3 turkey leg tendons to evaluate tissue change and explain MRI findings. All PUT tendons demonstrated perforation with increased laxity and maintained tensile strength. Laxity was determined by the ability to mobilize the tissue with constant manual pressure across the tendon (Fig. 7). Distraction tests demonstrated muscle failure before tendon corruption in all experiments.

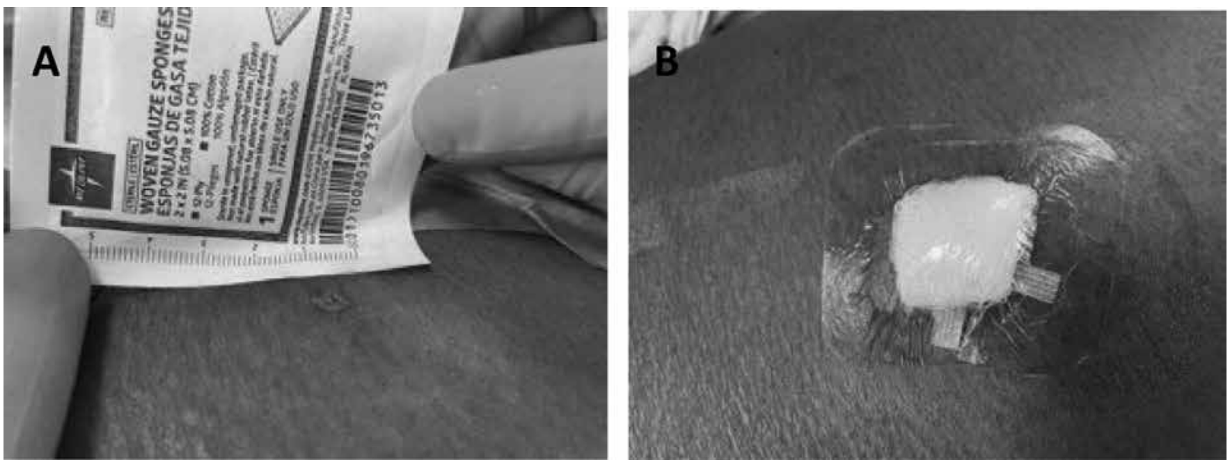

Fig.6. *(A) Incision is a small puncture wound < 1 cm in diameter. (B) The bandaged incision postprocedure.*

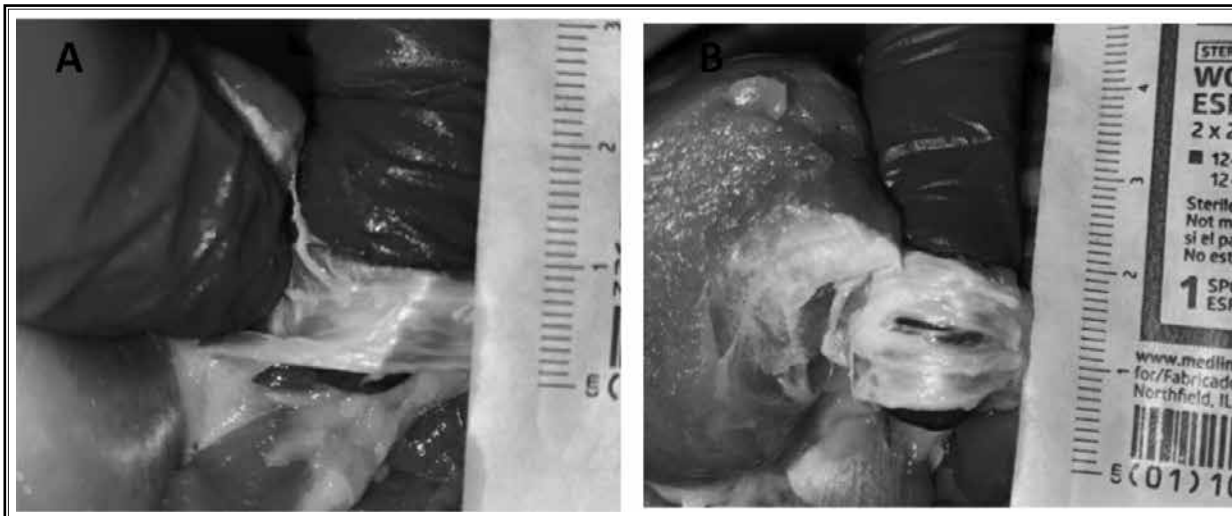

Fig. 7. *Normal turkey leg tendon (A). After PUT, the tendon is perforated with greater laxity, but preserved tensile strength (B) when force is applied across the tendon.*
PUT, percutaneous US tenotomy; US, ultrasound.

Results

Demographics

The patient population was almost exclusively women (91%), averaged 67 years, and a body mass index of 36.6 (11) (Table 1).

Forty-eight patients who underwent percutaneous tenotomy of the ITB were included in our study. The total number of hips in the study assessed was 56 (Table 1). The primary outcome measure was the NRS-11 collected at preprocedure and one-year visits. Additional secondary outcome measures also obtained at the one-year mark included side-lying tolerance, sit-to-stand tolerance, and walking tolerance. Patients were not provided pain medications after the procedure, unless they called and requested for it after the local anesthetic activity dulled. Two patients requested oral anti-inflammatory medications after the procedure, which continued for 10 days. There were no adverse outcomes in this study.

NRS-11

Median baseline NRS-11 score of all patients was 9 (IQR: 2). NRS-11 was then measured at one-year post-procedure endpoints with the median score of 5 (IQR: 5). Data is shown in box and whisker plot (Fig. 5).

Patients were paired to themselves before and after procedure to assess for significance using the Wilcoxon signed rank test. Preprocedural and one-year data was obtained for all patients included in the study.

Additional Outcome Measures

Subsequent outcome measures were obtained to analyze functional improvement and included side-lying, sit-to-stand, and walking tolerance collected at the one-year follow-up period. To collect this data, patients were asked subjectively if the procedure improved the associated outcome measure. Data is summarized in Fig. 8.

At one-year follow-up, sit-to-stand tolerance improved by 78% among all patients; 17% of the patients had no change in that status and only 3% reported worsening. Side lying improved in 57% of our patients; 41% reported no change and one patient experienced mild worsening. Walking tolerance improved in 66% of patients. No patient reported worsened walking tolerance.

Patient medications were tracked by EMR and then verified by the independent medical staff who conducted one-year follow-up visits. No patient required an increase in pain medications during this follow-up window. Additionally, no patients with at least 50% improvement required PT; one required a steroid injection.

Most patients reported satisfaction with the procedure at one-year follow-up (81%).

There were no adverse events reported. However, 5 patients reported postprocedure pain, in which MRI was performed to rule out ITB tendinitis or rupture. No ITB tears were identified. All patients with postprocedural pain were treated conservatively with a 10-day course of oral nonsteroidal anti-inflammatories and symptoms resolved to baseline within one week.

Table 1. *Demographics and BMI.*

Total Number of Patients	48
Total Number of Hips	56
Patients With Unilateral Procedure	40
Patients With Bilateral Procedure	8
Men	4
Women	44
Average Age (Range)	67 years (35-88 y)
Average BMI	36.6 kg/m^2

Discussion

Treatments for GTPS are limited in terms of their effectiveness over the long term. However, the authors here report on novel PUT of the ITB to treat this condition. Median NRS-11 was significantly improved by 4 points at one year ($P < 0.001$). Furthermore, the procedure demonstrated improvement in all functional measures. Though statistically significant, side-lying tolerance, and walking tolerance, did not improve as boldly as NRS-11. The authors surmise that this may be due to unrecognized GMed-related tendinopathy in these patients, for which another study evaluating ITB and GMed PUT may provide clarity.

There is minimal literature which describes a non-surgical treatment for patients with refractory GTPS.

Lateral hip pain is a common musculoskeletal complaint, which has historically been attributed to inflammation of the greater trochanteric bursa (18). Women are particularly susceptible to this condition because of a larger Q angle than men, which contributes to a higher degree of stress forces around the tendons which approximate the GT (2). Bird et al (11) concluded that bursal distension was uncommon and that it did not occur in the absence of GMed tendon pathology, suggesting tendinous pathogenesis of most lateral hip pain. This represents a paradigm shift from earlier teaching, which described the trochanteric bursa as the main pain

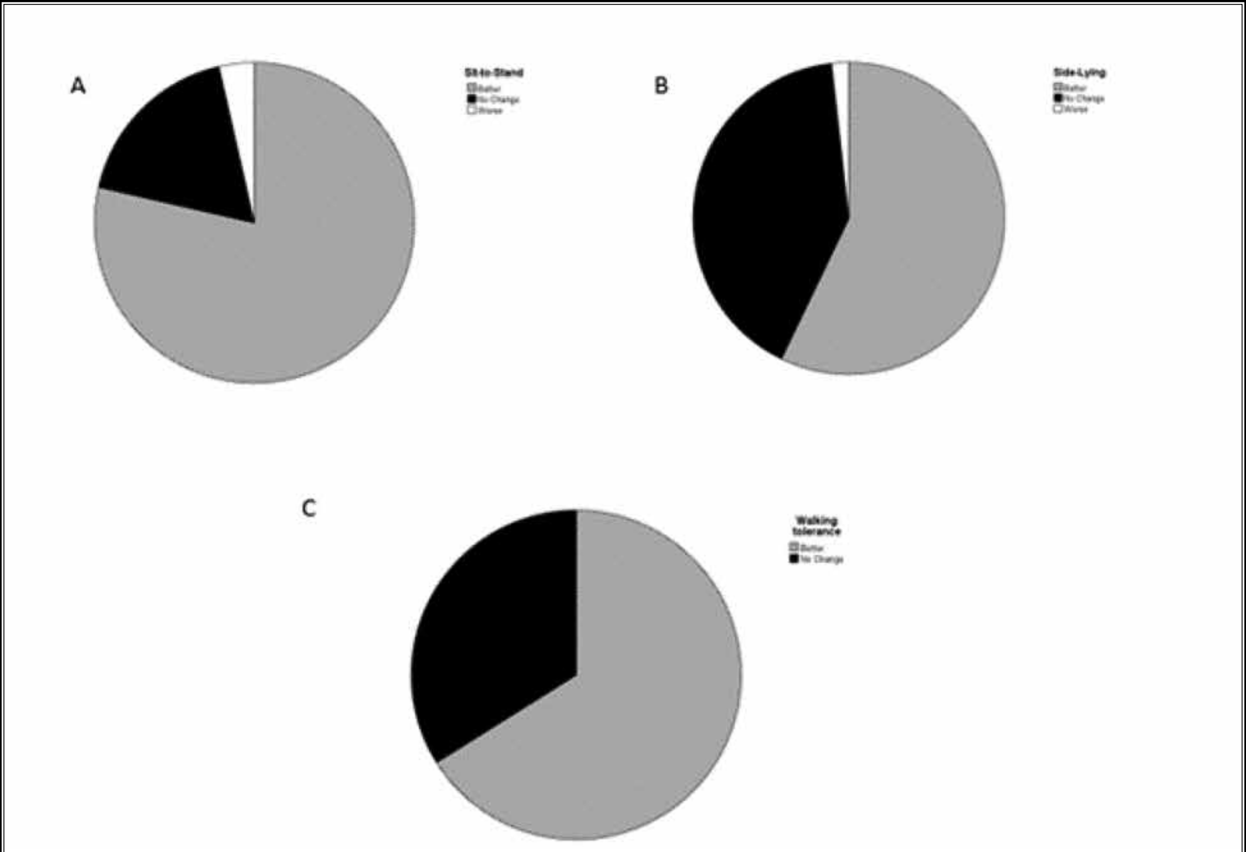

Fig 8. *One-year functional (A) sit-to-stand, (B) side-lying, and (C) walking tolerance data for all patients.*

source. The GT is classified by some as the rotator cuff of the hip due to the multitude of robust tendons and insertion points, each exerting an independent and forceful action on the hip (6). The high density of localized powerful musculature on this mobile joint makes each tendon vulnerable to defective motion and inflammation (6). The gluteal tendons are susceptible to injury due to the interaction of the trochanteric abductors (GMed and GMin) and the ITB-tensing muscles (upper gluteus maximus, tensor fascia lata, and vastus lateralis), which occurs during hip abduction: trochanteric abductors provide 70% of the force needed for pelvic control in a single-leg stance, while the ITB-tensing muscles provide 30% of the force (12). Because of the unequal sharing of forces of these 2 muscle groups, the ITB is prone to hypertrophy, while the GMed and GMin are prone to muscle atrophy and tears (12,20). Tendon thickening can lead to gross dysfunction with associated pain (12) (Fig. 6). This study shows that ITB PUT may be a safe, effective, and durable therapeutic option in patients with refractory GTPS (20-22).

While corticosteroid injection (CSI) remains the current standard of care for GTPS refractory to PT and oral medication, the duration and efficacy for any of these interventions is based on limited data (18,23-25). Though there is strong evidence of a short-term benefit with CSI for GTPS, this benefit diminishes after 3-6 months. Studies (18,24,26) show significant early improvement of GTPS up to 3 months, with greatest effect at 6 weeks, but often recurrence in the longer term. Baker et al (27) has demonstrated that PUT offers durable pain control compared to traditional therapy (28-30). While Baker et al (27) has shown that PUT can be an effective treatment for recalcitrant GTPS in patients with GMed tendinopathy, our study highlights the performance of ITB PUT at the GT for the treatment of recalcitrant non-GMed GTPS (10,16).

A proposed mechanism of action of PUT is high-frequency energy debridement of pathologic tissue under continuous irrigation to convert a chronic degeneration into an acute inflammatory process, thereby promoting tendon healing. However, based on the ex vivo analysis indicated in this manuscript, the authors submit that the mechanism of pain improvement is likely a consequence of direct tissue alteration, as pain relief was immediate without a postprocedure pain flare-up phase commonly described after acute inflammatory reactions (27). Furthermore, subcutaneous lidocaine was the only analgesic used during the procedure and no steroid was injected, thereby arguing against a medication-related explanation for durable pain relief. In addition, prescribed and over-the-counter medications were logged by our research team, thereby limiting the influence of unknown pain medications as a possible complicating factor.

An incidental, but not unexpected finding during US analysis, was the presence of a very sharp trochanteric ridge or osteophyte present in 20/56 hips. All patients with sharp GT ridges improved in this study. Therefore, the authors submit that this anatomical feature created local shearing of the overlying ITB and caused tendinopathy (4,31). Thickened ITB (> 6 mm) at the GT was identified in 42/56 hips, supporting this feature is an important factor in patient selection for future studies. The authors submit that GT ridges increase ITB shearing over the GT which, in turn, causes chronic ITB tendinopathy. These results suggest that the involvement of ITB-related GTPS is underreported. Hypoechoic ITBs were identified in 15/56 hips. Thickened hypoechoic tendons were not identified, and hypoechogenicity was more commonly associated with tendons < 6 mm in thickness. These anatomical findings suggest clinically important factors in identifying patients who may respond to PUT of the ITB.

Our results demonstrate that 70% of patients had appreciable and durable pain improvement in one year. Secondary functional outcomes, such as side-lying, sit-to-stand, and walking tolerance, improved in most patients. These outcomes were selected because they correlate with GTPS disability (1). Our results suggest that some of the patients in our study, who had partial pain improvement, may have been experiencing ITB pain primarily due to GMed pathology, in addition to ITB tendinopathy. A strength of this study also lies inherent in patient selection criteria; patients served as their own controls by response failure to standard CMM. We report that ITB PUT may be a safe, durable, and effective percutaneous surgery for refractory GTPS. However, prospective, randomized controlled trials (RCTs) are needed to validate our findings.

In summary, activity modification and daily exercise regimens are patient-dependent and, therefore, lack standardization. Long-term treatment with NSAIDs can lead to gastrointestinal mucosal, cardiovascular, and renal injuries (32). CSI has shown to provide modest pain relief for acute periods only (33). Fluoroscopy-guided injections have been shown to add no additional benefit (26). An updated paradigm for the treatment of GTPS is essential for the long-term pain relief in this population. The results of this study of selected patients with chronic GTPS demonstrate that sonographically guided tenotomy had no complications and resulted in a statistically significant reduction in mean IQR pain scores. The long-term effects, as based on the data from Baker et al (27), showed a median pain score 9 preprocedure to 5 at 12 months, indicating a long-term benefit not shown with CSIs. Some patients who did not improve were later diagnosed with concomitant hip arthritis and endorsed improvement after hip replacement or intraarticular injections; this demonstrates the importance of identifying and addressing complicating sources of pain, which may marginalize the relief provided by this technique.

The authors are currently collecting 2-3-year data from this retrospective case series and hope to prepare it for publication in the near future.

Limitations

Although this is a modestly sized study showing promising data for the treatment of refractory GTPS, the authors understand the limitation of retrospective analysis and the lack of a control arm. In addition, the retrospective nature of this investigation lends itself to potential selection bias due to the lack of regulated patient selection criteria. Though the patients improved with ITB percutaneous tenotomy despite failing multiple other conservative therapies, the lack of comparative cohorts limit the interpretative value of the results. A control would have allowed for statistical comparison of treated and nontreated patients to develop a justifiable measure of procedure benefit. We believe that our results must be confirmed with an RCT.

Conclusions

The authors submit that PUT of the ITB offers promise as a pain therapy for patients who have failed PT, activity modification, oral analgesics, and landmark-guided CSI. An RCT is needed to verify these results.

Acknowledgment

This manuscript is dedicated in memory of Champ Baker, a friend and mentor to most who knew him.

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